
**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 12, 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 2.02. Results of Operations and Financial Condition.

On October 12, 2023, Morphic Holding, Inc. (the “Company”) announced that as of September 30, 2023, it had preliminary cash, cash equivalents and marketable securities totaling approximately \$725 million.

The Company’s unaudited financial statements as of and for the three and nine months ended September 30, 2023 are not yet available. Accordingly, the information presented reflects the Company’s preliminary financial data subject to the completion of the Company’s financial closing procedures and any adjustments that may result from the completion of the quarterly review of the Company’s financial statements. Actual financial results that will be reflected in the Company’s Quarterly Report on Form 10-Q as of and for the three and nine months ended September 30, 2023 when they are completed and publicly disclosed may differ from the preliminary results presented here.

The information in this Item 2.02 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On October 12, 2023, the Company presented additional data from its 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 and 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 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 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 Company’s filings with the SEC, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on February 23, 2023 and its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2023 filed with the SEC on August 3, 2023. 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 Presentation
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: October 12, 2023

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



EMERALD-1
Full Data Presentation
October 12, 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 June 30, 2023 filed with the SEC on August 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 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.



Phase 2a Study Designed to Confirm Efficacy Signal: Results Exceeded Expectations

- Primary endpoint achieved, with consistent and expected clinical improvement seen across key measures
- PK in patients consistent with healthy volunteers
- RO and T-cell subsets consistent with healthy volunteers
- Generally well tolerated with no safety signal observed
- Further clinical improvement in patients continuing treatment beyond week 12, especially in refractory patients

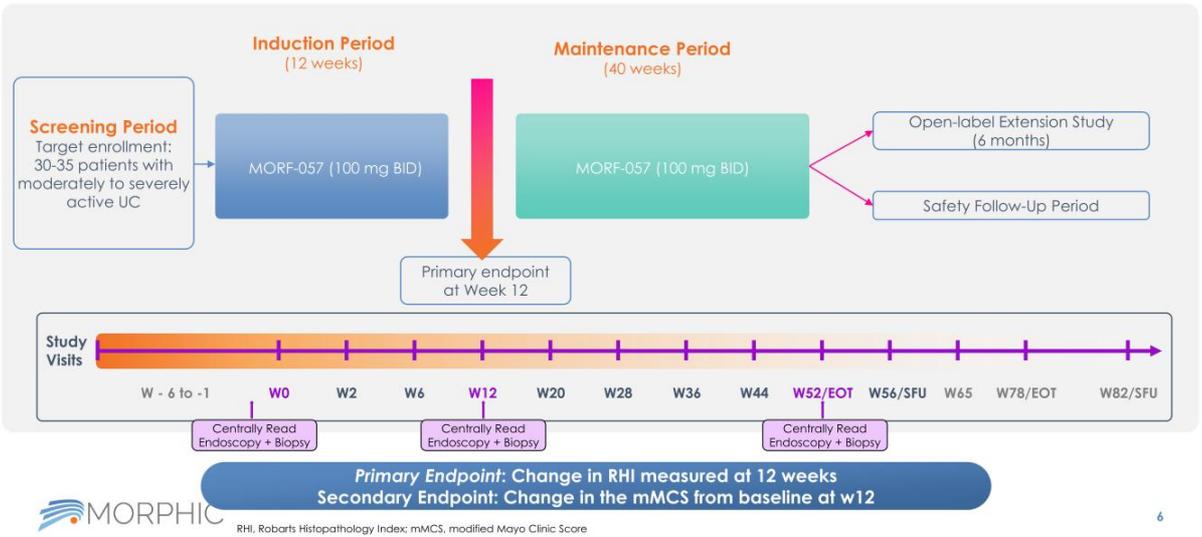
Agenda

- Welcome and Introduction
 - Chris Erdman, SVP Investor & Corporate Communications
- Trial Design, Patient Disposition, Safety, PK/PD
 - Dr. Brihad Abhyankar, SVP Clinical Development, Morphic Therapeutic
- Detailed Clinical Efficacy Results
 - Dr. Bruce Rogers, President, Morphic Therapeutic
- Concluding Thoughts and Corporate Update
 - Dr. Marc Schegerin, COO & CFO, Morphic Therapeutic
- Q&A
 - Dr. Brian Feagan
 - Morphic Team



EMERALD-1
Trial Design and
Patient Disposition





Baseline Patient Demographics: a Moderately-to-Severely Active UC population with High Disease Burden

Category		Patients, N=35
Age, mean \pm SD	Years	39.2 \pm 14.1
Sex, n (%)	Female	16 (45.7)
Geography, n (%)	Poland	28 (80.0)
	United States	7 (20.0)
Duration of disease, mean \pm SD	Years	7.5 \pm 8.0
Extent of disease, n (%)	Proctosigmoiditis	12 (34.3)
	L-sided colitis	10 (28.6)
	Pancolitis	10 (28.6)
RHI Score, mean \pm SD	Points	22.7 \pm 7.3
mMCS, mean \pm SD	Points	6.7 \pm 1.1
MES, n (%)	2	18 (51.4)
	3	17 (48.6)
Corticosteroid use, n (%)	No	26 (74.3)
	Yes	9 (25.7)
Previous use of AT*, n (%)	Naïve	21 (60.0)
	Experienced	14 (40.0)

AT, advanced therapy; MES, Mayo endoscopic score; mMCS, modified Mayo Clinic score; RHI, Roberts histopathology index; SD, standard deviation

*The number of AT-experienced patients was updated from n=13/35 to n=14/35 during re-review of data for presentation at a medical conference. During this re-review, it was determined that one patient had received an investigational agent deemed to be an advanced therapy before the MORF-057-201 trial. This change does not impact any of the clinical efficacy data presented from the EMERALD-1 study.

Demographics and Baseline Characteristics by Prior Treatment Status & Mayo Endoscopic Score

Baseline Characteristics	Main Cohort (N=35)	AT-N (N=21, 60%)	AT-E (N=14, 40%)	MES =2 (N=18, 51.4%)	MES =3 (N= 17, 48.6%)
Age, years, mean (SD)	39.2 (14.10)	39.9 (14.89)	38.3 (13.32)	40.1 (11.22)	38.4 (16.95)
Sex, n (%) Male/ Female	19 (54.3) / 16 (45.7)	10 (47.6) / 11 (52.4)	9 (64.3) / 5 (35.7)	9 (50.0) / 9 (50.0)	10 (58.8) / 7 (41.2)
Geography, n (%) USA / Poland	7 (20.0) / 28 (80.0)	5 (23.8) / 16 (76.2)	2 (14.3) / 12 (85.7)	4 (22.2) / 14 (77.8)	3 (17.6) / 14 (82.4)
RHI, mean (SD)	22.7 (7.32)	22.0 (7.51)	23.6 (7.19)	21.1 (8.04)	24.3 (6.30)
mMCS (central), mean (SD)	6.7 (1.07)	6.4 (1.12)	7.2 (0.80)	6.2 (1.06)	7.2 (0.83)
Total Mayo Clinic Score (tMCS), mean (SD)	8.9 (1.35)	8.5 (1.47)	9.6 (0.85)	8.2 (1.31)	9.7 (0.92)
Mayo Endoscopy Score (MES), n (%): 2/3	18 (51.4) / 17 (48.6)	14 (66.7) / 7 (33.3)	4 (28.6) / 10 (71.4)	18 (100) / 0	0 / 17 (100)
Previous Use of AT, n (%) Naive/Experienced	21 (60.0) / 14 (40.0)	21 (100) / 0	0 / 14 (100)	14 (77.8) / 4 (22.2)	7 (41.2) / 10 (58.8)
Corticosteroid Use at Baseline, n (%) No/Yes	26 (74.3) / 9 (25.7)	17 (81.0) / 4 (19.0)	9 (64.3) / 5 (35.7)	14 (77.8) / 4 (22.2)	12 (70.6) / 5 (29.4)



AT, advanced therapies; MES, Mayo endoscopic score; mMCS, modified Mayo Clinic score; RHI, Roberts histopathology index; SD, standard deviation



Safety and
Tolerability



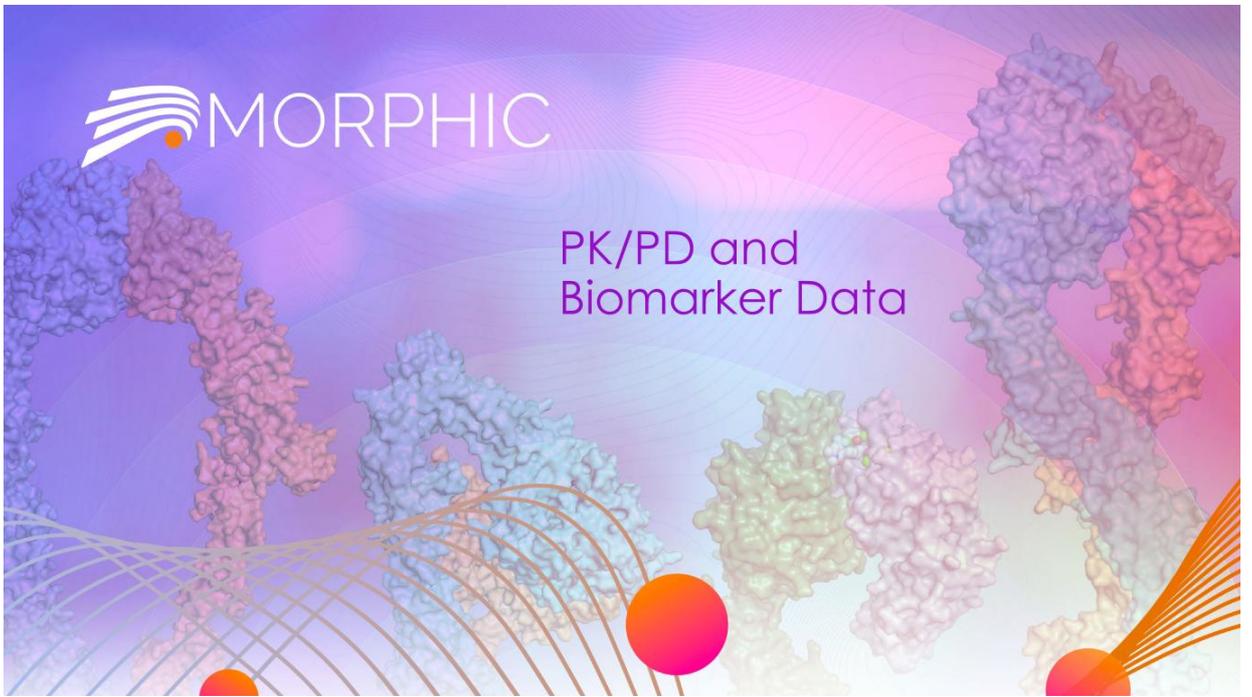
MORF-057: Generally Well-Tolerated in EMERALD-1 No Safety Signal Observed (as of 10/10/23)

Endpoint	Patients, N = 35
Patients with ≥ 1 TEAE, n (%)	12 (34.3)
Serious TEAEs, n (%)	0
Patients with AE leading to death, n (%)	0
Patients with any grade 3 TEAEs, n (%) UC exacerbation ^a	2 (5.7)
Common TEAEs (>5%), n (%) UC exacerbation Anemia ^{b,c}	4 (11.4) 3 (8.6)
Treatment-related TEAE, n (%)	2 (5.7)

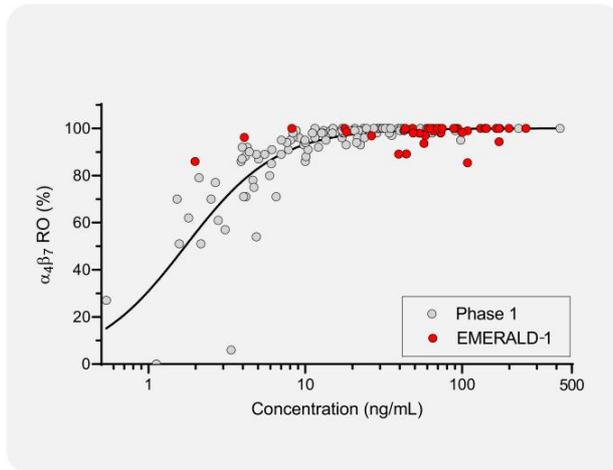
a. One UC exacerbation led to early discontinuation.
b. All anemia events occurred in patients who had anemia at baseline and continued on study with iron supplements.
c. A third of patients with inflammatory bowel disease have iron-deficiency anemia.
TEAE, treatment-emergent adverse event; UC, ulcerative colitis.
*Data shown for 12-week induction period: as of 10/10/23, patients have been on EMERALD-1 study beyond the 12-week induction period and no other safety signals or SAEs have been reported.



PK/PD and
Biomarker Data



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



RO: Receptor Occupancy; BLQ, Below Limit of Quantification

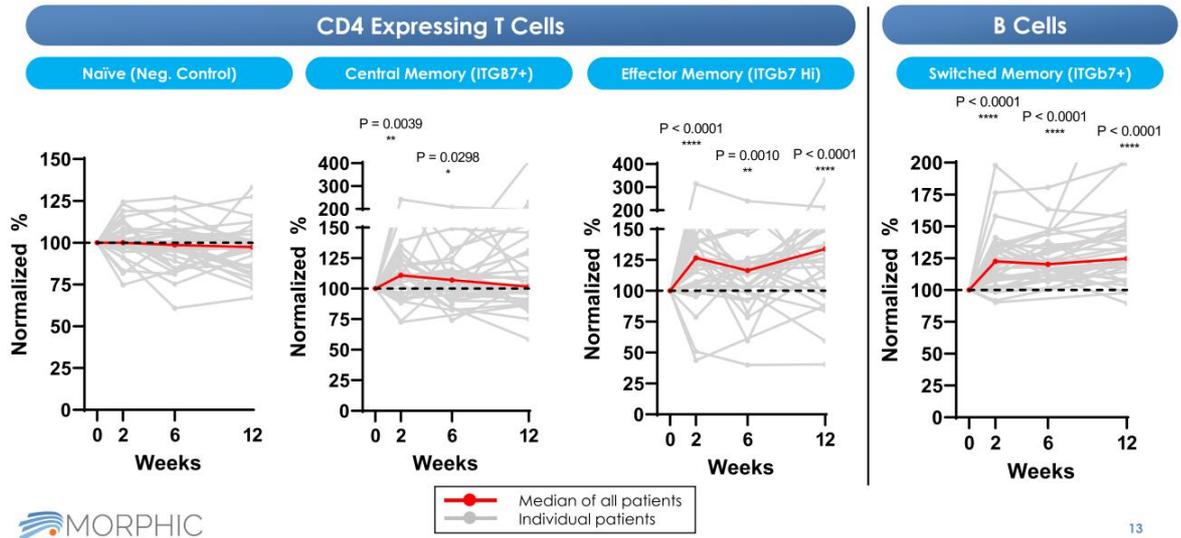


$\alpha 4\beta 7$ selectivity over $\alpha 4\beta 1$ consistent with Phase 1 results

RO at 12 weeks		
	$\alpha 4\beta 7$	$\alpha 4\beta 1$
Mean	>98%	BLQ
Median	>99%	BLQ

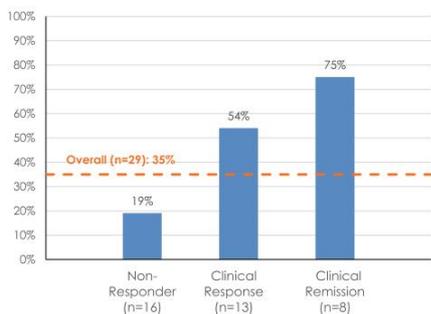
- $\alpha 4\beta 7$ RO achieved early and sustained saturating levels
- $\alpha 4\beta 1$ RO remained at low levels
- No lymphocytosis or changes to circulating naïve T-cells were observed
- $\alpha 4\beta 1$ projected RO was below the limit of quantitation with mean trough value estimated to be <15%

Substantial Lymphocyte Subset Changes Observed, Consistent With Engagement Of $\alpha 4\beta 7$

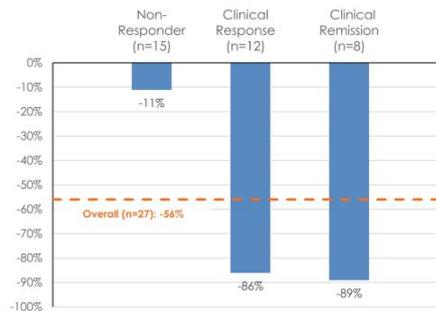


Fecal Calprotectin Decreases Correlated with Disease Improvement

Proportion of Patients with Fecal Cal < 250 mg/kg at Week 12
(Baseline > 250 mg/kg), n=29



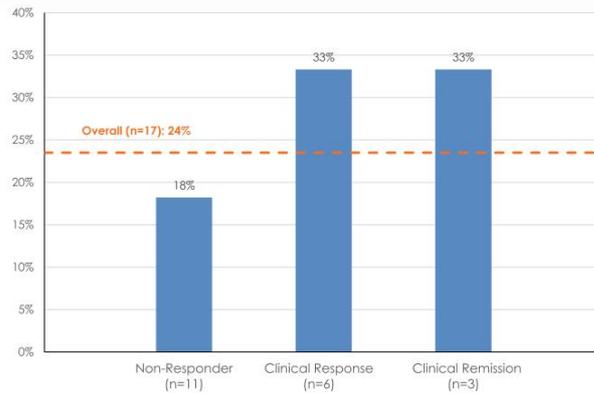
Percentage Reduction From Baseline in Fecal Cal at Week 12
(Baseline > 250 mg/kg & Week 12 data available), n=27^a



n = Patients with baseline FC > 250 mg/kg. No inclusion/exclusion criteria for FC levels
Patients experiencing clinical remission also included in clinical response
a. Data unavailable for 2 patients at week 12

Expected Changes in C-Reactive Protein Observed

Proportion of Patients with hs-CRP < 3 mg/L at week 12 (Baseline > 3 mg/L)



No inclusion/exclusion criteria for CRP levels: n= 17 pts with baseline > 3 mg/L
Patients experiencing clinical remission also included in clinical response

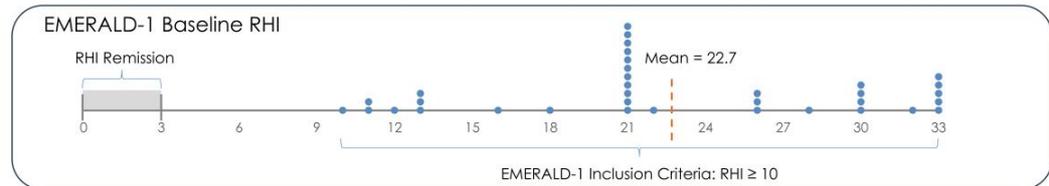


Clinical Efficacy Results



Robarts Histopathology Index for UC

- RHI: a validated histology index derived from the Geboes Score and designed to be reproducible and responsive to clinically meaningful change in disease activity in UC over time
- Calculated by evaluating 4 centrally read, individually weighted histologic items, each on a scale from 0 to 3
- $RHI = (1 \times \text{chronic inflammatory infiltrate score}) + (2 \times \text{lamina propria neutrophils score}) + (3 \times \text{neutrophils in epithelium score}) + (5 \times \text{erosion or ulceration score})$
 - Thus, total RHI Score ranges from 0 (no disease activity) to 33 (severe disease activity)
- Remission: $RHI \leq 3$



Modified Mayo Clinic Score for UC

Stool Frequency (SFS)

0	Normal
1	1-2/day > Normal
2	3-4/day > Normal
3	5+/day > Normal

Rectal Bleeding (RBS)

0	None
1	Streaks
2	Obvious
3	Mostly Blood

Endoscopy / Mucosa (MES)

0	Normal
1	Mild Friability
2	Moderate Friability
3	Spontaneous Bleeding

0-9 Total

• Modified Mayo Clinic Score (mMCS)

- Three component score
- 0 to 9 scale with moderate to severe UC 5 to 9
- Clinical Remission
 - SFS \leq 1
 - RBS = 0
 - MES \leq 1 without friability
- Endoscopic Response / Improvement: MES \leq 1
- Symptomatic Remission: SFS = 0 (or = 1 with \geq 1 point decrease from baseline) and RBS = 0
- PRO2: SFS + RBS

Primary Endpoint Met with High Statistical Significance

Consistent Effects Observed Among All Exploratory Measures

Endpoint @ Week 12	Overall (N=35)
Change in RHI, Mean (SD)	-6.4 (11.18) p=0.0019
RHI remission, n (%)	8 (22.9%)
Clinical response (mMCS) ¹ , n (%)	16 (45.7%)
Clinical remission (mMCS) ² , n (%)	9 (25.7%)
Endoscopic Response/Improvement ³ , n (%)	9 (25.7%)
Change from baseline to Week 12 in the Modified MCS, Mean (SD)	-2.3 (2.14)

1. Clinical response (mMCS): 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

2. Clinical remission (mMCS): rectal bleeding subscore of 0; a stool frequency subscore of ≤ 1 ; and an MES of ≤ 1 without friability

3. Endoscopic response / improvement: MES ≤ 1

EMERALD-1 Efficacy Results by AT Status and MES

Endpoint @ Week 12	Overall N=35	AT-naïve n=21	AT- experienced n=14	MES =2 n=18	MES =3 n= 17
Change in RHI, mean ± SD	-6.4 ± 11.2	-7.4 ± 11.9	-4.8 ± 10.3	-6.9 ± 12.1	-5.8 ± 10.4
RHI change ≥ 7 points, n (%)	17 (48.6)	12 (57.1)	5 (35.7)	10 (55.6)	7 (41.2)
RHI remission ¹ , n (%)	8 (22.9)	6 (28.6)	2 (14.3)	6 (33.3)	2 (11.8)
RHI reduction ≥ 50%, n (%)	12 (34.3)	9 (42.9)	3 (21.4)	9 (50.0)	3 (17.6)
Change in mMCS, mean ± SD	-2.3 ± 2.1	-2.9 ± 2.4	-1.6 ± 1.5	-2.7 ± 2.3	-1.9 ± 1.9
Clinical response (mMCS) ² , n (%)	16 (45.7)	11 (52.4)	5 (35.7)	9 (50)	7 (41.2)
Clinical remission (mMCS) ³ , n (%)	9 (25.7)	9 (42.9)	0	6 (33.3)	3 (17.6)
Symptomatic remission ⁴ , n (%)	11 (31.4)	10 (47.6)	1 (7.1)	7 (38.9)	4 (23.5)
Endoscopic response / improvement ⁵ , n (%)	9 (25.7)	9 (42.9)	0	6 (33.3)	3 (17.6)
Change in SF, mean ± SD	-0.8 ± 1.1	-1.0 ± 1.2	-0.5 ± 0.7	-0.9 ± 1.3	-0.6 ± 0.8
Change in RB, mean ± SD	-1.1 ± 0.8	-1.1 ± 0.9	-0.9 ± 0.8	-1.4 ± 0.8	-0.7 ± 0.7

AT, advanced therapy; MCS, Mayo Clinic Score; mMCS, modified MCS; RHI, Roberts histopathology index; SF, Stool Frequency; RB, Rectal Bleeding; SD, standard deviation

1. RHI Remission: RHI ≤ 2

2. Clinical response (mMCS): decrease from baseline in the mMCS ≥ 2 points and ≥ 30% from baseline, plus a decrease in rectal bleeding subscore ≥ 1 or an absolute rectal bleeding subscore ≤ 1

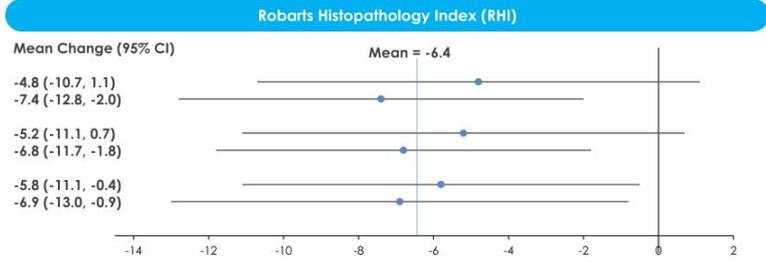
3. Clinical remission (mMCS): rectal bleeding subscore of 0; a stool frequency subscore of ≤ 1; and an MES of ≤ 1 without friability

4. Symptomatic remission: SF5 = 0 (or = 1 with ≥ 1 point decrease from baseline) and RBS = 0

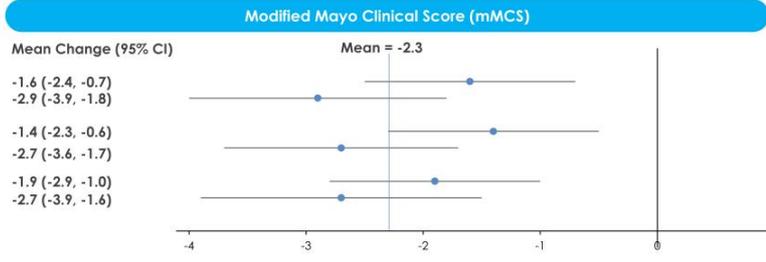
5. Endoscopic response/improvement: MES ≤ 1

Consistent “Across-the-Board” Efficacy Signals Observed

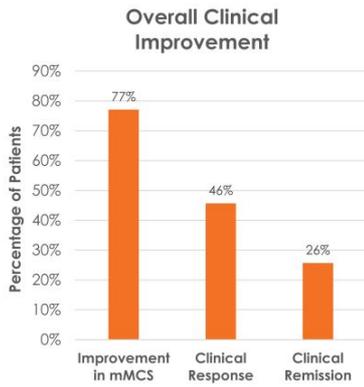
Subgroup
AT-Experienced
 Yes (n=14)
 No (n=21)
Corticosteroid Use at Baseline
 Yes (n=9)
 No (n=26)
Baseline MES
 3 (n=17)
 2 (n=18)



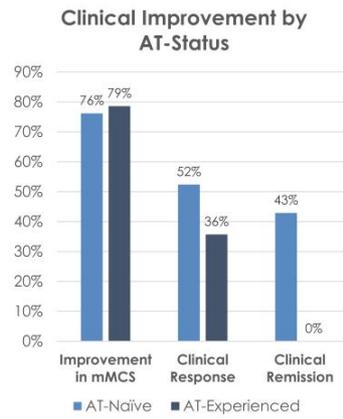
Subgroup
AT-Experienced
 Yes (n=14)
 No (n=21)
Corticosteroid Use at Baseline
 Yes (n=9)
 No (n=26)
Baseline MES
 3 (n=17)
 2 (n=18)



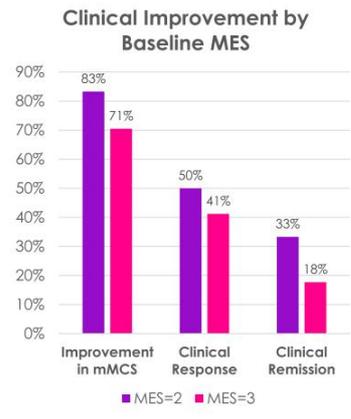
Clinical Improvement in >75% of All Patients, Regardless of Prior Therapy and Baseline MES



N=35

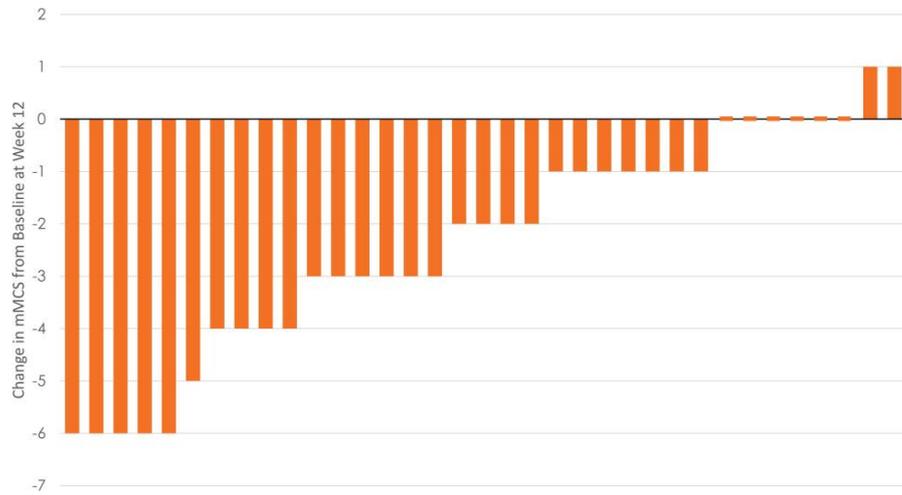


AT-Naïve: n=21; AT-Experienced: n=14



Baseline MES=2: n=18; Baseline MES=3: n=17

Change in Central mMCS By Patient from Baseline at Week 12





Data Beyond 12 weeks

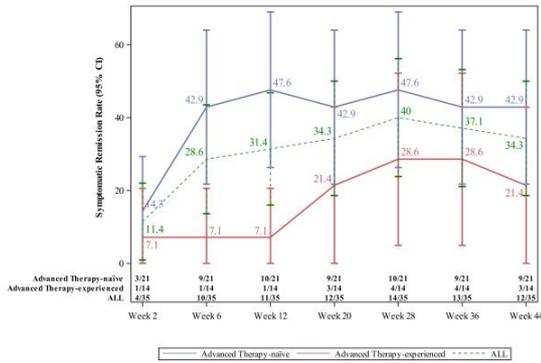


Symptomatic Remission By AT-Status: Week 44

Intent to Treat (ITT): Denominator includes all enrolled patients (N=35)

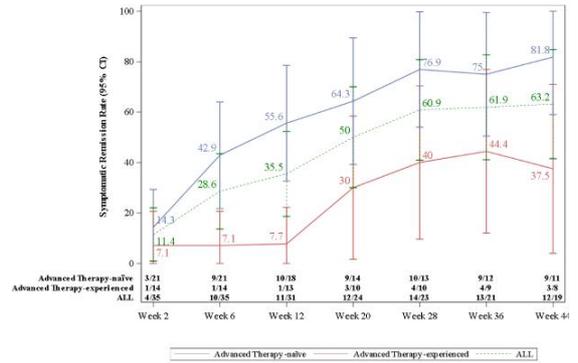
As observed: Denominator includes only patients who completed the visit

Symptomatic Remission by AT-Status



Symptomatic remission is defined as a stool frequency subscore=0 (or =1 with a ≥ 1 -point decrease from baseline) and rectal bleeding subscore=0

Symptomatic Remission by AT-Status



Symptomatic remission is defined as a stool frequency subscore=0 (or =1 with a ≥ 1 -point decrease from baseline) and rectal bleeding subscore=0



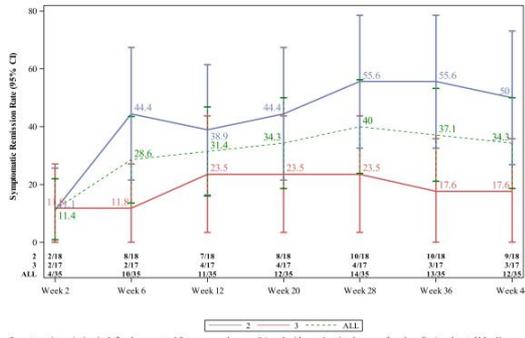
Note: These are ad hoc analyses and are subject to change during the quality control and trial completion processes

Symptomatic Remission By Baseline MES: Week 44

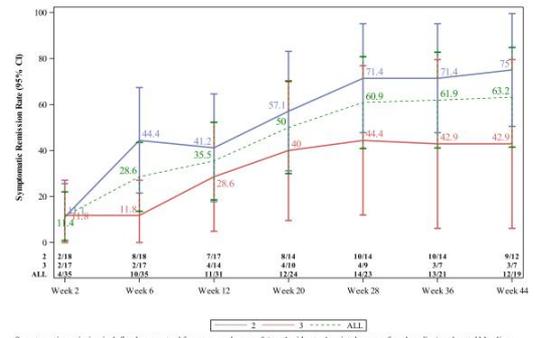
ITT: Denominator includes all enrolled patients (N=35)

As observed: Denominator includes only patients who completed the visit

Symptomatic Remission by Baseline Endoscopy Score



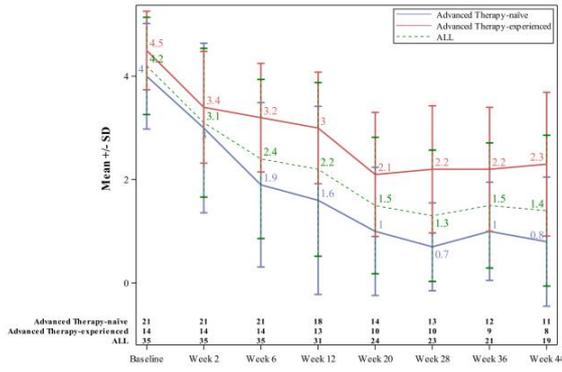
Symptomatic Remission by Baseline Endoscopy Score



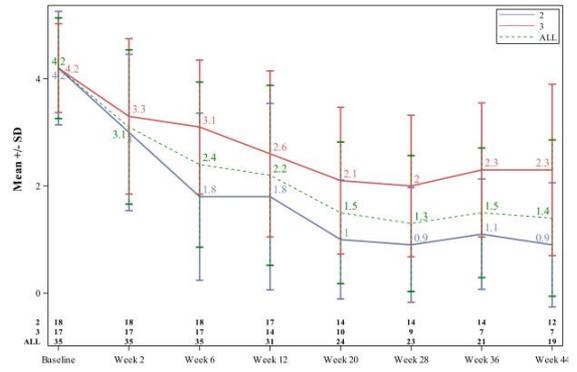
Note: These are ad hoc analyses and are subject to change during the quality control and trial completion processes

PRO2 (SFS+RBS) Scores by Subgroup: Week 44

PRO2 (Sum of Stool Frequency and Rectal Bleeding Scores) by AT-Status



PRO2 (Sum of Stool Frequency and Rectal Bleeding Scores) by Baseline Endoscopy Score



Note: These are ad hoc analyses and are subject to change during the quality control and trial completion processes

Phase 2a Study Designed to Confirm Efficacy Signal: Results Exceeded Expectations

- Primary endpoint achieved, with consistent and expected clinical improvement seen across key measures
- PK in patients consistent with healthy volunteers
- RO and T-cell subsets consistent with healthy volunteers
- Generally well tolerated with no safety signal observed
- Further clinical improvement in patients continuing treatment beyond week 12, especially in refractory patients



Corporate Update



MORF-057 and Corporate Guidance



MORF-057

- EMERALD-1 maintenance phase continuing on track
- EMERALD-2 enrolling on track
 - 1H25 primary endpoint data
- Phase 2b in Crohn's on track for '24 initiation



Corporate Status

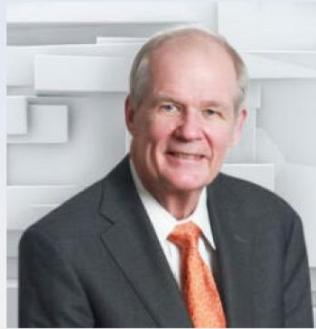
- \$725m in cash, cash equivalents and marketable securities as of 09/30/2023
 - Well funded to execute with cash into 2H27
 - Cash and guidance reflect fully burdened operating plan

Q&A Participants

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- Brian G. Feagan, MD
- Brihad Abhyankar, FRCS
- Bruce Rogers, PhD
- Marc Schegerin, MD
- Chris Erdman, MPH

Brian G. Feagan, MD



Dr. Brian Feagan is a gastroenterologist, with training in Clinical Epidemiology and Biostatistics. His research focus is the design, conduct and execution of large-scale randomized controlled trials (RCTs) in Crohn's disease (CD) and ulcerative colitis (UC), and over the past 30 years, has been Principal Investigator in over 140 multi-center RCTs. His research has been devoted to the development, validation and optimization of outcome measures to assess the efficacy of novel therapeutics in CD and UC. Dr. Feagan is Professor of Medicine at the Schulich School of Medicine & Dentistry, a gastroenterologist at London Health Sciences Centre and Senior Scientific Director of Alimentiv Inc.

