September 4, 2024

Zacks Small-Cap Research

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CytoSorbents Corporation (NASDAQ: CTSO)

CTSO: CytoSorbents reports solid 2nd quarter 2024 financial results which were above our expectations. The company remains on track to submit DrugSorb-ATR for regulatory approval in Q3 2024.

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 (9/3/24)	$1.02
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. First half 2024 product sales improved 12% from last year while product gross margins rose to 75%. 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 during cardiac surgery. Based on the results of its pivotal U.S. and Canadian STAR-T trial, the company plans to submit for FDA De Novo and Health Canada marketing approvals in Q3 2024.

SUMMARY DATA

52-Week High	**$4.29**
52-Week Low	**$0.78**
One-Year Return (%)	**-74.8**
Beta	**0.62**
Average Daily Volume (sh)	**100,932**
Shares Outstanding (mil)	**45.2**
Market Capitalization ($mil)	**$54.6**
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)
2022	$8.7 A	$8.5 A	$8.1 A	$9.4 A	$34.7 A
2023	$9.4 A	$9.4 A	$8.8 A	$8.7 A	$36.3 A
2024	$9.8 A	$9.9 A	$9.8 E	$10.2 E	$39.7 E
2025					$44.5 E

EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.21 A	-$0.25 A	-$0.28 A	-$0.02 A	-$0.75 A
2023	-$0.17 A	-$0.14 A	-$0.21 A	-$0.12 A	-$0.64 A
2024	-$0.12 A	-$0.08 A	-$0.08 E	-$0.05 E	-$0.33 E
2025					-$0.12 E

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

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WHAT'S NEW



Source: CytoSorbents investor presentation

2nd Quarter 2024 Financial Results

CytoSorbents reported 2nd quarter 2024 results on August 13th and the results were mostly above our expectations. For the 2nd quarter of 2024, total revenues increased approximately 5.0% to $9.9 million. Total product sales were $8.8 million, an increase of 9.5% from the 2nd quarter of 2023. Grant income was $1.05 million in the 2nd quarter of 2024 compared to $1.35 million in the prior year period.

Product gross margin in the 2nd quarter increased to approximately 75% compared to 74% in the prior year period primarily due to greater efficiencies being realized at the new manufacturing facility in Princeton, New Jersey. As product revenues continue to grow, gross margins are expected to reach 80% over time.

During the 2nd quarter, research and development expenses were approximately $1.5 million compared to approximately $3.7 million for the 2nd quarter of 2023. This decrease was primarily due to a decrease in clinical trial costs related to the completion of the STAR-T trial in 2023.

Net loss for the 2nd quarter was ($4.1) million, which was an improvement from a net loss of ($6.1) million in the prior year period. Operating cash flow was a use of cash of ($4.8) million. The company's burn rate is expected to improve throughout 2024 as cost saving measures take effect and the company's product sales continue to increase total revenues.

Liquidity and Capital Resources

As of June 30, 2024, the company had current assets of approximately $21.9 million and current liabilities of approximately $10.3 million. At the end of the 2nd quarter, $25 million of the total shelf amount was allocated to the ATM facility, of which approximately $20.3 million is still available. During the 1st half of 2024, the company sold 53,290 shares at an average selling price of $1.03 per share, generating net proceeds of approximately $53,200.

In the 2nd quarter, the company closed on a $20 million credit facility of which $15 million was released to the company before the end of the quarter. $10 million of this is being held as unrestricted cash and $5 million is held as a long-term asset as restricted cash and will be released pending the DrugSorb-ATR submission to the FDA. (see more details below)

On December 13, 2023, the Company closed on a $10.3 million registered direct offering for the sale of 7,733,090 shares of registered common stock and warrants to purchase up to 2,706,561 shares of common stock. Each share of common stock and accompanying warrant to purchase up to 0.35 shares of common stock, were sold together for a combined purchase price of $1.33, for an aggregate purchase price of approximately $10,285,000. The company received net proceeds of approximately $9,785,000.

For the 2nd quarter of 2024, the company reduced its operating loss 48% year over year from $6.6 million a year ago to $3.4 million. The company also disclosed cutting an additional $5.0 million in operating expenses after the 2nd quarter closed.

As of June 30, 2024, the company had approximately $14.9 million in cash including approximately $8.4 million in unrestricted cash and $6.5 million in restricted cash. This should be sufficient to fund the company's operations into the 2nd quarter of 2025.

CytoSorbents Releases Newly Redesigned Company and Product Website

On July 29th the company announced the release of a newly designed website. The new website was built from the ground up and unifies corporate and product information into a single, cohesive and comprehensive information hub for healthcare professionals, investors, and other stakeholders. Key features include:

- User-Friendly Layout and Intuitive Navigation - with easy access to essential information and optimized for both desktop and mobile browsing.
- Enhanced Easy-to-Understand Content - tailored for different stakeholders.
- News and Updates - dedicated to the latest developments and events.
- Comprehensive and Searchable Resource Library - from a collection of 1,000+ peer-reviewed publications, poster presentations, abstracts, white papers and case reports highlighting the use of therapies in many applications.
- Introduction to Our Experts - who are there to provide guidance and support.
- Voices Around the World - with insights and feedback from users worldwide.
- Dedicated Investor Relations site - for quick access to investor materials.
- Improved Contact Forms - facilitating faster communications and interactions.

CytoSorbents Secures $20 Million Credit Facility

On July 2nd, the company announced that they had secured a $20 million non-dilutive credit facility. The credit agreement, which has an initial term of three years, provides up to $20 million in total term loan proceeds including an initial tranche of $15 million. $10 million will be immediately available and an additional $5 million will be held in restricted cash and will be released with the acceptance by the FDA of the company's planned De Novo application for DrugSorb-ATR and certain liquidity requirements. A second tranche of $5 million would be available in the 2nd half of 2025 with FDA marketing clearance for DrugSorb-ATM to help support an anticipated launch of the therapy in the United States.

CytoSorbents Announces the Launch and Availability of the PuriFi Blood Pump in the EU

On June 13th, the company announced the launch and immediate availability of its PuriFi™ hemoperfusion machine in the EU, following approval and certification under the EU Medical Device Regulation (MDR).

The PuriFi peristaltic blood pump features a number of innovations that separate it from other hemoperfusion pumps including a pre-assembled adult and pediatric blood line kit, auto-priming, an auto-leveling bubble catcher, an intuitive touchscreen graphical user interface with a step-by-step user-friendly set-up guide, optional blood warming, and a rapid 10-minute set-up time. These unique features enable an easy and fast method to administer the CytoSorb® blood purification cartridge for critically ill and cardiac surgery patients.

More information can be found here.

CytoSorbents Announces Regulatory Approval of CytoSorb in Taiwan

On June 24th, the company announced the regulatory approval of CytoSorb in Taiwan by the Taiwan Food and Drug Administration (TFDA). The approved indications include the extracorporeal removal of

cytokines (cytokine storm, sepsis), bilirubin (liver disease), and myoglobin (trauma) from a patient's circulating blood. The removal of the antithrombotic drugs Brilinta® (ticagrelor, AstraZeneca) and Xarelto® (rivaroxaban, Janssen/Bayer) during cardiothoracic surgery is also approved, with the goal of reducing perioperative bleeding. CytoSorb will be distributed throughout Taiwan by Hemoscien Corporation.

Valuation and Estimates

Our 2024 revenue estimate is $39.7 million and our 2024 EPS estimate is adjusted to a loss of ($0.33) per share based on improved cost controls at the company. We believe 2025 revenues could reach $44.5 million. Our 2025 EPS estimate is a loss of ($0.12) per share.

The company has 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. The benefit of these cost cuts on operating expenses, particularly the headcount reductions, will become more apparent going forward as notice periods and severance payments are completed.

In addition, the company has worked diligently to optimize manufacturing efficiencies. In the 2nd quarter of 2024, CytoSorb product gross margins were 75%. In the near-term, the company expects product gross margins to be more consistently in the 75-80% range on a quarterly basis in 2024 compared to an average of 72% in 2023.

We are still confident the company can generate substantial levels of free cash flow over time, particularly if the approval and commercialization of DrugSorb-ATR is successful in 2025. We maintain our price target of **$4.00** per share.

Review of STAR-T Trial

Brilinta® (ticagrelor, AstraZeneca) is one of the leading anti-thrombotic drugs used as part of dual-antiplatelet therapy in patients with acute coronary syndrome. However, up to 10% of these patients will need to undergo CABG surgery and risk serious bleeding complications if the surgery is performed within the first few days from the last ticagrelor dose. Waiting in the hospital to washout the drug over the span of 3-5 days is the only acceptable alternative but comes with potential clinical risk for complications while waiting, and higher added hospital costs. The goal of DrugSorb-ATR is to allow patients to safely get the critical CABG surgery they need without requiring extensive drug washout. This was investigated in the U.S. and Canadian pivotal STAR-T (Safe and Timely Antithrombotic Removal of Ticagrelor) randomized controlled trial.

April 2024 Cardiothoracic Surgery Conference STAR-T Presentation

On April 28, 2024, the company announced that data from the pivotal STAR-T randomized controlled trial were presented for the first time publicly by Principal Investigator Dr. Michael Mack during a Breakout Presentation at the American Association for Thoracic Surgery (AATS) Annual

Meeting. This event, held in collaboration with the Society of Cardiovascular Anesthesiologists (SCA), took place in Toronto, Canada. Previously, the data were under embargo, as required by AATS to be eligible for presentation at the conference, one of the world's most prestigious cardiothoracic surgery events.

Following the event, Principal Investigators Drs. Mack and C. Michael Gibson discussed the results of the study, stating that the results demonstrated a reduction in fatal and severe surgical bleeds and chest tube drainage in a WIN ratio analysis.

The link to the interview can be found here.

This follows the initial disclosure on December 28, 2023, when the company announced an update on the primary safety and effectiveness endpoints and the final independent Data and Safety Monitoring Board (DSMB) analysis of the study. The DSMB performed the final review of the full unblinded data on all 140 patients in the STAR-T trial and concluded there were no issues with device safety, thus meeting the primary safety endpoint of the study. The company also performed the initial data analysis on the primary efficacy endpoint of STAR-T, which was a hierarchical composite endpoint covering the full spectrum of perioperative bleeding including:

- Fatal bleeding within 48 hours
- Universal Definition of Perioperative Bleeding (UDPB ≥ 2)
- Chest tube drainage in 24 hours

Based on this analysis, the study did not meet the primary effectiveness endpoint in the overall patient population that underwent different types of cardiac surgeries. However, the study demonstrated reduced bleeding complications in patients in the prespecified isolated coronary artery bypass graft (CABG) surgery population, which represented more than 90% of the overall study population. Due to the conference data embargo, no data were presented at that time.

New Data Presented for the First Time

In the AATS presentation, the use of DrugSorb-ATR resulted in a statistically significant reduction (as calculated by the WIN ratio) in the severity of perioperative bleeding. This was measured by a prespecified alternative composite primary efficacy endpoint consisting of fatal bleeding, UDPB ≥ 3 (severe bleeding), and 24-hour chest tube drainage in the isolated CABG per protocol population.

For CABG patients with moderate bleeding events (UDPB = 2), investigators noted that moderate bleeders in the DrugSorb arm were less serious than moderate bleeders in the control arm. Patients in the DrugSorb-ATR arm required 50% fewer units of blood transfusion products, with a total mean transfusion volume of 537 mL in the DrugSorb-ATR arm versus 1,066 mL in the control arm (p=0.025). In a post-hoc sensitivity analysis, Principal Investigators conducted a blinded re-adjudication of all CABG patients with at least moderate bleeding events, aiming to identify patients with real clinical evidence of bleeding versus those receiving prophylactic transfusions (reclassified to mild bleeding). When this analysis was performed, the data achieved statistical significance in the original composite endpoint including moderate to severe bleeding (UDPB ≥ 2) as well as the alternative composite endpoint including only severe bleeding (UDPB ≥ 3).

Additionally, in an exploratory "major bleeding" analysis in patients with either severe UDPB events (UDPB ≥ 3) or 24-hour chest tube drainage > 1L, there was a 73% relative reduction, or 16% absolute reduction, in major bleeding in the DrugSorb-ATR arm (6%) versus control (22%). This indicates a Number Needed to Treat (NNT) of six patients, meaning that for every six patients treated, one severe bleed was prevented. This was noted to be a compelling number.

The reason for the original missed primary endpoint was clarified with the definition of the "per protocol" population, which excluded patients undergoing "other surgeries" or with major protocol deviations. Despite being a randomized trial, there was an imbalance in the number of non-CABG "other surgeries" in the DrugSorb-ATR arm (10.6%) versus control (4.5%). Patients undergoing "other surgeries" had worse pre-operative risk scores, longer surgeries, longer cardiopulmonary bypass times, more chest tube drainage, more moderate to severe perioperative bleeding, and longer ICU and hospital stays. Additionally, there were more patients with major protocol deviations in the treatment arm (12.1%) versus control (4.5%), with the most common major protocol deviation being acute normovolemic hemodilution (ANH) in 8 of the 11 cases. According to Dr. Mack, ANH is an excluded practice in the study as it removes up to a liter of blood containing ticagrelor at the beginning of the procedure, then transfuses it back into the patient after surgery, circumventing DrugSorb-ATR's removal of the drug and increasing the risk of perioperative bleeding.

The investigators concluded:

- Primary safety endpoint was met
- Primary efficacy endpoint was not met in the all-comer surgery population
- Severe bleeding efficacy endpoint was met in the I-CABG per protocol population
- In isolated CABG patients, the intraoperative use of DrugSorb-ATR was associated with:
  - Reduced bleeding severity by either UDPB grade or chest tube drainage volume
  - NNT of 6 to prevent a major bleed (UDPB 3 event or >1 L chest tube drainage
  - Overall favorable benefit-to-risk profile

Virtual KOL and Analyst/Investor Day

During 2nd quarter on May 6, 2024, the company hosted an informative Key Opinion Leader roundtable that discussed the significant challenge of severe perioperative bleeding in patients undergoing heart surgery while on blood thinners such as Brilinta® (ticagrelor, AstraZeneca), recapped the STAR-T data presentation at AATS (see above) with comments by all of the Principal Investigators, and added a real-world perspective from Europe where CytoSorb (which uses an equivalent polymer technology to DrugSorb-ATR) is already approved for this indication.

The event featured Michael J. Mack, MD (Baylor Scott & White Health), C. Michael Gibson, MS, MD (Harvard University), and Richard Whitlock, MD, PhD, FRCSC (McMaster University) - Principal Investigators of the STAR-T randomized controlled trial - and Michael Schmoeckel, MD (Ludwig Maximilians University of Munich).

A replay of the event can be found here.

During the investor day, the company discussed DrugSorb-ATR's FDA Breakthrough Device Designation, which is a formal acknowledgment by the FDA that perioperative bleeding in cardiac surgery due to ticagrelor is a major unmet medical need with no approved or cleared alternatives. DrugSorb-ATR has a second FDA Breakthrough Device Designation to remove direct oral anticoagulants such as Eliquis® (apixaban, Pfizer, BMS) and Xarelto® (rivaroxaban, Bayer, Janssen). The Breakthrough Device program provides timely access to medical devices by speeding up development, assessment, and review for 510(k), De Novo, and PMA filings. The presentation highlights that since 2015, the FDA has granted Breakthrough status to only 192 cardiovascular and 83 gastrointestinal/urology devices and diagnostics, which includes the pair at CytoSorbents. Breakthrough devices receive priority review from the FDA but must still meet safety and efficacy requirements.

Based on the guidance of internal and external regulatory experts, the company is planning parallel submissions of the DrugSorb®-ATR system for marketing approval to the FDA under the De Novo pathway leveraging its Breakthrough Device Designation, and to Health Canada in the 3rd quarter of

2024. The De Novo pathway is for low-to-moderate risk devices for which special controls like clinical data provide reasonable assurance of safety and effectiveness, where no predicate device exists. There is a heavy emphasis on the probable benefit and risk of the device in the intended population. Based on standard and published FDA timelines, and that FDA Breakthrough Devices typically receive priority review, a decision on FDA De Novo clearance could potentially range between 6-12 months following submission.

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 below), 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®.

Additional Commentary on FDA Approvals

The U.S. Food and Drug Administration (FDA) has typically shown regulatory flexibility in approving novel therapies, encompassing medical devices, drugs, and biologics, particularly those that address significant unmet medical needs. This flexibility is evident in cases where pivotal trials have either missed primary endpoints or demonstrated marginal efficacy.

In a retrospective cross-sectional analysis published in JAMA Internal Medicine in 2021, Johnston et al. scrutinized FDA approvals from 2016 to 2020 for high-risk therapeutic medical devices that did not meet the primary endpoints of pivotal studies. These devices underwent evaluation through the FDA's premarket approval (PMA) regulatory pathway, known for its stringent requirements in assessing device safety and efficacy. The analysis revealed that, during this period, 13.1% of the 107 approved high-risk therapeutic devices did not meet at least one pivotal study primary endpoint. More than half of these cases were related to cardiovascular or cardiothoracic surgery applications. It is important to note the FDA's tendency to justify approvals based on post hoc analyses, success in alternative primary endpoints, and positive trends in secondary outcome measures. In addition, the FDA mandated a post-approval clinical study for 11 of these device approvals. Recently, the FDA granted approval for Medtronic's radiofrequency renal denervation system, Symplicity®, for the treatment of uncontrolled adult hypertension, despite a slim 7-6 majority vote against its risks and benefits by an FDA advisory panel.

This pattern extends to drugs and biologics as well. In another publication in JAMA Internal Medicine in 2023, Johnston et al. reported that between 2018 and 2021, 10% of the 210 new FDA drug approvals missed one or more primary efficacy endpoints in pivotal trials. All these therapies were either first-in-class or designated orphan drugs (affecting < 200,000 patients per year in the U.S.). The FDA's rationale for approval often included success in other pivotal studies, positive findings from secondary or exploratory endpoints, and favorable post hoc analyses. Similar to the medical device space, many approvals necessitated post-market studies to address lingering clinical uncertainties.

Based on information released by CytoSorbents, the DrugSorb-ATR device appears to be safe and relatively low risk, showing clinical benefit in the majority of patients in the study (isolated CABG population), representing the typical expected use-case for DrugSorb-ATR. Considering its designation as an FDA Breakthrough Device for this application, its "first-in-class" status, its apparent favorable benefit-to-risk ratio, and its potential to address a major unmet medical need, we believe it aligns well with the profile of other FDA-approved therapies that have encountered challenges with pivotal trial primary endpoints.

If CytoSorbents chooses to submit a regulatory application, and provided further data analyses from the study are corroborative of device efficacy, we anticipate a receptive FDA audience and the potential for

approval, albeit with the requirement for a post-market confirmatory study. If approved, we believe the narrower label for use only in isolated CABG will not materially impact DrugSorb-ATR's total addressable U.S. and Canadian market and will likely increase adoption of CytoSorb internationally for this E.U. approved indication.

Given these factors and the existing high margin international CytoSorb business, which generated over $31 million in sales in 2023, we believe the negative market reaction to the STAR-T trial press release is excessive, and we maintain our current price target of **$4.00????**.

References:

[1] Johnston JL, Dhruva SS, Ross JS, Rathi VK. Assessment of FDA Approval for New High-risk Therapeutic Devices Not Meeting Pivotal Study Primary End Points, 2016-2020. *JAMA Intern Med.* 2021;181(10):1409–1412. doi:10.1001/jamainternmed.2021.3042

[2] Johnston JL, Ross JS, Ramachandran R. US Food and Drug Administration Approval of Drugs Not Meeting Pivotal Trial Primary End Points, 2018-2021. *JAMA Intern Med.* 2023;183(4):376–380. doi:10.1001/jamainternmed.2022.6444

Review of DrugSorb-ATR Need

Coronary artery bypass graft (CABG) surgery to bypass blocked heart arteries is the most common type of open heart surgery performed in the U.S. and worldwide. Approximately 300,000 CABG surgeries are performed each year. An estimated 100,000 of these patients are at risk of excessive bleeding due to blood thinners with approximately half of them on Brilinta®. The current CytoSorb product, which uses an equivalent polymer technology to DrugSorb®-ATR, is already approved and is increasingly used in the E.U. to remove Brilinta®/Brilique® and reduce bleeding risk in this indication. The initial results from the International STAR Registry reporting on this real-world experience have shown favorably low rates of serious perioperative bleeding.

Cardiothoracic surgeons in the U.S., Canada, and abroad continue to confirm the difficult and serious clinical and economic problem that blood thinners cause patients, surgeons, and hospitals. For patients, delaying surgery to wash out the drug puts those with active ischemic heart disease at risk, while going to CABG surgery without waiting risks serious perioperative bleeding associated with longer hospital stays and increased risk of worsened clinical outcomes and even death.

For surgeons, excessive intraoperative bleeding due to blood thinners is difficult and unpredictable to manage, often complicating the surgery and requiring significant additional operative time to achieve hemostasis. Postoperatively, bleeding complicates and delays recovery and disposition, and if rapid or persistent, may require expensive and time-consuming re-exploratory surgery.

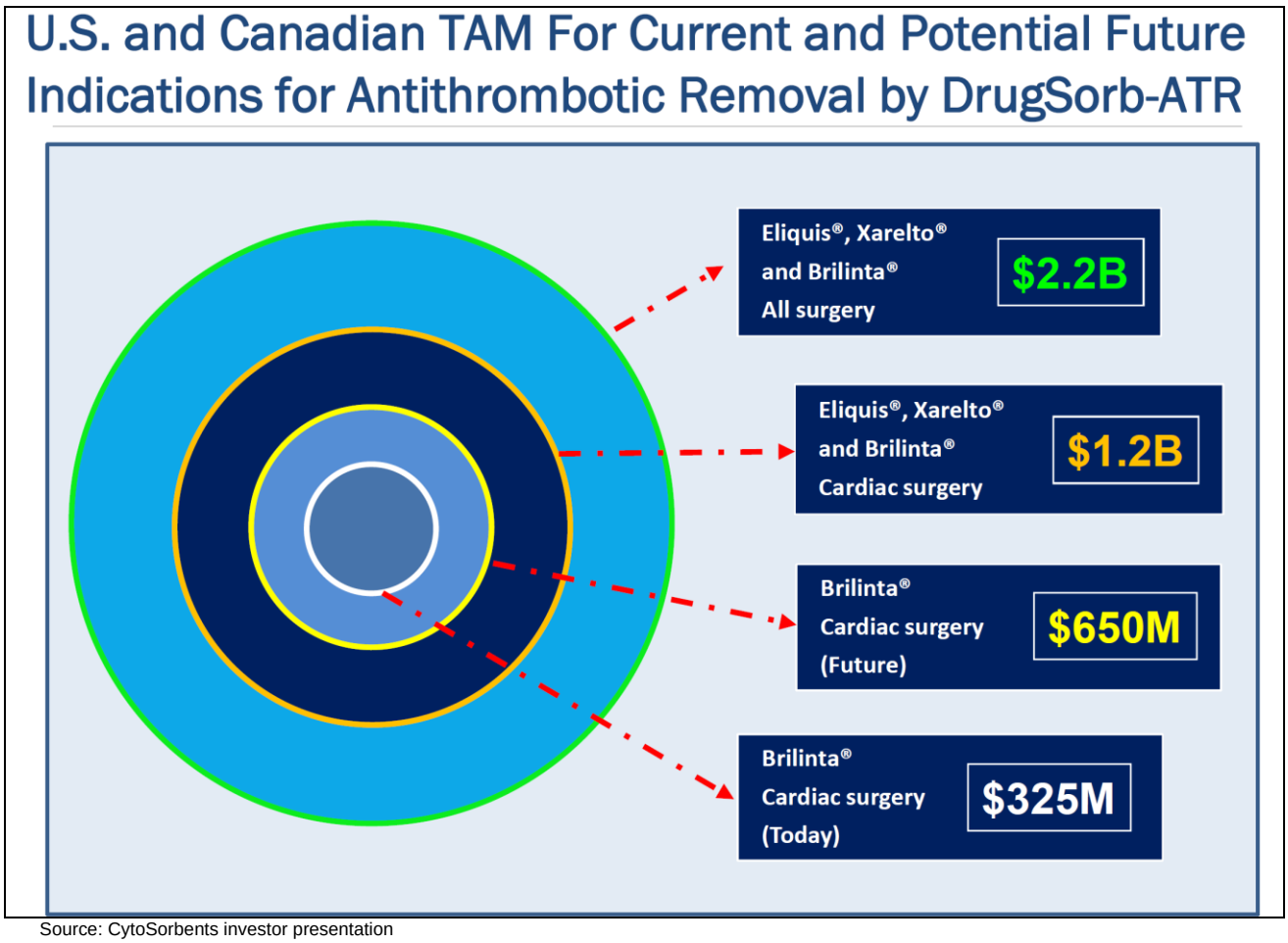
For hospitals, patients on blood thinners consume scarce resources and complicate patient logistics. Preoperatively, patients in the U.S. occupy hospital beds for 3 to 5 days to washout the drug, costing $6,000 to $30,000 to wait, depending on the severity of their condition, based upon an approximate daily cost of $6,000 in the ICU, $4,000 in the ICU step-down, and $2,000-$3,000 for a cardiac monitored ward bed.

Intraoperatively, the inability to stop bleeding delays completion of the case and is very expensive. Shorter overall operative times have been cited in a previous study when CytoSorb was used intraoperatively in patients undergoing cardiac surgery while on Brilinta. Based on average published operating room charges from the Cleveland Clinic hospital system, each additional 30 minute increment adds more than $4,000 in cost to the operation.

Perioperatively, bleeding complications are very expensive as well, due to the need for blood transfusions, reoperations, and longer ICU and hospital stays. Recently, in a study published in the

American Journal of Cardiovascular Drugs, Cohen et al. modeled the projected cost savings of less perioperative bleeding that DrugSorb-ATR could provide in the U.S. in patients undergoing surgery before completing washout of Brilinta® – a similar cohort being evaluated in the STAR-T trial.

Using assumptions based on published studies, they found the use of DrugSorb-ATR in these cases had a cost-dominant value proposition based on delivering improved clinical outcomes for patients and substantial cost savings (inclusive of the cost of the device) to the hospital. Finally, outcomes in CABG surgery such as death rates, readmissions, and postoperative hemorrhage reflect heavily in the Hospital's Quality Star Rating patient safety rating, as defined by the U.S. Centers of Medicare & Medicaid Services (CMS). The hospital's overall Star rating is critical as it helps to differentiate the hospital on objective quality measures from others in the area, important in driving patient traffic and procedure revenue to the hospital, and with direct implications on overall profitability.



Source: CytoSorbents investor presentation

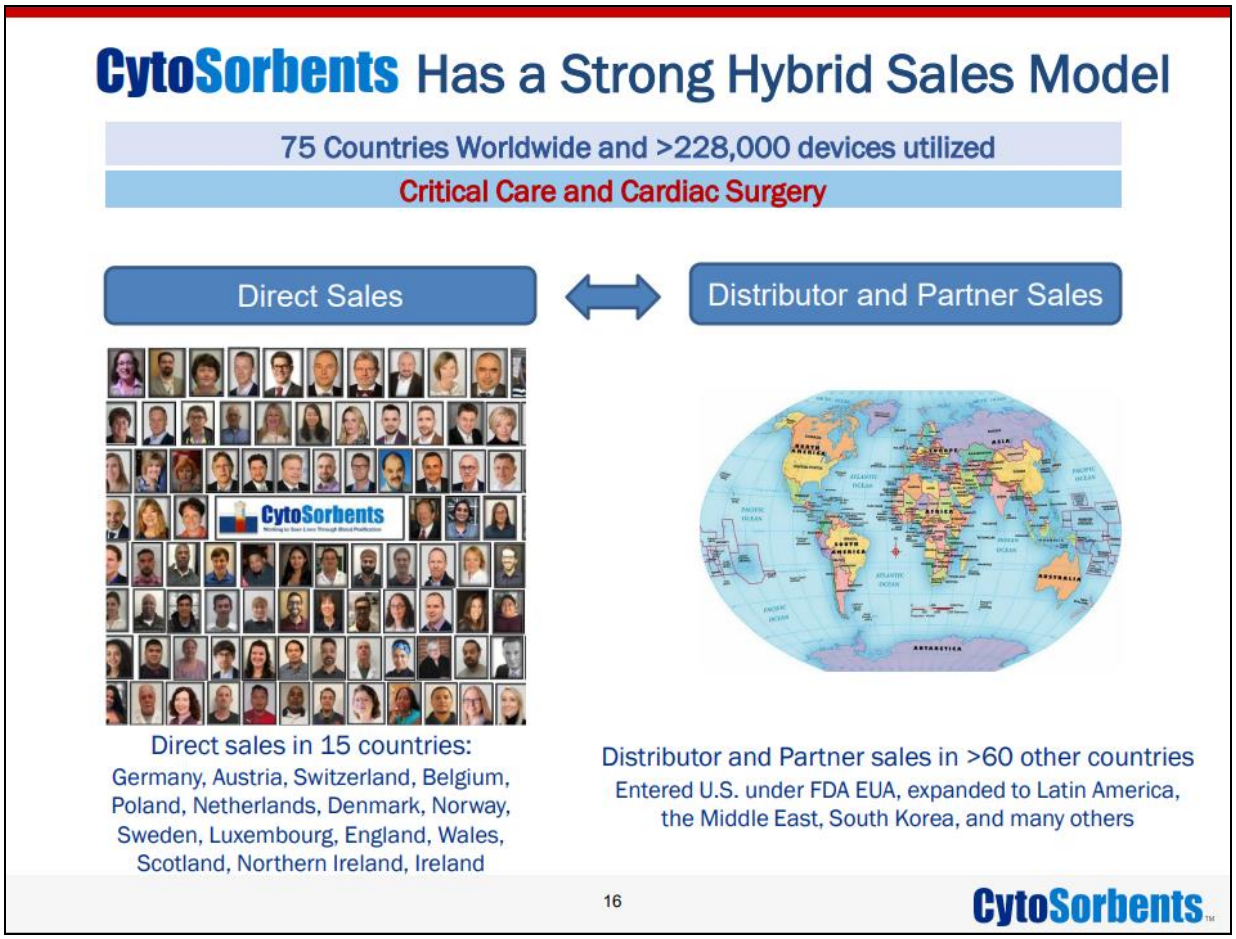
Because of this, DrugSorb-ATR could represent a "win-win-win" for patients, surgeons and hospital administrators by potentially allowing safe and timely surgery by actively removing the drug from the bloodstream, while reducing the serious bleeding risk and unnecessary costs in such patients. With the appropriate approvals, the company intends to commercialize CytoSorb in the U.S. and Canada primarily with a direct sales force focused regionally at high volume cardiac surgery centers, including clinical trial centers, and supplemented with cardiac surgery-focused distributors or strategic partners. Product level gross margins of DrugSorb-ATR could exceed 90% and based on revenue and operating expense projections, U.S. operations could achieve breakeven financial results in the first year of commercialization.

Germany Sales

Direct sales of CytoSorb in Germany represent about 40% of company-wide product sales. German hospitals are still working through the effects of the COVID-19 pandemic with staff shortages, decreased hospital beds, fewer patients, and fewer elective revenue generating procedures. Notwithstanding this market backdrop, the costs and challenges that physicians and healthcare workers continue to face in the management of critical illness and cardiac surgery still exist. Given the numerous applications, both old and new, that the company's products can help to address, and other initiatives such as its preferred supplier agreement with the largest private hospital networks in Germany, there is believed to be many opportunities to return to significant growth in the country.

The company pointed out that in July 2023, Germany's federal and state governments issued a consensus white paper that could result in new laws that change how hospitals are funded. Government payments to hospitals would de-emphasize the DRG (diagnosis-related group) "lump sum" payment system that incentivizes revenue generation through more patients treated and procedures performed, and instead emphasize base payments focused on quality measures and appropriate patient care.

This is expected to favor a shift of routine operations and procedures to outpatient centers, consolidation of smaller hospitals into larger ones, and importantly, an increased focus of remaining hospitals on sicker patients, more complex operations such as cardiothoracic surgery and organ transplant, and on therapies that help reduce the severity of illness and help patients recover faster. This potential reform may favor CytoSorbents business over the long term.



Source: CytoSorbents investor presentation

KEY INVESTMENT POINTS



Source: CytoSorbents investor presentation

- CytoSorbents Corporation (NASDAQ: CTSO) is vertically integrated U.S. based international medical device company that manufactures and markets the European Union approved CytoSorb® blood purification cartridge in 75 countries worldwide, generating $31.1 million in product sales in 2023 and $32.9 million in trailing 12-month product sales as of the end of the 2nd quarter of 2024 with 75% product gross margins reported in the 2nd quarter of 2024.

- The CytoSorb cartridge treats cytokine storms and massive uncontrolled inflammation in life-threatening conditions such as sepsis, COVID-19, shock, lung failure, pancreatitis, and many other applications.

- The company is seeking U.S. FDA and Health Canada approvals for DrugSorb-ATR, an equivalent polymer technology to CytoSorb, to reduce perioperative bleeding during cardiac surgery in patients on the blood thinner, Brilinta®. The pivotal U.S. and Canadian STAR-T trial commenced in October 2021 and was completed in the summer of 2023. Despite missing the primary efficacy endpoint of its pivotal STAR-T trial in an all-comer population, data from the important prespecified isolated CABG subpopulation was presented for the first time in April 2024 at the American Association for Thoracic Surgery (AATS) annual meeting and again at the company-sponsored "KOL and Analyst/Investor Day" in May 2024, demonstrate a statistically significant decrease in severe bleeding complications in an alternate primary efficacy endpoint and support a favorable benefit-to-risk profile of the therapy.

- In the 3rd quarter of 2024, the company plans to file for DrugSorb-ATR marketing approval to U.S FDA under the De Novo pathway, and to Health Canada. DrugSorb-ATR was awarded one of two FDA Breakthrough Device Designations for DrugSorb-ATR which will facilitate a priority review of the application in the U.S. Pending FDA agreement with the De Novo pathway, the company expects a potential decision from FDA between 6-12 months.

- The company's business model incorporates a "razor blade" business model in which the CytoSorb device can be utilized across an installed base of blood pumps such as dialysis, CRRT, ECMO, and heart-lung machines.

- CytoSorbents is led by an experience management team including CEO Phillip Chan and COO and President Vincent Capponi who led the company through the E.U. approval and commercialization of the CytoSorb device.

- The company has approximately $15.9 million in total cash on the balance sheet and $13.7 million in debt as of 6/30/24. We believe the company has funds to support planned operations through at least the 2nd quarter of 2025.

- The company uplisted to the NASDAQ in December 2013 and currently has a market capitalization of approximately $56.0 million.

- We believe CTSO stock is worth **$4.00** based on a conservative discounted cash flow (DCF) calculation and a peer multiple comparison.

RISKS

- The company has experienced substantial operating losses since inception. As of December 31, 2022, the accumulated deficit was $253,997,878. 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 in order 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.

LONG-TERM GROWTH DRIVERS

Stand-alone blood pump strategy:

There are many applications where a simple, low-cost hemoperfusion pump is adequate to implement the CytoSorb blood purification technology, without the complexity of a large dialysis or continuous renal replacement therapy (CRRT) machine, without the need for a dialysis technician, and where patients do not need to have failed kidneys. This would greatly simplify treatment with CytoSorb in the ICU and potentially enable its more ubiquitous and earlier use on more patients while opening the door for more new applications in the emergency room, surgery suites, and elsewhere.

Expansion of direct sales territories

Although opening new countries with a direct sales force requires time, cost, and effort, it also allows the company to directly lead the effort, drive results, and benefit from more profitable sales. With the announcement of expansion of direct sales into the U.K., Ireland and France, CytoSorbents now sell direct in three of the E.U.'s Big 5 Economies (Germany, France and the U.K.) and a total of 15 countries direct overall. The company also works with distributors or partners in Italy and Spain.

Investment in important clinical studies in shock, liver failure, cardiac surgery, ATR, etc

The company is committed to funding company-sponsored studies in key areas that will potentially drive international adoption and usage, with the goal of becoming a standard of care for those applications.

New Products

Over the past couple of years, there has been increasing momentum around two additional marketed products, ECOS-300CY for ex vivo organ perfusion (EVOP) in solid organ transplant under the EU CE mark, and VetResQ in the U.S. for the treatment of companion animals. In particular, prominent research in the field of heart, lung and liver organ transplant highlights the benefits of this technology in controlling inflammation and improving organ function during EVOP.

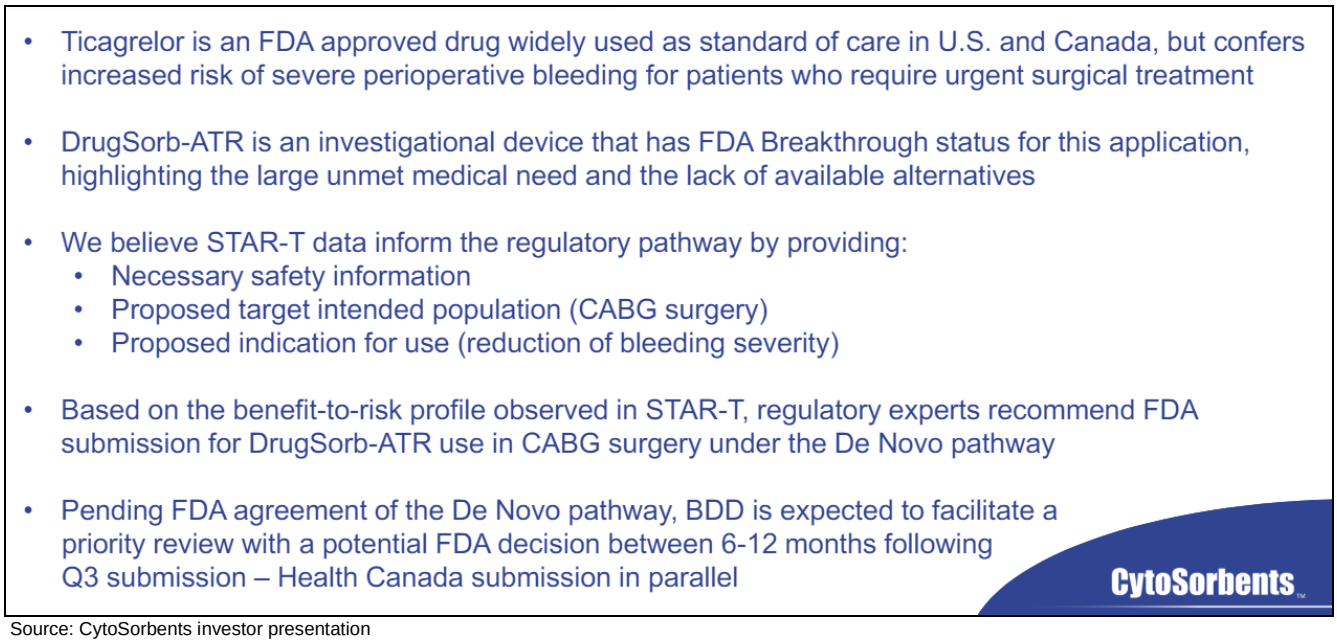
SUMMARY

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 and Turkey. 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 recently presented 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. Insiders have been accumulating large amounts of stock in the open market in the December 2023 financing, as well as through voluntary reductions in salary in exchange for stock options. Because of this, we believe the stock to be significantly undervalued at this time.



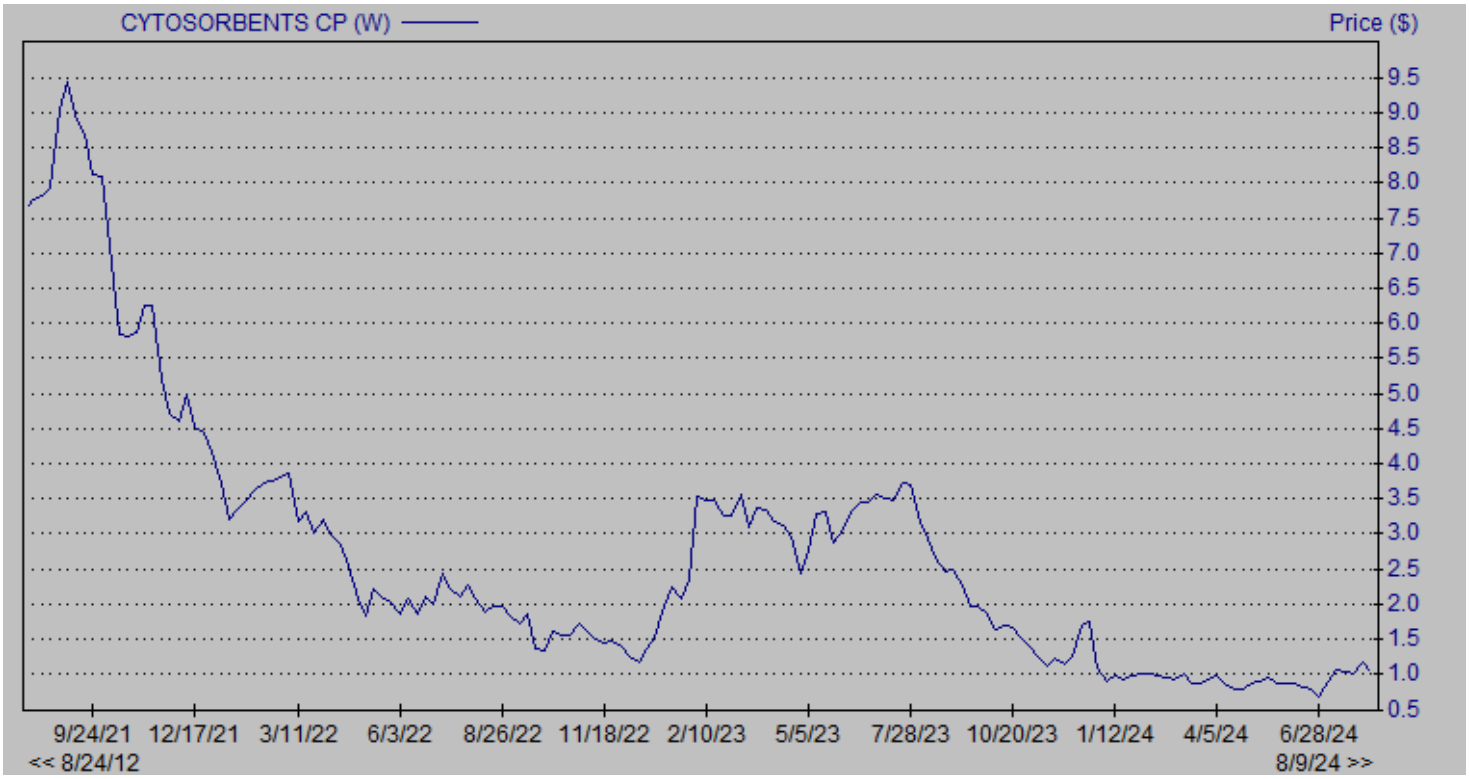
Source: CytoSorbents investor presentation

FINANCIAL PROJECTIONS

Income Statement	Dec-22	Dec-23	Dec-24	Dec-25	Dec-26
Net Sales	**34,688,809**	**36,349,000**	**39,721,928**	**44,488,559**	**53,386,271**
Growth	*-19.6%*	*4.8%*	*9.3%*	*12.0%*	*20.0%*
Cost of Goods Sold	**13,073,379**	**12,494,564**	**11,770,917**	**12,293,656**	**13,951,593**
%	*37.7%*	*34.4%*	*29.6%*	*27.6%*	*26.1%*
Depreciation & Amort	**882,621**	**1,462,436**	**1,599,047**	**1,599,047**	**1,599,047**
Gross Profit	**20,732,809**	**22,392,000**	**26,351,964**	**30,595,857**	**37,835,631**
Margin	*59.8%*	*61.6%*	*66.3%*	*68.8%*	*70.9%*
SG&A Expenses	**34,288,134**	**33,600,000**	**30,898,401**	**27,808,561**	**26,418,133**
% of sales	*98.8%*	*92.4%*	*77.8%*	*62.5%*	*49.5%*
Other	**2,847,899**	**4,272,000**	**3,077,243**	**2,307,933**	**1,730,949**
% of sales	*8.2%*	*11.8%*	*7.7%*	*5.2%*	*3.2%*
Research & Development	**15,118,907**	**15,729,000**	**6,806,741**	**6,126,067**	**5,819,764**
% of sales	*43.6%*	*43.3%*	*17.1%*	*13.8%*	*10.9%*
Amortization	**0**	**0**	**0**	**0**	**0**
% of sales	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**(31,522,131)**	**(31,209,000)**	**(14,430,422)**	**(5,646,704)**	**3,866,785**
Margin	*-90.9%*	*-85.9%*	*-36.3%*	*-12.7%*	*7.2%*
EBITDA	**(30,639,510)**	**(29,746,564)**	**(12,831,375)**	**(4,047,657)**	**5,465,832**
Margin	*-88.3%*	*-81.8%*	*-32.3%*	*-9.1%*	*10.2%*
Other Expenses/(Income)	**2,383,289**	**(2,046,000)**	**2,724,338**	**(100,000)**	**(120,000)**
%	*6.9%*	*-5.6%*	*6.9%*	*-0.2%*	*-0.2%*
EBIT	**(33,905,420)**	**(29,163,000)**	**(17,154,760)**	**(5,546,704)**	**3,986,785**
%	*-97.7%*	*-80.2%*	*-43.2%*	*-12.5%*	*7.5%*
Total Interest Exp (net)	**0**	**158,000**	**924,653**	**924,653**	**924,653**
%	*0.0%*	*0.4%*	*2.3%*	*2.1%*	*1.7%*
Net Profit Before Tax	**(33,905,420)**	**(29,321,000)**	**(18,079,413)**	**(6,471,357)**	**3,062,132**
%	*-97.7%*	*-80.7%*	*-45.5%*	*-14.5%*	*5.7%*
Income Tax	**(1,092,585)**	**(814,000)**	**(91,268)**	**(32,669)**	**306,213**
% Effective Rate	*3.2%*	*2.8%*	*0.5%*	*0.5%*	*10.0%*
% Cash Tax Rate	*3.2%*	*2.8%*	*0.5%*	*0.5%*	*10.0%*
Minority Interests or Preferred Stock	**0**	**0**	**0**	**0**	**0**
Net Profit	**(32,812,835)**	**(28,507,000)**	**(17,988,144)**	**(6,438,688)**	**2,755,919**
%	*-94.6%*	*-78.4%*	*-45.3%*	*-14.5%*	*5.2%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	43,573,215	44,656,391	54,364,708	54,364,708	54,364,708
Reported FD EPS					
Zacks Cash EPS	**(0.75)**	**(0.64)**	**(0.33)**	**(0.12)**	**0.05**
Zacks EPS	**(0.75)**	**(0.64)**	**(0.33)**	**(0.12)**	**0.05**

Source: Zacks analyst

HISTORICAL STOCK PRICE



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