UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 1, 2023

Morphic Holding, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38940**	**47-3878772**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

35 Gatehouse Drive, A2	
Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 996-0955

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	MORF	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2023, Morphic Holding, Inc. (the "Company") issued a press release (the "Press Release") announcing its financial results for the quarter ended September 30, 2023. The Press Release is attached hereto as Exhibit 99.1.

The information in Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officer; Compensatory Arrangements of Certain Officers.

As previously announced on September 26, 2023, Praveen P. Tipirneni, M.D., the Company's Chief Executive Officer and a member of the Company's board of directors (the "Board"), is taking a temporary medical leave of absence from his role as Chief Executive Officer. In connection with Dr. Tipirneni's leave of absence, effective November 1, 2023, the Board has appointed Bruce N. Rogers, Ph.D., the Company's President, as the Company's interim principal executive officer until Dr. Tipirneni's return. Dr. Rogers continues to serve as the Company's President during this interim period.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Morphic Holding, Inc. dated November 3, 2023.
104	The cover page on this Current Report on Form 8-K, formatted in Inline XBRL

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MORPHIC HOLDING, INC.

Date: November 3, 2023

By: /s/ Marc Schegerin

Marc Schegerin, M.D.
Chief Financial Officer and Chief Operating Officer

Exhibit 99.1

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

-Presented positive EMERALD-1 Phase 2a data for MORF-057 in patients with moderate to severe ulcerative colitis at UEG Week 2023-
-Continued enrollment on target in EMERALD-2 Phase 2b trial of MORF-057 in ulcerative colitis-
-Ended third quarter with $725.1 million in cash, cash equivalents, and marketable securities providing runway into the second half of 2027-

WALTHAM, Mass. – November 3, 2023 – 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 2023.

"Morphic presented a comprehensive set of positive results from the 12-week induction phase of the EMERALD-1 study of MORF-057 in UC, showing consistent efficacy across-the-board for patients, while demonstrating no safety signals. These results are particularly impressive, given that enrollment was skewed towards the severe end of the spectrum of moderately-to-severely active UC. Notably, we continue to observe improvement in these difficult to treat patients beyond the induction phase of the study in 44-week data presented recently," commented Bruce Rogers, PhD, President of Morphic Therapeutic. "The Phase 2a study of MORF-057 clearly signaled everything we believed it would at this point in development and we are excited to continue enrolling patients in our ongoing EMERALD-2 Phase 2b study. On a separate note, what the company continues to accomplish, while Praveen is on medical leave, is a testament to the quality the team that he put in place, and we are all wishing him the very best in his continued recovery."

Third Quarter 2023 and Recent Corporate Highlights

Chief Executive Officer of Morphic Therapeutic, Praveen Tipirneni, MD, continues to improve while remaining on a medical leave of absence after suffering an emergent medical event in late September. Dr. Tipirneni is expected to return after he recovers.

In the EMERALD-1 Phase 2a trial of MORF-057 in UC, additional positive data, presented at UEGW 2023 and in a company conference call, indicate that in a moderately-to-severely-active UC population with severe disease burden, MORF-057:

- Continues to be generally well tolerated with no safety signal observed to date
- Achieved primary endpoint with high statistical significance in reduction of RHI of 6.4 points (p=0.0019)
- Showed clinical improvement consistently across key measures at week 12, including remission and response (mMCS remission of 25.7%; 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 76% of patients, including advanced therapy-experienced patients
- PK/PD results confirm those seen in healthy volunteer studies
    - Median RO >99% and sustained saturation at week 12
    - 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

Ongoing MORF-057 EMERALD Phase 2 Development Program Updates

- Continued the 40-week maintenance phase of the EMERALD-1 study as planned
- EMERALD-2 global Phase 2b randomized, double-blind, placebo-controlled trial of MORF-057 in patients with moderate-to-severe UC continues to 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
- The Phase 2b study of MORF-057 in Crohn's Disease is anticipated to begin in the first half of 2024

MORF-057 Preclinical Studies

- Presented preclinical data on rational selection of combination therapy for inflammatory bowel disease (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

- Continued late-stage preclinical work in the MORF-088 small molecule αvβ8 inhibitor program, with initiation of clinical trials anticipated in the first half of 2024
    - αvβ8 inhibition holds promise as a novel mechanism to treat myelofibrosis, a rare blood cancer, because the αvβ8 integrin is an activator of TGF-β which is believed to play a central role in the pathogenesis of myelofibrosis

Financial Results for the Third Quarter 2023

- Net loss for the quarter ended September 30, 2023, was $36.2 million or $0.73 per share compared to net income of $30.0 million or $0.78 per share for the same quarter last year
- Revenue was $0 million for the quarter ended September 30, 2023, compared to $2.1 million for the same quarter last year due to the conclusion of the Company's research and development collaborations with AbbVie and Janssen
- Research and development expenses were $34.4 million for the quarter ended September 30, 2023, as compared to $25.2 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 $10.4 million for the quarter ended September 30, 2023, compared to $8.3 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 September 30, 2023, Morphic had cash, cash equivalents and marketable securities of $725.1 million, compared to $731.4 million as of June 30, 2023. Based on its current operating plan, Morphic believes its existing cash, cash equivalents and marketable securities as of September 30, 2023, will be sufficient to fund 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 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 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 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 αvβ8 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 September 30, 2023 filed with the SEC on November 3, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ —	$ 2,055	$ 521	$ 64,673
Operating expenses:				
Research and development	34,364	25,245	100,532	77,360
General and administrative	10,384	8,303	29,244	24,128
Total operating expenses	44,748	33,548	129,776	101,488
Loss from operations	(44,748)	(31,493)	(129,255)	(36,815)
Other income:				
Interest income, net	8,612	1,657	18,139	2,326
Other income (expense), net	7	(156)	9	(144)
Total other income, net	8,619	1,501	18,148	2,182
Loss before provision for income taxes	(36,129)	(29,992)	(111,107)	(34,633)
Provision for income taxes	(83)	(29)	(253)	(31)
Net loss	$ (36,212)	$ (30,021)	$ (111,360)	$ (34,664)
Net loss per share, basic and diluted	$ (0.73)	$ (0.78)	$ (2.65)	$ (0.91)
Weighted average common shares outstanding, basic and dilutive	49,548,947	38,490,910	41,979,245	37,961,262

Morphic Holding, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	September 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and marketable securities	$ 725,067	$ 348,248
Other current assets	13,030	13,934
Total current assets	738,097	362,182
Other assets	5,505	6,407
Total assets	$ 743,602	$ 368,589
Liabilities and Stockholders' Equity		
Current liabilities	$ 19,298	$ 17,126
Long-term liabilities	1,136	2,344
Total liabilities	20,434	19,470
Total stockholders' equity	723,168	349,119
Total liabilities and stockholders' equity	$ 743,602	$ 368,589

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Contacts
Morphic Therapeutic
Chris Erdman
chris.erdman@morphictx.com
617.686.1718