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 11, 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 November 11, 2021, Metacrine, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 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 November 11, 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 12, 2021

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

Exhibit 99.1

METACRINE REPORTS THIRD-QUARTER 2021 RESULTS

SAN DIEGO – November 11, 2021 -- Metacrine, Inc. (NASDAQ:MTCR), a clinical-stage biopharmaceutical company pioneering differentiated therapies for patients with gastrointestinal and liver diseases, today reported its third-quarter 2021 financial results.

“Our recent monotherapy and combination trial results demonstrate the strong therapeutic profile of our FXR program in non-alcoholic steatohepatitis (NASH), while also highlighting the potential of these agents as an important part of combination therapy,” said Preston Klassen, M.D., MHS, CEO, Metacrine. “Primarily because of the significant capital required to continue advancing our product candidates, we’ve halted future clinical development of our FXR program in NASH and will focus our financial resources and clinical development effort on moving MET642 into a Phase 2 trial in ulcerative colitis in the first half of 2022. In addition, we continue to advance our HSD discovery program as an exciting target in NASH and other liver diseases.”

Recent Clinical Development Milestones & Outlook

- **A strategic re-prioritization of the Company’s clinical development programs –** After a rigorous assessment of its NASH and inflammatory bowel disease programs, including the significant capital required to progress these large clinical development programs, the Company recently announced it is prioritizing its financial resources and clinical development effort to advance MET642 into a Phase 2 trial in ulcerative colitis in the first half of 2022. Metacrine has halted future development of its FXR program in NASH.

- **MET642 Phase 2a monotherapy trial interim results –** Metacrine reported interim results from its Phase 2a clinical trial evaluating the efficacy and safety of MET642 in approximately 60 NASH patients after 16 weeks of treatment. MET642 lowered liver fat content, with mean relative reductions of 26.9±27.8 percent in the 3 mg cohort and 9.3±55.8 percent in the 6 mg cohort, compared with 7.5±21.0 percent in the placebo arm. MET642 was generally well-tolerated, with no treatment-related serious adverse events (AEs). Mild-moderate pruritus was reported in one patient in the 3 mg cohort and one patient in the 6 mg cohort. No pruritus-related treatment discontinuations occurred. The Company expects to report completed topline study results in the first half of 2022.

- **MET409 Phase 2a combination trial results** – Metacrine reported topline results from its Phase 2a trial evaluating MET409 in combination with empagliflozin (Jardiance®), a sodium-glucose cotransport-2 (SGLT2) inhibitor, in patients with type 2 diabetes and NASH. All regimens had favorable safety profiles and were generally well-tolerated, with no treatment-related serious 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. 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.

Third-Quarter 2021 Financial Results

- **Cash Balance -** Cash, cash equivalents and short-term investments were $61.7 million as of September 30, 2021.

- **R&D Expenses -** Research and development expenses were $14.1 million for the three months ended September 30, 2021, as compared to $6.2 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 September 30, 2021, as compared to $2.7 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 $18.3 million for the three months ended September 30, 2021, as compared to $9.1 million for prior-year quarter.

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, 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; and plans for advancing the clinical development of Metacrine’s FXR program. 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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 14,072	$ 6,217	$ 36,297	$ 19,973
General and administrative	4,007	2,693	11,695	6,087
Total operating expenses	18,079	8,910	47,992	26,060
Loss from operations	(18,079)	(8,910)	(47,992)	(26,060)
Total other income (expense)	(249)	(144)	(689)	(428)
Net loss	$ (18,328)	$ (9,054)	$ (48,681)	$ (26,488)

Metacrine, Inc.

Unaudited Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash, cash equivalents, and short-term investments	$ 61,728	$ 96,176
Prepaid expenses and other current assets	3,852	5,847
Total current assets	65,580	102,023
Property and equipment, net	415	634
Operating lease right-of-use asset	1,077	1,579
Other non-current assets	438	-
Total assets	$ 67,510	$ 104,236
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 323	$ 334
Accrued and other current liabilities	9,574	3,692
Current portion of long-term debt	459	-
Total current liabilities	10,356	4,026
Long-term debt, net of debt discount	9,106	9,372
Other long-term liabilities	926	1,559
Stockholders' equity	47,122	89,279
Total liabilities and stockholders' equity	$ 67,510	$ 104,236