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): **June 8, 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 7.01. Regulation FD Disclosure.

On June 8, 2023, Cingulate Inc. (the "Company") issued a press release announcing the completion of the Phase 3 adult dose-optimization trial for its lead candidate, CTx-1301 (dexmethylphenidate). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "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, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events.

On June 8, 2023, the Company announced the completion of the Phase 3 adult dose-optimization trial for its lead candidate, CTx-1301 (dexmethylphenidate); results from the trial are expected in 3Q 2023. The Company also confirmed its plan to initiate its pivotal Phase 3 fixed-dose pediatric and adolescent study and its pivotal dose-optimization onset and duration trial in pediatric patients in 3Q 2023.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 8, 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: June 8, 2023

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

Exhibit 99.1

Cingulate Completes Phase 3 Adult Trial of CTx-1301 (dexmethylphenidate) for ADHD

Study Assessed Onset and Duration of CTx-1301 in Adults, Results Expected 3Q 2023

Pivotal Phase 3 Trials in Pediatric/Adolescent Patients on Schedule for 3Q 2023 Initiation

KANSAS CITY, KANSAS – June 8, 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 it has completed its Phase 3 adult dose-optimization trial of its lead candidate, CTx-1301 (dexmethylphenidate), a novel, investigational treatment being developed as a true, once-daily stimulant medication for attention deficit/hyperactivity disorder (ADHD), upon approval from the U.S. Food and Drug Administration (FDA).

The Phase 3 CTx-1301-022 study (**NCT05631626**) assessed the onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting. Results from the trial are expected in 3Q 2023 and will be submitted for presentation at a future medical meeting.

“Currently available stimulant medications have failed to address the large and growing unmet need for true once-daily dosing in ADHD treatment, and onset and duration are two of the most important efficacy parameters that Cingulate plans to improve upon to achieve this,” said Raul R. Silva, M.D., Chief Science Officer, Cingulate. “If the Phase 3 CTx-1301-022 study results are positive, these data will add to the growing body of evidence from earlier trials showing that CTx-1301 has the potential to offer patients best-in-class onset and duration.”

The United States Centers for Disease Control (CDC) has cited a 10 percent increase in stimulant medicine prescriptions in the adult ADHD population. Of the multitude of ADHD medications available, no methylphenidate medication offers a single oral dose that provides patients entire active-day efficacy.

“Stimulant medications are the most effective tools we have to address ADHD symptoms in patients, but their short half-life require that more than 60 percent of patients be prescribed booster doses – a primary source of non-compliance and misuse of this class of medicines,” said Ann Childress, M.D., President, Center for Psychiatry and Behavior Medicine, Inc., and lead investigator in the Phase 3 CTx-1301-022 study.

“Cingulate’s formulation of dexmethylphenidate is designed to cover a patient’s entire active day and, if the Phase 3 trials are successful, would give physicians the ability to avoid the booster dose, and ultimately provide patients a single administration to improve outcomes.” Dr. Childress continued, “The American Professional Society of ADHD and Related Disorders (APSARD) announced plans to develop and publish guidelines for the diagnosis and treatment of ADHD in adults. As there are currently no guidelines in the United States, the APSARD guidelines will address this critical need for health care providers, patients, and the public.” Dr. Childress is the President of APSARD through 2023.

In addition to the Phase 3 adult dose-optimization study, Cingulate plans to initiate its pivotal Phase 3 fixed-dose pediatric and adolescent study and its pivotal dose-optimization onset and duration trial in pediatric patients in 3Q 2023. Assuming positive clinical results from the Phase 3 trials, Cingulate plans to submit a New Drug Application (NDA) for CTx-1301 in mid-2024 under the Section 505(b)(2) pathway.

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 the CTx-1301 Phase 3 Adult Dose-Optimization Study

The first Phase 3 study (CTx-1301-022, **NCT05631626**) for CTx-1301 is a single-center, dose-optimized, double-blind, randomized, placebo-controlled, parallel efficacy and safety adult laboratory classroom (ALC) study with CTx-1301 in 21 adults (age range: 18-55 years) with ADHD. The study was comprised of a screening period, a dose-optimization phase, a double-blind randomized phase, and a seven-day safety follow-up period. Subjects underwent a screening visit prior to entering a five-week dose-optimization phase.

During the dose-optimization phase, subjects had weekly visits and were titrated to doses ranging between 25 mg and 50 mg of CTx-1301. Cingulate utilized an ALC, which enabled it to facilitate repeated assessments over the course of a day to evaluate the onset and duration of efficacy provided by CTx-1301. Eligible subjects were randomized to their optimal dose or placebo in a 1:1 ratio after completing a practice visit with four Permanent Product Measure of Performance (PERMP) assessments. Subjects took their assigned/randomized dose over the following seven-day period. On the seventh day, subjects completed a full ALC visit. The duration of the full ALC visit was approximately 17 hours. Subjects had an in-clinic safety follow-up visit within seven days after the full ALC visit.

The primary objective of CTx-1301-022 was to evaluate the efficacy of CTx-1301 compared to placebo in treating adults with ADHD in an ALC study. Secondary objectives included determination of the onset and duration of clinical effect of CTx-1301 in treating ADHD in adults in an ALC study and to determine safety and tolerability of CTx-1301 compared to placebo. The study also evaluated the quality and satisfaction of prior medication to CTx-1301. The Phase 3 clinical trial program for CTx-1301 is being conducted in the U.S. and is instrumental for the filing of the NDA to the FDA, expected in mid-2024.

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 remains, providing patients 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 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. For more information visit Cingulate.com/technology.

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 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.

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Investor Relations:

Matt Kreps
Darrow Associates
mkreps@darrowir.com
(214) 597-8200

Thomas Dalton
Vice President, Investor & Public Relations, Cingulate
tdalton@cingulate.com
(913) 942-2301

Media Relations

Melyssa Weible
Elixir Health Public Relations
mweible@elixirhealthpr.com
(201) 723-5805