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Cingulate, Inc. (CING - NASDAQ)

CING: CRL Remediation Advances and Launch Planning Continues

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 (11/20/2026)	$4.51
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 (dexmethylphenidate) 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. A CRL was issued in mid-2026. The company is addressing the questions & expects a resubmission around year end 2026.

Additional pipeline candidates include CTx-2103 (buspirone) & CTx-1302 (dextroamphetamine), both utilizing PTR technology. CTx-2103 may advance next with also following the 505(b)(2) regulatory path.

SUMMARY DATA

52-Week High	**11.89**
52-Week Low	**3.16**
One-Year Return (%)	**30.4**
Beta	**-0.9**
Average Daily Volume (sh)	**178,206**
Shares Outstanding (mil)	**15.0**
Market Capitalization ($mil)	**67.7**
Short Interest Ratio (days)	**9.4**
Institutional Ownership (%)	**19.1**
Insider Ownership (%)	**27.5**
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 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 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (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 A	$0.0 E	$0.0 E
2027					$19.7 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	-$0.53 A	-$0.54 E	-$2.36 E
2027					-$2.49 E
2028					-$1.02 E

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WHAT'S NEW

Cingulate, Inc. (NASDAQ: CING) reported third quarter 2026 results on November 13th, 2026. During the three-month period, the company generated no revenue and recorded operating expense of $7.5 million. Net loss was $7.7 million and net loss per share was $0.53. Since the second quarter report, CEO Shane Schaffer provided updates on the company's progress by participating in the Indegene Digital Summit and an Innovators podcast. In parallel, substantial work has been underway to address the FDA's questions related to the Complete Response Letter (CRL) that was issued in June. After generating stability data, Cingulate expects to resubmit the New Drug Application (NDA) for CTx-1301 in the December 2026/January 2027 timeframe. This sets up CTx-1301 for a 2H:27 launch if the product is approved.

The company is working with Bend Bioscience to complete the requested Chemistry, Manufacturing and Controls (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 advance efforts on pricing, reimbursement, market access and patient assistance activities during the pre-commercialization period.

3Q:26 Financial and Operational Results

Cingulate reported 3Q:26 results in a press release and Form 10-Q filing with the SEC on November 13th. For the quarter ended September 30th, 2026, the company reported an operational loss of $7.5 million and net loss of $7.7 million or $0.53 per share. For 3Q:26 versus the same prior year period:

- Research and development expenses were $2.9 million, up 2% from $2.8 million. The change was attributable to higher drug manufacturing costs which rose by $1.3 million, or almost 150%. These expenditures were traceable to work required to address items listed in the CRL. Lower clinical operations costs and the absence of regulatory costs and amounts related to the contingent bonus plan present in the prior year period, partially offset the overall increase;
- Selling, general & administrative expenses rose 46% to $4.6 million from $3.1 million on account of spending on commercial readiness planning and pre-commercialization costs for the planned launch of CTx-1301, including increased headcount and market access, pricing, reimbursement, and medical affairs activities conducted through Indegene. Occupancy and other expenses also rose but were partially offset by small declines in personnel expenses and insurance;
- Net interest and other expenses were $171,000 vs $573,000 related to interest payments for the note with Avondale partially offset by interest income;
- Other expense of $69,000 related to the change in the fair value of derivatives related to the purchase agreement with Lincoln Park;
- Net loss was $7.7 million versus $7.3 million or $0.53 and $1.35 per share, respectively.

As of September 30th, 2026, cash totaled $23.2 million. This amount compares to the $11.0 million cash balance held at the end of 2025. Cash burn for the first nine months of 2026 was $20.4 million, more than offset by $32.6 million in financing cash contributions from the issuance of common stock and sales from the at-the-market (ATM) sales agreement offset by principal payments on notes payable. Following the end of the third quarter, Cingulate raised an additional $0.5 million from the Lincoln Park arrangement. Also following quarter end, Cingulate extinguished $1.0 million of principal for 85,440 shares of common stock along with a $560,000 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 November 19th, 2026, Cingulate announced that the US Patent and Trademark Office (USPTO) had issued patent #12,797,335 titled Trimodal, Precision-Timed Release Tablet. It was issued on November 17th. The patent covers a buspirone tablet formulation incorporating Cingulate's proprietary PTR technology, which is designed to release medication at three separate, predetermined times throughout the day from a single tablet. The patented formulation supports Cingulate's development of CTx-2103. The patent is expected to provide protection until 2043.

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 483[1] by the FDA following a February 2026 facility inspection which yielded three observations. Two observations were related to the Contract Development and Manufacturing Organization's (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 is now preparing responses to the CRL and conducting stability studies to generate data that will be included in the resubmission. Management is guiding towards the December 2026/January 2027 timeframe for resubmission which should support the commercial launch of CTx-1301 during 2H:27 if approved by the FDA.

Management Interviews

Innovators with Jane King
CEO Shane Schaffer participated in a video podcast in early November 2026 called Innovators with Jane King. Dr. Schaffer elaborated on CTx-1301 and the FDA review with its host, Jane King. The near eight-minute discussion shares the anticipated timeline for resubmission of CTx-1301 and when management believes they will be able to begin commercialization of the ADHD asset. Beyond the timeline, the CEO reviewed the topics the FDA brought up in the CRL and emphasized that all of the critical aspects of the resubmission have been completed and the remaining outstanding item is the stability study. He concluded the interview by laying out the commercialization strategy that plans to keep critical management functions and competitive advantages inside the company and outsource the omni-channel marketing plan and other functions that require scaling to best-in-class operators.

Indegene Digital Summit
CEO Shane Schaffer and Chief Commercial Officer (CCO) Bryan Downey participated in the Indegene Digital Summit on September 22nd, 2026 in Philadelphia, Pennsylvania. Cingulate and Indegene have a commercial services agreement where the latter will provide services to help prepare CTx-1301 for market and support commercialization. The scope of Indegene's role includes sales, marketing, pricing and reimbursement, market access, medical affairs, medical communications, pharmacovigilance, regulatory support and commercial operations. Cingulate's management team participated in two sessions at the summit.

Dr. Schaffer spoke with Indegene's Dr. Sanjay Parikh on the topic of "The SMART Launch: Rethinking Go-To-Market for Emerging Pharma Launches." Details from the conversation include the risks and rewards of a small pharmaceutical company launching a product itself. Cingulate estimated that a traditional product launch would cost from $100 to $150 million, creating substantial dilution to shareholders. On the other hand, selling the asset to an established pharmaceutical company would give away a substantial amount of the value that Cingulate had created. A middle ground would maintain critical competitive advantages inside the company and use partnerships with others to support an omnichannel strategy.

CCO Bryan Downey participated in another panel entitled "Small & Mid-Size Pharma. Big-Time Launches: Reinventing the Launch Playbook." This discussion also included executives from CG Oncology and IDEAYA Biosciences. The discussion addressed the challenges that mid-size pharmaceutical companies face when launching a product. They are forced to be very efficient and fast-acting to address the limitations that smaller companies face. The moderator raised the topic of artificial intelligence and had panelists discuss its role in taking on many of the responsibilities of commercialization. Mr. Downey emphasized the importance of maintaining the competitive advantage in-house while outsourcing functions that need to be scaled. Attractive partners for outsourced functions will demonstrate proof of ability before being brought on when needed as scaling moves forward. Another important element that Bryan raised was the importance of having a team in place prior to commercialization to reach out to stakeholders at managed care plans and to those involved with market access and pricing.

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 to 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

[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.

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
- USPTO issuance of US Patent #12,797,335 – November 2026
- Resubmission of CTx-1301 – December 2026 / January 2027
- FDA response to resubmission of CTx-1301 – mid-year 2027
- CTx-1301 anticipated launch – 2H:27

Summary

Cingulate reported third quarter 2026 results, continuing its progress on addressing the items in the CRL, conducting stability work and building product inventory that can be used for sale if CTx-1301 is approved. Management is guiding towards a resubmission in the December 2026 to January 2027 timeframe, after which we expect a Class 2 resubmission, placing an FDA response about six months later. We expect to hear an update from the management team following the CTx-1301 resubmission and further details on anticipated timelines at that point.

PROJECTED FINANCIALS

Cingulate, Inc. - Income Statement

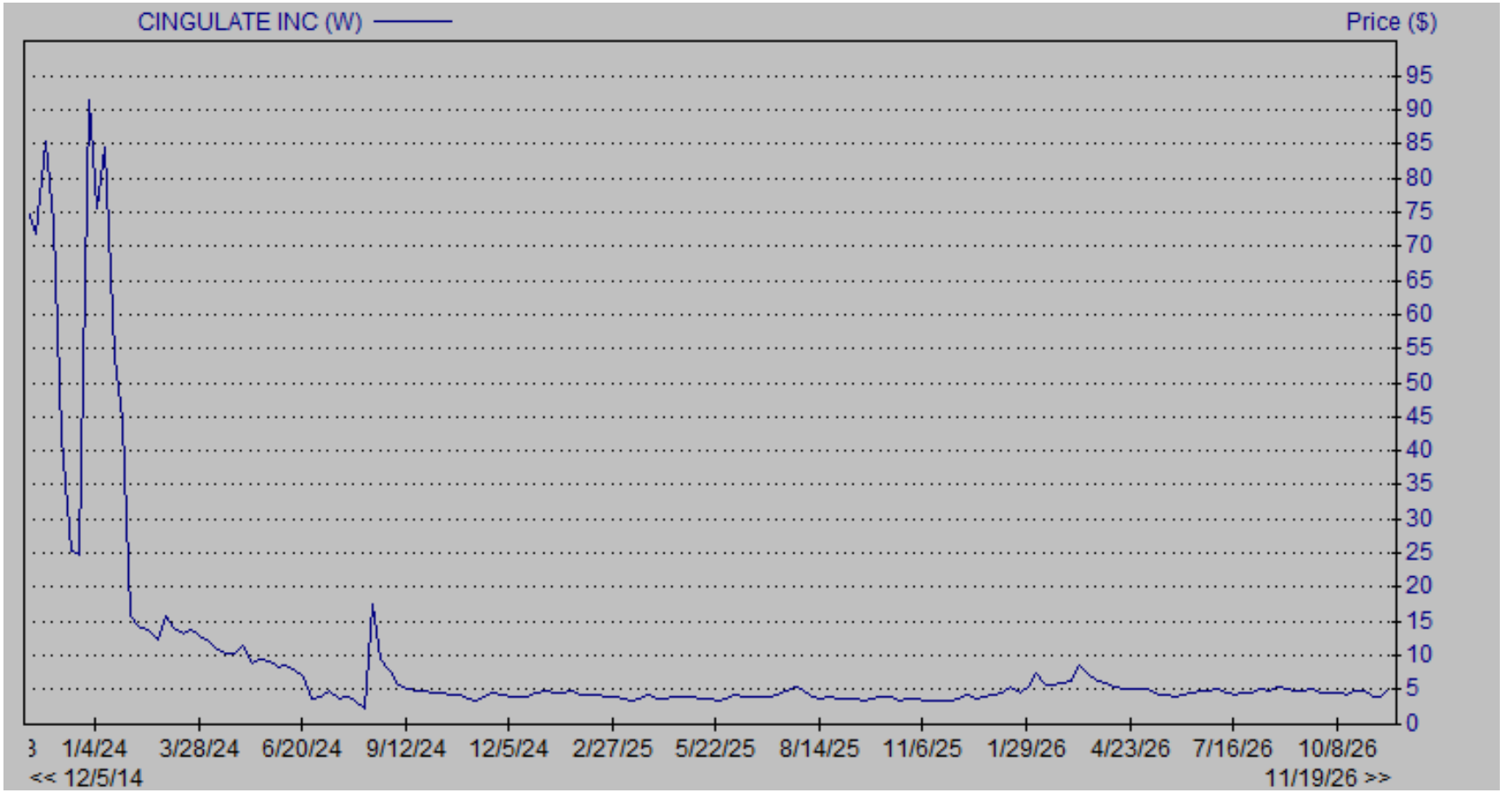
Cingulate, Inc.	2025 A	Q1 A	Q2 A	Q3 A	Q4 E	2026 E	2027 E	2028 E
Revenues (US$'000)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$19,734**	**$56,319**
Revenue Growth								185%
Cost of Product Sales	$0	$0	$0	$0	$0	$0	$5,920	$16,333
Gross Margin							70%	71%
Research & Development	$9,774	$2,184	$1,487	$2,911	$1,400	$7,982	$6,100	$5,000
Selling, General & Administrative	$10,164	$5,739	$3,928	$4,580	$6,101	$20,348	$45,000	$50,000
Operating Income	($19,938)	($7,923)	($5,415)	($7,491)	($7,501)	($28,330)	($37,286)	($15,013)
Interest Expense & Other, net	($1,361)	($537)	($141)	($171)	($540)	($1,389)	($2,150)	($2,150)
Change in Derivative Fair Value	($1,151)	($852)	($314)	($69)	$0	($1,235)	$0	$0
Loss Before Income Taxes	($22,450)	($9,312)	($5,870)	($7,731)	($8,041)	($30,955)	($39,436)	($17,163)
Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Net Loss	**($22,450)**	**($9,312)**	**($5,870)**	**($7,731)**	**($8,041)**	**($30,955)**	**($39,436)**	**($17,163)**
Net Loss Per Share	**($4.44)**	**($0.95)**	**($0.45)**	**($0.53)**	**($0.54)**	**($2.36)**	**($2.49)**	**($1.02)**
Weighted Average Shares	5,055	9,778	13,186	14,547	15,000	13,128	15,820	16,890

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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