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 June 30, 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	**86-3825535**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1901 W. 47th Place **Kansas City, KS**	**66205**
(Address of principal executive offices)	(Zip Code)

(913) 942-2300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.0001 per share	CING	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Warrants, exercisable for one share of common stock	CINGW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Indicate by check mark whether the registrant (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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 August 11, 2023, 15,658,798 shares of the registrant's common stock, $0.0001 par value, were issued and outstanding.

Cingulate Inc.
Form 10-Q for the Quarter Ended June 30, 2023

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this report with the Securities and Exchange Commission (the "SEC") and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our ability to maintain compliance with the continued listing requirements of The Nasdaq Capital Market;
- 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 this report, our other SEC filings and 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)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 349,831	$ 5,356,276
Miscellaneous receivables	35,470	234,432
Prepaid expenses and other current assets	1,652,556	2,278,944
Total current assets	2,037,857	7,869,652
Property and equipment, net	2,685,993	2,904,787
Operating lease right-of-use assets	503,597	630,618
Total assets	**5,227,447**	**11,405,057**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,612,216	762,357
Accrued expenses	1,018,270	894,635
Note payable	8,000,000	5,000,000
Finance lease liability, current	15,917	16,053
Operating lease liability, current	348,499	339,755
Total current liabilities	10,994,902	7,012,800
Long-term liabilities:		
Finance lease liability, net of current	13,723	21,487
Operating lease liability, net of current	317,343	488,748
Total long-term liabilities	331,066	510,235
Total liabilities	**11,325,968**	**7,523,035**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 12,056,788 and 11,309,412 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1,206	1,131
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of June 30, 2023 and December 31, 2022	-	-
Additional Paid-in-Capital	73,929,965	73,289,387
Accumulated deficit	(80,029,692)	(69,408,496)
Total stockholders' equity	**(6,098,521)**	**3,882,022**
Total liabilities and stockholders' equity	**$ 5,227,447**	**$ 11,405,057**

See notes to consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 4,455,927	$ 2,178,226	$ 6,584,543	$ 4,940,510
General and administrative	1,906,442	1,870,591	3,627,821	4,117,651
Operating loss	**(6,362,369)**	**(4,048,817)**	**(10,212,364)**	**(9,058,161)**
Interest and other income (expense), net	(253,940)	8,370	(408,832)	14,203
Loss before income taxes	(6,616,309)	(4,040,447)	(10,621,196)	(9,043,958)
Income tax benefit (expense)	-	-	-	-
Net loss	(6,616,309)	(4,040,447)	(10,621,196)	(9,043,958)
Other comprehensive income (loss):				
Change in unrealized loss on short-term investments	-	(466)	-	(3,414)
Comprehensive loss	**$ (6,616,309)**	**$ (4,040,913)**	**$ (10,621,196)**	**$ (9,047,372)**
Net loss per share of common stock, basic and diluted	$ (0.57)	$ (0.36)	$ (0.92)	$ (0.80)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	11,694,823	11,309,412	11,503,182	11,309,412

See notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in-	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Capital	Deficit	Income	Equity
Balance January 1, 2022	**11,309,412**	**1,131**	**$ 72,574,510**	**$ (51,732,264)**	**$ 165**	**$ 20,843,542**
Activity for the three months to March 31, 2022:						
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)
Balance March 31, 2022	**11,309,412**	**$ 1,131**	**$ 72,756,028**	**$ (56,735,775)**	**$ (2,783)**	**$ 16,018,601**
Activity for the three months to June 30, 2022:						
Unrealized losses on available for sale investments	-	-	-	-	(466)	(466)
Stock-based compensation expense	-	-	207,186	-	-	207,186
Net loss	-	-	-	(4,040,447)	-	(4,040,447)
Balance June 30, 2022	**11,309,412**	**$ 1,131**	**$ 72,963,214**	**$ (60,776,222)**	**$ (3,249)**	**$ 12,184,874**
Balance January 1, 2023	**11,309,412**	**1,131**	**$ 73,289,387**	**$ (69,408,496)**	**$ -**	**$ 3,882,022**
Activity for the three months to March 31, 2023:						
Stock-based compensation expense	-	-	204,479	-	-	204,479
Net loss	-	-	-	(4,004,887)	-	(4,004,887)
Balance March 31, 2023	**11,309,412**	**$ 1,131**	**$ 73,493,866**	**$ (73,413,383)**	**$ -**	**$ 81,614**
Activity for the three months to June 30, 2023:						
Issuance of common shares, net of fees	747,376	75	218,723			218,798
Stock-based compensation expense	-	-	217,376	-	-	217,376
Net loss	-	-	-	(6,616,309)	-	(6,616,309)
Balance June 30, 2023	**12,056,788**	**$ 1,206**	**$ 73,929,965**	**$ (80,029,692)**	**$ -**	**$ (6,098,521)**

See notes to consolidated financial statements

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Operating activities:		
Net loss	$ (10,621,196)	$ (9,043,958)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	255,930	202,858
Stock-based compensation	421,855	388,705
Changes in operating assets and liabilities:		
Miscellaneous receivables	198,962	550,135
Prepaid expenses and other current assets	626,388	(67,926)
Operating lease right-of-use assets	127,021	109,818
Trade accounts payable and accrued expenses	973,494	(272,149)
Other current liabilities	8,744	18,502
Operating lease liabilities	(171,405)	(162,661)
Net cash used in operating activities	(8,180,207)	(8,276,676)
Investing activities:		
Purchase of property and equipment	(37,136)	(10,400)
Proceeds from sale of short-term investments	-	933
Other	-	(3,415)
Net cash used in investing activities	**(37,136)**	**(12,882)**
Financing Activities:		
Proceeds from issuance of common stock, net of fees	218,798	-
Proceeds from note payable	3,000,000	-
Principal payments on finance lease obligations	(7,900)	(7,427)
Net cash provided by (used in) financing activities	**3,210,898**	**(7,427)**
Cash and cash equivalents:		
Net decrease in cash and cash equivalents	(5,006,445)	(8,296,985)
Cash and cash equivalents at beginning of year	5,356,276	16,492,745
Cash and cash equivalents at end of year	**$ 349,831**	**$ 8,195,760**
Cash payments:		
Interest paid	$ 9,833	$ 9,619

See notes to consolidated financial statements

(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 (dexmethylphenidate) 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 completed its first Phase 3 clinical trial for CTx-1301 with two additional Phase 3 trials in process. 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 periods ended June 30, 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. The Company received net proceeds of $355,238 during the three months ended June 30, 2023 and $1,764,596 subsequent to June 30, 2023, relating to an at the market offering agreement and purchase agreement as further described in Note 9. On August 11, 2023, the Company issued 1,823,155 shares of its common stock to Werth Family Investment Associates LLC (WFIA) in a private placement at a purchase price per share of $0.5485, resulting in gross proceeds to the Company of approximately $1.0 million. However, the Company will need additional funding for operations and development. Management is evaluating various strategies to obtain additional funding, which may include additional offerings of 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 June 30, 2023, the consolidated statements of operations and comprehensive loss for the three and six-month periods ended June 30, 2023 and 2022, the consolidated statement of stockholders' equity for the three and six-month periods ended June 30, 2023 and 2022, the consolidated statements of cash flows for the six-month periods ended June 30, 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 as of and for the year ended December 31, 2022.

(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 as of June 30, 2023 primarily consist of employee retention tax credits for payroll costs incurred in 2020 and included employee retention tax credits and research and development tax credits as of December 31, 2022. The Company analogized to IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*, in accounting for these receivables. As of June 30, 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 or six-month periods ended June 30, 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 10.

(3) Prepaid Expenses

Prepaid expenses consisted of the following at June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Research and development	$ 658,959	$ 1,377,391
Insurance	664,515	472,152
Active pharmaceutical ingredients	15,029	209,156
Deferred capital raise costs	196,012	100,339
Professional fees	38,775	61,524
Dues and subscriptions	58,568	37,684
Other	20,698	20,698
	$ 1,652,556	$ 2,278,944

(4) Property and Equipment

Property and equipment, net consisted of the following at June 30, 2023 and December 31, 2022:

	Estimated Useful Life (in years)	June 30, 2023	December 31, 2022
Equipment	2-7	$ 4,342,832	$ 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	-	-	1,739,699
		5,001,989	4,964,853
Less: accumulated depreciation		(2,315,996)	(2,060,066)
		$ 2,685,993	$ 2,904,787

Depreciation expense for the six months ended June 30, 2023 was $255,930 and for the six months ended June 30, 2022 was $202,858. Depreciation expense for the three months ended June 30, 2023 was $155,300 and for the three months ended June 30, 2022 was $101,429.

(5) Accrued Expenses

Accrued expenses consisted of the following at June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Interest	$ 732,339	$ 292,339
Research and development	4,199	-
Professional fees	90,000	314,446
Employee bonuses	175,625	175,625
Other	16,107	112,225
	$ 1,018,270	$ 894,635

(6) Contingencies

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

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

(7) Related Party Note Payable

On August 10, 2022, the Company received $5.0 million of debt financing from 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. 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.

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. WFIA has not demanded payment on the note. 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 June 30, 2023 and December 31, 2022, the entire principal amounts of $8.0 million and $5.0 million, respectively, were outstanding on the note.

During the three months ended June 30, 2023, the Company recognized $252,500 of interest expense relating to this note. During the six months ended June 30, 2023, the Company recognized $440,000 of interest expense relating to this note. All interest expense relating to this note is included in accrued expenses on the consolidated balance sheet.

(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 June 30, 2023, and December 31, 2022, of which 12,056,788 and 11,309,412 shares of common stock were issued and outstanding as of June 30, 2023 and December 31, 2022, respectively. The Company has not issued any shares of preferred stock.

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

(9) Sale of Common Stock

Purchase Agreement with Lincoln Park

On April 24, 2023, the Company entered into a purchase agreement (the "LP Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). Pursuant to the terms of the LP Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to $12 million of the Company's common stock subject to certain limitations and satisfaction of the conditions set forth in the LP Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC a registration statement to register for resale under the Securities Act 4.5 million shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement.

Pursuant to the terms of the LP Purchase Agreement, at the time the Company signed the LP Purchase Agreement and the Registration Rights Agreement, the Company issued 368,023 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the LP Purchase Agreement. The commitment shares were valued at $400,409 and recorded as an addition to equity for the issuance of the common stock and treated as a reduction to equity as a cost of capital to be raised under the LP Purchase Agreement.

During the quarter ended June 30, 2023, the Company sold 270,000 shares of common stock under the LP Purchase Agreement, for net proceeds of $254,260. Subsequent to June 30, 2023, the Company sold 240,000 shares of common stock under the LP Purchase Agreement, for net proceeds of $196,167.

At the Market Offering

On January 3, 2023, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("HCW") pursuant to which the Company may issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $4.97 million in at-the-market offerings sales. HCW will act as sales agent and will be paid a 3% commission on each sale under the ATM Agreement. The Company's common stock will be sold at prevailing market prices at the time of the sale, and, as a result, prices will vary. During the quarter ended June 30, 2023, the Company sold 109,353 shares of common stock under the ATM Agreement, for net proceeds of $100,978. Subsequent to June 30, 2023, the Company sold 1,538,855 shares of common stock under the Sales Agreement, for net proceeds of $1,595,429.

(10) Stock-Based Compensation

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

The maximum number of shares of common stock available for issuance in connection with options and other awards granted under the 2021 Plan is 2,786,310 and as of June 30, 2023, 1,436,631 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 $421,853 during the six months ended June 30, 2023 and $388,707 during the six months ended June 30, 2022. The Company recorded stock-based compensation expense of $217,375 during the three months ended June 30, 2023 and $207,189 during the three months ended June 30, 2022, all relating to options issued during 2021, 2022 and 2023. As of June 30, 2023 and December 31, 2022, there was $2,314,144 and $2,637,895, 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 and six months ended June 30, 2023 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2023	861,019			
Granted	384,500	$ 1.75	9.92	-
Exercised	-			
Forfeitures or expirations	(5,615)			
Outstanding at March 31, 2023	1,239,904	$ 3.16	9.01	
Granted	127,758	$ 0.96	9.98	-
Exercised	-			
Forfeitures or expirations	(17,983)			
Outstanding at June 30, 2023	1,349,679	$ 3.16	9.01	
Vested and expected to vest at June 30, 2023	1,349,679			
Exercisable at June 30, 2023	300,067			

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 period ending June 30, 2023 and March 31, 2023 were as follows, shown on a weighted average basis:

	June 30, 2023	March 31, 2023
Risk-free interest rate	3.608%	3.662%
Expected term (in years)	5.7	6
Expected volatility	1.28	1.13
Expected dividend yield	0%	0%

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

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

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

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

The grant-date fair value of options granted during the three months ended June 30, 2023, ranged from $0.80 to $0.86, and the grant date fair value of the options granted during the three months ended March 31, 2023, ranged from ranged from $0.81 to $1.53

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 $0.93 as of June 30, 2023, and $1.00 as of December 31, 2022, based upon the closing price of our common stock on the Nasdaq Capital Market on those dates.

(11) 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 June 30, 2023, and 2022 or the six-month periods ended June 30, 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:

	Three Months Ended June 30, 2023		Six Months Ended June 30, 2023	
Federal income tax benefit at statutory rate	$ (1,389,425)	$ (848,475)	$ (2,230,451)	$ (1,888,057)
State income tax benefit	(365,882)	(223,432)	(587,352)	(497,189)
Permanent differences	4,634	3,098	8,303	8,763
Change in valuation allowance	1,780,851	1,077,408	2,871,687	2,439,294
Other	(30,178)	(8,599)	(62,187)	(62,811)
Total income tax expense	$ -	$ -	$ -	$ -

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 $8,770,634 as of June 30, 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 June 30, 2023 or December 31, 2022.

	June 30, 2023	December 31, 2022
Deferred income tax assets:		
Current:		
Research and development costs	$ 620,738	$ 343,087
Other	59,018	59,018
Non-current:		
Net operating losses	5,223,238	3,381,215
Research and development costs	2,900,375	1,762,716
Research and development tax credit	131,681	-
Unvested stock options	341,951	204,380
Patents	86,617	92,417
Right-of-use assets	51,807	63,563
Gross deferred income tax assets	9,415,425	5,906,396
Less: valuation allowance	(8,770,634)	(5,580,595)
Net deferred income tax asset	644,791	325,801
Deferred income tax liabilities:		
Current:		
Accrual to cash	(7,694)	(11,228)
Non-current		
Property and equipment	(637,097)	(314,573)
Gross deferred income tax liabilities	(644,791)	(325,801)
Net deferred tax asset (liability)	$ -	$ -

(12) Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share for the three and six months ended June 30, 2023 and 2022:

	Three Months Ended June 30, 2023		Six Months Ended June 30, 2023	
Numerator:				
Net loss	$ (6,616,309)	$ (4,040,447)	$ (10,621,196)	$ (9,043,958)
Denominator:				
Weighted average common shares outstanding	11,694,823	11,309,412	11,503,182	11,309,412
Net loss per share, basic and diluted	$ (0.57)	$ (0.36)	$ (0.92)	$ (0.80)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows for the three and six-month periods ended June 30, 2023 and June 30, 2022:

	June 30, 2023	June 30, 2022
Stock options issued under the 2021 Equity Incentive Plan	1,349,670	883,801
Common stock purchase warrants outstanding	4,999,998	4,999,998
Total	6,349,668	5,883,799

(13) 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 June 30, 2023.

(14) 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 $18,000 for both the six months ended June 30, 2023 and 2022 and $9,000 for both the three months ended June 30, 2023 and 2022, which approximates fair value. As of June 30, 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. The full principal balance of $8.0 million was outstanding as of June 30, 2023 and the initial principal balance of $5.0 million was outstanding as of December 31, 2022. Interest expense of $252,500 and $187,500 was recognized during the three months ended June 30, 2023 and March 31, 2023, respectively. $732,339 and $292,339 of accrued interest relating to this note was outstanding as of June 30, 2023 and December 31, 2022.

(15) Subsequent Events

Management evaluated events that occurred subsequent to June 30, 2023, through August 14, 2023, which is the date the interim financial statements were issued.

Subsequent to June 30, 2023, the Company sold 240,000 shares of common stock under the LP Purchase Agreement, for net proceeds of $169,167 and sold 1,538,855 shares of common stock under the ATM Agreement, for net proceeds of $1,595,429.

On August 11, 2023, the Company entered into a Securities Purchase Agreement with WFIA and issued, in a private placement priced at the market under Nasdaq rules, 1,823,155 shares of its common stock at a purchase price per share of $0.5485, resulting in gross proceeds to the Company of approximately $1.0 million. Peter Werth, a member of the Company’s Board of Directors, is the manager of WFIA.

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) and in this report, as well as disclosures in this report and our other reports filed with the Securities and Exchange Commission (SEC), for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company using our proprietary Precision Timed Release™ (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 $72.2 million as of June 30, 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 $6.6 million and $4.0 million for the three-month periods ended June 30, 2023 and 2022, respectively, and $10.6 million and $9.0 million for the six-month periods ended June 30, 2023 and 2022, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of June 30, 2023, we had an accumulated deficit of $80.0 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.

Clinical, Manufacturing and Business Update

***CTx-1301*:** We have designed our clinical program for CTx-1301 (dexmethylphenidate), 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 completed a Phase 3 adult dose-optimization study in June 2023. Our Phase 3 CTx-1301-022 study (NCT05631626), which assessed efficacy and safety along with onset and duration of CTx-1301 in 21 adults (age range: 18-55 years) with ADHD in an adult laboratory classroom setting did not achieve statistical significance on the primary efficacy endpoint but demonstrated a trend towards significance despite its modest sample size in improving ADHD symptoms with a rapid onset of action and entire active-day duration. After a 5-week dose optimization period, subjects were either randomized to their optimized dose of CTx-1301 or placebo.

The overall Permanent Product Measure of Performance (PERMP) data showed a trend toward significance with a p-value of 0.089 despite the modest sample size. A meta-analysis conducted by Faraone and Glatt (Clinical Psychiatry 71:6 June 2010) using 11 published studies with long-acting stimulants in adults demonstrated the average effect size to be 0.73 (approximate range 0.5 to 0.9). In this trial, subjects randomized to CTx-1301 demonstrated an effect size of 1.41 at 30 minutes and an effect size of 0.98 at 16 hours with an average effect size of 1.79 (range 0.88 to 2.60). Effect size represents the magnitude of a change in an outcome or the strength of a relationship, the practical significance. Effect size measures the magnitude of differences in outcomes between two groups in a study.

In addition, the secondary outcome using the Clinical Global Impression (CGI) Scale for severity of illness was associated with a decrease in the severity of illness in subjects randomized to CTx-1301 compared to placebo. This is noteworthy as the purpose of this study was to obtain estimates of effect size and it was not anticipated that significant treatment differences would be observed. CTx-1301 was well tolerated; 9% (n=1) of the subjects that were randomized to CTx-1301 experienced treatment emergent adverse events (TEAEs), while 30% (n=3) of subjects that were randomized to placebo experienced TEAEs. Patient reported outcomes on the overall satisfaction with CTx-1301 compared to subject's prior ADHD medication was favorable.

The pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study commenced in late July 2023, with results expected in the first quarter of 2024.

In addition, we initiated a Phase 3 pediatric dose-optimization onset and duration study in early August 2023, with results 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 the second half of 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 (dexmethylphenidate), to Societal, which has produced a scalable supply of CTx-1301 for our 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 (dexmethylphenidate). 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 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 fourth quarter of 2023 to allow for a potential IND filing in the first quarter of 2024.

***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 U.S. In addition, we are evaluating opportunities to expand our relationship with BDD Pharma Limited.

Debt Financing

On August 10, 2022, we received $5.0 million of debt financing from Werth Family Investment Associates LLC (WFIA). On May 9, 2023, we received an additional $3.0 million of debt financing (2023 WFIA Debt Financing) from WFIA by amending the restating the promissory note in favor of WFIA (WFIA Note) to increase the principal amount to $8.0 million. 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. 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. To date, we have not received a demand notice from WFIA. 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 June 30, 2023, the accrued interest on the WFIA Note was $0.7 million. See "Liquidity and Capital Resources" below.

At the time of the 2023 WFIA Debt Financing, WFIA owned 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, owned 21,849 shares of our common stock. Our Audit Committee and Board of Directors reviewed the terms of the WFIA Note pursuant to our Policy and Procedures for Related Person Transactions and determined that the WFIA Note is in our best interest and the best interests of our stockholders.

Common Stock Purchase Agreement

In April 2023, we entered into a purchase agreement (Lincoln Park Agreement) and a registration rights agreement (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. During the three months ended June 30, 2023, we sold 270,000 shares of common stock pursuant to the Lincoln Park Agreement, for net proceeds of $254,260 and subsequent to June 30, 2023, we sold an additional 240,000 shares of common stock pursuant to the Lincoln Park Agreement, for net proceeds of $196,167.

Components of Operating Results

Revenue

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

Operating Expenses

Research and Development Expenses

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

- expenses incurred under third party agreements with contract research organizations (CROs), and investigative sites, that conducted or will conduct our clinical trials and a portion of our pre-clinical activities;
- costs of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- expenses, including salaries and benefits of employees engaged in research and development activities;
- costs of manufacturing equipment, depreciation and other allocated expenses; and
- fees paid for contracted regulatory services as well as fees paid to regulatory authorities including the FDA for review and approval of our product candidates.

We expense all research and development costs as incurred, other than manufacturing equipment used in research and development which is capitalized and amortized over its estimated 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 June 30, 2023 and June 30, 2022:

The following table summarizes our results of operations for the three months ended June 30, 2023 and June 30, 2022:

(in thousands)	Three Months ended June 30, 2023	Three Months ended June 30, 2022	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 4,456	$ 2,178	$ 2,278	104.6%
General and administrative	1,906	1,870	36	1.9%
Loss from operations	(6,362)	(4,048)	2,314	(57.2%)
Interest and other income (expense), net	(254)	8	(262)	**NM**
Net Loss	$ (6,616)	$ (4,040)	$ 2,052	(50.8%)

Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended June 30, 2023 and June 30, 2022:

(in thousands)	Three Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 1,858	$ 693	$ 1,165	168.1%
Drug manufacturing and formulation	1,838	801	1,037	129.5%
Personnel expenses	623	654	(31)	(4.7%)
Regulatory costs	137	30	107	356.7%
Total research and development expenses	$ 4,456	$ 2,178	$ 2,278	104.6%

R&D expenses were $4.5 million for the three months ended June 30, 2023, an increase of $2.2 million or 104.6% from the three months ended June 30, 2022. This change was the result of both increased manufacturing and clinical activity as we initiated the Phase 3 adult dose-optimization study for CTx-1301 in late 2022 and completed it in June 2023. Additionally, during the three months ended June 30, 2023, we completed manufacturing of Phase 3 clinical supply for CTx-1301, and incurred start-up activities for two Phase 3 studies for CTx-1301: the pediatric dose optimization onset and duration study and the fixed dose pediatric and adolescent safety and efficacy study. During the three months ended June 30, 2022, we incurred minimal clinical costs related to certain study start-up costs for the Phase 3 fixed dose pediatric and adolescent safety and efficacy study.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended June 30, 2023 and June 30, 2022:

(in thousands)	Three Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 682	$ 546	$ 136	24.9%
Legal and professional fees	586	401	185	46.1%
Occupancy	122	118	4	3.4%
Insurance	383	670	(287)	(42.8%)
Other	133	135	(2)	(1.5%)
Total general and administrative expenses	$ 1,906	$ 1,870	$ 36	1.9%

Total G&A expenses were $1.9 million for the three months ended June 30, 2023, an increase of $0.04 million or 1.9% from the three months ended June 30, 2022. This change was primarily the result of an increase in legal fees incurred relating to capital raise activities and an increase in personnel expenses relating to annual compensation increases, offset by a decrease in insurance costs which 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 June 30, 2023 and June 30, 2022:

(in thousands)	Three Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Interest and other income (expense), net	$ (254)	$ 8	$ (262)	**NM**

Total interest and other income (expense), net in the three months ended June 30, 2023 primarily related to interest on the initial $5.0 million related party note payable to WFIA, dated August 2022, which was subsequently increased to $8.0 million in May 2023, offset by interest earned on invested balances.

Total interest and other income (expense), net in the three months ended June 30, 2022 primarily related to interest earned during the period, offset by interest expense incurred on a financing lease and insurance premium financing.

Comparison of the six months ended June 30, 2023 and June 30, 2022:

The following table summarizes our results of operations for the six months ended June 30, 2023 and June 30, 2022:

(in thousands)	Six Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 6,584	$ 4,941	$ 1,643	33.3%
General and administrative	3,628	4,117	(489)	(11.9%)
Loss from operations	(10,212)	(9,058)	1,154	(12.7%)
Interest and other income (expense), net	(409)	14	(423)	**NM**
Net Loss	$ (10,621)	$ (9,044)	$ 731	(8.1%)

Research and development expenses

The following table summarizes our research and development (R&D) expenses for the six months ended June 30, 2023 and June 30, 2022:

(in thousands)	Six Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 2,725	$ 1,501	$ 1,224	81.5%
Drug manufacturing and formulation	2,437	2,154	283	13.1%
Personnel expenses	1,258	1,237	21	1.7%
Regulatory costs	164	49	115	234.7%
Total research and development expenses	$ 6,584	$ 4,941	$ 1,643	33.3%

R&D expenses were $6.6 million for the six months ended June 30, 2023, an increase of $1.6 million or 33.3% from the six months ended June 30, 2022. The increase was the result of significant clinical activity in the first half of 2023 as we initiated the Phase 3 adult dose-optimization study for CTx-1301 in late 2022 and completed it in June 2023. Additionally, in the first half of 2023, we incurred expenses in connection with the pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study and the Phase 3 pediatric dose-optimization onset and duration study, both for CTx-1301, which were in study start-up phase. Manufacturing activity also increased in 2023, as we completed the manufacturing of clinical supply for the CTx-1301 Phase 3 studies.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the six months ended June 30, 2023 and June 30, 2022:

(in thousands)	Six Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 1,351	$ 1,229	$ 122	9.9%
Legal and professional fees	984	1,048	(64)	(6.1%)
Occupancy	252	246	6	2.4%
Insurance	775	1,343	(568)	(42.3%)
Other	266	251	15	6.0%
Total general and administrative expenses	$ 3,628	$ 4,117	$ (489)	(11.9%)

Total G&A expenses were $3.6 million for the six months ended June 30, 2023, a decrease of $0.5 million or 11.9% from the six months ended June 30, 2022. This change was primarily the result of a decrease in insurance costs of $0.6 million related to a decline in the annual directors' and officers' insurance policy premium which was renewed in December of 2022, offset by an increase in personnel expenses resulting from annual compensation increases.

Interest and other income (expense), net

The following table summarizes interest and other income (expense), net for the six months ended June 30, 2023 and June 30, 2022:

(in thousands)	Six Months ended June 30, 2023	2022	Increase (Decrease)	% Increase (Decrease)
Interest and other income (expense), net	$ (408)	$ 14	$ (422)	**NM**

Total interest and other income (expense), net in the six months ended June 30, 2023 primarily related to interest on the initial $5.0 million related party note payable to WFIA, dated August 2022, which was subsequently increased to $8.0 million in May 2023, offset by interest earned on invested balances.

Total interest and other income (expense), net in the six months ended June 30, 2022 primarily related to interest earned during the period, offset by interest expense incurred on a financing lease and insurance premium financing.

Cash Flows

	Six Months ended June 30, 2023	2022
Net cash (used in) operating activities	$ (8,180)	$ (8,277)
Net cash (used in) investing activities	(37)	(13)
Net cash (used in) provided by financing activities	3,211	(7)
Net decrease in cash and cash equivalents	$ (5,006)	$ (8,297)

Cash Flows from Operating Activities

Net cash used in operating activities was $8.2 million for the six months ended June 30, 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 $10.6 million, prior to the effects of two noncash items, stock-based compensation expense of $0.4 million and depreciation expense of $0.3 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 $0.6 million primarily due to the utilization of a deposit made to our CDMO for the build out of our new manufacturing suite and the utilization of deposits made to our CROs, and an increase in trade accounts payable and accrued expenses of $1.0 million due to increased clinical and manufacturing amounts resulting from increased development activity, an increase in interest accrued due to the WFIA Note and an increase in legal fees payable relating to legal activity incurred primarily in connection with capital raise activities.

Net cash used in operating activities was $8.3 million for the six months ended June 30, 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 $9.0 million, prior to the effects of two noncash items, stock-based compensation expense of $0.4 million and depreciation of $0.2 million. Changes in operating assets and liabilities included a decrease in miscellaneous receivables resulting from the receipt in early 2022 of a significant portion of the payroll and research and development tax credits owed to us, and a decrease in accrued liabilities resulting from the final payments made on the second manufacturing press which were accrued at the end of 2021.

Cash Flows from Investing Activities

Net cash used in investing activities for both the six-month periods ended June 30, 2023 and June 30, 2022 was related to the purchase of equipment to support our research and development.

Cash Flows from Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2023 was primarily related to $3.0 million received from the 2023 WFIA Debt Financing. In addition, we received $0.3 million in net proceeds from the Lincoln Park Agreement and $0.1 million from the ATM Agreement (as defined below) during the six months ended June 30, 2023.

Net cash used in financing activities for the six months ended June 30, 2022 was related to principal payments on finance lease obligations.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012 through June 30, 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 sale of common stock pursuant to the Lincoln Park Agreement and the ATM Agreement after June 30, 2023 and prior to the filing of this report, along with the WFIA Private Placement (described below), we expect our cash and cash equivalents will be sufficient to fund our development and operating expenditures into September 2023.

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

We entered into an At The Market Offering Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC, as sales agent (HCW), in January 2023 as amended in May 2023, pursuant to which we may offer and sell, from time to time through HCW, shares of our common stock for aggregate proceeds of up to $4.97 million (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). During the three months ended June 30, 2023, we sold 109,353 shares of common stock pursuant to the ATM Agreement, for net proceeds of $100,978 after deducting $3,187 of compensation to HCW and other administration fees, and subsequent to June 30, 2023, we sold an additional 1,538,855 shares of common stock pursuant to the ATM Agreement, for net proceeds of $1,595,429 after deducting $49,502 of compensation to HCW and other administration fees.

During the three months ended June 30, 2023, we sold 270,000 shares of common stock pursuant to the Lincoln Park Agreement, for net proceeds of $254,260 and subsequent to June 30, 2023, we sold an additional 240,000 shares of common stock pursuant to the Lincoln Park Agreement, for net proceeds of $196,167.

On August 11, 2023, the Company entered into a Securities Purchase Agreement with WFIA and issued, in a private placement priced at the market under Nasdaq rules, 1,823,155 shares of its common stock at a purchase price per share of $0.5485, resulting in gross proceeds to the Company of approximately $1.0 million (WFIA Private Placement).

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 the second half of 2024 for potential FDA approval, we believe that we will need approximately $30.0 million of capital, in addition to the proceeds from the WFIA Private Placement. 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 or if our debt is converted to equity, 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 June 30, 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 pivotal Phase 3 fixed-dose pediatric and adolescent safety and efficacy study for CTx-1301, which commenced in late July 2023, and the Phase 3 pediatric dose-optimization, onset and duration study, which commenced in early August 2023. We have entered into agreements with a CDMO and other third parties for manufacture of the registration batches for CTx-1301 which will be needed for submission of the NDA. 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 and six-month periods ending June 30, 2023 and 2022 and had accumulated losses of $80.0 million since inception to June 30, 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, the ATM Agreement, the Lincoln Park Agreement, the WFIA debt financings and the WFIA Private Placement. 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 these 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 June 30, 2023, have concluded that our disclosure controls and procedures were effective as of June 30, 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 June 30, 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.

Except as set forth below, there were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 10, 2023.

Future sales of our common stock, warrants, or securities convertible into our common stock may depress our stock price.

The price of our common stock or warrants could decline as a result of sales of a large number of shares of our common stock or warrants or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional shares of common stock, warrants or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. We may also issue additional shares of common stock to satisfy our outstanding promissory note in favor of Werth Family Investment Associates LLC, an entity controlled by Peter Werth, a member of our Board of Directors. Any such issuances could result in substantial dilution to our existing stockholders and could cause the price of our common stock or warrants to decline.

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

Our common stock and warrants are currently listed for trading on Nasdaq. On May 16, 2023, we received a notice from Nasdaq stating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing. We submitted a plan of compliance to Nasdaq on June 30, 2023. On July 28, 2023, Nasdaq notified us that that it granted an extension until November 13, 2023 to regain compliance with the minimum stockholders' equity requirement, conditioned upon achievement of certain milestones included in the plan of compliance previously submitted to Nasdaq, including a plan to raise additional capital. If we fail to evidence compliance upon filing our periodic report for the quarter ending September 30, 2023 by November 13, 2023, we may be subject to delisting. If Nasdaq determines to delist our securities, we will have the right to appeal to a Nasdaq hearings panel. There can be no assurance that we will be able to regain compliance with the applicable Nasdaq listing requirements.

In addition, on July 28, 2023, we received notice from Nasdaq indicating that we are not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq. We were provided a compliance period of 180 calendar days from the date of the notice, or until January 24, 2024, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). We may be eligible for an additional 180 calendar day compliance period. There can be no assurance that we will regain compliance with the minimum closing bid requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements.

We will continue to monitor the closing bid price of our common stock and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock and/or warrants.

We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum stockholders' equity of $2.5 million and a minimum closing bid price of $1.00 per share or risk delisting, which could have a material adverse effect on our business. If our common stock and warrants are delisted from Nasdaq, it could materially reduce the liquidity of our common stock and warrants and result in a corresponding material reduction in the price of our common stock and warrants as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. If our common stock and warrants are delisted, it could be more difficult to buy or sell our common stock and warrants or to obtain accurate quotations, and the price of our common stock and warrants could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Cingulate Inc.	10-K	3.1	3/28/2022
3.2	Amended and Restated Bylaws of Cingulate Inc.	10-K	3.2	3/28/2022
10.1	Securities Purchase Agreement, dated August 11, 2023, by and beween the Company and Werth Family Investment Associates LLC	8-K	10.1	8/14/2023
10.2	Purchase Agreement, dated April 24, 2023, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.1	4/25/2023
10.3	Registration Rights Agreement, dated April 24, 2023, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.2	4/25/2023
10.4	Amended and Restated Promissory Note, dated May 9, 2023, between Cingulate Therapeutics, LLC and Werth Family Investment Associates LLC	8-K	10.1	5/10/2023
10.5	Amendment to ATM Agreement, dated May 2, 2023, by and between Cingulate Inc. and H.C. Wainwright & Co., LLC	10-Q	10.5	5/10/2023
31.1*	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.			
31.2*	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.			
32.1**	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.			
32.2**	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.			
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

* Filed Herewith

** Furnished Herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CINGULATE INC.

Date: August 14, 2023

By: */s/ Shane J. Schaffer*
Shane J. Schaffer
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: August 14, 2023

By: */s/ Louis G. Van Horn*
Louis G. Van Horn
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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 June 30, 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: August 14, 2023

/s/ Shane J. Schaffer

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

Exhibit 31.2

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 June 30, 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: August 14, 2023

/s/ Louis G. Van Horn

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

Exhibit 32.1

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 June 30, 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: August 14, 2023

By: */s/ Shane J. Schaffer*
Shane J. Schaffer
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 June 30, 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: August 14, 2023

By: */s/ Louis G. Van Horn*
Louis G. Van Horn
Chief Financial Officer
(Principal Financial Officer)