Madrigal Pharmaceuticals Provides Clinical and Business Updates and Reports 2022 Second Quarter Financial Results

August 4, 2022

- *Madrigal remains on track to announce topline data from the Phase 3 MAESTRO-NASH biopsy study in the fourth quarter*

CONSHOHOCKEN, Pa., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Madrigal Pharmaceuticals, Inc. (NASDAQ:MDGL), a clinical-stage biopharmaceutical company pursuing novel therapeutics for nonalcoholic steatohepatitis (NASH), today provides a summary of recent corporate accomplishments and reports its second quarter 2022 financial results.

Paul Friedman, M.D., Chief Executive Officer of Madrigal, stated, “We believe resmetirom, a once-daily oral medication that targets the steatohepatitis and resulting fibrosis in the liver, has the potential to transform the treatment of NASH. As we enter an important period for the company, I’m confident in our strategic plan and operational readiness: we’ve continued to advance our Phase 3 MAESTRO program, expanded our market development activities in the U.S., and improved our financial position with the term loan agreement announced last quarter. Madrigal is well-positioned for the road ahead.”

Becky Taub, M.D., Chief Medical Officer and President of Research & Development of Madrigal, stated, "The MAESTRO-NAFLD-1 results we recently presented at EASL reinforce our understanding of the favorable safety and tolerability profile of resmetirom, and we remain on track for topline data from the pivotal MAESTRO-NASH biopsy study in the fourth quarter. These studies are intended to serve as the foundation for a new drug application filing for resmetirom in the noncirrhotic NASH population in the first half of next year.”

Remy Sukhija, Chief Commercial Officer of Madrigal, added, “As we continue to lay the foundation for a potential first-to-market launch in the U.S., our engagement with key stakeholders has accelerated in recent months. In June we launched the ‘NASH Explored’ disease education campaign for healthcare providers and announced expanded partnerships with key patient advocacy groups. Additionally, our Market Access and Medical Affairs teams have conducted NASH disease education sessions with payers that together account for more than 80% of all branded prescriptions in the U.S. All stakeholder groups recognize the serious unmet need for approved therapies to treat NASH with liver fibrosis and extensive market research has reinforced our confidence in the commercial potential of resmetirom.”

Financial Results for the Six Months Ended June 30, 2022

As of June 30, 2022, Madrigal had cash, cash equivalents and marketable securities of $211.8 million, compared to $270.3 million at December 31, 2021. The decrease in cash and marketable securities resulted primarily from cash used in operations of $107.3 million, partially offset by the capital raised under the Loan Facility (“Loan Facility”) with Hercules Capital, Inc. (“Hercules”).

Operating expenses were $70.3 million and $127.9 million for the three month and six month periods ended June 30, 2022, compared to $61.7 million and $114.7 million in the comparable prior year periods.

Research and development expenses for the three and six month periods ended June 30, 2022 were $58.5 million and $106.4 million, compared to $51.6 million and $97.4 million in the comparable prior year periods. The increase is attributable primarily to additional activities related to the Phase 3 clinical trials, and an increase in head count.

General and administrative expenses for the three and six month periods ended June 30, 2022 were $11.8 million and $21.4 million, compared to $10.1 million and $17.3 million in the comparable prior year periods. The increase is due primarily to increases in commercial preparation activities, including an increase in headcount and an increase in non-cash stock compensation.

Interest income for the three and six month periods ended June 30, 2022 was $0.3 million and $0.4 million, compared to $0.1 million and $0.3 million in the comparable prior year periods. The increase in interest income was due primarily to a higher average interest rates in 2022.

Interest expense for the three and six month periods ended June 30, 2022 was $0.8 million and $0.8 million, compared to $0 million and $0 million in the comparable prior year periods. The increase in interest expense was as a result of the Loan Facility we entered with Hercules.

About the Resmetirom Phase 3 Registration Program for the Treatment of NASH

Madrigal is currently conducting two Phase 3 clinical trials, MAESTRO-NASH and MAESTRO-NAFLD-1, to demonstrate the safety and efficacy of resmetirom for the treatment of NASH.

MAESTRO-NASH is a multicenter, randomized, double-blind, placebo-controlled Phase 3 study of resmetirom in patients with liver biopsy-confirmed NASH and was initiated in March 2019. The study targeted enrollment of 900 patients with biopsy-proven NASH (fibrosis stage 2 or 3, at least 450 fibrosis stage 3), randomized 1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, or placebo. After 52 weeks of treatment, a second biopsy is performed. The dual primary surrogate endpoints on biopsy are NASH resolution with ≥2-point reduction in NAS (NAFLD Activity Score), and with no worsening of fibrosis OR a 1-point decrease in fibrosis with no worsening of NASH. Either primary endpoint can be achieved for a successful trial outcome. A key secondary endpoint is lowering of LDL-C. The planned target enrollment was announced as completed on June 30, 2021.

The first 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. The study is expected to continue for up to 54 months to accrue and measure hepatic clinical outcome events including progression to cirrhosis on biopsy (52 weeks and 54 months) and hepatic decompensation events.

MAESTRO-NAFLD-1 was initiated in December 2019 and the 52-week multicenter, randomized, placebo-controlled Phase 3 study of resmetirom in over 1,200 patients with NAFLD, presumed NASH, has completed the double-blind arms and an open-label 100 mg arm. An additional open-label active treatment arm in patients with early (well-compensated) NASH cirrhosis is ongoing. The primary endpoint is to evaluate the safety and tolerability of resmetirom. An open-label extension study (MAESTRO-NAFLD-OLE) is ongoing.

Patients in the 52-week phase of MAESTRO-NAFLD-1 were randomized 1:1:1:1 to receive once-daily resmetirom 80 mg, resmetirom 100 mg, placebo in double-blind arms or resmetirom 100 mg in an open-label arm. MAESTRO-NAFLD-1 (unlike MAESTRO-NASH), did not include a liver biopsy and represents a “real-life” NASH study. Patients with 3 metabolic risk factors were documented with NASH or NAFLD by historical liver biopsy or noninvasive techniques. Using noninvasive measures, MAESTRO-NAFLD-1 was 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 included LDL-C, apolipoprotein B, and triglyceride lowering; and reduction of liver fat as determined by MRI-PDFF. Additional secondary and exploratory endpoints were assessed including reduction in liver enzymes, FibroScan, and MRE scores and other NASH biomarkers.

Data from the 52-week portion of MAESTRO-NASH, together with data from MAESTRO-NAFLD-1 and other data, including safety parameters, will form the basis for a potential subpart H submission to FDA for accelerated approval of resmetirom for treatment of NASH.

In May 2022, Madrigal announced plans to expand the resmetirom development program by initiating MAESTRO-NASH Outcomes, a randomized double-blind placebo-controlled study in approximately 700 patients with early NASH cirrhosis to allow for noninvasive monitoring of progression to liver decompensation events. A positive outcome is expected to support the full approval of resmetirom for noncirrhotic NASH, potentially accelerating the timeline to full approval. In addition, this study has the potential to broaden the label for resmetirom to include NASH patients with compensated cirrhosis.

About Madrigal Pharmaceuticals

Madrigal Pharmaceuticals, Inc. (Nasdaq: MDGL) 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. Resmetirom is currently being evaluated in two Phase 3 clinical studies (MAESTRO-NASH and MAESTRO-NAFLD-1) designed to demonstrate multiple benefits in patients with NASH. For more information, visit www.madrigalpharma.com.

Forward Looking Statements

This communication includes “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: anticipated or estimated future results, including the risks and uncertainties associated with our future operating performance and financial position; our possible or assumed future results of operations and expenses, business strategies and plan (including ex-US. Launch/partnering plans), including incurrence of indebtedness and compliance with debt covenants under the Loan and Security Agreement with Hercules Capital, Inc., as agent and lender, market trends, market sizing, competitive position, industry environment and potential growth opportunities, among other things; our ability to delay certain research activities and related clinical expenses as necessary; our clinical trials, including the anticipated timing of disclosure, presentations of data from, or outcomes from our trials; research and development activities, and the timing and results associated with the future development of our lead product candidate, resmetirom (formerly known as MGL-3196), including projected market size, sector leadership, and patient treatment estimates for NASH and NAFLD patients; the timing and completion of projected future clinical milestone events, including enrollment, additional studies, top-line data and open label projections; plans, objectives and timing 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 for noncirrhotic NASH patients with compensated cirrhosis; our primary and key secondary study endpoints for resmetirom and the potential for achieving such endpoints and projections, including NASH resolution, safety, fibrosis treatment, cardiovascular effects, and lipid treatment with resmetirom; 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; the potential efficacy and safety of resmetirom for noncirrhotic NASH patients and cirrhotic NASH patients; the potential for resmetirom to become the best-in-class and/or first-to-market treatment option for patients with NASH and liver fibrosis; anticipated or estimated future results of operations and expenses as we expand our resmetirom clinical development program and our commercial development program; ex-U.S. launch/partnering plans; the ability to develop clinical evidence demonstrating the utility of noninvasive tools and techniques to screen and diagnose NASH and/or NAFLD patients; the predictive power of liver fat reduction with resmetirom, as measured by noninvasive tests, on NASH resolution and/or fibrosis reduction or improvement, and potential NASH or NAFLD patient risk profile benefits with resmetirom; the predictive power of liver fat, liver volume changes or MAST scores for NASH and/or NAFLD patients; the predictive power of NASH resolution and/or liver fibrosis reduction or improvement with resmetirom using noninvasive tests, including the use of ELF, FibroScan, MRE and/or MRI-PDFF; the predictive power of noninvasive tests generally, including for purposes of diagnosing NASH, monitoring patient response to resmetirom, or recruiting and conducting a NASH clinical trial; market demand for and acceptance of our products; research, development and commercialization of new products; obtaining and maintaining regulatory approvals, including, but not limited to, potential regulatory delays or rejections; risks associated with meeting the objectives of our clinical studies, including, but not limited to our ability to achieve enrollment objectives concerning patient numbers (including an adequate safety database), outcomes objectives and/or timing objectives for our studies, any delays or failures in enrollment, the occurrence of adverse safety events, and the risks of successfully conducting trials that are substantially larger, and have patients with different disease states, than our past trials; risks related to the effects of resmetirom’ s mechanism of action and our ability to accomplish our business and business development objectives and realize the anticipated benefit of any such transactions; the achievement of enrollment objectives concerning patient number, safety database and/or timing for our studies; and assumptions underlying any of the foregoing.

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 “accelerate,” “achieve,” “allow,” “anticipates,” “appear,” “be,” “believes,” “can,” “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: our clinical development of resmetirom; 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; our potential inability to raise sufficient capital to fund our ongoing operations as currently planned or to obtain financings on terms similar to those we have arranged in the past; our ability to service our indebtedness and otherwise comply with our 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 our prior studies; limitations associated with early stage or non-placebo controlled study data; 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 or furnished 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 appearing in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on February 25, 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 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Total revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	58,499	51,632	106,428	97,402
General and administrative	11,774	10,110	21,432	17,319
Total operating expenses	70,273	61,742	127,860	114,721
Loss from operations	(70,273)	(61,742)	(127,860)	(114,721)
Interest income, net	323	91	392	251
Interest expense	(780)	-	(780)	-
Other income	-	-	-	273
Net loss	$ (70,730)	$ (61,651)	$ (128,248)	$ (114,197)
Basic and diluted net loss per common share	$ (4.14)	$ (3.72)	$ (7.50)	$ (7.05)
Basic and diluted weighted average number of common shares outstanding	17,103,395	16,571,322	17,103,395	16,207,880

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

	June 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	$ 211,766	$ 270,346
Other current assets	2,780	1,338
Other non-current assets	1,846	1,648
Total assets	$ 216,392	$ 273,332
Liabilities and Equity		

Current liabilities	$	84,009	$	76,838
Long-term liabilities		48,848		387
Stockholders' equity		83,535		196,107
Total liabilities and stockholders' equity	$	216,392	$	273,332

Source: Madrigal Pharmaceuticals, Inc.