Filed Pursuant to Rule 424(b)(3)
Registration No. 333-259408

Prospectus Supplement No. 3 Dated November 14, 2022
(To Prospectus Dated April 19, 2022)

Cingulate Inc.

4,791,665 Shares of Common Stock Issuable Upon Exercise of Previously Issued Warrants

This Prospectus Supplement No. 3 supplements the prospectus of Cingulate Inc. (the "**Company**", "**we**", "**us**", or "**our**") dated April 19, 2022 (as supplemented to date, the "**Prospectus**") with the following attached document which we filed with the Securities and Exchange Commission:

A. Our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2022.

This Prospectus Supplement No. 3 should be read in conjunction with the Prospectus, which is required to be delivered with this Prospectus Supplement. This prospectus supplement updates, amends and supplements the information included in the Prospectus. If there is any inconsistency between the information in the Prospectus and this prospectus supplement, you should rely on the information in this Prospectus Supplement.

This Prospectus Supplement is not complete without, and may not be delivered or utilized except in connection with, the Prospectus, including any amendments or supplements to it.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should carefully consider the risk factors for our common stock, which are described in the Prospectus, as amended or supplemented.

You should rely only on the information contained in the Prospectus, as supplemented or amended by this Prospectus Supplement No. 3 and any other prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement No. 3 is November 14, 2022

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	Annex
The Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2022	A

ANNEX A

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2022

or

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

For the transition period from_____ to_____.

Commission File Number: 001-40874

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 3, 2022, 11,309,412 shares of the registrant's common stock, $0.0001 par value, were issued and outstanding.

Cingulate Inc.
Form 10-Q for the Quarter Ended September 30, 2022

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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. These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. These forward-looking statements speak only as of the date of filing this report with the SEC and include, without limitation, statements about the following:

- our lack of operating history and need for additional capital;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for CTx-1301, CTx-1302, and CTx-2103;
- the timing of our New Drug Application (NDA) submissions for CTx-1301, CTx-1302, and CTx-2103;
- the timing of and our ability to obtain and maintain regulatory approvals for CTx-1301, CTx-1302, CTx-2103, or any other future product candidate;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expected use of cash;
- our competitive position and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue and expenses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 28, 2022, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements.

Cingulate Inc.
Consolidated Balance Sheets (unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,795,570	$ 16,492,745
Short-term investments	-	933
Miscellaneous receivables	47,349	690,248
Prepaid expenses and other current assets	1,991,493	1,698,353
Total current assets	11,834,412	18,882,279
Property and equipment, net	2,851,491	3,145,378
Operating lease right-of-use assets	690,772	858,600
Total assets	**15,376,675**	**22,886,257**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	392,798	264,687
Accrued expenses	670,651	601,300
Current installments of obligations under finance leases	15,810	15,096
Note payable	5,000,000	-
Other current liabilities	326,742	295,595
Total current liabilities	6,406,001	1,176,678
Long-term liabilities:		
Obligations under finance leases	25,591	37,534
Operating lease liabilities	578,551	828,503
Total long-term liabilities	604,142	866,037
Total liabilities	**7,010,143**	**2,042,715**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 11,309,412 shares issued and outstanding as of September 30, 2022 and December 31, 2021	1,131	1,131
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of September 30, 2022 and December 31, 2021	-	-
Additional Paid-in-Capital	73,168,870	72,574,510
Accumulated other comprehensive income	-	165
Accumulated deficit	(64,803,469)	(51,732,264)
Total stockholders' equity	**8,366,532**	**20,843,542**
Total liabilities and stockholders' equity	**$ 15,376,675**	**$ 22,886,257**

See notes to consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 2,123,114	$ 5,791,407	$ 7,063,626	$ 7,147,513
General and administrative	1,845,248	9,488,082	5,963,067	10,884,759
Operating loss	**(3,968,362)**	**(15,279,489)**	**(13,026,693)**	**(18,032,272)**
Interest and other income (expense), net	(58,885)	(10,559)	(44,512)	(23,994)
Loss before income taxes	(4,027,247)	(15,290,048)	(13,071,205)	(18,056,266)
Income tax benefit (expense)	-	-	-	-
Net loss	(4,027,247)	(15,290,048)	(13,071,205)	(18,056,266)
Other comprehensive income (loss):				
Change in unrealized gain (loss) loss on short-term investments	3,249	-	(166)	-
Comprehensive loss	**$ (4,023,998)**	**$ (15,290,048)**	**$ (13,071,371)**	**$ (18,056,266)**
Net loss per share of common stock, basic and diluted	$ (0.36)	-	$ (1.16)	-
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	11,309,412	-	11,309,412	-

See notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in-	Members'	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Capital	Capital	Deficit	Income	Equity
Balance January 1, 2021	**-**	**$ -**	**$ -**	**$ 32,314,441**	**$ (31,022,336)**	**$ 165**	**$ 1,292,270**
Member contributions			-	1,385,688			1,385,688
Net loss	-	-	-	-	(1,333,923)	-	(1,333,923)
Balance March 31, 2021	-	**$ -**	**$ -**	**$ 33,700,129**	**$ (32,356,259)**	**$ 165**	**$ 1,344,035**
Activity for the three months to June 30, 2021:							
Member contributions	-	-	-	1,987,640	-	-	1,987,640
Net loss	-	-	-	-	(1,432,295)	-	(1,432,295)
Balance June 30, 2021	-	**$ -**	**$ -**	**$ 35,687,769**	**$ (33,788,554)**	**$ 165**	**$ 1,899,380**
Activity for the three months to September 30, 2021:							
Member contributions	-	-	-	3,731,731	-	-	3,731,731
Conversion of LLC units to common stock in connection with Reorganization Merger	**11,115,780**	**1,112**	39,418,388	(39,419,500)	-	-	-
Modification of profits interests units in connection with Reorganization Merger	-	-	12,738,088	-	-	-	12,738,088
Net loss	-	-	-	-	(15,290,048)	-	(15,290,048)
Balance September 30, 2021	**11,115,780**	**$ 1,112**	**$52,156,476**	**$ -**	**$ (49,078,602)**	**$ 165**	**$ 3,079,151**
Balance January 1, 2022	**11,309,412**	**1,131**	**$72,574,510**	-	**$ (51,732,264)**	**$ 165**	**$ 20,843,542**
Activity for the three months to March 31, 2022:							
Unrealized losses on available for sale investments	-	-	-	-	-	(2,948)	(2,948)
Stock-based compensation expense	-	-	181,518	-	-	-	181,518
Net loss	-	-	-	-	(5,003,511)	-	(5,003,511)
Balance March 31, 2022	**11,309,412**	**$ 1,131**	**$72,756,028**	**$ -**	**$ (56,735,775)**	**$ (2,783)**	**$ 16,018,601**
Activity for the three months to June 30, 2022:							
Unrealized losses on available for sale investments	-	-	-	-	-	(466)	(466)
Stock-based compensation expense	-	-	207,186	-	-	-	207,186
Net loss	-	-	-	-	(4,040,447)	-	(4,040,447)
Balance June 30, 2022	**11,309,412**	**$ 1,131**	**$72,963,214**	**$ -**	**$ (60,776,222)**	**$ (3,249)**	**$ 12,184,874**
Activity for the three months to September 30, 2022:							
Unrealized losses on available for sale investments	-	-	-	-	-	3,249	3,249
Stock-based compensation expense	-	-	205,656	-	-	-	205,656
Net loss	-	-	-	-	(4,027,247)	-	(4,027,247)
Balance September 30, 2022	**11,309,412**	**$ 1,131**	**$73,168,870**	**$ -**	**$ (64,803,469)**	**$ -**	**$ 8,366,532**

See notes to consolidated financial statements

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Nine Months Ended September 30, 2022	2021
Operating activities:		
Net loss	$ (13,071,205)	$ (18,056,266)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	304,287	528,809
Noncash compensation expense relating to modification of profits interest units	-	12,738,088
Stock-based compensation	594,360	-
Changes in operating assets and liabilities:		
Miscellaneous receivables	642,899	(205,290)
Prepaid expenses and other current assets	(293,140)	(2,844,046)
Operating lease right-of-use assets	167,828	48,226
Trade accounts payable and accrued expenses	197,462	2,078,643
Other current liabilities	31,147	87,962
Operating lease liabilities	(249,952)	(186,135)
Net cash used in operating activities	(11,676,314)	(5,810,009)
Investing activities:		
Purchase of property and equipment	(10,400)	(104,729)
Proceeds from sale of short-term investments	933	-
Other	(165)	-
Net cash used in investing activities	**(9,632)**	**(104,729)**
Financing Activities:		
Members' capital contributions	-	7,104,959
Payments on notes payable	-	(150,000)
Proceeds from note payable	5,000,000	-
Principal payments on finance lease obligations	(11,229)	(322,478)
Net cash provided by financing activities	**4,988,771**	**6,632,481**
Cash and cash equivalents:		
Net decrease in cash and cash equivalents	(6,697,175)	717,743
Cash and cash equivalents at beginning of year	16,492,745	1,197,672
Cash and cash equivalents at end of year	**$ 9,795,570**	**$ 1,915,415**
Cash payments:		
Interest paid	$ 10,291	$ 8,090

See notes to consolidated financial statements

(1) Nature of the Business and Liquidity

Organization

Cingulate Inc. is a biopharmaceutical company focused on the development of products utilizing its drug delivery platform technology that enables the formulation and manufacture of once-daily tablets of multi-dose therapies, with an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). The Company is developing two proprietary, first-line stimulant medications, CTx-1301 (dexmethylphenidate) and CTx-1302 (dextroamphetamine), for the treatment of ADHD intended for all patient segments: children, adolescents, and adults. CTx-1301 and CTx-1302 utilize a flexible core tableting technology with target product profile designed to deliver a rapid onset and last the entire active day with a controlled descent of plasma drug level and have favorable tolerability. The Company is preparing to start a Phase 3 clinical trial for CTx-1301 in late 2022. In addition, the Company has a third product to treat anxiety, CTx-2103, in a formulation stage.

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

CTx is the predecessor of Cingulate for financial reporting purposes. The consolidated financial statements and notes for the periods ended September 30, 2022 and the year ended December 31, 2021 represent the full consolidation of Cingulate and its subsidiaries, including CTx and all references to the Company represent this full consolidation. For periods prior to the year ended December 31, 2021, the consolidated financial statements and notes represent the full consolidation of CTx and its subsidiaries.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception. As a pre-revenue entity, the Company is dependent on the ability to raise capital to support operations until such time as the product candidates under development are U.S Food and Drug Administration (FDA) approved, manufactured, commercially available to the marketplace and produce revenues. The IPO, which was completed in December 2021, provided the Company the ability to continue its research and development activities. In addition, the Company received proceeds of $5.0 million from a promissory note as further described in Note 7. However, the Company will need additional funding for operations and development. Management is evaluating various strategies to obtain additional funding which may include additional offerings of common stock, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions. Successful implementation of these plans involves both the Company's efforts and factors that are outside its control, such as market factors and FDA approval of product candidates. The Company can give no assurance that its plans will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above, which results in substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation and Principles of Consolidation

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

(b) Unaudited Interim Financial Information

The accompanying consolidated balance sheet as of September 30, 2022, the consolidated statements of operations and comprehensive loss for the three and nine-month periods ended September 30, 2022 and 2021, the consolidated statements of stockholders' equity for the three and nine-month periods ended September 30, 2022 and 2021, the consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021, and the related interim disclosures are unaudited. These unaudited consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto.

(c) Concentration of Credit Risk

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

(d) Miscellaneous Receivables

Miscellaneous receivables consist of payroll tax credits generated from the Company's 2020 and 2019 federal income tax returns, which have not yet been received as of September 30, 2022, as well as employee retention tax credits for payroll costs incurred in 2020 and the first three quarters of 2021. As of September 30, 2022, and December 31, 2021, the Company determined that there was no allowance necessary relating to these receivables.

(e) Impairment of Long-lived Assets

The Company assesses the carrying value of its long-lived assets, including property and equipment, as well as lease right of use (ROU) assets, when events or circumstances indicate that the carrying value of such assets may not be recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, the Company evaluates recoverability by a comparison of the carrying amount of the assets to future undiscounted cash flows expected to be generated by the assets. If the sum of the expected future cash flows is less than the carrying amount, the Company would recognize an impairment loss. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value of the long-lived asset groups. No impairment was recognized during the three or nine-month periods ended September 30, 2022, or 2021.

(f) Stock-Based Compensation

The Company measures employee and director stock-based compensation expense for all stock-based awards based on their grant date fair value using the Black-Scholes option-pricing model. For stock-based awards with service conditions, stock-based compensation expense is recognized over the requisite service period using the straight-line method. Forfeitures are recognized as they occur. See additional information in Note 11.

(3) Prepaid Expenses

Prepaid expenses consisted of the following at September 30, 2022, and December 31, 2021:

	September 30, 2022	December 31, 2021
Insurance	$ 537,678	$ 761,594
Active pharmaceutical ingredients	209,155	264,361
Research and development	1,008,502	643,917
Legal fees	128,385	-
Other	107,773	28,481
	$ 1,991,493	$ 1,698,353

(4) Property and Equipment

Property and equipment, net consists of the following at September 30, 2022, and December 31, 2021:

	Estimated Useful Life (in years)	September 30, 2022	December 31, 2021
Equipment	2-7	$ 2,509,126	$ 2,509,126
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	41,898	41,898
Leasehold improvements	5	471,505	471,505
Construction-in-process- equipment	-	1,653,550	1,643,150
		4,821,833	4,811,433
Less: accumulated depreciation		(1,970,342)	(1,666,055)
		$ 2,851,491	$ 3,145,378

Depreciation expense for the nine months ended September 30, 2022, was $304,287 and for the nine months ended September 30, 2021, was $528,809. Depreciation expense for the three months ended September 30, 2022, was $101,429 and for the three months ended September 30, 2021, was $77,797.

(5) Accrued Expenses

Accrued expenses consisted of the following at September 30, 2022, and December 31, 2021:

	September 30, 2022	December 31, 2021
Research and development	$ 250,000	$ 250,000
Legal and other	315,812	71,570
CIP- Equipment	-	279,730
Interest	104,839	-
	$ 670,651	$ 601,300

(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 accrues for matters that are 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, the Company accrues 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 recognized 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.

As of September 30, 2022, the Company has recorded an accrual for a loss contingency related to an employment matter, which represents the low end of the Company's estimated range of loss.

(7) Related Party Note Payable

On August 10, 2022, the Company received $5,000,000 of debt financing from Werth Family Investment Associates LLC (WFIA). Peter Werth, manager of WFIA, is a member of the Company's Board of Directors. This promissory note is unsecured with interest accruing at 15% per annum. Outstanding principal and all accrued and unpaid interest are due and payable on August 8, 2025, or 120 days following written demand made by WFIA during the first five business days of a calendar quarter beginning April 1, 2023. The Company may prepay the note, in whole or in part, without premium or penalty; provided, that no amount repaid may be reborrowed. As of September 30, 2022, the entire $5,000,000 was outstanding on the note.

During the three months ended September 30, 2022, the Company recognized $104,839 of interest expense relating to this note. This interest expense is included in accrued expenses on the consolidated balance sheet at September 30, 2022.

(8) Members' Capital

Prior to the Reorganization Merger, the Company had multiple classes of Members' capital, comprised of Founders Units, Class B, D, E, F and G Preferred Units, and Class C Profits Interests. Class B, E, F and G Preferred Units had similar rights specifically related to cash distributions as a return of invested capital. Class D Preferred Units had all the rights of Founders and the other Classes of Preferred Units plus some additional rights noted below. All classes of Members' capital had voting rights. The Company maintained capital accounts for each Member. 3,243,201 Units of Class F and Class G were issued during the year ended December 31, 2021, prior to the Reorganization Merger. 614,137 Units of Class F and Class G were issued during the three months ended March 31, 2021, 948,804 units were issued during the three months ended June 30, 2021, and 1,680,260 units were issued during the three months ended September 30, 2021.

Class F Preferred Units

The CTx Board authorized 6,984,985 Class F Preferred Units in two tranches; all authorized Class F Units were issued prior to the Reorganization Merger. The Company raised a total of $11.3 million from issuance of Class F Units. The newly created Class F Units as authorized by the CTx Board and as reflected in the 3rd Amended and Restated Operating Agreement to reflect the creation of the Class F Units became effective on December 14, 2018.

Class G Preferred Units

The CTx Board authorized 12,000,000 Class G Preferred Units; 2,998,184 were issued prior to the Reorganization Merger. The Company raised a total of $6.7 million from issuance of Class G Units. The newly created Class G Units as authorized by the CTx Board became effective on February 9, 2021.

Distributions, if any, from the Company were to be made first to the holders of Class B, D, E, F and G Preferred Units, pro rata in proportion to each such Member's unreturned capital contributions. Distributions were then to be made to all Members including Founders Units, pro rata in proportion to the number of units held by each Member, with consideration given to the applicable distribution thresholds for Class C Profits Interests at which each was issued and as disclosed in each Profits Interest Unit agreement, as further described in Note 9.

Costs associated with issuance of the Units is immaterial. Pursuant to the terms of the Reorganization Merger, all Units were converted into shares of common stock of Cingulate, as further described in Note 1.

(9) Profits Interest Plan

During 2017, the CTx Board established and adopted the Cingulate Therapeutics LLC Equity Incentive Plan (the "Plan") to provide for issuance of Class C PIU's to employees, CTx Members, Board members and service providers of the Company, as defined in the Plan, eligible to receive PIU's as an incentive under the Plan. PIU's were granted at the discretion of the Board of Managers of the Company and in some cases at the discretion of the Chief Executive Officer of the Company based upon Board authorization. The PIU's were issued at a Distribution Threshold equal to the pre-money fair market valuation of the Company at the date of issuance. The Distribution Threshold was the amount by which a cash distribution, made pro rata to all Members, if any, must have been exceeded in order for a particular PIU holder to participate in the allocated distribution beyond that threshold. Based on the terms of the award, the Distribution Threshold was treated as a performance condition for purposes of financial statement recognition. The PIU's vesting period with respect to the service condition was defined in the PIU award agreement and ranged from 30 days to three years with an average vesting period for all PIU's granted of 107 days. As defined in the Company's Operating Agreement, all PIU's issued under the Plan entitled the holder to participate pro rata in the profits, if any, of the Company over the stated Distribution Threshold, assuming a cash distribution was generally made to all Members, subject to any preference or priorities of the other classes of Units. The Class C PIU's also held voting rights on a one-for-one basis.

Immediately prior to the Reorganization Merger and as of December 31, 2020, the Company had granted and issued 8,500,000 and 8,142,461 PIU's, net of forfeitures, respectively. In April 2021, the Company issued the remaining 357,539 PIU's. The Company accounted for these awards under FASB ASC Topic 718, *Compensation – Stock Compensation*, as equity classified awards. No compensation expense was recorded prior to the Reorganization Merger related to the PIU's as the future achievement of the thresholds and targets (the performance condition) to achieve payout was not deemed probable. This assessment was made based on the Company's history of operating losses and continued challenges in raising necessary equity capital to fund operations. In connection with the Reorganization Merger, 8.5 million PIU's were exchanged for 1,158,008 shares of Cingulate common stock. The exchange of PIU's for common stock created a modification of the terms, character and rights of the PIU's and achievement of performance was considered probable. This resulted in the Company recognizing a noncash modification charge equal to $12.7 million, which charge was calculated based on the Company's assessment of the fair value of the shares of Cingulate common stock on the date of the modification. $8.2 million of this charge was recorded to general and administrative expense and $4.5 million was recorded to research and development expense.

Prior to the Reorganization Merger, the Company had issued all units available under the Plan and all units had vested based upon the vesting period as outlined in the PIU agreement.

PIUs issued and outstanding prior to the Reorganization Merger, which was also the modification date, at the various distribution thresholds were as follows:

	Distribution Threshold $ (in millions):							
Year Granted	**$25**	**$40**	**$75**	**$80**	**$90**	**$120**	**$160**	**Total**
2017	4,753,000	125,200	-	-	-	-	-	4,878,200
2018	-	661,525	217,725	22,883	-	-	-	902,133
2019	-	-	-	-	377,524	458,924	-	836,448
2020	-	-	-	1,476,126	-	49,554	-	1,525,680
2021	-	-	-	-	-	-	357,539	357,539
Total	4,753,000	786,725	217,725	1,499,009	377,524	508,478	357,539	8,500,000

(10) Stockholders' Equity

The Company has authorized 240,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock at September 30, 2022, and December 31, 2021, of which 11,309,412 shares of common stock were issued and outstanding. The Company has not issued any shares of preferred stock.

7,142,746 shares of common stock issued and outstanding were issued in connection with the Reorganization Merger to convert Units of CTx outstanding immediately prior to the Reorganization Merger.

4,166,666 shares of common stock were issued at a price to the public of $6.00 per share in connection with the Company's IPO, which was completed in December 2021. The Company received net proceeds of approximately $20.4 million, after deducting underwriting discounts and commissions and other offering expenses.

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

(11) Stock-Based Compensation

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

The maximum number of shares of common stock available for issuance in connection with options and other awards granted under the 2021 Plan is 1,927,810 and as of September 30, 2022, 1,046,698 shares of common stock were available for issuance under the 2021 Plan. The number of shares of common stock available for issuance under the 2021 Plan will automatically increase on January 1st of each year until the expiration of the 2021 Plan, in an amount equal to 5% percent of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, on a fully diluted basis, unless the Board of Directors takes action prior thereto to provide that there will not be an increase in the share reserve for such year or that the increase in the share reserve for such year will be of a lesser number of shares of common stock than would otherwise occur. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, repurchased or are otherwise terminated by the Company under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan.

The Company recorded stock-based compensation expense of $594,360 during the nine months ended September 30, 2022, and $205,656 during the three months ended September 30, 2022, relating to options issued in 2021 and 2022. As of September 30, 2022, and December 31, 2021, there was $2,492,032 and $2,637,895 of unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the 2021 Plan, which is expected to be recognized over the next one to four years.

A summary of option activity under the Plan during the three and nine months ended September 30, 2022, is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2021	523,285	$ 6.00	9.94	
Grants	342,999	$ 1.82	9.91	
Exercised	—			
Forfeitures or expirations	—			
Outstanding at March 31, 2022	866,284	$ 4.35	9.78	$ 182,900
Grants	17,517	$ 1.46	7.78	
Exercised	—			
Forfeitures or expirations	—			
Outstanding at June 30, 2022	883,801	$ 4.29	9.49	$ 24,800
Grants	27,032	$ 1.29	9.95	
Exercised	—			
Forfeitures or expirations	(29,721)	$ 3.82		
Outstanding at September 30, 2022	881,112	$ 4.21	9.26	$ -
Options exercisable as of September 30, 2022	26,049			
Options unvested as of September 30, 2022	855,063			

The Company's stock options issued qualify for equity accounting treatment under ASC 718 and are measured at fair value as of their grant date accordingly. The fair value of the options were estimated using a Black-Scholes model. The assumptions that the Company used to estimate the grant-date fair value of stock options granted to employees during the nine-month period ending September 30, 2022, were as follows, shown on a weighted average basis:

Risk-free interest rate	1.71%
Weighted-average expected term (in years)	6.02
Expected volatility	1.12
Expected dividend yield	0%

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

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

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

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

The grant-date fair value of options granted during the year ended December 31, 2021 was $5.09 and the grant date fair value of the options issued during the three months ended March 31, 2022 ranged from $1.12 to $1.16. The grant date fair value of the options issued during the three months ended June 30, 2022 ranged from $1.04 to $1.34. The grant date fair value of the options issued during the three months ended September 30, 2022 ranged from $1.07 to $1.57.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock. The fair value per share of common stock was $1.07 as of September 30, 2022, based upon the closing price of our common stock on the Nasdaq Capital Market.

(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 as of September 30, 2022, for federal or state income taxes.

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

	Nine Months Ended September 30, 2022	Three Months Ended September 30, 2022
Federal income tax benefit at statutory rate	$ (2,733,779)	$ (845,722)
State income tax benefit	(719,896)	(222,707)
Permanent differences	11,920	3,157
Change in valuation allowance	3,685,697	1,246,403
Research and development tax credit adjustment	(131,681)	(131,681)
Other	(112,261)	(49,450)
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 $4,532,968 as of September 30, 2022 and $847,269 at December 31, 2021, which was recorded as a component of income tax expense on the accompanying consolidated statements of operations and other comprehensive loss.

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

The Company follows the provisions of FASB ASC 740, *Income Taxes*, to evaluate uncertain tax positions. This topic prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company has not identified any material uncertain tax positions requiring recognition in the consolidated financial statements as of September 30, 2022.

	September 30, 2022	December 31, 2021
Deferred income tax assets:		
Current:		
Contingent liability	$ 71,550	$ -
Other	-	4,050
Non-current:		
Net operating losses	2,616,726	1,201,974
Research and development costs	1,694,249	-
Unvested stock options	172,313	11,835
Research and development tax credits	131,681	-
Patents	104,726	90,480
Other	69,010	49,606
Gross deferred income tax assets	4,860,255	1,357,945
Less: valuation allowance	(4,532,968)	(847,269)
Net deferred income tax asset	327,287	510,676
Deferred income tax liabilities:		
Current:		
Accrual to cash	(3,843)	(105,075)
Non-current		
Property and equipment	(323,444)	(405,601)
Gross deferred income tax liabilities	(327,287)	(510,676)
Net deferred tax asset (liability)	$ -	$ -

(13) Net Loss Per Share

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

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
Numerator:		
Net loss	$ (4,027,247)	$ (13,071,205)
Denominator:		
Weighted average common shares outstanding	11,309,412	11,309,412
Net loss per share, basic and diluted	$ (0.36)	$ (1.16)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows as of September 30, 2022:

Stock options issued under the 2021 Equity Incentive Plan	881,112
Common stock purchase warrants outstanding	4,999,998
Total	5,881,110

(14) License Agreement

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

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

The Company has accrued the $250,000 milestone for CTx-1301 related to dosing of first patient in a Phase 3 Clinical Trial as management has deemed this milestone to be probable. The Company has not recorded any expense relating to the other milestones for any product as it has not deemed them probable of occurring as of September 30, 2022.

(15) Related Party Transactions

The general counsel of the Company is a partner with a law firm providing office facilities space that is leased by the Company. Rental expense incurred by the Company to the law firm was $27,000 for both the nine months ended September 30, 2022, and 2021 and $9,000 for both the three months ended September 30, 2022, and 2021, which approximates fair value. As of September 30, 2022, and December 31, 2021, the Company had no outstanding amounts payable under this lease.

A member of the Company’s Board of Directors, Peter Werth, is the manager of WFIA, the entity which provided $5.0 million in debt financing to the Company as described in Note 7. Interest expense of $104,839 was recognized during the three months ended September 30, 2022 related to this debt financing. The full principal balance of $5.0 million and accrued interest of $104,839 was outstanding as of September 30, 2022.

(16) Subsequent Events

Management evaluated events that occurred subsequent to September 30, 2022, through November 14, 2022, which is the date the interim financial statements were issued.

On October 24, 2022, the Company entered into a Master Services Agreement (the Agreement) with Societal CDMO, Inc. (Societal) for manufacturing services as specified by the Company at Societal’s Gainsville, Georgia manufacturing facility. The Agreement has an initial term that expires on October 24, 2027 and will automatically renew thereafter for successive 12-month periods unless terminated by either party under as specified in the Agreement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021 ("Form 10-K") for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company using our proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. We are initially focusing our efforts on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD). Our PTR platform incorporates a proprietary Erosion Barrier Layer (EBL) designed to allow for the release of drug substance at specific, pre-defined time intervals, unlocking the potential for once-daily, multi-dose tablets. We believe there remains a significant, unmet need within the current treatment paradigm for true once-daily ADHD stimulant medications with lasting duration and a superior side effect profile to better serve the needs of patients throughout their entire active-day.

Since inception in 2012, our operations have focused on developing our product candidates, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations through public and private capital raised. Cumulative capital raised from these sources, including debt financing, was approximately $68.8 million as of September 30, 2022.

We have incurred significant losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $4.0 million and $15.3 million for the three months ended September 30, 2022 and September 30, 2021, respectively and $13.1 million and $18.0 million for the nine months ended September 30, 2022 and September 30, 2021, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of September 30, 2022, we had an accumulated deficit of $64.8 million.

We expect to continue to incur significant expenses and increasing operating losses in the near term. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- seek regulatory approval for CTx-1301;
- continue research and development activities for our existing and new product candidates, primarily for CTx-1301;
- manufacture supplies for our preclinical studies and clinical trials, primarily for CTx-1301;
- operate as a public company; and
- establish or outsource commercial infrastructure to support sales and marketing for our product candidates.

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

Clinical and Business Update

We executed a master services agreement (MSA) with Societal CDMO, Inc. (Societal), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development. Societal will manufacture all clinical, registration, and commercial batches of our lead ADHD candidate, CTx-1301. Societal will dedicate a specific manufacturing suite within its Gainsville, GA facility and outfit it with proprietary equipment owned by us.

***CTx-1301*:** We have designed our clinical program for CTx-1301 (dexmethylphenidate), our lead investigational asset for the treatment of ADHD, based on U.S. Food and Drug Administration (FDA) feedback regarding our CTx-1301 initial Pediatric Study Plan (iPSP), and longstanding guidance on the expedited approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

We are preparing to initiate a Phase 3 adult dose-optimization study in December 2022 for CTx-1301, to assess onset and duration of efficacy and safety in adults with ADHD.

In addition, the CTx-1301 Phase 3 fixed-dose pediatric and adolescent safety and efficacy study is now expected to commence in mid-2023 after the final two dosage strengths for this study are completed by our new manufacturing partner, Societal. Results from the fixed-dose study are expected in late 2023.

In order to meet the pharmacology requirement for the CTx-1301 New Drug Application (NDA) submission, we initiated a food effect study in September 2022 which was completed in October of 2022, with results expected to be available in December 2022.

Assuming we receive positive clinical results from our Phase 3 trials and the food effect study, we plan to submit the NDA for CTx-1301 in the first half of 2024 under the Section 505(b)(2) pathway.

***CTx-2103*:** We have embarked on a program to develop CTx-2103 (buspirone) for the treatment of anxiety, which is the most common mental health concern in the U.S. We completed a formulation study in which the pharmacokinetics were evaluated for this trimodal tablet providing (3) precisely timed doses of buspirone versus one immediate release dose. In addition, scintigraphic imaging visualized transit of the tablets through the gastrointestinal tract to confirm both the site and onset of release, which will then be correlated with pharmacokinetic data to establish the full release profile of the CTx-2103 formulation. Based on the dissolution profile seen in the data, the CTx-2103 30 mg tablet achieved the solubility required to deliver a triple release of buspirone hydrochloride. The tablet was also able to deliver the intended doses at three time points. These results provide critical information as we move forward to designing our clinical program for anxiety.

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

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

Debt Financing

We received $5.0 million of debt financing (the “WFIA Debt Financing”) from Werth Family Investment Associates LLC (“WFIA”). The promissory note, dated August 9, 2022, in favor of WFIA is unsecured with interest accruing at 15% per annum. Outstanding principal and all accrued and unpaid interest is due and payable on August 8, 2025 unless accelerated due to an event of default. Beginning April 1, 2023, WFIA has the right during the first five business days of each calendar quarter to demand payment of all outstanding principal and interest 120 days following notice to us. We may prepay the note, in whole or in part, without premium or penalty; provided, that no amount repaid may be reborrowed. See “Liquidity and Capital Resources” below. As of September 30, 2022, the principal balance of $5.0 million and accrued interest of $0.1 million was outstanding.

WFIA owns 946,231 shares of our common stock and Peter J. Werth, a member of the Company’s Board of Directors and the manager of WFIA, owns 21,849 shares of our common stock. Our Audit Committee and Board of Directors reviewed the terms of the WFIA Debt Financing pursuant to our Policy and Procedures for Related Person Transactions and determined that the WFIA Debt Financing is in our best interest and the best interests of our stockholders. Due to the WFIA Debt Financing, our Board of Directors determined that Mr. Werth is no longer an independent director.

As of September 30, 2022, we had cash and cash equivalents of $9.8 million. Based on our operating plan, we believe that our cash and cash equivalents will enable us to fund our research and development and general and administrative expenses through the first quarter of 2023. In addition, in order to achieve the filing of our NDA for CTx-1301 in the first half of 2024 for potential FDA approval, we believe that we will need approximately $23.5 million of additional capital. We will also need additional capital to advance our other programs and commercialization efforts. See “Liquidity and Capital Resources” below.

Components of Operating Results

Revenue

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

Operating Expenses

Research and Development Expenses

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

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

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

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

General and Administrative Expenses

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

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

Interest and other income (expense), net

Interest and other income (expense), net consists of interest earned on our short-term investments and interest expense. The primary objective of our investment policy is liquidity and capital preservation.

Interest expense to date has consisted primarily of interest expense on notes payable to related parties. In addition, there has been interest charged by certain vendors, financing charge on insurance premiums and credit card interest.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we have identified several accounting policies that are critical to the judgements and estimates used in the preparation of our consolidated financial statements. These policies relate to research and development costs and stock-based compensation. A discussion of these policies can be found in the "Critical Accounting Policies and Significant Judgments and Estimates" section of our Form 10-K.

There have been no changes in our application of critical accounting policies since December 31, 2021.

Results of Operations

Comparison of the three months ended September 30, 2022 and September 30, 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and September 30, 2021:

(in thousands)	Three Months ended September 30, 2022	Three Months ended September 30, 2021	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 2,123	$ 5,791	$ (3,668)	(63.3%)
General and administrative	1,845	9,488	(7,643)	(80.6%)
Loss from operations	(3,968)	(15,279)	(11,311)	74.0%
Interest and other income (expense), net	(59)	(11)	48	436.4%
Net Loss	$ (4,027)	$ (15,290)	$ (11,263)	73.7%

Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended September 30, 2022 and September 30, 2021:

(in thousands)	Three Months ended September 30, 2022	Three Months ended September 30, 2021	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 581	$ 182	$ 399	**NM**
Drug manufacturing and formulation	673	671	2	0.3%
Personnel expenses	860	4,934	(4,074)	(82.6%)
Regulatory costs	9	4	5	125.0%
Total research and development expenses	$ 2,123	$ 5,791	$ (3,668)	(63.3%)

R&D expenses were $2.1 million for the three months ended September 30, 2022, a decrease of $3.7 million or 63.3% from the three months ended September 30, 2021. This was primarily related to the decrease in personnel expenses due to the recording of $4.6 million to R&D expense for a one-time noncash compensation charge for the modification of PIUs which occurred in the third quarter of 2021, partially offset by an increase in personnel expenses in 2022 resulting from added clinical and manufacturing personnel in late 2021 in anticipation of increased development activity as well as stock-based compensation incurred in 2022. In addition, there was an increase in clinical operations expense of $0.4 million. Clinical activity increased in the third quarter of 2022 as the Company was conducting the food effect study for CTx-1301 and incurred approximately $0.3 million in costs relating to this study.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended September 30, 2022 and September 30, 2021:

(in thousands)	Three Months ended September 30, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 595	$ 8,532	$ (7,937)	(93.0%)
Legal and professional fees	373	734	(361)	(49.2%)
Occupancy	109	109	-	-
Insurance	669	45	624	**NM**
Other	99	68	31	45.6%
Total general and administrative expenses	$ 1,845	$ 9,488	$ (7,643)	(80.6%)

Total G&A expenses were $1.8 million for the three months ended September 30, 2022, a decrease of $7.6 million or 80.6% from the three months ended September 30, 2021. This was primarily related to a decrease in personnel expenses due to the recording of $8.1 million to G&A personnel expenses of a one-time noncash compensation charge relating to the modification of PIUs which occurred in the third quarter of 2021 offset by an increase in personnel expenses of $0.2 million due to personnel added in late 2021 to prepare for increased development activity and increased administrative activity relating to operating as a public company as well as stock-based compensation which was incurred in 2022. In addition, there was a decrease in legal and professional fees of $0.4 million due to transaction costs relating to the IPO which had been expensed in the third quarter of 2021. These decreases were partially offset by an increase of $0.6 million in insurance costs relating to the directors and officers insurance premium which increased when the Company became public.

Interest and other income (expense)

The following table summarizes interest and other income (expense) for the three months ended September 30, 2022 and September 30, 2021:

(in thousands)	Three Months ended September 30, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Interest and other income (expense), net	$ (59)	$ (11)	$ 48	436.4%

Total interest and other income (expense), net primarily relates to interest expense incurred on related party note payables offset by interest and dividends earned on invested balances during the three months ended September 30, 2022. Interest expense increased by approximately $95,000 from the three months ended September 30, 2022 as compared to the three months ended September 30, 2021, due to interest incurred on the $5.0 million WFIA related party note payable, dated August 9, 2022, which was offset by an increase in interest income on invested balances of approximately $48,000 due to an increase in interest rates from 2021 to 2022.

Comparison of the nine months ended September 30, 2022 and September 30, 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and September 30, 2021:

(in thousands)	Nine Months ended September 30, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Operating Expenses:				
Research and development	$ 7,064	$ 7,147	$ (83)	(1.2%)
General and administrative	5,963	10,885	(4,922)	(45.2%)
Loss from operations	(13,027)	(18,032)	5,005	(27.8%)
Interest and other income (expense), net	(44)	(24)	20	83.3%
Net Loss	$ (13,071)	$ (18,056)	$ (4,985)	27.6%

Research and development expenses

The following table summarizes our R&D for the nine months ended September 30, 2022 and September 30, 2021:

(in thousands)	Nine Months ended September 30, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Clinical operations	$ 2,082	$ 260	$ 1,822	**NM**
Drug manufacturing and formulation	2,827	1,271	1,556	122.4%
Personnel expenses	2,097	5,591	(3,494)	(62.5%)
Regulatory costs	58	25	33	132.0%
Total research and development expenses	$ 7,064	$ 7,147	$ (83)	(1.2%)

R&D expenses were $7.1 million for the nine months ended September 30, 2022, a decrease of $0.1 million or 1.2% from the nine months ended September 30, 2021. This was primarily related to the decrease in personnel expense due to the recording of $4.6 million to R&D expense for a one-time noncash compensation charge for the modification of PIUs which occurred in the third quarter of 2021, partially offset by an increase in personnel expenses in 2022 resulting from added clinical and manufacturing personnel in late 2021 in anticipation of increased development activity as well as stock-based compensation incurred in 2022. In addition, there was an increase in clinical operations and drug manufacturing and formulation costs of $3.4 million. Development activity increased in 2022 due to the manufacture of Phase 3 clinical supply for CTx-1301 as well as the incurrence of study start-up costs for the Phase 3 fixed dose study for CTx-1301 and costs for the food effect study for CTx-1301 which were incurred in the third quarter of 2022.

General and administrative expenses

The following table summarizes our G&A expenses for the nine months ended September 30, 2022 and September 30, 2021:

(in thousands)	Nine Months ended September 30, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 1,803	$ 9,132	$ (7,329)	(80.3%)
Legal and professional fees	1,422	1,105	317	28.7%
Occupancy	353	322	31	9.6%
Insurance	2,013	124	1,889	**NM**
Other	372	202	170	84.2%
Total general and administrative expenses	$ 5,963	$ 10,885	$ (4,922)	(45.2%)

Total G&A expenses were $6.0 million for the nine months ended September 30, 2022, a decrease of $4.9 million or 45.2% from the nine months ended September 30, 2021. This was primarily related to the decrease in personnel expenses due to the recording of $8.1 million to G&A personnel expenses of a one-time noncash compensation charge relating to the modification of PIUs which occurred in the third quarter of 2021, offset by an increase in personnel expenses of $0.8 million due to personnel added in late 2021 to prepare for increased development activity and increased administrative activity relating to operating as a public company as well as stock-based compensation which was incurred in 2022. Additionally, there was an increase in insurance expense relating to the directors and officers insurance premiums which increased when the Company became public.

Interest and other income (expense)

The following table summarizes interest and other income (expense) for the nine months ended September 30, 2022 and September 30, 2021:

(in thousands)	Nine Months ended September 30, 2022	2021	Increase (Decrease)	% Increase (Decrease)
Interest and other income (expense), net	$ (44)	$ (24)	$ 20	83.3%

Total interest and other income (expense), net primarily relates to interest expense incurred on related party note payables offset by interest and dividends earned on invested balances during the nine months ended September 30, 2022. Interest expense increased by approximately $87,000 from the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021, due primarily to interest incurred on the $5.0 million WFIA related party note payable, dated August 9, 2022, which was partially offset by an increase in interest income on invested balances of approximately $67,000 due to an increase in interest rates from 2021 to 2022.

Cash Flows

	Nine Months ended September 30,	
	2022	**2021**
Net cash (used in) operating activities	$ (11,676)	$ (5,810)
Net cash (used in) investing activities	(10)	(105)
Net cash provided by financing activities	4,989	6,633
Net increase (decrease) in cash and cash equivalents	$ (6,697)	$ 718

Cash Flows from Operating Activities

Net cash used in operating activities was $11.7 million for the nine months ended September 30, 2022. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $13.1 million, prior to the effects of two noncash items, stock-based compensation expense of $0.6 million and depreciation of $0.3 million. Changes in operating assets and liabilities included a decrease in miscellaneous receivables resulting from the receipt in early 2022 of a significant portion of the payroll and research and development tax credits owed to us, and an increase in prepaid expenses and other current assets relating to prepaid amounts on clinical development activity.

Net cash used in operating activities was $5.8 million for the nine months ended September 30, 2021, prior to the effects of two significant noncash items, the one-time noncash PIU charge of $12.7 million and depreciation expense of $0.5 million. Changes in operating assets and liabilities included an increase in accounts payable and accrued expenses of $2.1 million mainly due to the timing of payments to our service providers and an increase in prepaid expenses of $2.8 million due to prepayments on insurance and development activity.

Cash Flows from Investing Activities

Net cash used in investing activities for both the nine months ended September 30, 2022 and September 30, 2021 was related to the purchase of equipment to support our research and development.

Cash Flows from Financing Activities

Net cash used in financing activities in the nine months ended September 30, 2022 was primarily related to the proceeds on the $5.0 million WFIA related party note payable received on August 10, 2022.

Net cash provided by financing activities in the six months ended September 30, 2021 was primarily related to proceeds of the issuance of $7.1 million of equity units of CTx prior to our IPO.

Liquidity and Capital Resources

Sources of Liquidity

On August 10, 2022, we received $5.0 million pursuant to the WFIA Debt Financing.

Since our inception in 2012 through September 30, 2022, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations. Based on our current operating plan, we expect our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through the first quarter of 2023. In addition, in order to achieve the filing of our NDA for CTx-1301 in the first half of 2024 for potential FDA approval, we believe that we will need approximately $23.5 million of additional capital which has increased by approximately $7.0 million from our prior estimate, partially due to an estimated additional three months of operating expenses resulting from the delay of the start of the Phase 3 fixed dose study to mid-2023. This delay was the result of operational resource issues at our previous CMO. The final two dosage strengths for this study will be manufactured by our new manufacturing partner, Societal. We have also included an additional study in our clinical plan for CTx-1301, prior to filing our NDA, the Phase 3 adult dose-optimization study, and certain other study costs have increased. We will need additional capital to advance our other programs and commercialization efforts. However, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents are invested primarily in money market funds which provide a minimal return.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

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

- the cost and timing of manufacturing the clinical supply of our product candidates;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the clinical development plans we establish for each product candidate;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration or license agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the cost and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, 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 on our own.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, including clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, licensing or similar strategic business transaction. In addition, we continue to evaluate commercial collaborations, which would provide us with more immediate access to marketing, sales, market access and distribution infrastructure.

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

Contractual Obligations

The following summarizes our contractual obligations as of September 30, 2022 that will affect our future liquidity.

We entered into a patent and know-how licensing agreement with BDD Pharma Limited in August 2018. See the "Business – Material Agreements" section of our Form 10-K for a description of this agreement. We may be required to pay BDD Pharma certain amounts in connection with clinical trial and regulatory milestones. The first milestone payment of $250,000 will likely become due in the next twelve months based on the dosing of the first patient in the Phase 3 fixed-dose pediatric and adolescent safety and efficacy study for CTx-1301. This payment is accrued in our September 30, 2022 financial statements.

We have signed a letter of intent with a CRO for the Phase 3 adult dose-optimization, onset and duration study for CTx-1301, in which we plan to enroll the first patient in December 2022. We have also entered into an agreement with a CRO for the Phase 3 fixed-dose pediatric and adolescent safety and efficacy study for CTx-1301, in which we plan to dose the first patient in mid-2023. We have entered into agreements with CMOs and other third parties for manufacture of the Phase 3 clinical supply of CTx-1301. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation and in some cases, wind-down costs and restoration costs. The exact amount of such obligations is dependent on the timing of termination and the terms of the related agreement and are not known.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change that is largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for one year after the issuance date of our financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We have incurred a net loss for the three and six-month periods ended September 30, 2022 and September 30, 2021 and had an accumulated deficit of $64.8 million since inception to September 30, 2022. 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 our IPO, the issuance of equity securities in connection with our IPO and the WFIA Debt Financing. Additional financings 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 financing will be available when needed or on acceptable terms.

Recently Issued Accounting Standards

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

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company". As an "emerging growth company," we are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for emerging growth companies.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply until the fifth anniversary of the completion of our IPO or until we no longer meet the requirements for being an "emerging growth company," whichever occurs first.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Our Disclosure Controls

We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of September 30, 2022, have concluded that our disclosure controls and procedures were effective as of September 30, 2022.

Evaluation of Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Our business is subject to substantial risks and uncertainties. Investing in our securities involves a high degree of risk. You should carefully consider the risk factors in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 28, 2022, together with the information contained elsewhere in this report, including Part I, Item 1 "Financial Statements" and Part I, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other SEC filings in evaluating our business. These risks and uncertainties could materially and adversely affect our business, financial condition, results of operations, prospects for growth, and the value of an investment in our securities.

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

On December 7, 2021, our registration statement on Form S-1 (Registration No. 333-259408) was declared effective by the SEC for our IPO pursuant to which we issued (i) an aggregate of 4,166,666 shares of our common stock and accompanying warrants to purchase 4,166,666 shares of common stock at a combined purchase price of $6.00 per share of common stock and accompanying warrant and (ii) warrants to purchase an additional 624,999 shares of common stock at an purchase price of $0.001 per warrant pursuant to an over-allotment option, resulting in aggregate net proceeds to us of approximately $20.4 million after deducting underwriting discounts and commissions and other offering expenses of approximately $4.6 million.

The remainder of the information required by this item regarding the use of our IPO proceeds has been omitted pursuant to SEC rules because such information has not changed since our last periodic report was filed.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Cingulate Inc.	10-K	3.1	3/28/2022
3.2	Amended and Restated Bylaws of Cingulate Inc.	10-K	3.2	3/28/2022
10.1	Promissory Note, dated August 9, 2022, between Cingulate Therapeutics, LLC and Werth Family Investment Associates	8-K	10.1	8/11/2022
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

* Filed Herewith

** Furnished Herewith

SIGNATURES

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

CINGULATE INC.

Date: November 14, 2022

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

Date: November 14, 2022

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

Exhibit 31.1

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

I, Shane J. Schaffer, certify that:

1. I have reviewed this Quartlery Report on Form 10-Q for the period ended September 30, 2022 of Cingulate Inc.;

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

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

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

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

   b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

   d) Disclosed in this report any change in the registrant's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 14, 2022

/s/ Shane J. Schaffer

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

Exhibit 31.2

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

I, Louis G. Van Horn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2022 of Cingulate Inc.;

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

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

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

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

   b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

   d) Disclosed in this report any change in the registrant's internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: November 14, 2022

/s/ Louis G. Van Horn

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

Exhibit 32.1

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended September 30, 2022 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

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

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

Dated: November 14, 2022

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

Exhibit 32.2

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended September 30, 2022 (the "Quarterly Report"), the undersigned hereby certifies in his capacity as an officer of the Company that to such officer's knowledge:

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

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

Dated: November 14, 2022

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