Morphic Announces Corporate Highlights and Financial Results for the Full Year 2023

February 22, 2024

-Reported positive results from EMERALD-1 phase 2a trial of MORF-057 in ulcerative colitis (UC)-

-Enrollment on target in EMERALD-2 phase 2b global randomized trial of MORF-057 in UC-

-GARNET phase 2 trial of MORF-057 in Crohn's disease (CD) expected to begin enrolling in the first half of 2024-

-Ended 2023 with $704.3 million in cash and equivalents; cash runway into second half of 2027-

WALTHAM, Mass., Feb. 22, 2024 (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 full year 2023.

"Today, our conviction in MORF-057 as a potential oral, well tolerated, and efficacious treatment for inflammatory bowel disease (IBD) is stronger than ever, based on the clear success of the EMERALD-1 trial in UC. Looking forward in 2024, we will work to translate this momentum into further progress with the GARNET phase 2 study in patients with moderately to severely active Crohn's disease running in parallel with the EMERALD-2 phase 2b study in UC," commented Praveen Tipirneni, Chief Executive Officer of Morphic. "Further, we are working to expand the pipeline of candidates generated by Morphic's MInT Platform, most notably with our α5β1 program for pulmonary hypertensive diseases and additional new projects against both integrin and non-integrin targets

"On a personal note, I am thankful to return to Morphic after an acute medical event and grateful for the immense support from friends and peers within the biotechnology community and especially the Morphic team," Tipirneni continued. "This experience has crystallized, for me, that Morphic's opportunity to fundamentally improve patients' lives is immense and that there is no time to waste."

2023 and Recent Corporate Highlights

EMERALD-1 Phase 2a trial of MORF-057 in UC:

- In the EMERALD-1 phase 2a trial of MORF-057 in ulcerative colitis (UC), topline data and additional data presented at UEGW 2023 indicated that in a moderately-to-severely-active UC population with severe disease burden, MORF-057:
  - Was generally well tolerated with no safety signal observed
  - Achieved the study's primary endpoint with statistical significance in reduction of Robarts Histopathology Index (RHI) Score from baseline to week 12 of 6.4 points (p=0.002)
  - Showed consistent clinical improvement across key measures at week 12, including modified Mayo Clinic Score (mMCS) remission of 25.7% and mMCS response of 45.7%
  - Demonstrated RHI change ≥7 points in 48.6% of patients and RHI remission in 22.9% of patients
  - Led to clinical improvement in mMCS within the 12-week induction period for 77% of patients
  - Pharmacokinetic and pharmacodynamic results confirmed the results seen in healthy volunteer studies
    - Median α4β7 RO >99% and sustained saturation at week 12
    - α4β1 inhibition below the limit of quantification, in line with the design of MORF-057
    - Predicted lymphocyte subset changes observed, consistent with engagement of α4β7
  - Demonstrated deepening of clinical effect beyond the 12-week induction period, with symptomatic remission rates continuing to increase out to 44 weeks in both advanced treatment-naïve and advanced treatment-experienced patients
- Announced completion of enrollment in the exploratory cohort of the EMERALD-1 study comprised of UC patients who have previously failed treatment with vedolizumab
- Continued the 40-week maintenance phase of the EMERALD-1 study as planned

EMERALD-2 Phase 2b trial of MORF-057 in UC:

- Continued to enroll the EMERALD-2 phase 2b study of MORF-057 in patients with moderately-to-severely active UC

- EMERALD-2 is a global phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in patients with moderate-to-severe UC
- The primary endpoint of EMERALD-2 is clinical remission rate as measured by mMCS at 12 weeks and is expected to report in the first half of 2025

GARNET Phase 2 trial of MORF-057 in Crohn's Disease:

- Announced that launch activities are underway for the randomized placebo-controlled GARNET Phase 2 study of MORF-057 in CD and that the study is anticipated to enroll its first patients in the first half of 2024
  - The GARNET study will evaluate 210 patients across three cohorts, each comprising 70 patients: 70 patients receiving MORF-057 200 mg BID (twice daily), 70 patients receiving MORF-057 100 mg BID and 70 patients receiving placebo
  - The primary endpoint of the GARNET study is the proportion of participants in endoscopic response (>=50% reduction) at week 14 as determined using Simple Endoscopic Score for Crohn's Disease (SES-CD)

MORF-057 Preclinical and Phase 1 Studies:

- Presented new biomarker data at DDW 2023, demonstrating increases in circulating plasmablasts, consistent with the increased antibody activity expected with anti-inflammatory mechanism of α4β7 inhibition, supporting MORF-057 program in UC
- Presented preclinical data on rational selection of combination therapy for IBD treatment using an established clinical mode at UEGW 2023
  - This study explored preclinical combination models in UC and preliminarily examined the potential utility and rationale of combining anti-inflammatory mechanisms with α4β7 integrin inhibition in IBD

Pipeline Programs:

- Announced α5β1 as the integrin target of Morphic's small molecule integrin inhibitor program in pulmonary hypertensive diseases
  - The inhibition of fibronectin integrins, including α5β1, suppresses pulmonary arterial smooth muscle cell proliferation and data to date indicate that inhibition of α5β1 contributes to improved cardiac output and the reversal of vascular remodeling
- Initiated discovery efforts that expand the Company's scope in the immunology space with oral programs targeting the IL-23 and TL1A pathways, among others

Financial Results for the Full Year 2023

- Net loss for the year ended December 31, 2023, was $152.1 million or $3.59 per share compared to a net loss of $59.0 million or $1.55 per share for the year ended December 31, 2022
- Revenue was $0.5 million for the year ended December 31, 2023, compared to $70.8 million for the year ended December 31, 2022. The change was primarily due to recognition of revenue due to the conclusion of the AbbVie collaboration in 2022 and to the amounts due at the conclusion of the Janssen collaboration in 2023
- Research and development expenses were $140.4 million for the year ended December 31, 2023, as compared to $102.1 million for the year ended December 31, 2022. The increase was primarily attributable to higher development costs along with increased clinical trial costs to support phase 2 clinical studies and development activities for MORF-057, as well as other research costs to support early development candidates
- General and administrative expenses were $38.8 million for the year ended December 31, 2023, compared to $32.1 million for the year ended December 31, 2022. The increase was due to increased personnel related costs and non-cash equity-based compensation, partially offset by decreases in consulting and insurance expenses
- Morphic raised approximately $444 million, net, through equity financings in 2023 comprised of approximately $100 million in proceeds from a PIPE offering, approximately $259 million in a public offering and approximately $85 million though use of the ATM facility
- As of December 31, 2023, Morphic had cash, cash equivalents and marketable securities of $704.3 million, compared to $348.2 million as of December 31, 2022. We believe that our cash, cash equivalents and marketable securities of $704.3 million as of December 31, 2023, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2027

About MORF-057

Morphic is developing MORF-057 as a selective, oral small molecule inhibitor of the α4β7 integrin for patients with inflammatory bowel disease (IBD). α4β7 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 α4β7 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 primary endpoint of EMERALD-1, change in Robarts Histopathology Index (RHI) from baseline at twelve weeks, was achieved with statistical significance. RHI is a validated instrument that measures histological disease activity in ulcerative colitis. Patients were eligible to continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment as well as an open-label extension period. Secondary and additional outcome measures in the EMERALD-1 study include change in the modified Mayo clinic score, safety, pharmacokinetic parameters and key pharmacodynamic measures including α4β7 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 (twice daily) 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 the GARNET Study

GARNET (MORF-057-203) is a global Phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in Crohn's disease. The primary endpoint of GARNET is the proportion of participants in endoscopic response (>=50% reduction) at week 14 as determined using Simple Endoscopic Score for Crohn's Disease, or SES-CD. The secondary endpoints will include the change in Crohn's Disease Activity Index, or CDAI, measures, as well as safety parameters. Patients enrolled in the GARNET study will be randomized to receive one of two active doses or a placebo: 200 mg BID (twice daily), 100 mg BID or a placebo that will cross over to MORF-057 after the 14-week induction phase. Following the 14-week induction phase, patients will move to a 38-week maintenance phase.

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 Platform's ability to discover drug candidates; our plans to develop and commercialize oral small-molecule integrin therapeutics and any proposed timing thereof; the initiation, execution and completion of clinical trials of MORF-057; any expectations about safety, efficacy, timing and ability to commence or complete clinical and pre-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 UC, CD, and other 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 our 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, among others, our or a partner's ability to complete a current or future clinical trial of any of our current or future product candidates, our ability to develop or obtain regulatory approval for or commercialize any product candidate, our ability to protect our intellectual property, 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 we specifically disclaim 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.

Morphic Holding, Inc.

Condensed Consolidated Statements of Operations

(unaudited)

(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Collaboration revenue	$ 521	$ 70,808
Operating expenses:		
Research and development	140,384	102,062
General and administrative	38,823	32,142

Total operating expenses	179,207	134,204
Loss from operations	(178,686)	(63,396)
Other income:		
Interest income, net	26,969	4,567
Other income (expense), net	2	(145)
Total other income, net	26,971	4,422
Loss before provision for income taxes	(151,715)	(58,974)
Provision for income taxes	(380)	(67)
Net loss	$ (152,095)	$ (59,041)
Net loss per share, basic and diluted	$ (3.59)	$ (1.55)
Weighted average common shares outstanding, basic and diluted	42,390,554	38,112,498

Morphic Holding, Inc.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands)

	December 31, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 704,349	$ 348,248
Other current assets	12,579	13,934
Total current assets	716,928	362,182
Other assets	5,586	6,407
Total assets	$ 722,514	$ 368,589
Liabilities and Stockholders' Equity		
Current liabilities	$ 24,776	$ 17,126
Long-term liabilities	716	2,344
Total liabilities	25,492	19,470
Total stockholders' equity	697,022	349,119
Total liabilities and stockholders' equity	$ 722,514	$ 368,589

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