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): December 16, 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.
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 7.01. Regulation FD Disclosure.

On December 16, 2021, Forma Therapeutics Holdings, Inc. (the Company) issued a press release titled "Forma Therapeutics' Investigational Olutasidenib in Combination with Azacitidine Yields Durable Complete Remission in Patients with mIDH1 Acute Myeloid Leukemia," a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including 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 8.01. Other Events.

On December 16, 2021, the Company announced olutasidenib, the company's investigational oral, selective mIDH1 inhibitor, combined with azacitidine yielded durable complete remission (CR) or CR with partial hematologic recovery (CRh) responses with favorable tolerability in patients with the mIDH1 form of acute myeloid leukemia (AML).

These positive findings, the first Phase 2 results of olutasidenib used in combination with a chemotherapy, were presented in an oral session on Dec. 13, 2021, at the 63rd American Society of Hematology (ASH) Annual Meeting. The findings support the potential of olutasidenib as the basis of combination therapy in patients with AML who have not achieved a durable response from prior therapy. In addition, a poster, presented on Dec. 12 at ASH, reported on the molecular characteristics of the mIDH1 of patients in the trial who responded to olutasidenib when administered as monotherapy.

The oral presentation reports an analysis of four patient cohorts from the pivotal open-label Phase 2 arm of an ongoing Phase 1/2 study, (2102-HEM-101, NCT02719574), who received olutasidenib dosed 150 milligrams (mg) twice daily continuously during 28-day cycles plus azacitidine, as of June 16, 2021. Azacitidine, a hypomethylating agent (HMA), was administered daily as an intravenous or subcutaneous injection therapy for days one to seven of each cycle.

Investigators enrolled patients into one of the four groups based on their disease status and prior therapy and recorded the best overall response for the primary endpoint of a composite complete remission (CR) plus CR with partial hematologic recovery (CRh) rate (CR/CRh). The group of patients who had not yet received therapy for their AML and were candidates for azacitidine as a first-line treatment had CR/CRh rate of 45% (5 out of 11). The other three groups enrolled patients who had relapsed/refractory AML (R/R AML) that, respectively, had prior HMA therapy; had prior therapy with an IDH1 inhibitor, including olutasidenib monotherapy; and were candidates for azacitidine as a first-line treatment. The CR/CRh rates for these groups were 38% (5 of 13), 30% (6 of 20), and 47% (9 of 19), respectively.

Olutasidenib with Azacitidine Well Tolerated

Olutasidenib was well tolerated in the trial in combination with azacitidine and the combination had a safety profile largely consistent with that of olutasidenib alone. Treatment-emergent adverse events (TEAEs) occurring in 25 percent or more of the participants included nausea (49 percent), constipation (40 percent), vomiting (35 percent), thrombocytopenia (32 percent), diarrhea (28 percent), and neutropenia (26 percent). TEAEs of grade 3 or 4 in more than 10 percent of participants included neutropenia (26 percent), thrombocytopenia (25 percent), anemia (19 percent), and febrile neutropenia (14 percent). TEAEs of QTc prolongation occurred in five participants (7 percent), of whom two experienced grade 3 QTc prolongation, and none discontinued olutasidenib.

TEAEs associated with liver enzyme abnormalities occurred in 15 participants (21 percent), with grade 3/4 in six (8 percent). Investigator-assessed IDH1 differentiation syndrome in six (8 percent) patients, of whom most resolved with treatment interruption, dexamethasone, and/or supportive treatment, while two patients had concomitant leukocytosis.

Molecular Characteristics of Response to Olutasidenib in Patients with R/R AML

A poster presentation reported findings from a planned interim analysis of the trial's cohort of patients with R/R AML receiving olutasidenib alone, dosed 150 mg twice daily. The analysis examined expression of IDH1m variant allele frequency, prevalence of other genetic co-mutations in the trial's pivotal cohort, and associations between mutations and response. Responses were observed across all IDH1 mutation subtypes and response rates were lower amongst patients with concurrent FLT3 co-mutations. Patients with higher co-mutations at baseline had lower rates of response than those with low mutational burden. Similarly, patients with lower baseline IDH1 expression were more likely to respond than those with high expression.

Forward-Looking Statements

The disclosure under this Item 8.01 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 olutasidenib, including expectations regarding timing, success and data announcements of the Company's current clinical trials; therapeutic potential, clinical benefits, molecular characteristics, mechanisms of action and safety of olutasidenib; planned regulatory submissions; and the potential impact of COVID-19 on patient retention and enrollment, future operations, clinical trials or planned regulatory submissions for olutasidenib. 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 under this Item 8.01 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 under this Item 8.01, 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 olutasidenib; the timing and completion of the Company's ongoing Phase 1/2 clinical study in olutasidenib; the Company's ability to execute on its strategy 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 the Company's product candidates may not be successfully developed and commercialized; regulatory developments in the United States and foreign countries; the Company's ability to protect and maintain its intellectual property position; the impact of COVID-19 the supply chain and production as well as global economies and financial markets; and the Company's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, to be filed with the U.S. Securities and Exchange Commission (SEC) and subsequent filings with the SEC. The Company 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 under this Item 8.01 represent the Company's views only as of the date hereof and should not be relied upon as representing the Company's views as of any subsequent date.

Item 9.01. Exhibits

(d) Exhibits

99.1	Press release issued by Forma Therapeutics Holdings, Inc. on December 16, 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: December 16, 2021

By: /s/ Jeannette Potts
Jeannette Potts, Ph.D., J.D.
SVP, General Counsel

Forma Therapeutics' Investigational Olutasidenib in Combination with Azacitidine Yields Durable Complete Remission in Patients with mIDH1 Acute Myeloid Leukemia

First Phase 2 combination trial results presented in oral session at 2021 ASH Annual Meeting

Olutasidenib with azacitidine well tolerated with a safety profile largely consistent with olutasidenib alone

Molecular characteristics of olutasidenib monotherapy response reported in ASH poster presentation

WATERTOWN, Mass.—(BUSINESSWIRE)—Dec. 16, 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 announced the company's investigational oral, selective mIDH1 inhibitor combined with azacitidine yielded durable complete remission (CR) or CR with partial hematologic recovery (CRh) responses with favorable tolerability in patients with the mIDH1 form of acute myeloid leukemia (AML).

These positive findings, the first Phase 2 results of olutasidenib used in combination with a chemotherapy, were presented in an oral session on Dec. 13, 2021, at the 63rd American Society of Hematology (ASH) Annual Meeting. The findings support the potential of olutasidenib as the basis of combination therapy in patients with AML who have not achieved a durable response from prior therapy. In addition, a poster, presented on Dec. 12 at ASH, reported on the molecular characteristics of the mIDH1 of patients in the trial who responded to olutasidenib when administered as monotherapy.

"AML is a cancer that returns in about half of patients following initial treatment. Patients who are not achieving remission or suffer from an AML relapse are in need of new therapies with more durable outcomes. The data presented today at ASH increase our understanding of olutasidenib's potential to achieve durable complete responses when used as either first-line or second-line therapy along with a standard therapy for patients with mIDH1 AML," said Patrick Kelly, M.D., chief medical officer of Forma Therapeutics.

The oral presentation reports an analysis of four patient cohorts from the pivotal open-label Phase 2 arm of an ongoing Phase 1/2 study, (2102-HEM-101, NCT02719574), who received olutasidenib dosed 150 milligrams (mg) twice daily continuously during 28-day cycles plus azacitidine, as of June 16, 2021. Azacitidine, a hypomethylating agent (HMA), was administered daily as an intravenous or subcutaneous injection therapy for days one to seven of each cycle.

Investigators enrolled patients into one of the four groups based on their disease status and prior therapy and recorded the best overall response for the primary endpoint of a composite complete remission (CR) plus CR with partial hematologic recovery (CRh) rate (CR/CRh). The group of patients who had not yet received therapy for their AML and were candidates for azacitidine as a first-line treatment had CR/CRh rate of 45% (5 out of 11). The other three groups enrolled patients who had

relapsed/refractory AML (R/R AML) that, respectively, had prior HMA therapy; had prior therapy with an IDH1 inhibitor, including olutasidenib monotherapy; and were candidates for azacitidine as a first-line treatment. The CR/CRh rates for these groups were 38% (5 of 13), 30% (6 of 20), and 47% (9 of 19), respectively.

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Olutasidenib Presentations Details

- Abstract 698: Olutasidenib (FT-2102) in Combination with Azacitidine Induces Durable Complete Remissions in Patients with mIDH1 Acute Myeloid Leukemia.
  Session 616 on Monday, Dec. 13, at 3:00 PM ET
  Presenter: Jorge E. Cortes, M.D.
- Abstract 2351: Molecular Characteristics of Response to Olutasidenib (FT-2102) in Patients with Relapsed/Refractory mIDH1 Acute Myeloid Leukemia
  Session: 616 on Sunday, Dec. 12, at 6:00 PM ET
  Presenter: Stéphane de Botton, M.D., Ph.D.

For more information, please visit https://www.formatherapeutics.com/clinical-trials/ or https://clinicaltrials.gov/ct2/show/NCT02719574.

About AML

Acute myeloid leukemia (AML) is a cancer that starts in a person's bone marrow but often quickly moves into the blood. AML develops from immature blood cells, known as myeloid cells, that are supposed to mature into white blood cells. However, the diseased myeloid cells do not function properly. They instead multiply rapidly, which causes normal blood cell production to fail. AML occurs primarily in adults and accounts for about 1 percent of all adult cancers. The American Cancer Society estimates that about 20,940 new cases, most in adults, arose in 2021 in the United States alone.[1]

Relapsed AML affects about half of all patients who, following treatment and remission, experience a return of leukemia cells in the bone marrow.[2] Refractory AML, which affects between 10 and 40 percent of newly diagnosed patients, occurs when a patient fails to achieve remission even after intensive treatment.[3]

About Olutasidenib

Olutasidenib is an oral, potent and small molecule investigational agent designed to selectively bind to and inhibit mutated IDH1 enzymes. This targeted treatment has the potential to provide therapeutic benefit by reducing 2-HG levels and restoring normal cellular differentiation. IDH1 is a natural enzyme that is part of the normal metabolism of all cells. When mutated, IDH1 activity can promote blood malignancies and solid tumors. IDH1 mutations are present in 6 to 8 percent of patients with AML.

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.

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Source: Forma Therapeutics Holdings, Inc.

References

1. The American Cancer Society. Key statistics for acute myeloid leukemia (AML). Revised January 12, 2021. Accessed Dec. 2, 2021 at https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html.

2. Leukaemia Care. (2019). *Relapse in Acute Myeloid Leukaemia (AML).* Version 3. Reviewed October 2021. Accessed Dec 2, 2021 at https://media.leukaemiacare.org.uk/wp-content/uploads/Relapse-in-Acute-Myeloid-Leukaemia-AML-Web-Version.pdf.

3. Thol F, Schlenk RF, Heuser M, Ganser A. How I treat refractory and early relapsed acute myeloid leukemia. Blood. 2015 Jul 16;126(3):319-27. doi: 10.1182/blood-2014-10-551911. Epub 2015 Apr 7. PMID: 25852056.