
**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): **March 30, 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.
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 2.02 Results of Operations and Financial Condition

On March 30, 2021, Forma Therapeutics Holdings, Inc. announced its financial results for the year ended December 31, 2020. 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 7.01 Regulation FD Disclosure

On March 30, 2021, Forma Therapeutics Holdings, Inc. issued a press release, a copy of which is furnished herewith as Exhibit 99.2 to this Report on Form 8-K.

The information in this Item 7.01, including Exhibit 99.2 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 March 30, 2021, the Company announced new data from its ongoing randomized, placebo-controlled, multi-center Phase 1 trial of FT-4202 in patients with sickle cell disease (SCD) that support the evaluation of safety and efficacy of FT-4202 in a Phase 2/3 trial. FT-4202 is a novel investigational selective red blood cell pyruvate kinase-R (PKR) activator being developed by the Company as a disease-modifying therapy for the treatment of SCD. Aggregate findings from the placebo-controlled cohorts of the Phase 1 trial demonstrated 10 of 14 patients (71%) who received FT-4202 achieved a hemoglobin increase of greater than or equal to 1 g/dL from baseline with once-daily dosing of FT-4202 during 14 days of treatment. Based on a trend toward increasing response over the treatment period, the potential exists for additional benefit when dosing beyond 14 days; this is being explored in the ongoing open label extension, which is dosing patients at 400 mg daily for 12 weeks.

The data also showed activation of PKR by FT-4202 increased sickle RBC survival and reduced intravascular hemolysis in patients with SCD based on a reduction in reticulocytes, bilirubin and LDH levels.

Change in hematologic and hemolytic parameters at end of 14-day treatment as compared to baseline in FT-4202-treated patients (median change)				
Dose Cohort	Hb \geq 1 g/dL	Reticulocytes \downarrow	LDH \downarrow	Bilirubin \downarrow
300 mg	6/7 (1.2 g/dL)	7/7 (-60%)	6/7 (-36%)	7/7 (-35%)
600 mg	4/7 (1.0 g/dL)	7/7 (-45%)	4/7 (-5%)	7/7 (-41%)
Combined	10/14 (1.2 g/dL)	14/14 (-57%)	10/14 (-20%)	14/14 (-37%)

While the data from the 600 mg cohort of patients remain blinded, initial analysis of the cohort suggests FT-4202 has a similar safety and tolerability profile as the 300 mg cohort, despite the doubling of the dose. No dose-limiting toxicities or treatment-related adverse events (AE) were reported, and the overall AE profile of the 600 mg cohort was consistent with the 300 mg cohort.

Unblinded 600 mg cohort data are expected to be reported at an upcoming medical conference in Summer 2021, in addition to initial results from the ongoing open label extension.

Statements contained under this Item 8.01, including Exhibit 99.2, regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to: the Company's guidance regarding its business plans and objectives for FT-4202, including the therapeutic potential and clinical benefits thereof, as well as the safety and tolerability of FT-4202 and future clinical development plans; expected timing and results of the Company's ongoing open label extension trial for FT-4202; and the potential impact of COVID-19 on patient retention, strategy, future operations and clinical trials.

Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: risks related to the impact of public health epidemics affecting countries or regions in which we have operations or

do business, such as COVID-19, which has been labelled a pandemic by the World Health Organization, including potential negative impacts on the Company's employees, manufacturers, supply chain and production as well as on global economies and financial markets; the company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States; and risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01.Exhibits

(d) Exhibits

- 99.1 [Press release issued by Forma Therapeutics Holdings, Inc. on March 30, 2021, furnished herewith.](#)
- 99.2 [Press release issued by Forma Therapeutics Holdings, Inc. on March 30, 2021, furnished herewith.](#)

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: March 30, 2021

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



Forma Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

Strong organizational foundation laid in 2020; continued pipeline execution amid the COVID-19 and raised gross capital of \$595.1 million

Key pipeline achievements include proof of concept for FT-4202 in sickle cell disease; successful interim analysis of registrational Phase 2 trial of olutasidenib in R/R AML with IDH1m; and commencement of Phase 1 trial for FT-7051 in mCRPC

2021 milestones already achieved; top-line results from 600mg dose cohort of Phase 1 FT-4202 trial, enrolling patients in Phase 2/3 FT-4202 trial, and first patient dosed in Phase 1 FT-7051 trial in mCRPC

Anticipated 2021 milestones include initial results from FT-4202 open label extension in second quarter and initial FT-7051 Phase 1 results in the second half of the year

WATERTOWN, Mass. – Mar. 30, 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 fourth quarter and full year ended December 31, 2020. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

“2020 was a very productive year for Forma, starting with our initial public offering in June and including positive clinical data and progress on our key development programs targeting sickle cell disease, AML and glioma, as well as prostate cancer,” said Frank Lee, president and chief executive officer of Forma. “With important events in 2021 for our compounds in development, we look forward to furthering our mission to bring breakthrough therapies to people living with rare hematologic diseases and cancers.”

Key Business and Clinical Highlights

PKR Program in Sickle Cell Disease (SCD):

- **Positive Phase 1 results of FT-4202 presented at scientific conferences.** At the European Hematology Association Annual Congress in June 2020, results from a single ascending dose trial demonstrated a favorable tolerability profile and pharmacokinetic/pharmacodynamic (PK/PD) effects in patients with SCD who were administered a 700mg dose of FT-4202. Subsequently, at the American Society of Hematology (ASH) Annual Meeting and Exposition in December 2020, data were presented from the ongoing randomized, placebo-controlled Phase 1 multiple ascending dose (MAD) trial. Results from the 300mg MAD1 dose cohort following 14 days of treatment showed an increase in hemoglobin of 1g/dL or greater in 6 of 7 (86%) patients vs. 0% of patients receiving placebo. In addition, markers of hemolysis such as indirect bilirubin, reticulocytes and lactate dehydrogenase were improved, and measures of oxygen affinity and deformability suggested improvement in RBC health. FT-4202 was generally well-tolerated with no serious adverse events attributed to treatment with the compound.
- **Positive FT-4202 600 mg multiple ascending dose cohort data support doses being evaluated in Phase 2/3 registrational trial, called the Hibiscus Study.** Doubling the dose of FT-4202 to 600 mg daily for 14 days compared to the previous 300 mg cohort was well-tolerated with no dose-limiting toxicities or treatment-related adverse events observed. Improvements in hematologic (hemoglobin and

reticulocytes) and hemolytic (bilirubin and LDH) parameters were comparable to that observed with 300 mg dose, with best response typically at the end of the 14-day treatment period. Across 300 mg and 600 mg cohorts, 10 of 14 (71%) patients on FT-4202 for 14 days achieved a hemoglobin increase ≥ 1 g/dL from baseline. The phase 2/3 Hibiscus Study is currently enrolling people living with sickle cell disease (SCD). This adaptive, randomized, placebo-controlled, double-blind, multi-center trial is expected to enroll approximately 344 adults and adolescents with SCD. FT-4202 doses of 200 mg and 400 mg administered once-daily are being evaluated in the Phase 2 portion of the trial. Primary endpoints in the Phase 3 portion of the trial are hemoglobin response rate at week 24 (increase of > 1 g/dL from baseline), and annualized vaso-occlusive crisis rate during the 52-week blinded treatment period.

CPB/p300 Program in Prostate Cancer:

- **Preclinical data presented at scientific conference.** At the American Association for Cancer Research (AACR) virtual meeting in June 2020, a poster was presented with preclinical data for FT-6876, a potent and selective inhibitor of CBP/p300, a known co-activator of the androgen receptor (AR) and a driver of metastatic castration-resistant prostate cancer (mCRPC). The data demonstrated antitumor activity of FT-6876 in AR-dependent breast cancer cell lines and highlight the possible role of CBP/p300 in proliferation and survival of AR-dependent tumors, such as prostate cancer. FT-6876 is a research compound related to FT-7051, although with differing PK/PD properties.
- **FT-7051 Phase 1 clinical trial initiated for the treatment of metastatic castration-resistant prostate cancer (mCRPC).** In January 2021, Forma announced that the first patient was dosed in the ongoing Phase 1 trial. The trial is a multicenter, open-label evaluation of the safety and tolerability, preliminary anti-tumor activity (PSA and radiographic responses), and pharmacokinetics/pharmacodynamics (PK/PD) of FT-7051 in men with mCRPC who have progressed despite prior therapy with at least one anti-androgen therapy. The trial will include genetic mutation analysis to identify tumors with AR-v7 splice variants, against which there are no approved therapies. This is an adaptive trial design, intended to accelerate the escalation to potentially therapeutic doses and yield important safety information, as well as the identification of biomarkers of clinical benefit such as prostate specific antigen (PSA).

IDH1 Program in AML and Glioma:

- **Announced positive data for olutasidenib in relapsed/refractory acute myeloid leukemia (R/R AML).** In October 2020, Forma announced positive results from the planned interim analysis (IA2) of the Phase 2 registration trial in R/R AML patients with isocitrate dehydrogenase 1 gene mutations (IDH1m). Olutasidenib demonstrated favorable tolerability as a monotherapy and achieved the primary endpoint of composite complete remission (CR+CRh, or complete remission plus complete remission with partial hematologic recovery) rate of 33.3% (30% CR and 3% CRh). While a median duration of CR/CRh has not been reached, a sensitivity analysis (with a hematopoietic stem cell transplant as the end of a response) indicated a median duration of CR/CRh to be 13.8 months. Safety results were consistent with previously reported Phase 1 clinical trial results. Additional data and analyses indicate that the overall response rate (ORR), comprised CR, CRh, CRi, partial response (PR), and morphologic leukemia-free state (MLFS), was 46% and the median duration of ORR was 11.7 months. The median overall survival (OS) was 10.5 months. For patients with CR/CRh, the median OS has not yet been reached, but the estimated 18-month survival is 87%. The most frequently reported treatment emergent adverse events ($\geq 20\%$) were nausea (38%), constipation (25%), increased white blood cell count (25%), decreased RBC count (24%), pyrexia (23%), febrile neutropenia (22%), and fatigue (21%). Grade 3/4 adverse events occurring in greater than 10% of patients, regardless of causality, were febrile neutropenia (20%), decreased RBC count (19%), decreased platelet count (16%), and decreased neutrophil count (13%).
- **An exploratory Phase 1 trial of olutasidenib for glioma showed evidence of disease control.** Data presented at the American Society of Clinical Oncology meeting in June 2020 demonstrated the brain

penetrant properties of FT-2102 and preliminary clinical activity, which suggest potential for response and prolonged disease control in the enhanced (grade III/IV) R/R IDH1-mutated glioma. Among 24 evaluable patients treated (4 grade II, 13 grade III, 7 grade IV), one patient had a partial response and 11 patients had stable disease, as determined by investigator response assessment in neuro-oncology, or RANO, criteria. Twenty-two of the patients' responses were also evaluated by volumetric changes at a central review, where four patients had more than 50% tumor reduction, one patient had 25% to 50% tumor reduction, and an additional seven patients had prolonged stable disease.

Corporate Achievements:

- **Successful initial public offering in June 2020 and follow-on equity offering in December 2020.** On June 23, 2020, the Company completed an initial public offering (IPO) in which the Company issued and sold 15,964,704 shares of its common stock at a public offering price of \$20.00 per share. The Company raised approximately \$293.3 million in net proceeds after deducting underwriting discounts and commissions and offering expenses. On December 15, 2020, the Company completed an underwritten public offering of 6,095,000 shares of its common stock at a public offering price of \$45.25 per share. The Company raised approximately \$258.6 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.
- **Three new board of directors appointments.** In July 2020, Wayne A.I. Frederick, M.D., was elected to serve on Forma's board of directors. Dr. Frederick is the President of Howard University, as well as the Charles R. Drew Professor in Surgery at Howard University's College of Medicine, and a distinguished researcher and practicing surgeon.

In September 2020, Forma announced the appointment of industry veteran Thomas G. Wiggans to its board of directors. Mr. Wiggans has led successful biopharmaceutical companies from start-up stage into the clinic and later global commercialization and served on the boards of numerous public and private companies

In January 2021, Forma announced the appointment of Selwyn M. Vickers, M.D., to its board of directors. Dr. Vickers is a world-renowned surgeon, pancreatic cancer researcher and pioneer in health disparities research. He currently serves as senior vice president of medicine and dean of the School of Medicine at The University of Alabama at Birmingham (UAB).

Upcoming Milestones

- **Phase 1 FT-4202 randomized cohorts successfully completed; open label extension ongoing.** Patients with sickle cell disease are now directly enrolling into the 12-week open label extension (OLE) with the 400mg daily dose, which was previously limited to patients who completed the 600mg dose cohort. Initial results from the ongoing 400mg 12-week open label extension are anticipated to be announced at a scientific congress in the second quarter of 2021, and full results expected at a scientific congress in late 2021.
- **Initial Phase 1 clinical results from FT-7051 in mCRPC anticipated later this year.** This adaptive trial is designed to assess multiple doses of FT-7051 with dose escalation dependent upon safety and tolerability. Initial results are anticipated in the second half of 2021, which may include safety/tolerability, PK/PD results and preliminary biomarker data.
- **NDA being prepared for olutasidenib in R/R AML.** Forma is preparing a new drug application (NDA) for submission to the U.S. Food and Drug Administration for refractory/relapsing AML patients with an IDH1 mutation. In addition, a manuscript is being prepared for publication of Phase 1 glioma results.
- **Possibility of COVID-19 impact remains.** The COVID-19 pandemic remains a factor in the successful completion of these milestones. Many clinical trials across the biopharma industry have been impacted

by the COVID-19 pandemic, with clinical trial sites implementing new policies in response to COVID-19, resulting 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 \$645.6 million as of December 31, 2020, as compared to \$173.2 million as of December 31, 2019. Current cash runway is projected through the third quarter of 2024.
- **Research and Development (R&D) Expenses:** R&D expenses were \$24.9 million and \$93.4 million for the quarter and year ended December 31, 2020, compared to \$27.0 million and \$111.3 million for the quarter and year ended December 31, 2019. The decline was attributable to a decrease in spending on internal research and development primarily due to restructuring in January 2019, and reductions in spending on olutasidenib and FT-8225, which were partially offset by increases in FT-4202 expenses to conduct the Phase 1 trial, clinical product manufacturing, and preparations for the pivotal Phase 2/3 trial.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$7.9 million and \$30.8 million for the quarter and year ended December 31, 2020, compared to \$6.8 million and \$24.4 million for the quarter and year ended December 31, 2019. The increase in general and administrative expense was primarily attributable to a \$3.2 million increase in stock compensation expense; \$1.2 million increase in insurance related expenses; \$1.2 million increase in professional fees, \$0.5 million increase in personnel-related costs due to executive and staff hiring, recruiting and an increase in facilities, and IT related expenses of \$0.2 million.
- **Net Income/Loss:** Net loss was \$28.6 million and \$70.4 million for the quarter and year ended December 31, 2020, compared to \$24.7 million and \$34.8 million for the quarter and year ended December 31, 2019.

Forma will conduct a conference call and webcast on March 30th at 8 a.m. Eastern Standard Time (EST) to discuss 2020 year-end financial results and business update. The call can be accessed by dialing (833) 301-1146 in the U.S., and (914) 987-7386 internationally, with conference ID 5893542. 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 FT-4202, and FT-7051 and olutasidenib, including expectations regarding timing and success of the current ongoing clinical trials, therapeutic potential, and clinical benefits and safety thereof, planned regulatory submissions, including an NDA for olutasidenib, and upcoming milestones for the company’s other product candidates; growth as a company and the anticipated contribution of the members of our board of directors to our operations and

progress; 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 of capital, expenses and other 2020 financial results or in the future, and the potential impact of COVID-19 on patient retention, strategy, future operations, clinical trials or IND submissions. 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, strategy, goals and anticipated milestones; the therapeutic potential of FT-4202 and FT-7051, and the timing associated with the initiation or continuation of any of FT-4202 trials and success of ongoing clinical trials of FT-4202 and FT-7051; the initiation of our phase I clinical trial of FT-7051; Forma’s ability to execute on its strategy; the submission and acceptance of a new drug application for submission to the U.S. Food and Drug Administration 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 the final prospectus dated December 10, 2020 and filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the United States Securities and Exchange Commission (SEC) and elsewhere in Forma’s filings and reports 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 December 31,		For the Year Ended December 31,	
	2020	2019	2020	2019
Revenue	\$ —	\$ 7,444	\$ —	\$ 100,557
Operating expenses				
Research and development	24,866	27,042	93,367	111,315
General and administrative	7,941	6,771	30,782	24,402
Restructuring charges	—	(330)	63	5,290
Total operating expenses	32,807	33,483	124,212	141,007
Loss from operations	(32,807)	(26,039)	(124,212)	(40,450)
Other income, net	1,029	752	24,079	3,809
Loss before taxes	(31,778)	(25,287)	(100,133)	(36,641)
Income tax benefit	(3,190)	(631)	(29,719)	(1,848)
Net loss	<u>\$ (28,588)</u>	<u>\$ (24,656)</u>	<u>\$ (70,414)</u>	<u>\$ (34,793)</u>
Preferred return and accretion of preferred return and cumulative dividends on preferred securities	—	(568)	(3,736)	(2,963)
Loss on extinguishment of Series A, Series B-1 and Series B-2 convertible preferred stock	—	(3,584)	—	(3,584)
Distribution to holders of preferred securities in excess of accrued preferred return	—	—	—	(11,347)
Tax distribution to holders of Enterprise.1 Incentive Shares	—	—	—	(60)
Net loss allocable to shares of common stock, basic	<u>\$ (28,588)</u>	<u>\$ (28,808)</u>	<u>\$ (74,150)</u>	<u>\$ (52,747)</u>
Change in fair value attributable to warrants to purchase preferred securities	—	(447)	—	(962)
Net loss allocable to shares of common stock, diluted	<u>\$ (28,588)</u>	<u>\$ (29,255)</u>	<u>\$ (74,150)</u>	<u>\$ (53,709)</u>
Net loss per share of common stock:				
Basic	<u>\$ (0.68)</u>	<u>\$ (11.31)</u>	<u>\$ (3.22)</u>	<u>\$ (20.70)</u>
Diluted	<u>\$ (0.68)</u>	<u>\$ (11.48)</u>	<u>\$ (3.22)</u>	<u>\$ (21.08)</u>
Weighted-average shares of common stock outstanding,				
Basic and diluted	<u>42,239,451</u>	<u>2,547,937</u>	<u>23,056,975</u>	<u>2,547,927</u>

Selected Balance Sheet Items:

	December 31, 2020	December 31, 2019
Cash, cash equivalents, and marketable securities	\$ 645,588	\$ 173,180
Total assets	\$ 680,971	\$ 183,035
Accounts payable, accrued expenses, and other current liabilities	\$ 31,399	\$ 23,629
Redeemable convertible and convertible preferred stock outside of stockholders' equity	\$ —	\$ 138,131
Total stockholders' equity	\$ 648,244	\$ 18,246

Investor Contact:

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Forma Therapeutics
mcorso@formatherapeutics.com

SOURCE: Forma Therapeutics Holdings, Inc.



Forma Therapeutics Announces Positive FT-4202 600 mg Multiple Ascending Dose Cohort Data Supporting the Doses Being Evaluated in Phase 2/3 Registrational Trial, Called The Hibiscus Study

Blinded data from the 600 mg dose cohort support the doses (400 mg v 200 mg v placebo) being evaluated in the Hibiscus Study currently enrolling people living with sickle cell disease (SCD)

Doubling the dose of FT-4202 to 600 mg daily for 14 days compared to the previous 300 mg cohort was well-tolerated with no dose-limiting toxicities or treatment-related adverse events observed

Improvements in hematologic (hemoglobin and reticulocytes) and hemolytic (bilirubin and LDH) parameters were comparable to that observed with 300 mg dose, with best response typically at the end of the 14-day treatment period

Across 300 mg and 600 mg cohorts, 10 of 14 (71%) patients on FT-4202 for 14 days achieved a hemoglobin increase ≥ 1 g/dL from baseline

WATERTOWN, Mass. – March 30, 2021 – [Forma Therapeutics Holdings, Inc.](#) (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on rare hematologic diseases and cancers, today announced new data from its ongoing randomized, placebo-controlled, multi-center Phase 1 trial of FT-4202 in patients with sickle cell disease (SCD) that further support the development of this novel investigational agent, a selective red blood cell (RBC) pyruvate kinase-R (PKR) activator, as a potential disease-modifying therapy. Data previously presented at the 2020 American Society of Hematology (ASH) Annual Meeting were based on the first cohort of patients in the Phase 1 trial dosed with 300 mg of FT-4202 or placebo once daily for 14 days and a 7-day follow up period. The new findings include an analysis of the blinded data from the second cohort of patients randomly assigned to receive 600 mg of FT-4202 or placebo once daily for 14 days and a 7-day follow up period.

“We are excited to see the favorable safety and tolerability profile of FT-4202 at a 600 mg dose, coupled with the overlap of pharmacodynamic activity and biologic effects across the 300 and 600 mg doses, supporting the evaluation of safety and efficacy at an upper range of 400 mg in our Phase 2/3 trial,” said Patrick Kelly, M.D., chief medical officer of Forma. “These results after only 14 days of treatment support the potential of FT-4202 to treat the underlying pathophysiology of the disease by increasing hemoglobin and reducing hemolysis, which may reduce the number and severity of vaso-occlusive crises SCD patients may experience annually.”

Aggregate findings from the placebo-controlled cohorts of the Phase 1 trial demonstrated 10 of 14 patients (71%) who received FT-4202 achieved a hemoglobin increase of greater than or equal to 1 g/dL from baseline with once-daily dosing of FT-4202 during 14 days of treatment. Based on a trend toward increasing response over the treatment period, the potential exists for additional benefit when dosing beyond 14 days; this is being explored in the ongoing open label extension, which is dosing patients at 400 mg daily for 12 weeks.

The data also showed activation of PKR by FT-4202 increased sickle RBC survival and reduced intravascular hemolysis in patients with SCD based on a reduction in reticulocytes, bilirubin and LDH levels.

Change in hematologic and hemolytic parameters at end of 14-day treatment as compared to baseline in FT-4202-treated patients (median change)				
Dose Cohort	Hb \geq 1 g/dL	Reticulocytes \downarrow	LDH \downarrow	Bilirubin \downarrow
300 mg	6/7 (1.2 g/dL)	7/7 (-60%)	6/7 (-36%)	7/7 (-35%)
600 mg	4/7 (1.0 g/dL)	7/7 (-45%)	4/7 (-5%)	7/7 (-41%)
Combined	10/14 (1.2 g/dL)	14/14 (-57%)	10/14 (-20%)	14/14 (-37%)

While the data from the 600 mg cohort of patients remain blinded, initial analysis of the cohort suggests FT-4202 has a similar safety and tolerability profile as the 300 mg cohort, despite the doubling of the dose. No dose-limiting toxicities or treatment-related adverse events (AE) were reported, and the overall AE profile of the 600 mg cohort was consistent with the 300 mg cohort.

Unblinded 600 mg cohort data are expected to be reported at an upcoming medical conference in Summer 2021, in addition to initial results from the ongoing open label extension.

Ongoing Trials

The blinded, randomized, placebo-controlled portion of the ongoing Phase 1 study is now complete. People with SCD are now directly enrolling into the 12-week open label cohort receiving 400 mg of FT-4202 daily.

Forma is currently enrolling adults and adolescents with SCD into the Hibiscus Study, a registrational Phase 2/3 randomized, placebo-controlled, double-blind, multicenter trial to further evaluate the safety and efficacy of FT-4202 in this patient population. For more information, please visit clinicaltrials.gov/NCT04624659.

About Sickle Cell Disease

SCD is one of the most common single-gene disorders and is estimated to affect approximately 100,000 people in the United States, as well as approximately 30,000 in France, Germany, Italy, Spain and the United Kingdom. The National Institutes of Health (NIH) reports that prevalence is estimated at more than 20 million individuals globally. From 2010 to 2050, the annual number of newborns with SCD is expected to rise globally by approximately one-third.¹ Despite recent advances in treatment, most patients with SCD still suffer from pain crises, lifelong disability, significant morbidity and reduced quality of life.

About FT-4202

FT-4202 is a novel investigational selective red blood cell (RBC) pyruvate kinase-R (PKR) activator designed to be a disease-modifying therapy for the treatment of sickle cell disease (SCD). Employing a multimodal approach, FT-4202 is designed to work upstream by activating the RBCs' natural PKR activity to decrease 2,3-DPG levels, which leads hemoglobin to hold on to oxygen molecules longer to reduce RBC sickling. The downstream activity of FT-4202 is designed to increase ATP levels, the fuel that provides energy to cells, to improve RBC health and survival. Together, these effects are anticipated to increase hemoglobin levels and decrease painful vaso-occlusive crises. In preclinical safety studies, FT-4202 did not inhibit aromatase activity or affect steroidogenesis, important biological processes responsible for sexual development. FT-4202 has been granted Fast Track, Rare Pediatric Disease and Orphan Drug designations from the U.S. Food and Drug Administration (FDA), and Orphan Drug

Designation from the European Commission based on a positive opinion from the Committee for Orphan Medicinal Products of the European Medicines Agency for the treatment of patients with SCD.

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 our beliefs and expectations regarding: our ability to complete our ongoing clinical trials for FT-4202, including their timing and success, our expectations of the therapeutic benefits related to FT-4202, whether positive interim results from a clinical study are predictive of the results of ongoing or future clinical studies, our presentation of additional data at upcoming scientific conferences, and other preclinical data in 2021, our expectations around our future regulatory filings and our growth as a company. 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 therapeutic potential of FT-4202, and the timing and success of ongoing clinical trials of FT-4202; 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; and other risks identified in our SEC filings, including those risks discussed under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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 its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

1 Piel, F. B., Hay, S. I., Gupta, S., Weatherall, D. J., & Williams, T. N. (2013). Global burden of sickle cell anaemia in children under five, 2010-2015: Modelling based on demographics, excess mortality, and interventions. *PLOS Medicine*, 10(7). Retrieved from link.

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