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 7, 2020

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))

Securities registered pursuant to Section 12(b) of the Exchange 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 May 7, 2020 Madrigal Pharmaceuticals, Inc. (the "Company") issued a press release announcing the Company's financial results for its first fiscal quarter ended March 31, 2020. 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 7, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL file)

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/ Marc R. Schneebaum
Name: Marc R. Schneebaum
Title: SVP and Chief Financial Officer

Date: May 7, 2020

Madrigal Pharmaceuticals Reports 2020 First Quarter Financial Results and Highlights

CONSHOHOCKEN, Pa., May 7, 2020 — Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its first quarter 2020 financial results and highlights:

“Madrigal continued to make progress toward our clinical development and business objectives during the first quarter of 2020, despite challenges associated with the COVID-19 pandemic. Importantly, we continued to screen and enroll patients in our Phase 3 studies, MAESTRO-NASH and MAESTRO-NAFLD-1,” stated Paul Friedman, M.D., Chief Executive Officer of Madrigal. “We are also pleased that Remy Sukhija has joined Madrigal as Senior Vice President and Chief Commercial Officer. Remy brings extensive commercial experience to Madrigal, having successfully launched multiple products in specialty, primary care and rare disease markets over his 27 years in pharmaceutical/biotech industry. His expertise in product launch, sales and marketing, and market access will be valuable as we continue to execute our Phase 3 clinical programs and continue to explore the market opportunity for resmetirom.”

Becky Taub, M.D., CMO and President, Research & Development of Madrigal stated, “In response to the COVID-19 pandemic, and related direction from regulatory agencies, we rapidly implemented guidance to permit more flexible processes at those clinical sites impacted and allow patients to progress through the screening process or continue their enrollment in our Phase 3 NASH studies. Also, as a result of the pandemic and the resulting postponement or cancellation of two significant medical conferences, we were pleased to have the opportunity to announce new data from previous studies, which demonstrate that reductions in liver fat achieved by resmetirom predict NASH resolution and fibrosis improvement. Specifically, as we have showed, once daily oral 80 mg and 100 mg Phase 3 doses of resmetirom deliver at least 50% to more than 60% reductions in liver fat, respectively, and, based on new analyses of Phase 2 data, are associated with a statistically significant 64% NASH resolution ($p<0.0001$), of which >60% had fibrosis reduction.”

Financial Results for the Three Months Ended March 31, 2020

As of March 31, 2020, Madrigal had cash, cash equivalents and marketable securities of $408.5 million, compared to $439.0 million at December 31, 2019. The decrease in cash and marketable securities resulted primarily from cash used in operations of $30.5 million.

Operating expenses were $38.0 million for the three month period ended March 31, 2020, compared to $18.1 million in the comparable prior year period.

Research and development expenses for the three month period ended March 31, 2020 were $33.4 million, compared to $12.4 million in the comparable prior year period. The increases are primarily attributable to the initiation of the Phase 3 clinical trial in NASH, an increase in head count, and an increase in non-cash stock compensation from stock option awards.

General and administrative expenses for the three month period ended March 31, 2020 were $4.6 million, compared to $5.7 million in the comparable prior year period. The decrease in general and administrative expenses for the latest three month period was due primarily to a decrease in non-cash stock compensation from stock option awards, which was partially offset by increases in other general and administrative expenses.

Interest income for the three month period ended March 31, 2020 was $1.9 million, as compared to $3.0 million in the comparable prior year period. The decrease in interest income for the latest three month period was due primarily to lower average principal balances in our investment accounts in 2020, and lower interest rates.

About Resmetirom (MGL-3196)

Thyroid hormone, through activation of its ß-receptor in hepatocytes, plays a central role in liver function impacting a range of health parameters from levels of serum cholesterol and triglycerides to the pathological buildup of fat in the liver. Thyroid hormone receptor (THR)-ß action in the liver is key to proper function of the liver, including regulation of mitochondrial activity such as breakdown of liver fat and control of the level of normal, healthy mitochondria. Patients with NASH have reduced levels of thyroid hormone activity in the liver with resultant impaired hepatic function, in part due to the inflamed state of the liver that causes degradation of thyroid hormone.

To exploit the thyroid hormone receptor (THR)-ß pathway for therapeutic purposes in cardio-metabolic and liver diseases, it is important to avoid activity at the THR-α receptor, the predominant systemic receptor for thyroid hormone that is responsible for activity outside the liver including in heart and bone. The lack of selectivity of older thyromimetic compounds, chemically-related toxicities and undesirable distribution in the body led to safety concerns. Madrigal recognized that greater selectivity for thyroid hormone receptor (THR)-ß and liver targeting might overcome these challenges and deliver the full therapeutic potential of THR-ß agonism. Resmetirom has been shown to be highly selective based on 1) THR-ß receptor functional selectivity based on both in vitro and in vivo assays 2) specific uptake into the liver, its site of action, virtually avoiding any uptake into tissues outside the liver. In short and long term human and animal studies, resmetirom has been confirmed to be safe and devoid of activity at the THR-α receptor and without impact on bone or cardiac parameters. Resmetirom does not impact the thyroid axis hormones, including the central thyroid axis. Madrigal believes that resmetirom is the first orally administered, small-molecule, liver-directed, truly ß-selective THR agonist.

About the Phase 3 Registration Program for the Treatment of NASH (Non-alcoholic steatohepatitis)

Analyses from the resmetirom Phase 2 NASH study demonstrate that the magnitude of liver fat reduction accurately predicts NASH resolution and liver fibrosis reduction and, specifically, that the resmetirom doses being used in Madrigal's Phase 3 MAESTRO-NASH trial could achieve the level of fat reduction predictive of NASH resolution and fibrosis reduction [Madrigal COVID and ABSTRACT Press Release_20200414].

The Phase 3 MAESTRO-NASH trial is expected to enroll 900 patients with biopsy-proven NASH (fibrosis stage 2 or 3), randomized 1:1:1 to receive resmetirom 80 mg once a day, 100 mg once a day, or placebo. After 52 weeks of treatment a second biopsy is performed. The primary surrogate endpoint on biopsy will be NASH resolution, with at least a 2-point reduction in NAS (NASH Activity Score), and with no worsening of fibrosis. Two key secondary endpoints are liver fibrosis improvement of at least one stage, with no worsening of NASH, and lowering of LDL-cholesterol [ClinicalTrials.gov/NCT03900429].

A second 52-week Phase 3 multi-center, double-blind, randomized, placebo-controlled study of resmetirom, MAESTRO-NAFLD-1, was initiated in December 2019 in 700 patients with non-alcoholic fatty liver disease (NAFLD), presumed NASH, randomized 1:1:1 to receive resmetirom 80 mg once a day, 100 mg once a day, or placebo. MAESTRO-NAFLD-1 also includes a 100 mg resmetirom open label arm in up to 100 patients. Unlike MAESTRO-NASH, MAESTRO-NAFLD-1 is a non-biopsy study and represents a "real-life" NASH study. NASH or presumed NASH is documented using historical liver biopsy or non-invasive techniques including fibroscan and MRI-PDFF. Using non-invasive measures, MAESTRO-NAFLD-1 is 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. These key secondary endpoints include LDL-cholesterol, apolipoprotein B and triglyceride (TG) lowering; reduction of liver fat as determined by magnetic resonance imaging, proton density fat fraction (MRI-PDFF); and reduction of PRO-C3, a NASH fibrosis biomarker. [ClinicalTrials.gov/NCT04197479] Additional secondary and exploratory endpoints will be assessed including reduction in liver enzymes, fibroscan scores and other fibrosis and inflammatory biomarkers. These and other data, including safety parameters, form the basis for potential subpart H submission to FDA for accelerated approval for the treatment of NASH. The original 900 patients in the MAESTRO-NASH study will continue on therapy after the initial 52-week treatment period; up to another 1,100 patients are to be added using the same randomization plan and the study is expected to continue for up to 54 months to accrue and measure clinical events, most relevantly progression to cirrhosis.

About Resmetirom's Potential to Confer Cardiovascular Risk Reduction in NASH patients

Additionally, resmetirom lowers multiple atherogenic lipids, including LDL cholesterol, apolipoprotein B, triglycerides, and lipoprotein (a), as demonstrated in Phase 2, a key differentiating factor compared with other NASH therapeutics. The magnitude of reduction of these lipids support a potential indication for treatment of hyperlipidemia in NASH patients and predicts a potential for benefit on cardiovascular (CV) events in NASH patients who die most frequently of CV, not liver disease.

Because of their diabetes, dyslipidemia, hypertension, obesity in concert with an inflamed, fatty liver, NASH patients, particularly those with advanced fibrosis, are at a substantially increased CV risk compared to the general population. Resmetirom's ability to decrease liver fat, which is an independent risk factor for CV events, and resmetirom's effect to reduce atherogenic lipids are being further evaluated in several key secondary endpoints in both MAESTRO Phase 3 clinical studies.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) is a clinical-stage biopharmaceutical company pursuing novel therapeutics that target a specific thyroid hormone receptor pathway in the liver, which is a key regulatory mechanism common to a spectrum of cardio-metabolic and fatty liver diseases with high unmet medical need. Madrigal's lead candidate, resmetirom, is a first-in- class, orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR)-ß selective agonist that is in currently in two Phase 3 clinical studies, MAESTRO-NASH and MAESTRO-NAGLD-1, designed to demonstrate multiple benefits across a broad spectrum of NASH (non-alcoholic steatohepatitis) and NAFLD (non-alcoholic fatty liver disease) patients. For more information, visit www.madrigalpharma.com.

Forward-Looking Statements

This communication contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, that are based on our beliefs and assumptions and on information currently available to us, but are subject to factors beyond our control. Forward-looking statements include but are not limited to statements or references concerning: our clinical trials, research and development activities, and the timing and results associated with the future development of our lead product candidate, MGL-3196 (resmetirom); our primary and secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections; optimal dosing levels for resmetirom; projections regarding potential future NASH resolution, safety, fibrosis treatment, cardiovascular effects, lipid treatment or biomarker effects with resmetirom; the predictive power of liver fat reduction on NASH resolution with fibrosis reduction or improvement; the achievement of enrollment objectives concerning patient number, safety database and/or timing for our studies; potential NASH or NAFLD patient risk profile benefits with resmetirom; and our possible or assumed future results of operations and expenses, business strategies and plans, capital needs and financing plans, trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things. Forward-looking statements: reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events; include all statements that are not historical facts; and can be identified by terms such as "anticipates," "be," "believes," "continue," "could," "demonstrates," "design," "estimates," "expects," "forecasts," "future," "goal," "intends," "may," "might," "plans," "potential," "predicts," "predictive," "projects," "seeks," "should," "will," "would" or similar expressions and the negatives of those terms. Although management presently believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements.

Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to: our clinical development of resmetirom; enrollment uncertainties, generally and in relation to COVID-19 mandatory lock-down measures and individual precautionary measures that may be implemented for an uncertain period of time; outcomes or trends from competitive studies; the risks of achieving potential benefits in studies that includes substantially more patients than our 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 filings with the U.S. Securities and Exchange Commission 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. We specifically discuss these risks and uncertainties in greater detail in the section entitled "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, as well as in our other filings with the SEC.

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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 March 31,	
	2020	2019
Revenues:		
Total revenues	$ —	$ —
Operating expenses:		
Research and development	33,400	12,373
General and administrative	4,605	5,746
Total operating expenses	38,005	18,119
Loss from operations	(38,005)	(18,119)
Interest income (expense), net	1,870	3,039
Other income	—	—
Net loss	$ (36,135)	$ (15,080)
Basic and diluted net loss per common share	$ (2.34)	$ (0.98)
Basic and diluted weighted average number of common shares outstanding	15,429,154	15,364,465

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

	March 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	$ 408,510	$ 439,045
Other current assets	976	1,152
Other non-current assets	1,971	1,859
Total assets	$ 411,457	$ 442,056
Liabilities and Equity		
Current liabilities	$ 25,703	$ 25,130
Long-term liabilities	279	361
Stockholders' equity	385,475	416,565
Total liabilities and stockholders' equity	$ 411,457	$ 442,056