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 10, 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 March 10, 2023, Cingulate Inc. issued a press release announcing its financial results for the year ended December 31, 2022 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 March 10, 2023
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 10, 2023

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

Exhibit 99.1

Cingulate Inc. Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Clinical and Business Update

CTx-1301 Phase 3 Adult Dose-Optimization Study Ongoing; Results Expected 3Q 2023

Positive Top-Line Data from CTx-1301 Fed/Fast Study Announced, Full Results Submitted for Presentation at Forthcoming Medical Meeting

CTx-1301 Pivotal Phase 3 Trial in Pediatric/Adolescent Patients Planned to Begin Mid-2023

KANSAS CITY, Kan., March 10, 2023 — 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 and 12 months ended December 31, 2022, and provided a clinical and business update. Highlights include multiple clinical updates on CTx-1301, the Company's lead candidate being investigated as a true, once-daily treatment for attention deficit/hyperactivity disorder (ADHD).

"The fourth quarter of 2022 was instrumental for Cingulate, during which we executed a Master Services Agreement with Societal CDMO to manufacture CTx-1301, and successfully initiated our Phase 3 Adult Onset and Duration Trial," said Shane J. Schaffer, PharmD, Cingulate Chairman and CEO. "With the first of two CTx-1301 Phase 3 studies underway and the second planned to begin mid-2023, we've made significant progress towards bringing the first true, once-daily stimulant to market that addresses all major unmet needs in ADHD."

CTx-1301 is a novel, investigational, trimodal, extended-release tablet formulation of dexmethylphenidate, a compound approved by the FDA for the treatment of ADHD.

Phase 3 Adult Dose-Optimization Trial on Track for Q3 2023 Results

The Phase 3 CTx-1301-022 (NCT05631626) trial is evaluating the efficacy and safety of CTx-1301 in adults with ADHD in an laboratory classroom setting, which has been used extensively to evaluate the efficacy of ADHD medications. Following initiation in December, the dose optimization phase for the first cohort has commenced.

The trial is being led by Ann C. Childress, MD, practicing psychiatrist and president of the American Professional Society for ADHD and Related Disorders (APSARD). Dr. Childress has conducted over 180 clinical studies and is considered a preeminent global ADHD expert.

"While we have many approved stimulant medications at our disposal as clinicians, my long-standing desire in over 20-years of clinical practice is to utilize a product that provides entire active-day efficacy, providing a quick onset of action and a duration into the early evening. Afternoon booster doses are our current work-around, but these lead to issues with adherence, optimal efficacy, and the potential for abuse and diversion, and may be accompanied with unwanted side effects. Having a product like CTx-1301 would be beneficial to patients and providers, as it is designed to avoid booster doses and address the long-standing unmet needs facing our patients with ADHD," said Dr. Childress.

Clinical Update

- **CTx-1301:** Cingulate advanced its clinical program for CTx-1301 on the streamlined approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. As part of that effort:

  Cingulate initiated a CTx-1301 Phase 3 adult dose-optimization study in December 2022 to assess onset and duration of efficacy and safety in adults with ADHD, dose optimization of the first cohort has commenced and results are expected in the third quarter of 2023.

  In addition, the CTx-1301 Phase 3 fixed-dose pediatric and adolescent safety and efficacy study is expected to commence in mid-2023; results are expected in the first quarter of 2024.

  In order to meet the pharmacology requirement for the CTx-1301 New Drug Application (NDA) submission, Cingulate completed a food effect study in October of 2022, which demonstrated that CTx-1301 can be taken with our without food.

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

- **CTx-2103:** Cingulate is constructing a clinical program for CTx-2103 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 the desired triple release of buspirone. These positive 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, which is expected to occur in the third quarter of 2023 to allow for a potential IND filing in the fourth quarter of 2023.

- **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 mid-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 late 2024 or early 2025.

Fourth Quarter and Full Year Results

- **Cash Position:** As of December 31, 2022, Cingulate had $5.4 million in cash and cash equivalents, as compared to $16.5 million in cash and cash equivalents as of December 31, 2021. Based on the Company's current operating plan, Cingulate expects its cash and cash equivalents will enable the Company to fund its research and development and general and administrative expenditures into the second quarter of 2023. In January 2023, Cingulate entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), pursuant to which we may offer and sell, from time to time through Wainwright, shares of our common stock for aggregate proceeds of up to $2.65 million. To date, Cingulate has not made any sales under the ATM Agreement. In addition, Cingulate is evaluating other alternatives to raise additional capital, including equity and debt financing.

Research & Development (R&D) Expenses: R&D expenses were $1.9 million for the three months ended December 31, 2022, compared to $1.3 million for the same period in 2021. R&D expenses were $9.0 million for the year ended December 31, 2022, as compared to $8.4 million for the year ended December 31, 2021. This increase was related to a significant increase in clinical and manufacturing costs for CTx-1301 as Cingulate completed a food effect study in the fourth quarter of 2022 and initiated the Phase 3 adult dose-optimization study in late 2022. In addition, the Company's manufacturing costs increased in 2022 relating to the production of clinical supply for Phase 3 trials of CTx-1301. These increases were offset by a decrease in personnel expenses due to the recording of $4.6 million to R&D expense in 2021 for a one-time noncash compensation charge for the modification of profits interest units (PIUs). The decrease in personnel costs due to the one-time noncash charge was offset by annual pay increases in 2022 and added personnel in late 2021 in anticipation of increased clinical activity.

- **General and Administrative (G&A) Expenses:** G&A expenses were $2.5 million for the three months ended December 31, 2022, compared to $1.4 million for the same period in 2021. G&A expenses were $8.5 million for the year ended December 31, 2022, as compared to $12.3 million for the year ended December 31, 2021. Personnel expenses decreased, primarily related to the recording of $8.1 million to G&A personnel expenses of a one-time noncash compensation charge in 2021 relating to the modification of PIUs. This decrease in personnel expenses due to the noncash compensation charge was offset by an increase in salaries expense due to the addition of personnel in late 2021 as the Company was preparing to operate as a public company. The decrease in personnel expenses was offset by increases in other expenses, including legal fees and audit fees primarily due to increased activity in late 2022 in preparation for future capital raises. In addition, insurance costs increased significantly due to the directors and officers insurance premium which is much higher for a publicly traded company.

- **Net Loss:** Net loss was $4.6 million for the three months ended December 31, 2022, compared to $2.7 million for the same period in 2021. Net loss was $17.7 million for the year ended December 31, 2022, as compared to $20.7 million for the year ended December 31, 2021. The decrease in net loss for the full year primarily relate to a one-time non-cash compensation charge totaling $12.7 million for the modification of profits interest units in the third quarter of 2021, partially offset by increased development activity as well as the increase in G&A expenses relating to additional costs to operate as a public company in 2022, both 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 28, 2022. 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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and short-term investments	$ 5,356,276	$ 16,493,678
Working capital	$ 856,852	$ 17,705,601
Total assets	$ 11,405,057	$ 22,886,257
Total liabilities	$ 7,523,035	$ 2,042,715
Accumulated deficit	$ (69,408,496)	$ (51,732,264)
Total stockholders' equity	$ 3,882,022	$ 20,843,542

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 1,931,654	$ 1,262,976	$ 8,995,280	$ 8,410,489
General and administrative	2,543,371	1,384,150	8,506,438	12,268,909
Operating loss	**(4,475,025)**	**(2,647,126)**	**(17,501,718)**	**(20,679,398)**
Interest and other income (expense), net	(130,002)	(6,599)	(174,514)	(30,593)
Loss before income taxes	(4,605,027)	(2,653,725)	(17,676,232)	(20,709,991)
Income tax benefit (expense)	-	-	-	-
Net loss	(4,605,027)	(2,653,725)	(17,676,232)	(20,709,991)
Net loss per share of common stock, basic and diluted	$ (0.41)	$ (0.32)	$ (1.56)	$ (2.79)

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