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):
August 13, 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 2.02. Results of Operations and Financial Condition.

On August 13, 2026, Cingulate Inc. issued a press release announcing its financial results for the quarter ended June 30, 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

Exhibit No.	Description
99.1	Press Release dated August 13, 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: August 13, 2026

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

Exhibit 99.1

Cingulate Inc. Reports Second Quarter 2026 Financial Results and Provides Update on CTx-1301 CMC Progress Towards NDA Resubmission and Commercial Readiness

Cash and Cash Equivalents of $28.4 Million as of June 30, 2026 Providing Runway Through Mid-2027; Company Advances Chemistry, Manufacturing and Controls (CMC) Work Toward NDA Resubmission

KANSAS CITY, Kan., August 13, 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 June 30, 2026, and provided a corporate update.

"While the regulatory process continues, our priorities remain clear: complete the remaining manufacturing work, submit a comprehensive response to the FDA, and continue preparing the organization for commercialization," said Cingulate Chairman and CEO Shane J. Schaffer. "We believe CTx-1301 has the potential to address a significant unmet need in ADHD treatment, and we remain committed to bringing this innovative therapy to patients as quickly as possible, pending FDA approval."

Regulatory Update: CTx-1301 NDA Resubmission Progress

Cingulate continues to make progress on the CMC work needed to support resubmission of the NDA for CTx-1301 (dexmethylphenidate HCl), its lead ADHD asset. The Company is working closely with its manufacturing partner to complete this work and plans to resubmit the NDA to the FDA as promptly as practicable.

This work follows a Complete Response Letter issued by the FDA on June 1, 2026, which identified specific requests for additional CMC information and did not identify any concerns regarding the clinical safety or efficacy of CTx-1301.

Intellectual Property Update

On June 16, 2026, the U.S. Patent and Trademark Office issued U.S. Patent No. 12,653,791 covering CTx-1301, following a Notice of Allowance issued on March 17, 2026. The patent, titled "Trimodal, Precision-Timed Pulsatile Release Tablet," includes composition-of-matter, formulation, structural and method-of-treatment claims and protects key aspects of CTx-1301's formulation and method of use through December 2042. This is the first U.S. patent wholly owned by Cingulate covering CTx-1301, further strengthening the Company's intellectual property portfolio surrounding its PTR platform.

Commercial Readiness Update

Cingulate continues to advance commercialization preparations for CTx-1301, contingent upon FDA approval. Current activity is concentrated on market access, payer readiness and manufacturing, the workstreams that must be advanced furthest ahead of any launch. Key areas of focus include:

- Commercial Manufacturing: Working with Bend Bioscience, the Company's contract development and manufacturing organization, to complete the requested CMC work and advance process validation for CTx-1301, which would serve as launch inventory if approved.

- Product Distribution: On July 21, 2026, the Company signed an exclusive services agreement with Prasco, LLC to establish the commercial distribution infrastructure for the launch of CTx-1301, providing integrated third-party logistics and distribution capabilities designed to support broad national availability across major wholesalers as well as direct distribution to approximately 19,000 independent and smaller regional pharmacy accounts served under Prasco's UNLIMIT program.

- Market Access and Payer Strategy: Advancing payer segmentation, value proposition, pricing and contracting strategy, and to support formulary positioning ahead of a potential launch.

- Commercial Operations and Omnichannel Infrastructure: Building marketing, commercial operations and digital capabilities through the Company's master services agreement with Indegene, Inc., including dedicated market access, medical education, agency of record, and prescriber and patient marketing teams.

- Field Deployment Planning: Under its agreement with IQVIA Inc., the Company will deploy field-based sales representatives in addition to its currently deployed corporate account directors to align with the timing of a potential approval and launch.

Second Quarter and First Half 2026 Financial Results

Cash and Working Capital: As of June 30, 2026, Cingulate had approximately $28.4 million in cash and cash equivalents, compared to $11.0 million as of December 31, 2025. The increase was primarily driven by capital raised in the first and second quarters, including the close of a $12.0 million private placement in the first quarter and $19.0 million of capital raised on Cingulate's At-the-Market Agreement with AGP and Purchase Agreement with Lincoln Park Capital, offset by $12.8 million in cash used for operations. Cingulate had approximately $21.6 million in working capital as of June 30, 2026, an increase of $19.9 million as compared to December 31, 2025.

Under its current business plan, the Company believes its cash and cash equivalents will be sufficient to fund operations into mid-2027, including costs associated with completing the requested CMC work, seeking regulatory approval for CTx-1301, and continuing the build-out of commercial readiness capabilities.

R&D Expenses: Research and development (R&D) expenses were $1.5 million for the three months ended June 30, 2026, a decrease of 44.9% from $2.7 million for the three months ended June 30, 2025, driven primarily by lower clinical operations costs following the conclusion of clinical study activities in early 2025 and the absence of the increased regulatory costs incurred in the prior-year period in connection with preparing the CTx-1301 NDA. For the six months ended June 30, 2026, R&D expenses were $3.7 million, a decrease of 25.4% from $5.0 million for the six months ended June 30, 2025, partially offset by increased manufacturing activities and personnel costs in the first half of 2026.

SG&A Expenses: Selling**,** general and administrative (SG&A) expenses were $3.9 million for the three months ended June 30, 2026, compared to $1.9 million for the three months ended June 30, 2025, an increase of 101.5%. For the six months ended June 30, 2026, SG&A expenses were $9.7 million, compared to $3.4 million for the six months ended June 30, 2025, an increase of 181.7%. The increases were driven primarily by the build-out of commercial readiness capabilities, including increased headcount and expanded market access, pricing, reimbursement and medical affairs activity conducted through Indegene, the Company's commercialization partner.

Net Loss: Net loss was $5.9 million for the three months ended June 30, 2026, compared to $5.0 million for the three months ended June 30, 2025. For the six months ended June 30, 2026, net loss was $15.2 million, compared to $8.8 million for the six months ended June 30, 2025, primarily reflecting the increase in SG&A expenses described above.

Cingulate Inc.
Consolidated Balance Sheet Data

	June 30, 2026	December 31, 2025
Cash and cash equivalents	$ 28,402,819	$ 10,953,383
Total assets	$ 33,066,321	$ 15,073,263
Total liabilities	$ 9,599,286	$ 12,564,356
Working Capital	$ 21,577,149	$ 1,695,633
Accumulated deficit	$ (147,557,384)	$ (132,375,031)
Total stockholders' equity	$ 23,467,035	$ 2,508,907

Cingulate Inc.
Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 1,486,825	$ 2,700,939	$ 3,671,143	$ 4,923,565
Selling, general and administrative	3,928,150	1,949,035	9,667,054	3,432,444
Operating loss	**(5,414,975)**	**(4,649,974)**	**(13,338,197)**	**(8,356,009)**
Change in fair value of derivative	(314,013)	(194,526)	(1,166,043)	(244,513)
Interest and other income (expense), net	(141,276)	(138,761)	(678,113)	(235,417)
Loss before income taxes	(5,870,264)	(4,983,261)	(15,182,353)	(8,835,939)
Income tax benefit (expense)	-	-	-	-
Net loss	(5,870,264)	(4,983,261)	(15,182,353)	(8,835,939)

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 (dexmethylphenidate 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, the FDA accepted for review the NDA for CTx-1301 and assigned a PDUFA target action date of May 31, 2026. On June 1, 2026, the FDA issued a Complete Response Letter for the CTx-1301 NDA; the Company is working to complete the requested CMC work and plans to resubmit the NDA as promptly as practicable. There can be no assurance regarding the timing of any resubmission or whether approval will occur.

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.

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, the timing and outcome of any resubmission of the CTx-1301 NDA, market opportunity, competitive position, business strategies, potential growth opportunities, 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, our Quarterly Report on Form 10-Q for the period ended June 30, 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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