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): January 8, 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 No.)**	**(I.R.S. Employer Identification No.)**

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

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

(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 8.01. Other Events

On January 8, 2024, Madrigal Pharmaceuticals, Inc. (the "Company") posted to its website a corporate presentation slide deck that the Company intends to use for investor communications. A copy of the corporate presentation slide deck is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibits are filed as part of this report:

Exhibit Number	Description
99.1	Corporate Presentation of Madrigal Pharmaceuticals, Inc. (January 8, 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, thereunto duly authorized.

Madrigal Pharmaceuticals, Inc.
(the Registrant)

Date: January 8, 2024

By: /s/ Brian J. Lynch
Brian J. Lynch
Senior Vice President and General Counsel

Exhibit 99.1

Madrigal Pharmaceuticals

Corporate Presentation

January 2024

Resmetirom is an investigational therapy and has not been approved by the FDA (or any other regulatory authority). Resmetirom is only available for use in a clinical trial setting (ClinicalTrials.gov NCT03900429, NCT04197479, NCT05500222).

NASDAQ: MDGL

Forward Looking Statements

This presentation 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; projections or objectives for obtaining accelerated or full approval for resmetirom, including all statements concerning potential clinical benefit to support accelerated approval and/or potential approval; and statements or references concerning - the relationship between NASH progression and adverse patient outcomes; the estimated clinical burden of uncontrolled NASH; analyses for patients with NASH with significant fibrosis concerning potential progression to cirrhosis, decompensated cirrhosis, liver transplant or death, and cardiovascular risks, comorbidities and outcomes; health economics assessments or projections, 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, 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 patient populations, our launch focus on patients, pricing for resmetirom, and potential patient benefits with resmetirom, including future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment, and/or biomarker effects with resmetirom 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" 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; our ability to prevent and/or mitigate cyber-attacks, unauthorized exfiltration of data or other security incidents; 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; the uncertainties inherent in clinical testing; 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, 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 Part II, Item 1A of its Quarterly Reports on Form 10-Q for the quarters ended June 30, 2023 and September 30, 2023, and as updated from time to time by Madrigal's other filings with the SEC.

Madrigal

The Madrigal Opportunity

Building the Leading Biopharmaceutical Company in NASH

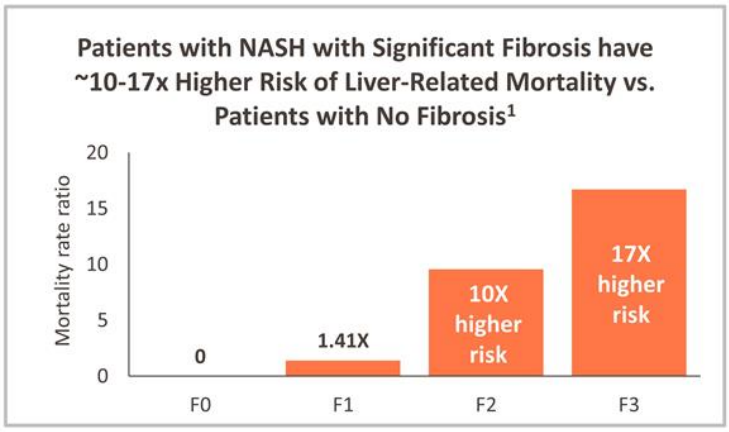
NASH, nonalcoholic steatohepatitis; THR-β, thyroid hormone receptor-β

Taking on a Serious Liver Disease

NASH with Significant Fibrosis Carries a High Burden for Patients

NASH increases risk of cirrhosis, liver failure, liver cancer, and premature mortality

- Risk of liver-related mortality increases substantially once significant fibrosis develops[1,2]
- Incidence of associated HCC expected to double between 2015 and 2030[3]
- Leading cause of liver transplants in the U.S. for women, soon to be overall[4]



Goal: Treat NASH with significant fibrosis prior to negative patient outcomes

~22% of patients with stage 3 fibrosis progress to cirrhosis within 2 years[5]

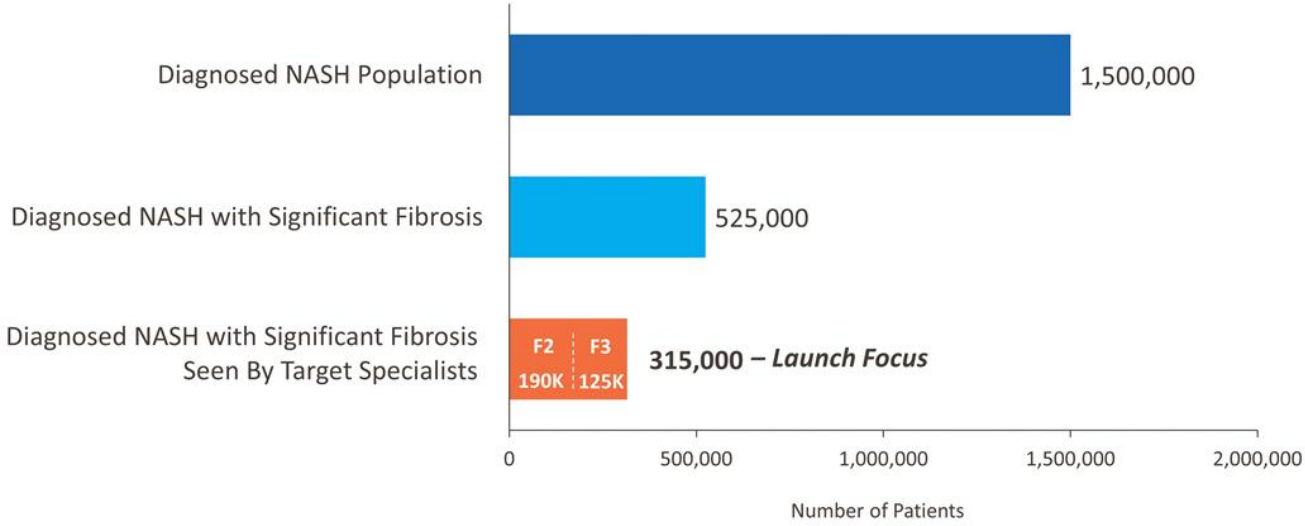
HCC, hepatocellular carcinoma

1. Angulo P, et al. *Gastroenterology*. 2015;149:389-397. 2. Dulai PS, et al. *Hepatology*. 2017;65:1557-1565. 3. Estes C, et al. *Hepatology*. 2018 Jan;67(1):123-133. 4. Noureddin M, et al. *Am J Gastroenterol*. 2018 Nov;113(11):1649-1659. 5. Loomba R, Adams L. *Hepatology*. 2019;70(6):1885-1888.

Focusing on Patients Who are Most in Need

Specialty Launch Will Focus on Patients With Significant Fibrosis (Consistent with F2/F3) Seen by Heps/GIs

U.S. NASH Waterfall at Launch[1]



Heps, hepatologists; GIs, gastroenterologists

1. Forian Claims Data; Clearview Analysis; Fishman J, et al. Poster presented at: ISPOR 2023; May 7-10, 2023; Boston, MA.

A Liver-directed Oral Therapy

Resmetirom to Become the FIRST Foundational Therapy for NASH with Significant Fibrosis

Differentiated Mode of Action

THR-ß selective agonist that normalizes the liver's critical role in fat metabolism

MOA differentiated vs. injectable therapies that treat NASH indirectly

Compelling Product Profile

Liver-directed oral therapy

Efficacy in resolving NASH and **improving fibrosis**

Favorable emerging **safety and tolerability** profile

Robust Evidence to Support Value

Health economics outcomes research supports resmetirom value

ICER cost-effectiveness range of **$39,600 – $50,100** per year[1]

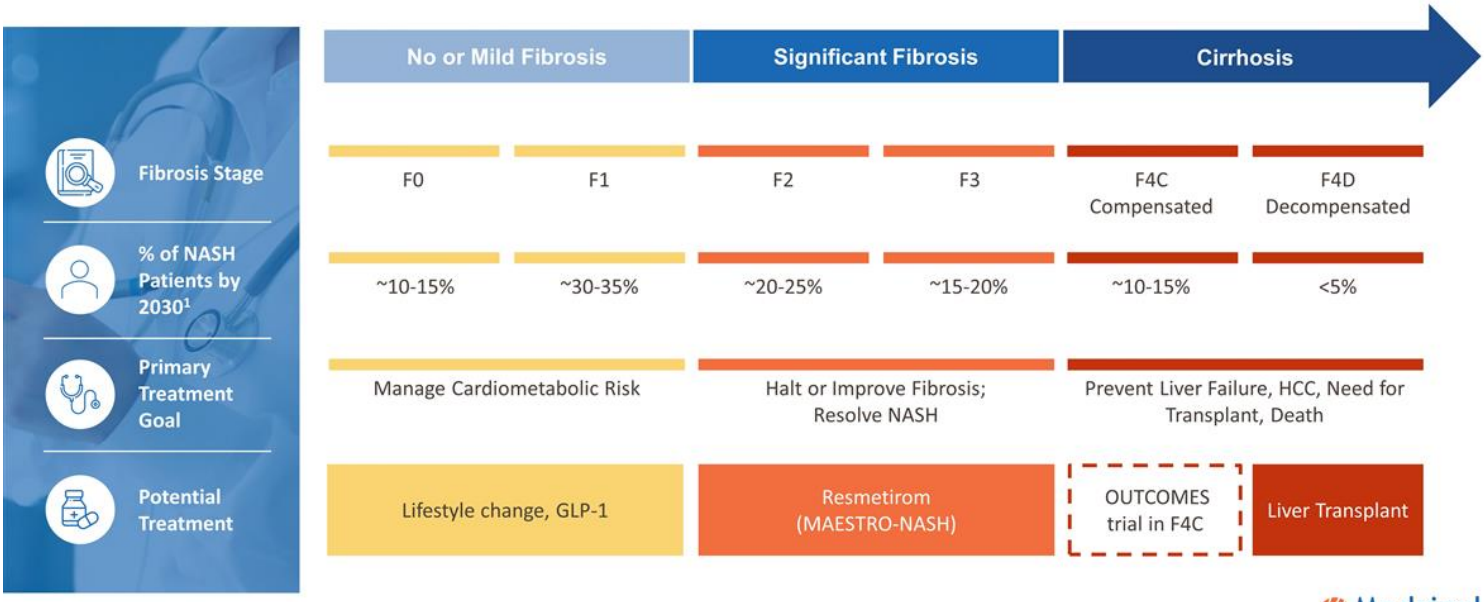
Resmetirom is an investigational therapy and has not been approved by the FDA (or any other regulatory authority)

MOA, mechanism of action

1. Institute for Clinical and Economic Review (ICER). Final Evidence Report and Meeting Summary. Last accessed December 4, 2023.

Resmetirom Position in the NASH Treatment Paradigm

Significant Opportunity for Resmetirom Where Unmet Need is Highest



1. Estes C, et al. *Hepatology*. 2018 Jan;67(1):123-133.

The MAESTRO Phase 3 Program

The Most Advanced and Comprehensive Clinical Development Program in NASH

MAESTRO-NASH Significant Fibrosis	MAESTRO-NAFLD-1 Safety	MAESTRO-NASH OUTCOMES Compensated Cirrhosis
Evaluates NASH resolution and/or fibrosis improvement on liver biopsy and composite clinical events	Evaluates safety & tolerability as measured by incidence of adverse events	Event-driven trial evaluating progression to hepatic decompensation
52 weeks biopsy (completed) 54 months clinical outcomes	52 weeks (completed)	~36 months
~1700 patients (ongoing)	**~1200** patients, including 200 with compensated cirrhosis	**~700** patients (recruiting)

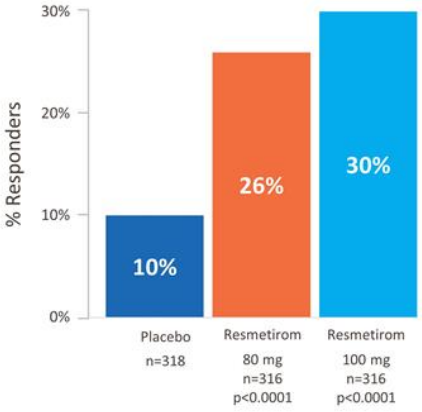
Madrigal

The Pivotal Phase 3 MAESTRO-NASH Trial

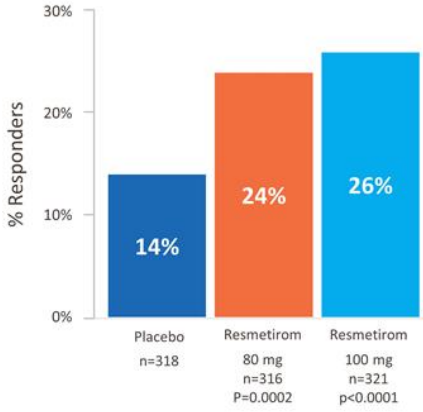
FIRST Phase 3 Trial to Achieve NASH Resolution and Fibrosis Improvement Primary Endpoints

Primary Endpoints

NASH Resolution[1]

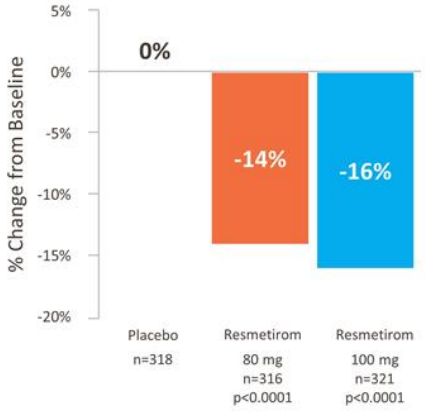


≥1 Stage Fibrosis Improvement[1]



Secondary Endpoint[2]

LDL Cholesterol



Both primary liver biopsy endpoints and the key secondary endpoint of LDL cholesterol lowering were met

1. NASH Resolution (ballooning score=0, inflammation score=0/1, & ≥2-point reduction in NAFLD Activity Score (NAS)) with no worsening of fibrosis; ≥1 Stage Fibrosis Improvement with no worsening of NAS.
2. LDL cholesterol secondary endpoint measured at Week 24

The Pivotal Phase 3 MAESTRO-NASH Trial

Favorable Emerging Safety and Tolerability Profile

n (%)	Resmetirom 80mg (n=322)	Resmetirom 100mg (n=323)	Placebo (n=321)
≥1 TEAEs	**296 (91.9)**	**296 (91.6)**	**269 (92.2)**
Grade 1 (mild)	71 (22.0)	65 (20.1)	77 (24.0)
Grade 2 (moderate)	180 (55.9)	183 (56.7)	167 (52.0)
≥ Grade 3 (severe)	45 (14.0)	48 (14.9)	52 (16.2)
≥1 drug-related TEAEs	122 (37.9)	134 (41.5)	86 (26.8)
≥1 serious TEAEs	**38 (11.8)**	**41 (12.7)**	**39 (12.1)**
≥1 drug-related serious TEAEs	2 (0.6)	0	1 (0.3)
TEAEs leading to study discontinuation (in 52 Weeks)	**6 (1.9)**	**22 (6.8)**	**8 (2.5)**
Fatal TEAE	**1 (0.3)**	**1 (0.3)**	**1 (0.3)**
3-pt MACE* (adjudicated)	**1 (0.3)**	**1 (0.3)**	**1 (0.3)**
Other cardiovascular events (adjudicated)	**0**	**1 (0.3)**	**3 (0.9)**

Study discontinuations in the 100 mg arm were increased relative to placebo only during the first 12 weeks and were similar in all treatment groups for the remaining period of the first 52 weeks; after 52 weeks, placebo discontinuations were higher than drug treatment arms

Most AE discontinuations in the 100 mg arm were **GI-related.** No increase in the incidence of diarrhea and nausea was noted among resmetirom-treated patients relative to placebo-treated patients after the first few weeks of treatment

No drug-induced liver injury events (adjudicated)

*Nonfatal stroke, nonfatal myocardial infarction, & cardiovascular death.

Madrigal

Building for the Future

First-to-Market Advantage Provides a Long-Term NASH Leadership Opportunity

Build Organization

- Hire, train and deploy teams

Develop Market

- Educate stakeholders, establish path from Dx to Rx fulfillment, secure market access

Execute Specialty Launch

- Target specialists (Heps, GIs) + Patients with NASH with significant fibrosis (315,000)