



CytoSorbents™

Working to Save Lives Through Blood Purification

CytoSorbents 2016 – Driving Toward the Inflection Point

Growth Trajectory Continues with Record CytoSorb® Sales of Approximately \$1.5M in Q4 2015 and Approximately \$4.0M in 2015

MONMOUTH JUNCTION, N.J., January 11, 2016 -- 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 worldwide, issues a letter to its stockholders from Chief Executive Officer, Dr. Phillip Chan.

2015 Financial Highlights:

- **We expect to report record quarterly CytoSorb® sales of approximately \$1.5 million (range \$1.4-1.6M), an approximately 40% increase over Q3 2015 (range 30-50%) and an approximately 70% increase over Q4 2014 (range 60-80%).**
- **Full year 2015 CytoSorb® sales are expected to be approximately \$4.0 million (range \$3.9-4.1M)**
- **Gross product margins for Q4 2015 and full year 2015 are expected to be greater than 60%**
- **Adjusted for the decline in the Euro, Q4 2015 and full year 2015 CytoSorb® sales would have been in the range of \$1.6-1.8M and \$4.6-4.8M, respectively**

Dear Fellow Stockholders and Friends,

It certainly has been a tumultuous beginning of 2016, with a devaluation of the Chinese currency, a 12-year low in the price of oil, and concerns of a potential global recession leading to a major drop in stock markets worldwide, and the worst start of the year in the U.S. markets ever. For all of us, it has been an especially challenging time as our stock has seen more than its fair share of selling in this volatile market.

That said, no, the sky is NOT falling. We finished the best year in our Company's history, with record Q4 and full-year 2015 sales of CytoSorb® in the range of \$1.5 million and \$4.0 million, respectively. The acceleration in product revenue was powered by strong direct sales that tripled from a year ago, consisting of a good balance of orders from both existing and new customers, and was derived from a direct customer base that has doubled in the interim.

Healthy growth from distributors and partners also contributed to the record quarter, including new product orders from Fresenius Medical Care, the world's largest dialysis company and our partner in 6 countries in Europe, and continued orders from Biocon, the largest biotechnology company in India. Fresenius is preparing for a multi-country launch of CytoSorb® shortly. CytoSorb® is now distributed in 32 countries around the world, with the 2015 additions of Italy, Australia, New Zealand, Israel, and Vietnam, as well as Saudi FDA approval of CytoSorb®. As we mentioned previously, CytoSorb® has been registered and is actively being sold in approximately half of these countries with the majority of the other countries expected to come on-line in 2016. Among the many potential 2016 catalysts to growth, we look forward to following Fresenius' product launch, hearing about tender orders submitted last year for the Middle East, getting first orders from Russia where we hope to finally obtain product registration, expanding into Canada, and others. We also are in discussions with distributors and strategic partners about expansion to many additional countries this year.

We are pleased to have achieved year over year growth in every quarter since the commercial launch of CytoSorb®. In 2015, we worked diligently to overcome a number of obstacles such as the restructuring of our sales force, a 20% drop in the Euro to dollar conversion rate from the start of 2014 to the end of 2015, and slower than expected product registrations and launches in key territories, to achieve these results.

Most importantly, we continue to obtain feedback from users of CytoSorb® that treatment has been safe and that they are using it successfully to help their patients. Usage has grown to more than 9,000 human treatments. In 2016 alone, we expect the submission of more than a half dozen publications of case series or clinical trials where safety and efficacy have been evaluated. Our International CytoSorb® Registry that is collecting treatment data from around the world now has 94 sites registered, with data from 78 patients. The first interim analysis on these patients will be completed shortly by the University of Jena and the registry's scientific steering committee.

Driving Toward the Inflection Point

There comes a point in every successful business where it reaches a critical mass and all of the laid groundwork, growth initiatives, building of credibility, and positioning begins to bear fruit. Selling is easier, growth is faster, strategic partner interest is greater, revenues begin to accelerate, and profitability is within sight. The business just begins to click. This is the revered “inflection point” and we believe our business is rapidly approaching this important juncture.

CytoSorb® has been on the market for three years in Germany, a market that was developed approximately one year ahead of the rest of most of our other territories. During that period of time, it has gone from zero market recognition to now being considered one of the only viable treatment options for patients in many different diseases and conditions in the intensive care unit (ICU) and cardiac surgery. More than 70% of German university hospitals and most of the major public hospitals are customers. We have added many of the small to mid-tier hospitals as customers as well. We have expanded throughout the world and continue our geographic push. The number of treatments continues to grow, and the feedback from physicians on usage has been very positive. Attendance at our research symposia and conferences are at an all-time high, often exceeding our seating capacity. And the quality and quantity of our speakers and users continues to expand. We are seeing orders being placed by hospitals without sales calls. Data is being generated by many ongoing studies. And we are working with, and in contact with, more strategic partners than at any time previously.

So where is the disconnect between our potential and our current revenues? The short answer is that there is no disconnect. We believe we are simply on track and are nearing, but have not yet reached, the inflection point.

As a reminder, we have a high margin, high value, repeat order disposables business. We sell a “razorblade” that works with the existing “razor” dialysis and cardiac surgery blood pump infrastructure in hospitals worldwide today. Our results are neither padded by, nor limited by, one-time sales of expensive and lower margin pieces of hardware with small value disposables. So although we can’t post initial numbers like these other mixed medical equipment/disposables businesses where the more they sell, the more they often lose, our business is ideally suited to generate cash flow. Our current product gross margins allow us to capture more than sixty cents of every dollar in product we sell, and channel it towards driving growth, funding next generation life-saving products, and achieving the goal of future profitability. By controlling our own manufacturing, and with volume and scale, we anticipate being able to increase our gross margins on direct sales

in excess of 80%, while still keeping the therapy affordable and cost-effective for the physicians and hospitals who are using it to help their patients.

So how do we get to the inflection point? We believe the answer is to continue on the path that we have established from the beginning to build long-term, sustainable growth and profitability. Our strategy for CytoSorb® is fairly straight-forward:

- ✓ Continue producing high quality product that is affordable while reducing costs and driving margin expansion
- ✓ Pick and support the best partners to make CytoSorb® broadly available and to get it to the market as quickly as possible
- ✓ Establish collaborations and support high quality basic and clinical research to maximize our understanding of the technology and how best to apply it
- ✓ Invest in a broad strategy to obtain clinical data (e.g. company sponsored and 50+ investigator-initiated studies, International CytoSorb® Registry) needed to make CytoSorb® a mainstream standard care therapy and to establish reimbursement worldwide
- ✓ Foster strategic partnerships and leverage their reach and resources to expand more quickly
- ✓ Be opportunistic and take calculated risks when opportunities arise
- ✓ Strive to be a leader in the markets we serve, doing so ethically and honestly, always with the patient's safety and well-being as the priority
- ✓ Ensure that the business is well-funded to support the above activities

As with most things, perhaps easier said than done. Although we have generally been executing well against our plan, and even though many things are out of our direct control, we need to do it better and faster, and that is a fundamental goal for the entire CytoSorbents team in 2016.

Bringing the CytoSorb® Story Home to the U.S.

REFRESH | Update

Although we don't need approval in the U.S. to be successful, a major company objective is to obtain U.S. FDA regulatory approval for CytoSorb® for use in cardiac surgery. There are approximately 1,000,000 open heart surgeries (e.g. coronary artery bypass graft surgery, valve replacement, aortic reconstruction, congenital defect repair, heart-lung transplant, and others) each year in the U.S. and European Union. This application was

chosen because, with the aging baby boomer population, it represents a \$1 billion growing total addressable market and unmet medical need, and has lower regulatory risk than sepsis or other critical illnesses.

The **RE**duction in **FR**ee **H**emoglobin **I** (REFRESH I) cardiac surgery trial is a 40-patient randomized, controlled safety and feasibility study using CytoSorb® intra-operatively in elective, non-emergent complex cardiac surgery patients. The goal is to safely reduce free hemoglobin and other inflammatory toxins that can potentially cause dangerous post-operative complications such as organ failure, and is intended to lead to a REFRESH II pivotal trial targeting U.S. approval. REFRESH I is currently 10% enrolled with the majority of sites up and running. Though too early to draw any conclusions, free hemoglobin levels and incidence of adverse events are tracking to the published literature and to our expectations, which supports the trial design and patient selection procedures of REFRESH I. We plan another update in the near future and are focused on completing REFRESH I by the summer.

Next Steps for Sepsis in the U.S.

By now, most of you know that we will not pursue the Expedited Access Pathway (EAP) “fast-track” program for CytoSorb® and the treatment of sepsis due to the feedback from the FDA that they will require 28-all-cause mortality as a primary endpoint for a pivotal study. But given the exaggerated reaction to this news, perhaps more color is needed than what we provided in our press release.

First, to clear up a common misperception: An approval for EAP designation would NOT have been an approval to begin selling CytoSorb® in the U.S. Instead, it would have been just a first step of a fast-track process where we would still have to conduct a large pivotal trial in sepsis patients. The time frame was still years to approval, but it would have meant that we could have run a trial using less risky endpoints for approval. However, the program would also have committed us to running a much larger and expensive trial in the post-market period to prove a definitive mortality benefit.

Second, we were not relying on the EAP program in sepsis to gain U.S. approval for CytoSorb®. That has been and remains the primary purpose of the REFRESH trials in cardiac surgery – a much less risky approach and potentially faster path to U.S. approval. Instead, our application to obtain EAP designation was a good example of trying to be opportunistic for what appeared to be a change in heart by the FDA to get products that

address major unmet medical needs, such as sepsis, to market sooner given the absolute lack of effective therapies to help critically-ill patients.

There are many published articles by well-respected intensivists that have questioned the FDA's insistence on 28-day all-cause mortality - an endpoint that no therapy has been able to hit in a pivotal study, with the exception of Xigris (which was withdrawn from the market in 2011). As a physician, having something to offer a patient who is dying that has been used safely in thousands of procedures and credited with saving many lives, is a far better option than doing nothing. However, we also understand the FDA's long-standing skepticism on sepsis therapies, given the many failures of pivotal sepsis studies in the past. But it was one of those situations where we had to try. Like you, we believed that CytoSorb® was a perfect fit for the program (and may still be in the future for other illnesses) and the acceptance of surrogate, less stringent end points could have been very helpful. There was no way we could have predicted the FDA's response until we had a full proposal in front of them. We took our best shot, and the outcome was not in our favor. Life goes on. We believe our business has NOT been adversely affected by this decision at all, and at the end of the day, may ultimately give us an opportunity to refine our proposed sepsis study to have an even better chance for a successful U.S. sepsis trial, and do so on our terms and timeline and potentially avoid the need for an expensive post-market study.

Finally, in terms of other advantages of the EAP program, sepsis is already considered a disease that would receive expedited review, so we should benefit from a kind of "fast-track" when we get there.

In the meantime, we plan to move forward with our sepsis program in both the U.S. and in Europe. Remember, if it were easy, someone would have cracked the code for sepsis by now. No one has. That said, we think we have the best solution that attacks sepsis from multiple angles, and a good handle on subgroups where we think we can have a definitive impact. Stay tuned.

Spreading the Word

One of our major goals in 2016 is to continue spreading the word on CytoSorbents as we drive to the inflection point for our business. When we up-listed to the NASDAQ in December of 2014, we did not have the benefit of a national initial public offering roadshow to introduce our company and technology to investors. With the help of a number of different investment banks, we spent a significant amount of time and effort

in the past year in meetings with investors in New York, San Francisco, Los Angeles, Boston, Philadelphia, Chicago, Milwaukee, and Atlanta. The vast majority of investors did not know who we were, but the general responses to our presentations were very positive. We were told that it often takes several quarters for investors to make an investment decision after meeting a company for the first time. We have also met with many new analysts at various micro-cap and mid-tier banks who also have provided us very good feedback on our company. We were selected for the Russell Microcap Index in June 2015, and our institutional ownership has also grown, though still small, with some well-known names now as shareholders. We were recently featured in a video segment on TheStreet.com, and have had numerous mentions in the trade press. Topping off a solid year, we had the honor of [ringing the opening bell at the NASDAQ Stock Market](#) on December 23, 2015 to commemorate the first anniversary of CytoSorbents' listing, a truly energizing and wonderful event. I'd like to share my remarks with you here:

“Good morning everyone. It is certainly a pleasure to be here, not just to ring the opening bell, but to also reunite, during this holiday season, so many of the people, both past and present, who have made today a possibility.

All of us here, as well as those at home who could not be here with us today, share a common vision. That vision is to help those greatest in need with our unique CytoSorb® blood purification technology. In doing so, we look to build CytoSorbents into a respected world leader in the treatment of life-threatening conditions in the intensive care unit as well as during high risk cardiac surgery.

With approximately 60 employees across 2 countries, major strategic partnerships, significant key opinion leader support, and committed business partners worldwide, we are making excellent progress and look forward to a strong year of growth in 2016.

In just a moment, I would like to bring up the entire executive management team who I have the honor and privilege to work with every day, and who have been critical to the success of CytoSorbents so far.

- Vince Capponi – Chief Operating Officer
- Kathy Bloch – Chief Financial Officer
- Dr. Christian Steiner – Vice President of Sales and Marketing, and
- Chris Cramer – Vice President of Business Development.

Together, we have been guiding this company to a bigger and brighter future.

I would also like to thank the guidance of our Board of Directors: Our chairman, Al Kraus, Dr. Ed Jones, Alan Sobel, and Michael Bator, as well as our former Board Director Jim Gunton, and in memoriam, one of our founders and former Directors, Joe Rubin, who I am sure is smiling on us today.

Last but not least, I would like to thank the hard work and dedication of our employees, our respective families whose support means so much, our global partners and advisors, our investors, the many healthcare professionals using CytoSorb® to help critically-ill and cardiac surgery patients all over the world, and finally our patients and their families for putting their trust in us.

So look around you. Be proud of our collective accomplishments. Today is a celebration...of the lives we have saved and the lives we will save in the future together! “

Finally, no matter the size of your investment, we know that it is your hard-earned money on the line. We know that you are putting your faith and trust in us. We know that you share our vision of helping to save lives. We take it very seriously and we thank you for your continued support. Just know that like you, we are all shareholders of this company and have the goal of making this a successful company for all. Best wishes to you and your families for a happy, healthy and prosperous 2016!

Dr. Phillip Chan, MD, PhD
Chief Executive Officer
CytoSorbents Corporation
January 11, 2016

About CytoSorbents Corporation (NASDAQ: CTSO)

CytoSorb® is approved in the European Union with distribution in 32 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. CytoSorb® has been used safely in more than 9,000 human treatments to date.

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