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John D. Vandermosten
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
101 N. Wacker Drive, Chicago, IL 60606

Cingulate, Inc. (CING - NASDAQ)

CING: Third Quarter 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 (11/14/2025)	$3.49
Valuation	**$35.00**

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 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. 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	**6.01**
52-Week Low	**3.21**
One-Year Return (%)	**-20.7**
Beta	**-0.8**
Average Daily Volume (sh)	**181,673**
Shares Outstanding (mil)	**6.8**
Market Capitalization ($mil)	**23.7**
Short Interest Ratio (days)	**1.4**
Institutional Ownership (%)	**4.4**
Insider Ownership (%)	**1.5**
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 2025 Estimate	**N/A**
P/E using 2026 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 A	$0.0 A	$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	-$1.35 A	-$0.38 E	-$3.65 E
2026					-$0.95 E
2027					-$0.04 E

WHAT'S NEW

Cingulate, Inc. (NASDAQ: CING) reported third quarter 2025 results on November 13th, 2025. No revenues were recorded and operating expense totaled $6.0 million. The new drug application (NDA) to the FDA was accepted and a PDUFA date of May 31st, 2026 was given. Cingulate also saw changes in its management ranks as the company's focus shifts to pre-commercialization activities which included the appointment of Bryan Downey as Chief Commercial Officer. Company representatives have participated in investor and medical conferences, highlighted by Dr. Ann Childress' podium presentation at AACAP and attendance at the Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) conference. In the financing sphere, 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 leading up to the anticipated approval next year.

3Q:25 Financial and Operational Results

Cingulate reported third quarter results in a press release and Form 10-Q filing with the SEC on November 13th. For the quarter ending September 30th, 2025, the company reported a net loss of ($7.3) million or ($1.359) per share. For 3Q:25 versus the same prior year period:

- Research and development expenses were $2.8 million, nearly doubling from $1.4 million. The change was attributable to an increase in personnel expenses, manufacturing costs and regulatory costs. Personnel costs were further broken down into separation costs for an executive recognized in August 2025 and the payment of a contingent bonus plan that were payable upon acceptance of the NDA by the FDA. Manufacturing costs were related to preparation for product validation batches of CTx-1301. Regulatory costs were up as the team prepared to submit the NDA;
- General & administrative expenses rose 70% to $3.1 million from $1.9 million on account of increased personnel and other expenses, higher costs related to the arrangement with Indegene and personnel expenses related to the contingent bonus plan earned upon FDA acceptance of the NDA;
- Net interest and other expense were ($1.3) million compared to ($844,000) related to derivative change in fair value issued to Lincoln Park and its share purchase commitment and interest expense incurred on the promissory note;
- Net loss was ($7.3) million vs. ($4.1) million or ($1.35) and ($3.60) per share respectively.

As of September 30th, 2025, cash totaled $6.1 million. This amount compares to the $12.2 million cash balance held at the end of 2024. Cash burn was ($13.7) million for the first nine months of 2025, partially offset by $7.6 million in financing cash contributions from the ATM Agreement with H.C. Wainwright and the Lincoln Park Purchase Agreement. After quarter end, Cingulate issued additional shares through the ATM and Purchase Agreement to raise additional capital. It also exchanged shares to repay $850,000 in principal of the existing promissory note. A new promissory note with a face value of $6.57 million was issued in November to support near-term financing needs as Cingulate looks at multiple sources of capital as it prepares for commercialization. Management estimates that the company will need approximately $7 million in additional capital to support operations until the anticipated approval of CTx-1301.

Dr. Ann Childress AACAP Podium Presentation

Data from the CTx-1301 trials were presented at the American Academy of Child and Adolescent Psychiatry (AACAP) Annual Meeting in Chicago on October 24th, 2025. Dr. Ann Childress, President of the Center for Psychiatry and Behavioral Medicine and principal investigator on the CTx-1301 trials, gave the presentation. The data was generated in a randomized, double-blind, pediatric and adolescent, placebo-controlled study.

The data showed that CTx-1301 produced a rapid onset of effect and sustained efficacy through the evening hours. Safety and tolerability were consistent with the stimulant class, with no unexpected adverse events reported. Dr. Childress, quoted in the press release, said: "In summary, CTx1301 demonstrated dose dependent efficacy in improving ADHD symptoms in children and adolescents. The 37.5mg dose demonstrated the largest effect size in symptom reduction and effect sizes were pretty substantial, considering this was a forced dose and not a dose optimization study. The safety profile did not show anything that would be of concern, as it looks like other methylphenidates."

In our view, the selection of CTx-1301 for a podium presentation reflects increasing recognition of the product's potential to address unmet needs in ADHD. The timed delivery of three doses throughout the day recognizes the half-life limitations of dexmethylphenidate and the needs of ADHD patients which extend from morning to evening, but not beyond. We further see this recognition as an indication of broad interest among providers that prescribe the drug.

Exhibit I – Dr. Ann Childress

Source: Cingulate Video Interview, YouTube

To watch other videos in this series with Dr. Childress click the links below.

- Podium Presentation at AACAP
- Importance of Drug Half Life
- The Fastest Growing ADHD Population
- Difficult Times to Treat ADHD
- CTx-1301 Accepted By The FDA
- Forced Dose Titration Study
- CTx-1301 Adult Data
- CTx-1301 History
- Non-Stimulant ADHD Medications
- ADHD During COVID
- Animals, AI & AACAP

CTx-1301 FDA Submission Timeline

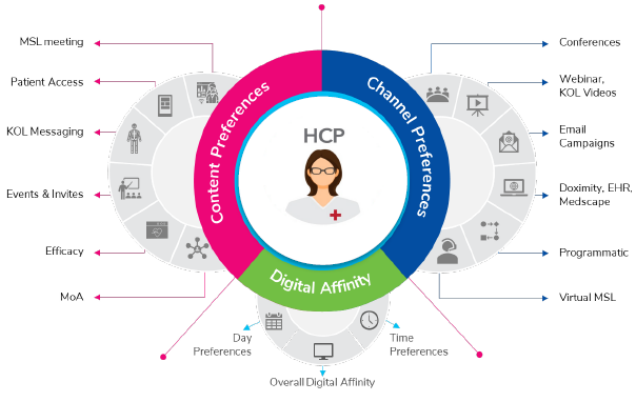
On August 6th, Cingulate announced that it had submitted its NDA to the FDA for CTx-1301. On October 14th, it announced that the NDA had been accepted and a PDUFA date of May 31st, 2026 was assigned.

Assuming that CTx-1301 is approved, commercialization could start as soon as next year. Cingulate will work with Indegene[1] 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.

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

Exhibit II – Indegene's Integrated Commercial Model

Traditional	• Hundreds of reps target inaccessible HCPs (60-75%) • Expensive, inefficient and ineffective • Reps and multiple individual channels are not integrated
Cingulate + Indegene	• Proprietary AI and ML identify best mix of channels with highest probability of driving return • Sales reps and AI drive traditional and nontraditional channels with integration • Market Access (PRMA) Strategy • Positioned to maximize revenue and ROI • Optimize capital with scalability



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 was placed 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.

In November, Cingulate announced that it had named Bryan Downey as Chief Commercial Officer. Mr. Downey has more than 25 years of experience in commercial strategy, leadership, and business transformation, including pharmaceutical product launches. Most recently, he has served as Managing Director at CRA's advisory practice. Previously, he held senior executive roles at Alfasigma USA and Jubilant Pharma, leading commercial operations and product commercialization efforts. Bryan also spent nearly two decades at Sanofi, where he served as Vice President and Head of the U.S. Cardiovascular and Allergy Business Unit where he oversaw multiple product launches and brand strategies across diverse therapeutic areas.

Bryan began his role with long "To Do" list. He is working on pricing reimbursement and market access, scientific publications and awareness and building out the omnichannel. He will also be working with key account managers to evaluate options for contracting.

Objectives Over the Next Twelve Months

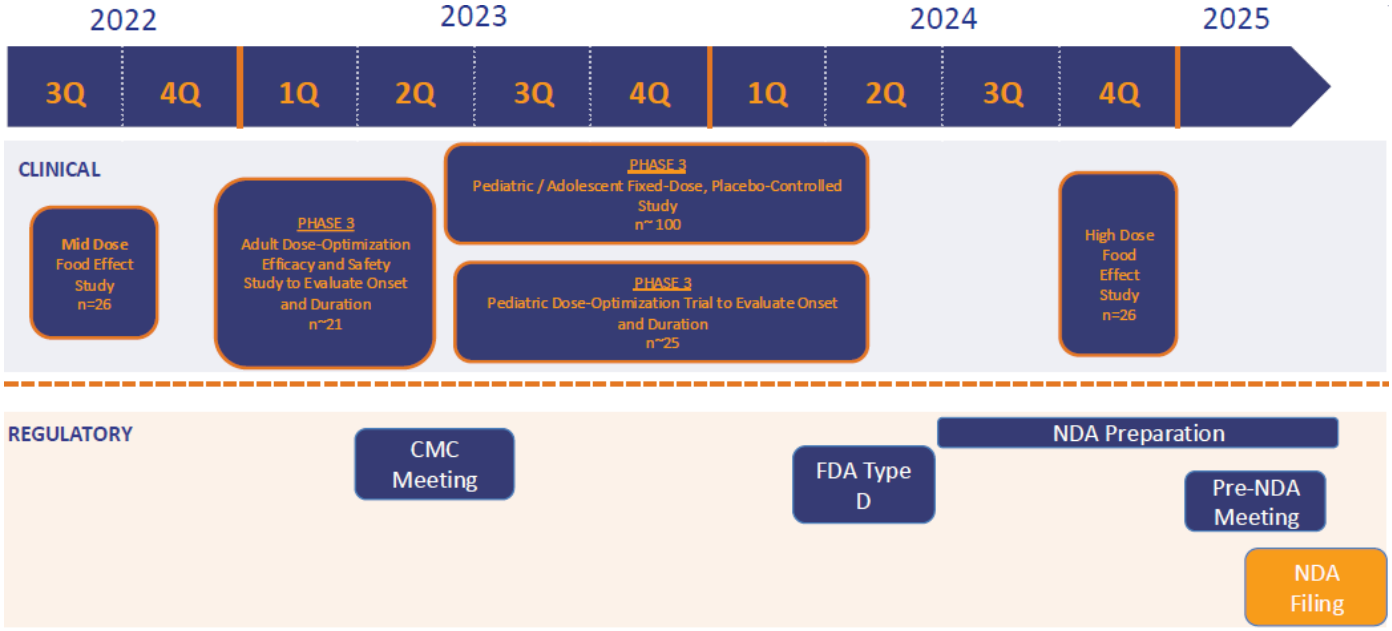
With the submission of CTx-1301 now complete, and acceptance granted in October, we now look ahead to the PDUFA date in May 2026. In parallel with the regulatory process, Cingulate management and related parties will participate in investor and medical conferences to communicate the value of its product. 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 dexmethylphenidate 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.

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
- Jay Roberts appointed as executive chairman – August 2025
- Bryan Downey appointed as Chief Commercial Officer – November 2025
- Participation in the CHADD conference in Kansas City – November 2025
- Completion of $6 million financing – November 2025
- CTx-1301 PDUFA Date – May 31st, 2026
- Partnership development – 2025/2026

Exhibit III – Clinical and Regulatory Timeline



Cingulate May 2025 Investor Presentation

Valuation

We update our valuation to reflect updated claims on equity and debt. This includes existing shares and debt as well as anticipated new issuances over the next year. Our enterprise value does not change. The result of our updates generates a target price of $35.00 per share.

Summary

The company's profile has improved materially since the beginning of the year. The NDA has been submitted and accepted, a PDUFA date of May 31st, 2026 has been assigned and new executives have been added. Cingulate is now focused on pre-commercialization activities, manufacturing preparation and manufacturing of inventory. Company executives and representatives have participated in medical and investor meetings communicating the findings of the data submitted to the FDA to a broader audience. This includes the AACAP and CHADD conferences held in Chicago and Kansas City respectively. Now with a dedicated CCO, we expect to hear further details on Cingulate's commercialization strategy, especially regarding the relationship with Indegene in the near-term.

PROJECTED FINANCIALS

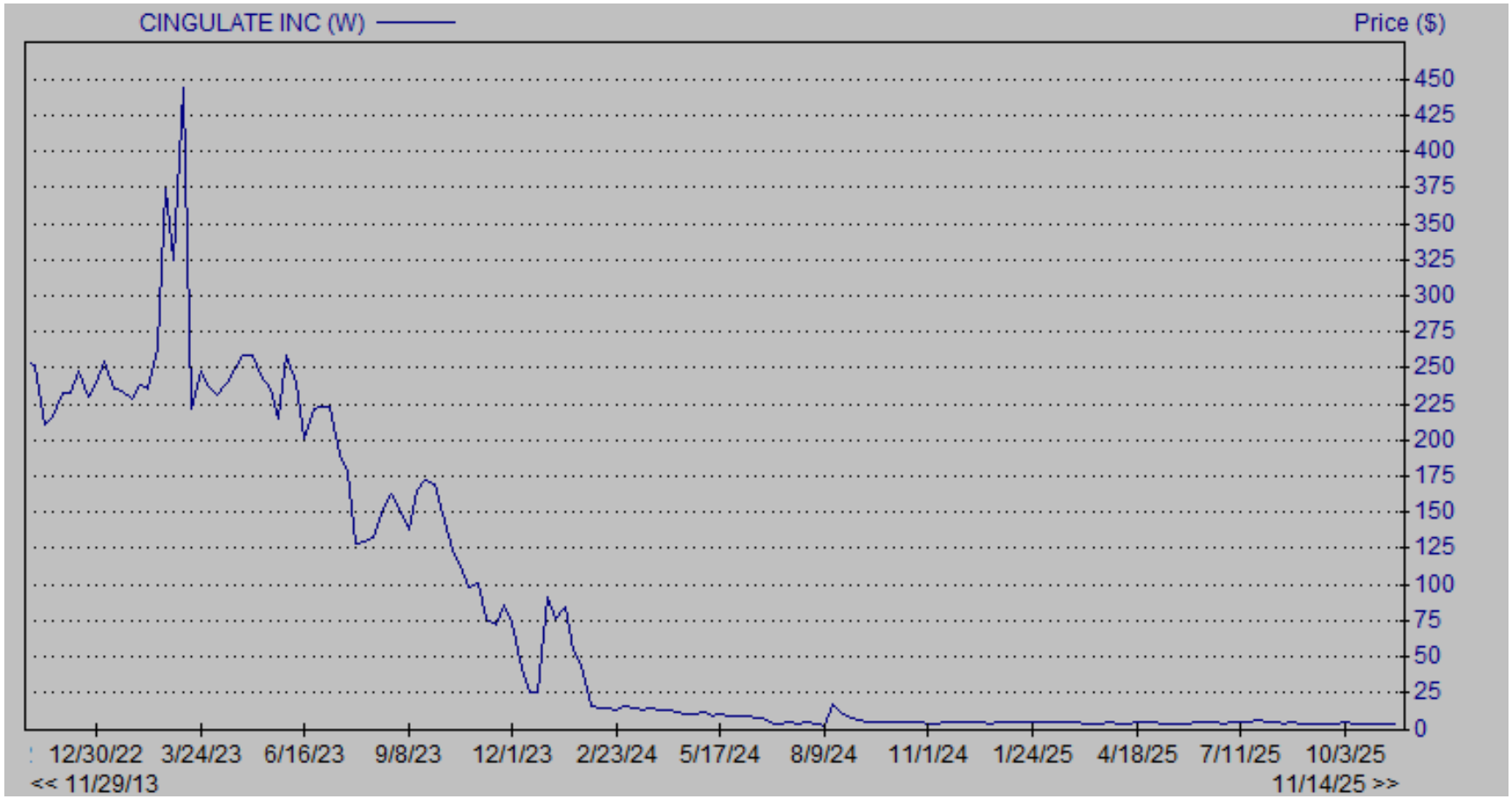
Cingulate, Inc. - Income Statement

Cingulate, Inc.	2024 A	Q1 A	Q2 A	Q3 A	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	$2,849	$945	$8,717	$6,500	$7,890
General & Administrative	$6,200	$1,483	$1,949	$3,147	$1,600	$8,180	$9,125	$12,680
Operating Income	($15,645)	($3,706)	($4,650)	($5,996)	($2,545)	($16,897)	($7,851)	($351)
Operating Margin								
Interest Expense & Other, net	$99	($97)	($139)	($1,345)	$0	($1,581)	$0	$0
Loss Before Income Taxes	($15,546)	($3,803)	($4,789)	($7,341)	($2,545)	($18,477)	($7,851)	($351)
Income Tax								
Net Loss	**($15,546)**	**($3,803)**	**($4,789)**	**($7,341)**	**($2,545)**	**($18,477)**	**($7,851)**	**($351)**
Net Loss Per Share	**($10.20)**	**($1.04)**	**($1.09)**	**($1.35)**	**($0.38)**	**($3.65)**	**($0.95)**	**($0.04)**
Weighted Average Shares	1,525	3,647	4,389	5,431	6,757	5,056	8,248	9,437

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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