

Cingulate, Inc.

(CING - NASDAQ)

CING: NDA Submitted

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 (8/22/2025) **\$4.19**
Valuation \$45.00

OUTLOOK

Cingulate is developing its Precision Timed Release (PTR) technology to deliver ADHD medicines to improve onset & efficacy of previously approved products. It licensed rights to manufacturing a 3-layer tablet that releases dexamethylphenidate (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. In July 2025, the NDA was submitted.

Other candidates include CTx-1302 (dextroamphetamine) for ADHD and CTx-2103 (buspirone), both of 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 **11.88**
 52-Week Low **3.02**
 One-Year Return (%) **-63.1**
 Beta **-0.8**
 Average Daily Volume (sh) **130,927**

Shares Outstanding (mil) **5.4**
 Market Capitalization (\$mil) **22.7**
 Short Interest Ratio (days) **2.1**
 Institutional Ownership (%) **5.5**
 Insider Ownership (%) **1.9**

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				
2025	\$0.0 A	\$0.0 A	\$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	-\$1.09 A	-\$0.53 E	-\$0.44 E	-\$2.91 E
2026					-\$1.29 E
2027					-\$0.05 E

WHAT'S NEW

Cingulate, Inc. (NASDAQ: CING) [reported](#) second quarter 2025 results on August 19th, 2025. No revenues were recorded and operating expense of \$4.7 million was recognized. The company has now submitted its new drug application for CTx-1301 and is looking ahead to October for an anticipated acceptance by the FDA. Cingulate also saw changes in the management ranks as the company's focus shifts to pre-commercialization activities and communication at investor and medical conferences. A purchase agreement was signed with Lincoln Park Capital, which is expected to augment the in place at-the-market (ATM) facility and support the crescendo of activities into anticipated approval in the middle of 2026.

2Q:25 Financial and Operational Results

Cingulate [reported](#) second quarter results in a press release and [Form 10-Q](#) filing with the SEC on August 19th. For the quarter ending June 30th, 2025, the company reported a net loss of (\$4.8) million or (\$1.09) per share. For 2Q:25 versus the same prior year period:

- Research and development expenses were \$2.7 million, up 44% from \$1.9 million, attributable to an increase in clinical operations and regulatory costs partially offset by a decline in manufacturing costs. The increase in clinical operations costs was attributable to the close-out and recognition of analytical activities required for NDA submission of CTx-1301. Regulatory costs were up as the team prepared for the pre-NDA meeting with the FDA and the NDA submission;
- General & administrative expenses rose 47% to \$1.9 million from \$1.3 million on account of higher legal and professional fees;
- Net interest and other expense were (\$139,000) compared to (\$3,000) related to interest incurred on outstanding notes payable offset by interest earned on cash balances;
- Net loss was (\$4.8) million vs. (\$3.2) million or (\$1.09) per share in 1Q:25.

As of June 30th, 2025, cash totaled \$8.9 million. This amount compares to the \$12.2 million cash balance held at the end of 2024. Cash burn was (\$9.4) million for the first half, partially offset by \$6.1 million largely consisting of financing cash contributions from the ATM Agreement with H.C. Wainwright and the Lincoln Park Purchase Agreement. After quarter end, Cingulate raised an additional \$690,000 through the ATM and Purchase Agreement.

CTx-1301 FDA Submission Timeline

Safety results from Cingulate's Phase III studies were submitted to the FDA this spring. 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 50 mg dose of CTx-1301.

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.

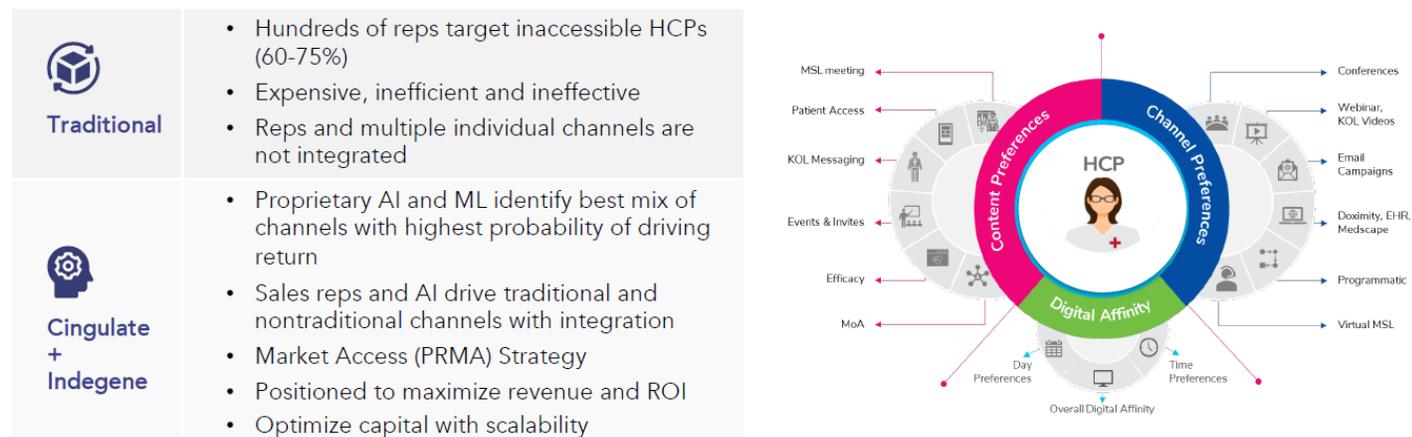
A summary of the FDA's minutes as provided by Cingulate is below.

- 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.

On August 6th, Cingulate [announced](#) that it had submitted its NDA to the FDA for CTx-1301. It expects to hear whether or not the submission has been accepted within 60 days of submission. If accepted, this sets up the application to potentially receive approval by mid-2026.

Assuming normal review and approval timelines, commercialization could start as soon as next year. Cingulate will work with Indegene¹ to commercialize the product in the United States and may also 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.

Exhibit I – Indegene’s Integrated Commercial Model



Cingulate April 2025 Investor Presentation

Management Changes

On August 15th, Cingulate provided a management update informing investors of the appointment of CFO Jennifer Callahan as interim CEO and board member Jay Roberts as Executive Chairman. Shane Schaffer is on administrative leave in connection with ongoing legal matters unrelated to the company and its operations. While any change in management calls for a review of the team, the heavy lifting for the next year has been accomplished with the successful submission of the NDA for CTx-1301. We expect the team to begin a measured ramp of pre-commercialization activities.

Objectives Over the Next Twelve Months

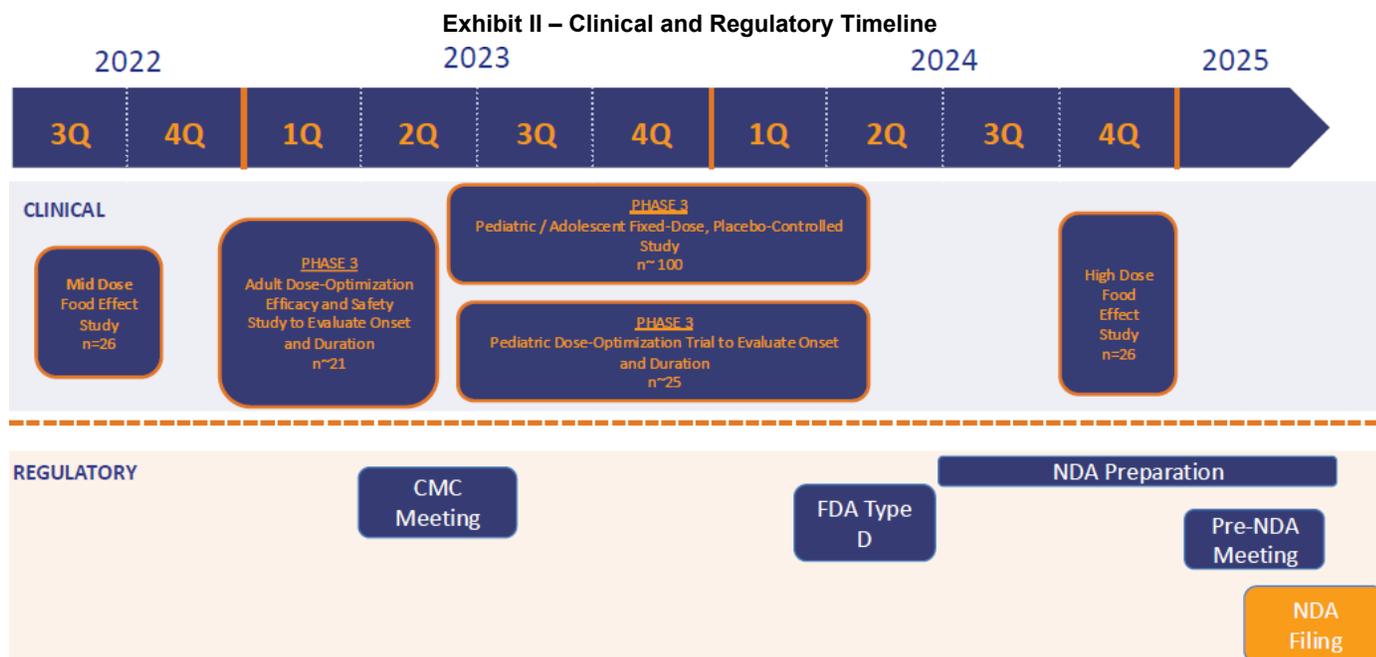
With the submission of CTx-1301 now complete, we expect to see acceptance of the NDA in early October. In parallel with the regulatory process, Cingulate management and related parties will participate in investor and medical conferences to communicate the value of its product. CEO Jennifer Callahan, Vice President of Corporate Communications Thomas Dalton and co-founders Dr. Matthew Brams and Dr. Raul Silva are all participating in the messaging effort on behalf of the company. A key opinion leader in the attention-deficit/hyperactivity disorder (ADHD) space and advisor for Cingulate, Dr. Ann Childress, will also present at medical conferences over the next several months. This includes the American Academy of Child and Adolescent Psychiatry (AACAP) conference in October where she will be presenting on behalf of the company.

Pre-commercialization activities have also moved to the forefront. Cingulate has announced its non-binding arrangement with Indegene to commercialize CTx-1301 in the United States on a fee for service basis. In preparation, management is now conducting market access research to better understand how its time release version of dex-methylphenidate can be successfully adopted, reimbursed, and used by patients. The company will also soon sign its commercial supply agreement and begin the manufacturing of process validation batches. The resulting drug product will be saleable and can be used to fulfill pre-launch inventory.

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

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
- CTx-1301 NDA submitted to FDA – July 31st, 2025
- Jennifer Callahan appointed as interim CEO - August 2025
- John Roberts appointed as executive chairman – August 2025
- Partnership development – 2025/2026



Cingulate May 2025 Investor Presentation

Summary

The company's profile has shifted materially since the first quarter update: the NDA has been submitted, an acceptance from the FDA is expected in a few weeks, key leaders have changed and the activities of the company are now focused on precommercialization and manufacturing preparation. Upcoming events include an anticipated acceptance of the NDA in October and a mid-year 2026 approval. As we move into the fall, we expect the management team and others associated with Cingulate to participate in medical and investor meetings communicating the findings of the data submitted to the FDA to a broader audience. We expect to hear more from Cingulate management on its commercialization strategy, especially regarding the relationship with Indegene in the near term.

PROJECTED FINANCIALS

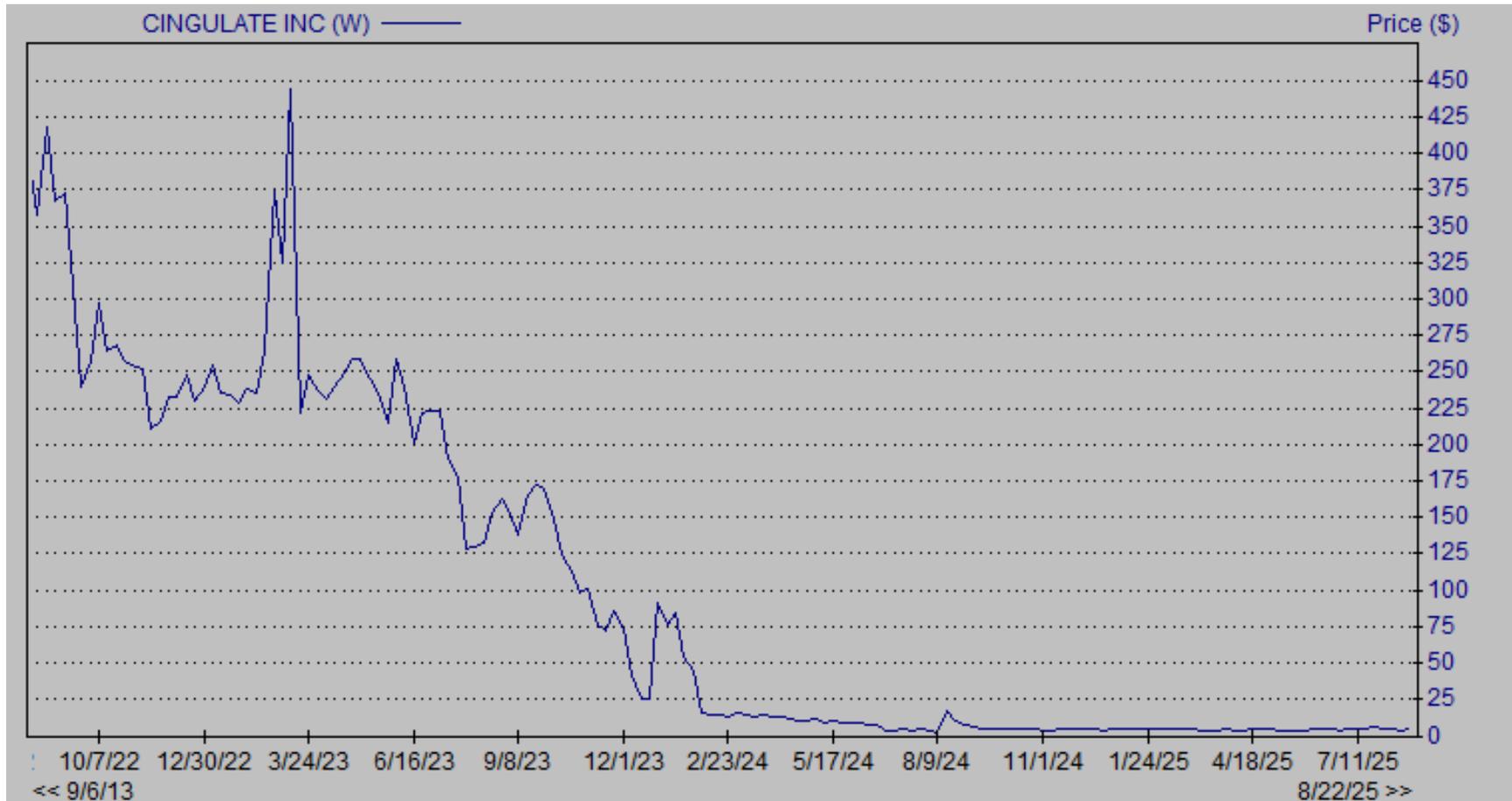
Cingulate, Inc. - Income Statement

Cingulate, Inc.	2024 A	Q1 A	Q2 A	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	\$2,701	\$1,300	\$945	\$7,169	\$6,500	\$7,890
General & Administrative	\$6,200	\$1,483	\$1,949	\$1,588	\$1,600	\$6,620	\$9,125	\$12,680
Operating Income	(\$15,645)	(\$3,706)	(\$4,650)	(\$2,888)	(\$2,545)	(\$13,789)	(\$7,851)	(\$351)
<i>Operating Margin</i>								
Interest Expense & Other, net	\$99	(\$97)	(\$139)	\$0	\$0	(\$235)	\$0	\$0
Loss Before Income Taxes	(\$15,546)	(\$3,803)	(\$4,789)	(\$2,888)	(\$2,545)	(\$14,024)	(\$7,851)	(\$351)
Income Tax								
Net Loss	(\$15,546)	(\$3,803)	(\$4,789)	(\$2,888)	(\$2,545)	(\$14,024)	(\$7,851)	(\$351)
Net Loss Per Share	(\$10.20)	(\$1.04)	(\$1.09)	(\$0.53)	(\$0.44)	(\$2.91)	(\$1.29)	(\$0.05)
Weighted Average Shares	1,525	3,647	4,389	5,400	5,850	4,822	6,100	6,600

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

HISTORICAL STOCK PRICE

Cingulate, Inc. – Share Price Chart²



² Source: Zacks Research System

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