

**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):
February 12, 2024

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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Effective February 12, 2024, the Board of Directors (the “Board”) of Cingulate Inc. (the “Company”) fixed the number of directors constituting the Board at five directors and appointed: Bryan Lawrence, 58, as a Class III director to serve until the Company’s 2024 annual meeting of stockholders, and each of Jeffrey S. Ervin, 46, and John A. Roberts, 65, as a Class II director to serve until the Company’s 2026 annual meeting of stockholders.

Mr. Lawrence has been an entrepreneur and philanthropist since October 2007. Mr. Lawrence has previously held positions at Xcenda, a division of AmerisourceBergen, Johnson & Johnson Health Care Systems, Janssen Pharmaceutica and Sandoz Pharmaceuticals Corporation. Mr. Lawrence also has experience in healthcare consulting and has held roles at Navigant Consulting and Applied Health Outcome. Mr. Lawrence is currently a member of the University of Kansas School of Pharmacy Advisory Council. He did a two-year Pharmacoeconomics Fellowship from Glaxo Inc. and the University of South Carolina. Mr. Lawrence earned a Doctor of Pharmacy from University of Kansas School of Pharmacy and a Master of Business Administration from the Wharton School at the University of Pennsylvania.

Mr. Ervin co-founded IMAC Holdings, Inc. (NASDAQ: BACK), a provider of medical care, in March 2015, and currently serves as its Chief Executive Officer and a member of its board of directors. From October 2011 to January 2015, Mr. Ervin joined Medicare.com parent and its parent, Medx Publishing as a senior financial officer tasked with building administrative functions to satisfy rapid growth in the CMS education sector. Prior to that, Mr. Ervin was the Senior Financial Analyst and Vice President of Finance for the Baptist Hospital System of Nashville from June 2005 to October 2011, responsible for sourcing and managing direct investments to satisfy pension obligations. Mr. Ervin earned his Master of Business Administration from Vanderbilt University and his Bachelor of Science in Finance from Miami University.

Mr. Roberts is currently serving as a Venture Partner for DigiLife Fund II, a position he has held since September 2023. From April 2018 to February 2023, he served as Chief Executive Officer and President of Vyant Bio, Inc., a biotechnology company formerly listed on Nasdaq. Prior to that, Mr. Roberts had been the interim Chief Executive Officer of Vyant Bio, Inc. since February 2018. Mr. Roberts had previously served as Vyant Bio, Inc.’s Chief Operating Officer since July 2016. From July 2015 to June 2016, Mr. Roberts served as the Chief Financial Officer for VirMedica, Inc., a company that provides an end-to-end platform that enables specialty drug manufacturers and pharmacies to optimize product commercialization and management. Prior to VirMedica, from August 2011 to July 2015, Mr. Roberts was the Chief Financial and Administrative Officer for AdvantEdge Healthcare Solutions, a global healthcare analytics and services organization. Prior to that, Mr. Roberts was the Chief Financial Officer and Treasurer for InfoLogix, Inc., a publicly-traded healthcare-centric mobile software and solutions provider. He has also held CFO roles at leading public medical device and healthcare services firms including Clariant, Inc., a publicly-traded provider of diagnostic laboratory services and Daou Systems, Inc., a publicly-traded healthcare IT software development and services firm. In addition, he has held senior executive roles with MEDdecision, Inc., HealthOnline, Inc. and the Center for Health Information. Mr. Roberts currently serves on the board of directors of Vyant Bio, Inc., Caidya, Inc., a global, multi-therapeutic clinical research organization, Navipoint Health, Inc., a biotechnology company, VeriSkin, Inc., a medical device company, and Cohere-Med Inc., a clinical analytics company. He also is a member of the Fellows of the Drug Information Association, a global neutral forum enabling drug developers and regulators access to education and collaboration. Mr. Roberts earned a Bachelor of Science and a master’s degree in business administration from the University of Maine.

The Board has affirmatively determined that each of Messrs. Lawrence, Ervin and Roberts (the “new directors”) (i) is independent under the rules of The Nasdaq Stock Market LLC (“Nasdaq”) and (ii) meets the heightened standards of independence for compensation and audit committee membership under the applicable rules of the U.S. Securities and Exchange Commission (“SEC”) and Nasdaq. The Board has determined that Mr. Roberts qualifies as an “audit committee financial expert” under the criteria set forth in Item 407(d)(5) of Regulation S-K.

The Board appointed each of the new directors to serve on the Audit Committee, the Compensation Committee and the Nominating and Corporate Governance Committee of the Board.

The new directors will be compensated in accordance with the Company’s standard non-employee director compensation plan. In addition, the Company intends to enter into an indemnification agreement with each of the new directors in substantially the form filed as Exhibit 10.10 to the Company’s Registration Statement on Form S-1 filed with the SEC on September 9, 2021.

There is no arrangement or understanding between any of the new directors and any other person pursuant to which any of the new directors was appointed as a director of the Company and there are no familial relationships between any of the new directors and any of the Company's directors or executive officers. There are no transactions to which the Company is a party and in which any of the new directors has a direct or indirect material interest that would be required to be disclosed under Item 404(a) of Regulation S-K.

Item 7.01. Regulation FD Disclosure.

On February 13, 2024, the Company issued a press release announcing the appointment of the new directors. A copy of the press release is furnished as Exhibit 99.1 hereto and shall not be deemed "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, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

As previously reported, on May 16, 2023, the Company received a notice from the Listing Qualifications Staff (the "Staff") of Nasdaq stating that the Company no longer complies with the minimum stockholders' equity requirement of \$2.5 million under the Nasdaq Stock Market Listing Rule 5550(b)(1) (the "Minimum Stockholders' Equity Rule") for continued listing. The Company submitted a plan of compliance to Nasdaq on June 30, 2023. On July 28, 2023, Nasdaq notified the Company 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, the Company 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, subject to the Company's request for a hearing before the Nasdaq Hearings Panel (the "Panel"). We timely requested a hearing before Panel and Nasdaq granted our request, which had the effect of staying all suspension and delisting action pending the conclusion of the hearings process.

As a result of the Company's previously disclosed public offering that closed on February 6, 2024, as of the date of this Current Report on Form 8-K, the Company believes it has stockholders' equity above \$2.5 million.

As previously reported, on December 26, 2023, the Company received a letter from the Staff indicating that, based upon the resignation of three members of the Board on December 12, 2023 and December 13, 2023, the Company no longer complied with the independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605. As a result of the appointment of the new directors described above, we believe we are in compliance with Nasdaq's board composition requirements.

Until Nasdaq has reached a final determination that we have regained compliance with all of the applicable continued listing requirements, including the Minimum Stockholders' Equity Rule and the board composition requirements, there can be no assurances regarding the continued listing of our common stock on Nasdaq and we could be subject to delisting.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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99.1	Press Release dated February 13, 2024
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104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
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SIGNATURES

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: February 13, 2024

By: /s/ Shane J. Schaffer

Name: Shane J. Schaffer

Title: Chief Executive Officer

Cingulate Appoints Jay Roberts, Bryan Lawrence, and Jeff Ervin to its Board of Directors

Announcement Follows Recent Public Offering and Successful Capital Raising Activity

KANSAS CITY, Kan., February 13 2024 — **Cingulate Inc. (NASDAQ: CING)**, a biopharmaceutical company utilizing its proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products, announced today that it has appointed three new directors to its board: Jay Roberts, Bryan Lawrence, and Jeff Ervin.

The appointment of the new directors follows the completion of the Company's recent follow-on offering of \$7.5 million in February 2024, sales under the Company's at-the-market offering (ATM) facility in January 2024 of \$3.2 million, as well as the conversion of \$3.3 million of outstanding debt into equity at a 10 percent premium to market.

"We always look forward to adding directors who complement our management team, mission and overall vision, and we are pleased to welcome Jay, Bryan and Jeff to our board," said Cingulate Chairman and CEO Shane J. Schaffer. "We believe their collective experience in business, public markets, finance, healthcare and pharmaceuticals will be instrumental to the Company as we move forward with our clinical trials and business opportunities."

About the Directors**Jay Roberts**

Jay Roberts has been a senior strategic executive in the healthcare industry for over 30 years. He is serving as a Venture Partner for DigiLife Fund II, leading fundraising, due diligence, and investment decisions along with members of the DigiLife team and syndicate investment funds. He currently serves as a member of the Board of Directors for Caidya, Inc.; Veriskin, Inc.; NaviPoint Health, Inc.; Vyant Bio, Inc. and is a member of the Fellows of DIA.

Jay has held CEO, COO, and CFO positions for publicly traded and venture and private equity backed healthcare technology, diagnostics, software solutions and manufacturing companies throughout a successful industry career.

Bryan Lawrence

Bryan Lawrence has nearly 25 years of experience in the pharmaceutical and healthcare industries, serving in a variety of research-based capacities in Pharmacoeconomics and Managed Care Outcomes Research departments at Novartis (formerly Sandoz) and Janssen Pharmaceutica (J&J), as well as some diverse commercial roles.

Bryan served as Director, Managed Care Marketing, and was a member of the Aciphex® Launch Team at Janssen. He was also responsible for contracting efforts with United Healthcare for nine Johnson & Johnson operating companies as a Corporate Account Director at Johnson & Johnson Health Care Systems.

Dr. Lawrence has significant experience in healthcare consulting and has held roles at Navigant Consulting and Applied Health Outcomes, and was one of four owners/partners who rebranded Applied Health Outcomes as Xcenda, a diverse consulting company that worked with pharmaceutical industry clients. Dr. Lawrence was serving as Xcenda's Vice President, Marketing and Business Development, when Xcenda was acquired by AmerisourceBergen Corporation.

Bryan holds a Doctor of Pharmacy degree from the University of Kansas, a two-year Pharmacoeconomics Fellowship from Glaxo Inc. and the University of South Carolina, and an MBA from the Wharton School at the University of Pennsylvania. He is also a member of the University of Kansas School of Pharmacy Advisory Council.

Jeff Ervin

Jeff Ervin has more than 20 years of experience as an executive and investor in high growth businesses. Mr. Ervin has held the position of Chairman and CEO of IMAC Holdings (NASDAQ: BACK) since 2015.

Prior to IMAC, Mr. Ervin served as senior financial officer for Medicare.com and its parent company Medx Publishing. He launched his post-MBA career as Senior Financial Analyst for the Baptist Hospital System of Nashville where he was responsible for evaluating direct equity placement and managing portfolio investments in healthcare.

Mr. Ervin holds an MBA from the Owen School of Management at Vanderbilt University and a Bachelor of Science in Finance from Miami University.

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 condition is marked by an ongoing pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development. In the U.S., approximately 6.4 million children and adolescents (11 percent) aged under the age of 18 have been diagnosed with ADHD. Among this group, approximately 80 percent receive treatment, with 65-90 percent demonstrating clinical ADHD symptoms that persist into adulthood. Adult ADHD prevalence is estimated at approximately 11 million patients (4.4 percent), almost double the size of the child and adolescent segment combined, however, only an estimated 20 percent receive treatment.

About CTx-1301

Cingulate's lead candidate, CTx-1301, utilizes Cingulate's proprietary PTR drug delivery platform to create a breakthrough, multi-core formulation of the active pharmaceutical ingredient dexamethylphenidate, a compound approved by the FDA for the treatment of ADHD. Dexamethylphenidate is part of the stimulant class of medicines and increases norepinephrine and dopamine activity in the brain to affect attention and behavior.

While stimulants are the gold-standard of ADHD treatment due to their efficacy and safety, the long-standing challenge continues to be providing patients entire active-day duration of action. CTx-1301 is designed to precisely deliver three releases of medication at the predefined time, ratio, and style of release to optimize patient care in one tablet. The result is a rapid onset and entire active-day efficacy, with the third dose being released around the time when other extended-release stimulant products begin to wear off.

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. 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 10, 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.

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