

Cingulate, Inc.

(CING - NASDAQ)

CING: Second 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 (8/18/2026) **\$5.20**
Valuation **\$25.00**

OUTLOOK

Cingulate is developing its Precision Timed Release (PTR) technology to enhance ADHD treatments by improving onset and duration of action using established active ingredients. Its lead product, CTx-1301, is a once-daily, multi-core tablet delivering three precisely timed releases of active medication (dexamethylphenidate) designed to deliver symptom control throughout the day. The product potentially eliminates the need for booster doses, reducing diversion risk and simplifying dosing.

CTx-1301 targets a large market, with approximately 93 million ADHD prescriptions written in the U.S. in 2023.

Phase III trials demonstrated strong efficacy, a favorable safety profile, and full-day symptom coverage. CTx-1301 is being developed under the FDA's 505(b)(2) regulatory pathway. The NDA was submitted in July 2025.

Additional pipeline candidates include CTx-2103 (buspirone) & CTx-1302 (dextroamphetamine), both utilizing PTR technology. CTx-2103 may advance next with a potentially clearer regulatory path.

SUMMARY DATA

52-Week High **11.89**
52-Week Low **3.16**
One-Year Return (%) **25.0**
Beta **-0.9**
Average Daily Volume (sh) **429,253**

Shares Outstanding (mil) **14.5**
Market Capitalization (\$mil) **75.4**
Short Interest Ratio (days) **6.3**
Institutional Ownership (%) **12.6**
Insider Ownership (%) **28.3**

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 2026 Estimate **N/A**
P/E using 2027 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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2025	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A
2026	\$0.0 A	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E
2027					\$26.2 E
2028					\$56.3 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2025	-\$1.04 A	-\$1.09 A	-\$1.35 A	-\$0.96 A	-\$4.44 A
2026	-\$0.95 A	-\$0.45 A	-\$0.55 E	-\$0.54 E	-\$2.38 E
2027					-\$2.30 E
2028					-\$1.02 E

WHAT'S NEW

Cingulate, Inc. (NASDAQ: CING) reported second quarter 2026 results on August 13th, 2026. During the three-month period, the company generated no revenue and recorded operating expense of \$5.4 million. Since the end of the first quarter, cash balances have increased from accessing the at-the-market (ATM) and Lincoln Park facilities.

To keep investors apprised of the company's latest efforts, CEO Shane Schaffer participates in a video series. He breaks down the details behind the Complete Response Letter (CRL), outlines the next steps in the resubmission process and provides his insight on news and events in the Attention-Deficit/Hyperactivity Disorder (ADHD) space.

In the operational realm, earlier this year it became apparent that the FDA would issue a CRL for CTx-1301 due to specific Chemistry, Manufacturing and Controls (CMC) information requests. Management believes that the issues will be resolved and noted that no clinical safety or efficacy concerns were identified in the CRL. The company is working with [Bend Bioscience](#) to complete the requested CMC work and advance process validation for CTx-1301. The resulting drug product would serve as launch inventory if approved. The company also signed an agreement with Prasco, who will help support the distribution of CTx-1301 post approval. As it traverses the regulatory process, Cingulate will maintain its focus on pricing, reimbursement, market access and patient assistance activities during the pre-commercialization period.

Management believes that it can maintain its anticipated 1H:27 launch of CTx-1301.

2Q:26 Financial and Operational Results

Cingulate reported 2Q:26 results in a [press release](#) and [Form 10-Q](#) filing with the SEC on August 13th. For the quarter ended June 30th, 2026, the company reported a net loss of \$5.9 million or \$0.45 per share. For 2Q:26 versus the same prior year period:

- Research and development expenses were \$1.5 million, down 44% from \$2.7 million. The change was attributable to lower clinical operations costs as clinical study activities concluded in early 2025 in connection with preparing the CTx-1301 NDA. These trends were partially offset by a rise in personnel expenses;
- Selling, general & administrative expenses rose 102% to \$3.9 million from \$1.9 million on account of spending on commercial readiness planning for the potential launch of CTx-1301, including increased headcount and market access, pricing, reimbursement, and medical affairs activities conducted through Indegene. Occupancy, insurance and other expenses fell;
- Net interest and other expenses were \$141,000 vs \$139,000 related to interest payments for the note with Avondale partially offset by interest income;
- Other expense of \$314,000 related to the change in the fair value of derivatives related to the LP purchase agreement with Lincoln Park;
- Net loss was \$5.9 million vs \$5.0 million or \$0.45 and \$1.14 per share, respectively.

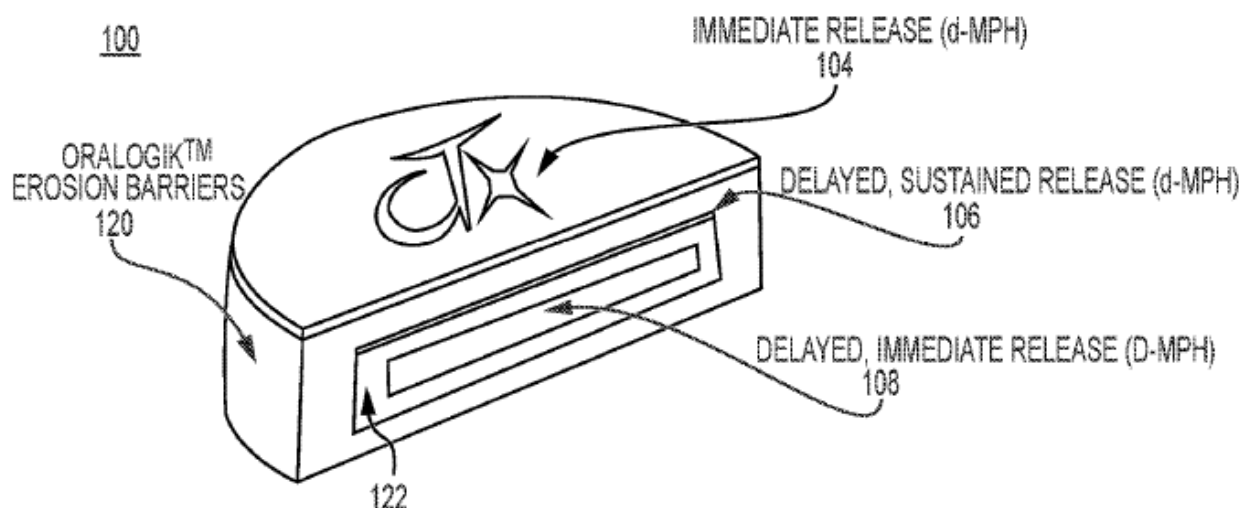
As of June 30th, 2026, cash totaled \$28.4 million. This amount compares to the \$11.0 million cash balance held at the end of 2025. Cash burn for the first six months of 2026 was \$12.9 million, more than offset by \$30.4 million in financing cash contributions from the issuance of common stock and sales from the ATM sales agreement offset by principal payments on notes payable. Following the end of the second quarter, Cingulate raised an additional \$1.4 million from the ATM and \$1.1 million from the Lincoln Park arrangement. Also following quarter end, Cingulate extinguished \$1.3 million of principal for 140,000 shares of common stock along with a \$600,000 cash payment related to the promissory note with Avondale.

Cingulate management believes it holds sufficient capital to fund operations into mid-2027, including the costs of seeking regulatory approval for CTx-1301 and the build-out of internal and external support for the commercial launch of CTx-1301.

Key Patent Issued

On June 16th, 2026, the US Patent and Trademark Office issued patent [#12,653,791](#) to Cingulate, entitled Trimodal, Precision-Timed Pulsatile Release Tablet. The intellectual property includes claims for composition-of-matter, formulation, structural and method-of-treatment. It protects these critical aspects of Cingulate's work through December 2042.

Exhibit I – Patent #12,653,791 Cross Section Image of CTx-1301



Source: US Patent #12,653,791, Figure 2

CTx-1301 FDA Submission Timeline and Commercial Launch

Following the July 2025 New Drug Application (NDA) submission and the October 2025 FDA acceptance of the NDA, the agency assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 31, 2026. In the 2025 Form 10-K filed in March 2026, Cingulate reported that its manufacturing partner was issued a Form 483¹ by the FDA following a February 2026 facility inspection which yielded three observations. Two observations were related to the CDMO's facility and one observation was specific to CTx-1301. The CMC issues ultimately led to the issuance of a Complete Response Letter (CRL) for CTx-1301. Cingulate must resubmit its NDA after the observations at the manufacturer have been addressed. Management has emphasized that it will be able to maintain its 1H:27 target for launch of CTx-1301.

Management Interview

Exhibit II – Cingulate CEO Shane Schaffer



Source: Cingulate Video Interview, YouTube

¹ An FDA Form 483, or inspectional observation, is a document issued at the conclusion of an FDA inspection when investigators find conditions that may violate Food, Drug and Cosmetic (FD&C) Act regulations. It highlights potential deficiencies in procedures, equipment, or processes, requiring a written response and corrective action plan.

CEO Shane Schaffer participated in a video interview where he discussed near-term milestones for Cingulate, how CTx-1301 changes ADHD treatment and some of the larger trends impacting the space. Access the videos in the series using the links below.

- [Complete Response Letter](#)
- [ADHD Medicine Shortage](#)
- [CTx-1301 Labeling](#)
- [Cingulate Resubmission](#)

Prasco Arrangement

On July 21st, 2026, Cingulate signed an exclusive services agreement with [Prasco, LLC](#) to establish the commercial distribution infrastructure for the commercialization of CTx-1301. Prasco is based in Mason, Ohio and assists companies commercialize products in the US market and manage them post launch. Some of the core services Prasco provides are private label commercialization, distribution & logistics, warehousing & supply chain, market access using its [Unlimit](#) network and specialty logistics partnerships among other services. This partner can be useful for a small biotech company that lacks its own sales and distribution network. Cingulate notes in the 10-Q filing that Prasco has direct distribution to approximately 19,000 independent and small regional pharmacy accounts.

Milestones

- Close of \$12 million private placement – February 2026
- FDA pre-approval inspection of Gainesville facility – February 2026
- FDA issues CRL for CTx-1301 citing CMC – June 2026
- USPTO issuance of US Patent [#12,653,791](#) – June 2026
- Cingulate added to Russell 3000E – July 2026
- Exclusive service agreement with Prasco – July 2026
- CTx-1301 anticipated launch – 1H:27

Summary

Cingulate reports second quarter 2026 results, continuing to build cash while advancing the resubmission effort. CEO Schaffer updates investors on the latest efforts at the company and shares his thoughts on the industry. Since the last financial update, the FDA delivered the CRL to Cingulate setting in motion a series of responses to the agency and the resubmission process. Despite the setback, the expected CTx-1301 launch remains on track for 1H:27. While navigating the regulatory process, Cingulate is maintaining its focus on pricing, reimbursement, market access and patient assistance efforts in preparation for launch. The extra time should allow the company to build up commercial supply, further develop relationships and contract with the key payors and PBMs while aligning the availability of CTx-1301 with the payors' plan year.

PROJECTED FINANCIALS

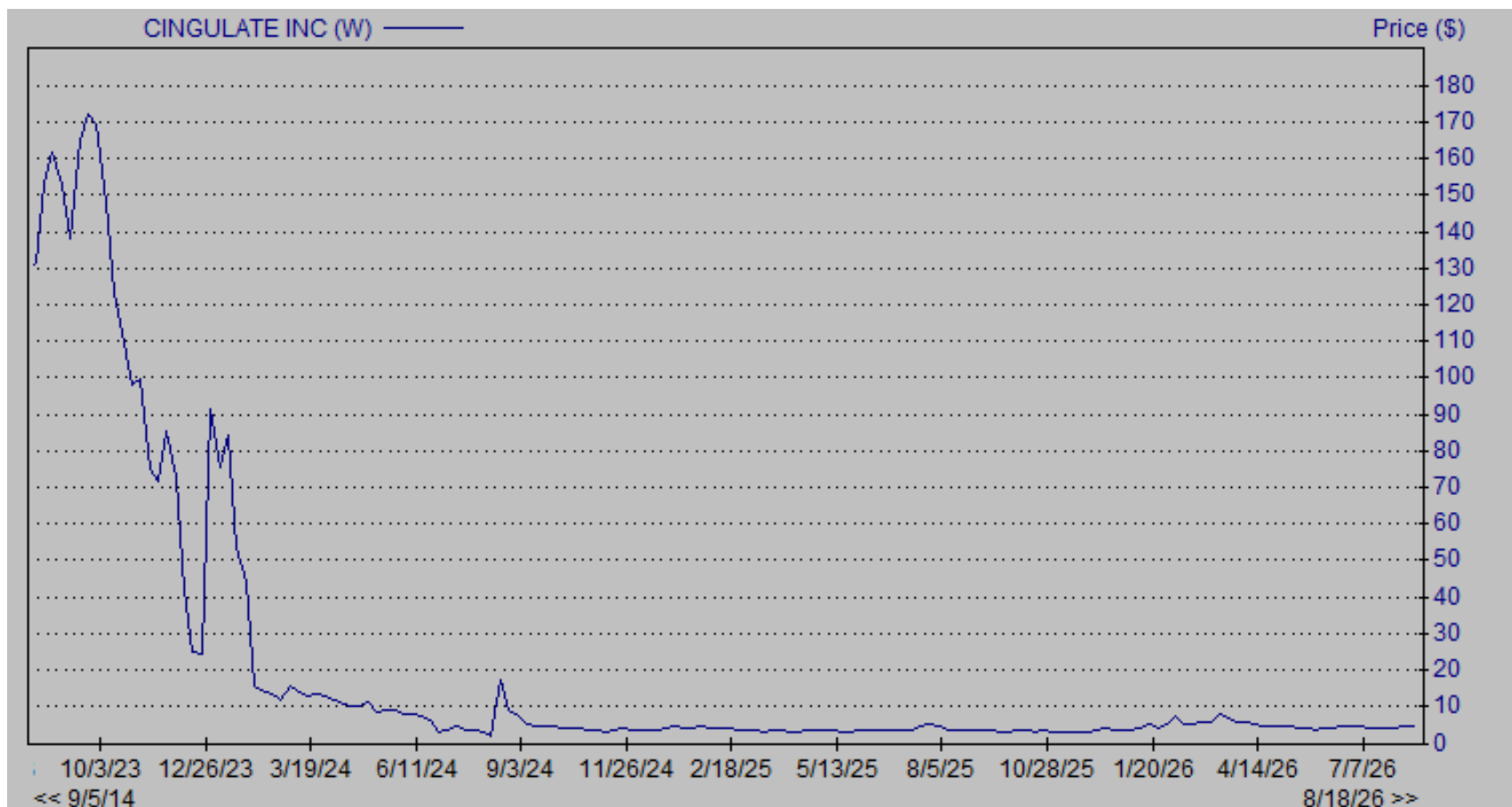
Cingulate, Inc. - Income Statement

Cingulate, Inc.	2025 A	Q1 A	Q2 A	Q3 E	Q4 E	2026 E	2027 E	2028 E
Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$26,204	\$56,319
Revenue Growth								115%
Cost of Product Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$7,861	\$16,333
Gross Margin							70%	71%
Research & Development	\$9,774	\$2,184	\$1,487	\$1,510	\$1,400	\$6,581	\$6,100	\$5,000
Selling, General & Administrative	\$10,164	\$5,739	\$3,928	\$5,970	\$6,101	\$21,738	\$45,000	\$50,000
Operating Income	(\$19,938)	(\$7,923)	(\$5,415)	(\$7,480)	(\$7,501)	(\$28,319)	(\$32,757)	(\$15,013)
Operating Margin								
Interest Expense & Other, net	(\$1,361)	(\$537)	(\$141)	(\$540)	(\$540)	(\$1,758)	(\$2,150)	(\$2,150)
Change in Derivative Fair Value	(\$1,151)	(\$852)	(\$314)	\$0	\$0	(\$1,166)	\$0	\$0
Loss Before Income Taxes	(\$22,450)	(\$9,312)	(\$5,870)	(\$8,020)	(\$8,041)	(\$31,243)	(\$34,907)	(\$17,163)
Income Tax	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net Loss	(\$22,450)	(\$9,312)	(\$5,870)	(\$8,020)	(\$8,041)	(\$31,243)	(\$34,907)	(\$17,163)
Net Loss Per Share	(\$4.44)	(\$0.95)	(\$0.45)	(\$0.55)	(\$0.54)	(\$2.38)	(\$2.30)	(\$1.02)
Weighted Average Shares	5,055	9,778	13,186	14,633	14,935	13,133	15,200	16,890

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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