

**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):
December 26, 2023

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:

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 one share of 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing

On December 26, 2023, Cingulate Inc. (the “Company,” “we” or “us”) received a letter from the Listing Qualifications Staff (the “Staff”) of The Nasdaq Stock Market LLC (“Nasdaq”) indicating that, based upon the resignation of three members of our Board of Directors on December 12, 2023 and December 13, 2023, we no longer comply with Nasdaq’s independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605 (the “Independent Director Rule”). The Staff indicated that this non-compliance serves as additional and separate bases for desilting of our securities from Nasdaq.

As previously disclosed, on November 14, 2023, we received a letter from Nasdaq indicating that, based upon our continued non-compliance the minimum stockholders’ equity requirement in Listing Rule 5550(b)(1) (the “Minimum Stockholders’ Equity Rule”) for continued listing on Nasdaq, the Staff had determined to delist our securities from Nasdaq. We timely requested a hearing before the Nasdaq Hearings Panel (the “Panel”) and Nasdaq granted our request.

At the Panel hearing, which is expected to take place in February 2024, we will submit our plan to regain compliance, as well as our ability to sustain long-term compliance, with all applicable requirements for continued listing on Nasdaq, including compliance with the Minimum Stockholders’ Equity Rule and the Independent Director Rule.

The delisting action by the Staff will be stayed pending the Panel hearing and the expiration of any additional extension period granted by the Panel following the hearing. We intend to continue to take definitive steps in an effort to evidence compliance with the Minimum Stockholders’ Equity Rule, the Independent Director Rule and other Nasdaq listing requirements; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the Minimum Stockholders’ Equity Rule, the Independent Director Rule and other Nasdaq listing requirements within any extension period that may be granted by the Panel.

Item 8.01. Other Events

Clinical, Manufacturing and Business Update

CTx-1301: We received guidance from the U.S. Food and Drug Administration (FDA) regarding its clinical program for CTx-1301 (dexmethylphenidate), its lead investigational product candidate for the treatment of ADHD. Based on this guidance, we expect to submit the NDA for CTx-1301 in the first half of 2025 under the Section 505(b)(2) pathway with Focalin® XR as the reference listed drug, using its efficacy and safety data on file with the FDA as a basis for approval, together with bioavailability/bioequivalence data and efficacy/safety data from our CTx-1301 clinical program.

Accordingly, we have stopped enrollment in the pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study that commenced in late July 2023 and the Phase 3 pediatric dose-optimization onset and duration study that commenced in early August 2023. All enrolled patients in these studies can complete the study and data will be reported accordingly. Furthermore, Cingulate will update the CTx-1301 initial Pediatric Study Plan (iPSP). Prior to filing the NDA for CTx-1301, we will manufacture registration batches and generate required stability data.

In order to achieve the filing of our NDA for CTx-1301 for potential FDA approval, we believe that we will need approximately \$17-21 million of capital. This capital requirement is approximately \$9-13 million less than initially anticipated. We would also need additional capital to accelerate the development of other assets and commercialization efforts. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval for CTx-1301. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. We have limited cash resources and need to raise this capital through public or private debt or equity financings (including pursuant to the At The Market Offering Agreement dated January 3, 2023) or strategic transactions to license our product candidates.

CTx-1302: We plan to initiate its clinical plan for CTx-1302 (dextroamphetamine), our second investigational asset for the treatment of ADHD, as soon as 2025 pending additional capital resources.

CTx-2103: We are in active license conversations and pending a definitive agreement, development of CTx-2103 (buspirone) for the treatment of anxiety may begin as soon as 2025 pending additional capital resources.

Risk Factors

We are including the below update to our risk factors, for the purpose of supplementing and updating the disclosure contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 10, 2023 and our Quarterly Reports on Form 10-Q for the periods ended June 30, 2023 and September 30, 2023, filed with the SEC on August 14, 2023 and November 13, 2023, respectively.

If we fail to regain compliance with the continued listing requirements of Nasdaq, our common stock and/or warrants may be delisted and the price of our common stock and/or warrants and our ability to access the capital markets could be negatively impacted.

Our common stock and warrants are currently listed for trading on Nasdaq. On May 16, 2023, we received a notice from Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") stating that we no longer comply with the minimum stockholders' equity requirement of \$2.5 million under Nasdaq Listing Rule 5550(b)(1) (the "Minimum Stockholders' Equity Rule") for continued listing. We submitted a plan of compliance to Nasdaq on June 30, 2023. On July 28, 2023, Nasdaq notified us that that it granted an extension until November 13, 2023 to regain compliance with the Minimum Stockholders' Equity Rule, conditioned upon achievement of certain milestones included in the plan of compliance previously submitted to Nasdaq, including a plan to raise additional capital. On November 14, 2023, we received a letter from Nasdaq indicating that, based upon the Company's continued non-compliance with the Minimum Stockholders' Equity Rule, the Staff had determined to delist the Company's securities from Nasdaq.

We timely requested a hearing before the Nasdaq Hearings Panel (the "Panel") and Nasdaq granted our request. At the Panel hearing, which is expected to take place in February 2024, we will submit our plan to regain compliance, as well as our ability to sustain long-term compliance, with all applicable requirements for continued listing on Nasdaq, including compliance with the Minimum Stockholders' Equity Rule and the Independent Director Rule (defined below). The delisting action by the Staff will be stayed pending the hearing and the expiration of any additional extension period granted by the Panel following the Panel hearing. We intend to continue to take definitive steps in an effort to evidence compliance with the Minimum Stockholders' Equity Rule, the Independent Director Rule and other Nasdaq listing requirements; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the Minimum Stockholders' Equity Rule, the Independent Director Rule and other Nasdaq listing requirements within any extension period that may be granted by the Panel. Based on our current operating plan, we believe that we need to raise approximately \$15 million of additional capital by March 31, 2024 to comply with the Minimum Stockholders' Equity Rule as of that date.

On July 28, 2023, we received notice from Nasdaq indicating that we were not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on Nasdaq. We were provided a compliance period of 180 calendar days from the date of the notice, or until January 24, 2024, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On November 30, 2023, we effected a reverse stock split of our common stock, and on December 15, 2023, we received notice from Nasdaq that we have regained compliance with minimum closing bid price requirement. There can be no assurance that we will continue to maintain compliance with the minimum closing bid price requirement or the other Nasdaq listing requirements.

On December 26, 2023, we received a letter from the Staff indicating that, based upon the resignation of three members of our Board of Directors on December 12, 2023 and December 13, 2023, we no longer comply with the independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605 (the “Independent Director Rule”). Our Board of Directors currently consists of two directors, neither of whom are independent.

We are in the process of identifying potential new directors and intend to show progress in complying with the Independent Director Rule prior to the Panel hearing. There can be no assurance that we will regain compliance with the Independent Director Rule.

We must satisfy Nasdaq’s continued listing requirements, including, among other things, the Minimum Stockholders’ Equity Rule and the Independent Director Rule or risk delisting, which could have a material adverse effect on our business. If our common stock and warrants are delisted from Nasdaq, it could materially reduce the liquidity of our common stock and warrants and result in a corresponding material reduction in the price of our common stock and warrants as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. If our common stock and warrants are delisted, it could be more difficult to buy or sell our common stock and warrants or to obtain accurate quotations, and the price of our common stock and warrants could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

Forward-Looking Statements

This Current Report on Form 8-K 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 our ability to comply with the listing requirements of Nasdaq, development, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities 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 SEC, including the “Risk Factors” section of our Annual Report on Form 10-K filed with the SEC on March 10, 2023 and our Quarterly Reports on Form 10-Q filed with the SEC on August 14, 2023 and November 13, 2023. 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.

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: December 28, 2023

By: /s/ Shane J. Schaffer

Name: Shane J. Schaffer

Title: Chief Executive Officer
