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 14, 2021

FORMA THERAPEUTICS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39333**	**37-1657129**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Forma Therapeutics Holdings, Inc.
500 Arsenal Street, Suite 100
Watertown, Massachusetts 02472
(Address of principal executive offices, including zip code)

(617) 679-1970
(Registrant's telephone number, including area code)

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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**FMTX**	**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 2.02Results of Operations and Financial Condition

On May 14, 2021, Forma Therapeutics Holdings, Inc. announced its financial results for the quarter ended March 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Item 2.02 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01.Exhibits

(d) Exhibits

99.1	Press release issued by Forma Therapeutics Holdings, Inc. on May 14, 2021, furnished herewith.

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.

FORMA THERAPEUTICS HOLDINGS, INC.

Date: May 14, 2021

By: /s/ Todd Shegog
Todd Shegog
Chief Financial Officer
(Principal Financial and Accounting Officer)

Forma Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

Development pipeline progressing to key upcoming clinical milestones

Multiple-ascending dose (MAD) cohorts of FT-4202 Phase 1 trial in sickle cell disease completed; hemoglobin increase ≥ 1 g/dL in approximately 71% of patients and improved hematologic and hemolytic markers consistent with improved red blood cell (RBC) health

Updated MAD results and initial open-label extension trial (OLE) results to date be presented at European Hematology Association (EHA) Virtual Congress in June

Phase 1 trial of FT-7051 in metastatic castration-resistant prostate cancer (mCRPC) ongoing, initial results expected fourth quarter of 2021

Olutasidenib relapsed/refractory AML results presentation in June at the American Society of Clinical Oncology (ASCO), new drug application (NDA) preparation ongoing

WATERTOWN, Mass. – May 14, 2021 – Forma Therapeutics Holdings, Inc. (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on rare hematologic diseases and cancers, today reported financial results for the first quarter ended March 31, 2021. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

"During the first quarter we successfully completed the multiple ascending dose portion of our Phase 1 trial of FT-4202 in sickle cell disease, called The Hibiscus Study, and despite challenges from the COVID-19 pandemic, also began enrolling patients in the Phase 2/3 trial, as well as in the Phase 1 trial of FT-7051 for metastatic castration resistant prostate cancer," said Frank Lee, President and Chief Executive Officer of Forma. "We look forward to sharing additional results over the course of 2021 in our mission to transform the lives of people living with rare hematologic diseases and cancers."

Key Business and Clinical Highlights

PKR Program in Sickle Cell Disease (SCD):

- **MAD g dose cohorts completed with approximately 71% of participants achieving hemoglobin increase ≥ 1 g/dL from baseline, and improvement across markers of RBC health.** Doubling the dose of FT-4202 to 600 mg daily for 14 days compared to the previous 300 mg cohort was well-tolerated with no dose-limiting toxicities or treatment-related adverse events observed. Improvements in hematologic (hemoglobin and reticulocytes) and hemolytic (bilirubin and lactate dehydrogenase) parameters were comparable to that observed with the 300 mg dose, with best response typically observed at the end of the 14-day treatment period. In the combined cohorts, 10 of 14 (71%) patients on FT-4202 achieved a hemoglobin increase ≥ 1 g/dL from baseline to Day 14. Improvement in RBC health was evidenced by

increased sickle RBC survival and reduced intravascular hemolysis in patients with SCD based on a reduction in reticulocytes, bilirubin and LDH levels.

- **Patient enrollment began in Phase 2/3 registrational trial, the Hibiscus Study.** The phase 2/3 Hibiscus Study is currently enrolling people living with sickle cell disease (SCD). This adaptive, randomized, placebo-controlled, double-blind, multi-center trial is expected to enroll approximately 344 adults and adolescents with SCD. FT-4202 doses of 200mg and 400mg administered once-daily are being evaluated in the Phase 2 portion of the trial. Primary endpoints in the Phase 3 portion of the trial are hemoglobin response rate at week 24 (increase of > 1 g/dL from baseline), intended to support accelerated approval, and annualized vaso-occlusive crisis rate during the 52-week blinded treatment period, which if positive is expected to support full approval.

CPB/p300 Program in Prostate Cancer:

- **FT-7051 Phase 1 clinical trial initiated for the treatment of (mCRPC)**. In January 2021, Forma announced that the first patient was dosed in the ongoing Phase 1 clinical trial evaluating FT-7051 for the treatment of mCRPC. The trial is a multicenter, open-label evaluation of the safety and tolerability, preliminary anti-tumor activity (prostate specific antigen (PSA)and radiographic responses), and pharmacokinetics/pharmacodynamics (PK/PD) of FT-7051 in men with mCRPC who have progressed despite prior therapy with at least one anti-androgen therapy. The trial will include genetic mutation analysis to identify the basis of resistance to standard-of-care and will also evaluate expression of the AR-v7 splice variant, for which there are no approved therapies. The trial utilizes an adaptive trial design, intended to accelerate the escalation to potentially therapeutic doses and yield important safety information, as well as to identify biomarkers of clinical benefit such as prostate specific antigen (PSA) response.

IDH1 Program in AML and Glioma:

- **Olutasidenib NDA preparation for R/R AML.** With the conclusion of the Phase 2 R/R AML trial, Forma has begun preparing a NDA for submission to the U.S. Food and Drug Administration (FDA).

Upcoming Milestones

- **Presentation of updated Phase 1 FT-4202 results in SCD**. A poster presentation on FT-4202 in SCD is scheduled for the European Hematology Association (EHA) Virtual Congress taking place June 9-17, 2021. The presentation will include combined unblinded data from the two-week MAD cohorts as well as initial OLE results to date. In addition, full results from the MAD dose cohorts and the OLE are expected to be presented at a scientific congress in late 2021.
- **Initial Phase 1 clinical results from FT-7051 in mCRPC anticipated later this year.** This adaptive trial is assessing multiple doses of FT-7051 with dose escalation dependent upon safety and tolerability. Initial results anticipated in the fourth quarter of 2021 may include safety/tolerability, PK/PD results and preliminary biomarker data.
- **Olutasidenib results presentation in R/R AML.** Phase 2 registrational results of olutasidenib in R/R AML will be presented at the 2021 ASCO Annual Meeting taking place from June 4-8, 2021, and the EHA Virtual Congress taking place June 9-17, 2021.
- **Possibility of COVID-19 impact remains**. The COVID-19 pandemic remains a factor in the successful completion of these milestones. Many clinical trials across the biopharma industry, including our, have been impacted by the COVID-19 pandemic, with clinical trial sites implementing new policies in response to COVID-19, resulting in potential delays to enrollment of clinical trials or changes in the ability to access sites participating in clinical trials.

Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $603.7 million as of March 31, 2021, as compared to $645.6 million as of December 31, 2020. Current cash runway is projected through the third quarter of 2024.
- **Research and Development (R&D) Expenses**: R&D expenses were $26.3 million for the quarter ended March 31, 2021, compared to $23.2 million for the quarter ended March 31, 2020. The increase was primarily attributable to increases in FT-4202 development expenses, partially offset by reduced spending on olutasidenib development.
- **General and Administrative (G&A) Expenses:** G&A expenses were $9.9 million for the quarter ended March 31, 2021, compared to $8.9 million for the quarter ended March 31, 2020. The increase in general and administrative expense was primarily attributable to stock compensation expense and insurance, partially offset by a reduction in professional fees.
- **Net Income/Loss:** Net loss was $36.0 million for the quarter ended March 31, 2021, compared to net income of $11.2 million for the quarter ended March 31, 2020.

Forma will conduct a conference call and webcast May 14th at 8 a.m. Eastern Daylight Time (EDT) to discuss first quarter 2021 results and business update. The call can be accessed by dialing (833) 301-1146 in the U.S., and (914) 987-7386 internationally, with conference ID 8597396.

The live webcast will be available in the "News & Investors" section of Forma's website www.formatherapeutics.com.

About Forma Therapeutics

Forma Therapeutics is a clinical-stage biopharmaceutical company focused on the research, development and commercialization of novel therapeutics to transform the lives of patients with rare hematologic diseases and cancers. Our R&D engine combines deep biology insight, chemistry expertise and clinical development capabilities to create drug candidates with differentiated mechanisms of action focused on indications with high unmet need. Our work has generated a broad proprietary portfolio of programs with the potential to provide profound patient benefit. For more information, please visit www.FormaTherapeutics.com or follow us on Twitter @FORMAInc and LinkedIn.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, express or implied statements regarding the company's beliefs and expectations regarding its: business plans and objectives; future plans for FT-4202, FT-7051 and olutasidenib, including expectations regarding timing and success of the current ongoing clinical trials, therapeutic potential, clinical benefits and safety thereof, planned regulatory submissions, including an NDA for olutasidenib, and upcoming milestones for the company's other product candidates; growth as a company; presentation of additional data at upcoming scientific conferences, and other preclinical data and potential data publications in 2021; the potential commercial and collaboration opportunities, including potential future collaborators and parties, as well as value and market, for our product candidates; uses and need of capital, expenses and other 2021 financial results currently or in the future, and the potential impact of COVID-19 on patient retention and enrollment , future operations, clinical trials or investigational new drug (IND) applications. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties associated with the following: the impact of the COVID-19 pandemic on the company's business, operations, patient enrollment and retention , strategy, goals and anticipated milestones; the therapeutic potential of FT-4202 and FT-7051 and olutasidenib, and the timing associated with the initiation or continuation of any of FT-4202 trials and success of ongoing clinical trials of FT-4202 and FT-7051; Forma's ability to execute on its strategy; the submission and acceptance of a new drug application (NDA) for submission to the U.S. Food and Drug Administration (FDA) for olutasidenib; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; any one or more of Forma's product candidates may not be successfully developed and commercialized; regulatory developments in the United States and foreign countries; Forma's ability to protect and maintain our intellectual property position; the impact of COVID-19 affecting countries or regions in which we have operations or do business, including potential negative impacts on our employees, customers, supply chain and production as well as global economies and financial markets; Forma's ability to fund operations; Forma's ability to identify satisfactory collaboration opportunities, as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the United States Securities and Exchange Commission (SEC) and subsequent filings with the SEC. Forma disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Forma's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Forma explicitly disclaims any obligation to update any forward-looking statements.

Selected Financial Information
(in thousands except share and per share data)
(unaudited)

Statement of Operations Items:	For the Three Months Ended March 31, 2021	2020
Collaboration revenue	$ —	$ —
Operating expenses:		
Research and development	26,343	23,210
General and administrative	9,867	8,933
Restructuring charges	—	83
Total operating expenses	36,210	32,226
Loss from operations	(36,210)	(32,226)
Other income, net	258	23,971
Loss before taxes	(35,952)	(8,255)
Income tax expense (benefit)	8	(19,485)
Net (loss) income	$ (35,960)	$ 11,230
Accretion of cumulative dividends on Series D redeemable convertible preferred stock	—	(1,936)
Undistributed earnings allocable to participating securities	—	(3,456)
Net (loss) income allocable to shares of common stock, basic	$ (35,960)	$ 5,838
Change in fair value attributable to warrants to purchase Series B-3 convertible preferred shares	—	(20)
Accretion of cumulative dividends on Series D redeemable convertible preferred stock	—	1,936
Net (loss) income allocable to shares of common stock, diluted	$ (35,960)	$ 7,754
Net (loss) income per share of common stock:		
Basic	$ (0.76)	$ 2.29
Diluted	$ (0.76)	$ 0.36
Weighted-average shares of common stock outstanding:		
Basic	47,295,013	2,548,079
Diluted	47,295,013	21,392,760

Selected Balance Sheet Items:	March 31, 2021	December 31, 2020
Cash, cash equivalents, and marketable securities	$ 603,724	$ 645,588
Total assets	$ 650,236	$ 680,971
Accounts payable, accrued expenses, and other current liabilities	$ 25,142	$ 31,399
Total stockholders' equity	$ 616,465	$ 648,244

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SOURCE: Forma Therapeutics Holdings, Inc.