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Cingulate, Inc. (CING - NASDAQ)

CING: 2024 Financial and Operational 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 (4/9/2025)	$3.68
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.

Cingulate signed an agreement with Indegene to 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 (%)	**-69.6**
Beta	**-0.9**
Average Daily Volume (sh)	**106,277**
Shares Outstanding (mil)	**3.8**
Market Capitalization ($mil)	**14.0**
Short Interest Ratio (days)	**1.0**
Institutional Ownership (%)	**2.4**
Insider Ownership (%)	**2.8**
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)
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 A	$0.0 A
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	-$1.91 A	-$10.20 A
2025					-$2.33 E
2026					-$0.27 E

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WHAT'S NEW

Cingulate, Inc. (NASDAQ: CING) reported 2024 results on March 26th, 2025. No revenues were recorded and operating expense of $15.6 million was recognized. Over the last several months, Cingulate has raised meaningful capital, completed its fast-fed study and reported safety results from its Phase III trials. As we review the checklist for the FDA submission, Cingulate held its pre-new drug application (NDA) meeting last week, continues document preparation and stability analysis and anticipates filing its NDA with the agency by mid-2025. We expect to see further safety data from the consolidated Phase III studies presented at an upcoming but as yet unidentified scientific conference. Lastly, the company received a $3 million grant from a private foundation to advance its preclinical anxiety asset CTx-2103. The funds should be sufficient to support the development of CTx-2103's investigational new drug (IND) application.

2024 Financial and Operational Results

Cingulate reported 2024 results in a press release and Form 10-K filing with the SEC on March 26th. For the year ending December 31st, 2024, Cingulate reported a net loss of ($15.5) million or ($10.20) per share. For 2024 versus the same prior year period:

- General & Administrative expenses were $6.2 million, down 15% from $7.3 million, attributable to lower personnel expenses and insurance. A reduction in headcount and temporary salary decreases were behind the compensation changes. Lower directors' and officers' insurance also contributed to the year over year decline. Areas of expense that rose include professional fees, including legal fees related to patent activity, and legal costs associated with special meetings, the reverse stock split and capital raises;
- Research and development expenses fell 39% to $9.4 million from $15.5 million as a result of decreased clinical activity and lower manufacturing costs. Prior year period expenses included significant costs related to two Phase III studies for CTx-1301, the fixed dose pediatric and adolescent safety and efficacy study and the pediatric dose optimization and duration study. Enrollment in these two studies was closed in early 2024 and the company will soon wind down the remaining analytical activities required for an NDA submission;
- Net interest and other expense were $99,000 compared to ($776,000) with prior year amounts related to promissory note's conversion to equity in 2023;
- Net loss was ($15.5) million vs. ($23.5) million or ($10.20) per share in 2024.

As of December 31st, 2024, cash totaled $12.2 million. This amount compares to the $52,000 cash balance held at the end of 2023. Net cash from financing was $30.8 million. Several financing transactions took place this year to generate these cash proceeds. This includes the issuance of common stock related to the ATM Agreement, the Lincoln Park Agreement, the February 2024 Offering, the June 2024 Warrant Inducement and the December $5 million financing transaction. So far in 2025, Cingulate raised an additional $1.7 million through its ATM and Lincoln Park Purchase Agreement.

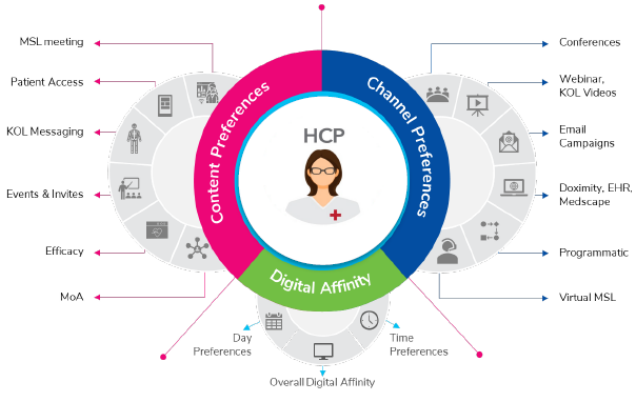
CTx-1301 Next Steps

Cingulate is completing the final requirements for its new drug application (NDA) submission. The company held its pre-NDA meeting with the FDA last week, which will provide final guidance needed to submit an approvable package to the agency. It usually takes about a month for the official meeting minutes to be shared with the sponsor, so we expect Cingulate will receive them by early May. These minutes are important as they document the key discussion points, any agreements reached and the FDA's recommendations. They serve as an official record of the meeting and can be referenced throughout the drug development and approval process. This will provide sufficient time to deliver the package to the FDA by mid-2025. 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 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 recently attended the Drug, Chemical & Associated Technologies (DCAT) meeting which yielded a number of further prospects for business development and licensing.

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

Exhibit I – 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

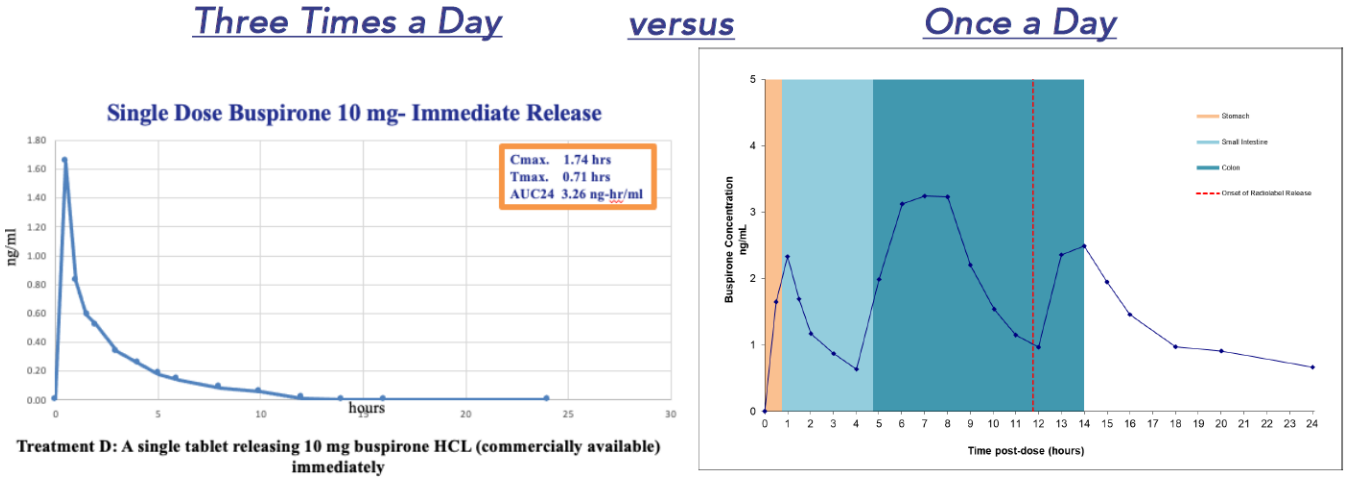
The pathway forward for FDA submission includes several parallel efforts which include updating stability data on 2024 batches of CTx-1301, completing the analysis of the fast fed study and attendance at the pre-NDA meeting with the FDA which was held last week. Notes from the meeting are expected in about a month, 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.

$3 Million Grant for Development of CTx-2103

An unnamed private foundation awarded a $3 million grant to Cingulate to develop its preclinical anxiety candidate CTx-2103. The grant will be disbursed in three tranches of $1 million with the first cash flow to be paid on May 1st. The second and third tranches will be paid on achievement of specified milestones. If commercially successful, Cingulate will owe a royalty to the foundation that will begin six months after commercialization begins. Payments of $500,000 per quarter will be made, until the maximum cumulative royalty of $3.5 million is reached.

The award is valuable to Cingulate not only for the funding that it provides but also as a validation of the Precision Timed Release (PTR) platform. Based on the support provided by this award, the attractiveness of the asset and its anticipated regulatory pathway, we believe that CTx-2103 will take the baton from CTx-1301 providing Cingulate with its follow-on development candidate.

Exhibit II – CTx-2103: Buspirone HCl for the Treatment of Anxiety



Cingulate April 2025 Investor Presentation

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 ($AUC_{0\text{-}\infty}$).

Video Interview Series

CEO Shane Schaffer explains the Precision Timed Release technology, discusses the CTx-1301 program and provides an estimated timeline for FDA submission in a series of videos, which can be accessed via the links below.

Exhibit III – Cingulate CEO Dr. Shane Schaffer



Source: Cingulate Video Series December 2024

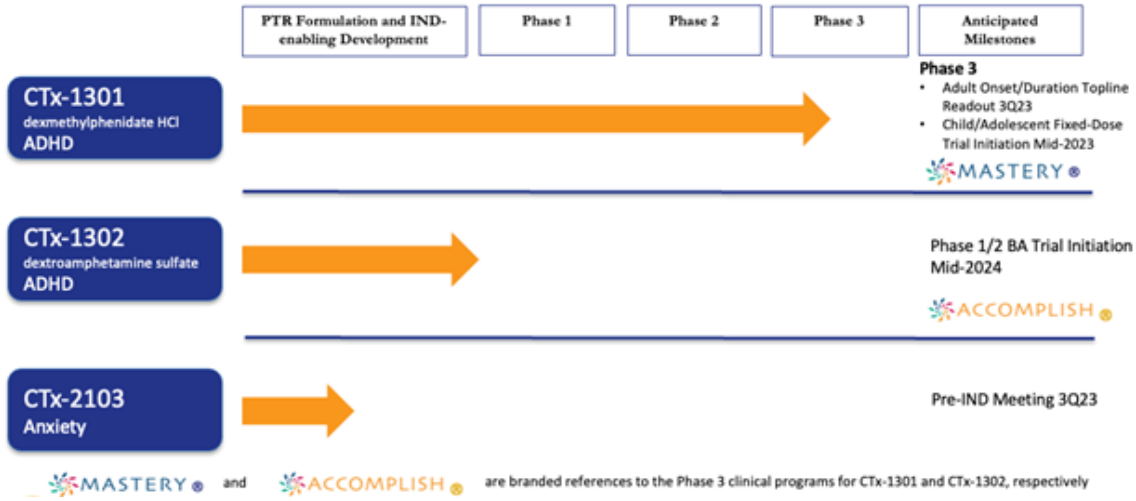
- Timeline to FDA Submission
- CTx-1301 Provides Active Day Coverage
- Precision Timed Release Technology
- Fireside Chat with CEO Shane Schaffer
- Final Stages of Development for CTx-1301
- ADHD Symptoms and Disorder Dynamics
- Why Will Patients be Willing to Pay for CTx-1301?

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.

So far in 2025, Cingulate has raised additional funds under the at-the-market (ATM) agreement and the Lincoln Park Agreement. In total, the company sold 366,000 shares and raised $1,676,000.

Exhibit IV – Cingulate Pipeline

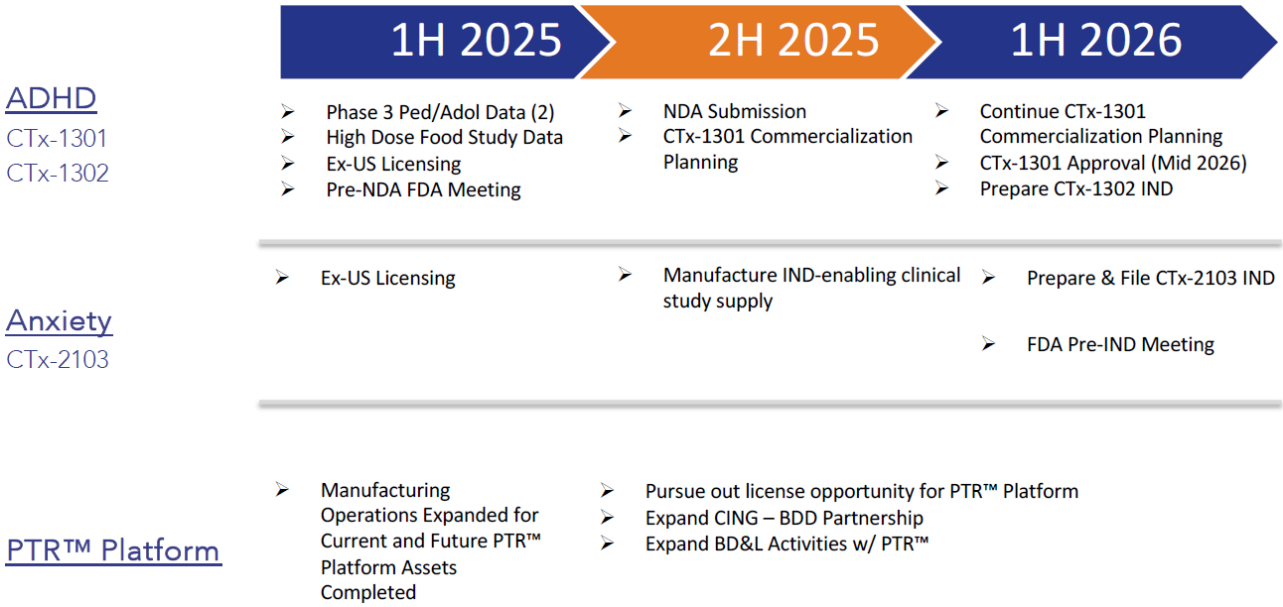


Cingulate Website

Milestones

- Complete Registration Batches for NDA Filing – 1H:24
- FDA clearance of CTx-1301 for NDA submission (505(b)(2)) – May 2024
- Launch of CTx-1301 food effect study – September 2024
- NDA Preparation for CTx-1301 – 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

Exhibit V – 2025 and 2026 Goals



Cingulate April 2025 Investor Presentation

Summary

Over the last few months, Cingulate has made significant progress preparing for NDA submission and communicating with stakeholders. Recent activity includes reporting financial results for 2024, completing a successful pre-NDA meeting with the FDA, securing a $3 million grant for the advancement of CTx-2103 and engaging in business development initiatives during the DCAT meeting. The team remains on track for NDA submission in mid-2025. Additionally, recent capital raises have provided Cingulate with further funds to support operations and commercial preparation activities for CTx-1301.

PROJECTED FINANCIALS

Cingulate, Inc. - Income Statement

Cingulate, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 A	2024 A	2025 E	2026 E
Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$7,774**
Research & Development	$15,493	$1,807	$1,881	$1,429	$4,329	$9,445	$5,228	$3,000
General & Administrative	$7,266	$1,141	$1,325	$1,854	$1,880	$6,200	$7,481	$6,125
Operating Income	($22,759)	($2,948)	($3,206)	($3,282)	($6,208)	($15,645)	($12,709)	($1,351)
Operating Margin								
Interest Expense & Other, net	($776)	($24)	($3)	$50	$77	$99	$0	$0
Loss Before Income Taxes	($23,535)	($2,972)	($3,210)	($3,232)	($6,132)	($15,546)	($12,709)	($1,351)
Income Tax								
Net Loss	**($23,535)**	**($2,972)**	**($3,210)**	**($3,232)**	**($6,132)**	**($15,546)**	**($12,709)**	**($1,351)**
Net Loss Per Share	**($311.99)**	**($7.21)**	**($5.47)**	**($1.83)**	**($1.91)**	**($10.20)**	**($3.04)**	**($0.27)**
Weighted Average Shares	75	412	586	1,766	3,212	1,525	4,174	5,050

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

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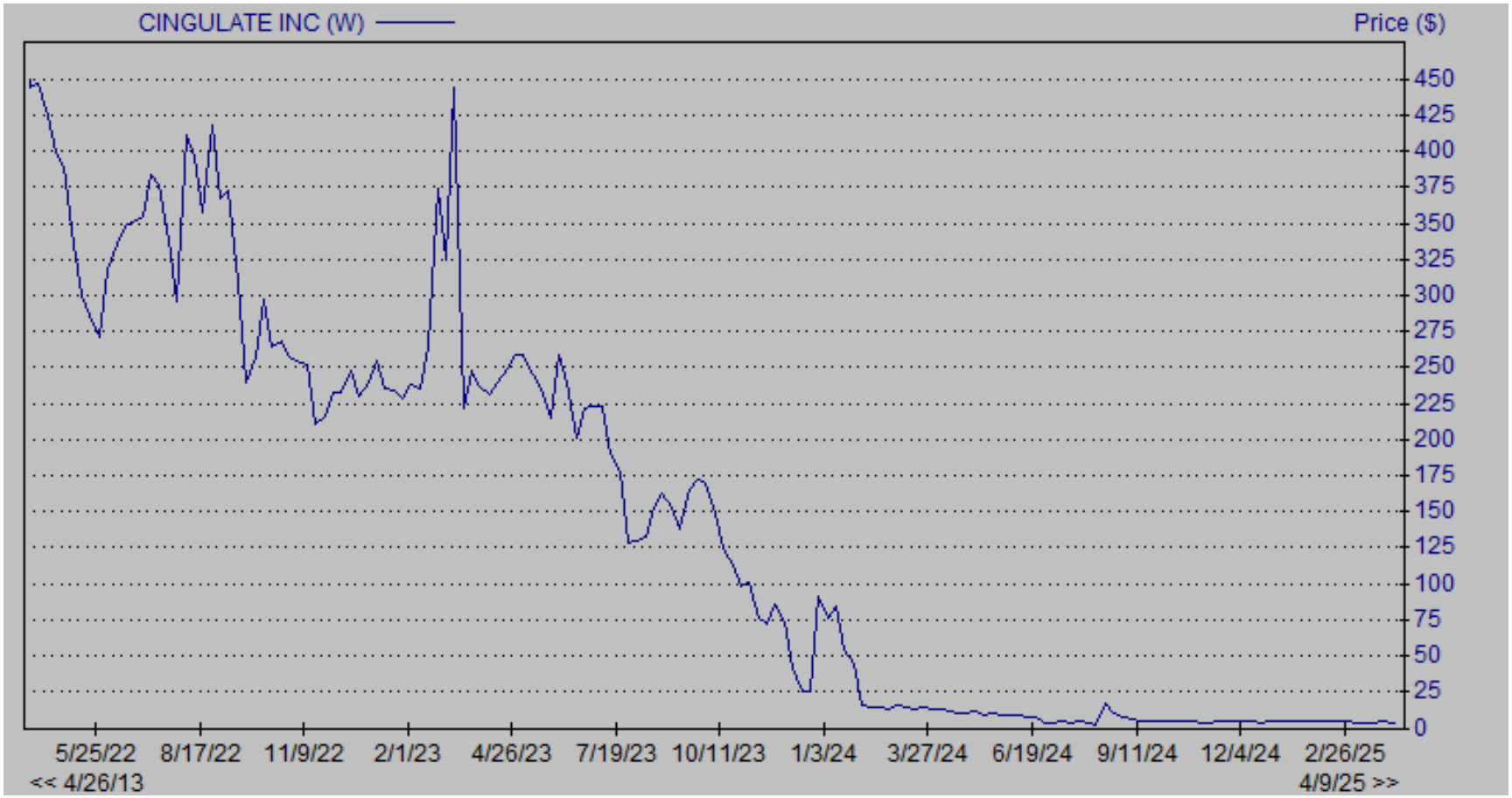
HISTORICAL STOCK PRICE

Cingulate, Inc. – Share Price Chart[2]



[2] Source: Zacks Research System

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