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 8, 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 August 8, 2023, Madrigal Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company's financial results for the fiscal quarter ended June 30, 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 August 8, 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: August 8, 2023

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

- *Resmetirom new drug application (NDA) submitted to the U.S. Food and Drug Administration*
- *NASH disease education and market development activities expand to support potential first-to-market launch in the U.S.*

CONSHOHOCKEN, PA, August 8, 2023 – Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), today provides a summary of recent corporate accomplishments and reports second quarter 2023 financial results.

Paul Friedman, M.D., Chief Executive Officer of Madrigal, stated, “The recent submission of the resmetirom NDA represents an important milestone for Madrigal and the NASH community. Based on the depth and breadth of efficacy and safety data we have generated through the MAESTRO program, I believe we are well-positioned to support the FDA’s review of resmetirom. In parallel with our regulatory activities, our Commercial and Medical Affairs teams are intently focused on preparing for a potential first-to-market launch in the U.S.”

Becky Taub, M.D., Chief Medical Officer and President of Research & Development of Madrigal, stated, “In addition to the positive biopsy results supporting our regulatory filings in the U.S. and Europe, the MAESTRO program has generated extensive biomarker and imaging data to help advance noninvasive strategies that may be used in real-world clinical practice to identify appropriate patients for resmetirom and monitor treatment response. The MAESTRO-NASH results were featured in the opening session of the EASL Congress earlier this summer, and we look forward to presenting additional noninvasive data from the study at future scientific congresses.”

Remy Sukhija, Chief Commercial Officer of Madrigal, added, “As a once-daily, oral medication that is intended to treat the underlying causes of NASH in the liver, resmetirom has a unique opportunity to become the foundational therapy for patients with NASH with liver fibrosis. Our conviction in resmetirom’s potential is grounded in extensive market research with hepatologists and gastroenterologists. Based on the efficacy and safety data observed in the MAESTRO-NASH trial, these liver specialist physicians report strong intent-to-prescribe resmetirom for appropriate patients, if approved.”

Mr. Sukhija continued, “NASH care pathways are evolving rapidly in anticipation of an approved treatment, and the new recommendation from the American Diabetes Association to screen for NASH in patients with type 2 diabetes, alongside similar existing recommendations from hepatology and gastroenterology medical societies, should expand the population of identified patients in need of treatment. Additionally, Madrigal’s efforts to improve disease education – including the ‘NASH Explored’ campaign and the new ‘Taking on Fatty Liver and NASH’ campaign – are gaining momentum and driving engagement with healthcare providers, patients and payers.”

Recent Corporate Highlights

- Madrigal announced submission of the NDA seeking accelerated approval of resmetirom for the treatment of NASH with liver fibrosis. The clinical development program for resmetirom is comprised of 18 clinical studies supporting the NDA: twelve Phase 1 studies, two Phase 2 studies, and four Phase 3 studies.
- Madrigal presented the Phase 3 MAESTRO-NASH primary results during the opening general session of the EASL Congress™. This first scientific presentation of detailed MAESTRO-NASH results confirmed achievement of the primary endpoints across multiple patient subgroups. Noninvasive imaging and biomarker data supported findings on liver biopsy and demonstrated broad treatment response to resmetirom. Further analyses of the results reinforced the resmetirom safety and tolerability profile.
- Madrigal highlighted its support for International NASH Day and announced expanded partnerships with patient advocacy groups focused on NASH disease education.
- Madrigal launched Taking on Fatty Liver and NASH, a new disease education campaign and website that is designed to educate, inform, and inspire people with NASH with liver fibrosis to find the right care team, understand their risk, and manage their liver health. It provides information about NASH disease progression, noninvasive testing options, and community resources from patient advocacy groups.
- The Institute for Clinical and Economic Review (ICER) published a Final 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.

Financial Results for the Six Months Ended June 30, 2023

As of June 30, 2023, Madrigal had cash, cash equivalents and marketable securities of $298.4 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 $159.4 million, partially offset by the capital raised under the Loan Facility (“Loan Facility”) with Hercules Capital, Inc. (“Hercules”) and our at-the-market sales agreement.

Operating expenses were $86.5 million and $164.8 million for the three month and six month periods ended June 30, 2023, compared to $70.3 million and $127.9 million in the comparable prior year periods.

Research and development expenses for the three and six month periods ended June 30, 2023 were $68.6 million and $130.8 million, compared to $58.5 million and $106.4 million in the comparable prior year periods. The increase is attributable primarily to additional activities related to the Phase 3 clinical trials, and an increase in head count.

General and administrative expenses for the three and six month periods ended June 30, 2023 were $17.8 million and $34.0 million, compared to $11.8 million and $21.4 million in the comparable prior year periods. The increase is due primarily to increases in commercial preparation activities, including an increase in headcount and an increase in non-cash stock compensation.

Interest income for the three and six month periods ended June 30, 2023 was $3.6 million and $7.3 million, compared to $0.3 million and $0.4 million in the comparable prior year periods. The increase in interest income was due primarily to a higher average interest rate in 2023.

Interest expense for the three and six month periods ended June 30, 2023 was $2.9 million and $5.2 million, compared to $0.8 million and $0.8 million in the comparable prior year periods. The increase in interest expense was as a result of the Loan Facility we entered with Hercules.

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

Resmetirom is a once daily, oral, thyroid hormone receptor (THR)-b selective agonist designed to target key underlying causes of NASH in the liver.

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. The portion of the study designed to support a subpart H approval enrolled more than 1,000 patients with biopsy-proven NASH with fibrosis, randomized 1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, or placebo. 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 after 52 weeks of treatment. Achievement of either primary endpoint was considered a successful trial outcome.

In December 2022, Madrigal announced that both daily oral doses of resmetirom achieved both MAESTRO-NASH primary liver biopsy endpoints. Multiple secondary endpoints were also achieved, including statistically significant reductions by resmetirom as compared with placebo in atherogenic lipids and lipoproteins, liver enzymes, fibrosis biomarkers, and imaging tests.

Resmetirom was generally safe and well-tolerated at both the 80 mg and 100 mg doses. Consistent with previous Phase 2 and Phase 3 data, the most common adverse event reported with greater frequency in the resmetirom groups versus placebo was an excess of generally mild and transient diarrhea and nausea at the beginning of therapy.

Patients enrolled in MAESTRO-NASH (approximately 1,750 total enrollment) 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. This portion of the study is designed to generate confirmatory data that, if positive, will help verify resmetirom's clinical benefit and support full approval.

MAESTRO-NAFLD-1 was a 52-week multicenter, randomized, placebo-controlled, double-blind Phase 3 study of resmetirom in ~1,200 patients with NAFLD, presumed NASH. MAESTRO-NAFLD-1 might be considered a "real-world" NASH study in that diagnosis was based on noninvasive measures rather than liver biopsy. The primary endpoint was to evaluate the safety and tolerability of resmetirom.

Patients in the MAESTRO-NAFLD-1 study were randomized 1:1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, or placebo in double-blind arms or resmetirom 100 mg in an open-label arm. 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 of MAESTRO-NAFLD-1 and key secondary endpoints were achieved: resmetirom was safe, well-tolerated and provided statistically significant improvements in LDL-C, apolipoprotein B, triglycerides, and liver fat as measured by MRI-PDFF.

An additional open-label active treatment arm in 180 patients with early (well-compensated) NASH cirrhosis was conducted. Resmetirom was safe and well tolerated in the MAESTRO-NAFLD-1 open-label cohort of patients with well-compensated NASH cirrhosis. As observed in patients with noncirrhotic NASH, mild GI adverse events were seen at the beginning of therapy. Resmetirom reduced LDL-C, other atherogenic lipids and lipoproteins, and MRI-PDFF in patients with NASH cirrhosis and also reduced liver and spleen volume.

A separate 52 week Phase 3 clinical trial, an open-label active treatment extension study of MAESTRO-NAFLD-1 (MAESTRO-NAFLD-OLE), in about 700 patients is ongoing.

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, form the basis for Madrigal's subpart H submission to FDA for accelerated approval of resmetirom for treatment of NASH with liver fibrosis.

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.

In NASH, thyroid hormone beta activity in the liver is impaired, leading to a reduction in mitochondrial function and beta-oxidation of fatty acids, which in turn drive inflammation and liver fibrosis.

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 the first specialty therapy for NASH patients with significant liver fibrosis; statements concerning potential accelerated approval; 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, demonstrating clinical benefit to support accelerated approval, 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; 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 amended by our Form 10-K/A filed with the SEC on March 3, 2023, and as updated from time to time by Madrigal's other filings with the SEC.

Investor Contact

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Media 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,	
	2023	2022	2023	2022
Revenues:				
Total revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	68,605	58,499	130,759	106,428
General and administrative	17,845	11,774	34,027	21,432
Total operating expenses	86,450	70,273	164,786	127,860
Loss from operations	(86,450)	(70,273)	(164,786)	(127,860)
Interest income, net	3,551	323	7,327	392
Interest expense	(2,901)	(780)	(5,237)	(780)
Net loss	$ (85,800)	$ (70,730)	$ (162,696)	$ (128,248)
Basic and diluted net loss per common share	$ (4.69)	$ (4.14)	$ (8.91)	$ (7.50)
Basic and diluted weighted average number of common shares outstanding	18,310,952	17,103,395	18,249,778	17,103,395

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

	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$298,418	$ 358,774
Other current assets	3,177	2,595
Other non-current assets	866	1,203
Total assets	$302,461	$ 362,572
Liabilities and Equity		
Current liabilities	$ 99,706	$ 115,894
Long-term liabilities	99,249	49,289
Stockholders' equity	103,506	197,389
Total liabilities and stockholders' equity	$302,461	$ 362,572