

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

**FORM 10-Q**

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

For the quarterly period ended **June 30, 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**

(State or other jurisdiction of  
incorporation or organization)

**86-3825535**

(I.R.S. Employer  
Identification No.)

**1901 W. 47<sup>th</sup> Place  
Kansas City, KS**

(Address of principal executive offices)

**66205**

(Zip Code)

**(913) 942-2300**

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of August 4, 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 June 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)**

	<b>June 30, 2022</b>	<b>December 31, 2021</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 8,195,760	\$ 16,492,745
Short-term investments	-	933
Miscellaneous receivables	140,113	690,248
Prepaid expenses and other current assets	1,766,279	1,698,353
<b>Total current assets</b>	<b>10,102,152</b>	<b>18,882,279</b>
Property and equipment, net	2,952,920	3,145,378
Operating lease right-of-use assets	748,782	858,600
<b>Total assets</b>	<b>13,803,854</b>	<b>22,886,257</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	282,265	264,687
Accrued expenses	311,573	601,300
Current installments of obligations under finance leases	15,570	15,096
Other current liabilities	314,097	295,595
<b>Total current liabilities</b>	<b>923,505</b>	<b>1,176,678</b>
Long-term liabilities:		
Obligations under finance leases	29,633	37,534
Operating lease liabilities	665,842	828,503
<b>Total liabilities</b>	<b>1,618,980</b>	<b>2,042,715</b>
Stockholders' Equity		
Common Stock, \$0.0001 par value; 240,000,000 shares authorized and 11,309,412 shares issued and outstanding as of June 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 June 30, 2022 and December 31, 2021	-	-
Additional Paid-in-Capital	72,963,214	72,574,510
Accumulated other comprehensive income	(3,249)	165
Accumulated deficit	(60,776,222)	(51,732,264)
<b>Total stockholders' equity</b>	<b>12,184,874</b>	<b>20,843,542</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 13,803,854</b>	<b>\$ 22,886,257</b>

See notes to consolidated financial statements.

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
<b>Operating expenses:</b>				
Research and development	\$ 2,178,226	\$ 793,587	\$ 4,940,510	\$ 1,356,106
General and administrative	1,870,591	629,032	4,117,651	1,396,677
<b>Operating loss</b>	<b>(4,048,817)</b>	<b>(1,422,619)</b>	<b>(9,058,161)</b>	<b>(2,752,783)</b>
Interest and other income (expense), net	8,370	(9,676)	14,203	(13,435)
Loss before income taxes	(4,040,447)	(1,432,295)	(9,043,958)	(2,766,218)
Income tax benefit (expense)	-	-	-	-
Net loss	<u>(4,040,447)</u>	<u>(1,432,295)</u>	<u>(9,043,958)</u>	<u>(2,766,218)</u>
<b>Other comprehensive income (loss):</b>				
Change in unrealized loss on short-term investments	(466)	-	(3,414)	-
<b>Comprehensive loss</b>	<b>\$ (4,040,913)</b>	<b>\$ (1,432,295)</b>	<b>\$ (9,047,372)</b>	<b>\$ (2,766,218)</b>
Net loss per share of common stock, basic and diluted	<u>\$ (0.36)</u>	<u>-</u>	<u>\$ (0.80)</u>	<u>-</u>
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	<u>11,309,412</u>	<u>-</u>	<u>11,309,412</u>	<u>-</u>

See notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in-Capital	Members' Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Stockholders' Equity
	Shares	Amount					
<b>Balance January 1, 2021</b>	-	-	\$ -	<u>32,314,441</u>	<u>\$ (31,022,336)</u>	\$ 165	<u>\$ 1,292,270</u>
Member contributions			-	1,385,688			1,385,688
Net loss	-	-	-		(1,333,923)	-	(1,333,923)
<b>Balance March 31, 2021</b>	-	\$ -	\$ -	<u>\$33,700,129</u>	<u>\$ (32,356,259)</u>	\$ 165	<u>\$ 1,344,035</u>
<b>Activity for the three months to June 30, 2021:</b>							
Member contributions	-	-	-	1,987,640	-	-	1,987,640
Net loss	-	-	-	-	(1,432,295)	-	(1,432,295)
<b>Balance June 30, 2021</b>	-	\$ -	\$ -	<u>\$35,687,769</u>	<u>\$ (33,788,554)</u>	\$ 165	<u>\$ 1,899,380</u>
<b>Balance January 1, 2022</b>	11,309,412	1,131	\$ 72,574,510	-	\$ (51,732,264)	\$ 165	\$ 20,843,542
<b>Activity for the three months to March 31, 2022:</b>							
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)
<b>Balance March 31, 2022</b>	11,309,412	\$ 1,131	\$ 72,756,028	\$ -	\$ (56,735,775)	\$ (2,783)	\$ 16,018,601
<b>Activity for the three months to June 30, 2022:</b>							
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)
<b>Balance June 30, 2022</b>	11,309,412	\$ 1,131	\$ 72,963,214	\$ -	\$ (60,776,222)	\$ (3,249)	\$ 12,184,874

See notes to consolidated financial statements

**Cingulate Inc.**  
**Consolidated Statements of Cash Flows (unaudited)**

	<b>Six Months Ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
<b>Operating activities:</b>		
Net loss	\$ (9,043,958)	\$ (2,766,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	202,858	351,286
Stock-based compensation	388,705	-
Changes in operating assets and liabilities:		
Miscellaneous receivables	550,135	(128,528)
Prepaid expenses and other current assets	(67,926)	(1,190,416)
Operating lease right-of-use assets	109,818	(1,739)
Trade accounts payable and accrued expenses	(272,149)	541,672
Other current liabilities	18,502	46,732
Operating lease liabilities	(162,661)	(77,501)
<b>Net cash used in operating activities</b>	<b>(8,276,676)</b>	<b>(3,224,712)</b>
<b>Investing activities:</b>		
Purchase of property and equipment	(10,400)	(88,955)
Proceeds from sale of short-term investments	933	-
Other	(3,415)	-
<b>Net cash used in investing activities</b>	<b>(12,882)</b>	<b>(88,955)</b>
<b>Financing Activities:</b>		
Members' capital contributions	-	3,373,163
Principal payments on finance lease obligations	(7,427)	(212,853)
<b>Net cash provided by (used in) financing activities</b>	<b>(7,427)</b>	<b>3,160,310</b>
<b>Cash and cash equivalents:</b>		
Net decrease in cash and cash equivalents	(8,296,985)	(153,357)
Cash and cash equivalents at beginning of year	16,492,745	1,197,672
<b>Cash and cash equivalents at end of year</b>	<b>\$ 8,195,760</b>	<b>\$ 1,044,315</b>
Property and equipment accrued but not yet paid at end of period	\$ -	\$ 164,365
<b>Cash payments:</b>		
Interest paid	\$ 9,619	\$ 4,880

See notes to consolidated financial statements

## **(1) Nature of the Business and Liquidity**

### *Organization*

Cingulate Inc. is a clinical stage 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 (dexamethylphenidate) 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 Phase 3 clinical trials for CTx-1301 in the second half of 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 June 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; however, the Company will need additional funding for operations and development in order to meet its obligations. Management is evaluating various strategies to obtain additional funding for operations and development which may include additional offerings of common stock, issuance of debt, potential strategic research and development partners, and licensing and/or marketing arrangements with pharmaceutical companies. Successful implementation of these plans involves both the Company's efforts and factors that are outside its control, such as market factors and FDA approval of product candidates. The Company can give no assurance that its plans will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above, which results in substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

## **(2) Summary of Significant Accounting Policies**

### **(a) Basis of Presentation and Principles of Consolidation**

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

### **(b) Unaudited Interim Financial Information**

The accompanying consolidated balance sheet as of June 30, 2022, the consolidated statements of operations for the three and six-month periods ended June 30, 2022 and 2021 and, the consolidated statement of stockholders' equity for the three and six-month periods ended June 30, 2022 and 2021, the consolidated statements of cash flows for the six months ended June 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 June 30, 2022, as well as employee retention tax credits for payroll costs incurred in 2020 and the first three quarters of 2021. As of June 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 six-month periods ended June 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 10.

**(3) Fair Value of Assets and Liabilities**

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair values based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

*Level 1*—Inputs represent unadjusted quoted prices for identical assets exchanged in active markets.

*Level 2*—Inputs include directly or indirectly observable inputs other than Level 1 inputs such as quoted prices for similar assets exchanged in active or inactive markets; quoted prices for identical assets exchanged in inactive markets; other inputs that are considered in fair value determinations of the assets, such as interest rates and yield curves that are observable at commonly quoted intervals.

*Level 3*—Inputs include unobservable inputs used in the measurement of assets. Management is required to use its own assumptions regarding unobservable inputs because there is little, if any, market activity in the assets or related observable inputs that can be corroborated at the measurement date. Measurements of certain investments carried at fair value are based primarily on valuation models, discounted cash flow models or other valuation techniques that are believed to be used by market participants. Unobservable inputs require management to make certain projections and assumptions about the information that would be used by market participants in pricing assets.

The categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The Company's policy is to recognize significant transfers between the levels at the actual date of the event. There were no transfers in or out of Levels 1, 2, or 3 during the three or six-month periods ended June 30, 2022 or June 30, 2021.

The Company has no Level 2 or Level 3 investments. The cash and short-term investments held by the Company are categorized as Level 1 investments as quoted market prices are readily available for these investments.

Assets measured and carried at fair value on a recurring basis are summarized below:

	<b>June 30, 2022</b>					
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value of Current Assets</b>	<b>Fair Value of Non-Current Assets</b>	<b>Fair Value of Total Assets</b>
Money Market Fund	<b>\$7,519,009</b>	-	<b>\$ (3,413)</b>	<b>\$7,515,596</b>	-	<b>\$7,515,596</b>

	<b>December 31, 2021</b>					
	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value of Current Assets</b>	<b>Fair Value of Non-Current Assets</b>	<b>Fair Value of Total Assets</b>
Mutual Fund	<b>\$ 920</b>	<b>\$ 13</b>		<b>\$ 933</b>	-	<b>\$ 933</b>

#### (4) Prepaid Expenses

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

	<b>June 30, 2022</b>	<b>December 31, 2021</b>
Insurance	\$ 1,137,786	\$ 761,594
Active pharmaceutical ingredients	224,381	264,361
Research and development	116,432	643,917
Legal fees	154,858	-
Other	132,822	28,481
	<u>\$ 1,766,279</u>	<u>\$ 1,698,353</u>

## (5) Property and Equipment

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

	<b>Estimated Useful Life (in years)</b>	<b>June 30, 2022</b>	<b>December 31, 2021</b>
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	-	1,653,550	1,643,150
		<u>4,821,833</u>	<u>4,811,433</u>
Less: accumulated depreciation		<u>(1,868,913)</u>	<u>(1,666,055)</u>
		<u>\$ 2,952,920</u>	<u>\$ 3,145,378</u>

Depreciation expense for the six months ended June 30, 2022 was \$202,858 and for the six months ended June 30, 2021 was \$351,286. Depreciation expense for the three months ended June 30, 2022 was \$101,429 and for the three months ended June 30, 2021 was \$76,853.

## (6) Accrued Expenses

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

	<b>June 30, 2022</b>	<b>December 31, 2021</b>
Professional and consulting fees	\$ 15,000	\$ 15,000
Research and development	250,000	250,000
CIP- Equipment	-	279,730
Other	46,573	56,570
	<u>\$ 311,573</u>	<u>\$ 601,300</u>

## (7) 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 and 948,804 units were issued during the three months ended June 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 3<sup>rd</sup> 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 8.

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.

### (8) 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:

Year Granted	Distribution Threshold \$ (in millions):							Total
	\$25	\$40	\$75	\$80	\$90	\$120	\$160	
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
<b>Total</b>	<u>4,753,000</u>	<u>786,725</u>	<u>217,725</u>	<u>1,499,009</u>	<u>377,524</u>	<u>508,478</u>	<u>357,539</u>	<u>8,500,000</u>

## (9) Stockholders' Equity

The Company has authorized 240,000,000 shares of \$0.0001 par value common stock and 10,000,000 shares of \$0.0001 par value preferred stock at June 30, 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.

## (10) Stock-Based Compensation

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

The maximum number of shares of common stock available for issuance in connection with options and other awards granted under the 2021 Plan is 1,927,810 and as of June 30, 2022, 1,044,009 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 \$388,705 during the six months ended June 30, 2022, and \$207,189 during the three months ended June 30, 2022, relating to options issued in 2021 and 2022. As of June 30, 2022 and December 31, 2021, there was \$2,669,011 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 six months ended June 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	10.00	
Exercised	—			
Forfeitures or expirations	—			
Outstanding at June 30, 2022	883,801	\$ 4.29	9.49	\$ 24,800
Options exercisable as of June 30, 2022	11,017			
Options unvested as of June 30, 2022	872,784			

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 six-month period ended June 30, 2022 were as follows; shown on a weighted average basis:

Risk-free interest rate	1.60%
Weighted-average expected term (in years)	6.07
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 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 \$1.46 as of June 30, 2022, based upon the closing price of our common stock on the Nasdaq Capital Market.

## (11) Income Taxes

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

	<b>Six Months Ended June 30, 2022</b>	<b>Three Months Ended June 30, 2022</b>
Federal income tax benefit at statutory rate	\$ (1,888,057)	\$ (848,475)
State income tax benefit	(497,189)	(223,432)
Permanent differences	8,763	3,098
Change in valuation allowance	2,439,294	1,077,408
Other	(62,811)	(8,599)
Total income tax expense	<u>\$ -</u>	<u>\$ -</u>

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 \$3,285,986 as of June 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 June 30, 2022.

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Deferred income tax assets:		
Current:		
Research and development costs	\$ 962,910	\$ -
Unvested stock options	116,786	11,835
Other	-	4,050
Non-current:		
Patents	102,317	90,480
Net operating losses	2,410,153	1,201,974
Other	74,615	49,606
Gross deferred income tax assets	<u>3,666,781</u>	<u>1,357,945</u>
Less: valuation allowance	<u>(3,285,986)</u>	<u>(847,269)</u>
Net deferred income tax asset	380,795	510,676
Deferred income tax liabilities:		
Current:		
Accrual to cash	(29,963)	(105,075)
Non-current		
Property and equipment	(350,832)	(405,601)
Gross deferred income tax liabilities	<u>(380,795)</u>	<u>(510,676)</u>
Net deferred tax asset (liability)	<u>\$ -</u>	<u>\$ -</u>

## (12) Net Loss Per Share

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

	<u>Three Months Ended June 30, 2022</u>	<u>Six Months Ended June 30, 2022</u>
Numerator:		
Net loss	\$ (4,040,447)	\$ (9,043,958)
Denominator:		
Weighted average common shares outstanding	<u>11,309,412</u>	<u>11,309,412</u>
Net loss per share, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.80)</u>

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

Stock options issued under the 2021 Equity Incentive Plan	883,801
Common stock purchase warrants outstanding	4,999,998
Total	<u>5,883,799</u>

### **(13) License Agreement**

CTx has a licensing agreement with a company related to the patents and licensed know-how for use in the development of CTx-1301, CTx-1302, and CTx-2103. 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 either product as it has not deemed them probable of occurring as of June 30, 2022.

### **(14) Related Party Transactions**

The general counsel of the Company is a partner with a law firm providing office facilities space that is leased by the Company. Rental expense incurred by the Company to the law firm was \$18,000 for both the six months ended June 30, 2022 and 2021 and \$9,000 for both the three months ended June 30, 2022 and 2021, which approximates fair value. As of June 30, 2022 and December 31, 2021, the Company had no outstanding amounts payable under this lease.

### **(15) Subsequent Events**

Management evaluated events that occurred subsequent to June 30, 2022 through August 11, 2022, which is the date the interim financial statements were issued.

On August 10, 2022, the Company received \$5.0 million of debt financing from Werth Family Investment Associates LLC (WFIA). Peter Werth, manager of WFIA, is a member of the Company's Board of Directors. The promissory note executed 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 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.



## 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 clinical stage biopharmaceutical company using our proprietary Precision Timed Release<sup>TM</sup> (PTR<sup>TM</sup>) 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, was approximately \$63.8 million as of June 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 \$1.4 million for the three months ended June 30, 2022 and June 30, 2021, respectively and \$9.0 million and \$2.8 million for the six months ended June 30, 2022 and June 30, 2021, respectively. As of June 30, 2022, we had an accumulated deficit of \$60.8 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.

## **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.

WFIA owns 871,731 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.

**CTx-1301:** We have designed our clinical program for CTx-1301 (dexamethylphenidate), 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 have commenced study start-up activities for the CTx-1301 Phase 3, fixed-dose, pediatric and adolescent safety and efficacy study, and anticipate dosing of the first patient in late 2022. We have been experiencing delays in the manufacturing and delivery of clinical supply for this study due to operational resource issues at our contract manufacturing organization (CMO). Manufacturing of the final two dosage strengths, which are necessary to dose the first patient, is expected to begin in the second half of this year. Results from the fixed-dose study are expected in the second half of 2023. In order to meet the pharmacology requirement for the CTx-1301 New Drug Application (NDA) submission, we plan to complete a food effect study in the fourth quarter of 2022. Assuming we receive positive clinical results from our Phase 3 trial and food effect study, we still plan to submit the NDA for CTx-1301 in late 2023 under the Section 505(b)(2) pathway.

In addition to the studies noted above, we plan to initiate an adult dose-optimization study (Phase 3b) to assess the onset and duration of efficacy in the second half of 2023. This Phase 3b trial is supplementary and is not required for the CTx-1301 NDA submission.

**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 2023 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 with results expected in 2025.

**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. Furthermore, this trial extends the potential of the PTR platform where multiple daily doses are required and the timing, style, and ratio of this medication delivery is paramount. We initiated a human formulation study for CTx-2103 in May 2022 at BDD Pharma in Glasgow, Scotland, UK. Results from the study are expected by the end of August 2022.

As of June 30, 2022, we had cash and cash equivalents of \$8.2 million. Based on our operating plan and with the proceeds from the WFIA Debt Financing, 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 late 2023 for potential FDA approval, we believe that we will need approximately \$16.5 million of additional capital. We will also need additional capital to advance our other programs. We are evaluating alternatives to raise additional capital, including equity and debt financing and non-dilutive strategic collaborations in the U.S. and abroad. In addition, we continue to evaluate commercial collaborations, which would provide us with more immediate access to marketing, sales, market access and distribution infrastructure. See “Liquidity and Capital Resources” below.

## **Impact of the COVID-19 Pandemic**

We are continuing to monitor the impact of the COVID-19 pandemic on our business, the extent of which will depend on a number of factors, including, but not limited to, the extent and severity of the impact on our service providers, suppliers, contract research organizations and our preclinical and clinical trials, all of which are uncertain and cannot be predicted.

While the full impact of the pandemic continues to evolve, the financial markets have been subject to significant volatility that may adversely impact our ability to enter into, modify, and negotiate favorable terms and conditions relative to equity and debt financing initiatives. The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values may also affect our ability to enter into collaborations, joint ventures, and license and royalty agreements. The outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. We may face difficulties recruiting or retaining patients in our ongoing and planned preclinical and clinical trials if patients are affected by the virus or are fearful of traveling to our clinical trial sites. We and our third-party CMOs, clinical research organizations (CROs), and clinical sites may also face disruptions in procuring items that are essential to our research and development activities, including, for example, medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, that are sourced from abroad or for which there are shortages because of ongoing efforts to address the outbreak.

The extent to which the COVID-19 pandemic may in the future impact our financial condition, liquidity or results of operations is uncertain. While the pandemic did not materially affect our financial results and business operations in the quarter ended June 30, 2022, we are unable to predict the impact that COVID-19 may have on our financial position and operating results in future periods due to numerous uncertainties. Management continues to actively monitor the situation and the possible effects on our financial condition, operations, suppliers, vendors, our workforce and the overall industry. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see the “Risk Factors” section in our Form 10-K.

## **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 or 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 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, including potential collaborations with other companies or other strategic transactions.

#### *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, interest charged by certain vendors, financing charge on insurance premiums and credit card interest. All related party notes were paid in full in December 2021 with proceeds from our IPO.

#### **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 June 30, 2022 and June 30, 2021

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

(in thousands)	Three Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Operating Expenses:				
Research and development	\$ 2,178	\$ 794	\$ 1,384	174.3%
General and administrative	1,870	629	1,241	197.3%
Loss from operations	(4,048)	(1,423)	(2,625)	184.5%
Interest and other income (expense), net	8	(9)	17	188.9%
Net Loss	\$ (4,040)	\$ (1,432)	\$ (2,608)	182.1%

### Research and development expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2022 and June 30, 2021:

(in thousands)	Three Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Clinical operations	\$ 693	\$ 56	\$ 637	NM
Drug manufacturing and formulation	801	353	448	126.9%
Personnel expenses	654	359	295	82.2%
Regulatory costs	30	26	4	15.4%
Total research and development expenses	\$ 2,178	\$ 794	\$ 1,384	174.3%

Research and development (R&D) expenses were \$2.2 million for the three months ended June 30, 2022, an increase of \$1.4 million or 174.3% from the three months ended June 30, 2021. This increase was related to increased development activity as we prepare for a Phase 3 clinical trial for CTx-1301. Manufacturing clinical supply began in the first quarter of 2022 and continued through the second quarter and study start-up activities have been occurring since late 2021. In addition, the Company added clinical and manufacturing personnel in late 2021 in anticipation of the increased development activity.

*General and administrative expenses*

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

(in thousands)	Three Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Personnel expenses	\$ 546	\$ 314	\$ 232	73.9%
Legal and professional fees	401	107	294	274.8%
Occupancy	118	111	7	6.3%
Insurance	670	38	632	NM
Other	135	59	76	127.3%
Total general and administrative expenses	\$ 1,870	\$ 629	\$ 1,241	197.1%

Total G&A expenses were \$1.9 million for the three months ended June 30, 2022, an increase of \$1.2 million or 197.1% from the three months ended June 30, 2021. The overall increase in G&A expenses is the result of operating as a public company in 2022 as compared to operating as a private company in 2021. Personnel expenses increased by \$0.3 million as legal and accounting personnel were added in late 2021, insurance costs increased by \$0.6 million which relates to the directors and officers insurance policy, and legal and professional fees increased by \$0.3 million which relates to increased investor and public relations fees, board compensation fees and audit fees.

*Interest and other income (expense)*

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

(in thousands)	Three Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Interest and other income (expense), net	\$ 8	\$ (9)	\$ 17	188.9%

Total interest and other income (expense), net primarily relates to interest and dividends earned on invested balances during the three months ended June 30, 2022 and relates to interest incurred on outstanding notes payable during the three months ended June 30, 2021. All notes payable were paid in full in December 2021 with proceeds from our IPO.

*Comparison of the six months ended June 30, 2022 and June 30, 2021*

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

(in thousands)	Six Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Operating Expenses:				
Research and development	\$ 4,941	\$ 1,356	\$ 3,585	264.4%
General and administrative	4,117	1,397	2,720	194.7%
Loss from operations	(9,058)	(2,753)	(6,305)	229.0%
Interest and other income (expense), net	14	(13)	27	207.7%
Net Loss	\$ (9,044)	\$ (2,766)	\$ (6,278)	227.0%

### Research and development expenses

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

(in thousands)	Six Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Clinical operations	\$ 1,501	\$ 77	\$ 1,424	NM
Drug manufacturing and formulation	2,154	600	1,554	259.0%
Personnel expenses	1,237	658	579	88.0%
Regulatory costs	49	21	28	133.3%
Total research and development expenses	<u>\$ 4,941</u>	<u>\$ 1,356</u>	<u>\$ 3,585</u>	<u>264.4%</u>

R&D expenses were \$4.9 million for the six months ended June 30, 2022, an increase of \$3.6 million or 264.4% from the six months ended June 30, 2021. This increase was related to increased development activity as we prepare for a Phase 3 clinical trial for CTx-1301. Manufacturing clinical supply began in the first quarter of 2022 with continued activity in the second quarter and study start-up activities have been occurring since late 2021. In addition, the Company added clinical and manufacturing personnel in late 2021 in anticipation of the increased development activity.

### General and administrative expenses

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

(in thousands)	Six Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Personnel expenses	\$ 1,229	\$ 595	\$ 634	106.6%
Legal and professional fees	1,048	371	677	182.5%
Occupancy	246	212	34	16.0%
Insurance	1,343	79	1,264	NM
Other	251	140	111	79.3%
Total general and administrative expenses	<u>\$ 4,117</u>	<u>\$ 1,397</u>	<u>\$ 2,720</u>	<u>194.7%</u>

Total G&A expenses were \$4.1 million for the six months ended June 30, 2022, an increase of \$2.7 million or 194.7% from the six months ended June 30, 2021. The overall increase in G&A expenses is the result of operating as a public company in 2022 as compared to operating as a private company in 2021. Personnel expenses increased by \$0.6 million as legal and accounting personnel were added in late 2021, insurance costs increased by \$1.3 million which relates to the directors and officers insurance policy, and legal and professional fees increased by \$0.7 million which relates to increased investor and public relations fees, board compensation fees and audit fees.

### Interest and other income (expense)

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

(in thousands)	Six Months ended June 30,		Increase (Decrease)	% Increase (Decrease)
	2022	2021		
Interest and other income (expense), net	\$ 14	\$ (13)	\$ 27	207.7%

Total interest and other income (expense), net primarily relates to interest and dividends earned on invested balances during the six months ended June 30, 2022 and relates to interest incurred on outstanding notes payable during the six months ended June 30, 2021. All notes payable were paid in full in December 2021 with proceeds from our IPO.

## Cash Flows

	Six Months ended June 30,	
	2022	2021
Net cash (used in) operating activities	\$ (8,277)	\$ (3,224)
Net cash (used in) investing activities	(13)	(89)
Net cash (used in) provided by financing activities	(7)	3,160
Net decrease in cash and cash equivalents	<u>\$ (8,297)</u>	<u>\$ (153)</u>

### *Cash Flows from Operating Activities*

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

Net cash used in operating activities was \$3.2 million for the six months ended June 30, 2021. 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 \$2.9 million, offset primarily by depreciation. Changes in operating assets and liabilities included a decrease in accounts payable and accrued expenses of \$0.3 million mainly due to the timing of payments to our service providers.

### *Cash Flows from Investing Activities*

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

Net cash provided by financing activities in the six months ended June 30, 2021 was primarily related to proceeds of the issuance of \$1.6 million of equity units of CTx.

## **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 June 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 and with the proceeds from the WFIA Debt Financing, 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 late 2023 for potential FDA approval, we believe that we will need approximately \$16.5 million of additional capital. We will also need additional capital to advance our other programs. 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 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, in-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 June 30, 2022 that will affect our future liquidity. Based on our current operating plan, we plan to satisfy the obligations identified below with cash and cash equivalents as of June 30, 2022.

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 June 30, 2022 financial statements.

We 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 late 2022. We also entered into agreements with a CMO 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. 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 and 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 June 30, 2022 and June 30, 2021 and had accumulated losses of \$60.8 million since inception to June 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 the Reorganization Merger, 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 June 30, 2022, have concluded that our disclosure controls and procedures were effective as of June 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 June 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.**

We are not a party to any material pending legal proceedings. From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of business.

### **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 3. Defaults Upon Senior Securities.**

None.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

### **Item 5. Other Information.**

None.

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Incorporated by Reference</b>		
		<b>Form</b>	<b>Exhibit</b>	<b>Filing Date</b>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Cingulate Inc.</a>	10-K	3.1	3/28/2022
3.2	<a href="#">Amended and Restated Bylaws of Cingulate Inc.</a>	10-K	3.2	3/28/2022
10.1*+	<a href="#">Amendment to Employment Agreement, effective April 1, 2022, between Cingulate Therapeutics LLC and Raul R. Silva</a>			
31.1*	<a href="#">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.</a>			
31.2*	<a href="#">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.</a>			
32.1**	<a href="#">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.</a>			
32.2**	<a href="#">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.</a>			
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

\* Filed Herewith

\*\* Furnished Herewith

+ Indicates a management contract or compensatory arrangement

**SIGNATURES**

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

**CINGULATE INC.**

Date: August 11, 2022

By: /s/ Shane J. Schaffer

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

Date: August 11, 2022

By: /s/ Louis G. Van Horn

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

## AMENDMENT TO EMPLOYMENT AGREEMENT

This AMENDMENT is made and effective as of April 1, 2022 by and between **CINGULATE THERAPEUTICS LLC**, a Delaware Limited Liability Company, whose principal address is 1901 W. 47<sup>th</sup> Place, 3<sup>rd</sup> Floor, Kansas City, KS 66205 (the “Company”) and **RAUL R. SILVA**, whose address is [\*\*] (the “Executive”). (The Company and the Executive hereinafter sometimes referred to as the “Parties”).

## WITNESSETH:

**WHEREAS**, the Parties are subject to an Employment Agreement effective the 23rd day of September, 2021 (the “Employment Agreement”); and

**WHEREAS**, the Company desires to continue to employ the Executive and the Executive desires to be employed by the Company on the terms contained herein.

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

The following amendments are made to the Employment Agreement;

Part 1: Section 3(a) Base Salary is revised to read as follows:

The Executive’s annual base salary shall be in the amount of Thirty-Five Thousand Six Hundred Sixty-Five (\$35,665.00) Dollars (based upon Part-Time twenty-five (25%) percent effort to the Company). The Executive’s base salary shall be reviewed annually by the Board in consultation with the Company’s annual budget, and the Board may, but shall not be required to, increase the base salary. However, the Executive’s base salary may not be decreased by the Board other than as part of an across-the-board salary reduction that applies in the same manner to all senior executives. The base salary in effect at any given time is referred to herein as “Base Salary.” The Base Salary shall be payable in a manner that is consistent with the Company’s usual payroll practices for senior executives. Notwithstanding the foregoing, solely for purposes of Section 3(e) (bonus compensation), Section 5(b) (severance payments), and Section 6 (change in control payments), “Base Salary” means One Hundred Thousand (\$100,000.00) Dollars.

Part 2: Section 3(c) Employee Benefits is revised to read as follows:

Employee Benefits.

(i) *Generally*. The Executive shall be entitled to participate in all employee benefit plans, policies, practices and programs maintained by the Company, as in effect from time to time, to the extent consistent with applicable law and the terms of the applicable employee benefit plans, policies, practices and programs, including without limitation any 401k plan and equity plans. The Executive understands that, except when prohibited by applicable law, the Company’s benefit plans may be amended by the Company from time to time in its sole discretion.

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(ii) *Quarterly Equity Grants*. On the last business day of each calendar quarter during the term of employment with the Company and unless prohibited under the Cingulate Inc. 2021 Omnibus Equity Incentive Plan (the “Plan”), the Executive will be granted a non-qualified stock option (each, an “Option”) to purchase Cingulate Inc. (CING) common stock pursuant the Plan having a value as of the date of grant of no less than Sixteen Thousand and Eighty-Four (\$16,084.00) Dollars with the number of shares subject to each Option determined by dividing such dollar amount by the closing price of a share of CING common stock on the date of grant (the “Option Shares”). The per share exercise price for the Option Shares shall be equal to the closing price of a share of CING common stock on the date of grant. Each Option shall be fully vested on the date of grant. All other terms and conditions of such awards shall be governed by the terms and conditions of the Plan and the applicable option grant agreement.

Part 3: All other provisions of the Employment Agreement remain unchanged; and

Part 4: This Amendment shall become effective immediately.

IN WITNESS WHEREOF, the Parties have executed this Amendment effective on the date and year first above written.

**CINGULATE THERAPEUTICS LLC**

*/s/ Raul Silva*

\_\_\_\_\_  
RAUL SILVA, Chief Science Officer

*/s/ Shane J. Schaffer*

\_\_\_\_\_  
SHANE J. SCHAFFER, Chief Executive Officer

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

I, Shane J. Schaffer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 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: August 11, 2022

*/s/ Shane J. Schaffer*

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

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

I, Louis G. Van Horn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 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: August 11, 2022

*/s/ Louis G. Van Horn*

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

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended June 30, 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: August 11, 2022

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

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended June 30, 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: August 11, 2022

By: /s/ Louis G. Van Horn

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

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