# Madrigal Pharmaceuticals Reports 2017 Second Quarter Financial Results

August 10, 2017

***- Completed patient enrollment in Phase 2 clinical study of MGL-3196, a liver-directed thyroid hormone receptor (THR) beta selective agonist, for treatment of NASH -***

***- Raised $35 million financing to provide significant additional funding for Madrigal's product development plans -***

CONSHOHOCKEN, Pa., Aug. 10, 2017 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL) today announced its second quarter 2017 financial results, including a $35 million financing in June. Madrigal also recently completed patient enrollment in a Phase 2 clinical study of its lead compound, MGL-3196, a first-in-class, oral, once-daily, liver-directed, thyroid hormone receptor (THR) β-selective agonist, in patients with non-alcoholic steatohepatitis (NASH). The Company had also initiated a Phase 2 clinical study of MGL-3196 in patients with heterozygous familial hypercholesterolemia (HeFH) in the first quarter of 2017.

"Completion of enrollment in our Phase 2 NASH clinical study is an important milestone, and enrollment is continuing as planned in our Phase 2 clinical study of MGL-3196 for patients with HeFH," said Paul Friedman, M.D., Chief Executive Officer of Madrigal. "We are also encouraged by the support of four top-tier institutional investors who made a $35 million equity investment in our June 2017 financing; this positions Madrigal very well to pursue its strategic goals through 2018."

"Both NASH and HeFH are conditions with major unmet patient needs that we believe can be safely and effectively addressed by MGL-3196. We look forward to data readouts from these studies which, if positive, should enable us to initiate Phase 3 registration trials in 2018," said Rebecca Taub, M.D., CMO and Executive VP, Research & Development of Madrigal. "The Data and Safety Monitoring Board ("DSMB") held a pre-scheduled meeting in May to review data from our Phase 2 clinical NASH trial and recommended that the Company continue the study with no changes to the protocol."

**Clinical Program Summaries for MGL-3196**

*NASH*
*Non-alcoholic Steatohepatitis (*NASH) is a common liver disease in the United States and worldwide, unrelated to alcohol use, that is characterized by a build-up of fat in the liver, inflammation, damage (ballooning) of hepatocytes and increasing fibrosis. Although people with NASH may feel well and often do not know they have the disease, NASH can lead to permanent damage, including cirrhosis and impaired liver function in a high percentage of NASH patients.

In October 2016, the first patient was treated in Madrigal's Phase 2 trial of MGL-3196 for the treatment of NASH. The randomized, double-blind, placebo-controlled, multi-center study enrolled 125 patients 18 years of age and older with biopsy-confirmed NASH and more than 10% liver fat as confirmed by a magnetic resonance imaging-proton density fat fraction (MRI-PDFF).

In this trial, patients were randomized 2:1 to receive either MGL-3196 or placebo. The primary endpoint of the trial is the reduction of liver fat, assessed by MRI-PDFF at 12 weeks. Recent published data show a high correlation of reduction of liver fat measured by MRI-PDFF to NASH scoring on liver biopsy.

Efficacy will be confirmed at the end of the trial (36 weeks) by repeat MRI-PDFF and conventional liver biopsy to examine histological evidence for the resolution of NASH. Additional secondary endpoints include changes in clinically relevant biomarkers at 12 and 36 weeks, improvement in fibrosis by at least one stage, improvement of NASH, and safety and tolerability. Top-line results for the primary endpoint of the trial, the reduction of liver fat, assessed by MRI-PDFF at 12 weeks, are expected by year-end.

*HeFH*
Heterozygous familial hypercholesterolemia (HeFH) is a severe genetic dyslipidemia, typically caused by an inactivating mutation in one copy of the LDL receptor gene that leads to early onset cardiovascular disease. With conventional therapy, including statins and ezetimibe, the majority of HeFH and virtually all homozygous familial hypercholesterolemia (HoFH) patients fail to reach their cholesterol (LDL-C) reduction goals. Based on evidence of impressive LDL cholesterol lowering in Phase 1, and data suggesting that MGL-3196 has a mechanism of action that is different from and complementary to statins, Madrigal initiated a Phase 2 proof-of-concept trial in HeFH. Top-line results of this trial are also expected by year-end or in early 2018.

The 12-week, randomized, double-blind, placebo-controlled, multi-center study is expected to enroll up to 105 patients with HeFH randomized in a 2:1 ratio to receive either MGL-3196 or placebo, in addition to their current drug regimen (including high dose statins and ezetimibe). The primary endpoint of the study is reduction of LDL cholesterol, with secondary endpoints including reductions in triglycerides, Lp(a), and ApoB, as well as safety. Lp(a) is a severely atherogenic lipid particle, commonly elevated in familial hypercholesterolemia patients and poorly controlled by existing lipid lowering therapies. THR-β agonism is one of the few therapeutic approaches that can substantially lower Lp(a). As previously announced, the first patient in this study was dosed in February 2017.

*HoFH*
Homozygous familial hypercholesterolemia (HoFH) is a much rarer form of severe genetic dyslipidemia, which results from inactivating mutations in both copies of the LDL receptor gene, and can produce cardiovascular disease before age 20. The protocol for a Phase 2, open-label study of MGL-3196 in HoFH is in development.

**Financial Results for the Three Months and Six Months Ended June 30, 2017**

As of June 30, 2017, Madrigal had cash, cash equivalents and marketable securities of $67.2 million, compared to $40.5 million at December 31, 2016. The increase in cash and marketable securities resulted primarily from the net proceeds of $34.9 million from the Company's private placement of equity in June 2017, and $3.4 million of net proceeds from issuances of common stock in the first quarter of 2017 pursuant to the Company's at-the-market sales agreement, partially offset by cash used in operations of $11.4 million.

Operating expenses were $8.4 million and $14.5 million for the three month and six month periods ended June 30, 2017, compared to $2.6 million and $3.4 million in the comparable prior year periods.

Research and development expenses for the three month and six month periods ended June 30, 2017 increased to approximately $6.8 million and $11.2 million, respectively, as compared to $2.1 million and $2.6 million in the comparable prior year periods. These increases are primarily attributable to higher expenses for personnel, particularly non-cash stock based compensation, and increased expenses for our Phase 2 clinical development programs for MGL-3196 in NASH and HeFH.

General and administrative expenses for the three month and six month periods ended June 30, 2017 increased to approximately $1.6 million and $3.3 milion, respectively, as compared to $0.6 million and $0.8 million in the comparable prior year periods. These increases are primarily attributable to higher expenses for personnel, particularly non-cash stock based compensation, and professional services related to Madrigal becoming a public company in mid-2016.

Interest income (expense), net, for the three month and six month periods ended June 30, 2017 was $92 thousand and $168 thousand, respectively, as compared to $(238) thousand and $(1.2) million for the comparable prior year periods. These decreases in interest expense in 2017 were due to the conversion of convertible debt to shares of common stock in connection with the Company's merger, which closed on July 22, 2016.

**About Madrigal Pharmaceuticals**
Madrigal Pharmaceuticals, Inc. (Nasdaq:MGDL) 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. The Company's lead candidate, MGL-3196, is a first-in-class, orally administered, small-molecule, liver-directed, thyroid hormone receptor (THR) β-selective agonist that is currently in Phase 2 development for NASH and HeFH. 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. Such statements contain words such as "expect," "could," "may," "will," "believe," "estimate," "continue," "future,"or the negative thereof or comparable terminology and the use of future dates. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they 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, the company's clinical development of MGL-3196, the timing and outcomes of clinical studies of MGL-3196, 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.*

**Madrigal Pharmaceuticals, Inc.**
**Condensed Consolidated Statements of Operations**
**(in thousands, except share and per share amounts)**
**(unaudited)**

| | Three Months Ended March 31, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2017** | **2016** | **2017** | **2016** |
| Revenues: | | | | |
| Total revenues | $ - | $ - | $ - | $ - |
| Operating expenses: | | | | |
| Research and development | 6,816 | 2,088 | 11,196 | 2,604 |
| General and administrative | 1,623 | 551 | 3,318 | 773 |
| Total operating expenses | 8,439 | 2,639 | 14,514 | 3,377 |
| Loss from operations | (8,439) | (2,639) | (14,514) | (3,377) |
| Interest income (expense), net | 92 | (238) | 168 | (1,213) |
| Net loss | $ (8,347) | $ (2,877) | $ (14,346) | $ (4,590) |
| | | | | |
| Basic and diluted net loss per common share | $ (0.69) | $ (16.33) | $ (1.20) | $ (26.06) |
| Basic and diluted weighted average number of common shares outstanding | 12,039,005 | 176,158 | 11,997,602 | 176,158 |

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

| | June 30, 2017 | December 31, 2016 |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and marketable securities | $ 67,166 | $ 40,500 |
| Other current assets | 781 | 707 |
| Other non-current assets | 120 | 3 |
| Total assets | $ 68,067 | $ 41,210 |
| **Liabilities and Equity** | | |
| Current liabilities | $ 6,436 | $ 4,800 |
| Long-term liabilities | - | - |
| Stockholders' equity | 61,631 | 36,410 |
| Total liabilities and stockholders' equity | $ 68,067 | $ 41,210 |

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