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Cingulate, Inc. (CING - NASDAQ)

CING: First Quarter 2025 Results

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 (5/14/2025)	$4.25
Valuation	**$45.00**

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 fast/fed 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.

Cingulate signed an agreement with Indegene to support commercialization of CTx-1301, but 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 (%)	**-56.3**
Beta	**-0.9**
Average Daily Volume (sh)	**102,450**
Shares Outstanding (mil)	**4.2**
Market Capitalization ($mil)	**17.5**
Short Interest Ratio (days)	**2.0**
Institutional Ownership (%)	**2.3**
Insider Ownership (%)	**2.6**
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-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2025	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2026					$7.8 E
2027					$20.2 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024	-$7.21 A	-$5.47 A	-$1.83 A	-$1.91 A	-$10.20 A
2025	-$1.04 A	-$0.62 E	-$0.52 E	-$0.44 E	-$2.48 E
2026					-$1.50 E
2027					-$0.05 E

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WHAT'S NEW

Cingulate, Inc. (NASDAQ: CING) reported first quarter 2025 results on May 8th, 2025. No revenues were recorded and operating expense of $3.7 million was recognized. Over the last several months, Cingulate has raised capital, completed its fast-fed study, reported its safety results and completed its pre-NDA meeting with the FDA. Cingulate continues to prepare documents and conduct final requirements to support filing its new drug application (NDA) with the agency by mid-2025.

1Q:25 Financial and Operational Results

Cingulate reported first quarter results in a press release and Form 10-Q filing with the SEC on May 8th. For the quarter ending March 31st, 2025, the company reported a net loss of ($3.8) million or ($1.04) per share. For 1Q:25 versus the same prior year period:

- General & Administrative expenses were $1.5 million, up 30% from $1.1 million, attributable to an increase in personnel expenses and legal and professional fees. The increase in personnel costs resulted from the reinstatement of base salaries in September 2024 following salary reduction measures implemented in late 2023. Legal and professional fees rose on an increase in financial, accounting and investor relations fees;
- Research and development expenses rose 23% to $2.2 million from $1.8 million from higher personnel and regulatory costs. Higher personnel costs stemmed from the reinstatement of base salaries in September 2024;
- Net interest and other expense were ($97,000) compared to ($24,000) related to interest incurred on outstanding notes payable offset by interest earned on invested balances;
- Net loss was ($3.8) million vs. ($3.0) million or ($1.04) per share in 1Q:25.

As of March 31st, 2025, cash totaled $9.5 million. This amount compares to the $12.2 million cash balance held at the end of 2024. Cash burn was ($4.6) million for the quarter partially offset by financing cash contributions from the At-The-Market (ATM) Agreement with H.C. Wainwright and the Lincoln Park Purchase Agreement. After quarter end, Cingulate raised an additional $1.6 million through the ATM and Purchase Agreement.

CTx-1301 Regulatory and Commercialization Steps

Safety results from Cingulate's Phase III studies were submitted to the FDA in preparation for the upcoming pre-NDA meeting which was held on April 2nd, 2025. A March 4th press release provided a preview of the 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.

Cingulate is completing the final requirements for its NDA submission. The company held its pre-NDA meeting, which will provide final guidance needed to submit an approvable package to the agency. A May 14th press release announced that the notes from the meeting had been received and that the NDA was on track for submission this summer. These minutes are important as they document the key discussion points, any agreements reached and the FDA's recommendations. The notes serve as an official record of the meeting and provide a reference throughout the drug development and approval process. A summary of the FDA's minutes as provided by Cingulate is below.

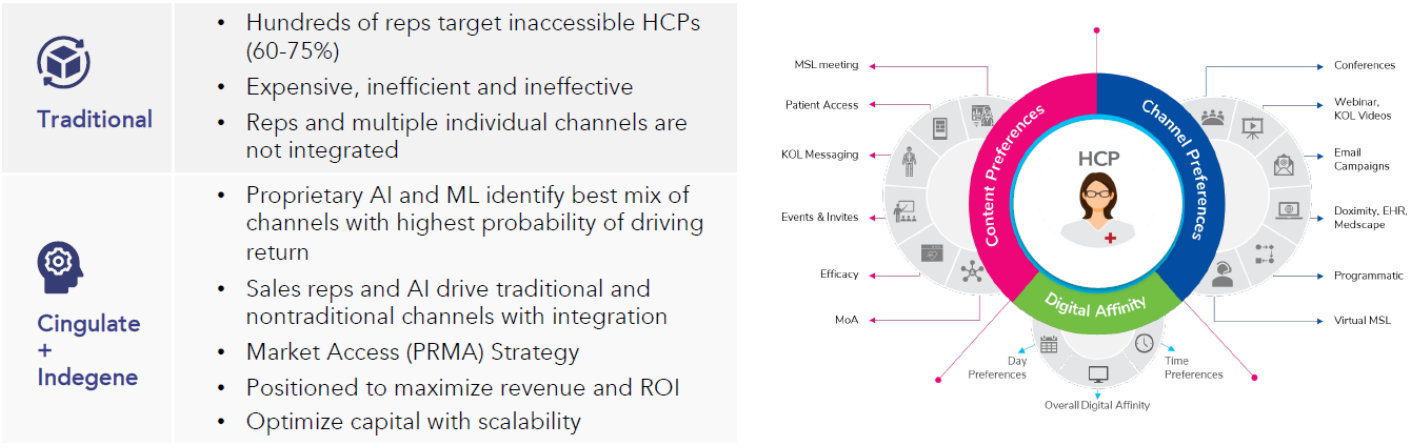
- FDA agreed to a post-NDA approval commitment of additional stability data for CTx-1301;
  - Shelf-life may be extended to 24 months at launch;
- Available nonclinical safety data appears to support a filing;
- CTx-1301 may rely on Focalin XR's efficacy and safety data;
- Cingulate's proposed approach to the integrated safety summary and integrated summary of efficacy appears reasonable.

Assuming normal review and approval timelines, commercialization could start as soon as next year. 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 also pursue a co-promote that would leverage the strengths of multiple parties. Outside the

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

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.

Exhibit I – Indegene's Integrated Commercial Model



Cingulate April 2025 Investor Presentation

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 to be measured include:

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

An April 29th press release summarized top-line results from the study. It demonstrated that the 50 mg CTx-1301 dose can be taken with or without food. PK measurements were taken and adverse events were found to be consistent with previous results and indicate a favorable tolerability profile. Full results from the study will be presented at a future medical meeting.

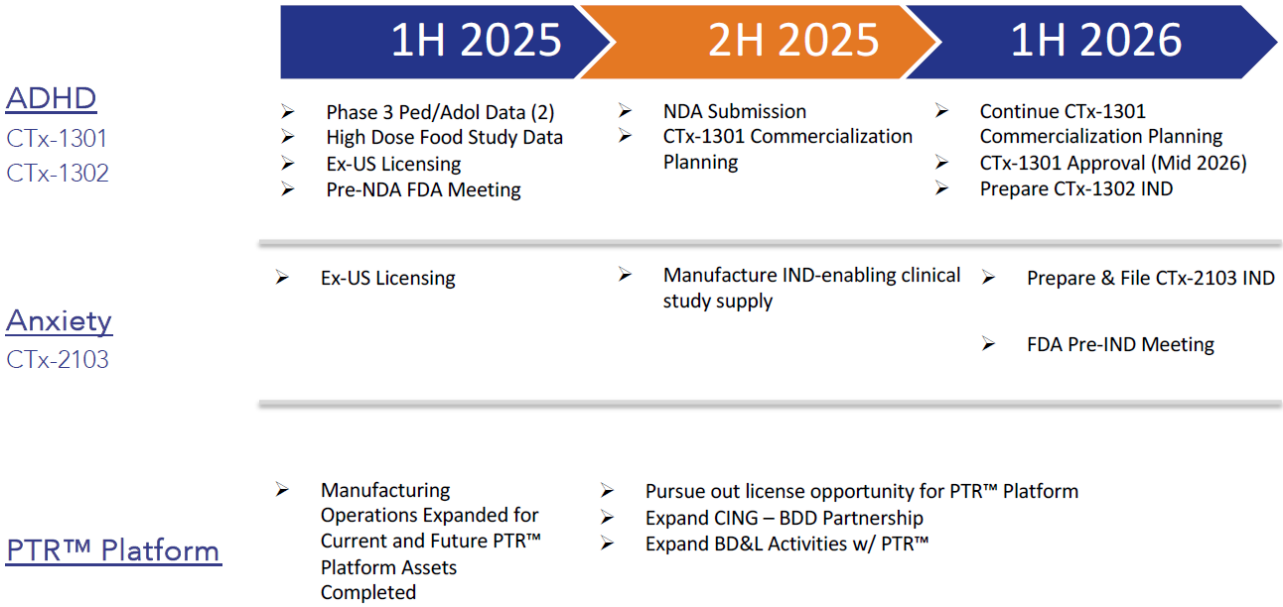
Valuation

We adjust our valuation to reflect the actual and anticipated number of shares outstanding over the next year and other claims on equity including options and warrants. While our enterprise value remains the same, the increase in the estimated shares generates a valuation of $45 per share.

Milestones

- High dose food effect study, CTx-1301 completed – January 2025
- DCAT Association Meeting in New York – 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 – Summer 2025
- Partnership development – 2025/2026

Exhibit II – 2025 and 2026 Goals



Cingulate April 2025 Investor Presentation

Summary

With the report of first quarter earnings, Cingulate updates investors on progress with the NDA submission process including the pre-NDA meeting and receipt of FDA notes. After the FDA interaction, the ball is now in Cingulate's court to polish its application and deliver it to the agency. We expect to hear more from Cingulate management on its commercialization strategy, especially regarding the relationship with Indigene in the near term.

PROJECTED FINANCIALS

Cingulate, Inc. - Income Statement

Cingulate, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$7,774**	**$20,219**
Research & Development	$9,445	$2,223	$1,100	$1,008	$945	$5,276	$6,500	$7,890
General & Administrative	$6,200	$1,483	$1,512	$1,588	$1,600	$6,183	$9,125	$12,680
Operating Income	($15,645)	($3,706)	($2,612)	($2,596)	($2,545)	($11,459)	($7,851)	($351)
Operating Margin								
Interest Expense & Other, net	$99	($97)	$0	$0	$0	($97)	$0	$0
Loss Before Income Taxes	($15,546)	($3,803)	($2,612)	($2,596)	($2,545)	($11,556)	($7,851)	($351)
Income Tax								
Net Loss	**($15,546)**	**($3,803)**	**($2,612)**	**($2,596)**	**($2,545)**	**($11,556)**	**($7,851)**	**($351)**
Net Loss Per Share	**($10.20)**	**($1.04)**	**($0.62)**	**($0.52)**	**($0.44)**	**($2.48)**	**($1.50)**	**($0.05)**
Weighted Average Shares	1,525	3,647	4,200	4,950	5,850	4,662	5,250	6,600

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

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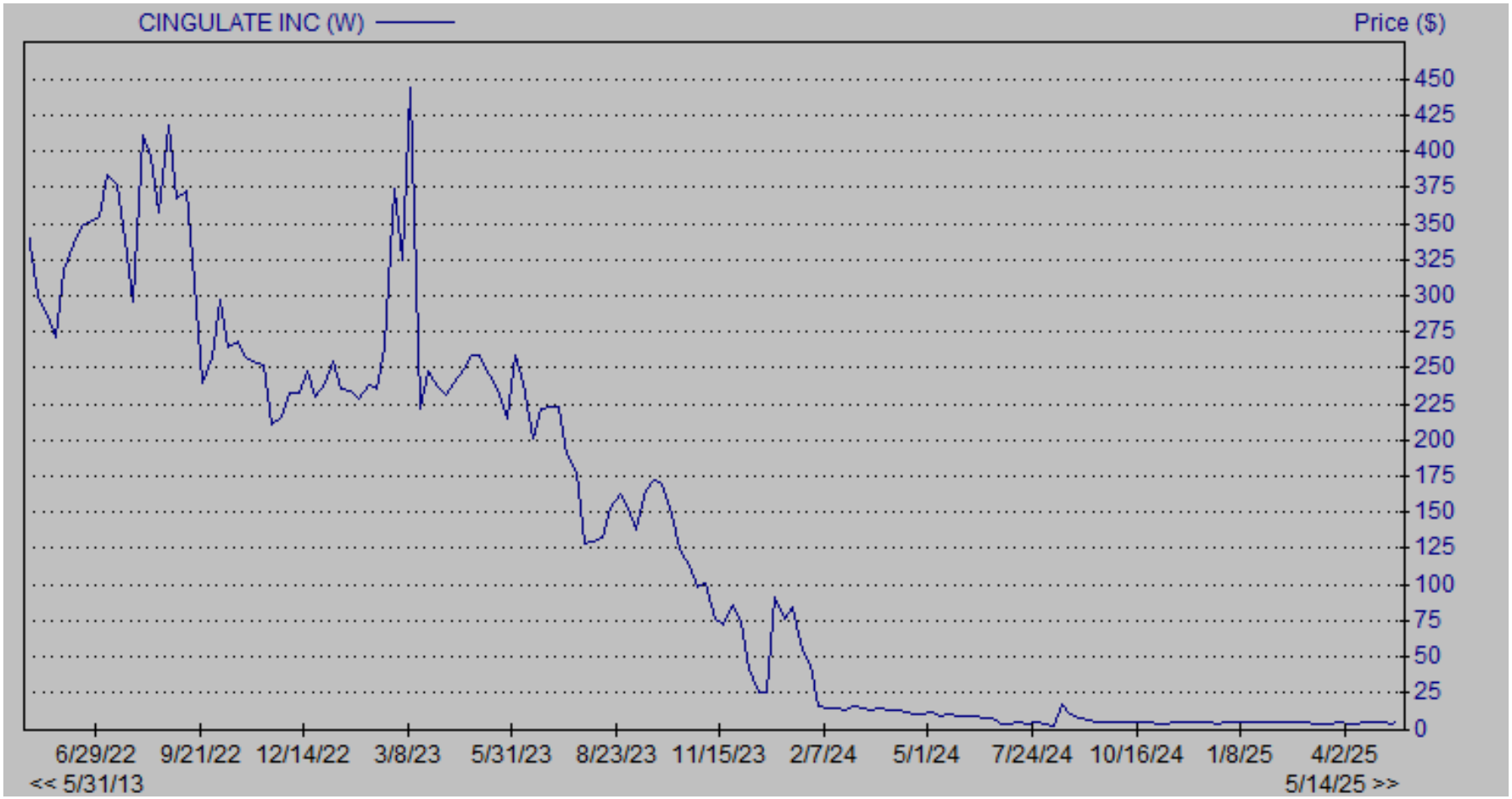
HISTORICAL STOCK PRICE

Cingulate, Inc. – Share Price Chart[2]



[2] Source: Zacks Research System

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