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): August 12, 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 2.02 Results of Operations and Financial Condition.

On August 12, 2021, Metacrine, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained under this Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) The following exhibit is furnished with this Current Report.

Exhibit Number	Description
99.1	Press release dated August 12, 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: August 12, 2021

By: /s/ Patricia Millican
Patricia Millican
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 99.1

METACRINE UPDATES MET642 CLINICAL DEVELOPMENT MILESTONE AND REPORTS SECOND-QUARTER 2021 RESULTS

Interim data from the Phase 2a trial of MET642 in patients with NASH now expected early in the fourth quarter of 2021

Topline results from a Phase 2a trial of MET409 in combination with empagliflozin in patients with NASH and type 2 diabetes on track to be reported in the fourth quarter of 2021

SAN DIEGO – August 12, 2021 -- Metacrine, Inc. (NASDAQ:MTCR), a clinical-stage biopharmaceutical company pioneering differentiated therapies for patients with liver and gastrointestinal diseases, today updated a key clinical development milestone and reported its second-quarter 2021 financial results.

“We are just a few months away from important clinical data readouts for both our MET409 and MET642 programs,” said Preston Klassen, M.D., MHS, CEO, Metacrine. “We now expect to report data from an interim analysis of the MET642 trial in non-alcoholic steatohepatitis (NASH) patients early in the fourth quarter of 2021. We also affirmed that we are on track for our MET409 combination trial readout before the end of the year. Our team has done a fantastic job achieving enrollment targets for both studies, as we get ready to select the best candidate to move forward into late-stage development in both NASH and our planned expansion into inflammatory bowel disease (IBD) in 2022.”

Klassen continued, “Our potentially best-in-class FXR agonist platform supports our vision of bringing new therapies to patients that have no treatment options today. The wider therapeutic index of our NASH program is achieved through balanced FXR activation in both the liver and intestine to deliver an optimal risk/benefit profile. With capital that takes us through our critical milestones in 2022, we remain focused on executing against our key objectives in the months ahead.”

Key Clinical Development Milestones & Outlook

- **MET642 Phase 2a monotherapy trial interim analysis now expected early in the fourth quarter of 2021** - The Company plans to report topline data of an interim analysis from its Phase 2a, 16-week, randomized, placebo-controlled, multi-center trial evaluating MET642 in patients with NASH early in the fourth quarter of 2021 (previously fourth quarter of 2021) after 60 patients have completed 16 weeks of treatment. Topline trial results of up to 180 patients are still anticipated in the first half of 2022. The MET642 Phase 2a clinical trial is evaluating 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), changes in liver enzymes, LDL-C levels and overall pruritis rate, at 3 mg and 6 mg dose levels. The trial completed enrollment of the first 60 patients in May 2021.

- **MET409 Phase 2a combination trial results expected in the fourth quarter of 2021** - Metacrine expects to report topline data from its Phase 2a trial evaluating MET409 (50 mg) in combination with empagliflozin (Jardiance®), a sodium-glucose cotransport-2 (SGLT-2) inhibitor in patients with both type 2 diabetes (T2D) and NASH, in the fourth quarter of 2021. 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 benefit patients with NASH and T2D, who are believed to be at greater risk for liver disease progression. The MET409 Phase 2a clinical trial is a 12-week, randomized, placebo-controlled, multi-center trial evaluating the safety, tolerability and pharmacological activity, as measured by MRI-PDFF. The trial completed enrollment with over 120 patients in June 2021.

Other Business Highlights

- On July 9, 2021, Metacrine presented new preclinical data in IBD at the European Crohn’s and Colitis Organisation (ECCO) 2021 Virtual Congress. The new data provide compelling evidence that FXR activation can improve commonly dysregulated pathways in IBD. The Company plans to host a virtual R&D Day for analysts and investors on Wednesday, September 15, 2021 at 12:00 p.m. ET. The event will showcase Metacrine’s programs in NASH and IBD, featuring management presentations and discussions by prominent key opinion leaders (KOL). The agenda will also include the introduction of the Company’s new discovery program and a KOL presentation highlighting the value of combination therapies in patients with both T2D and NASH.

Second-Quarter 2021 Financial Results

- **Cash Balance -** Cash, cash equivalents and short-term investments were $74.8 million as of June 30, 2021. Metacrine believes it has sufficient capital to fund its current operating plan through 2022.

- **R&D Expenses -** Research and development expenses were $11.4 million for the three months ended June 30, 2021, as compared to $7.4 million for the prior-year period. The increase was primarily driven by higher clinical development costs related to the advancement of the Company’s MET409 and MET642 programs.

- **G&A Expenses -** General and administrative expenses were $4.0 million for the three months ended June 30, 2021, as compared to $1.8 million for the same period in the prior year. The increase was attributable to higher employee-related costs and expenses associated with operating as a publicly traded company.

- **Net Loss -** Net loss was $15.6 million for the three months ended June 30, 2021, as compared to $9.3 million for prior-year quarter.

About Metacrine

Metacrine, Inc. is a clinical-stage biopharmaceutical company building a pipeline of differentiated therapies to treat liver and gastrointestinal diseases. Metacrine has developed a proprietary farnesoid X receptor (FXR) platform utilizing a unique chemical scaffold, which has demonstrated an improved therapeutic profile in clinical trials. The Company's two product candidates, MET409 and MET642, are currently being investigated in clinical trials as potential new treatments for NASH. MET409 has completed a 12-week monotherapy trial in patients with NASH and is being evaluated in a 12-week combination trial with empagliflozin in patients with both NASH and type 2 diabetes. MET642 has completed a 14-day Phase 1 trial in healthy volunteers and is being evaluated in a 16-week monotherapy trial in patients with NASH. 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, statements about the design, progress, timing, scope and results of clinical trials; the anticipated timing of disclosure of results of clinical trials; plans for initiating future clinical trials and studies; statements regarding the therapeutic potential of MET409 and MET642; the differentiated nature of Metacrine's FXR program; plans for advancing the clinical development of Metacrine's FXR program; the potential best-in-class nature of Metacrine's FXR program; the potential for its FXR product candidates to be long-term therapies for NASH and IBD; and Metacrine's belief that it has sufficient capital to fund its current operating plan through 2022. Words such as "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: 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

Steve Kunszabo
Metacrine, Inc.
+1 (858) 369-7892
skunszabo@metacrine.com

Metacrine, Inc.

Unaudited Condensed Consolidated Statements of Operations
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 11,368	$ 7,395	$ 22,225	$ 13,756
General and administrative	3,992	1,793	7,688	3,394
Total operating expenses	15,360	9,188	29,913	17,150
Loss from operations	(15,360)	(9,188)	(29,913)	(17,150)
Total other income (expense)	(225)	(134)	(440)	(284)
Net loss	$ (15,585)	$ (9,322)	$ (30,353)	$ (17,434)

Metacrine, Inc.

Unaudited Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents, and short-term investments	$ 74,813	$ 96,176
Prepaid expenses and other current assets	4,841	5,847
Total current assets	79,654	102,023
Property and equipment, net	488	634
Operating lease right-of-use asset	1,248	1,579
Total assets	$ 81,390	$ 104,236
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 261	$ 334
Accrued and other current liabilities	7,231	3,692
Total current liabilities	7,492	4,026
Long-term debt, net of debt discount	9,498	9,372
Other long-term liabilities	1,141	1,559
Stockholders' equity	63,259	89,279
Total liabilities and stockholders' equity	$ 81,390	$ 104,236