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, 2022

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, 2022, Cingulate Inc. issued a press release announcing its financial results for the fourth quarter of 2021 and year ended December 31, 2021 and 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, 2022
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: March 10, 2022

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 2021 Results and Provides Clinical and Business Update

Completed Initial Public Offering, Raising Gross Proceeds of $25.0 Million

Expedited Clinical Program for CTx-1301 Expected to Reduce Capital Requirements and Time to Approval

KANSAS CITY, Kan., March 10, 2022 — Cingulate Inc. (NASDAQ: CING), a clinical-stage 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, 2021, and provided a clinical and business update.

"Our recent initial public offering was a significant milestone for Cingulate in advancing our mission to help Attention Deficit/Hyperactivity Disorder (ADHD) patients overcome their significant unmet needs in using currently available treatment options," said Shane J. Schaffer, PharmD, Chairman and Chief Executive Officer of Cingulate. "We look forward to initiating our pivotal Phase 3 study for CTx-1301 in the second quarter of 2022 and beginning to dose patients as we progress toward our goal of filing a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the second half of 2023."

Matthew Brams, M.D., Chief Medical Officer, added, "As a practicing psychiatrist for over 30 years, I'm proud to be a part of the Cingulate team in realizing our vision to provide patients and providers with a true once-daily medication to overcome the long-standing unmet needs in ADHD. Our clinical plan will further demonstrate our products' ability to achieve a fast onset of action and provide entire active-day efficacy without the need for booster or recovery doses."

Clinical and Business Update

CTx-1301: Cingulate has updated its clinical program for CTx-1301 (dexmethylphenidate), its lead investigational asset for the treatment of ADHD, based on FDA feedback regarding the Company's CTx-1301 initial Pediatric Study Plan (iPSP), and longstanding guidance on the accelerated approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

Cingulate plans to commence two CTx-1301 Phase 3 clinical studies in 2022: (1) a fixed-dose pediatric and adolescent safety and efficacy study, which will enroll its first patient in the second quarter of 2022; and (2) a pediatric safety and efficacy dose-optimization study to assess the onset and duration of efficacy, which is targeted to begin in the second half of 2022. Cingulate's clinical plan will also investigate several exploratory elements critical to ADHD patients, providers, payers, and the larger medical community, such as the use of booster/recovery doses, the abuse and diversion associated with short-acting medications, and the crash/rebound effects of early medication wear off. Results from the fixed dose study are expected in late 2022. The entire Phase 3 clinical program is expected to include approximately 350 patients. Assuming Cingulate receives positive clinical results from its Phase 3 trials, the Company plans to submit an NDA for CTx-1301 in the second half of 2023 under the Section 505(b)(2) pathway.

Cingulate believes the updated clinical program for CTx-1301 accelerates the study timeline by condensing the number and design of studies, therefore potentially reducing the time and expense to submission of the NDA for CTx-1301 to the FDA for potential approval.

In order to achieve an expected second half 2023 NDA submission for potential FDA approval, the Company believes it will need approximately $15 million of additional capital and is evaluating alternatives to raise additional capital, including equity and debt financing and non-dilutive strategic collaborations in the U.S. and abroad. A commercial collaboration or strategic relationship with an established pharmaceutical company, which is a key Company initiative, would provide more immediate access to marketing, sales, market access and distribution infrastructure.

CTx-1302: Cingulate plans to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 (dextroamphetamine), its second investigational asset for the treatment of ADHD, in 2023 and, if the results from this study are successful, the Company plans to initiate pivotal Phase 3 clinical trials in all patient segments for CTx-1302 in late 2023 with results expected in late 2024.

CTx-2103: Cingulate has embarked on a program to develop CTx-2103 (buspirone), which would expand the PTR platform within the anxiety therapeutic category. The Company plans to initiate a clinical trial for CTx-2103 in the first half of 2022.

Fourth Quarter and Full Year Results

Cash Position: As of December 31, 2021, Cingulate had $16.5 million in cash and cash equivalents, as compared to $1.2 million in cash and cash equivalents as of December 31, 2020. Cash and cash equivalents as of December 31, 2021 reflect the net proceeds of our IPO of approximately $20.4 million, which closed on December 10, 2021. Based on the Company's current operating plan, Cingulate expects its cash and cash equivalents as of December 31, 2021 will enable the Company to fund its research and development and general and administrative expenditures through late 2022.

R&D Expenses: Research and development expenses were $1.3 million for the three months ended December 31, 2021, compared to $0.6 million for the same period in 2020. Research and development expenses were $8.4 million for the year ended December 31, 2021, compared to $5.1 million for the year ended December 31, 2020. The increase in the three-month period was primarily related to costs incurred in late 2021 in preparation of the manufacturing of Phase 3 clinical supply of CTx-1301. The increase from 2020 to 2021 was related to the recognition of $4.6 million of R&D expense for a one-time, noncash compensation charge in the third quarter of 2021 due to the exchange of Profits Interest Units (PIUs) in Cingulate Therapeutics LLC for common stock of Cingulate Inc. prior to the IPO, which was based on the fair value of the common stock at the time of the exchange, partially offset by a decrease in clinical operations expense of $1.2 million due to a decrease in clinical activity. In early 2020, the Company incurred significant clinical costs relating to the completion of the Phase 1/2 comparative bioavailability study for CTx-1301. During 2021, clinical activity primarily consisted of study startup costs for the fixed dose Phase 3 study for CTx-1301.

G&A Expenses: General and administrative expenses were $1.4 million for the three months ended December 31, 2021, compared to $0.5 million for the same period in 2020. General and administrative expenses were $12.3 million for the year ended December 31, 2021, compared to $2.0 million for the year ended December 31, 2020. The increase in the three-month period was primarily due to an increase in personnel costs relating to annual compensation increases and the addition of personnel in late 2021, as well as an increase in directors' and officers' insurance costs and professional fees related to legal and investor relations, as the Company was preparing to operate as a public company. The increase from 2020 to 2021 was primarily related to the recognition of $8.1 million of G&A personnel expenses for a one-time, noncash compensation charge in the third quarter of 2021 due to the exchange of Profits Interest Units (PIUs) in Cingulate Therapeutics LLC for common stock of Cingulate Inc. described above. In addition, the increase was due to an increase in personnel costs relating to annual compensation increases and the addition of personnel in late 2021, as well as an increase in directors' and officers' insurance costs and professional fees related to legal, consulting, audit and investor relations, as the Company was preparing to operate as a public company.

Net Loss: Net loss was $2.7 million for the three months ended December 31, 2021, compared to $1.2 million for the same period in 2020. Net loss was $20.7 million for the year ended December 31, 2021, compared to $7.2 million for the year ended December 31, 2020. The increase in the net loss from 2020 to 2021 primarily relates to a one-time, noncash compensation charge of $12.7 million in the third quarter of 2021 due to the exchange of PIUs in Cingulate Therapeutics LLC for common stock of Cingulate Inc. described above.

About Cingulate®

Cingulate Inc. is a clinical-stage 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. 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 prospectus filed with the SEC on December 9, 2021. 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

	As of December 31,	
	2021	**2020**
Cash, cash equivalents and short-term investments	$ 16,493,678	$ 1,198,605
Total current assets	18,882,279	1,789,873
Total assets	22,886,257	5,787,556
Total liabilities	2,042,715	4,495,121
Accumulated deficit	(51,732,264)	(31,022,106)
Total stockholders' equity	20,843,542	1,292,435

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 1,262,976	$ 629,866	$ 8,410,489	$ 5,093,277
General and administrative	1,384,150	523,153	12,268,909	1,990,086
Operating loss	**(2,647,126)**	**(1,153,019)**	**(20,679,398)**	**(7,083,363)**
Interest and other income (expense), net	(6,599)	(40,606)	(30,593)	(100,252)
Loss before income taxes	(2,653,725)	(1,193,625)	(20,709,991)	(7,183,615)
Income tax benefit (expense)	-	-	-	-
Net loss	$ (2,653,725)	$ (1,193,625)	$ (20,709,991)	$ (7,183,615)
Net loss per share of common stock, basic and diluted	$ (0.32)	$ n/a	$ (2.79)	$ n/a
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	8,229,702	n/a	7,413,579	n/a

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