
**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): October 24, 2022

Morphic Holding, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38940
(Commission
File Number)

47-3878772
(I.R.S. Employer
Identification No.)

35 Gatehouse Drive, A2
Waltham, Massachusetts
(Address of principal executive offices)

02451
(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 8.01 Other Events

On October 24, 2022, Morphic Holding, Inc. (the “Company”) issued a press release announcing the completion of targeted enrollment of the main cohort and ongoing enrollment of an exploratory cohort of patients who have previously failed treatment with vedolizumab in the EMERALD-1 clinical trial (MORF-057-201), which 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 (“UC”) in the United States and Poland.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by Morphic Holding, Inc. dated October 24, 2022.
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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MORPHIC HOLDING, INC.

Date: October 24, 2022

By: /s/ Marc Schegerin

Marc Schegerin, M.D.

Chief Financial Officer and Chief Operating Officer



Morphic Announces Complete Enrollment of EMERALD-1 Main Cohort Ahead of Projections

Phase 2a trial of MORF-057 in patients with ulcerative colitis will extend enrollment to allow patients currently screened to enter study if eligible

WALTHAM, Mass. – October 24, 2022 – Morphic Therapeutic (Nasdaq: MORF), a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, today announced the completion of targeted enrollment of 30 patients ahead of schedule for the main cohort of the EMERALD-1 phase 2a study of MORF-057 in patients with moderate to severe ulcerative colitis (UC).

“The completion of enrollment in the main cohort of the EMERALD-1 ahead of target is a significant accomplishment and a testament to the efficiency and commitment of the Morphic development teams,” commented Carolyn Soo, PharmD, Vice President of Clinical Operations of Morphic Therapeutic. “MORF-057 was designed to treat IBD via the validated mechanism of inhibition of the $\alpha 4\beta 7$ integrin and the EMERALD-1 study was planned to provide proof of concept that an oral inhibitor of $\alpha 4\beta 7$ has the potential to benefit patients suffering from UC. This milestone brings us one step closer to realizing this important vision and I would like to thank the patients and investigators for their ongoing commitment this program.”

Based on the rapid enrollment and substantial demand accrued to enter EMERALD-1, there were a significant number of patients in screening at the time of the 30th patient’s enrollment; these patients will be eligible to enter the study if the eligibility criteria are met. Enrollment in the exploratory cohort of up to ~10 patients who have previously failed treatment with vedolizumab is ongoing.

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 EMERALD-1 study is planned to enroll up to 30 patients with moderate to severe ulcerative colitis who will be treated with 100 mg BID (twice daily) at sites in the United States and Europe and 5 patients who have previously failed on advanced UC therapies. The primary endpoint of the trial is 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 then continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment. 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 $\alpha 4\beta 7$ receptor occupancy and lymphocyte subset trafficking.

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 Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD) comprises several autoimmune and immune-mediated conditions characterized by chronic inflammation of the gastrointestinal tract. Ulcerative colitis and Crohn’s disease are two most common types of IBD. In ulcerative colitis, inflammation is limited to the lining of the colon, whereas in Crohn’s disease inflammation can segmentally affect any part of the gastrointestinal tract through the entire thickness of the bowel.

wall. Symptoms of these conditions include persistent diarrhea, abdominal pain, rectal bleeding, weight loss, and fatigue. Approved medications may not adequately control symptoms for many patients, and some develop complications that require surgical removal of the colon and rectum. Among FDA approved therapies for use in moderate to severe IBD is vedolizumab, an injectable monoclonal antibody inhibitor of the integrin $\alpha4\beta7$.

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 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, Morphic'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 Morphic'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 Morphic'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, Morphic'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 Morphic 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.

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