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Zacks Small-Cap Research

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CytoSorbents Corporation (NASDAQ: CTSO)

CTSO: CytoSorbents announced the De Novo denial on DrugSorb-ATR was upheld by the FDA. However, a path to approval was also provided by the agency. The decision also found no safety issues with DrugSorb-ATR.

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 (8/19/25)	$1.08
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. Based on the results of its STAR-T trial, the company submitted for FDA De Novo approval and Health Canada licensure in late 2024 and is currently navigating the appeal process with both agencies. Final regulatory decisions are expected in 2025. Based on $36.1 million in high margin TTM revenue and the near-term potential of DrugSorb-ATR, we believe CTSO stock to be significantly undervalued at this time.

SUMMARY DATA

52-Week High	**$1.61**
52-Week Low	**$0.70**
One-Year Return (%)	**21.8**
Beta	**0.78**
Average Daily Volume (sh)	**179,025**
Shares Outstanding (mil)	**62.5**
Market Capitalization ($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	$9.3 E	$10.1 E	$37.8 E
2026					$42.5 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	-$0.06 E	-$0.05 E	-$0.20 E
2026					-$0.11 E

Quarterly revenues may not equal annual revenues due to rounding. Quarterly EPS may not equal annual EPS due to rounding, dilution, or intangibles. Q2 EPS is adjusted EPS.

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WHAT'S NEW



Source: CytoSorbents investor presentation

Regulatory Update on DrugSorb-ATR

On August 20, 2025, the company announce 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 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 to have interactive discussions with the FDA for further clarification on the proposal. The FDA also noted another avenue for appeal to a higher level within the FDA, specifically with the Director of the FDA's Center for Devices and Radiologic Health (CDRH), that must be filed within 30 days of the appeal decision, which CytoSorbents is currently evaluating.

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. Importantly, the FDA has invited further discussions on a path forward to market authorization, providing a potential avenue to unlock significant commercial opportunity. 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.

Valuation and Estimates

Our 2025 revenue estimate is adjusted to $37.8 million, and our 2025 EPS estimate is an adjusted loss of ($0.20) based on better than expected EPS in the 2nd quarter of 2025. We believe 2026 revenues could exceed $41.0 million with the approval and commercialization of DrugSorb-ATR. Our 2026 GAAP EPS estimate is a loss of ($0.11) per share.

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 point in late 2025, which will free up cash for investment in the expected DrugSorb-ATR launch later this year and into 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.

As of June 30, 2025, the company had total cash of $11.7 million (including $10.2 million unrestricted and $1.5 million restricted cash) and total debt of $14.4 million. During the quarter, the company sold certain New Jersey NOLs and R&D tax credits, resulting in a net increase in cash of $1.7 million. Current assets were approximately $23.0 million and current liabilities were $9.8 million. Net working capital was positive at $13.2 million. Upon FDA approval of DrugSorb-ATR, the company will be able to access an additional $5.0 million from its lending facility if necessary.

We believe the company is fully funded to support its business model through the expected regulatory approval of DrugSorb-ATR and the subsequent commercial launch in late 2025 or early 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.

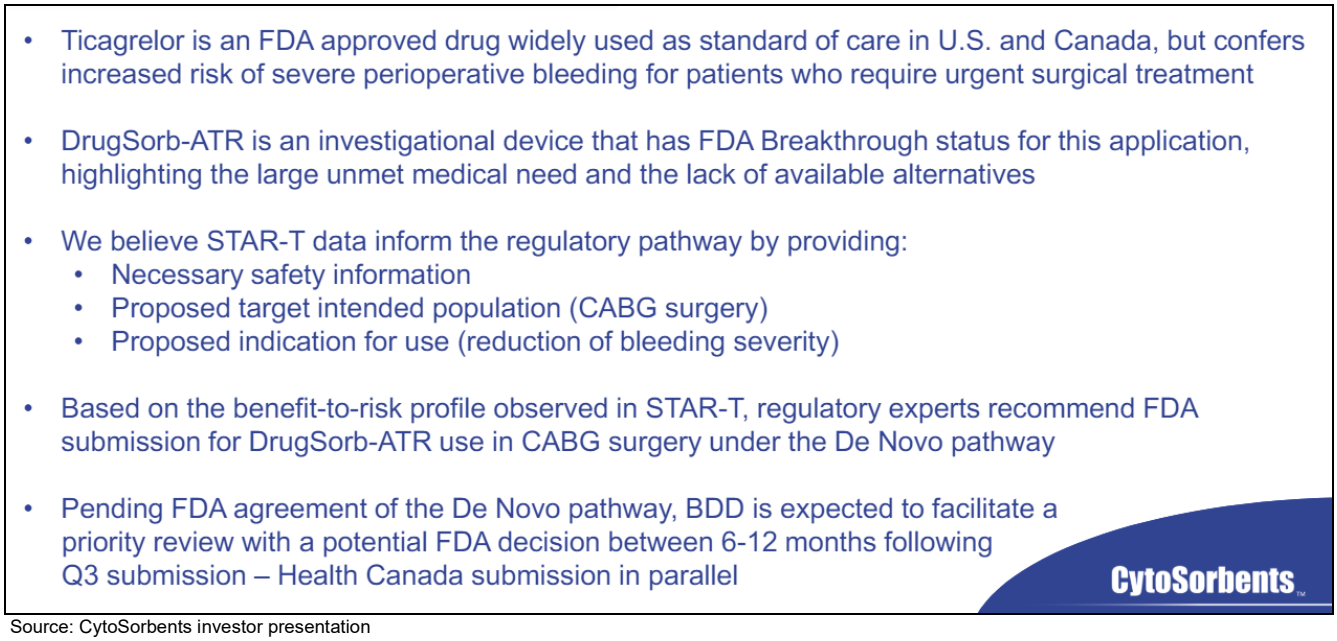
SUMMARY

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®.

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.



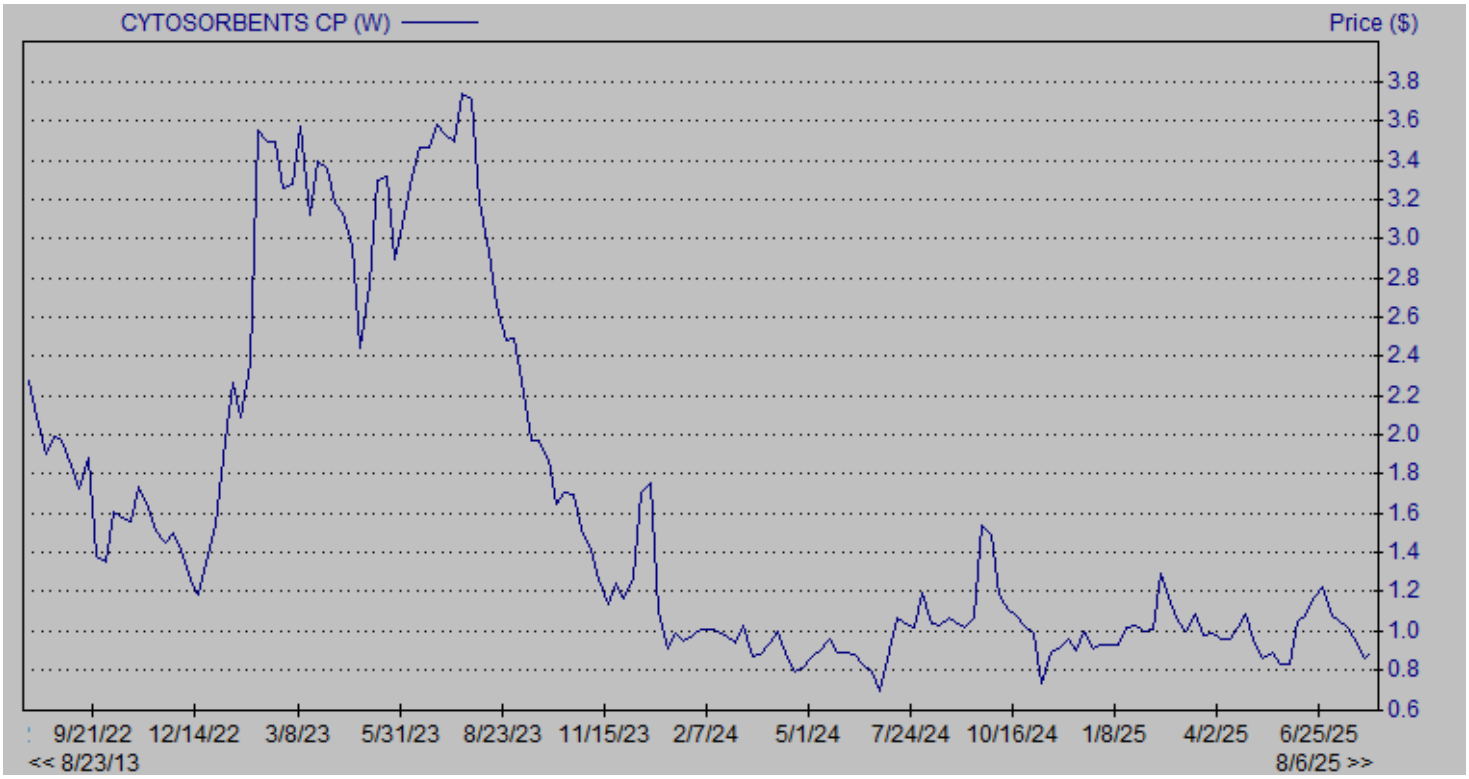
Source: CytoSorbents investor presentation

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**	**37,845,220**	**42,575,872**
Growth	*-26.8%*	*5.9%*	*14.5%*	*6.3%*	*12.5%*
Cost of Goods Sold	**0**	**7,672,650**	**8,898,425**	**9,219,720**	**9,094,908**
%	*0.0%*	*24.7%*	*25.0%*	*24.4%*	*21.4%*
Depreciation & Amort	**0**	**1,459,066**	**1,570,104**	**1,535,000**	**1,535,000**
Gross Profit	**0**	**21,953,237**	**25,125,991**	**27,090,500**	**31,945,964**
Margin	*0.0%*	*70.6%*	*70.6%*	*71.6%*	*75.0%*
SG&A Expenses	**0**	**38,307,415**	**34,995,749**	**35,658,784**	**32,092,905**
% of sales	*0.0%*	*123.2%*	*98.3%*	*94.2%*	*75.4%*
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**	**5,461,419**	**4,915,277**
% of sales	*0.0%*	*50.2%*	*19.4%*	*14.4%*	*11.5%*
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)**	**(14,029,702)**	**(5,062,218)**
Margin	*0.0%*	*-102.8%*	*-47.2%*	*-37.1%*	*-11.9%*
EBITDA	**0**	**(30,489,554)**	**(15,215,835)**	**(12,494,702)**	**(3,527,218)**
Margin	*0.0%*	*-98.1%*	*-42.7%*	*-33.0%*	*-8.3%*
Other Expenses/(Income)	**0**	**(2,046,012)**	**4,224,751**	**(3,013,984)**	**0**
%	*0.0%*	*-6.6%*	*11.9%*	*-8.0%*	*0.0%*
EBIT	**0**	**(29,902,608)**	**(21,010,690)**	**(11,015,718)**	**(5,062,218)**
%	*0.0%*	*-96.2%*	*-59.0%*	*-29.1%*	*-11.9%*
Total Interest Exp (net)	**0**	**157,981**	**1,399,092**	**2,453,134**	**2,207,821**
%	*0.0%*	*0.5%*	*3.9%*	*6.5%*	*5.2%*
Net Profit Before Tax	**0**	**(30,060,589)**	**(22,409,782)**	**(13,468,852)**	**(7,270,039)**
%	*0.0%*	*-96.7%*	*-63.0%*	*-35.6%*	*-17.1%*
Income Tax	**0**	**(813,739)**	**(1,690,825)**	**0**	**0**
% Effective Rate	*0.0%*	*2.7%*	*7.5%*	*0.0%*	*0.0%*
% Cash Tax Rate	*0.0%*	*2.7%*	*7.5%*	*0.0%*	*0.0%*
Minority Interests or Preferred Stock	**0**				
Net Profit	**0**	**(29,246,850)**	**(20,718,957)**	**(13,468,852)**	**(7,270,039)**
%	*0.0%*	*-94.1%*	*-58.2%*	*-35.6%*	*-17.1%*
	0.0%				
Non-recurring income (expense)	-				
	0				
Average Diluted Shares Outstanding	-	44,656,391	54,441,811	66,557,765	67,166,377
Reported FD EPS					
Zacks Cash EPS	**0.00**	**(0.65)**	**(0.38)**	**(0.20)**	**(0.11)**
Zacks EPS	**0.00**	**(0.65)**	**(0.38)**	**(0.20)**	**(0.11)**

Source: Zacks analyst

HISTORICAL STOCK PRICE



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