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): **October 14, 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 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 October 14, 2025, Cingulate Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has accepted for review the New Drug Application ("NDA") for CTx-1301 (dexmethylphenidate), the Company's lead candidate for the treatment of attention deficit/hyperactivity ("ADHD") for children and adults. The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target action date of May 31, 2026. 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 October 14, 2025, the Company announced that the FDA has accepted for review the NDA for CTx-1301 (dexmethylphenidate), the Company's lead candidate for the treatment of ADHD for children and adults. The FDA has assigned a PDUFA target action date of May 31, 2026.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated October 14, 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: October 14, 2025

By: */s/ Jennifer L. Callahan*
Name: Jennifer L. Callahan
Title: Interim Chief Executive Officer and
Chief Financial Officer

Exhibit 99.1

FDA Accepts Cingulate's New Drug Application for CTx-1301 in Attention-Deficit/Hyperactivity Disorder (ADHD) and sets a May 31, 2026 PDUFA Date

- *Once-daily Precision Timed Release™ (PTR™) stimulant designed to deliver rapid onset of effect and entire active-day duration*
- *NDA accepted under the FDA's 505(b)(2) regulatory pathway*

KANSAS CITY, Kan., October 14, 2025 — Cingulate Inc. (NASDAQ: CING) a biopharmaceutical company developing and advancing a pipeline of next-generation pharmaceutical products utilizing its proprietary Precision Timed Release™ (PTR™) drug-delivery platform, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for CTx-1301 (dexmethylphenidate), the company's lead candidate for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children and adults. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 31, 2026. NDA acceptance signifies that the Agency has determined the submission is sufficiently complete to permit substantive review.

A Key Regulatory Milestone Under the 505(b)(2) Pathway

This marks a major regulatory inflection point for Cingulate and for the CTx-1301 program. CTx-1301 is being reviewed under the FDA's 505(b)(2) regulatory pathway, which allows sponsors to reference existing data on previously approved active ingredients while demonstrating novel clinical benefit through a differentiated delivery mechanism. For Cingulate, this pathway offers the opportunity to leverage the extensive safety and efficacy data of dexmethylphenidate—an established and well-characterized stimulant—while enabling CTx-1301 to demonstrate rapid onset of effect and entire active-day duration through its proprietary multi-core PTR™ technology.

The NDA submission follows completion of adult and pediatric Phase 3 trials, completion of all FDA-requested studies, and a positive pre-NDA meeting in April 2025 confirming adequacy of the clinical and Chemistry, Manufacturing, and Controls (CMC) data packages for review. The FDA's acceptance validates that Cingulate's application meets the Agency's standards for completeness and marks the beginning of the formal review period.

Clinical Results Support Differentiated Profile

In Phase 3 clinical trials, CTx-1301 improved ADHD signs and symptoms across multiple metrics in adult and pediatric patients (ages 6 years and older). Effect size measurements were large throughout the day, demonstrating that CTx-1301 provides a rapid onset of effect and sustained efficacy into the afternoon and evening, which may address long-standing gaps in ADHD management.

Key findings include:

- Adult dose-optimization study: Achieved clinically meaningful improvements on the Permanent Product Measure of Performance (PERMP) and Adult ADHD Investigator Symptom Rating Scale (AISRS).
- Pediatric fixed-dose study: Demonstrated dose-dependent improvements on the ADHD rating scale 5 (ADHD-RS-5), Clinical Global Impression–Improvement (CGI-I), and Clinical Global Impression–Severity (CGI-S) scales.
- Safety and tolerability: No serious treatment-emergent adverse events were reported across studies, and the tolerability profile was consistent with that of other long-acting methylphenidate products.

Management Commentary

“FDA acceptance of our NDA marks a defining milestone for Cingulate,” said Cingulate Executive Chairman Jay Roberts. “CTx-1301 was engineered to address the practical shortcomings of today’s stimulant therapies—multiple daily dosing, midday rebound, and adherence challenges—through a single, once-daily tablet. This milestone affirms the robustness of our clinical and regulatory strategy, and positions Cingulate to transition from a development-stage to a commercial-stage company in 2026, pending FDA approval of CTx-1301.”

Matt Brams, MD, Chief Medical Officer, added, “The acceptance of our NDA reflects the FDA’s recognition of the completeness of our submission and the strong body of evidence supporting CTx-1301’s efficacy, safety, and patient-centric design. Our adult and pediatric studies consistently demonstrated rapid symptom relief, sustained performance and the flexibility of dosing with or without food—attributes that we believe will resonate strongly with both physicians and patients.”

Launch Readiness

With the NDA now accepted, the FDA will conduct its full review of CTx-1301’s efficacy, safety, and overall risk–benefit profile. In parallel, Cingulate continues advancing key commercial readiness activities to ensure timely launch preparedness following potential approval. Through its exclusive manufacturing partnership with Bend Bio Sciences, Cingulate has completed process transfer and scale-up production using commercial-grade equipment, providing early validation and ensuring a reliable supply chain in preparation for launch.

On the commercial front, Cingulate’s partnership with Indegene delivers an integrated, AI-driven omnichannel platform that combines advanced analytics with targeted field engagement to optimize prescriber reach, payer access, and patient support. Early payer research indicates strong formulary receptivity for once-daily CTx-1301, underscoring the product’s alignment with key clinical and adherence priorities in ADHD care.

About Attention-Deficit/Hyperactivity Disorder (ADHD)

ADHD is a chronic neurodevelopmental disorder affecting an estimated 20 million individuals in the U.S., including approximately 8 million children and 12 million adults. The condition is characterized by inattention, hyperactivity, and impulsivity that impair academic, professional, and social functioning. Stimulant medications remain the gold-standard therapy; however, most currently available extended-release formulations require multiple doses per day and often fail to provide consistent coverage across the entire active day.

About CTx-1301

CTx-1301 (dexmethylphenidate) is a once-daily, multi-core tablet utilizing Cingulate’s proprietary Precision Timed Release™ (PTR™) platform to deliver three precisely timed releases of active medication across the day. This design aims to provide rapid onset of effect and entire active-day duration. CTx-1301 is being evaluated for the treatment of ADHD under the FDA’s 505(b)(2) pathway.

About Cingulate Inc.

Cingulate Inc. (NASDAQ: CING) is a biopharmaceutical company utilizing its proprietary Precision Timed Release™ platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve patient outcomes in conditions characterized by burdensome daily dosing and suboptimal therapeutic coverage. Cingulate’s lead candidate, CTx-1301, is in late-stage development for ADHD, with additional candidates in anxiety and other neuropsychiatric indications. Cingulate is headquartered in Kansas City, Kansas. 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, the potential approval and commercialization of CTx-1301 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 27, 2025, 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 & Media Contact

Thomas Dalton, Vice President, Corporate Communications
Cingulate Inc.
Email: tdalton@cingulate.com | Phone: (913) 942-2301