

**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): May 28, 2021

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	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 May 28, 2021, Morphic Holding, Inc. (“Morphic”) announced that the new Phase 1 data for MORF-057 will be presented in an ePoster at the Congress of European Crohn’s and Colitis Organisation (ECCO) 2021 Virtual Congress on July 9, 2021. The complete ePoster is anticipated to report 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 May 28, 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
<u>99.1</u>	<u>Press release dated May 28, 2021, issued by Morphic Holding, Inc.</u>
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: June 1, 2021

By: /s/ Marc Schegerin

Marc Schegerin

Chief Financial Officer and Chief Operating Officer



Morphic Therapeutic to Present Positive Phase 1 Data for MORF-057 at ECCO'21 Virtual Congress

May 28, 2021

Presentation will include summary safety, pharmacokinetic and pharmacodynamic data from single ascending dose (SAD), food effect and multiple ascending dose (MAD) studies

All dosing regimens well-tolerated across Phase 1

High receptor occupancy (RO) in Phase 1 SAD study confirmed by MAD results with increasing RO over time: receptor saturation at 100 mg BID dose

WALTHAM, Mass., May 28, 2021 (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 announced that new Phase 1 data for MORF-057 will be presented in an ePoster at the Congress of European Crohn's and Colitis Organisation (ECCO) 2021 Virtual Congress on July 9, 2021.

The abstract for this e-presentation is now available on the ECCO website and contains data that provide additional support for the tolerability, pharmacokinetic and pharmacodynamic profile of MORF-057 as a twice-daily oral treatment candidate for inflammatory bowel disease (IBD). The complete ePoster is anticipated to report the full Phase 1 results, including data from an additional dose cohort from the MAD study and further pharmacokinetic (PK) endpoint data from a food effect study that were ongoing at the time of abstract submission.

"These data confirm the tolerability and pharmacodynamic profile that was reported with the initial MORF-057 SAD data. In these results, we observed $\alpha 4\beta 7$ RO levels that exceeded our expectations across a range of doses, each of which was well tolerated," said Peter Linde, M.D., chief medical officer at Morphic Therapeutic. "We are incredibly excited about the results from this Phase 1 study that strongly support our upcoming Phase 2 ulcerative colitis program."

Data contained in the abstract demonstrate that single and multiple ascending doses of MORF-057 were well tolerated, with only mild, non-serious adverse events observed. MORF-057 also demonstrated a favorable PK profile with systemic exposure that was predictable and generally proportional to dose. In addition, these MORF-057 clinical data are consistent with non-clinical drug metabolism and PK (DMPK) profiling which will also be presented in a separate poster at the ECCO'21 Virtual Congress.

High levels of target engagement of the $\alpha 4\beta 7$ integrin receptor were observed in the Phase 1 MORF-057 SAD study. As previously reported, the mean $\alpha 4\beta 7$ RO's for the 100 mg, 150 mg and 400 mg SAD cohorts were greater than 95%. These observations were confirmed in the MAD study, with increasing RO levels at steady state in all doses tested. Increased duration of dosing demonstrated increasing mean RO and decreasing inter-subject RO variability. In these new data, results from two of the three MAD cohorts were available at the time of abstract publication. The mean $\alpha 4\beta 7$ RO for the 50 mg cohort receiving twice-daily (BID) administration of MORF-057 for 14 days was greater than 90% at steady state. The mean $\alpha 4\beta 7$ RO in the 100 mg BID cohort at steady state was greater than 99%, or complete receptor saturation.

MORF-057 Abstracts at ECCO'21 Virtual Congress

The full title of the MORF-057 Phase 1 ePoster (P306) is: *MORF-057, an oral selective $\alpha 4\beta 7$ integrin inhibitor for Inflammatory Bowel Disease, leads to specific target engagement in a single and multiple ascending dose study in healthy subjects*

The full title of the MORF-057 non-clinical DMPK ePoster (P037) is: *Nonclinical pharmacokinetics and absorption, distribution, metabolism, and excretion properties of MORF-057 support its clinical development as an oral selective $\alpha 4\beta 7$ integrin inhibitor*

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 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 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 execution and completion of the MORF-057 Phase 1 clinical trial as designed, any expectations about safety, efficacy, timing and ability to commence or complete clinical studies 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 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 Morpic’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 Morpic’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, Morpic’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 Morpic 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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