

**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 14, 2026

CINGULATE INC.

(Exact name of registrant as specified in its charter)

Delaware
*(State or other jurisdiction of
incorporation)*

001-40874
*(Commission
File Number)*

86-3825535
*(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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 2.02. Results of Operations and Financial Condition.

On May 14, 2026, Cingulate Inc. issued a press release announcing its financial results for the quarter ended March 31, 2026 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 and incorporated by reference. The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed “filed” for 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, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 14, 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: May 14, 2026

By: /s/ Jennifer L. Callahan

Name: Jennifer L. Callahan

Title: Chief Financial Officer

Cingulate Inc. Reports First Quarter 2026 Financial Results and Provides an Update of Commercial Readiness Efforts On Track for lead ADHD Asset CTx-1301

Cash Position Grows to \$25.9 Million

KANSAS CITY, Kan., May 14, 2026 (GLOBE NEWSWIRE) -- 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 reported financial results for the quarter ended March 31, 2026, and provided a corporate update.

“Cingulate remains focused on disciplined execution in 2026 and we believe we are well positioned to bring our lead ADHD asset, CTx-1301, to market,” said Cingulate CEO Shane J. Schaffer. “We continue to engage constructively with the FDA on our new drug application while advancing commercial readiness and manufacturing capabilities, and believe our current resources provide an extended cash runway into 2027.”

Strengthened Balance Sheet

Cingulate enters the second quarter of 2026 with a meaningfully stronger financial position, having grown its cash and cash equivalents to \$25.9 million as of March 31, 2026 — a \$14.9 million increase from December 31, 2025 — driven by the successful close of a \$12.0 million at-the-market private placement in February 2026 alongside opportunistic usage of the Company’s at-the-market and stock purchase agreements. Working capital increased to \$17.0 million from \$1.7 million at year-end, reflecting the Company’s significantly improved liquidity. Management believes this capital base is sufficient to fund operations into 2027, supporting key value-creating milestones including the pursuit of regulatory approval and launch readiness for CTx-1301.

Regulatory Update

Cingulate is actively collaborating with the FDA to provide responses to information requests related to the manufacturing and CMC elements of its CTx-1301 NDA. The Company remains committed to working efficiently with the Agency and will provide updates as the review process progresses.

Commercial Readiness Update

Cingulate continues to advance its commercialization preparations, with dedicated teams established across all key functional areas. The Company’s launch strategy leverages a commercialization strategy augmented by AI-driven tools designed to optimize targeting, decision-making, and performance measurement — positioning Cingulate for a rapid commercial launch contingent upon FDA approval. Key areas of focus include:

- **Market Access and Payer Engagement:** Advancing payer strategy and reimbursement frameworks
 - **Distribution and Supply Chain:** Preparing distribution infrastructure and supply chain capabilities
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- **Omnichannel Infrastructure:** Deploying a comprehensive AI-augmented marketing technology to support targeting and performance optimization across channels
- **Commercial Manufacturing:** Scaling manufacturing operations and advancing process validation batch preparation for CTx-1301, which will serve as launch inventory if approved
- **Field Force Optimization:** Building out Cingulate’s sales team through an agreement with IQVIA Inc. for deployment upon potential FDA approval

First Quarter Results

Cash and Working Capital: As of March 31, 2026, Cingulate had approximately \$25.9 million in cash and cash equivalents, a \$14.9 million increase from December 31, 2025. The increase in cash was primarily driven by capital raised in the first quarter, including the close of a \$12.0 million private placement. As of March 31, 2026, Cingulate had approximately \$17.0 million in working capital, an increase of \$15.3 million as compared to \$1.7 million as of December 31, 2025.

R&D Expenses: R&D expenses were \$2.2 million for the three months ended March 31, 2026, a decrease of 1.8% from the three months ended March 31, 2025. The decrease is the result of lower clinical operations costs as clinical study activities concluded in early 2025, offset by an increase in regulatory and manufacturing activities in the first quarter of 2026 relating to the NDA review of CTx-1301.

G&A Expenses: General and administrative expenses were \$5.7 million for the three months ended March 31, 2026 compared to \$1.5 million for the same period in 2025. This increase is primarily the result of costs incurred relating to the build-out of the commercial infrastructure for the launch of CTx-1301, pending FDA approval, including increased headcount.

Net Loss: Net loss was \$9.3 million for the three months ended March 31, 2026, compared to \$3.9 million for the three months ended March 31, 2025. The increase in the net loss primarily relates to increased G&A expenses as described above as well as the change in fair value of derivative and interest on our notes payable.

Cingulate Inc. Consolidated Balance Sheet Data

	March 31, 2026	December 31, 2025
Cash and cash equivalents	\$ 25,893,210	\$ 10,953,383
Total assets	\$ 30,861,701	\$ 15,073,263
Total liabilities	\$ 11,996,835	\$ 12,564,356
Working Capital	\$ 16,952,085	\$ 1,695,633
Accumulated deficit	\$ (141,687,120)	\$ (132,375,031)
Total stockholders’ equity	\$ 18,864,866	\$ 2,508,907

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	\$ 2,184,318	\$ 2,222,626
General and administrative	5,738,904	1,483,409
Operating loss	(7,923,222)	(3,706,035)
Change in fair value of derivative	(852,030)	(49,987)
Interest and other income (expense), net	(536,837)	(96,656)
Loss before income taxes	(9,312,089)	(3,852,678)
Income tax benefit (expense)	-	-
Net loss	<u>(9,312,089)</u>	<u>(3,852,678)</u>

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 US 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 (dexamethylphenidate HCl) 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](https://www.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 commercialization of CTx-1301, if approved, our progress with commercial readiness and manufacturing scale-up activities, statements regarding our expected cash runway, and anticipated capital needs and financing plans. 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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