Forma Therapeutics Reports Third Quarter 2020 Financial Results and Provides Business Update

November 12, 2020

Strong pipeline progress amid challenging COVID-19 environment

Oral presentation of MAD1 results at upcoming 2020 ASH Virtual Annual Meeting from the randomized, placebo-controlled multi-center Phase 1 trial evaluating FT-4202 in people with sickle cell disease

MAD2 cohort of the Phase 1 trial now enrolling with 600 mg dose

Registrational Phase 2/3 trial of FT-4202 on track to begin enrolling people living with sickle cell disease in the first quarter of 2021

Phase 1 trial evaluating FT-7051 in metastatic castration-resistant prostate cancer on track to begin enrolling patients before end of 2020

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 12, 2020-- Forma Therapeutics Holdings, Inc. (Nasdaq: FMTX), a clinical-stage biopharmaceutical company focused on rare hematologic diseases and cancers, today reported financial results for the third quarter ended September 30, 2020. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

"We are very pleased with our strong pipeline progress during the quarter amid such challenging times," said Frank Lee, President and Chief Executive Officer of Forma. "We look forward to presenting new data from our ongoing Phase 1 trial of FT-4202 in sickle cell disease at the ASH meeting in December, as well as beginning enrollment of patients for our Phase 1 trial of FT-7051 in men living with metastatic castration-resistant prostate cancer. The recent positive top-line results from the olutasidenib registrational Phase 2 clinical trial in relapsed/refractory acute myeloid leukemia with an IDH1 mutation further underscores our commitment to developing transformative therapies for patients."

Key Business and Clinical Highlights

PKR Program in Sickle Cell Disease (SCD):

- **Both planned dose cohorts enrolling in the multiple ascending dose (MAD) trial.** The MAD1 cohort is designed to dose 9-12 SCD patients with 300 mg of FT-4202. Clinical measures being assessed include change in hemoglobin, indirect bilirubin, reticulocytes and lactate dehydrogenase, as well as the monitoring of tolerability and safety during the 14-day dosing and 7-day follow-up period. The MAD2 cohort is assessing a higher 600 mg dose and is now enrolling patients**.** Patients completing the 600 mg MAD2 cohort may enter the 12-week Open Label Extension (OLE) portion of the trial.
- **FT-4202 abstract selected for oral presentation at the virtual 62nd American Society of Hematology (ASH) Annual Meeting and Exposition December 5-8, 2020.** The FT-4202 abstract describes blinded data from three patients receiving the 300 mg dose, measuring changes in parameters over the 14-day treatment and 7-day follow-up period including hemoglobin and reticulocytes, as well as tolerability and safety. Updated data will be presented at the ASH annual meeting on December 7, 2020.

CPB/p300 Program in Prostate Cancer:

- **Phase 1 clinical trial of FT-7051 for the treatment of metastatic castration-resistant prostate cancer (mCRPC) on track to start by year end.** This trial will enroll patients who have progressed while on standard anti-androgen therapy. Patients' prostate cancer will be profiled for mutations in the androgen receptor (AR)-signaling pathway that drive resistance to AR-receptor antagonists, such as ARv7 mutations.

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 a favorable tolerability profile as a monotherapy, and for the primary efficacy endpoint of composite complete remission (CR+CRh, or complete remission plus complete remission with partial hematologic recovery), achieved a 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) indicates the median duration of CR/CRh to be 13.8 months. Safety results are consistent with previously reported Phase 1 clinical trial results.
- Olutasidenib is also being evaluated in an exploratory Phase 1 trial for glioma as presented at the American Society of Clinical Oncology meeting in June 2020, as well as in other IDH1m solid tumor indications.

Corporate:

- **In September 2020, Forma announced the appointment of industry veteran Thomas G. Wiggans to Forma's board of directors**. Mr. Wiggans has led successful biopharmaceutical companies from start-up stage into the clinic and later global commercialization, served on the boards of numerous public and private companies, and was instrumental in the formation of the Biotechnology Industry Organization, now Biotechnology Innovation Organization (BIO).

Upcoming Milestones

- **Results from the ongoing randomized placebo-controlled multicenter Phase 1 trial evaluating FT-4202 in patients with SCD to be presented at ASH.** Clinical data on the safety results, PK/PD and laboratory measurements in 9-12 patients from the 300 mg MAD1 cohort will be presented during an oral presentation at the virtual, 62nd American Society of Hematology (ASH) Annual Meeting and Exposition December 5-8, 2020. Subsequently, results from the MAD2 600 mg cohort are expected in the first quarter of 2021, and 12-week OLE results are anticipated in the second quarter of 2021.
- **Initiation of registrational trial of FT-4202 for people living with SCD**: The global pivotal Phase 2/3 trial is expected to initiate in the first quarter of 2021. This adaptive, randomized, placebo-controlled, double-blind, multi-center study will enroll approximately 344 adults and adolescents with SCD. The trial will evaluate FT-4202 doses of 200 mg and 400 mg administered once daily in the Phase 2 portion. 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.
- **Initiation of FT-7051 Clinical Development in mCRPC:** Patient enrollment in the Phase 1 trial of FT-7051 in mCRPC patients is expected to begin prior to the end of 2020. Safety and tolerability data from the trial are anticipated in 2021 and clinical activity results in 2022.
- **Non-core Partnering Strategy:** Following the recent positive registrational trial results in R/R AML with an IDH1 mutation, Forma remains focused on partnership opportunities for olutasidenib, as well as for the non-core FASN inhibitor for NASH (FT-8225).
- **Possibility of COVID-19 Impact**: 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.

Upcoming Investor Events

- **Dec. 7, 2020**: Forma will conduct a conference call and webcast on Dec. 7 at 6 p.m. Eastern Standard Time (EST) to discuss updated results from the ongoing Phase 1 trial of FT-4202 in SCD, as well as an overview of the company's development plans for FT-4202. A live webcast will be available in the "News & Investors" section of Forma's website www.formatherapeutics.com.

Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $384.3 million as of September 30, 2020, as compared to $173.2 million as of December 31, 2019.
- **Research and Development (R&D) Expenses**: R&D expenses were $24.8 million for the quarter ended September 30, 2020, compared to $27.6 million for the quarter ended September 30, 2019. The decrease was primarily due to planned reductions in spending on FT-2102, FT-4101, FT-8225, research activities, and internal R&D personnel-related costs, 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 $7.5 million for the quarter ended September 30, 2020, compared to $7.0 million for the quarter ended September 30, 2019. The increase in general and administrative expense was primarily attributable to a $1.3 million increase in equity-based compensation, and a $0.6 million increase in insurance related expense, and a $0.5 million increase in other related general and administrative costs, partially offset by a reduction of $2.0 million related to legal, consulting and other professional fee expenses.
- **Net Income/Loss:** Net loss was $27.6 million for the quarter ended September 30, 2020, compared to $31.0 million for the quarter ended September 30, 2019.

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, including expectations regarding timing and success of the current ongoing clinical trials, therapeutic potential and clinical benefits thereof, 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 in 2020; 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 impact of the COVID-19 pandemic on the company's business, operations, strategy, goals and anticipated milestones; the therapeutic potential of FT-4202, and the timing associated with the initiation or continuation of any of FT-4202 trials; the initiation of our phase I clinical trial of FT-7051; Forma'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 foreign countries; 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 June 22, 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:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenue	$ -	$ 3,377	$ -	$ 93,113
Operating expenses				
Research and development	24,780	27,558	68,501	84,273
General and administrative	7,460	7,025	22,841	17,631
Restructuring charges	-	545	63	5,620
Total operating expenses	32,240	35,128	91,405	107,524
Loss from operations	(32,240)	(31,751)	(91,405)	(14,411)
Other income, net	818	766	23,050	3,057
Loss before taxes	(31,422)	(30,985)	(68,355)	(11,354)
Income tax benefit	(3,806)	-	(26,529)	(1,217)
Net loss	$ (27,616)	$ (30,985)	$ (41,826)	$ (10,137)
Preferred return and accretion of preferred return and cumulative dividends on preferred securities	-	(607)	(3,736)	(2,395)
Distribution to holders of preferred securities in excess of accrued preferred return	-	-	-	(11,347)
Tax distribution to holders of Enterprise.1 Incentive Shares	-	(60)	-	(60)
Net loss allocable to shares of common stock, basic	$ (27,616)		$ (45,562)	
Change in fair value attributable to warrants to purchase common stock	(8)		-	
Net loss allocable to shares of common stock, diluted	$ (27,624)		$ (45,562)	
Net loss allocable to shares of Common 1, basic		$ (31,652)		$ (23,939)
Change in fair value attributable to warrants to purchase preferred securities		(198)		(515)
Net loss allocable to shares of Common 1, diluted		$ (31,850)		$ (24,454)
Net loss per share of common stock:				
Basic	$ (0.67)		$ (2.74)	
Diluted	$ (0.67)		$ (2.74)	
Net loss per share of Common 1:				
Basic		$ (12.42)		$ (9.40)
Diluted		$ (12.50)		$ (9.60)
Weighted-average shares of common stock outstanding:				

Basic	41,088,261		16,616,143	
Diluted	41,088,924		16,616,143	
Weighted-average shares of Common 1 outstanding, basic and diluted		2,547,924		2,547,924

Selected Balance Sheet Items:

	September 30, 2020	December 31, 2019
Cash, cash equivalents, and marketable securities	$ 384,346	$ 173,180
Total Assets	$ 447,396	$ 183,035
Accounts payable, accrued expenses, and other current liabilities	$ 30,215	$ 23,629
Redeemable convertible and convertible preferred stock outside of stockholders' equity	-	$ 138,131
Total stockholders' equity	$ 415,602	$ 18,246

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