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 September 30, 2024

or

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

For the transition period from_____ to_____.

Commission File Number: 001-40874

Cingulate Inc.
(Exact name of registrant as specified in its charter)

Delaware	**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 every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	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 November 6, 2024, 3,212,233 shares of the registrant's common stock, $0.0001 par value, were issued and outstanding.

Cingulate Inc.
Form 10-Q for the Quarter Ended September 30, 2024

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this report with the Securities and Exchange Commission (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 Stock Market LLC (Nasdaq);
- our lack of operating history and need for additional capital;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for CTx-1301, CTx-1302, and CTx-2103;
- the timing of our New Drug Application (NDA) submissions for CTx-1301, CTx-1302, and CTx-2103;
- the timing of and our ability to obtain and maintain regulatory approvals for CTx-1301, CTx-1302, CTx-2103, or any other future product candidate;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to identify strategic partnerships;
- our expected use of cash;
- our competitive position and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (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 in this report and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on April 1, 2024, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

PART I — FINANCIAL INFORMATION

Cingulate Inc.
Consolidated Balance Sheets (unaudited)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,040,149	$ 52,416
Other receivables	2,247	14,622
Prepaid expenses and other current assets	1,301,215	511,556
Total current assets	11,343,611	578,594
Property and equipment, net	2,066,515	2,545,965
Operating lease right-of-use assets	169,978	366,877
Total assets	**13,580,104**	**3,491,436**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	906,215	5,199,106
Accrued expenses	402,152	1,651,518
Note payable	-	3,000,000
Finance lease liability, current	8,806	17,057
Operating lease liability, current	225,368	358,085
Total current liabilities	1,542,541	10,225,766
Long-term liabilities:		
Finance lease liability, net of current	-	4,436
Operating lease liability, net of current	-	130,663
Total long-term liabilities	-	135,099
Total liabilities	**1,542,541**	**10,360,865**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 3,044,165 and 97,293 shares issued and outstanding as of September 30, 2024 and December 31, 2023	305	10
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	-	-
Additional Paid-in-Capital	114,394,459	86,074,004
Accumulated deficit	(102,357,201)	(92,943,443)
Total stockholders' equity	**12,037,563**	**(6,869,429)**
Total liabilities and stockholders' equity	**$ 13,580,104**	**$ 3,491,436**

See notes to consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 1,428,504	$ 3,923,852	$ 5,116,582	$ 10,508,395
General and administrative	1,853,583	1,825,822	4,319,902	5,453,643
Operating loss	**(3,282,087)**	**(5,749,674)**	**(9,436,484)**	**(15,962,038)**
Interest and other income (expense), net	50,483	(229,380)	22,726	(638,212)
Loss before income taxes	(3,231,604)	(5,979,054)	(9,413,758)	(16,600,250)
Income tax benefit (expense)	-	-	-	-
Net loss and comprehensive loss	**$ (3,231,604)**	**$ (5,979,054)**	**$ (9,413,758)**	**$ (16,600,250)**
Net loss per share of common stock, basic and diluted	$ (1.83)	$ (72.60)	$ (10.06)	$ (278.84)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	1,766,362	82,361	936,118	59,533

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, 2023	**47,123**	**5**	**$ 73,290,513**	**$ (69,408,496)**	**$ -**	**$ 3,882,022**
Activity for the three months to March 31, 2023:						
Unrealized losses on available for sale investments	-	-	-	-	-	-
Stock-based compensation expense	-	-	204,479	-	-	204,479
Net loss	-	-	-	(4,004,887)	-	(4,004,887)
Balance March 31, 2023	**47,123**	**$ 5**	**$ 73,494,992**	**$ (73,413,383)**	**$ -**	**$ 81,614**
Activity for the three months to June 30, 2023:						
Unrealized losses on available for sale investments	3,114	-	218,798	-	-	218,798
Stock-based compensation expense	-	-	217,376	-	-	217,376
Net loss	-	-	-	(6,616,309)	-	(6,616,309)
Balance June 30, 2023	**50,237**	**$ 5**	**$ 73,931,166**	**$ (80,029,692)**	**$ -**	**$ (6,098,521)**
Activity for the three months to September 30, 2023:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	7,412	1	$ 1,621,938			1,621,939
Issuance of common stock in connection with private placement with WFIA	7,596	1	$ 999,999			1,000,000
Issuance of common stock and pre-funded warrants sold for cash in public offering, net of fees	7,167	1	3,310,550			3,310,551
Issuance of pre-funded warrants in connection with the conversion of related party note payable	-	-	3,949,765			3,949,765
Capital contribution in connection with conversion of related party note payable			1,862,735			1,862,735
Stock-based compensation expense	-	-	236,251	-	-	236,251
Net loss	-	-	-	(5,979,054)	-	(5,979,054)
Balance September 30, 2023	**72,412**	**$ 8**	**$ 85,912,404**	**$ (86,008,746)**	**$ -**	**$ (96,334)**
Balance January 1, 2024	**97,293**	**10**	**$ 86,074,004**	**$ (92,943,443)**	**$ -**	**$ (6,869,429)**
Activity for the three months to March 31, 2024:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	23,650	2	3,115,282	-	-	3,115,284
Issuance of common stock in public offering, net of fees	296,000	30	6,432,862	-	-	6,432,892
Issuance of pre-funded warrants in connection with the conversion of related party note payable	-	-	2,734,739	-	-	2,734,739
Capital contribution in connection with conversion of related party note payable	-	-	586,511	-	-	586,511
Issuance of restricted common stock	596	-	24,024	-	-	24,024
Stock-based compensation expense	-	-	164,575	-	-	164,575
Net loss	-	-	-	(2,972,477)	-	(2,972,477)
Balance March 31, 2024	**417,539**	**$ 42**	**$ 99,131,997**	**$ (95,915,920)**	**$ -**	**$ 3,216,119**
Activity for the three months to June 30, 2024:						
Issuance of common stock upon exercise of pre-funded warrants	86,334	9	(9)			-
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	121,279	12	1,109,990	-	-	1,110,002
Warrant inducement	143,958	14	1,614,549	-	-	1,614,563
Issuance of restricted common stock	11,652	1	98,433	-	-	98,434
Stock-based compensation expense	-	-	254,331	-	-	254,331
Net loss	-	-	-	(3,209,677)	-	(3,209,677)
Balance June 30, 2024	**780,762**	**$ 78**	**$ 102,209,291**	**$ (99,125,597)**	**$ -**	**$ 3,083,772**
Activity for the three months to September 30, 2024:						
Issuance of common stock upon exercise of pre-funded warrants	16,498	2	(2)			-

Share adjustment due to fractional rounding of August 2024 reverse split	130,602	13	(13)			-
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	2,116,303	212	11,791,412	-	-	11,791,624
Stock-based compensation expense	-	-	393,771	-	-	393,771
Net loss	-	-	-	(3,231,604)	-	(3,231,604)
Balance September 30, 2024	**3,044,165**	**$ 305**	**$ 114,394,459**	**$ (102,357,201)**	**$ -**	**$ 12,037,563**

See notes to consolidated financial statements

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Operating activities:		
Net loss	$ (9,413,758)	$ (16,600,250)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	492,788	410,593
Stock-based compensation	935,135	658,106
Changes in operating assets and liabilities:		
Other receivables	12,375	228,596
Prepaid expenses and other current assets	(789,659)	1,368,658
Operating lease right-of-use assets	196,899	194,125
Trade accounts payable and accrued expenses	(5,542,256)	1,517,952
Current portion of operating lease liability	(132,718)	13,428
Long-term portion of operating lease liability	(130,663)	(263,380)
Net cash used in operating activities	(14,371,857)	(12,472,172)
Investing activities:		
Purchase of property and equipment	(13,338)	(37,136)
Net cash used in investing activities	**(13,338)**	**(37,136)**
Financing Activities:		
Proceeds from the issuance of common stock and pre-funded common stock purchase warrants, net of fees	24,385,615	6,151,288
Proceeds from note payable	-	3,000,000
Principal payments on finance lease obligations	(12,687)	(11,943)
Net cash provided by financing activities	**24,372,928**	**9,139,345**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	9,987,733	(3,369,963)
Cash and cash equivalents at beginning of year	52,416	5,356,276
Cash and cash equivalents at end of period	**$ 10,040,149**	**$ 1,986,313**
Cash payments:		
Interest paid	$ 6,160	$ 10,266

See notes to consolidated financial statements

(1) Nature of the Business and Liquidity

Organization

Cingulate Inc. (Cingulate, or the Company), a Delaware corporation, is a biopharmaceutical company focused on the development of products utilizing its drug delivery platform technology that enables the formulation and manufacture of once-daily tablets of multi-dose therapies, with an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The Company is developing two proprietary, first-line stimulant medications, CTx-1301 (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 is progressing with the remaining clinical requirements for CTx-1301 and is targeting a New Drug Application (NDA) for CTx-1301in mid-2025. In addition, the Company has a third product to treat anxiety, CTx-2103, in a formulation stage.

The consolidated financial statements and notes for the periods ended September 30, 2024 and 2023, represent the full consolidation of Cingulate and its subsidiaries, including Cingulate Therapeutics LLC (CTx) and all references to the Company represent this full consolidation.

Liquidity

The Company has incurred operating 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. On September 30, 2024, the Company had cash and cash equivalents of approximately $10.0 million, and an accumulated deficit of approximately $102.4 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 equity, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions. Successful implementation of these plans involves both the Company's efforts and factors that are outside its control, such as market factors and FDA approval of product candidates. The Company can give no assurance that its plans will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above, which results in substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation and Principles of Consolidation

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

(b) Unaudited Interim Financial Information

The accompanying consolidated balance sheets as of September 30, 2024 and December 31, 2023, the consolidated statements of operations and comprehensive loss for the three and nine-month periods ended September 30, 2024 and 2023, the consolidated statement of stockholders' equity for the three and nine-month periods ended September 30, 2024 and 2023, the consolidated statements of cash flows for the nine-month periods ended September 30, 2024 and 2023, and the related interim disclosures are unaudited. These unaudited consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying consolidated financial statements should be read in conjunction with the Company's 2023 audited consolidated financial statements and the notes thereto.

(c) Concentration of Credit Risk

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

(d) Impairment of Long-lived Assets

The Company assesses the carrying value of its long-lived assets, including property and equipment, as well as lease right of use (ROU) assets, when events or circumstances indicate that the carrying value of such assets may not be recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, the Company evaluates recoverability by a comparison of the carrying amount of the assets to future undiscounted cash flows expected to be generated by the assets. If the sum of the expected future cash flows is less than the carrying amount, the Company would recognize an impairment loss. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value of the long-lived asset groups. No impairment was recognized during the nine-month periods ended September 30, 2024 or 2023.

(e) Stock-Based Compensation

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

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Research and development	$ 1,088,696	$ 183,452
Insurance	128,941	31,302
Active pharmaceutical ingredients	29,025	97,324
Dues and subscriptions	20,092	-
Deferred capital raise costs	13,763	178,780
Other	20,698	20,698
	$ 1,301,215	$ 511,556

(4) Property and Equipment

Property and equipment, net consisted of the following at September 30, 2024 and December 31, 2023:

	Estimated Useful Life (in years)	September 30, 2024	December 31, 2023
Equipment	2-7	$ 4,358,260	$ 4,321,816
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	46,994	41,897
Leasehold improvements	5	474,462	471,505
Construction-in-process- equipment	-	176,816	207,976
		5,202,286	5,188,948
Less: accumulated depreciation		(3,135,771)	(2,642,983)
		$ 2,066,515	$ 2,545,965

Depreciation expense was $492,788 and $410,593, respectively, for the nine-month periods ended September 30, 2024 and 2023. Depreciation expense was $165,406 and $154,663, respectively, for the three-month periods ended September 30, 2024 and 2023.

(5) Accrued Expenses

Accrued expenses consisted of the following at September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Research and development	$ 202,741	$ 155,220
Professional fees	91,961	213,922
State franchise taxes	80,000	120,570
Employee compensation	-	593,022
Interest	-	290,000
CIP- Equipment	-	155,800
Insurance	-	56,088
Other	27,450	66,896
	$ 402,152	$ 1,651,518

(6) Contingencies

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

The Company records legal costs associated with loss contingencies as incurred and establishes reserves when those matters present material loss contingencies that management determines to be both probable and reasonably estimable in accordance with ASC 450, *Contingencies*. If a range of loss is estimated, and some amount within that range appears to be a better estimate than any other amount within that range, then that amount is accrued. If no amount within the range can be identified as a better estimate than any other amount, we accrue the minimum amount in the range. These amounts are not reduced by amounts that may be recovered under insurance or claims against third parties, but undiscounted receivables from insurers or other third parties may be accrued separately if recovery is considered probable. Management's judgment is required related to loss contingencies because the outcomes are difficult to predict, and the ultimate resolution may differ from our current analysis. The Company revises accruals in light of new information. While it is not possible to predict the outcome of loss contingencies with certainty, management is of the opinion that adequate provision for potential losses associated with any such matters has been made in the financial statements. No accruals for loss contingencies were recorded in the consolidated balance sheets as of September 30, 2024 or 2023.

(7) Related Party Note Payable

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

On September 8, 2023, the Company and CTx entered into a note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the original principal amount of $5.0 million under the note plus all accrued interest on the original principal, or $5,812,500, by issuing pre-funded warrants to purchase 28,493 shares of the Company's common stock at a conversion price per pre-funded warrant of $204.00. The closing price of the Company's common stock on Nasdaq on September 8, 2023, was $138.60 per share. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of $0.0024 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended (Exchange Act), no more than 19.99% of the outstanding shares of common stock of the Company.

On January 25, 2024, the Company and CTx entered into another note conversion agreement with WFIA, pursuant to which WFIA agreed to convert the remaining principal amount of the note payable of $3.0 million plus all accrued interest, or $3,287,500 by issuing pre-funded warrants to purchase 57,254 shares of the Company's common stock at a conversion price per pre-funded warrant of $57.42. The closing price of the Company's common stock on Nasdaq on January 24, 2024, was $52.20 per share. The pre-funded warrants had no expiration date and were exercisable immediately at an exercise price of $0.0012 per share, to the extent that after giving effect to such exercise, WFIA and its affiliates would beneficially own, for purposes of Section 13(d) of the Exchange Act, no more than 19.99% of the outstanding shares of common stock of the Company. In March of 2024, the Company issued to WFIA an additional pre-funded warrant to purchase 588 shares of common stock as a result of an error in the interest calculation, on the same form and at the same conversion price as the January pre-funded warrants.

WFIA exercised all of its pre-funded warrants in April 2024, as described in Note 9.

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

(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 September 30, 2024 and December 31, 2023, of which 3,044,165 and 97,293 shares of common stock were issued and outstanding, respectively. The Company has not issued any shares of preferred stock.

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

Reverse Stock Splits

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

On August 9, 2024, the Company completed a one-for-twelve reverse stock split (2024 Reverse Stock Split), which reduced the number of shares of the Company's common stock that were issued and outstanding immediately prior to the effectiveness of the 2024 Reverse Stock Split. The number of shares of the Company's authorized common stock was not affected by the 2024 Reverse Stock Split and the par value of the Company's common stock remained unchanged at $0.0001 per share. No fractional shares were issued in connection with the 2024 Reverse Stock Split.

Except where disclosed, all amounts related to number of shares and per share amounts have been retrospectively restated in these financial statements to reflect the 2023 Reverse Stock Split and the 2024 Reverse Stock Split.

(9) Securities Issuances

At the Market Offering

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

On March 18, 2024, the Company increased the maximum aggregate offering price of the shares of the Company's common stock issuable under the ATM Agreement from $4.97 million to $8.47 million and filed a prospectus supplement for an aggregate of $3.5 million. In connection with the filing of the prospectus supplement, on March 17, 2024, the Company received a waiver from the purchaser in the February 2024 Offering (as defined below) under the securities purchase agreement, dated February 2, 2024, by and between the Company and such purchaser. In consideration of the waiver set forth therein, the Company agreed to lower the exercise price of the Series A Warrants to purchase up to an aggregate of 28,855 shares of common stock and Series B Warrants to purchase up to an aggregate of 14,428 shares of common stock to $13.56, which warrants were previously issued by the Company to such purchaser on September 13, 2023 and to extend the exercise term of the Series A Warrants to March 17, 2029 and the term of the Series B Warrants to March 17, 2026. The modifications to the warrants had no impact on the consolidated financial statements.

On August 19, 2024, the Company increased the maximum aggregate offering price of the shares of the Company's common stock issuable under the ATM Agreement from $8.47 million to $11.33 million and filed a prospectus supplement for an aggregate of $2.86 million.

On September 3, 2024, the Company increased the maximum aggregate offering price of the shares of the Company's common stock issuable under the ATM Agreement from $11.33 million to $15.2 million and filed a prospectus supplement for an aggregate of $3.87 million.

During the three months ended March 31, 2024, the Company sold 23,650 shares of common stock under the ATM Agreement, for net proceeds of $3,115,284. During the three months ended June 30, 2024, the Company sold 31,858 shares of common stock under the ATM Agreement, for net proceeds of $354,259. During the three months ended September 30, 2024, the Company sold 902,300 shares of common stock under the ATM Agreement, for net proceeds of $5,804,393.

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 registration statements to register for resale under the Securities Act 2,685,417 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement.

During the three months ended March 31, 2024, the Company sold 89,420 shares of common stock under the LP Purchase Agreement, for net proceeds of $755,703. No shares of common stock were sold under the LP Purchase Agreement during the three months ended June 30, 2024. During the three months ended September 30, 2024, the Company sold 1,092,337 shares of common stock under the LP Purchase Agreement, for net proceeds of $6,081,814.

Public Offering

On February 2, 2024, the Company completed a public offering (the February 2024 Offering) pursuant to which the Company issued 114,583 shares of its common stock and accompanying Series A and Series B warrants at a combined price of $24.00 per share, and pre-funded warrants to purchase up to an aggregate of 197,917 shares of its common stock and accompanying Series A and Series B warrants at a combined purchase price of $23.988 per pre-funded warrant, which represents the public offering price for the common stock less the $0.0012 per share exercise price per share for each pre-funded warrant. The pre-funded warrants were exercisable at any time after the date of issuance and have no expiration date. The holders of pre-funded warrants may not exercise the warrants if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. Each share of common stock and each pre-funded warrant were sold along with one Series A and 0.5 Series B warrants. The February 2024 Offering resulted in gross proceeds to the Company of $7.5 million before deducting $750,950 of placement agent fees and other offering expenses. As of September 30, 2024, all of the pre-funded warrants had been exercised.

Warrant Inducement

On June 28, 2024, the Company entered into an inducement offer letter agreement (the June 2024 Warrant Inducement), in which certain holders (Holders) of certain of its existing warrants to purchase 265,625 shares of the Company's common stock issued to the Holders in connection with the February 2024 Offering (the February 2024 Warrants) agreed to exercise for cash their February 2024 Warrants at a reduced exercise price of $7.02 per share. In consideration for the exercise of the February 2024 Warrants, the Holders received, in addition to the reduced exercise price, new Series C common stock purchase warrants to purchase an aggregate of 354,167 shares of the Company's common stock and new Series D common stock purchase warrants to purchase an aggregate of 177,083 shares of the Company's common stock. The June 2024 Warrant Inducement is considered a modification of the existing warrants under ASC Subtopic 815-40, *Derivatives and Hedging, Contracts in Entity's Own Equity*. This modification is consistent with the equity issuance classification under ASC Subtopic 815-40 as the reason for the modification was to induce the holders of the existing warrants to exercise their warrants, which raised equity capital and generated net proceeds to the Company of approximately $1.6 million, after deducting the placement agent fees and other offering expenses payable by the Company. The modified warrants were classified as equity instruments before and after the modification, and the modification is directly attributable to an equity offering. The Company recognized the effect of modification of approximately $2.0 million as an equity issuance cost and accounting effect of the inducement is recognized in the Statement of Stockholders' Equity. The Company received net proceeds of $1.6 million on the closing of the June 2024 Warrant Inducement, which occurred on July 1, 2024.

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.

At the Company's June 2024 annual meeting, shareholders approved an amendment to the 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder by 104,167 shares to 125,577. As of September 30, 2024, 34,352 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 $812,691 and $658,105 during the nine months ended September 30, 2024 and 2023, respectively. The Company recorded stock-based compensation expense of $393,786 and $235,251 during the three months ended September 30, 2024 and September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023, there was $1,219,737 and $1,278,981, respectively, of unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the 2021 Plan, which is expected to be recognized over the next one to four years.

A summary of option activity under the Plan during the three and nine-month periods ended September 30, 2024 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2024	4,821			
Granted	15,994	$ 14.15	9.93	-
Exercised	-			
Forfeitures or expirations	(628)			
Outstanding at March 31, 2024	20,187			
Granted	69,038	13.44	9.95	-
Exercised	-			
Forfeitures or expirations	-			
Outstanding at June 30, 2024	89,225			
Granted	2,000	5.04	10.0	-
Exercised	-			
Forfeitures or expirations	-			
Outstanding at September 30, 2024	91,225			
Vested and expected to vest at September 30, 2024	91,225			
Exercisable at September 30, 2024	40,677			

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 nine-month period ending September 30, 2024 were as follows, shown on a weighted average basis:

	September 30, 2024
Risk-free interest rate	4.26%
Expected term (in years)	5.45
Expected volatility	1.46
Expected dividend yield	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 September 30, 2024 was $5.04 and the grant date fair value of the options granted during the nine months ended September 30, 2024 ranged from $4.00 to $14.00.

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 $5.04 as of September 30, 2024, and $91.80 as of December 31, 2023, based upon the closing price of our common stock on the Nasdaq Capital Market on those dates or the last trading date prior to those dates if those dates were not a trading date.

(11) Common Stock Purchase Warrants

For the 312,500 shares of common stock and pre-funded warrants issued in the February 2024 Offering, the Company issued Series A warrants to purchase up to 312,500 shares of common stock and Series B warrants to purchase up to 156,250 shares of common stock. The Series A and Series B warrants have an exercise price of $24.00 per share and became exercisable on the effective date of stockholder approval of the shares issuable pursuant to the warrants. The Series A warrants have a five-year term and the Series B warrants have a two-year term from the initial exercise date of February 5, 2024.

The Company evaluated the pre-funded warrants and the Series A and B warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and ASC Topic 815, *Derivatives and Hedging*, and determined that equity treatment was appropriate. The Company valued the pre-funded warrants to purchase 197,917 shares of common stock based on their issuance date fair value of $24.00. As of September 30, 2024, all of the pre-funded warrants had been exercised.

In connection with the February 2024 Offering, the Company issued placement agent warrants to purchase up to 12,500 shares of common stock. The placement agent warrants have an exercise price of $30.00 per share. These warrants have a five-year term ending February 2, 2029.

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

	Fair Value	Percent of Total Fair Value	Amount Allocated
Common Stock	$ 2,750,000	26.50%	$ 1,987,500
Pre-Funded Warrants	4,750,000	45.77%	3,432,750
Series A, B and Placement Agent Warrants	2,878,126	27.73%	2,079,750
Total	$ 10,378,126	100.00%	$ 7,500,000

Certain of the Series A and Series B warrants issued in connection with the February 2024 Offering were exercised as part of the June 2024 Warrant Inducement as described in Note 9. In addition, Series C and Series D warrants were issued as part of the June 2024 Warrant Inducement. The June 2024 Warrant Inducement closed on July 1, 2024, on which date the shares relating to the exercise of the Series A and B warrants and the Series C and D warrants were settled. The Company evaluated the Series C and D warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, and ASC Topic 815, and determined that equity treatment was appropriate.

The following table summarizes the Company's outstanding common stock purchase warrants as of September 30, 2024 :

	Number of Warrants	Exercise Price	Issuance Date Fair Value per Warrant	Issuance Date Fair Value Total
December 2021 Initial Public Offering Warrants	19,965	$ 1,440.00	$ 1,144.80	$ 22,855,932
December 2021 Placement Agent Warrants	868	$ 1,800.00	$ 1,113.48	966,501
September 2023 Public Offering Series A Warrants	28,855	$ 13.56	$ 129.84	3,746,533
September 2023 Public Offering Series B Warrants	14,428	$ 13.56	$ 101.04	1,457,805
September 2023 Placement Agent Warrants	1,443	$ 172.80	$ 127.56	184,069
February 2024 Public Offering Series A Warrants	135,417	$ 24.00	$ 14.04	1,901,255
February 2024 Public Offering Series B Warrants	67,708	$ 24.00	$ 11.88	804,371
February 2024 Placement Agent Warrants	12,500	$ 30.00	$ 13.80	172,500
June 2024 Series C Warrants	354,167	$ 7.020	$ 3.24	1,147,501
June 2024 Series D Warrants	177,083	$ 7.020	$ 2.40	424,999
July 2024 Placement Agent Warrants	21,250	$ 8.780	$ 2.23	47,388
Balance- September 30, 2024	833,684			$ 33,708,854

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

(12) Income Taxes

Cingulate Inc. is taxed as a C corporation under the Internal Revenue Code. Cingulate Inc. records deferred income taxes to reflect the impact of temporary differences between the recorded amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. CTx is a wholly-owned disregarded entity of Cingulate Inc., and all of the activity for CTx, along with its wholly-owned subsidiary Cingulate Works Inc., is included in the calculation of the current and deferred tax assets and liabilities for Cingulate Inc. No deferred income tax benefit or expense was recorded for the three-month periods ended September 30, 2024 and 2023 or the nine-month periods ended September 30, 2024 and 2023, for federal or state income taxes.

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

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Federal income tax benefit at statutory rate	$ (678,639)	$ (1,255,601)	$ (1,976,891)	$ (3,486,052)
State income tax benefit	(233,562)	(330,642)	(579,614)	(917,994)
Permanent differences	3,233	6,154	9,307	14,457
Change in valuation allowance	1,832,122	2,218,188	3,500,000	5,089,875
Research and development tax credits	(972,372)	(620,630)	(972,372)	(620,630)
Other	49,218	(17,469)	19,570	(79,656)
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 $16,121,058 as of September 30, 2024 and $12,631,033 at December 31, 2023, the current year portion which was recorded as a component of income tax expense on the accompanying consolidated statements of operations and other comprehensive loss.

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

The Company follows the provisions of FASB ASC 740, *Income Taxes*, to evaluate uncertain tax positions. This topic prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has not identified any material uncertain tax positions requiring recognition in the consolidated financial statements as of September 30, 2024 or December 31, 2023.

(13) Subsequent Events

Management evaluated events that occurred subsequent to September 30, 2024, through November 7, 2024, which is the date the interim financial statements were issued.

Subsequent to September 30, 2024, the Company sold 213,522 shares of common stock under the LP Purchase Agreement, for net proceeds of $899,991.

On October 15, 2024, the Company increased the maximum aggregate offering price of the shares of the Company’s common stock issuable under the ATM Agreement from $15.2 million to $19.7 and filed a prospectus supplement for an aggregate of $8.34 million.

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, 2023 (Form 10-K) and in this report, as well as disclosures in this report and our other reports filed with the 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. With an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) and anxiety, we are identifying and evaluating additional therapeutic areas where our PTR technology may be employed to develop future product candidates. 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 $106.4 million as of September 30, 2024.

We have incurred significant losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $3.2 million and $6.0 million for the three months ended September 30, 2024 and 2023, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of September 30, 2024, we had an accumulated deficit of $102.4 million.

We expect to continue to incur significant expenses and operating losses in the near term, as we:

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

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

2024 Reverse Stock Split

On August 9, 2024, we completed a one-for-twelve reverse stock split (2024 Reverse Stock Split), which reduced the number of shares of our common stock that were issued and outstanding immediately prior to the effectiveness of the 2024 Reverse Stock Split. The number of shares of our authorized common stock was not affected by the 2024 Reverse Stock Split and the par value of our common stock remained unchanged at $0.0001 per share. No fractional shares were issued in connection with the 2024 Reverse Stock Split. All share and per share amounts in this report have been adjusted to reflect the 2024 Reverse Stock Split.

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 clinical plan, and longstanding guidance on the streamlined approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

We initiated two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients- a fixed dose study and a dose-optimized onset and duration study in a laboratory classroom setting in the third quarter of 2023. Based upon written communication with the FDA that further conduct of these pediatric and adolescent studies is not required for the submission of an NDA, we closed enrollment on both Phase 3 trials. We are performing the data consolidation and analytical activities for these trials. In addition, per FDA guidance, we initiated a food effect study utilizing CTx-1301's highest dosage strength, 50-mg, in September 2024 and is expected to be completed by the end of 2024. Appropriate data will be included in the NDA, targeted for a mid-2025 submission.

We were issued a European patent for CTx-1301 for the treatment of ADHD on August 14, 2024. The patent application includes up to 30 European territories, including the United Kingdom.

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

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

We continue to evaluate strategic partnerships under which we would license CTx-1301 in the United States and/or internationally. In March 2023, we entered into a joint commercialization agreement (the Commercialization Agreement) with Indegene, Inc. (Indegene) in the United States. We are able to utilize Indegene for commercialization services for CTx-1301, including marketing, sales, market access and distribution, on a fee for service, at our discretion.

Securities Issuances

Public Offering

On February 2, 2024, we entered into agreements, including a Securities Purchase Agreement, with investors, pursuant to which we issued 114,583 shares of our common stock, pre-funded warrants to purchase up to an aggregate of 197,917 shares of our common stock, Series A warrants to purchase up to 312,500 shares of our common stock and Series B warrants to purchase up to 156,250 shares of our common stock (the "February 2024 Offering"). The February 2024 Offering closed on February 6, 2024. The combined purchase price per share of common stock and accompanying Series A and Series B warrants was $24.00. The combined purchase price per prefunded warrant and accompanying Series A and Series B warrants was $23.99, which represents the public offering price per share of common stock and accompanying warrants less the $0.0012 per share exercise price for each prefunded warrant. The pre-funded warrants are exercisable at any time after the date of issuance and have no expiration date. The holder of pre-funded warrants may not exercise the warrants if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise. The Series A warrants have an exercise price of $24.00 per share, were exercisable immediately, and will expire five years after the issuance date, and the Series B warrants have an exercise price of $24.00 per share, were exercisable immediately, and will expire two years after the issuance date. We received gross proceeds of approximately $7.5 million, before deducting $750,950 of placement agent's fees and other offering expenses, pursuant to the February 2024 Offering. As of September 30, 2024, all pre-funded warrants had been exercised. Holders of Series A warrants to purchase 177,084 shares and Series B warrants to purchase 88,500 shares gave notice of exercise in connection with the June 2024 Warrant Inducement (as defined below) on June 28, 2024.

Warrant Inducement

On June 28, 2024, we entered into an inducement offer letter agreement (June 2024 Warrant Inducement), pursuant to which certain holders (Holders) of certain of our existing warrants to purchase 265,625 shares of common stock issued to the Holders on February 6, 2024 (February 2024 Warrants) agreed to exercise for cash their February 2024 Warrants at a reduced exercise price of $7.02 per share. In consideration for the exercise of the February 2024 Warrants, the Holders received new Series C common stock purchase warrants to purchase an aggregate of 354,167 shares of common stock and new Series D common stock purchase warrants to purchase an aggregate of 177,083 shares of common stock. Such new warrants have an exercise price of $7.02 per share. We received net proceeds of $1.6 million from the closing of the June 2024 Warrant Inducement, which occurred on July 1, 2024.

ATM Agreement

We entered into an At The Market Offering Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC (HCW), as sales agent, in January 2023 as amended in May 2023, pursuant to which we may offer and sell, from time to time through HCW, shares of our common stock for aggregate proceeds of up to $19.7 million based on prospectus supplements filed with the SEC through the date of this report (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). In the three months ended September 30, 2024, we sold 902,300 shares of common stock under the ATM Agreement, for net proceeds of approximately $5.8 million, after deducting $0.2 million of compensation to HCW and other administration fees. In the nine months ended September 30, 2024, we sold 957,808 shares of common stock under the ATM Agreement, for net proceeds of approximately $9.3 million, after deducting $0.3 million of compensation to HCW and other administration fees.

Equity Line of Credit

In April 2023, we entered into a purchase agreement (Lincoln Park Agreement) with Lincoln Park Capital Fund LLC (Lincoln Park). Pursuant to the Lincoln Park Agreement, Lincoln Park has agreed to purchase from us up to an aggregate of $12.0 million of common stock (upon the terms and subject to the conditions and limitations set forth in the Lincoln Park Agreement) from time to time and at our sole discretion over the 36-month term of the Lincoln Park Agreement. During the quarter ended September 30, 2024, we sold 1,092,337 shares of common stock under the Lincoln Park Agreement, for net proceeds of approximately $6.1 million. During the nine months ended September 30, 2024, we sold 1,181,757 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of approximately $6.8 million. Subsequent to September 30, 2024, we sold 213,522 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of approximately $0.9 million.

Components of Operating Results

Revenue

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

Operating Expenses

Research and Development Expenses

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

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

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

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

General and Administrative Expenses

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

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

Interest and other income (expense), net

Interest and other income (expense), net consisted of interest expense on our related party notes payable until the last of those obligations were converted to equity in the first quarter of 2024, and interest earned on our cash and cash equivalents, including money market funds. The primary objective of our investment policy is liquidity and capital preservation.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Results of Operations

Comparison of the three months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Increase	% Increase
(in thousands)	2024	2023	(Decrease)	(Decrease)
Operating Expenses:				
Research and development	$ 1,428	$ 3,924	$ (2,496)	(63.6)%
General and administrative	1,854	1,826	28	1.5%
Operating Loss	(3,282)	(5,750)	(2,468)	(42.9)%
Interest and other income (expense), net	50	(229)	279	121.8%
Net Loss	$ (3,232)	$ (5,979)	$ (2,189)	(36.6)%

Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended September 30, 2024 and 2023:

(in thousands)	Three Months Ended September 30, 2024	2023	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 398	$ 2,346	$ (1,948)	(83.0)%
Drug manufacturing and formulation	533	817	(284)	-34.8%
Personnel expenses	441	644	(203)	(31.5)%
Regulatory costs	56	117	(61)	-52.1%
Total research and development expenses	$ 1,428	$ 3,924	$ (2,496)	(63.6)%

R&D expenses were $1.4 million for the three months ended September 30, 2024, a decrease of $2.5 million or 63.6% from the three months ended September 30, 2023. This change was primarily the result of decreased clinical activity in the three months ended September 30, 2024 as compared to the same period in 2023. During the third quarter of 2023, we incurred significant costs relating to two Phase 3 studies for CTx-1301, the fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose optimization and duration study. Enrollment in these two studies was closed in early 2024 and we are progressing with the remaining close-out and analytical activities required for an NDA submission. Manufacturing costs also decreased, as the activity in 2023 was more significant for the manufacture of clinical supply for the Phase 3 studies. In 2024, manufacturing activity included the completion of registration batches of CTx-1301. The decrease in personnel costs is the result of lower headcount and the cost containment measures, which were implemented in late 2023 in order to conserve cash, including salary reductions ranging from 5-55% for all employees. This decrease was offset by the reinstatement of 2023 base salaries for all employees in September 2024.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended September 30, 2024 and 2023:

(in thousands)	Three Months Ended September 30, 2024	2023	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 515	$ 672	$ (157)	(23.4)%
Legal and professional fees	828	511	317	62.0%
Occupancy	76	144	(68)	(47.2)%
Insurance	236	398	(162)	(40.7)%
Other	199	101	98	97.0%
Total general and administrative expenses	$ 1,854	$ 1,826	$ 28	1.5%

Total G&A expenses were $1.9 million for the three months ended September 30, 2024, an increase of 1.5% from the three months ended September 30, 2023. This is primarily the result of an increase in legal and professional fees, offset by a decrease in personnel expenses and insurance. The increase in legal and professional fees was due to the increased use of consultants in connection with the special shareholders meetings, the 2024 Reverse Stock Split and capital raising activity. This increase was offset by a decrease in personnel expenses primarily due to lower headcount and the cost containment measures, which we implemented in late 2023 in order to conserve cash, including salary reductions ranging from 5-55% for all employees. 2023 base salaries for all employees were reinstated in September 2024. In addition, there was a decrease in the annual directors' and officers' insurance premium from 2023 to 2024.

Interest and other income (expense), net

The following table summarizes interest and other income (expense), net for the three months ended September 30, 2024 and 2023:

(in thousands)	Three Months Ended September 30, 2024	2023	Increase	% Increase
Interest and other income (expense), net	$ 50	$ (229)	$ 279	121.8%

Total interest and other income (expense), net for the three months ended September 30, 2023, primarily relates to interest incurred on outstanding notes payable, offset by interest earned on invested balances. Total interest and other income for the three months ended September 30, 2024 relates to interest earned on invested balances, resulting from the increase in the Company's cash balance relating to capital raise activities in the third quarter of 2024.

Comparison of the nine months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

(in thousands)	Nine Months Ended September 30, 2024	2023	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 5,116	$ 10,508	$ (5,392)	(51.3)%
General and administrative	4,320	5,454	(1,134)	(20.8)%
Operating Loss	(9,436)	(15,962)	(6,526)	(40.9)%
Interest and other income (expense), net	23	(638)	661	103.6%
Net Loss	$ (9,413)	$ (16,600)	$ (5,865)	(35.3)%

Research and development expenses

The following table summarizes our R&D expenses for the nine months ended September 30, 2024 and 2023:

(in thousands)	Nine Months Ended September 30, 2024	2023	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 1,541	$ 5,071	$ (3,530)	(69.6)%
Drug manufacturing and formulation	2,336	3,254	(918)	-28.2%
Personnel expenses	1,091	1,902	(811)	(42.6)%
Regulatory costs	148	281	(133)	-47.3%
Total research and development expenses	$ 5,116	$ 10,508	$ (5,392)	(51.3)%

R&D expenses were $5.1 million for the nine months ended September 30, 2024, a decrease of $5.4 million or 51.3% from the nine months ended September 30, 2023. This change was primarily the result of decreased clinical activity in the nine months ended September 30, 2024 as compared to the same period in 2023. During the first nine months of 2023, we incurred significant costs relating to two Phase 3 studies for CTx-1301, the fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose optimization and duration study. Enrollment in these two studies was closed in early 2024 and we are progressing with the remaining close-out and analytical activities required for an NDA submission. Manufacturing costs also decreased, as the activity in 2023 was more significant for the manufacture of clinical supply for the Phase 3 studies. In 2024, manufacturing activity included the completion of registration batches of CTx-1301. The decrease in personnel costs is the result of lower headcount and the cost containment measures, which were implemented in late 2023 in order to conserve cash, including salary reductions ranging from 5-55% for all employees. This decrease was offset by the reinstatement of 2023 base salaries for all employees in September 2024.

General and administrative expenses

The following table summarizes our G&A expenses for the nine months ended September 30, 2024 and 2023:

(in thousands)	Nine Months Ended September 30, 2024	2023	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 1,332	$ 2,023	$ (691)	(34.2)%
Legal and professional fees	1,638	1,495	143	9.6%
Occupancy	251	396	(145)	(36.6)%
Insurance	718	1,173	(455)	(38.8)%
Other	381	367	14	3.8%
Total general and administrative expenses	$ 4,320	$ 5,454	$ (1,134)	(20.8)%

Total G&A expenses were $4.3 million for the nine months ended September 30, 2024, a decrease of $1.1 million or 20.8% from the nine months ended September 30, 2023. This is primarily the result of a decrease in personnel expenses and insurance. The decrease in personnel expenses is the result of lower headcount and the cost containment measures which we implemented in late 2023 in order to conserve cash, including salary reductions ranging from 5-55% for all employees. 2023 base salaries for all employees were reinstated in September 2024. In addition, there was a decrease in the annual directors' and officers' insurance premium from 2023 to 2024. The decrease was offset by an increase in legal and professional fees due to the increased use of consultants in connection with the special shareholders meetings, the 2024 Reverse Stock Split and capital raising activity.

Interest and other income (expense), net

The following table summarizes interest and other income (expense), net for the nine months ended September 30, 2024 and 2023:

(in thousands)	Nine Months Ended September 30, 2024	2023	Increase (Decrease)	% Increase (Decrease)
Interest and other income (expense), net	$ 23	$ (638)	$ (661)	103.6%

Total interest and other income (expense), net for the nine months ended September 30, 2023, primarily relates to interest incurred on outstanding notes payable, offset by interest earned on invested balances. Total interest and other income for the nine months ended September 30, 2024 relates to interest earned on invested balances, resulting from the increase in the Company's cash balance relating to capital raise activities.

Cash Flows

	Nine Months Ended September 30, 2024	2023
Net cash (used in) operating activities	$ (14,372)	$ (12,472)
Net cash (used in) investing activities	(13)	(37)
Net cash (used in) financing activities	$ 24,373	$ 9,139
Net increase (decrease) in cash and cash equivalents	$ 9,988	$ (3,370)

Cash Flows from Operating Activities

Net cash used in operating activities was $14.4 million for the nine months ended September 30, 2024. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $9.4 million, prior to the effects of two noncash items, stock-based compensation expense of $0.9 million and depreciation expense of $0.5 million. Changes in operating assets and liabilities included a decrease in trade accounts payable and accrued expenses of $5.5 million primarily due to the payment of vendor balances in the first quarter of 2024 with the cash proceeds from the issuance of common stock pursuant to our ATM Agreement in January 2024 and the issuance of equity in the February 2024 Offering.

Net cash used in operating activities was $12.5 million for the nine months ended September 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 $16.6 million, prior to the effects of two noncash items, stock-based compensation expense of $0.7 million and depreciation expense of $0.4 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 $1.4 million primarily due to the utilization of a deposit made to our contract manufacturing organization (CMO) 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 $1.5 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.

Cash Flows from Investing Activities

Net cash used in investing activities for both the nine months ended September 30, 2024 and 2023 was primarily related to the purchase of equipment to support our research and development.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine-month period ended September 30, 2024 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement, the Lincoln Park Agreement, the February 2024 Offering and the June 2024 Warrant Inducement.

Net cash provided by financing activities for the nine months ended September 30, 2023 was primarily related to gross proceeds of approximately $4.0 million from the capital raise in September 2023, gross proceeds of approximately $1.0 million from the WFIA Private Placement and proceeds from the issuance of shares of common stock pursuant to the Lincoln Park Agreement and the ATM Agreement. In addition, we received $3.0 million from the 2023 WFIA Debt Financing .

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012 through September 30, 2024, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations.

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

On July 1, 2024, we received net proceeds of approximately $1.6 million from the closing of the June 2024 Warrant Inducement.

In the three months ended September 30, 2024, we sold 902,300 shares of common stock under the ATM Agreement, for net proceeds of approximately $5.8 million, after deducting $0.2 million of compensation to HCW and other administration fees. In the nine months ended September 30, 2024, we sold 957,808 shares of common stock under the ATM Agreement, for net proceeds of approximately $9.3 million, after deducting $0.3 million of compensation to HCW and other administration fees.

During the three months ended September 30, 2024, we sold 1,092,337 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of $6,081,814. During the nine months ended September 30, 2024, we sold 1,181,757 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of approximately $6.8 million . Subsequent to September 30, 2024, we sold 213,522 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of approximately $0.9 million.

As of September 30, 2024, we had cash and cash equivalents of $10 million. We believe our cash will satisfy our capital needs into the third quarter of 2025 under our current business plan. We are targeting to file our NDA submission for CTx-1301 in mid-2025. We will need additional capital to advance our other programs and commercialization efforts. While we aware of the clinical and manufacturing requirements and estimated costs for an NDA submission of CTx-1301, it is difficult to predict spending for additional 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 losses from operations for at least the next several years as we continue to develop our product candidates, primarily CTx-1301 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 licensing arrangement. We are actively seeking a strategic pharmaceutical partnership under which we would license CTx-1301 in the United States, internationally, or both. In March 2023, we entered into a Joint Commercialization Agreement with Indegene. Should we be unable to identify an appropriate pharmaceutical partnership, if we receive FDA approval for CTx-1301, Indegene would provide commercialization services for CTx-1301, including marketing, sales, market access and distribution, on a fee for service basis.

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

Contractual Obligations

The following summarizes our contractual obligations as of September 30, 2024 that will affect our future liquidity.

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

We entered into agreements with vendors to complete the data consolidation and analysis for the two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients for which we closed enrollment in early 2024 based on FDA guidance regarding our clinical program. Total estimated cost of these agreements is $1.8 million.

We entered into an agreement with a CRO on August 22, 2024 to complete the final required study for CTx-1301, a fast fed study utilizing our highest dosage strength, 50mg. Total estimated cost of this agreement is $1.5 million.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change that is largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for one year after the issuance date of our financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We have incurred a net loss for the three months ended September 30, 2024 and 2023 and had accumulated losses of $102.4 million since inception to September 30, 2024. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our sources of capital have included private capital raises in various classes of units of CTx prior to the Reorganization Merger, the issuance of equity securities in connection with our initial public offering (IPO), public offerings, including the February 2024 Offering, sales of common stock under our ATM Agreement and Lincoln Park Agreement, a private placement with WFIA, the WFIA Note which was subsequently converted to equity, and the June 2024 Warrant Inducement. Additional capital will be needed by us to fund our operations, to complete development of and to commercially develop our product candidates. There is no assurance that such capital will be available when needed or on acceptable terms.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012 (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 September 30, 2024, have concluded that our disclosure controls and procedures were effective as of September 30, 2024.

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 September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Our business is subject to substantial risks and uncertainties. Investing in our securities involves a high degree of risk. You should carefully consider the risk factors in Part I, Item 1A of our Form 10-K, 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 Form 10-K.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our securities from Nasdaq, 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 The Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq to maintain the listing of our securities on The Nasdaq Capital Market.

On May 16, 2023, we received a notice from the Listing Qualifications Staff (Staff) of Nasdaq stating that we no longer complied with the minimum stockholders' equity requirement of $2.5 million under the Nasdaq Listing Rule 5550(b)(1) (Minimum Stockholders' Equity Rule) for continued listing. We submitted a plan of compliance to Nasdaq on June 30, 2023. On July 28, 2023, Nasdaq notified us that it had granted an extension until November 13, 2023 to regain compliance with the Minimum Stockholders' Equity Rule, conditioned upon achievement of certain milestones included in the plan of compliance previously submitted to Nasdaq, including a plan to raise additional capital. On November 14, 2023, we received a letter from Nasdaq indicating that, based upon our non-compliance with the Minimum Stockholders' Equity Rule, the Staff had determined to delist our securities from Nasdaq, subject to our request for a hearing before the Nasdaq Hearings Panel Panel).

On December 26, 2023, we received an additional letter from the Staff indicating that, based upon the resignation of three members of our board of directors on December 12, 2023 and December 13, 2023, we no longer compiled with the independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605. We timely requested a hearing before the Panel, which was held on February 13, 2024. On February 22, 2024, the Panel notified us that (i) as a result of the appointment of three independent board members on February 12, 2024, we had regained compliance with the board composition requirements of Nasdaq set forth in Nasdaq Listing Rule 5605 and (ii) it granted our request for an exception to evidence continued compliance with the Minimum Stockholders' Equity Rule through May 13, 2024. On May 21, 2024, we were formally notified that the Panel determined that we had regained compliance with the Minimum Stockholders' Equity Rule. Pursuant to Nasdaq Listing Rule 5815(d)(4)(A), we will be subject to a discretionary panel monitor through May 21, 2025 (Panel Monitor). If, within that one-year monitoring period, we fail to maintain compliance with any Nasdaq continued listing requirement, the Staff will issue a Delist Determination Letter and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. Notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to any deficiency that arises during the one-year monitoring period, and the Staff will not be permitted to grant additional time for us to regain compliance with respect to any deficiency.

On July 28, 2023, we received a notice from Nasdaq indicating that we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq (Minimum Bid Price Rule). 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 Bid Price Rule, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On November 30, 2023, we effected a reverse stock split of our common stock, and on December 15, 2023, we received notice from Nasdaq that we had regained compliance with the Minimum Bid Price Rule.

On June 17, 2024, we received a notice from Nasdaq indicating that, based upon our non-compliance with the Minimum Bid Price Rule, the Staff had determined to delist our securities from Nasdaq unless we timely requested a hearing before the Panel. Because we are subject to the Panel Monitor, the Staff did not grant additional time for the Company to regain compliance with the Minimum Bid Price Rule. We timely requested a hearing before the Panel, which was held on July 25, 2024. Our request for a hearing stayed any suspension or delisting action by the Staff. At such hearing we requested an extension within which to evidence compliance with the Minimum Bid Price Rule. On August 2, 2024, we received a notice from Nasdaq stating that the Panel determined to grant our request for an exception through August 23, 2024 to demonstrate compliance with the Minimum Bid Price Rule. Accordingly, the Panel granted our request for continued listing on Nasdaq, subject to: 1) on or before August 9, 2024, the Company effecting a reverse stock split at a ratio of between 1-for-3 and 1-for-15; and 2) on or before August 23, 2024, the Company demonstrating compliance with the Minimum Bid Price Rule by evidencing a closing bid price of $1.00 or more per share for a minimum of ten consecutive trading sessions. On August 9, 2024, we completed a one-for-twelve reverse stock split in an effort to evidence compliance with the Minimum Bid Price Rule. On September 9, 2024, we were formally notified that the Panel determined the Company has regained compliance with the Minimum Bid Price Rule.

In the event that our closing bid price again falls below $1.00 per share for more than 30 consecutive business days, we will no longer be in compliance with the Minimum Bid Price Rule, and as a result of the Panel Monitor, we would receive a Delist Determination Letter and we would have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. There can be no assurance that we will continue to maintain compliance with the Minimum Bid Price Rule or the other Nasdaq listing requirements.

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

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

None.

Item 5. Other Information

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

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Cingulate Inc., as amended to date	10-Q	3.1	8/13/2024
3.2	Amended and Restated Bylaws of Cingulate Inc.	10-K	3.2	3/28/2022
4.1	Form of New Warrant	8-K	4.1	7/1/2024
4.2	Form of Placement Agent Warrant	8-K	4.2	7/1/2024
10.2	Form of Inducement Letter	8-K	10.1	7/1/2024
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: November 7, 2024

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

Date: November 7, 2024

By: */s/ Jennifer L. Callahan*
Jennifer L. Callahan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 September 30, 2024 of Cingulate Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

/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, Jennifer L. Callahan, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2024 of Cingulate Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 7, 2024

/s/ Jennifer L. Callahan
Jennifer L. Callahan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 September 30, 2024 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

(1) The Quarterly Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2024

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 September 30, 2024 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

(1) The Quarterly Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 7, 2024

By: /s/ Jennifer L. Callahan
Jennifer L. Callahan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)