

# Zacks Small-Cap Research

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## CytoSorbents Corporation (NASDAQ: CTSO)

**CTSO: CytoSorbents reports 4<sup>th</sup> quarter and full year 2025 results which showed solid improvements in gross margins. We maintain our price target of \$5.00 based on expectations of cash flow breakeven status in late 2026.**

Utilizing a DCF valuation process containing conservative estimates combined with other valuation methodologies, we believe CTSO could be worth **\$5.00** per share.

Current Price (4/2/26) \$0.58  
Valuation **\$5.00**

### 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 \$37.1 million in high margin 2025 revenue and the DrugSorb-ATR potential in 2026-27, 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 (%) 23.7  
Beta 1.33  
Average Daily Volume (sh) 112.8

Shares Outstanding (mil) 62.5  
Market Capitalization (\$mil) \$45.0  
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	\$9.2 A	\$37.1 A
2026	\$9.3 E	\$9.8 E	\$9.9 E	\$10.1 E	\$39.1 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	-\$0.09 A	-\$0.13 A
2026	-\$0.06 E	-\$0.05 E	-\$0.04 E	-\$0.04 E	-\$0.19 E

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

## WHAT'S NEW



Source: CytoSorbents investor presentation

### 2025 Financial Results & Business Update

On March 25, 2026, the company announced 4<sup>th</sup> quarter and full year 2025 financial and operating results. In the 4<sup>th</sup> quarter, revenues increased 1.0% to \$9.2 million compared to the prior year period and were down 8.0% on a constant currency basis. Gross margin improved to 74% in the quarter compared to 70% in Q4 2024 due to improved operating efficiencies. The operating loss, which included a restructuring charge of approximately \$0.5 million due to workforce and cost reduction programs, was (\$4.6) million, compared to (\$3.7) million in Q4 2024. Net loss was (\$5.5) million or (\$0.09) per share, compared to a net loss of (\$7.6) million or (\$0.14) per share in Q4 2024. Adjusted net loss was (\$4.3) million or (\$0.07) per share, compared to an adjusted net loss of (\$1.7) million or (\$0.03) per share in Q4 2024. Adjusted EBITDA loss was (\$3.2) million compared to a loss of (\$2.4) million in Q4 2024.

For the full year 2025, revenues grew by 4% to \$37.1 million led by a 13.0% increase in direct sales outside of Germany to \$8.6 million and an 11.4% increase in distributor sales to \$16.5 million. Those together accounted for approximately 68% of total sales. This was offset by a 10% reduction in direct Germany sales to \$11.8 million which reflects the near-term impact of proactive restructuring of German sales operations and the implementation of strategies that are expected to drive more consistent and scalable growth. These improvements include enhanced customer targeting, structured weekly sales planning, increased focus on new account development, and improved allocation of sales resources. So far in 2026, the company has seen improving commercial activity, including increased customer engagement and new account development in Germany.

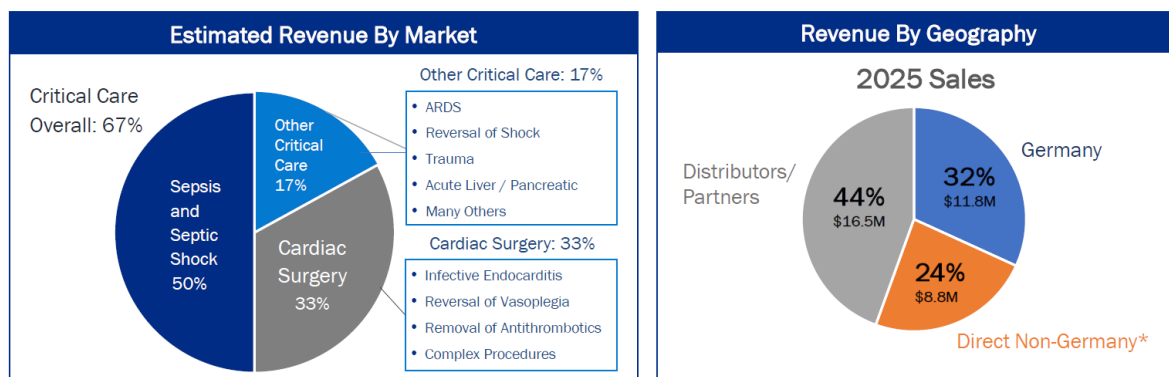
Gross margin for the year improved to 71% from 70% in the prior year, reflecting continued strength in product mix and cost discipline. Operating loss narrowed 10% year over year to (\$14.7) million from (\$16.5) million, indicating improved operating efficiency despite ongoing profitability challenges. Net loss improved to (\$8.2) million, or (\$0.13) per share, compared to a net loss of (\$20.7) million, or (\$0.38) per share in 2024. Adjusted EBITDA loss improved to (\$10.5) million from (\$11.5) million in 2024 as progress continued to narrow core operating losses.

Total cash balances were \$7.8 million on December 31, 2025, compared to \$9.1 million as of September 30, 2025. Total debt was \$16.7 million with no near-term maturities.

In the 4<sup>th</sup> quarter of 2025, the company implemented a strategic workforce and cost reduction program which reduced headcount by 10% while also lowered expenses and realigned operating and production spend. These production efficiencies resulted in an increased inventory buffer which enables a reduction in 2026 production expenditures which should help reduce cash burn this year. CytoSorb now anticipates achieving cash flow breakeven in the 2<sup>nd</sup> half of 2026 while maintaining adequate cash balances.

## CytoSorb Commercialization Focus

- We sell CytoSorb in more than 70 countries worldwide with more than 300,000 treatments to date
- Sell Direct in Germany and 9 other countries & through Distributors and partners in the remainder



\* Austria, Switzerland, Poland, Netherlands, England, Wales, North Ireland, Scotland, Ireland

Source: CytoSorbents investor presentation

### DrugSorb®-ATR Regulatory Update

In January 2026, the company had a formal pre-submission meeting with the FDA and continues to actively engage with the FDA to clarify and confirm the requirements for a new De Novo submission (see below for details and background on DrugSorb-ATR regulatory events). As these interactive discussions are ongoing, the company expects to provide an update on the anticipated timing of the submission once final requirements are established. Following submission, a regulatory decision is typically expected within a 150-day review period, although the timeline may be accelerated or extended based on the nature and scope of FDA interactions during the review process. CytoSorbents appears to be moving towards a patient and diligent approach to the submission in order to ensure accuracy and to position the initiative for success and ultimate approval.

In the meantime, the U.S. and Canadian pivotal STAR-T randomized, controlled trial results have now been published in the [Journal of Thoracic and Cardiovascular Surgery \(2026\)](#), which is the leading peer-reviewed cardiothoracic surgery journal in the U.S. The authors summarized the results in the [graphical abstract](#) and concluded in the central message of the article that, *"Intraoperative DrugSorb-ATR use for ticagrelor removal is safe and can reduce the severity of bleeding after isolated CABG in patients operated within 2 days of drug discontinuation."*

### Nasdaq Minimum Bid Price Requirement Compliance

On April 1, 2026, the company received a 180-day extension from the Listing Qualifications Staff of the Nasdaq Stock Market, to regain compliance with the Nasdaq requirement to maintain a minimum bid price of \$1.00 per share for continued listing on the exchange, by September 28, 2026. If at any time prior to September 28, 2026, the bid price of the company's common stock closes at \$1.00 per share or more for a minimum of 10 consecutive trading days, the company will regain compliance with the Minimum Bid Price Requirement. The company intends to actively monitor its stock price and continue considering all options to regain compliance. The stock will continue to be listed on Nasdaq during this period, and the company will continue to have reporting requirements with the SEC.

## Clinical Updates

In 2025, the company reached a key milestone of more than 300,000 cumulative CytoSorb® treatments delivered globally. This is an increase of more than 50% over the past few years which highlights the broad and growing adoption of CytoSorb therapies across more than 70 countries and a across a wide range of clinical applications.

Recently, a steady stream of new clinical data continues to support the use of CytoSorb across multiple critical care indications. Sepsis and septic shock remain among the leading use cases.

- A recent multinational survey of 442 physicians and published in *Intensive Care Medicine Experimental* (2026), found that more than three-quarters of respondents use extracorporeal blood purification primarily for refractory septic shock, with broad-spectrum hemoadsorption such as CytoSorb identified as the most commonly used and preferred modality (43%).
- During World Sepsis Day and Sepsis Awareness Month in September 2025, the company hosted a webinar entitled, "*Turning the Tide in Sepsis and Septic Shock*" highlighting why and how CytoSorb is used to control deadly inflammation, stabilize patients, reverse capillary leak, and facilitate fluid removal from patients.
- Interim results from the septic shock cohort of the prospective COSMOS registry, published in *Annals of Intensive Care* (2026), showed CytoSorb treatment was associated with significant reductions in interleukin-6 and vasopressor use, along with improved fluid balance, oxygenation, and organ function.
- These findings are consistent with a large meta-analysis published in the *Journal of Clinical Medicine* (2025), which compared 449 CytoSorb-treated patients plus standard of care to 295 control patients. CytoSorb use was associated with improved hemodynamics, reduced vasopressor needs, lower in-hospital mortality ( $p=0.04$ ), and a halving of 28 - 30 day mortality ( $p=0.003$ ).
- Additional retrospective data published in the *Journal of Intensive Care Medicine* (2025) demonstrated that early and intensive use of CytoSorb was associated with nearly doubled survival rates (70% observed vs. 37% predicted). These findings align with prior research published in the *Journal of Critical Care* (2021), showing that higher treatment volumes and longer duration correlate with improved survival outcomes.

By treating the "*Right Patients, at the Right Time, with the Right Dose*," the company believes it can improve sepsis outcomes even more. To support earlier and more effective treatment and to remove the therapy from dependence on other extracorporeal machines, the company is scaling up the distribution of [PuriFi® hemoperfusion pumps](#), with now more than 100 pumps placed internationally. These efforts expand an easy-to-use blood purification infrastructure that we expect will fuel device and disposables usage in the future. In addition, the company also recently announced the launch and immediate availability of HotSwap™, an innovative solution designed to enable rapid and seamless exchange of CytoSorb adsorbers during the treatment of critically ill patients, ensuring the "right dose". HotSwap is also expected to facilitate the safe return of valuable blood from used devices back to the patient, while streamlining workflows for busy ICU staff, reducing nursing burden, and improving treatment consistency.

## Other Critical Conditions

Beyond sepsis, a growing body of evidence supports the use of CytoSorb in other critical conditions. These include Acute Live Failure, Cardiogenic Shock, and Cardiac Surgery. We believe CytoSorb is uniquely positioned as one of the only therapies (drug, biologic, or device) that can broadly address key drivers of critical illness, including massive inflammation and cytokine storm, toxin overload, capillary leak, shock, and other serious complications.

A full description of these potential uses in other critical conditions can be found [here](#).

The image is a collage of promotional materials for CytoSorbents. At the top, a banner reads "CytoSorb Supported by a Wealth of Clinical Data". Below this, there are several panels:

- Website Screenshot:** Shows the CytoSorbents website interface with a "Literature Database" section. It lists several articles, including "Hemoadsorption in Critical Care: Real World Outcomes from the International COSMOS Registry" and "The International, Prospective COSMOS (CytoSorb® Treatment Of Critically Ill Patients) Registry: Results from the first 300 patients".
- Webinar Announcements:** Two circular graphics announce "2025 WEBINAR" events. One is titled "Turning the Tide in Sepsis and Septic Shock: Real World Insights with CytoSorb®" featuring speakers PD Dr. Kevin Pilarczyk, Prof. Zsolt Molnar, Dr. Tobias Hübner, and Dr. Phillip Chan, scheduled for Wednesday, Sep 10, 2025, 5pm CEST / 11am EDT. The other is titled "New insights on hemoadsorption in endocarditis" featuring Prof. T. Folliguet and Prof. D. Wendt, scheduled for Sept 3, 2025, 17:00-18:00 CEST.
- Clinical Data Highlights:** A central panel titled "CytoSorb® in Septic Shock: New meta-analysis highlights promising benefits of adjunctive hemoadsorption therapy". Below it, another panel states "Targeted use of CytoSorb linked to improved survival and hemodynamic stability".
- Other News:** A panel on the left titled "What's new in Rhabdomyolysis?" featuring Prof. J. Kielstein and Dr. V. Humbert. Another panel on the right titled "New Insights on Hemoadsorption in Septic Shock" featuring Dr. Ricard Ferrer.

The CytoSorbents logo is visible in the bottom right corner of the collage.

Source: CytoSorbents investor presentation

## Valuation and Estimates

Based on 2025 results and management commentary, we adjust our full year 2026 revenue estimate to \$39.1 million and adjust our 2026 loss per share to (\$0.19). We believe 2027 revenues can reach \$42.2 million without the commercialization of DrugSorb-ATR.

In the 4<sup>th</sup> quarter, the company implemented a strategic workforce and cost reduction program which reduced headcount by 10% while also lowering expenses and realigning operating and production spend. According to the company recent earnings call, it continues *"to adjust and reduce our operating and production cost as we begin 2026,"* and now expects to achieve breakeven in the second half of 2026. We expect to see the benefit of these actions in lowered cash burn in the first half of 2026 and believe the core business (i.e. the existing CytoSorb business) could reach cash flow breakeven at some point in the 2<sup>nd</sup> half of 2026.

Based on ongoing cost controls and the additional production efficiencies, we believe gross margins in 2026 will improve over the 71% range achieved in 2025.

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 better sales growth in the region.

We maintain our price target of **\$5.00** 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 or 2027.

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## OTHER RECENT NEWS

### Regulatory and Clinical Update on DrugSorb-ATR

Following a formal July 2025 appeal meeting regarding the initial April 2025 De Novo denial, the FDA, in an appeal decision issued in August 2025, confirmed there were no concerns regarding device safety – an essential factor for De Novo authorization, which is based on a favorable benefit-to-risk profile. However, the FDA upheld its denial, citing the need for additional information to support our proposed label indication. Based on subsequent FDA feedback, the Company elected to not pursue further appeals with the CDRH Director’s office but rather submit a new De Novo application incorporating additional information, including accumulating real-world data from the expanding use of the device for blood thinner removal worldwide that are captured with high fidelity in the international STAR Registry. The Company believes these new real-world data, combined with the recently published results from the STAR-T trial and the already-established safety profile of DrugSorb-ATR, will further support a favorable benefit-to-risk profile consistent with De Novo authorization standards. Additionally, the FDA indicated its openness to focusing the review of a new submission on the remaining open items, potentially providing a more streamlined and efficient regulatory pathway forward.

The Company held a formal pre-submission meeting with the FDA in late-January 2026 and continues to actively engage with the Agency to clarify and confirm the requirements for a new De Novo submission. As these interactive discussions are ongoing, The Company expects to provide an update on the anticipated timing of the submission once final requirements are established. Following submission, a regulatory decision is typically expected within a 150-day review period, although the timeline may be accelerated or extended based on the nature and scope of FDA interactions during the review process.

Meanwhile, the U.S. and Canadian pivotal STAR-T randomized, controlled trial results have now been published in the [Journal of Thoracic and Cardiovascular Surgery \(2026\)](#) - the leading peer-reviewed cardiothoracic surgery journal in the U.S.. The authors summarized the results in the [graphical abstract](#) and concluded in the central message of the article that, *“Intraoperative DrugSorb-ATR use for ticagrelor removal is safe and can reduce the severity of bleeding after isolated CABG in patients operated within 2 days of drug discontinuation.”*

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents, stated, *“We continue to make progress with the FDA to align on the content and timing of a new De Novo submission for DrugSorb-ATR™ and look forward to providing further updates in the future. 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.

**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.



Source: CytoSorbents investor presentation

In addition, a growing body of published literature highlights consistent findings from real-world use of CytoSorb®, which is approved in the European Union for the intraoperative removal of both Brilinta®/Brilique® and Xarelto® (rivaroxaban, Janssen/Johnson & Johnson) during cardiac surgery. The use of CytoSorb for antithrombotic removal (ATR) is increasingly being adopted as a standard-of-care practice at leading cardiac surgery centers worldwide. At the same time, the evidence supporting the clinical and economic value of reducing bleeding in patients on blood thinners continues to expand.

- Real-world evidence from the international Safe and Timely Antithrombotic Removal (STAR) Registry, recently published in Cardiovascular Revascularization Medicine (2026) and the Journal of Cardiothoracic Surgery (2025), demonstrates CytoSorb's ability to reduce perioperative bleeding risk in patients receiving antithrombotic therapies. Across more than 160 patients undergoing CABG or valve surgery while on direct oral anticoagulants (DOACs), such as Eliquis® (apixaban, Bristol Myers Squibb/Pfizer) and Xarelto®, or on Brilinta®, studies report low rates of severe bleeding (approximately 3-15%), minimal reoperations, and no device-related adverse events - even when surgery is performed within 24 hours of the last drug dose.
- Landmark data presented at the 2025 European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting included randomized data on the intraoperative removal of Eliquis® and Xarelto® during urgent cardiac surgery, presented by Professor Richard Whitlock. Additional data presented by Professor Matthias Thielmann demonstrated that intraoperative removal of ticagrelor during urgent CABG was associated with significantly reduced bleeding compared with Plavix® (clopidogrel, Bristol-Myers Squibb/Sanofi).
- Similarly, at the annual meeting of the German Society of Thoracic and Cardiovascular Surgery (DGTHG) earlier this year, multiple presentations reinforced the dominant value proposition of our technology in cardiac surgery. These findings showed not only improved clinical outcomes, but also meaningful improvements in care delivery that translate into substantial cost savings. At this

meeting, Professor Michael Schmoeckel, co-principal investigator of the international STAR Registry, presented pooled data from the STAR-T trial and STAR Registry demonstrating that reductions in bleeding among ticagrelor-treated patients undergoing urgent CABG were consistently observed in both controlled clinical trials and real-world clinical practice.

For DrugSorb-ATR, continued evidence generation, thought leadership, and visibility within the cardiovascular community remain key pillars of our anticipated launch strategy. The Company is maintaining this momentum with multiple new analyses and data presentations at major cardiovascular conferences throughout the year, further underscoring the clinical benefits of antithrombotic removal in cardiac surgery.

At the upcoming EuroPCR meeting in Paris in May 2026, The Company expects to feature two oral presentations within the scientific program:

- Professor Uwe Zeymer will present additional data from the STAR Registry demonstrating bleeding reductions associated with intraoperative removal of DOACs during urgent cardiac surgery.
- Professor Matthias Thielmann will present new data on the impact of P2Y12 inhibitor choice and intraoperative device use on bleeding after CABG. These findings suggest, for the first time, that ticagrelor may offer not only superior efficacy compared with clopidogrel in acute coronary syndromes, but also a potential safety advantage due to its ability to be actively removed during surgery.

Looking ahead, the company has submitted multiple original analyses for presentation at the 2026 European Society of Cardiology (ESC) Congress in Munich in August 2026 and the 2026 EACTS Annual Meeting in Barcelona in October 2026.

Finally, important market dynamics are expected to further support adoption. Since mid-2025, lower cost generic ticagrelor became broadly available in the U.S. from multiple manufacturers. As a result, its use in heart attack patients is expected to increase significantly from its current U.S. market share of approximately 50%, driven by its faster onset of action, more potent platelet inhibition, and improved cost competitiveness relative to generic Plavix® (clopidogrel).

In parallel, the unmet need for effective reversal strategies for blood thinners continues to grow. This need has been further amplified following the withdrawal of Andexxa® (AstraZeneca), previously the only approved reversal agent for certain direct oral anticoagulants such as Eliquis® and Xarelto® in cases of life-threatening bleeding, from the U.S. market in December 2025.

#### Workforce and Cost Reduction Program

In 2025, 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 followed 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 2<sup>nd</sup> half of 2026.

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## 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.

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## 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 1<sup>st</sup> 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.

## A Clear and Compelling Value Proposition

### We believe we have a sound plan to build and maximize shareholder value

- ✓ CytoSorb is an established, international core business in critical care and cardiac surgery with \$37.1M in high margin product sales and an excellent “razorblade” business model with expectations for strong future growth due to:
  - Significant critical care and cardiac surgery market opportunity worldwide, targeting major unmet medical needs, with new products helping to drive usage and the value proposition
  - A wealth of clinical data that we are leveraging in the market
  - Active measures to restore Germany back to growth
- ✓ A commitment to bringing DrugSorb-ATR to the North American market with a planned De Novo submission pending completion of interactive discussions with the FDA
- ✓ Goal is to drive to cash flow breakeven in 2H 2026 and have taken significant steps with our amended credit facility and workforce and cost reduction plan to advance this target

Source: CytoSorbents investor presentation

## ANNUAL FINANCIAL PROJECTIONS

<u>Income Statement</u>	<u>Dec-22</u>	<u>Dec-23</u>	<u>Dec-24</u>	<u>Dec-25</u>	<u>Dec-26</u>
<b>Product Sales</b>	<b>29,359,910</b>	<b>31,084,953</b>	<b>35,594,520</b>	<b>37,063,238</b>	<b>39,097,976</b>
<i>Growth</i>	-26.8%	5.9%	14.5%	4.1%	5.5%
<b>Cost of Goods Sold</b>	<b>0</b>	<b>7,672,650</b>	<b>8,898,425</b>	<b>9,338,000</b>	<b>8,967,602</b>
<i>%</i>	0.0%	24.7%	25.0%	25.2%	22.9%
<b>Depreciation &amp; Amort</b>	<b>0</b>	<b>1,459,066</b>	<b>1,570,104</b>	<b>1,234,000</b>	<b>1,431,102</b>
<b>Gross Profit</b>	<b>0</b>	<b>21,953,237</b>	<b>25,125,991</b>	<b>26,491,238</b>	<b>28,699,272</b>
<i>Margin</i>	0.0%	70.6%	70.6%	71.5%	73.4%
<b>SG&amp;A Expenses</b>	<b>0</b>	<b>38,307,415</b>	<b>34,995,749</b>	<b>35,645,000</b>	<b>34,597,013</b>
<i>% of sales</i>	0.0%	123.2%	98.3%	96.2%	88.5%
<b>Other</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>510,000</b>	<b>0</b>
<i>% of sales</i>	0.0%	0.0%	0.0%	1.4%	0.0%
<b>Research &amp; Development</b>	<b>0</b>	<b>15,594,442</b>	<b>6,916,181</b>	<b>5,085,000</b>	<b>3,676,266</b>
<i>% of sales</i>	0.0%	50.2%	19.4%	13.7%	9.4%
<b>Amortization</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<i>% of sales</i>	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Operating Income</b>	<b>0</b>	<b>(31,948,620)</b>	<b>(16,785,939)</b>	<b>(14,748,762)</b>	<b>(9,574,006)</b>
<i>Margin</i>	0.0%	-102.8%	-47.2%	-39.8%	-24.5%
<b>EBITDA</b>	<b>0</b>	<b>(30,489,554)</b>	<b>(15,215,835)</b>	<b>(13,514,762)</b>	<b>(8,142,904)</b>
<i>Margin</i>	0.0%	-98.1%	-42.7%	-36.5%	-20.8%
<b>Other Expenses/(Income)</b>	<b>0</b>	<b>(2,046,012)</b>	<b>4,224,751</b>	<b>(8,762,000)</b>	<b>0</b>
<i>%</i>	0.0%	-6.6%	11.9%	-23.6%	0.0%
<b>EBIT</b>	<b>0</b>	<b>(29,902,608)</b>	<b>(21,010,690)</b>	<b>(5,986,762)</b>	<b>(9,574,006)</b>
<i>%</i>	0.0%	-96.2%	-59.0%	-16.2%	-24.5%
<b>Total Interest Exp (net)</b>	<b>0</b>	<b>157,981</b>	<b>1,399,092</b>	<b>2,612,134</b>	<b>2,652,000</b>
<i>%</i>	0.0%	0.5%	3.9%	7.0%	6.8%
<b>Net Profit Before Tax</b>	<b>0</b>	<b>(30,060,589)</b>	<b>(22,409,782)</b>	<b>(8,598,896)</b>	<b>(12,226,006)</b>
<i>%</i>	0.0%	-96.7%	-63.0%	-23.2%	-31.3%
<b>Income Tax</b>	<b>0</b>	<b>(813,739)</b>	<b>(1,690,825)</b>	<b>(401,000)</b>	<b>(200,000)</b>
<i>% Effective Rate</i>	0.0%	2.7%	7.5%	4.7%	1.6%
<i>% Cash Tax Rate</i>	0.0%	2.7%	7.5%	4.7%	1.6%
<b>Minority Interests or Preferred Stock</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Net Profit</b>	<b>0</b>	<b>(29,246,850)</b>	<b>(20,718,957)</b>	<b>(8,197,896)</b>	<b>(12,026,006)</b>
<i>%</i>	0.0%	-94.1%	-58.2%	-22.1%	-30.8%
<i>0.0%</i>					
Non-recurring income (expense)	-	-	-	-	-
	<b>0</b>				
Average Diluted Shares Outstanding	-	44,656,391	54,441,811	62,231,771	62,804,088
Reported FD EPS	-				
<b>Zacks Cash EPS</b>	<b>0.00</b>	<b>(0.65)</b>	<b>(0.38)</b>	<b>(0.13)</b>	<b>(0.19)</b>
<b>Zacks EPS</b>	<b>0.00</b>	<b>(0.65)</b>	<b>(0.38)</b>	<b>(0.13)</b>	<b>(0.19)</b>

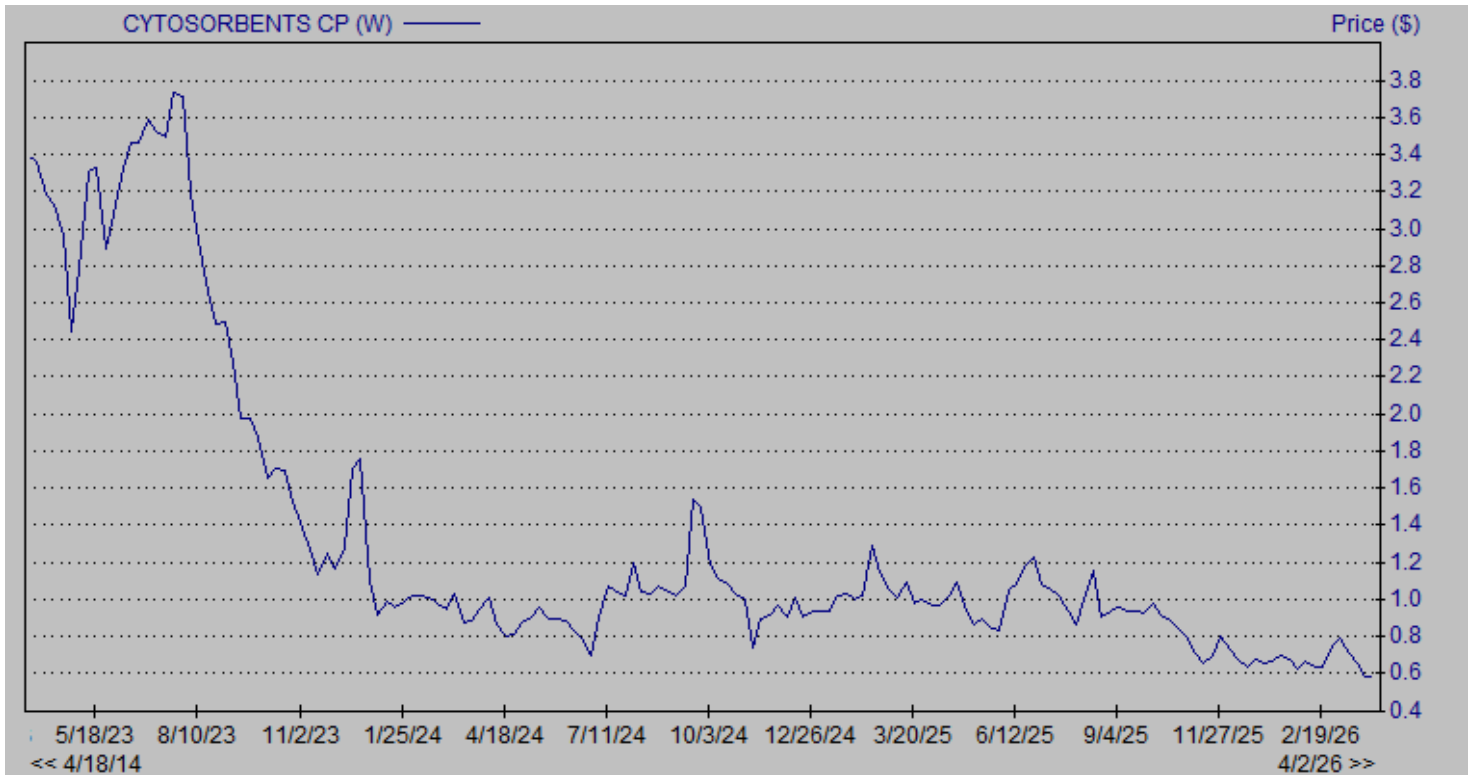
Source: Zacks analyst

## QUARTERLY FINANCIAL PROJECTIONS

	Q1/26E	Q2/26E	Q3/26E	Q4/26E
Product Revenues	9,326,340	9,792,657	9,890,584	10,088,395
Cost of Goods Sold	2,079,774	2,232,726	2,304,506	2,350,596
%	22.3%	22.8%	23.3%	23.3%
Depreciation	371,475	362,188	353,133	344,305
Gross Profit	6,875,091	7,197,743	7,232,944	7,393,494
%	73.7%	73.5%	73.1%	73.3%
SG&A Expenses	8,891,100	8,713,278	8,539,012	8,453,622
%	95.3%	89.0%	86.3%	83.8%
Other Expenses/(Income)	0	0	0	0
%	0.0%	0.0%	0.0%	0.0%
Research & Development	1,056,550	950,895	855,806	813,015
%	15.4%	13.2%	11.8%	11.0%
Amortization	0	0	0	0
%	0.0%	0.0%	0.0%	0.0%
Operating Income	(3,072,559)	(2,466,430)	(2,161,874)	(1,873,143)
%	-32.9%	-25.2%	-21.9%	-18.6%
<b>EBITDA</b>	<b>(2,701,084)</b>	<b>(2,104,242)</b>	<b>(1,808,740)</b>	<b>(1,528,838)</b>
%	-29.0%	-21.5%	-18.3%	-15.2%
Other Expenses/(Income)	0	0	0	0
%	0.0%	0.0%	0.0%	0.0%
EBIT	(3,072,559)	(2,466,430)	(2,161,874)	(1,873,143)
%	-32.9%	-25.2%	-21.9%	-18.6%
Total Interest Exp. (net)	746,000	616,000	645,000	645,000
%	8.0%	6.3%	6.5%	6.4%
Net Profit Before Tax	(3,818,559)	(3,082,430)	(2,806,874)	(2,518,143)
%	-40.9%	-31.5%	-28.4%	-25.0%
Income Tax	0	0	0	(200,000)
% Effect Rate	0.0%	0.0%	0.0%	7.9%
Minority Interest & Preferred Stock	0	0	0	0
Net Profit	(3,818,559)	(3,082,430)	(2,806,874)	(2,318,143)
%	-40.9%	-31.5%	-28.4%	-23.0%
Non-recurring income (expense)				
Shares Outst.	62,804,088	62,804,088	62,804,088	62,804,088
Reported FD EPS				
<b>Fully Diluted EPS</b>	<b>(0.06)</b>	<b>(0.05)</b>	<b>(0.04)</b>	<b>(0.04)</b>

Source: Zacks analyst

## HISTORICAL STOCK PRICE



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