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Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: CytoSorbents reports 2nd 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 $6.00 per share.

Current Price (8/2/23)	$3.35
Valuation	**$6.00**

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	**$1.03**
One-Year Return (%)	**66.7**
Beta	**0.77**
Average Daily Volume (sh)	**134,572**
Shares Outstanding (mil)	**44.4**
Market Capitalization ($mil)	**$149.3**
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	$9.4 E	$9.6 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	-$0.10 E	-$0.08 E	-$0.49 E
2024					-$0.24 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 2nd quarter 2023 results on August 1st which showed strong product revenue growth. 2nd quarter revenues increased 10.1% and grant income increased 15.7%. The increase in the Euro to U.S. dollar exchange rate positively impacted product sales by approximately $187,000. 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 2nd quarter of 2023 and the 2nd quarter of 2022. Total revenues were $9.4 million for the 2nd quarter of 2023, as compared to total revenues of approximately $8.5 million for the prior year period, an increase of 10.9%.

The product gross margin increased to 74% from approximately 67% 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 2nd quarter of 2022 that did not recur in the 2nd second quarter of 2023.

Research & Development expenses were $3.7 million in the 2nd quarter compared to $4.2 million in the prior year period. The decrease was primarily due to a decrease in clinical trial activities of approximately $627,000 related to the pause of the STAR-D trial in November 2022.

The net loss for the quarter was ($6.15) million which was a substantial improvement from ($10.9) million in the 2nd quarter of 2022. Operating cash flow was a use of cash of ($10.0) million for the first six months of 2023, which was an improvement from the use of cash of ($16.1) million for the first six months of 2022.

As of the end of the 2nd quarter, the company had current assets of approximately $23.6 million and current liabilities of approximately $10.4 million. The company has unrestricted cash of $13.1 million and long-term debt of $5.0 million. There is still $22.8 million available under the company's ATM equity facility. 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 early 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. It is expected that the quarterly burn rate for the remaining quarters of 2023 will be in the $4.0-$4.5 million range. We believe the company has sufficient cash and resources to fund operations at least until the 1st quarter of 2024.

Recent Operating Highlights

- The important STAR-T trial completed enrollment ahead of company projections among 30 participating trial centers in the U.S. and Canada. This follows the recommendation by the independent Data and Safety Monitoring Board (DSMB) in June 2023 to complete the trial without modifications after it finished the second scheduled safety review at 80 patients enrolled.

- More than 212,000 CytoSorb devices have been cumulatively delivered across more than 75 countries worldwide as of the end of the 2nd quarter.

- The company appointed Alexander D'Amico as Chief Financial Officer, who has over 20 years of broad finance, SEC reporting, merger and acquisition, fundraising, and accounting experience. He is expected to start August 7, 2023. Interim CFO Kathy Bloch will continue to serve in a consulting capacity.

- The company introduced Michael Bator as the new Chairman of the Board of Directors at the Annual Meeting in June, following the retirement of Al Kraus as former Chairman. A director of CytoSorbents since July 2015, Michael is founder and Partner of Quartz Advisory Group, a capital markets investment bank, and was formerly Managing Director of Healthcare Research at Jennison Associates, a multi-strategy buy-side family of investment funds with more than $175 billion of assets under management.

- CytoSorbents announced a theranostic collaboration with Humedics in the field of liver disease which, focuses on a joint promotion of CytoSorb, a superior extracorporeal liver support blood purification therapy, and Humedics' LiMAx® test, a rapid and precise E.U. approved diagnostic using its innovative breath analysis technology to quantitatively assess liver function.

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, *"We are pleased to report another successful quarter of executing on our three key business objectives for 2023. Most importantly, we expect to complete the pivotal STAR-T randomized, controlled trial imminently, following the 30-day follow-up of the last patient, which we believe puts us on target for topline data before the end of the year".*

Three Key Business Objectives

1) Opening the U.S. and Canadian markets with DrugSorb®-ATR

CytoSorbents continues to move towards the goal of opening the U.S. and Canadian markets with DrugSorb-ATR through the STAR-T (Safe and Timely Antithromobotic Removal of Ticagrelor) and pending STAR-D programs. The company reported that the independent DSMB, following two scheduled reviews of unblinded safety data on the first 80 patients, recommended completion of the study without modifications in June.

The company has been working with centers in parallel during the STAR-T study to ensure timely entry and monitoring of data, and despite enrolling the final 60 patients in the last 2.5 months of the study with a lot of work ongoing, the company expects to formally complete the study soon and drive data cleaning and database lock in the next several months. This will be followed by statistical analysis of the data, which will enable the company to achieve the goal of announcing topline data before the end of 2023. Regulatory personnel at the company have been coordinating resources to assemble the regulatory dossier needed to submit for marketing approval to FDA and Health Canada, which can occur soon after receiving positive clinical study data. The submission will be followed by a formal presentation of the data at a major U.S. cardiovascular conference. In 2024, the company expects to execute its pre-commercialization strategy and begin building sales and marketing infrastructure next year.

When appropriate, the company plans to continue the STAR (Safe and Timely Antithrombotic Removal) program with the resumption of the STAR-D trial, that will evaluate the use of DrugSorb-ATR to remove the direct oral anticoagulant (DOAC) Factor Xa inhibitors, Eliquis and Xarelto (among the highest revenue generating pharmaceuticals in the world), and to reduce bleeding risk in cardiothoracic surgery patients on these agents. The company plans to leverage the same site network as in STAR-T and based on their feedback that they routinely encounter patients on DOACs needing cardiac surgery and their proven track record of trial execution, the company believes the STAR-D trial can be run quickly and cost-effectively.

In addition, the Centers for Medicare & Medicaid Services (CMS) recently announced details surrounding the Transitional Coverage for Emerging Technologies (TCET) program and are currently in the public comment period. The current proposed program falls short of what was widely anticipated by the medical device community and its trade organization, Advamed, providing a transparent pathway for securing dedicated CMS national coverage of FDA Breakthrough Designated Devices within 6 months of FDA clearance or approval, but departing from the automatic four-year national coverage upon FDA approval of qualified Breakthrough Devices that was discussed by CMS previously. The company expects there to be ongoing discussion and possible modification of the program. CytoSorbents believes DrugSorb-ATR, as a Breakthrough Designated Device whose core target population is in the age group covered by Medicare would still be an excellent candidate for this TCET program and the company will continue to follow the story as it develops. In the meantime, the STAR-T trial is expected to provide significant health economics data to support reimbursement through traditional private and public insurance pathways.

2) Return to Sales Growth for CytoSorb

CytoSorb targets the massive critical care and cardiac surgery markets primarily in European countries and control deadly inflammation and other life-threatening conditions such as sepsis, lung injury, trauma, burn injury, liver failure, complications of surgery, and cytokine release syndrome in cancer immunotherapy. Following a post-COVID slowdown in hospital-based markets globally in 2022, the company reported their third consecutive quarter of sequential product sales growth and a 10% increase in the 2nd quarter of 2023 compared to the prior year period.

With many new growth initiatives and new leadership in key positions in therapy area verticals and the overall commercialization organization, the company anticipates further momentum of the business going forward. Product gross margins have rebounded 700 basis points to 74%, a trend consistent with earlier guidance of returning to 75-80% product gross margins on a quarterly basis in 2023.

After 200,000 human treatments and numerous positive studies, the company has distilled the CytoSorb message to *Right Patient, Right Timing, Right Dose.* The concept of treating the right patient at the right time with the right dose to have good clinical outcomes is relevant to most therapies. For example, antibiotics are some of the most commonly used drugs in the intensive care unit and are a perfect analogy for CytoSorb. One needs antibiotics to kill the pathogen and to survive a life-threatening infection, just as you need to control the deadly massive inflammatory response in sepsis with CytoSorb. But despite antibiotics and the best standard of care (excluding CytoSorb), approximately 20-25% of patients with sepsis and organ dysfunction will die, and 35-50% of patients with septic shock will still die. A lot of these failures can be traced back to not following the “Right Patient, Right Timing, Right Dose” mantra. For example, if a patient with an infection is misdiagnosed and treated with the wrong antibiotic, it will not work (e.g., treating COVID-19 with penicillin instead of Paxlovid®). Or if an infection is not treated with antibiotics until the infection has spiraled out of control and the patient develops sepsis – then this is “too little too late.”’ Or if the dose of the antibiotic is not adjusted for the severity of illness, the antibiotic may not work optimally. In the past several years, the company has been emphasizing the “Right patient, right timing, and right dose” with the early and aggressive treatment of patients with clear evidence of hyperinflammation.

Current company-sponsored trials, such as the PROCYSS refractory septic shock randomized trial, and the international COSMOS critical illness registry, incorporate evolving understanding of how to achieve better and more consistent results with CytoSorb. The company has also been working to drive earlier usage of CytoSorb in the appropriate patients through a number of different ways, including pursuing a theranostic strategy (i.e. using a diagnostic test to guide patient selection and timing of CytoSorb therapy) which is similar the collaboration with Humedics in the field of liver disease, or by selling a simple-to-use, relatively low cost hemoperfusion machine that can run CytoSorb quickly and efficiently, without needing to wait for patients to develop kidney failure and go on dialysis.

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 half of 2023 averaged approximately $4.5 million, down significantly from the average quarterly burn in the first half of 2022 of approximately $11 million. Cash at the end of the quarter stood at approximately $14.8 million. We expected the quarterly burn rate to remain in the $4.0-$4.5 million range for the rest of 2023.

CytoSorbents CEO stated, *"Overall, we are excited about completing the STAR-T trial and potentially being on the cusp of reporting topline data by the end of the year and the full data set analysis shortly thereafter. If positive, these data could lead to U.S. FDA and Health Canada marketing approval for DrugSorb-ATR, and importantly, commercial revenue targeting an initial $300 million total addressable market in these two countries alone. Meanwhile, the gradual but steady recovery we are seeing for CytoSorb is expected to build momentum as the hospital markets recover, with anticipated future growth of the therapy in so many different clinical indications addressing multi-billion dollar markets. If we are successful, we believe CytoSorb and DrugSorb-ATR could transform CytoSorbents into a dual U.S. and international growth company, fueled by two major high margin revenue engines, helping to drive significant shareholder value."*

Valuation and Estimates

We are lowering our 2nd half 2023 revenues and earnings estimates due to slower than expected recovery of open ICU beds in European markets. We expect total quarterly revenues to remain in the $9 million range. We are adjusting our 2023 revenue estimates to $37.9 million and adjusting our full year EPS estimate to a loss of ($0.49). These estimates may prove to be conservative if the company's major cost saving initiatives are greater than expected and sales increases from the German hospital market are realized sooner than expected.

There are no changes to our valuation target of **$6.00** at this time as we believe that over the long term, the company can generate substantial levels of free cash flow, 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 is expected to complete full enrollment 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 $13.2 million in unrestricted cash on the balance sheet and $5.0 million in debt as of 06/30/23. 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 $149.0 million.

- We believe CTSO stock is worth **$6.00** 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.

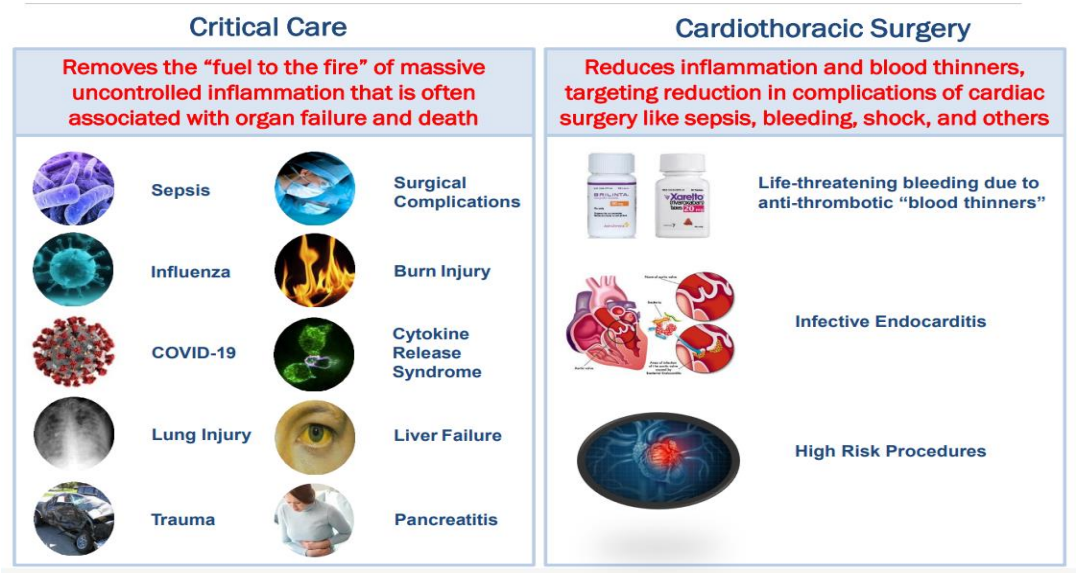
As of June 30, 2023, more than 212,000 CytoSorb devices have been used cumulatively. CytoSorb was originally launched in the European Union under CE mark as the first cytokine adsorber. Additional CE mark extensions were granted for bilirubin and myoglobin removal in clinical conditions such as liver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

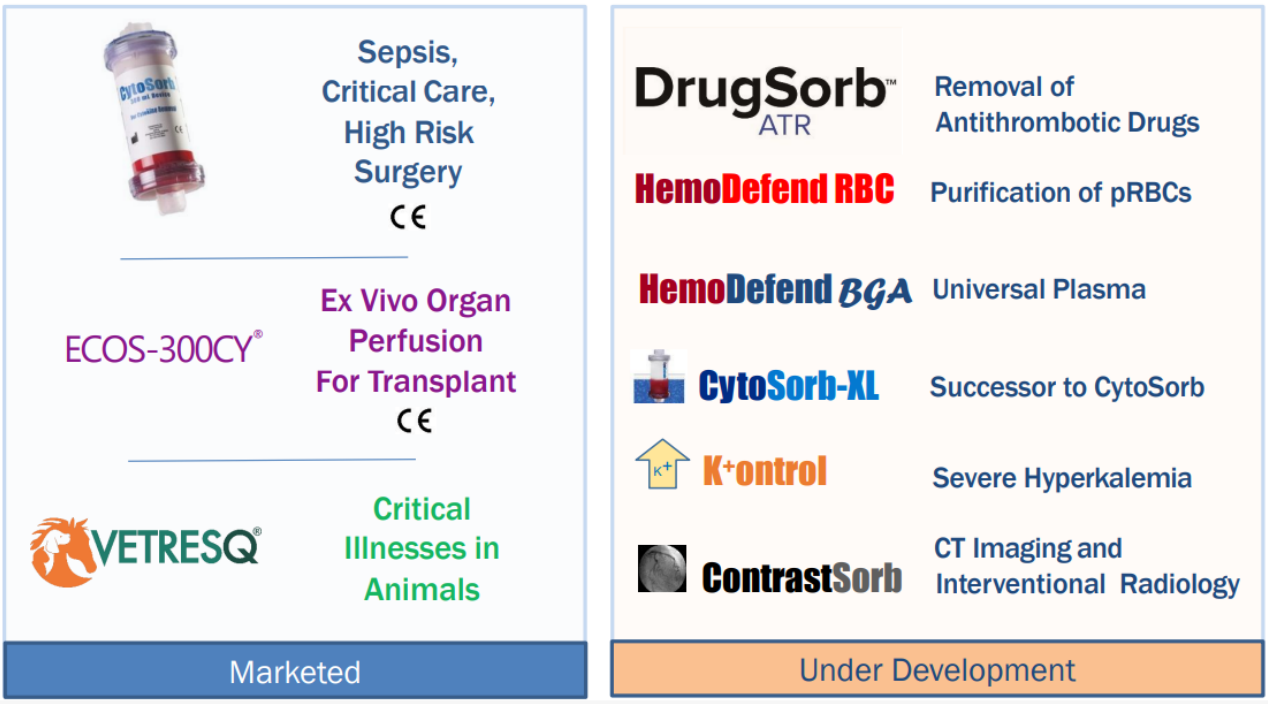
In September 2022, the company announced that it had received ISO 13485 Certification for its new manufacturing facility in Princeton, New Jersey from its European Union (E.U.) notified body. This clears the way for full manufacturing of CytoSorb®, DrugSorb®-ATR, and ECOS-300CY® from this site with capacity 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

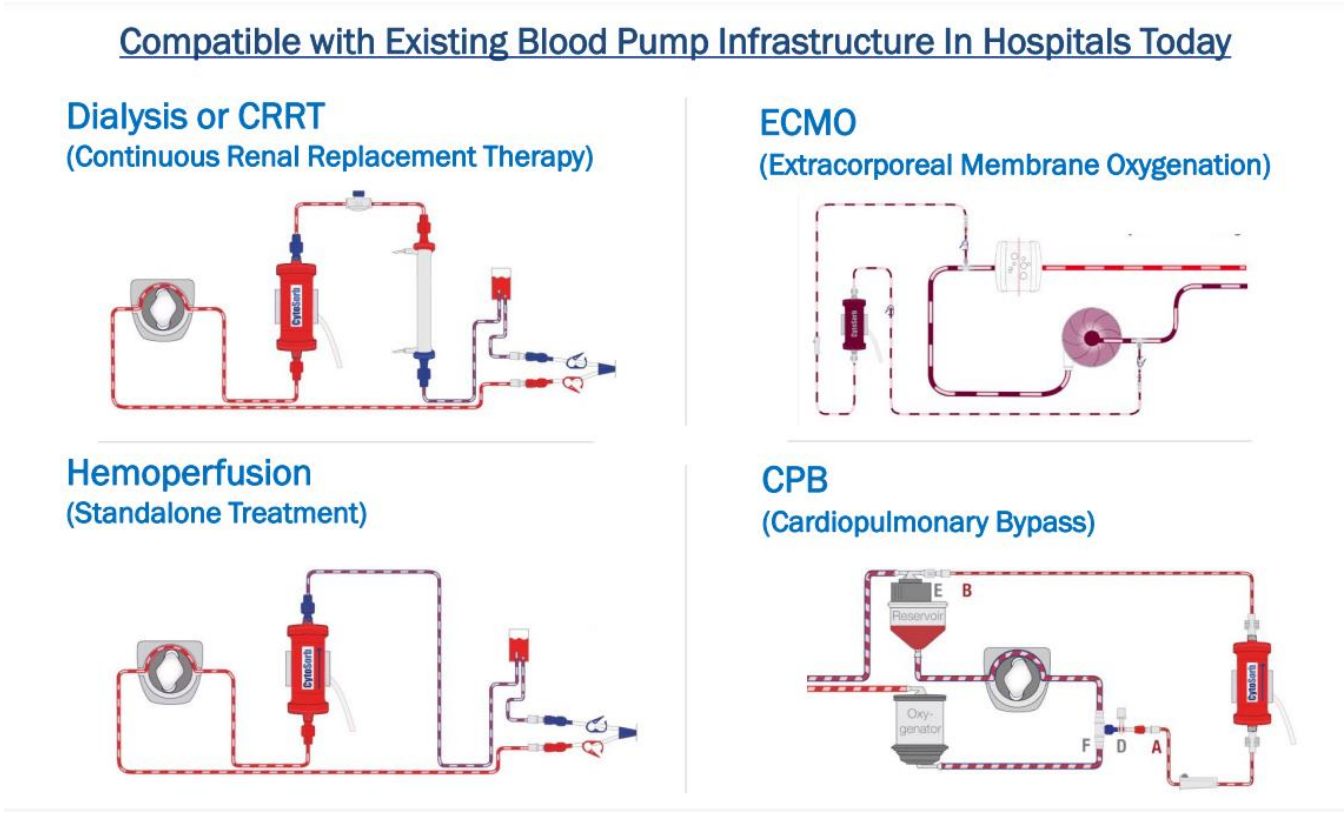


Source: CytoSorbents investor presentation

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.

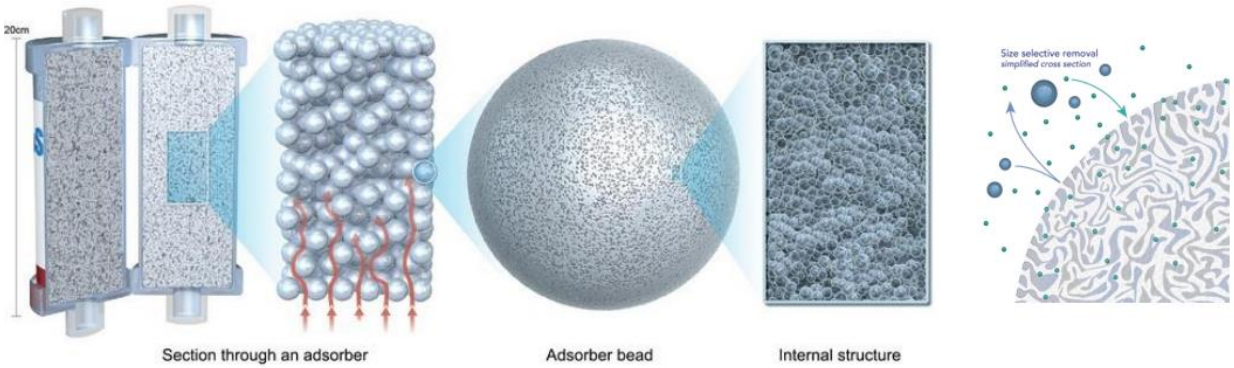
The cartridges incorporate industry standard connectors at either end of the device, which connect directly to the extracorporeal circuit (bloodlines) in series with a dialyzer as a standalone device. The extra-corporeal circuit consists of plastic blood tubing, the company’s blood filtration cartridges 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 outcome, 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.

DRUGSORB-ATR & STAR-T TRIAL

The company is currently conducting an FDA-approved, 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. This important study intends to support both U.S. FDA and Health Canada marketing approval of DrugSorb-ATR in the United States and Canada.

Today, increased ticagrelor usage is being heavily prescribed because according to the Centers of Disease Control and Prevention (CDC), heart disease is the leading cause of mortality in the U.S. which accounts for approximately 20% of all deaths. Coronary artery disease is the most common form of heart disease killing nearly 400,000 people from heart attacks each year. The CDC states that someone in the U.S. has a heart attack every 40 seconds, or more than 800,000 people annually. This is relevant for ticagrelor because when patients have signs and symptoms of having a heart attack and cannot get a stent placed or coronary artery bypass graft (CABG) surgery right away, they are often placed on dual antiplatelet therapy (DAPT) in the hospital consisting of aspirin and a “super-aspirin” like ticagrelor which thins the blood and reduces the risk of a worsening heart attack and death. If they are not candidates for a stent, they may require surgery but could face the risk of severe or uncontrolled bleeding because of DAPT intervention. The risk of bleeding depends on when the surgery takes place, but the risk of major fatal or life-threatening CABG-related bleeding can be higher than 50% if the surgery happens that day. Ticagrelor is expected to be available to be marketed on a generic basis in 2024 which is expected significantly increase its usage. The goal of DrugSorb-ATR® is to allow patients to get the critical surgery

that they need without delay while reducing or preventing this bleeding risk by actively removing the drug during the surgery.

The STAR-T trial will be followed by the STAR-D (Safe and Timely Antithrombotic Removal Direct Oral Anticoagulants) pivotal trial evaluating the intraoperative use of DrugSorb-ATR to reduce perioperative bleeding risk in patients undergoing cardiothoracic surgery and taking direct oral anticoagulants such as apixaban and rivaroxaban. The company originally planned a simultaneous STAR-T and STAR- D trial but decided to pause the STAR-D trial and divert all its attention to the STAR-T efforts. This STAR-D pause also contributes to significant cost savings in 2023 which could be upwards of $4 million.

On November 14, 2022, the company announced that 40 of the targeted 120 patients had been enrolled in the study. Dr. Michael J. Mack, Director of the Cardiovascular Service line at Baylor Scott & White Health System and co-Principal Investigator of the STAR-T trial stated, *"Reaching our first trial enrollment milestone of 40 patients is a critical first step in the execution of the landmark STAR-T trial. Currently, cardiac surgeons are either forced to delay life-saving heart surgery in patients who are on antithrombotic drugs or proceed to operation when they are at very high risk for bleeding. The DrugSorb-ATR device is novel approach that could potentially allow these high-risk surgeries to proceed in a safe and timely manner."*

Dr. Efthymios N. Deliargyris, Chief Medical Officer of CytoSorbents commented, *"We are pleased to have enrolled a third of our STAR-T pivotal study, which now triggers the first safety review by the independent DSMB of the study. We are now working diligently to complete the necessary operational steps including data collection and validation to support the upcoming DSMB safety review which is estimated in approximately 2 months."*

On December 21, 2022, the company received the recommendation from the independent DSMB to continue the pivotal STAR-T trial as planned without any modifications. The company expects to reach the second milestone of 80 enrolled patients in the spring of 2023 which would trigger the next unblinded data review by the Data and Safety Monitoring Board (DSMB) and to complete enrollment of all 120 patients in the summer of 2023. If positive results occur, FDA and Health Canada regulatory submissions are planned upon the completion of the trial.

CytoSorbents believes the STAR-T will provide valuable health economics data to support market pricing and standard reimbursement of DrugSorb-ATR from both private and government insurers such as Centers for Medicare and Medicaid Services (CMS) where the cost-benefit message may be very compelling. The company is also pursuing alternative form of reimbursement through the designation of DrugSorb-ATM as a “Breakthrough Device” by the FDA. This would be through the "Medicare Coverage for Innovative Technologies" (MCIT) rule which was designed to stimulate innovation in the medical device industry by offering up to four years of automatic reimbursement for approved or cleared FDA Breakthrough Devices.

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 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 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.

Alexander D'Amico
Chief Financial Officer
Mr. D'Amico has over 20 years of broad finance, SEC reporting, merger and acquisition, fundraising, and accounting experience. Most recently, Mr. D'Amico was the Chief Financial Officer of Trulieve Cannabis Corporation (CSE: TRUL; OTCQX: TCNNF), an industry leading, vertically integrated cannabis company and multi-state operator in the U.S., overseeing more than 7,600 employees, including more than 250 finance, accounting, shared service, human resource and investor relations professionals. Through strategic organic growth and eleven separate acquisitions with a transaction value totaling $2.5 billion, including the largest industry transaction in the U.S., Mr. D'Amico helped to engineer a rapid expansion of annual revenue from $250M to more than $1.2 billion, leveraging more than 4 million square feet of cultivation and processing space, and 180 retail stores across 12 states.

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

VALUATION

The addressable market that CytoSorbents is focused on is expected to produce above average growth rates for an extended period of time. We expect revenues to grow at a compound annual growth rate (CAGR) of approximately 15% over the next 10 years. Annual device sales could reach $60 million by the year 2025.

Although the company expects a return to gross margins of 80%, we take a more conservative approach due to ongoing inflationary pressures and uncertainties in their primary hospital end markets. We expect company gross margins to grow from 76% in 2023 to 80% by 2025.

Our primary valuation tool utilizes a Discounted Cash Flow process. Our base case includes revenues growing at a CAGR of 15%, cash flow breakeven in 2025 and net profitability to be achieved in 2025 as well. Under this scenario, our DCF based valuation target is approximately **$6.00**. This DCF value utilizes a conservative 15% discount rate. Applying a traditional profitable smallcap company discount rate of 12% would add $2.00-$3.00 to the target value.

In addition, we believe $6.00 to be a conservative estimate as revenue growth rates could greatly exceed our estimates as a result of new product commercialization being achieved sooner than expected, in particular the approval and commercialization of DrugSorb-ATR. In addition, the company's goal of product gross margins of 80% may be realized sooner than we expect. Lastly, it's possible that the increasing operating efficiencies of the company would shorten the timeline to when meaningful profits are generated.

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.

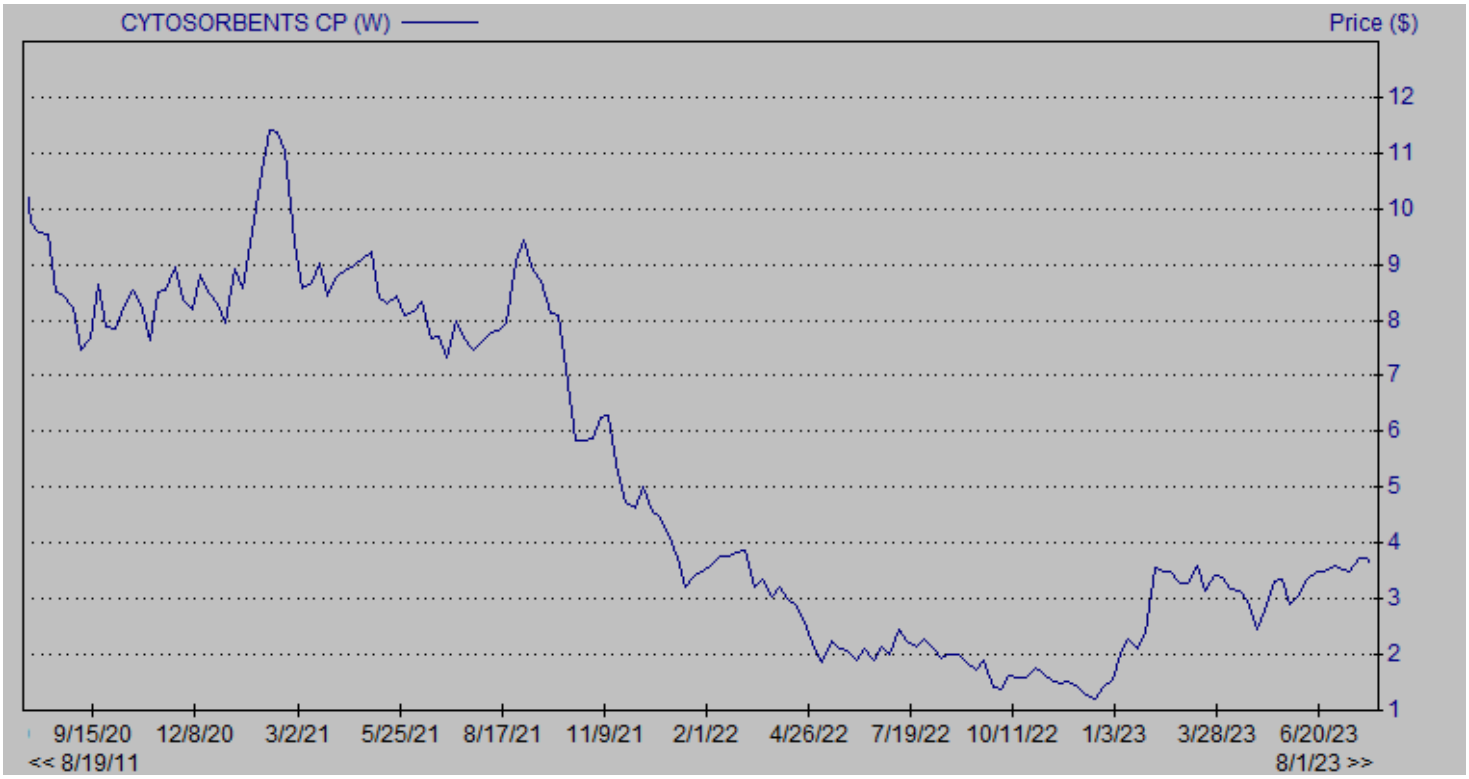
We believe CytoSorbents has the potential to grow both revenues and earnings at very robust double-digit growth rates if it is able to execute on the commercialization of its product pipeline. The company's current stock price does not likely reflect that potential level of profitable growth going forward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

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**	**11,025,854**	**12,930,714**	**14,011,096**
%		*23.9%*	*37.7%*	*29.1%*	*25.6%*	*24.1%*
Depreciation & Amort		**731,578**	**882,621**	**1,525,804**	**1,525,804**	**1,525,804**
Gross Profit		**32,118,177**	**20,733,000**	**25,394,683**	**36,140,189**	**42,705,714**
Margin		*74.4%*	*59.8%*	*66.9%*	*71.4%*	*73.3%*
SG&A Expenses		**35,750,477**	**34,288,134**	**30,495,848**	**28,971,056**	**28,391,635**
% of sales		*82.8%*	*98.8%*	*80.4%*	*57.3%*	*48.7%*
Other		**2,731,515**	**2,847,899**	**3,267,998**	**3,300,678**	**3,333,685**
% of sales		*6.3%*	*8.2%*	*8.6%*	*6.5%*	*5.7%*
Research & Development		**16,380,930**	**15,118,907**	**14,984,189**	**14,234,980**	**13,523,231**
% of sales		*14`%*	*43.6%*	*39.5%*	*28.1%*	*23.2%*
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)**	**(23,353,353)**	**(10,366,525)**	**(2,542,837)**
Margin		*-52.7%*	*-90.9%*	*-61.5%*	*-20.5%*	*-4.4%*
EBITDA		**(22,013,167)**	**(30,639,319)**	**(21,827,549)**	**(8,840,721)**	**(1,017,033)**
Margin		*-51.0%*	*-88.3%*	*-57.5%*	*-17.5%*	*-1.7%*
Other Expenses/(Income)		**2,549,906**	**2,383,289**	**(1,873,625)**	**4,806**	**32,517**
%		*5.9%*	*6.9%*	*-4.9%*	*0.0%*	*0.1%*
EBIT		**(25,294,651)**	**(33,905,229)**	**(21,479,728)**	**(10,371,330)**	**(2,575,354)**
%		*-58.6%*	*-97.7%*	*-56.6%*	*-20.5%*	*-4.4%*
Total Interest Exp (net)		**0**	**0**	**89,633**	**89,633**	**400,000**
%		*0.0%*	*0.0%*	*0.2%*	*0.2%*	*0.7%*
Net Profit Before Tax		**(25,294,651)**	**(33,905,229)**	**(21,569,361)**	**(10,460,963)**	**(2,975,354)**
%		*-58.6%*	*-97.7%*	*-56.8%*	*-20.7%*	*-5.1%*
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)**	**(21,569,361)**	**(10,460,963)**	**(2,975,354)**
%		*-56.9%*	*-94.6%*	*-56.8%*	*-20.7%*	*-5.1%*
Non-recurring income (expense)						
Average Diluted Shares Outstanding		43,359,186	43,573,215	44,190,898	44,190,898	44,190,898
Reported FD EPS						
Zacks Cash EPS		**(0.57)**	**(0.75)**	**(0.49)**	**(0.24)**	**(0.07)**
Zacks EPS		**(0.57)**	**(0.75)**	**(0.49)**	**(0.24)**	**(0.07)**

Source: Zacks analyst projections

HISTORICAL STOCK PRICE



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