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):
April 1, 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 April 1, 2024, Cingulate Inc. issued a press release announcing its financial results for the year ended December 31, 2023, 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 April 1, 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: April 1, 2024

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

Exhibit 99.1

Cingulate Inc. Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Clinical and Business Update

$17.8 Million Raised Since Beginning of 2023
$9.1 Million of Debt Converted to Equity at a Premium
Phase 3 ADHD Data Continues to Impress

KANSAS CITY, Kan., April 1, 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 twelve months ended December 31, 2023, and provided a clinical and business update. Highlights include capital raised from multiple sources and the addition of three independent board members.

"I am pleased to report that Cingulate is stronger today than the end of last year," said Shane J. Schaffer, Chairman and CEO of Cingulate Inc. "With the addition of three independent directors, each of whom possess deep experience in the pharmaceutical industry, small-cap publicly traded companies, and hold executive leadership roles within pharma, the Cingulate board is equipped to overcome the challenges ahead."

"Our lead asset CTx-1301 continues to impress clinical investigators and key opinion leaders as we share our Phase 3 results. In addition, pharmaceutical companies in the U.S., Europe, and other territories have engaged in licensing discussions regarding their interest to commercialize our product. These tailwinds put Cingulate in a position to obtain non-dilutive capital and expand our pipeline of assets."

"We are encouraged to see the capital markets improving as evidenced by our ability to raise more than $17 million over the past year. Looking ahead, Cingulate has several financial instruments in place to raise additional capital while fighting to preserve shareholders' equity."

"Overall, I am very pleased with the progress made by our team in 2023 and into 2024. Our focus remains on executing our strategic plan and submitting CTx-1301 to the FDA."

CTx-1301 Data Exhibits Strong Effect Size

On January 20, 2024, Cingulate presented 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), at the 2024 American Professional Society of ADHD and Related Disorders (APSARD) conference in Orlando, FL.

The results were previously presented at the 36th Annual Psych Congress in September 2023, where the data was selected as a finalist for the Psych Congress's First Annual Poster Awards.

The Cingulate poster presented at APSARD provided additional insight regarding CTx-1301's impressive effect size. Effect size conveys clinical significance rather than statistical significance, is not reliant on sample size, and allows for comparison across trials. The poster presented may be viewed here. The study was not intended nor did it achieve statistical significance on the primary endpoint but demonstrated a trend towards significance despite its modest sample size in improving ADHD symptoms with a rapid onset of action and entire active-day duration.

Cingulate Receives Guidance from FDA on Path Forward for Anxiety Asset CTx-2103 (buspirone)

In December 2023, Cingulate received input from the FDA regarding the regulatory pathway for CTx-2103, and the design of clinical studies for filing of an IND. Based on this FDA feedback, we believe that we can seek and win approval of CTx-2103 under the 505(b)(2) pathway, which typically requires less time and resources than the 505(b)(1) full NDA pathway.

$10.7 Million of Capital Raised and $3.3 Million of Debt Converted to Equity in 2024

Since January 1, 2024, the Company sold shares of common stock under its At the Market Offering Agreement with H.C. Wainwright & Co., LLC for gross proceeds of $3.2 million. In February 2024, the Company 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, at a public offering price of $2.00 per share (or common stock equivalent in lieu thereof) and accompanying warrants. Additionally, 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.

$7.1 Million of Capital Raised and $5.8 Million of Debt Converted to Equity in 2023

In September 2023, Cingulate closed a $4.0 million public offering of shares of common stock (or common stock equivalents in lieu thereof) and Series A and Series B warrants to purchase shares of common stock, at public offering price of $11.55 per share (or common stock equivalent in lieu thereof) and accompanying warrants.

In addition, during 2023, Cingulate sold shares of common stock through its ATM Agreement and its Purchase Agreement with Lincoln Park Capital Fund, LLC for aggregate gross proceeds of $2.1 million. Finally, in August 2023, WFIA purchased shares of common stock for $1.0 million through a private placement priced at the market, and in September 2023, WFIA converted at a 47% premium to market $5.8 million of outstanding debt and accrued interest into pre-funded warrants to purchase shares of common stock.

Jennifer Callahan Promoted to CFO

In January 2024, Cingulate promoted longtime Controller Jennifer Callahan to Chief Financial Officer, succeeding Lou Van Horn, who retired from the company in December 2023.

Three Independent Directors Appointed to Cingulate Board

In February 2024, Cingulate appointed three independent directors to its board: Jay Roberts, Bryan Lawrence, and Jeff Ervin. Please visit Cingulate.com for more information about the new directors.

Fourth Quarter and Full Year Results

Cash Position: As of December 31, 2023, Cingulate had $52,416 in cash and cash equivalents. Additionally, we have raised $10.7 million from the sale of securities in 2024 to date and we believe that our cash will satisfy our capital needs through late in the second quarter of 2024 under our current business plan. 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.

R&D Expenses: Research and development expenses were $5.0 million for the three months ended December 31, 2023, compared to $1.9 million for the same period in 2022. Research and development expenses were $15.5 million for the year ended December 31, 2023, compared to $9.0 million for the year ended December 31, 2022. These increases were primarily the result of increased clinical activity in 2023 as compared to 2022. During the third quarter of 2023, we initiated two Phase 3 studies for CTx-1301, the pediatric dose optimization onset and duration study and the fixed dose pediatric and adolescent safety and efficacy study. In addition, the Phase 3 adult dose-optimization study for CTx-1301 was completed in June 2023. Manufacturing for these Phase 3 studies also occurred during 2023.

G&A Expenses: General and administrative expenses were $1.8 million for the three months ended December 31, 2023, compared to $2.5 million for the same period in 2022. General and administrative expenses were $7.3 million for the year ended December 31, 2023, compared to $8.5 million for the year ended December 31, 2022. These decreases were primarily the result of a decrease in our directors' and officers' insurance premium from 2022 to 2023. The decrease in directors' and officers' insurance premium was offset by increases in certain professional fees primarily the result of the timing of services performed relating to our annual audit.

Net Loss: Net loss was $6.9 million for the three months ended December 31, 2023, compared to $4.6 million for the same period in 2022. Net loss was $23.5 million for the year ended December 31, 2023, compared to $17.7 million for the year ended December 31, 2022. The increase in the net loss from 2022 to 2023 primarily relates to a significant increase in development activity as described above.

Cingulate Inc.
Consolidated Balance Sheet Data

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 52,416	$ 5,356,276
Total assets	$ 3,491,436	$ 11,405,057
Total liabilities	$ 10,360,865	$ 7,523,035
Accumulated deficit	$ (92,943,443)	$ (69,408,496)
Total stockholders' equity	$ (6,869,429)	$ 3,882,022

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 4,984,909	$ 1,931,654	$ 15,493,304	$ 8,995,280
General and administrative	1,812,242	2,543,371	7,265,885	8,506,438
Operating loss	**(6,797,151)**	**(4,475,025)**	**(22,759,189)**	**(17,501,718)**
Interest and other income (expense), net	(137,546)	(130,002)	(775,758)	(174,514)
Loss before income taxes	(6,934,697)	(4,605,027)	(23,534,947)	(17,676,232)
Income tax benefit (expense)	-	-	-	-
Net loss	**$ (6,934,697)**	**$ (4,605,027)**	**$ (23,534,947)**	**$ (17,676,232)**

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.

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