

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): April 25, 2023

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 April 25, 2023, Morphic Holding, Inc. (the “Company”) presented data from the main cohort (n=35) of the EMERALD-1 open-label, single-arm Phase 2a trial of MORF-057 at a dose of 100 mg twice daily in patients with moderate to severe ulcerative colitis. A copy of the presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K 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 statements regarding the clinical development of MORF-057. 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 the Company’s 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 the Company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties disclosed in this Current Report on Form 8-K and other risks set forth in the Company’s filings with the Securities and Exchange Commission. Forward-looking statements in this Current Report on Form 8-K 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	EMERALD-1 Phase 2a Data Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: April 25, 2023

By: /s/ Marc Schegerin
Marc Schegerin, M.D.
Chief Financial Officer and Chief Operating Officer



EMERALD-1
Topline Data

April 25, 2023



Forward Looking Statements

This presentation contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to statements regarding the timing and success of Morphic's ongoing clinical trials and related data, updates and results from Morphic's clinical trials and the potential therapeutic benefits of MORF-057.

Certain data in this presentation are based on cross-study comparisons and are not based on any head-to-head clinical trials. Cross-study comparisons are inherently limited and may suggest misleading similarities and differences. The values shown in the cross-study comparisons are directional and may not be directly comparable.

Statements including words such as "believe," "plan," "continue," "expect," "will," "develop," "signal," "potential," 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 or implied by any forward-looking statement, including risks and uncertainties related to the forward-looking statements in this presentation and other risks set forth in our filings with the Securities and Exchange Commission (SEC), including the Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023 and the Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2023 filed with the SEC on April 25, 2023. 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.

Note regarding trademarks: all third-party trademarks, including names, logos and brands, referenced by in this presentation are the property of their respective owners. All references to third-party trademarks are for identification purposes only and shall be considered nominative fair use under trademark law.



Agenda and Participants

Introductory Remarks: **Praveen Tipirneni**

UC Treatment Landscape: **Dr. Bruce Sands**

EMERALD-1 Overview & Safety: **Brihad Abhyankar**

Clinical Data: **Bruce Rogers**

Closing Remarks: **Praveen Tipirneni**

Q&A



Present for Q&A: Management and Key Opinion Leader



Bruce Sands, MD

Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai,
Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Health System



Praveen Tipirneni, MD

Chief Executive Officer



Bruce Rogers, PhD

President



Marc Schegerin, MD

Chief Operating Officer & Chief Financial Officer



Brihad Abhyankar, MBBS, FRCS

Senior Vice President of Clinical Development

The Unmet Need in IBD Treatment



Compelling
Clinical Efficacy

Safe and Well
Tolerated

Convenient
Oral
Administration

EMERALD-1 Trial Overview



Phase 2a open-label single-arm study of MORF-057 (100mg BID) in patients with moderately to severely active ulcerative colitis (UC)

– N=35 in main cohort

- Inclusion criteria:
 - History of insufficient response, loss of response, or intolerance to conventional and/or advanced therapies
 - Modified Mayo clinical score (mMCS) of 5-9
 - Centrally read endoscopy sub-score of ≥ 2
 - Roberts Histopathology Index (RHI) score of ≥ 10
- Exclusion criteria:
 - Prior exposure to vedolizumab or other integrin inhibitors
- Primary endpoint: Change in RHI measured at 12 weeks
- Secondary endpoints: mMCS change from baseline, safety
- Pre-specified exploratory endpoints:
 - RHI remission
 - mMCS remission
 - mMCS response
 - Multiple PK/PD parameters
 - Relevant biomarkers

Baseline Patient Demographics

A moderately-to-severely active UC population with high disease burden

	N=35
Age, years, mean (SD)	39.2 (14.1)
Sex, n (%), female/male	16 (45.7%) / 19 (54.3%)
Geography, n (%), Poland/US	28 (80%) / 7 (20%)
Baseline RHI, mean (SD)	22.7 (7.3)
mMCS, mean (SD)	6.7 (1.1)
Mayo Endoscopy Score (MES), n (%), 2/ 3	18 (51.4%) / 17 (48.6%)
Advanced Treatment Experienced, n (%)	13 (37.1%)
Baseline steroid use, n (%)	9 (25.7%)

MORF-057: Generally Well-Tolerated in EMERALD-1

No Safety Signal Observed

Adverse Event (AE) profile consistent with underlying disease state

Patients with at least one AE	12 (34.3%)
Patients with any serious AE	0
Patients with AE leading to death	0
Patients with any grade 3 AE	2 (5.7%)¹
Patients with treatment-related AE	2 (5.7%)
Common (>5%) AEs	
Exacerbation of UC	4 (11.4%)
Anemia	3 (8.6%)²

1. Both UC exacerbations, one led to early discontinuation

2. All anemic at baseline and continued on study with iron supplements

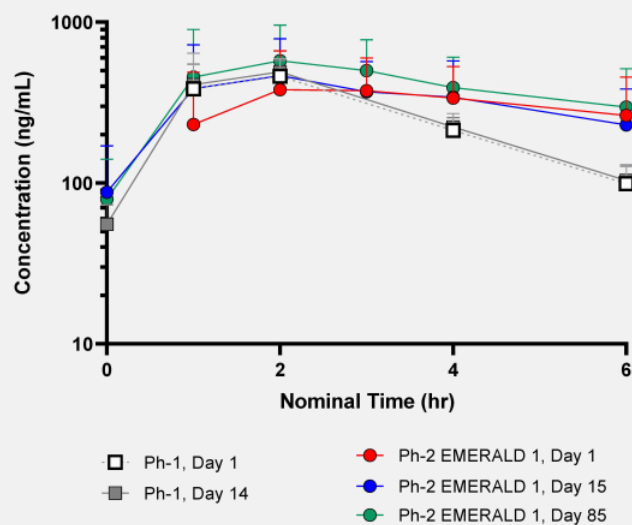
*As of 4/25/23 patients have been on EMERALD-1 study beyond the 12-week induction period and no other safety signals or SAEs have been reported.



Topline Clinical Data

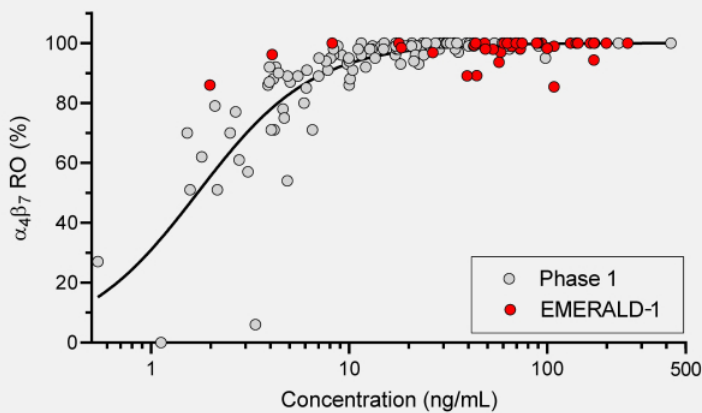


Patient PK Consistent with Healthy Volunteer PK



- Serum drug concentrations conform highly to Phase 1 healthy volunteer data
- Mean PK data demonstrate consistency from start of dosing through week 12
- MORF-057 trough concentrations sufficient for saturation of $\alpha 4\beta 7$ receptor in the blood

Patient $\alpha 4\beta 7$ Receptor Occupancy (RO) Consistent with Healthy Volunteer RO



$\alpha 4\beta 7$ selectivity over $\alpha 4\beta 1$ consistent with Phase 1 results

RO at 12 weeks

	$\alpha 4\beta 7$	$\alpha 4\beta 1$
Mean	>98%	BLQ
Median	>99%	BLQ

- $\alpha 4\beta 7$ RO achieved early and sustained saturating levels
- $\alpha 4\beta 1$ RO remained at low levels
- No lymphocytosis or changes to circulating naïve T-cells were observed
- $\alpha 4\beta 1$ projected RO was below the limit of quantitation with mean trough value estimated to be <15%

Consistent Clinical Improvement Across Key Measures

Change in RHI from Baseline

Primary Endpoint

-6.4
(p=.0019)

mMCS Mean Change from Baseline

Secondary Endpoint

-2.3

mMCS Remission

mMCS: Rectal bleeding sub-score of 0; a stool frequency sub-score of ≤ 1 ; and an MES of ≤ 1 without friability

25.7%

mMCS Response

Decrease from baseline in the mMCS ≥ 2 points and $\geq 30\%$ from baseline, plus a decrease in rectal bleeding subscore ≥ 1 or an absolute rectal bleeding subscore ≤ 1

45.7%

RHI Remission

RHI ≤ 3

22.9%



All measures at 12 weeks

Strong RHI Results Support MORF-057

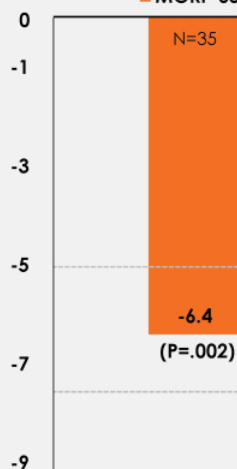
Mean RHI Reduction from Baseline

EMERALD¹

- Baseline RHI:
 - 22.7 (7.32)
- 12-week timepoint
- 37% advanced therapy experienced patients
- Open-label, single arm

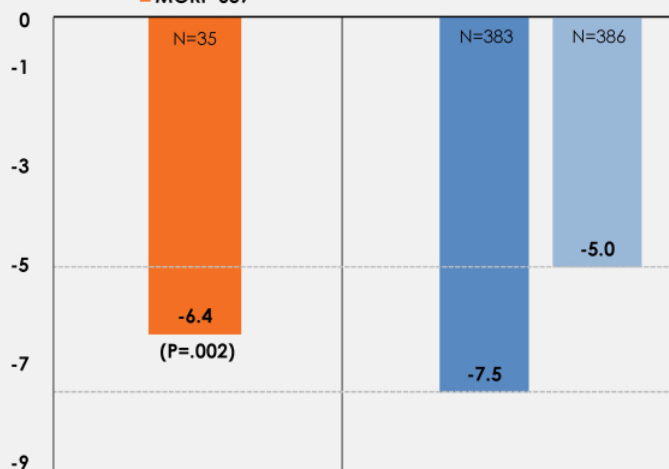
EMERALD-1

■ MORF-057



VARSITY

■ ENTYVIO ■ HUMIRA



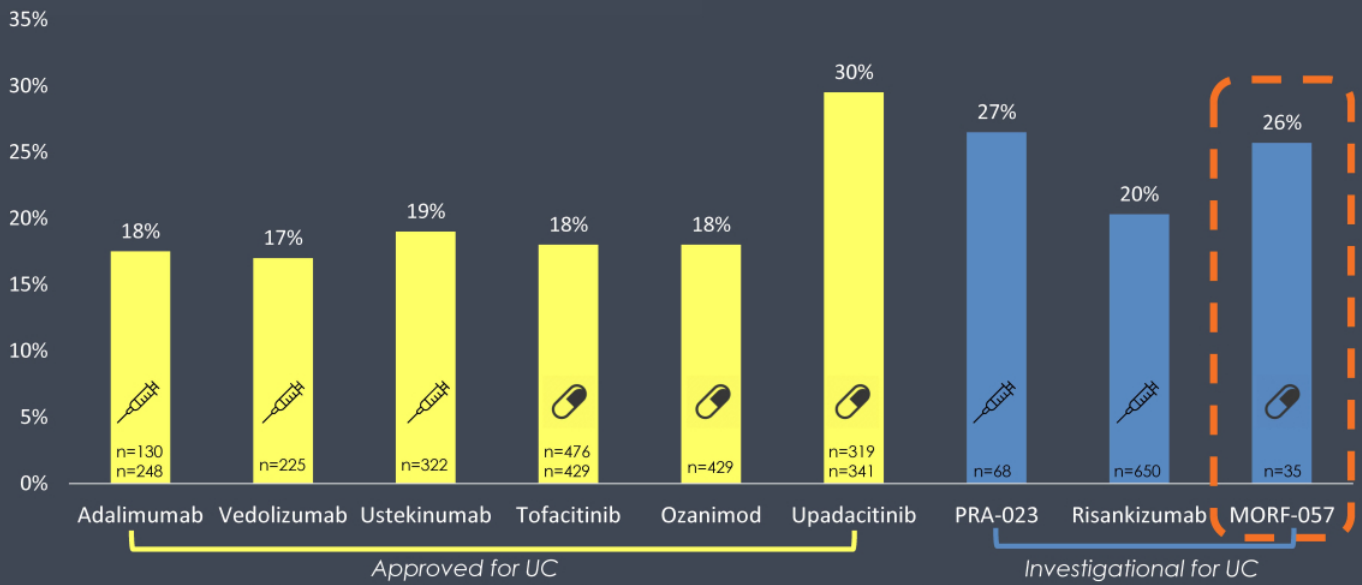
VARSITY

- Baseline RHI:
 - ENTYVIO® - 19.5 (8.7)
 - HUMIRA® - 19.6 (8.9)
- 14-week timepoint
- 19% advanced therapy experienced patients
- Double-blind, double dummy



Comparing the results from different trials may be unreliable due to different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that may not be the same between trials. Therefore, cross-study comparisons provide very limited information about the efficacy or safety of a drug. Results of a head-to-head comparison may differ significantly from those set forth herein.

UC Absolute Clinical Remission Data at Induction Selected Approved and Investigational Agents



- PRA-023 and MORF-057 data from Phase 2 trials; all other data from RCT Phase 3 studies. Graphic is not meant to represent a head-to-head study. Comparing the results from different trials may be unreliable due to different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that may not be the same between trials. Therefore, cross-study comparisons provide very limited information about the efficacy or safety of a drug.
- Remission data is based on mMCS for all drugs except adalimumab, vedolizumab, and tofacitinib, which are based on IMCS
- MORF-057 EMERALD-1 study consisted of n=35, a significantly smaller number of patients than reflected in the other datasets represented on this slide. In larger trials of MORF-057 the clinical activity suggested by our EMERALD-1 trial may not be replicated.
- N's are from active arms only, data sourced from following trials respectively: UC-1/UC-2, Gemini-1, UC-1/UC-1, UC-2, TRUE NORTH, U-ACHIEVE-1/U-ACHIEVE-2, APOLLO-UC, INSPIRE and EMERALD-1

The Unmet Need in IBD Treatment



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Q&A

Key Opinion Leader



Bruce Sands, MD

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Executive Management



Praveen Tipirneni, MD

Chief Executive Officer



Marc Schegerin, MD

Chief Operating Officer & Chief Financial Officer



Bruce Rogers, PhD

President



Brihad Abhyankar, MBBS, FRCS

Senior Vice President of Clinical Development



Thank You

