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 13, 2023

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 November 13, 2023, Cingulate Inc. issued a press release announcing its financial results for the third quarter of 2023 and providing a clinical and business update. A copy of the press release is furnished as Exhibit 99.1 and incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated November 13, 2023
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 hereunto duly authorized.

CINGULATE INC.

Dated: November 13, 2023

By: */s/ Louis G. Van Horn*
Name: Louis G. Van Horn
Title: Chief Financial Officer

Exhibit 99.1

Cingulate Inc. Reports Third Quarter 2023 Financial Results and Provides Clinical and Business Update

Phase 3 Adult Efficacy and Safety Trial Data Presented at Psych Congress
Cingulate Closed a $4M Public Offering
$5.8M of Debt Converted into CING Equity

KANSAS CITY, Kan., November. 13, 2023 — Cingulate Inc. (NASDAQ: CING) (Cingulate or the Company), 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 provided financial results for the quarter ended September 30, 2023, as well as a clinical and business update.

Among other highlights, the Company announced data from its Phase 3 adult efficacy and safety trial, closed a $4 million public offering in September 2023 and converted of $5.8 million of debt into Cingulate equity in September 2023.

“We are pleased with the full data received from the Phase 3 adult efficacy and safety trial, and believe it amplifies our view that the effect size seen with CTx-1301 is positioned to provide substantial benefit to the millions of ADHD patients,” said Cingulate Chairman and CEO Shane J. Schaffer.

Cingulate Closed a $4M Public Offering

On September 11, 2023, Cingulate entered into a Securities Purchase Agreement pursuant to which it issued 1,720,000 shares of common stock, pre-funded warrants to purchase up to an aggregate of 5,205,208 shares of common stock, Series A warrants to purchase up to 6,925,208 shares of common stock and Series B warrants to purchase up to 3,462,604 shares of common stock. The offering closed on September 13, 2023. The combined purchase price per share of common stock and accompanying warrants was $0.5776. The combined purchase price per pre-funded warrant and accompanying warrants was $0.5775, which represents the public offering price per share of common stock and accompanying warrants less the $0.0001 per share exercise price for each pre-funded warrant. The Series A warrants have an exercise price of $0.5776 per share and will expire November 3, 2028, and the Series B warrants have an exercise price of $0.5776 per share and will expire November 3, 2025. The Company’s stockholders approved the issuance of common stock upon the exercise of the Series A and Series B warrants at a special meeting held on November 3, 2023. H.C. Wainwright & Co. acted as the exclusive placement agent for the offering.

Werth Family Investment Associates Converted $5.8M of Debt into Cingulate Equity

On September 8, 2023, Werth Family Investment Associates, LLC ("WFIA"), the manager of which is Peter J. Werth, a member of the Cingulate board of directors, converted $5.8 million of debt and accrued interest into pre-funded warrants to purchase 6,838,235 shares of Cingulate common stock, at a conversion price of $0.85 per pre-funded warrant. The closing price of Cingulate's common stock on Nasdaq on September 8, 2023 was $0.5776 per share. The pre-funded warrants issued to WFIA have no expiration date and are exercisable immediately at an exercise price of $0.0001 per share, subject to a beneficial ownership blocker of 19.99%.

Clinical Update

- **CTx-1301:** Cingulate presented full results from the Phase 3 adult efficacy and safety study of its lead candidate, CTx-1301 (dexmethylphenidate), for the treatment of attention deficit/hyperactivity disorder (ADHD), on September 8, 2023, at the 36th Annual Psych Congress, in Nashville, TN. A poster describing this data was selected as a finalist for the Psych Congress's First Annual Poster Awards.

  The Phase 3 CTx-1301-022 study (**NCT05631626**) assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting. The study was not powered for statistical significance, nor was it achieved on the primary efficacy endpoint, but demonstrated a trend toward significance in improving Permanent Product Measure of Performance (PERMP) scores with CTx-1301 compared to placebo. Clinical Global Impression Scale [CGI-S]) scores with CTx-1301 compared to placebo also showed significant improvements with a 28.6% reduction and a p-value of < 0.001. CTx-1301 demonstrated a reduction in Adult ADHD Investigator Symptom Rating Scale (AISRS) scores during the dose-optimization period. During the randomized placebo-controlled period, CTx-1301 demonstrated a reduction in AISRS scores with an effect size of 5.45 and a p-value of <0.001.

  Cingulate commenced the pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study in late July 2023 and a Phase 3 pediatric dose-optimization onset and duration study in early August 2023, with results expected in the first half of 2024.

  Assuming positive clinical results from the upcoming Phase 3 trials, Cingulate plans to submit a New Drug Application (NDA) for CTx-1301 in the second half of 2024 under the Section 505(b)(2) pathway.

- **CTx-2103:** Cingulate is constructing a clinical program for CTx-2103 (buspirone) for the treatment of anxiety on the streamlined approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Based on the pharmacokinetic profile seen in the formulation study, which was completed in September 2022, CTx-2103 achieved a triple release of buspirone. These results provided the critical information required to allow the Company to request a Pre-IND meeting with the FDA to discuss the design of the Company's clinical and regulatory programs for CTx-2103. Based on feedback from the FDA, the Company will work towards an IND filing in the first half of 2024.

- **CTx-1302:** A Phase 1/2 bioavailability study in ADHD patients for CTx-1302 (dextroamphetamine), Cingulate's second asset for the treatment of ADHD, is planned for the second half of 2024. If results from this study are successful, pivotal Phase 3 clinical trials in all patient segments for CTx-1302 are expected to begin in 2025.

Third Quarter Results

Cash Position: As of September 30, 2023, Cingulate had $2.0 million in cash and cash equivalents. Cingulate expects its cash and cash equivalents will enable the Company to fund its research and development and operating expenditures through mid-November 2023.

Management continues to evaluate additional strategies to obtain funding, which may include additional equity offerings, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions.

Research & Development (R&D) Expenses: R&D expenses were $3.9 million for the three months ended September 30, 2023, compared to $2.1 million for the same period in 2022. R&D expenses were $10.5 million for the nine months ended September 30, 2023, compared to $7.1 million for the same period in 2022. These changes are the result of increased development activity in 2023 as compared to 2022. The Company incurred expenses in connection with two Phase 3 studies for CTx-1301 that were initiated during the third quarter of 2023, the pivotal fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose-optimization onset and duration study. In addition, the Company initiated the Phase 3 adult dose-optimization study for CTx-1301 in late 2022 and completed it in June 2023.

General and Administrative (G&A) Expenses: G&A expenses were $1.8 million for both the three months ended September 30, 2023 and the three months ended September 30, 2022. G&A expenses were $5.5 million for the nine months ended September 30, 2023, compared to $6.0 million for the same period in 2022. Insurance costs decreased during the three and nine months ended September 30, 2023 related to a decline in the annual directors' and officers' insurance policy premium, which was renewed in December of 2022. These decreases were offset by an increase in legal fees related to capital raise activities and an increase in personnel expenses resulting from the addition of clinical personnel and annual compensation increases for the three and nine months ended September 30, 2023, respectively.

Net Loss: Net loss was $6.0 million for the three months ended September 30, 2023, compared to $4.0 million for the same period in 2022. Net loss was $16.6 million for the nine months ended September 30, 2023, compared to $13.0 million for the same period in 2022. The increases in net loss are primarily due to the increases in development activity as described above.

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 March 10, 2023. 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.

Cingulate Inc.
Consolidated Balance Sheet Data

	September 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 1,986,313	$ 5,356,276
Total assets	$ 5,870,258	$ 11,405,057
Total liabilities	$ 5,966,592	$ 7,523,035
Accumulated deficit	$ (86,008,746)	$ (69,408,496)
Total stockholders' equity	$ (96,334)	$ 3,882,022

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 3,923,852	$ 2,123,114	$ 10,508,395	$ 7,063,626
General and administrative	1,825,822	1,845,248	5,453,643	5,963,067
Operating loss	**(5,749,674)**	**(3,968,362)**	**(15,962,038)**	**(13,026,693)**
Interest and other income (expense), net	(229,380)	(58,885)	(638,212)	(44,512)
Loss before income taxes	(5,979,054)	(4,027,247)	(16,600,250)	(13,071,205)
Income tax benefit (expense)	-	-	-	-
Net loss	(5,979,054)	(4,027,247)	(16,600,250)	(13,071,205)
Net loss per share of common stock, basic and diluted	$ (0.30)	$ (0.36)	$ (1.16)	$ (1.16)

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