



# CytoSorbents™

Working to Save Lives Through Blood Purification

## CytoSorbents Issues Letter to Shareholders

MONMOUTH JUNCTION, N.J., April 24, 2015 -- CytoSorbents Corporation ([NASDAQ: CTSO](#)), a critical care immunotherapy company commercializing its European Union approved CytoSorb® blood filter to treat deadly inflammation in critically-ill and cardiac surgery patients, issued a letter to its shareholders as part of its annual report, from its Chief Executive Officer, Dr. Phillip Chan, which reads as follows:

Dear Fellow Shareholders and Friends,

By all measures, 2014 was an outstanding year for CytoSorbents, highlighted by many significant achievements. We exceeded our internal forecasts for CytoSorb® sales growth, fueled by broadening physician interest and usage in a growing number of countries. We established or strengthened key strategic partnerships with Fresenius Medical Care, Biocor, and a major global cardiac surgery company, and expanded distribution of CytoSorb® to 29 countries worldwide. These initiatives have the potential to catalyze significant future growth. We also began the clinical trial process needed to bring CytoSorb® home to the U.S., initially for the application of cardiac surgery, and possibly later for other applications. Finally, with the support of our shareholders, we became a NASDAQ-listed company, giving CytoSorbents much broader visibility in the investment community and significantly increasing liquidity for shareholders.

With that said, the most exciting part of this journey has been the growing number of stories of how CytoSorb® has helped, in some way, save the lives of ordinary people like you and me. These patients find themselves in the intensive care unit because of common life-threatening conditions such as sepsis and infection, lung injury, trauma, burn injury, pancreatitis, liver failure, and many others where inflammation plays a potentially deadly role. Left untreated, severe uncontrolled inflammation can lead to multiple organ failure, where patients spiral out of control and become unresponsive to therapy, leaving families and physicians with the difficult prospect of having to

potentially withdraw life-support. The fact that CytoSorb® therapy has been used to reduce the “fuel to the fire” of this inflammation and help bring many of these people back from the brink of death is, to me as a physician, nothing short of remarkable.

To be clear, the diseases we treat are some of the most complex life-threatening conditions in medicine for which no effective therapies exist, and where the risk of death is still one in every three patients despite the best medical treatment. We have no expectation that CytoSorb® will work every time. But with the collaboration and experience of a growing number of physicians who have collectively performed more than 5,500 human treatments to date, we have made significant progress toward identifying which diseases and patients best respond to CytoSorb® therapy. Centralized data from our recently launched International CytoSorb® Registry and from the more than 50 planned investigator-initiated and company-sponsored studies (a dozen of which are already enrolling patients), will also be invaluable to understanding the full potential of CytoSorb®. We now have the funding and clinical development team to advance our trial agenda more aggressively, particularly in the areas of sepsis and cardiac surgery – our two largest markets.

A significant new opportunity has emerged that may accelerate U.S. approval of CytoSorb® for critical illnesses such as sepsis. The FDA has recently issued new guidance on two related topics: the Expedited Access Pathway (EAP) program and the Balancing of Pre-market and Post-market Data Collection for Devices Subject to Premarket Approval. Together, the EAP and Data Collection programs are designed to facilitate and expedite the U.S. approval of medical devices that treat life-threatening or irreversibly debilitating conditions that have no approved alternative treatments. Similar to “Breakthrough Therapy Designation” for drugs and biologics, devices that achieve EAP Designation would be eligible for more intensive FDA guidance and collaboration with senior managers, and priority review. Meanwhile, the FDA and Device Sponsor would work together to specify the clinical trial design and “least burdensome” efficacy and safety data needed for early marketing approval, leaving the proof of more stringent efficacy to the post-market period. The end result is that devices that are safe and achieve EAP Designation have an opportunity to get to U.S. approval and commercialization much faster, and with less regulatory risk. We believe this new program could benefit CytoSorbents as CytoSorb® currently targets the treatment of many life-threatening conditions such as sepsis, acute respiratory distress syndrome, severe acute pancreatitis, trauma, and many others that do not have effective treatments. As we move forward with our REFRESH cardiac surgery trial in the

U.S., we plan to aggressively pursue this EAP opportunity for critical care applications in parallel, and foster open collaboration with the FDA.

We have started 2015 in the strongest financial and commercial position in our history, well-capitalized with a healthy cash position, no debt, and the highest international awareness and interest in our CytoSorb® therapy that we have ever seen. Although we face some potential challenges such as the weakness in the Euro, the need to strengthen our direct sales force, and the unpredictability of timely country-specific product registrations, we continue to believe that the many potential opportunities for significant future growth greatly outweigh these near-term concerns. As detailed in our April 7, 2015 press release responding to *Frequently Asked Questions*, we have a clear strategy and plan on how to drive long-term, sustainable growth of our business.

Before I conclude, I should comment on the potential use of CytoSorb® as a rescue therapy for “cytokine release syndrome”, or CRS, that can lead to cytokine storm in activated T-cell immunotherapy cancer treatments. This is one of the most promising and exciting areas of cancer research where a patient’s own white blood cells (T-cells) are engineered to recognize and kill cancer cells. This is a strategy being pursued by major corporate and university alliances such as Novartis/University of Pennsylvania, Juno Therapeutics/Memorial Sloan Kettering/Fred Hutchinson Cancer Center/Seattle Children’s Research Institute, Celgene/Bluebird Bio, Kite Pharma/National Cancer Institute, GlaxoSmithKline/Adaptimmune, Merck KGaA/Intrexon/MD Anderson, and Pfizer/Cellectis. In a number of studies, the use of activated T-cells has led to the “cure” or remission of many refractory leukemias and other cancers. Common to all of these activated T-cell therapies is the potent stimulation of the inflammatory response, leading to an expected extended “flu-like” syndrome in patients, characterized by high levels of cytokines. However, CRS can spiral out of control, despite the use of tocilizumab and other prophylactic measures, leading rapidly to multiple organ failure and often death. CRS is exactly what CytoSorb® was designed to control and we believe that CytoSorb® represents a potentially unique rescue therapy to treat immune overstimulation in T-cell immunotherapy. While we are still in the beginning phases of exploring this new opportunity, CytoSorbents already has several initiatives underway.

After a fantastic 2014, we are tremendously excited about the opportunities this year and beyond. We are deeply grateful for the continued faith and effort of our extended CytoSorbents family: our patients and their families, the physicians and nurses on the front lines using our therapy, our shareholders, advisors, Board of Directors, distributors, strategic partners, research collaborators, and importantly, our more than

50 dedicated employees and consultants both here and in Berlin, Germany. Together, we can help revolutionize the treatment of deadly inflammation, and help give patients a fighting chance.

Finally, we fondly remember Joseph Rubin (1938-2014), our co-founder and Board Director, whose unwavering faith in the potential of our CytoSorb® technology to help people remains an inspiration to us all.

Sincerely,

**Dr. Phillip Chan, MD, PhD**  
**Chief Executive Officer**  
**CytoSorbents Corporation**

#### **About CytoSorbents Corporation**

CytoSorbents Corporation is a critical care focused immunotherapy company using blood purification to control severe inflammation -- with the goal of preventing or treating multiple organ failure in life-threatening illnesses. Organ failure is the cause of nearly half of all deaths in the intensive care unit, with little to improve clinical outcome. CytoSorb®, the Company's flagship product, is approved in the European Union with distribution established in 29 countries around the world, as a safe and effective extracorporeal cytokine adsorber, designed to reduce the "cytokine storm" that could otherwise cause massive inflammation, organ failure and death in common critical illnesses such as sepsis, burn injury, trauma, lung injury, and pancreatitis. These are conditions where the risk of death is extremely high, yet no effective treatments exist. CytoSorb® is also being used during and after cardiac surgery to remove inflammatory mediators, such as cytokines and free hemoglobin, which can lead to post-operative complications, including multiple organ failure.

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. CytoSorbents has numerous products under development based upon this unique blood purification technology, protected by 32 issued US patents and multiple applications pending, including HemoDefend™, ContrastSorb, DrugSorb, and others. Additional information is available for download on the Company's website: <http://www.cytosorbents.com/>.

## **Forward-Looking Statements**

This press release includes forward-looking statements intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions and are not historical facts and typically are identified by use of terms such as “may,” “should,” “could,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements in this press release represent management’s current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. Factors which could cause or contribute to such differences include, but are not limited to, the risks discussed in our Annual Report on Form 10-K, filed with the SEC on March 31, 2015, as updated by the risks reported in our Quarterly Reports on Form 10-Q, and in the press releases and other communications to shareholders issued by us from time to time which attempt to advise interested parties of the risks and factors which may affect our business. We caution you not to place undue reliance upon any such forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, other than as required under the Federal securities laws.

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