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): May 9, 2023

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)**

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

(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))

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. ☐

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

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2023, Madrigal Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company's financial results for the fiscal quarter ended March 31, 2023. A copy of the press release is furnished herewith 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 Dated May 9, 2023.
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/ Brian J. Lynch
Name: Brian J. Lynch
Title: Senior Vice President and General Counsel

Date: May 9, 2023

Madrigal Pharmaceuticals Provides Corporate Updates and Reports First Quarter 2023 Financial Results

- *Resmetirom new drug application (NDA) filing on track for Q2 2023*
- *Resmetirom has received Breakthrough Therapy designation from FDA*
- *Multiple resmetirom abstracts accepted for presentation at EASL, including primary results and additional data from the Phase 3 MAESTRO-NASH trial*

CONSHOHOCKEN, PA, May 9, 2023 – Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), today provides a summary of corporate updates and reports first quarter 2023 financial results.

Paul Friedman, M.D., Chief Executive Officer of Madrigal, stated, "In the first quarter of 2023, the Madrigal team made significant progress advancing our regulatory preparations, disease education initiatives, and market access strategy. Additionally, we continue to execute against our clinical development objectives, and have completed enrollment of the MAESTRO-NASH trial. We are working diligently on the resmetirom approval process and recently announced that we obtained Breakthrough Therapy designation for resmetirom, reinforcing our confidence in our regulatory strategy and the planned NDA filing in Q2 2023."

Becky Taub, M.D., Chief Medical Officer and President of Research & Development of Madrigal, stated, "The MAESTRO-NASH primary trial data will be the opening presentation in the first general session of EASL's International Liver Meeting in June; we look forward to sharing additional results from the study and engaging in scientific exchange at this important scientific forum. In addition to our primary oral presentation focused on the MAESTRO-NASH biopsy results, we'll be presenting several abstracts from the MAESTRO program that provide a broader view of resmetirom treatment response."

Recent Corporate Highlights

- Madrigal announced that resmetirom has received Breakthrough Therapy designation from the FDA for the treatment of patients with NASH with liver fibrosis. A drug that receives Breakthrough Therapy designation is eligible for more intensive guidance on an efficient drug development program and organizational commitment involving senior managers from FDA.
- The MAESTRO-NASH registrational trial in noncirrhotic NASH has completed enrollment.
- Patient recruitment remains focused on MAESTRO-NASH-OUTCOMES, a noninvasive Phase 3 clinical outcome trial evaluating resmetirom in patients with well-compensated NASH cirrhosis with goals to support an additional indication in NASH cirrhosis and support long-term clinical benefit and full approval for noncirrhotic NASH.

- The Institute for Clinical and Economic Review (ICER) published an updated Evidence Report for its value assessment of resmetirom and obeticholic acid. The Evidence Report indicates that resmetirom has the potential to be a cost-effective treatment for patients with at-risk NASH.

Resmetirom Data Presentations at EASL

Multiple resmetirom abstracts have been accepted at EASL's International Liver Congress taking place June 21-24 in Vienna:

- Oral presentation: "Primary results from MAESTRO-NASH a pivotal phase 3 52-week serial liver biopsy study in 966 patients with NASH and fibrosis" [Thursday, June 22 at 10:30 AM. Presenter: Stephen Harrison]
- Poster: "Characterizing the histologic implications of resmetirom-induced liver volume reduction using artificial intelligence-powered digital pathology" [Presenter: Janani Iyer]
- Poster: "Resmetirom helps regulate thyroid hormone levels within the liver in patients with nonalcoholic fatty liver disease" [Presenter: Stephen Harrison]
- Poster: "Resmetirom improves the lipid/lipoprotein profile in patients with nonalcoholic fatty liver disease" [Presenter: Naim Alkhouri]
- Poster: "Imaging and biomarker thresholds to accurately diagnose NASH cirrhosis in a 180 patient biopsy confirmed cohort" [Presenter: Rohit Loomba]

NASH Epidemiology and Health Economics Outcomes Research Presentations at ISPOR

Five Madrigal posters focused on NASH epidemiology and health economics outcomes research are being presented at the ISPOR 2023 meeting taking place this week (May 7-10) in Boston:

- "NASH Progression Rates Based on Fibrosis and Inflammation (NAS): A Paired Biopsy Analysis from a Natural History Cohort in the US" [Presenter: Jesse Fishman]
- "The Impact of Treatment-related Changes in Lipids on the Cost-effectiveness of Resmetirom and Obeticholic Acid for Treatment of Nonalcoholic Steatohepatitis" [Presenter: Jesse Fishman]
- "Impact of Different Non-invasive Tests on Estimated Prevalence of Presumed Nonalcoholic Steatohepatitis Among US Adults, NHANES 2017-2020" [Presenter: Tom O'Connell]
- "Systematic Literature Review, Network Meta-analysis, and Cost-effectiveness Analysis of Resmetirom for the Treatment of Nonalcoholic Steatohepatitis" [Presenter: Jesse Fishman]]
- "Primary Cardiovascular Event Risk Associated With Nonalcoholic Steatohepatitis Among US Adults, NHANES 2017-2020" [Presenter: Tom O'Connell]

Financial Results for the Three Months Ended March 31, 2023

As of March 31, 2023, Madrigal had cash, cash equivalents and marketable securities of $329.5 million, compared to $358.8 million at December 31, 2022. The decrease in cash and marketable securities resulted primarily from cash used in operations of $84.1 million, partially offset by cash provided by financing and option exercise activities.

Operating expenses were $78.3 million for the three month period ended March 31, 2023, compared to $57.6 million in the comparable prior year period.

Research and development expenses for the three month period ended March 31, 2023 were $62.2 million, compared to $47.9 million in the comparable prior year period. The increase is attributable primarily to additional activities related to the Phase 3 clinical trial activities, including the MAESTRO-NASH Outcomes for which no expenses were incurred in the prior year quarter, and an increase in headcount.

General and administrative expenses for the three month period ended March 31, 2023 were $16.2 million, compared to $9.7 million in the comparable prior year period. The increase in general and administrative expenses for the latest three month period is due primarily to increases in commercial preparation activities, including an increase in headcount.

Interest income for the three month period ended March 31, 2023 was $3.8 million, compared to $0.1 million in the comparable prior year period. The increase in interest income was attributable primarily to higher interest rates and a greater principal balance.

Interest expense for the three month period ended March 31, 2023 was $2.3 million, compared to $0.0 million in the comparable prior year period. The increase in interest expense was attributable to the Loan Facility we entered into in May 2022.

About the Resmetirom Phase 3 Registration Program for the Treatment of NASH

Madrigal is currently conducting four Phase 3 clinical trials to demonstrate the safety and efficacy of resmetirom for the treatment of NASH: MAESTRO-NASH, MAESTRO-NAFLD-1, MAESTRO-NAFLD-OLE, and MAESTRO-NASH-OUTCOMES.

MAESTRO-NASH is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study of resmetirom in patients with liver biopsy-confirmed NASH and was initiated in March 2019. The subpart H portion of the study enrolled more than 1,000 patients with biopsy-proven NASH (at least half with F3 (advanced) fibrosis, the remainder F2 or F1B (moderate fibrosis) with a few earlier F1 patients, randomized 1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, or placebo. After 52 weeks of treatment, a second liver biopsy is performed. The dual primary surrogate endpoints on biopsy were NASH resolution with ≥2-point reduction in NAS (NAFLD Activity Score), and with no worsening of fibrosis OR a 1-point decrease in fibrosis with no worsening of NAS. Achievement of either primary endpoint was considered a successful trial outcome. A key secondary endpoint was lowering of LDL-C.

Patients enrolled in the MAESTRO-NASH study (approximately 1,750) continue on therapy after the initial 52-week treatment period for up to 54 months to accrue and measure hepatic clinical outcome events including progression to cirrhosis on biopsy (52 weeks and 54 months) and hepatic decompensation events, as well as all-cause mortality.

MAESTRO-NAFLD-1 was initiated in December 2019 and the 52-week multicenter, randomized, placebo-controlled Phase 3 study of resmetirom in over 1,200 patients with NAFLD, presumed NASH, has completed the double-blind arms and an open-label 100 mg arm. An additional open-label active treatment arm in patients with early (well-compensated) NASH cirrhosis is ongoing. The primary endpoint was to evaluate the safety and tolerability of resmetirom. A separate 52 week Phase 3 clinical trial, an open-label extension study of MAESTRO-NAFLD-1 (MAESTRO-NAFLD-OLE), is ongoing.

Patients in the 52-week Phase 3 MAESTRO-NAFLD-1 study were randomized 1:1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, placebo in double-blind arms or resmetirom 100 mg in an open-label arm. MAESTRO-NAFLD-1 (unlike MAESTRO-NASH), did not include a liver biopsy and represents a “real-life” NASH study. Patients with 3 metabolic risk factors were documented with NASH or NAFLD by historical liver biopsy or noninvasive techniques. Using noninvasive measures, MAESTRO-NAFLD-1 was designed to provide incremental safety information to support the NASH indication as well as provide additional data regarding clinically relevant key secondary efficacy endpoints to better characterize the potential clinical benefits of resmetirom on cardiovascular- and liver-related endpoints. The primary safety endpoint and several key secondary endpoints were met, including LDL-C, apolipoprotein B, and triglyceride lowering and reduction of liver fat as determined by MRI-PDFF. Additional secondary and exploratory endpoints were assessed including reduction in liver enzymes, FibroScan, and MRE scores, and other NASH biomarkers.

Data from the 52-week first 1,000 patient portion of MAESTRO-NASH, together with data from MAESTRO-NAFLD-1, MAESTRO-NAFLD-OLE, Phase 2 and Phase 1 data, including safety parameters, will form the basis for a planned subpart H submission to FDA for accelerated approval of resmetirom for treatment of NASH.

In August 2022, Madrigal initiated MAESTRO-NASH-OUTCOMES, a randomized double-blind placebo-controlled study in approximately 700 patients with early NASH cirrhosis to allow for noninvasive monitoring of progression to liver decompensation events. A positive outcome is expected to support the full approval of resmetirom for noncirrhotic NASH, potentially accelerating the timeline to full approval. In addition, this study has the potential to support an additional indication for resmetirom in patients with well-compensated NASH cirrhosis.

About NASH

Nonalcoholic steatohepatitis (NASH) is a more advanced form of nonalcoholic fatty liver disease (NAFLD). NAFLD is estimated to afflict more than 20% of adults globally, about 30% in the United States. Of that population, 20% may have NASH.

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 NASH progresses to significant liver fibrosis (stages F2 and F3) the risk of adverse liver outcomes increases dramatically. NASH is rapidly becoming the leading cause of liver transplantation in the U.S. There are currently no FDA-approved therapies available for the treatment of NASH.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), a liver disease with high unmet medical need. Madrigal's lead candidate, resmetirom, is a once daily, oral, thyroid hormone receptor (THR)-b selective agonist designed to target key underlying causes of NASH in the liver. For more information, visit www.madrigalpharma.com.

Forward Looking Statements

This communication 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, including the examples in the paragraph below; resmetirom's potential to be a cost-effective specialty therapy for NASH patients with significant liver fibrosis; and statements or references concerning—the potential efficacy and safety of 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, and the timing and results associated with the future development of resmetirom, the timing and completion of projected future clinical milestone events, including enrollment, additional studies, top-line data and open label projections, plans, objectives, timing and support for making for making a Subpart H (Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) submission to FDA, projections or objectives for obtaining accelerated or full approval for resmetirom, Madrigal's primary and key secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections, the potential to support an additional indication for resmetirom in patients with well-compensated NASH cirrhosis, optimal dosing levels for resmetirom and projections regarding potential NASH or NAFLD and potential patient benefits with resmetirom, including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment, and/or biomarker effects with resmetirom.

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" 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; 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 resmetirom's mechanism of action; the achievement of enrollment objectives concerning patient number, safety database and/or timing for Madrigal's studies; enrollment and trial conclusion uncertainties, generally and in relation to COVID-19 related measures and individual precautionary measures that may be implemented or continued for an uncertain period of time; market demand for and acceptance of our products; 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; the risks of achieving potential benefits in studies that includes substantially more patients, and patients with different disease states, than prior studies; the timing and outcomes of clinical studies of resmetirom; and the uncertainties inherent in clinical testing. 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 section appearing in Part I, Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 23, 2023, as updated from time to time by Madrigal's other filings with the SEC.

Investor Contact

Alex Howarth, Madrigal Pharmaceuticals, Inc., IR@madrigalpharma.com

Media Contact

Christopher Frates, Madrigal Pharmaceuticals, Inc., 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 March 31,	
	2023	2022
Revenues:		
Total revenues	$ —	$ —
Operating expenses:		
Research and development	62,154	47,929
General and administrative	16,182	9,658
Total operating expenses	78,336	57,587
Loss from operations	(78,336)	(57,587)
Interest income, net	3,776	69
Interest expense	(2,336)	—
Net loss	$ (76,896)	$ (57,518)
Basic and diluted net loss per common share	$ (4.23)	$ (3.36)
Basic and diluted weighted average number of common shares outstanding	18,187,924	17,103,395

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

	March 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 329,477	$ 358,774
Other current assets	1,807	2,595
Other non-current assets	1,165	1,203
Total assets	$ 332,449	$ 362,572
Liabilities and Equity		
Current liabilities	$ 98,348	$ 115,894
Long-term liabilities	83,965	49,289
Stockholders' equity	150,136	197,389
Total liabilities and stockholders' equity	$ 332,449	$ 362,572