Madrigal Pharmaceuticals

Fact Sheet

MDGL

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NASDAQ

MADRIGAL PHARMACEUTICALS

QUICK REFERENCE

Madrigal Pharmaceuticals
NASDAQ: MDGL
www.MADRIGALPHARMA.com

BUSINESS SUMMARY

Madrigal Pharmaceuticals, Inc. 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)-β selective agonist designed to target key underlying causes of NASH in the liver.

The company has advanced its lead candidate, resmetirom, a once daily, oral, thyroid hormone receptor (THR) β-selective agonist, into four Phase 3 clinical trials in NASH. Based on positive results reported to date, Madrigal believes resmetirom has the potential to become the first medication approved for the treatment of patients with NASH.

NASH is a growing global health burden in all regions of the world. There are an estimated 22 million people living with NASH in the U.S. alone, and 8 million who have NASH with significant liver fibrosis.

NASH: A Disease with No FDA-Approved Treatment

Non-alcoholic steatohepatitis (NASH) is a more advanced form of non-alcoholic 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% have NASH.

PROGRAMS

Late-stage Clinical Program

Madrigal is conducting an extensive Phase 3 clinical program to support registration in the U.S., the EU and beyond. The long-term goal of the resmetirom development program is to demonstrate benefit to patients with NASH by reversing liver disease and/or preventing progression to more serious conditions including cirrhosis and liver cancer.

- MAESTRO-NASH: A Phase 3 Safety and Efficacy Study
- MAESTRO-NAFLD-1: A Phase 3 Safety and Tolerability Study
- An Open Label Arm Study Will Assess Non-Invasive Measures of Safety and Efficacy in Non-cirrhotic and Cirrhotic Populations
- MAESTRO-NASH Outcomes: A Noninvasive Phase 3 Outcomes Study in Patients with Compensated NASH Cirrhosis
- Resmetirom Reduced Liver Fat and Helped Patients Achieve NASH Resolution in a Phase 2 Study

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

Madrigal Pharmaceuticals Provides an Overview of Upcoming Resmetirom Data Presentations and Reports 2022 Third Quarter Financial Results

- Two resmetirom oral abstracts to be presented at the AASLD Liver Meeting®:
  - Phase 3 MAESTRO-NAFLD-1 data demonstrate the potential of resmetirom for the treatment of patients with compensated NASH cirrhosis
  - Screening data from the Phase 3 MAESTRO-NASH biopsy study provide new insights on noninvasive strategies for patient identification
- Madrigal remains on track to announce topline data from the Phase 3 MAESTRO-NASH biopsy study in the fourth quarter

Nov. 03, 2022 -- Madrigal Pharmaceuticals, Inc. today provides an overview of upcoming resmetirom Phase 3 data presentations and reports third quarter 2022 financial results.

Presentations at the AASLD Liver Meeting
The following abstracts have been accepted for presentation at the AASLD Liver Meeting, taking place November 4-8 in Washington, DC:

Oral Presentation (abstract 100): Sunday, November 6th
A 52-week Phase 3 clinical trial of resmetirom in 180 patients with well-compensated NASH cirrhosis. Presenter: Stephen Harrison
In patients with well-compensated cirrhosis included in an open-label active resmetirom treatment arm of the Phase 3 MAESTRO-NAFLD-1 safety study, resmetirom lowered markers of cardiovascular risk and NASH fibrosis. Following 52 weeks of treatment with resmetirom, patients achieved reductions in magnetic resonance imaging proton density fat fraction (MRI-PDFF), FibroScan controlled attenuation parameter (CAP), FibroScan vibration-controlled transient elastography (VCTE), magnetic resonance elastography (MRE), liver and spleen volume, ALT, AST, GGT, LDL-C, triglycerides, ApoB, and lipoprotein (a). Resmetirom appeared safe and was well-tolerated during 52 weeks of treatment.

Oral Presentation (abstract 102): Sunday, November 6th
Utility of FIB-4, MRE, MRI and FibroScan to identify patients with at-risk F2-F3 NASH based on screening data from a 2000 patient biopsy confirmed cohort of the resmetirom Phase 3 clinical trial, MAESTRO-NASH. Presenter: Rohit Loomba
FIB-4 of ≥1.3 is frequently used to identify potential at-risk patients with NASH, but an analysis of screening data from the MAESTRO-NASH biopsy study found this threshold lacked the sensitivity to accurately identify patients with NASH with significant fibrosis (F2-F3). The authors concluded the influence of age on FIB-4 may require an age adjustment to ensure younger patients are not removed from consideration for therapy. MRE, MAST (MRI-AST) and FAST (FibroScan-AST) showed reasonable accuracy for identifying patients with NASH with significant fibrosis.

Financial Results for the Nine Months Ended September 30, 2022
As of September 30, 2022, Madrigal had cash, cash equivalents and marketable securities of $153.2 million, compared to $270.3 million at December 31, 2021. This decrease in cash and marketable securities resulted primarily from cash used in operations for the nine months ended September 30, 2022 of $166.3 million, partially offset by the net proceeds ($49 million) from the Loan Facility ("Loan Facility") with Hercules Capital, Inc. ("Hercules").

Madrigal Pharmaceuticals to Participate in the H.C. Wainwright 24th Annual Global Investment Conference

Sept. 07, 2022 -- Madrigal Pharmaceuticals, Inc. announced today its management team will participate in a fireside chat at the H.C. Wainwright 24th Annual Global Investment Conference on Monday, September 12, 2022 at 9:30 am ET.

The fireside chat will be webcast and an archived recording will be available for replay in the Investors & Media section of the Madrigal website following the event.

Madrigal Pharmaceuticals Initiates the MAESTRO-NASH Outcomes Study Evaluating Resmetirom for the Treatment of Patients with Compensated NASH Cirrhosis

Aug. 31, 2022 -- Madrigal Pharmaceuticals, Inc. announced initiation of the "MAESTRO-NASH Outcomes" study of resmetirom (recruiting, first patient screened). MAESTRO-NASH Outcomes is a Phase 3, double-blind, randomized, placebo-controlled study that will noninvasively measure progression to liver decompensation events in approximately 700 patients with compensated NASH cirrhosis. It is the fourth Phase 3 MAESTRO study of resmetirom, joining the MAESTRO-NAFLD-1 safety study, which reported positive data in January 2022, the ongoing MAESTRO-NAFLD Open-Label Extension study, and the pivotal MAESTRO-NASH biopsy study, which is on track for a topline data readout in Q4 2022.

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