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Zacks Small-Cap Research

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CytoSorbents Corporation (NASDAQ: CTSO)

CTSO: CytoSorbents reports 4th quarter and full year 2023 results. The company highlighted STAR-T trial data presentation at AATS later this month and also provided updates on its product pipeline.

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 (4/3/24)	$0.93
Valuation	**$4.00**

OUTLOOK

CytoSorbents is commercializing its E.U. approved CytoSorb blood purification technology to treat life-threatening conditions in the intensive care unit and cardiac surgery. The company also seeks U.S. and Canadian approval of a second product, DrugSorb-ATR, to reduce perioperative bleeding risk in patients on the blood thinner, ticagrelor, undergoing cardiac surgery. Despite missing the primary efficacy endpoint of its pivotal STAR-T trial, data from the important prespecified isolated CABG subpopulation will be presented for the first time at the AATS congress later this month where CytoSorbents sees benefit. We again highlight FDA's track record in approving therapies that missed primary endpoints but address major unmet medical needs.

SUMMARY DATA

52-Week High	**$4.29**
52-Week Low	**$0.84**
One-Year Return (%)	**-74.1**
Beta	**0.58**
Average Daily Volume (sh)	**160,189**
Shares Outstanding (mil)	**56.4**
Market Capitalization ($mil)	**$52.4**
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 2022 Estimate	**N/A**
P/E using 2023 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	$10.2 E	$9.4 E	$9.7 E	$10.2 E	$39.5 E
2025					$44.1 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	-$0.11 E	-$0.10 E	-$0.08 E	-$0.06 E	-$0.34 E
2025					-$0.09 E

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

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WHAT'S NEW

4th Quarter and Full Year 2023 Results

For the full year 2023, total revenues increased approximately 5.0% to $36.3 million. Total product sales were $31.1 million, an increase of 6.0% from 2022. 2022 sales benefitted from $0.7 million in other non-CytoSorb sales and $0.3 million in COVID-19 related sales that did not recur in 2023. Core (non-Covid-19 related) CytoSorb sales grew 10% in 2023. Grant income was approximately $5,2 million in 2023 compared to approximately $5.3 million in 2022, a decrease of 1.0%. Product gross margins increased to 72% from approximately 70% in 2022. The net loss in 2023 was ($28.5) million, or ($0.64) per share.

In the 4th quarter of 2023, total revenue was $8.7 million compared to $9.4 million in the prior year period, a decrease of approximately 8%. Total product sales were $7.3 million in 2023 versus $7.6 million in the 4th quarter of 2022, a decrease of approximately $0.3 million or 4%. Core CytoSorb sales in the 4th quarter of 2023 were $7.3 million compared to $7.4 million in the 4th quarter of 2022, a decrease of approximately $0.1 million or 1.0%.

Sales Highlights

The company provided additional color on its three main areas of sales and distribution.

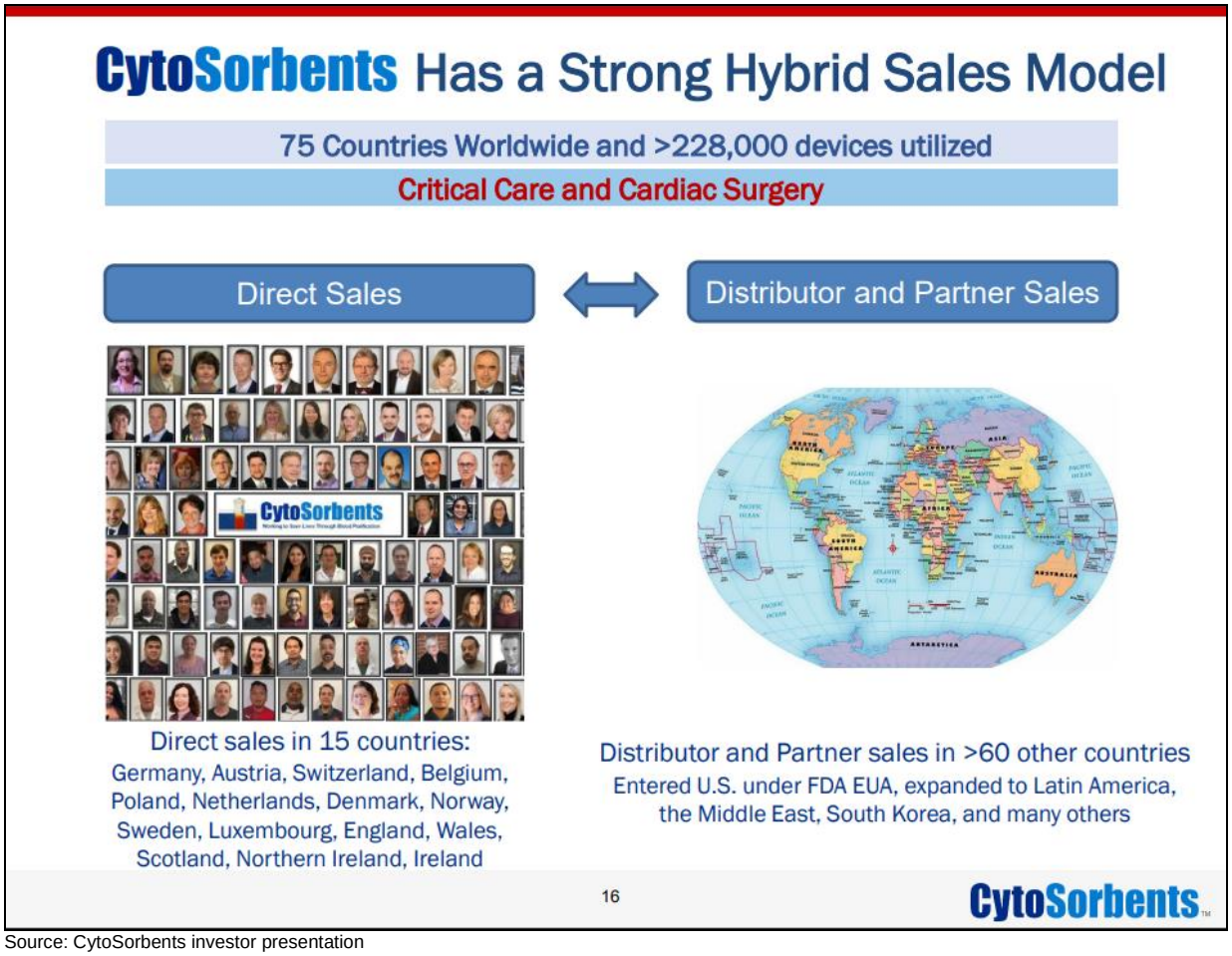
International Direct – This sales division, which represents 14 countries excluding Germany, showed strong sales growth increasing 27% to approximately $6.0 million. This represented 19% of total product sales in 2023.

Distributor and Partner **–** This sales division, which represents more than 60 countries, grew 18% (excluding U.S. distributor sales in 2022) in the first three quarters of 2023. Based on a stand-alone pump initiative that is expected to catalyze sales of CytoSorb in countries with less developed dialysis capabilities, the company had budgeted higher growth in the 4th quarter for this division. For a number of different reasons, it became clear that Nikkiso's PureAdjust® hemoperfusion machine was not the long-term solution for the company's stand-alone pump initiative and it was mutually agreed upon to not renew the distributor agreement in September 2023. The company pivoted to an alternative strategy, focused on the launch of its own hemoperfusion machine called PuriFi which is expected to launch later in 2024. Anticipation of this machine led to some order slippage from distributors to the new year, resulting in lower than expected 4th quarter sales. For the year, Distributor and Partner sales grew 9% (excluding U.S. distributor sales in 2022) to $12.1 million, which was 39% of 2023 product sales.

Direct Sales Germany – This is the company's own direct salesforce to healthcare facilities in Germany. Sales grew 3% to $13.0 million for the year, which represented 42% of 2023 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

April 2024 Cardiothoracic Surgery Conference

The company announced that the pivotal STAR-T trial was selected for a Breakout Presentation at the American Association for Thoracic Surgery (AATS) Annual Meeting being held April 27-30, 2024 in Toronto, Canada. The conference is one of the world's most prestigious cardiothoracic surgery events. This year, the meeting will be in collaboration with the Society of Cardiovascular Anesthesiologists (SCA), who are often managing blood product usage due to intraoperative bleeding during surgical procedures. The conference is targeted towards cardiothoracic surgeons and physicians in related specialties; perfusionists; non-physician health care providers involved in the care of cardiothoracic surgical patients; as well as fellows, residents, and medical students in cardiothoracic surgery. These are the stakeholders who directly witness and need to manage the perioperative bleeding complications of their patients on blood thinners and who would use DrugSorb-ATR in clinical practice.

Update on STAR-T Trial

On December 28, 2023, the company announced an update on the initial data analysis of the primary safety and effectiveness endpoints and the final independent Data and Safety Monitoring Board ("DSMB") analysis for the important U.S. and Canadian STAR-T (Safe and Timely Antithrombotic Removal of Ticagrelor) randomized controlled trial that was completed in August 2023.

The DSMB met recently to perform 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, which met 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 that covered the spectrum of perioperative bleeding in cardiothoracic surgery 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 did demonstrate evidence of 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. This suggests a favorable benefit-to-risk profile in this population that represents the vast majority of ticagrelor-treated patients requiring cardiac surgery.

The company believes the STAR-T safety and effectiveness data may support the regulatory submission of DrugSorb-ATR to U.S. FDA and Health Canada specifically in patients on ticagrelor undergoing isolated CABG surgery, particularly as an FDA Breakthrough Device. FDA Breakthrough Device Designation for DrugSorb-ATR highlights the major unmet clinical need for which no approved or cleared alternatives exist in the U.S. and Canada and may help expedite the regulatory review of the application.

For context, ticagrelor 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.

DrugSorb-ATR has been previously granted U.S. FDA Breakthrough Device Designation, acknowledging that perioperative bleeding in cardiac surgery due to ticagrelor is a major unmet medical need. There are currently no approved or cleared therapies for this unmet need in the U.S. or Canada. Outside of the U.S. and Canada, only CytoSorb® is specifically approved for this indication. The Breakthrough Devices Program provides for more effective treatment of life-threatening or irreversibly debilitating diseases or conditions - in this case the need to reduce serious or life-threatening perioperative bleeding due to ticagrelor in emergent or urgent cardiac surgery.

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.

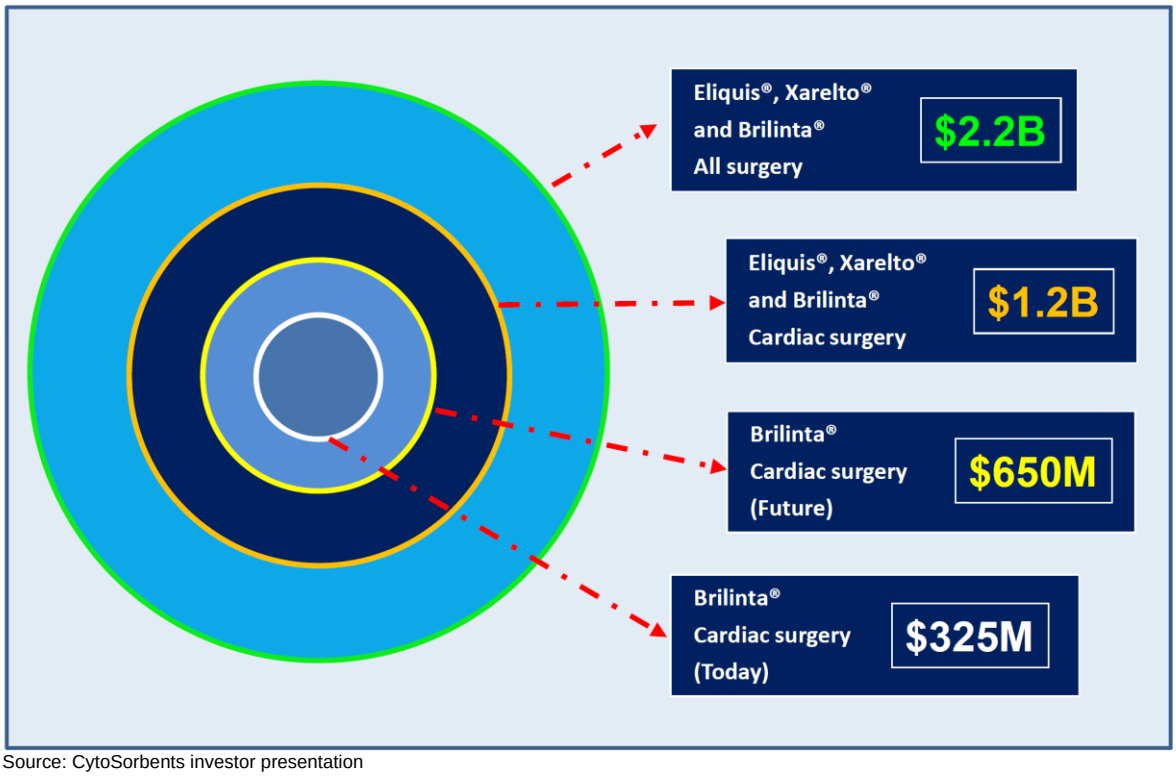
For hospitals, patients on blood thinners consume scarce resources and complicate patient logistics. Preoperatively, patients in the U.S. occupy hospital beds for 3 to 5 days to washout the drug, costing $6,000 to $30,000 to wait, depending on the severity of their condition, based upon an approximate 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 hospitals 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.

U.S. and Canadian TAM For Current and Potential Future Indications for Antithrombotic Removal by DrugSorb-ATR

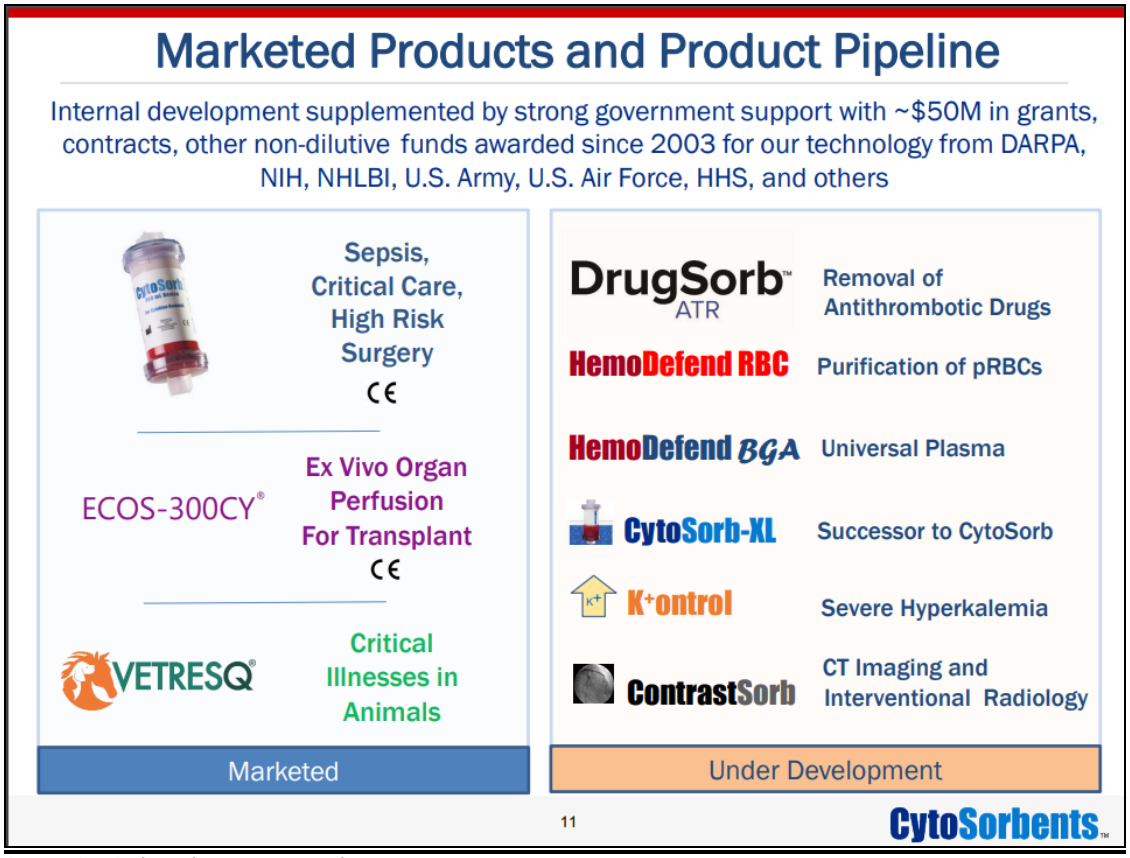


Source: CytoSorbents investor presentation

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.

Highlighted Other Products

Although not large contributors to revenue yet, CytoSorbents discussed three important products, two of which are currently being commercialized, that address new markets. Beyond revenue, these products represent technologies that can be potentially monetized through M&A or licensing opportunities. We believe these technologies have been discounted by investors and have been attributed zero enterprise value. However, should CytoSorbents be able to unlock the value in these assets through successful commercialization, they could represent meaningful contributors to the company’s financial results.



Source: CytoSorbents investor presentation

ECOS-300CY

The ECOS-300CY sorbent cartridge is approved in the European Union for ex vivo organ perfusion and for solid organ transplant. Solid organ transplant is the main treatment option in advanced organ failure but is limited by the availability of suitable and healthy organs. Ex vivo organ perfusion, otherwise known as EVOP, with temperature-controlled oxygenated nutrient rich fluid or blood is being increasingly used as an alternative to transporting the organ on ice to improve functioning of transplanted organs and to salvage substandard ones that would otherwise be discarded. However, it does not directly control inflammation within the organ that is often the core to the organ dysfunction that is seen perioperatively.

ECOS-300CY is specifically E.U. approved to reduce inflammatory mediators during EVOP. The goals and cited benefits of ECOS-300CY in early data are that it reduces inflammatory mediators and helps to recondition poorly functioning organs that would normally be discarded, helping to increase the donor pool of organs. In both pig and early human lung transplantation studies, the technology has been shown to reduce rates of primary graft dysfunction, helping to improve clinical outcomes. Primary graft dysfunction, or the development of severe lung injury within the first 72 hours of lung transplantation, occurs in 10%-30% of all lung transplants, and is the primary driver of early morbidity and mortality.

VetResQ

VetResQ, is essentially CytoSorb but for companion animals. The COVID pandemic has driven companion animal ownership and currently 45% of U.S. households own a dog and 26% own a cat according to the American Veterinary Medical Society. Companion animals are prone to a wide variety of medical emergencies ranging from drug intoxication, heat stroke, infections such as leptospirosis, sepsis and septic shock, trauma and others. VetResQ brings the power of CytoSorb to veterinary medicine with three sizes of cartridges intended to treat the full size range of companion animals. In 2023, the company

had a limited but successful U.S. launch of VetResQ to a number of regional veterinary centers and in 2024, they will debut an integrated all-in-one solution that includes a hemoperfusion pump for vets.

HemoDefend-BGA

HemoDefend-BGA is a second product in the HemoDefend family that is designed to create “universal plasma” by removing anti-A and anti-B antibodies that make plasma blood-type specific. Currently, blood banks have to maintain stores of Type A, Type B, Type AB and Type O plasma. But universal plasma would simplify those logistics to use a simple unit called universal plasma that could be given off-the-shelf to a patient regardless of their blood type. Many applications of life-saving plasma include trauma resuscitation, treatment of critically ill patients and component purification, such as the isolation of clotting factors for hemophilia, albumin for critical illness and intravenous immunoglobulin for autoimmune disease treatment and infectious disease. CytoSorbents has received approximately $17 million in non-dilutive grant and contract funding for this program.

Liquidity and Capital Resources

As of December 31, 2023, the company had current assets of approximately $25.7 million and current liabilities of approximately $14.5 million. At the end of the year, $25 million of the company’s total shelf amount was allocated to the ATM facility, of which approximately $20.3 million remained available. During the year, the company sold 2,656,464 shares at an average selling price of $1.76 per share which generated net proceeds of approximately $4,532,000.

In March 2024, the company received approximately $880,000 in cash from the approved sale of net operating losses and research and development credits from New Jersey.

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.

As of December 31, 2023, the company had approximately $15.6 million in cash including approximately $14.1 million and $1.5 million in unrestricted and restricted cash, respectively. This should be sufficient to fund the company’s operations into the 4th quarter of 2024.

Valuation and Estimates

We now estimate 2024 revenues to be $39.5 million and our 2024 EPS estimate is a loss of ($0.34) per share. We believe 2025 revenues could reach $44.1 million.

The company has implemented significant cost cutting measures to reduce the cash burn, including a 15% reduction of 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 and the company expects CytoSorb product gross margins to be 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 and we maintain our price target of **$4.00** per share.

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 with 72% product gross margins.

- 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 by removing blood thinners. 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, data from the important prespecified isolated CABG subpopulation will be presented for the first time at the American Association for Thoracic Surgery (AATS) annual meeting later this month, where CytoSorbents sees benefit in reducing bleeding complications.

- The company was awarded two FDA Breakthrough Device Designations for DrugSorb-ATR which is often considered a “fast track” path for device approvals addressing major unmet clinical needs.

- 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 $15.6 million in total cash on the balance sheet and $5.4 million in debt as of 12/31/23.

- We believe the company has funds to support planned operations through at least the end of 2024.

- The company uplisted to the NASDAQ in December 2013 and currently has a market capitalization of approximately $52.4 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.

- If the company is unable to obtain and maintain patent protection for its products and future product candidates, competitors could develop and commercialize similar products.

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

SUMMARY

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

The company is also seeing positive signs of restored growth of its core CytoSorb device in European markets. There is a strong pipeline of positive data on the device from both critical care and cardiac surgery events. The company is also improving cross-functional synergy internally based on new therapy area vertical strategy and leadership. The company is also seeing increased opportunities outside of Germany such as the U.K., Israel 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.

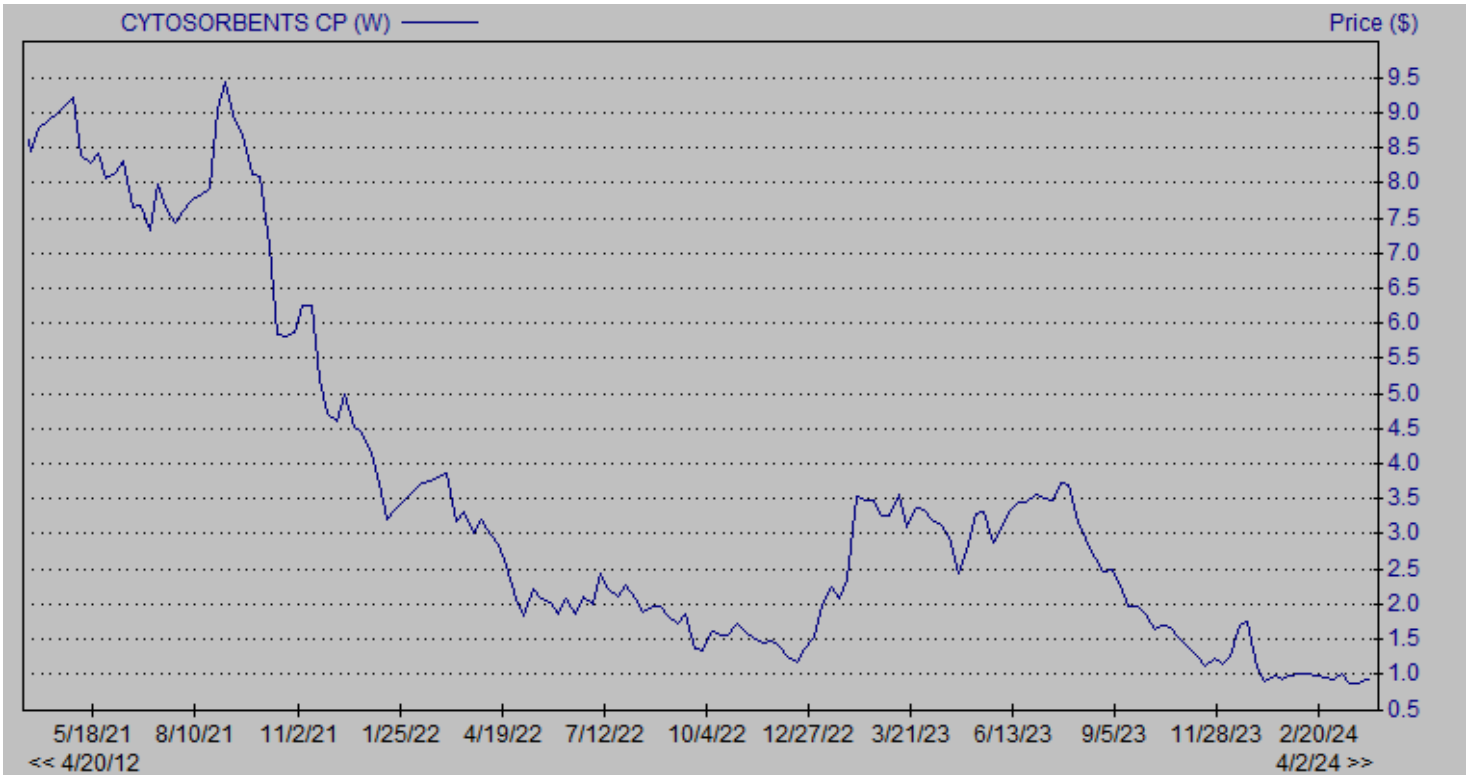
Based upon established FDA precedent, the apparent favorable benefit-to-risk profile of the DrugSorb-ATR therapy, its designation as an FDA Breakthrough Device, and the major unmet medical need to prevent perioperative bleeding due to ticagrelor in cardiac surgery patients, we believe CytoSorbents will find a receptive FDA and the potential for marketing approval of DrugSorb-ATR, despite missing the STAR-T pivotal trial primary efficacy endpoint. Investors will have a first look at data following presentation of STAR-T trial results at the AATS Annual Meeting in Toronto later this month, a potential catalyst.

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.

FINANCIAL PROJECTIONS

Income Statement	Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Net Sales	**43,165,527**	**34,688,809**	**36,349,000**	**39,510,519**	**44,107,829**
Growth	*5.3%*	*-19.6%*	*4.8%*	*8.7%*	*11.6%*
Cost of Goods Sold	**10,315,772**	**13,073,379**	**12,494,564**	**12,100,511**	**12,626,329**
%	*23.9%*	*37.7%*	*34.4%*	*30.6%*	*28.6%*
Depreciation & Amort	**731,578**	**882,621**	**1,462,436**	**1,578,556**	**1,578,556**
Gross Profit	**32,118,177**	**20,732,809**	**22,392,000**	**25,831,451**	**29,902,943**
Margin	*74.4%*	*59.8%*	*61.6%*	*65.4%*	*67.8%*
SG&A Expenses	**35,750,477**	**34,288,134**	**33,600,000**	**27,500,000**	**24,750,000**
% of sales	*82.8%*	*98.8%*	*92.4%*	*69.6%*	*56.1%*
Other	**2,731,515**	**2,847,899**	**4,272,000**	**2,738,304**	**2,053,728**
% of sales	*6.3%*	*8.2%*	*11.8%*	*6.9%*	*4.7%*
Research & Development	**16,380,930**	**15,118,907**	**15,729,000**	**14,853,706**	**13,368,335**
% of sales	*14`%*	*43.6%*	*43.3%*	*37.6%*	*30.3%*
Amortization	**0**	**0**	**0**	**0**	**0**
% of sales	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income	**(22,744,745)**	**(31,522,131)**	**(31,209,000)**	**(19,260,558)**	**(10,269,120)**
Margin	*-52.7%*	*-90.9%*	*-85.9%*	*-48.7%*	*-23.3%*
EBITDA	**(22,013,167)**	**(30,639,510)**	**(29,746,564)**	**(17,682,002)**	**(8,690,564)**
Margin	*-51.0%*	*-88.3%*	*-81.8%*	*-44.8%*	*-19.7%*
Other Expenses/(Income)	**2,549,906**	**2,383,289**	**(2,046,000)**	**(361,965)**	**(100,000)**
%	*5.9%*	*6.9%*	*-5.6%*	*-0.9%*	*-0.2%*
EBIT	**(25,294,651)**	**(33,905,420)**	**(29,163,000)**	**(18,898,593)**	**(10,169,120)**
%	*-58.6%*	*-97.7%*	*-80.2%*	*-47.8%*	*-23.1%*
Total Interest Exp (net)	**0**	**0**	**158,000**	**252,680**	**203,440**
%	*0.0%*	*0.0%*	*0.4%*	*0.6%*	*0.5%*
Net Profit Before Tax	**(25,294,651)**	**(33,905,420)**	**(29,321,000)**	**(19,151,273)**	**(10,372,560)**
%	*-58.6%*	*-97.7%*	*-80.7%*	*-48.5%*	*-23.5%*
Income Tax	**(736,003)**	**(1,092,585)**	**(814,000)**	**(574,538)**	**(311,177)**
% Effective Rate	*2.9%*	*3.2%*	*2.8%*	*3.0%*	*3.0%*
% Cash Tax Rate	*2.9%*	*3.2%*	*2.8%*	*3.0%*	*3.0%*
Minority Interests or Preferred Stock	**0**	**0**	**0**	**0**	**0**
Net Profit	**(24,558,648)**	**(32,812,835)**	**(28,507,000)**	**(18,576,735)**	**(10,061,383)**
%	*-56.9%*	*-94.6%*	*-78.4%*	*-47.0%*	*-22.8%*
Non-recurring income (expense)					
Average Diluted Shares Outstanding	43,359,186	43,573,215	44,656,391	54,293,555	54,293,555
Reported FD EPS					
Zacks Cash EPS	**(0.57)**	**(0.75)**	**(0.64)**	**(0.34)**	**(0.19)**
Zacks EPS	**(0.57)**	**(0.75)**	**(0.64)**	**(0.34)**	**(0.19)**

HISTORICAL STOCK PRICE



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