UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2026

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 August 12, 2026, 14,541,826 shares of the registrant's common stock, $0.0001 par value, were issued and outstanding.

Cingulate Inc.
Form 10-Q for the Quarter Ended June 30, 2026

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project,", "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 ability to obtain approval for CTx-1301 and the timing of any such approval;
- 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, 2025, filed with the SEC on March 18, 2026 (Form 10-K), 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)

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,402,819	$ 10,953,383
Other receivables	38,447	8,013
Prepaid expenses and other current assets	1,766,714	1,046,862
Total current assets	30,207,980	12,008,258
Property and equipment, net	1,634,754	1,725,919
Operating lease right-of-use assets	1,223,587	1,339,086
Total assets	**33,066,321**	**15,073,263**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,985,870	2,035,685
Accrued expenses	1,322,536	1,742,116
Note payable, current	5,067,293	6,295,960
Operating lease liability, current	255,132	238,864
Total current liabilities	8,630,831	10,312,625
Long-term liabilities:		
Operating lease liability, net of current	968,455	1,100,222
Note payable	-	1,151,509
Total long-term liabilities	968,455	2,251,731
Total liabilities	**9,599,286**	**12,564,356**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 13,894,882 and 7,250,299 shares issued and outstanding as of June 30, 2026 and December 31, 2025	1,389	725
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of June 30, 2026 and December 31, 2025	-	-
Additional Paid-in-Capital	171,023,030	134,883,213
Accumulated deficit	(147,557,384)	(132,375,031)
Total stockholders' equity	**23,467,035**	**2,508,907**
Total liabilities and stockholders' equity	**$ 33,066,321**	**$ 15,073,263**

See notes to unaudited consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 1,486,825	$ 2,700,939	$ 3,671,143	$ 4,923,565
Selling, general and administrative	3,928,150	1,949,035	9,667,054	3,432,444
Operating loss	**(5,414,975)**	**(4,649,974)**	**(13,338,197)**	**(8,356,009)**
Change in fair value of derivative	(314,013)	(194,526)	(1,166,043)	(244,513)
Interest and other income (expense), net	(141,276)	(138,761)	(678,113)	(235,417)
Loss before income taxes	(5,870,264)	(4,983,261)	(15,182,353)	(8,835,939)
Income tax benefit (expense)	-	-	-	-
Net loss and comprehensive loss	**$ (5,870,264)**	**$ (4,983,261)**	**$ (15,182,353)**	**$ (8,835,939)**
Net loss per share of common stock, basic and diluted	$ (0.45)	$ (1.14)	$ (1.32)	$ (2.20)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	13,186,057	4,389,465	11,477,983	4,020,231

See notes to unaudited consolidated financial statements.

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

	Common Stock		Preferred Stock		Additional Paid-in-	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Income	Equity
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
Issuance of restricted common stock	24,122	2	-	-	96,667	-	-	96,669
Change in fair value of derivative	-	-	-	-	194,526	-	-	194,526
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**
Balance January 1, 2026	**7,250,299**	**$ 725**	**-**	**$ -**	**$ 134,883,213**	**$ (132,375,031)**	**$ -**	**$ 2,508,907**
Activity for the three months to March 31, 2026:								
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	1,824,664	182	-	-	10,143,153	-	-	10,143,335
Issuance of common stock relating to Streeterville Promissory Note	460,122	46	-	-	2,308,901	-	-	2,308,947
Issuance of common stock in connection with Private Placement	2,147,472	215	-	-	10,816,421	-	-	10,816,636
Issuance of preferred stock in connection with Private Placement	-	-	954	-	954,000	-	-	954,000
Preferred stock to common stock conversion	189,300	19	(954)	-	(19)	-	-	-
Preferred stock dividend	2,524	-	-	-	-	-	-	-
Change in fair value of derivative	-	-	-	-	852,030	-	-	852,030
Stock-based compensation expense, net of taxes	33,935	3	-	-	593,097	-	-	593,100
Net loss	-	-	-	-	-	(9,312,089)	-	(9,312,089)
Balance March 31, 2026	**11,908,316**	**$ 1,190**	**-**	**$ -**	**$ 160,550,796**	**$ (141,687,120)**	**$ -**	**$ 18,864,866**
Activity for the three months to June 30, 2026:								
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	1,839,265	184	-	-	9,136,009	-	-	9,136,193
Issuance of common stock relating to Avondale Promissory Note	147,301	15	-	-	659,985	-	-	660,000

Change in fair value of derivative	-	-	-	-	314,013	-	-	314,013
Stock-based compensation expense, net of taxes	-	-	-	-	362,227	-	-	362,227
Net loss	-	-	-	-	-	(5,870,264)	-	(5,870,264)
Balance June 30, 2026	**13,894,882**	**$ 1,389**	**-**	**$ -**	**$ 171,023,030**	**$ (147,557,384)**	**$ -**	**$ 23,467,035**

See notes to unaudited consolidated financial statements.

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Six Months Ended June 30,	
	2026	**2025**
Operating activities:		
Net loss	$ (15,182,353)	$ (8,835,939)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	219,428	312,280
Stock-based compensation	955,327	545,039
Accretion of discount on note payable	239,670	15,353
Amortization of debt issue costs	5,562	155,135
Loss on debt extinguishment	488,900	-
Change in fair value of derivative	1,166,043	244,513
Changes in operating assets and liabilities:		
Other receivables	(30,434)	6,740
Prepaid expenses and other current assets	(719,852)	(879,743)
Operating lease right-of-use assets	115,499	(1,348,209)
Trade accounts payable and accrued expenses	45,244	(935,266)
Current portion of operating lease liability	16,268	92,971
Long-term portion of operating lease liability	(131,767)	1,223,587
Net cash used in operating activities	(12,812,465)	(9,403,539)
Investing activities:		
Purchase of property and equipment	(128,263)	(5,925)
Net cash used in investing activities	**(128,263)**	**(5,925)**
Financing activities:		
Proceeds from the issuance of common stock and common stock purchase warrants, net of fees	31,050,164	6,102,756
Principal payments on notes payable	(660,000)	-
Principal payments on finance lease obligations	-	(4,430)
Net cash provided by financing activities	**30,390,164**	**6,098,326**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	17,449,436	(3,311,138)
Cash and cash equivalents at beginning of year	10,953,383	12,211,321
Cash and cash equivalents at end of period	**$ 28,402,819**	**$ 8,900,183**
Cash paid for interest	**$ 803**	**$ 16,250**

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. CTx1301 is in late-stage development, and we plan to initiate the clinical plan for CTx-1302 pending additional capital resources. 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. On June 2, 2026, the Company announced that the FDA issued a Complete Response Letter for the CTx-1301 NDA, which identified specific requests for additional Chemistry, Manufacturing and Controls information. A failure to receive FDA approval for CTx-1301, or a delay in receiving such approval, will likely have a material adverse impact on the Company's financial results and strategic position. For more information, please see "Risk Factors" below in Part II of this report.

The consolidated financial statements and notes for the periods ended June 30, 2026 and 2025, 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 FDA approved, manufactured, commercially available to the marketplace and produce revenues. On June 30, 2026, the Company had cash and cash equivalents of approximately $28.4 million, and an accumulated deficit of approximately $147.6 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 June 30, 2026 and December 31, 2025, the consolidated statements of operations and comprehensive loss for the three and six-month periods ended June 30, 2026 and 2025, the consolidated statements of stockholders' equity for the three and six-month periods ended June 30, 2026 and 2025, the consolidated statements of cash flows for the six-month periods ended June 30, 2026 and 2025, 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 2025 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 six-month periods ended June 30, 2026 or 2025.

(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 June 30, 2026.

(g) Reclassifications

In connection with the preparation of the interim financial statements as of and for the three and nine months ended September 30, 2025, the Company identified certain errors in its accounting for the Original LP Purchase Agreement in previously issued consolidated financial statements. Accordingly, the comparative financial statements included in this report differ from our previously filed Quarterly Report on Form 10-Q as of and for the three and six months ended June 30, 2025, 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 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 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 statements of operations and comprehensive loss were as follows:

	Three Months Ended June 30, 2025		Six Months Ended June 30, 2025	
	As Reported	As Corrected	As Reported	As Corrected
Change in fair value of derivative	-	(194,526)	-	(244,513)
Net loss and comprehensive loss	**$ (4,788,735)**	**$ (4,983,261)**	**$ (8,591,426)**	**$ (8,835,939)**
Net loss per share of common stock, basic and diluted	$ (1.09)	$ (1.14)	$ (2.14)	$ (2.20)

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, 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:

	Six Months Ended June 30, 2025	
	As Reported	As Corrected
Operating activities:		
Net loss	$ (8,591,426)	$ (8,835,939)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative	-	244,513
Net cash used in operating activities	(9,403,539)	(9,403,539)

(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 June 30,		Six Months Ended June 30,	
Operating expenses:	**2026**	**2025**	**2026**	**2025**
Research and development				
Clinical operations	$ 36,619	$ 763,860	$ 90,397	$ 1,871,334
Drug manufacturing	909,471	1,110,084	2,076,208	1,490,437
Personnel	585,096	409,220	1,356,528	970,554
Regulatory	(44,361)	417,775	148,010	591,240
Total research and development	1,486,825	2,700,939	3,671,143	4,923,565
Selling, general and administrative				
Pre-commercialization costs	1,687,919	98,850	5,213,238	110,850
Personnel	868,974	459,336	1,985,184	1,030,866
Legal and professional fees	1,039,172	968,987	1,708,102	1,474,487
Occupancy	46,536	88,359	140,380	149,986
Insurance	149,506	174,449	299,012	370,045
Other	136,043	159,054	321,138	296,210
Total selling, general and administrative	3,928,150	1,949,035	9,667,054	3,432,444
Operating loss	(5,414,975)	(4,649,974)	(13,338,197)	(8,356,009)
Change in fair value of derivative	(314,013)	(194,526)	(1,166,043)	(244,513)
Interest and income (expense), net	(141,276)	(138,761)	(678,113)	(235,417)
Loss before income taxes	(5,870,264)	(4,983,261)	(15,182,353)	(8,835,939)
Income tax benefit (expense)	-	-	-	-
Net loss and comprehensive loss	$ (5,870,264)	$ (4,983,261)	$ (15,182,353)	$ (8,835,939)

(3) Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following at June 30, 2026 and December 31, 2025:

	June 30, 2026	December 31, 2025
Manufacturing materials	$ 1,396,266	$ 813,381
Professional fees	180,000	-
Marketing fees	75,000	125,000
Dues and subscriptions	41,588	11,743
Insurance	14,953	16,655
Deferred capital raise costs	-	59,383
Other	58,907	20,700
	$ 1,766,714	$ 1,046,862

(4) Property and Equipment

Property and equipment, net consisted of the following at June 30, 2026 and December 31, 2025:

	Estimated Useful Life (in years)	June 30, 2026	December 31, 2025
Equipment	2-7	$ 4,662,280	$ 4,662,280
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	46,994	46,994
Leasehold improvements	5	489,395	474,462
Construction-in-process	-	346,727	233,397
		5,691,150	5,562,887
Less: accumulated depreciation		(4,056,396)	(3,836,968)
		$ 1,634,754	$ 1,725,919

Depreciation expense was $219,428 and $312,280, respectively, for the six-month periods ended June 30, 2026 and 2025. Depreciation expense was $98,243 and $146,989, respectively, for the three-month periods ended June 30, 2026 and 2025.

(5) Accrued Expenses

Accrued expenses consisted of the following at June 30, 2026 and December 31, 2025:

	June 30, 2026	December 31, 2025
Interest	$ 388,702	$ 563,883
Pre-commercialization costs	255,070	393,076
Manufacturing materials	221,397	-
Manufacturing activities	157,275	-
State franchise taxes	106,000	44,000
Employee compensation	86,817	455,177
Professional fees	80,000	31,542
Research and development	-	166,696
Other	27,275	87,742
	$ 1,322,536	$ 1,742,116

(6) Contingencies

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

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

(7) Unsecured Promissory Note

On December 20, 2024, the Company entered into a note purchase agreement (2024 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 (2024 Note) in the amount of $5,480,000. The 2024 Note included an original issue discount of $450,000 and Lender expenses payable by the Company of $30,000. In exchange for the 2024 Note, the Lender paid a purchase price of $5,000,000 in cash. The 2024 Note bore interest at a rate of 9% per annum and had a maturity of 18 months after its issuance date.

From time to time, beginning on July 2, 2025, Lender could redeem a portion of the 2024 Note. Pursuant to the terms of the 2024 Note, the Company was charged a monitoring fee equal to the outstanding principal balance on the 90-day anniversary of the effective date of the 2024 Note divided by 0.85 less the outstanding balance on such date. Subject to the terms and conditions set forth in the 2024 Note, the Company could prepay all or any portion of the outstanding balance of the 2024 Note at any time. The Company entered into several exchange agreements with Lender to exchange a total of $6,983,947 of principal, monitoring fee and interest for 1,627,422 shares of common stock, and the 2024 Note was extinguished in February 2026. 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 the date the 2024 Note was extinguished, the full monitoring fee of $989,309 had been recognized as a loss on debt extinguishment within interest and other income (expense), net and the interest expense on the monitoring fee was $79,977.

In connection with the 2024 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 2024 Note and were amortized over the term of the 2024 Note using the effective interest rate method. The Company wrote-off the debt issuance costs and debt discount over the life of the 2024 Note in connection with the debt extinguishments described above and recognized as a loss on debt extinguishment within interest and other income (expense), net of $153,423. As of June 30, 2026, the aggregate amount of unamortized debt discount and debt issuance costs was $0.

As of June 30, 2026 and December 31, 2025, the outstanding balances relating to the 2024 Note were as follows:

	June 30, 2026	December 31, 2025
2024 Note:		
Principal	$ -	$ 805,000
Monitoring fee on pro rata portion of exchanges	-	671,792
Unamortized discounts/deferred financing	-	(83,922)
Total outstanding debt	$ -	$ 1,392,870
Accrued Interest	$ -	$ 474,598

On November 7, 2025, the Company entered into a note purchase agreement (2025 Note Purchase Agreement) with Avondale Capital, LLC, a Utah limited liability company (Avondale), pursuant to which the Company issued and sold to Avondale an unsecured promissory note in the amount of $6,570,000 (2025 Note). The principal amount includes an original issue discount of $540,000 and expenses payable by the Company of $30,000. In exchange for the 2025 Note, Avondale paid a purchase price of $6,000,000 in cash. The 2025 Note bears interest at a rate of 9% per annum and matures 18 months after its issuance date.

From time to time, beginning on May 7, 2026, Avondale may redeem a portion of the 2025 Note, not to exceed an amount of $660,000 per month. The Company was charged a monitoring fee equal to the outstanding balance on the 90-day anniversary of the effective date of the 2025 Note 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. Subject to the terms and conditions set forth in the 2025 Note, the Company may prepay all or any portion of the outstanding balance of the 2025 Note at any time. As of June 30, 2026, the Company has entered into several exchange agreements with Avondale to exchange a total of $1,320,000 of principal for 147,301 shares of common stock and aggregate cash payments of $660,000, thereby extinguishing a portion of the 2025 Note. In connection with the exchange agreements for common stock, 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 June 30, 2026, the pro rata portion of the monitoring fee of $96,475 had been recognized as a loss on debt extinguishment within interest and other income (expense), net and the interest expense on the pro rata portion of the monitoring fee was $3,511. As the redemptions are outside of the control of the Company, the Company has recorded the gross amount of the expected fiscal year 2026 Avondale redemptions within current note payable on the consolidated balance sheet.

The 2025 Note provides for customary events of default (each as defined in the 2025 Note, 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, Avondale may increase the outstanding balance of the 2025 Note by 15%, and upon the occurrence of an Event of Default that is deemed a “Minor Trigger Event” as defined in the 2025 Note, Avondale may increase the outstanding balance of the 2025 Note by 5%. Avondale 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, Avondale may declare all amounts owed under the 2025 Note immediately due and payable. In addition, upon the occurrence of an Event of Default, upon the election of Avondale, interest shall begin accruing on the outstanding balance of the 2025 Note from the date of the Event of Default equal to the lesser of 22% per annum and the maximum rate allowable under law.

The debt discount of $540,000 and the expenses payable by the Company of $30,000 have been recorded as a reduction in the carrying amount of the 2025 Note and are being amortized over the term of the 2025 Note using the effective interest rate method. The Company wrote-off a pro-rate 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 $55,644. As of June 30, 2026, the aggregate amount of unamortized debt discount and debt issuance costs was $279,182.

As of June 30, 2026 and December 31, 2025 the outstanding balances relating to the 2025 Note were as follows:

	June 30, 2026	December 31, 2025
2025 Note:		
Principal	5,250,000	6,570,000
Monitoring fee on pro rata portion of exchanges	96,475	-
Unamortized discounts/deferred financing	(279,182)	(515,401)
Total	$ 5,067,293	$ 6,054,599
Accrued Interest	$ 388,702	$ 89,285

The following table provides a breakdown of interest expense (income) for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Interest expense - promissory notes	$ 236,375	$ 213,711	$ 584,690	$ 423,382
Interest expense - loss on debt extinguishment	152,119	-	488,900	-
Interest expense - other	-	16,250	803	16,295
Interest income	(249,981)	(93,031)	(407,613)	(205,963)
	$ 138,513	$ 136,930	$ 666,780	$ 233,714

(8) Stockholders' Equity

The Company has authorized 240,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock at June 30, 2026 and December 31, 2025, of which 13,894,882 and 7,250,299 shares of common stock were issued and outstanding, respectively.

In connection with the Private Placement (as defined in Note 9), on February 13, 2026, the Company issued 954 shares of non-voting, Series A convertible preferred stock, par value of $.001 and stated value of $1,000. The preferred shares were entitled to receive a dividend of 12% per annum. The preferred stock plus accrued dividends automatically converted into 191,824 shares of common stock on March 24, 2026 at a conversion price of $5.04 upon shareholder approval of the transaction at a special meeting of shareholders on March 24, 2026.

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.

(9) Securities Issuances

At the Market Offering

The Company entered into the At-the-Market Agreement (2023 ATM Agreement) with H.C. Wainwright & Co., LLC (HCW) in January 2023, as amended in May 2023, pursuant to which the Company could issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $31.9 million in at-the-market offering sales. HCW acted as sales agent and was paid a 3% commission on each sale under the 2023 ATM Agreement. The Company's common stock was sold at prevailing market prices at the time of the sale, and, as a result, prices varied. The Company terminated the 2023 ATM Agreement, effective March 23, 2026.

During the three months ended June 30, 2025, the Company sold 364,963 shares of common stock under the 2023 ATM Agreement, for net proceeds of $1,578,731. During the six months ended June 30, 2026 and 2025, the Company sold 210,158 and 565,447 shares of common stock, respectively, under the 2023 ATM Agreement, for net proceeds of $1,304,011 and $2,599,099.

On March 24, 2026, the Company entered into an ATM Sales Agreement (2026 ATM Agreement) with A.G.P./Alliance Global Partners, as sales agent (AGP), pursuant to which the Company may offer and sell, from time to time through AGP, shares of the Company's common stock for aggregate gross proceeds of up to $100,000,000 in at-the-market offering sales. AGP acts as sales agent and is paid a 3% commission on each sale under the 2026 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 June 30, 2026, the Company sold 806,893 shares of common stock under the 2026 ATM Agreement, for net proceeds of $4,347,364. During the six months ended June 30, 2026, the Company sold 809,593 shares of common stock under the 2026 ATM Agreement, for net proceeds of $4,364,909.

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 June 30, 2026.

During the three months ended June 30, 2026 and 2025, the Company sold 1,032,372 shares of common stock under the 2025 LP Purchase Agreement and 674,006 shares of common stock under the Original LP Purchase Agreement, for net proceeds of $5,058,975 and $2,613,247, respectively. During the six months ended June 30, 2026, the Company sold 2,644,178 shares of common stock under the 2025 LP Purchase Agreement and 897,415 shares of common stock under the Original LP Purchase Agreement, for net proceeds of $14,065,761 and $3,513,236, respectively. Changes in fair value associated with the derivative instrument are recorded in change in fair value of derivative in the consolidated statements of operations and comprehensive loss. The Company recorded $314,013 and $194,526 for the three-month periods ended June 30, 2026 and 2025, respectively, associated with the change in fair value of the derivative instrument. The Company recorded $1,166,043 and $244,513 for the six-month periods ended June 30, 2026 and 2025, respectively, associated with the change in fair value of the derivative instrument.

Private Placement

On January 27, 2026, the Company entered into a securities purchase agreement (Purchase Agreement) with several purchasers, including certain officers, directors and other affiliates of the Company (Purchasers), for the private placement (Private Placement) of: (i) 2,147,472 shares of the Company's common stock, (ii) 954 shares of Series A convertible preferred stock with a stated value of $1,000 and a conversion price equal to a $5.04 per share of common stock and (iii) a warrant to purchase 1,869,415 shares of common stock (Warrant Shares) for aggregate gross proceeds of approximately $12.0 million, at a price per share of $5.14 per share of common stock (including $0.10 per Warrant Share). The Warrant Shares have an exercise price of $5.04 per share of common stock, subject to adjustment as provided in the Warrant.

The closing of the Private Placement occurred on February 6 and 13, 2026. At the special meeting of stockholders on March 24, 2026, stockholders approved the issuance of common stock upon conversion of the preferred stock and the exercise of the warrant. Upon stockholder approval (i) the preferred stock, without any further action by the Company or the holder, automatically converted into 191,824 shares of common stock determined by dividing the stated value plus all unpaid accrued and accumulated preferential dividends on such share by the $5.04 conversion price and (ii) the warrant became exercisable.

Falcon Creek Capital Advisor LLC, on behalf of the Purchasers that it manages has designated two (2) individuals to serve on the Company's Board of Directors (each a Falcon Creek Director); provided, that (1) one Falcon Creek Director shall be required to resign from the Board of Directors if the Purchasers managed by Falcon Creek no longer beneficially owns at least 15% of the outstanding common stock of the Company and (2) the remaining Falcon Creek Director shall be required to resign from the Board of Directors if the Purchasers managed by Falcon Creek no longer beneficially owns at least 5% of the outstanding common stock of the Company.

Except as provided in the Purchase Agreement, during the period commencing on and including the date of the Purchase Agreement and continuing through and including the 180th day following the date of the Purchase Agreement (such period being referred to as the Lock-up Period), each Purchaser could not, without the prior written consent of the Company, sell, offer to sell, contract to sell or lend any shares of common stock or Warrant Shares (Securities). The Purchase Agreement also provides that during the Lock-up Period, the Purchasers could not (i) effect any short sale, or establish or increase any "put equivalent position" or liquidate or decrease any "call equivalent position" of any Securities; (ii) pledge, hypothecate or grant any security interest in any Securities; (iii) in any other way transfer or dispose of any Securities; (iv) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (v) grant any proxies or powers of attorney with respect to any Securities, deposit any Securities into a voting trust, or enter into a voting agreement or similar arrangement or commitment with respect to any Securities; or (vi) publicly announce the intention to do any of the foregoing.

The Purchase Agreement includes a standstill provision for a period of twenty-four (24) months following the closing date, whereby each Purchaser has agreed that, without the prior written consent of the Company, the Purchaser will not: (i) acquire, offer to acquire, or agree to acquire any additional securities of the Company if such acquisition would result in the Purchaser and its affiliates beneficially owning more than 40% of the Company's outstanding common stock on an as-converted basis; (ii) make, or in any way participate in, any solicitation of proxies or consents with respect to any securities of the Company; or (iii) propose or participate in any merger, tender offer, business combination, recapitalization, or similar transaction involving the Company.

(10) Stock-Based Compensation

In September 2021, the Company's board of directors and stockholders adopted the 2021 Equity Incentive Plan (EIP), 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 EIP on or after September 24, 2031, but the EIP will continue thereafter while previously granted awards remain outstanding.

At the Company's 2024 annual meeting and 2025 annual meeting, stockholders approved an amendment to the EIP to increase the number of shares of common stock authorized for issuance. As of June 30, 2026, 458,888 shares of common stock were available for issuance under the EIP. The number of shares of common stock available for issuance under the EIP will automatically increase on January 1st of each year until the expiration of the EIP, in an amount equal to 5% 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 EIP will be added back to the shares of common stock available for issuance under the EIP.

The Company recorded stock-based compensation expense of $1,073,941 and $448,370 during the six months ended June 30, 2026 and 2025, respectively. The Company recorded stock-based compensation expense of $347,920 and $90,721 during the three months ended June 30, 2026 and 2025, respectively. As of June 30, 2026 and December 31, 2025, there was $2,546,323 and $2,449,227, respectively, of unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the EIP, which is expected to be recognized over the next one to four years.

A summary of option and share activity under the EIP during the six-month periods ended June 30, 2026 and 2025 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
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			
Vested and expected to vest at June 30, 2025	398,839			
Exercisable at June 30, 2025	2,643			
Outstanding at January 1, 2026	956,017			
Granted	198,862	$ 5.95	9.89	-
Released	(55,436)			
Exercised	-			
Forfeitures or expirations	-			
Outstanding at March 31, 2026	1,099,443			
Granted	3,860	$ 5.47	10	-
Exercised	-			
Forfeitures or expirations	-			
Outstanding at June 30, 2026	1,103,303			
Vested and expected to vest at June 30, 2026	1,103,303			
Exercisable at June 30, 2026	502,918			

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 six-month periods ended June 30, 2026 and 2025 were as follows, shown on a weighted average basis:

	June 30, 2026	June 30, 2025
Risk-free interest rate	3.83%	4.35%
Expected term (in years)	5.91	5.73
Expected volatility	1.35	1.58
Expected dividend yield	0%	0%

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

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

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

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

The grant-date fair value of options granted during the three months ended June 30, 2026 was $4.79 and the grant-date fair value of options and shares granted during the six months ended June 30, 2026 ranged from $4.29 to $6.85.

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 June 30, 2026 and December 31, 2025.

On each of July 8, 2025 and November 3, 2025, the Company granted a non-qualified stock option award to an officer of the Company to purchase 30,000 shares of common stock at an exercise price of $4.51 and $3.80, respectively. These grants were inducement awards in accordance with Nasdaq Listing Rule 5635(c)(4) and were not granted from the EIP. The term of these options is ten years with vesting over four years. The Company recorded stock-based compensation expense of $14,233 and $28,540 during the three and six months ended June 30, 2026. As of June 30, 2026, there was $181,545 of unrecognized compensation cost related to nonvested share-based compensation related to the inducement grants, which is expected to be recognized over the next one to four years.

(11) Common Stock Purchase Warrants

Private Placement

Pursuant to the Private Placement, the Company issued warrants to purchase up to 1,869,415 shares of common stock. These warrants have an exercise price of $5.04 per share, a three-year term and became exercisable upon stockholder approval at the Company's special meeting held on March 24, 2026.

The Company evaluated the Private Placement warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, Distinguishing Liabilities from Equity, and ASC Topic 815, Derivatives and Hedging, and determined that equity treatment was appropriate. The Company valued the Private Placement warrants based on their issuance date fair value of $3.74. None of the Private Placement warrants were exercised in the three or six months ended June 30, 2026.

The Private Placement warrants were valued using a Black-Scholes model with a risk-free rate of 3.8%-3.9%, the term of three years, and a volatility of 1.02. The estimated volatility of the Company's common stock at the date of measurement is based on an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. The risk-free rate is based on the expected term of the warrants based on the constant maturity of U.S. Treasury securities with similar maturities as of the date of grant. The expected term has been estimated using the contractual term of the warrants.

The gross proceeds of Private Placement were allocated to the common stock and Private Placement warrants using the relative fair value method shown as follows. Fair value of the warrants was recorded to Additional Paid-in-Capital on the Company's consolidated balance sheet.

	Fair Value	Percent of Total Fair Value	Amount Allocated
Common Stock	$ 5,019,388	41.8%	$ 5,020,598
Private Placement Warrants	6,991,612	58.2%	6,990,402
Total	$ 12,011,000	100.0%	$ 12,011,000

The following table summarizes the Company's outstanding common stock purchase warrants as of June 30, 2026:

	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 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 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
February 2026 Private Placement Warrants	1,869,415	$ 5.040	$ 3.74	6,991,612
Balance- June 30, 2026	2,620,963			$ 38,438,290

(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 June 30, 2026 and 2025 or the six-month periods ended June 30, 2026 and 2025, for federal or state income taxes.

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

	Three Months Ended June 30, 2026	Three Months Ended June 30, 2025	Six Months Ended June 30, 2026	Six Months Ended June 30, 2025
Federal income tax benefit at statutory rate	$ (1,232,755)	$ (1,044,568)	$ (3,188,294)	$ (1,853,641)
State income tax benefit	(198,492)	(245,082)	(516,821)	(439,546)
Discount on FMV of shares issued	65,943	39,790	244,869	50,287
Permanent differences	4,104	3,346	10,641	6,650
Change in valuation allowance	1,361,199	1,247,371	3,449,604	2,237,364
Other	1	(857)	1	(1,114)
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 $25,667,954 as of June 30, 2026 and $22,218,350 at December 31, 2025, 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 2021.

The Company follows the provisions of FASB ASC 740, *Income Taxes*, to evaluate uncertain tax positions. This topic prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has not identified any material uncertain tax positions requiring recognition in the consolidated financial statements as of June 30, 2026 or December 31, 2025.

On July 4, 2025, H.R. 1, commonly known as the One Big Beautiful Bill Act (the "OBBB"), was signed into law. This includes significant changes to the federal corporate tax provisions and extends certain otherwise expiring provisions of the 2017 Tax Cuts and Jobs Act. Among other things, the legislation reinstates expensing for domestic research and experimental expenditures, imposes new limitations on interest expense deductibility, and expands disallowed deductions for certain employee remuneration. FASB ASC 740 Income Taxes requires the effects of changes in tax rates and laws on deferred tax balances to be recognized in the period in which the relevant legislation is enacted. The OBBB may affect the Company's gross tax assets and liabilities in future periods. The Company accounted for the tax effects of the legislation during the year ended December 31, 2025, and elected to deduct domestic research and development expenses in 2025 and 2026 rather than amortize over multiple years.

(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 $1,223,587, the current portion of the operating lease liability was $255,132 and the long-term portion of the lease liability was $968,455 as of June 30, 2026.

(14) Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted-average number of common shares and pre-funded warrants outstanding during the period. The following table set forth the computation of the basic and diluted net loss per share for the three and six months ended June 30, 2026 and 2025:

	Three Months Ended June 30, 2026	Three Months Ended June 30, 2025	Six Months Ended June 30, 2026	Six Months Ended June 30, 2025
Numerator:				
Net loss	$ (5,870,264)	$ (4,983,261)	$ (15,182,353)	$ (8,835,939)
Preferred share dividend	-	-	(12,720)	-
	(5,870,264)	(4,983,261)	(15,195,073)	(8,835,939)
Denominator:				
Weighted average common shares outstanding	13,186,057	4,389,465	11,477,983	4,020,231
Net loss per share, basic and diluted	$ (0.45)	$ (1.14)	$ (1.32)	$ (2.20)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows for the periods ended June 30, 2026 and 2025:

	June 30, 2026	June 30, 2025
Stock options issued and outstanding	1,163,303	398,839
Common stock purchase warrants outstanding	2,620,963	833,684
Total	3,784,266	1,232,523

(15) Related Party Transactions

The following officers, directors and other affiliates participated, directly or indirectly, in the Private Placement that closed on February 6, 2026 and purchased the number of shares of our common stock and warrant shares set forth after their name: Shane J. Schaffer (6,809 common shares and 5,447 Warrant Shares); Jennifer L. Callahan (4,864 common shares and 3,891 Warrant Shares); Matthew N. Brams (1,946 common shares and 1,556 Warrant Shares; Peter J. Werth (19,455 common shares and 15,564 Warrant Shares); and Larry Schaffer, the father of Shane Schaffer (58,366 common shares and 46,693 Warrant Shares). The total of all common stock and warrant shares was $470,000 and is included in proceeds from the issuance of common stock and common stock purchase warrants, net of fees on the consolidated statement of cash flows for the six months ended June 30, 2026.

(16) Subsequent Events

Management evaluated events that occurred subsequent to June 30, 2026, through August 13, 2026, which is the date the interim financial statements were issued.

On July 9, 2026, the Company's stockholders approved an amendment to the EIP, increasing the number of shares of common stock authorized for issuance under the EIP by 625,000 shares.

Subsequent to June 30, 2026, the Company entered into several exchange agreements with Avondale to exchange a total of $1,320,000 in principal for 139,751 shares of common stock and cash payments of $600,000, thereby extinguishing that portion of the 2025 Note. See Note 7 for additional information regarding the 2025 Note.

Subsequent to June 30, 2026, the Company sold 220,476 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $1,068,525.

Subsequent to June 30, 2026, the Company sold 271,717 shares of common stock under the 2026 ATM Agreement, for net proceeds of $1,394,179.

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 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) with an estimated US market size of approximately 100 million prescriptions of stimulants as of September 2025, 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 $160.4 million as of June 30, 2026.

We have incurred significant losses since our inception. Our net losses were $5.9 million and $5.0 million for the three months ended June 30, 2026 and 2025, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of June 30, 2026, we had an accumulated deficit of $147.6 million.

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

- complete the CMC work necessary to support resubmission of the NDA for CTx-1301 and seek regulatory approval;
- continue research and development activities for our existing and new product candidates;
- continue manufacturing activities, primarily the manufacture of process validation batches relating to CTx-1301;
- advance commercialization efforts for CTx-1301; and
- operate as a public company.

As of June 30, 2026, we had cash and cash equivalents of $28.4 million, which we believe will be sufficient to fund our operations into mid 2027, including costs associated with completing the requested CMC work and seeking regulatory approval for CTx-1301 and the build-out of internal and external support for the commercial launch of CTx-1301, if approved. We will need additional capital to advance other potential development 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.

Clinical, Manufacturing, Regulatory 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.

In October 2025, we announced that the FDA accepted for review our NDA for CTx-1301 and assigned a Prescription Drug User Fee Act (PDUFA) targeted action date of May 31, 2026. On June 1, 2026, we received a Complete Response Letter (CRL) from the FDA regarding the NDA for CTx-1301. The CRL identified specific requests for additional CMC information and did not raise any concerns regarding the clinical safety or efficacy of CTx-1301. We and our CDMO (defined below) are working to complete the CMC work necessary to support a resubmission of the NDA as promptly as practicable. There can be no assurance regarding the timing of any resubmission, that any resubmission will be accepted by the FDA, that approval of CTx-1301 will occur following any resubmission, or that approval will occur at all. See Risk Factors section in Part II of this report for more information about the risks related to regulatory approval of CTx-1301.

Bend Bioscience, a contract development and manufacturing organization (CDMO), will manufacture all clinical, registration, and, if approved, commercial batches of our lead ADHD candidate, CTx-1301. Manufacturing will occur at a suite within the CDMO's Gainesville, GA facility that is outfitted with equipment supplied by us.

If approved, we plan to commercialize CTx-1301 in the United States. We continue to advance our commercialization preparations, with dedicated teams established across all key functional areas. Our launch strategy leverages a commercialization strategy augmented by AI-driven tools designed to optimize targeting, decision-making, and performance measurement — positioning us for a rapid commercial launch contingent upon FDA approval. Key areas of focus include:

- Commercial Manufacturing: Working with Bend Bioscience, the Company's contract development and manufacturing organization, to complete the requested CMC work and advance process validation for CTx-1301, which would serve as launch inventory if approved.

- Product Distribution: On July 21, 2026, the Company signed an exclusive services agreement with Prasco, LLC to establish the commercial distribution infrastructure for the launch of CTx-1301, providing integrated third-party logistics and distribution capabilities designed to support broad national availability across major wholesalers as well as direct distribution to approximately 19,000 independent and smaller regional pharmacy accounts served under Prasco's UNLIMIT program.

- Market Access and Payer Strategy: Advancing payer segmentation, value proposition, pricing and contracting strategy, and to support formulary positioning ahead of a potential launch.

- Commercial Operations and Omnichannel Infrastructure: Building marketing, commercial operations and digital capabilities through the Company's master services agreement with Indegene, Inc., including dedicated market access, medical education, agency of record, and prescriber and patient marketing teams.

- Field Deployment Planning: Under its agreement with IQVIA Inc., the Company will deploy field-based sales representatives in addition to its currently deployed corporate account directors to align with the timing of a potential approval and launch.

We have an agreement with Indegene, Inc. (Indegene) for them to provide commercialization services for CTx-1301, including marketing, market access and pricing, commercial operations, and an omnichannel platform on a fee for service basis in the United States. We also have dedicated teams in place at Indegene across key functional areas including market access, medical education, prescriber and patient marketing, and digital infrastructure. Additionally, field-based sales representatives and corporate account directors will augment omnichannel promotional efforts through an agreement with IQVIA Inc.

Intellectual Property

On June 16, 2026, the United States Patent and Trademark Office issued U.S. Patent No. 12,653,791 covering CTx-1301. The patent protects key aspects of CTx-1301's formulation and method of use through December 2042 and represents the first U.S. patent wholly owned by the Company covering CTx-1301, further strengthening our intellectual property portfolio surrounding our PTR platform.

Securities Issuances

Private Placement

On January 27, 2026, the Company entered into a securities purchase agreement (Purchase Agreement) with several purchasers, including certain officers, directors and other affiliates of the Company (Purchasers), for the private placement (Private Placement) of: (i) 2,147,472 shares of the Company's common stock, (ii) 954 shares of Series A convertible preferred stock with a stated value of $1,000 and a conversion price equal to a $5.04 per share of common stock and (iii) a warrant to purchase 1,869,415 shares of common stock (Warrant Shares) for aggregate gross proceeds of approximately $12.0 million, at a price per share of $5.14 per share of common stock (including $0.10 per Warrant Share). The Warrant Shares have an exercise price of $5.04 per share of common stock, subject to adjustment as provided in the Warrant.

The closing of the Private Placement occurred on February 6 and 13, 2026. At the special meeting of stockholders on March 24, 2026, stockholders approved the issuance of common stock upon conversion of the preferred stock and the exercise of the warrant. Upon stockholder approval (i) the preferred stock, without any further action by the Company or the holder, automatically converted into 191,824 shares of common stock determined by dividing the stated value plus all unpaid accrued and accumulated preferential dividends on such share by the $5.04 conversion price and (ii) the warrant became exercisable.

Falcon Creek Capital Advisor LLC, on behalf of the Purchasers that it manages has designated two (2) individuals to serve on the Company's Board of Directors (each a Falcon Creek Director); provided, that (1) one Falcon Creek Director shall be required to resign from the Board of Directors if the Purchasers managed by Falcon Creek no longer beneficially owns at least 15% of the outstanding common stock of the Company and (2) the remaining Falcon Creek Director shall be required to resign from the Board of Directors if the Purchasers managed by Falcon Creek no longer beneficially owns at least 5% of the outstanding common stock of the Company.

Except as provided in the Purchase Agreement, during the period commencing on and including the date of the Purchase Agreement and continuing through and including the 180th day following the date of the Purchase Agreement (such period being referred to as the Lock-up Period), each Purchaser could not, without the prior written consent of the Company, sell, offer to sell, contract to sell or lend any shares of common stock or Warrant Shares (Securities). The Purchase Agreement also provides that during the Lock-up Period, the Purchasers could not (i) effect any short sale, or establish or increase any "put equivalent position" or liquidate or decrease any "call equivalent position" of any Securities; (ii) pledge, hypothecate or grant any security interest in any Securities; (iii) in any other way transfer or dispose of any Securities; (iv) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (v) grant any proxies or powers of attorney with respect to any Securities, deposit any Securities into a voting trust, or enter into a voting agreement or similar arrangement or commitment with respect to any Securities; or (vi) publicly announce the intention to do any of the foregoing.

The Purchase Agreement includes a standstill provision for a period of twenty-four (24) months following the closing date, whereby each Purchaser has agreed that, without the prior written consent of the Company, the Purchaser will not: (i) acquire, offer to acquire, or agree to acquire any additional securities of the Company if such acquisition would result in the Purchaser and its affiliates beneficially owning more than 40% of the Company's outstanding common stock on an as-converted basis; (ii) make, or in any way participate in, any solicitation of proxies or consents with respect to any securities of the Company; or (iii) propose or participate in any merger, tender offer, business combination, recapitalization, or similar transaction involving the Company.

ATM Agreements

We entered into the At-the-Market Agreement (2023 ATM Agreement) with H.C. Wainwright & Co., LLC (HCW) in January 2023, as amended in May 2023, pursuant to which we could issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $31.9 million in at-the-market offering sales. HCW acted as sales agent and was paid a 3% commission on each sale under the 2023 ATM Agreement. Our common stock sold at prevailing market prices at the time of the sale, and, as a result, prices varied. We terminated the 2023 ATM Agreement, effective March 23, 2026.

During the three months ended June 30, 2025, we sold 364,963 shares of common stock, respectively, under the 2023 ATM Agreement, for net proceeds of $1,578,731, after deducting $54,363 of compensation to HCW and other administration fees.

On March 24, 2026, we entered into an ATM Sales Agreement (2026 ATM Agreement) with A.G.P./Alliance Global Partners, as sales agent (AGP), pursuant to which we may offer and sell, from time to time through AGP, shares of our common stock for aggregate gross proceeds of up to $100,000,000 in at-the-market offering sales. AGP acts as sales agent and is paid a 3% commission on each sale under the 2026 ATM Agreement. Our 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 June 30, 2026, we sold 806,893 shares of common stock under the 2026 ATM Agreement, for net proceeds of $4,347,364, after deducting $136,364 of compensation to A.G.P. and other administration fees. Subsequent to June 30, 2026, we sold 271,717 shares of common stock under the 2026 ATM Agreement, for net proceeds of $1,394,179, after deducting $43,751 of compensation to A.G.P. and other administration fees.

Equity Line of Credit

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.

In July 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. During the three months ended June 30, 2026, we sold 1,032,372 shares of common stock to Lincoln Park, under the 2025 LP Purchase Agreement, for net proceeds of $5,058,975. Subsequent to June 30, 2026, we sold 220,476 shares of common stock to Lincoln Park, under the 2025 LP Purchase Agreement, for net proceeds of $1,068,525.

Debt for Equity Exchanges

In December 2024, we entered into a note purchase agreement with Streeterville Capital, LLC, a Utah limited liability company (Lender), pursuant to which we issued and sold to Lender an unsecured promissory note in the amount of $5,480,000 (2024 Note).

During the three months ended March 31, 2026, we entered into exchange agreements with Lender to exchange an aggregate of $2,308,947 in principal, monitoring fee and interest for 460,122 shares of common stock, thereby extinguishing the 2024 Note.

In November 2025, we entered into a 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 (2025 Note). From time to time, beginning on May 7, 2026, Avondale may redeem a portion of the 2025 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 with respect to CTx-1301, 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 2025 Note will be increased by 1% of the outstanding balance on the date of the deferral.

During the three months ended June 30, 2026, the Company entered into exchange agreements with Avondale to exchange an aggregate of $1,320,000 in principal for 147,301 shares of common stock and aggregate cash payments of $660,000, thereby extinguishing that portion of the promissory note with Avondale. Subsequent to June 30, 2026, the Company entered into exchange agreements with Avondale to exchange an aggregate of $1,320,000 in principal for 139,751 shares of common stock and a cash payments of $600,000, thereby extinguishing that portion of the promissory note with Avondale.

See Note 7 to our consolidated financial statements for additional information regarding the 2024 Note and 2025 Note.

Components of Operating Results

Revenue

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

Operating Expenses

Research and Development Expenses

Research and development (R&D) 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 R&D 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 R&D 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.

R&D activities are central to our business model. Subject to successful regulatory approval and commercialization of CTx-1301, we expect that our R&D 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 R&D costs have primarily related to the development of CTx-1301. We expect to fund our R&D expenses from our current cash and cash equivalents and any future equity or debt financings, or other capital sources.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses consist primarily of (i) professional fees for legal, accounting, audit, tax and consulting services, (ii) salaries and related costs for our employees in administrative, executive and finance functions and (iii) pre-commercialization expenses for CTx-1301. SG&A expenses also include insurance, office, and travel expenses.

We expect that our SG&A expenses will increase in the future as we increase our SG&A headcount to support our growing operations, including the potential commercialization of CTx-1301, and incur costs related to pre-commercialization activities. 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.

Change in fair value of derivative and interest and other income (expense), net

Change in fair value of derivative relates to 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, 2025.

Results of Operations

Comparison of the three months ended June 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended June 30, 2026 and 2025:

	Three Months Ended June 30,		Increase	% Increase
(in thousands)	2026	2025	(Decrease)	(Decrease)
Operating Expenses:				
Research and development	$ 1,487	$ 2,701	$ (1,214)	(44.9)%
Selling, general and administrative	3,928	1,949	1,979	101.5%
Operating Loss	(5,415)	(4,650)	765	16.5%
Change in fair value of derivative	(314)	(194)	120	61.9%
Interest and income (expense), net	(141)	(139)	2	1.4%
Net Loss	$ (5,870)	$ (4,983)	$ 887	17.8%

Research and development expenses

The following table summarizes our R&D expenses for the three months ended June 30, 2026 and 2025:

(in thousands)	Three Months Ended June 30, 2026	2025	Increase	% Increase
Clinical operations	$ 37	$ 764	$ (727)	(95.2)%
Drug manufacturing	909	1,110	(201)	(18.1)%
Personnel expenses	585	409	176	43.0%
Regulatory costs	(44)	418	(462)	(110.5)%
Total research and development expenses	$ 1,487	$ 2,701	$ (1,214)	(44.9)%

R&D expenses decreased $1.2 million, or 44.9%, to $1.5 million for the three months ended June 30, 2026, from $2.7 million for the three months ended June 30, 2025. The decrease was driven primarily by lower clinical operations costs following the conclusion of clinical study activities in early 2025, and by the absence of the regulatory costs incurred in the second quarter of 2025 in connection with preparing the CTx-1301 NDA, which was submitted on July 31, 2025.

Selling, general and administrative expenses

The following table summarizes our SG&A expenses for the three months ended June 30, 2026 and 2025:

(in thousands)	Three Months Ended June 30, 2026	2025	Increase (Decrease)	% Increase (Decrease)
Pre-commercialization costs	$ 1,688	$ 99	$ 1,589	NM
Personnel expenses	869	459	410	89.3%
Legal and professional fees	1,039	969	70	7.2%
Occupancy	47	88	(41)	(46.6)%
Insurance	149	175	(26)	(14.9)%
Other	136	159	(23)	(14.5)%
Total selling, general and administrative expenses	$ 3,928	$ 1,949	$ 1,979	101.5%

Total SG&A expenses increased $2.0 million, or 101.5%, to $3.9 million for the three months ended June 30, 2026, from $1.9 million for the three months ended June 30, 2025. The increase was driven primarily by commercial readiness planning for the potential launch of CTx-1301, including increased headcount and market access, pricing, reimbursement, and medical affairs activities conducted through Indegene, our primary commercial partner.

Change in fair value of derivative and interest and other income (expense), net

The following table summarizes the change in fair value of derivative and interest and other income (expense), net for the three months ended June 30, 2026 and 2025:

(in thousands)	Three Months Ended June 30, 2026	2025	Increase (Decrease)	% Increase (Decrease)
Change in fair value of derivative	$ (314)	$ (194)	$ 120	61.9%
Interest and other income (expense), net	(141)	(139)	2	1.4%

Change in fair value of derivative for the three months ended June 30, 2026 and June 30, 2025 relates to the 2025 LP Purchase Agreement and the change in fair value of the derivative asset or liability. Interest expense, net for the three months ended June 30, 2026 and June 30, 2025 relates to interest incurred on the 2024 Note and 2025 Note, offset by interest earned on invested balances.

Comparison of the six months ended June 30, 2026 and 2025

The following table summarizes our results of operations for the six months ended June 30, 2026 and 2025:

(in thousands)	Six Months Ended June 30, 2026	2025	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 3,671	$ 4,924	$ (1,253)	(25.4)%
Selling, general and administrative	9,667	3,432	6,235	181.7%
Operating Loss	(13,338)	(8,356)	4,982	59.6%
Change in fair value of derivative	(1,166)	(244)	922	377.9%
Interest and income (expense), net	(678)	(236)	442	187.3%
Net Loss	$ (15,182)	$ (8,836)	$ 6,346	71.8%

Research and development expenses

The following table summarizes our R&D expenses for the six months ended June 30, 2026 and 2025:

(in thousands)	Six Months Ended June 30, 2026	2025	Increase	% Increase
Clinical operations	$ 91	$ 1,872	$ (1,781)	(95.1)%
Drug manufacturing	2,076	1,490	586	39.3%
Personnel expenses	1,356	970	386	39.8%
Regulatory costs	148	592	(444)	(75.0)%
Total research and development expenses	$ 3,671	$ 4,924	$ (1,253)	(25.4)%

R&D expenses decreased approximately $1.3 million, or 25.4%, to $3.7 million for the six months ended June 30, 2026, from $4.9 million for the six months ended June 30, 2025. The decrease was driven primarily by lower clinical operations costs following the conclusion of clinical studies in early 2025 and the absence of increased NDA-preparation regulatory costs incurred in the prior-year period, partially offset by increased manufacturing activities in the first half of 2026 related to CTx-1301 as well as increased personnel costs.

Selling, general and administrative expenses

The following table summarizes our SG&A expenses for the six months ended June 30, 2026 and 2025:

(in thousands)	Six Months Ended June 30, 2026	2025	Increase (Decrease)	% Increase (Decrease)
Pre-commercialization costs	$ 5,213	$ 111	$ 5,102	NM
Personnel expenses	1,985	1,030	955	92.7%
Legal and professional fees	1,708	1,474	234	15.9%
Occupancy	141	150	(9)	(6.0)%
Insurance	299	371	(72)	(19.4)%
Other	321	296	25	8.4%
Total selling, general and administrative expenses	$ 9,667	$ 3,432	$ 6,235	181.7%

Total SG&A expenses increased approximately $6.2 million, or 181.7%, to $9.7 million for the six months ended June 30, 2026, from $3.4 million for the six months ended June 30, 2025, reflecting the progressive build-out of commercial readiness capabilities across the first half of the year, including headcount additions and expanded market access, pricing, reimbursement, and medical affairs activity through Indegene, our primary commercialization partner.

Change in fair value of derivative and interest and other income (expense), net

The following table summarizes the change in fair value of derivative and interest and other income (expense), net for the six months ended June 30, 2026 and 2025:

(in thousands)	Six Months Ended June 30, 2026	2025	Increase (Decrease)	% Increase (Decrease)
Change in fair value of derivative	$ (1,166)	$ (244)	$ 922	NM
Interest and other income (expense), net	(678)	(236)	442	187.3%

Change in fair value of derivative for the six-months ended June 30, 2026 relates to the 2025 LP Purchase Agreement and remeasurement of the associated derivative asset or liability. Interest expense, net reflects interest incurred on the 2024 Note and 2025 Note, partially offset by interest earned on invested cash balances.

Cash Flows

	Six Months Ended June 30,	
	2026	**2025**
Net cash used in operating activities	$ (12,813)	$ (9,403)
Net cash used in investing activities	(128)	(6)
Net cash provided by financing activities	30,390	6,098
Net increase (decrease) in cash and cash equivalents	$ 17,449	$ (3,311)

Cash Flows from Operating Activities

Net cash used in operating activities was $12.8 million for the six months ended June 30, 2026. 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 $15.2 million, including the effects of significant noncash items, stock-based compensation expense of $1.0 million, change in fair value of derivative of $1.2 million, loss on debt extinguishment of $0.5 million, accretion of discount on note payable of $0.2 million and depreciation expense of $0.2 million. Changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of $0.7 million primarily due to payments for manufacturing materials and professional fees.

Net cash used in operating activities was $9.4 million for the six months ended June 30, 2025. 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 $8.8 million, including the effects of significant noncash items, stock-based compensation expense of $0.5 million and depreciation expense of $0.3 million. Changes in operating assets and liabilities included a decrease in trade accounts payable and accrued expenses of $0.9 million primarily due to the payment of vendor balances in the first quarter of 2025 and an increase in prepaid expenses and other current assets of $0.9 million primarily due to payments for professional and marketing fees.

Cash Flows from Investing Activities

Net cash used in investing activities for the six-month period ended June 30, 2026 was primarily related to the purchase of equipment to support our R&D activities.

Cash Flows from Financing Activities

Net cash provided by financing activities for the six-month period ended June 30, 2026 was related to the cash proceeds from the issuance of securities pursuant to the Private Placement, 2023 ATM Agreement, 2026 ATM Agreement and the 2025 LP Purchase Agreement.

Net cash provided by financing activities for the six-month period ended June 30, 2025 was related to the cash proceeds from the issuance of common stock pursuant to the 2023 ATM Agreement and the Original LP Purchase Agreement.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2026, we had cash and cash equivalents of $28.4 million. Under our current business plan, we believe our cash will satisfy our capital needs into mid 2027. 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.

Since our inception in 2012 through June 30, 2026, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations. We have funded our operations primarily through private and public equity and debt financings. In February 2026, we received gross proceeds of $12,011,000 from the Private Placement.

In the three months ended June 30, 2026, we sold 806,893 shares of common stock under the 2026 ATM Agreement, for net proceeds of $4,347,364, after deducting $136,364 of compensation to A.G.P. and other administration fees. Subsequent to June 30, 2026, we sold 271,717 shares of common stock under the 2026 ATM Agreement, for net proceeds of $1,394,179, after deducting $43,751 of compensation to A.G.P. and other administration fees.

During the three months ended June 30, 2026, we sold 1,032,372 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $5,058,975. Subsequent to June 30, 2026, we sold 220,476 shares of common stock under the 2025 LP Purchase Agreement, for net proceeds of $1,068,525.

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 seek marketing approval for CTx-1301 . Subsequent to potential marketing approval for CTx-1301, we will incur sales, marketing, operational and manufacturing expenses.

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

- whether we receive FDA approval for CTx-1301 and the timing of such approval;
- the cost and timing of the FDA review process for CTx-1301;
- 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 R&D, 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 2025 Note Purchase Agreement with Avondale, we are subject to certain restrictions on our ability to issue securities during the term of the 2025 Note. 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 2025 Note Purchase Agreement, we may be obligated to indemnify Avondale for loss or damage arising as a result of any breach or alleged breach by us of the 2025 Note Purchase Agreement, which may affect our business operations and financial condition. Additionally, the 2025 Note provides that following an event of default under the 2025 Note, Avondale has 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 2025 Note. Avondale also has 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 2025 Note, unless it contains a closing condition that the 2025 Note are paid in full upon consummation of the transaction or Avondale has provided its 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 June 30, 2026 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 final milestone payment of $250,000 will be due to BDD 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 Bend Bioscience, our CDMO, for CMC work to be completed relating to the resubmission of our NDA for CTx-1301 including the manufacturing of our verification batches with a total cost of approximately $1.6 million.

We entered into an agreement with Bend Bioscience, our CDMO, for the manufacture of process validation batches of CTx-1301 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 $1,223,587, the current portion of the operating lease liability was $255,132 and the long-term portion of the lease liability was $968,455 as of June 30, 2026.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and R&D 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 R&D. There can be no assurance that our R&D 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 June 30, 2026 and 2025 and had accumulated losses of $147.6 million since inception to June 30, 2026. 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 2023 ATM Agreement and 2026 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, the issuance of the 2024 Note, which was subsequently converted to equity, and 2025 Note and the Private Placement in February 2026. 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 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, which occurred in December 2021, 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 our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of June 30, 2026, has concluded that our disclosure controls and procedures were effective as of June 30, 2026.

Evaluation of Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2026 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.

Reference is made to Part I Item 1A. Risk Factors in our Annual Report on Form 10–K for the year ended December 31, 2025, which sets forth information relating to important risks and uncertainties that could materially adversely affect our business, financial condition or operating results. Except as set forth below, there have been no material changes to the risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2025.

We depend heavily on the success of CTx-1301. We received a Complete Response Letter from the FDA citing certain manufacturing deficiencies and other non-clinical issues, which may delay or prevent approval of CTx-1301.

Our most advanced product candidate currently is CTx-1301, for which we submitted a NDA with the FDA in July 2025. We do not currently generate revenues from any FDA approved drug products and our other product candidates are in the early stages of development. There is no guarantee that our clinical trials will be successful or that we will continue with clinical studies to support an approval from the FDA of any of our product candidates for any indication. We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends heavily on the successful development, regulatory approval and commercialization of CTx-1301, which may never occur. In June 2026, we received a Complete Response Letter ("CRL") for our New Drug Application ("NDA") for CTx-1301. The CRL identified specific Chemistry, Manufacturing and Controls (CMC) information requests. While the CRL did not raise any current concerns regarding the clinical safety or efficacy of CTx-1301, we are in the process of generating additional data as requested.

Moreover, we will rely in large part on Bend Bioscience, our contract development and manufacturing organization ("CDMO") to remediate the identified deficiencies.

If we or our CDMO cannot sufficiently address the issues set forth in the CRL, we may not be able to resubmit the NDA, or resubmission may not result in approval. If we do resubmit the NDA, the FDA may conduct a re-inspection of our CDMO, and there can be no assurance that the facility will be found compliant or that additional deficiencies will not be identified. As a result, approval of CTx-1301 may be significantly delayed, limited, or may not be obtained at all, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

Premarket review of our product candidates by the FDA or other regulatory authorities is a lengthy and uncertain process and approval may be delayed, limited or denied, any of which would adversely affect our ability to generate operating revenues.

We are not permitted to market our drug product candidates in the United States until we receive the respective approval of a NDA from the FDA. The time required to obtain approval, if any, by the FDA is unpredictable, but typically takes multiple years following the commencement of clinical trials, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Our most advanced product candidate currently is CTx-1301, for which we submitted a NDA with the FDA in July 2025. We received a CRL for our NDA for CTx-1301 in June 2026.

We plan to resubmit our NDA, however, the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of the resubmission. The FDA may also conduct a re-inspection of our CDMO, and there can be no assurance that the facility will be found compliant or that additional deficiencies will not be identified. For additional information, see "*—We depend heavily on the success of CTx-1301. We received a Complete Response Letter from the FDA citing certain manufacturing deficiencies, which may delay or prevent approval of CTx-1301*".

Our efforts (and those of our contract manufacturer) to develop, make and win approval for CTx-1301 continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of CTx-1301 and/or the third party facilities used to manufacture CTx-1301 could be further delayed or not obtained. There can be no assurance that a resubmission of the NDA of CTx-1301 will be approved or that such resubmission will occur at all, which would significantly harm our business, results of operations and prospects.

We must ensure our CDMO complies with cGMP, and regulatory inspections or findings could interrupt supply and delay development.

We must ensure that our CDMO complies with cGMP regulations. Manufacturing deviations, documentation errors, or quality system gaps at CDMOs can lead to Form 483 observations, warning letters, or import alerts, jeopardizing clinical supply continuity. Pre-approval inspections assess readiness for commercial production and can reveal issues that require significant remediation time and investment. In February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility and one observation was specific to CTx-1301. Our CDMO is working on responses to these observation, with our input where relevant. The FDA may also conduct a re-inspection of our CDMO if and when we resubmit our NDA for CTx-1301, and there can be no assurance that the facility will be found compliant or that additional deficiencies will not be identified. For additional information, see "*—We depend heavily on the success of CTx-1301. We received a Complete Response Letter from the FDA citing certain manufacturing deficiencies and other non-clinical issues, which may delay or prevent approval of CTx-1301.*" Our efforts continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of CTx-1301 and/or our CDMO's facility used to manufacture CTx-1301 could be further delayed or not obtained.

Moreover, changes to manufacturing processes or facilities can trigger comparability assessments or bridging studies, adding regulatory complexity. If our CDMO loses licensure or fails to meet cGMP standards, transitioning to an alternate CDMO may be lengthy and costly, potentially delaying development and commercialization. See "*—We rely on third-parties, many of whom are our single source for services, products and/or supplies, over whom we have limited control. Should the cost, delivery and/or quality of services, products or supplies provided by these third-parties vary to our disadvantage, our business operations could suffer significant harm*."

We rely on third-parties, many of whom are our single source for services, products and/or supplies, over whom we have limited control. Should the cost, delivery and/or quality of services, products or supplies provided by these third-parties vary to our disadvantage, our business operations could suffer significant harm.

We are a research and development company and have limited experience in commercial manufacturing. To conduct late-stage clinical trials, as well as manufacture and commercialize our drug candidates, we engage a CDMO and suppliers in the U.S. to manufacture our drug candidates on a large scale at a competitive cost and in accordance with cGMP and regulatory requirements, as applicable. We also rely on third parties for filling, labeling and storage for studies inside and outside the U.S.

Moreover, while we will try to obtain multiple sources whenever possible, similar to other clinical stage pharmaceutical companies, all stages of our manufacturing process are currently completed by a single CDMO, which could expose us to a number of risks related to our supply chain if and when we become a commercial stage company, including delivery failure and drug shortages. To date, we have no qualified alternative sources. Any manufacturing failures or compliance issues experienced by our CDMO could cause delays in our clinical studies or commercialization of our drug candidates.
In June 2026, we received a CRL for our NDA for CTx-1301. The CRL identified specific Chemistry, Manufacturing and Controls (CMC) information requests. We will need to rely in large part on our CDMO to remediate the identified deficiencies, and our ability to resolve these issues is subject to factors outside our control.

Remediation may require facility upgrades, quality system enhancements, equipment requalification, and additional validation studies or testing, any of which could be costly and time-consuming. If our CDMO is unable to adequately or timely remediate the identified deficiencies, we may need to transfer manufacturing operations to an alternative facility, which would involve significant time, expense and regulatory risk. . For example, in October 2022, we announced a new CDMO. The CTx-1301 fixed-dose study was delayed while the manufacturing process with the new CDMO was established to manufacture the final dosage strengths needed for the fixed-dose study. We also may be unable to identify or establish manufacturing at an adequate alternative facility.

In order for us to establish our own commercial manufacturing facility, we would require substantial additional funds and we would need to acquire a manufacturing facility, make facility modifications, hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to such a facility. The commercial manufacturing facility would also need to be licensed for the production of our drug candidates by the FDA and meet other regulatory standards. We therefore work with our CDMO under established manufacturing arrangements that comply with the FDA's requirements and other regulatory standards, although there is no assurance that the manufacturing will be successful.

Use of third-party manufacturing facilities limits our control over and ability to monitor the manufacturing process. As a result, we may not be able to detect a variety of problems that may arise and may face additional costs in the process of interfacing with and monitoring the progress of our CDMO. If our CDMO fails to meet our manufacturing needs in an acceptable manner or fail to comply with regulatory requirements, we would face delays and additional costs while we develop internal manufacturing capabilities or find alternate sources. It may not be possible to have multiple manufacturers ready to supply us with needed material at all or without incurring significant costs. Our dependence upon third-party manufacturing facilities for the manufacture of our products may adversely affect our profit margins and our ability to develop, manufacture, sell and deliver products on a timely and competitive basis. Any manufacturing failures, supply chain delays or compliance issues could cause delays in our clinical studies for our drug candidates, FDA approval of our product candidates, and, if approved, commercialization of our product candidates.

Prior to approval of CTx-1301 or any product candidate, the FDA must review and approve validation studies for both drug substance and drug product. In February 2026, the FDA conducted a pre-approval inspection of our CDMO's facility used to manufacture CTx-1301. This facility was issued a Form 483 by the FDA at the conclusion of the inspection with three observations. Two observations were related to the facility, and one observation was specific to CTx-1301. The FDA may also conduct a re-inspection of our CDMO if and when we resubmit our NDA for CTx-1301, and there can be no assurance that the facility will be found compliant or that additional deficiencies will not be identified. For additional information, see "*—We depend heavily on the success of CTx-1301. We received a Complete Response Letter from the FDA citing certain manufacturing deficiencies and other non-clinical issues, which may delay or prevent approval of CTx-1301*". Our efforts continue to be subject to inspection and approval by the FDA and other factors outside of our control, and there remains a risk that the required FDA approvals of CTx-1301 and/or our CDMO's facility used to manufacture CTx-1301 could be further delayed or not obtained.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our product candidates, and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

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

From May 11, 2026 through July 7, 2026, we issued the securities described below in transactions that were not registered under the Securities Act of 1933, as amended (Securities Act).

On May 11, 2026, we issued 38,343 shares of common stock at a value of $5.22 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 May 27, 2026, we issued 55,928 shares of common stock at a value of $4.47 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 May 28, 2026, we issued 53,030 shares of common stock at a value of $3.96 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 July 7, 2026, we issued 67,924 shares of common stock at a value of $5.30 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 August 10, 2026, we issued 71,827 shares of common stock at a value of $5.01 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 second quarter of 2026, no director or officer (as defined in Exchange Act Rule 16a-1(f)) of the Company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement for the purchase or sale of securities of the Company, within the meaning of Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Cingulate Inc., as amended to date	10-Q	3.1	8/13/2024
3.2	Amended and Restated Bylaws of Cingulate Inc.	10-K	3.2	3/28/2022
10.1	Amendment to Employment Agreement, effective June 30, 2026, between Cingulate Therapeutics, LLC and Matthew N. Brams	8-K	10.1	7/2/2026
10.2	Amendment No. 3 to the Cingulate Inc. 2021 Omnibus Equity Incentive Plan	8-K	10.1	7/14/2026
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101.INS*	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

* Filed herewith

** Furnished herewith

+ 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: August 13, 2026

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

Date: August 13, 2026

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

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shane J. Schaffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended June 30, 2026 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: August 13, 2026

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

Exhibit 31.2

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 June 30, 2026 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: August 13, 2026

/s/ Jennifer L. Callahan
Jennifer L. Callahan
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended June 30, 2026 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

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

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

Dated: August 13, 2026

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

Exhibit 32.2

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended June 30, 2026 (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: August 13, 2026

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