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): **November 10, 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 November 10, 2026, Cingulate Inc. (Company) issued a press release announcing that its Chairman and CEO, Shane J. Schaffer, in an interview on *Innovators with Jane King* discusses the Company's ongoing efforts to address the U.S. Food and Drug Administration's (FDA) Complete Response Letter (CRL) regarding the CTx-1301 new drug application (NDA), progress made to date, and the anticipated timeline for NDA resubmission. 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.

In October 2025, we announced that the FDA accepted for review our NDA for CTx-1301 and assigned a Prescription Drug User Fee Act (PDUFA) targeted action date of May 31, 2026. On June 1, 2026, we received a CRL from the FDA regarding the NDA for CTx-1301. The CRL identified specific requests for additional chemistry, manufacturing and controls (CMC) information and did not raise any concerns regarding the clinical safety or efficacy of CTx-1301. We and our contract drug manufacturing organization have substantially completed the manufacturing work required to address the CMC requests in the CRL and are finalizing the supporting data and documentation for a resubmission of the NDA, which we currently expect to submit between December 2026 and January 2027. Upon receipt of a resubmission, the FDA is expected to classify it as either a Class 1 or a Class 2 resubmission, carrying review goals of two months and six months, respectively. Subject to receipt of FDA approval, we currently expect that the commercial launch of CTx-1301 could commence in the third quarter of 2027, although there can be no assurance regarding the timing or occurrence of any such commercial launch. Moreover, there can be no assurance that we will resubmit the NDA within the expected timeframe or at all, how the FDA will classify any resubmission, that any resubmission will be accepted by the FDA, that approval of CTx-1301 will occur following any resubmission, or that approval will occur at all.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 10, 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: November 10, 2026

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

Exhibit 99.1

Shane Schaffer, Cingulate Chairman and CEO, Provides Update on CTx-1301 in Interview with *Innovators with Jane King*

KANSAS CITY, Kan., November 10, 2026, — Cingulate Inc. (NASDAQ: CING), a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform to develop next-generation pharmaceutical products, announced today that Chairman and CEO Shane J. Schaffer has provided an update on the regulatory progress of CTx-1301(dexmethylphenidate HCl), the company's lead asset for the treatment of attention deficit/hyperactivity disorder (ADHD).

In an interview airing this morning on *Innovators with Jane King*, Dr. Schaffer discusses the company's ongoing efforts to address the FDA's Complete Response regarding the CTx-1301 New Drug Application (NDA), progress made to date, and the anticipated timeline for NDA resubmission.

"We recognize that our shareholders have been waiting patiently for a meaningful update on CTx-1301, and we sincerely thank them for their continued support, confidence, and commitment to Cingulate as we complete the work addressing the items in the FDA's Complete Response."

Innovators with Jane King

Watch Dr. Schaffer's full interview:

Innovators with Jane King

In addition to discussing the anticipated NDA resubmission, Dr. Schaffer provides insight into Cingulate's commercialization preparations and highlights recent presentations he and Chief Commercial Officer Bryan Downey delivered at the Indegene Digital Summit, addressing evolving strategies for pharmaceutical commercialization and successful product launches.

Indegene Digital Summit

Watch full-length discussions featuring Cingulate Chairman and CEO Shane J. Schaffer and Chief Commercial Officer Bryan Downey discussing commercialization at the Indegene Digital Summit:

Chairman & CEO Shane Schaffer presents the "Smart Launch" Approach

Chief Commercial Officer Bryan Downey discusses "Reinventing the Launch Playbook"

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 and 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.

Investors & Media:

Thomas Dalton
Vice President, Corporate and Government Relations, Cingulate
tdalton@cingulate.com
(480) 529-5434