

**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): November 12, 2021**

**FORMA THERAPEUTICS HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39333**  
(Commission  
File Number)

**37-1657129**  
(I.R.S. Employer  
Identification No.)

**Forma Therapeutics Holdings, Inc.**  
**300 North Beacon Street, Suite 501**  
**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
<b>Common Stock, \$0.001 par value per share</b>	<b>FMTX</b>	<b>The Nasdaq Global Market</b>

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 November 12, 2021, Forma Therapeutics Holdings, Inc. announced its financial results for the quarter ended September 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, as amended (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, as amended 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 November 12, 2021, furnished herewith.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: November 12, 2021

By: /s/ Todd Shegog

Todd Shegog

Chief Financial Officer

(Principal Financial and Accounting Officer)

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## Forma Therapeutics Reports Third Quarter 2021 Financial Results and Provides Business Update

*Significant progress achieved on three clinical stage programs focused on rare hematologic diseases and cancers*

*Etavopivat Phase 1 open label extension enrollment in sickle cell disease (SCD) complete, updated results to be presented at American Society of Hematology (ASH) Annual Meeting December 11-14*

*Initial Phase 1 results presented in men with metastatic castration-resistant prostate cancer (mCRPC ) showed FT-7051 well-tolerated with evidence of clinical activity*

*Olutasidenib combination data in relapsed/refractory acute myeloid leukemia (R/R/ AML) to be presented at ASH Annual Meeting December 11-14*

**WATERTOWN, Mass. – Nov. 12, 2021** – Forma Therapeutics Holdings, Inc. (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on sickle cell disease, prostate cancer and other rare hematologic diseases and cancers, today reported financial results for the third quarter ended Sept. 30, 2021. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

“During the third quarter, we made significant progress pursuing our commitment not only to serving the needs of people living with sickle cell disease with our lead program, etavopivat, but also targeting prostate cancer with initial FT-7051 results, in addition to new olutasidenib clinical data accepted for presentation at ASH next month” said Frank Lee, president and chief executive officer of Forma.

### **Key Business and Clinical Highlights**

#### **PKR Program in Sickle Cell Disease (SCD):**

- **Enrollment in etavopivat open label extension completed.** Full enrollment of 15 patients in the open label extension (OLE) was completed during the quarter. Patients in the OLE are being administered etavopivat 400 mg once daily for up to 12 weeks and assessed for hematologic and hemolytic response, and improvement in markers of red blood cell (RBC) health, including oxygenation and deformability, and systemic biomarkers of SCD.

#### **CPB/p300 Program in Prostate Cancer:**

- **Initial FT-7051 Phase 1 clinical trial results presented at NCI/AACR/EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.** Preliminary results included data as of Sept. 1, 2021, from eight men enrolled in the trial. FT-7051 was administered in 28-day cycles, with 21 days of dosing followed by seven days of no dosing. The initial pharmacokinetic (PK) analysis of FT-7051 documented rapid absorption, with drug concentrations that approached the predicted efficacious dose based on estimates from preclinical animal models. Skin biopsies of the men participating in the study demonstrated a reduction in H3K27AC, a marker of activity in the CBP/p300

pathway. The majority of the treatment-emergent adverse events (TEAEs) were mild or moderate, at Grade 2 or lower, with no events leading to treatment discontinuation. The first evaluable patient completing more than 90 days of treatment demonstrated an ongoing response of >80% decline in prostate-specific antigen (PSA80) from baseline with stable disease.

## **Corporate**

- **Upcoming investor conference participation.** Forma will participate in the Jefferies London Healthcare Conference taking place Nov. 16-19. The pre-recorded presentation will be available Nov. 18 at 8:00am Greenwich Mean Time (GMT) in the “News & Investors” section of Forma’s website at [www.FormaTherapeutics.com](http://www.FormaTherapeutics.com).
- **Investor briefing to discuss results presented at ASH.** Forma will hold an investor briefing Dec. 13 at 8:00 am Eastern Time (ET). The live webcast will be available in the “News & Investors” section of Forma’s website [www.FormaTherapeutics.com](http://www.FormaTherapeutics.com).

## **Upcoming Milestones**

- **Updated initial Phase 1 open label extension results for etavopivat in SCD to be presented at ASH December 11-14.** Results to be presented will include approximately 15 patients being administered etavopivat 400mg once daily for up to 12 weeks and assessed for hematologic and hemolytic response, and improvements in markers of RBC health including oxygenation and deformability, and systemic markers of SCD.
- **Patient enrollment continues in Phase 2/3 registrational trial, the Hibiscus Study.** The Hibiscus study includes two co-primary end points (hemoglobin and vaso-occlusive crises) that support the traditional approval pathway. Based on ongoing feedback from the FDA, although accelerated approval is still an available regulatory pathway, Forma will need to provide additional information to support hemoglobin response as a surrogate endpoint eligible for accelerated approval for etavopivat. The company plans to continue to seek accelerated approval for etavopivat utilizing hemoglobin response rates as a surrogate endpoint by providing additional data to support that hemoglobin response rates predict for a clinical benefit.
- **Additional etavopivat trials to begin late 2021/1H:22.** Forma plans to initiate a Phase 2 trial in transfusion dependent SCD and both transfusion dependent and independent thalassemia prior to the end of the year, and a pediatric SCD trial beginning in the first half of 2022.
- **Olutasidenib results in R/R AML to be presented at ASH December 11-14.** Results from the Phase 2 trial will show the impact of the combination of olutasidenib and azacitidine on rates of remission and transfusion independence in patients with mutant isocitrate dehydrogenase 1 (mIDH1) AML. Analyses of safety and efficacy will be presented at the ASH annual meeting.
- **Additional FT-7051 clinical results in mCRPC to be presented in 2022.** Men with mCRPC continue to be enrolled in the dose escalation portion of the Phase 1 trial. Forma plans to present updated results from the trial at a scientific conference in mid-2022.

## **Financial Results**

- **Cash Position:** Cash, cash equivalents and marketable securities were \$531.8 million as of Sept. 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 \$30.7 million for the quarter ended Sept. 30, 2021, compared to \$24.8 million for the quarter ended Sept. 30, 2020. The increase was primarily attributable to an increase in research and development staff to support advancement

of etavopivat and other programs, an increase in equity-based compensation, and increases in external predevelopment and preclinical programs, conduct of the Phase II/III etavopivat trial in SCD patients and study start-up costs related to a trial in thalassemia/transfusion dependence.

- **General and Administrative (G&A) Expenses:** G&A expenses were \$12.7 million for the quarter ended Sept. 30, 2021, compared to \$7.5 million for the quarter ended Sept. 30, 2020. The increase was primarily attributable to equity-based compensation, costs due to executive and staff hiring, legal, consulting, and other professional fee expenses, and other related general and administrative costs.
- **Net Loss:** Net loss was \$43.3 million for the quarter ended Sept. 30 2021, compared to net loss of \$27.6 million for the quarter ended Sept. 30, 2020.

Forma will conduct a conference call and webcast Nov. 12 at 8:00 a.m. Eastern Daylight Time (EDT) to discuss third 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 6662686.

The live webcast will be available in the “News & Investors” section of Forma’s website [www.FormaTherapeutics.com](http://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](http://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 and for the FT-7051 Phase 1 clinical trial; therapeutic potential, clinical benefits, mechanisms of action and safety of our product candidates; planned regulatory submissions; upcoming milestones and planned additional trials for the company’s product candidates; growth as a company; presentation of additional data at upcoming scientific conferences, and other preclinical data and potential data publications in 2021 and 2022; 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 our Phase 1 clinical study in FT-7051 and final audit and quality controlled verification of initial data and related analyses; the timing associated with the initiation or continuation of any trials and success of ongoing clinical trials of etavopivat and FT-7051; our ability to execute on our strategy; 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 our product candidates may not be successfully developed and commercialized; regulatory developments in the United States and foreign countries; our ability to protect and maintain our intellectual property position; the impact of COVID-19 our supply chain and production as well as global economies and financial markets; and our ability to fund operations; 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 September 30, 2021, to be filed with the United States Securities and Exchange Commission (SEC) and subsequent filings with the SEC. We disclaim 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 our views only as of the date hereof and should not be relied upon as representing our views as of any subsequent date.

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

Statement of Operations Items:	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	30,684	24,780	88,614	68,501
General and administrative	12,749	7,460	35,087	22,841
Restructuring charges	—	—	—	63
Total operating expenses	43,433	32,240	123,701	91,405
Loss from operations	(43,433)	(32,240)	(123,701)	(91,405)
Other income:				
Gain on Hit Discovery divestiture	—	—	—	23,312
Interest income	216	870	770	2,406
Other (expense) income, net	(70)	(52)	215	(2,668)
Total other income, net	146	818	985	23,050
Loss before taxes	(43,287)	(31,422)	(122,716)	(68,355)
Income tax expense (benefit)	7	(3,806)	123	(26,529)
Net loss and comprehensive loss	\$ (43,294)	\$ (27,616)	\$ (122,839)	\$ (41,826)
Accretion of cumulative dividends on Series D redeemable convertible preferred stock	—	—	—	(3,736)
Net loss allocable to shares of common stock, basic	\$ (43,294)	\$ (27,616)	\$ (122,839)	\$ (45,562)
Change in fair value attributable to warrants to purchase common stock	—	(8)	—	—
Net loss allocable to shares of common stock, diluted	\$ (43,294)	\$ (27,624)	\$ (122,839)	\$ (45,562)
Net loss per share of common stock:				
Basic	\$ (0.91)	\$ (0.67)	\$ (2.60)	\$ (2.74)
Diluted	\$ (0.91)	\$ (0.67)	\$ (2.60)	\$ (2.74)
Weighted-average shares of common stock outstanding:				
Basic	47,365,704	41,088,261	47,333,652	16,616,143
Diluted	47,365,704	41,088,924	47,333,652	16,616,143

**Selected Balance Sheet Items:**

	September 30, 2021	December 31, 2020
Cash, cash equivalents, and marketable securities	\$ 531,769	\$ 645,588
Total assets	\$ 602,225	\$ 680,971
Accounts payable, accrued expenses, and other current liabilities	\$ 28,048	\$ 31,399
Total stockholders' equity	\$ 542,831	\$ 648,244

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SOURCE: Forma Therapeutics Holdings, Inc.

