



Morphic Announces Corporate Highlights and Financial Results for the Third Quarter 2022

November 2, 2022

Completed enrollment of EMERALD-1 phase 2a trial of MORF-057 in patients with ulcerative colitis ahead of schedule

EMERALD-2 phase 2b global randomized study of MORF-057 to begin fourth quarter

WALTHAM, Mass., Nov. 02, 2022 (GLOBE NEWSWIRE) -- [Morphic Therapeutic](#) (Nasdaq: MORF), a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, today reported corporate highlights and financial results for the third quarter of 2022.

Third Quarter 2022 and Recent Corporate Highlights

- Completed target enrollment ahead of schedule for the main cohort of 30 patients in the EMERALD-1 (MORF-057-201), an open-label phase 2a multi-center study of patients with moderate to severe ulcerative colitis (UC) receiving 100 mg BID of MORF-057
 - Primary endpoint data from the EMERALD-1 main cohort expected second quarter of 2023
 - The original target of 30 patients in the main cohort will be exceeded as Morphic plans to include eligible patients who were in screening at the time of the 30th patient being enrolled, per protocol allowance and ethical trial conduct
 - An exploratory cohort of up to 10 patients who have previously failed treatment with advanced UC therapies is ongoing
- Affirmed that EMERALD-2 (MORF-057-202), a global phase 2b randomized double-blind placebo-controlled trial of MORF-057, is planned to begin dosing patients in the fourth quarter of 2022
 - Patients will be randomized to receive one of three active arms or a placebo arm
 - MORF-057 100 mg BID (twice daily) arm
 - MORF-057 200 mg BID arm
 - MORF-057 QD (once daily) dose arm
 - Placebo (to cross over to MORF-057 after induction phase)
 - The primary endpoint of this study is clinical remission rate as measured by the modified Mayo score at 12 weeks
 - Secondary endpoints will include change in Robarts Histopathological Index (RHI), pharmacokinetic and pharmacodynamic measures as well as safety parameters
 - Following the 12-week induction phase, patients will move to a 40-week maintenance phase
 - Top line data, including the primary endpoint results of EMERALD-2, are expected in the first half of 2025
- Presented new data at United European Gastroenterology (UEG) Week 2022 providing deeper information on the safety and dose-activity relationship of MORF-057, including A4B7 receptor saturation and statistically significant increases in key circulating T lymphocyte populations at multiple doses
- Presented new data on MORF-057 at the American College of Gastroenterology (ACG) 2022 Annual Scientific Meeting that further reinforce and build upon the favorable pharmacokinetic and pharmacodynamic profile for MORF-057 seen in previous studies
- Noted pioneering achievements by members of the Morphic Team
 - Applauded Dr. Albert Lin and Dr. Timothy Springer for their recent publication in *Cell* describing key conformation changes integrin receptors; a discovery that led to the formation of Morphic Therapeutic
 - Celebrated the award of the 2022 Albert Lasker Basic Medical Research Award to Dr. Timothy Springer for his role in the discovery of the integrin receptor

"Excellent efforts by the Morphic Team have led to major advances in the MORF-057 phase 2 program, with the EMERALD-1 phase 2a study

completing enrollment ahead of schedule and the EMERALD-2 phase 2b study now poised to commence,” commented Praveen Tipirneni, MD, Chief Executive Officer of Morphe Therapeutic. “We are excited for clinical progress during the remainder of 2022 and especially looking forward to 2023.”

Financial Results for the Third Quarter 2022

- Net loss for the quarter ended September 30, 2022 was \$30.0 million or \$0.78 per share compared to a net loss of \$25.0 million or \$0.69 per share for the same quarter last year
- Revenue was \$2.1 million for the quarter ended September 30, 2022, compared to \$3.1 million for the same quarter last year
- Research and development expenses were \$25.2 million for the quarter ended September 30, 2022, as compared to \$21.0 million for the same quarter last year. The increase was primarily attributable to higher clinical and development costs along with higher pre-clinical and phase 2 clinical trial costs to support our lead product candidate MORF-057
- General and administrative expenses were \$8.3 million for the quarter ended September 30, 2022, compared to \$7.3 million for the same quarter last year. The increase was due to increased non-cash stock-based compensation expense and higher payroll costs

As of September 30, 2022, Morphe had cash, cash equivalents and marketable securities of \$371.8 million, compared to \$397.6 million as of June 30, 2022. Morphe believes its cash, cash equivalents and marketable securities as of September 30, 2022, will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2025.

About Morphe Therapeutic

Morphe Therapeutic is a biopharmaceutical company developing a portfolio of oral integrin therapies for the treatment of serious chronic diseases, including autoimmune, cardiovascular, and metabolic diseases, fibrosis, and cancer. Morphe is also advancing its pipeline and discovery activities in collaborations with Janssen and Schrödinger using its proprietary MINT technology platform which leverages the Company’s unique understanding of integrin structure and biology. For more information, visit www.morphictx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking” statements within the meaning of the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, and of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the MINT Platform’s ability to discover drug candidates, Morphe’s plans to develop and commercialize oral small-molecule integrin therapeutics and any proposed timing thereof, the initiation, execution and completion of MORF-057 phase 2 clinical trials, any expectations about safety, efficacy, timing and ability to commence or complete clinical studies and/or trials and to obtain regulatory approvals for MORF-057 and other candidates in development, the timing of further data presentation and the ability of MORF-057 to treat inflammatory bowel disease, including ulcerative colitis, or related indications. Statements including words such as “believe,” “plan,” “continue,” “expect,” “will be,” “develop,” “signal,” “potential,” “anticipate” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause Morphe’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Morphe’s or a partner’s ability to complete a current or future clinical trial of any of our current or future product candidates, develop or obtain regulatory approval for or commercialize any product candidate, Morphe’s ability to protect intellectual property, the potential impact of the COVID-19 pandemic, and the sufficiency of our cash, cash equivalents and investments to fund our operations. These forward-looking statements speak only as of the date hereof and Morphe specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

-Financial Tables to Follow-

Morphe Holding, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	\$ 2,055	\$ 3,124	\$ 64,673	\$ 10,238
Operating expenses:				
Research and development	25,245	20,966	77,360	64,131
General and administrative	8,303	7,276	24,128	20,367
Total operating expenses	33,548	28,242	101,488	84,498
Loss from operations	(31,493)	(25,118)	(36,815)	(74,260)
Other income:				
Interest income, net	1,657	77	2,326	140
Other expense, net	(156)	—	(144)	(20)

Total other income, net	1,501	77	2,182	120
Loss before provision for income taxes	(29,992)	(25,041)	(34,633)	(74,140)
Provision for income taxes	(29)	—	(31)	—
Net loss	<u>\$ (30,021)</u>	<u>\$ (25,041)</u>	<u>\$ (34,664)</u>	<u>\$ (74,140)</u>
Net loss per share, basic and diluted	<u>\$ (0.78)</u>	<u>\$ (0.69)</u>	<u>\$ (0.91)</u>	<u>\$ (2.09)</u>
Weighted average common shares outstanding, basic, and diluted	<u>38,490,910</u>	<u>36,547,222</u>	<u>37,961,262</u>	<u>35,392,153</u>

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and marketable securities	\$ 371,760	\$ 408,135
Other current assets	10,650	10,199
Total current assets	382,410	418,334
Other assets	6,771	7,956
Total assets	<u>\$ 389,181</u>	<u>\$ 426,290</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 18,586	\$ 38,264
Long-term liabilities	5,534	51,327
Total liabilities	24,120	89,591
Total stockholders' equity	365,061	336,699
Total liabilities and stockholders' equity	<u>\$ 389,181</u>	<u>\$ 426,290</u>

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