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):
March 26, 2025

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 March 26, 2025, Cingulate Inc. issued a press release announcing its financial results for the year ended December 31, 2024 and providing 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 March 26, 2025
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: March 26, 2025

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

Exhibit 99.1

Cingulate Inc. Reports Full Year 2024, Fourth Quarter Results, and Provides Development Update on Major Milestones Achieved

In-Person FDA Meeting Scheduled for April 2; New Drug Application Submission Targeted for Mid-2025

$17.5 million increase in Working Capital; Cash Runway Extending into Q4, Well Beyond Target Date for NDA Submission

KANSAS CITY, Kan., March 26, 2025 — 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 twelve months ended December 31, 2024, and provided a clinical and business update. Highlights include the announcement of safety results from Cingulate's final Phase 3 trials for lead ADHD asset CTx-1301 (dexmethylphenidate), and confirmation of a scheduled in-person Pre-NDA meeting with the FDA.

"The capital raised over the past year has allowed us to strengthen our balance sheet and complete all required clinical trials for NDA submission for CTx-1301. We look forward to meeting with the FDA next week, submitting our new drug application this summer, and, assuming approval by the FDA, bringing to market the first, true, once-daily stimulant medication to treat ADHD over the entire active day," said Cingulate Chairman and CEO Shane J Schaffer.

LEAD ASSET CTx-1301 HIGHLIGHTS

- Cingulate is on-target for the NDA submission in mid-2025, following an in-person, pre-NDA meeting scheduled for April 2, 2025.

- March 2025 - Cingulate released safety data from two Phase 3 pediatric and adolescent studies – a fixed dose study and a dose optimization study as well as its high-dose food effect study, noting no serious treatment emergent adverse events and confirming that the safety profile of CTx-1301 has remained remarkably consistent and unprecedented over the course of nine clinical trials. A final analysis that combines both adult and pediatric safety data will be prepared and included in the NDA submission.

- January 2025 - Cingulate completed its final FDA-required study, a food effect study utilizing a single 50-mg dose of CTx-1301, the highest dosage being studied. The medical findings are consistent with the previous study performed with the 25mg dose which showed that CTx-1301 could be taken with or without food.

- August 2024 - European patent for CTx-1301 issued. The patent application was granted on August 14, 2024, as EP Patent No. 3261625, and includes up to 30 European territories, including the United Kingdom. Cingulate holds additional patents in Australia, Canada and Israel. Patents are pending in Hong Kong, the Republic of Korea, and the United States.

- July 2024 - Cingulate commissioned a managed care payor study in 2024 evaluating CTx-1301. The participants in the study represented over 121 million covered lives in the United States. The study reviewed current coverage and reimbursement status for ADHD treatments, assessed unmet medical needs and expectations for management of the category in the future, and tested the product profile to explore payer's perceptions and expectations, including perceived value, differentiation, and expected pricing, reimbursement and contracting potential. Key findings showed CTx-1301 to be the most valuable ADHD prospective treatment and is likely to gain coverage through the contracting process.

- Cingulate continues to explore licensing agreements both inside and outside the United States.

BUSINESS UPDATE

- Cingulate has increased its working capital by $17.5 million as compared to December 31, 2023, extending its cash runway into 4Q 2025, which is beyond the targeted NDA submission.

    - In 2024, Cingulate sold shares of common stock under its At-the-Market Offering Agreement with H.C. Wainwright & Co., LLC for net proceeds of $9.4 million and under its Purchase Agreement with Lincoln Park Capital for gross proceeds of $8 million.

- In December 2024, Cingulate executed a $5.5 million non-convertible, unsecured promissory note with an accredited investor which provided net proceeds of $5 million.

- On July 1, 2024, Cingulate closed a warrant inducement transaction for net proceeds of $1.6 million 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. In consideration for the exercise of these warrants, the holders received new Series C and Series D common stock purchase warrants.

- In February 2024, Cingulate closed a $7.5 million public offering of its common stock (or pre-funded warrants in lieu thereof) and Series A and Series B warrants to purchase shares of common stock.

- In January 2024, Werth Family Investment Associates, LLC (WFIA), the manager of which is Peter J. Werth, a member of the Cingulate board of directors, converted at a 10 percent premium to market the remaining $3.3 million of outstanding debt plus accrued interest into pre-funded warrants to purchase shares of common stock, demonstrating his continued support of the Company.

FULL YEAR AND FOURTH QUARTER RESULTS

- **Cash Position:** As of December 31, 2024, Cingulate had approximately $12.2 million in cash and cash equivalents, a $12.1 million increase from December 31, 2023, providing the Company with an extended cash runway into the fourth quarter of 2025, beyond its targeted submission of the NDA for CTx-1301.

- **Working Capital** (current assets less current liabilities): As of December 31, 2024, Cingulate had approximately $7.5 million in working capital, an increase of $17.2 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. Cingulate believes working capital is meaningful to investors as a measure of short-term financial health.

- **R&D Expenses:** Research and development expenses were $9.4 million for the year ended December 31, 2024, compared to $15.5 million for the year ended December 31, 2023. Research and development expenses were $4.3 million for the three months ended December 31, 2024, compared to $5.0 million for the same period in 2023. This change was primarily the result of completed clinical activity in 2024 as compared to 2023. During 2023, two Phase 3 trials were initiated for CTx-1301, the fixed-dose pediatric and adolescent safety and efficacy study in addition to the pediatric dose optimization and duration study. Enrollment in these two trials was closed in early 2024 and the final data analysis will be included in the NDA submission for CTx-1301 which is targeted for mid-2025. Personnel costs also decreased in 2024 as the result of lower headcount and cost containment measures, which were implemented in late 2023 in order to conserve cash, including salary reductions ranging from 5-55% for all employees. 2023 base salaries were reinstated in September 2024.

- **G&A Expenses:** General and administrative expenses were $6.2 million for the year ended December 31, 2024, compared to $7.3 million for the year ended December 31, 2023. General and administrative expenses remained consistent in the three months ended December 31, 2024, as compared to the three months ended December 31, 2023. The year over year decrease was primarily the result of a decrease in the personnel expenses, a decrease in the renewal premium for directors' and officers' insurance, offset with an increase in professional fees, including legal and investor relations related to our financing and shareholder communications.

- **Net Loss**: Net loss was $15.5 million for the year ended December 31, 2024, compared to $23.5 million for the year ended December 31, 2023. Net loss was $6.1 million for the three months ended December 31, 2024, compared to $6.9 million for the same period in 2023. The decrease in the net loss relates to the completion in development activity over these periods as well as a decrease in personnel costs.

Cingulate Inc.
Consolidated Balance Sheet Data

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 12,211,321	$ 52,416
Total assets	$ 14,864,489	$ 3,491,436
Working Capital	$ 7,539,938	$ (9,647,172)
Total liabilities	$ 7,408,984	$ 10,360,865
Accumulated deficit	$ (108,489,180)	$ (92,943,443)
Total stockholders' equity	$ 7,455,504	$ (6,869,429)

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Operating expenses:	.			
Research and development	$ 4,328,683	$ 4,984,909	$ 9,445,265	$ 15,493,304
General and administrative	1,879,806	1,812,242	6,199,708	7,265,885
Operating loss	**(6,208,489)**	**(6,797,151)**	**(15,644,973)**	**(22,759,189)**
Interest and other income (expense), net	76,510	(137,546)	99,236	(775,758)
Loss before income taxes	(6,131,979)	(6,934,697)	(15,545,737)	(23,534,947)
Income tax benefit (expense)	-	-	-	-
Net loss	**$ (6,131,979)**	**$ (6,934,697)**	**$ (15,545,737)**	**$ (23,534,947)**

About Attention Deficit/Hyperactivity Disorder (ADHD)

ADHD is a chronic neurobiological and developmental disorder that affects millions of children and often continues into adulthood. The condition is marked by an ongoing pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. In the U.S., over 20 million patients have been diagnosed with ADHD. Among this group, 12 million are adults and over 8 million are under the age of 17. According to the CDC, just 53.6 percent of all children and teens with ADHD reported they were actively treating their symptoms with medication in 2022, with 65-90 percent demonstrating clinical ADHD symptoms that persist into adulthood. Current market trends demonstrate, that adult ADHD prevalence is larger and growing faster than the child and adolescent segments combined.

About CTx-1301

Cingulate's lead candidate, CTx-1301, utilizes Cingulate's proprietary PTR drug delivery platform to create a breakthrough, multi-core formulation of the active pharmaceutical ingredient dexmethylphenidate, a compound approved by the FDA for the treatment of ADHD. Dexmethylphenidate is part of the stimulant class of medicines and increases norepinephrine and dopamine activity in the brain to affect attention and behavior. While stimulants are the gold standard of ADHD treatment due to their efficacy and safety, the long-standing challenge continues to be providing patients with an entire active-day duration of action. CTx-1301 is designed to precisely deliver three releases of medication at the predefined time, ratio, and style of release to optimize patient care in one tablet. The result is a rapid onset and entire active-day efficacy, with the third dose being released around the time when other extended-release stimulant products begin to wear off.

About Precision Timed Release™ (PTR™) Platform Technology

Cingulate is developing ADHD and anxiety disorder product candidates capable of achieving true once-daily dosing using Cingulate's innovative PTR drug delivery platform technology. It incorporates a proprietary Erosion Barrier Layer (EBL) providing control of drug release at precise, pre-defined times with no release of drug prior to the intended release. The EBL technology is enrobed around a drug-containing core to give a tablet-in-tablet dose form. It is designed to erode at a controlled rate until eventually the drug is released from the core tablet. The EBL formulation, Oralogik™, is licensed from BDD Pharma. Cingulate intends to utilize its PTR technology to expand and augment its clinical-stage pipeline by identifying and developing additional product candidates in other therapeutic areas in addition to Anxiety and ADHD where one or more active pharmaceutical ingredients need to be delivered several times a day at specific, predefined time intervals and released in a manner that would offer significant improvement over existing therapies. To see Cingulate's PTR Platform, click **here**.

About Cingulate Inc.

Cingulate Inc. (NASDAQ: CING), is a biopharmaceutical company utilizing its proprietary 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 ADHD, Cingulate is identifying and evaluating additional therapeutic areas where PTR technology may be employed to develop future product candidates, including to treat anxiety disorders. Cingulate is headquartered in Kansas City. 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