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 2, 2026**

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 June 2, 2026, Cingulate Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has issued a Complete Response Letter ("CRL") for its New Drug Application for CTx-1301 (dexmethylphenidate HCl) for the treatment of Attention Deficit/Hyperactivity Disorder ("ADHD"). A copy of the press release is attached hereto as Exhibit 99.1.

The information included in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K is not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall this Item 7.01 and Exhibit 99.1 be incorporated by reference into the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such future filing.

Item 8.01 Other Events.

On June 2, 2026, the Company announced that the FDA has issued a CRL for its New Drug Application for CTx-1301. The FDA identified specific Chemistry, Manufacturing and Controls information requests in the CRL and did not raise any current concerns regarding the clinical safety or efficacy of CTx-1301. The Company expects a prompt resubmission to FDA of the remaining requested information addressing issues raised in the CRL.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 2, 2026
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 2, 2026

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

Exhibit 99.1

Cingulate Receives Complete Response Letter from FDA for CTx-1301

No Clinical Safety or Efficacy Concerns Currently Identified
Agency Feedback Primarily Focused on CMC-Related Requests
Company Plans Prompt Response and Submission of Requested Information
Company is Well Capitalized with Nearly $30 Million Cash on Hand

KANSAS CITY, Kan., June 2, 2026 — Cingulate Inc. (NASDAQ: CING), a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform to develop a pipeline of next-generation products, today announced that the U.S. Food and Drug Administration ("FDA") has issued a Complete Response Letter for its New Drug Application ("NDA") for CTx-1301 (dexmethylphenidate HCl) for the treatment of Attention Deficit/Hyperactivity Disorder (ADHD).

The response identified specific Chemistry, Manufacturing and Controls (CMC) information requests and did not raise any current concerns regarding the clinical safety or efficacy of CTx-1301. Cingulate expects a prompt submission to FDA of the requested information addressing issues raised.

"We are encouraged that the FDA's response was limited to specific information requests related to CMC and did not currently identify any issues related to the clinical safety or efficacy of CTx-1301," said Cingulate CEO Shane J. Schaffer. "Our immediate priority is to complete the CMC work already underway with our manufacturing partner; we believe the outstanding requests will be addressed quickly as we move efficiently toward resubmission. Importantly, we have nearly $30 million in cash reserves, which we believe provides sufficient capital to address the issues raised and execute on the resubmission process and continue pre-commercial activities into 2027."

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 estimated market size of the U.S. ADHD market is approximately 100 million annual prescriptions. The condition is marked by an ongoing pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. In the U.S., over 20 million patients have been diagnosed with ADHD. Among this group, 12 million are adults and over 8 million are under the age of 17. **According to the CDC**, just 53.6 percent of all children and teens with ADHD reported they were actively treating their symptoms with medication in 2022, with 65-90 percent demonstrating clinical ADHD symptoms that persist into adulthood. Current market trends demonstrate that adult ADHD prevalence is larger and growing faster than the child and adolescent segments combined.

About CTx-1301

CTx-1301 (dexmethylphenidate HCI) 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. In October 2025, Cingulate announced that the U.S. Food and Drug Administration (FDA) had accepted for review the New Drug Application (NDA) for CTx-1301 and had assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 31, 2026. NDA acceptance signifies that the FDA has determined the submission is sufficiently complete to permit substantive review. NDA acceptance does not imply approval, nor does it guarantee any specific outcome or timing.

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. Specifically, these statements include, but are not limited to, the timing and process for regulatory approval of CTx-1301 and the potential timing of resubmission to FDA of requested information, statements regarding our expected cash runway, and anticipated addressability of FDA requests. 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 18, 2026 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.

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