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): **May 3, 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 May 3, 2023, Cingulate Inc. (the "Company") issued a press release announcing the successful transfer of its proprietary PTR™ manufacturing processes for its lead candidate, CTx-1301 (dexmethylphenidate), to Societal CDMO, Inc. ("Societal"), which is ready to produce a scalable supply of CTx-1301 for the Company's Phase 3 trials. 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 May 3, 2023, the Company announced the successful transfer of its proprietary PTR™ manufacturing processes for its lead candidate, CTx-1301 (dexmethylphenidate) to Societal, which is ready to produce a scalable supply of CTx-1301 for the Company's Phase 3 trials. Assuming positive clinical results from the Phase 3 trials, the Company plans to submit a New Drug Application for CTx-1301 in mid-2024 under Section 505(b)(2) pathway.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated May 3, 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: May 3, 2023

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

Exhibit 99.1

Cingulate Announces Successful Transfer of CTx-1301 (dexmethylphenidate) Proprietary PTR™ Manufacturing Processes to Societal CDMO

Scalable Supply of CTx-1301 Ready to be Produced with Cingulate on Track to Meet Previously Announced Clinical Timelines for Phase 3 Trial Program

KANSAS CITY, KANSAS – May 03, 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 the successful completion of the manufacturing transfer of its lead candidate, CTx-1301 (dexmethylphenidate), to Societal CDMO, Inc. (NASDAQ: SCTL), a bi-coastal contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development.

Cingulate announced in October 2022 the execution of a Master Services Agreement (MSA) with Societal CDMO to manufacture all clinical, registration and commercial batches of Cingulate's lead candidate, CTx-1301, a novel, investigational treatment being developed as a true, once-daily stimulant medication for attention deficit/hyperactivity disorder (ADHD).

"Stimulants have been used in clinical practice for over 50 years, and subsequent formulations have grown in complexity as companies tried to extend the efficacy of these compounds," said Shane J Schaffer, Chairman and CEO, Cingulate. "With our proprietary Precision Timed Release technology, CTx-1301 is designed to deliver dexmethylphenidate at three precise, pre-defined times throughout the day and stands to provide patients with efficacy through the entire active day – unlike traditionally formulated, extended-release therapies on the market today. Cingulate is pleased to announce that with the successful transfer of CTx-1301 manufacturing processes to Societal CDMO, we are now ready to produce the tablet supply needed for our ongoing and upcoming pivotal Phase 3 studies."

As outlined in the terms of the MSA, Societal CDMO has successfully completed the construction of a manufacturing suite outfitted with equipment supplied by Cingulate that will accommodate the Company's proprietary manufacturing processes.

"After laying the groundwork and completing the transfer of Cingulate's proprietary manufacturing processes to our facility in Gainsville, Georgia, we're ready to produce the supply of CTx-1301 needed for the Company's Phase 3 trials and regulatory milestones," said David Enloe, CEO of Societal CDMO. "We are pleased with the progress we've made in this partnership thus far, particularly as it pertains to our ability to implement the new manufacturing approach required for Cingulate's innovative PTR platform. With the successful transfer of these manufacturing processes complete, we look forward to continuing to grow our relationship with Cingulate through its multiple upcoming clinical milestones planned for this year."

Cingulate has completed the first cohort of its Phase 3 adult onset and duration trial and has now initiated the second cohort, with results expected in the third quarter of 2023. In addition to the Phase 3 adult dose-optimization study, the Company plans to commence its pivotal Phase 3 fixed-dose pediatric and adolescent study in mid-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 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.

Although there is no single medical, physical, or genetic test for ADHD, qualified mental health care professionals and physicians can provide a diagnostic evaluation after gathering information from multiple sources, including: ADHD symptom checklists, standardized behavior rating scales, detailed histories of past and current functioning, and information obtained from family members or significant others who know the person well. Some practitioners will also conduct tests of cognitive ability and academic achievement to rule out a possible learning disability.

About CTx-1301

Cingulate's lead candidate, CTx-1301, utilizes the Company'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.

The Company has initiated the first of two Phase 3 clinical studies of CTx-1301 to support its NDA submission. The pivotal, Phase 3 fixed-dose trial in children and adolescents is scheduled to begin in mid-2023.

About Precision Timed Release™ (PTR™) Platform Technology

Cingulate is developing ADHD and anxiety disorder product candidates capable of achieving true once-daily dosing using the Company'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.

About Societal CDMO

Societal CDMO (NASDAQ: SCTL) is a bi-coastal contract development and manufacturing organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, Societal CDMO is a leading CDMO providing therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified-release dosage forms, Societal CDMO has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

Societal CDMO: Bringing Science to Society. For more information about Societal CDMO's customer solutions, visit societalcdmo.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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