# 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): **July 11, 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**<br>**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 July 11, 2023, Cingulate Inc. (the "Company") issued a press release announcing positive top-line results from its Phase 3 adult efficacy and safety 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 (ADHD), upon approval from the U.S. Food and Drug Administration (FDA). 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 July 11, 2023, the Company announced positive top-line results from its Phase 3 efficacy and safety trial of its lead candidate, CTx-1301 (dexmethylphenidate), a novel, investigational treatment being developed as a true, once-daily stimulant medication for ADHD, upon approval from the FDA.

The Phase 3 CTx-1301-022 study (NCT05631626), which assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting, demonstrated a meaningful trend in improving ADHD symptoms with a rapid onset of action and entire active-day duration. After a 5-week dose optimization period, subjects were either randomized to their optimized dose of CTx-1301 or placebo. Subjects who were randomized to their optimized dose of CTx-1301 showed improvements on the Permanent Product Measure of Performance (PERMP) (effect size 0.88 to 2.6; with an average of 1.79) compared to subjects randomized to placebo.

The overall effect size showed a trend toward significance with a p-value of 0.089 despite the modest sample size. A Meta-Analysis conducted by Faraone and Glatt (Clinical Psychiatry 71:6 June 2010) using 11 published studies with long-acting stimulants in adults demonstrated the average effect size to be 0.73 (approximate range 0.5 to 0.9). Subjects randomized to CTx-1301 demonstrated an effect size of 1.41 at 30 minutes and an effect size of 0.98 at 16 hours. Effect size represents the magnitude of a change in an outcome or the strength of a relationship, the practical significance. The practical significance shows that the effect is large enough to be meaningful in the real world. The larger the effect size the more meaningful the outcome.

In addition, the secondary outcome using the Clinical Global Impression (CGI) Scale for severity of illness was associated with a decrease in the severity of illness in subjects randomized to CTx-1301 compared to placebo. This is noteworthy as the purpose of this study was to obtain estimates of effect size and it was not anticipated that significant treatment differences would be observed. CTX-1301 was well tolerated; 9% of the subjects that were randomized to CT-x-1301 experienced treatment emergent adverse events (TEAEs), while 30% of subjects that were randomized to placebo experienced TEAEs. Patient reported outcomes on the overall satisfaction with CTx-1301 compared to subject's prior ADHD medication was favorable.

Full results from the Phase 3 CTx-1301-022 trial, including safety data and patient reported outcomes from a pre- and post-trial questionnaire, are being submitted for presentation at upcoming medical meetings.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release dated July 11, 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: July 11, 2023

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

**Exhibit 99.1**

**Cingulate Announces Positive Top-Line Results from Phase 3 Adult Efficacy and Safety Trial of CTx-1301 (dexmethylphenidate) for ADHD**

*Results Indicative that CTx-1301 Provides Entire Active-Day Efficacy with Optimal Onset and Duration*

**KANSAS CITY, KANSAS** – July 11, 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 positive top-line results from its Phase 3 adult 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).

Ann Childress, M.D., President, Center for Psychiatry and Behavior Medicine, Inc., and lead investigator in the Phase 3 CTx-1301-022 who conducted the primary efficacy evaluations, AISRS and PERMP, stated, "From my observation the changes in the Adult ADHD Investigator Symptom Rating Scale (AISRS; a scale that measures aspects of ADHD in adults) demonstrated a positive effect in subjects that received CTx-1301 versus subjects that received placebo. I was also impressed with the overall improvement (change from baseline) of PERMP scores in subjects who were randomized to CTx-1301 compared to placebo. Although a secondary endpoint, the established CGI scale for severity of illness demonstrated clinical improvement in severity of illness. Overall, this in combination with the favorable safety profile, bodes well for future Phase 3 studies."

The Phase 3 CTx-1301-022 study (NCT05631626), which assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting, demonstrated a meaningful trend in improving ADHD symptoms with a rapid onset of action and entire active-day duration. After a 5-week dose optimization period, subjects were either randomized to their optimized dose of CTx-1301 or placebo. Subjects who were randomized to their optimized dose of CTx-1301 showed improvements on the Permanent Product Measure of Performance (PERMP) (effect size 0.88 to 2.6; with an average of 1.79) compared to subjects randomized to placebo.

The overall effect size showed a trend toward significance with a p-value of 0.089 despite the modest sample size. A Meta-Analysis conducted by Faraone and Glatt (Clinical Psychiatry 71:6 June 2010) using 11 published studies with long-acting stimulants in adults demonstrated the average effect size to be 0.73 (approximate range 0.5 to 0.9). Subjects randomized to CTx-1301 demonstrated an effect size of 1.41 at 30 minutes and an effect size of 0.98 at 16 hours. Effect size represents the magnitude of a change in an outcome or the strength of a relationship, the practical significance. The practical significance shows that the effect is large enough to be meaningful in the real world. The larger the effect size the more meaningful the outcome.

In addition, the secondary outcome using the Clinical Global Impression (CGI) Scale for severity of illness was associated with a decrease in the severity of illness in subjects randomized to CTx-1301 compared to placebo. This is noteworthy as the purpose of this study was to obtain estimates of effect size and it was not anticipated that significant treatment differences would be observed. CTX-1301 was well tolerated; 9% of the subjects that were randomized to CT-x-1301 experienced treatment emergent adverse events (TEAEs), while 30% of subjects that were randomized to placebo experienced TEAEs. Patient reported outcomes on the overall satisfaction with CTx-1301 compared to subject's prior ADHD medication was favorable.

“I’m incredibly proud of our team for reaching this important clinical milestone. This Phase 3 trial is a major validation of what Cingulate has set out to accomplish: create the only ADHD medication that overcomes the major unmet needs of available treatments with clear and unmatched differentiation,” said Shane J. Schaffer, PharmD, Chairman and CEO, Cingulate. “We believe that the analysis of the full data set from this trial, along with completing our two upcoming trials in pediatric and adolescent patients, will allow us to submit a New Drug Application for CTx-1301 by mid-2024, and most importantly, provide patients, physicians, and payors a product that can provide exceptional ADHD treatment.”

Full results from the Phase 3 CTx-1301-022 trial, including safety data and patient reported outcomes from a pre- and post-trial questionnaire, are being submitted for presentation at upcoming medical meetings.

In addition to the Phase 3 adult dose-optimization study, Cingulate plans to initiate its pivotal Phase 3 fixed-dose pediatric and adolescent study this month and a dose-optimization onset and duration trial in pediatric patients in August 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 was a single-center, dose-optimized, double-blind, randomized, placebo-controlled, parallel efficacy and safety adult laboratory classroom (ALC) study of 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 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 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 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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