



Forma Therapeutics Reports Fourth Quarter and Year-End 2021 Financial Results and Provides Business Update

March 1, 2022

Clinical stage programs focused on rare hematologic diseases and cancers

Comprehensive etavopivat Phase I SCD trial completed with results supporting tolerability and benefits in hematologic biomarkers and red blood cell health; pivotal Phase II/III trial enrolling

Initial FT-7051 Phase I results in mCRPC showed tolerability/safety and signs of pharmacodynamic and clinical activity; escalating dose results expected mid-2022

Well-capitalized with nearly \$500 million in cash providing runway through the third quarter of 2024

WATERTOWN, Mass.--(BUSINESS WIRE)--Mar. 1, 2022-- [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 reported financial results for the year ended December 31, 2021. The company also highlighted recent progress and upcoming milestones for its pipeline programs.

"2021 was a year of continued growth for Forma as we completed our comprehensive Phase 1 etavopivat trial, and further advanced the importance of assessing red blood cell health," said Frank Lee, president and chief executive officer of Forma. "2022 represents a year of expansion for Forma, expanding the breadth of the etavopivat development plan into new indications, proof of concept readout for FT-7051 in metastatic prostate cancer and a new development candidate emerging from our research pipeline."

Key Business and Clinical Highlights

Pyruvate Kinase-R (PKR) Program in Sickle Cell Disease (SCD):

- **Comprehensive etavopivat Phase I trial completed.** Open label extension (OLE) results for 15 patients administered etavopivat 400 mg once daily for up to 12 weeks with a data cutoff as of November 23, 2021 were presented at the American Society of Hematology (ASH) annual meeting in December 2021. Improvements were observed in measures of hematologic and hemolytic response, and biomarkers of red blood cell (RBC) health, including oxygenation and deformability, as well as systemic biomarkers of SCD. Etavopivat administered for up to 12 weeks reduced anemia by significantly raising and sustaining hemoglobin levels and also significantly increased the lifespan of RBCs with decreased hemolysis. In addition, an analysis of all patients in the 12-week open label cohort showed a decreasing trend in vaso-occlusive crises (VOCs) requiring hospitalization when compared to the rate 12 months prior to trial entry. Etavopivat was well tolerated in the trial and safety was consistent with underlying SCD.

CBP/p300 Program in metastatic Castration- Resistant Prostate Cancer (mCRPC):

- **FT-7051 well tolerated with signs of clinical activity in initial Phase I clinical trial results.** Initial results from eight men in the trial were presented at the NCI/AACR/EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics in October 2021. Pharmacokinetic (PK) analysis of FT-7051 documented rapid absorption, with drug concentrations that approached the predicted efficacious dose based on estimates from preclinical models. In addition, skin biopsies demonstrated a reduction in a marker of activity in the CBP/p300 pathway. The majority of treatment-emergent adverse events (TEAEs) observed were mild or moderate with no events leading to treatment discontinuation. The first evaluable patient completing 12 weeks of treatment demonstrated a >80% decline in prostate-specific antigen (PSA80) from baseline at 16 weeks with stable disease.

IDH1 Program in Acute Myeloid Leukemia (AML)

- **First Phase II results of olutasidenib used in combination with a chemotherapy were presented at the ASH annual meeting in December 2021.** The trial included patients who had not yet received therapy and were candidates for azacitidine as a first-line treatment, and also patients with relapsed/refractory (R/R) AML that had prior therapy with a hypomethylating agent (HMA) or an IDH1 inhibitor. The results support the potential of olutasidenib as the basis of combination therapy in patients with AML who have not achieved a durable response from prior therapy. Olutasidenib was well tolerated in the trial in combination with azacitidine and the combination had a safety profile largely consistent with that of olutasidenib alone. Forma is progressing a new drug application (NDA) for the treatment of R/R AML.

Corporate

- **Appointed Ifeyinwa (Ify) Osunkwo, MD, MPH, as the company's inaugural chief patient officer and senior vice president.** Dr. Osunkwo will be responsible for realizing Forma's vision to transform the lives of patients, including improving access and care through partnerships with global patient and community stakeholders.
- **Launched formabridge and grants program.** Through formabridge grants, Forma has committed \$1 million in funding for promising and innovative initiatives that address unmet needs in transition from pediatric to adult care in SCD.
- **Upcoming investor conference participation.** Forma will participate in the Oppenheimer Healthcare Conference taking place March 15-16, 2022. The presentation webcast will be available in the "News & Investors" section of Forma's website at www.FormaTherapeutics.com.
- **Virtual Research and Development (R&D) review to be held in May, 2022.** The company will provide an overview of its internal research pipeline strategy and review compounds in clinical and pre-clinical development. The live webcast will be available in the "News & Investors" section of Forma's website www.FormaTherapeutics.com.

Upcoming Milestones

- **Patient enrollment in global pivotal Phase II/III trial of etavopivat for the treatment of SCD, the Hibiscus Study.** The first interim analysis (IA1) in the Hibiscus Study is expected to be reached by the end of 2022, with dose selection for the Phase III portion of the trial.
- **Etavopivat development plans expanding.** Forma began a Phase 2 trial in transfusion dependent SCD and both transfusion dependent and non-transfusion dependent thalassemia in late 2021, with initial results expected in late 2022. During 2022, Forma plans to begin clinical trials in pediatric SCD and low-risk myelodysplastic syndrome (MDS).
- **Additional FT-7051 clinical trial results in mCRPC.** Men with mCRPC continue to be enrolled in the dose escalation portion of the Phase I trial. Forma plans to present updated results from the trial in mid-2022.
- **Possibility of COVID-19 impact remains.** The COVID-19 pandemic remains a factor in the successful completion of these milestones and ongoing clinical trials. Many clinical trials across the biopharma industry, including Forma's, have been impacted by the COVID-19 pandemic. Clinical trial sites implementing new policies in response to COVID-19 have impacted enrollment of clinical trials or and the ability to access sites participating in clinical trials.

Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$490.3 million as of December 31, 2021, as compared to \$645.6 million as of December 31, 2020. Current cash runway is projected through the third quarter of 2024.
- **R&D Expenses:** R&D expenses were \$37.0 million and \$125.7 million for the quarter and year ended December 31, 2021, compared to \$24.9 million and \$93.4 million for the quarter and year ended December 31, 2020. The increase was primarily attributable to the conduct of etavopivat Phase II/III and Phase I trials in SCD patients, as well as start-up costs related to the thalassemia trial, manufacturing activities, and increases in research and development staff, equity-based compensation and investment in preclinical programs.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$13.2 million and \$48.3 million for the quarter and year ended December 31, 2021, compared to \$7.9 million and \$30.8 million for the quarter and year ended December 31, 2020. The increase was primarily attributable to increases in an equity-based compensation, personnel-related costs related to executive and staff hiring, professional fees, and insurance related expenses.
- **Net Loss:** Net loss was \$50.1 million and \$173.0 million for the quarter and year ended December 31, 2021, compared to net loss of \$28.6 million and \$70.4 million for the quarter and year ended December 31, 2020.

Forma will conduct a conference call and webcast March 1, 2022 at 8:00 a.m. Eastern Daylight Time (EDT) to discuss year end 2021 results and business updates. The call can be accessed by dialing (833) 301-1146 in the U.S., and (914) 987-7386 internationally, with conference ID 3322907.

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 etavopivat, FT-7051 and olutasidenib, including expectations regarding potential development expansion plans as well as the timing, success and data announcements of planned and ongoing clinical trials; therapeutic potential, clinical benefits, mechanisms of action and safety of our product candidates; planned regulatory submissions; upcoming milestones and planned additional trials for the company's product candidates; growth as a company; presentation of additional data at upcoming scientific conferences, and other preclinical data and potential data publications in 2022; uses and need of capital, expenses and other financial results currently or in the future; and the potential impact of COVID-19 on patient retention and enrollment, future operations or clinical trials. 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, supply chain patient enrollment and retention, strategy, goals and anticipated milestones, as well as global economies and financial markets; the therapeutic potential of our product candidates and the timing and completion of our clinical trials and related data analyses; 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 our product candidates may not be successfully developed and commercialized; regulatory developments in the United States and foreign countries; our ability to protect and maintain our intellectual property position; and our ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption “Risk Factors” in our most recent annual report on Form 10-K filed with the United States Securities and Exchange Commission (SEC) and subsequent filings with the SEC. 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.

Selected Financial Information

(in thousands except share and per share data)

(unaudited)

Statement of Operations Items:	For the Three Months Ended		For the Year Ended December	
	December 31,		31,	
	2021	2020	2021	2020
Collaboration revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	37,047	24,866	125,661	93,367
General and administrative	13,238	7,941	48,325	30,782
Restructuring charges	—	—	—	63
Total operating expenses	50,285	32,807	173,986	124,212
Loss from operations	(50,285)	(32,807)	(173,986)	(124,212)
Other income:				
Gain on Hit Discovery divestiture	—	—	—	23,312
Interest income	284	1,022	1,054	3,428
Other income (expense), net	(93)	7	122	(2,661)
Total other income, net	191	1,029	1,176	24,079
Loss before taxes	(50,094)	(31,778)	(172,810)	(100,133)
Income tax expense (benefit)	31	(3,190)	154	(29,719)

Net loss and comprehensive loss	\$ (50,125) \$ (28,588) \$ (172,964) \$ (70,414)
Accretion of cumulative dividends and issuance costs on Series D redeemable convertible preferred stock	—	—	—	(3,736)
Net loss allocable to shares of common stock, basic and diluted	\$ (50,125) \$ (28,588) \$ (172,964) \$ (74,150)
Net loss per share of common stock, basic and diluted	\$ (1.06) \$ (0.68) \$ (3.65) \$ (3.22)
Weighted-average shares of common stock outstanding, basic and diluted	47,387,969	42,239,451	47,347,343	23,056,975	

Selected Balance Sheet Items:

	December 31, 2021	December 31, 2020
Cash, cash equivalents, and marketable securities	\$ 490,273	\$ 645,588
Total assets	\$ 561,061	\$ 680,971
Accounts payable, accrued expenses, and other current liabilities	\$ 35,018	\$ 31,399
Total stockholders' equity	\$ 498,356	\$ 648,244

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Source: Forma Therapeutics Holdings, Inc.