



Morphic Announces Corporate Highlights and Financial Results for the Second Quarter 2023

August 3, 2023

-Reported positive topline results from EMERALD-1 study of MORF-057 in ulcerative colitis-

-Continued enrollment on target in EMERALD-2 Phase 2b trial of MORF-057 in ulcerative colitis-

-Greater than \$730 million in cash and equivalents at 6/30/23; extended cash runway into second half of 2027-

-New clinical trials of MORF-057 in Crohn's disease and MORF-088 in myelofibrosis to begin in the first half of 2024-

WALTHAM, Mass., Aug. 03, 2023 (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 second quarter of 2023.

"Morphic rides a wave of momentum into the 2nd half of 2023, bolstered by the compelling and consistent dataset derived from the EMERALD-1 Phase 2a study of MORF-057 in ulcerative colitis. These data paved the way to a fortress balance sheet, catalyzing the broader advancement of our pipeline," commented Praveen Tipirneni, MD, Chief Executive Officer of Morphic Therapeutic. "The MORF-057 development program moves ahead with on-track enrollment of ulcerative colitis patients in the EMERALD-2 Phase 2b study and with the preparation for a Phase 2 trial in Crohn's Disease, planned to begin in the first half of 2024. Our robust financial position opens the gates to additional investment in therapeutic areas beyond IBD, enabled by the MInT Platform.

"In particular, our $\alpha\text{v}\beta 8$ inhibitor program continues to stir enthusiasm, buoyed by compelling pre-clinical data and the potentially central role of TGF- β in the pathogenesis of myelofibrosis. On the strength of these advancements, we have formally nominated MORF-088, a selective small molecule inhibitor of $\alpha\text{v}\beta 8$, as our development candidate for myelofibrosis and expect this program to enter the clinic in the first half of 2024."

Second Quarter 2023 and Recent Corporate Highlights

In the EMERALD-1 Phase 2a trial of MORF-057 in UC, topline data indicate that MORF-057:

- Was generally well tolerated with no safety signal observed
- Achieved the study's primary endpoint and demonstrated consistent, clinically meaningful improvements across secondary and exploratory measures
- Demonstrated a statistically significant reduction of 6.4 points ($p=0.002$) from baseline at Week 12 in the Robarts Histopathology Index (RHI) Score
- Achieved 26% clinical remission as measured by Modified Mayo Clinic Score (mMCS)
- Demonstrated positive biomarker results, including the saturation of the $\alpha 4\beta 7$ receptor and $\alpha 4\beta 7$ lymphocyte subset changes consistent with Phase 1 MORF-057 data

Ongoing MORF-057 EMERALD Phase 2 Development Program Updates

- Continued the 40-week maintenance phase of the EMERALD-1 study as projected with top-line data anticipated in the first half of 2024
 - Patients who completed the 12-week induction phase of the EMERALD-1 Phase 2a study were eligible to continue participating in a 40-week maintenance phase of the EMERALD-1 open-label single-arm study
- Announced completion of enrollment in the exploratory cohort of the EMERALD-1 study comprised of UC patients who have previously failed treatment with vedolizumab
- Announced that the EMERALD-2 global Phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in patients with moderate-to-severe UC continued to ramp-up and enroll as projected
 - The primary endpoint of EMERALD-2 is the clinical remission rate as measured by mMCS at 12 weeks and is expected to report in the first half of 2025
- Announced that the Phase 2b study of MORF-057 in Crohn's Disease is anticipated to begin in the first half of 2024
- Announced the acceptance of a moderated poster presentation of the EMERALD-1 study results at the UEG Week 2023 in October in Copenhagen

MORF-057 Preclinical Studies

- Presented new biomarker data at Digestive Disease Week 2023, demonstrating increases in circulating fibroblasts, consistent with previous findings and adding new support to mechanistic understanding of MORF-057's activity in a non-human primate model of UC. These data further support the ongoing EMERALD Phase 2 clinical trials of MORF-057 in IBD

Equity Financing

- Morphic strengthened its balance sheet with a total of approximately \$345 million in new capital during the second quarter through:
 - \$276 million in gross proceeds from a public offering of 6,133,334 shares of its common stock at \$45 per share, including full exercise of the underwriters' overallotment option following the release of the positive and consistent EMERALD-1 Phase 2a topline data in ulcerative colitis
 - ~\$69 million in gross proceeds through the use of its ATM facility at a volume-weighted average price of \$56.20 per share

Financial Results for the Second Quarter 2023

- Net loss for the quarter ended June 30, 2023, was \$39.0 million or \$0.92 per share compared to net income of \$26.8 million or \$0.68 per share for the same quarter last year
- Revenue was \$0 million for the quarter ended June 30, 2023, compared to \$60.2 million for the same quarter last year due to the conclusion of the Company's research and development collaboration with AbbVie
- Research and development expenses were \$35.7 million for the quarter ended June 30, 2023, as compared to \$25.7 million for the same quarter last year. The increase was primarily attributable to higher manufacturing 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 \$9.6 million for the quarter ended June 30, 2023, compared to \$8.2 million for the same quarter last year. The increase was due to increased non-cash stock-based compensation expenses and higher payroll costs

As of June 30, 2023, Morphic had cash, cash equivalents and marketable securities of \$731.4 million, compared to \$421.3 million as of March 31, 2023. Based on its current operating plan, Morphic believes its existing cash, cash equivalents and marketable securities as of June 30, 2023, will be sufficient to fund operating expenses and capital expenditure requirements into the second half of 2027.

Upcoming Morphic Investor and Medical Meeting Presentations

- Canaccord Genuity 43rd Annual Growth Conference, Boston
 - Corporate presentation, August 9, 2023
- Wells Fargo Healthcare Conference, Boston
 - Fireside Chat, September 6, 2023
- UEG Week 2023, Copenhagen
 - EMERALD-1 moderated poster presentation, October 15, 2023

About MORF-057

Morphic is developing MORF-057 as a selective, oral small molecule inhibitor of the $\alpha 4\beta 7$ integrin for patients with inflammatory bowel disease (IBD). $\alpha 4\beta 7$ has been clinically validated as a target for the treatment of IBD by the success of the approved injectable antibody therapeutic vedolizumab. MORF-057, like vedolizumab, is designed to block the interactions between $\alpha 4\beta 7$ on the surface of lymphocytes and the mucosal endothelial cell ligand MAdCAM-1, substantially reducing lymphocyte migration from the bloodstream into intestinal mucosal tissues and avoiding inflammation that is associated with IBD.

About the EMERALD-1 Study

EMERALD-1 (MORF-057-201) is an open-label multi-center phase 2a trial designed to evaluate the efficacy, safety, and tolerability of MORF-057 in adults with moderate to severe ulcerative colitis. The 35 patients enrolled in the main cohort of the EMERALD-1 study have been treated with 100 mg BID (twice daily) at sites in the United States and Poland. The primary endpoint of the trial was the change in Robarts Histopathology Index (RHI), a validated instrument that measures histological disease activity in ulcerative colitis at 12 weeks compared to baseline. Patients will continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment. Secondary and additional pre-specified measures in the EMERALD-1 study include change in the modified Mayo clinic score, safety, pharmacokinetic parameters and key pharmacodynamic measures including $\alpha 4\beta 7$ receptor occupancy and lymphocyte subset trafficking.

About the EMERALD-2 Study

[EMERALD-2 \(MORF-057-202\)](#) is a global phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 that is currently enrolling patients

with moderate-to-severe ulcerative colitis. The primary endpoint of EMERALD-2 is clinical remission rate as measured by the Modified Mayo Clinic Score (mMCS) at 12 weeks. EMERALD-2 will also measure several secondary and exploratory endpoints based on the mMCS as well as histologic, pharmacokinetic and pharmacodynamic measures, and safety parameters. Patients in the EMERALD-2 study will be randomized to receive either 200 mg BID MORF-057, 100 mg BID MORF-057, a QD (once daily) dose of MORF-057, or a placebo dose. Following the 12-week induction phase, all patients will receive MORF-057 for 40 weeks of maintenance dosing. For more information about the EMERALD clinical trials of MORF-057, please click [here](#).

About Morphic Therapeutic

Morphic 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. Morphic is also advancing its pipeline and discovery activities in collaboration with 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 technology platform's ability to discover drug candidates; Morphic's plans to develop and commercialize oral small-molecule integrin therapeutics and any proposed timing thereof; the execution, timing and completion of the EMERALD-1 and EMERALD-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, MORF-088 and other candidates in development; the timing of further data presentation; the ability of MORF-057 to treat IBD, including ulcerative colitis, or related indications; the ability of $\alpha\text{v}\beta 8$ small molecule inhibitors, including MORF-088, to treat myelofibrosis; the ability for additional integrin targets to treat pulmonary hypertensive diseases; the company's cash position and anticipated runway. 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 Morphic's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties disclosed in this press release and other risks set forth in our filings with the Securities and Exchange Commission, including Morphic's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 filed with the SEC on August 23, 2023. These forward-looking statements speak only as of the date hereof and Morphic specifically disclaims any obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

-Financial Tables to Follow-

Morphic Holding, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ —	\$ 60,236	\$ 521	\$ 62,618
Operating expenses:				
Research and development	35,719	25,652	66,168	52,115
General and administrative	9,583	8,234	18,860	15,825
Total operating expenses	45,302	33,886	85,028	67,940
(Loss) income from operations	(45,302)	26,350	(84,507)	(5,322)
Other income:				
Interest income, net	6,427	482	9,527	669
Other income, net	—	11	2	12
Total other income, net	6,427	493	9,529	681
(Loss) income before provision for income taxes	(38,875)	26,843	(74,978)	(4,641)
Provision for income taxes	(138)	(2)	(170)	(2)
Net (loss) income	\$ (39,013)	\$ 26,841	\$ (75,148)	\$ (4,643)
Net (loss) income per share, basic	\$ (0.92)	\$ 0.70	\$ (1.82)	\$ (0.12)
Net (loss) income per share, diluted	\$ (0.92)	\$ 0.68	\$ (1.82)	\$ (0.12)
Weighted average common shares outstanding, basic	42,373,407	38,244,547	41,249,157	37,692,049
Weighted average common shares outstanding, diluted	42,373,407	39,554,651	41,249,157	37,692,049

Morphic Holding, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	\$ 731,356	\$ 348,248
Other current assets	11,265	13,934
Total current assets	<u>742,621</u>	<u>362,182</u>
Other assets	6,099	6,407
Total assets	<u><u>\$ 748,720</u></u>	<u><u>\$ 368,589</u></u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 17,809	\$ 17,126
Long-term liabilities	1,550	2,344
Total liabilities	<u>19,359</u>	<u>19,470</u>
Total stockholders' equity	<u>729,361</u>	<u>349,119</u>
Total liabilities and stockholders' equity	<u><u>\$ 748,720</u></u>	<u><u>\$ 368,589</u></u>

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