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Zacks Small-Cap Research

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CytoSorbents Corporation (NASDAQ: CTSO)

CTSO: CytoSorbents Announces New Real-World Data Demonstrating Significant Reduction in Severe Bleeding Using CytoSorb in CABG Patients on Ticagrelor and Updates Recent DrugSorb-ATR FDA Pre-Submission Meetings

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 (9/2/26) \$0.38
Valuation **\$4.00**

SUMMARY DATA

52-Week High \$1.04
52-Week Low \$0.30
One-Year Return (%) -59.3
Beta 1.33
Average Daily Volume (sh) 154,932

Shares Outstanding (mil) 62.5
Market Capitalization (\$mil) \$24.1
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 2026 Estimate N/A
P/E using 2027 Estimate N/A

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 early 2027. Based on the likelihood of operating cash flow breakeven before year end, \$37.2 million in high margin TTM revenue, the DrugSorb-ATR potential in 2027 and 2028, and the new strategic value of HemoDefend-BGA, we believe CTSO stock to be significantly undervalued at this time.

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 A	\$9.5 A	\$9.2 A	\$37.0 A
2026	\$8.9 A	\$9.6 A	\$9.7 E	\$9.9 E	\$38.1 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	-\$0.08 A	-\$0.05 A	-\$0.05 E	-\$0.04 E	-\$0.22 E

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

WHAT'S NEW



Source: CytoSorbents investor presentation

New Findings Presented at European Society of Cardiology (ESC) Congress 2026

On September 2, 2026, the company announced an independent new patient-level matched analysis of real-world data demonstrating that intraoperative use of CytoSorb was associated with a significant reduction in severe perioperative bleeding among patients undergoing urgent coronary artery bypass grafting (CABG) surgery on the blood thinner, ticagrelor (Brilinta®/Brilique®, AstraZeneca). The findings were presented at the European Society of Cardiology (ESC) Congress 2026, the world's largest cardiovascular conference, on August 29, 2026.

Patients requiring urgent cardiac surgery after recent exposure to potent blood thinners face substantially higher risks of severe bleeding, transfusions, complications, longer hospital stays, and increased costs, historically necessitating a 3–7 day delay to allow the drugs to clear. CytoSorb offers a potentially significant alternative as the only specifically approved therapy in the E.U. for removing ticagrelor and rivaroxaban during cardiopulmonary bypass. A patient-level matched analysis of 587 urgent CABG patients following recent ticagrelor exposure compared 198 patients treated intraoperatively with CytoSorb in the STAR-T Registry with 389 matched patients from a previously published individual patient data meta-analysis who underwent surgery without the device, with the independent analysis demonstrating meaningful clinical benefits.

- A significant 37% relative reduction in BARC-4 severe bleeding with CytoSorb use (21.8% vs 34.5% in controls; $p=0.002$).
- Number of patients needed to be treated (NNT) with CytoSorb to prevent one severe bleeding event after urgent CABG was eight (8).
- Significant reductions in 24-hour chest tube drainage ($p=0.039$) and red blood cell transfusions ($p=0.003$) with CytoSorb use were also observed.
- No serious device-related adverse events were reported.

Prof. Dr. Uwe Zeymer, Vice Director of the Institute for Heart Attack Research in Ludwigshafen, Germany and Co-Principal Investigator of the STAR-T (**S**afe and **T**imely **A**ntithrombotic **R**emoval – **T**icagrelor) Registry stated, *"Today's presentation at the ESC meeting using robust statistical adjustments, demonstrates that in real world patients on ticagrelor undergoing urgent CABG, the use of CytoSorb is associated with significant reductions in severe bleeding rates compared with rates observed when patients on ticagrelor are operated without the device. Based on these results, the number of patients needed to be treated with the device to prevent a severe bleeding event after urgent CABG is 8, which is a clinically important result and is highly consistent with the NNT of 6 to prevent a major bleeding event demonstrated in the double-blind randomized STAR-T trial published earlier this year. Therefore, these results validate the testimonials from cardiac surgeons throughout Europe who have made CytoSorb their standard of care when operating urgently on patients on blood thinners. We plan to continue building the evidence base on antithrombotic removal during cardiac surgery beyond ticagrelor to include*

the direct oral anticoagulants, like apixaban and rivaroxaban, that are also very frequently present in patients requiring urgent cardiac surgery."

Phillip Chan, CEO of CytoSorbents stated, *"These real-world findings are highly encouraging and provide important new evidence of CytoSorb's performance in routine clinical practice in CABG patients facing this critical clinical dilemma. Importantly, we expect this new analysis to serve as a core component of additional clinical evidence - initially proposed by the FDA as part of last year's appeal - in a new De Novo submission for DrugSorb-ATR to help support its probable benefit in reducing the severity of perioperative bleeding in patients on Brilinta® undergoing urgent cardiac surgery. These data have not yet been submitted or reviewed by the Agency but are expected to increase approximately five-fold the number of patients treated with our technology in a new De Novo submission, to roughly 250 patients. We believe this substantially expanded body of clinical evidence will further strengthen the case for DrugSorb-ATR and help address the FDA's prior requests for additional supportive data."*

FDA Pre-Submission Meetings with FDA

CytoSorbents reported continued constructive engagement with the FDA regarding DrugSorb-ATR and its potential use in cardiac surgery patients taking ticagrelor (Brilinta). Recent Pre-Submission discussions helped align the Company and FDA on the mechanistic data and evaluation model needed to support the application. CytoSorbents plans to incorporate the FDA's feedback and conduct the study, with a new De Novo submission targeted for early 2027 under its Breakthrough Device designation. The submission is expected to include data from the STAR-T randomized trial, patient-level real-world evidence, new mechanistic and usability data, benchtop testing, and previously generated safety data, for which the FDA has identified no major safety concerns.

In parallel, the Company is pursuing a second regulatory pathway for DrugSorb-ATR in cardiac surgery patients taking direct oral anticoagulants (DOACs), including Eliquis and Xarelto. A recent FDA meeting addressed a number of questions and provided further clarity on the potential regulatory path, with a follow-up meeting expected in the near term. Management believes the combination of real-world evidence, consistent STAR-T trial results, and progress with the FDA provides a stronger foundation for future De Novo submissions and could ultimately support U.S. availability of DrugSorb-ATR for patients facing elevated bleeding risks during urgent cardiac surgery.

Valuation and Estimates

Based on 2nd quarter 2026 results and management commentary, we adjust our full year 2026 revenue estimate to \$38.1 million and adjust our 2026 non-GAAP loss per share to (\$0.22). We believe 2027 revenues can reach over \$40.0 million without the commercialization of DrugSorb-ATR.

In the 4th quarter of 2025, 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's recent earnings call, it continues to expect to achieve breakeven in the second half of 2026. We did see the results of these actions in the 2nd quarter as the going forward burn rate was reduced to approximately \$200,000 per quarter.

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 **\$4.00** per share due to the uncertainty of the timing of the DrugSorb-ATR submission and subsequent approval (if approved) in 2027.

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 2027.

DrugSorb®-ATR Regulatory Update

In January 2026, the company had a formal pre-submission meeting with the FDA and continued 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). Based on these interactions, the FDA has requested additional mechanistic data to be included alongside of the previously requested analysis of real-world evidence that was intended to support the De Novo standard that “probable benefit exceeds probable risk” within a new De Novo submission. FDA has already acknowledged the safety of DrugSorb-ATR for this application, hence a low probable risk.

The request for additional mechanistic data typically means the FDA wants more evidence explaining how the device works biologically to corroborate the observed positive clinical effect. The blood thinning drug Brilinta works as an anti-platelet drug that prevents platelets from sticking to each other, thereby preventing blood clotting. The presumed mechanism of action of DrugSorb-ATR is to remove the drug and reduce the inhibitory effect on platelets. It is generally well-accepted that the clinical effect of a drug or device is what is critical in the treatment of patients. Many FDA approved drugs and devices with a clear clinical benefit have been approved without a clear mechanism of action.

The company has evaluated various options to produce the additional mechanistic data on an expedited basis and has scheduled another pre-submission meeting with the FDA in August to discuss and align on the proposed approach. Following this meeting, the company expects to finalize the testing protocol, which may require an additional meeting with the FDA. Once finalized, the anticipated completion of the required testing and submitting a new De Novo application is expected in early 2027.

This submission timeline is later than previously expected, however, the company now has a clearer direction and is committed to obtaining the new information and filing a new De Novo submission as soon as reasonably possible. Following submission, a regulatory decision would generally be expected within the FDA’s targeted 150-day MDUFA review timeline, although the actual review period may be shorter or longer depending on the nature and extent of interactive review questions from the FDA.

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.”*

In addition, the findings of an important comparative real-world analysis entitled “Intraoperative ticagrelor removal to reduce bleeding after urgent CABG: Matched comparison of patient level observational data” was presented at the European Society of Cardiology’s ESC 2026 conference (August 28-31, 2026) in Munich, Germany. This data, released at the world’s largest cardiovascular conference, provided real-world evidence that will be provided to the FDA in a new De Novo submission, giving investors an opportunity to assess for themselves whether or not the “probable benefit exceeds the probable risk” of the technology.

DOAC Update: A Potential Parallel Path to DrugSorb-ATR FDA Marketing Approval

CytoSorbents is also accelerating its strategy to pursue an FDA indication for its DrugSorb-ATR device to remove direct oral anticoagulants (DOACs), which include Eliquis and Xarelto, during cardiac surgery, building on its existing focus on Brilinta removal. The company has scheduled a separate pre-submission meeting in August with the FDA to review the data currently available for the DOAC indication that include drug removal data from benchtop testing and data from real-world use and determine what, if any, additional information may be required to support a parallel De Novo submission for DOAC removal.

This effort is backed by the company's FDA Breakthrough Device Designation for DOAC removal and is driven by a clear clinical need. An estimated 5%-10% of emergent cardiac surgery cases involve patients actively on DOAC therapy, putting them at serious risk of life-threatening bleeding. Real-world adoption of the technology for this purpose is already growing, reflecting broad global demand given that tens of millions of patients are on long-term DOACs for conditions like atrial fibrillation, deep vein thrombosis, and pulmonary embolism.

Blood Thinners and Cardiac Surgery

- Tens of millions of patients globally take Direct Oral Anticoagulants (e.g. DOACs like Eliquis® and Xarelto®) and antiplatelet agents (e.g. Brilinta®) either chronically or acutely to reduce risk of heart attack, stroke, and other serious thrombotic complications
- Each year, an estimated 10% will require emergent or urgent surgery, including cardiac surgery
 - ~5-10% of emergency cardiac surgeries involve patients on chronic DOAC therapy
 - ~5-10% of heart attack patients on antiplatelet agents are not eligible for a stent and require CABG surgery
- Blood thinners significantly increase the risk of perioperative bleeding in cardiac surgery. Delay of surgery for multiple days for drug clearance is typically recommended to reduce this risk
- There is a major unmet need in patients awaiting urgent cardiothoracic surgery
 - Many patients cannot wait due to the need for emergency surgery
 - Waiting for drug washout may increase the risk of poor patient outcomes (e.g. thrombotic events, clinical instability, and sudden death) and wastes valuable hospital resources
- DrugSorb-ATR has received two FDA Breakthrough Designations, highlighting the lack of available effective therapies for this problem. We believe DrugSorb-ATR has the potential to address this pervasive and serious unmet medical need



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DrugSorb-ATR is an investigational medical device in the U.S. and Canada and is not yet cleared or approved. Brilinta®, Eliquis®, and Xarelto® are trademarks of AstraZeneca, Bristol-Myers Squibb, and Bayer, respectively

Source: CytoSorbents 2nd quarter 2026 investor presentation

The commercial opportunity is substantial. Eliquis alone generated roughly \$14.4 billion in global sales in 2025, ranking among the world's top-selling drugs, while Xarelto added another \$5.1 billion. Serious or life-threatening perioperative bleeding of patients on DOACs who require emergent cardiac surgery is a routine and major problem. With the voluntary withdrawal of Andexxa by AstraZeneca from the U.S. market in December 2025 after failing to get full FDA approval due to serious adverse events, there is no approved reversal agent for the DOACs in the U.S. Importantly, Andexxa was never indicated to reverse DOAC bleeding risk in cardiac surgery patients. CytoSorbents estimates the combined U.S. addressable market for DrugSorb-ATR across both Brilinta and DOAC indications at \$500 million - \$1 billion annually.

Nasdaq Listing 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 stock will continue to be listed on Nasdaq during this period, and the company will continue to have reporting requirements with the SEC.

On June 29, 2026, the company received a letter from the Staff of Nasdaq that the Company was not in compliance with Nasdaq Listing Rule 5550(b)(2) because the Company's minimum Market Value of Listed Securities was below the minimum of \$35 million required for continued listing on the Nasdaq Capital Market (the "MVLS Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), Nasdaq has provided the Company with 180 calendar days, or until December 28, 2026, to regain compliance with the MVLS Requirement.

Management's plans with respect to the company's continued listing requirements include actively monitoring the bid price and market value of the company's common stock, pursuing potential capital-raising transactions, and, if necessary, effecting a reverse stock split to regain compliance with the minimum bid price requirement. The company may also seek to satisfy an alternative continued listing standard, such as by increasing its stockholders' equity to at least \$2.5 million. There can be no assurance that the Company will regain compliance with the applicable Nasdaq continued listing requirements, that any such actions will result in a sustained increase in the Company's stock price or market value of listed securities, or that the Company's common stock will continue to be listed on Nasdaq.

On August 14, 2026, CytoSorbents filed an SEC Form 8-K disclosing that shareholders, at the Company's Annual Shareholder Meeting held August 13, 2026, had approved to effect a reverse stock split of the stock at a ratio of not less than 1-for-5 and not greater than 1-for-20, with the exact ratio to be determined by the Board at any time prior to the one year anniversary of the Annual Meeting.

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.

Cost-Effectiveness of CytoSorb in Sepsis



Article

Impact of CytoSorb Hemoadsorption Therapy on Cost-Effectiveness and Length of Stay in Critical Care Patients: A Preliminary Study from a Swiss High-Volume Center

Tobias Hühner^{1,2,*} and Oliver Schöffski²

- Retrospective, observational study in 246 septic shock patients (104 standard of care (SOC) vs 142 SOC + CytoSorb)
- Despite significantly higher initial disease severity at baseline, CytoSorb-treated patients demonstrated significantly:
 - Shorter ICU length of stay (median 408.5 vs 554 hours, $p=0.001$)
 - Shorter hospital length of stay (23.5 vs 30.0 days, $p=0.008$)
 - Shorter mechanical ventilation times (164.0 vs 336.0 hours, $p=0.014$)
 - Lower nursing workload, (>20% NEMS point reduction, $p=0.015$)
 - Better net financial result (revenue minus costs) with significantly higher earnings per case compared to SOC alone (+17,125 vs -1,930 Swiss Francs)
- These results highlight the cost-effectiveness of CytoSorb therapy and the ability to achieve clinical, operational, and economic benefits in a resource-intensive critical care setting

} Each approximately 6-7 days difference

* NEMS: Nine Equivalents of Nursing Manpower Use Score. A concise, 9-item therapeutic index used to measure nursing workload and intensity in intensive care units.

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Source: CytoSorbents investor presentation

- 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, 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 Liver 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.

CytoSorb Supported by a Wealth of Clinical Data

Literature Database

2025 WEBINAR
Turning the Tide in Sepsis and Septic Shock: Real World Insights with CytoSorb®
 PD Dr. Kevin Pilarczyk, Prof. Zolt Molnar, Dr. Tobias Hubner, Dr. Phillip Chan
 Wednesday, Sep 10, 2025 5pm CEST / 11am EDT
 REGISTER NOW

2025 WEBINAR
New insights on hemoadsorption in endocarditis
 Prof. T. Folliguet, Prof. D. Wendt
 Sept 3, 2025 17:00-18:00 CEST
 REGISTER NOW

What's new in Rhabdomyolysis?
 Prof. J. Kielstein, Dr. V. Humbert
 Recording now available!

CytoSorb® in Septic Shock:
 New meta-analysis highlights promising benefits of adjunctive hemoadsorption therapy
 Targeted use of CytoSorb linked to improved survival and hemodynamic stability

New Insights on Hemoadsorption in Septic Shock
 Dr. Ricard Ferrer
 Recording now available!

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Source: CytoSorbents investor presentation

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

OTHER RECENT NEWS

2nd Quarter 2026 Financial Results

On August 6, 2026, CytoSorbents released 2nd quarter financial and operating results. Revenue remained stable at \$9.6 million in the 2nd quarter, while profitability continued to improve as the company expanded gross margin to 73%, up from 69% in the prior quarter and 71% a year earlier. The higher margin, combined with disciplined cost management, drove a 27% reduction in operating loss to (\$2.6) million, demonstrating continued progress toward improving operating leverage despite a flat revenue environment.

Reported results were affected by non-cash foreign currency translation losses, resulting in a net loss of (\$4.4) million, or (\$0.07) per share, compared with net income of \$1.9 million or \$0.03 per share in the prior year period. Excluding these non-cash foreign exchange impacts and stock-based compensation, core profitability improved meaningfully, with adjusted net loss narrowing 22% to (\$2.8) million or (\$0.05) per share and adjusted EBITDA loss improved 38% to (\$1.6) million.

Total cash and equivalents (including restricted cash) was approximately \$5.9 million on June 30, 2026, compared to \$6.3 million as of March 31, 2026. Total cash burn in the 2nd quarter was reduced to \$0.4 million, inclusive of approximately \$0.2 million in restructuring-related payments. Going forward, we expect the quarterly cash burn for the rest of the year to be approximately \$200,000 per quarter.

Revenue in the quarter was driven by strong growth across distributor and strategic partner channels, as well as direct sales outside of Germany and was partially offset by weaker sales in Germany following the transition to a more focused sales organization. Management indicated that sales productivity and

execution in Germany have improved and plans to hire an additional three to five sales representatives through early 2027 to restore full market coverage and improve revenue growth.

The company also continued to improve operational efficiency during the quarter, with gross margin expanding to 73%, operating loss declining 27%, and adjusted EBITDA loss improving 38%. Operating cash burn, excluding restructuring payments, was reduced to approximately \$200,000, reflecting manufacturing optimization, improved working capital management, stronger commercial execution, and tighter cost controls. Based on these trends, the company believes it remains on track to achieve operating cash flow breakeven during the 2nd half of 2026.

Four Value Drivers

In the press release, management outlined four largely independent business drivers over the next 6-18 months that are expected to increase shareholder value and provide meaningful long-term growth.

➤ **Achieving Operating Cash Flow Breakeven**

The first value driver is reducing financial risk by achieving sustainable operating cash flow breakeven. Over the past year, the company has focused relentlessly on improving the economics of the overall business. Product gross margin improved to 73% during the 2nd quarter through manufacturing optimization, improved sourcing, and production efficiencies. The company also lowered its cash burn through improved commercial execution, collections, and working capital management while continuing to streamline the total organization. Since September 2025, there has been a 23% workforce reduction which has created a leaner and more focused company. This is an important milestone because it fundamentally changes the company's historical financial profile. Every dollar of operating cash burn eliminated reduces future financing needs, strengthens the balance sheet, increases strategic flexibility, and allows a greater proportion of future growth to accrue to shareholders.

➤ **Returning the CytoSorb Business to Sustainable, Profitable Growth**

The second value driver is returning the core CytoSorb business to sustainable, profitable growth. Underlying business trends remained mostly positive during the 2nd quarter, with 16% growth in distributor and strategic partner sales and 9% growth in direct sales outside Germany. This was partially offset by a 24% decline in Germany following the company's sales force restructuring. Management expects Germany to return to growth as territory coverage is restored through planned sales related hiring. Customer adoption of the company's PuriFi® pump platform and HotSwap® technology continued to increase, supporting earlier treatment, improved therapy delivery, and more consistent utilization of CytoSorb products. These, and other initiatives, particularly the operational investments and commercial restructuring completed over the past year, have positioned CytoSorbents for greater sales effectiveness that can strengthen both clinical adoption and long-term profitable growth of the franchise.

➤ **Opening the U.S. Market Through DrugSorb-ATR**

The third value driver is obtaining FDA marketing approval for DrugSorb-ATR and opening what is likely the company's most important long-term growth opportunity. DrugSorb-ATR targets a significant unmet need in cardiac surgery by removing commonly prescribed blood thinners during cardiopulmonary bypass for patients requiring urgent procedures. Supported by positive STAR-T trial results and expanding real-world evidence for Brilinta®, Eliquis®, and Xarelto®, the company believes the technology has strong global commercial potential. In the U.S. and Canada alone, the initial addressable market is estimated at **\$500 million to \$1 billion**, with additional expansion opportunities across other surgical indications.

The company has two FDA pre-submission meetings scheduled in August to advance its Brilinta® and direct oral anticoagulant (DOAC) programs. Management expects these discussions to clarify the remaining requirements for De Novo submissions, including a planned Brilinta® filing in early 2027 supported by expanded real-world clinical data. Regulatory approval would establish a second commercial franchise alongside the international CytoSorb business, expand access to the U.S. market, and support higher margins and long-term growth.

In addition, the findings of an important comparative real-world analysis entitled “Intraoperative ticagrelor removal to reduce bleeding after urgent CABG: Matched comparison of patient level observational data” was presented at the European Society of Cardiology’s ESC 2026 conference (August 28-31, 2026) in Munich, Germany. This data, released at the world’s largest cardiovascular conference, provided real-world evidence that will be provided to the FDA in a new De Novo submission, giving investors an opportunity for the first time to assess for themselves the strength of these new data and how it may impact the chances of a successful second De Novo submission.

➤ **Unlocking the Strategic Value of HemoDefend-BGA**

The fourth value driver is realizing the strategic value of HemoDefend-BGA which is a technology that is not likely reflected in today’s valuation. HemoDefend-BGA is a sophisticated blood filter designed to remove anti-A and anti-B antibodies from plasma and platelet products, enabling the production of ‘universal’ blood products that can be transfused regardless of recipient blood type. This can be done without electricity, capital equipment, or complex processing and was supported by approximately \$16 million in no-dilutive government funding.

This product has the potential to transform blood product management by simplifying inventories, reducing waste and costs, and improving access to critical blood products. Validated with support from leading blood centers, the technology could enable universal plasma and platelet products, reducing complexity in hospital blood banks and expanding the availability of life-saving transfusions in emergency settings, including ambulances, first responders, and military applications. Put simply, imagine the simplification and cost savings to hospital blood banks from currently maintaining 4 types of plasma (A, B, AB, O) and 4 types of platelets to just 1 universal plasma and 1 universal platelet product in the future.

Over the past year, the company completed product development and received constructive FDA feedback in July 2026 regarding the anticipated clinical pathway. The company also continues to engage with U.S. government agencies regarding potential non-dilutive funding opportunities to support future clinical development.

HemoDefend-BGA could represent a valuable strategic asset for CytoSorbents with multiple potential pathways to create shareholder value, including commercial partnerships, licensing opportunities, government funding, or other strategic alternatives.

We view HemoDefend-BGA as an exciting wild card for investors, as the program has clearly made significant progress since our last update. The importance of universal blood products, such as plasma and platelets that can be administered to patients regardless of blood type, has become increasingly visible amid ongoing global conflicts. The company noted that the first FDA approval of freeze-dried plasma technology occurred less than a month ago. When potentially combined with the low-titer “universal” plasma produced by HemoDefend-BGA, this technology could create “freeze-dried universal plasma.” This would represent the “holy grail” of plasma products: a solution that could be stored and stockpiled without refrigeration, then reconstituted and administered on demand simply by adding water. We believe this asset has significant strategic potential for the company and could emerge as a meaningful value driver for investors.

CytoSorb Published Literature

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 EuroPCR meeting in Paris in May 2026, the company featured two oral presentations within the scientific program:

- Professor Uwe Zeymer presented additional data from the STAR Registry demonstrating bleeding reductions associated with intraoperative removal of DOACs during urgent cardiac surgery.
- Professor Matthias Thielmann presented 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.

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.

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 of the core CytoSorb franchise going forward, the potential for a favorable FDA review of DrugSorb-ATR, unlocking the value of the HemoDefend-BGA asset, and importantly the expected achievement of operating cash flow breakeven in the second half of 2026. 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 certain 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 1st 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.

Finally, we view HemoDefend-BGA as an exciting wild-card for investors, as it clearly has made significant progress from the last time we were updated on the program, and the importance of universal blood products like plasma and platelets that can be given to any patient regardless of blood type, has grown more visible with the war in Iran. The company noted that the first FDA approval of freeze dried plasma technology occurred less than a month ago, which when potentially combined with low-titer “universal” plasma produced by HemoDefend-BGA, would create “freeze dried universal plasma”. This is the “holy grail” of plasma that can be stored and stockpiled without the need for refrigeration and then given on demand simply by adding water. The company highlights the potential for non-dilutive government funding to fund clinical trials through FDA approval. We agree this asset has high strategic potential for the company and could be a significant value driver for investors.

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

Income Statement	Dec-23	Dec-24	Dec-25	Dec-26	Dec-27
Product Sales	31,084,953	35,594,520	37,063,238	38,150,247	41,202,266
<i>Growth</i>	5.9%	14.5%	4.1%	2.9%	8.0%
Cost of Goods Sold	7,672,650	8,898,425	9,338,000	9,145,206	9,547,205
<i>%</i>	24.7%	25.0%	25.2%	24.0%	23.2%
Depreciation & Amort	1,459,066	1,570,104	1,234,000	1,526,101	1,526,101
Gross Profit	21,953,237	25,125,991	26,491,238	27,478,939	30,128,960
<i>Margin</i>	70.6%	70.6%	71.5%	72.0%	73.1%
SG&A Expenses	38,307,415	34,995,749	35,645,000	31,644,393	28,163,510
<i>% of sales</i>	123.2%	98.3%	96.2%	82.9%	68.4%
Other	0	0	510,000	0	0
<i>% of sales</i>	0.0%	0.0%	1.4%	0.0%	0.0%
Research & Development	15,594,442	6,916,181	5,085,000	5,028,015	4,273,813
<i>% of sales</i>	50.2%	19.4%	13.7%	13.2%	10.4%
Amortization	0	0	0	0	0
<i>% of sales</i>	0.0%	0.0%	0.0%	0.0%	0.0%
Operating Income	(31,948,620)	(16,785,939)	(14,748,762)	(9,193,469)	(2,308,362)
<i>Margin</i>	-102.8%	-47.2%	-39.8%	-24.1%	-5.6%
EBITDA	(30,489,554)	(15,215,835)	(13,514,762)	(7,667,368)	(782,261)
<i>Margin</i>	-98.1%	-42.7%	-36.5%	-20.1%	-1.9%
Other Expenses/(Income)	(2,046,012)	4,224,751	(8,762,000)	1,228,000	0
<i>%</i>	-6.6%	11.9%	-23.6%	3.2%	0.0%
EBIT	(29,902,608)	(21,010,690)	(5,986,762)	(10,421,469)	(2,308,362)
<i>%</i>	-96.2%	-59.0%	-16.2%	-27.3%	-5.6%
Total Interest Exp (net)	157,981	1,399,092	2,612,134	3,450,000	3,105,000
<i>%</i>	0.5%	3.9%	7.0%	9.0%	7.5%
Net Profit Before Tax	(30,060,589)	(22,409,782)	(8,598,896)	(13,871,469)	(5,413,362)
<i>%</i>	-96.7%	-63.0%	-23.2%	-36.4%	-13.1%
Income Tax	(813,739)	(1,690,825)	(401,000)	0	0
<i>% Effective Rate</i>	2.7%	7.5%	4.7%	0.0%	0.0%
<i>% Cash Tax Rate</i>	2.7%	7.5%	4.7%	0.0%	0.0%
Minority Interests or Preferred Stock					
Net Profit	(29,246,850)	(20,718,957)	(8,197,896)	(13,871,469)	(5,413,362)
<i>%</i>	-94.1%	-58.2%	-22.1%	-36.4%	-13.1%
Non-recurring income (expense)				(1,181,000.0)	
Average Diluted Shares Outstanding	44,656,391	54,441,811	62,231,771	62,738,827	62,738,827
Reported FD EPS				(0.24)	
Zacks Cash EPS	(0.65)	(0.38)	(0.13)	(0.22)	(0.09)
Zacks EPS	(0.65)	(0.38)	(0.13)	(0.22)	(0.09)

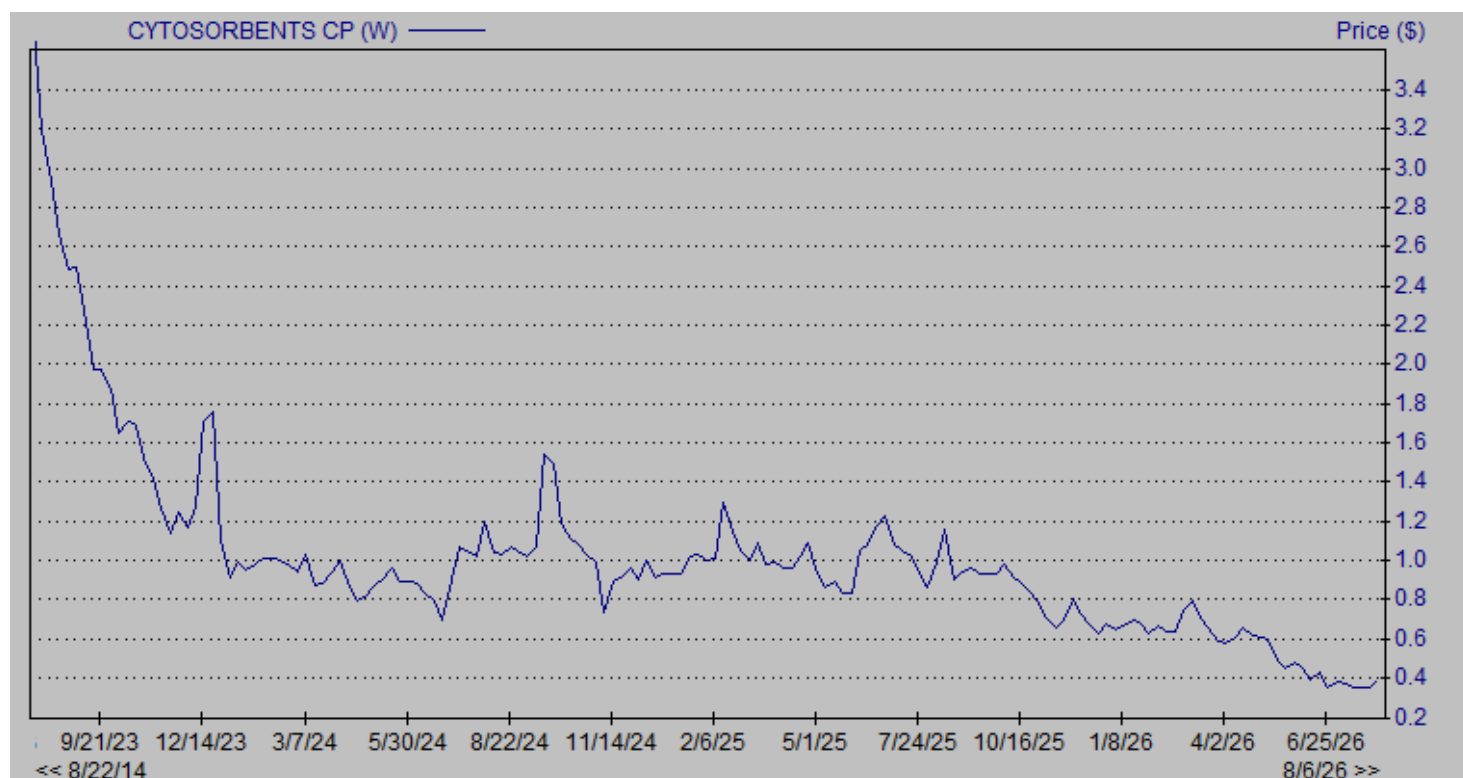
Source: Zacks analyst

QUARTERLY FINANCIAL PROJECTIONS

	Q1/26A	Q2/26A	Q3/26E	Q4/26E
Product Revenues	8,864,000	9,633,000	9,729,330	9,923,917
Cost of Goods Sold	2,384,000	2,182,000	2,266,934	2,312,273
%	22.3%	22.8%	23.3%	23.3%
Depreciation	350,000	402,000	391,950	382,151
Gross Profit	6,130,000	7,049,000	7,070,446	7,229,493
%	69.2%	73.2%	72.7%	72.8%
SG&A Expenses	8,149,000	7,964,000	7,804,720	7,726,673
%	91.9%	82.7%	80.2%	77.9%
Other Expenses/(Income)	0	0	0	0
%	0.0%	0.0%	0.0%	0.0%
Research & Development	1,025,000	1,453,000	1,307,700	1,242,315
%	16.7%	20.6%	18.5%	17.2%
Amortization	0	0	0	0
%	0.0%	0.0%	0.0%	0.0%
Operating Income	(3,044,000)	(2,368,000)	(2,041,974)	(1,739,495)
%	-34.3%	-24.6%	-21.0%	-17.5%
EBITDA	(2,694,000)	(1,966,000)	(1,650,024)	(1,357,344)
%	-30.4%	-20.4%	-17.0%	-13.7%
Other Expenses/(Income)	1,228,000	0	0	0
%	13.9%	0.0%	0.0%	0.0%
EBIT	(4,272,000)	(2,368,000)	(2,041,974)	(1,739,495)
%	-48.2%	-24.6%	-21.0%	-17.5%
Total Interest Exp. (net)	857,000	868,000	868,000	857,000
%	9.7%	9.0%	8.9%	8.6%
Net Profit Before Tax	(5,129,000)	(3,236,000)	(2,909,974)	(2,596,495)
%	-57.9%	-33.6%	-29.9%	-26.2%
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	(5,129,000)	(3,236,000)	(2,909,974)	(2,596,495)
%	-57.9%	-33.6%	-29.9%	-26.2%
Non-recurring income (expense)		(1,181,000)		
Shares Outst.	62,738,827	62,806,694	62,806,694	62,806,694
Reported FD EPS		(0.07)		
Fully Diluted EPS	(0.08)	(0.05)	(0.05)	(0.04)

Source: Zacks analyst

HISTORICAL STOCK PRICE



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