



Metacrine Reports Business Updates and Third Quarter 2020 Financial Results

November 12, 2020

Upcoming Data at AASLD Support Robust, Sustained FXR Activation by MET409 in Patients with NASH

\$85 Million Initial Public Offering Completed

SAN DIEGO, Nov. 12, 2020 (GLOBE NEWSWIRE) -- Metacrine, Inc. (Nasdaq: MTCR), a clinical-stage biopharmaceutical company focused on discovering and developing differentiated therapies for patients with liver and gastrointestinal diseases, today reported recent business highlights and third quarter 2020 financial results.

"2020 has been a transformational year for Metacrine, as we advanced the development of our proprietary FXR platform, including our MET409 and MET642 clinical programs, and made the important transition into a publicly traded company," said Preston Klassen, M.D., MHS, president and chief executive officer of Metacrine. "As we look to the rest of the year, we plan to present new data from our MET409 Phase 1b proof-of-concept clinical trial in patients with NASH at AASLD, which further support the continued advancement of these potential best-in-class FXR programs. Additionally, we have selected the antidiabetic agent, an SGLT-2 inhibitor, to be evaluated with MET409 in our planned combination trial, which is on-track to initiate in the first half of next year. With additional capital and an established leadership team of talented industry veterans, we stand in a strong position to continue advancing both MET409 and MET642, while also exploring additional opportunities in our early-stage pipeline to expand our portfolio and support our future growth."

Program Highlights

- **New MET409 Data to be Presented at AASLD's The Liver Meeting Digital Experience:** [Two posters highlighting pharmacokinetic and pharmacodynamic data along with early prediction of longer term changes in liver fat content on the company's lead clinical candidate, MET409](#), a farnesoid X receptor (FXR) agonist for the treatment of non-alcoholic steatohepatitis (NASH), will be presented at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting Digital Experience™. The virtual meeting is taking place November 13-16, 2020
- **SGLT-2 Inhibitor Selected as Combination Agent for MET409 Phase 2a Combination Trial:** Metacrine has selected empagliflozina sodium-glucose cotransport-2 (SGLT-2) inhibitor, to be evaluated in combination with MET409 in the company's planned Phase 2a clinical trial for the treatment of patients with both NASH and type 2 diabetes. SGLT-2 inhibitors, in addition to affording glycemic control and cardiovascular/renal benefits, have demonstrated positive effects on liver fat reduction. A daily oral combination treatment with an FXR agonist and SGLT-2 inhibitor could be beneficial for patients with NASH and type 2 diabetes, who are believed to be at a greater risk of liver disease progression. The company anticipates beginning the combination trial in the first half of 2021.
- **Positive MET409 Phase 1b Clinical Data in NASH Patients Presented at the Digital International Liver Congress™ 2020:** In August, Metacrine presented positive, final results from its 12-week, randomized, placebo-controlled Phase 1b study of MET409 in patients with NASH in a late-breaking poster presentation as part of the Digital International Liver Congress. In the Phase 1b proof-of-concept trial, 58 patients with NASH were randomized 1:1:1 to receive oral, once-daily MET409 at 50 mg or 80 mg, or to placebo. Study findings show that MET409 meaningfully lowered and normalized liver fat content compared to placebo with a reassuring safety and tolerability profile. The full findings can be seen [here](#).
- **MET409 Received FDA Fast Track Designation for the Treatment of NASH:** In August, Metacrine announced that the FDA granted Fast Track designation to MET409 for the treatment of NASH. Fast Track is a process designed to facilitate the development and expedite the review of drugs designed to treat serious diseases or conditions and that have the potential to fill an unmet medical need for such diseases or conditions. This designation was granted to MET409 based on data from a completed Phase 1b study in NASH patients as well as preclinical studies.

Recent Business Highlights

- **Successful Initial Public Offering (IPO) Completed:** On September 15, 2020, Metacrine sold 6,540,000 shares of its common stock at a public offering price of \$13.00 per share. The gross proceeds to Metacrine from the offering, before deducting underwriting discounts and commissions and other offering expenses payable by Metacrine, were approximately \$85.0 million.

Anticipated Milestones

- Metacrine expects to announce topline results from its Phase 1 clinical study in healthy volunteers of MET642 before the end of 2020.

Upcoming Investor Conference Presentation

Preston Klassen, M.D., MHS, president and chief executive officer of Metacrine, will participate in a fireside chat during the Jefferies Virtual London Healthcare Conference on Thursday, Nov. 19, 2020 at 7:20 p.m. GMT/11:20 a.m. PT.

The live webcast will be available in the investor section of the company's website at www.metacrine.com. The webcast will be archived for 60 days following the presentation.

Third Quarter Financial Results

- **Cash Balance:** Cash, cash equivalents and short-term investments were \$109.2 million as of September 30, 2020, which includes \$85.0 million in gross proceeds from the company's IPO completed in September 2020.
- **R&D Expenses:** Research and development (R&D) expenses were \$6.2 million for the three months ended September 30, 2020, as compared to \$7.6 million for the same period in the prior year. The decrease in research and development expenses was primarily attributable to manufacturing, preclinical and toxicology work performed during 2019 to support the initiation of the Phase 1 clinical trial of MET642 in March 2020.
- **G&A Expenses:** General and administrative (G&A) expenses were \$2.7 million for the three months ended September 30, 2020, as compared to \$1.1 million for the same period in the prior year. The increase in general and administrative expenses was primarily attributable to increased headcount and non-cash stock-based compensation charges.
- **Net Loss:** Net loss was \$9.1 million for the three months ended September 30, 2020, as compared to \$8.5 million for the same period in the prior year.

About Metacrine

Metacrine, Inc. (Nasdaq: MTCR) is a clinical-stage biopharmaceutical company building a differentiated pipeline of therapies to treat liver and gastrointestinal (GI) diseases. The company's most advanced programs, MET409 and MET642, target the farnesoid X receptor (FXR), which is central to modulating liver and GI diseases. Both MET409 and MET642 are currently being investigated in clinical trials as potential new treatments for non-alcoholic steatohepatitis (NASH).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, statements regarding the therapeutic potential of MET409 and MET642; statements regarding Metacrine's timelines; the differentiated nature of Metacrine's FXR program; plans underlying Metacrine's clinical trials; plans for advancing the clinical development of Metacrine's FXR program; the potential best-in-class nature of Metacrine's FXR program; and the potential for its FXR product candidates to be long-term therapies for NASH; and the potential benefits of MET409's Fast Track designation. Words such as "may," "will," "expect," "plan," "aim," "anticipate," "estimate," "intend," "potential," "prepare" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Metacrine's expectations and assumptions that may never materialize or prove to be incorrect. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those projected in any forward-looking statements due to numerous risks and uncertainties, including but not limited to: risks and uncertainties regarding regulatory approvals for MET409 or MET642; potential delays in initiating, enrolling or completing any clinical trials; potential adverse side effects or other safety risks associated with Metacrine's product candidates; competition from third parties that are developing products for similar uses; and Metacrine's ability to obtain, maintain and protect its intellectual property. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in Metacrine's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 12, 2020, and in Metacrine's other filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except as required by law, Metacrine assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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Metacrine, Inc.

Unaudited Condensed Consolidated Statements of Operations

(In thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 6,217	\$ 7,647	\$ 19,973	\$ 19,497
General and administrative	2,693	1,069	6,087	3,057
Total operating expenses	8,910	8,716	26,060	22,554
Loss from operations	(8,910)	(8,716)	(26,060)	(22,554)
Total other income (expense)	(144)	251	(428)	1,018

Net loss	\$ (9,054)	\$ (8,465)	\$ (26,488)	\$ (21,536)
Net loss per share, basic and diluted	\$ (1.41)	\$ (3.51)	\$ (6.89)	\$ (9.17)
Weighted average shares of common stock outstanding, basic and diluted	6,436,546	2,409,227	3,845,793	2,349,635

Metacrine, Inc.

Unaudited Condensed Consolidated Balance Sheets

(In thousands)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash, cash equivalents, and short-term investments	\$ 109,239	\$ 55,651
Prepaid expenses and other current assets	1,663	1,692
Total current assets	110,902	57,343
Property and equipment, net	690	735
Operating lease right-of-use asset	1,740	2,203
Total assets	<u>\$ 113,332</u>	<u>\$ 60,281</u>
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 655	\$ 239
Accrued and other current liabilities	3,447	4,149
Total current liabilities	4,102	4,388
Long-term debt, net of debt discount	9,309	9,099
Other long-term liabilities	1,758	2,566
Convertible preferred stock	-	122,465
Stockholders' equity (deficit)	98,163	(78,237)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 113,332</u>	<u>\$ 60,281</u>

Metacrine, Inc.

Unaudited Condensed Consolidated Statements of Cash Flows

(In thousands)

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net loss	\$ (26,488)	\$ (21,536)
Non-cash adjustments	4,025	1,505
Changes in operating assets and liabilities	(1,658)	1,361
Net cash used in operating activities	<u>(24,121)</u>	<u>(18,670)</u>
Investing activities:		
Purchases of property and equipment	(172)	(56)
Proceeds from short-term investments	29,089	11,398
Net cash provided by investing activities	<u>28,917</u>	<u>11,342</u>
Financing activities:		
Proceeds from issuance of common stock from initial public offering, net of issuance costs	77,750	-
Proceeds from issuance of long-term debt, net of issuance cost	-	9,717
Proceeds from other financing activities	67	29
Net cash provided by financing activities	<u>77,817</u>	<u>9,746</u>
Net increase in cash and cash equivalents	82,613	2,418
Cash and cash equivalents at beginning of period	15,668	15,965
Cash and cash equivalents at end of period	<u>\$ 98,281</u>	<u>\$ 18,383</u>