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): November 2, 2021

Metacrine, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39512**	**47-2297384**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3985 Sorrento Valley Blvd., Suite C **San Diego, California** **(Address of Principal Executive Offices)**	**92121** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 369-7800

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	MTCR	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 8.01 Other Events.

On November 2, 2021, Metacrine, Inc. (the "Company") issued a press release announcing the results for the Company's MET409 Phase 2a Combination Trial in Patients with Type 2 Diabetes and non-alcoholic steatohepatitis. A copy of such release is attached hereto as Exhibit 99.1, and is hereby incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued on November 2, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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 thereunto duly authorized.

Metacrine, Inc.

Date: November 2, 2021

By: /s/ Catherine Lee
Catherine Lee
EVP, General Counsel and Corporate Secretary

Exhibit 99.1

METACRINE REPORTS TOPLINE RESULTS FOR MET409 PHASE 2A COMBINATION TRIAL IN PATIENTS WITH TYPE 2 DIABETES AND NASH

- Validates therapeutic benefit of combination approaches for a large segment of NASH patients

- Demonstrates additive efficacy results and favorable tolerability profile

SAN DIEGO – November 2, 2021 – Metacrine, Inc. (NASDAQ:MTCR), a clinical-stage biopharmaceutical company pioneering differentiated therapies for patients with gastrointestinal and liver diseases, today reported topline results from its Phase 2a trial evaluating MET409, a farnesoid X receptor (FXR) agonist, in combination with empagliflozin (Jardiance®), a sodium-glucose cotransport-2 (SGLT2) inhibitor, in patients with type 2 diabetes and non-alcoholic steatohepatitis (NASH).

The Phase 2a study (NCT04702490) is a 12-week, randomized, placebo-controlled, multi-center trial that evaluated the safety, tolerability and pharmacological activity, as measured by reductions in liver fat content with magnetic resonance imaging-derived proton density fat fraction (MRI-PDFF), of MET409 (50 mg) and empagliflozin (10 mg) versus individual treatments and placebo. A total of 132 patients were randomized (33 per treatment group).

All regimens had favorable safety profiles and were generally well-tolerated, with no treatment-related serious adverse events (AEs). Mild-moderate pruritus was reported in 0%-6% of patients across all groups. No pruritus-related treatment discontinuations occurred in any of the cohorts. LDL-cholesterol increases with MET409 were consistent with previous studies and were comparable alone or in combination with empagliflozin. Secondary assessment of liver fat content at 12 weeks indicated reduction in liver fat, as measured by MRI-PDFF, in both monotherapy arms and demonstrated additive effects in the combination regimen.

“NASH is closely linked to several co-morbidities, with an estimated 65% of type 2 diabetes patients also having NASH,” said Hubert C. Chen, M.D., chief medical officer, Metacrine. “These results showcase the multiple mechanisms that drive NASH and the promise of novel combination approaches in bringing new therapies to patients. We are pleased by the MET409 combination trial results, as this product candidate achieved improvements in liver fat both as a monotherapy and additively when combined with empagliflozin. Treating this large and important patient segment effectively will likely require combination therapies.”

MET409 Phase 2a Combination Trial Selected Data

Endpoint	Placebo	MET409 50 mg	Empagliflozin 10 mg	MET409 50 mg + Empagliflozin 10 mg
Mean relative liver fat change (±SD)	3% ± 24%	-16% ± 45%	-16% ± 22%	-28% ± 33%
% of patients with >30% relative liver fat reduction	3%	50%	23%	47%
Mean change in LDL-C	0%	12%	-2%	9%
Overall pruritus rate	0%	6%	0%	3%
Pruritus-related treatment discontinuation	0%	0%	0%	0%

MET409 Phase 2a Combination Trial Monotherapy Arm and MET642 Phase 2a Interim Results Comparison

Endpoint (12 weeks for MET409, 16 weeks for MET642)	MET409 50 mg	MET642 3 mg
Relative liver fat reduction (Placebo-corrected)	19%	19%
% of patients with >30% relative liver fat reduction	50%	47%
Mean change in LDL-C (Placebo-corrected)	12%	15%

Overall pruritus rate	6%	5%
Pruritus-related treatment discontinuation	0%	0%

Chen continued, “With the additional data from this study’s MET409 individual cohort, it has also become clear that MET409 and MET642 have comparable therapeutic profiles. Both compounds were developed from the same unique chemical scaffold, and these data along with the MET642 interim results we recently shared provide a comprehensive view of our FXR program and highlight the similarity of these two assets.”

As the Company previously stated, it has halted future development of its FXR program in NASH and is prioritizing its clinical development effort and resources to advance MET642 into a Phase 2 trial in inflammatory bowel disease (IBD).

About Metacrine

Metacrine, Inc. is a clinical-stage biopharmaceutical company building a pipeline of differentiated therapies to treat gastrointestinal and liver diseases. Metacrine has developed a proprietary farnesoid X receptor (FXR) platform utilizing a unique chemical scaffold. To learn more, visit www.metacrine.com.

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, the potential for MET409 to be used in combination therapies; the potential for MET409 to be used in therapies for patients with both NASH and type 2 diabetes, the uncertainties inherent in clinical testing; future plans or expectations for MET409 or MET642, as well as the dosing, safety and tolerability of MET409 or MET642, plans for initiating future clinical trials and studies; statements regarding the therapeutic potential of MET409 or MET642. Words such as “could,” “may,” “will,” “expect,” “plan,” “aim,” “projected,” “likely,” ”anticipate,” “estimate,” “intend,” “potential,” “prepare,” “perceived,” “believes” 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: positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies, 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 August 12, 2021, 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.

Investor & Media Contact

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