

**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, 2023

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)

**86-3825535**

(I.R.S. Employer  
Identification No.)

**1901 W. 47<sup>th</sup> Place**

**Kansas City, KS**

(Address of principal executive offices)

**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 and posted on its corporate Web site, if any, 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 and post 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 4, 2023, 11,704,142 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, 2023

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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 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 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 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; 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, 2022, filed with the SEC on March 10, 2023, 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>2023</u>	<u>December 31,</u> <u>2022</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,738,760	\$ 5,356,276
Miscellaneous receivables	31,953	234,432
Prepaid expenses and other current assets	1,982,692	2,278,944
<b>Total current assets</b>	<u>3,753,405#</u>	<u>7,869,652</u>
Property and equipment, net	2,841,293	2,904,787
Operating lease right-of-use assets	568,259	630,618
<b>Total assets</b>	<u>\$ 7,162,957</u>	<u>\$ 11,405,057</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 599,033	\$ 762,357
Accrued expenses	699,182	894,635
Note payable	5,000,000	5,000,000
Finance lease liability, current	16,300	16,053
Operating lease liability, current	344,026	339,755
<b>Total current liabilities</b>	<u>6,658,541</u>	<u>7,012,800</u>
Long-term liabilities:		
Finance lease liability, net of current	17,320	21,487
Operating lease liability, net of current	405,482	488,748
<b>Total long-term liabilities</b>	<u>422,802</u>	<u>510,235</u>
<b>Total liabilities</b>	<u>7,081,343</u>	<u>7,523,035</u>
Stockholders' Equity		
Common Stock, \$0.0001 par value; 240,000,000 shares authorized and 11,309,412 shares issued and outstanding as of March 31, 2023 and December 31, 2022	1,131	1,131
Preferred Stock, \$0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Additional Paid-in-Capital	73,493,866	73,289,387
Accumulated deficit	(73,413,383)	(69,408,496)
<b>Total stockholders' equity</b>	<u>81,614</u>	<u>3,882,022</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 7,162,957</u>	<u>\$ 11,405,057</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>2023</b>	<b>2022</b>
Operating expenses:		
Research and development	\$ 2,128,616	\$ 2,762,284
General and administrative	1,721,379	2,247,060
<b>Operating loss</b>	<b>(3,849,995)</b>	<b>(5,009,344)</b>
Interest and other income (expense), net	(154,892)	5,833
Loss before income taxes	(4,004,887)	(5,003,511)
Income tax benefit (expense)	-	-
<b>Net loss</b>	<b>(4,004,887)</b>	<b>(5,003,511)</b>
<b>Other comprehensive loss:</b>		
Change in unrealized gain on short-term investments	-	(2,948)
<b>Comprehensive loss</b>	<b>\$ (4,004,887)</b>	<b>\$ (5,006,459)</b>
Net loss per share of common stock, basic and diluted	\$ (0.35)	\$ (0.44)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	11,309,412	11,309,412

See notes to consolidated financial statements.

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

	<u>Common Stock</u>		<u>Additional</u>	<u>Members'</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Stockholders'</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in-Capital</u>			<u>Other</u>	
				<u>Capital</u>	<u>Deficit</u>	<u>Income</u>	<u>Equity</u>
<b>Balance January 1, 2022</b>	<b>11,309,412</b>	<b>\$ 1,131</b>	<b>\$ 72,574,510</b>	<b>-</b>	<b>\$ (51,732,264)</b>	<b>\$ 165</b>	<b>\$ 20,843,542</b>
<b>Activity for the three months to</b>							
<b>March 31, 2022:</b>							
Unrealized losses on available for sale investments	-	-	-	-	-	(2,948)	(2,948)
Stock-based compensation expense	-	-	181,518	-	-	-	181,518
Net loss	-	-	-	-	(5,003,511)	-	(5,003,511)
<b>Balance March 31, 2022</b>	<b>11,309,412</b>	<b>\$ 1,131</b>	<b>\$ 72,756,028</b>	<b>\$ -</b>	<b>\$ (56,735,775)</b>	<b>\$ (2,783)</b>	<b>\$ 16,018,601</b>
<b>Balance January 1, 2023</b>	<b>11,309,412</b>	<b>\$ 1,131</b>	<b>\$ 73,289,387</b>	<b>-</b>	<b>\$ (69,408,496)</b>	<b>\$ -</b>	<b>\$ 3,882,022</b>
<b>Activity for the three months to</b>							
<b>March 31, 2023:</b>							
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>\$ -</b>	<b>\$ (73,413,383)</b>	<b>\$ -</b>	<b>\$ 81,614</b>

See notes to consolidated financial statements

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Operating activities:</b>		
Net loss	\$ (4,004,887)	\$ (5,003,511)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	100,629	101,429
Stock-based compensation	204,479	181,518
Other	-	(2,948)
Changes in operating assets and liabilities:		
Miscellaneous receivables	202,479	38,877
Prepaid expenses and other current assets	296,252	391,216
Operating lease right-of-use assets	62,359	53,889
Trade accounts payable and accrued expenses	(358,777)	446,374
Current portion of operating lease liability	4,271	7,668
Long-term portion of operating lease liability	(83,266)	(78,995)
<b>Net cash used in operating activities</b>	<b>(3,576,461)</b>	<b>(3,864,483)</b>
<b>Investing activities:</b>		
Purchase of property and equipment	(37,135)	(10,400)
Proceeds from sale of short-term investments	-	-
Other	-	-
<b>Net cash used in investing activities</b>	<b>(37,135)</b>	<b>(10,400)</b>
<b>Financing Activities:</b>		
Principal payments on finance lease obligations	(3,920)	(3,682)
<b>Net cash provided by financing activities</b>	<b>(3,920)</b>	<b>(3,682)</b>
<b>Cash and cash equivalents:</b>		
Net decrease in cash and cash equivalents	(3,617,516)	(3,878,565)
Cash and cash equivalents at beginning of period	5,356,276	16,492,745
<b>Cash and cash equivalents at end of period</b>	<b>\$ 1,738,760</b>	<b>\$ 12,614,180</b>
Property and equipment accrued but not yet paid at end of period	\$ -	\$ 10,400
<b>Cash payments:</b>		
Interest paid	\$ 555	\$ 793

See notes to consolidated financial statements

## GINGULATE INC.

Notes to Consolidated Financial Statements (unaudited)

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

#### *Organization*

Cingulate Inc. 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 initiated Phase 3 clinical trials for CTx-1301, with first patients in the adult dose-optimization study dosed in early 2023. In addition, the Company has a third product to treat anxiety, CTx-2103, in a formulation stage.

On November 14, 2012, Cingulate Therapeutics LLC (CTx), a Delaware limited liability company, was formed. On May 10, 2021, Cingulate Inc. (Cingulate, or the Company), a Delaware corporation and wholly-owned subsidiary of CTx, was formed to serve as a holding company, in anticipation of the Company becoming publicly traded. Through a Reorganization Merger which occurred in the third quarter of 2021, Cingulate effectively acquired CTx and all outstanding units of CTx were converted into shares of Cingulate common stock. CTx remains the entity through which the Company conducts operations.

The consolidated financial statements and notes for the three-month periods ended March 31, 2023 and 2022, 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 initial public offering, which was completed in December 2021, provided approximately \$20.4 million in net proceeds. In addition, the Company received proceeds of \$5.0 million from a promissory note in August 2022 and an additional \$3.0 million when the promissory note was amended and restated in May 2023, as further described in Note 7. However, the Company will need additional funding for operations and development. In January 2023, the Company entered into an At The Market Offering Agreement (the ATM Agreement) with H.C. Wainwright & Co., LLC, as sales agent (Wainwright), pursuant to which the Company may offer and sell, from time to time through Wainwright, shares of its common stock for aggregate proceeds of up to \$4.97 million. In April 2023, the Company entered into a purchase agreement with Lincoln Park Capital Fund, LLC (Lincoln Park), pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of \$12.0 million of common stock (subject to certain limitations and satisfaction of the conditions set forth in the purchase agreement) from time to time and at the Company's sole discretion over the 36-month term of the purchase agreement. Management is evaluating various strategies to obtain additional funding, which may include additional offerings of common stock, 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, 2023, the consolidated statements of operations and comprehensive loss for the three-month periods ended March 31, 2023 and 2022, the consolidated statements of stockholders’ equity for the three-month periods ended March 31, 2023 and 2022, the consolidated statements of cash flows for the three-month periods ended March 31, 2023 and 2022, 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 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) Miscellaneous Receivables**

Miscellaneous receivables consist of payroll tax credits generated from the Company’s 2020 and 2019 federal income tax returns, which have not yet been received, as well as employee retention tax credits for payroll costs incurred in 2020 and the first three quarters of 2021. The Company analogized to IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, in accounting for these receivables. As of March 31, 2023 and December 31, 2022, the Company determined that there was no allowance necessary relating to these receivables.

### **(e) 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, 2023 or 2022.

#### (f) 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 9.

#### (3) Prepaid Expenses

Prepaid expenses consisted of the following at March 31, 2023 and December 31, 2022:

	March 31, 2023	December 31, 2022
Research and development	\$ 901,601	\$ 1,377,391
Insurance	569,155	472,152
Active pharmaceutical ingredients	209,156	209,156
Deferred capital raise costs	146,456	100,339
Professional fees	20,775	61,524
Dues and subscriptions	73,976	37,684
Other	61,573	20,698
	<u>\$ 1,982,692</u>	<u>\$ 2,278,944</u>

#### (4) Property and Equipment

Property and equipment, net consisted of the following at March 31, 2023, and December 31, 2022:

	Estimated Useful Life (in years)	March 31, 2023	December 31, 2022
Equipment	2-7	\$ 2,576,171	\$ 2,565,997
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	41,898	41,898
Leasehold improvements	5	471,505	471,505
Construction-in-process- equipment	-	1,766,661	1,739,699
		5,001,989	4,964,853
Less: accumulated depreciation		(2,160,696)	(2,060,066)
		<u>\$ 2,841,293</u>	<u>\$ 2,904,787</u>

Depreciation expense was \$100,629 and \$101,429 for the three-month periods ended March 31, 2023 and 2022.

## (5) Accrued Expenses

Accrued expenses consisted of the following at March 31, 2023, and December 31, 2022:

	March 31, 2023	December 31, 2022
Interest	\$ 479,839	\$ 292,339
Professional fees	15,000	314,446
Employee bonuses	175,625	175,625
Other	28,718	112,225
	<u>\$ 699,182</u>	<u>\$ 894,635</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 first 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.

## (7) Related Party Note Payable

On August 10, 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. This promissory note is unsecured with interest accruing at 15% per annum. Outstanding principal and all accrued and unpaid interest are due and payable on August 8, 2025, or 120 days following written demand made by WFIA during the first five business days of a calendar quarter beginning April 1, 2023. WFIA did not demand payment in April 2023. The Company may prepay the note, in whole or in part, without premium or penalty; provided, that no amount repaid may be reborrowed. As of March 31, 2023, and December 31, 2022, the entire \$5.0 million was outstanding on the note.

On May 9, 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.

During the three months ended March 31, 2023, the Company recognized \$187,500 of interest expense relating to this note. This interest expense is included in accrued expenses on the consolidated balance sheet at March 31, 2023.

## (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, 2023, and December 31, 2022, of which 11,309,412 shares of common stock were issued and outstanding. 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.

## (9) 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 2,786,310 and as of March 31, 2023, 1,546,406 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 \$204,479 and \$181,518 during the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, and December 31, 2022, there was \$2,423,282 and \$2,089,509, 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, 2023 and 2022, is as follows:

	<u>Shares</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Remaining Contractual Term (years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at January 1, 2022	523,285	\$ 6.00	9.94	
Granted	342,999	\$ 1.82	9.91	
Exercised	-			
Forfeitures or expirations	-			
Outstanding at March 31, 2022	<u>866,284</u>	\$ 4.35	9.78	\$ 182,900
Vested and expected to vest at March 31, 2022	<u>866,284</u>			
Exercisable at March 31, 2022	<u>-</u>			
Outstanding at January 1, 2023	861,019			
Granted	384,500	\$ 1.75	9.93	-
Exercised	-			
Forfeitures or expirations	(5,615)			
Outstanding at March 31, 2023	<u>1,239,904</u>			
Vested and expected to vest at March 31, 2023	<u>1,239,904</u>			
Exercisable at March 31, 2023	<u>286,230</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, 2023 and 2022 were as follows, shown on a weighted average basis:

	<b>March 31, 2023</b>	<b>March 31, 2022</b>
Risk-free interest rate	3.662%	1.540%
Expected term (in years)	6	6
Expected volatility	1.13	1.12
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, 2023, ranged from \$0.81 to \$1.53 and the grant date fair value of the options granted during the three months ended March 31, 2022, ranged from \$1.12 to \$1.16.

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 \$0.99 as of March 31, 2023, and \$1.97 as of March 31, 2022, based upon the closing price of our common stock on the Nasdaq Capital Market on those dates.

#### **(10) 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, 2023 and 2022, 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>	
	<b>2023</b>	<b>2022</b>
Federal income tax benefit at statutory rate	\$ (841,026)	\$ (1,039,582)
State income tax benefit	(221,470)	(273,757)
Permanent differences	3,669	5,665
Change in valuation allowance	1,090,836	1,361,886
Other	(32,009)	(54,212)
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 \$6,989,779 as of March 31, 2023 and \$5,580,595 at December 31, 2022, 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, 2023 or December 31, 2022.

	<u>March 31, 2023</u>	<u>December 31, 2022</u>
<b>Deferred income tax assets:</b>		
Current:		
Research and development costs	\$ 450,718	\$ 343,087
Other	59,018	59,018
Non-current:		
Net operating losses	4,250,020	3,381,215
Research and development costs	2,098,416	1,762,716
Unvested stock options	283,259	204,380
Patents	89,517	92,417
Right-of-use assets	58,012	63,563
Gross deferred income tax assets	<u>7,288,960</u>	<u>5,906,396</u>
Less: valuation allowance	<u>(6,989,779)</u>	<u>(5,580,595)</u>
Net deferred income tax asset	299,181	325,801
<b>Deferred income tax liabilities:</b>		
Current:		
Accrual to cash	(11,228)	(11,228)
Non-current		
Property and equipment	<u>(287,953)</u>	<u>(314,573)</u>
Gross deferred income tax liabilities	<u>(299,181)</u>	<u>(325,801)</u>
Net deferred tax asset (liability)	<u>\$ -</u>	<u>\$ -</u>

#### **(11) Net Loss Per Share**

The following table sets forth the computation of the basic and diluted net loss per share for the three months ended March 31, 2023 and March 31, 2022:

	<b>Three Months Ended March 31,</b>	
	<u>2023</u>	<u>2022</u>
<b>Numerator:</b>		
Net loss	\$ (4,004,887)	\$ (5,003,511)
<b>Denominator:</b>		
Weighted average common shares outstanding	<u>11,309,412</u>	<u>11,309,412</u>
Net loss per share, basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.44)</u>

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows as of March 31, 2023 and March 31, 2022:

	<b>March 31, 2023</b>	<b>March 31, 2022</b>
Stock options issued under the 2021 Equity Incentive Plan	1,239,904	866,284
Common stock purchase warrants outstanding	4,999,998	4,999,998
<b>Total</b>	<b>6,239,902</b>	<b>5,866,282</b>

## **(12) License Agreement**

CTx has a licensing agreement with a company related to the patents and licensed know-how for use in the development of CTx-1301, CTx-1302, and CTx-2103. Payments are to be made upon the occurrence of the following milestone events:

- \$250,000 Milestone payment upon dosing of first patient in a Phase 3 Clinical Trial for each product in the field, payable on a per product basis.
- \$250,000 Milestone payment upon licensee filing of new drug application for each product in the field, payable on a per product basis.
- \$250,000 Milestone payment for CTx-1301 and CTx-1302 and \$500,000 Milestone payment for CTx-2103 upon receipt of first marketing approval from the FDA, payable on a per product basis.
- \$250,000 Milestone payment for CTx-2103 upon receipt of first marketing approval from the EMA (European Medicines Agency)

As of December 31, 2022, the \$250,000 milestone for CTx-1301 relating to the dosing of first patient in a Phase 3 Clinical Trial was accrued as management deemed the milestone probable of occurring. In early 2023, the Company paid this amount as the first patient in a CTx-1301 Phase 3 Clinical Trial was dosed. The Company has not recorded any expense relating to the other milestones for any other product as it has not deemed them probable of occurring as of March 31, 2023.

## **(13) Related Party Transactions**

The general counsel of the Company is a partner with a law firm providing office facilities space that is leased by the Company. Rental expense incurred by the Company to the law firm was \$9,000 for both the three months ended March 31, 2023, and 2022, which approximates fair value. As of March 31, 2023, and December 31, 2022, the Company had no outstanding amounts payable under this lease.

A member of the Company's Board of Directors, Peter Werth, is the manager of WFIA, the entity which provided \$8.0 million in debt financing to the Company as described in Note 7. Interest expense of \$187,500 was recognized during the three months ended March 31, 2023. The full principal balance of \$5.0 million pursuant to the original note was outstanding as of March 31, 2023 and December 31, 2022 and \$479,839 and \$292,339 of accrued interest relating to this note was outstanding as of March 31, 2023 and December 31, 2022.

## **(14) Subsequent Events**

Management evaluated events that occurred subsequent to March 31, 2023, through May 10, 2023, which is the date the interim financial statements were issued.

On April 24, 2023, the Company entered into a purchase agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of \$12.0 million of common stock (subject to certain limitations and satisfaction of the conditions set forth in the purchase agreement) from time to time and at the Company's sole discretion over the 36-month term of the purchase agreement. Pursuant to the terms of the purchase agreement, on April 24, 2023, the Company issued 368,023 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock under the purchase agreement.

On May 9, 2023, the Company received \$3.0 million of debt financing from WFIA by amending and restating the original note payable to WFIA to increase the principal amount from \$5.0 million to \$8.0 million. All other terms of the original note remained the same.

## Item 2. 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, 2022 (“Form 10-K”) 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™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. We initially focused on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD); however, we have expanded our pipeline to include a product candidate for the treatment of anxiety. 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 \$68.8 million as of March 31, 2023.

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 \$4.0 million and \$5.0 million for the three-month periods ended March 31, 2023 and 2022, respectively. See “Results of Operations” below for an explanation of the fluctuations in our net losses. As of March 31, 2023, we had an accumulated deficit of \$73.4 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;
- manufacture supplies for our development studies and clinical trials, primarily for CTx-1301;
- 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.

### ***Debt Financing***

On May 9, 2023, we received an additional \$3.0 million of debt financing (the “2023 WFIA Debt Financing”) from Werth Family Investment Associates LLC (“WFIA”). The \$5.0 million promissory note, dated August 9, 2022, in favor of WFIA (the “Original Note”) was amended and restated to increase the principal amount to \$8.0 million (the “WFIA Note”). The WFIA Note is unsecured with interest accruing at 15% per annum. Outstanding principal and all accrued and unpaid interest is due and payable on August 8, 2025 unless accelerated due to an event of default. Beginning July 1, 2023, WFIA has the right during the first five business days of each calendar quarter to demand payment of all outstanding principal and interest 120 days following notice to us. We may prepay the WFIA Note, in whole or in part, without premium or penalty; provided, that no amount repaid may be reborrowed. As of March 31, 2023, the accrued interest on the Original Note was \$0.5 million. See “Liquidity and Capital Resources” below.

WFIA owns 975,165 shares of our common stock and Peter J. Werth, a member of the Company’s Board of Directors and the manager of WFIA, owns 21,849 shares of our common stock. Our Audit Committee and Board of Directors reviewed the terms of the 2023 WFIA Debt Financing pursuant to our Policy and Procedures for Related Person Transactions and determined that the 2023 WFIA Debt Financing is in our best interest and the best interests of our stockholders.

### ***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 a Phase 3 adult dose-optimization study in December 2022 to assess onset and duration and efficacy and safety in adults with ADHD, the first cohort has been completed and the second cohort is near completion. Results are expected in the third quarter of 2023.

The Phase 3 fixed-dose pediatric and adolescent safety and efficacy study is expected to commence in mid-2023. Results are expected in the first quarter of 2024.

In addition, we are planning to initiate a Phase 3 pediatric and adolescent dose-optimization classroom study in the third quarter of 2023 to assess onset and duration and efficacy and safety in patients with ADHD. Results are expected in the first quarter of 2024.

In order to meet the pharmacology requirement for the CTx-1301 New Drug Application (NDA) submission, we completed a food effect study in October of 2022, which demonstrated that CTx-1301 can be taken with or without food.

Assuming we receive positive clinical results from our Phase 3 trials, we expect to submit the NDA for CTx-1301 in mid-2024 under the Section 505(b)(2) pathway.

Societal CDMO, Inc. (Societal), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development, will manufacture all clinical, registration, and commercial batches of our lead ADHD candidate, CTx-1301. In April 2023, we successfully completed the transfer of our proprietary PTR™ manufacturing processes for our lead candidate, CTx-1301 (dexamethylphenidate), to Societal, which is producing a scalable supply of CTx-1301 for our ongoing and upcoming Phase 3 trials in the manufacturing suite within Societal’s Gainesville, GA facility that is outfitted with equipment supplied by us.

In March 2023, we announced a joint commercialization agreement with Indegene, a comprehensive life sciences commercialization company, to provide commercial support for our lead candidate CTx-1301 (dexamethylphenidate). The agreement spans cross-functional services through an omnichannel marketing approach uniquely designed to successfully manage pre-commercial support during our Phase 3 clinical trials and to effectively commercialize CTx-1301 nationwide following potential FDA approval.

**CTx-2103:** We have embarked on a program to develop CTx-2103 (buspirone) for the treatment of anxiety, which is the most common mental health concern in the U.S. 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 the desired triple release of buspirone. These positive 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 we expect to occur in the third quarter of 2023 to allow for a potential IND filing in the fourth quarter of 2023.

**CTx-1302:** We plan to initiate a Phase 1/2 bioavailability study in ADHD patients for CTx-1302 (dextroamphetamine), our second investigational asset for the treatment of ADHD, in mid-2024 and, if the results from this study are successful, subsequently initiate pivotal Phase 3 clinical trials in all patient segments in late 2024 or early 2025.

**PTR™ Platform:** We continue to evaluate opportunities to out-license our PTR platform and to license our product candidates outside of the United States. In addition, we are evaluating opportunities to expand our relationship with BDD Pharma Limited.

## 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 or 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 all research and development costs as incurred, other than manufacturing equipment used in research and development which is capitalized and amortized over its useful life. 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 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 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.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe the following accounting policies are those most critical to the judgements and estimates used in the preparation of our consolidated financial statements. These policies relate to research and development costs and stock-based compensation. 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, 2022.

## Results of Operations

### Comparison of the three months ended March 31, 2023 and March 31, 2022:

The following table summarizes our results of operations for the three months ended March 31, 2023 and March 31, 2022:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2023	2022		
Operating Expenses:				
Research and development	\$ 2,129	\$ 2,762	\$ (633)	(22.9%)
General and administrative	1,721	2,247	(526)	(23.4%)
Operating Loss	(3,850)	(5,009)	(1,159)	23.1%
Interest and other income (expense), net	(155)	6	(161)	NM
Net Loss	\$ (4,005)	\$ (5,003)	\$ (998)	19.9%

#### Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended March 31, 2023 and March 31, 2022:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2023	2022		
Clinical operations	\$ 868	\$ 808	\$ 60	7.4%
Drug manufacturing and formulation	599	1,353	(754)	-55.7%
Personnel expenses	635	583	52	8.9%
Regulatory costs	27	18	9	50.0%
Total research and development expenses	\$ 2,129	\$ 2,762	\$ (633)	(22.9%)

R&D expenses were \$2.1 million for the three months ended March 31, 2023, a decrease of \$0.6 million or 22.9% from the three months ended March 31, 2022. This change was primarily a result of a decrease in manufacturing costs for CTx-1301 during the three month period ended March 31, 2023, as the three month period ended March 31, 2022 included the manufacturing of clinical supply for Phase 3 CTx-1301 clinical trials; whereas the manufacturing activity in the three months ended March 31, 2023 primarily included expenses related to the build out of our manufacturing suite at our CDMO. This decrease in manufacturing expense was slightly offset by an increase in clinical and regulatory costs as we initiated a Phase 3 clinical trial for CTx-1301 in the first quarter of 2023.

#### General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended March 31, 2023 and March 31, 2022:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2023	2022		
Personnel expenses	\$ 668	\$ 662	\$ 6	0.9%
Legal and professional fees	398	648	(250)	(38.6%)
Occupancy	130	126	4	3.2%
Insurance	392	674	(282)	(41.8%)
Other	133	137	(4)	(2.9%)
Total general and administrative expenses	\$ 1,721	\$ 2,247	\$ (526)	(23.4%)

Total G&A expenses were \$1.7 million for the three months ended March 31, 2023, a decrease of \$0.5 million or 23.4% from the three months ended March 31, 2022. This change was primarily the result of a decrease in legal and professional fees of \$0.3 million and a decrease in insurance costs of \$0.3 million. The decrease in professional fees was related to the timing of services performed for our annual audits, and the decrease in insurance costs was related to a decline in the annual directors and officers insurance policy premium which was renewed in December of 2022.

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

The following table summarizes interest and other income (expense), net for the three months ended March 31, 2023 and March 31, 2022:

(in thousands)	Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
	2023	2022		
Interest and other income (expense), net	\$ (155)	\$ 6	\$ (161)	NM

Total interest and other income (expense), net in the three months ended March 31, 2023 primarily related to interest on the \$5.0 million related party note payable to WFIA, dated August 2022, offset by interest earned on invested balances.

Total interest and other income (expense), net in the three months ended March 31, 2022 primarily related to interest incurred on outstanding notes payable, offset by interest earned on invested balances.

### **Cash Flows**

	Three Months Ended March 31,	
	2023	2022
Net cash (used in) operating activities	\$ (3,576)	\$ (3,864)
Net cash (used in) investing activities	(37)	(10)
Net cash (used in) financing activities	(4)	(4)
Net increase (decrease) in cash and cash equivalents	\$ (3,617)	\$ (3,878)

#### *Cash Flows from Operating Activities*

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 CDMO 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.

Net cash used in operating activities was \$3.9 million for the three months ended March 31, 2022. 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 \$5.0 million, prior to the effects of two noncash items, stock-based compensation expense of \$0.2 million and depreciation of \$0.1 million. Changes in operating assets and liabilities included a decrease in prepaid expenses of \$0.4 million primarily due to a significant down payment made on the directors and officers insurance policy in late 2021, which is being amortized over the policy period, as well as an increase in accounts payable and accrued expenses of \$0.4 million due to increased development activity on CTx-1301 resulting in increased billings and amounts owed as of March 31, 2022.

#### *Cash Flows from Investing Activities*

Net cash used in investing activities for both the three month periods ended March 31, 2023 and March 31, 2022 was related to the purchase of equipment to support our research and development.

## *Cash Flows from Financing Activities*

Net cash used in financing activities for both the three month periods ended March 31, 2023 and March 31, 2022 was related to principal payments on finance lease obligations.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

On May 9, 2023, we received \$3.0 million pursuant to the 2023 WFIA Debt Financing.

Since our inception in 2012 through March 31, 2023, we have not generated revenue and have incurred significant operating losses and negative cash flow from our operations. Based on our current operating plan and with the proceeds from the 2023 WFIA Debt Financing, we expect our cash and cash equivalents will be sufficient to fund our development and operating expenditures into the third quarter of 2023.

We entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), in January 2023, pursuant to which we may offer and sell, from time to time through Wainwright, shares of our common stock for aggregate proceeds of up to \$4.97 million (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). During the three months ended March 31, 2023, we did not make any sales pursuant to the ATM Agreement. Subsequent to March 31, 2023, we sold 16,707 shares of common stock pursuant to the ATM Agreement, for net proceeds of \$17,369, after deducting Wainwright's commission of \$546 and other fees.

In April 2023, we entered into a purchase agreement (the "Lincoln Park Agreement") and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund LLC. 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. Pursuant to the terms of the Registration Rights Agreement, we filed with the SEC a registration statement to register for resale under the Securities Act 4.5 million shares that have been or may be issued to Lincoln Park under the Lincoln Park Agreement. Upon the signing of the Lincoln Park Agreement, we issued 368,023 shares of common stock to Lincoln Park as consideration for their commitment to purchase our common stock under the Lincoln Park Agreement. We have sold 10,000 shares of common stock under the Lincoln Park Agreement, for net proceeds of \$10,430.

Management is also evaluating additional strategies to obtain funding, which may include additional offerings of common stock, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions.

In order to achieve the filing of our NDA for CTx-1301 in mid-2024 for potential FDA approval, we believe that we will need approximately \$25.0 million of capital, in addition to the proceeds from the 2023 WFIA Debt Financing. 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 have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, licensing or similar strategic business transaction. In March 2023, we entered into a Joint Commercialization Agreement with Indegene, Inc., which will provide us with commercialization services for CTx-1301, upon approval from the FDA, 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, 2023 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 10, 2023 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 have entered into agreements with CROs for the Phase 3 adult dose-optimization, onset and duration study for CTx-1301, which was initiated in December 2022, the Phase 3 fixed-dose pediatric and adolescent safety and efficacy study for CTx-1301, which is expected to commence in mid-2023 and the Phase 3 pediatric dose-optimization, onset and duration classroom study, which we plan to initiate in the third quarter of 2023. We have entered into agreements with a CDMO and other third parties for manufacture of the Phase 3 clinical supply of CTx-1301. We have also entered into a joint commercialization agreement with Indegene, Inc., pursuant to which Indegene will provide commercialization services for CTx-1301, upon approval from the FDA, including marketing, sales, market access and distribution, on a fee for service basis. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation and in some cases, wind-down costs and restoration costs. The exact amount of such obligations is dependent on the timing of termination and the terms of the related agreement and are not known.

### **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-month periods ending March 31, 2023 and 2022 and had accumulated losses of \$73.4 million since inception to March 31, 2023. 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 and the WFIA debt financing. Additional financings will be needed by us to fund our operations and to complete development of and commercialize our product candidates. See “Liquidity and Capital Resources” above for details relating to certain agreements which we have entered into in 2023 as potential sources of additional capital. There is no assurance that such financing will be available when needed or on acceptable terms.

### **Recently Issued Accounting Standards**

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* which significantly changes the way entities recognize impairment of many financial assets by requiring immediate recognition of estimated credit losses expected to occur over their remaining life, instead of when incurred. In November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which amends Subtopic 326-20 (created by ASU 2016-13) to explicitly state that operating lease receivables are not in the scope of Subtopic 326-20. Additionally, in April 2019, the FASB issued ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*; in May 2019, the FASB issued ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief*; in November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, and ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*; and in March 2020, the FASB issued ASU 2020-03, *Codification Improvements to Financial Instruments*, to provide further clarifications on certain aspects of ASU 2016-13. The changes (as amended) are effective for the Company for annual and interim periods in fiscal years beginning after December 15, 2022. The Company does not expect the adoption of ASU 2016-13 to have a material effect on its consolidated financial statements.



## **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, 2023, have concluded that our disclosure controls and procedures were effective as of March 31, 2023.

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

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, 2023 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, 2022, filed with the SEC on March 10, 2023, 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 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.</a>	10-K	3.1	3/28/2022
3.2	<a href="#">Amended and Restated Bylaws of Cingulate Inc.</a>	10-K	3.2	3/28/2022
10.1+	<a href="#">Amendment to Employment Agreement, effective January 1, 2023, between Cingulate Therapeutics LLC and Raul R. Silva</a>	10-K	10.10	3/10/2023
10.2	<a href="#">At The Market Offering Agreement, dated January 3, 2023, by and between Cingulate Inc. and H.C. Wainwright &amp; Co., LLC</a>	S-3	1.2	1/3/2023
10.2	<a href="#">Joint Commercialization Agreement, dated March 7, 2023, by and between Cingulate Therapeutics, LLC and Indegene, Inc.</a>	10-K	10.19	3/10/2023
10.3	<a href="#">Purchase Agreement, dated April 24, 2023, by and between the Company and Lincoln Park Capital Fund, LLC</a>	8-K	10.1	4/25/2023
10.4	<a href="#">Registration Rights Agreement, dated April 24, 2023, by and between the Company and Lincoln Park Capital Fund, LLC</a>	8-K	10.2	4/25/2023
10.5*	<a href="#">Amendment to ATM Agreement, dated May 2, 2023, by and between Cingulate Inc. and H.C. Wainwright &amp; Co., LLC</a>			
10.6	<a href="#">Amended and Restated Promissory Note, dated May 9, 2023, between Cingulate Therapeutics, LLC and Werth Family Investment Associates</a>	8-K	10.1	5/11/2023
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

+ Indicates a management contract or compensatory plan

**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 10, 2023

By: /s/ Shane J. Schaffer

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

Date: May 10, 2023

By: /s/ Louis G. Van Horn

Louis G. Van Horn  
Chief Financial Officer  
(Principal Financial Officer)

May 2, 2023

Cingulate Inc.  
1901 W. 47<sup>th</sup> Place  
Kansas City, Kansas 66205  
Attention: Shane J. Schaffer, Chief Executive Officer

Dear Mr. Schaffer:

Reference is made to the At The Market Offering Agreement, dated as of January 3, 2023 (the "ATM Agreement"), between Cingulate Inc. (the "Company") and H.C. Wainwright & Co., LLC (the "Manager"). This letter (the "Amendment") constitutes an agreement between the Company and the Manager to amend the ATM Agreement as set forth herein. Defined terms that are used but not defined herein shall have the meanings ascribed to such terms in the ATM Agreement.

1. The defined term "Agreement" in the ATM Agreement is amended to mean the ATM Agreement as amended by this Amendment.
2. Section 4(h) of the ATM Agreement is hereby amended and restated as follows:

"Subsequent Equity Issuances. The Company shall not deliver any Sales Notice hereunder (and any Sales Notice previously delivered shall not apply during such three Business Days) for at least three (3) Business Days prior to any date on which the Company or any Subsidiary offers, sells, issues, contracts to sell, contracts to issue or otherwise disposes of, directly or indirectly, any other shares of Common Stock or any Common Stock Equivalents (other than the Shares), subject to Manager's right to waive this obligation, provided that, without compliance with the foregoing obligation, the Company may issue and sell Common Stock pursuant to any employee equity plan, stock ownership plan or dividend reinvestment plan of the Company in effect at the time of the respective Sales Notice and the Company may issue Common Stock issuable upon the conversion or exercise of Common Stock Equivalents outstanding at the time of the respective Sales Notice, and provided, further, that the foregoing obligation shall not apply in connection with the Company's sale of shares of Common Stock under an equity line of credit pursuant to a definitive agreement entered into on April 24, 2023 with Lincoln Park Capital, LLC (the "Equity Line"), provided that, on any single given Trading Day, the Company shall only deliver either (i) a Sales Notice for the sale of Shares hereunder or (ii) any notice for the sale of shares of Common Stock under the Equity Line."

3. The Company and the Manager hereby agree that the date of this Amendment shall be a Representation Date under the ATM Agreement and the deliverables under Section 4(k), 4(l) and 4(m) of the ATM Agreement shall be required on the date of this Amendment.

4. The Agreement shall continue in full force and effect after the execution of this Amendment and shall not be in any way changed, modified or superseded by the terms set forth herein.

5. This Amendment may be executed in two or more counterparts and by facsimile or ".pdf" signature or otherwise, and each of such counterparts shall be deemed an original and all of such counterparts together shall constitute one and the same agreement.

*[Remainder of page intentionally left blank]*

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In acknowledgment that the foregoing correctly sets forth the understanding reached by the Company and the Manager, please sign in the space provided below, whereupon this Amendment shall constitute a binding amendment to the ATM Agreement as of the date indicated above.

Very truly yours,

**H.C. WAINWRIGHT & CO., LLC**

By: /s/ Mark W. Viklund

Name: Mark W. Viklund

Title: Chief Executive Officer

Accepted and Agreed:

**CINGULATE INC.**

By: /s/ Shane Schaffer

Name: Shane Schaffer

Title: Chief Executive Officer

[SIGNATURE PAGE TO CING AMENDMENT TO ATM AGREEMENT]

**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, 2023 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 10, 2023

*/s/ Shane J. Schaffer*

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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, Louis G. Van Horn, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2023 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 10, 2023

*/s/ Louis G. Van Horn*  
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Louis G. Van Horn  
Chief Financial Officer  
(Principal Financial 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, 2023 (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 10, 2023

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, 2023 (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 10, 2023

By: /s/ Louis G. Van Horn

Louis G. Van Horn  
Chief Financial Officer  
(Principal Financial Officer)

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