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 5, 2022

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.
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
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 2.02 Results of Operations and Financial Condition

On August 5, 2022, Forma Therapeutics Holdings, Inc. (the Company) announced its financial results for the quarter ended June 30, 2022. 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 August 5, 2022, 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 5, 2022

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

Forma Therapeutics Reports Second Quarter 2022 Financial Results and Provides Business Update

Announced analyses from Phase I study of etavopivat in sickle cell disease indicated reduction of reported pain-related adverse events, supporting potential to reduce vaso-occlusive crises

Recently entered into an exclusive license agreement with Rigel Pharmaceuticals, Inc. for olutasidenib, a mutant IDH1 inhibitor for the potential treatment of relapsed or refractory acute myeloid leukemia

Highlighted progress across portfolio at inaugural Research and Development (R&D) Day

Appointed new members of Executive Team to prepare for growth in late-stage clinical development and commercialization

Cash balance of $395.9 million positions company with runway through the third quarter of 2024

WATERTOWN, Mass.--(BUSINESS WIRE)--August 5, 2022-- 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 second quarter ended June 30, 2022. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

“In the second quarter, we announced encouraging new analyses from the etavopivat program in sickle cell disease at our inaugural R&D Day. We also recently appointed two new members of our executive team to help drive our next phase of global development and commercialization and entered into a license agreement for olutasidenib,” said Frank Lee, President and Chief Executive Officer of Forma. “We are well-positioned to continue to advance our pipeline and are actively managing expenses as we progress in our mission to deliver transformative medicines to patients with rare hematologic diseases and cancers.”

Key Business Updates

- **On July 27, 2022 Forma entered into an exclusive worldwide license agreement with Rigel Pharmaceuticals, Inc. to develop, manufacture, and commercialize olutasidenib.** Olutasidenib is a mutant isocitrate dehydrogenase-1 (mIDH1) inhibitor for the treatment of relapsed or refractory acute myeloid leukemia. Under the terms of the agreement, Forma will receive an upfront payment of $2.0 million, and is eligible to receive an additional $17.5 million upon the achievement of certain near-term regulatory, approval, and first commercial sale milestones. In addition, Forma is eligible to receive a total of up to an additional $215.5 million in connection with the achievement of certain development and commercial milestones. Forma is also eligible to receive tiered royalties in the low-teens to mid-thirties. The U.S. Food and Drug Administration (FDA) has accepted Forma’s new drug application (NDA) for olutasidenib. The Prescription Drug User Fee Act (PDUFA) target action date is February 15, 2023.
- **Agustín Melián, M.D., named Executive Vice President, Head of Research and Development.** Dr. Melián is a physician-scientist with over 20 years of experience developing patient-centric, rare, and orphan disease therapeutics across multiple therapeutic areas, modalities, and phases of development.

- **Linea Aspesi named Senior Vice President, Chief Human Resources Officer.** Ms. Aspesi brings over 25 years of human resources leadership experience in life sciences and health care services and has a track record of aligning talent plans to company vision and strategy while fostering an equitable and inclusive environment.
- **Forma presented new data on the etavopivat clinical development program at multiple hematology conferences.** Presentations included analyses from the Phase I open-label extension study of etavopivat in sickle cell disease indicating that etavopivat decreased the frequency and severity of pain-related adverse events, and the design of the Phase II Gladiolus study of etavopivat in patients with sickle cell disease (SCD) receiving chronic transfusions or transfusion-dependent or non-transfusion-dependent thalassemia. These data were presented at the European Hematology Association (EHA) 2022 Hybrid Congress, the Foundation for Sickle Cell Disease Research (FSCDR) Sickle Cell Disease Research and Educational Symposium and Sickle Cell Disease Scientific Meeting, and the Global Congress on Sickle Cell Disease (GCSCD).
- **Forma hosted its first Research and Development (R&D) Day.** The company provided an overview of its clinical development programs and research pipeline strategy.

Upcoming Milestones

- **Patient enrollment ongoing in global pivotal Phase II/III trial of etavopivat for the treatment of SCD, the Hibiscus Study.** The first interim analysis (IA1) in the Hibiscus Study is expected to be reached by the end of 2022. IA1 is designed to select the dose for the Phase III portion of the trial.
- **Additional etavopivat development programs.** Forma has initiated a Phase II trial in patients with either TD-SCD, TD-thalassemia, or non-TD-thalassemia, with initial results expected in late 2022. By year-end 2022, Forma plans to begin clinical trials in pediatric SCD and lower-risk myelodysplastic syndrome (MDS).
- **Update on FT-7051 clinical trial in mCRPC.** Forma is planning to evaluate an alternative dosing schedule in a less heavily pretreated population and is currently processing the protocol amendment. Forma plans to provide updated results in the first half of 2023.
- **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 trials, have been impacted by the COVID-19 pandemic. Clinical trial sites implementing new policies in response to COVID-19 have impacted enrollment of clinical trials and/or the ability to access sites participating in clinical trials.

Financial Results

- Cash Position: Cash, cash equivalents and marketable securities were $395.9 million as of June 30, 2022, as compared to $490.3 million as of December 31, 2021. Current cash runway is projected through the third quarter of 2024.
- R&D Expenses: R&D expenses were $39.1 million for the quarter ended June 30, 2022, as compared to $31.6 million for the quarter ended June 30, 2021. The increase was primarily attributable to the increase in research and development staff to support the advancement of etavopivat and other programs, including the conduct of our Phase II/III Hibiscus trial in SCD patients and Phase II trial of etavopivat in thalassemia.
- General and Administrative (G&A) Expenses: G&A expenses were $13.9 million for the quarter ended June 30, 2022, as compared to $12.5 million for the quarter ended June 30, 2021. The increase was primarily attributable to professional services, costs due to executive and staff hiring, and other related general and administrative costs.

- Net Loss: Net loss was $52.6 million for the quarter ended June 30, 2022, as compared to net loss of $43.6 million for the quarter ended June 30, 2021.

Forma will conduct a conference call and webcast August 5, 2022 at 8:00 a.m. Eastern Daylight Time (EDT) to discuss second quarter 2022 results and business updates. Investors may participate in the call by using the registration link here. Once registered, participants will receive a dial-in number as well as a PIN to enter the event.

A live webcast of the conference call will be available in the "News & Investors" section of Forma's website at 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 pipeline is led by etavopivat, an investigational, once-daily, selective pyruvate kinase-R (PKR) activator designed to be a disease-modifying therapy with the potential to improve red blood cell (RBC) health and transform the lives of people living with sickle cell disease, thalassemia, and lower risk MDS. 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 and FT-7051, including expectations regarding potential development and expansion plans relating to, as well as the enrollment, timing, success and data announcements of, planned and ongoing clinical trials; therapeutic and market potential, clinical benefits, mechanisms of action and safety of our product candidates; upcoming milestones and potential payments related thereto; growth as a company; the anticipated contributions of new members of our executive team to our operations and progress; uses and need of capital, expenses and other financial results currently or in the future as well as the expected cash runway through the third quarter of 2024; and the potential impact of COVID-19 on patient retention and enrollment, future operations or clinical trials. 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, supply chain, patient enrollment and retention, clinical trials, strategy, goals and anticipated milestones, as well as global economies and financial markets; the therapeutic potential of our product candidates and the timing and completion of our clinical trials and related data analyses; 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; and our ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in our most recent quarterly report on Form 10-Q 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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	39,059	31,587	70,332	57,930
General and administrative	13,939	12,471	27,075	22,338
Total operating expenses	52,998	44,058	97,407	80,268
Loss from operations	(52,998)	(44,058)	(97,407)	(80,268)
Other income:				
Interest income	599	309	888	571
Other (expense) income, net	(192)	272	(227)	268
Total other income, net	407	581	661	839
Loss before taxes	(52,591)	(43,477)	(96,746)	(79,429)
Income tax (benefit) expense	(13)	108	(10)	116
Net loss and comprehensive loss	$ (52,578)	$ (43,585)	$ (96,736)	$ (79,545)
Net loss allocable to shares of common stock, basic and diluted	$ (52,578)	$ (43,585)	$ (96,736)	$ (79,545)
Net loss per share of common stock, basic and diluted	$ (1.10)	$ (0.92)	$ (2.03)	$ (1.68)
Weighted-average shares of common stock outstanding, basic and diluted	47,805,493	47,339,464	47,684,236	47,317,361

Selected Balance Sheet Items:

	June 30, 2022	December 31, 2021
Cash, cash equivalents, and marketable securities	$ 395,903	$ 490,273
Total assets	$ 475,169	$ 561,061
Accounts payable, accrued expenses, and other current liabilities	$ 33,421	$ 35,018
Total stockholders' equity	$ 414,492	$ 498,356

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Source: Forma Therapeutics Holdings, Inc.