



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

March 30, 2021

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

Key 2020 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.--(BUSINESS WIRE)--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 200mg and 400mg 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 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 registrational 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 a 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 olutasidenib 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	\$(28,588)	\$(24,656)	\$(70,414)	\$(34,793)
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	\$(28,588)	\$(28,808)	\$(74,150)	\$(52,747)
Change in fair value attributable to warrants to purchase preferred securities	—	(447)	—	(962)

Net loss allocable to shares of common stock, diluted	\$ (28,588)	\$ (29,255)	\$ (74,150)	\$ (53,709)
Net loss per share of common stock:				
Basic	\$ (0.68)	\$ (11.31)	\$ (3.22)	\$ (20.70)
Diluted	\$ (0.68)	\$ (11.48)	\$ (3.22)	\$ (21.08)
Weighted-average shares of common stock outstanding,				
Basic and diluted	42,239,451	2,547,937	23,056,975	2,547,927

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

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