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):
January 7, 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 7.01. Regulation FD Disclosure.

On January 7, 2025, Cingulate Inc. (the "Company") issued a press release announcing that it had completed its final FDA-required study, which is a food effect study, for CTx-1301 (dexmethylphenidate) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). A copy of the press release is furnished as Exhibit 99.1 hereto and shall not be deemed "filed" for the 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 it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On January 7, 2025, the Company announced that it had completed its final FDA-required study, which is a food effect study, for CTx-1301 (dexmethylphenidate) for the treatment of ADHD. No serious adverse events were reported. A data readout regarding bioavailability with or without food is expected in the second quarter of 2025. A New Drug Application submission with the FDA is targeted for mid-2025.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 7, 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: January 7, 2025

By: */s/ Shane J. Schaffer*
Name: Shane J. Schaffer
Title: Chief Executive Officer

Exhibit 99.1

Final Study Completed for Cingulate's Lead Asset CTx-1301

No Serious Adverse Events Reported

Submission of New Drug Application Targeted for Mid 2025

KANSAS CITY, Kan., January 7, 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, announced today that it has completed its final FDA-required study, which is a food effect study, for CTx-1301 (dexmethylphenidate) for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The subjects in the study were given a single 50mg dose of CTx-1301, Cingulate's highest dosage, to determine if the medication can be taken in fed and fasted states. No serious adverse events were reported. A data readout regarding bioavailability with or without food is expected in 2Q 2025.

A study conducted in 2022 using a single 25mg dose of CTx-1301 demonstrated that it could be taken with or without food.

"We are developing CTx-1301 to be the first true, once-daily stimulant medication that treats ADHD over an entire active day, and crucial to this is ensuring a pharmacokinetic profile customized for the unique attributes of stimulant medications and ADHD, regardless of food intake and dosage size," said Cingulate Chairman and CEO Shane J. Schaffer. "The completion of this study marks another important milestone and is one of the final activities required for NDA submission to the FDA, which is targeted for mid 2025."

About the Food Effect Study

- An open-label, randomized, single-dose, two-sequence, two-period, in-clinic crossover study in 26 healthy adult subjects, 18 to 50 years of age. Subjects were randomized into one of two sequences (a fasted state, and a fed state [after a high-fat test meal]) and dosed with a 50mg dose of CTx-1301
- The primary PK endpoints were maximum concentration (expressed as C_{max}) during the first 28 hours after dosing, and the total amount of the active pharmaceutical ingredient (API), dexmethylphenidate, in the blood (expressed as the area the plasma drug concentration-time curve [AUC]) from dosing to the time of the last measured concentration ($AUC_{0\text{-}last}$) and from dosing taken to the limit as the end time becomes arbitrarily large ($AUC_{0\text{-}\infty}$)
- Results from the study are expected in Q2 2025 and will confirm how food impacts the absorption and bioavailability of CTx-1301

Pharmacokinetics (PK)

PK refers to the activity of drugs in the body over a period of time, including the extent of Absorption, Distribution, Metabolism and Excretion (ADME). A fundamental understanding of PK parameters is required to design an appropriate drug regimen for a patient, to help plan subsequent studies and to support labeling.

Overall, the effect of food on the PK of orally administered long-acting stimulants is generally minimal: following a high-fat meal, there is potential for the rate and extent of absorption to be either slightly decreased or increased compared to the fasted state. However, a thorough understanding of the unique PK profile and pharmacodynamic response of investigational formulations allows developers to optimize the most effective formulation of their therapy based on the clinical needs and dosing preferences of patients.

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., approximately 6.4 million children and adolescents (11 percent) aged under the age of 18 have been diagnosed with ADHD. Among this group, approximately 80 percent receive treatment, with 65-90 percent demonstrating clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence is estimated at approximately 11 million patients (4.4 percent), almost double the size of the child and adolescent segment combined. However, only an estimated 20 percent receive treatment.

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