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

August 5, 2025

- *Second-quarter 2025 Rezdiffra™ (resmetirom) net sales of $212.8 million*
- *As of June 30, 2025, more than 23,000 patients on Rezdiffra*
- *Received new U.S. Rezdiffra patent providing protection to Feb. 4, 2045*
- *Announced global licensing agreement for an oral GLP-1 development candidate*
- *In July, secured up to $500 million in senior secured credit to advance pipeline*
- *Presented compelling two-year F4c data at EASL Congress; provides estimates for U.S. F4c MASH patient population*
- *Received positive CHMP opinion recommending approval of Rezdiffra for the treatment of MASH in Europe*
- *Appointed Dan Brennan to Board of Directors*
- *Reports cash, cash equivalents, restricted cash and marketable securities of $802.0 million as of June 30, 2025*
- *Company to host conference call today, Aug. 5, 2025, at 8 a.m. EDT*

CONSHOHOCKEN, Pa., Aug. 05, 2025 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ: MDGL), a biopharmaceutical company focused on delivering novel therapeutics for metabolic dysfunction-associated steatohepatitis (MASH), today reports second-quarter 2025 financial results and provides corporate updates.

Bill Sibold, Chief Executive Officer of Madrigal, stated**:** “We’ve delivered another exceptional quarter driven by continued strong Rezdiffra demand. Additionally, we continued to execute on our strategy by securing a new U.S. patent extending Rezdiffra’s patent protection to 2045; advancing our pipeline with an oral GLP-1 development candidate; preparing to enter Europe following a positive CHMP opinion; presenting compelling new two-year data in F4c; and strengthening our balance sheet with access to up to $500 million in non-dilutive capital. I’m incredibly proud of the team’s execution and the progress we’ve made.”

Sibold continued, “These milestones reflect a clear and deliberate strategy: to secure Madrigal’s long-term leadership in MASH. We’re building a company with the potential to lead in this space for decades – and we plan to do so by scaling Rezdiffra across fibrosis stages and geographies, advancing a pipeline of complementary therapies, and delivering sustained value for patients, providers, and shareholders.”

Second-Quarter 2025 and Recent Corporate Updates

- **New U.S. Rezdiffra patent extends patent protection to 2045**
  - The U.S. Patent and Trademark Office (USPTO) is expected to issue today a new patent entitled, “Methods for treating a fatty liver disease” (U.S. Patent No. 12,377,104) that covers the FDA-approved use of Rezdiffra with claims directed to Rezdiffra’s commercial weight-threshold dosing regimen as prescribed in the FDA-approved label. This patent provides protection to Feb. 4, 2045, and will be listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The patent is expected to issue today, and will reflect an updated date extending the expiration to Feb. 4, 2045. Previously it was noted this patent had protection through Sept. 30, 2044.
- **Expanded pipeline with global rights to oral GLP-1 to combine with Rezdiffra**
  - In July, Madrigal announced a licensing agreement with CSPC Pharma for global rights to SYH2086, an oral glucagon-like peptide-1 (GLP-1) receptor agonist and orforglipron derivative. The license agreement supports Madrigal’s strategy to develop innovative combination treatments for MASH, anchored by its foundational therapy, Rezdiffra. SYH2086 is expected to enter the clinic in the first half of 2026.
- **Secured up to $500 million in senior secured credit to advance MASH pipeline**
  - In July, Madrigal entered into a senior secured credit facility with funds managed by Blue Owl Capital that provides up to $500 million to advance Madrigal’s pipeline to further extend its leadership position in MASH.
  - This non-dilutive financing consists of a $350 million initial term loan funded at closing, a portion of which was used to repay all outstanding obligations under the Hercules loan facility, and a $150 million delayed draw term loan facility available in multiple draws through 2027. The credit facility also provides for the possibility of incremental loans of up to $250 million to support potential additional strategic business development activity.
- **Presented compensated MASH cirrhosis (F4c) data demonstrating broad, sustained efficacy at two years; and provides estimates for market expansion opportunity in the U.S. F4c MASH population**
  - In May, Madrigal presented new Rezdiffra two-year open-label data at the European Association for the Study of the Liver (EASL) Congress demonstrating broad and sustained efficacy, with improvements in liver stiffness, clinically significant portal hypertension (CSPH) risk, liver fat, liver enzymes, liver injury biomarkers and lipids with statistical significance as compared to baseline.
  - Results further support 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. If approved, Rezdiffra is expected to be the first therapy available for F4c MASH patients in the U.S.

    - The estimated market opportunity in the U.S. for F4c consists of approximately 245,000 patients who are currently diagnosed and under the care of a liver specialist.
- **In June, received positive CHMP opinion for Rezdiffra, which, if approved, is expected to be the first medicine available in Europe for MASH**
    - Madrigal received a positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) based on Rezdiffra's favorable profile including positive results from the pivotal Phase 3 MAESTRO-NASH trial. The European Commission (EC) decision is expected in August 2025, and if approved, Rezdiffra is expected to be the first medication for people living with MASH in the EU.
    - Rezdiffra is already included in European clinical practice guidelines, which provide a framework for identifying and monitoring patients with noninvasive tests.
- **Appointed Dan Brennan to Board of Directors**
    - In August, Dan Brennan was appointed to Madrigal's Board of Directors. Most recently Mr. Brennan served as the Executive Vice President and Chief Financial Officer of Boston Scientific where he had responsibility for all global finance functions and corporate business development.

Second-Quarter 2025 Financial Results

- **Total revenues:** Second-quarter 2025 net revenues were $212.8 million, compared to $14.6 million in the comparable prior year period. The increase is due to increased demand for Rezdiffra.
- **Operating Expenses:** Second-quarter 2025 operating expenses were $260.0 million, compared to $177.2 million in the comparable prior year period.
    - **Cost of sales:** Second-quarter 2025 cost of sales was $9.1 million, compared to $0.6 million in the comparable prior year period.
    - **R&D Expense:** Second-quarter 2025 R&D expense was $54.1 million, compared to $71.1 million in the comparable prior year period. The decrease was primarily due to a reduction in clinical trial expenses.
    - **SG&A Expense:** Second-quarter 2025 SG&A expense was $196.9 million compared to $105.4 million in the comparable prior year period. The increase was primarily due to increases in commercial activities for Rezdiffra including corresponding increases in headcount to support commercialization efforts.
- **Interest Income:** Second-quarter 2025 interest income was $8.2 million compared to $14.2 million in the comparable prior year period. The decrease was primarily due to lower cash balances.
- **Interest Expense:** Second-quarter 2025 interest expense was $3.3 million compared to $3.7 million in the comparable prior year period. The decrease was primarily due to lower interest rates in 2025.
- **Cash, Cash Equivalents, Restricted Cash and Marketable Securities:** As of June 30, 2025, Madrigal had cash, cash equivalents, restricted cash, and marketable securities of $802.0 million, compared to $931.3 million as of Dec. 31, 2024. The decrease was due to funding of operations.

Conference Call and Webcast
At 8 a.m. EDT today, Aug. 5, 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 the leading cause of liver transplantation in women and the second leading cause of all liver transplantation in the U.S. It is the fastest-growing indication for liver transplantation in Europe.

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. Madrigal is focused on reaching approximately 315,000 patients with moderate to advanced fibrosis who are under the care of liver specialists in the U.S.

Patients with MASH 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. An estimated 245,000 patients with compensated MASH cirrhosis (consistent with F4c fibrosis) are currently under the care of liver specialists in the U.S.

As disease awareness improves and disease prevalence increases, the number of diagnosed patients with F2 to F4c MASH 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 the expected benefit of Madrigal's newly issued patent, the expected use of proceeds from Madrigal's credit facility, Madrigal's clinical development plans and timelines, Madrigal's leadership position in the MASH sector, 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 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 as updated from time to time by Madrigal's other filings with the SEC.

Madrigal Pharmaceuticals, Rezdiffra™ and associated logos are trademarks of Madrigal Pharmaceuticals, Inc.

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(tables follow)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
Product revenue, net	$ 212,802	$ 14,638	$ 350,052	$ 14,638
Operating expenses:				
Cost of sales	9,065	636	13,578	636
Research and development	54,081	71,091	98,253	142,328
Selling, general and administrative	196,858	105,448	364,734	186,249
Total operating expenses	260,004	177,175	476,565	329,213
Loss from operations	(47,202)	(162,537)	(126,513)	(314,575)
Interest income	8,227	14,222	17,597	22,556
Interest expense	(3,264)	(3,656)	(6,561)	(7,493)
Other expense	(42)	-	(42)	-
Net loss	$ (42,281)	$ (151,971)	$ (115,519)	$ (299,512)
Basic and diluted net loss per common share	$ (1.90)	$ (7.10)	$ (5.22)	$ (14.47)
Basic and diluted weighted average number of common shares outstanding	22,207,017	21,402,646	22,149,492	20,702,041

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

	June 30, 2025	December 31, 2024
Cash, cash equivalents, restricted cash and marketable securities	$ 802,024	$ 931,251
Trade receivables, net	79,231	53,822
Other current assets	122,101	47,854

Other non-current assets	12,025	9,320
Total assets	$ 1,015,381	$ 1,042,247
Liabilities and Equity		
Current liabilities	$ 196,503	$ 169,277
Long-term liabilities	122,900	118,587
Stockholders' equity	695,978	754,383
Total liabilities and stockholders' equity	$ 1,015,381	$ 1,042,247

Source: Madrigal Pharmaceuticals, Inc.