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 13, 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 August 13, 2024, Cingulate Inc. issued a press release announcing its financial results for the quarter ended June 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 August 13, 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: August 13, 2024

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

Exhibit 99.1

Cingulate Reports Second Quarter 2024 Financial Results and Provides Development Update on Major Milestones Achieved

FDA Clears Cingulate to File for Marketing Approval of CTx-1301 targeted in 1H 2025
Licensing Activity Continues

KANSAS CITY, Kan., August 13, 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 June 30, 2024, and provided a clinical and business update.

"Cingulate has achieved major development milestones in the second quarter of 2024 relating to our first product candidate, CTx-1301 for the treatment of ADHD. The combination of the Food and Drug Administration (FDA) clearance for filing for marketing approval and completion of the registration batches keeps us on the path to a targeted NDA submission in the first half of 2025. We are further encouraged by a recent M&A transaction announced in the ADHD space as we continue to explore licensing opportunities for CTx-1301 in and outside the United States," said Shane Schaffer, Chief Executive Officer of Cingulate.

FDA Clearance to File for Marketing Approval of CTx-1301 and Development Update

Cingulate achieved significant milestones relating to the development of CTx-1301 during the second quarter, including confirmation from the FDA of the remaining clinical requirements for the filing a New Drug Application (NDA). Cingulate is progressing with these clinical activities which include the completion of a Food Effect Study of the 50mg dose of the product and the data analysis of the Phase 3 adult dose optimization study and the Phase 3 fixed dose pediatric and adolescent safety and efficacy study. Cingulate expects to be positioned to schedule a pre-NDA meeting and move forward with the submission of the NDA which is targeted for the first half of 2025.

In addition, Cingulate completed the manufacturing of its twelve registration batches for CTx-1301. Registration batches are required by the FDA to be manufactured before submitting an NDA using the actual equipment, dosage strengths and procedures that will be used to commercialize the drug product candidate.

Business Development and Payer Study

Cingulate continues to explore additional licensing arrangements for CTx-1301 both inside and outside the US. As part of this process, Cingulate commissioned a payer study based on its product candidate and lead asset CTx-1301 (dexmethylphenidate) for the treatment of ADHD. CTx-1301 currently is in development, so the payers were interviewed in a blinded manner and asked about a Cingulate's product candidate that may or may not correspond to its final FDA-approved product label.

Ten payers, representing over 121 million covered lives, were interviewed. The study reviewed current coverage and reimbursement status and policies for ADHD treatments, assessed unmet needs and expectations for management of the category in the future, and tested the product profile to explore payers' perceptions and expectations, including perceived value, differentiation, and expected pricing, reimbursement and contracting potential. Key findings showed CTx-1301 to be a most valuable ADHD prospective treatment and is likely to gain coverage through the contracting process.

$1.6 Million of Capital Raised through a Warrant Inducement

In late June 2024, Cingulate entered into an inducement offer letter agreement pursuant to which holders of certain of its existing warrants from the February 2024 public offering, agreed to exercise their warrants at a reduced exercise price of $7.02 per share. In consideration for the exercise of these warrants, the holders received new Series C and Series D common stock purchase warrants. Cingulate received net proceeds of $1.6 million on the closing of this warrant inducement which occurred on July 1, 2024.

Nasdaq Listing Update

On August 2, 2024, the Nasdaq Hearings Panel (the Panel) notified Cingulate that it had granted its request for an exception to demonstrate compliance with the $1.00 Minimum Bid Price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the Bid Price Requirement) for continued listing through August 23, 2024 (the Exception). The Panel granted Cingulate's request for the Exception, subject to (i) Cingulate effecting a reverse stock split on or before August 9, 2024, at a ratio of between 1-for-3 and 1-for-15; and (ii) on or before August 23, 2024, Cingulate demonstrating compliance with the Bid Price Requirement by evidencing a closing bid price of $1.00 or more per share for a minimum of ten (10) consecutive trading sessions, and evidencing compliance with all applicable criteria for continued listing on Nasdaq. On August 9, 2024, Cingulate completed a one-for-twelve reverse stock split in an effort to evidence compliance with the Bid Price Requirement.

Second Quarter Results

Cash Position: As of June 30, 2024, Cingulate had $0.4 million in cash and cash equivalents. On July 1, 2024, Cingulate received the net proceeds of $1.6 million from the warrant inducement described above. Management believes this cash on hand will support operating and development costs late into the third quarter of 2024. Management intends to seek opportunities to access additional capital as needed, including non-dilutive capital in terms of potential licensing opportunities inside and outside of the US, and additional equity or debt capital.

Liabilities: As of June 30, 2024, total liabilities were $1.9 million, a decrease from December 31, 2023 of $8.3 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 June 30, 2024, total stockholders' equity was $3.1 million, an increase of $10.0 million from the end of 2023.

R&D Expenses: R&D expenses were $1.9 million for the three months ended June 30, 2024, a decrease of $2.6 million from the three months ended June 30, 2023. This change was primarily the result of decreased clinical activity in the three months ended June 30, 2024, as compared to the same period in 2023. During the second quarter of 2023, the Company 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 late 2023 and Cingulate is 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 as it related to the manufacture of clinical supply for the Phase 3 studies. In 2024, manufacturing activity included the completion of the manufacturing of registration batches of CTx-1301. In addition, there was a decrease in personnel costs is the result of lower headcount and the cost containment measures, which we implemented in late 2023 in order to conserve cash, which included salary reductions ranging from 5-55% for all employees.

G&A Expenses: Total G&A expenses were $1.3 million for the three months ended June 30, 2024, a decrease of $0.6 million from the three months ended June 30, 2023. This was primarily the result of a decrease in personnel expenses and insurance. The decrease in personnel expenses was the result of cost containment measures as described above.

Net Loss: Net loss was $3.2 million for the three months ended June 30, 2024, compared to $6.6 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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and short-term investments	$ 380,928	$ 52,416
Total assets	$ 5,126,907	$ 3,491,436
Total liabilities	$ 2,043,135	$ 10,360,865
Accumulated deficit	$ (99,125,597)	$ (92,943,443)
Total stockholders' equity	$ 3,083,772	$ (6,869,429)

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 1,881,093	$ 4,455,927	$ 3,688,078	$ 6,584,543
General and administrative	1,325,087	1,906,442	2,466,319	3,627,821
Operating loss	**(3,206,180)**	**(6,362,369)**	**(6,154,397)**	**(10,212,364)**
Interest and other income (expense), net	(3,497)	(253,940)	(27,757)	(408,832)
Loss before income taxes	(3,209,677)	(6,616,309)	(6,182,154)	(10,621,196)
Income tax benefit (expense)	-	-	-	-
Net loss	(3,209,677)	(6,616,309)	(6,182,154)	(10,621,196)
Net loss per share of common stock, basic and diluted	$ (5.47)	$ (6.79)	$ (12.28)	$ (11.08)

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