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): July 9, 2021

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	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 July 9, 2021, Morphic Holding, Inc. (“Morphic”) announced positive topline results from its Phase 1 clinical trial for MORF-057 which were presented at the Congress of European Crohn’s and Colitis Organization (ECCO) 2021 Virtual Congress on July 9, 2021. The complete ePoster reported the full Phase 1 results, including data from an additional dose cohort from the MAD study and further pharmacokinetic endpoint data from a food effect study that were ongoing at the time of abstract submission

On July 9, 2021, Morphic issued a press release, a copy of which is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	**Description**
99.1	Press release dated July 9, 2021, issued by Morphic Holding, Inc.
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: July 9, 2021

By: /s/ Marc Schegerin

Marc Schegerin

Chief Financial Officer and Chief Operating Officer

Morphic Reports New Data from Positive Phase 1 Study of MORF-057, Oral Integrin Inhibitor Candidate for IBD

MORF-057 well tolerated across all phase 1 cohorts

Dose-dependent α4β7 receptor occupancy (RO) observed with receptor saturation at 100 mg dose

Biomarker changes including lymphocyte subset migration and CCR9 transcript levels provide early proof of biology

Conference call today at 8:00 AM ET

WALTHAM, Mass. – July 9, 2021 – Morphic Therapeutic (Nasdaq: MORF), a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, today announced positive results from its full phase 1 clinical trial for MORF-057, an oral small molecule inhibitor of the α4β7 integrin in development for the treatment of inflammatory bowel disease (IBD). The data were shared today in an ePoster presentation at the Congress of European Crohn's and Colitis Organisation (ECCO) 2021 Virtual Congress. The additional data shared today include detail regarding the safety, pharmacokinetic (PK) and pharmacodynamic (PD) performance of MORF-057 in healthy subjects.

"The complete phase 1 clinical data set including a favorable safety profile, predictable PK and excellent PD results, confirm MORF-057 as a very strong candidate for oral therapy in inflammatory bowel disease. Notably, MORF-057's substantial effect on α4β7-expressing lymphocyte migration and CCR9 transcripts in a short two-week dosing period in healthy subjects provides evidence of the selective blockage of lymphocyte homing, a well-validated mechanism for combating the pathological inflammation in IBD," said Peter Linde, M.D., chief medical officer at Morphic Therapeutic. "We have high confidence as we prepare for a MORF-057 phase 2 clinical program in patients with ulcerative colitis. Our increased conviction is based on the expanded safety profile and even stronger RO data reported today, in combination with biomarker data which we believe provide us with strong evidence of proof of biology."

ECCO ePoster #306, titled *MORF-057, an oral selective α4β7 integrin inhibitor for Inflammatory Bowel Disease, leads to specific target engagement in a single and multiple ascending dose study in healthy subjects,* was presented today by Adrian S. Ray, PhD, Head of Biology and Translation at Morphic, is viewable on Morphic Therapeutic's website here.

The MORF-057 Phase 1 study included single ascending dose (SAD), multiple ascending dose (MAD), and food effect (FE) cohorts evaluating MORF-057 safety, PK, and PD. Healthy subjects were randomized 3:1 to receive a single dose of MORF-057 at 25, 50, 100, 150 and 400 mg or matching placebo in the SAD cohorts; or twice daily (BID) doses of 25, 50 and 100 mg MORF-057 or matching placebo for a total of 14 days in the MAD cohorts. A total of 67 eligible healthy subjects were enrolled into the studies, with 36 in the SAD, 9 in the FE and 22 in the

MAD cohorts. Sixty-six subjects completed study treatment and one from the 50 mg BID MAD cohort withdrew consent for personal reasons.

MORF-057 was well tolerated in all cohorts and no safety signals were identified. MORF-057 demonstrated a favorable PK profile, where target engagement was confirmed, and a clear PK and PD relationship was established. MORF-057 was rapidly absorbed and systemic exposure was confirmed to increase approximately dose proportionally. A slight reduction in exposure without effect on trough concentrations, was observed upon administration with a high fat meal in the food effect study. The results suggest food intake has no impact on trough MORF-057 levels and that MORF-057 can be administered without regard to food in planned studies in patients.

α4β7 receptor occupancy increased with dose and study day, achieving saturation (>99% RO) in individual patients from all cohorts above 25 mg by Day 14. In the 100 mg BID cohort, MORF-057 saturated the α4β7 receptor (mean RO >99%). Dose- and time-dependent changes in biomarkers including specific α4β7 high expressing immune cell populations were observed, adding to evidence of proof of biology for MORF-057. These changes were consistent with those reported with other integrin inhibitors including the antibody drug vedolizumab which is approved for the treatment of IBD.

In addition to the phase 1 presentation, John P. Jones, Ph.D., Director of Clinical Pharmacology at Morphic, presented MORF-057 non-clinical pharmacokinetic and metabolism data in poster P037: *Nonclinical pharmacokinetics and absorption, distribution, metabolism, and excretion properties of MORF-057 support its clinical development as an oral selective α4β7 integrin inhibitor* that is available here. These data provided the basis for Phase 1 dose selection. The human PK from the phase 1 trial reported today (P306) surpassed the predictions from animal models reported in poster P037.

Conference Call and Webcast Information
A live webcast of the call will be available on the Investors section of Morphic's website at www.morphictx.com. An archived replay will be available on the company's website following the conference call.

To participate in the live conference call, please use the following dial-in information:

US or Canada Toll-Free Dial-In Number: (844) 954-0202
International Dial-In Number: (661) 407-1533
Conference ID number: 6443786

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 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 causing inflammation that is associated with IBD.

About Morphic Therapeutic
Morphic Therapeutic is a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. In collaboration with AbbVie, Janssen and Schrödinger, Morphic is advancing its pipeline and discovery activities using its proprietary Morphic Integrin Technology (MInT) Platform which leverages the Company's unique understanding of integrin structure and biology. For more information, visit www.morphictx.com.

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, the initiation, execution and completion of the future MORF-057 Phase 2 clinical trial, 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," "develop," "signal," "potential," "anticipated," 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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