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): August 13, 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 August 13, 2021, Forma Therapeutics Holdings, Inc. announced its financial results for the quarter ended June 30, 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 August 13, 2021, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 13, 2021

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

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

Significant progress achieved with pipeline focused on rare hematologic diseases and cancers

Positive Phase 1 results in patients with sickle cell disease (SCD) presented at European Hematology Association (EHA) Virtual Congress supporting etavopivat's potential to significantly impact RBC health and lifespan

Phase 1 trial of FT-7051 enrolling men with metastatic castration-resistant prostate cancer (mCRPC); initial results to be presented in October at the NCI/AACR/EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics

Olutasidenib data in relapsed/refractory acute myeloid leukemia (R/R AML) presented at the American Society of Clinical Oncology (ASCO) and EHA Virtual Congress; new drug application (NDA) preparation ongoing

WATERTOWN, Mass. – Aug. 13, 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 second quarter ended June 30, 2021. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

"During the second quarter, we presented positive results from our ongoing Phase 1 trial demonstrating etavopivat's highly differentiated profile and multimodal mechanism of action to improve markers of sickle cell disease and red blood cell health that are associated with vaso-occlusion" said Frank Lee, president and chief executive officer of Forma. "These results, in addition to the progress on our other clinical programs this quarter, position us well to deliver on our mission of transforming the lives of patients with rare hematologic diseases and cancers."

Key Business and Clinical Highlights

PKR Program in Sickle Cell Disease (SCD):

Clinical data presented at EHA Virtual Congress support potential of investigational agent etavopivat to significantly impact RBC health and lifespan. Updated results were presented from the two week multiple ascending dose (MAD) cohorts and initial open-label extension (OLE) results administering etavopivat for up to 12 weeks, including:

- **Sustained increases in hemoglobin levels.** In the MAD cohorts 73% of patients (11/15) achieved a hemoglobin increase of ≥ 1 g/dL at the end of two weeks of treatment. In the OLE, hemoglobin levels increased >1g/dL in 88% of patients (7/8) receiving once-daily treatment for at least two weeks, and this increase was sustained in those patients receiving continued treatment for up to 12 weeks.

- **Improvements in RBC oxygenation and deformability.** RBC's from 14 patients in the MAD cohorts showed increased hemoglobin-oxygen affinity, a significant shift in the point of sickling (POS), and improved deformability.
- **Significant reduction in hemolysis with markers approaching normal levels.** Reticulocyte counts were reduced in 100% of patients (15/15), with normalization in some patients at the end of two weeks of treatment. The majority of patients demonstrated a marked decrease in lactate dehydrogenase levels (LDH) and indirect bilirubin levels as compared to baseline levels.
- **Reduction in systemic biomarkers related to inflammation and hypercoagulability.** Initial results from the OLE showed improvement in systemic biomarkers such as lower levels of TNF-alpha, a marker of inflammation, and decreases in prothrombin 1.2 and D-dimer, markers of coagulation activation.
- **Etavopivat was well tolerated with a safety profile consistent with underlying sickle cell disease**. Etavopivat was well tolerated at doses up to 600mg daily (150% of the maximum dose in the ongoing Phase 2/3 Hibiscus Study).

CPB/p300 Program in Prostate Cancer:

- **FT-7051 Phase 1 clinical trial enrollment is ongoing.** In January 2021, Forma announced the first patient 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, pharmacokinetics/pharmacodynamics (PK/PD), and preliminary anti-tumor activity, of FT-7051 in men with mCRPC who have progressed despite prior therapy with at least one anti-androgen therapy. The adaptive trial design is intended to accelerate the dose escalation to potentially therapeutic doses and yield important safety information, as well as to identify biomarkers of clinical benefit such as PSA response. Genetic mutation analysis will be conducted to correlate genetic changes with resistance to standard-of-care and will also evaluate expression of the AR-v7 splice variant, for which there are no approved therapies.

IDH1 Program in AML and Glioma:

- **Phase 2 registrational results for olutasidenib in R/R AML were presented at scientific conferences.** Olutasidenib data in R/R AML were presented at both the annual ASCO and EHA meetings in June 2021. The primary efficacy evaluable population, comprised of 123 patients, received 150 mg of olutasidenib twice daily for at least six months prior to the planned interim analysis. The primary endpoint, a composite complete remission (CR) or CR plus CR with partial hematologic recovery (CRh), was achieved in 33.3% (30% CR and 3% CRh) of patients. While the median duration of response was not yet reached, in a sensitivity analysis with hematopoietic stem cell transplant considered as the end of a response, the median duration was 13.8 months. The median overall survival (OS) was 10.5 months. Although a median OS has not yet been reached for the CR/CRh population, 18-month survival is estimated at 87% for that response category, and median survival is 15.0 months for non-CR/CRh responders. In addition, among patients with a CR who were transfusion-dependent at baseline, 56-day transfusion independence was achieved in 100% of patients as measured by platelets and 80% as measured by RBC's. Olutasidenib was well-tolerated, and adverse events were consistent with the late stage disease in this heavily pre-treated patient population. Based upon these results, Forma is preparing an NDA for the R/R AML indication.

Corporate

- **In June 2021, Forma announced the appointment of John E. Bishop, Ph.D., as chief technology officer.** Dr. Bishop leads chemistry, manufacturing and control (CMC)-related functions and quality, encompassing Forma's early pipeline through commercial product. Dr. Bishop's background includes extensive expertise with CMC development in oncology and hematology. Prior to joining Forma, Dr. Bishop served as senior vice president of pharmaceutical sciences at Epizyme, Inc., where he was a member of the executive team and held overall responsibility for the CMC and quality assurance functions.

Upcoming Milestones

- **Scientific conference presentation of updated Phase 1 etavopivat results in SCD.** Updated results of safety, clinical activity, and biomarkers from the 12-week OLE are expected to be presented at a scientific congress in late 2021. Up to 20 patients are being administered etavopivat 400mg once daily and assessed for hematologic and hemolytic response, improvements in RBC oxygenation and deformability, and systemic markers of SCD.
- **Initiation of etavopivat trials in thalassemia and pediatric sickle cell patients**. Enrollment in a Phase 2 trial of etavopivat in thalassemia patients is expected to begin prior to the end of the year, with results anticipated in 2022. The trial may enroll up to 60 patients with either thalassemia or SCD who are receiving chronic red blood cell transfusions, or thalassemia without chronic red blood cell transfusions. A trial in pediatric sickle cell disease patients is planned to begin in the first half of 2022.
- **Scientific conference presentation of initial Phase 1 FT-7051 clinical results in mCRPC.** An abstract from this ongoing trial has been accepted for presentation at the NCI/AACR/EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics taking place Oct. 7-10, 2021. The presentation will include preclinical data and initial clinical results on safety, tolerability and PK/PD from patients undergoing dose escalation.
- **Possibility of COVID-19 impact remains**. The COVID-19 pandemic remains a factor in the successful completion of these milestones and ongoing clinical trials. Many clinical trials across the biopharma industry, including Forma's, have been impacted by the COVID-19 pandemic. Clinical trial sites implementing new policies in response to COVID-19 may result 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 $570.8 million as of June 30, 2021, as compared to $645.6 million as of Dec. 31, 2020. Current cash runway is projected through the third quarter of 2024.
- **Research and Development (R&D) Expenses**: R&D expenses were $31.6 million for the quarter ended June 30, 2021, compared to $20.5 million for the quarter ended June 30, 2020. The increase was primarily attributable to etavopivat development, as well as increases in staff and stock-based compensation.
- **General and Administrative (G&A) Expenses:** G&A expenses were $12.5 million for the quarter ended June 30, 2021, compared to $6.4 million for the quarter ended June 30, 2020. The increase in was primarily attributable to increased stock-based compensation, executive and staff hiring, professional fees, and insurance.
- **Net Loss:** Net loss was $43.6 million for the quarter ended June 2021, compared to net loss of $25.4 million for the quarter ended June 30, 2020.

Forma will conduct a conference call and webcast Aug. 13 at 8:00 a.m. Eastern Daylight Time (EDT) to discuss second quarter 2021 results and business updates. The call can be accessed by dialing (833) 301-1146 in the U.S., and (914) 987-7386 internationally, with conference ID 9155938.

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 etavopivat, FT-7051 and olutasidenib, including expectations regarding timing, success and data announcements of our current ongoing clinical trials; initial results for the etavopivat open label extension cohort of our Phase 1 clinical trial; therapeutic potential, clinical benefits, mechanisms of action and safety of our product candidates, 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 etavopivat, FT-7051, and olutasidenib, the timing and completion of our Phase 1 clinical study in etavopivat and final audit and quality controlled verification of initial data and related analyses, and the timing associated with the initiation or continuation of any trials and success of ongoing clinical trials of etavopivat 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, 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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	31,587	20,511	57,930	43,721
General and administrative	12,471	6,448	22,338	15,381
Restructuring charges	—	(20)	—	63
Total operating expenses	44,058	26,939	80,268	59,165
Loss from operations	(44,058)	(26,939)	(80,268)	(59,165)
Other income (expense):				
Gain on Hit Discovery divestiture	—	—	—	23,312
Interest income	309	895	571	1,536
Other income (expense), net	272	(2,634)	268	(2,616)
Total other income (expense), net	581	(1,739)	839	22,232
Loss before taxes	(43,477)	(28,678)	(79,429)	(36,933)
Income tax expense (benefit)	108	(3,238)	116	(22,723)
Net loss and comprehensive loss	$ (43,585)	$ (25,440)	$ (79,545)	$ (14,210)
Accretion of cumulative dividends on Series D redeemable convertible preferred stock	—	(1,800)	—	(3,736)
Net loss allocable to shares of common stock, basic and diluted	$ (43,585)	$ (27,240)	$ (79,545)	$ (17,946)
Net loss per share of common stock, basic and diluted	$ (0.92)	$ (4.58)	$ (1.68)	$ (4.23)
Weighted-average shares of common stock outstanding, basic and diluted	47,339,464	5,943,165	47,317,361	4,245,622

Selected Balance Sheet Items:	June 30, 2021	December 31, 2020
Cash, cash equivalents, and marketable securities	$ 570,793	$ 645,588
Total assets	$ 613,369	$ 680,971
Accounts payable, accrued expenses, and other current liabilities	$ 29,104	$ 31,399
Total stockholders' equity	$ 579,395	$ 648,244

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