

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended **March 31, 2024**

or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: **001-40874**

**Cingulate Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**1901 W. 47<sup>th</sup> Place**  
**Kansas City, KS**  
(Address of principal executive offices)

**86-3825535**  
(I.R.S. Employer  
Identification No.)

**66205**  
(Zip Code)

**(913) 942-2300**

(Registrant's telephone number, including area code)

**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 one share of common stock	CINGW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of May 3, 2024, 6,046,479 shares of the registrant's common stock, \$0.0001 par value, were issued and outstanding.

Cingulate Inc.  
Form 10-Q for the Quarter Ended March 31, 2024

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## CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This report 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, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this report with the Securities and Exchange Commission (the “SEC”) and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our ability to regain and maintain compliance with the continued listing requirements of The Nasdaq Stock Market LLC (“Nasdaq”);
- our lack of operating history and need for additional capital;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for CTx-1301, CTx-1302, and CTx-2103;
- the timing of our New Drug Application (“NDA”) submissions for CTx-1301, CTx-1302, and CTx-2103;
- the timing of and our ability to obtain and maintain regulatory approvals for CTx-1301, CTx-1302, CTx-2103, or any other future product candidate;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to identify strategic partnerships;
- our expected use of cash;
- our competitive position and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”);
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives;
- the identified material weaknesses in our internal control over financial reporting; and
- our estimates regarding future revenue and expenses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the “Risk Factors” section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on April 1, 2024, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

**Cingulate Inc.**  
**Consolidated Balance Sheets (unaudited)**

	<u>March 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,113,830	\$ 52,416
Miscellaneous receivables	2,247	14,622
Prepaid expenses and other current assets	1,610,765	511,556
<b>Total current assets</b>	<u>2,726,842</u>	<u>578,594</u>
Property and equipment, net	2,463,874	2,545,965
Operating lease right-of-use assets	303,799	366,877
<b>Total assets</b>	<u><u>5,494,515</u></u>	<u><u>3,491,436</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	737,949	5,199,105
Accrued expenses	1,117,638	1,651,519
Note payable	-	3,000,000
Finance lease liability, current	17,326	17,057
Operating lease liability, current	372,338	358,085
<b>Total current liabilities</b>	<u>2,245,251</u>	<u>10,225,766</u>
Long-term liabilities:		
Finance lease liability, net of current	-	4,436
Operating lease liability, net of current	33,145	130,663
<b>Total long-term liabilities</b>	<u>33,145</u>	<u>135,099</u>
<b>Total liabilities</b>	<u><b>2,278,396</b></u>	<u><b>10,360,865</b></u>
Stockholders' Equity		
Common Stock, \$0.0001 par value; 240,000,000 shares authorized and 5,010,470 and 1,167,521 shares issued and outstanding as of March 31, 2024 and December 31, 2023	502	118
Preferred Stock, \$0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023	-	-
Additional Paid-in-Capital	99,131,537	86,073,896
Accumulated deficit	(95,915,920)	(92,943,443)
<b>Total stockholders' equity</b>	<u><b>3,216,119</b></u>	<u><b>(6,869,429)</b></u>
<b>Total liabilities and stockholders' equity</b>	<u><b>\$ 5,494,515</b></u>	<u><b>\$ 3,491,436</b></u>

See notes to consolidated financial statements.

**Cingulate Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss (unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Operating expenses:		
Research and development	\$ 1,806,985	\$ 2,128,616
General and administrative	1,141,232	1,721,379
<b>Operating loss</b>	<b>(2,948,217)</b>	<b>(3,849,995)</b>
Interest and other income (expense), net	(24,260)	(154,892)
Loss before income taxes	(2,972,477)	(4,004,887)
Income tax benefit (expense)	-	-
<b>Net loss and comprehensive loss</b>	<b>\$ (2,972,477)</b>	<b>\$ (4,004,887)</b>
Net loss per share of common stock, basic and diluted	\$ (0.60)	\$ (7.08)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	4,945,507	565,471

See notes to consolidated financial statements.

**Cingulate Inc.**  
**Consolidated Statements of Stockholders' Equity (unaudited)**

	<u>Common Stock</u>		<u>Additional Paid-in- Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
<b>Balance January 1, 2023</b>	<b>11,309,412</b>	<b>1,131</b>	<b>\$73,289,387</b>	<b>\$ (69,408,496)</b>	<b>\$ -</b>	<b>\$ 3,882,022</b>
<b>Activity for the three months to March 31, 2023:</b>						
Unrealized losses on available for sale investments	-	-	-	-	-	-
Stock-based compensation expense	-	-	204,479	-	-	204,479
Net loss	-	-	-	(4,004,887)	-	(4,004,887)
<b>Balance March 31, 2023</b>	<b>11,309,412</b>	<b>\$ 1,131</b>	<b>\$73,493,866</b>	<b>\$ (73,413,383)</b>	<b>\$ -</b>	<b>\$ 81,614</b>
<b>Balance January 1, 2024</b>	<b>1,167,520</b>	<b>118</b>	<b>\$86,073,896</b>	<b>\$ (92,943,443)</b>	<b>\$ -</b>	<b>\$ (6,869,429)</b>
<b>Activity for the three months to March 31, 2024:</b>						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	283,800	28	3,115,256	-	-	3,115,284
Issuance of common stock in public offering, net of fees	3,552,000	355	6,432,537	-	-	6,432,892
Issuance of pre-funded warrants in connection with the conversion of related party note payable	-	-	2,734,739	-	-	2,734,739
Capital contribution in connection with conversion of related party note payable	-	-	586,511	-	-	586,511
Issuance of restricted common stock	7,150	1	24,023	-	-	24,024
Stock-based compensation expense	-	-	164,575	-	-	164,575
Net loss	-	-	-	(2,972,477)	-	(2,972,477)
<b>Balance March 31, 2024</b>	<b>5,010,470</b>	<b>\$ 502</b>	<b>\$99,131,537</b>	<b>\$ (95,915,920)</b>	<b>\$ -</b>	<b>\$ 3,216,119</b>

See notes to consolidated financial statements.

**Cingulate Inc.**  
**Consolidated Statements of Cash Flows (unaudited)**

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Operating activities:</b>		
Net loss	\$ (2,972,477)	\$ (4,004,887)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	163,600	100,629
Stock-based compensation	164,575	204,479
Changes in operating assets and liabilities:		
Miscellaneous receivables	12,375	202,479
Prepaid expenses and other current assets	(1,099,209)	296,252
Operating lease right-of-use assets	63,078	62,359
Trade accounts payable and accrued expenses	(4,995,037)	(358,777)
Current portion of operating lease liability	14,253	4,271
Long-term portion of operating lease liability	(97,518)	(83,266)
<b>Net cash used in operating activities</b>	<b>(8,746,360)</b>	<b>(3,576,461)</b>
<b>Investing activities:</b>		
Purchase of property and equipment	(81,508)	(37,135)
<b>Net cash used in investing activities</b>	<b>(81,508)</b>	<b>(37,135)</b>
<b>Financing Activities:</b>		
Proceeds from the issuance of common stock and pre-funded common stock purchase warrants, net of fees	9,893,450	-
Principal payments on finance lease obligations	(4,167)	(3,920)
<b>Net cash provided by (used in) financing activities</b>	<b>9,889,283</b>	<b>(3,920)</b>
<b>Cash and cash equivalents:</b>		
Net increase (decrease) in cash and cash equivalents	1,061,415	(3,617,516)
Cash and cash equivalents at beginning of year	52,415	5,356,276
<b>Cash and cash equivalents at end of year</b>	<b>\$ 1,113,830</b>	<b>\$ 1,738,760</b>
Property and equipment accrued but not yet paid at end of period	\$ 160,800	\$ -
<b>Cash payments:</b>		
Interest paid	\$ 308	\$ 555

See notes to consolidated financial statements

**(1) Nature of the Business and Liquidity**

*Organization*

Cingulate Inc. (Cingulate, or the Company), a Delaware corporation, is a biopharmaceutical company focused on the development of products utilizing its drug delivery platform technology that enables the formulation and manufacture of once-daily tablets of multi-dose therapies, with an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The Company is developing two proprietary, first-line stimulant medications, CTx-1301 (dexamethylphenidate) and CTx-1302 (dextroamphetamine), for the treatment of ADHD intended for all patient segments: children, adolescents, and adults. CTx-1301 and CTx-1302 utilize a flexible core tableting technology with target product profile designed to deliver a rapid onset and last the entire active day with a controlled descent of plasma drug level and have favorable tolerability. The Company has closed enrollment of Phase 3 clinical trials for CTx-1301 and plans to submit a New Drug Application (NDA) for CTx-1301 in the first half of 2025. In addition, the Company has a third product to treat anxiety, CTx-2103, in a formulation stage.

The consolidated financial statements and notes for the three-month periods ended March 31, 2024 and 2023, represent the full consolidation of Cingulate and its subsidiaries, including CTx and all references to the Company represent this full consolidation.

*Liquidity*

The Company has incurred losses and negative cash flows from operations since inception. As a pre-revenue entity, the Company is dependent on the ability to raise capital to support operations until such time as the product candidates under development are U.S. Food and Drug Administration (FDA) approved, manufactured, commercially available to the marketplace and produce revenues. The Company's initial public offering, which was completed in December 2021, provided approximately \$20.4 million in net proceeds. Since that time, net proceeds from capital sources have totalled \$27 million, including a related party note that was subsequently converted to equity as described in Note 7, utilization of the At the Market Agreement with H.C. Wainwright and Purchase Agreement with Lincoln Park Capital LLC, a private placement, and public offerings including the February 2024 Offering with gross proceeds of \$7.5 million, as further described in Note 9. However, the Company will need additional funding for operations and development. Management is evaluating various strategies to obtain additional funding, which may include additional offerings of equity, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions. Successful implementation of these plans involves both the Company's efforts and factors that are outside its control, such as market factors and FDA approval of product candidates. The Company can give no assurance that its plans will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above, which results in substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

**(2) Summary of Significant Accounting Policies**

**(a) Basis of Presentation and Principles of Consolidation**

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The consolidated financial statements include the accounts of Cingulate and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.



**(b) Unaudited Interim Financial Information**

The accompanying consolidated balance sheet as of March 31, 2024, and the consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the three-month periods ended March 31, 2024 and 2023, and the related interim disclosures are unaudited. These unaudited consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying consolidated financial statements should be read in conjunction with the Company's 2023 audited consolidated financial statements and the notes thereto.

**(c) Concentration of Credit Risk**

The Company maintains cash equivalent deposits, which at various times throughout the fiscal year exceeded the amounts insured by the Federal Deposit Insurance Corporation limit of \$250,000 (without regard to reconciling items). Management monitors the soundness of these financial institutions and does not believe the Company is subject to any material credit risk relative to the uninsured portion of the deposits.

**(d) Impairment of Long-lived Assets**

The Company assesses the carrying value of its long-lived assets, including property and equipment, as well as lease right of use (ROU) assets, when events or circumstances indicate that the carrying value of such assets may not be recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, the Company evaluates recoverability by a comparison of the carrying amount of the assets to future undiscounted cash flows expected to be generated by the assets. If the sum of the expected future cash flows is less than the carrying amount, the Company would recognize an impairment loss. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value of the long-lived asset groups. No impairment was recognized during the three-month periods ended March 31, 2024 or 2023.

**(e) Stock-Based Compensation**

The Company measures employee and director stock-based compensation expense for all stock-based awards based on their grant date fair value using the Black-Scholes option-pricing model. For stock-based awards with service conditions, stock-based compensation expense is recognized over the requisite service period using the straight-line method. Forfeitures are recognized as they occur. See additional information in Note 10.

### (3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Research and development	\$ 1,367,638	\$ 183,452
Insurance	119,420	31,302
Active pharmaceutical ingredients	42,731	97,324
Deferred capital raise costs	-	178,780
Dues and subscriptions	60,278	-
Other	20,698	20,698
	<u>\$ 1,610,765</u>	<u>\$ 511,556</u>

### (4) Property and Equipment

Property and equipment, net consisted of the following at March 31, 2024 and December 31, 2023:

	Estimated Useful Life (in years)	March 31, 2024	December 31, 2023
Equipment	2-7	\$ 4,341,005	\$ 4,321,816
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	41,897	41,897
Leasehold improvements	5	471,505	471,505
Construction-in-process- equipment	-	270,297	207,976
		<u>5,270,458</u>	<u>5,188,948</u>
Less: accumulated depreciation		<u>(2,806,584)</u>	<u>(2,642,983)</u>
		<u>\$ 2,463,874</u>	<u>\$ 2,545,965</u>

Depreciation expense was \$163,600 and \$100,629, respectively, for the three-month periods ended March 31, 2024 and 2023.

### (5) Accrued Expenses

Accrued expenses consisted of the following at March 31, 2024 and December 31, 2023:

	March 31, 2024	December 31, 2023
Employee compensation	\$ -	\$ 593,022
Interest	-	290,000
Professional fees	183,812	213,922
Research and development	582,887	155,220
CIP- Equipment	155,800	155,800
State franchise taxes	120,570	120,570
Insurance	-	56,088
Other	74,569	66,897
	<u>\$ 1,117,638</u>	<u>\$ 1,651,519</u>

## **(6) Contingencies**

The Company may, from time to time, be subject to legal proceedings and claims arising in the ordinary course of business and otherwise. A substantial legal liability against us could have an adverse effect on our business, financial condition and results of operations.

The Company records legal costs associated with loss contingencies as incurred and establishes reserves when those matters present material loss contingencies that management determines to be both probable and reasonably estimable in accordance with ASC 450, *Contingencies*. If a range of loss is estimated, and some amount within that range appears to be a better estimate than any other amount within that range, then that amount is accrued. If no amount within the range can be identified as a better estimate than any other amount, we accrue the minimum amount in the range. These amounts are not reduced by amounts that may be recovered under insurance or claims against third parties, but undiscounted receivables from insurers or other third parties may be accrued separately if recovery is considered probable. Management's judgment is required related to loss contingencies because the outcomes are difficult to predict, and the ultimate resolution may differ from our current analysis. The Company revises accruals in light of new information. While it is not possible to predict the outcome of loss contingencies with certainty, management is of the opinion that adequate provision for potential losses associated with any such matters has been made in the financial statements. No accruals for loss contingencies were recorded in the consolidated balance sheets as of March 31, 2024 or 2023.

## **(7) Related Party Note Payable**

In August 2022, the Company received \$5.0 million of debt financing from Werth Family Investment Associates LLC (WFIA). Peter Werth, manager of WFIA, is a member of the Company's Board of Directors. The promissory note, dated August 9, 2022, was unsecured with interest accruing at 15% per annum. In May 2023, the Company received an additional \$3.0 million of debt financing from WFIA by amending and restating the note to increase the principal amount to \$8.0 million. All other terms of the note remained the same.

On September 8, 2023, the Company and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the original principal amount of \$5.0 million under the note plus all accrued interest on the original principal, or \$5,812,500, by issuing pre-funded warrants to purchase 341,912 shares of the Company's common stock at a conversion price per pre-funded warrant of \$17.00. The closing price of the Company's common stock on Nasdaq on September 8, 2023, was \$11.55 per share. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of \$0.002 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), no more than 19.99% of the outstanding shares of common stock of the Company.

On January 25, 2024, the Company and CTx entered into another note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the remaining principal amount of the note payable of \$3.0 million plus all accrued interest, or \$3,287,500 by issuing pre-funded warrants to purchase 687,043 shares of the Company's common stock at a conversion price per pre-funded warrant of \$4.785. The closing price of the Company's common stock on Nasdaq on January 24, 2024, was \$4.35 per share. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of \$0.0001 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of common stock of the Company. In March of 2024, the Company issued to WFIA an additional pre-funded warrant to purchase 7,053 shares of common stock as a result of an error in the interest calculation, on the same form and at the same conversion price as the January pre-funded warrants.

WFIA exercised all of its pre-funded warrants in April 2024.

The Company considered ASC 470-60, *Troubled Debt Restructurings by Debtors*, in accounting for the debt conversions. The difference between the fair value of the pre-funded warrants issued and the carrying value of the debt and accrued interest settled in each transaction was recognized as a capital contribution in the Statement of Stockholders' Equity based on the related party nature of the counterparty.

During the three months ended March 31, 2024 and 2023, the Company recognized \$31,250 and \$187,500, respectively, of interest expense relating to this note.

## **(8) Stockholders' Equity**

The Company has authorized 240,000,000 shares of \$0.0001 par value common stock and 10,000,000 shares of \$0.0001 par value preferred stock at March 31, 2024 and December 31, 2023, of which 5,010,470 and 1,167,521 shares of common stock were issued and outstanding, respectively. The Company has not issued any shares of preferred stock.

The holders of common stock are entitled to one vote for each share of common stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, after the payment or provision for payment of all debts and liabilities of the Company, the holders of common stock shall be entitled to share in the remaining assets of the Company available for distribution, if any. Holders of the shares of common stock are entitled to dividends when, as and if declared by the Board of Directors.

### *Reverse Stock Split*

On November 30, 2023, the Company completed a one-for-twenty reverse stock split (Reverse Stock Split), which reduced the number of shares of the Company's common stock that were issued and outstanding immediately prior to the effectiveness of the Reverse Stock Split. The number of shares of the Company's authorized common stock was not affected by the Reverse Stock Split and the par value of the Company's common stock remained unchanged at \$0.0001 per share. No fractional shares were issued in connection with the Reverse Stock Split. Except where disclosed, all amounts related to number of shares and per share amounts have been retrospectively restated in these financial statements.

## **(9) Sale of Securities**

### At the Market Offering

In January 2023, the Company entered into the At-the-Market Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC (HCW) pursuant to which the Company could issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to \$4.97 million in at-the-market offerings sales. HCW acts as sales agent and is paid a 3% commission on each sale under the ATM Agreement. The Company's common stock is sold at prevailing market prices at the time of the sale, and, as a result, prices will vary.

In January 2024, the Company sold 283,800 shares of common stock under the ATM Agreement, for net proceeds of \$3,115,303. On March 18, 2024, the Company increased the maximum aggregate offering price of the shares of the Company's common stock issuable under the ATM Agreement from \$4.97 million to \$8.47 million and filed a prospectus supplement for an aggregate of \$3.5 million. In connection with the filing of the prospectus supplement, on March 17, 2024, the Company received a waiver from the purchaser in the February 2024 Offering (the February 2024 Offering) under the securities purchase agreement, dated February 2, 2024, by and between the Company and such purchaser. In consideration of the waiver set forth therein, the Company agreed to lower the exercise price of the Series A Warrants to purchase up to an aggregate of 346,261 shares of common stock and Series B Warrants to purchase up to an aggregate of 173,131 shares of common stock to \$1.13, which warrants were previously issued by the Company to such purchaser on September 13, 2023 and to extend the exercise term of the Series A Warrants to March 17, 2029 and the term of the Series B Warrants to March 17, 2026. The modifications to the warrants had no impact on the consolidated financial statements.

### Conversion of Related Party Note

The Company issued pre-funded warrants to purchase 694,096 shares of the Company's common stock pursuant to a note conversion agreement with WFIA, dated January 25, 2024, to convert the remaining principal amount of the note payable to WFIA, as described in Note 7.

In April 2024, WFIA exercised all of its pre-funded warrants, including pre-funded warrants it received in September 2023, as described in Note 7.

### Public Offering

On February 2, 2024, the Company completed a public offering (the February 2024 Offering) pursuant to which the Company issued 1,375,000 shares of its common stock and accompanying Series A and Series B warrants at a combined price of \$2.00 per share, and pre-funded warrants to purchase up to an aggregate of 2,375,000 shares of its common stock and accompanying Series A and Series B warrants at a combined purchase price of \$1.999 per pre-funded warrant, which represents the public offering price for the common stock less the \$0.0001 per share exercise price per share for each pre-funded warrant. The pre-funded warrants were exercisable at any time after the date of issuance and have no expiration date. The holders of pre-Funded warrants may not exercise the warrants if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each share of common stock and each pre-funded warrant were sold along with one Series A and 0.5 Series B warrants. The February 2024 Offering resulted in gross proceeds to the Company of \$7.5 million before deducting \$750,950 of placement agent fees and other offering expenses. As of March 31, 2024, 2,177,000 of the pre-funded warrants had been exercised.

### **(10) Stock-Based Compensation**

In September 2021, the Company's board of directors and stockholders adopted the 2021 Equity Incentive Plan (the 2021 Plan), which provides for the grant of incentive stock options and non-qualified stock options to purchase shares of the Company's common stock, stock appreciation rights, restricted stock units, restricted or unrestricted shares of common stock, performance shares, performance units, incentive bonus awards, other stock-based awards and other cash-based awards. No awards may be made under the 2021 Plan on or after September 24, 2031, but the 2021 Plan will continue thereafter while previously granted awards remain outstanding.

The maximum number of shares of common stock available for issuance in connection with options and other awards granted under the 2021 Plan is 256,926 and as of March 31, 2024, 15,169 shares of common stock were available for issuance under the 2021 Plan. The number of shares of common stock available for issuance under the 2021 Plan will automatically increase on January 1st of each year until the expiration of the 2021 Plan, in an amount equal to 5% percent of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, on a fully diluted basis, unless the board of directors takes action prior thereto to provide that there will not be an increase in the share reserve for such year or that the increase in the share reserve for such year will be of a lesser number of shares of common stock than would otherwise occur. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan.

The Company recorded stock-based compensation expense of \$164,575 and \$204,479 during the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024 and December 31, 2023, there was \$1,327,356 and \$1,278,981, respectively, of unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the 2021 Plan, which is expected to be recognized over the next one to four years.

A summary of option activity under the Plan during the three-month periods ending March 31, 2024 and 2023, is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2023	43,051			
Granted	19,225	\$ 35.00	9.93	-
Exercised	-			
Forfeitures or expirations	(281)			
Outstanding at March 31, 2023	<u>61,995</u>			
Vested and expected to vest at March 31, 2023	<u>61,995</u>			
Exercisable at March 31, 2023	<u>14,312</u>			
Outstanding at January 1, 2024	57,300			
Granted	191,834	\$ 1.18	9.93	
Exercised	-			
Forfeitures or expirations	(7,488)			
Outstanding at March 31, 2024	<u>241,646</u>			
Vested and expected to vest at March 31, 2024	<u>241,646</u>			
Exercisable at March 31, 2024	<u>23,402</u>			

The Company's stock options issued qualify for equity accounting treatment under ASC 718, *Compensation- Stock Compensation*, and are measured at fair value as of their grant date accordingly. The fair value of the options were estimated using a Black-Scholes model. The assumptions that the Company used to estimate the grant-date fair value of stock options granted to employees during the three-month periods ending March 31, 2024 and 2023 were as follows, shown on a weighted average basis:

	March 31, 2024	March 31, 2023
Risk-free interest rate	3.980%	3.662%
Expected term (in years)	5.55	6
Expected volatility	1.56	1.13
Expected dividend yield	0%	0%

*Risk-Free Interest Rate:* The Company based the risk-free interest rate over the expected term of the options based on the constant maturity of U.S. Treasury securities with similar maturities as of the date of grant.

*Expected Term:* The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting dates and the end of the contractual term.)

*Expected Volatility:* The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding volatility of its own stock price becomes available.

*Expected Dividend Yield:* The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

The grant-date fair value of options granted during the three months ended March 31, 2024 ranged from \$0.81 to \$1.53 and the grant date fair value of the options granted during the three months ended March 31, 2023 ranged from \$22.40 to \$23.20.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock. The fair value per share of common stock was 1.10 as of March 31, 2024, and 19.70 as of March 31, 2023, based upon the closing price of our common stock on the Nasdaq Capital Market on those dates or the last trading date prior to those dates if those dates were not a trading date.

## (11) Common Stock Purchase Warrants

For each of the 3,750,000 shares of common stock and pre-funded warrants issued in the February 2024 Offering, the Company issued Series A warrants to purchase up to 3,750,000 shares of common stock and Series B warrants to purchase up to 1,875,000 shares of common stock. The Series A and Series B warrants have an exercise price of \$2.00 per share and became exercisable on the effective date of stockholder approval of the shares issuable pursuant to the warrants. The Series A warrants have a five-year term and the Series B warrants have a two-year term from the initial exercise date of February 5, 2024.

The Company evaluated the warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and ASC Topic 815, *Derivatives and Hedging*, and determined that equity treatment was appropriate. The Company valued the pre-funded warrants to purchase 2,375,000 shares of common stock based on their issuance date fair value of \$2.00. As of March 31, 2024, 2,177,000 of the pre-funded warrants relating to the February 2024 Offering had been exercised.

In connection with the February 2024 Offering, the Company issued placement agent warrants to purchase up to 150,000 shares of common stock. The placement agent warrants have an exercise price of \$2.50 per share. These warrants have a five-year term ending February 2, 2029.

The Series A, Series B and placement agent warrants issued in the February 2024 Offering were valued using a Black-Scholes model with a risk-free rate of 4.0%-5.0%, the respective terms of five and two years, and a volatility of 1.56-1.83. The estimated volatility of the Company's common stock at the date of measurement is based on an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. The risk-free rate is based on the expected term of the warrants based on the constant maturity of U.S. Treasury securities with similar maturities as of the date of grant. The expected term has been estimated using the contractual term of the warrants.

The following table summarizes the Company's outstanding common stock purchase warrants as of March 31, 2024:

	<u>Number of Warrants</u>	<u>Exercise Price</u>	<u>Issuance Date Fair Value per Warrant</u>	<u>Issuance Date Fair Value Total</u>
December 2021 Initial Public Offering	239,584	\$ 120.00	\$ 95.40	\$ 22,856,314
December 2021 Underwriter Warrants	10,418	\$ 150.00	\$ 92.79	966,686
September 2023 WFIA Pre-funded Warrants	341,912	\$ 0.002	\$ 11.55	3,949,084
September 2023 Public Offering Series A Warrants	346,261	\$ 11.55	\$ 10.82	3,746,544
September 2023 Public Offering Series B Warrants	173,131	\$ 11.55	\$ 8.42	1,457,763
September 2023 Placement Agent Warrants	17,316	\$ 14.40	\$ 10.63	184,069
January 2024 WFIA Pre-funded Warrants	694,086	\$ 0.0001	\$ 4.35	3,019,274
February 2024 Public Offering Series A Warrants	3,750,000	\$ 2.00	\$ 1.17	4,387,500
February 2024 Public Offering Series B Warrants	1,875,000	\$ 2.00	\$ 0.99	1,856,250
February 2024 Placement Agent Warrants	150,000	\$ 2.50	\$ 1.15	172,500
February 2024 Pre-funded warrants	198,000	\$ 0.0001	\$ 2.00	396,000
Balance- March 31, 2024	<u>7,795,708</u>			<u>\$ 42,991,984</u>

In April 2024, WFIA exercised all of its pre-funded warrants, including pre-funded warrants it received in September 2023, as described in Note 7.

The Company has accounted for these warrants as equity-classified instruments under ASC Subtopic 815-40, *Derivatives and Hedging; Contracts in Entity's Own Equity*, as they are indexed to the Company's common stock, and they meet all other conditions for equity classification. The gross proceeds of the February 2024 Offering was allocated to the common stock and common stock purchase warrants using the relative fair value method shown as follows. Fair value of the warrants was recorded to Additional Paid-in-Capital on the Company's balance sheet.

	<u>Fair Value</u>	<u>Percent of Total Fair Value</u>	<u>Amount Allocated</u>
Common Stock	\$ 2,750,000	19.76%	\$ 1,482,000
Pre-Funded Warrants	4,750,000	34.13%	2,559,750
Series A, B and Placement Agent Warrants	6,416,250	46.11%	3,458,250
Total	<u>\$ 13,916,250</u>	<u>100.00%</u>	<u>\$ 7,500,000</u>

## (12) Income Taxes

Cingulate Inc. is taxed as a C corporation under the Internal Revenue Code. Cingulate Inc. records deferred income taxes to reflect the impact of temporary differences between the recorded amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. CTx is a wholly-owned disregarded entity of Cingulate Inc., and all of the activity for CTx, along with its wholly-owned subsidiary Cingulate Works Inc., is included in the calculation of the current and deferred tax assets and liabilities for Cingulate Inc. No deferred income tax benefit or expense was recorded for the three-month periods ended March 31, 2024 and 2023, for federal or state income taxes.

Income tax expense differed from the expected expense computed by applying the U.S. Federal income tax rate as follows:

	<b>Three Months Ended March 31,</b>	
	<u>2024</u>	<u>2023</u>
Federal income tax benefit at statutory rate	\$ (588,266)	\$ (841,026)
State income tax benefit	(154,910)	(221,470)
Permanent differences	3,654	3,669
Change in valuation allowance	770,439	1,090,836
Other	(30,917)	(32,009)
Total income tax expense	<u>\$ -</u>	<u>\$ -</u>

Evaluating the need for, and amount of, a valuation allowance for deferred tax assets often requires significant judgment and extensive analysis of all available evidence on a jurisdiction-by-jurisdiction basis. Such judgments require the Company to interpret existing tax law and other published guidance as applied to its circumstances. As part of this assessment, the Company considers both positive and negative evidence about its profitability and tax situation. A valuation allowance is provided if, based on available evidence, it is more likely than not that all or some portion of a deferred tax asset will not be realized. The Company determined that it was more likely than not that it would not realize its deferred tax assets, based on historical levels of income and future forecasts of taxable income, among other items. The Company recorded a valuation allowance of its net deferred tax assets totaling \$13,373,133 as of March 31, 2024 and \$12,631,033 at December 31, 2023, the current year portion which was recorded as a component of income tax expense on the accompanying consolidated statements of operations and other comprehensive loss.

The Company files income tax returns in the U.S. federal and various state jurisdictions. The Companies are not subject to U.S. federal and state income tax examinations by tax authorities for years before 2018.

The Company follows the provisions of FASB ASC 740, *Income Taxes*, to evaluate uncertain tax positions. This topic prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has not identified any material uncertain tax positions requiring recognition in the consolidated financial statements as of March 31, 2024 or December 31, 2023.



## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023 (Form 10-K) and in this report, as well as disclosures in this report and our other reports filed with the Securities and Exchange Commission (SEC), for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

#### Overview

We are a biopharmaceutical company using our proprietary Precision Timed Release<sup>TM</sup> (PTR<sup>TM</sup>) 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. We are initially focusing our efforts on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). Our PTR platform incorporates a proprietary Erosion Barrier Layer (EBL) designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets. We believe there remains a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their entire active-day.

Since inception in 2012, our operations have focused on developing our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations through public and private capital raised. Cumulative capital raised from these sources, including debt financing, was approximately \$91.3 million as of March 31, 2024.

We have incurred significant losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were \$3.0 million and \$4.0 million for the three months ended March 31, 2024 and 2023, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of March 31, 2024, we had an accumulated deficit of \$95.9 million.

We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- seek regulatory approval for CTx-1301;
- continue research and development activities for our existing and new product candidates, primarily for CTx-1301;
- continue manufacturing activities, primarily relating to CTx-1301;
- seek licensing partners and/or outsource commercial infrastructure to support sales and marketing for CTx-1301; and
- operate as a public company.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

## ***Clinical, Manufacturing and Business Update***

**CTx-1301:** We have designed our clinical program for CTx-1301 (dexamethylphenidate), our lead investigational product candidate for the treatment of ADHD, based on U.S. Food and Drug Administration (FDA) feedback regarding our CTx-1301 initial Pediatric Study Plan (iPSP), and longstanding guidance on the streamlined approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

We initiated two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients- a fixed dose study and a dose-optimized onset and duration study in a laboratory classroom setting in the third quarter of 2023. Based upon recent written communication with the FDA that further conduct of these pediatric and adolescent studies is not required for the submission of an NDA, we have closed enrollment on both Phase 3 trials. Per FDA guidance, however, we will conduct a Phase 1 food effect study utilizing CTx-1301's highest dosage strength, 50-mg. Appropriate data will be included in the NDA, remaining on track for a 1H 2025 submission.

**CTx-2103:** We have embarked on a program to develop CTx-2103 (buspirone), for the treatment of anxiety, which is one of the most common mental health concerns in the United States. We completed a formulation study in which the pharmacokinetics were evaluated for this trimodal tablet providing three precisely timed doses of buspirone versus one immediate release dose. In addition, scintigraphic imaging visualized transit of the tablets through the gastrointestinal tract to confirm both the site and onset of release, which will then be correlated with pharmacokinetic data to establish the full release profile of the CTx-2103 formulation. Based on the pharmacokinetic profile seen in the data, CTx-2103 achieved a triple release of buspirone. These results provided the critical information required to allow us to request a Pre-IND meeting with the FDA to discuss the design of our clinical and regulatory program for CTx-2103 which occurred in the fourth quarter of 2023. We received input from the FDA regarding the regulatory pathway for CTx-2103, and the design of clinical studies for filing of an IND. Based on this FDA feedback, we believe that we can seek and win approval of CTx-2103 under the 505(b)(2) pathway, which typically requires less time and resources than the 505(b)(1) full NDA pathway.

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

We are actively seeking a strategic pharmaceutical partnership under which we would license CTx-1301 in the United States, internationally, or both. In March 2023, we entered into a joint commercialization agreement (the "Commercialization Agreement") with Indegene, Inc. ("Indegene"). Should we be unable to identify an appropriate pharmaceutical partnership, if we receive FDA approval for CTx-1301, Indegene would provide commercialization services for CTx-1301, including marketing, sales, market access and distribution, on a fee for service basis.

## ***Securities Issuances***

### **ATM Agreement**

We entered into an At The Market Offering Agreement (the ATM Agreement) with H.C. Wainwright & Co., LLC (HCW), as sales agent, in January 2023 as amended in May 2023, pursuant to which we may offer and sell, from time to time through HCW, shares of our common stock for aggregate proceeds of up to \$ 8.47 million (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). In the three months ended March 31, 2024, we sold 283,800 shares of common stock under the ATM Agreement, for net proceeds of \$3,115,303, after deducting \$97,512 of compensation to HCW and other administration fees.

On March 18, 2024, we increased the maximum aggregate offering price of the shares of our common stock issuable under the ATM Agreement from \$4.97 million to \$8.47 million and filed a prospectus supplement for an aggregate of \$3.5 million. In connection with the filing of the prospectus supplement, on March 17, 2024, we received a waiver from the purchaser in the February 2024 Offering (as defined below). In consideration of the waiver, we agreed to lower the exercise price of the Series A warrants to purchase up to an aggregate of 346,261 shares of common stock and Series B warrants to purchase up to an aggregate of 173,131 shares of common stock to \$1.13, which warrants were previously issued by us to such purchaser on September 13, 2023 in connection with our public offering that closed on September 13, 2023, and to extend the exercise term of the Series A warrants to March 17, 2029 and the term of the Series B warrants to March 17, 2026.

### **Equity Line of Credit**

In April 2023, we entered into a purchase agreement (Lincoln Park Agreement) with Lincoln Park Capital Fund LLC (Lincoln Park). Pursuant to the Lincoln Park Agreement, Lincoln Park has agreed to purchase from us up to an aggregate of \$12.0 million of common stock (upon the terms and subject to the conditions and limitations set forth in the Lincoln Park Agreement) from time to time and at our sole discretion over the 36-month term of the Lincoln Park Agreement. We did not sell any shares of common stock pursuant to the Lincoln Park Agreement during the first quarter of 2024.

## Debt Conversion

In August 2022, Cingulate Therapeutics LLC (CTx), a wholly-owned subsidiary of Cingulate Inc., issued a Promissory Note (Original Note) to Werth Family Investment Associates LLC (WFIA) with a principal amount of \$5.0 million (the “Original Principal Amount”), and in May 2023, CTx issued an Amended and Restated Promissory Note (the “WFIA Note”) increasing the principal amount under the Original Note by \$3.0 million to \$8.0 million (the “2023 WFIA Debt Financing”).

On September 8, 2023, Cingulate Inc. and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the Original Principal Amount under the WFIA Note plus all accrued interest thereon, or \$5,812,500, into pre-funded warrants (the “September WFIA Pre-Funded Warrants”) to purchase 341,912 shares of our common stock at a conversion price per September WFIA Pre-Funded Warrant of \$17.00. The closing price of our common stock on Nasdaq on September 8, 2023 was \$11.55 per share. The September WFIA Pre-Funded Warrants had no expiration date and were exercisable immediately at an exercise price of \$0.002 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of our common stock.

On January 25, 2024, Cingulate Inc. and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the remaining \$3.0 million of principal under the WFIA Note plus all accrued interest thereon, or \$3,287,500, into pre-funded warrants (the “January WFIA Pre-Funded Warrants”) to purchase 687,043 shares of our common stock, at a conversion price per January WFIA Pre-Funded Warrant of \$4.785. The closing price of our common stock on Nasdaq on January 24, 2024 was \$4.35 per share. The January WFIA Pre-Funded Warrants had no expiration date and were exercisable immediately at an exercise price of \$0.0001 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of our common stock. In March of 2024, we issued to WFIA an additional pre-funded warrant to purchase 7,053 shares of common stock as a result of an error in the interest calculation, on the same form and at the same conversion price as the January WFIA Pre-Funded Warrants.

WFIA exercised all of its pre-funded warrants in April 2024.

## Public Offering

On February 2, 2024, we entered into agreements, including a Securities Purchase Agreement, with investors, pursuant to which we issued 1,375,000 shares of our common stock, pre-funded warrants to purchase up to an aggregate of 2,375,000 shares of our common stock, Series A warrants to purchase up to 3,750,000 shares of our common stock and Series B warrants to purchase up to 1,875,000 shares of our common stock (the “February 2024 Offering”). The February 2024 Offering closed on February 6, 2024. The combined purchase price per share of common stock and accompanying Series A and Series B warrants was \$2.00. The combined purchase price per pre-funded warrant and accompanying Series A and Series B warrants was \$1.9999, which represents the public offering price per share of common stock and accompanying warrants less the \$0.0001 per share exercise price for each pre-funded warrant. The pre-funded warrants are exercisable at any time after the date of issuance and have no expiration date. The holder of pre-funded warrants may not exercise the warrants if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. The Series A warrants have an exercise price of \$2.00 per share, were exercisable immediately, and will expire five years after the issuance date, and the Series B warrants have an exercise price of \$2.00 per share, were exercisable immediately, and will expire two years after the issuance date. We received gross proceeds of approximately \$7.5 million, before deducting \$750,950 of placement agent’s fees and other offering expenses, pursuant to the February 2024 Offering. As of March 31, 2024, 2,177,000 of the pre-funded warrants issued in the February 2024 Offering had been exercised.

## Components of Operating Results

### Revenue

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration of license agreements.

### Operating Expenses

#### *Research and Development Expenses*

Research and development expenses consist of costs incurred in the discovery and development of our product candidates, and primarily include:

- expenses incurred under third party agreements with contract research organizations (CROs), and investigative sites, that conducted or will conduct our clinical trials and a portion of our pre-clinical activities;

- costs of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- expenses, including salaries and benefits of employees engaged in research and development activities;
- costs of manufacturing equipment, depreciation and other allocated expenses; and
- fees paid for contracted regulatory services as well as fees paid to regulatory authorities including the FDA for review and approval of our product candidates.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued costs.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue clinical development for our product candidates, as well as adding additional PTR product candidates to our pipeline. As products enter later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Historically, our research and development costs have primarily related to the development of CTx-1301. As we advance CTx-1301, CTx-1302, and CTx-2103, as well as identify any other potential product candidates, we will continue to allocate our direct external research and development costs to the products. We expect to fund our research and development expenses from our current cash and cash equivalents and any future equity or debt financings, or other capital sources.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs for our employees in administrative, executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, office, and travel expenses.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our growing operations including the potential commercialization of our product candidates. We have experienced, and will continue to experience, increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services; director and officer insurance; and investor and public relations costs.

#### *Interest and other income (expense), net*

Interest and other income (expense), net consists of interest expense on our related party notes payable and interest earned on our cash and cash equivalents, including money market funds. The primary objective of our investment policy is liquidity and capital preservation.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during a reporting period. Actual results could differ from estimates.

A discussion of these policies can be found in the “Critical Accounting Policies and Significant Judgments and Estimates” section of our Form 10-K. There have been no changes in our application of critical accounting policies since December 31, 2023.

## Results of Operations

### Comparison of the three months ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2024	2023		
Operating Expenses:				
Research and development	\$ 1,807	\$ 2,129	\$ (322)	(15.1)%
General and administrative	1,117	1,721	(604)	(35.1)%
Operating Loss	(2,924)	(3,850)	(926)	24.1%
Interest and other income (expense), net	(24)	(155)	(131)	84.5%
Net Loss	\$ (2,948)	\$ (4,005)	\$ (1,057)	26.4%

#### Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended March 31, 2024 and 2023:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2024	2023		
Clinical operations	\$ 1,077	\$ 868	\$ 209	24.1%
Drug manufacturing and formulation	341	599	(258)	(43.1)%
Personnel expenses	306	635	(329)	(51.8)%
Regulatory costs	83	27	56	207.4%
Total research and development expenses	\$ 1,807	\$ 2,129	\$ (322)	(15.1)%

R&D expenses were \$1.8 million for the three months ended March 31, 2024, a decrease of \$0.3 million or 15.1% from the three months ended March 31, 2023. This change was the result of increased clinical activity in the three months ended March 31, 2024 as compared to the same period in 2023, offset by decreased manufacturing activity and personnel expenses in the three months ended March 31, 2024 as compared to the same period in 2023. During the first quarter of 2024, we incurred significant costs relating to two Phase 3 studies for CTx-1301, the fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose optimization and duration study. In the first quarter of 2023, we incurred costs for the manufacturing of clinical supply for these two studies. The decrease in personnel costs is the result of lower headcount and the cost containment measures, which we implemented in late 2023 in order to conserve cash, which included salary reductions ranging from 5-55% for all employees.

### General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended March 31, 2024 and 2023:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2024	2023		
Personnel expenses	\$ 413	\$ 668	\$ (255)	(38.2)%
Legal and professional fees	292	398	(106)	(26.6)%
Occupancy	101	130	(29)	(22.3)%
Insurance	241	392	(151)	(38.5)%
Other	70	133	(63)	(47.4)%
Total general and administrative expenses	<u>\$ 1,117</u>	<u>\$ 1,721</u>	<u>\$ (604)</u>	<u>(35.1)%</u>

Total G&A expenses were \$1.1 million for the three months ended March 31, 2024, a decrease of \$0.6 million or 33.7% from the three months ended March 31, 2023. This is primarily the result of a decrease in personnel expenses and insurance. The decrease in personnel expenses is the result of lower headcount and the cost containment measures which we implemented in late 2023 in order to conserve cash, which included salary reductions ranging from 5-55% for all employees. In addition, there was a decrease in the annual directors' and officers' insurance premium from 2023 to 2024.

### Interest and other income (expense), net

The following table summarizes interest and other income (expense), net for the three months ended March 31, 2024 and 2023:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2024	2023		
Interest and other income (expense), net	\$ (24)	\$ (155)	\$ (131)	84.5%

Total interest and other income (expense), net for the three months ended March 31, 2024 and 2023, relates to interest incurred on outstanding notes payable, offset by interest earned on invested balances. The decrease is the result of the conversion to equity of the related party note payable to WFIA in two transactions, which occurred in August 2023 and January 2024.

### Cash Flows

	Three Months Ended March 31,	
	2024	2023
Net cash (used in) operating activities	\$ -	\$ (3,576)
Net cash (used in) investing activities	-	(37)
Net cash (used in) financing activities	-	(4)
Net increase (decrease) in cash and cash equivalents	<u>\$ -</u>	<u>\$ (3,617)</u>

### *Cash Flows from Operating Activities*

Net cash used in operating activities was \$8.7 million for the three months ended March 31, 2024. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$3.0 million, prior to the effects of two noncash items, stock-based compensation expense of \$0.2 million and depreciation expense of \$0.2 million. Changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of \$1.1 million primarily due to a deposit made to Societal CDMO, Inc., our contract manufacturing organization (CMO), for registration batch activity for CTx-1301. In addition, there was a decrease in trade accounts payable and accrued expenses of \$5.0 million due to the payment of vendor balances with the cash proceeds from the issuance of common stock pursuant to our ATM Agreement in January 2024 and the issuance of equity in the February 2024 Offering.

Net cash used in operating activities was \$3.6 million for the three months ended March 31, 2023. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of \$4.0 million, prior to the effects of two noncash items, stock-based compensation expense of \$0.2 million and depreciation expense of \$0.1 million. Changes in operating assets and liabilities included a decrease in miscellaneous receivables of \$0.2 million primarily due to collection of an amount recoverable on an insurance claim which had been recorded as a receivable as of December 31, 2022, a decrease of prepaid expenses and other current assets of \$0.3 million primarily due to the utilization of a deposit made to our CMO for the build out of our new manufacturing suite, and a decrease in trade accounts payable and accrued expenses of \$0.4 million due to the payment of certain professional fees and franchise taxes which had been accrued as of December 31, 2022, as well as general timing variances of trade payables.

### *Cash Flows from Investing Activities*

Net cash used in investing activities for both the three months ended March 31, 2024 and 2023 was primarily related to the purchase of equipment to support our research and development.

### *Cash Flows from Financing Activities*

Net cash provided by financing activities for the three-month period ended March 31, 2024 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement in January 2024 and the issuance of in the February 2024 Offering.

Net cash used in financing activities for the three-month period ended March 31, 2023 was related to principal payments on finance lease obligations.

### ***Liquidity and Capital Resources***

#### ***Sources of Liquidity***

Since our inception in 2012 through March 31, 2024, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations.

In the first quarter of 2024, we sold 283,800 shares of common stock under the ATM Agreement, for net proceeds of \$3,115,303, after deducting \$97,512 of compensation to HCW and other administration fees. On March 18, 2024, we increased the maximum aggregate offering price of the shares of our common stock issuable under the ATM Agreement from \$4.97 million to \$8.47 million and filed a prospectus supplement for an aggregate of \$3.5 million.

In February 2024, we received gross proceeds of approximately \$7.5 million, before deducting \$750,950 of placement agent's fees and other offering expenses in the February 2024 Offering.

As of March 31, 2024, we had cash and cash equivalents of \$1.1 million. We believe our cash will satisfy our capital needs through late in the second quarter of 2024 under our current business plan. In addition, in order to achieve the filing of our NDA for CTx-1301 in the first half of 2025 for potential FDA approval, we believe that we will need approximately \$11-13 million of additional capital, which is an increase of approximately \$2 million from the previously disclosed amount. This increase is related to the addition of a 50mg Fast Fed study for CTx-1301 (see "Overview - Clinical, Manufacturing and Business Update" above). We will also need additional capital to advance our other programs and commercialization efforts. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. 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.

Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents are invested primarily in money market funds which are currently providing only a minimal return given the current interest rate environment.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the cost and timing of manufacturing the clinical supply of our product candidates;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the clinical development plans we establish for each product candidate;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration or license agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the cost and timing of the implementation of commercial scale manufacturing activities; and
- the cost and timing of outsourcing our commercialization efforts, including, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, including clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We are actively seeking a strategic pharmaceutical partnership under which we would license CTx-1301 in the United States, internationally, or both. In March 2023, we entered into a Joint Commercialization Agreement with Indegene, Inc. (Indegene). Should we be unable to identify an appropriate pharmaceutical partnership, if we receive FDA approval for CTx-1301, Indegene would provide commercialization services for CTx-1301, including marketing, sales, market access and distribution, on a fee for service basis.



If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

### ***Contractual Obligations***

The following summarizes our contractual obligations as of March 31, 2024 that will affect our future liquidity.

We entered into a patent and know-how licensing agreement with BDD Pharma Limited in August 2018. See “Item 1. Business – Material Agreements” section of our Form 10-K for a description of this agreement. We are required to pay BDD Pharma certain amounts in connection with clinical trial and regulatory milestones. The first milestone payment of \$250,000 was paid in February 2023 upon dosing of the first patient in the Phase 3 adult onset and duration study for CTx-1301. Additional payments will become due upon completion of certain milestones as defined in the agreement.

We entered into agreements for two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients- a fixed dose study and a dose-optimized onset and duration study in a laboratory classroom setting. Based on guidance received from the FDA regarding our clinical program for CTx-1301, we completed enrollment in these two studies and no further conduct of these studies is required. We are evaluating the final costs to be incurred.

### **Going Concern**

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change that is largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for one year after the issuance date of our financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We have incurred a net loss for the three months ended March 31, 2024 and 2023 and had accumulated losses of \$95.9 million since inception to March 31, 2024. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our sources of capital have included private capital raises in various classes of units of CTx prior to the Reorganization Merger, the issuance of equity securities in connection with our initial public offering (IPO), public offerings, including the February 2024 Offering, sales of common stock under our ATM Agreement and Lincoln Park Agreement, a private placement with WFIA and the WFIA Debt Financing which was subsequently converted to equity. Additional capital will be needed by us to fund our operations, to complete development of and to commercially develop our product candidates. There is no assurance that such capital will be available when needed or on acceptable terms.

## **JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an “emerging growth company,” we are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for emerging growth companies.

Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation. These exemptions will apply until the fifth anniversary of the completion of our IPO or until we no longer meet the requirements for being an “emerging growth company,” whichever occurs first.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Not applicable.

### **Item 4. Controls and Procedures.**

#### *Evaluation of Our Disclosure Controls*

We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to the our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of March 31, 2024, have concluded that our disclosure controls and procedures were effective as of March 31, 2024.

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on April 1, 2024, management previously identified a material weakness in our internal controls over financial reporting related to the lack of independent members of our board of directors as of December 31, 2023. Specifically, our board of directors did not have sufficient members who are independent of management allowing them to be objective in their oversight of the development and performance of internal control. Effective February 12, 2024, our board of directors fixed the number of directors constituting the board at five directors and appointed Bryan Lawrence as a Class III director to serve until our 2024 annual meeting of stockholders, and each of Jeffrey S. Ervin, and John A. Roberts, as a Class II director to serve until our 2026 annual meeting of stockholders. Based on management’s evaluation, this material weakness was remediated as of March 31, 2024, as a result of the appointment of such directors.

#### *Evaluation of Changes in Internal Control over Financial Reporting*

Except as part of our remediation of the material weakness described above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II — OTHER INFORMATION

### Item 1. Legal Proceedings.

See Part I, Item 1, Notes to Consolidated Financial Statements, Note 6 – Contingencies, of this report.

### Item 1A. Risk Factors.

Our business is subject to substantial risks and uncertainties. Investing in our securities involves a high degree of risk. You should carefully consider the risk factors in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on April 1, 2024, together with the information contained elsewhere in this report, including Part I, Item 1 “Financial Statements” and Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and in our other SEC filings in evaluating our business. These risks and uncertainties could materially and adversely affect our business, financial condition, results of operations, prospects for growth, and the value of an investment in our securities.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 1, 2024, the Company issued 7,150 shares of common stock at a value of \$3.36 per share to a consultant. Such issuance was exempt from registration under 4(a)(2) of the Securities Act of 1933, as amended.

### Item 5. Other Information

In the first quarter of 2024, no director or officer (as defined in Exchange Act Rule 16a-1(f)) of the Company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement for the purchase or sale of securities of the Company, within the meaning of Item 408 of Regulation S-K.

### Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Cingulate Inc., as amended to date</a>	S-1	3.1	1/12/2024
3.2	<a href="#">Amended and Restated Bylaws of Cingulate Inc.</a>	10-K	3.2	3/28/2022
4.1	<a href="#">Form of January 2024 WFIA Pre-Funded Warrant</a>	8-K	4.1	1/29/2024
4.2	<a href="#">Form of February 2024 Pre-Funded Warrant</a>	8-K	4.1	2/7/2024
4.3	<a href="#">Form of February 2024 Series A Warrant</a>	8-K	4.2	2/7/2024
4.4	<a href="#">Form of February 2024 Series B Warrant</a>	8-K	4.3	2/7/2024
4.5	<a href="#">Form of February 2024 Placement Agent Warrant</a>	8-K	4.4	2/7/2024
4.6	<a href="#">Form of March 2024 WFIA Pre-Funded Warrant</a>	10-K	4.16	4/1/2024
10.1	<a href="#">Employment Agreement, dated January 25, 2024, between Cingulate Therapeutics LLC, and Jennifer L. Callahan</a>	8-K	10.2	1/29/2024
10.2	<a href="#">Amendment to Employment Agreement, effective January 1, 2024, between Cingulate Therapeutics, LLC and Matthew N. Brams</a>	S-1	10.26	1/12/2024
10.3	<a href="#">Note Conversion Agreement, dated January 25, 2024, by and between the Company, Cingulate Therapeutics, LLC and Werth Family Investment Associates LLC</a>	8-K	10.1	1/29/2024
10.4	<a href="#">Form of February 2024 Securities Purchase Agreement</a>	8-K	10.1	2/7/2024
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>			
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>			
32.1**	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>			
32.2**	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>			
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

\* Filed Herewith

\*\* Furnished Herewith

**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 thereunto duly authorized.

**CINGULATE INC.**

Date: May 8, 2024

By: /s/ Shane J. Schaffer

Shane J. Schaffer  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Date: May 8, 2024

By: /s/ Jennifer L. Callahan

Jennifer L. Callahan  
Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT  
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Shane J. Schaffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2024 of Cingulate Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2024

*/s/ Shane J. Schaffer*  
\_\_\_\_\_  
Shane J. Schaffer  
Chief Executive Officer  
(Principal Executive Officer)

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT  
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jennifer L. Callahan, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2024 of Cingulate Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2024

*/s/ Jennifer L. Callahan*

Jennifer L. Callahan

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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**Certification Pursuant to  
18 U.S.C. Section 1350,  
as Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended March 31, 2024 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

- (1) The Quarterly Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2024

By: /s/ Shane J. Schaffer

Shane J. Schaffer  
Chief Executive Officer  
(Principal Executive Officer)

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**Certification Pursuant to  
18 U.S.C. Section 1350,  
as Adopted Pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002**

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended March 31, 2024 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

- (1) The Quarterly Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2024

By: /s/ Jennifer L. Callahan

Jennifer L. Callahan

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

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