

**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 6, 2023

MADRIGAL PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33277
(Commission
File No.)

04-3508648
(I.R.S. Employer
Identification No.)

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

19428
(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))

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 8.01 Other Events.

On December 19, 2022, Madrigal (“Madrigal” or the “Company”) announced (and reported on Form 8-K) MAESTRO-NASH primary endpoint results from its Phase 3 MAESTRO-NASH clinical trial of resmetirom for the treatment of nonalcoholic steatohepatitis (NASH), which are summarized in the first chart below as Table 1. On January 6, 2023, Madrigal announced (via press release that was posted to the Company’s website coincident with its public release) an additional supportive analysis, which is summarized in the second chart below as Table 2. This additional supportive analysis was subsequently presented by the Company at the NASH-TAG Conference in Park City, Utah. The supportive analysis is a “consensus read” by the central pathologists of digitized biopsy images, which supplements the topline results summarized in Table 1 below.

All baseline and Week 52 biopsies in MAESTRO-NASH were read independently by two central pathologists (glass slides) for the primary analysis read (see the first chart below, Table 1). Each pathologist’s scores showed a similar statistically significant magnitude of response at both doses for both liver biopsy endpoints.

As a supportive analysis, a “consensus read” of digitized biopsy images (see the second chart below, Table 2) was conducted in cases where the two pathologists scores disagreed as to whether there was a response for either the NASH resolution or fibrosis improvement primary endpoints.

Table 1. Dual Primary Endpoints (52 Weeks) – Primary Analysis

Primary Endpoint	Resmetirom 80 mg (n=316)	p-value	Resmetirom 100 mg (n=321)	p-value	Placebo (n=318)
NASH resolution (ballooning 0, inflammation 0,1) with ≥ 2 -point reduction in NAS and no worsening of fibrosis	26%	<0.0001	30%	<0.0001	10%
≥ 1 -stage improvement in fibrosis with no worsening of NAS	24%	0.0002	26%	<0.0001	14%

Table 2. Dual Primary Endpoints (52 Weeks) – Consensus Read Supportive Analysis

Primary Endpoint	Resmetirom 80 mg (n=316)	p-value	Resmetirom 100 mg (n=321)	p-value	Placebo (n=318)
NASH resolution (ballooning 0, inflammation 0,1) with ≥ 2 -point reduction in NAS and no worsening of fibrosis	24%	<0.0001	28%	<0.0001	8%
≥ 1 -stage improvement in fibrosis with no worsening of NAS	24%	<0.0001	26%	<0.0001	12%

MAESTRO-NASH is an ongoing blinded Phase 3 clinical trial, and enrolled patients continue on therapy after the Week 52 liver biopsy for up to a total of 54 months to accrue hepatic clinical outcome events including histologic conversion to cirrhosis and hepatic decompensation events.

Forward Looking Statements

This Current Report 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 include: all statements that are not historical facts; statements referenced by forward-looking statement identifiers, including the examples in the paragraph below; 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,” “continue,” “could,” “demonstrates,” “design,” “estimates,” “expectation,” “expects,” “forecasts,” “future,” “goal,” “help,” “hopeful,” “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, 2021, filed with the SEC on February 24, 2022, as updated by the risk factors discussed in Part II, Item 1A of the Quarterly Report on Form 10-Q filed with the SEC on May 9, 2022, as well as in Madrigal’s other filings with the SEC.

SIGNATURES

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

Madrigal Pharmaceuticals, Inc.

Date: January 10, 2023

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