Zacks Small-Cap Research
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Cingulate, Inc. (CING - NASDAQ)

CING: April Pre-NDA Meeting

Cingulate's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. We apply a success probability of 85% to the CTx-1301 program. The model includes contributions from the United States.

Current Price (3/7/2025)	$3.86
Valuation	**$62.00**

OUTLOOK

Cingulate is developing its Precision Timed Release (PTR) technology to deliver ADHD drugs to improve onset & efficacy of previously approved products. It licensed rights to manufacturing a 3-layer tablet that releases dexmethylphenidate (CTx-1301) over the active day. CTx-1301 provides immediate onset, eliminates the need for a booster dose, reduces diversion & simplifies dosing among other benefits. This addresses a large market encompassing ~93 million US ADHD scripts in 2023.

Phase III clinical work has shown an impressive size effect, safe use of CTx-1301 & evidence of all day coverage. Cingulate's candidates will pursue the 505(b)(2) regulatory path used for a new release mechanism & approved underlying API. A fed/fast study & additional stability data are needed before FDA submission and approval which is expected in 2025.

Other candidates include CTx-1302 (dextroamphetamine) for ADHD and CTx-2103 (buspirone) which also use the PTR technology. We may see CTx-2103 emerge as the follow-on product to -1301 due to a clear regulatory path forward.

An agreement with Indegene has been signed which will support commercialization of CTx-1301. Cingulate maintains the option to partner with others or be bought out without further obligation to Indegene.

SUMMARY DATA

52-Week High	**20.83**
52-Week Low	**1.80**
One-Year Return (%)	**-73.0**
Beta	**-0.8**
Average Daily Volume (sh)	**143,472**
Shares Outstanding (mil)	**3.2**
Market Capitalization ($mil)	**12.4**
Short Interest Ratio (days)	**1.1**
Institutional Ownership (%)	**2.8**
Insider Ownership (%)	**3.3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Tech Devices**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023					-$312 A
2024	-$7.21 A	-$5.47 A	-$1.83 A	-$1.49 E	-$9.50 E
2025					-$2.33 E
2026					-$0.27 E

WHAT'S NEW

Since the report of third quarter results, Cingulate, Inc. (NASDAQ: CING) has executed a $5 million capital raise, completed its fast-fed study and reported safety results from its Phase III trials. As we move down the home stretch towards the FDA submission, Cingulate has a pre-new drug application (NDA) meeting scheduled for early April and anticipates filing its NDA with the agency by mid-2025. We also expect to see further safety data from the consolidated Phase III studies at an upcoming but as yet unidentified scientific conference.

Management is looking forward to commercialization which could start in 2026. Cingulate has a non-binding arrangement with Indegene[1] to commercialize the product in the United States on a fee for service basis. Cingulate may pursue a co-promote that would leverage the strengths of multiple parties. Outside the US, Cingulate is looking for partners to commercialize CTx-1301. Beyond international sales, the goal of these relationships is to obtain upfront amounts that will support CTx-1301's launch in the United States. While the team has not affirmed any specific discussions, we believe that they have had at least initial talks with prospective global partners. Management is looking ahead to the Drug, Chemical & Associated Technologies (DCAT) meeting later in March which may yield further prospects for business development and licensing.

The pathway forward for FDA submission includes several parallel efforts which include updating stability data on 2024 batches of CTx-1301, completing the analysis of the fast fed study and attendance at the pre-NDA meeting with the FDA in early April. Notes from the meeting are expected about a month later, which will provide final details required for completing the NDA. NDA submission is expected by mid-2025. We anticipate a 10-to-12-month turnaround time by the agency from initial submission. Upon acceptance of the NDA, the FDA will provide a firm target action date, which we forecast to fall in 2Q:26 or mid-2026.

Safety Results Submitted to FDA

Safety results from Cingulate's Phase III studies were submitted to the FDA in preparation for the upcoming pre-NDA meeting which is scheduled for April 2nd, 2025. A March 4th press release shared safety data from two Phase III pediatric and adolescent studies. This included a fixed dose study, a dose optimization study, a food effect study with healthy adults, using a single 50mg dose of CTx-1301. While some of the data from the food effect study are still being analyzed, broadly speaking, data from the studies revealed:

- No subjects experienced a serious treatment emergent adverse event (TEAE), a serious TEAE or a TEAE leading to death;
- There were no clinically relevant trends in TEAEs overall;
- Medical findings for the 50 mg dose are consistent with the previous study performed with the 25mg dose, which showed that CTx-1301 could be taken with or without food.

Completion of Fast/Fed Study

A fast-fed study is required as part of the NDA submission. This effort was completed and measured the effect of food on the rate and extent of absorption and the overall bioavailability of CTx-1301 at the highest dose of 50 mg by measuring serum drug levels. The study was conducted at a site near the company's headquarters in Kansas City and enrolled 26 healthy adults using a crossover design. It was designed as an open-label, randomized, single-dose, two-sequence, two-period, in-clinic study. Subjects were randomized into one of two sequences: a fasted state, and a fed state, after a high-fat test meal. Partial data was submitted to the FDA as part of the pre-NDA meeting submission and additional data from the study are expected in 2Q:25.

The primary pharmacokinetic (PK) endpoints as reported in the January 7th press release were:

- Maximum concentration (C_{MAX}) during the first 28 hours after dosing;
- Total amount of the active pharmaceutical ingredient (API), dexmethylphenidate, in the blood.

In the study, PK endpoints were expressed as the area under the plasma drug concentration-time curve (AUC) from dosing until the time of the last measured concentration ($AUC_{0\text{-last}}$) and over the time from dosing taken to the limit as the end time moves towards infinity ($AUC_{0\text{-}\infty}$).

[1] See our initiation for further details on the Indegene Joint Commercialization Agreement.

Video Interview Series

CEO Shane Schaffer explains the Precision Timed Release technology, discusses the CTx-1301 program, and estimates the timeline to FDA submission for the ADHD candidate in a series of videos with links to the features below. See below for links to each of the interviews.

Exhibit I – Cingulate CEO Dr. Shane Schaffer

Source: Cingulate Video Series December 2024

- Timeline to FDA Submission
- CTx-1301 Provides Active Day Coverage
- Precision Timed Release Technology
- Fireside Chat with CEO Shane Schaffer
- Final Stages of Development for CTx-1301
- ADHD Symptoms and Disorder Dynamics
- Why Will Patients be Willing to Pay for CTx-1301?

Capital Raise

A few days before Christmas, Cingulate completed a financing which raised net proceeds of $5 million. The securities sale was made to an accredited investor and was structured as a non-convertible, unsecured promissory note with a principal amount of $5,480,000. The note will accumulate interest of 9% per annum and will mature 18 months after issuance in June 2026. Proceeds will be used to fund clinical, manufacturing, and regulatory activities along with other operating costs.

Milestones

- Complete Phase III Clinical Development Plan – 1H:24
- Complete Registration Batches for NDA Filing – 1H:24
- FDA clearance of CTx-1301 for NDA submission (505(b)(2)) – May 2024
- Issuance of EU patent entitled Tripulse release stimulant formulations – August 2024
- Launch of CTx-1301 food effect study – September 2024
- NDA Preparation for CTx-1301 – 2H:24
- Registrational stability data – 2H:24
- High dose food effect study, CTx-1301 completed – January 2025
- DCAT Association Meeting in New York – March 2025
- Roth Conference attendance, Dana Point, California – March 2025
- 2024 operating and earnings report – near month end March 2025
- Final data from CTx-1301 fast-fed study – April 2025
- FDA pre-NDA meeting – April 2nd, 2025
- Written notes from pre-NDA meeting – May 2025
- File CTx-1301 NDA – mid-2025
- Partnership development – 2025/2026

Summary

Cingulate completes the final study required to prepare its NDA and submits safety data to the FDA in preparation for its pre-NDA meeting in early April. We expect the notes from the meeting to be available in May, which will help finalize the new drug application which should be ready for submission by mid-2025. A recent capital raise gives the company sufficient liquidity to continue into 2026. This does not include any potential licensing deals with ex-US entities that could provide additional capital to support the launch of CTx-1301. We expect to hear an update from the company in a couple weeks as it reports 2024 results.

PROJECTED FINANCIALS

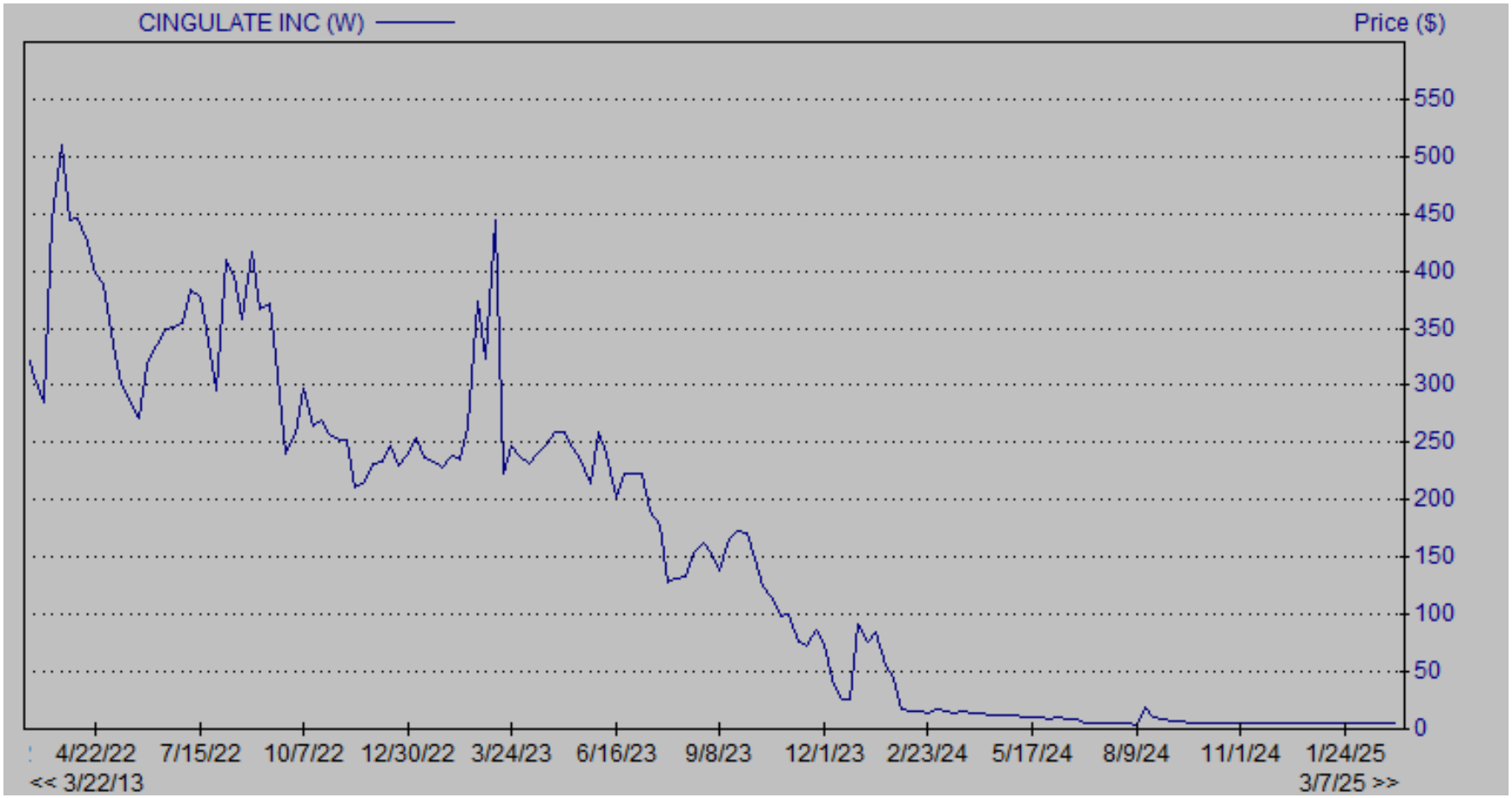
Cingulate, Inc. - Income Statement

Cingulate, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$7,774**
Research & Development	$15,493	$1,807	$1,881	$1,429	$3,525	$8,642	$4,478	$3,000
General & Administrative	$7,266	$1,141	$1,325	$1,854	$1,275	$5,595	$5,230	$6,125
Operating Income	($22,759)	($2,948)	($3,206)	($3,282)	($4,800)	($14,236)	($9,708)	($1,351)
Operating Margin								
Interest Expense & Other, net	($776)	($24)	($3)	$50	$0	$23	$0	$0
Loss Before Income Taxes	($23,535)	($2,972)	($3,210)	($3,232)	($4,800)	($14,214)	($9,708)	($1,351)
Income Tax								
Net Loss	**($23,535)**	**($2,972)**	**($3,210)**	**($3,232)**	**($4,800)**	**($14,214)**	**($9,708)**	**($1,351)**
Net Loss Per Share	**($311.99)**	**($7.21)**	**($5.47)**	**($1.83)**	**($1.49)**	**($9.50)**	**($2.33)**	**($0.27)**
Weighted Average Shares	75	412	586	1,766	3,220	1,496	4,174	5,050

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Cingulate, Inc. – Share Price Chart[2]



[2] Source: Zacks Research System

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