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): October 7, 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)

500 Arsenal Street, Suite 100
Watertown, Massachusetts 02472
(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 October 7, 2021, Forma Therapeutics Holdings, Inc. (the "Company") issued a press release titled "Forma Therapeutics' FT-7051 is Well-tolerated and Demonstrates Evidence of Activity in Initial Results from Ongoing Phase 1 Courage Study in Men with Metastatic Castration-resistant Prostate Cancer," 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, 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, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On June 11, 2021, the Company announced positive initial results from a Phase 1 trial of its novel CBP/p300 inhibitor, the oral small molecule FT-7051, in men with metastatic castration-resistant prostate cancer (mCRPC). Initial clinical data from the Courage Study, an ongoing first-in-human Phase 1 trial presented at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, showed an encouraging safety profile of FT-7051, as well as high specificity to the CBP/p300 pathway.

Preliminary results reported today include data as of September 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. Three patients remain on study; five patients left the study (four due to disease progression and one withdrawal of consent). The adaptive trial design is intended to efficiently explore safe and efficacious doses of FT-7051. Prior to enrollment, all of the men had received diagnoses of mCRPC, castration-levels of serum testosterone and rising levels of the biomarker prostate specific antigen (PSA) after the failure of at least two lines of therapy with an approved androgen-receptor pathway inhibitor.

The initial pharmacokinetic (PK) analysis of FT-7051 documented rapid absorption, which produced maximum blood concentrations within two hours. The 150 mg dose achieved drug concentrations that approached the predicted efficacious dose based on modeling with preclinical results. Skin biopsies of the men participating in the study demonstrated a reduction in H3K27AC, a marker of activity in the CBP/p300 pathway, the target of FT-7051.

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. One patient experienced Grade 3 hyperglycemia, which was medically managed. Following a dose reduction, this patient remained on treatment and experienced an ongoing PSA decline of greater than 50% at 12 weeks and greater than 80% at 16 weeks. Based upon these safety results, dose escalation is ongoing. The trial is continuing according to its adaptive design to further understand the safety and tolerability of FT-7051, gather data on clinical response including PSA and radiographic tumor response, as well as the assessment of secondary endpoints of clinical response.

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: initial results to date for the FT-7051 open label Phase 1 clinical trial; the therapeutic potential, clinical benefits and anticipated safety related to FT-7051; whether initial results from the Company's clinical trials are predictive of final trial results or future clinical studies; the Company's ability to enroll patients in a timely manner and retain such patients throughout the course of the study; and the Company's planned presentation of data at the 2021 AACR-NCI-EORTC Virtual Conference. 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 related the Company's ability to execute on its strategy; the therapeutic potential and safety of FT-7051; the timing and completion of the Phase 1 study of FT-7051 (the Courage Study) and final audit and quality controlled verification of initial data and related analyses; positive results from initial data analyses may not be

predictive of final results; risks related to patient enrollment and retention in the Company's clinical trials; risks related to the Company's planned regulatory submissions and developments; and other risks identified in the Company's filings with the Securities and Exchange Commission (SEC), including those risks discussed under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, as well as other risks detailed in our subsequent filings with the SEC. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. 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 its views as of any subsequent date.

Item 9.01. Exhibits

(d) Exhibits

99.1	Press release issued by Forma Therapeutics Holdings, Inc. on October 7, 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: October 7, 2021

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

Forma Therapeutics' FT-7051 is Well-tolerated and Demonstrates Evidence of Activity in Initial Results from Ongoing Phase 1 Courage Study in Men with Metastatic Castration-resistant Prostate Cancer

Initial eight patients treated in ongoing first-in-human, open-label, dose-finding trial of CBP/p300 inhibitor in late-line mCRPC patients

Adaptive trial design intended to efficiently explore safe and efficacious doses of FT-7051

First evaluable patient completing more than 90 days of treatment demonstrated an ongoing PSA50 response

Pharmacodynamic evidence of activity demonstrated via skin biomarker; no discontinuations due to adverse events

WATERTOWN, Mass. – Oct. 7, 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 positive initial results from a Phase 1 trial of its novel CBP/p300 inhibitor, the oral small molecule FT-7051, in men with metastatic castration-resistant prostate cancer (mCRPC). Initial clinical data from the Courage Study, an ongoing first-in-human Phase 1 trial presented at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, showed an encouraging safety profile of FT-7051, as well as high specificity to the CBP/p300 pathway.

"Preliminary data from the Courage Study are promising," said Andrew J. Armstrong, M.D., principal investigator of the Courage Study, and Professor of Medicine, Pharmacology and Cancer Biology, and Director of Research at the Duke Cancer Institute Center for Prostate and Urologic Cancers. "Managing the balance between safety, tolerability and efficacy is a key element of targeting this pathway, and thus far the doses studied are achieving pharmacodynamic target engagement with acceptable tolerability."

Preliminary results reported today include 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. Three patients remain on study; five patients left the study (four due to disease progression and one withdrawal of consent). The adaptive trial design is intended to efficiently explore safe and efficacious doses of FT-7051. Prior to enrollment, all of the men had received diagnoses of mCRPC, castration-levels of serum testosterone and rising levels of the biomarker prostate specific antigen (PSA) after the failure of at least two lines of therapy with an approved androgen-receptor pathway inhibitor.

The initial pharmacokinetic (PK) analysis of FT-7051 documented rapid absorption, which produced maximum blood concentrations within two hours. The 150 mg dose achieved drug concentrations that approached the predicted efficacious dose based on modeling with preclinical results. Skin biopsies of the men participating in the study demonstrated a reduction in H3K27AC, a marker of activity in the CBP/p300 pathway, the target of FT-7051.

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. One patient experienced Grade 3 hyperglycemia, which was medically managed. Following a dose reduction, this patient remained on treatment and experienced an ongoing PSA decline of greater than 50% at 12 weeks and greater than 80% at 16 weeks. Based upon these safety results, dose escalation is ongoing. The trial is continuing according to its adaptive design to further understand the safety and tolerability of FT-7051, gather data on clinical response including PSA and radiographic tumor response, as well as the assessment of secondary endpoints of clinical response.

“There is substantial need for new therapies to treat those with mCRPC as they progress while on existing lines of anti-androgen or chemotherapy,” said David N. Cook, Ph.D., senior vice president, Forma Therapeutics’ chief scientific officer. “Thanks to the eight patients who participated in the Courage Study to date, we have made progress in understanding the potential of CBP/p300 inhibition in prostate cancer and look forward to continuing our dose escalation study.”

Presentation Details

- Abstract P202: Initial Findings from an Ongoing First-in-human Phase 1 Study of the CBP/p300 Inhibitor FT-7051 in Men with Metastatic Castration-Resistant Prostate Cancer
- Abstract P204: Targeting the p300/CBP Epigenetic Pathway to Overcome Hormone Therapy Resistance in Advanced Prostate Cancer

Forma continues to enroll men into the Courage Study. For more information, please visit https://www.formatherapeutics.com/clinical-trials/ or https://clinicaltrials.gov/ct2/show/NCT04575766.

About CBP/p300

Tumor resistance to anti-androgen therapies can arise due to mutations and other changes within the androgen receptor (AR). Androgen binds to two paired proteins in ARs, CBP and p300, in a location that is highly resistant to mutations known as the bromodomain. FT-7051 is designed to attach to the CBP/p300 bromodomain potently and selectively, which then blocks androgen binding and reduces AR activation. In preclinical studies, FT-7501 demonstrated activity in both prostate cancer models that were sensitive or resistant to the approved androgen-inhibitor medicine enzalutamide.

About Prostate Cancer

Prostate cancer is the second most frequent cancer in men globally, accounting for more than 1.4 million new diagnoses and 6.8 percent of all male cancer deaths in 2020.[1] In the United States, more than 248,000 men will be diagnosed with prostate cancer in 2021, and the disease will account for more than 34,000 deaths.[2] When cancer has spread beyond the prostate and surgery or radiation are not an option, first-line treatment suppresses the male hormone androgen because it can stimulate prostate cancer cell growth.[3,4] This treatment, called medical castration, slows progression for about two years, but most men will develop resistance and their cancer will progress.[5,6] The five-year survival rate of men with metastatic prostate cancer is 30 percent.[7]

About Forma Therapeutics

Forma Therapeutics (Nasdaq: FMTX) 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. Our investigational medicine, etavopivat, is in a Phase 2/3 trial for sickle cell disease. For more information, please visit www.FormaTherapeutics.com or follow us on Twitter @FORMAInc and LinkedIn. Forma Therapeutics' is located in Watertown, MA.

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 our beliefs and expectations regarding: initial results to date for the FT-7051 open label Phase 1 clinical trial; the therapeutic potential, clinical benefits and anticipated safety related to FT-7051; whether initial results from our clinical trials are predictive of final trial results or future clinical studies; our ability to enroll patients in a timely manner and retain such patients throughout the course of our study; and our planned presentation of data at the 2021 AACR-NCI-EORTC Virtual Conference. 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 related our ability to execute on our strategy; the therapeutic potential and safety of FT-7051; the timing and completion of our Phase 1 study of FT-7051 (the Courage Study) and final audit and quality controlled verification of initial data and related analyses; positive results from initial data analyses may not be predictive of final results; risks related to patient enrollment and retention in our clinical trials; risks related to our planned regulatory submissions and developments; and other risks identified in our filings with the Securities and Exchange Commission (SEC), including those risks discussed under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, as well as other risks detailed in our subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. 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.

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References

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2 Prostate At a Glance. American Cancer Society. Cancer Statistics Center. 2018. https://cancerstatisticscenter.cancer.org/#!/cancer-site/Prostate. Accessed September 18, 2021.

3 Hormone Therapy for Prostate Cancer. American Cancer Society. May 27, 2021. https://www.cancer.org/cancer/prostate-cancer/treating/hormone-therapy.html. Accessed September 18, 2021.

4 Merseburger AS, Alcaraz A, von Klot CA. Androgen deprivation therapy as backbone therapy in the management of prostate cancer. *Onco Targets Ther*. 2016;9:7263-7274. Published 2016 Nov 29. doi:10.2147/OTT.S117176.

5 Ibid.

6 Sternberg CN, Baskin-Bey ES, Watson M, Worsfold A, Rider A, Tombal B. Treatment patterns and characteristics of European patients with castration-resistant prostate cancer. BMC Urol. 2013;13:58.

7 Survival Rates for Prostate Cancer. American Cancer Society. May 27, 2021. https://www.cancer.org/cancer/prostate-cancer/detection-diagnosis-staging/survival-rates.html. Accessed September 18, 2021.