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 March 31, 2025

or

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

For the transition period from_____ to_____.

Commission File Number: 001-40874

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

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

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

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

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

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

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

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

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

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

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

As of May 7, 2025, 4,245,713 shares of the registrant's common stock, $0.0001 par value, were issued and outstanding.

Cingulate Inc.
Form 10-Q for the Quarter Ended March 31, 2025

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of filing this report with the Securities and Exchange Commission (SEC) and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our ability to maintain compliance with the continued listing requirements of The Nasdaq Stock Market LLC (Nasdaq);
- our lack of operating history and need for additional capital;
- our plans to develop and commercialize our product candidates;
- the timing of our planned clinical trials for CTx-1301, CTx-1302, and CTx-2103;
- the timing of our New Drug Application (NDA) submissions for CTx-1301, CTx-1302, and CTx-2103;
- the timing of and our ability to obtain and maintain regulatory approvals for CTx-1301, CTx-1302, CTx-2103, or any other future product candidate;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to identify strategic partnerships;
- our expected use of cash;
- our competitive position and projections relating to our competitors or our industry;
- our ability to identify, recruit, and retain key personnel;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (JOBS Act);
- our plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding future revenue and expenses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the "Risk Factors" section in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 27, 2025, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

PART I — FINANCIAL INFORMATION

Cingulate Inc.
Consolidated Balance Sheets (unaudited)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,518,966	$ 12,211,321
Other receivables	41,573	26,325
Prepaid expenses and other current assets	944,433	423,157
Total current assets	10,504,972	12,660,803
Property and equipment, net	1,939,384	2,104,675
Operating lease right-of-use assets	25,232	99,011
Total assets	**12,469,588**	**14,864,489**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	855,150	1,270,280
Accrued expenses	601,840	1,039,625
Note payable, current	4,124,935	2,527,108
Finance lease liability, current	-	4,430
Operating lease liability, current	33,145	130,662
Total current liabilities	5,615,070	4,972,105
Long-term liabilities:		
Note payable	923,698	2,436,879
Total long-term liabilities	923,698	2,436,879
Total liabilities	**6,538,768**	**7,408,984**
Stockholders' Equity		
Common Stock, $0.0001 par value; 240,000,000 shares authorized and 3,826,199 and 3,402,306 shares issued and outstanding as of March 31, 2025 and December 31, 2024	382	340
Preferred Stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of March 31, 2025 and December 31, 2024	-	-
Additional Paid-in-Capital	118,222,309	115,944,345
Accumulated deficit	(112,291,871)	(108,489,180)
Total stockholders' equity	**5,930,820**	**7,455,505**
Total liabilities and stockholders' equity	**$ 12,469,588**	**$ 14,864,489**

See notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 2,222,626	$ 1,806,985
General and administrative	1,483,409	1,141,232
Operating loss	**(3,706,035)**	**(2,948,217)**
Interest and other income (expense), net	(96,656)	(24,260)
Loss before income taxes	(3,802,691)	(2,972,477)
Income tax benefit (expense)	-	-
Net loss and comprehensive loss	**$ (3,802,691)**	**$ (2,972,477)**
Net loss per share of common stock, basic and diluted	$ (1.04)	$ (7.21)
Weighted average number of shares used in computing net loss per share of common stock, basic and diluted	3,646,893	412,126

See notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in-	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Capital	Deficit	Income	Equity
Balance January 1, 2024	**97,293**	**10**	**$ 86,074,004**	**$ (92,943,443)**	**$ -**	**$ (6,869,429)**
Activity for the three months to March 31, 2024:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	23,650	2	3,115,282	-	-	3,115,284
Issuance of common stock in public offering, net of fees	296,000	30	6,432,862	-	-	6,432,892
Issuance of pre-funded warrants in connection with the conversion of related party note payable	-	-	2,734,739	-	-	2,734,739
Capital contribution in connection with conversion of related party note payable	-	-	586,511	-	-	586,511
Issuance of restricted common stock	596	-	24,024	-	-	24,024
Stock-based compensation expense	-	-	164,575	-	-	164,575
Net loss	-	-	-	(2,972,477)	-	(2,972,477)
Balance March 31, 2024	**417,539**	**$ 42**	**$ 99,131,997**	**$ (95,915,920)**	**$ -**	**$ 3,216,119**
Balance January 1, 2025	**3,402,306**	**$ 340**	**$ 115,944,345**	**$ (108,489,180)**	**$ -**	**$ 7,455,505**
Activity for the three months to March 31, 2025:						
Issuance of common stock in connection with At the Market Offering and Purchase Agreement, net of fees	423,893	42	1,920,315	-	-	1,920,357
Stock-based compensation expense	-	-	357,649	-	-	357,649
Net loss	-	-	-	(3,802,691)	-	(3,802,691)
Balance March 31, 2025	**3,826,199**	**$ 382**	**$ 118,222,309**	**$ (112,291,871)**	**$ -**	**$ 5,930,820**

See notes to consolidated financial statements

Cingulate Inc.
Consolidated Statements of Cash Flows (unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating activities:		
Net loss	$ (3,802,691)	$ (2,972,477)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	165,291	163,600
Stock-based compensation	357,649	164,575
Accretion of discount on note payable	7,670	-
Amortization of debt issue costs	76,976	-
Changes in operating assets and liabilities:		
Other receivables	(15,248)	12,375
Prepaid expenses and other current assets	(521,276)	(1,099,209)
Operating lease right-of-use assets	73,779	63,078
Trade accounts payable and accrued expenses	(852,914)	(4,995,037)
Current portion of operating lease liability	(97,518)	14,253
Long-term portion of operating lease liability	-	(97,518)
Net cash used in operating activities	(4,608,282)	(8,746,360)
Investing activities:		
Purchase of property and equipment	-	(81,508)
Net cash used in investing activities	**-**	**(81,508)**
Financing activities:		
Proceeds from the issuance of common stock and pre-funded common stock purchase warrants, net of fees	1,920,357	9,893,450
Principal payments on finance lease obligations	(4,430)	(4,167)
Net cash provided by financing activities	**1,915,927**	**9,889,283**
Cash and cash equivalents:		
Net increase (decrease) in cash and cash equivalents	(2,692,355)	1,061,415
Cash and cash equivalents at beginning of year	12,211,321	52,415
Cash and cash equivalents at end of period	**$ 9,518,966**	**$ 1,113,830**
Cash payments:		
Interest paid	$ 45	$ 308

See notes to consolidated financial statements

(1) Nature of the Business and Liquidity

Organization

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

The consolidated financial statements and notes for the periods ended March 31, 2025 and 2024, represent the full consolidation of Cingulate and its subsidiaries, including Cingulate Therapeutics LLC (CTx) and all references to the Company represent this full consolidation.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception. As a pre-revenue entity, the Company is dependent on the ability to raise capital to support operations until such time as the product candidates under development are U.S. Food and Drug Administration (FDA) approved, manufactured, commercially available to the marketplace and produce revenues. On March 31, 2025, the Company had cash and cash equivalents of approximately $9.5 million, and an accumulated deficit of approximately $112.3 million. However, the Company will need additional funding for operations and development. Management is evaluating various strategies to obtain additional funding, which may include additional offerings of equity, issuance of debt, or other capital sources, including potential collaborations with other companies or other strategic transactions. Successful implementation of these plans involves both the Company's efforts and factors that are outside its control, such as market factors and FDA approval of product candidates. The Company can give no assurance that its plans will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above, which results in substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not reflect any adjustments that might result from the outcome of this uncertainty.

(2) Summary of Significant Accounting Policies

(a) Basis of Presentation and Principles of Consolidation

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

(b) Unaudited Interim Financial Information

The accompanying consolidated balance sheets as of March 31, 2025 and December 31, 2024, the consolidated statements of operations and comprehensive loss for the three-month periods ended March 31, 2025 and 2024, the consolidated statements of stockholders' equity for the three-month periods ended March 31, 2025 and 2024, the consolidated statements of cash flows for the three-month periods ended March 31, 2025 and 2024, and the related interim disclosures are unaudited. These unaudited consolidated financial statements include all adjustments necessary, consisting of only normal recurring adjustments, to fairly state the financial position and the results of operations and cash flows for interim periods in accordance with U.S. GAAP. Interim period results are not necessarily indicative of results of operations or cash flows for a full year or any subsequent interim period. The accompanying consolidated financial statements should be read in conjunction with the Company's 2024 audited consolidated financial statements and the notes thereto.

(c) Concentration of Credit Risk

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

(d) Impairment of Long-lived Assets

The Company assesses the carrying value of its long-lived assets, including property and equipment, as well as lease right of use (ROU) assets, when events or circumstances indicate that the carrying value of such assets may not be recoverable. These events or changes in circumstances may include a significant deterioration of operating results, changes in business plans, or changes in anticipated future cash flows. If an impairment indicator is present, the Company evaluates recoverability by a comparison of the carrying amount of the assets to future undiscounted cash flows expected to be generated by the assets. If the sum of the expected future cash flows is less than the carrying amount, the Company would recognize an impairment loss. An impairment loss would be measured by comparing the amount by which the carrying value exceeds the fair value of the long-lived asset groups. No impairment was recognized during the three-month periods ended March 31, 2025 or 2024.

(e) Stock-Based Compensation

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

(f) Segments

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

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

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development		
Clinical operations	$ 1,107,474	$ 1,077,190
Drug manufacturing and formulation	380,353	341,199
Personnel	561,334	305,952
Regulatory	173,465	82,644
Total research and development	2,222,626	1,806,985
General and administrative		
Personnel	571,530	413,277
Legal and professional fees	505,500	315,685
Occupancy	61,627	100,687
Insurance	195,596	241,524
Other	149,156	70,059
Total general and administrative	1,483,409	1,141,232
Operating loss	(3,706,035)	(2,948,217)
Interest and other income (expense), net	(96,656)	(24,260)
Loss before income taxes	(3,802,691)	(2,972,477)
Income tax benefit (expense)	-	-
Net loss and comprehensive loss	$ (3,802,691)	$ (2,972,477)

(3) Prepaid Expenses and Other Current Assets

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

	March 31, 2025	December 31, 2024
Research and development	$ 409,211	$ 334,692
Professional fees	298,376	-
Marketing fees	125,000	-
Dues and subscriptions	39,750	4,575
Active pharmaceutical ingredients	29,025	29,025
Insurance	22,371	-
Other	20,700	54,865
	$ 944,433	$ 423,157

(4) Property and Equipment

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

	Estimated Useful Life (in years)	March 31, 2025	December 31, 2024
Equipment	2-7	$ 4,358,261	$ 4,358,261
Furniture and fixtures	7	145,754	145,754
Computer equipment	5	46,994	46,994
Leasehold improvements	5	474,462	474,462
Construction-in-process- equipment	-	375,278	375,278
		5,400,749	5,400,749
Less: accumulated depreciation		(3,461,365)	(3,296,074)
		$ 1,939,384	$ 2,104,675

Depreciation expense was $165,291 and $163,600, respectively, for the three-month periods ended March 31, 2025 and 2024.

(5) Accrued Expenses

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

	March 31, 2025	December 31, 2024
Research and development	$ 338,007	$ 341,956
Interest	140,114	15,089
State franchise taxes	34,750	200,000
CIP- Equipment	31,160	31,160
Other	22,809	56,476
Employee compensation	20,000	355,475
Professional fees	15,000	5,000
Insurance	-	34,469
	$ 601,840	$ 1,039,625

(6) Contingencies

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

The Company records legal costs associated with loss contingencies as incurred and establishes reserves when those matters present material loss contingencies that management determines to be both probable and reasonably estimable in accordance with ASC 450, *Contingencies.* If a range of loss is estimated, and some amount within that range appears to be a better estimate than any other amount within that range, then that amount is accrued. If no amount within the range can be identified as a better estimate than any other amount, we accrue the minimum amount in the range. These amounts are not reduced by amounts that may be recovered under insurance or claims against third parties, but undiscounted receivables from insurers or other third parties may be accrued separately if recovery is considered probable. Management's judgment is required related to loss contingencies because the outcomes are difficult to predict, and the ultimate resolution may differ from our current analysis. The Company revises accruals in light of new information. While it is not possible to predict the outcome of loss contingencies with certainty, management is of the opinion that adequate provision for potential losses associated with any such matters has been made in the financial statements. No accruals for loss contingencies were recorded in the consolidated balance sheets as of March 31, 2025 or December 31, 2024.

In December 2023, the Company implemented salary reductions for all employees and the Board approved a contingent bonus plan in which the Company will pay to each employee three months after the filing date of the New Drug Application for CTx-1301, an amount equal to the base salary that was not paid to the employee plus 20%. Base salaries were reinstated in September 2024. This contingent bonus had not yet been deemed probable as of March 31, 2025 per the requirements of ASC Topic 450, *Contingencies*, thus was not recorded in the financial statements; however, it is reasonably possible that it will become due. The unpaid salary amounts plus 20%, estimated to be $722,824, may be paid in a combination of cash and equity awards, at the discretion of the Board.

(7) Unsecured Promissory Note

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

From time to time, beginning on July 2, 2025, Lender may redeem a portion of the Promissory Note, not to exceed an amount of $550,000 per month. In the event the Promissory Note is outstanding on the 90-day anniversary of the effective date of the Promissory Note, the Company will be charged and record a monitoring fee equal to the outstanding principal balance on such date divided by 0.85 less the outstanding balance on such date. The monitoring fee and interest accrued on the monitoring fee will be forgiven, on a pro rata basis, each time the Company makes a cash payment on the Promissory Note. Subject to the terms and conditions set forth in the Promissory Note, the Company may prepay all or any portion of the outstanding balance of the Promissory Note at any time.

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

In connection with the Promissory Note, the Company incurred $46,277 of debt issuance costs. The debt issuance costs, the debt discount of $450,000 and the expenses payable by the Company of $30,000 have been recorded as a reduction in the carrying amount of the Promissory Note and are being amortized over the term of the Promissory Note using the effective interest rate method. As of March 31, 2025, the collective amount of unamortized debt discount and debt issuance costs were $431,366, respectively.

As of March 31, 2025, the outstanding principal balance of the Promissory Note plus accrued interest was $5,620,114.

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

	Three Months Ended March 31,	
	2025	**2024**
Interest expense - Streeterville Capital	$ 209,671	$ -
Interest expense - other	45	308
Interest expense - WFIA	-	31,250
Interest income	(112,932)	(7,298)
	$ 96,784	$ 24,260

(8) Stockholders' Equity

The Company has authorized 240,000,000 shares of $0.0001 par value common stock and 10,000,000 shares of $0.0001 par value preferred stock at March 31, 2025 and December 31, 2024, of which 3,826,199 and 3,402,306 shares of common stock were issued and outstanding, respectively. The Company has not issued any shares of preferred stock.

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

Reverse Stock Splits

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

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

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

(9) Securities Issuances

At the Market Offering

The Company entered into the At-the-Market Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC (HCW) in January 2023, as amended in May 2023, pursuant to which the Company can issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $23.5 million in at-the-market offerings sales. HCW acts as sales agent and is paid a 3% commission on each sale under the ATM Agreement. The Company's common stock is sold at prevailing market prices at the time of the sale, and, as a result, prices will vary.

During the three months ended March 31, 2025 and 2024, the Company sold 200,484 and 23,650 shares of common stock, respectively, under the ATM Agreement, for net proceeds of $1,020,368 and $3,115,303.

Purchase Agreement with Lincoln Park

In April 2023, the Company entered into a purchase agreement (the LP Purchase Agreement) and a registration rights agreement (the Registration Rights Agreement) with Lincoln Park Capital Fund, LLC (Lincoln Park). Pursuant to the terms of the LP Purchase Agreement, Lincoln Park has agreed to purchase from the Company up to $12 million of the Company's common stock subject to certain limitations and satisfaction of the conditions set forth in the LP Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, the Company filed with the SEC registration statements to register for resale under the Securities Act 2,685,417 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement.

During the three months ended March 31, 2025, the Company sold 223,409 shares of common stock under the LP Purchase Agreement, for net proceeds of $899,989.

(10) Stock-Based Compensation

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

At the Company's 2024 annual meeting, shareholders approved an amendment to the 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder by 104,167 shares to 125,577. As of March 31, 2025, 4,000 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 $357,649 and $164,575 during the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025 and December 31, 2024, there was $1,026,469 and $343,612, respectively, of unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the 2021 Plan, which is expected to be recognized over the next one to four years.

A summary of option activity under the 2021 Plan during the three-month periods ended March 31, 2025 and 2024 is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2024	4,821			
Granted	15,994	$ 14.15	9.93	-
Exercised	-			
Forfeitures or expirations	(628)			
Outstanding at March 31, 2024	20,187			
Vested and expected to vest at March 31, 2024	20,187			
Exercisable at March 31, 2024	1,945			
Outstanding at January 1, 2025	89,406			
Granted	248,428	$ 4.44	9.87	-
Exercised	-			
Forfeitures or expirations	-			
Outstanding at March 31, 2025	337,834			
Vested and expected to vest at March 31, 2025	337,834			
Exercisable at March 31, 2025	124,069			

The Company's stock options issued qualify for equity accounting treatment under ASC 718, *Compensation- Stock Compensation,* and are measured at fair value as of their grant date accordingly. The fair value of the options were estimated using a Black-Scholes model. The assumptions that the Company used to estimate the grant-date fair value of stock options granted to employees and directors during the three-month periods ending March 31, 2025 and 2024 were as follows, shown on a weighted average basis:

	March 31, 2025	March 31, 2024
Risk-free interest rate	4.43%	3.980%
Expected term (in years)	5.79	5.55
Expected volatility	1.63	1.56
Expected dividend yield	0%	0%

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

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

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

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

The grant-date fair value of options granted during the three months ended March 31, 2025 ranged from $4.20 to $4.22 and the grant-date fair value of options granted during the three months ended March 31, 2024 ranged from $0.81 to $1.53.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock. Because there were no stock options with exercise prices lower than the fair value of the Company's common stock, the aggregate intrinsic value is zero as of March 31, 2025 and December 31, 2024.

(11) Common Stock Purchase Warrants

The following table summarizes the Company's outstanding common stock purchase warrants as of March 31, 2025:

	Number of Warrants	Exercise Price	Issuance Date Fair Value per Warrant	Issuance Date Fair Value Total
December 2021 Initial Public Offering Warrants	19,965	$ 1,440.00	$ 1,144.80	$ 22,855,932
December 2021 Placement Agent Warrants	868	$ 1,800.00	$ 1,113.48	966,501
September 2023 Public Offering Series A Warrants	28,855	$ 13.56	$ 129.84	3,746,533
September 2023 Public Offering Series B Warrants	14,428	$ 13.56	$ 101.04	1,457,805
September 2023 Placement Agent Warrants	1,443	$ 172.80	$ 127.56	184,069
February 2024 Public Offering Series A Warrants	135,417	$ 24.00	$ 14.04	1,901,255
February 2024 Public Offering Series B Warrants	67,708	$ 24.00	$ 11.88	804,371
February 2024 Placement Agent Warrants	12,500	$ 30.00	$ 13.80	172,500
June 2024 Series C Warrants	354,167	$ 7.020	$ 3.24	1,147,501
June 2024 Series D Warrants	177,083	$ 7.020	$ 2.40	424,999
July 2024 Placement Agent Warrants	21,250	$ 8.780	$ 2.23	47,388
Balance- March 31, 2025	833,684			$ 33,708,854

(12) Income Taxes

Cingulate Inc. is taxed as a C corporation under the Internal Revenue Code. Cingulate Inc. records deferred income taxes to reflect the impact of temporary differences between the recorded amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws and regulations. CTx is a wholly-owned disregarded entity of Cingulate Inc., and all of the activity for CTx, along with its wholly-owned subsidiary Cingulate Works Inc., is included in the calculation of the current and deferred tax assets and liabilities for Cingulate Inc. No deferred income tax benefit or expense was recorded for the three-month periods ended March 31, 2025 and 2024 for federal or state income taxes.

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

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Federal income tax benefit at statutory rate	$ (798,576)	$ (588,266)
State income tax benefit	(194,464)	(154,910)
Permanent differences	3,304	3,654
Change in valuation allowance	989,993	770,439
Other	(257)	(30,917)
Total income tax expense	$ -	$ -

Evaluating the need for, and amount of, a valuation allowance for deferred tax assets often requires significant judgment and extensive analysis of all available evidence on a jurisdiction-by-jurisdiction basis. Such judgments require the Company to interpret existing tax law and other published guidance as applied to its circumstances. As part of this assessment, the Company considers both positive and negative evidence about its profitability and tax situation. A valuation allowance is provided if, based on available evidence, it is more likely than not that all or some portion of a deferred tax asset will not be realized. The Company determined that it was more likely than not that it would not realize its deferred tax assets, based on historical levels of income and future forecasts of taxable income, among other items. The Company recorded a valuation allowance of its net deferred tax assets totaling $18,423,145 as of March 31, 2025 and $17,405,569 at December 31, 2024, the current year portion which was recorded as a component of income tax expense on the accompanying consolidated statements of operations and 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 March 31, 2025 or December 31, 2024.

(13) Subsequent Events

Management evaluated events that occurred subsequent to March 31, 2025, through May 8, 2025, which is the date the interim financial statements were issued.

On April 8, 2025, the Company entered into a Grant Agreement (the “Grant Agreement”) with a private family foundation (the “Foundation”). Pursuant to the Grant Agreement, the Company will receive a grant of $3 million in three equal payments of $1 million (the “Grant Funds”) to support the clinical and manufacturing development of CTx-2103 (Buspirone) (the “Purpose”). The first payment is expected to be received in May 2025, the second payment is expected to be received upon completion of a formulation study for CTX-2103, and the third payment is expected to be received upon completion of development batches required for CTx-2103. The Company is not required to return any Grant Funds received from the Foundation unless the Purpose has ended, in which case the Company will return any remaining Grant Funds to the Foundation. The Company will pay the Foundation a royalty, contingent on the commercialization of CTx-2103, of $500,000 per quarter, beginning six months after the first sale of CTx-2103, with a maximum cumulative payout of $3.5 million.

Subsequent to March 31, 2025, the Company sold 205,826 shares of common stock under the ATM Agreement, for net proceeds of $868,520.

Subsequent to March 31, 2025, the Company sold 197,104 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of $749,991.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2024 (Form 10-K) and in this report, as well as disclosures in this report and our other reports filed with the SEC, for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company using our proprietary Precision Timed Release™ (PTR™) drug delivery platform technology to build and advance a pipeline of next-generation pharmaceutical products designed to improve the lives of patients suffering from frequently diagnosed conditions characterized by burdensome daily dosing regimens and suboptimal treatment outcomes. With an initial focus on the treatment of Attention Deficit/Hyperactivity Disorder (ADHD) and anxiety, we are identifying and evaluating additional therapeutic areas where our PTR technology may be employed to develop future product candidates. Our PTR platform incorporates a proprietary Erosion Barrier Layer (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, primarily CTx-1301, organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting clinical trials. We do not have any product candidates approved for sale and have not generated any revenue. We have funded our operations through public and private capital raised. Cumulative capital raised from these sources, including debt financing, was approximately $109.3 million as of March 31, 2025.

We have incurred significant losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and commercialization of one or more of our product candidates. Our net losses were $3.8 million and $3.0 million for the three months ended March 31, 2025 and 2024, respectively. See "Results of Operations" below for an explanation of the fluctuations in our net losses. As of March 31, 2025, we had an accumulated deficit of $112.3 million.

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

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

We are targeting to file our NDA submission for CTx-1301 in mid-2025 and believe our cash will satisfy our capital needs into the fourth quarter of 2025 under our current business plan. We will need additional capital to advance our other programs and commercialization efforts for CTx-1301. See "Liquidity and Capital Resources" below.

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

Clinical, Manufacturing and Business Update

CTx-1301: We have designed our clinical program for CTx-1301 (dexmethylphenidate), our lead investigational product candidate for the treatment of ADHD, based on U.S. Food and Drug Administration (FDA) feedback regarding our CTx-1301 clinical plan, and longstanding guidance on the streamlined approval pathway under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

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

We initiated two CTx-1301 Phase 3 clinical studies in pediatric and adolescent patients- a fixed dose study and a dose-optimized onset and duration study in a laboratory classroom setting in the third quarter of 2023. Based upon written communication with the FDA that further conduct of these pediatric and adolescent studies is not required for the submission of an NDA, we closed enrollment on both Phase 3 trials. We are performing the data consolidation and analytical activities for these trials. Analysis of the safety data from the two closed Phase 3 trials and the 50mg dose food effect study revealed that no subjects experienced a serious treatment emergent adverse event (TEAE), a serious TEAE or a TEAE leading to death and there were no clinically relevant trends in TEAEs overall. A final analysis that combines both adult and pediatric safety and efficacy data will be included in the NDA submission for CTx-1301.

On April 2, 2025, we held a Pre-NDA meeting with FDA to discuss the NDA submission for CTx-1301, targeted for a mid-2025.

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

On April 8, 2025, we entered into a Grant Agreement (the "Grant Agreement") with a private family foundation (the "Foundation"). Pursuant to the Grant Agreement, we received a grant of $3 million in three equal installments of $1 million (the "Grant Funds") to support the clinical and manufacturing development of CTx-2103 (the "Purpose). The first installment is expected to be received in May 2025, the second installment is expected to be received upon completion of a formulation study for CTX-2103, and the third installment is expected to be received upon completion of development batches required for CTx-2103. We are not required to return any Grant Funds received from the Foundation unless the Purpose has ended, in which case we will return any remaining Grant Funds to the Foundation. We will pay the Foundation a royalty, contingent on the commercialization of CTx-2103, of $500,000 per quarter, beginning six months after the first sale of CTx-2103, with a maximum cumulative payout of $3.5 million.

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

We continue to evaluate strategic partnerships under which we would license CTx-1301 in the United States and/or internationally. In March 2023, we entered into a joint commercialization agreement, which was replaced with a master services agreement in May 2025 with Indegene, Inc. (Indegene) in the United States . We are able to utilize Indegene for commercialization services for CTx-1301, including marketing, sales, market access and distribution, on a fee for service, at our discretion.

Securities Issuances

ATM Agreement

We entered into an At The Market Offering Agreement (ATM Agreement) with H.C. Wainwright & Co., LLC (HCW), as sales agent, in January 2023 as amended in May 2023, pursuant to which we may offer and sell, from time to time through HCW, shares of our common stock for aggregate proceeds of up to $23.5 million based on prospectus supplements filed with the SEC through the date of this report (upon the terms and subject to the conditions and limitations set forth in the ATM Agreement). In the three months ended March 31, 2025, we sold 200,484 shares of common stock under the ATM Agreement, for net proceeds of $1,020,368, after deducting $33,754 of compensation to HCW and other administration fees. Subsequent to March 31, 2025, we sold 205,826 shares of common stock under the ATM Agreement, for net proceeds of $868,520, after deducting $30,617 of compensation to HCW and other administration fees.

Equity Line of Credit

In April 2023, we entered into a purchase agreement (Lincoln Park Agreement) with Lincoln Park Capital Fund LLC (Lincoln Park). Pursuant to the Lincoln Park Agreement, Lincoln Park has agreed to purchase from us up to an aggregate of $12.0 million of common stock (upon the terms and subject to the conditions and limitations set forth in the Lincoln Park Agreement) from time to time and at our sole discretion over the 36-month term of the Lincoln Park Agreement. During the quarter ended March 31, 2025, we sold 223,409 shares of common stock under the Lincoln Park Agreement, for net proceeds of $899,989. Subsequent to March 31, 2025, we sold 197,104 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of $749,991.

Components of Operating Results

Revenue

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

Operating Expenses

Research and Development Expenses

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

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

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

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

General and Administrative Expenses

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

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

Interest and other income (expense), net

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Results of Operations

Comparison of the three months ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,			
(in thousands)	2025	2024	Increase	% Increase
Operating Expenses:				
Research and development	$ 2,223	$ 1,807	$ 416	23.0%
General and administrative	1,483	1,141	342	30.0%
Operating Loss	(3,706)	(2,948)	758	25.7%
Interest and other income (expense), net	(97)	(24)	73	304.2%
Net Loss	$ (3,803)	$ (2,972)	$ 831	28.0%

Research and development expenses

The following table summarizes our research and development (R&D) expenses for the three months ended March 31, 2025 and 2024:

(in thousands)	Three Months Ended March 31, 2025	2024	Increase	% Increase
Clinical operations	$ 1,108	$ 1,077	$ 31	2.9%
Drug manufacturing and formulation	380	341	39	11.4%
Personnel expenses	561	306	255	83.3%
Regulatory costs	174	83	91	109.6%
Total research and development expenses	$ 2,223	$ 1,807	$ 416	23.0%

R&D expenses were $2.2 million for the three months ended March 31, 2025, an increase of $0.4 million or 23.0% from the three months ended March 31, 2024. This change was primarily the result of an increase in personnel expenses and regulatory costs in the three months ended March 31, 2025 as compared to the same period in 2024. The increase in personnel costs is the result of the reinstatement of base salaries in September 2024 following salary reduction measures which had been implemented in late 2023. Regulatory costs increased in the three months ended March 31, 2025 as compared to the same period in 2024 due to preparation for the pre-NDA meeting with the FDA.

General and administrative expenses

The following table summarizes our general and administrative (G&A) expenses for the three months ended March 31, 2025 and 2024:

(in thousands)	Three Months Ended March 31, 2025	2024	Increase (Decrease)	% Increase (Decrease)
Personnel expenses	$ 571	$ 413	$ 158	38.3%
Legal and professional fees	505	316	189	59.8%
Occupancy	62	101	(39)	(38.6%)
Insurance	196	241	(45)	(18.7%)
Other	149	70	79	112.9%
Total general and administrative expenses	$ 1,483	$ 1,141	$ 342	30.0%

Total G&A expenses were $1.5 million for the three months ended March 31, 2025, an increase of $0.3 million or 30.0% from the three months ended March 31, 2024. This is primarily the result of an increase in legal and professional fees and personnel expenses. The increase in professional fees was due to an increase in certain financial, accounting and investor relations fees. The increase in personnel costs is the result of reinstatement of base salaries in September 2024 following salary reduction measures which had been implemented in late 2023.

Interest and other income (expense), net

The following table summarizes interest and other income (expense), net for the three months ended March 31, 2025 and 2024:

(in thousands)	Three Months Ended March 31, 2025	2024	Increase	% Increase
Interest and other income (expense), net	$ (97)	$ (24)	$ 73	304.2%

Total interest and other income (expense), net for the three months ended March 31, 2025 and March 31, 2024 relates to interest incurred on outstanding notes payable, offset by interest earned on invested balances. The increase in interest expense for the period ended March 31, 2025 is related to interest expense incurred on the $5.4 million promissory note which was executed in December 2024.

Cash Flows

	Three Months Ended March 31, 2025	2024
Net cash (used in) operating activities	$ (4,608)	$ (8,746)
Net cash (used in) investing activities	-	(82)
Net cash (used in) financing activities	1,916	9,889
Net increase (decrease) in cash and cash equivalents	$ (2,692)	$ 1,061

Cash Flows from Operating Activities

Net cash used in operating activities was $4.6 million for the three months ended March 31, 2025. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $3.8 million, prior to the effects of two noncash items, stock-based compensation expense of $0.4 million and depreciation expense of $0.2 million. Changes in operating assets and liabilities included a decrease in trade accounts payable and accrued expenses of $0.9 million primarily due to the payment of vendor balances in the first quarter of 2025 and an increase in prepaid expenses and other current assets of $0.5 million primarily due to payments for professional and marketing fees.

Net cash used in operating activities was $8.7 million for the three months ended March 31, 2024. Cash used in operating activities was primarily due to the use of funds in our operations to develop our product candidates resulting in a net loss of $3.0 million, prior to the effects of two noncash items, stock-based compensation expense of $0.2 million and depreciation expense of $0.2 million. Changes in operating assets and liabilities included an increase in prepaid expenses and other current assets of $1.1 million primarily due to a deposit made to Societal CDMO, Inc., our contract manufacturing organization (CMO), for registration batch activity for CTx-1301. In addition, there was a decrease in trade accounts payable and accrued expenses of $5.0 million due to the payment of vendor balances with the cash proceeds from the issuance of common stock pursuant to our ATM Agreement in January 2024 and the issuance of equity in February 2024.

Cash Flows from Investing Activities

Net cash used in investing activities for the three months ended March 31, 2024 was primarily related to the purchase of equipment to support our research and development.

Cash Flows from Financing Activities

Net cash provided by financing activities for the three-month period ended March 31, 2025 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement and the Lincoln Park Agreement.

Net cash provided by financing activities for the three months ended March 31, 2024 was related to the cash proceeds from the issuance of common stock pursuant to the ATM Agreement in January 2024 and the issuance of common stock in February 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2012 through March 31, 2025, we have not generated any revenue and have incurred significant operating losses and negative cash flow from our operations.

In the three months ended March 31, 2025, we sold 200,484 shares of common stock under the ATM Agreement, for net proceeds of $1,020,368, after deducting $33,754 of compensation to HCW and other administration fees. Subsequent to March 31, 2025, we sold 205,826 shares of common stock under the ATM Agreement, for net proceeds of $868,520, after deducting $30,617 of compensation to HCW and other administration fees.

During the three months ended March 31, 2025, we sold 223,409 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of $899,989. Subsequent to March 31, 2025, we sold 197,104 shares of common stock under the Lincoln Park Purchase Agreement, for net proceeds of $749,991.

As of March 31, 2025, we had cash and cash equivalents of $9.5 million. We believe our cash will satisfy our capital needs into the fourth quarter of 2025 under our current business plan, which is beyond the targeted date to file our NDA submission for CTx-1301 of mid-2025. We will need additional capital to advance our commercialization efforts for CTx-1301 as well as our other programs. Changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents are invested primarily in money market funds which are currently providing only a minimal return given the current interest rate environment.

We expect to continue to incur substantial additional operating losses for the near term as we continue to develop our product candidates, primarily CTx-1301 and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

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

- the cost and timing of manufacturing the clinical supply of our product candidates;
- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the clinical development plans we establish for each product candidate;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration or license agreements we may choose to execute;

- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the cost and timing of the implementation of commercial scale manufacturing activities; and
- the cost and timing of outsourcing our commercialization efforts, including, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, including clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or licensing arrangement. We are actively seeking a strategic pharmaceutical partnership under which we would license CTx-1301 in the United States, internationally, or both. In March 2023, we entered into a joint commercialization agreement, which was replaced with a master services agreement in May 2025, with Indegene. Should we be unable to identify an appropriate pharmaceutical partnership, if we receive FDA approval for CTx-1301, Indegene would provide commercialization services for CTx-1301, including marketing, sales, market access and distribution, on a fee for service basis.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

For example, pursuant to the Note Purchase Agreement, we are subject to certain restrictions on our ability to issue securities during the term of the Note. Specifically, we have agreed, among other things, to obtain Lender's consent prior to issuing any debt securities or certain equity securities where the pricing of such equity securities is tied to the public trading price of our common stock and to refrain from entering into any agreement or covenant that locks up, restricts or otherwise prohibits us from entering into a variable rate transaction with Lender or any of its affiliates, or from issuing common stock or other equity or debt securities to Lender or any of its affiliates. If we are unable to obtain Lender's consent prior to issuing any debt or certain equity securities, such issuance may be a breach of the Note Purchase Agreement, and we may be obligated to indemnify Lender for loss or damage arising as a result of any breach or alleged breach by us of the Note Purchase Agreement, which may affect our business operations and financial condition. Additionally, the Note provides that following an event of default under the Note, Lender has the right to seek and receive injunctive relief from a court or an arbitrator prohibiting us from issuing any of our common stock or preferred stock to any party unless fifty percent of the gross proceeds received by us in connection with such issuance are simultaneously used to make a payment under the Note. Lender also has the right to seek and receive injunctive relief from a court or arbitrator to prevent the consummation of any fundamental transaction, as defined in the Note, unless it contains a closing condition that the Note is paid in full upon consummation of the transaction or Lender has provided its written consent to such transaction.

Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

Contractual Obligations

The following summarizes our contractual obligations as of March 31, 2025 that will affect our future liquidity.

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

We entered into agreements with Societal, our CMO, for both the manufacturing of pre-process validation batches of our lead asset, CTx-1301 and active pharmaceutical ingredients and materials to be used in process validation batches with a total estimated cost of approximately $1.8 million.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change that is largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for one year after the issuance date of our financial statements. The accompanying consolidated financial statements have been prepared on a going concern basis. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We have incurred a net loss for the three months ended March 31, 2025 and 2024 and had accumulated losses of $112.3 million since inception to March 31, 2025. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our sources of capital have included private capital raises in various classes of units of CTx prior to the Reorganization Merger, the issuance of equity securities in connection with our initial public offering (IPO), public offerings, including the September 2023 Offering and the February 2024 Offering, sales of common stock under our ATM Agreement and Lincoln Park Agreement, a private placement with WFIA, the WFIA Note, which was subsequently converted to equity, the June 2024 Warrant Inducement and the issuance of the Promissory Note in December 2024. Additional capital will be needed by us to fund our operations, to complete development of and to commercially develop our product candidates. There is no assurance that such capital will be available when needed or on acceptable terms.

JOBS Act

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Our Disclosure Controls

We maintain a system of disclosure controls and procedures that is designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Our 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 March 31, 2025, have concluded that our disclosure controls and procedures were effective as of March 31, 2025.

Evaluation of Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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

Except as set forth below, there were no material changes to the risk factors previously disclosed in our Form 10-K.

Item 5. Other Information

Rule 10b5-1 Trading Arrangements

In the first quarter of 2025, no director or officer (as defined in Exchange Act Rule 16a-1(f)) of the Company adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement for the purchase or sale of securities of the Company, within the meaning of Item 408 of Regulation S-K.

Agreement with Indegene, Inc.

On March 7, 2023, we entered into a Joint Commercialization Agreement (the "Commercialization Agreement") with Indegene, Inc. ("Indegene"). On May 7, 2025, the Commercialization Agreement was terminated and we and Indegene entered into a Master Services Agreement (the "Indegene MSA").

Like the Commercialization Agreement prior to its termination, the Indegene MSA governs the general terms under which Indegene will provide commercialization services, upon our request. Pursuant to the Indegene MSA, the parties will enter into statements of work that will set forth, among other things, the services to be performed by Indegene, the deliverables for such services, and the fees to be paid by us. Each statement of work will be governed by the terms of the Indegene MSA unless expressly modified in such statement of work. We may elect to receive the following services from Indegene: (a) medical affairs & pharmacovigilance; (b) pricing, reimbursement and market access; (c) commercial operations; and (d) marketing (including field force).

In the event that we intend to outsource any services within the scope of services that Indegene has the capability to perform, we shall allow Indegene to participate in our request for proposals; provided, that we may, in our sole discretion, select the party that will provide such services.

Indegene personnel will not be assigned to or interact with any other Indegene customer engaged in similar or competing projects within the same therapeutic area for which such personnel are providing services to us. This restriction does not restrict Indegene from offering similar or competing services to other customers through separate personnel, teams or affiliates; provided, that Indegene complies with the terms and conditions of the Indegene MSA, including the confidentiality provisions.

The Indegene MSA has a three-year term. The Indegene MSA may not be terminated for convenience during the initial twelve (12) months following the first commercial sale of CTx-1301 or eighteen (18) months from the effective date of the Indegene MSA, whichever is earlier. Thereafter, either party may terminate the Indegene MSA upon six (6) months prior written notice to the other party. Either party may terminate the Indegene MSA upon thirty (30) days prior, written notice for material, uncured breaches or immediately in the event of the other party's bankruptcy.

The Indegene MSA contains representations, warranties, confidentiality and indemnity obligations customary for agreements of this type.

The description of the Indegene MSA does not purport to be complete and is qualified in its entirety by reference to the full text of the Indegene MSA, which has been filed as Exhibit 10.4 to this report and is incorporated herein by reference.

Item 6. Exhibits

		Incorporated by Reference		
Exhibit Number	**Exhibit Description**	**Form**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation of Cingulate Inc., as amended to date	10-Q	3.1	8/13/2024
3.2	Amended and Restated Bylaws of Cingulate Inc.	10-K	3.2	3/28/2022
10.1	Amendment to Employment Agreement, effective January 1, 2025, between Cingulate Therapeutics LLC and Matthew N. Brams	8-K	10.1	1/24/2025
10.2	Amendment No. 1 to Master Services Agreement, effective February 12, 2025, between Cingulate Therapeutics LLC and Societal CDMO, Inc. (DBA Bend Biosciences)	10-K	10.3	3/27/2025
10.3	Grant Agreement dated April 8, 2025	8-K	10.1	4/9/2025
10.4*	Master Services Agreement, effective May 7, 2025, between Indegene, Inc. and Cingulate Therapeutics LLC			
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.			
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH*	Inline XBRL Taxonomy Extension Schema			
101.CAL*	Inline XBRL Extension Calculation Linkbase			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase			
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase			
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase			
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)			

* Filed Herewith

** Furnished Herewith

SIGNATURES

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

CINGULATE INC.

Date: May 8, 2025

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

Date: May 8, 2025

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

Exhibit 10.4

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "**Agreement**") is made on May 7, 2025 (the "**Effective Date**") by and between **Indegene, Inc.,** a Delaware corporation having its place of business at Suite 104, 150 College Road W, Princeton, NJ 08540 (hereinafter referred to as "**Indegene**") and **Cingulate Therapeutics LLC**, a Delaware limited liability company having its corporate office at 1901 W 47th Place, 3rd Floor, Kansas City, KS 66205 (hereinafter referred to as "**Cingulate**"). Indegene and Cingulate may be referred to individually as a "**Party**" and together referred to as the "**Parties**". Capitalized terms in the Agreement not otherwise defined shall have the meaning set forth in Section 1 below.

RECITALS

WHEREAS Indegene is in the business of providing an integrated end-to-end commercialization solution to healthcare organizations and pharmaceutical enterprises including agile operations, co-commercialization and consulting in clinical, regulatory, safety, medical affairs, analytics, pricing, reimbursement & market access, marketing and customer experience;

WHEREAS, during the Term of this Agreement, Indegene is willing to furnish certain services to Cingulate as shall be set forth in one or more Statements of Work;

NOW, THEREFORE, in consideration of the mutual promises, covenants, conditions and provisions contained in or referenced by this Agreement, the Parties have reviewed and accepted all referenced material and any appendices, exhibits or other attachments and agree to be bound by the terms and conditions set forth in this Agreement as follows:

1. DEFINITIONS

Unless the context otherwise requires, when used in this Agreement.

1.1 **"Affiliate"** means, with respect to a Party, any Person, that, directly or indirectly, controls, is controlled by or is under common control with such Party, for so long as such control exists. For purposes of this definition, "control" shall be defined as shall mean direct or indirect ownership of at least fifty percent (50%) of the outstanding voting securities or other equity interests of such Person and the power to direct or cause the direction of the management, policies and affairs of such Person. Neither Party shall be deemed to be an "Affiliate" of the other. A Person shall cease to be an "Affiliate" of a Party hereunder upon the date that such Person no longer satisfies the requirements set forth in this definition. For purposes of this definition only, the term "Person" shall exclude any and all natural persons.

1.2 "**Change Order**" has the meaning set forth in Section 3.1.

1.3 **"Confidential Information"** means any and all information that is disclosed hereunder on or after the Effective Date, whether orally or in means any and all information, including, but not limited to, information relating to products, designs, patents, patent applications, copyrights, target molecules, biological targets, methods of manufacture, development or research or to the business operations that is disclosed hereunder on or after the Effective Date, whether orally or in written, electronic or other tangible form, by or on behalf of a Party or any of its Affiliates (each a "**Disclosing Party**") to, the other Party or any of its Affiliates (each, a "**Receiving Party**"), that in each case: (i) if disclosed in writing or other tangible form, is labeled or identified as "Confidential", "Proprietary" or the like by cover letter or by the use of an appropriate proprietary stamp or legend, prior to or at the time of disclosure by the Disclosing Party to the Receiving Party; (ii) if disclosed in writing or other tangible form and not so labeled or identified, or if disclosed visually or orally, is within thirty (30) days after disclosure described in a written document(s) delivered by the Disclosing Party to the Receiving Party that identifies such information as "Confidential", "Proprietary" or the like and, if applicable, references the place and date of such oral, visual or written disclosure and the names of the Representatives of the Receiving Party to whom such disclosure was made; or (iii) if disclosed in any form, it would be apparent to a reasonable person, familiar with the Disclosing Party's business and the industry in which it operates, that such information is of a confidential or proprietary nature the maintenance of which is important to the Disclosing Party. Notwithstanding anything to the contrary, subject to Cingulate making payment of the applicable, undisputed Fees to Indegene, all Deliverables shall be deemed to be Confidential Information of Cingulate, and not Confidential Information of Indegene (and Cingulate shall be deemed to be the Disclosing Party, and Indegene the Receiving Party, with respect to any such Confidential Information).

1.4 **"Deliverable**" means any reports and other documents, data, information, software, tangible material or other items or work product produced in the course of performing the Services and/or delivered by Indegene to Cingulate as may be specified in the respective SOW or is otherwise provided by Indegene during the Term.

1.5 "**Intellectual Property**" means any and all intellectual property rights including, without limitation, patents (including patent applications and patents arising from such applications, and continuations of or relating to patents), trademarks, copyrights, registered designs, rights of license, assignment, use, right of confidence in know-how or technical or commercial information generally and any other such rights or interests in intellectual property whether or not protected under any law in force.

1.6 "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, Indegene, partnership or other business entity, or any government or agency or political subdivision thereof.

1.7 "**Services**" means the services to be performed by Indegene as set forth in any Statement of Work.

1.8 "**Statement Of Work**" or "**SOW**" means a document which is executed by both Parties which specifies the Services to be obtained by Cingulate from Indegene and shall include a written description in reasonably sufficient detail of (a) the specific Services to be conducted pursuant to such SOW; (b) required Deliverables with respect to such Services and SOW; (c) the fees payable by Cingulate to Indegene for such Services; (d) the key performance indicators ("**KPIs**") and service levels applicable to such SOW, and consequences for failing to meet such KPIs or service levels and (e) any additional terms and conditions agreed to by the Parties (i.e., in addition to those set forth elsewhere in this Agreement) with respect to such SOW.

1.9 "**Subcontractor**" means a third party engaged by Indegene to provide products and/or services used by Indegene in rendering the Services.

2. SCOPE OF SERVICES

2.1 **Services**. During the Term, Indegene will perform such Services for Cingulate as agreed in the respective SOWs. The Parties acknowledge that (a) the required services may vary over time depending on the different stages in Cingulate's overall plans and (b) a list of potential services that may be agreed upon by the Parties in the Statements of Work (is attached to this Agreement as **Appendix-A**). Any deviation to the SOW shall be only through a mutual agreed and executed Change Order. Each SOW shall be subject to the terms and conditions of this Agreement. In the event of a conflict between the terms and conditions of any SOW and this Agreement, the terms and conditions of this Agreement shall control unless such SOW specifically references a Section of this Agreement and expressly states that such Section is intended to be changed or amended by such SOW. Upon execution by both Parties, each SOW shall be incorporated into and made a part of this Agreement. Indegene shall perform all Services using at least commercially reasonable efforts and shall adhere to all key performance indicators, diligence obligations and milestones set forth in the applicable SOW. The Parties acknowledge that payment agreed in the respective SOW for services rendered may include certain risk from Indegene on account of agreed service level and Indegene's performance against the said service level. The Parties shall agree to the specific service levels and the performance matrix in the respective SOWs. Unless, the service level and performance matrix is expressed in the SOW, the same shall not be applicable.

2.2 **Standard of Performance**. Indegene shall perform the Services in accordance the applicable SOW and Change Order (if any) under this Agreement. In addition, Indegene shall perform the Services (a) in conformance with generally accepted professional standards of care and conduct; (b) in compliance with all laws, regulations and guidance (provided, however, that Indegene shall have no liability under this Agreement for any breach of this clause (b) if such breach arises out of Indegene's adherence to an instruction of Cingulate that is inconsistent with this Agreement and Indegene has previously notified Cingulate's CEO, in writing, if Indegene believes that the Company is asking Indegene to act illegally or immorally) and (c) with a level of timeliness, staffing, skill, effort and quality at least as high as that an established, global pharmaceutical company with a portfolio of commercialized, patent-protected pharmaceutical products would achieve in performing similar services for its own account in connection with the pre-launch preparation, launch and post-launch commercialization of a product. Cingulate acknowledges that Indegene's agreement to perform the Services is not a guarantee that such Services will produce specific results.

2.3 **Indegene Right to Participate.** In the event that Cingulate intends to outsource any services within the scope of services that Indegene has the capability to perform, Cingulate shall allow Indegene to participate in Cingulate's request for proposals; provided, that Cingulate may, in its sole discretion, select the party that will provide such services.

3. SERVICES AND PROJECT MANAGEMENT

3.1 **Changes to Services**. Either Party may request a change order ("**Change Order**") in the event of actual or anticipated change(s) to the agreed scope of Services, Deliverables, project schedule, fee, or any other aspect of an applicable Statement of Work. Indegene will prepare a Change Order reflecting the proposed changes, including but not limited to the impact on the Deliverables, project schedule, and fee. Absent a Change Order signed by the Parties, Indegene shall not be bound to perform (and Cingulate shall not be bound to pay for) any additional or out-of-scope services beyond what is stated in any applicable SOW. The Parties agree to negotiate all Change Order requests expeditiously and in good faith. The Parties further agree that Indegene may at its discretion undertake and accomplish tasks of a de minimis nature necessary to perform its obligations under a SOW at no additional cost to Cingulate and without requiring the execution of a Change Order. A template Change Order is attached hereto as **Schedule 2**.

3.2 **Acceptance**. Cingulate may test and review all Deliverables using testing and review procedures agreed by both parties in the respective SOW. The standard of review of the Deliverable(s) shall be a working Deliverable that is in material conformance with any agreed specifications under an applicable SOW and is otherwise free of material defects. Unless otherwise agreed in an applicable SOW, within fifteen (15) days of receipt of any Deliverables (the "**Review Period**"), Cingulate will submit a written statement (a "**Deliverable Review Statement**") to Indegene (or, if specified an applicable SOW, the appropriate Indegene project manager) indicating acceptance of the Deliverable(s) ("**Acceptance**") or specifying in detail how the submitted Deliverable(s) fails to materially conform to the agreed specification(s) or otherwise contains material defects, in which case Indegene shall be afforded a commercially reasonable period of time not less than twenty (20) business days to correct any nonconformities at no cost to Cingulate, whereupon the review cycle will recommence. Deliverables will be deemed to be fully and finally accepted by Cingulate in the event Cingulate has not submitted a Deliverable Review Statement to Indegene before the expiration of the applicable Review Period, or when Cingulate uses the Deliverable in its commercially released product, whichever occurs first. Services provided on time and in material compliance with this Agreement and the applicable SOW are deemed accepted upon provision of the same. Unless otherwise agreed in an applicable SOW, all Deliverables that are provided in physical form will be made available to Cingulate EXW (Incoterms 2020) a facility in the United States designated by Indegene in writing. Cingulate shall pay all costs of shipping, handling and insuring such Deliverables supplied to Cingulate hereunder.

3.3 **Access to Cingulate Facility**. In the event that Indegene is required to provide the Services on-site at Cingulate's facility, Cingulate shall, at no cost to Indegene, provide Indegene and its personnel access to all facilities that may be reasonably required by Indegene for Indegene to provide the Services, including but not limited to computing resources, clerical support and reprographic facilities. Indegene shall follow any applicable policies and procedures provided by Cingulate to Indegene with respect to access to Cingulate's facilities and networks.

3.4 **Service Locations.** Each of the Services shall be provided from the applicable service location expressly set forth in the applicable SOW (the "**Service Locations**"). The Services may only be provided from another Service Location after approval by Cingulate in writing. Indegene shall ensure that each of its Service Locations comply with the safety and security procedures and standards and other requirements set forth in this Agreement.

3.5 **Subcontracting.** Indegene may subcontract any of the Services to any of its Affiliates or to third party provided that (a) Indegene will not subcontract any significant portion of the Services to anyone other than an Affiliate except as expressly set forth in a SOW or as otherwise approved by Cingulate in writing (such approval not to be unreasonably withheld) and (b) in all cases, Indegene will be responsible to Cingulate for performance of any Services by any of its Affiliates or other Subcontractors. Indegene will notify and receive consent of Cingulate in case of (a) any material change in the location of the work performed or (b) any significant change in the portion of the Services to subcontractors It is hereby clarified that, Cingulate agrees that, for the term of this Agreement, Cingulate will not (a) enter into any agreement, transaction or arrangement directly or indirectly with any of the Subcontractors which Indegene has mentioned in the SOW (b) by-pass, compete, avoid, circumvent, or attempt to circumvent Indegene by directly receiving services from the Subcontractors named in the SOW without Indegene's prior written approval. Any breach of this clause shall be a material breach deemed an attempt to circumvent Indegene.

3.6 **Service Personnel.**

a. **Service Personnel Qualifications.** Indegene shall ensure that all personnel who provide any of the Services (the "**Service Personnel**") are, and at all times while they are involved in providing the Services shall be: (i) of suitable experience, training and skills to provide the Services pursuant to such SOW, including properly trained personnel fluent in the English language, (ii) adequately experienced and trained by Indegene, before such Indegene personnel are assigned to perform the Services pursuant to such SOW and (iii) authorized to work in the country in which the Service Location is located. Indegene shall provide Cingulate with resumes and any other documents required by Cingulate to determine the qualifications of each proposed Service Personnel. Indegene shall ensure that all Service Personnel comply with all applicable provisions of this Agreement.

b. **Service Personnel Roster.** Indegene will maintain and provide Cingulate with real-time access to an up-to-date roster of all Service Personnel.

c. **Background Screening Requirements.** Indegene will ensure that each of the Service Personnel have passed the background check and exclusion screening requirements set forth in the applicable SOW (the "**Background Screening Requirements**") before such Service Personnel begins any work on the Services. Indegene will provide Cingulate with all results of the Background Screening Requirements upon request, except for any information that Indegene cannot provide under applicable law.

d. **Service Personnel Restrictions; Exclusivity.** Service Personnel shall not be assigned to or interact with any other Indegene customer engaged in similar or competing projects within the same therapeutic area for which such Service Personnel are providing Services to Cingulate ("**Competing Projects**"). Indegene shall implement appropriate internal safeguards, including industry-standard information and physical, operational, and technological separation to prevent the exchange of Confidential Information between Service Personnel and Indegene personnel providing services to other Indegene customers engaged in Competing Projects.

The exclusivity obligations under this Section apply solely to the Service Personnel and do not restrict Indegene from offering similar or competing services to other customers, including Competing Projects, through separate personnel, teams or Affiliates; provided, that Indegene complies with the terms and Conditions of this Agreement, including the confidentiality provisions.

e. **Dedicated Personnel.** To the extent SOW provides that Indegene will provide Service Personnel who are dedicated to providing Services for Cingulate ("**Dedicated Personnel**"): (i) each individual who is proposed by Indegene to be included in the Dedicated Personnel are subject to being approved by Cingulate in writing before becoming Dedicated Personnel, (ii) each of the Dedicated Personnel shall be dedicated to providing Services solely for Cingulate and (iii) Indegene shall not reassign or replace, or permit the reassignment or replacement of, any Dedicated Personnel unless (A) Indegene has received the prior written consent of Cingulate for such reassignment or replacement or (B) such Dedicated Personnel ceases performance of the Services due to (1) voluntary resignation from employment with Indegene, (2) dismissal from employment with Indegene for misconduct (e.g., fraud, drug abuse or theft), (3) removal of such Dedicated Personnel following his or her failure to perform obligations pursuant to this Agreement or (4) death or disability of such Dedicated Personnel.

f. **Removal of Service Personnel.** Cingulate's CEO may at any time request the removal of any of the Service Personnel from performing Services, with cause (as reasonably determined by Cingulate), and Indegene will immediately comply with such requests and shall provide replacement personnel of necessary skill, knowledge and training, subject to the requirements of this Section 3.6.

g. **Training of New Service Personnel.** During the transition period for new Service Personnel, Indegene shall provide any training necessary to bring them up to date at no charge to Cingulate.

h. **Relationship Manager.** Indegene will appoint a relationship manager for the Services under each SOW who shall: (i) have overall responsibility for managing and coordinating the performance of Indegene's obligations under such SOW; (ii) act as the primary contact person and focal point for all communications related to such SOW; and (iii) be authorized to act for, and on behalf of, Indegene with respect to all matters relating to such SOW. Indegene's appointment of any such project manager shall be subject to Cingulate's prior, written consent.

i. **Responsibility for Service Personnel.** As between the Parties, Indegene will be solely responsible for payment of the Service Personnel's salaries, unemployment insurance, worker's compensation, employee benefits, employee-related taxes and other employment-related charges and deductions. No Service Personnel shall have any entitlement to any compensation from Cingulate or to participate in any benefit plan of Cingulate. Indegene acknowledges that while Cingulate determines the overall strategy and direction of the Services, Cingulate does not exercise any control or influence over the professional judgment of any Service Personnel.

3.7 **Safety and Security Procedures; Data Security Requirements.** Indegene shall maintain and enforce at Indegene's Service Locations safety and security procedures (including, but not limited to, procedures with respect to the screening of employees, physical security procedures and information technology security procedures) that: (i) comply in all respects with the other terms and conditions of this Agreement and (ii) without limiting the foregoing, are at least equal to industry best practices followed at the U.S. facilities of major business process outsourcing companies.

3.8 **DRBC Plan.** Indegene has and at all times shall maintain a disaster recovery and business continuity plan to enable the continued provision of the Services by Indegene at each Service Location in accordance with this Agreement upon the occurrence of any disaster or other business disruption (the "**DRBC Plan**"). A copy of the then-current DRBC Plan will be provided by Indegene to Cingulate upon request. Indegene will test the DRBC Plan on an annual basis and will provide Cingulate with the results of such testing upon request. In addition, Indegene will review the DRBC Plan on an annual basis and update the DRBC Plan to align with then-current best practices prevalent in the business process outsourcing industry. Indegene will consult with Cingulate with respect to any such updates and will provide Cingulate with a copy of each updated DRBC Plan.

3.9 **Third Party Audit**. Indegene will have an independent third-party audit firm conduct, on an annual basis for as long as the Services are being provided, a SOC 1 (SSAE16), if required and agreed under SOW and SOC 2 Type II (with trust principles of Confidentiality, Integrity, Availability, Security and Privacy) audits with respect to Indegene, including its control policies and procedures at all Service Locations. Indegene will provide Cingulate with copies of all reports generated pursuant to such audits and will promptly correct all deficiencies identified in such audit reports. Indegene will provide a bridge letter for any interim period as requested by Cingulate's external audit firm. Please note that with respect to financial reporting controls as envisaged under SOC 1 (SSAE16), Indegene shall furnish it's audited financial statements audited by an independent auditor under the Companies Act of India, 2013 which provides an assurance over financial reporting controls.

3.10 **Access to Deliverables.** Indegene shall at all times provide Cingulate with full access to (and upon Cingulate's request Indegene shall promptly deliver to Cingulate) copies of any and all Deliverables, regardless of the stage of completion, as well as any data, information and materials made available to Indegene by or on behalf of Cingulate.

3.11 Records and Audit.

a. **Records.** At its own expense, Indegene will create and maintain all records reasonably documenting the performance of the Services, including, but not limited to: (i) records related to any payments made in connection with the Services, (ii) records to support the accuracy and completeness of any Deliverables and (iii) any records that are expressly required to be created or maintained under any Statement of Work or applicable laws or regulations (collectively, "**Records**"). Indegene will maintain all Records for the longer of (i) five (5) years from the date of creation or (ii) any period prescribed by applicable law or stated expressly in this Agreement. During the Term (as defined below) and thereafter for as long as Indegene is required to maintain the Records, Indegene will allow Cingulate to inspect (and, upon request, Indegene will promptly furnish Cingulate with copies of) all Records.

b. **Audit by Cingulate.** During the Term, upon reasonable notice and at reasonable times, no more than once per calendar year, Cingulate will have the right to audit and examine all contracts, documents, correspondence, books, time sheets, account records and other material which relate to the Services. This right of audit will extend to the actual performance of Services as well (including, but not limited to, any equipment, other materials and facilities being used in any phase of the conduct of any Services, and the data and results generated from such performance, including, without limitation, notes, schedules, written reports, or other work product, which document work done and results achieved, and quality assurance or control records). Audits may be implemented by any employee, agent, representative, attorney, accountant or auditor authorized by Cingulate. The expense of such audit or examination will be borne by Cingulate except that Cingulate will not be responsible for Indegene's costs incurred in facilitating such audit. Indegene shall address any audit findings in a corrective and preventive action plan that is reasonably acceptable to Cingulate. In addition to Indegene's obligations under Section 3.10 and Section 9.2, it is hereby agreed that after the Term of this Agreement and for a period of one (1) year, Cingulate may request Indegene to provide certain documents and clarifications related to this Agreement for review (at no cost to Indegene) and Indegene will within a reasonable time provide such documents to Cingulate.

4. CONSIDERATION; TERMS OF PAYMENT

4.1 **Fees** - The fees payable for the Services shall be mutually agreed by the Parties and will be detailed in each SOW (the "**Fees**"). Further, it is agreed that, unless otherwise agreed in the SOW, all invoices shall be raised by Indegene at the beginning of the respective month during the Term of the SOW.

4.2 **Taxes**. All sales, use, gross receipts, compensating, value-added, or other taxes, duties, registrations, tariffs, customs fees, license fees, and other amounts assessed by any tax jurisdiction, U.S. Customs or foreign equivalent, or any other regulatory authority (excluding Indegene's net income and franchise taxes) ("**Taxes**"), on or for Services, prior to or upon provision or sale to Indegene or Cingulate, as the case may be, whether assessed on Indegene or Cingulate, are the responsibility of Cingulate, whether paid by Indegene or Cingulate, and either Cingulate shall reimburse Indegene for all such Taxes paid by Indegene or such sums will be added to invoices directed to Cingulate. If any deduction or withholding in respect of Taxes or otherwise is required by law to be made from any of the sums payable hereunder, then such amount will be deducted from such payment and timely paid to the appropriate taxing authority, in which event Cingulate will secure and send to Indegene proof of any such Taxes withheld and paid by Cingulate for the benefit of Indegene, and cooperate with any reasonable request to help ensure that amounts withheld and/or paid are reduced and/or recovered to the extent permitted by the relevant jurisdiction.

4.3 **Payment Terms**. Except for any amounts disputed by Cingulate in good faith, Cingulate shall make payment to Indegene within thirty (30) days of receipt of an invoice from Indegene. Indegene reserves the right to charge interest on undisputed past due amounts from the date past due until paid, at the rate of twelve percent (12%) per annum. In the event of payment default of undisputed fees, Indegene may suspend any or all Services upon ten (10) days written notice to Cingulate and/or to modify the payment terms, and to request full payment before any additional performance is rendered by Indegene.

4.4 **Disputed Payments**. If Cingulate wishes to dispute any amount invoiced by Indegene hereunder, Cingulate must notify Indegene within thirty (30) days after the date of invoice by Indegene, such notice to specify the amount disputed and provide a reasonably detailed description of the basis for such dispute. Invoices not disputed within 30 (thirty) days of receipt shall be deemed undisputed. The Parties shall attempt to resolve any such dispute in good faith. Cingulate shall pay all undisputed amounts within thirty (30) days after the date of invoice by Indegene and may withhold payment only of disputed amounts during the pendency of the Parties attempts to resolve such dispute. Indegene may suspend the provision of all Services during the pendency of any such dispute.

5. REPRESENTATIONS, WARRANTIES AND COVENANTS

5.1 **Mutual Representations and Warranties**. Each Party hereby represents, warrants and covenants to the other Party that, as of the Effective Date and at all times thereafter during the Term:

5.1.1 such Party is duly organized and validly existing under the laws of the jurisdiction of its incorporation or organization.

5.1.2 such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

5.1.3 this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium, and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any third party the right to accelerate, terminate or modify any agreement or instrument to which such Party;

5.1.4 such Party has and shall maintain all right, power, and authority to enter into this Agreement and to perform its obligations under this Agreement (including, without limitation, to make the assignments and grant the licenses made and granted hereunder);

5.1.5 no consent by any third party or governmental body is required with respect to the execution and delivery of this Agreement; and

5.1.6 no Deliverable or other item provided by or on behalf of either Party to the other Party in connection with this Agreement infringes, misappropriates or otherwise violates any Intellectual Property or other rights of any third party.

5.2 **Trade Sanctions Compliance**. Each Party warrants that as of the date of this Agreement it or any entity or person that has direct or indirect control of fifty percent or more of its shares ("**Beneficiaries**") are not subject to any economic, trade or financial sanctions or other trade restrictions administered or enforced by the United Nations, the European Union, the United States of America or any other relevant jurisdiction, including, without limitation, the EU Consolidated list of persons, groups and entities subject to EU financial sanctions, the U.S. Treasury Department Office of Foreign Assets Control list of Specially Designated Nationals and Blocked Persons or any similar list maintained by any EU member state or the country of registration of Indegene or Cingulate ("**Sanctions**"). A breach of this warranty shall be a material default for the purpose of termination. Should either party discover or otherwise become aware of violation of the Sanctions, the Party who first becomes aware of the violation of the Sanctions shall notify the other Party, and the Parties shall cooperate in order to take all necessary corrective actions. Each Party agrees that if at any time after the date of formation of the Agreement it or any of its Beneficiaries become subject to any Sanctions, whether introduced before or after such date, which prohibit or restrict a Party's performance of or rights under the Agreement, or the performance of the Agreement exposes such Party, or creates a risk of such party being exposed, to any Sanctions, including, without limitation, any extraterritorial or secondary sanctions, the other Party may suspend or terminate the affected Services upon such Sanctions becoming effective.

5.3 **No Debarment.** Indegene represents, warrants and covenants that neither Indegene, nor any of its Affiliates, has been debarred or is subject to debarment under section 306 of the Federal Food, Drug, and Cosmetic Act (or any other analogous law or regulation) and neither Indegene, nor any of its Affiliates, shall use in any capacity, in connection with this Agreement, any Person who has been debarred, or who is the subject of a conviction in any jurisdiction, for acts or omissions relating to the development, regulatory approval, marketing or sale of a medical device or drug product.

5.4 **DISCLAIMER**. **EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, INDEGENE MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE SERVICES, DELIVERABLES, OR ANY INTELLECTUAL PROPERTY RIGHTS OWNED OR CONTROLLED BY INDEGENE, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, VALIDITY OF ANY INTELLECTUAL PROPERTY RIGHTS OR OTHERWISE, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE**.

6. CONFIDENTIALITY, DATA PROTECTION & CYBER SECURITY

6.1 Each Party may disclose to the other, orally or in writing, or a Party may otherwise obtain, through observation or otherwise, Confidential Information. The Receiving Party must: (i) protect, and cause all its representatives to protect, all Confidential Information from disclosure in violation of this Article; (ii) restrict the use of Confidential Information to the intended purpose of this Agreement; (iii) limit dissemination of Confidential Information to only those representatives that require disclosure for performance of obligations hereunder; and (iv) clearly and completely convey the requirements of this clause to such representatives to ensure such requirements are understood and followed. If requested by either Party, the other Party shall secure written commitments from its representatives to comply with the confidentiality requirements of this Agreement.

6.2 During the term of this Agreement, and (a) for a period of five (5) years following the expiration or earlier termination hereof in the case of Confidential Information that has not been identified as a trade secret and (b) perpetually in the case of Confidential Information that has been identified as a trade secret, each Party shall use the Confidential Information of the other Party solely for performing its obligations or exercising its rights under this Agreement and shall hold such Confidential Information in confidence and not disclose or otherwise provide it to third parties without the prior written consent of the other Party. Notwithstanding the foregoing, (i) the Receiving Party may make any disclosure of such Confidential Information to which the Disclosing Party gives its prior written consent; (ii) any of the Confidential Information of the Disclosing Party may be disclosed by the Receiving Party to its representatives who need to know such information in connection with performing the Receiving Party's obligations hereunder, in each case who are informed of the confidential nature of such information and of the terms of this Agreement and who are bound by written obligations of confidentiality and non-use (or, in the case of attorneys, legally enforceable professional obligations) at least as restrictive as those contained herein. The Receiving Party shall be responsible for any breach of this Agreement by any of its representatives or such other parties, and agrees, at its sole expense, to take reasonable measures to restrain its representatives and such parties from prohibited or unauthorized disclosure or use of the Confidential Information. Notwithstanding anything contained in this Agreement to the contrary, this Agreement shall not prohibit the Receiving Party from disclosing Confidential Information of the Disclosing Party to the extent required in order for the Receiving Party to comply with laws, provided that the Receiving Party provides prior written notice of such required disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the extent of such disclosure

6.3 The obligations of the Receiving Party specified in this Article 6 shall not apply, and the Receiving Party shall have no further obligations, with respect to any Confidential Information to the extent that such Confidential Information:

a. a Party already knew of prior to disclosure hereunder as documented by prior written records; or
b. is or becomes public knowledge other than by breach of this provision by a Party; or
c. a Party receives in good faith from a third party not in violation of an obligation of confidentiality; or
d. a Party develops independently of any Confidential Information disclosed hereunder as documented by written records; or

e. a Party is obliged to disclose in accordance with a regulatory submission or other requirement of law; provided that said Party shall first notify the other Party, so that it may seek a protective order or similar relief if appropriate or available.

Notwithstanding the foregoing, nothing in this Section 6.3 (other than Section 6.3(b)) shall relieve Indegene of any of its obligations under this Article 6 with respect to any Deliverables.

6.4 Upon termination or expiration of this Agreement, or earlier if so agreed in writing by the Parties, each Party shall either return all copies of the Confidential Information it may have received or destroy in a secure manner all such copies of the Confidential Information if so instructed by the other Party except for one copy which may be retained for the purpose of establishing that Party's compliance with its obligations under this Agreement.

6.5 Where personal data is processed in relation with this Agreement, the Parties shall comply with applicable laws and regulations, including but not limited to Regulation (EU) 2016/679 ("**General Data Protection Regulation**", or "**GDPR**"). Each Party represents and guarantees to the other Party that it will strictly comply with the applicable data protection and privacy laws for any processing of personal data related to this Agreement. Notwithstanding anything to the contrary, the Parties will not be liable under this Agreement insofar as compliance with the applicable data protection and privacy laws prevents them from executing any obligation contemplated herein.

6.6 In the event that the activities contemplated by the Agreement involve the processing as such terms are defined under the GDPR of which Cingulate is the controller, as defined in GDPR, regardless of whether such personal data constitutes Cingulate's data, then Cingulate and Indegene agree to complete/execute a Personal Data Processing Agreement or comply with the Standard Contractual Clauses to the extent to which the GDPR applies to such processing.

7. INTELLECTUAL PROPERTY

7.1 **Background IP**. Each Party retains all right, title and interest in and to any Intellectual Property (i) owned or controlled by such Party as of the Effective Date or (ii) which, after the Effective Date, is developed or becomes controlled by such Party outside the scope of this Agreement and without use of or reference to any Confidential Information of the other Party ("**Background IP**"). Cingulate hereby grants to Indegene during the Term this Agreement a non-exclusive, worldwide, non-transferable and non-sublicensable license (except to Indegene's permitted Subcontractors) under Cingulate's Background IP, solely for the purposes of Indegene performing the Services in accordance with this Agreement and any applicable SOW.

7.2 **Cingulate Inventions**. Indegene agrees that: (a) all Deliverables and all Intellectual Property rights embodied therein that are not an Indegene Invention (as defined below) or Background IP of Indegene (collectively, "**Cingulate Inventions**"), shall become and remain the property of Cingulate; and (b) subject to payment of applicable, undisputed Fees towards the respective Deliverables, Indegene hereby assigns (and shall cause each of its Affiliates and any of its and their respective personnel and contractors to assign) to Cingulate all rights in the United States and throughout the world to the Cingulate Inventions. Indegene shall execute and deliver (and shall cause each of its Affiliates and any of its and their respective personnel and contractors to execute and deliver) such agreements, assignments, documents and instruments as may be reasonably requested by Cingulate to further reflect or evidence Cingulate's ownership of the Cingulate Inventions, to transfer to Cingulate any and all rights and interests Indegene may have in and to such Cingulate Inventions, and to insure that Cingulate has the legal right and ability to transfer, assign and enforce its rights in and to the Cingulate Inventions. Cingulate agrees that portions of the Deliverables that are or to the extent they contain Background IP of Indegene or Indegene Inventions (collectively, "**Indegene IP**") shall be and remain the sole and exclusive property of Indegene and shall not be subject to assignment to Cingulate pursuant to this Section 7.2 or otherwise (but rather shall be licensed to Cingulate pursuant to Section 7.4).

7.3 **Indegene Inventions**. The Parties acknowledge and agree that in the course of providing the Services, Indegene will be using technology, platforms, systems and methods of providing the Services that are owned or controlled by Indegene (collectively, "**Indegene Platform Technology**"). Cingulate agrees that all Intellectual Property covering or embodied in the Indegene Platform Technology, including any developments, improvements and modifications made by or on behalf of Indegene that relate to the Indegene Platform Technology, whether made in the course of providing the Services or otherwise (collectively, "**Indegene Inventions**"), shall be and remain the sole and exclusive property of Indegene and shall not be subject to assignment to Cingulate pursuant to Section 7.2 or otherwise. Indegene's rights in Indegene Inventions shall not be diluted in any manner whatsoever on account of Indegene using or making Indegene Inventions in the course of providing the Services to Cingulate. This Agreement shall not be construed to grant any license or other rights to Cingulate in any Intellectual Property owned or controlled by Indegene except as specifically granted herein.

7.4 **License to Cingulate.** To the extent any Indegene IP is incorporated in any Deliverable, or is necessary or useful for the use of any Deliverable, Indegene hereby grants Cingulate a perpetual, irrevocable, royalty-free, paid-up, transferable, worldwide, nonexclusive license under such Indegene IP, with the right to grant sublicenses, to make, have made, use, sell, offer to sell, import, reproduce, distribute, prepare derivative works, perform, display and otherwise fully exploit any such Deliverable and any items derived therefrom. Notwithstanding anything mentioned in this Agreement, Cingulate and/or any 3rd party shall not utilize the Indegene Background IP other than with a Deliverable or an item derived from a Deliverable.

7.5 **Output**. Indegene may retain and curate output of the Services performed at any time ("**Output**") for internal use for the purposes of personnel training, or for internal use to develop and/or improve Indegene's Platform Technology and other products and services including, but not limited to, developing, testing and/or validating artificial intelligence or machine learning algorithms, provided that all such Output shall subject to de-identification, anonymization and aggregation with other similarly curated records and no identifiable characteristics of Cingulate, or its products, customers, business, samples, original study design or the primary use of the Output shall be revealed ("**Anonymized and Aggregated Output**"). In the event Output is shared with Indegene's agents, consultants and partners, it shall only be shared in the form of Anonymized and Aggregated Output via designated channels for secure data with agents, consultants and partners who have demonstrated secure data upload and storage practices as assessed by Indegene.

7.6 **Residual Knowledge**. Indegene may use for any purpose any information which may be retained in the unaided memories of personnel performing the Services such as ideas, concepts, know-how, experience and techniques which do not contain any Cingulate Confidential Information. An employee's memory is unaided if the employee has not intentionally memorized the information for the purpose of retaining and subsequently using or disclosing it.

7.7 **Third Party IP.** Indegene will not incorporate any inventions, works of authorship, data or other materials that are covered by any Intellectual Property of any third party (the "**Third Party IP**") into any Deliverable without, in each particular instance, either (a) obtaining the prior, written approval of Cingulate, which approval Cingulate may grant or withhold in its sole and absolute discretion or (b) ensuring that Cingulate gets a license or sublicense to such Third Party IP on the same basis as which Indegene IP is licensed to Cingulate under Section 7.4 or (c) identifying such Third Party IP in the applicable SOW, along with the terms that will govern Cingulate's use of such Third Party IP.

8. TERM AND TERMINATION

8.1 **Term**. The term of this Agreement shall commence on the Effective Date, and, unless terminated earlier as set forth below or extended by the mutual written agreement of the Parties, shall expire three (3) years after the Effective Date (the "**Term**").

8.2 **Termination for Material Breach**. A Party may terminate this Agreement upon thirty (30) days prior, written notice to the other Party if the other Party has materially breached this Agreement indicating such breach and the notifying Party's intent to terminate this Agreement; provided, however, that this Agreement will not terminate (a) if such breach is cured by the end of such thirty (30) day period or (b) if such breach is not capable of being cured within 30 days and the breaching party has initiated the cure within 30 days of notice (in which case this Agreement will terminate if such breach in not cured within 90 days of the initial notice from the non-breaching Party or any other timeline which the Parties agree in writing).

8.3 **Termination by Parties for Convenience**. Neither party can terminate this Agreement for convenience during the initial twelve (12) months following the first commercial sale of CTx-1301 or eighteen (18) months from the Effective Date of this Agreement, whichever is earlier. Thereafter, either party can terminate this Agreement for convenience upon providing six (6) months notice irrespective of whether Dedicated Personnel are engaged. Notwithstanding anything mentioned in this Agreement, the termination right under convenience is only for the entire Agreement and not part of the Agreement and/or any SOW.

8.4 **Termination for Bankruptcy**. Either Party may terminate this Agreement immediately without further action if the other Party files a petition in bankruptcy, enters into an agreement with its creditors, applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator for its affairs, makes an assignment for the benefit of creditors, suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent where such order is not discharged within thirty (30) days, or takes any equivalent or similar action in consequence of debt in any jurisdiction.

9. CONSEQUENCES OF TERMINATION

9.1 **Pre-Existing Obligations**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. In the event of termination of this Agreement by either Party, Indegene shall be entitled to payments of Fees for Services completed in accordance with this Agreement prior to the effective date of termination, for contractual commitments made prior to the notice of termination to the extent that liability for such commitments cannot be mitigated, and for such reasonable costs and expenses as are necessary to terminate the Services.

9.2 **Transition Assistance**. Following any termination (in whole or in part) or expiration of any of the Services, if requested by Cingulate, Indegene shall provide to Cingulate, or at Cingulate's request to Cingulate's designee, termination assistance so as to allow the terminated Services to continue without interruption or adverse effect and to facilitate the orderly transfer of such Services to Cingulate or its designee ("**Transition Assistance**"), subject to Cingulate's payment of fees (at such rates as are reasonable and agreed upon by the Parties in writing) for time spent by Indegene personnel in providing the Transition Assistance. If requested by Cingulate, Indegene and Cingulate shall jointly develop a plan to effect the orderly transition and migration to Cingulate or its designee of all such Services then being performed by Indegene (a "**Transition Plan**"), and Indegene shall provide the Transition Assistance in accordance with such Transition Plan. Indegene shall provide Transition Assistance for a period beginning when a notice of termination is delivered by one Party to the other pursuant to this Agreement and continuing until Transition Assistance is no longer reasonably required by Cingulate (or until the Transition Plan is completed, as applicable), but in no event to exceed 12 consecutive months from the effective date of expiration or termination of the applicable SOW's, unless otherwise agreed by the Parties.

9.3 Notwithstanding anything contained herein to the contrary, if Cingulate terminates this Agreement or a SOW for convenience before expiration during the first twelve (12) months of the Term, or if Indegene terminates this Agreement or a SOW early due to Cingulate's material breach during the first twelve (12) months of the Term, then, in addition to any outstanding fees owed at termination, Cingulate shall pay Indegene, if applicable, any early termination fee set forth in any SOW that is so terminated. For purposes of illustration, the early termination fee may include the following types of items:

9.3.1 The depreciated cost/amortized value of any equipment that Indegene acquired to provide the Services under this Agreement and that Indegene cannot, using reasonable efforts, repurpose for other clients of Indegene.

9.3.2 Costs Indegene must pay to Service Personnel it hired to perform the Services under this Agreement whom Indegene cannot, using reasonable efforts, reassign to other projects or clients of Indegene.

9.3.3 All costs, including early termination fees, that Indegene incurs under agreements with third parties, including but not limited to facility leases, equipment leases, and software licenses, that Indegene entered into in order to provide the Services and that Indegene cannot: (i) assign to Customer; or (ii) cancel or terminate without cost.

9.3.4 The startup and committed costs identified in the applicable SOW.

9.3.5 Any other identified and agreed cost under the applicable SOW.

10. INDEMNITY AND LIMITATION OF LIABILITY

10.1 **Indemnification by Cingulate for Third Party Claims**. Cingulate shall indemnify, defend and hold Indegene and its Affiliates and its and their respective directors, officers, members, managers, employees, contractors and agents (the "**Indegene Indemnitees**") harmless from and against any and all liability, damages, loss settlement payments, awards, fines, and cost or expense of defense (including reasonable attorneys' fees) (collectively, "**Losses**") arising out of any suits, claims, demands, proceedings, investigations including Subpoena or causes of action brought by a third party ("**Third Party Claims**") to the extent resulting from or caused by: (a) the gross negligence, recklessness or willful misconduct of any Cingulate Indemnitee (as defined below); (b) Cingulate's breach of its obligations, warranties, or representations under this Agreement; (c) breach of warranty by Cingulate or any product liability claims with respect to Cingulate products for which Indegene performs Services, whether arising out of warranty, negligence, strict liability (including manufacturing, design, warning or instruction claims) or any other product based statutory claim; (d) misappropriation and/or infringement of Intellectual Property by Cingulate products or any other material provided /approved by Cingulate; or (e) any assertions Indegene makes about Cingulate or Cingulate's product or services in any materials that are approved by Cingulate for use in Indegene's performance under this Agreement; except in each of the foregoing cases to the extent that a Third Party Claim arises out of or results from the negligence, recklessness or willful misconduct of any Indegene Indemnitee or Indegene's breach of its obligations, warranties, or representations under this Agreement.

10.2 **Indemnification by Indegene for Third Party Claims**. Indegene shall indemnify, defend and hold harmless Cingulate and its Affiliates and its and their respective directors, officers, members, managers, employees, contractors and agents (the "Cingulate Indemnitees") from and against any and all Losses arising out of any Third Party Claims brought against any Cingulate Indemnitees to the extent resulting from or caused by: (a) the gross negligence, recklessness or willful misconduct of any Indegene Indemnitee; or (b) Indegene's breach of its obligations, warranties, or representations under this Agreement except in each case to the extent that a Third Party Claim arises out of or results from the negligence, recklessness or willful misconduct of any Cingulate Indemnitee, or Cingulate's breach of its obligations, warranties, or representations under this Agreement. In addition, Indegene shall indemnify, defend and hold harmless the Cingulate Indemnitees from any Losses arising out of any Third Party Claims arising out of or relating to any assertion that any of the Cingulate Indemnitees should be deemed the employer or joint employer of any of the Service Personnel.

10.3 **Indemnification Conditions and Procedures**. Each Party's agreement to indemnify, defend and hold harmless the other Party is conditioned on the indemnified Party: (a) providing written notice to the indemnifying Party of any Third Party Claim for which is it seeking indemnification hereunder promptly after the indemnified Party has knowledge of such claim; (b) permitting the indemnifying Party to assume full control over the defense and settlement of such Third Party Claim, except that the indemnified Party may participate in the defense at its own expense using its own counsel; (c) providing reasonable cooperation, information and assistance to the indemnifying Party, at the indemnifying Party's reasonable expense, with respect to the defense and settlement of such Third Party Claim; and (d) not compromising, settling, or admitting any liability for such Third Party Claim without the indemnifying Party's written consent. Notwithstanding the foregoing, the indemnifying Party shall not enter into any settlement that admits the fault of the indemnified Party or otherwise materially adversely prejudices the indemnified Party without such indemnified Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

10.4 **Limitation of Liability.**

A. **Direct Damages**: Subject to Section 10.4 (C), the total aggregate liability of Indegene under this Agreement (whether in contract, tort (including negligence)) shall not exceed the Fees paid or payable to Indegene hereunder.
B. **Indirect Damages**: Except for breach of Confidentiality, the Parties disclaim any indirect, special, consequential, or incidental damages or loss of revenue or business profits, however caused.

C. **Exclusions**: The foregoing limits under clause 10.4 (A) shall not apply to: (i) misappropriation or infringement of the other Party's Intellectual Property; (ii) breach of confidentiality obligations under this Agreement or (iii) under clause 10.2, indemnification obligation the Parties' respective indemnification obligations under Section 10.1 and Section 10.2 with respect to Third Party Claims. For clarity purposes, all Losses covered under Section 10.1 and Section 10.2 are deemed to be Direct Damages.

10.5 **Insurance.** Indegene shall carry and maintain in force during the term of the Agreement the following insurance coverage with one or more insurance companies that have a rating of A minus or better and a financial size category of VIII or larger, (both as determined by A. M. Best & Indegene): (a) Commercial General Liability insurance with limits of at least three million dollars ($3,000,000) per occurrence and five million dollars ($5,000,000) in the aggregate; (b) Professional Liability insurance with limits of at least three million dollars ($3,000,000) per occurrence and five million dollars ($5,000,000) in the aggregate, (c) Cyber / Privacy Liability Insurance coverage for data breaches and intrusions by a third parties to nonpublic personal information, with limits of at least five million dollars ($5,000,000) per occurrence, (d) Employer's liability insurance with limits of at least one million dollars ($1,000,000) per occurrence and (e) worker's compensation and related insurance as prescribed by the law of each jurisdiction in which Services are performed. Indegene shall, upon request by Cingulate, furnish certificates or adequate proof of the foregoing insurance. Cingulate shall be notified in writing at least thirty (30) days prior to any cancellation of, or material change to, an applicable policy. Except for Worker's Compensation insurance, all policies shall name the Cingulate (and at Cingulate's request, any Affiliates that are receiving the Services) as an additional insured. Certificates for all policies shall stipulate that coverage provided thereunder shall be primary and not excess of, or contributory with, any other insurance, and that subrogation rights are waived. At the time of and following commercial launch of a product, Cingulate will maintain appropriate insurance in commercially reasonable amounts with financially capable carriers, including product liability insurance in the amount of at least ten million dollars ($10,000,000). Cingulate shall name Indegene as an additional insured on such product liability insurance coverage. In addition, upon written request, Cingulate will provide Indegene with evidence of coverage complying with this Section.

11 SAVINGS CLAUSE:

11.1 The Parties agree that Indegene's timely provision of Services under this Agreement is dependent on timely provision of inputs. Where approval, acceptance, consent or similar action by Cingulate is required under this Agreement, such action will not be unreasonably delayed, conditioned or withheld.

11.2 Indegene's non-performance of its obligations under this Agreement will be excused if and to the extent such non-performance results from Cingulate's failure to perform its responsibilities hereunder.

12 IMPORT/EXPORT CONTROLS

12.1 The Parties acknowledge that certain software and technical data exchanged/ accessed pursuant to this Agreement may be subject to import/export controls under the Laws of the United States and other countries. Neither Party will import, export or re-export any such items, any direct product of those items, or any technical data in violation of applicable import/export control Laws.

12.2 Each Party will be responsible for compliance with import/export control Laws with respect to any items it is deemed under such Laws to have imported or exported, including responsibility for preparing and filing all required documentation and obtaining all licenses, permits and authorizations required for compliance. Each Party will cooperate with the other Party in that Party's efforts to comply with applicable import/export control Laws.

13 MISCELLANEOUS

13.1 **Severability**. Should any part of this Agreement be declared illegal or unenforceable, the Parties will co-operate in all the ways open to them to obtain substantially the same result or as much thereof as may be possible, including taking appropriate steps to amend, modify or alter this Agreement. If any term or provision of this Agreement shall be hereafter declared by a final adjudication of any tribunal or court of competent jurisdiction to be illegal, such adjudication shall not alter the validity or enforceability of any other term or provision unless the terms and provisions declared (by any of the Parties) shall be one expressly defined as a condition precedent or as of the essence of this Agreement, or comprising an integral part of, or inseparable from the remainder of this Agreement.

13.2 **Assignment**. Neither Party shall assign its rights or obligations under this Agreement, in whole or in part, by operation of law or otherwise, without the prior express written consent of the other Party; provided, however, that notwithstanding the foregoing, a Party may, without the consent of the other Party, assign this Agreement (including all of such Party's rights and obligations hereunder to any of its Affiliates or (ii) in connection with a merger, consolidation, sale of equity interests, sale of all or substantially all assets or change of control transaction involving such Party (or, in the case of Cingulate, sale of all or substantially all assets of its business related to the any product that is the subject of the Services. Any purported assignment in violation of this article shall be null and void.

13.3 **Notice**. Any consent, notice or report required or permitted to be given or made under this Agreement by one Party to the other Party shall be in writing, delivered personally, by facsimile (and promptly confirmed by personal delivery, U.S. first class mail, courier or nationally-recognized delivery service), U.S. first class mail postage prepaid, courier or nationally-recognized delivery service, and addressed to the other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor. Except as otherwise provided in this Agreement, such consent, notice or report shall be effective upon receipt by the addressee.

If to Indegene:

For the attention of: Legal Department
Address:Indegene, Inc.,
150 College Rd W, Suite 104
Princeton, NJ 08540

If to Cingulate:

For the attention of: Legal Department
Address:Cingulate Therapeutics LLC
1901 W47th Place
Kansas City, KS 66205

13.4 **Waiver**. The failure, with or without intent, of any Party hereto to insist upon the performance of the terms of this Agreement by the other Party, shall not be treated as, or be deemed to constitute, a modification of any terms or stipulations of this Agreement nor shall such failure or election be deemed to constitute a waiver of the right of such Party, at any time whatsoever thereafter, to insist upon performance by the other, strictly in accordance with any terms or provisions hereof. All terms, conditions and obligations under this Agreement shall remain in full force and effect at all times during the subsistence of this Agreement except where otherwise amended or modified by the Parties by mutual written Agreement.

13.5 **Publicity**. Neither Party shall issue a press release or public announcement relating to this Agreement without the prior written approval of the other Party, which approval shall not be unreasonably withheld, conditioned or delayed, except that a Party may (i) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (ii) issue a press release or public announcement as required, in the reasonable judgment of such Party, by law or applicable exchange rules.

13.6 **Force Majeure.** If the performance by either Party hereto, of any of its obligations hereunder is prevented, restricted or interfered with by reason of fire, or other causality or accident; strike or labour disputes; war or other violence; any law, or regulation of any government; any condition which is unforeseeable, unavoidable and beyond the reasonable control of such Party (each such occurrence being hereinafter referred to as a "*Force Majeure*"), then such Party shall be excused from such performance to the extent of such prevention, restriction or interference; provided, however, that such Party shall give prompt notice within a period of 15 days from the date of Force Majeure occurrence and providing a description to the other Party of such Force Majeure in such notice, including a description, in reasonable specificity, of the cause of the Force Majeure; and provided further that such Party shall use reasonable efforts to avoid or remove such cause of non-performance and shall continue performance hereunder whenever such causes are removed. If a Force Majeure event restricts the performance of Services for a period of greater than three (3) months, then the Party that is not subject to such Force Majeure event may terminate this Agreement or any SOW impacted by such Force Majeure event and Indegene shall only be paid in accordance with Section 9.1.

13.7 **Entire Agreement**. The Parties confirm and acknowledge that this Agreement (including the Schedules and Appendices hereto, and any SOWs) shall constitute the entire agreement between them and shall supersede and override all previous communications, either oral or written, between the Parties with respect to the subject matter of this Agreement, and no agreement or understanding varying or extending the same shall be binding upon any Party unless arising out of the specific provisions of this Agreement and is in writing.

13.8 **Non-Solicitation**. During the term of this Agreement and for a period of twelve (12) months thereafter, neither Party shall, directly or indirectly, in any manner solicit or induce for employment any person who performed any work under this Agreement, who is then in the employment of the other Party, unless the Parties mutually agree to waive this, in writing. A general advertisement or notice of a job listing or opening or other similar general publication of a job search or availability to fill employment positions, including on the internet, not specifically targeted at Indegene's employees, shall not be construed as a solicitation or inducement for the purposes of this Section and the hiring of any such employees or independent contractor who freely responds thereto shall not be a breach of this Section.

13.9 **Survival**. The provisions of Section 1 ("Definitions"), Section 3.10 ("Access to Deliverables"), Section 3.11 ("Records and Audit"), Section 5 ("Representations, Warranties and Covenants"), Section 6 ("Confidentiality, Data Protection and Cybersecurity"), Section 7 ("Intellectual Property"), Section 9 ("Consequences of Termination"), Section 10 ("Indemnity and Limitation of Liability")Section 12 ("Import/Export Controls") and Section 13 ("Miscellaneous") and any other provisions of this Agreement which by their nature or intent are intended to survive the termination or expiration of this Agreement, shall survive the termination or expiration of this Agreement and continue in effect.

13.10 **Independent Contractor**. This Agreement is not intended to create nor shall be construed to create any relationship between the Parties other than that of independent entities contracting for the purpose of effecting the provisions of this Agreement. Neither of the Parties nor any of their representatives shall be construed to be the agent, employer, employee or representative of the other. Additionally, nothing in the execution of this Agreement or in its performance shall be construed to establish a joint venture by or partnership between the Parties.

13.11 **Applicable Law**. This Agreement shall be governed by and construed in accordance with the laws of Delaware without giving effect to principles of conflict of laws thereof, regardless of the place of making or performance.

13.12 **Dispute Resolution.**

13.12.1 **Dispute Escalation**. Upon the written request of either Party to the other Party, either Party may refer any claim, dispute, or controversy or claim arising out of or related to this Agreement (a "**Dispute**") to senior executive officers of Cingulate and Indegene for resolution (the "**Executive Officers**"). If the Executive Officers are unable to resolve such matter within thirty (30) days after the initial written request, then, upon the written demand of either Party, the Parties shall resolve such matter by binding arbitration, as provided in Section 13.12.2. Any Disputes about the propriety of commencing arbitration or the scope or applicability of the agreement to arbitrate shall be finally settled by the arbitral tribunal.

13.12.2 **Arbitration**. In the event that a Dispute is not resolved between the Parties or their Executive Officers as set forth in Section 13.12.1, then a Party seeking further resolution of the Dispute may submit the Dispute to resolution by final and binding arbitration. Whenever a Party determines to institute arbitration proceedings, it will give written notice to that effect to the other Party. Arbitration will be held in New York City, New York, and administered by JAMS pursuant to its Streamlined Arbitration Rules then in effect (the "**Rules**"), except as otherwise provided herein and applying the substantive law specified in Section 13.11. The arbitration will be conducted by a single arbitrator appointed in accordance with the Rules, provided that such arbitrator must have significant business or legal experience in the pharmaceutical business. After conducting any hearing and taking any evidence deemed appropriate for consideration, the arbitrator will render his/her opinion within thirty (30) days of the final arbitration hearing. Decisions of the arbitrator that conform to the terms of this Section 13.12.2 will be final and binding on the Parties and judgment on the award so rendered may be entered in any court of competent jurisdiction and the Parties undertake to carry out any award without delay. The losing Party, as determined by the arbitrator, will pay all of the JAMS administrative costs and fees of the arbitration and the fees and costs of the arbitrator, and the arbitrator will be directed to provide for payment or reimbursement of such fees and costs by the losing Party. If the arbitrator determines that there is no losing Party, the Parties will each be responsible for one-half of those costs and fees and the arbitrator's award will so provide. Notwithstanding anything to the contrary in the foregoing, each Party shall be responsible for its own attorneys' fees, expert or witness fees, and any other fees and costs, and no such fees or costs will be shifted to the other Party.

13.12.3 **Injunctive Relief; Court Actions.** Either Party may apply to the arbitrator for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Notwithstanding anything to the contrary: (a) either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any interim injunctive or other interim relief in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding and (b) either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Intellectual Property rights, and no such claim shall be subject to arbitration pursuant to Section 13.12.2.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by and through their duly authorized representatives as of the Effective Date.

Indegene, Inc.	**Cingulate Therapeutics LLC**
Sign. */s/ Gaurav Kapoor*	Sign */s/ Shane J. Schaffer*
Name Gaurav Kapoor	Name Shane J. Schaffer
Title: EVP	Title: CEO

SCHEDULE 1
MASTER SERVICE AGREEMENT
STATEMENT OF WORK NO. XXXXX/ XXX
(Only Template)

This Statement Of Work is entered into as of _____ by and between ____ _____ ("____"), with an office at _____ and **Indegene, Inc.**, a Delaware corporation having its place of business at Suite 104, 150 College Road W, Princeton, NJ 08540 and affiliates (hereinafter collectively referred to as Parties) pursuant to the terms of the Master Services Agreement between Indegene, Inc. and _____ dated _____ ("MSA").

In the event of any inconsistency or conflict between the terms of this Statement of Work on the one hand and the terms of the MSA, the terms of this Statement of Work shall prevail to the extent of such inconsistency or conflict.

PART I: PROJECT INFORMATION

A. Project Title
B. Scope of Services
C. [Work Schedule] [and] [Deliverables]. [The relevant milestones, completion dates, and terms associated with this SOW are as follows:
D. Key Assumptions
E. Receivables from Customer
F. [Permitted [Subcontractors/Delegates]. The following subcontractors are permitted [subcontractors/delegates] under Section [NUMBER] of the Master Agreement: [SUBCONTRACTOR/DELEGATE NAMES].]
G. Customer Obligation

PART II: COSTS AND PAYMENT SCHEDULE

The total cost for the project described in this Statement of Work shall be _____.

PART III: SERVICE LEVEL AND PERFORMANCE MATRIX

PART IV: Early Termination Fees:

PART V: MISCELLANEOUS

- Invoices are due upon receipt and if not paid within credit period of thirty (30) days, a penalty of 1.5% shall be charged to the outstanding balance due on a monthly basis.
- The above pricing is exclusive of taxes and pass-through costs.
- Any VAT/GST/sales tax payable on services, will be charged by Indegene on invoice and collected from Customer.
- Indegene will submit a request for a Cost-Of-Living Adjustment ("COLA") to Cingulate in writing by April 1st each year and the parties will review the relevant facts presented justifying the adjustment. For example, Indegene will submit a request for a COLA adjustment along with published CPI index or publicly available published human resources data and market insights reported by Human Resources consulting firms to justify the COLA. The parties will negotiate the adjustment in good faith and such negotiated adjustments will become effective on August 1st of each year.
- Indegene should receive full invoice value without any withholding tax deduction. Any document required in order not to deduct taxes will be mutually coordinated between the parties to avail tax treaty benefits.
- Cingulate may identify and communicate the discrepancies in invoices within three (3) weeks from invoice generation, else the invoice will be presumed as accepted. Any discrepancy shall be resolved in mutually coordinated way within the Parties. In case there is any partial discrepancy, the undisputed part shall be paid by Cingulate without delay.
- Any expenses of Cingulate that relate to payment of fees, creation of purchase order, vendor management system and any related activities, shall be dealt by Cingulate to the complete exclusion of Indegene. Any such expenses if deducted in any payments made by Cingulate shall be added back into the next consecutive invoice and Cingulate shall be obligated to pay this back to Indegene.

PART V: COMMUNICATIONS

All communications provided for in this Agreement shall be mailed postage prepaid and addressed to the respective parties as follows:

To ____:	**To Indegene:**

IN WITNESS WHEREOF, the parties hereto have caused this Statement of Work to be executed by their respective duly authorized representatives as of the day and year first above written.

CINGULATE	**INDEGENE, INC.**
By:	By:
Name:	Name:
Title:	Title:

SCHEDULE 2

Change Order Template
(Only Template)

Once the project plan and assumptions are approved, all changes to the timeline, budget, or scope (deliverable requirements) should be funneled through the change management process.

The Indegene program manager (PM) will be the single point of contact through whom all change requests should be funneled on the Indegene side. ____ will establish a single point of contact, who will have ultimate approval authority over all change requests.

The Indegene PM will document all change requests on the Indegene Change Request Form.

Indegene recommends that Cingulate assign a backup single point of contact with the same approval authority as the primary single point of contact, in the absence of the primary single point of contact. Indegene will assign a similar back up single point of contact at their end.

CHANGE REQUEST FORM	
Request Name:	
Project Phase:	**Date Issued:**
Deliverable Due Date:	**Request #:**
Description of Change(s):	
Reason(s) for Change(s):	
Amount and Nature of Significant Cost Increase (if applicable) as a result of the Change(s):	
Timetable for implementation of the Change(s):	
Expected impact of the Change(s) on project schedule or Service Levels under the SOW:	
Process of Implementation (if applicable):	
Other information:	
All capitalized terms used in this Change Order will have the meanings given to them in the SOW or the Agreement unless otherwise defined in this Change Order.	
The modifications, amendments or alterations set forth in this Change Order do not amend or waive any other provision of the Agreement or any SOW thereunder.	
Cingulate:	**Indegene:**
Name: **Signature:** **Date :**	**Name:** **Signature:** **Date :**

SCHEDULE 1
TEMPLATE CHANGE ORDER

Appendix A
Description of Services

An illustration for the 'Key Services' across the different functional domains for overall program is mentioned below. Exact Services with specificity to be outlined with detailed descriptions in respective SOW's.

Medical Affairs & Pharmacovigilance Services

Pre-Launch

Medical Operations

- **Medical Director (Provides Operations Support)-** Medical strategy planning and set up of process and cross functional coordination and content strategy for healthcare professionals (HCPs).
- **Recruit Medical Director-** Recruit, Hire, & on-board Medical Director
- **Medical Strategy -** Establish medical strategic planning by defining processes and cross functional coordination regarding the product lexicon, review of content, and engagement of healthcare professionals (HCPs) as advisors, authors and speakers
- **Scientific Platform Setup/Management -** Define scientific platform with key product safety, efficacy, usage and medical/clinical messages and differentiation

Medical Communications

- **Medical Communication & Pub. Plan -** Develop publication plan – determine key congress activities for release of scientific data and/or publication, provide ad hoc support for development medical communication materials including abstracts, posters, presentations, company sponsored medical education, infographics, standard response documents (SRDs) and others

Pharmacovigilance

- **Safety Database Setup -** Host safety database for Cingulate and migrate all legacy cases from existing database
- **Safety Database Operations -** Safety database hosting & managed services
- **Comprehensive Clinical Safety Services -** Project and Study Setup, Safety Case Processing, Medical Review, & Safety Monitoring, Project Reporting, CSR + ISS / ISE review, and DB Lock support.

Pre-Launch

Medical Operations

- **Medical Director & Operations Support-** Continued support on medical strategy planning and execution
- **Medical Operations Lead-** Manage overall medical activities and operations
- **Launch Plan & SOPs/Guidelines -** Launch plan & SOPs including compliant engagement of HCPs, publication authorship, material review/approval & document management, payments to HCPs, & documentation in CRM
- **Scientific Platform Management -** Maintain scientific platform for medical communications based on the new data from both internal clinical trials and competitive analysis
- **Material Review Setup -** Define processes for material review and implement, create Medical Affairs reporting dashboard(s)
- **MSL Staffing -** Recruit, hire, on-board and train MSLs
- **KOL Engagement Plan** – Mapping of target KOLs to MSLs. Ensure scientific/clinical exchange in adequate frequency. Interactions can be both virtual/F2F based on the preference of HCPs.

Medical Communications

- **Medical Communication Materials -** Develop materials per plan for publications, tools and training content for MSLs & HCPs (includes proactive and reactive communication (infographics, MSL slide decks/tools), create summary reports from key congresses for medical team to share with HCPs and provide adhoc support of any additional med comm & publication deliverables
- **Advisory Board Support -** Execute advisory board(s) in alignment with medical strategy & needs assessment gaining HCP perspective on data, gaps & future development

Medical Information

- **Medical Information Setup -** Delineate process for handling medical inquiries and providing responses to Healthcare Professionals (HCPs)
- **Style Guide, Templates & FAQs** – Establish formats, create standard and custom response documents (SRDs and CRDs) and FAQs
- **Integrated Call Center Setup -** Launch contact center, corporate website and publish med info toll free number
- **Insight Tracking & Reporting -** Track & report medical inquiry types, insight on potential gaps/customer needs, product complaints & adverse events

Medical Operations

- **Medical Director & Operations Support**- Continued support on medical strategy planning and execution
- **Medical Operations Lead**- Manage overall medical activities and operations
- **SOP & Policy Updates -** Periodic update of processes and policies for optimization, curation of approved materials and maintain document repository
- **Scientific Platform Management -** Maintain scientific platform for medical communications based on the new data from both internal clinical trials and competitive analysis
- **Material Review -** Material review (MLR) for assets which includes routing and approval
- **MSL Support** - Reporting dashboard(s) for KPIs across medical affairs functions, KOL engagement, execution & MSL performance management

Medical Communications

- **Medical Communication Materials/Support** - Develop HCP training content for key groups: PAs, Family Nurse Practitioners (FNPs), Pharmacists and Nurses, support targeted/systematic literature review to extract, curate & interpret scientific data, synthesize results & summarize key competitive data
- **Advisory Board Support** - Execute advisory board(s) in alignment with medical strategy & needs assessment gaining HCP perspective on data, gaps & future development
- **Ad Hoc Publication Support** - Ad hoc publication support (manuscripts, abstracts, posters and medical team tools)

Medical Information Support

- **Style Guide, Templates & FAQs** – Periodic update of style guide/lexicon, templates, FAQs, & content based internal and customer feedback and new data
- **Inquiry Management** (inc. AE & PQC intake) - Inquiry management from multiple sources: contact center, web site and field teams
- **Insight Tracking & Reporting** - Track & report medical inquiry types, insight on potential gaps/customer needs, product complaints & adverse events

Pricing, Reimbursement and Market Access Services

Pre-Launch

Pricing, Reimbursement & Market Access

- **Landscape & Gap Analysis (w/ Booster Research) -** Build upon Cingulate's understanding of the current landscape and expected development in ADHD, collaborate with Cingulate team & provide landscape assessment concerning competition and reimbursement environment
    - Booster Research - Research will explore payer understanding, perception of the rebound, crash, and potential need for a booster for target patients to continue benefit of treatment. Abuse and diversion potential will also be assessed in this research
- **MCO Payer Qualitative Research** - Understand current coverage, reimbursement & contracting status for ADHD products & payers' perceptions around CTx-1301
- **Physician Quantitative Research** - Understand physician's use & satisfaction with current ADHD products & examine perceptions/expected use of CTx-1301 in various pricing scenarios
- **Initial Pricing Strategy** - Provide initial pricing strategy recommendations
- **PIE Deck** – Develop a pre-approval information exchange (PIE) deck for use with external stakeholders (part of HEOR publications)
- **Focus Group** - 3-hr Virtual focus group with n=8 physicians (mixture of psychiatrists and primary care physicians, recommended even split). Research will explore perceptions of CTx-1301, appropriate patients, willingness to prescribe, impact of payer restrictions and access on adoption / prescribing.

Pre-Launch

Pricing, Reimbursement & Market Access

- **Access Valuation, Payer Segmentation & Contract Guidelines -** Analysis of different access and utilization management to show the market share lift or suppression, deliverables include excel based analysis on the value of access and utilization management, payer segmentation at the channel level, contract guidelines at the channel level
- **Redo MCO Payer Qualitative Research** - Redo the exercise. Understand changes in payers' perceptions and expectations towards CTx-1301
- **Final Pricing Strategy Assessment** - Work on final pricing strategy assessment, provide a coordinated market access, pricing and reimbursement strategy for CTx-1301
- **Payer Communication Materials** – Develop payer communication deck including value story proposition/messages for CTx-1301
- **Budget Impact Model** - Economic model to demonstrate benefit/ value of CTx-1301 vs current options from a payer perspective to be used in payer communications allowing Cingulate to show savings in PMPM and additional costs. Model includes a user friend dashboard and instructions so that inputs may be modified
- **AMCP Dossier** - Building upon Cingulate's assumptions for CTx-1301 and findings from primary and secondary research, document will be developed to use with decision makers. This document will provide the clinical and economic story for CTx-1301 to gain reimbursement and formulary placement in the US. It may be developed pre-or post-launch

Post-Launch

Pricing, Reimbursement & Market Access

- **Access Diagnostic Evaluation** – Access diagnostic evaluation; perform re-assessment on a quarterly basis using DRG data.

Commercial Operations Services

Pre-Launch

General Management

- General Manager- Leads Pre-Launch with Cingulate Leadership
- Project Plan Creation
- Communication Plan Creation

- Develop Commercial Operating Plan (w/ Strategic Plan)

Training

- **TBD**

Technology Management

- **TBD**

Commercial Data & Analytics

- **Market Research Support** - Surveys, secondary research validation, conducting primary research, HCP digital channel preference and adoption, patient awareness & compliance
- **Market & Opportunity Assessment** - Understanding market size, patient population, key specialties and competition
- **Disease Landscaping** - Disease understanding, risk factors, causative factors of disease, classification/staging, disease pathway and biomarker
- **Commercial Data Warehouse Begin Setup** – Begin design and build of a cloud based integrated data platform for reporting and analytics capabilities
- **KOL Profiling & Mapping-** Identification, profiling, and mapping of KOLs from publication, clinical trial registries, conferences, guidelines, advisory boards, CMS open payments, industry & faculty affiliation, network & influencer mapping & social Profile

Pre-Launch

General Management

- General Manager Leads Pre-Launch and Approval Activities with Cingulate Leadership
- Develop Commercial Operating Plan

Training

- **Disease State Training (with Certification Quiz)** - Disease state overview covering broad training on ADHD and nervous system
- **Product Training (with Certification Quiz)** - Competitive Landscape, PRMA, guidelines & treatment options for ADHD, & product profile - patient journey, PTR technology, CTx-1301
- **Selling Skills Training (with Certification Quiz) -** Objection handling, CVA walkthrough, vILTs on disease state overview, product profile, competitive landscape, objection handling, PRMA and selling skills with virtual facilitation and game-based certification quiz (questions & associated points increase difficulty as user moves forward)
- **Learning Management System** - Indegene proprietary SCORM compliant Learning Management System to host the training materials for Cingulate

Technology Management

- **Strategy & Roadmap** - Strategy & planning, needs assessment, solution architecture, platform package selection, integration requirement, architecture, & roadmap development
- **Technology Implementation** - Identify & setup governance, monitor tech implementation, manage change controls through appropriate governance
- **Web Infrastructure & Site Enablement Setup** - Infrastructure sizing, security enablement, website template setup, component enablement and configuration, integrations with required systems, GTM setup, procure web licenses & initiate website development for up to 4 websites (2 simple, 2 med complex)

Commercial Data & Analytics

- **Market Research Support** - Surveys, secondary research validation, conducting primary research, HCP digital channel preference and adoption, patient awareness & compliance
- **Competitor Landscape & Activity Tracking** - Monitoring and tracking of competitors in disease/therapy area - clinical, news, regulatory, conference (1 indication)
- **Brand Performance Launch Analytics Design** –Design reporting frameworks and define variables customized to track key Brand Launch and Ahead; performance Indicators
- **CDW Finalize Setup & CDW Operations** – Finalize setup and begin maintenance, administration, support, enhancement and additional data management activities
- **Social Media Listening** - Sentiment analysis, perception, awareness, preferences for 1-2 social channels, including competitor analysis for defined segment
- **KOL Profiling & Mapping** – Identification, profiling and mapping of 300 - 400 KOLs from publication, clinical trial registries, conferences, guidelines, advisory boards, CMS open payments, industry & faculty affiliation, network & influencer mapping & social Profile - 1 indication, 1

country. This also includes topic modelling as a one-time activity

- **Pipeline Forecasting** – Cloud-based, scalable forecasting model for pipeline products which eliminates the inefficiencies of proliferating Excels
- **Incentive Compensation Design–**This is part of Sales force planning activity. Includes operations setup. It includes defining motivation goals for the sales reps aligning with the org strategy, design payout curves with guiding principles of fairness, simplicity & commercial viability

General Management

- General Manager Leads Launch Activities with Cingulate Leadership
- Execute Commercial Operating Plan
- Ongoing Management, Delivery and Cross-Functional Operation Alignment
- Lead Post-Launch Activities with Cingulate Leadership

Training

- **Learning Management System –** Making the Learning Management System available post launch as well, for sales reps to utilize the training materials
- **Learning Sustainment** - Executive summaries, clinical trial backgrounders, infographics, regular virtual touchpoints to reinforce content, share best practices, and continue to practice verbalization, NEXT Learning Retention – Indegene's web-based confidence enhancement platform for paced assessment integrates the concepts of spaced learning for better retention using repetition and confidence-based assessments to assess knowledge and the confidence of learners

Technology Management

- **Technology Governance/Maintenance -** Lead cross platform governance & manage new technology capability requirements, make informed decision to prioritize the technology upgrades, manage various platform & technology subscriptions, renewals, security, compliance, contracts, etc., create & manage tech ecosystem architecture across workstream (Safety, Med Affairs, PRMA, Patient, HCP), work across different workstream and enable the technology platform solutions, validate the use cases and manage any priority enablement
- **Web Infrastructure & Site Enablement** – Launch & maintain websites, enable on page SEO, define reporting framework & publish website related reports

Commercial Data & Analytics

- **Market Research Support** - Surveys, secondary research validation, conducting primary research, HCP digital channel preference and adoption, patient awareness & compliance
- **CDW Operations** - Maintenance, administration, support, enhancement and additional data management activities
- **Inline Forecasting** – Design and build of required data & inline forecasting models, reporting and visualization of forecasting model
- **Competitor Landscape & Tracking** - Monitoring and tracking of competitors in disease/therapy area - clinical, news, regulatory, conference (1 indication)
- **Social Media Listening** - Sentiment analysis, perception, awareness, preferences for 1-2 social channels, including competitor analysis for defined segment
- **KOL Mapping Refresh** – It is a continuous activity which results is achieving higher accuracy in mapping KOLS and correctly identifying their networks throughout the engagement. This also includes topic modelling as a one-time activity
- **Brand Performance Launch Analytics –** A library of KPIs, frameworks and business rules customized to client needs, customized insights and recommendations driving key business actions to drive efficiency
- **Sales Force Operations** (Call planning / IC Admin)- Call planning exercises based on market feedback and calibration of incentives & compensation

Marketing (may include Field Force) Services

Pre-Launch

Payer

- **TBD**

HCP (may include Field Force)

- **Marketer**- Hire & On-board marketer to oversee all the marketing operations
- **HCP Research –** Identifying target audience and market
- **Brand Guidelines & Strategy** - Brand guidelines development which includes brand logo, tone, color palette, typography, fonts, commanding claims, visual branding, application examples etc.
- **Strategic Positioning** - Marketing & competitive analysis based on the research reports received, develop brand personality/personas and value proposition
- **Omnichannel Strategy & Planning** - Setting the omnichannel content brief & developing the content plan
- **Develop Pharmacy Dispensing Strategy/Wholesale/Trade Assets –** Create pharmacy strategy plan
- **Develop HCP, Tactical Planning** – Create a plan that illustrates all the key tactics that will drive revenue and how it latter up to the business goals

Patient, Caregiver & Advocacy

- **Strategic Positioning** - Marketing & competitive analysis based on the research reports received, develop brand personality/personas and value proposition

Medical Education

- **Convention Planning –** Coordination of events and post event activities

Payer

- **Recruit KAMs -** Profiles developed, screening and & interviews timed to make offers just prior to payer engagements, medical aligned training timed to prep market & meet with payers in alignment with planned implementation
- **Hire & Train KAM Team -** Profiles developed, screening and & interviews timed to make offers just prior to payer engagements, medical aligned training timed to prep market & meet with payers in alignment with planned implementation (2 hired L-12, 3 hired L-6)
- **Payer Communication Planning –** Plan for communication between payers and KAMs according to project timelines
- **Develop Communication Materials** – Develop payer value narrative and contract guidelines (includes Pre-Launch Strategy/Research)
- **Trade Kit & Wholesaler Fact Sheet** – Key materials about product to payors, vendors and distributors
- **Create Day 1 Promotional Materials** – Key priority materials that will be used in promotion of product upon approval
- **Early Payer Discussions -** Early discussions with Payers, first pass completed prior to KAM hiring, KAM sets appointments while training

HCP (may include Field Force)

- **Campaign Theme & Modular Content** - Develop core campaign theme, modular content pack, concept creation & launch readiness plan
- **Asset Planning & Creation** – Creation as per customer & channel matrix including MOA video, website, banner, emails, press release, & master pack design
- **HCP Segmentation & Targeting** – Utilize proprietary data sources & algorithms to identify, target, profile and create smart segmentation of HCPs
- **Campaign Setup** – Use AI & ML to develop strategic insights and enable a highly targeted marketing approach in a custom digital omnichannel experience using SFMC & HCP CRM
- **HCP Communications Plan** – aligned sales and marketing communication business plan to promote to HCPs including business rules and strategies
- **SF Sizing & Territory Design -** Utilize Rx potential, access & digital affinity to design territories and sales force sizing
- **Hire National Sales Manager** - Timing connected to completion of sizing exercise, backed into from launch date
- **Hire & Train SF -** Profiles developed, sourcing at geographical footprint, screening & interviews to align for offers as territories complete approval
- **Direct to Pharmacy Operations Setup** - Setup process flow for Rx triage to preferred pharmacy network to reduce substitution and increase fill rate, document management in accordance with pharmacy standards
- **Pharmacy Research –** Research to inform pharmacy strategy plan

Patient, Caregiver & Advocacy

- **Patient CRM, App & Portal Setup** - Build and support patient app and portal for patients to consume multiple support services, tools and resources. Integrated pharmacy and co-pay support, platform setup to facilitate patient-facing mobile App, consent management, and multi-channel communication, pharmacy distribution, reimbursement and co-pay support
- **Copay Operations Setup** - Integrated pharmacy and co-pay support; co-pay offer to eligible patients on website or at the time of drug dispense at pharmacy
- **Patient Education Materials Setup** - Develop disease education materials, including patient starter kit, patient brochure/FAQ, email campaign, and social media campaign, create consumer marketing materials.
- **Create Consumer Marketing Materials & Account Management –** Marketing in market tactics to promote to patients, and overall management of patient engagement program
- **Creative Campaign Creation** - Develop core campaign theme, modular content pack, concept creation & launch readiness plan
- **Omnichannel Strategy & Planning** - Setting the omnichannel content brief & developing the content plan
- **Patient Strategy & Segmentation** – Define patient journey, promotional strategy and segmentation
- **Patient Research** – Patient market research to inform strategy

Medical Education

- **Convention Activity and Asset Development -** Asset development and KOL speaker programs to educate HCPs on the benefits, risks, and best practices of prescribing CTx-1301
- **KOL Education Materials & Training –** Creation of KOL education training materials and speaker training programs for events
- **KOL Ad Board Planning –** Planning and coordination for planning & execution which includes KOL identification, content support (Invites, slide decks, post congress summary & event analytics)
- **Speaker Identification –** Identification of KOL for conventions and ad-board events

Payer

- **KAM Support** - Retain top customers and maintain/nurture key relationships over time. Act as strategic partner and advisor to the client and identify new opportunities to work together for mutual benefit.
- **KAM Alignment** - Adjust KAM alignment if necessary - quarterly review/confirmation post launch
- **Performance Management** – Manage KAM performance through pre decided guidelines, KPIs
- **Execute On Formulary Pull Through Launch Materials** – Pull-through materials for field force and KAMs to on prince and reimbursement promotional claims
- **Pull Through Announcements** – Create digital and printed templates to be used as announcements for each payor wins

HCP (may include Field Force)

- **Asset Planning & Creation** – Asset creation continues as per customer & channel matrix
- **Update HCP Segmentation & Targeting** – Update HCP segmentation & targeting as needed
- **Data Reporting & KPI Tracking** - Track & confirm KPIs / data reports are meeting needs and program performance evaluation
- **Campaign Deployment & Optimization** - Fully integrated omni-channel fully deployed (SF, VSRs & NPP), optimize channel mix through campaign analytics
- **Campaign Refresh**- Update Omnichannel campaign as per the learnings from campaign analytics
- **Launch Meeting** - Preparation planning to execute post approval and FF/KAM onboarding, align to early payer engagement for KAMs
- **POA Meetings** - Quarterly meetings (2x f2f, 2x virtual)
- **Sales Force Alignment** - Adjust sales force alignment if necessary - quarterly review/confirmation post launch
- **Sales Force Staffing** - Process and guidance set prior to launch and ongoing Performance Management
- **Direct to Pharmacy Operations** - Management and support - Outbound calls to patients/healthcare providers, Rx clarifications, document management in accordance with pharmacy standards, benefit verification, process prior authorization, fulfil and dispense medication

Patient, Caregiver & Advocacy

- **Patient CRM, App & Portal Operations** - Technology support and maintenance for patient portal and app
- **Ongoing Co-pay Eligibility & Claims Operations** - Co-pay management and support: Co-pay offer to eligible patients through website or at the time of drug dispense at pharmacy, processing and reporting
- **Patient Education Materials Refresh** - Refresh and development of branded materials in preparation for launch. Materials include patient starter kick, patient brochure/FAQ, email campaign, and social media campaign
- **OPDP Prep/Submission of Brand Materials –** Prepare in market materials to proactively gather FDA feedback prior to market release.
- **Advocacy Group Awareness and Meetings–** Develop relationships and deliver educational/promotional materials to advocacy groups
- **Deploy & Optimize Omnichannel -** Deploy omnichannel program, gather insights and creation new best action. Includes content production and refresh.

Medical Education

- **Speaker Training –** Coordination and facilitation of the speaker program along with the speaker training assistance from Medical SME (Medical director)
- **KOL Ad Board activity -** Planning and coordination for planning & execution which includes KOL identification, content support (Invites, slide decks, post congress summary & event analytics)
- **Speaker Programs, Convention Activity, and Asset Development –** Asset development and KOL speaker programs to educate HCPs on the benefits, risks, and best practices of prescribing CTx-1301

Exhibit 31.1

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

I, Shane J. Schaffer, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2025 of Cingulate Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2025

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

Exhibit 31.2

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

I, Jennifer L. Callahan, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2025 of Cingulate Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2025

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

Exhibit 32.1

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended March 31, 2025 (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: May 8, 2025

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

Exhibit 32.2

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

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Quarterly Report on Form 10-Q of Cingulate Inc. (the "Company") for the period ended March 31, 2025 (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: May 8, 2025

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