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 7, 2024

CINGULATE INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40874**	**86-3825535**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

1901 W. 47th Place
Kansas City, KS 66205
(Address of principal executive offices) (Zip Code)

(913) 942-2300
(Registrant's telephone number, including area code)

(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 (see General Instruction A.2. below):

☐ 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 exchange on which registered
Common Stock, par value $0.0001 per share	CING	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Warrants, exercisable for one share of common stock	CINGW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 Novermber 7, 2024, Cingulate Inc. issued a press release announcing its financial results for the quarter ended September 30, 2024 and provided a clinical and business update. A copy of the press release is furnished as Exhibit 99.1 and incorporated by reference. The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 7, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

CINGULATE INC.

Dated: November 7, 2024

By: */s/ Jennifer L. Callahan*
Name: Jennifer L. Callahan
Title: Chief Financial Officer

Exhibit 99.1

Cingulate Reports Third Quarter 2024 Financial Results Reflecting
$19.5 Million Increase in Working Capital to Advance ADHD Drug to Market

On Target for Mid-2025 New Drug Application (NDA) Submission of lead ADHD asset CTx-1301

KANSAS CITY, Kan., Nov. 7, 2024 -- Cingulate Inc. (NASDAQ: CING), a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, today announced its financial results for the three months ended September 30, 2024, and provided a clinical and business update.

"The capital raised this quarter has allowed us to focus on advancing the remaining activities required for NDA submission of our lead ADHD asset, CTx-1301, targeted for mid 2025," said Cingulate Chairman and CEO Shane J. Schaffer. "The granting of European patents for CTx-1301 in up to 30 territories, including the United Kingdom, helps Cingulate expand its reach beyond the United States and makes a positive impact on the growing ADHD markets abroad. Overall, Cingulate finds itself in a stronger position financially and looks forward to filing its first NDA next year."

Cingulate Initiates Final Study for Lead ADHD Asset CTx-1301

In September, Cingulate commenced its final FDA-required study, which is a food effect study, for CTx-1301. A data readout from the study is expected by the end of 2024.

European Patent Granted for Lead Asset CTx-1301 for the Treatment of ADHD

Cingulate was issued a European patent for its lead asset CTx-1301 for the treatment of ADHD during the third quarter of 2024. This patent will include up to 30 European territories, including the United Kingdom. In addition to the European patent, Cingulate has patents in Australia, Canada and Israel, as well as pending patents in Hong Kong, the Republic of Korea, and the United States.

Nasdaq Listing Update

On September 9, 2024, the Nasdaq Hearings Panel notified Cingulate that it had regained compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2).

Over $12 Million of Capital Raised in the Third Quarter

Cingulate raised approximately $12.5 million of capital in the third quarter of 2024. The capital raised provides the Company the cash runway to fund the clinical, manufacturing, and regulatory activities, as well as operating activities, into the third quarter of 2025, based on planned expenditures. Cingulate is targeting mid-2025 for the NDA submission of CTx-1301 (dexmethylphenidate) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Third Quarter Results

Cash Position: As of September 30, 2024, Cingulate had approximately $10 million in cash and cash equivalents, a significant increase from December 31, 2023, providing the Company with an extended cash runway into the third quarter of 2025, as noted above.

Working Capital: As of September 30, 2024, Cingulate had approximately $9.8 million in working capital, an increase of $19.5 million from December 31, 2023. This increase in working capital is reflective of a significant strengthening of the Company's balance sheet resulting from capital raised in 2024.

Liabilities: As of September 30, 2024, total liabilities were $1.5 million, a decrease from December 31, 2023 of $8.8 million, including the conversion of the related party note payable in the amount of $3.3 million which occurred in the first quarter of 2024.

Stockholders' Equity: As of September 30, 2024, total stockholders' equity was $12.0 million, an increase of $18.9 million from the end of 2023.

R&D Expenses: R&D expenses were $1.4 million for the three months ended September 30, 2024, a decrease of $2.5 million from the three months ended September 30, 2023. This change was primarily the result of decreased clinical activity in the three months ended September 30, 2024 as compared to the same period in 2023. During the third quarter of 2023, we incurred significant costs relating to two Phase 3 studies for CTx-1301, the fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose optimization and duration study. Enrollment in these two studies was completed in early 2024 and we are progressing with the remaining close-out and analytical activities required for an NDA submission. Manufacturing costs also decreased as the activity in 2023 was more significant for the manufacture of clinical supply for the Phase 3 studies. In 2024, manufacturing activity included the completion of registration batches of CTx-1301.

G&A Expenses: Total G&A expenses were $1.9 million for the three months ended September 30, 2024, which was relatively consistent to the three months ended September 30, 2023.

Net Loss: Net loss was $3.2 million for the three months ended September 30, 2024, compared to $6.0 million for the same period in 2023. The decrease in the net loss primarily related to a decrease in R&D and G&A expenses described above.

Cingulate Inc.
Consolidated Balance Sheet Data

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 10,040,149	$ 52,416
Total assets	$ 13,580,104	$ 3,491,436
Working Capital	$ 9,801,070	$ (9,647,172)
Total liabilities	$ 1,542,541	$ 10,360,865
Accumulated deficit	$ (102,357,201)	$ (92,943,443)
Total stockholders' equity	$ 12,037,563	$ (6,869,429)

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended September 30,		Six Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 1,428,504	$ 3,923,852	$ 5,116,582	$ 10,508,395
General and administrative	1,853,583	1,825,822	4,319,902	5,453,643
Operating loss	**(3,282,087)**	**(5,749,674)**	**(9,436,484)**	**(15,962,038)**
Interest and other income (expense), net	50,483	(229,380)	22,726	(638,212)
Loss before income taxes	(3,231,604)	(5,979,054)	(9,413,758)	(16,600,250)
Income tax benefit (expense)	-	-	-	-
Net loss	**(3,231,604)**	**(5,979,054)**	**(9,413,758)**	**(16,600,250)**

About Cingulate®

Cingulate Inc. is a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD), Cingulate is identifying and evaluating additional therapeutic areas where its PTR technology may be employed to develop future product candidates, such as anxiety disorders.

Cingulate is headquartered in Kansas City, KS. For more information visit **Cingulate.com**.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include all statements, other than statements of historical fact, regarding our current views and assumptions with respect to future events regarding our business, including statements with respect to our plans, assumptions, expectations, beliefs and objectives with respect to product development, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature. These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. Readers are cautioned that any forward-looking information provided by us or on our behalf is not a guarantee of future performance. Actual results may differ materially from those contained in these forward-looking statements as a result of various factors disclosed in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our Annual Report on Form 10-K filed with the SEC on April 1, 2024 and our other filings with the SEC. All forward-looking statements speak only as of the date on which they are made, and we undertake no duty to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

Investor & Public Relations:

Thomas Dalton
Vice President, Investor & Public Relations, Cingulate
tdalton@cingulate.com
(913) 942-2301

Matt Kreps
Darrow Associates
mkreps@darrowir.com
(214) 597-8200