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, 2025

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 shares 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 11, 2025, 6,757,070 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, 2025

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this report with the Securities and Exchange Commission (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 our product candidates;
- the timing of our New Drug Application (NDA) submissions for our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 27, 2025, 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.

Cingulate Inc.
Consolidated Balance Sheets (unaudited)

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,118,710	$ 12,211,321
Other receivables	19,041	26,325
Prepaid expenses and other current assets	1,295,559	423,157
Total current assets	7,433,310	12,660,803
Property and equipment, net	1,691,538	2,104,675
Operating lease right-of-use assets	1,394,044	99,011
Total assets	**10,518,892**	**14,864,489**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	866,245	1,270,280
Accrued expenses	1,600,152	1,039,625
Note payable, current	3,184,765	2,527,108
Finance lease liability, current	-	4,430
Operating lease liability, current	231,123	130,662
Total current liabilities	5,882,285	4,972,105
Long-term liabilities:		
Operating lease liability, net of current	1,162,921	-
Note payable	-	2,436,879
Total long-term liabilities	1,162,921	2,436,879
Total liabilities	**7,045,206**	**7,408,984**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 5,977,358 and 3,402,306 shares issued and outstanding as of September 30, 2025 and December 31, 2024	596	340
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024	-	-
Additional Paid-in-Capital	129,575,211	117,380,285
Accumulated deficit	(126,102,121)	(109,925,120)
Total stockholders' equity	**3,473,686**	**7,455,505**
Total liabilities and stockholders' equity	**$ 10,518,892**	**$ 14,864,489**

See notes to unaudited consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 2,848,544	$ 1,428,504	$ 7,772,109	$ 5,116,582
General and administrative	3,147,291	1,853,583	6,579,735	4,319,902
Operating loss	**(5,995,835)**	**(3,282,087)**	**(14,351,844)**	**(9,436,484)**
Issuance cost and change in fair value of derivative	(772,169)	(894,039)	(1,016,682)	(914,747)
Interest and other income (expense), net	(573,058)	50,483	(808,475)	22,726
Loss before income taxes	(7,341,062)	(4,125,643)	(16,177,001)	(10,328,505)
Income tax benefit (expense)	-	-	-	-
Net loss and comprehensive loss	**$ (7,341,062)**	**$ (4,125,643)**	**$ (16,177,001)**	**$ (10,328,505)**
Net loss per share of common stock, basic and diluted	$ (1.35)	$ (2.34)	$ (3.60)	$ (11.03)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	5,431,206	1,766,362	4,495,724	936,118

See notes to unaudited 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, 2024	**97,293**	**10**	**$ 86,496,076**	**$ (93,365,515)**	**$ -**	**$ (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**	**$ 99,554,069**	**$ (96,337,992)**	**$ -**	**$ 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
Change in fair value of derivative	-	-	20,708	-	-	20,708
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	-	-	-	(3,230,385)	-	(3,230,385)
Balance June 30, 2024	**780,762**	**$ 78**	**$ 102,652,071**	**$ (99,568,377)**	**$ -**	**$ 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
Change in fair value of derivative	-	-	894,039	-	-	894,039
Stock-based compensation expense	-	-	393,771	-	-	393,771
Net loss	-	-	-	(4,125,643)	-	(4,125,643)
Balance September 30, 2024	**3,044,165**	**$ 305**	**$ 115,731,278**	**$ (103,694,020)**	**$ -**	**$ 12,037,563**
Balance January 1, 2025	**3,402,306**	**$ 340**	**$ 117,380,285**	**$ (109,925,120)**	**$ -**	**$ 7,455,505**
Activity for the three months to March 31, 2025:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	423,893	42	1,920,315	-	-	1,920,357
Change in fair value of derivative	-	-	49,987	-	-	49,987
Stock-based compensation expense	-	-	357,649	-	-	357,649
Net loss	-	-	-	(3,852,678)	-	(3,852,678)
Balance March 31, 2025	**3,826,199**	**$ 382**	**$ 119,708,236**	**$ (113,777,798)**	**$ -**	**$ 5,930,820**
Activity for the three months to June 30, 2025:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	1,038,969	104	4,182,295	-	-	4,182,399
Change in fair value of derivative	-	-	194,526	-	-	194,526
Issuance of restricted common stock	24,122	2	96,667	-	-	96,669
Stock-based compensation expense	-	-	90,721	-	-	90,721
Net loss	-	-	-	(4,983,261)	-	(4,983,261)
Balance June 30, 2025	**4,889,290**	**$ 488**	**$ 124,272,445**	**$ (118,761,059)**	**$ -**	**$ 5,511,874**
Activity for the three months to September 30, 2025:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net	373,157	37	1,462,844	-	-	1,462,881

of fees						
Issuance cost and change in fair value of derivative	120,424	12	772,157			772,169
Issuance of restricted common stock	-	-	-	-	-	-
Issuance of common stock in connection with Promissory Note exchange agreements	594,487	59	2,474,941	-	-	2,475,000
Stock-based compensation expense	-	-	592,824	-	-	592,824
Net loss	-	-	-	(7,341,062)	-	(7,341,062)
Balance September 30, 2025	**5,977,358**	**$ 596**	**$ 129,575,211**	**$ (126,102,121)**	**$ -**	**$ 3,473,686**

See notes to unaudited consolidated financial statements

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Nine Months Ended September 30,	
	2025	**2024**
Operating activities:		
Net loss	$ (16,177,001)	$ (10,328,505)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	419,062	492,788
Stock-based compensation	1,137,863	935,135
Accretion of discount on note payable	222,113	-
Amortization of debt issue costs	21,831	-
Loss on debt extinguishment	451,834	-
Issuance cost and change in fair value of derivative	1,016,682	914,747
Changes in operating assets and liabilities:		
Other receivables	7,284	12,375
Prepaid expenses and other current assets	(872,402)	(789,659)
Operating lease right-of-use assets	(1,295,033)	196,899
Trade accounts payable and accrued expenses	156,492	(5,542,256)
Current portion of operating lease liability	100,461	(132,718)
Long-term portion of operating lease liability	1,162,921	(130,663)
Net cash used in operating activities	**(13,647,893)**	**(14,371,857)**
Investing activities:		
Purchase of property and equipment	(5,925)	(13,338)
Net cash used in investing activities	**(5,925)**	**(13,338)**
Financing activities:		
Proceeds from the issuance of common stock and pre-funded common stock purchase warrants, net of fees	7,565,637	24,385,615
Principal payments on finance lease obligations	(4,430)	(12,687)
Net cash provided by financing activities	**7,561,207**	**24,372,928**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	(6,092,611)	9,987,733
Cash and cash equivalents at beginning of year	12,211,321	52,416
Cash and cash equivalents at end of period	**$ 6,118,710**	**$ 10,040,149**
Cash paid for interest	**$ 18,695**	**$ 6,160**

See notes to unaudited 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. In addition, the Company has a third product to treat anxiety, CTx-2103, in a formulation stage. The Company submitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) on July 31, 2025 for lead asset CTx-1301 and received confirmation of acceptance of the NDA in early October 2025 with a Prescription Drug User Fee Act (PDUFA) target action date of May 31, 2026.

The consolidated financial statements and notes for the periods ended September 30, 2025 and 2024, 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 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, 2025, the Company had cash and cash equivalents of approximately $6.1 million, and an accumulated deficit of approximately $126.1 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, 2025 and December 31, 2024, the consolidated statements of operations and comprehensive loss for the three and nine-month periods ended September 30, 2025 and 2024, the consolidated statements of stockholders' equity for the three and nine-month periods ended September 30, 2025 and 2024, the consolidated statements of cash flows for the nine-month periods ended September 30, 2025 and 2024, 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 2024 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, 2025 or 2024.

(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.

(f) Derivative Instruments

The Company evaluates all financial instruments, including certain equity-linked contracts, to determine if such instruments or any embedded components qualify as derivatives under ASC 815, *Derivatives and Hedging*.

The Company evaluated the 2025 LP Purchase Agreement (as defined in Note 9) that includes the right to require Lincoln Park (as defined in Note 9) to purchase shares of common stock in the future ("purchased put right") considering the guidance in ASC 815-40, *Derivatives and Hedging*, and concluded that it is an equity-linked contract that does not qualify for equity classification, and therefore requires fair value accounting as a derivative asset (liability). The Company has analyzed the terms of the purchased put right and has concluded that it had insignificant value as of September 30, 2025.

(g) Reclassifications

In connection with the preparation of the interim financial statements as of and for the three and and nine months ended September 30, 2025, the Company identified certain errors in its accounting for the Lincoln Park Purchase Agreement in previously issued consolidated financial statements. Accordingly, the comparative financial statements included in this Report differ from our previously filed Quarterly Reports on Form 10-Q as of and for the three and six months ended June 30, 2025 and as of and for the three and nine months ended September 30, 2024 and Annual Report on Form 10-K as of and for the year ended December 31, 2024, reflecting the error correction for the misclassification of the commitment shares issued on the Original LP Purchase Agreement and change in fair value of the derivative initially recorded as a deduction to additional paid-in-capital on the consolidated statements of stockholders' equity and now expensed through issuance cost and change in fair value of derivative on the consolidated statements of operations and comprehensive loss. The correction of this error resulted in an increase in issuance cost and change in fair value of derivative and net loss and net comprehensive loss; however, no change to total stockholders' equity or net cash used in operating activities on the consolidated statements of cash flows. In evaluating whether the Company's previously issued consolidated financial statements were materially misstated, the Company performed an analysis of quantitative and qualitative factors in accordance with Staff Accounting Bulletin ("SAB") No. 99, *Materiality*, and SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, and considered the guidance in ASC Topic 250, *Accounting Changes and Error Corrections*. The Company believes the adjustments recorded for correction of the error are immaterial to the previously issued consolidated financial statements either individually or in the aggregate for each of the respective comparative periods.

The corrections to the Company's consolidated balance sheet were as follows:

	December 31, 2024	
	As Reported	As Corrected
Common stock	340	340
Additional paid-in-capital	115,944,345	117,380,285
Accumulated deficit	(108,489,180)	(109,925,120)
Total stockholders' equity	**$ 7,455,505**	**$ 7,455,505**

The corrections to the Company's consolidated statements of operations and comprehensive loss were as follows:

	Three Months Ended September 30, 2024		Nine Months Ended September 30, 2024	
	As Reported	As Corrected	As Reported	As Corrected
Issuance cost and change in fair value of derivative	-	(894,039)	-	(914,747)
Net loss and comprehensive loss	**$ (3,231,604)**	**$ (4,125,643)**	**$ (9,413,758)**	**$ (10,328,505)**
Net loss per share of common stock, basic and diluted	$ (1.83)	$ (2.34)	$ (10.06)	$ (11.03)

The corrections to the Company's statement of stockholders' equity were as follows:

	Additional Paid-in-Capital		Accumulated Deficit		Stockholders' Equity	
	As Reported	As Corrected	As Reported	As Corrected	As Reported	As Corrected
Balance January 1, 2024	**86,074,004**	**$ 86,496,076**	**(92,943,443)**	**(93,365,515)**	**(6,869,429)**	**(6,869,429)**
Balance March 31, 2024	**$ 99,131,997**	**$ 99,554,069**	**$ (95,915,920)**	**$ (96,337,992)**	**$ 3,216,119**	**$ 3,216,119**
Activity for the three months to June 30, 2024:						
Change in fair value of derivative	-	20,708	-	-	-	20,708
Net loss	-	-	(3,209,677)	(3,230,385)	(3,209,677)	(3,230,385)
Balance June 30, 2024	**$102,209,291**	**$102,652,071**	**$ (99,125,597)**	**$ (99,568,377)**	**$ 3,083,772**	**$ 3,083,772**
Activity for the three months to September 30, 2024:						
Change in fair value of derivative	-	894,039	-	-	-	894,039
Net loss	-	-	(3,231,604)	(4,125,643)	(3,234,604)	(4,125,643)
Balance September 30, 2024	**$114,394,459**	**$115,731,278**	**$(102,357,201)**	**$(103,694,020)**	**$12,037,563**	**$12,037,563**
Balance January 1, 2025	**$115,944,345**	**$117,380,285**	**$(108,489,180)**	**$(109,925,120)**	**$ 7,455,505**	**$ 7,455,505**
Activity for the three months to March 31, 2025:						
Change in fair value of derivative	-	49,987	-	-	-	49,987
Net loss	-	-	(3,802,691)	(3,852,678)	(3,802,691)	(3,852,678)
Balance March 31, 2025	**$118,222,309**	**$119,708,236**	**$(112,291,871)**	**$(113,777,798)**	**$ 5,930,820**	**$ 5,930,820**
Activity for the three months to June 30, 2025:						
Change in fair value of derivative	-	194,526	-	-	-	194,526
Net loss	-	-	(4,788,735)	(4,983,261)	(4,788,735)	(4,983,261)
Balance June 30, 2025	**$122,591,992**	**$124,272,445**	**$(117,080,606)**	**$(118,761,059)**	**$ 5,511,874**	**$ 5,511,874**

The corrections of the Company's statement of cash flows were as follows:

	Nine Months Ended September 30, 2024	
	As Reported	As Corrected
Operating activities:		
Net loss	$ (9,413,758)	$ (10,328,505)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance cost and change in fair value of derivative	-	914,747
Net cash used in operating activities	(14,371,857)	(14,371,857)

(h) Segments

Operating segments are defined as components of an enterprise for which discrete financial information is available and regularly reviewed by the chief operating decision maker (CODM) in deciding how to allocate resources and in assessing performance. The Company manages its business activities on a consolidated basis and operates as a single operating segment dedicated to the research and development and manufacturing of its product candidates. The Company's CODM is its Chief Executive Officer. The CODM uses net loss, as reported in the Company's Consolidated Statements of Operations and Comprehensive Loss, in evaluating performance of its segment and determining how to allocate resources of the Company as a whole, including investing in its research and development activities.

The measure used by the CODM for segment assets is reported in the Consolidated Balance Sheets as total consolidated assets.

The following table presents the operating results of the Company's segment:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Operating expenses:	**2025**	**2024**	**2025**	**2024**
Research and development				
Clinical operations	$ 435,572	$ 398,367	$ 2,306,906	$ 1,541,523
Drug manufacturing and formulation	912,965	532,823	2,403,402	2,336,541
Personnel	1,128,867	441,234	2,099,421	1,090,948
Regulatory	371,140	56,080	962,380	147,570
Total research and development	2,848,544	1,428,504	7,772,109	5,116,582
General and administrative				
Personnel	1,280,120	515,133	2,310,986	1,332,996
Legal and professional fees	877,086	828,543	2,351,573	1,638,696
Occupancy	92,636	75,616	242,622	250,149
Insurance	191,440	235,661	561,485	718,709
Other	706,009	198,630	1,113,069	379,352
Total general and administrative	3,147,291	1,853,583	6,579,735	4,319,902
Operating loss	(5,995,835)	(3,282,087)	(14,351,844)	(9,436,484)
Issuance cost and change in fair value of derivative	(772,169)	(894,039)	(1,016,682)	(914,747)
Interest and other income (expense), net	(573,058)	50,483	(808,475)	22,726
Loss before income taxes	(7,341,062)	(4,125,643)	(16,177,001)	(10,328,505)
Income tax benefit (expense)	-	-	-	-
Net loss and comprehensive loss	$ (7,341,062)	$ (4,125,643)	$ (16,177,001)	$ (10,328,505)

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
Manufacturing materials	$ 890,378	$ 29,025
Marketing fees	175,000	-
Professional fees	104,459	-
Insurance	24,496	-
Dues and subscriptions	13,250	4,575
Research and development	-	334,692
Other	87,976	54,865
	$ 1,295,559	$ 423,157

(4) Property and Equipment

Property and equipment, net consisted of the following at September 30, 2025 and December 31, 2024:

	Estimated Useful Life (in years)	September 30, 2025	December 31, 2024
Equipment	2-7	$ 4,358,261	$ 4,358,261
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	46,994	46,994
Leasehold improvements	5	474,462	474,462
Construction-in-process- equipment	-	381,203	375,278
		5,406,674	5,400,749
Less: accumulated depreciation		(3,715,136)	(3,296,074)
		$ 1,691,538	$ 2,104,675

Depreciation expense was $419,062 and $492,788, respectively, for the nine-month periods ended September 30, 2025 and 2024. Depreciation expense was $106,782 and $165,406, respectively, for the three-month periods ended September 30, 2025 and 2024.

(5) Accrued Expenses

Accrued expenses consisted of the following at September 30, 2025 and December 31, 2024:

	September 30, 2025	December 31, 2024
Employee compensation	$ 942,950	$ 355,475
Interest	388,971	15,089
Commercial costs	135,776	-
State franchise taxes	73,000	200,000
Research and development	-	341,956
Insurance	-	34,469
CIP- Equipment	-	31,160
Professional fees	-	5,000
Other	59,455	56,476
	$ 1,600,152	$ 1,039,625

(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.

In December 2023, the Company implemented salary reductions for all employees and the Board approved a contingent bonus plan in which the Company will pay to each employee three months after the filing date of the NDA for CTx-1301, an amount equal to the base salary that was not paid to the employee plus 20%. Base salaries were reinstated in September 2024. Based on the filing of the NDA for CTx-1301 with the FDA on July 31, 2025, this contingent bonus was deemed probable per the requirements of ASC Topic 450, *Contingencies* as of September 30, 2025, thus was recorded in the financial statements. The unpaid salary amounts plus 20% was $542,623.

(7) Unsecured Promissory Note

On December 20, 2024, the Company entered into a note purchase agreement with Streeterville Capital, LLC, a Utah limited liability company (Lender), pursuant to which the Company issued and sold to Lender an unsecured promissory note (Promissory Note) in the amount of $5,480,000. The Promissory Note included an original issue discount of $450,000 and Lender expenses payable by the Company of $30,000. In exchange for the Promissory Note, the Lender paid a purchase price of $5,000,000 in cash. The Promissory Note bears interest at a rate of 9% per annum and matures 18 months after its issuance date.

From time to time, beginning on July 2, 2025, Lender could begin redeeming a portion of the Promissory Note, not to exceed an amount of $550,000 per month, unless additional redemptions are agreed to by the Company. On the 90-day anniversary of the effective date of the Promissory Note, the Company was charged a monitoring fee equal to the outstanding principal balance on such date divided by 0.85 less the outstanding balance on such date. The monitoring fee and interest accrued on the monitoring fee will be forgiven, on a pro rata basis, each time the Company makes a cash payment on the Promissory Note. Subject to the terms and conditions set forth in the Promissory Note, the Company may prepay all or any portion of the outstanding balance of the Promissory Note at any time. As of September 30, 2025, the Company has entered into several exchange agreements with Lender to exchange a total of $2,475,000 of principal for 594,487 shares of common stock, thereby extinguishing a portion of the Promissory Note. In connection with the exchange agreements, the Company recorded the pro rata portion of the monitoring fee as well as accrued interest on the pro rata portion of the monitoring fee. As of September 30, 2025, the pro rata portion of the monitoring fee recognized was $358,185 as a loss on debt extinguishment within interest and other income (expense), net and the accrued interest on the pro rata portion of the monitoring fee was $17,422.

The Promissory Note provides for customary events of default (each, an Event of Default), including, among other things, the event of nonpayment of principal, interest, fees or other amounts, a representation or warranty proving to have been incorrect when made, failure to perform or observe covenants within a specified cure period, a cross-default to certain other indebtedness and material agreements of the Company, and the occurrence of a bankruptcy, insolvency or similar event affecting the Company. Upon the occurrence of an Event of Default that is deemed a "Major Trigger Event" as defined in the Promissory Note, Lender may increase the outstanding balance of the Promissory Note by 15%, and upon the occurrence of an Event of Default that is deemed a "Minor Trigger Event" as defined in the Promissory Note, Lender may increase the outstanding balance of the Promissory Note by 5%. Lender can exercise its right to increase the outstanding balance upon a Major or Minor Trigger Event three times each. Upon the occurrence of an Event of Default, Lender may declare all amounts owed under the Promissory Note immediately due and payable. In addition, upon the occurrence of an Event of Default, upon the election of Lender, interest shall begin accruing on the outstanding balance of the Promissory Note from the date of the Event of Default equal to the lesser of 22% per annum and the maximum rate allowable under law.

In connection with the Promissory Note, the Company incurred $46,277 of debt issuance costs. The debt issuance costs, the debt discount of $450,000 and the expenses payable by the Company of $30,000 have been recorded as a reduction in the carrying amount of the Promissory Note and are being amortized over the term of the Promissory Note using the effective interest rate method. The Company wrote-off a pro rata portion of the debt issuance costs and debt discount in connection with the debt extinguishments described above and recognized as a loss on debt extinguishment within interest and other income (expense), net of $93,649. As of September 30, 2025, the aggregate amount of unamortized debt discount and debt issuance costs was $178,420.

As of September 30, 2025, the outstanding principal balance of the Promissory Note plus accrued interest was $3,752,156.

(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, 2025 and December 31, 2024, of which 5,977,358 and 3,402,306 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 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

The Company entered into the At-the-Market Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC (HCW) in January 2023, as amended in May 2023, pursuant to which the Company can issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $23.5 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.

During the three months ended September 30, 2025 and 2024, the Company sold 82,048 and 902,300 shares of common stock, respectively, under the ATM Agreement, for net proceeds of $412,996 and $5,804,393. During the nine months ended September 30, 2025 and 2024, the Company sold 647,495 and 957,808 shares of common stock, respectively, under the ATM Agreement, for net proceeds of $3,012,095 and $9,273,956.

Purchase Agreement with Lincoln Park

In April 2023, the Company entered into a purchase agreement (the Original 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 Original LP Purchase Agreement, Lincoln Park agreed to purchase from the Company up to $12 million of the Company's common stock. 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 the shares of common stock that were issued to Lincoln Park under the Original LP Purchase Agreement. As of June 30, 2025, the Company sold to Lincoln Park the maximum dollar value worth of common stock pursuant to the Original LP Purchase Agreement, and the Original LP Purchase Agreement thereupon expired in accordance with its terms.

On July 21, 2025, the Company entered into a second purchase agreement with Lincoln Park (2025 LP Purchase Agreement), pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $25.0 million of the Company's common stock (subject to certain limitations and satisfaction of the conditions set forth in the 2025 LP Purchase Agreement) from time to time and at the Company's sole discretion over the 36-month term of the 2025 LP Purchase Agreement. Pursuant to the terms of the 2025 LP Purchase Agreement, on July 21, 2025, the Company issued 120,424 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock under the 2025 LP Purchase Agreement. The commitment shares were valued at $681,600 and recorded as an addition to equity for the issuance of the common stock and recorded as an expense in issuance cost and change in fair value of derivative on the consolidated statements of operations and comprehensive loss under the 2025 LP Purchase Agreement. The Company evaluated the 2025 LP Purchase Agreement under ASC 815-40 *Derivatives and Hedging-Contracts on an Entity's Own Equity* as it represents the right to require Lincoln Park to purchase shares of common stock in the future, similar to a put option. The Company concluded that the 2025 LP Purchase Agreement represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. The Company analyzed the terms of the contract and concluded that the derivative instrument had insignificant value as of September 30, 2025. During the three months ended September 30, 2025 and 2024, the Company sold 291,109 shares of common stock under the 2025 LP Purchase Agreement and 1,092,337 shares of common stock under the Original LP Purchase Agreement, for net proceeds of $1,147,727 and $6,081,814, respectively.

The Company evaluated the 2025 LP Purchase Agreement under ASC 815-40 *Derivatives and Hedging-Contracts on an Entity's Own Equity* as it represents the right to require Lincoln Park to purchase shares of common stock in the future, similar to a put option. The Company concluded that the 2025 Purchase Agreement represents a freestanding derivative instrument that does not qualify for equity classification and therefore requires fair value accounting. The Company analyzed the terms of the contract and concluded that the derivative asset or liability had insignificant value as of September 30, 2025. Changes in fair value associated with the derivative instrument are recorded in issuance cost and change in fair value of derivative in the consolidated statements of operations and comprehensive loss. The Company recorded $1,016,682 and $914,747 for the nine-month periods ended September 30, 2025 and 2024, respectively, and $772,169 and $894,039 for the three-month periods ended September 30, 2025 and 2024 associated with the change in fair value of the derivative instrument.

(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 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. At the Company's 2025 annual meeting, shareholders approved an amendment to the 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder by 800,000 shares to 1,141,826. As of September 30, 2025, 190,166 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 $1,041,194 and $812,691 during the nine months ended September 30, 2025 and 2024, respectively. The Company recorded stock-based compensation expense of $592,824 and $393,786 during the three months ended September 30, 2025 and 2024, respectively. As of September 30, 2025 and December 31, 2024, there was $2,804,015 and $343,612, 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 2021 Plan during the nine-month periods ended September 30, 2025 and 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	0
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			
Outstanding at January 1, 2025	89,406			
Granted	248,428	$ 4.44	9.87	-
Exercised	-			
Forfeitures or expirations	-			
Outstanding at March 31, 2025	337,834			
Granted	61,005	4.14	9.98	
Exercised	-			
Forfeitures or expirations	-			
Outstanding at June 30, 2025	398,839			
Granted	552,838	4.41	9.23	
Exercised	-			
Forfeitures or expirations	-			
Outstanding at September 30, 2025	951,677			
Vested and expected to vest at September 30, 2025	951,677			
Exercisable at September 30, 2025	194,659			

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 was 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 and directors during the nine-month periods ending September 30, 2025 and 2024 were as follows, shown on a weighted average basis:

	September 30, 2025	September 30, 2024
Risk-free interest rate	4.15%	4.26%
Expected term (in years)	5.83	5.45
Expected volatility	1.44	1.46
Expected dividend yield	0%	0%

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

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

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

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

The grant-date fair value of options granted during the three months ended September 30, 2025 ranged from $3.44 to $4.04 and the grant-date fair value of options granted during the nine months ended September 30, 2025 ranged from $3.92 to $4.76.

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. Because there were no stock options with exercise prices lower than the fair value of the Company's common stock, the aggregate intrinsic value is zero as of September 30, 2025 and December 31, 2024.

On July 8, 2025, the Company granted a non-qualified stock option award to an officer of the Company to purchase a total of 30,000 shares of common stock at an exercise price of $4.51. This grant was an inducement award in accordance with Nasdaq Listing Rule 5635(c)(4) and was not granted from the 2021 Equity Incentive Plan. The option award will vest over four years, with 25% of the shares underlying the option vesting on the one-year anniversary of the grant date and the remaining 75% vesting in approximately equal monthly installments over the following thirty-six months, subject to the officer being continuously employed by the Company through each vesting date. As of September 30, 2025, there was $124,143 of unrecognized compensation cost related to nonvested share-based compensation related to the inducement grant, which is expected to be recognized over the next one to four years.

(11) Common Stock Purchase Warrants

The following table summarizes the Company's outstanding common stock purchase warrants as of September 30, 2025:

	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, 2025	833,684			$ 33,708,854

(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, 2025 and 2024 or the nine-month periods ended September 30, 2025 and 2024, 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, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Federal income tax benefit at statutory rate	$ (1,541,623)	$ (866,387)	$ (3,395,265)	$ (2,168,988)
State income tax benefit	169,777	(233,562)	(269,769)	(579,614)
Permanent differences	166,826	190,981	223,764	201,404
Change in valuation allowance	1,227,625	1,832,122	3,464,989	3,500,000
Research and development tax credits	(538,971)	(972,372)	(540,085)	(972,372)
Other	516,366	49,218	516,366	19,570
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 $20,898,141 as of September 30, 2025 and $17,405,569 at December 31, 2024, the current year portion which was recorded as a component of income tax expense on the accompanying consolidated statements of operations and 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, 2025 or December 31, 2024.

(13) Leases

In May 2025, the Company executed a lease agreement to renew the office space for its headquarters in Kansas City, Kansas. The lease has a 60-month term that commenced on June 1, 2025 with total rent of $33,145 per month over the lease term. The operating lease right-of-use asset was $1,394,044, the current portion of the operating lease liability was $231,123 and the long-term portion of the lease liability was $1,162,921 as of September 30, 2025.

(14) Subsequent Events

Management evaluated events that occurred subsequent to September 30, 2025, through November 13, 2025, which is the date the interim financial statements were issued.

Subsequent to September 30, 2025, the Company paid the contingent bonus of $542,623, as described in Note 6.

Subsequent to September 30, 2025, the Company entered into several exchange agreements with Lender to exchange a total of $850,000 in principal for 218,917 shares of common stock, thereby extinguishing that portion of the Promissory Note. See Note 7 for additional information regarding the Promissory Note.

Subsequent to September 30, 2025, the Company sold 561,839 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $2,090,280.

Subsequent to September 30, 2025, the Company sold 138,289 shares of common stock under the ATM Agreement, for net proceeds of $562,479.

On November 7, 2025, the Company entered into a note purchase agreement with Avondale Capital, LLC, a Utah limited liability company, pursuant to which the Company issued and sold to Avondale an unsecured promissory note in the amount of $6,570,000, including an original issue discount of $540,000 and Avondale expenses payable by the Company of $30,000. In exchange for the promissory note, Avondale paid a purchase price of $6,000,000 in cash. The promissory note bears interest at a rate of 9% per annum and matures 18 months after its issuance date. The first redemption is due six months from the execution date with two optional one-month extensions at at the Company’s discretion. The note includes no prepayment penalties.

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, 2024 (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 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, primarily CTx-1301, 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 $116.1 million as of September 30, 2025.

We have incurred significant losses since our inception. Our net losses were $7.3 million and $4.1 million for the three months ended September 30, 2025 and 2024, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of September 30, 2025, we had an accumulated deficit of $126.1 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;
- advance commercialization efforts for CTx-1301; and
- operate as a public company.

Taking into account the $6 million we received from the debt issuance described below, we believe our cash will satisfy our capital needs into the second quarter of 2026 under our current business plan. To advance our commercialization efforts for CTx-1301 through our Prescription Drug User Fee Act (PDUFA) date of May 31, 2026, we believe we will need to raise approximately $9 million of additional capital. We will also need additional capital to advance our other programs. See "Liquidity and Capital Resources" below.

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

Debt Issuance

On November 7, 2025, we entered into a note purchase agreement (2025 Note Purchase Agreement) with Avondale Capital, LLC, a Utah limited liability company (Avondale), pursuant to which we issued and sold to Avondale an unsecured promissory note in the amount of $6,570,000. The principal amount includes an original issue discount of $540,000 and expenses payable by us of $30,000. In exchange for the promissory note, Avondale paid a purchase price of $6,000,000 in cash. The promissory note bears interest at a rate of 9% per annum and matures 18 months after its issuance date. Our wholly-owned subsidiaries Cingulate Therapeutics LLC and Cingulate Works, Inc., provided a guarantee of our obligations to Avondale under the promissory note and the other transaction documents. We intend to use the net proceeds from the sale of the promissory note for working capital and other general corporate purposes.

From time to time, beginning on May 7, 2026, Avondale may redeem a portion of the promissory note, not to exceed an amount of $660,000 per month; and provided that we have not previously received a "complete response letter" from the FDA, we may defer up to two redemptions for up to thirty (30) days each. If we exercise our deferral right, the outstanding balance of the promissory note will be increased by 1% of the outstanding balance on the date of the deferral. In the event the promissory note is outstanding on the 90-day anniversary of the effective date of the promissory note, we will be charged a monitoring fee equal to the outstanding balance on such date divided by 0.85 less the outstanding balance on such date. Subject to the terms and conditions set forth in the promissory note, we may prepay all or any portion of the outstanding balance of the promissory note at any time.

Pursuant to the 2025 Note Purchase Agreement, while the promissory note is still outstanding, we will not enter into any arrangement that prohibits us from entering into a variable rate transaction, as defined in the 2025 Note Purchase Agreement, with Avondale or its affiliates, or from issuing our securities to Avondale or its affiliates. The Company is also prohibited from entering into a variable rate transaction while the Note is outstanding, subject to certain exceptions. At any time while the promissory note is still outstanding, Avondale will have the right, but not the obligation, with our consent, to reinvest up to an additional $5.0 million in one or more tranches on the same terms and conditions as the promissory note. Additionally, so long as the promissory note is outstanding, upon any issuance by us of any debt security with any economic term or condition more favorable to the holder of such security that was not provided to Avondale pursuant to the promissory note, then, at Avondale's option, such additional term shall become part of the promissory note and related documents for the benefit of Avondale.

Management Update

Effective November 3, 2025, Bryan Downey was hired as our Chief Commercial Officer. In this role, Mr. Downey will lead all commercial activities focused on the potential launch of CTx-1301 in mid-2026 pending FDA approval.

On August 7, 2025, the employment of Laurie A. Myers, our former Executive Vice President and Chief Operating Officer, was terminated.

On August 9, 2025, Shane Schaffer, Chairman and Chief Executive Officer, was charged with one count of aggravated domestic battery. On August 14, 2025, the Board (i) placed Shane Schaffer on administrative leave pending the resolution of the legal proceedings, (ii) appointed Jennifer Callahan, our current Chief Financial Officer, to serve as interim Chief Executive Officer and (iii) appointed John A. Roberts, a current member of the Board, to serve as Executive Chairman of the Board. Ms. Callahan will continue to serve as Chief Financial Officer while serving as interim Chief Executive Officer until further action by the Board. In his role as Executive Chairman, Mr. Roberts will among other services, provide operational support to our executive management team. On October 28, 2025, Dr. Schaffer's charge was amended to one count of domestic battery (misdemeanor).

Clinical, Manufacturing and Business Update

CTx-1301: We 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.

In order to meet the pharmacology requirement for the CTx-1301 NDA submission, we completed a food effect study in October 2022 (25mg dose) and December 2024 (50mg dose). Each study demonstrated that CTx-1301 can be taken with or without food.

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. Analysis of the safety data from the two closed Phase 3 trials and the 50mg dose food effect study revealed that no subjects experienced a serious treatment emergent adverse event (TEAE), a serious TEAE or a TEAE leading to death and there were no clinically relevant trends in TEAEs overall. A final analysis that combines both adult and pediatric safety and efficacy data was included in the NDA submission for CTx-1301 which was submitted to the FDA on July 31, 2025. The FDA accepted for review the NDA for CTx-1301 and assigned a PDUFA target action date of May 31, 2026.

We executed a commercial supply agreement with CoreRx, Inc., DBA Bend Bioscience on August 27, 2025.

CTx-2103: We have embarked on a program to develop CTx-2103 (buspirone), for the treatment of anxiety, the most common mental health disorder 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 (Investigational New Drug) 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 capital resources will be required to continue 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 entered into a master services agreement with Indegene, Inc. (Indegene) to partner in the commercialization of CTx-1301 in the United States. Indegene's comprehensive commercialization infrastructure includes marketing, sales, market access and pricing, commercial operations, pharmacovigilance, and an unparalleled omnichannel platform. We continue to negotiate potential international licensing agreements while remaining open to a strategic partnership in the United States.

Securities Issuances

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 $23.5 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, 2025, we sold 82,048 shares of common stock under the ATM Agreement, for net proceeds of $412,996, after deducting $15,346 of compensation to HCW and other administration fees. Subsequent to September 30, 2025, we sold 138,289 shares of common stock under the ATM Agreement, for net proceeds of $562,479, after deducting $19,113 of compensation to HCW and other administration fees.

In April 2023, we entered into a purchase agreement (Original LP Purchase Agreement) with Lincoln Park Capital Fund LLC (Lincoln Park). Pursuant to the Original LP Purchase Agreement, Lincoln Park agreed to purchase from us up to an aggregate of $12.0 million of common stock. As of June 30, 2025, the Company sold to Lincoln Park the maximum dollar value worth of common stock pursuant to the Original LP Purchase Agreement, and the Original LP Purchase Agreement thereupon expired in accordance with its terms

On July 21, 2025, we entered into a second purchase agreement with Lincoln Park (2025 LP Purchase Agreement), pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $25.0 million of common stock (subject to certain limitations and satisfaction of the conditions set forth in the 2025 LP Purchase Agreement) from time to time and at the Company's sole discretion over the 36-month term of the 2025 LP Purchase Agreement. Pursuant to the terms of the 2025 LP Purchase Agreement, the Company issued 120,424 shares of common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock under the 2025 LP Purchase Agreement. During the quarter ended September 30, 2025, we sold 291,109 shares of common stock to Lincoln Park, under the 2025 LP Purchase Agreement, for net proceeds of $1,147,727. Subsequent to September 30, 2025, we sold 561,839 shares of common stock to Lincoln Park, under the 2025 LP Purchase Agreement, for net proceeds of $2,090,280.

During the quarter ended September 30, 2025, the Company entered into exchange agreements with Streeterville Capital, LLC to exchange an aggregate of $2,475,000 in principal for 594,487 shares of common stock, thereby extinguishing that portion of the promissory note with Streeterville Capital. Subsequent to September 30, 2025, the Company entered into exchange agreements with Streeterville Capital to exchange an aggregate of $850,000 in principal for 218,917 shares of common stock, thereby extinguishing that portion of the promissory note with Streeterville Capital.

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. The FDA accepted for review the NDA for CTx-1301 and assigned a PDUFA target action date of May 31, 2026.

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. Subject to successful regulatory approval and commercialization of CTx-1301, we expect that our research and development expenses will continue to increase 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 near future as we increase our general and administrative headcount to support our growing operations, including the potential commercialization of CTx-1301. 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.

Issuance cost and change in fair value of derivative and interest and other income (expense), net

Issuance cost and change in fair value of derivative relates to the consideration for Lincoln Park's commitment to purchase shares under the 2025 LP Purchase Agreement and the change in fair value of the derivative asset or liability. Interest and other income (expense), net consists of interest expense on our notes payable and interest earned on our cash and cash equivalents, including money market funds. The primary objective of our investment policy is liquidity and capital preservation.

Critical Accounting Policies and Significant Judgments and Estimates

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

A discussion of these policies can be found in the "Critical Accounting Policies and Significant Judgments and Estimates" section of our Form 10-K. There have been no changes in our application of critical accounting policies since December 31, 2024.

Results of Operations

Comparison of the three months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024 :

(in thousands)	Three Months Ended September 30, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 2,849	$ 1,428	$ 1,421	99.5%
General and administrative	3,147	1,854	1,293	69.7%
Operating Loss	(5,996)	(3,282)	2,714	82.7%
Issuance cost and change in fair value of derivative	(772)	(894)	(122)	(13.6%)
Interest and other income (expense), net	(573)	50	623	NM
Net Loss	$ (7,341)	$ (4,126)	$ 3,215	77.9%

Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended September 30, 2025 and 2024:

(in thousands)	Three Months Ended September 30, 2025	2024	Increase	% Increase
Clinical operations	$ 436	$ 398	$ 38	9.5%
Drug manufacturing and formulation	913	533	380	71.3%
Personnel expenses	1,129	441	688	156.0%
Regulatory costs	371	56	315	562.5%
Total research and development expenses	$ 2,849	$ 1,428	$ 1,421	99.5%

R&D expenses were $2.8 million for the three months ended September 30, 2025, an increase of $1.4 million or 99.5% from the three months ended September 30, 2024. This change was primarily the result of an increase in personnel expenses, manufacturing costs and regulatory costs in the three months ended September 30, 2025 as compared to the same period in 2024. Personnel expenses increased due to separation costs for an executive in August 2025 as well as costs related to the contingent bonus plan, which were accrued upon the NDA submission of CTx-1301 in the third quarter of 2025 when the payment became probable. The increase in manufacturing costs was due to more significant manufacturing costs in 2025 related to activity in preparation of the manufacturing of the process validation batches of CTx-1301. Regulatory costs increased due to preparation for the NDA submission.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended September 30, 2025 and 2024:

(in thousands)	Three Months Ended September 30, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 1,280	$ 515	$ 765	148.5%
Legal and professional fees	877	828	49	5.9%
Occupancy	93	76	17	22.4%
Insurance	191	236	(45)	(19.1%)
Other	706	199	507	254.8%
Total general and administrative expenses	$ 3,147	$ 1,854	$ 1,293	69.7%

Total G&A expenses were $3.1 million for the three months ended September 30, 2025, an increase of $1.3 million or 69.7% from the three months ended September 30, 2024. This is primarily the result of an increase personnel and other expenses. The increase in personnel expenses was due to costs related to the contingent bonus plan, which were accrued upon the NDA submission of CTx-1301 in the third quarter of 2025, when the payment became probable. Other costs increased primarily due to commercial costs related to our contract with Indegene.

Issuance cost and change in fair value of derivative and interest and other income (expense), net

The following table summarizes issuance cost and change in fair value of derivative and interest and other income (expense), net for the three months ended September 30, 2025 and 2024:

(in thousands)	Three Months Ended September 30, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Issuance cost and change in fair value of derivative	$ (772)	$ (894)	$ (122)	(13.6%)
Interest and other income (expense), net	(573)	50	623	NM

Issuance cost and change in fair value of derivative for the three months ended September 30, 2025 and September 30, 2024 relates to the consideration for Lincoln Park's commitment to purchase shares under the 2025 LP Purchase Agreement and the change in fair value of the derivative asset or liability. Interest and other income (expense), net for the three months ended September 30, 2025 and September 30, 2024 relates to interest incurred on the outstanding note payable, offset by interest earned on invested balances. The increase in interest expense for the period ended September 30, 2025 is related to interest expense incurred on the promissory note which was executed in December 2024, including loss on debt extinguishments.

Comparison of the nine months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the nine months ended September 30, 2025 and 2024 :

(in thousands)	Nine Months Ended September 30, 2025	2024	Increase	% Increase
Operating Expenses:				
Research and development	$ 7,772	$ 5,116	$ 2,656	51.9%
General and administrative	6,580	4,320	2,260	52.3%
Operating Loss	(14,352)	(9,436)	4,916	52.1%
Issuance cost and change in fair value of derivative	(1,017)	(915)	102	11.1%
Interest and other income (expense), net	(808)	23	831	NM
Net Loss	$ (16,177)	$ (10,328)	$ 5,849	56.6%

Research and development expenses

The following table summarizes our R&D expenses for the nine months ended September 30, 2025 and 2024:

(in thousands)	Nine Months Ended September 30, 2025	2024	Increase	% Increase
Clinical operations	$ 2,307	$ 1,541	$ 766	49.7%
Drug manufacturing and formulation	2,403	2,336	67	2.9%
Personnel expenses	2,100	1,091	1,009	92.5%
Regulatory costs	962	148	814	550.0%
Total research and development expenses	$ 7,772	$ 5,116	$ 2,656	51.9%

R&D expenses were $7.8 million for the nine months ended September 30, 2025, an increase of $2.7 million or 51.9% from the nine months ended September 30, 2024. This change was primarily the result of an increase in personnel expenses, regulatory costs and clinical operations in the nine months ended September 30, 2025 as compared to the same period in 2024. Personnel costs increased due to separation costs for an executive in August 2025, costs related to the contingent bonus plan, which were accrued upon the NDA submission of CTx-1301 in the third quarter of 2025 when the payment became probable and the reinstatement of base salaries in September 2024 following salary reduction measures which had been implemented in late 2023. Regulatory costs increased due to preparation for the pre-NDA meeting with the FDA in the second quarter of 2025 and the NDA submission. The increase in clinical operations costs is the result of the close-out and analytical activities required for NDA submission related 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.

General and administrative expenses

The following table summarizes our G&A expenses for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,			
(in thousands)	2025	2024	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 2,311	$ 1,332	$ 979	73.5%
Legal and professional fees	2,352	1,638	714	43.6%
Occupancy	243	251	(8)	(3.2%)
Insurance	561	718	(157)	(21.9%)
Other	1,113	381	732	192.1%
Total general and administrative expenses	$ 6,580	$ 4,320	$ 2,260	52.3%

Total G&A expenses were $6.6 million for the nine months ended September 30, 2025, an increase of $2.3 million or 52.3% from the nine months ended September 30, 2024. This is primarily the result of an increase in personal expenses, legal and professional fees and other expenses. Personnel costs increased due to costs related to the contingent bonus plan, which were accrued upon the NDA submission of CTx-1301 in the third quarter of 2025 when the payment became probable and the reinstatement of base salaries in September 2024 following salary reduction measures which had been implemented in late 2023. The increase in legal and professional fees was due to an increase in certain financial, accounting and legal fees. Other costs increased primarily due to commercial costs related to our contract with Indegene.

Issuance cost and change in fair value of derivative and interest and other income (expense), net

The following table summarizes issuance cost and change in fair value of derivative and interest and other income (expense), net for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,			
(in thousands)	2025	2024	Increase	% Increase
Issuance cost and change in fair value of derivative	$ (1,017)	$ (915)	$ 102	11.1%
Interest and other income (expense), net	(808)	23	831	NM

Issuance cost and change in fair value of derivative for the nine months ended September 30, 2025 and September 30, 2024 relates to the consideration for Lincoln Park's commitment to purchase shares under the 2025 LP Purchase Agreement and the change in fair value of the derivative asset or liability. Interest and other income (expense), net for the nine months ended September 30, 2025 and September 30, 2024 relates to interest incurred on outstanding notes payable, offset by interest earned on invested balances. The increase in interest expense for the period ended September 30, 2025 is related to interest expense incurred on the promissory note which was executed in December 2024, including loss on debt extinguishments.

Cash Flows

	Nine Months Ended September 30,	
	2025	**2024**
Net cash (used in) operating activities	$ (13,648)	$ (14,372)
Net cash (used in) investing activities	(6)	(13)
Net cash provided by financing activities	7,561	24,373
Net increase (decrease) in cash and cash equivalents	$ (6,093)	$ 9,988

Cash Flows from Operating Activities

Net cash used in operating activities was $13.6 million for the nine months ended September 30, 2025. Cash used in operating activities was primarily due to the use of funds in our operations and to develop CTx-1301 resulting in a net loss of $16.2 million, prior to the effects of four noncash items, stock-based compensation expense of $1.1 million, issuance cost and change in fair value of derivative of $1.0 million, loss on debt extinguishment of $0.5 million, accretion of discount on note payable of $0.2 million and depreciation expense of $0.4 million. Changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of $0.9 million primarily due to payments for materials, professional and marketing fees.

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 $10.3 million, prior to the effects of three noncash items, stock-based compensation expense of $0.9 million, issuance cost and change in fair value of derivative 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 February 2024.

Cash Flows from Investing Activities

Net cash used in investing activities for both the nine-month periods ended September 30, 2025 and September 30, 2024 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, 2025 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement, the Original LP Purchase Agreement and the 2025 LP Purchase Agreement.

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 Original LP Purchase Agreement, the issuance of equity in February 2024 and the warrant inducement transaction in June 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012 through September 30, 2025, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations.

In the three months ended September 30, 2025, we sold 82,048 shares of common stock under the ATM Agreement, for net proceeds of $412,996, after deducting $15,346 of compensation to HCW and other administration fees. Subsequent to September 30, 2025, we sold 138,289 shares of common stock under the ATM Agreement, for net proceeds of $562,479, after deducting $19,113 of compensation to HCW and other administration fees.

During the three months ended September 30, 2025, we sold 291,109 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $1,147,727. Subsequent to September 30, 2025, we sold 561,839 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $2,090,280.

As of September 30, 2025, we had cash and cash equivalents of $6.1 million. Taking into account the $6 million we received from our debt issuance to Avondale Capital, LLC on November 7, 2025, we believe our cash will satisfy our capital needs into the second quarter of 2026 under our current business plan. To advance our commercialization efforts through the May 31, 2026 PDUFA date for CTx-1301, we believe we will need to raise approximately $7 million of additional capital. Changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents are invested primarily in money market funds which are currently providing only a minimal return given the current interest rate environment.

We expect to continue to incur substantial additional operating losses for the near term as we continue to develop CTx-1301 and seek marketing approval and, subject to obtaining such approval, the eventual commercialization. If we obtain marketing approval for CTx-1301, 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.

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.

For example, pursuant to the note purchase agreements with Streeterville Capital, LLC and Avondale Capital, LLC, respectively, we are subject to certain restrictions on our ability to issue securities during the term of the promissory notes. Specifically, we have agreed, among other things, to refrain from entering into any agreement or covenant that locks up, restricts or otherwise prohibits us from entering into a variable rate transaction with the lenders or any of their affiliates, or from issuing common stock or other equity or debt securities to the lenders or any of their affiliates. If we breach the note purchase agreements, we may be obligated to indemnify the lender for loss or damage arising as a result of any breach or alleged breach by us of the note purchase agreements, which may affect our business operations and financial condition. Additionally, the promissory notes provide that following an event of default under the promissory notes, the lenders have the right to seek and receive injunctive relief from a court or an arbitrator prohibiting us from issuing any of our common stock or preferred stock to any party unless fifty percent of the gross proceeds received by us in connection with such issuance are simultaneously used to make a payment under the promissory notes. The lenders also have the right to seek and receive injunctive relief from a court or arbitrator to prevent the consummation of any fundamental transaction, as defined in the promissory notes, unless it contains a closing condition that the promissory notes are paid in full upon consummation of the transaction or the lenders have provided their written consent to such transaction.

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, 2025 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. The second milestone payment of $250,000 was paid in September 2025 upon submission of the NDA. The third milestone payment of $250,000 will become due upon FDA approval of CTx-1301. Additional royalty payments will become due upon potential sales of CTx-1301 pursuant to the terms of the agreement.

We entered into agreements with Societal, our CMO, for both the manufacturing of process validation batches of our lead asset, CTx-1301, including active pharmaceutical ingredients and materials. with a total estimated cost of approximately $7.0 million.

In May 2025, the Company executed a lease to renew the office space for its headquarters in Kansas City, Kansas. The lease has a five-year term that commenced on June 1, 2025 with total rent of $33,145 per month over the lease term. The operating lease right-of-use asset was $1,394,044, the current portion of the operating lease liability was $231,123 and the long-term portion of the lease liability was $1,162,921 as of September 30, 2025.

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, 2025 and 2024 and had accumulated losses of $126.1 million since inception to September 30, 2025. 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), follow-on public offerings in September 2023 and February 2024, sales of common stock under our ATM Agreement, Original LP Purchase Agreement and 2025 LP Purchase Agreement, a private placement with WFIA, the WFIA Note, which was subsequently converted to equity, the June 2024 warrant inducement and the issuance of the promissory note in December 2024. 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 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 Interim 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, 2025, has concluded that our disclosure controls and procedures were effective as of September 30, 2025.

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, 2025 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.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. In December 2023, two executive officers, including our Chief Financial Officer, and two clinical operations employees resigned. On January 25, 2024, we appointed Ms. Callahan as our Senior Vice President and Chief Financial Officer. In August 2025, the employment of our Chief Operating Officer was terminated. Also in August 2025, our Chairman and Chief Executive Officer was placed on administrative leave, and in connection with that action, our Chief Financial Officer was appointed to serve as interim Chief Executive Officer and a current member of our Board was appointed to serve as Executive Chairman of the Board .

In December 2023, four independent members of our Board resigned resulting in our Board consisting of two non-independent directors, one of whom is our Chief Executive Officer. On December 26, 2023, we received a letter from the Staff indicating that, based upon the resignation of three members of our Board on December 12, 2023 and December 13, 2023, we no longer comply with the independent director, audit committee, compensation committee and independent director oversight of director nominations requirements as set forth in Nasdaq Listing Rule 5605 (the "Independent Director Rule"). On February 12, 2024, our Board appointed three independent directors to the Board and subsequently regained compliance with the Independent Director Rule. There can be no assurance that we will be able to retain key management personnel and members of our Board or attract replacements in the event of their departure from the Company.

We maintain "key man" insurance policies on the lives of specific individuals but not on the lives of all critical employees. In order to retain valuable employees at our company, in addition to salary and cash incentives, we may provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Disruptions at the FDA and other government agencies caused by funding shortages could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times - including the most recent shutdown, which began October 1, 2025 -- and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

From September 15, 2025 through November 12, 2025, we issued the securities described below in transactions that were not registered under the Securities Act of 1933, as amended (Securities Act).

On September 16, 2025, we issued 64,666 shares of common stock at a value of $3.87 per share to a lender in exchange for a portion of the debt owed to such lender. Such issuance was exempt from registration under 3(a)(9) of the Securities Act.

On September 18, 2025, we issued 67,567 shares of common stock at a value of $3.70 per share to a lender in exchange for a portion of the debt owed to such lender. Such issuance was exempt from registration under 3(a)(9) of the Securities Act.

On October 2, 2025, we issued 63,775 shares of common stock at a value of $3.92 per share to a lender in exchange for a portion of the debt owed to such lender. Such issuance was exempt from registration under 3(a)(9) of the Securities Act.

On October 10, 2025, we issued 72,498 shares of common stock at a value of $4.14 per share to a lender in exchange for a portion of the debt owed to such lender. Such issuance was exempt from registration under 3(a)(9) of the Securities Act.

On November 12, 2025, we issued 82,644 shares of common stock at a value of $3.63 per share to a lender in exchange for a portion of the debt owed to such lender. Such issuance was exempt from registration under 3(a)(9) of the Securities Act.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

In the third quarter of 2025, 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

		Incorporated by Reference		
Exhibit Number	**Exhibit Description**	**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
10.1	Purchase Agreement, dated July 21, 2025, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.1	7/22/2025
10.2	Registration Rights Agreement, dated July 21, 2025, by and between the Company and Lincoln Park Capital Fund, LLC	8-K	10.2	7/22/2025
10.3+	Employment Agreement, dated July 8, 2025, between Cingulate Therapeutics LLC and Nilay D. Patel	10-Q	10.3	8/19/2025
10.4+	Amendment to Employment Agreement, effective July 7, 2025, between Cingulate Therapeutics, LLC and Raul A. Silva	S-1	10.11	7/22/2025
31.1*	Certification of Principal Executive Officer and 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 and 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

+ Indicates a management contract or compensatory plan

SIGNATURES

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

CINGULATE INC.

Date: November 13, 2025

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

Exhibit 31.1

CERTIFICATION 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, 2025 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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 13, 2025

/s/ Jennifer L. Callahan

Jennifer L. Callahan
Interim Chief Executive Officer and Chief Financial Officer
(Principal Executive 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, 2025 (the "Quarterly Report"), the undersigned hereby certifies in her 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 13, 2025

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