UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 7, 2024

MADRIGAL PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-33277**	**04-3508648**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Four Tower Bridge **200 Barr Harbor Drive, Suite 200** **West Conshohocken, Pennsylvania**	**19428**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (267) 824-2827

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	MDGL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2024, Madrigal Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company's financial results for the fiscal quarter ended June 30, 2024. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K and the accompanying Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, unless expressly incorporated by reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Madrigal Pharmaceuticals, Inc., dated August 7, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MADRIGAL PHARMACEUTICALS, INC.

By: /s/ Mardi C. Dier
Name: Mardi C. Dier
Title: Senior Vice President and Chief Financial Officer

Date: August 7, 2024

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

- *Second-quarter 2024 net sales of $14.6 million*
- *Rezdiffra™ (resmetirom) coverage in place for more than 50 percent of commercial lives; less than 5 percent of Rezdiffra-covered lives require biopsy*
- *Expert guidelines recommend Rezdiffra as first-line therapy for patients with F2/F3 NASH/MASH*
- *Plans to directly commercialize resmetirom in Europe following EMA decision expected mid-year 2025*
- *Reports cash, cash equivalents, restricted cash and marketable securities of $1.1 billion at June 30, 2024*
- *Company to host conference call today, August 7, 2024, at 8 a.m. EDT*

CONSHOHOCKEN, Pa., August 7, 2024 – Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a biopharmaceutical company focused on delivering novel therapeutics for nonalcoholic steatohepatitis (NASH)/metabolic dysfunction-associated steatohepatitis (MASH), today reports second-quarter 2024 financial results and provides corporate updates.

Bill Sibold, Chief Executive Officer of Madrigal, stated, "We're off to a strong start with our U.S. launch of Rezdiffra and are encouraged by the high enthusiasm and early demand from physicians and patients, as well as the favorable coverage from payers. Our efforts to help healthcare practices build patient care pathways are progressing well, setting the stage for future growth. Given the strong start in the U.S., we aim to extend Madrigal's global leadership in NASH by directly commercializing Rezdiffra in Europe next year upon regulatory approval."

Mr. Sibold continued, "The urgent unmet need in NASH, which is the leading cause of liver transplant among women in the U.S., is driving the strong reception to Rezdiffra as the first and only approved therapy for NASH. Data presented at the EASL Congress demonstrating 91% efficacy in halting or improving liver stiffness, a key noninvasive measure of fibrosis, at three years reinforce the Rezdiffra efficacy profile; and the new EASL guidelines position Rezdiffra as the foundational NASH therapy."

Second Quarter and Recent Corporate Updates

- **Rezdiffra U.S. launch update**
  - On April 9, 2024, the Company announced U.S. availability of Rezdiffra, a once-daily, oral, liver-directed, THR-b agonist designed to target the underlying causes of NASH, which is the number-one cause of liver transplants for women in the U.S.
  - Madrigal is continuing to execute the U.S. launch of Rezdiffra, which is focused on building the foundation for future growth by educating the community on the clinical benefits of Rezdiffra, supporting the creation of care pathways for patients at physician offices, driving breadth and depth of Rezdiffra prescribers, and engaging with payers to increase Rezdiffra coverage.

- As of June 30, 2024, coverage for Rezdiffra is in place for more than 50 percent of commercial lives covered by health insurance in the U.S., tracking well towards the Company's goal of 80 percent of commercial lives covered by year-end 2024. 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.

- **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 with liver fibrosis to receive approval in Europe.
  - The Company plans to directly commercialize resmetirom in Europe following a decision from the EMA on the Marketing Authorization Application (MAA), which is expected mid-year 2025.
- **Expert guidelines recommend Rezdiffra as first-line therapy for NASH/MASH**
  - In July, updated clinical practice guidelines co-authored by the European Association for the Study of the Liver (EASL), the European Association for the Study of Diabetes (EASD), and the European Association for the Study of Obesity (EASO) for MASH were published in the *Journal of Hepatology* and recommend Rezdiffra as first-line therapy for patients with F2/F3 NASH/MASH where the medicine is available. The guidelines noted that Rezdiffra is the only disease-specific agent in MASH with positive results from a registrational Phase 3 clinical trial.
  - In July, "Expert Panel Recommendations: Practical Clinical Applications for Initiating and Monitoring Resmetirom in Patients with MASH/NASH and Moderate to noncirrhotic Advanced Fibrosis" were published in the *Journal of Clinical Gastroenterology and Hepatology*. These recommendations were written by well-recognized experts in NASH/MASH and provide practical guidance for the appropriate use of Rezdiffra, including patient identification, assessment of response and general monitoring.
- **Multiple abstracts presented at the EASL Congress in June**
  - A late breaking oral presentation that leveraged innovative AI technology provided deeper insight from the Phase 3 MAESTRO-NASH study of the antifibrotic effect of Rezdiffra and the role of THR-b as a suppressor of disease progression.
  - New analyses from noninvasive test data pointed to a durable Rezdiffra treatment response through three years including a 91% improvement or stabilization of liver stiffness (a surrogate for fibrosis), and a positive quality-of-life analysis showing the benefit of Rezdiffra treatment on patient worry, health distress and stigma.
  - The Company also presented for the first time an analysis of Rezdiffra treatment in patients with probable metabolic dysfunction and alcohol-associated liver disease, known as MetALD, which demonstrated that patients achieved similar rates of fibrosis improvement and steatohepatitis resolution compared to the NASH population.
  - Two health economics outcomes research studies in Medicare patients concluded that NASH patients are at a higher risk of progression, which is associated with higher costs, particularly at advanced stages. These studies concluded that interventions that can delay or prevent progression may reduce morbidity and mortality and deliver cost benefits.

Second-Quarter 2024 Financial Results

- **Total revenues:** The Company shipped Rezdiffra beginning in April and generated second-quarter 2024 net revenues of $14.6 million. No product sales were recognized during the comparable prior year period.
- **Cost of sales:** Second-quarter 2024 cost of sales were $0.6 million. Cost of sales were not recognized during the comparable prior year period given that no product sales were recorded.
- **Operating Expenses:** Second-quarter 2024 operating expenses were $177.2 million, compared to $86.5 million in the comparable prior year period.
  - **R&D Expense:** Second-quarter 2024 R&D expense was $71.1 million, compared to $68.6 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:** Second-quarter 2024 SG&A expense was $105.4 million, compared to $17.8 million in the comparable prior year period. The increase is primarily attributable to increases in prelaunch and launch activities for Rezdiffra, including significant commercial headcount expansion and stock compensation expense.
- **Interest Income:** Second-quarter 2024 interest income was $14.2 million, compared to $3.6 million in the comparable prior year period. The increase in interest income is due primarily to higher principal balances and interest rates in 2024.
- **Interest Expense:** Second-quarter 2024 interest expense was $3.7 million, compared to $2.9 million in the comparable prior year period. The increase in interest expense was a result of a higher outstanding principal balance during the period under the Company's loan facility.
- **Cash, Cash Equivalents, Restricted Cash and Marketable Securities:** As of June 30, 2024, Madrigal had cash, cash equivalents, restricted cash and marketable securities of $1.1 billion, compared to $634.1 million at Dec. 31, 2023. The increase in cash and marketable securities was primarily attributable to $574 million of net proceeds from the Company's March 2024 public offering partially offset by funding of operations.

Conference Call and Webcast

At 8 a.m. EDT today, August 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-b 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; future growth of Rezdiffra sales; projections or objectives for obtaining approval from EMA for Rezdiffra (resmetirom) and

expected commercialization of Rezdiffra (resmetirom) in Europe; the final number of patients who randomize in the MAESTRO-NASH trial, the estimated study duration for such trial and the anticipated timeframe for topline data from such trial; the U.S. opportunity for Rezdiffra in patients with stage 4 fibrosis (F4)/compensated cirrhosis; 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; 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.

Investor Contact

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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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Product revenue, net	$ 14,638	$ —	$ 14,638	$ —
Operating expenses:				
Cost of sales	636	—	636	—
Research and development	71,091	68,605	142,328	130,759
Selling, general and administrative	105,448	17,845	186,249	34,027
Total operating expenses	177,175	86,450	329,213	164,786
Loss from operations	(162,537)	(86,450)	(314,575)	(164,786)
Interest income, net	14,222	3,551	22,556	7,327
Interest expense	(3,656)	(2,901)	(7,493)	(5,237)
Net loss	$ (151,971)	$ (85,800)	$ (299,512)	$ (162,696)
Basic and diluted net loss per common share	$ (7.10)	$ (4.69)	$ (14.47)	$ (8.91)
Basic and diluted weighted average number of common shares outstanding	21,402,646	18,310,952	20,702,041	18,249,778

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

	June 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents, restricted cash, and marketable securities	$1,062,794	$ 634,131
Other current assets	28,934	3,150
Other non-current assets	8,061	3,266
Total assets	$1,099,789	$ 640,547
Liabilities and Equity		
Current liabilities	$ 125,162	$ 118,548
Long-term liabilities	117,507	116,666
Stockholders' equity	857,120	405,333
Total liabilities and stockholders' equity	$1,099,789	$ 640,547