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Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: CytoSorbents reports 3rd quarter 2023 financial and operating results which showed strong product revenue growth and an improved cost structure.

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 (11/13/23)	$1.29
Valuation	**$4.00**

OUTLOOK

CytoSorbents Corporation is an established medical device company with lifesaving technology being provided by its key CytoSorb blood purification device. CytoSorb is helping to treat life-threatening conditions in the intensive care unit and cardiac surgery. The device is currently being sold in 75 international markets and the company has commenced a STAR-T trial for approval in the U.S. for a second product, DrugSorb-ATR. The company has other products in development that are related to their blood purification technology. Growth prospects are being developed beyond ICU and cardiac care. We believe the company has funds to support current operations through at least the 1st quarter of 2024.

SUMMARY DATA

52-Week High	**$4.59**
52-Week Low	**$1.03**
One-Year Return (%)	**-16.2**
Beta	**0.77**
Average Daily Volume (sh)	**72,617**
Shares Outstanding (mil)	**44.4**
Market Capitalization ($mil)	**$57.3**
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)
2021	$10.6 A	$12.0 A	$9.8 A	$10.8 A	$43.2 A
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	$10.3 E	$37.9 E
2024					$50.6 E

EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.10 A	-$0.11 A	-$0.15 A	-$0.21 A	-$0.57 A
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	-$0.10 E	-$0.61 E
2024					-$0.30 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

Financial Review

CytoSorbents reported 3rd quarter 2023 results on November 9th which showed strong product revenue growth. 3rd quarter product revenues increased 20% to $7.8 million and grant income decreased 35.9%. The increase in the Euro to U.S. dollar exchange rate positively impacted product sales by approximately $508,000. The company has lapped unfavorable Covid-19 comparisons as there were no sales related to the demand for CytoSorb to treat COVID-19 patients during the 3rd quarter of 2023 and the 3rd quarter of 2022. Total revenues were $8.8 million for the 3rd quarter of 2023, as compared to total revenues of approximately $8.1 million for the prior year period, an increase of 8.6%. The decrease in grant income was largely due to the timing of project completions.

The product gross margin increased to 72% from approximately 55% in the prior year period largely due to inefficiencies associated with the relocation of production activities to a new manufacturing facility in Princeton, New Jersey during the 3rd quarter of 2022 that did not recur in the most recent quarter..

Research & Development expenses were $3.7 million in the 3rd quarter compared to $3.3 million in the prior year period. The increase was primarily due to expenses related to the Star-T clinical trial which has since been completed.

The operating loss improved to ($7.3) million compared to an operating loss of ($9.0) million in the 3rd quarter of 2022. The net loss improved to ($9.2) million in the 3rd quarter compared to a net loss of ($12.2) million in the prior year period. Operating cash flow was a use of cash of ($15.2) million for the first nine months of 2023, which was an improvement from the use of cash of ($22.9) million for the first nine months of 2022.

As of the end of the 3rd quarter, the company had current assets of approximately $19.3 million and current liabilities of approximately $11.9 million. The company has unrestricted cash of $8.4 million and long-term debt of $5.0 million. There is still $22.8 million available under the company's ATM equity facility. The company has indicated that it had initiated an equity offering recently but canceled the process due to unfavorable market conditions. In April 2023, the company received approximately $1.0 million in cash from the approved sale of net operating losses and research and development credits from the State of New Jersey. The company still has substantial net operating loss carryforwards to help shield against future taxes.

In 2022, CytoSorbents began introducing tighter cost controls and have reduced headcount by 10% in order to reduce the cash burn rate. The company is currently actively engaged in making further reductions to total operating expenses to reduce the future cash burn. These include a major reduction in capital expenditures, restoration of gross margins to the 75%-80% range, reduced fixed overhead, realization of cost savings from work force reductions and significantly reduced clinical trial expenses. We believe the company has sufficient cash and resources to fund operations through at least the 1st quarter of 2024.

Recent Operating Highlights

1) Star-T trial

In August 2023, the company completed the STAR-T trial ahead of expectations with follow-up on 100% of the subjects which highlights the solid excellent execution of the trial by 30 U.S. and Canadian trial centers, CROs, and the company's own clinical team.

Following the second scheduled Data and Safety Monitoring Board (DSMB) data review of the first 80 patients enrolled in the pivotal STAR-T study, no device-related safety issues were raised and that the DSMB recommended completing the study without modification. The final DSMB review on the full STAR-T trial will occur after database lock in the near future.

The STAR-T study data remains blinded to all parties and will not be unblinded until after database lock which is when the final statistical analysis will occur. Because of this, the results of the study are currently unknown.

The company is working to complete the initial STAR-T data analysis before year-end. They intend to announce whether the results from STAR-T can support an FDA marketing approval application after that. With supportive results, our goal is to submit for U.S. FDA and Health Canada marketing approval in early-2024. Although there can be no certainty, based on published FDA review timelines, and dependent on the timing of regulatory filing and a favorable review of data by FDA, the company anticipates potential U.S. marketing approval of DrugSorb-ATR by late-2024 or early-2025.

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 vexing and serious clinical and economic problem that blood thinners cause patients, surgeons, and hospitals.

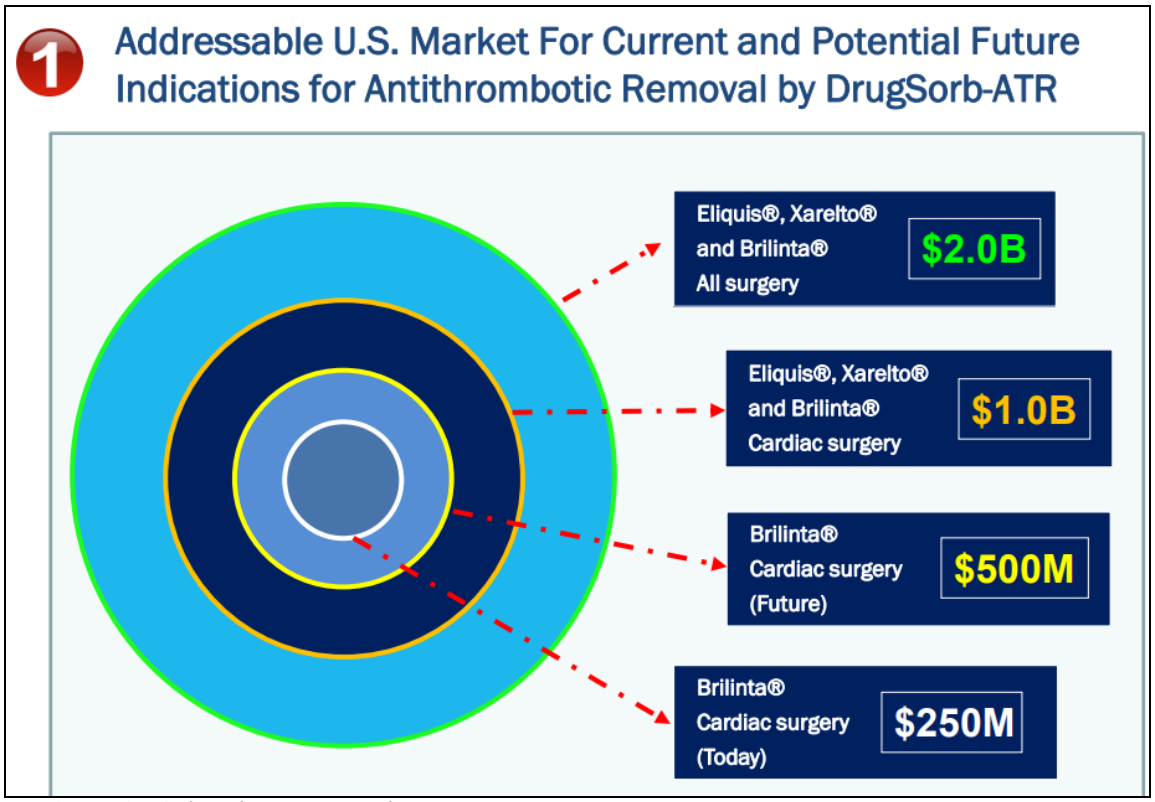
For patients, delaying surgery to wash out the drug puts those with active ischemic heart disease at risk, while going to CABG surgery without waiting risks serious perioperative bleeding associated with longer hospital stays and increased risk of worsened clinical outcomes and even death

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 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.



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.

2) CytoSorb growth

In the 3rd quarter of 2023, the company grew product sales 20% year-over-year in what is typically a highly seasonal quarter where most European businesses slow down due to the summer holidays. Quarterly core (non-COVID-19 related) sales grew for the third straight period year-over-year, with trailing 12-month product sales of approximately $31.4 million. Product gross margins were 72%, a significant improvement from the 55% reported a year ago, despite some continued manufacturing inefficiencies including overtime shifts to increase CytoSorb inventory levels. In the near term, product gross margins should be consistently in the range of 75-80%.

The growth in CytoSorb is taking advantage of some major macro trends in healthcare, such as the aging baby boomer population that are prone to life-threatening conditions such as infection and sepsis, trauma, structural and coronary heart disease, lung injury, and organ failure, or the use of blood thinners to reduce stroke and heart attack risk.

Second, the company has multiple initiatives underway that are helping to expand business opportunities. These include a standalone hemoperfusion pump initiative that can enable earlier and more frequent usage of blood purification therapies - particularly in countries that do not have a robust dialysis infrastructure. In addition, there is new leadership in the therapy area verticals in critical care, cardiac surgery, and liver/kidney applications that is intended to foster more focused market development. The company has also signed preferred supplier agreements with some of the largest private hospital networks in Germany.

Third, the company is expanding the reach of the CytoSorb to other areas besides cardiac surgery including the kidneys and the liver. Dialysis and related techniques are the most common blood purification technologies and are used to replace kidney function in the approximately 10-15% of ICU patients who develop kidney failure. CytoSorb is compatible with dialysis and CRRT machines, but functions like the liver and is capable of not just removing liver toxins, but a broad range of cytokines and other inflammatory mediators that can drive severe or massive inflammation in ICU patients. Left unchecked, this uncontrolled inflammation destabilizes patients, worsens the severity of critical illness, and can directly contribute to organ failure and death. In addition to the core markets mentioned above, with new data, the company is now adding major new applications including the treatment of liver disease, rhabdomyolysis, and acute respiratory distress syndrome (ARDS)

Fresenius Medical Care, the largest dialysis company in the world and a strategic partner, has publicly disclosed that its critical care business, focused primarily on kidney replacement therapy, is approximately €500 million to €1 billion worldwide and has both high strategic value and growth potential for the company. Last year Fresenius and CytoSorbents entered into a global marketing agreement where CytoSorb is helping to expand blood purification applications for both companies as the featured blood purification therapy for the removal of cytokines (e.g. sepsis and inflammation), bilirubin (e.g. liver disease), and myoglobin (e.g. trauma) on Fresenius’ critical care blood pump machines worldwide (excluding the U.S.). The goal is to drive growth of both companies by promoting concurrent utilization of

Fresenius' machines and disposables with CytoSorb on a much larger percentage of patients in the ICU. This partnership is expected to launch formally in 2024.

3) Reduce Cash Burn and Tight Control Over Expenses

Based on various cost controls implemented over the past 12 months, along with an improvement in sales and product gross margins, the quarterly cash burn during the first nine months of 2023 averaged approximately $4.6 million, down significantly from the average quarterly burn in the first half of 2022 of approximately $9.9 million. Unrestricted cash at the end of the quarter stood at approximately $8.4 million.

The company indicated it had commenced a confidential marketing process for an underwritten public offering of its common stock and decided to terminate the process. The termination resulted from an assessment by the Board of Directors and management team that current market conditions were not conducive for the offering that would be in the best interest of current shareholders. CytoSorbents continues to pursue alternative sources of capital, which may include debt financing, royalty financing, strategic or direct investments, equity financing, or a combination of those.

Valuation and Estimates

We are maintaining our 2023 revenue estimates at $37.9 million and adjusting our full year EPS estimate to a loss of ($0.61) based on 3rd quarter results. These estimates may prove to be conservative if the company's major cost saving initiatives are greater than expected and CytoSorb sales increases from the German hospital market are realized sooner than expected.

We adjust our target price to **$4.00** to account for the possibility of a dilutive capital raise at the end of 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.

KEY INVESTMENT POINTS

CytoSorbents™
WORKING TO SAVE LIVES
Source: CytoSorbents investor presentation

- CytoSorbents Corporation (NASDAQ:CTSO) is U.S. based international medical device company that has developed and marketed the CytoSorb® blood purification cartridge which is European Union approved and sold in 75 countries worldwide.

- 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 approvals for DrugSorb-ATR, an equivalent polymer technology to CytoSorb, to reduce perioperative bleeding during cardiac surgery by removing blood thinners. The pivotal STAR-T trial commenced in October 2021 to support FDA approval for this product and enrollment of a third of the trial was reached in November 2022 and was completed in the summer of 2023.

- 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 is currently marketing three approved products and has six more under development, all of which are related to the company’s proprietary blood purification technology.

- 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.

- CytoSorb 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 $8.4 million in unrestricted cash on the balance sheet and $5.0 million in debt as of 09/30/23. We believe the company has funds to support planned operations through at least the 1st quarter of 2024.

- The company uplisted to the NASDAQ in December 2013 and currently has a market capitalization of approximately $57.2 million.

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

OVERVIEW

CytoSorbents™

Source: CytoSorbents investor presentation

CytoSorbents Corporation is a leader in the treatment of life-threatening conditions in the intensive care unit and in cardiac surgery through blood purification. Its lead product, CytoSorb®, is approved in the European Union and distributed in 75 countries worldwide. It is an extracorporeal cytokine adsorber that reduces "cytokine storm" or "cytokine release syndrome" in common critical illnesses that can lead to massive inflammation, organ failure and patient death.

In these diseases, the risk of death can be extremely high and there are few effective treatments. In certain critical illnesses, there are no approved treatments. CytoSorb is also used during and after cardiothoracic surgery to remove inflammatory mediators that can lead to postoperative complications, including multiple organ failure.

As of June 30, 2023, more than 212,000 CytoSorb devices have been used cumulatively. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver disease and trauma, respectively, and for ticagrelor and rivaroxaban removal in cardiothoracic surgery procedures.

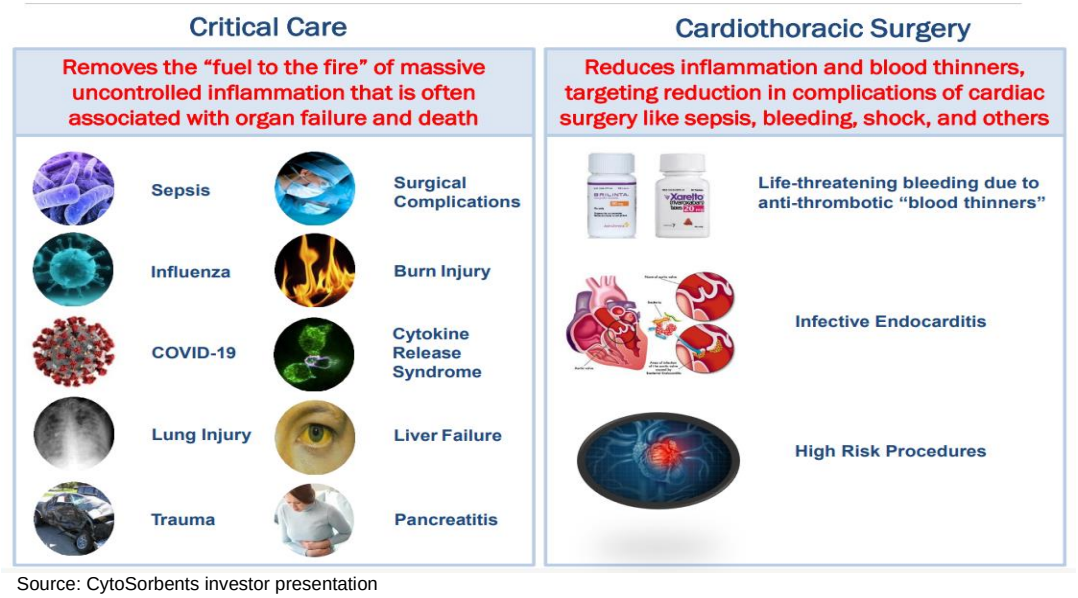
CytoSorb also had received FDA Emergency Use Authorization (EUA) in the U.S for use in adult critically ill COVID-19 patients with impending or confirmed respiratory failure. The DrugSorb-ATR antithrombotic

removal system, based on the same polymer technology as CytoSorb in the E.U., also received two FDA Breakthrough Device Designations, one for the removal of ticagrelor (Brilinta®) and another for the removal of the direct oral anticoagulants (DOAC) apixaban (Eliquis®) and rivaroxaban (Xarelto®) in a cardiopulmonary bypass circuit during urgent cardiothoracic procedures. This designation is expected to help expedite the company's regulatory goals.

The company has initiated two FDA-approved pivotal studies to support FDA marketing approval of DrugSorb-ATR in the U.S. The first is the randomized, controlled STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) study of 120 patients at 30 centers to evaluate whether intraoperative use of DrugSorb-ATR can reduce the perioperative risk of bleeding in patients receiving ticagrelor and undergoing cardiothoracic surgery. The second study is the STAR D (Safe and Timely Antithrombotic Removal-Direct Oral Anticoagulants) randomized, controlled trial of 120 patients at 30 centers evaluating the intraoperative use of DrugSorb-ATR to reduce perioperative bleeding risk in patients undergoing cardiothoracic surgery and taking direct oral anticoagulants, including apixaban and rivaroxaban. On November 3, 2022, the company announced they were pausing the STAR-D trial in order to focus on the STAR-T study and to reduce costs. The STAR-D trial is expected to resume in the future based on the financial condition of the company and available capital.

CytoSorbents' purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. The company's technologies have received non-dilutive grant, contract, and other funding of approximately $48 million from DARPA, the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), the U.S. Army, the U.S. Air Force, U.S. Special Operations Command (SOCOM), and Air Force Material Command (USAF/AFMC).

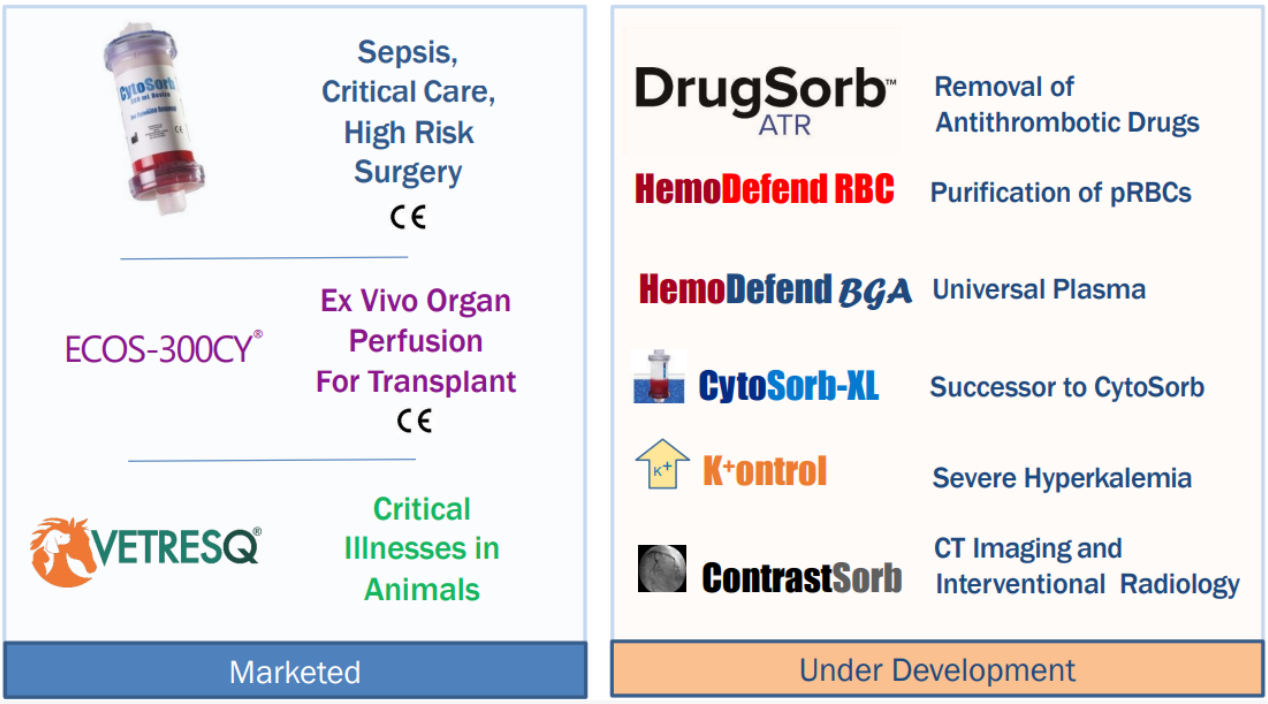
In September 2022, the company announced that it had received ISO 13485 Certification for its new manufacturing facility in Princeton, New Jersey from its European Union (E.U.) notified body. This clears the way for full manufacturing of CytoSorb®, DrugSorb®-ATR, and ECOS-300CY® from this site with capacity to add additional product lines under development. This state-of-the-art facility expands the company's manufacturing capacity to support up to $350-$400 million in sales of commercialized products and will be a key component in the regulatory application and expected commercial launch of DrugSorb-ATR in the U.S.



Source: CytoSorbents investor presentation

PRODUCT DESCRIPTIONS

The company's proprietary polymer technologies form the basis of a broad technology portfolio. Products and product candidates include:



Source: CytoSorbents investor presentation

Currently Marketed

- CytoSorb - an extracorporeal hemoperfusion cartridge approved in the EU for cytokine removal, with the goal of reducing SIRS and sepsis and preventing or treating organ failure.

- ECOS-300CY - an adsorption cartridge approved in the E.U. for use with ex vivo organ perfusion systems to remove cytokines and other inflammatory mediators in the organ perfusate, with the goal of maintaining or improving solid organ function. In 2021, commercialization of PerSorb™ and Aferetica's PerLife ex vivo organ perfusion system commenced in Italy.

- VetResQ - a broad spectrum blood purification adsorber designed to help treat deadly inflammation and toxic injury in animals with critical illnesses such as septic shock, toxic shock syndrome, severe systemic inflammation, toxin-mediated diseases, pancreatitis, trauma, liver failure, and drug intoxication. VetResQ is being commercialized in the U.S.

Products Under Development

- DrugSorb-ATR - an investigational extracorporeal antithrombotic removal system based on the same polymer technology as CytoSorb. This is being evaluated in the U.S. and Canadian STAR-T pivotal randomized, controlled trial to reduce the antithrombotic drugs, ticagrelor, apixaban and rivaroxaban to reduce bleeding complications in patients undergoing cardiothoracic surgery while on these drugs.

- CytoSorb XL - an intended next generation successor to CytoSorb currently in advanced pre-clinical testing designed to reduce a broad range of cytokines and inflammatory mediators, including lipopolysaccharide endotoxin, from blood.

- HemoDefend-RBC - a development-stage blood purification technology designed to remove non-infectious contaminants in blood transfusion products, with the goal of reducing transfusion reactions and improving the quality and safety of blood.

- HemoDefend-BGA - a development-stage purification technology that can remove anti-A and anti-B antibodies from plasma and whole blood, to enable “universal plasma,” and safer whole blood transfusions, respectively.

- K+ontrol - a development-stage blood purification technology designed to reduce excessive levels of potassium in the blood that can be fatal in severe hyperkalemia.

- ContrastSorb - a development-stage extracorporeal hemoperfusion cartridge designed to remove IV contrast from the blood of high-risk patients undergoing radiological imaging with contrast, or interventional radiology procedures such as cardiac catheterization and angioplasty. The goal of ContrastSorb is to prevent contrast-induced nephropathy.

- BetaSorb—a development-stage extracorporeal hemoperfusion cartridge designed to remove mid-molecular weight toxins, such as b2-microglobulin, that standard high-flux dialysis cannot remove effectively. The goal of BetaSorb is to improve the efficacy of dialysis or hemofiltration.

CYTOSORB DEVICE

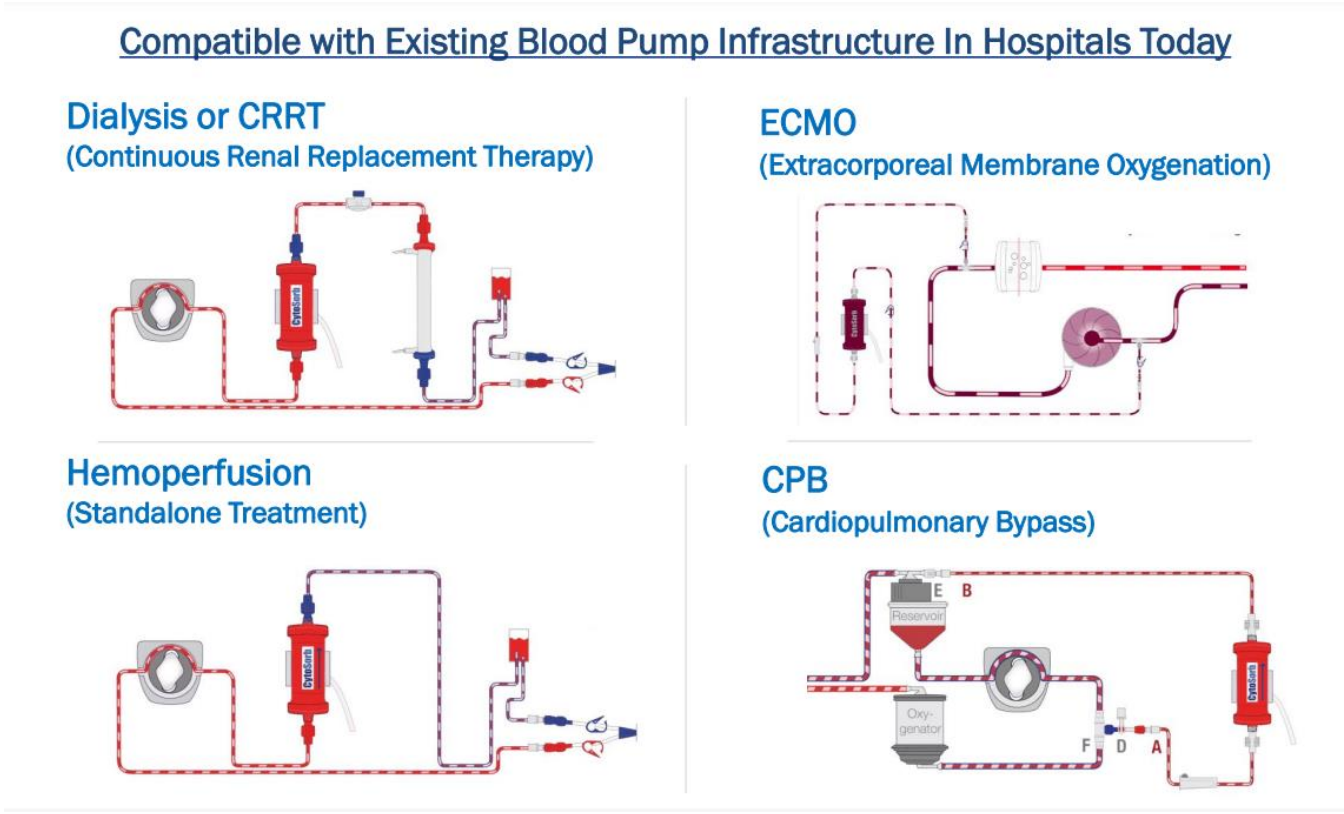


Source: CytoSorbents investor presentation

The company’s flagship products including CytoSorb, VetResQ, ECOS-300CY, and other product candidates under development such as DrugSorb-ATR, CytoSorb XL, BetaSorb, ContrastSorb, HemoDefend-RBC, HemoDefend-BGA, and K+ontrol consist of a cartridge containing adsorbent, porous polymer beads, although the polymers used in these devices are physically different.

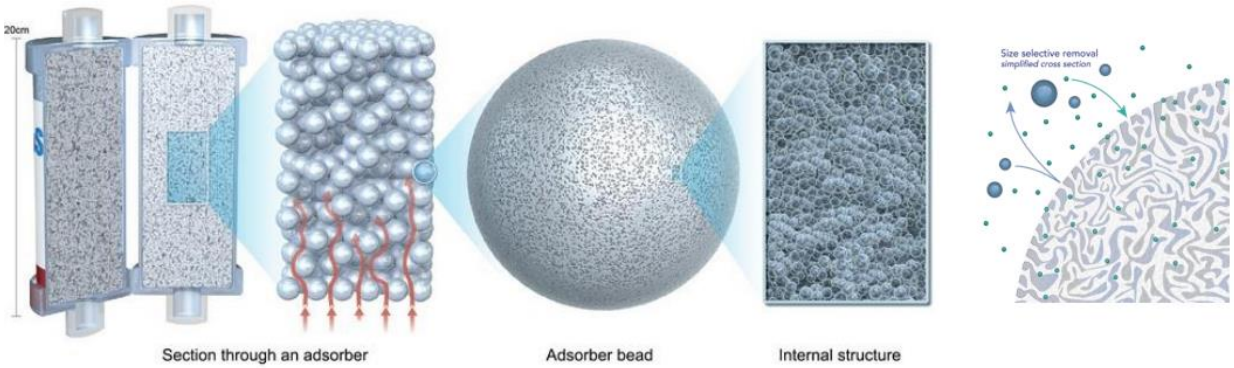
The cartridges incorporate industry standard connectors at either end of the device, which connect directly to the extracorporeal circuit (bloodlines) in series with a dialyzer as a standalone device. The extra-corporeal circuit consists of plastic blood tubing, the company’s blood filtration cartridges containing adsorbent polymer beads, pressure monitoring gauges, and a blood pump to maintain blood flow. The patient’s blood is accessed through a catheter inserted into a patient’s veins. The catheter is connected to the extracorporeal circuit and the blood pump draws blood from the patient, pumps it through the cartridge and returns it back to the patient in a closed loop system. All of CytoSorbents devices are expected to be compatible with standard blood pumps or hemodialysis machines used commonly in hospitals and won’t require hospitals to purchase additional expensive equipment and will require

minimal training. The polymer beads designed for the HemoDefend platform are intended to be used in multiple configurations, including a point of-transfusion in-line filter between the blood bag and the patient, as well as a patent-pending “Beads in a Bag” configuration, where the beads are placed directly into a blood storage bag.



Source: CytoSorbents investor presentation

These purification technologies are based on biocompatible, highly porous polymer beads that can actively remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. The technology is protected by 21 issued U.S. patents and multiple international patents, with other applications pending both in the U.S. and internationally.



Source: CytoSorbents investor presentation

The goal of a CytoSorb device is to prevent or treat organ failure by reducing cytokine storm and the potentially deadly systemic inflammatory response syndrome (SIRS) in diseases such as sepsis, trauma, burn injury, acute respiratory distress syndrome, pancreatitis, liver failure, and many other illnesses.

Organ failure is the leading cause of death in the ICU and remains a major unmet medical need with little more than supportive care therapy such as mechanical ventilation, dialysis, vasopressors, and fluid support as treatment options. By potentially preventing or treating organ failure, CytoSorb may improve clinical outcomes, including survival, while reducing the need for costly ICU treatment thereby potentially saving significant healthcare costs.

CytoSorb has been designed to achieve broad-spectrum removal of both pro and anti-inflammatory cytokines, preventing or reducing the accumulation of high concentrations in the bloodstream. It also removes a wide range of inflammatory mediators such as activated complement, bacterial toxins, myoglobin, free hemoglobin, bilirubin, and others. This approach is intended to modulate the immune response without causing damage to the immune system.

Cytokines are small proteins that normally stimulate and regulate the immune response. However, in certain diseases, particularly life-threatening conditions commonly seen in the ICU such as sepsis, infection, trauma, acute respiratory distress syndrome (ARDS), severe burn injury, liver failure, and acute pancreatitis – these cytokines are often produced excessively, a condition known as a cytokine storm. Left untreated, this cytokine storm can lead to severe maladaptive SIRS that can then cause cell death, multiple organ dysfunction syndrome, and multiple organ failure.

Major failure of vital organs such as the heart, lungs, and kidneys, accounts for approximately half of all deaths in the ICU despite the wide availability of life support therapies such as dialysis, mechanical ventilation, extracorporeal membrane oxygenation, and vasopressors. By replacing the function of failed organs, these supportive care therapies can initially help to keep patients alive, but do not help patients recover faster, and in many cases can increase the risk of dangerous complications. Unlike these supportive care therapies, the goal of the CytoSorb cytokine device is to proactively prevent or treat organ failure by reducing cytokine storm and reducing the maladaptive SIRS response. In doing so, CytoSorb targets the reduction in the severity of patient illness and the need for intensive care, while potentially improving clinical outcome and reducing overall healthcare costs.

ADDRESSABLE MARKET & GROWTH OPPORTUNITIES

CytoSorbent's devices address a large and growing need, largely due to an aging global population where the over 60-year-old demographic is expected to exceed 1 billion people in coming years. Millions of people worldwide are on blood thinners to reduce the risk of stroke and heart attack. The addressable market in just the U.S. alone is expected to exceed $1 billion.

The company's business model encompasses a classic razor / razorblade type model in which the CytoSorb device is a high margin recurring revenue source because it is compatible with the existing base of blood pumps including dialysis, continuous renal replacement therapy (CRRT), extracorporeal membrane oxygenation (ECMO), and heart-lung machines.

The average direct selling price for the CytoSorb device is approximately $1,000 per cartridge and one to five cartridges are typically used per patient depending on the type of treatment. For example, open heart surgery requires one to two cartridges, sepsis treatment requires three to five, and ECMO may require five or more.

In Germany, a key market for the company, there are 400 hospitals with over 400 beds and each hospital typically sees 300 to 600 sepsis patients per year. Based on the use of three to five cartridges per patient, that a potential revenue opportunity of $1 million to $3 million per year. There are currently hospitals in that country that have broadly adopted the company's offerings and generate in excess of $1 million in annual revenues.

Currently, roughly half of the device usage goes to treating sepsis and septic shock, 1/3rd goes to cardiac surgery, and the remaining applies to a variety of critical care conditions. Cardiac surgery issues include infective endocarditis, reversal of vasoplegia, and removal of antithrombotics. Critical care usage includes dealing with sepsis, trauma, acute respiratory distress syndrome, and reversal of shock.

In order to increase distribution on a global scale, the company entered into an enhanced marketing agreement with Fresenius Medical Care (FMC), a German based global provider of services to treat renal disease. The CytoSorb device will be featured on FMC's critical care platforms for the removal of cytokines, bilirubin, and myoglobin. FMC will be responsible for the worldwide marketing and promotion of CytoSorb with its other critical care products utilizing multiple prominent marketing channels and campaigns. Further, CytoSorbents' proprietary hemoadsorption CytoSorb therapy expands the dimensions of blood purification with regards to the FMC critical care product portfolio.

A stand-alone blood pump strategy is also in the early stage of rollout which has the potential to drive earlier and higher levels of usage for the CytoSorb device. This strategy could potentially expand the target market to an estimated 30%-40% of patients in an intensive care unit.

The company has developed partnerships with Asklepios Hospital Group and Helios which are two large private hospital networks in Germany. Combined, this represents over 250 healthcare facilities with the goals of reducing costs and improve clinical outcomes at these facilities. This partnership should create sales opportunities at a significantly larger number of clinics and hospitals.

The company is also aggressively exploring other therapeutic applications in the areas of lung failure and dysfunction, heart failure and transplants, kidney protection in myoglobinemia, and ex vivo organ perfusion to improve organ function.

These transplant opportunities are particular encouraging as the company's ECOS-300CY technologies will be helpful to increasing demand for more organ transplants. There are approximately 165,000 patients on organ transplant wait lists in the U.S. and Europe. This global demand for organ transplantation continues to outpace the supply of donor organs. Static Cold Storage (SCS) is the current standard for organ storage but presents physiologically adverse conditions for the organ. These donor organs are often irreversibly damaged due to hyperinflammation resulting in low utilization levels. As a result, it is estimated only 10-30% of donor organs are utilized leading to this high demand/supply imbalance. Ex-vivo perfusion (EVP) attempts to preserve or improve organs for transplant, however, because EVP does not reduce hyperinflammation, it represents a new opportunity for the company. The ECOS-300CY technology hopes to limit irreversible organ damage, restore organ function, and be used as a bridge to transplant by reducing cytokine release and removing harmful inflammatory mediators. The ECOS-300CY device is the key product being used for transplantable perfusion and production and was specifically E.U. approved in October 2020.

For the DrugSorb-ATR device, the total addressable market is estimated to be in the $300 million to $350 million range for the U.S. and Canadian markets. When ticagrelor become generically available in 2024, the addressable market could be double that range. The company is currently working with many leading cardiac surgery centers in both the U.S. and Canada that have historically been instrumental in driving innovation in the cardiac surgery field.

COMPANY HISTORY

The company was originally organized in August 1997 as Advanced Renal Technologies, LLC and changed its name to RenalTech International, LLC in November 1998. A subsequent name change to MedaSorb occurred in 2003. CytoSorbents Corporation was incorporated in Nevada in 2002 as Gilder Enterprises and was originally engaged in the business of installing and operating computer networks that provided high-speed access to the Internet. On June 30, 2006, the company disposed of this business and acquired all of the stock of MedaSorb Technologies. In November 2008, the name was changed to CytoSorbents, Inc.

The company has been engaged in research and development since inception and have raised approximately $215 million from investors. These proceeds have been used to fund the development of multiple product applications, conduct clinical studies, to establish in-house manufacturing capacity to meet commercial and clinical testing needs, and expand intellectual property through patents. The company has raised funds through various means including convertible note offerings, equity transactions, and bank loan facilities.

On July 24, 2020, CytoSorbents completed a secondary public offering of 6,052,631 shares of its common stock at an offering price of $9.50 per share. The company received gross proceeds of approximately $57.5 million and after fees and other deductions, net proceeds were approximately $53.8 million.

In 2019, the company entered into an Open Market Sale Agreement with Jefferies and B. Riley FBR in which the company could sell from time to time, at its option, shares of common stock of up to $25 million. All shares of common stock offered and sold, or to be offered and sold under the Sale Agreement would have been issued and sold pursuant to the company's 2018 Shelf offering by methods deemed to be an "at the market" (ATM) offering. During 2019, the Company sold 191,244 shares at an average selling price of $4.11 per share generating net proceeds of approximately $762,000. During 2020, the company sold 4,110,625 shares at an average selling price of $6.64 per share generating net proceeds of approximately $26.5 million.

MANAGEMENT

Phillip P. Chan, MD, PhD
Chief Executive Officer

Dr. Phillip Chan is the Chief Executive Officer of CytoSorbents. Over the past 15 years, Dr. Chan has led the company through the E.U. approval and commercialization of its flagship product, CytoSorb, a novel blood purification therapy to treat cytokine storm and control deadly inflammation seen in life-threatening illnesses in the intensive care unit and cardiac surgery. Prior to CytoSorbents, Dr. Chan led healthcare and life science investments as Partner for the $80 million NJTC Venture Fund, one of the largest seed and Series A early-stage venture investors in the greater New York region, and a top 1% performing fund for its vintage. Dr. Chan is also a co-founder and Vice Chairman of Medality Medical, formerly known as Andrew Technologies, a privately held medical device company pursuing a surgical cure of Type 2 diabetes through the removal of deep mesenteric metabolic fat with its FDA-approved HydraSolve™ advanced lipoplasty system. Dr. Chan received Board-certification in internal medicine, having completed his residency at Harvard Medical School at the Beth Israel Deaconess Medical Center. He received his MD/PhD from Yale University School of Medicine and his BS in cell and molecular biology from Cornell University.

Vincent Capponi, MS
President and Chief Operating Officer

Mr. Capponi has more than 20 years of management experience in medical device, pharmaceutical and imaging equipment at companies including Upjohn, Sims Deltec and Sabratek. Mr. Capponi joined CytoSorbents as the VP of Operations in 2002 until his promotion to Chief Operating Officer and President in 2020. Prior to joining CytoSorbents, he held several senior management positions at Sabratek and its diagnostics division GDS. Mr. Capponi was interim president of GDS diagnostics in 2001 and was responsible for the integration of the Baxter-Sabratek acquisition. From 1998 to 2000 Mr. Capponi was Senior VP and COO for Sabratek and VP Operations from 1996 to 1998. Mr. Capponi has extensive experience in process scale-up and high-volume medical disposables production. He received his MS in Chemistry and his BS in Chemistry and Microbiology from Bowling Green State University.

Kathleen Bloch, MBA, CPA
Chief Financial Officer

Ms. Bloch has more than 20 years of executive financial experience at both public and private companies and has been the CFO of CytoSorbents since 2013. From 2008 to 2010, she served as the Chief Operating Officer of PC Group, Inc., where she was hired as CFO in 2007. Prior to this, Ms. Bloch managed the day-to-day operations for The Silverman Group, a real estate and investment company. For ten years prior she was employed by Silver Line Building Products Corporation, a leading privately-held manufacturer of vinyl windows. She served as CFO from 1999 until 2006 when the company was acquired by Andersen Corporation. She holds a Master of Business Administration degree and a Bachelor of Science Accounting degree from LaSalle University. Ms. Block plans to retire from the company in March 2023.

Efthymios N. Deliargyris, MD, FACC, FESC, FSCAI
Chief Medical Officer

Dr. Efthymios “Makis” Deliargyris is triple board-certified in internal medicine, cardiology and interventional cardiologist with extensive industry experience. Prior to joining CytoSorbents, Dr. Deliargyris was CMO for PLX Pharma (NASDAQ: PLXP) and before that Global Medical Lead Cardiovascular at The Medicines Company (NASDAQ: MDCO). Dr. Deliargyris served as Director of Cardiology and Interventional Cardiology at Athens Medical Center in Greece and as Assistant Professor of Cardiology and Director of the Intravascular Ultrasound Laboratory at Wake Forest University Medical Center. Dr. Deliargyris’ original research on the role of inflammation in cardiovascular disease and in antithrombotic therapies has resulted in over 100 publications in top peer review journals including New England Journal of Medicine, Journal of the American College of Cardiology, Circulation and the European Heart Journal. He received his Medical Degree from the Kapodistrian University School of Medicine in Athens, Greece and completed his residency in internal medicine at Tufts University School of Medicine in Boston where he also served as Chief Resident. He also completed his fellowship in cardiology and interventional cardiology at the University of North Carolina at Chapel Hill where he also served as Chief Fellow.

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 with unrestricted cash balances of $22.1 million 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. The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect future company revenues and profitability.

- 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 and product. Commercial success will depend on the company's ability to obtain and maintain patent protection in the U.S. and other countries with respect to products and product candidates.

- 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. Additionally, clinical and pre-clinical data is susceptible to varying interpretations, which could delay, limit, reduce, or prevent additional regulatory clearances or product sales.

INSIDER TRADING AND OWNERSHIP

Insider ownership is approximately 7.0% according to the latest proxy filing. CEO Phillip Chan owns approximately 2.4% of the company.

Name of Beneficial Owner[1]	Number of Shares	Percentage of Common Stock[1]
Al W. Kraus	266,621[2]	*
Phillip P. Chan, MD, PhD	1,025,580[3]	2.4%
Vincent J. Capponi, MS	664,866[4]	1.5%
Kathleen P. Bloch, CPA, MBA	463,870[5]	1.1%
Efthymios Deliargyris, MD	233,925[6]	*
Michael G. Bator, MBA	97,950[7]	*
Edward R. Jones, MD, MBA	115,789[8]	*
Alan D. Sobel, CPA	95,450[9]	*
Jiny Kim, MBA	73,613[10]	*
All current directors, director nominees and executive officers as a group (8 persons)	3,037,664	7.0%

Source: CytoSorbents SEC filings

SUMMARY

We believe CytoSorbents disruptive blood purification technology will provide ample opportunities for high margin revenue growth going forward. The global addressable market for all of the company's products could exceed $3.0 billion. This growth will also be driven by the company aggressively exploring other therapeutic applications such as the areas of lung failure and dysfunction, heart failure, kidney protection, and transplantable perfusion and protection.

The company is also seeing positive signs for restoring growth to 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.

We believe CytoSorbents has the potential to grow both revenues and earnings at very robust double-digit growth rates if it is able to execute on the commercialization of its product pipeline. The company's current stock price does not likely reflect that potential level of profitable growth going forward and we believe the stock to be significantly undervalued at this time.



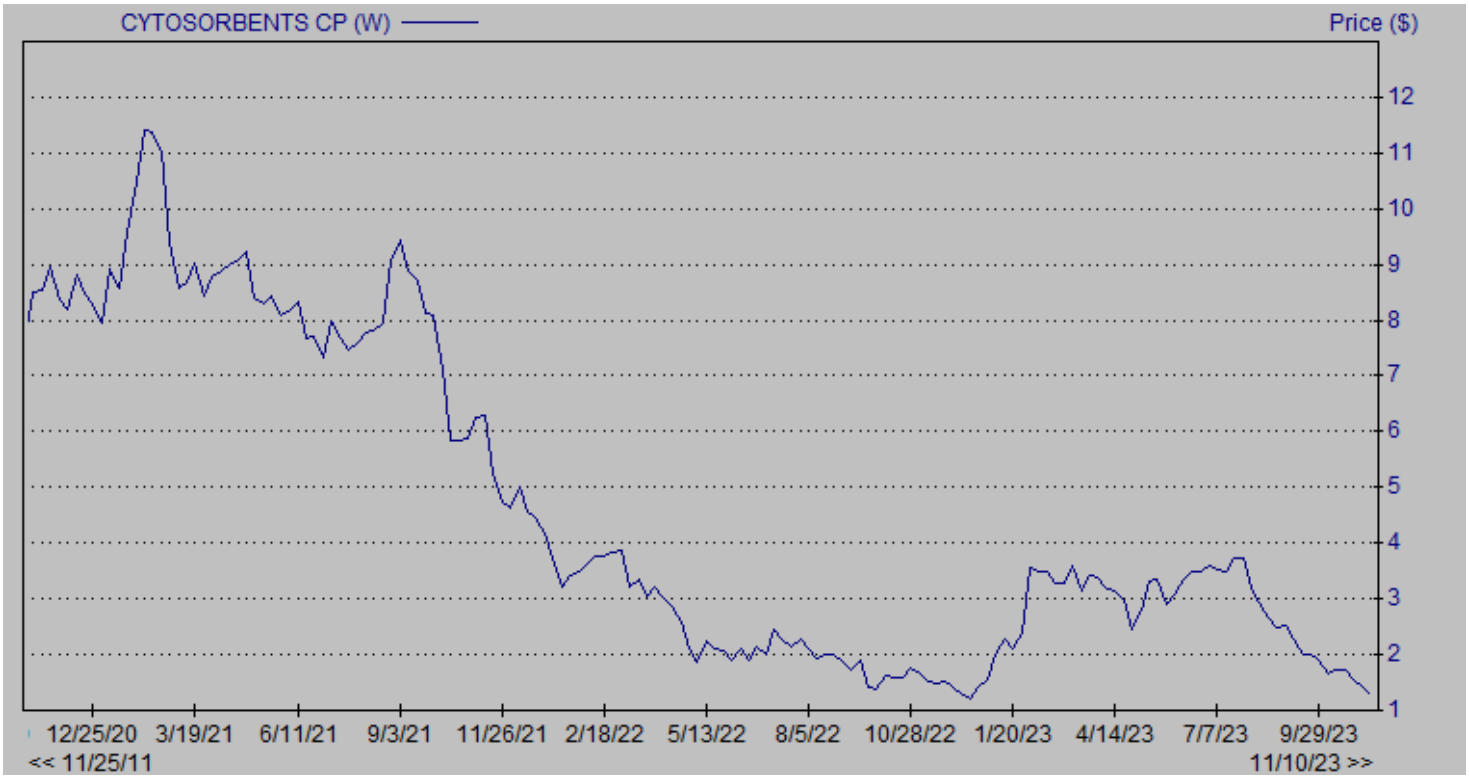
Source: CytoSorbents investor presentation

PROJECTED INCOME STATEMENT

Income Statement		Dec-21	Dec-22	Dec-23	Dec-24	Dec-25
Net Sales		**43,165,527**	**34,689,000**	**37,946,340**	**50,596,707**	**58,242,614**
Growth		*5.3%*	*-19.6%*	*9.4%*	*33.3%*	*15.1%*
Cost of Goods Sold		**10,315,772**	**13,073,379**	**11,790,963**	**13,950,892**	**15,185,438**
%		*23.9%*	*37.7%*	*31.1%*	*27.6%*	*26.1%*
Depreciation & Amort		**731,578**	**882,621**	**1,495,365**	**1,495,365**	**1,495,365**
Gross Profit		**32,118,177**	**20,733,000**	**24,660,012**	**35,150,450**	**41,561,811**
Margin		*74.4%*	*59.8%*	*65.0%*	*69.5%*	*71.4%*
SG&A Expenses		**35,750,477**	**34,288,134**	**31,990,791**	**30,391,252**	**29,783,427**
% of sales		*82.8%*	*98.8%*	*84.3%*	*60.1%*	*51.1%*
Other		**2,731,515**	**2,847,899**	**3,731,479**	**3,768,794**	**3,806,482**
% of sales		*6.3%*	*8.2%*	*9.8%*	*7.4%*	*6.5%*
Research & Development		**16,380,930**	**15,118,907**	**15,006,693**	**14,256,359**	**13,543,541**
% of sales		*14`%*	*43.6%*	*39.5%*	*28.2%*	*23.3%*
Amortization		**0**	**0**	**0**	**0**	**0**
% of sales		*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Operating Income		**(22,744,745)**	**(31,521,940)**	**(26,068,952)**	**(13,265,955)**	**(5,571,639)**
Margin		*-52.7%*	*-90.9%*	*-68.7%*	*-26.2%*	*-9.6%*
EBITDA		**(22,013,167)**	**(30,639,319)**	**(24,573,587)**	**(11,770,590)**	**(4,076,274)**
Margin		*-51.0%*	*-88.3%*	*-64.8%*	*-23.3%*	*-7.0%*
Other Expenses/(Income)		**2,549,906**	**2,383,289**	**765,975**	**39,518**	**82,539**
%		*5.9%*	*6.9%*	*2.0%*	*0.1%*	*0.1%*
EBIT		**(25,294,651)**	**(33,905,229)**	**(26,834,927)**	**(13,305,473)**	**(5,654,178)**
%		*-58.6%*	*-97.7%*	*-70.7%*	*-26.3%*	*-9.7%*
Total Interest Exp (net)		**0**	**0**	**139,349**	**139,349**	**400,000**
%		*0.0%*	*0.0%*	*0.4%*	*0.3%*	*0.7%*
Net Profit Before Tax		**(25,294,651)**	**(33,905,229)**	**(26,974,276)**	**(13,444,822)**	**(6,054,178)**
%		*-58.6%*	*-97.7%*	*-71.1%*	*-26.6%*	*-10.4%*
Income Tax		**(736,003)**	**(1,092,585)**	**0**	**0**	**0**
% Effective Rate		*2.9%*	*3.2%*	*0.0%*	*0.0%*	*0.0%*
% Cash Tax Rate		*2.9%*	*3.2%*	*0.0%*	*0.0%*	*0.0%*
Minority Interests or Preferred Stock		**0**	**0**	**0**	**0**	**0**
Net Profit		**(24,558,648)**	**(32,812,644)**	**(26,974,276)**	**(13,444,822)**	**(6,054,178)**
%		*-56.9%*	*-94.6%*	*-71.1%*	*-26.6%*	*-10.4%*
Non-recurring income (expense)						
Average Diluted Shares Outstanding		43,359,186	43,573,215	44,196,690	44,196,690	44,196,690
Reported FD EPS						
Zacks Cash EPS		**(0.57)**	**(0.75)**	**(0.61)**	**(0.30)**	**(0.14)**
Zacks EPS		**(0.57)**	**(0.75)**	**(0.61)**	**(0.30)**	**(0.14)**

Source: Zacks analyst projections

HISTORICAL STOCK PRICE



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