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Zacks Small-Cap Research

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CytoSorbents Corporation (NASDAQ: CTSO)

CTSO: CytoSorbents reports 3rd quarter 2025 financial results. The company plans to submit a new De Novo application for Drug-Sorb ATR in early 2026. As a reminder, the FDA found no safety issues with DrugSorb-ATR in their recent denial.

Utilizing a DCF valuation process containing conservative estimates combined with other valuation methodologies, we believe CTSO could be worth **$4.00** per share.

Current Price (11/14/25)	$0.66
Valuation	**$4.00**

OUTLOOK

CytoSorbents is commercializing its E.U. approved CytoSorb blood purification technology to treat life-threatening conditions in the intensive care unit and cardiac surgery. The company also seeks U.S. and Canadian approval of a second product, DrugSorb-ATR, to reduce perioperative bleeding risk in patients on blood thinners in cardiac surgery. After FDA denial in April 2025, the company plans to submit a new De Novo application to the FDA in 2026. Based on $37.0 million in high margin TTM revenue and the DrugSorb-ATR potential in 2026, we believe CTSO stock to be significantly undervalued at this time.

SUMMARY DATA

52-Week High	**$1.61**
52-Week Low	**$0.60**
One-Year Return (%)	**-30.5**
Beta	**0.78**
Average Daily Volume (sh)	**103,073**
Shares Outstanding (mil)	**62.5**
Market Capitalization ($mil)	**$68.1**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**36**
Insider Ownership (%)	**7.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**24.9**
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**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Medical Device**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	$7.9 A	$8.1 A	$7.8 A	$7.3 A	$31.1 A
2024	$9.0 A	$8.8 A	$8.6 A	$9.2 A	$35.6 A
2025	$8.7 A	$9.6 E	$9.5 A	$10.0 E	$37.8 E
2026	$9.7 E	$10.6 E	$10.5 E	$11.0 E	$41.8 E

EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.17 A	-$0.14 A	-$0.21 A	-$0.12 A	-$0.64 A
2024	-$0.11 A	-$0.08 A	-$0.05 A	-$0.14 A	-$0.38 A
2025	-$0.02 A	-$0.06 A	-$0.05 A	-$0.05 E	-$0.18 E
2026	-$0.03 E	-$0.02 E	-$0.02 E	-$0.01 E	-$0.09 E

Quarterly revenues may not equal annual revenues due to rounding. Quarterly EPS may not equal annual EPS due to rounding, dilution, or intangibles.

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WHAT'S NEW

Source: CytoSorbents investor presentation

Regulatory Update on DrugSorb-ATR

On August 20, 2025, the company announced that it had received an FDA appeal decision following its July 2025 in-person supervisory administrative review (appeal) meeting with FDA under 21 CFR 10.75. The appeal was in response to an April 25, 2025 FDA denial letter of the company's De Novo application for DrugSorb-ATR in the U.S.

In this appeal decision, the FDA found **no issues with device safety** but upheld its prior De Novo denial decision citing the need for additional information to support the company's desired label indication for this FDA Breakthrough Device. The FDA proposed a potential path forward for market authorization of DrugSorb-ATR and the company continues had interactive discussions with the FDA to further clarify the proposal.

The company recently completed a constructive meeting with the FDA to review the content of the appeal decision and to align on a path forward, with several key outcomes. Based on the meeting and other relevant information, the company has chosen this path forward:

1) The company has decided not to file a further final appeal with CDRH because of positive FDA upper management feedback for a reasonable path forward that would allow for a suitable and potentially expedited De Novo grant for the company's original desired label indication.

2) Based on this updated feedback, the company plans to file a new De Novo application with additional information that includes analyses of new real-world data to support its desired label indication. This information was not available at the time of the original De Novo submission a year ago and therefore was not part of the administrative record, nor was it eligible to be submitted and reviewed, for the appeal meeting and decision.

The company believes this new real-world data, drawn from a population consistent with the intended DrugSorb-ATR use population (patients on ticagrelor undergoing urgent coronary artery bypass graft [CABG] surgery), confirms the device's robust clinical performance in everyday medical practice. Combined with the previously submitted clinical data on DrugSorb-ATR, the company believes it further strengthens the favorable benefit-to-risk profile on which De Novo devices are evaluated.

3) Based on discussions with the FDA, it is the company's understanding that the review of the new submission will focus only on the remaining open items from the initial De Novo submission. As a reminder, the FDA found no safety issues in its prior review. The company expects the new application to be reviewed in an expedited fashion under the backing of the Breakthrough Device Designation previously granted for the device, which provides for priority and interactive review.

4) As part of the resubmission process, the company filed a pre-submission meeting request with supporting documentation to the FDA on November 7, 2025. A formal pre-submission meeting with the Agency is expected in the late 4th quarter of 2025 or early in 2026 to confirm the requirements for the new De Novo submission. Notwithstanding expected opportunities to accelerate the timeline, a standard regulatory decision is expected in mid-2026 following a timely De Novo submission and a typical 150-day review process.

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents, stated*, "We are encouraged by the continued constructive dialogue with the FDA to define a clear and expedited path forward. We plan to move as quickly as possible to have our pre-submission meeting with the FDA to finalize alignment and to file our new De Novo application, which is expected to heavily leverage our original filing. We continue to have confidence in the performance and clinical value of DrugSorb-ATR for this major unmet medical need and the importance of making this FDA Breakthrough Designated Device available to the American public."*

Additionally, the company had previously disclosed that it had filed a Level 1 "Request For Reconsideration" with Health Canada. However, following interactive discussions with the Medical Devices Directorate Bureau Director and the company's Canadian regulatory counsel, it was recommended that any subsequent review of DrugSorb-ATR in Canada be delayed until better clarity was received from the U.S. FDA. Therefore, the company has withdrawn the Request for Reconsideration and will provide a new Medical Device License application to Health Canada with improved visibility from the FDA.

CytoSorbents continues to advance its efforts toward FDA approval of DrugSorb-ATR, despite the recent decision to uphold the denial. The company has successfully resolved the majority of issues previously raised by the FDA, with no concerns identified regarding device safety, a critical factor in establishing the favorable benefit-to-risk profile required for De Novo authorization.

DrugSorb-ATR, designated an FDA Breakthrough Device, addresses a large and growing unmet need: tens of thousands of U.S. heart attack patients requiring urgent coronary artery bypass graft (CABG) surgery each year while on ticagrelor currently face the choice of delaying surgery or risking severe, life-threatening bleeding. With millions of patients worldwide on blood thinners, the market for effective perioperative bleeding solutions is substantial and expanding. Already in use internationally, DrugSorb-ATR positions CytoSorbents to capture a major market opportunity in the U.S. and Canada, with the potential to deliver both significant patient impact and long-term shareholder value.

3rd Quarter 2025 Financial & Operating Results

CytoSorbents reported 3rd quarter 2025 financial and operating results which exceeded our expectations. The company generated revenues of $9.5 million, an increase of 10.1%, or 4.0% on a constant currency basis, compared to $8.6 million in the prior year period. This increase was driven by record performance in distributor territories and strong performance in direct sales outside of Germany. Without Germany results, revenues increased approximately 17.0%.

Gross margin was 70.3% compared to 61.0% in the 3rd quarter of 2024. We expect gross margins to stabilize in the 71%-72% range throughout the rest of 2025. Long-term gross margins could increase to the mid-70% range as product volumes continue to grow over time as well as the commercialization of DrugSorb-ATR which carries higher margins.

Operating loss improved to ($3.5) million compared to ($4.8) million in the prior year period which was primarily driven by lower R&D expenses.

Net loss in the quarter was ($3.17) million or ($0.05) per share compared to ($2.8) million and ($0.05) in the prior year period. However, the 3rd quarter of 2024 had an unusually large foreign currency gain of $2.65 million on a pre-tax basis.

Adjusted EBITDA loss improved significantly to ($2.0) million compared to an adjusted EBITDA loss of ($3.6) million in the 3rd quarter of 2024 and was driven by higher gross margins and ongoing cost-cutting measures.

Liquidity and Capital Resources

As of September 30, 2025, the company had total cash of $9.1 million (including $7.5 million unrestricted and $1.5 million restricted cash) and total debt of $14.6 million. Current assets were $21.3 million and current liabilities were $10.1 million creating positive net working capital of $11.2 million. Pro-forma cash balances are $11.6 million assuming the $2.5 million in available loan capital was drawn upon (see below).

Amended Credit Agreement

The company also announced that it has amended its prior credit agreement with Avenue Capital Group effective November 13, 2025. The amendment provides immediate funding of an additional $2.5 million in term loan capital and an extension of the interest-only period to December 31, 2026 (previously July 1, 2026), followed by equal monthly installments of principal plus accrued and unpaid interest until maturity on July 1, 2027.

The Amendment requires that the company maintain certain operating cash burn targets only until U.S. FDA marketing approval of DrugSorb-ATR is achieved. At that point, the company will have access to an additional $2.5 million in term loan capital with a further six-month extension of the interest-only period to the July 1, 2027 maturity date upon the U.S. FDA approval of DrugSorb-ATR in 2026. CytoSorbents will issue warrants to Avenue Capital to purchase 1,428,571 shares of the company's common stock for cash at the exercise price of $0.70, which expire on November 13, 2030. The number of warrants and exercise price are fixed.

Workforce and Cost Reduction Program

CytoSorbents also announced they have implemented a strategic workforce and cost reduction plan to reduce costs, optimize operations, and accelerate the path to cash-flow profitability. This initiative follows a comprehensive internal review of its cost structure and operating model. As part of the strategic plan, CytoSorbents reduced its workforce by approximately 10%, reduced and realigned production and operating expenses, and now expects to reach operating cash flow break-even in the first quarter of 2026. The company expects to record a charge of up to $900,000 that will include severance and other charges related to the restructuring.

Valuation and Estimates

Our 2025 revenue estimate is adjusted to $37.8 million, and our 2025 EPS estimate is an adjusted loss of ($0.18) based on better than expected EPS in the 3rd quarter of 2025. We believe 2026 revenues could exceed $41.0 million and does not occur revenues from the commercialization of of DrugSorb-ATR. Our 2026 GAAP EPS estimate is a loss of ($0.09) per share.

We also introduce quarterly estimates for 2026.

With ongoing cost controls and the maintenance of gross margins above 70%, we believe the core business of the company (i.e. the existing CytoSorb business) could reach near cash flow breakeven at some in 2026.

Beginning in 2025, the company began a significant reorganization of the direct sales team and strategy in Germany (its largest market for the CytoSorb device). This includes the rebalancing of territories and hospital accounts with the goal of restoring sales growth through deeper customer engagement, more effective market development, and improved sales representative productivity. The company is pleased with the initial progress of this reorganization and remains confident it will lead to stronger execution, improved performance, and more robust sales growth in the region.

Last year, the company implemented significant cost-cutting measures to reduce the cash burn, including major reductions in headcount, termination of non-core R&D programs, termination of the STAR-D trial to focus on STAR-T, and a third consecutive year of salary freezes for executive management, with management voluntarily reducing salaries in exchange for stock options in 2024. The benefit of these cost cuts on operating expenses have been apparent in the significant cash burn reduction for the past four quarters.

In addition, the company has worked diligently to optimize manufacturing efficiencies. The company had product gross margins of 71.1% in the 1st quarter of 2025 and 70.9% in the 2nd quarter and we expect product gross margins for the rest of 2025 to be in the low 70% range. In the long term, we expect gross margins to expand to the mid-high 70% range after full commercialization of DrugSorb-ATR in North American markets.

Based on these factors, we maintain our price target of $**4.00** per share.

We believe the company has adequate liquidity and funding options to support its business model through the expected regulatory approval of DrugSorb-ATR and the subsequent commercial launch in 2026.

RISKS

- The company has experienced substantial operating losses since inception. The losses have resulted principally from costs incurred in the research and development of the company's polymer technology, clinical studies and general and administrative expenses.

- The company is currently well capitalized but may require additional financing in the future to complete additional clinical studies and to support the commercialization of proposed products.

- If users of the company's products are unable to obtain adequate reimbursement from third-party payers, or if reimbursement is not available in specific countries, or if new restrictive legislation is adopted, then market acceptance of products may be limited, and the company may not achieve anticipated revenues and profits.

- Clinical study results for the CytoSorb and/or DrugSorb-ATR device may not be indicative of future clinical study results, and no assurance can be made that any clinical study results will lead to results sufficient for necessary regulatory clearances or product sales.

SUMMARY

The company's current stock price likely does not reflect the potential for strong profitable growth going forward or the potential for a favorable FDA review of DrugSorb-ATR. We believe CTSO stock to be significantly undervalued at this time

We believe CytoSorbents disruptive blood purification technology will provide ample opportunities for high margin, double digit revenue growth going forward. The global addressable market for all of the company's products could exceed $20 billion. This growth will also be driven by the company aggressively investing in therapeutic applications such as sepsis and septic shock, circulatory failure, respiratory failure, liver dysfunction, kidney protection, and organ transplant perfusion and protection.

The company is also seeing positive signs of restored growth of its core CytoSorb device in European markets. There is a strong pipeline of positive data on the device from both critical care and cardiac surgery events. The company is also improving cross-functional synergy internally based on new therapy area vertical strategy and leadership. The company is also seeing increased opportunities outside of Germany such as the U.K., Israel, Turkey and Taiwan. Another important component in bottom line growth is the full transition to the new manufacturing facility which will increase total capacity and improve gross margins.

Based upon the positive data from STAR-T supporting a favorable benefit-to-risk profile of the DrugSorb-ATR therapy, its designation as an FDA Breakthrough Device, the major unmet medical need to prevent perioperative bleeding due to ticagrelor in cardiac surgery patients, and the established FDA precedent (see above), we believe CytoSorbents will find a receptive FDA and Health Canada despite missing the original STAR-T pivotal trial primary efficacy endpoint. We believe the data release has increased the visibility and probability of FDA and Health Canada marketing approval of DrugSorb-ATR to reduce the severity of bleeding in isolated CABG patients on Brilinta®.

- Brilinta®, an FDA-approved antiplatelet therapy widely used as standard of care in the U.S. and Canada, significantly increases the risk of severe perioperative bleeding in patients who require urgent surgery.

- DrugSorb-ATR is an investigational device with FDA Breakthrough Designation for this high-risk setting, underscoring the substantial unmet medical need and the absence of effective alternatives.

- As a De Novo 510(k)–eligible device, DrugSorb-ATR must demonstrate that its "probable benefits outweigh its probable risks" to achieve market authorization.

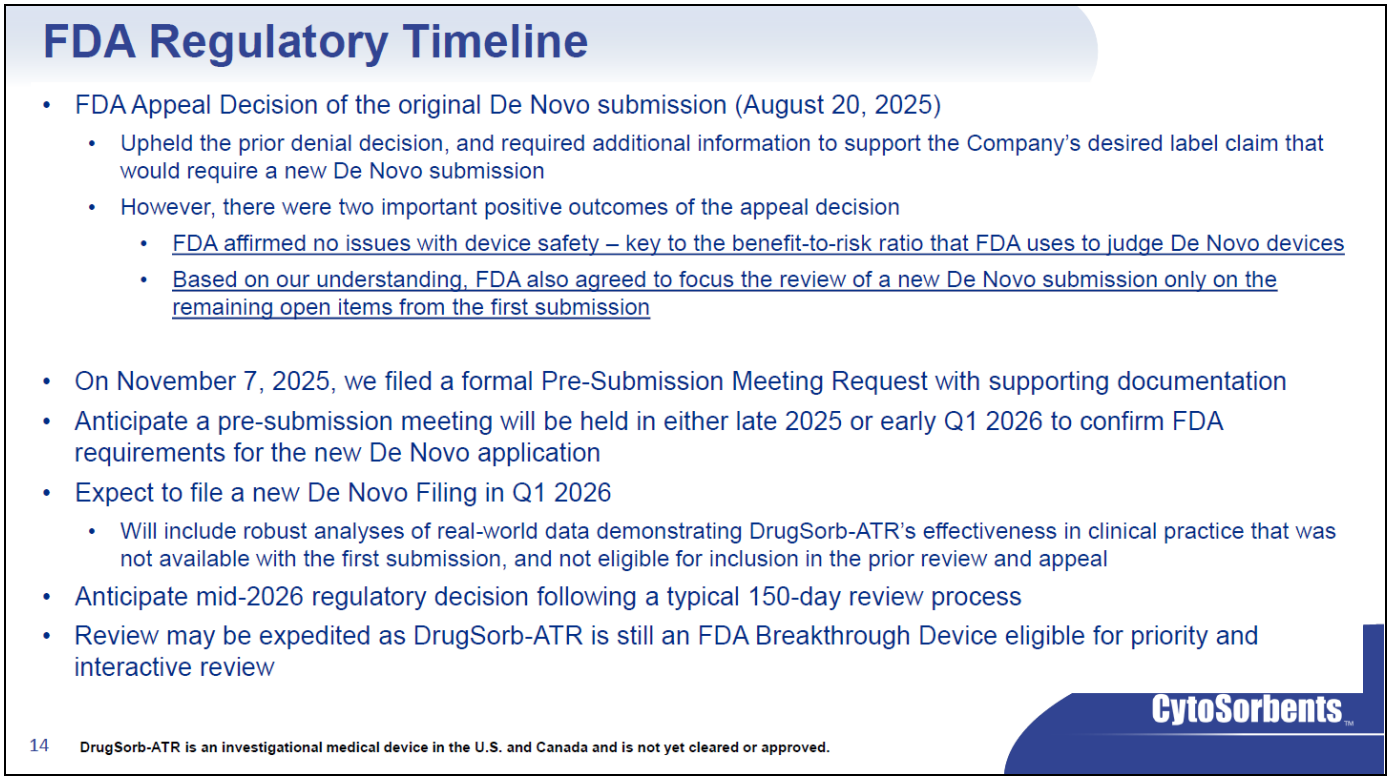
- While the company's initial De Novo submission was denied due to FDA's request for additional information to support the proposed labeling (interpreted primarily as requiring more efficacy data), the company has resolved most issues. Two important outcomes emerged from the first review cycle:

  1) FDA identified no safety concerns with DrugSorb-ATR, materially reducing the "probable risk" side of the De Novo equation. This is critical, as FDA precedent under Breakthrough Device, De Novo, and Least Burdensome guidelines, shows that for safe or low-risk medical devices, additional efficacy requirements can often be addressed post-market (e.g., via a registry) rather than as a condition of pre-market approval, helping avoid unnecessary delays.

  2) In subsequent discussions, based on the company's understanding, FDA agreed to limit its review of the new De Novo submission to only the remaining open items from the prior application. This is expected to expedite the review timeline. A primary remaining item is the need

for additional data supporting the intended label indication, which the company was previously unable to include due to FDA submission rules governing new and real-world data.

The company's anticipated timeline for the new De Novo submission is outlined below:



Source: CytoSorbents investor presentation

ANNUAL FINANCIAL PROJECTIONS

Income Statement	Dec-22	Dec-23	Dec-24	Dec-25	Dec-26
Product Sales	**29,359,910**	**31,084,953**	**35,594,520**	**37,803,191**	**41,797,775**
Growth	*-26.8%*	*5.9%*	*14.5%*	*6.2%*	*10.6%*
Cost of Goods Sold	**0**	**7,672,650**	**8,898,425**	**9,371,416**	**10,175,790**
%	*0.0%*	*24.7%*	*25.0%*	*24.8%*	*24.3%*
Depreciation & Amort	**0**	**1,459,066**	**1,570,104**	**1,535,000**	**1,431,102**
Gross Profit	**0**	**21,953,237**	**25,125,991**	**26,896,776**	**30,190,883**
Margin	*0.0%*	*70.6%*	*70.6%*	*71.1%*	*72.2%*
SG&A Expenses	**0**	**38,307,415**	**34,995,749**	**34,732,777**	**30,228,810**
% of sales	*0.0%*	*123.2%*	*98.3%*	*91.9%*	*72.3%*
Other	**0**	**0**	**0**	**0**	**0**
% of sales	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Research & Development	**0**	**15,594,442**	**6,916,181**	**4,751,745**	**2,864,891**
% of sales	*0.0%*	*50.2%*	*19.4%*	*12.6%*	*6.9%*
Amortization	**0**	**0**	**0**	**0**	**0**
% of sales	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**0**	**(31,948,620)**	**(16,785,939)**	**(12,587,746)**	**(2,902,819)**
Margin	*0.0%*	*-102.8%*	*-47.2%*	*-33.3%*	*-6.9%*
EBITDA	**0**	**(30,489,554)**	**(15,215,835)**	**(11,052,746)**	**(1,471,717)**
Margin	*0.0%*	*-98.1%*	*-42.7%*	*-29.2%*	*-3.5%*
Other Expenses/(Income)	**0**	**(2,046,012)**	**4,224,751**	**(2,949,984)**	**0**
%	*0.0%*	*-6.6%*	*11.9%*	*-7.8%*	*0.0%*
EBIT	**0**	**(29,902,608)**	**(21,010,690)**	**(9,637,762)**	**(2,902,819)**
%	*0.0%*	*-96.2%*	*-59.0%*	*-25.5%*	*-6.9%*
Total Interest Exp (net)	**0**	**157,981**	**1,399,092**	**2,511,134**	**2,551,000**
%	*0.0%*	*0.5%*	*3.9%*	*6.6%*	*6.1%*
Net Profit Before Tax	**0**	**(30,060,589)**	**(22,409,782)**	**(12,148,896)**	**(5,453,819)**
%	*0.0%*	*-96.7%*	*-63.0%*	*-32.1%*	*-13.0%*
Income Tax	**0**	**(813,739)**	**(1,690,825)**	**(401,000)**	**0**
% Effective Rate	*0.0%*	*2.7%*	*7.5%*	*3.3%*	*0.0%*
% Cash Tax Rate	*0.0%*	*2.7%*	*7.5%*	*3.3%*	*0.0%*
Minority Interests or Preferred Stock	**0**				
Net Profit	**0**	**(29,246,850)**	**(20,718,957)**	**(11,747,896)**	**(5,453,819)**
%	*0.0%*	*-94.1%*	*-58.2%*	*-31.1%*	*-13.0%*
	0.0%				
Non-recurring income (expense)	-				
	0				
Average Diluted Shares Outstanding	-	44,656,391	54,441,811	64,364,066	62,804,000
Reported FD EPS					
Zacks Cash EPS	**0.00**	**(0.65)**	**(0.38)**	**(0.18)**	**(0.09)**
Zacks EPS	**0.00**	**(0.65)**	**(0.38)**	**(0.18)**	**(0.09)**

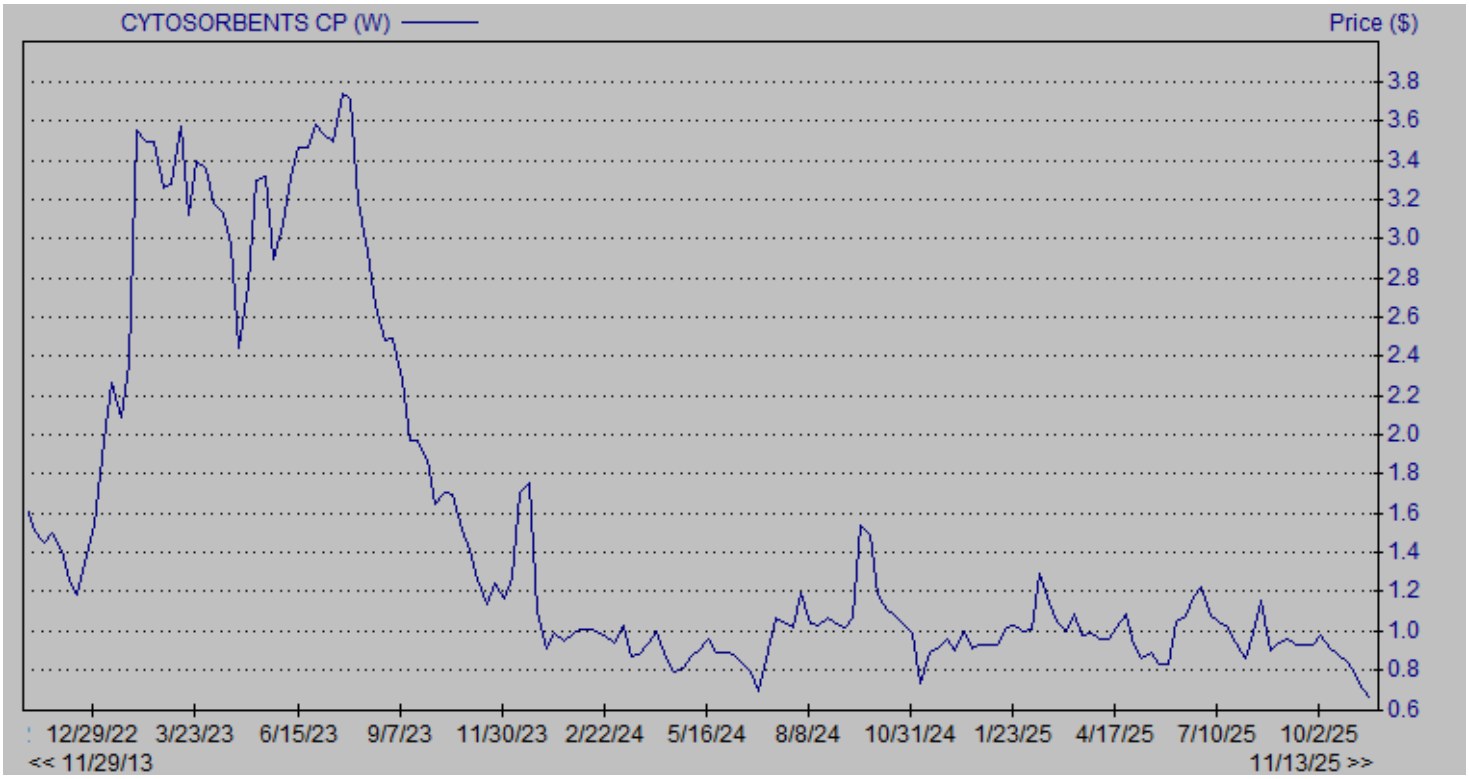
Source: Zacks analyst

QUARTERLY FINANCIAL PROJECTIONS

	Q1/26E	Q2/26E	Q3/26E	Q4/26E
Product Revenues	**9,687,234**	**10,597,934**	**10,471,440**	**11,041,166**
Cost of Goods Sold	**2,373,372**	**2,585,896**	**2,544,560**	**2,671,962**
%	*24.5%*	*24.4%*	*24.3%*	*24.2%*
Depreciation	**371,475**	**362,188**	**353,133**	**344,305**
Gross Profit	**6,942,387**	**7,649,850**	**7,573,747**	**8,024,899**
%	*71.7%*	*72.2%*	*72.3%*	*72.7%*
SG&A Expenses	**7,671,510**	**7,594,795**	**7,518,847**	**7,443,658**
%	*79.2%*	*71.7%*	*71.8%*	*67.4%*
Other Expenses/(Income)	**0**	**0**	**0**	**0**
%	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Research & Development	**727,056**	**719,785**	**712,588**	**705,462**
%	*10.5%*	*9.4%*	*9.4%*	*8.8%*
Amortization	**0**	**0**	**0**	**0**
%	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**(1,456,179)**	**(664,730)**	**(657,688)**	**(124,221)**
%	*-15.0%*	*-6.3%*	*-6.3%*	*-1.1%*
EBITDA	**(1,084,704)**	**(302,542)**	**(304,554)**	**220,084**
%	*-11.2%*	*-2.9%*	*-2.9%*	*2.0%*
Other Expenses/(Income)	**0**	**0**	**0**	**0**
%	*0.0%*	*0.0%*	*0.0%*	*0.0%*
EBIT	**(1,456,179)**	**(664,730)**	**(657,688)**	**(124,221)**
%	*-15.0%*	*-6.3%*	*-6.3%*	*-1.1%*
Total Interest Exp. (net)	**645,000**	**616,000**	**645,000**	**645,000**
%	*6.7%*	*5.8%*	*6.2%*	*5.8%*
Net Profit Before Tax	**(2,101,179)**	**(1,280,730)**	**(1,302,688)**	**(769,221)**
%	*-21.7%*	*-12.1%*	*-12.4%*	*-7.0%*
Income Tax	**0**	**0**	**0**	**0**
% Effect Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Minority Interest & Preferred Stock	**0**	**0**	**0**	**0**
Net Profit	**(2,101,179)**	**(1,280,730)**	**(1,302,688)**	**(769,221)**
%	*-21.7%*	*-12.1%*	*-12.4%*	*-7.0%*
Non-recurring income (expense)				
Shares Outst.	62,804,000	62,804,000	62,804,000	62,804,000
Reported FD EPS				
Fully Diluted EPS	**(0.03)**	**(0.02)**	**(0.02)**	**(0.01)**

Source: Zacks analyst

HISTORICAL STOCK PRICE



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