
**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): March 1, 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 2.02 Results of Operations and Financial Condition.

On March 1, 2021, MorpHic Holding, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2020. A copy of the press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 to this report, shall not be deemed to be “filed” for 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 1, 2021, the Company issued a press release announcing positive interim results from its single ascending dose (“SAD”) Phase 1 clinical trial of MORF-057.

In the Phase 1 SAD trial, MORF-057 was well tolerated in all 5 cohorts receiving MORF-057 in single doses ranging from 25 mg to 400 mg with no serious adverse events (SAEs) and no significant lab abnormalities in any subject. In the study, MORF-057 exhibited a generally dose proportional and predictable pharmacokinetic profile. The key pharmacodynamic measurement in the trial was receptor occupancy (RO), which indicated the percentage of $\alpha 4\beta 7$ bound by MORF-057 at 12 hours after the dose. MORF-057 achieved greater than 95% mean $\alpha 4\beta 7$ RO across the three highest dose cohorts, including the observation of >99% RO in subjects in each cohort, except the lowest dose cohort. These single dose data provide conviction that MORF-057 will be able to maintain saturating levels of receptor occupancy following twice daily oral administration. MORF-057 was specifically designed to be highly selective for $\alpha 4\beta 7$ and not $\alpha 4\beta 1$, a related integrin. Notably, the Company did not observe quantifiable levels of $\alpha 4\beta 1$ RO in the study.

The clinical trial is currently enrolling two additional groups in the MORF-057 Phase 1 program: a multiple ascending doses (“MAD”) study evaluating three dose cohorts of MORF-057 as well as a concurrent food-effect study in both fed and fasting states. The Company expects to present the full data set from the MORF-057 Phase 1 clinical trial at an appropriate medical meeting in mid-2021 after completion of the MAD and food effect portions of MORF-057’s clinical program.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein that do not describe historical facts, including, but not limited to: MorpHic’s plans to develop and commercialize oral small-molecule integrin therapeutics, the execution of the 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, and the ability of MORF-057 to treat inflammatory bowel disease or related indications. Such risks and uncertainties include, among others, the risks identified in MorpHic’s filings with the Securities and Exchange Commission (“SEC”), including its Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, filed with the SEC on November 9, 2020, and subsequent filings with the SEC. Any of these risks and uncertainties could materially and adversely affect MorpHic’s results of operations, which would, in turn, have a significant and adverse impact on MorpHic’s stock price. MorpHic cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. MorpHic undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made or to reflect the occurrence of unanticipated events.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	<u>Press release issued by Morphic Holding, Inc. regarding its financial results for the year ended December 31, 2020, dated March 1, 2021.</u>

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: March 1, 2021

By: /s/ Marc Schegerin

Marc Schegerin

Chief Financial Officer and Chief Operating Officer

Morphic Announces Corporate Highlights and Financial Results for the Full Year 2020

Announced positive preliminary results from Phase 1 SAD clinical trial of MORF-057

AbbVie exercised license option to $\alpha\text{v}\beta 6$ integrin inhibitor program for fibrotic diseases

Expanded research and development collaboration with Janssen through third integrin program

Conference call today at 8:00 a.m. ET

WALTHAM, Mass., March 1, 2021 – Morphic Therapeutic (Nasdaq: MORF), a biopharmaceutical company developing a new generation of oral integrin therapies for the treatment of serious chronic diseases, today reported corporate highlights and financial results for the full year 2020.

2020 and Recent Corporate Highlights

- Filed first IND of an oral integrin drug candidate, MORF-057, generated by Morphic's MInT Platform and initiated first clinical study of MORF-057 in healthy volunteers in Phase 1 clinical trial of oral IBD candidate, MORF-057, after *acceptance* of IND by Food and Drug Administration
- Announced positive preliminary results from Phase 1 single ascending dose portion of MORF-057 Phase 1 clinical trial including:
 - MORF-057 well tolerated in all five dose cohorts ranging from 25 mg to 400 mg
 - MORF-057 achieved greater than 95% mean receptor occupancy of $\alpha 4\beta 7$ at the three highest dose levels
 - Phase 1 multiple ascending dose and food effect trials ongoing with full data anticipated to be presented mid-year 2021
- Received \$20 million payment upon AbbVie exercise of a license option under the companies' research and development collaboration agreement to develop Morphic's $\alpha\text{v}\beta 6$ integrin inhibitors, including the compounds MORF-720 and MORF-627
- Expanded research and development collaboration with Janssen through a third integrin program
- Presented promising preclinical data supporting MORF-057 as an oral integrin targeting $\alpha 4\beta 7$ at UEG Week 2020, Digestive Disease Week 2020, European Crohn's and Colitis Organization (ECCO)
- Advanced novel integrin-targeted candidates generated by the MInT Platform against integrins $\alpha\text{v}\beta 1$ and $\alpha\text{v}\beta 8$ for the treatment of fibrosis and cancer
- Ended the year with \$228.3 million in cash and equivalents and marketable securities, providing runway into 2023

"The past year challenged how we work and live but the Morphic team came together to drive tremendous advances in the creation of oral integrin therapies. Most notably in 2020, our lead oral candidate in IBD, MORF-

057, completed preclinical testing with strong proof-of-concept and entered the clinic. In an important milestone for Morphic, we have already delivered positive preliminary results from the MORF-057 Phase 1 trial. The data show a favorable tolerability profile as well as strong pharmacodynamic data that suggest $\alpha 4\beta 7$ inhibition may be on par with the approved intravenous blockbuster, vedolizumab. Further, we expanded our strategic collaborations with AbbVie and Janssen to explore a broader scope of integrin drug targets and potentially boost our partnered pipeline,” commented Praveen Tipirneni, M.D., president and chief executive officer of Morphic Therapeutic. “In the year ahead, with a strong financial base, we are able to focus on advancing the clinical development of MORF-057 and our promising preclinical programs targeting $\alpha v\beta 1$ and $\alpha v\beta 8$, as well as continuing to expand the MInT platform that generates this pipeline of novel integrin therapeutic candidates.”

Financial Results for the Full Year 2020

- Net loss for the year ended December 31, 2020, was \$45.0 million or \$1.47 per share compared to a net loss of \$43.3 million or \$2.69 per share
- Revenue was \$44.9 million for the year ended December 31, 2020 compared to \$17.0 million for the year ended December 31, 2019. The increase was mainly due to AbbVie’s option exercise on our $\alpha v\beta 6$ integrin inhibitor program in the third quarter of 2020 for \$20 million
- Research and development expenses were \$73.6 million for the year ended December 31, 2020 as compared to \$53.7 million for the year ended December 31, 2019. The increase was primarily attributable to higher development and manufacturing costs associated with our lead product candidates, MORF-057 and MORF-720, as well as increased personnel-related costs to support continued progress with the company’s pipeline
- General and administrative expenses were \$18.5 million for the year ended December 31, 2020, compared to \$10.2 million for the year ended December 31, 2019. The increase was primarily attributable to increased headcount and higher professional and consulting fees associated with ongoing business activities and Morphic’s operating as a public company.

As of December 31, 2020, Morphic had cash, cash equivalents and marketable securities of \$228.3 million, compared to \$237.0 million as of December 31, 2019. Morphic believes its cash, cash equivalents and marketable securities as of December 31, 2020, will be sufficient to fund operating expenses and capital expenditure requirements into 2023.

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 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 “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: Morphic’s or our partners’

plans or ability to develop, obtain approval for any indication or disease and/or commercialize any oral small-molecule integrin therapeutics, including MORF-057, MORF-720, MORF-627, and any other candidates in development, the ability of MORF-057 to treat inflammatory bowel disease, the ability of MORF-720 and MORF-627 to treat idiopathic pulmonary fibrosis as well as other fibrotic diseases, the potential impact of the COVID-19 pandemic and the sufficiency of our cash, cash equivalents and investments to fund our operations. 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 related to Morphic’s ability to develop, obtain regulatory approval for and commercialize MORF-057, MORF-720, and other product candidates, the timing and results of preclinical studies and clinical trials, the potential impact of the COVID-19 pandemic, Morphic’s ability to protect intellectual property; and other risks set forth in our filings with the Securities and Exchange Commission. 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.

Webcast and Conference Call

Morphic will host a webcast and conference call at 8:00 AM ET today to discuss financial and operational results for fiscal year 2020 and the MORF-057 interim data from the SAD portion of ongoing MORF-057 Phase 1 clinical trial.

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: 6992416

FINANCIAL TABLES TO FOLLOW

Morphic Holding Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Collaboration revenue	\$ 44,945	\$ 16,977
Operating expenses:		
Research and development	73,630	53,732
General and administrative	18,495	10,233
Total operating expenses	92,125	63,965
Loss from operations	(47,180)	(46,988)
Other income:		
Interest income, net	1,630	4,666
Other expense, net	(19)	(94)
Total other income, net	1,611	4,572
Loss before provision for income taxes	(45,569)	(42,416)
Benefit from (provision for) income taxes	570	(912)
Net loss	\$ (44,999)	\$ (43,328)
Net loss per share, basic and diluted	(1.47)	(2.69)
Weighted average common shares outstanding, basic and diluted	30,594,897	16,101,928

Morphic Holding Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	December 31, 2020	December 31, 2019
Assets		
Cash, cash equivalents and marketable securities	\$ 228,264	\$ 237,016
Other current assets	11,171	6,557
Total current assets	239,435	243,573
Other assets	2,947	3,862
Total assets	<u>\$ 242,382</u>	<u>\$ 247,435</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 39,438	\$ 35,350
Long-term liabilities	57,747	71,167
Total liabilities	97,185	106,517
Total stockholders' equity	145,197	140,918
Total liabilities and stockholders' equity	<u>\$ 242,382</u>	<u>\$ 247,435</u>

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