Zacks Small-Cap Research

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Cytosorbents Cp (CTSO-OTCBB)

CTSO: Q2 Results / Operational Plan Moving Forward

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (08/14/12)	$0.14
Target Price	**$0.50**

OUTLOOK

CytoSorbents' novel blood purification technology aims to revolutionize the treatment of life-threatening illnesses in the ICU. Patients with critical care illnesses such as sepsis, trauma, burn injury, acute respiratory distress syndrome and pancreatitis are some of the most seriously-ill and difficult to treat patients in the hospital. Their CytoSorb device was CE Marked in March 2011 and subsequently commenced its initial commercialization. Near-term game-plan is to build awareness to facilitate broader roll-out in Europe. FDA approval is a longer-term goal, the quest for which is now in the planning stage.

As near-term revenue and contracts/grants (including a recently awarded DARPA contract) are not expected to be significant enough to fund operations, CTSO will need to continue to raise capital on an ongoing basis which introduces meaningful risk.

Despite certain risks, we feel the shares trade cheaper than warranted. We are maintaining our Outperform rating and $0.50/share price target.

SUMMARY DATA

52-Week High	**$0.30**
52-Week Low	**$0.07**
One-Year Return (%)	**N/A**
Beta	**0.13**
Average Daily Volume (sh)	**561,258**
Shares Outstanding (mil)	**194**
Market Capitalization ($mil)	**$28**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.0 A	0.0 A	0.0 A	36.1 A	36 A
2012	16.9 A	33.0 A	196.3 E	717.5 E	964 E
2013					5580 E
2014					10800 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-0.01 A	-0.01 A	-0.01 A	-0.01 A	-0.05 A
2012	-0.01 A	-0.01 A	-0.01 E	-0.01 E	-0.04 E
2013					-0.03 E
2014					-0.02 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 Results / DARPA Contract Awarded

CytoSorbents reported results for the second quarter ending June 30, 2012 on August 14th. Financial results as well as the operational update that the company provided were in-line with our expectations. We have made no material changes to our model or outlook for CytoSorbents following Q2 results and are maintaining our Outperform rating and $0.50/share price target.

Q2 revenue came in at $33k (compared to our $19k estimate), representing sales during the initial test market roll-out. Operating expenses were $1.03 million, slightly below our $1.15 million estimate. Net income and EPS were $(1.63) million and $(0.01) compared to our $(2.01) million and $(0.01) estimates. The majority of the difference in net income a result of less than modeled conversion of promissory notes to equity in the quarter (debt discount is immediately amortized to interest expense with conversion).

Cash
Cash used in operations was $1.15 million, roughly flat from the $1.07 million used in Q1. CTSO exited Q2 with $1.74 million in cash and equivalents, slightly down from $1.80 million at the end of Q1. During Q2 CTSO raised $1.1 million from the sale of about 8.9 million shares under the LPC stock purchase agreement.

Operational Update
On the operational side, in late-June CytoSorbents brought on a VP of Sales and Marketing (see our 6/12/2012 Investor Note here… http://bit.ly/OgLWMl) which also marked the official launch of CytoSorb in Germany. CytoSorbents also recently added three additional key sales people. CTSO notes that the sales team has now completed training and commenced calling on their already established network of customer contacts.

Also on the business development side, additional sites have started using CytoSorbents and the company has started to get some outside, unsolicited interest from doctors who've become aware of the device and CTSO's technology. CytoSorbents remains focused on building awareness and expects to attend several industry conferences and events in the coming months. We continue to expect a measured roll-out and incremental building of the sales force with no expectations for significant sales during the current year.

The most recent news came in early August that CTSO was awarded a milestone-based contract from DARPA worth up to $3.8 million over the next five years, including $1.5 million expected during year 1 (we think related revenue could commence as early as Q3). Relative to other grants and contracts, CTSO notes in the Q2 results update that following completion of the Phase I portion of the SBIR grant that they have now submitted for the Phase II grant, which could be worth up to $1 million.

CTSO Scores DARPA Contract (*from our August 6, 2012 Investor Note*)

This morning (8/6/2012) CytoSorbents Corp (CTSO) announced they were awarded a contract from DARPA worth up to $3.8 million over the next five years under the agency's Dialysis-Like Theraputics (DLT) program. As a reminder, CytoSorbents had been in contract negotiations with DARPA for use of the company's technology as part of the U.S. government agency's DLT program to develop a blood purification device in the treatment of sepsis (for reference on the DARPA proposal see our initiation report here http://scr.zacks.com/Theme/Zacks/files/June%205,%202012_CTSO_Initiating%20Coverage_Marckx_v001_d9enrx.pdf). The negotiations centered around the scope of work and contract value. The milestone-based contract is expected to pay $1.5 million in the first year and the remainder over the next four years, assuming all milestones are hit.

As DLT is a collaboration with several different companies and universities being awarded contracts related to the project, CytoSorbents is one piece of this puzzle. CytoSorbents contribution is developing their next-generation porous polymers which have already demonstrated efficacy in removing cytokines from the blood with targeted applications in sepsis as well as a variety of other acute care illnesses. Under the DLT program CytoSorb expects to broaden the scope of targeted substances to include a wide range of toxins in addition to cytokines. In addition, as the DARPA DLT Broad Agency Announcement strongly encourages technologies that do not require anticoagulation, CytoSorbents expects to incorporate that capability into its polymer technology.

We view the DARPA award as a significant positive not only from a near-to-mid term revenue perspective but perhaps more importantly as additional validation of CytoSorbent's technology and expanded opportunity in the commercial marketplace. Advanced development of CytoSorbent's polymer beads under this contract to include the targeting of a wider menu of toxins could potentially expand the targeted applications beyond what is already a very significant potential market for CytoSorbents.

We note that, prior to this morning's announcement, we had incorporated an assumed $2.8 million in total from an expected DARPA contract (which was our best-guess at the time), payable over 12-months beginning in Q4 2012. The potential $3.8 million contract over five years (assumed milestones are met), could provide some slight upside to our model. We now think CTSO could begin generating revenue under the awarded contract in Q3 of this year. CytoSorbents also indicates in the press release that they could be eligible for a separately funded DARPA DLT proposal - which we have yet to model and could provide further revenue upside.

BACKGROUND

CytoSorbents Corporation is a development-stage, critical-care focused medical device company attempting to revolutionize the treatment of life-threatening illnesses in the intensive care unit (ICU) using blood purification. Their goal is to prevent or treat multi-organ organ failure, the leading cause of death in the ICU, with an immunomodulatory approach that removes excessive cytokines, toxins and other inflammatory mediators that can damage vital organs. The approach uses a unique biocompatible porous polymer bead technology to remove a broad range of toxins from the circulatory system and other bodily fluids that cannot be removed by standard hemodialysis or hemofiltration.

In March 2011 CytoSorb, the company's flagship product, achieved CE Mark approval and can now be sold in the European Union as an extracorporeal (i.e. - outside the body) cytokine filter. CytoSorb is designed to treat critical care illnesses where an excessive production of cytokines, or “cytokine storm”, leads to organ failure including in conditions such as sepsis (i.e. - blood poisoning) and infection, trauma, acute respiratory distress syndrome, severe burns, and acute pancreatitis. Following its debut introduction at industry conferences in Europe during Q3 2011, the company began a test-market release of CytoSorb in Germany. The device is being manufactured at the company's ISO 13485-certified facility in New Jersey and is now generating some initial modest revenue in Germany, where it is reimbursed by insurance. CytoSorbents assembled an initial sales team in late Q2 and expects a broader market release in Germany later in 2012. Until then, sales are expected to be nominal as they gear up to implement the bigger launch. The company also expects to pursue distribution partnerships for sale of the device in Germany and other parts of Europe. The initial roll-out will target European countries with favorable market dynamics and insurance reimbursement.

A recently completed small multi-site European clinical trial showed CytoSorb treatment was safe and significantly reduced key cytokine levels in patients with both sepsis and respiratory failure - the company is currently in the manuscript preparation process. The current game plan is to conduct further clinical studies in sepsis and foster investigator-led trials in other critical care diseases where inflammation and organ failure are common themes. The aim is to generate additional clinical data and experience for marketing purposes, to increase the number of treated patients, and to support potential future publications. The company has initiated dosing studies related to longer use of CytoSorb which will generate additional data points and is expected to assist in the design of an optimized pivotal sepsis trial protocol. Assuming availability of adequate and timely funding, and continued positive results from clinical studies, the company intends to continue commercializing CytoSorb in Europe. The company's U.S. development and regulatory approval strategy (which would ultimately require U.S.-based studies) is designed to leverage an already FDA-approved IDE (investigational device exemption) application to run a small sepsis trial in the U.S. but may depend in part on results of the dosing sepsis studies.

CytoSorbents recently completed a Phase I (and submitted for a Phase II grant) Small Business Innovation Research (SBIR) grant from the U.S. Army to develop their technology to help treat trauma patients with rhabdomyolysis, which could also eventually lead to other military projects. In August 2012 CTSO announced that they were awarded a contract from DARPA worth up to $3.8 million over the next five years under the agency's Dialysis-Like Theraputics (DLT) program to use the CytoSorb technology as part of its program to develop a blood purification device in the treatment of sepsis. DARPA’s DLT program plans to develop an easy to use “smart” system to treat septic patients with a blood purification device that can sense cytokines, toxins, pathogens and activated cells in real time, and remove them from the body. We view the DARPA award as a significant positive

not only from a near-to-mid term revenue perspective but perhaps more importantly as additional validation of CytoSorbent's technology and expanded opportunity in the commercial marketplace.

Beyond CytoSorb, the company's R&D efforts include the development of their HemoDefend technology which is focused on removal of contaminants from the blood supply - with the intent of reducing risk of reactions from tainted blood in transfusion patients, to preserve the freshness of new blood, and increase blood shelf life. CytoSorbents is looking to out-license their HemoDefend technology and noted they received encouraging interest following introduction of the platform at the October 2011 American Association of Blood Banks conference.

CytoSorbents is headquartered in Monmouth Junction, N.J. The common stock is quoted on the OTC Bulletin Board under the ticker CTSO. Conversions of preferred stock into common along with multiple rounds of financing to fund operations have resulted in the outstanding share count growing from about 123 million at the end of 2010 to 194 million at the most recently (6/30/2011) reported quarter end - the fully diluted share count is well over double this amount (although on a fully-diluted basis, the market cap is still under $70MM). The company will need to raise additional capital to finance operations and to that end, in December 2011 they signed an agreement with an existing institutional investor to sell to them up to $8.5 million worth of common stock (at prevailing market prices) over the next 32 months. Through Q2 2012, CTSO sold $2.1 million worth of shares under this agreement.

ORGAN FAILURE: *Prevention as opposed to treatment…*

Patients with critical care illnesses such as sepsis, trauma, burn injury, acute respiratory distress syndrome and pancreatitis are some of the most seriously-ill and difficult to treat patients in the hospital. Treatments that exist today are primarily supportive care therapies that help keep the patient alive, but do not actively help patients get better. As an example, in severe lung injury, patients are placed on mechanical ventilation when they can no longer breathe on their own. Mechanical ventilation prevents the patient from dying of lung failure, with the hope that the lungs will eventually heal on their own. Unfortunately, the spontaneous healing process can take weeks, assuming the patient does not die first, and is often plagued by complications such as lung injury caused by the ventilator, hospital-acquired pneumonias and other infections. Another example is severe acute pancreatitis, in which digestive enzymes and caustic fluids from the pancreas leak into the abdominal cavity and blood, causing severe tissue damage, pain, inflammation, swelling and organ failure. This is a life-threatening condition where the only available treatment is pain control, aggressive hydration and organ-support when vital organs fail.

Despite the need for better treatments and the heavy cost to the healthcare system, little has been approved that can improve outcome in these complex diseases. One of the problems is that the attempted treatments have been too targeted. Normally, specific targeting is desirable as it can prevent unwanted adverse events but in these critical care illnesses, where the body’s entire physiology is massively deranged with multiple organ systems affected, targeted therapies are often “too little, too late”. These treatments, which attempt to restore balance, can themselves also be dangerous. Due to the difficulties associated with effectively managing critical care illnesses, the goal should be to prevent organ failure, as opposed to treating it after the fact. Preventing organ failure has proven a significant challenge, however, with few, if any, therapies capable of doing this. CytoSorbents' technology is focused on doing just that (i.e. - preventing organ failure) through the removal of toxins from the blood that are the major causes of organ injury.

The benefits to patient health of removing toxins from the blood and body is already widely known. A simple example is the drainage of pus from an abscess. Pus is a mixture of dead white blood cells, bacteria and inflammatory mediators like cytokines that causes swelling, pain and redness. Physicians have known for a long time that if the pus is drained from the body, the wound will quickly heal and the inflammation will subside. If, however, it is left undrained, the infection, pain and swelling will continue and potentially get worse. Similarly, in critical care illnesses, the levels of inflammation driven by cytokines, toxins and other substances are so severe that if left unchecked, it would lead to widespread cell death, organ failure and ultimately patient instability and death. While hemodialysis and hemofiltration have been used to try and remove these toxins from blood, they have largely proven ineffective due to the inability to remove these larger toxins. Clinical trial data has shown that CytoSorb is one of the first technologies to be capable of reducing many of these toxins, with the goal of preventing the cascade of events that leads to organ failure. CytoSorbents' clinical trial has shown promising data on improving organ function and survival in high-risk, critically ill septic shock and lung failure patients. As a result, CytoSorbents believes their technology has the potential to revolutionize the treatment of critical care illnesses.

PRODUCTS

The heart of CytoSorbents' products are biocompatible, highly porous polymer beads that can remove a wide range of toxic substances from blood and bodily fluids based on pore capture and surface adsorption. Each bead is approximately the size of a grain of salt, has millions of pores and channels that capture substances of a certain size, while excluding others. The uniqueness and competitive advantage of the technology lies in its biocompatibility, ease of modification and ultra-high purity. The technology is covered by 29 issued patents.

CytoSorb

CytoSorb is a CE-mark approved, sorbent-based cytokine filter that targets the treatment of life-threatening illnesses seen commonly in the ICU such as sepsis, acute respiratory distress syndrome, trauma, burn injury, and severe acute pancreatitis. These are diseases with few treatment options, very high mortality (often exceeding 30%), and burdensomely high treatment costs. Hospitals typically spend 15 - 20% of their overall budgets on critical care and routinely are forced to absorb losses estimated in the billions of dollars from very sick patients who exceed their allotted reimbursement. A 2010 study estimated that approximately 0.7% of the U.S. Gross Domestic Product, or approximately $82 billion, was spent on critical care medicine in the U.S. in 2005.

The CytoSorb device consists of a cartridge containing hemocompatible, highly porous, adsorbent polymer beads that are intended to remove toxins and other substances from blood and physiologic fluids. The cartridge incorporates industry standard connectors at either end of the device, which connect directly to an extra-corporeal circuit (bloodlines) on a stand-alone (i.e. not in series with a dialysis cartridge) basis. The extra-corporeal circuit consists of plastic tubing through which the blood flows, the CytoSorb cartridge containing adsorbent polymer beads, pressure monitoring gauges, and a blood pump (i.e. - conventional dialysis machine) to maintain blood flow. The patient's blood is accessed through a catheter inserted into the veins. The catheter is connected to the extra-corporeal 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, recirculating system. As blood passes over the polymer beads in the cartridge, toxins (cytokines) are adsorbed from the blood. Each treatment, which lasts about six hours and processes approximately 20 - 30 blood volumes, uses a new cartridge - representing a recurrent revenue source for CytoSorbents. As CytoSorb runs on existing dialysis machines, there is no upfront capital costs to hospitals and affords CytoSorbents a large target market to sell to.

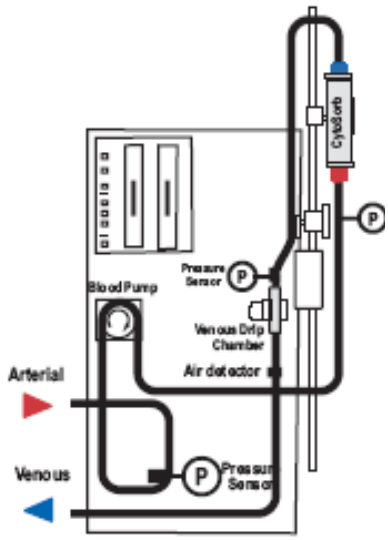
The underlying technology behind CytoSorb is protected by 29 U.S. and foreign patents covering composition of matter, resin characteristics, manufacturing techniques, and methods of clinical application. The oldest of the patents still has six years of patent life remaining.

CytoSorb was CE Marked for sale in Europe in March 2011. The target markets for CytoSorb are in the clinical care settings where cytokines are elevated ("cytokine storm") such as with sepsis, trauma, acute respiratory distress syndrome, severe burns and acute pancreatitis. It also can be used "on-label" in other acute conditions where cytokines are elevated such as in cardiac surgery or autoimmune disease flares. As such, CytoSorb targets a multi-billion dollar total addressable market where very few treatment alternatives exist. The route for U.S. regulatory approval (the initial U.S. target indication would likely be sepsis) would likely be the PMA pathway - which will require the company to conduct U.S.-based clinical trials - the scope, size, duration, cost, etc. of which are unknown but which may become more clear in the coming months. In 2007 the FDA approved an IDE for CytoSorbents to conduct a small U.S. sepsis safety study. Given the positive results of the European sepsis trial and the fact that the European trial incorporated much of the FDA's guidance from the IDE, CytoSorbents now hopes to use their positive European trial data to request an IDE modification to allow for U.S. efficacy-powered studies which would eventually support a PMA filing. CytoSorbents hopes to have the IDE amended for approval of either a large (~ 300 - 500 patients) pivotal study or a more targeted study (~150 patients) stratified for mortality risk factors (such as age and cytokine levels). Assuming positive results, CytoSorbents would then use data from one or more of these studies to support an eventual PMA submission. While a smaller study would incorporate a more narrow indication (e.g. aged 65 and over), it would likely require significantly less time and money to complete than would a larger study with a more diverse patient population. In addition, a more narrow indication would not necessarily meaningfully limit the commercial opportunity in the U.S. as physicians could use the device outside the approved indication (i.e. - off-label) and the vast majority of sepsis patients are 65+ years old and/or have elevated cytokine levels anyway. CytoSorbents hopes to meet with the FDA to discuss a possible modification to their IDE in the near-term (specific timelines have not been announced).

We note, however, that enrollment, completion and data analysis of even a smaller pivotal U.S. trial is not a near-term event and may require many millions of dollars to self-fund (a larger study would be longer and even more

costly). Another possible option that is on the table is to fund this though a co-development agreement with potential strategic partners, which could significantly reduce the amount of outside capital that CytoSorb would need to raise. In the meantime, CytoSorbents expects to focus on the European market, generate additional clinical data from smaller studies (including a confirmatory dosing study), publish existing data from their European sepsis trial, and further investigate (including discussions with the FDA) the requirements to gain U.S. approval of CytoSorb.





SOURCE: CytoSorbents

CytoSorb Reduces Cytokine Storm…

Cytokines are small proteins that, in moderation, normally help stimulate and regulate the immune system. They are secreted by cells and are used extensively in cell-to-cell communications. When the immune system fights pathogens, cytokines not only signal white blood cells to attack the infection, they also stimulate those cells to produce more cytokines. There are two types of cytokines that are produced, pro-inflammatory cytokines (such as tumor necrosis factor-alpha, interleukin-1, and interleukin-6) and anti-inflammatory cytokines (such as interleukin-10 and interleukin-1 receptor antagonist). Under normal circumstances the body regulates this "feedback loop", keeping the production of cytokines and immune cells at a safe level. In some instances, however, the body fails to properly regulate the level of cytokines, resulting in an excess of cytokines and rapid multiplication of immune cells. Elevated levels of cytokines can be harmful - in chronic yet less serious cases (when cytokines are only moderately elevated), this can cause autoimmune disorders such as rheumatoid arthritis. In acute cases where cytokine levels spike as a result of disease or infections, this is called a "cytokine storm". In a more mild form, such as might be experienced with the flu, cytokine storm can result in fever, chills, fatigue, nausea, and body aches. In more severe cases (which is common with intensive care unit patients), cytokine storm can result in very serious and sometimes fatal reactions by the body including blood clotting, shock, lung injury and cell death, leading to multiple organ failure and infection, frequently resulting in patient death.

CytoSorbents has a long-standing collaborative relationship with Dr. John Kellum at the University of Pittsburgh Medical Center who has performed most of the pre-clinical animal work using CytoSorb in animal models of sepsis, demonstrating the ability of CytoSorb to not only reduce cytokines, but to also improve survival in severe infection, without the use of antibiotics. Dr. Kellum is a tenured Professor of Critical Care Medicine and Vice Chair of Research at University of Pittsburgh and its medical center. The University of Pittsburgh is one of the largest critical care programs in the United States and a leader in critical care research. In addition to the known toxic effect of cytokine storm on cells and organs, and the known immunosuppressive effect of cytokine storm that can lead to additional life threatening infections, CytoSorbents cites recent research from Dr. Kellum's lab presented at a recent critical care conference. According to CytoSorbents, these data suggest that;

"Cytokine storm may have yet another major detrimental role in sepsis. Cytokines are normally produced in the area of infection and help direct activated white blood cells (a patient's 'soldiers against infection') to the infected site. During sepsis, however, the levels of cytokines are very high throughout the body, often causing these white cells to inadvertantly invade and attack 'innocent bystander' organs, leading to latent organ injury. When CytoSorb is used to treat these animals, this 'immune confusion' resolves, and many more white blood cells go to the true site of infection, killing more bacteria, while fewer cells go to non-infected organs like the lung, leading to less organ injury."

CytoSorbents' European Sepsis Trial showed that CytoSorb significantly reduced cytokines in patients with severe sepsis or septic shock in the setting of lung injury. The purpose of the trial, which was performed at 14 sites in Germany, was to demonstrate safety and statistically significant reduction of key cytokines such as interleukin-6 (IL-6) in patients with sepsis and respiratory failure. A secondary endpoint was reduction in mortality. Targeted enrollment was 100 patients, randomized to either treatment with CytoSorb for seven days plus standard of care (SOC) or only SOC (control). SOC included antibiotics, fluids, mechanical ventilation and other usual therapy consistent with the typical treatment of sepsis.

Taking into account all 100 patients, the treatment was well-tolerated with no serious device related adverse events reported in more than 300 human treatments in the trial. This is consistent with all studies to-date, which have shown no serious device-related adverse events in over 650 human treatments. Of the 100 patients enrolled, 4 ultimately withdrew, 22 were part of a sepsis pilot study, and 31 were used only for safety data due to a failure of the protocol for randomized enrollment at two trial sites that introduced bias into the trial and made the control and treatment arms not comparable. Safety and efficacy data were collected and analyzed on the remaining 43 patients (18 in treatment cohort, 25 control), most of which suffered from multiple organ failure. Of these patients, septic shock was present in 94% of treatment and 100% of control, acute respiratory distress syndrome in 67% of treatment and 56% of control, and renal failure in 39% of treatment and 24% of control. The 43-patient analysis showed CytoSorb statistically significantly ($p<0.05$) reduced circulating levels of key cytokines from whole blood on the average of 30%-50% over the 7 day treatment period. Specifically CytoSorb statistically significantly reduced the following cytokines; IL-6 by 49% ($p=0.01$), IL-1ra by 37% ($p=0.001$), MCP-1 by 50% ($p=0.002$), and IL-8 by 30% ($p=0.002$).

Additionally, an analysis of two subgroups of patients that were classified as being at high risk of death, specifically in patients with very high cytokine levels (IL-6 ≥ 1,000 pg/mL and/or IL-1ra ≥ 16,000 pg/mL) and patients aged 65 and over, was done which showed a statistically significantly reduction in mortality in CytoSorb treated patients. In the high cytokine level group, 28-day mortality (28 days is widely accepted as the standard time mortality endpoint in sepsis studies) was 0% in the CytoSorb cohort versus 63% in the control cohort (statistically significant $p=0.03$, $n=14$: 6 treatment / 8 control). It also showed a trend (i.e. - potentially meaningful but not statistically significant) to benefit in fewer patients on mechanical ventilation at 28 days (33% treatment vs. 88% control) and fewer days in the ICU (24 days treatment vs. 28 days control). In the 65 and over group, 14-day mortality was 0% in the CytoSorb cohort versus 36% in the control cohort (statistically significant $p=0.04$, $n=21$: 10 treatment / 11 control) suggesting a potential protective effect with treatment. With only 7 days of treatment, the mortality benefit in this 65+ year-old subgroup was not significantly different at 28 days (40% treatment vs. 45% control), though trends to benefit were observed with fewer mechanically ventilated patients at 28 days (60% treatment vs. 73% control), and improvements in the MODS organ failure scores during treatment. CytoSorbents noted that although the trial protocol did not allow CytoSorb therapy beyond the 7-day treatment period, the company and its scientific advisors believe that a longer duration of treatment may have yielded even greater benefit.

Relative to the subgroup analysis, as we noted earlier, in lieu of a larger, more expensive U.S. clinical study which might encompass a relatively diverse patient population, CytoSorbents may look to focus their efforts for U.S. regulatory approval on a more high-risk patient segment, such as 65+ years-old (this will likely be part of the near-term discussions with FDA related to modification of the IDE). Per the Centers for Disease Control and Prevention (CDC), patients 65 and older account for approximately two-thirds of all sepsis-related hospitalizations - which means a more narrow focus on high-risk patients (such as 65+ years old) may not substantially reduce the overall commercial opportunity for CytoSorb.

Sepsis: Highly Lethal and Difficult/Costly To Treat…

Sepsis, more commonly known as blood poisoning and one of the top 10 causes of death, is initially caused by a serious infection such as pneumonia or a urinary tract infection. However, it often triggers a massive cytokine-driven immune response, leading to severe inflammation throughout the entire body. The initial onset of fever, chills, fatigue, pain and nausea drive patients to seek medical care. Worsening cytokine storm can lead to more serious complications that need to be managed in the ICU such as cell death, circulatory collapse, organ failure, immune suppression and additional infections, loss of limbs, and frequently death.

Sepsis is aggressive and difficult to treat. Today, standard of care therapy focuses on trying to kill the causative organism (bacteria, virus, fungi) with antibiotics or anti-viral therapy. Additional therapy in the ICU includes supportive measures such as providing fluid support, nutrition, tight metabolic control, drugs to increase the blood pressure, and mechanical support such as mechanical ventilation and dialysis. Treatment often fails, however, as evidenced by the 30%+ sepsis-related mortality rate.

The problem is that while there are broad-spectrum antibiotics to treat the infection, there are currently no effective therapies to treat the out-of-control immune response and the production of cytokines and other toxins that are ultimately responsible for killing the patient via multiple organ failure and additional infections. CytoSorb is trying to address this problem with a broad spectrum cytokine filter that is designed to modulate the immune response - preventing or reducing the development of organ failure, and helping the immune system function properly so that it can fight infection and not damage the body.

In the U.S. and Europe, there are more than 1 million and 1.5 million new cases, respectively, of severe sepsis and septic shock annually - worldwide there are about 18 million cases per year. In Germany, CytoSorbents' initial geographic market with CytoSorb, there are approximately 150k cases of sepsis each year. CytoSorbents' value-added proposition for its device in the sepsis application is its effectiveness coupled with lower cost of treatment relative to existing therapy, which can be substantial. Relative to the burden and cost to treat sepsis, CytoSorbents notes that on average; sepsis patients are treated in the intensive care unit (ICU) for 16 days and for a total of 25 days in the hospital, treatment cost per day in ICU is ~$2k - $3k/patient (in both U.S. and Europe), total hospital cost is ~$50k/patient, overall cost of sepsis in the U.S. is ~$18 billion/year and in Germany is ~$6 billion/year (where it also accounts for ~1/3 of the total ICU budget).

Based on current reimbursement, CytoSorbents expects to sell their device for at least $500 per cartridge. With each treatment requiring a new cartridge and approximately seven treatments expected per patient for sepsis, CytoSorbents estimates the combined European and U.S sepsis opportunity at around $9 billion (~$3,500 per patient treatment x ~2.5 million patients). In Germany, with about 150k sepsis cases annually, the total addressable market opportunity is estimated to be roughly $500+ million (~$3,500 x 150k patients).

While CytoSorbents' trial focused on sepsis and lung injury, the company's cytokine reduction approach is designed to more broadly address the Systemic Inflammatory Response Syndrome (SIRS), a serious condition related to systemic inflammation, organ dysfunction, and organ failure. The company conducted its first major CytoSorb trial in sepsis and lung injury, both critical areas known to have high cytokine levels in need of modulation. CytoSorbents intends to continue research in other critical care applications that may benefit from this immuno-modulatory approach such as acute respiratory distress syndrome, trauma, burn injury, severe acute pancreatitis and autoimmune disease flares - which, the company notes, could increase the total addressable market in the U.S. and Europe to approximately $15 billion. CytoSorbents believes that CytoSorb could also be used in cardiac procedures where cardiopulmonary bypass (a machine used to bypass the heart and lungs that oxygenates and pumps blood to the rest of the body) is used, such as in coronary artery bypass graft (CABG) surgery for coronary artery disease, heart and lung transplant, left-ventricular assist device (LVAD) implantation, valve surgery, and others. Cardiopulmonary bypass is a well-known activator of excessive cytokine production that can lead to organ dysfunction or failure after the procedure. There are approximately 1 million cardiopulmonary bypass procedures done in the U.S. and Europe each year. CytoSorbents views this as a potential near-term opportunity and believes CytoSorb could offer a superior, simpler and more direct alternative to the conventional use of leukoreduction filters during cardiopulmonary bypass procedures which have shown to be ineffective in reducing cytokines.

Sepsis-Related Contracts / Grants…

Over the past decade CytoSorbents has been a recipient or participated in multiple grants related to the development of technology for the treatment of critical illnesses and sepsis.

- Sub-Award Under NIH and HHS Grants: Two government research grants by the National Institutes of Health (NIH) and Health and Human Services (HHS) were awarded to investigators at the University of Pittsburgh to explore the use of adsorbent polymers in the treatment of sepsis and organ transplant preservation. The University of Pittsburgh provided CytoSorbents "SubAwards" under these grants to develop polymers for use in these studies.

  In 2003 the University of Pittsburgh Medical Center was awarded a grant of $1 million for a project related to improving the quantity and viability of organs donated for transplant by using CytoSorb to detoxify the donor's blood (detailed below). Then in 2005 the University of Pittsburgh Medical Center was awarded a grant of approximately $7 million from NIH entitled "Systems Engineering of a Pheresis Intervention for Sepsis (SEPsIS)" to study the use of adsorbent polymer technology in the treatment of severe sepsis - CytoSorbents developed and provided polymers under a SubAward for this grant as well. CytoSorbents believes that the only polymers used in this study were polymers that they developed specifically for use in the study, which are similar to the polymers used in their current devices. CytoSorbents received approximately $402k under this SubAward from 2006 through 2010 (accounted for as an offset to R&D in the income statement).

- QTDP Grant: In October 2010 CytoSorbents was awarded a grant of approximately $489k from the federal Qualifying Therapeutic Discovery Project (QTDP) program for two products in its pipeline including the development of CytoSorb for the treatment of sepsis and other critical care illnesses. In this program, the Department of Health and Human Services (which governs Medicare/Medicaid, the FDA, the NIH, and the Centers of Disease Control and Prevention) judged grant applications based on the potential of the technology to impact a major unmet medical need and to reduce healthcare costs.

- U.S. Army SBIR Trauma Grants: In December 2011, the U.S. Army Medical Research and Materiel Command awarded CytoSorbents a Phase I Small Business Innovation Research (SBIR) grant entitled "Investigation of CytoSorb cytokine and myoglobin removal in the treatment of trauma" valued at $100,000 over six months. CTSO received $83k from this contract (accounted for as a reduction to R&D expense) through the 6 months ending 6/30/12. CTSO has since completed the Phase I portion (i.e. - planning phase) and submitted for the Phase II portion. The Phase II portion is worth up to $1M and will include animal studies. A Phase III grant could follow which would entail human studies. This program is intended to yield animal and human data that can be used to treat trauma patients in the future. This directly addresses the major reasons why warfighters dies - sepsis and infection, polytrauma, and burn injury - which could potentially open the door to other military funding programs if successful.

- DARPA Dialysis Like Therapeutics Program: The Defense Advanced Research Project Agency (DARPA) is part of the U.S. Defense Department which is responsible for funding "radical innovations" such as the internet, global positioning system (GPS) technology, and robotic surgery. In early 2011 DARPA issued a Broad Agency Announcement soliciting innovative research proposals under a program titled "*Dialysis-Like Therapeutics* (DLT)" to manage sepsis. CytoSorbents applied and in August 2012 the company announced that it was awarded a milestone-based contract worth up to $3.8 million (also assumes all milestones are met) over five years, including $1.5 million in the first year. As DLT is a collaboration with several different companies and universities being awarded contracts related to the project, CytoSorbents' technology is one piece of this puzzle.

  Per DARPA's 2/8/2011 Broad Agency Announcement describing the funding opportunity for the DLT program; "The goal of the DLT program is to develop a portable device that removes "dirty" blood from the body, separates harmful agents, and returns "clean" blood to the body in a manner similar to dialysis treatment of kidney failure. While the device could have an impact across multiple areas of medicine, the target application for this device is sepsis. The envisioned device will persistently interrogate the entire blood volume, providing early identification of the presence of a pathogen. Once the presence of pathogens has been confirmed, the DLT device will provide continuous "label-free" removal of pathogens, toxins and activated patient cells without pathogen identification or use of pathogen-specific binding chemistries. As a final step in the treatment process, the DLT device will enable closed-loop therapy based on continuous, reduced dimensionality modeling of patient health. Predictive modeling in this fashion will allow us to identify sepsis early, learn what we need to remove, and direct the most effective intervention to improve patient health. This cycle of sensing, adjustment, estimation, computation, and manipulation will modulate key health parameters faster than the underlying disease process and drive the patient towards a stable, healthy state.

  The envisioned device will be capable of removing at least 90% of unknown pathogens, toxins, and activated cells from a patient in one day. *In vivo* experiments in a clinically relevant animal model will validate the device for use in sepsis. At the completion of the program the device will be ready for transition to military medical commands and industry as well as clinical trials required for regulatory approval."

CytoSorbents contribution to the DLT program is developing their next-generation porous polymers and the company expects to broaden the scope of targeted substances to include a wide range of toxins in addition to cytokines. In addition, as the DARPA DLT Broad Agency Announcement strongly encourages technologies that do not require anticoagulation, CytoSorbents expects to incorporate that capability into its polymer technology.

We view the DARPA award as a significant positive not only from a near-to-mid term revenue perspective but perhaps more importantly as additional validation of CytoSorbent's technology and expanded opportunity in the

commercial marketplace. Advanced development of CytoSorbent's polymer beads under this contract to include the targeting of a wider menu of toxins could potentially expand the targeted applications beyond what is already a very significant potential market for CytoSorbents.

We think CTSO could begin generating revenue under the awarded contract in Q3 of this year. CytoSorbents also indicates in their August press release announcing the award that they could be eligible for a separately funded DARPA DLT proposal - which we have yet to model and could provide some revenue upside to our current revenue estimates.

Other Critical-Care Applications…

While sepsis has been the major targeted focus in CytoSorb's clinical trials to-date, the device may have utility in a variety of critical care applications where elevated cytokine levels can compromise patient health and lead to serious complications such as Multiple Organ Dysfunction Syndrome (MODS) and/or Multiple Organ Failure (MOF). Specifically, CytoSorbents points to patients with acute respiratory distress syndrome, severe burn injury, trauma, and pancreatitis as all potentially benefiting from treatment with their device (in fact most patients in the European Sepsis trial suffered from acute respiratory distress syndrome). CytoSorbents estimates that the combined U.S./Europe market opportunity for their device in all other critical care applications outside of sepsis is approximately $15 billion, including ~$900 million in Germany. Relative to these applications, CytoSorb hopes to pursue investigator-initiated studies - in both animals and human pilot studies - funding of which may be pursued solely by CytoSorbents, through grants, partnerships, or a combination of one or more of these. Meanwhile, CE Mark allows CytoSorb to be used in Europe in any application where cytokines are elevated.

The company is also investigating the use of CytoSorb in the prevention and treatment of post-operative complications of cardiopulmonary bypass surgery with the objective to reduce ventilator and oxygen therapy requirements and reduce post-surgical complications and costs. CytoSorbents previously commissioned the University of Pittsburgh to conduct a study to characterize the production of cytokines as a function of the surgical timeline for cardiopulmonary bypass surgery. An observational study of 32 patients was completed, and information was obtained with respect to the onset and duration of cytokine release. The company expects this information to aid them in defining the appropriate time to apply the CytoSorb device to maximize therapeutic impact.

Prevention and treatment of organ dysfunction in brain-dead organ donors is another area that CytoSorb may hold promise - although this is not a near-term focus for the company. The goal is to increase the number and quality of viable organs harvested from donors. If CytoSorb is able to prevent or reduce high-levels of cytokines from accumulating in the bloodstream of brain-dead organ donors, the company believes CytoSorb may be able to prevent cytokine-mediated organ damage, which results from severe inflammation following brain-death. A recent study at University of Washington using surgically-induced brain dead pigs demonstrated the ability of CytoSorb to reduce cytokine storm and prevent a loss of cardiac function otherwise seen in the control animals. The primary goals for this application are to improve the viability of organs that can be harvested from brain-dead organ donors, and increasing the likelihood of organ survival following transplant. Studies have been conducted under a $1 million grant from the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services. Researchers at the University of Pittsburgh Medical Center and the University of Texas, Houston Medical Center have completed the observational and dosing phases of the project. The results were published in Critical Care Medicine, January 2008. The next phase of this study, the treatment phase, would involve viable donors treated with the CytoSorb device. In this phase of the project, viable donors will be treated and the survival and function of organs in transplant recipients will be tracked and measured. The treatment phase would be contingent upon further discussion with the FDA and HRSA regarding study design, as well as obtaining additional funding.

Commercialization Strategy For CytoSorb…

CytoSorbents plans to sell direct in Germany with its own sales force and to then expand into other EU countries via independent distributors or strategic partners. The first commercial introduction of CytoSorb to the European market kicked off with its debut at the 2011 German Sepsis Society Conference in September 2011 with subsequent exhibitions at five additional critical care conferences to build greater awareness of the product, including hosting a research symposium at the well-known Symposium of Intensive Medicine and Intensive Care in Brussels, Belgium this past March.

In September 2011 the company began a "controlled market release of CytoSorb in select territories in Germany". This involved assembling the pieces of its initial introduction including a focus on; manufacturing, reimbursement, establishing a sales presence, financing, refining its messaging, increasing market awareness, establishing relationships with key opinion leaders, rebuilding its web presence, opening discussions with distributors and building its internal infrastructure. The company also generated some early revenue, helping transition itself from

what was an R&D company to now an early commercialization company. In early 2012, CytoSorbents opened its subsidiary in Berlin to manage European sales and distribution and obtained its registered trademark for CytoSorb in the US and EU. Then in June 2012 CTSO hired a VP of Sales and Marketing (see our 6/20/12 Investor Note here…http://bit.ly/OgLWMl), marking the official launch of CytoSorb in Germany and brought on additional key sales people. This initial sales team has now completed training and commenced calling on their already established network of customer contacts. We continue to expect a measured roll-out and incremental building of the sales force with no expectations for significant sales during the current year. Key points of the company's commercialization strategy in Germany and other areas include:

- **German Market**: Germany is the largest medical device market in Europe and the third largest in the world
- **Reimbursement:** Germany is particularly attractive as specific reimbursement has now been established for CytoSorb at more than $500 per device. This is in addition to standard DRG reimbursement. Currently, in other areas of Europe (as well as in the U.S.), there is no specific product reimbursement which means the cost of CytoSorb would be borne by the hospital. This could be an economic dis-incentive for the hospital unless the cost of CytoSorb is more than offset by reduced days in the ICU or hospital. Assuming success in Germany, CytoSorbents expects to apply for similar specific reimbursement in other countries in Europe including France, England, Italy and Spain.
- **Sales / Distribution:** CytoSorbents recently established a wholly-owned subsidiary, CytoSorbents Europe GmbH, with offices in Berlin, Germany to manage distribution, sales and marketing, and customer support for CytoSorb throughout Germany and later to other E.U. countries. To facilitate the roll-out in Europe, the company has been working on building awareness of CytoSorb through participation at industry conferences which, according to CytoSorb, has garnered interest from nearly twenty hospitals in Germany and another ~10 in other countries which have indicated interest in either evaluating CytoSorb or initiating investigator-led studies. CTSO notes in their Q2 earnings update that they will continue to get in front of industry experts and investors to build awareness and expects to attend 7 (additional) major conferences before year-end 2012. CytoSorbents brought on a highly experienced VP of Sales and Marketing and a handful of other key sales people since late Q2 to sell direct to the German market and is in discussions with distributors and potential partners to target other E.U. countries. Germany has ~2,100 hospitals - the initial focus is expected to be on the ~400 largest. Depending on the success in Germany and with gaining specific product reimbursement in other parts of Europe, the sales effort is expected to expand to other European countries. During the early commercialization the company's focus will be on early adopters of new medical technologies, generation of additional clinical study data for marketing purposes, and publications coming out on the sepsis study.
- **Manufacturing:** CytoSorbents is a vertically integrated manufacturer of CytoSorb. At its ISO 13485 certified manufacturing facility in New Jersey, the company manufactures and purifies its own polymer beads, assembles and packs each cartridge and performs all of the necessary quality control. The beads meet ISO 10993 biocompatibility testing and the product is very stable and easily sterilized, with a 3 year shelf-life at room temperature. Costs are expected to be driven down with increases in manufacturing volume and the company expects to eventually approach 80+% gross margins with greater economies of scale.
- **Marketed Application:** CE Mark allows CytoSorb to be marketed for and used in Europe in any application where cytokines are elevated. While sepsis was the specific focus of the multi-site European trial, CytoSorbents expects the device to be used for a variety of critical care applications such as acute respiratory distress syndrome and trauma as well as potentially intra-operatively to prevent complications associated with cardiopulmonary bypass surgery.
- **U.S. Strategy:** As the specific regulatory pathway and chances/timing of eventual FDA approval is still substantially uncertain at this point, so is the commercialization strategy for the U.S. market. With that in mind, the current near-term plan involves meeting with the FDA and, with the recent European Sepsis trial data in hand, requesting modification to its existing FDA-approved IDE to initiate pivotal U.S. studies. The outcome of the discussions will be a highly anticipated event. We see the best-case scenario as the FDA approving sepsis studies in targeted high-risk patients - assuming the modified IDE to initiate these studies is approved and CytoSorbents can begin enrollment by 2013, it's possible that the studies and data analysis could be completed by 2015. Assuming a PMA filing happens in 2015, it's possible FDA approval with fast-track evaluation (sepsis represents a major unmet medical need) and U.S. launch could occur by late-2015 to early-2016. This timeline, however, assumes no significant delays. It also assumes that the FDA does not require a larger, more diverse patient population for clinical trials, which might add another year or more to this estimated timeline (launch ~late-2016/early-2017?).

If and when CytoSorb does launch in the U.S., specific reimbursement may or may not be available - as it is currently, reimbursement is not available - if reimbursement is not available in the U.S. by the time CytoSorb reaches the domestic market, that would likely significantly impair demand for the device, at least initially anyway (unless CytoSorb can reduce ICU stay or other economic factors that allow it to "pay for itself" while improving outcomes). However, assuming the trial data shows good efficacy and safety, that would be an obvious positive in the eyes of third-party payers. Similarly, the ability to reduce healthcare costs could be very persuasive, especially to CMS (which makes coverage decisions for Medicare) given the recent federal legislation which encourages more efficient and less-costly procedures and services.

HemoDefend

HemoDefend, with expected applications in purification of blood used for transfusions, uses a new optimized version of CytoSorbents' polymer technology designed to capture contaminants in blood that can cause adverse events and transfusion reactions. Blood can become contaminated either from the donor or during storage as the blood ages. HemoDefend is designed to safeguard the quality and safety of the blood supply by removing contaminants such as antibodies, free hemoglobin, cytokines, and bioactive lipids in whole blood, packed red blood cells, and platelets that can cause transfusion reactions such as life-threatening Transfusion Related Acute Lung Injury (TRALI) and lethal allergic reactions. The technology uses a mixture of different beads and can be tailored to remove specific substances of interest.

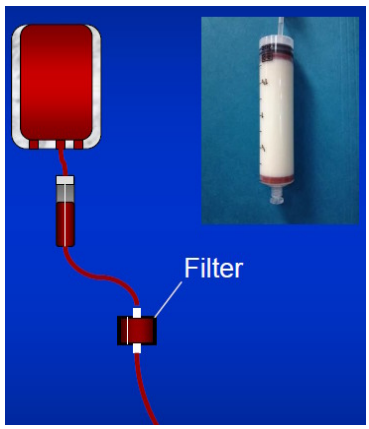
According to the World Health Organization (WHO), there are more than 80 million blood donations each year worldwide with each donation generating multiple blood transfusion products such as packed red blood cells (pRBCs), platelets, fresh frozen plasma, and cryoprecipitate. Every year there is an estimated 150 - 200 million transfusions administered worldwide with, according to the American Red Cross, more than 30 million in the U.S. alone. CytoSorbents' target market for the technology are pRBCs, platelets, and whole blood, which represent more than half of all blood transfusions annually. HemoDefend can be configured either as an in-line filter design or what the company has termed "Beads in a Bag".

With "**Beads in a Bag**" (currently CytoSorbents' main focus with HemoDefend) the beads are placed directly into a blood storage bag during bag manufacturing and blood or separated blood components are then later added to the bag. Purification begins instantly and continues throughout the duration of storage, maximizing removal efficiency. The beads are neutrally buoyant, eliminating the need for mixing and simplifying the purification process. An integrated filter in the bag prevents beads from leaving the bag during the transfusion process. The polymer beads meet ISO 10993 standards for biocompatibility, hemocompatibility, genotoxicity, cytotoxicity, acute sensitivity and complement activation and can therefore directly contact blood for extended periods of time. In addition, the beads are inert and stable at a wide range of temperatures, and do not contain any antibodies, recombinant proteins, ligands, or drugs. Because of this, they have a very long shelf life that is consistent with blood storage bag manufacturing standards. No special equipment or handling is required, making it ideal for mainstream and military applications, as well as for use in less developed countries.

"Beads in a Bag"



In-Line Filter Configuration



SOURCE: CytoSorbents

Applicability in Transfusions…
CytoSorbents cites the occurrence of potentially lethal adverse reactions during blood transfusions as a clear unmet need for a technology that can effectively remove toxins from the blood prior to transfusion. The incidence of transfusion reactions is roughly 3 - 5%, ranging from mild fever and itching, to potentially life-threatening reactions such as TRALI and anaphylaxis. Specifically, CytoSorbents notes that HemoDefend may be effective against preventing TRALI, which is associated with the transfusion of donor antibodies to the recipient and can result in the rapid development of acute respiratory distress. TRALI is one of the most serious transfusion-related reactions, occurring in about 1 in every 2k - 5k transfusions and with a mortality rate of about 10%.

Applicability in Blood Freshness…
CytoSorbents believes that HemoDefend may also have applicability in preserving the shelf-life of blood and in reducing potential toxicity of older blood. They cite a growing number of studies that have suggested administration of aged blood can lead to adverse outcomes, including increased mortality. Older blood accumulates many substances during storage such as free hemoglobin, bioactive lipids, cytokines, and others that can increase the risk of problems - HemoDefend could potentially be used to remove these substances and reduce the risk of adverse reactions.

About one-half of all transfusions use "packed red blood cells" (pRBC) - the refrigerated shelf-life of which is up to 42 days. There is some debate, however, about whether the use of older blood can increase the risk of transfusion reactions - a number of studies have indicated that this is the case. Two currently ongoing pivotal studies (RECESS in the U.S. and ABLE in Canada) are also attempting to determine whether aged blood may potentially be more toxic. CytoSorbents believes that if these studies do indeed indicate that older blood is associated with an increase in patient adverse events, that this could provide significant demand for HemoDefend (assuming eventual regulatory approval).

CytoSorbents is looking to out-license their HemoDefend technology and introduced the platform at the October 2011 American Association of Blood Banks conference. CytoSorbents noted that during the conference there was meaningful interest in HemoDefend and that they received a lot of positive feedback from transfusion medicine specialists and potential collaborators and strategic partners. Specifically, CytoSorbents' January 2011 shareholder letter notes that the "Beads in a Bag" configuration *"drew much praise, as no one thought this approach could be possible, and that it enabled blood purification during the storage period in an easy to use manner without the need for any other handling or equipment. Many people were impressed that, in contrast to filter technologies, we could easily add further functionality to the HemoDefend platform by simply adding new beads optimized to remove something new to the bead mixture. Several commented that our technology was one of the few truly innovative technologies that they have seen in a long time. For potential partners, the idea of converting a commodity, low margin blood storage bag into a higher margin blood treatment system seemed to resonate with them. However, they also liked the flexibility to be able to use the beads in an in-line filter system as well, which is an additional configuration option of our HemoDefend beads. Given that our goal is to out-license this technology, we are pleased with the ongoing discussions and continued interest we have been receiving."*

With development of HemoDefend still at a very early point and little visibility relative to the development and regulatory approval strategy or chances of (eventual) commercialization (as well as the commercial opportunity for the product), we do not currently incorporate any contribution from the technology in our model. If and when there is substantially more visibility and a reasonable chance of eventual commercialization or out-licensing revenue, we will update our model for HemoDefend accordingly.

BetaSorb

BetaSorb was the company's initial hemoperfusion device and was designed to improve the removal of mid-sized toxins from blood during dialysis in patients with end-stage renal disease (ESRD), or more commonly known as chronic kidney disease (CKD). BetaSorb is physically and largely functionally similar to CytoSorb but the two devices use different polymers and differ in their targeted uses - BetaSorb was developed for chronic use while CytoSorb targets acute care usage in the intensive care unit. BetaSorb is intended to be used in series with a dialysis cartridge, while CytoSorb can be used as a stand-alone device, or in series with a dialysis cartridge if the patient has kidney injury. Both are used with standard hemodialysis machines found in hospitals today.

BetaSorb was developed to remove β2 microglobulin (B2M) from the blood of chronic kidney failure patients who are on long-term dialysis. In people undergoing long-term dialysis, B2M can aggregate into fibrous proteins called amyloid fibers which can deposit in the joints (a disease known as "dialysis-related amyloidosis" or DRA), resulting in pain/stiffness and even bone fractures, eventually leading to disabling musculoskeletal complications. Actual prevalence of DRA is not known, although past studies (done prior to high-flux dialyzers becoming commonplace) have indicated that incidence is roughly 20% of patients that have been on dialysis after 2 to 4 years and at least 95% of patients that have been on dialysis for more than 15 years. High-flux dialyzers, which have larger pore sizes and do a better (but still inadequate) job of removing larger molecules (compared to standard dialyzers), have since become more commonplace. As a result, the incidence of DRA may now be lower than these past studies suggest, although DRA remains a significant issue with patients on long-term dialysis. According to the U.S. National Kidney Foundation there are over 340k Americans with chronic kidney disease on dialysis. As the incidence of DRA is largely unknown, it's difficult to peg the size of BetaSorb's potential market (assuming it gets to market) - a rough guess is the U.S. market would be in the range of 60k - 100k people.

BetaSorb was used safely in four human pilot studies in the U.S. and Europe involving a total of 20 patients with chronic kidney failure and demonstrated the efficient removal of B2M. The studies included approximately 345 treatments (~ 4-hours/each) with some patients using BetaSorb for up to 24 weeks (treatments 3x/week). In 2000, Fresenius Medical Care signed an exclusive agreement for the global marketing and distribution of BetaSorb with CytoSorbents that technically still remains in effect. However, given the anticipated complexity and length of regulatory approval needed to demonstrate benefit in ESRD, along with business considerations such as pricing, volume, and reimbursement, CytoSorbents shifted its focus to the higher potential critical care arena with the development of CytoSorb. One of the hurdles for BetaSorb is that recurrent (i.e. - chronic) use can result in the removal of essential substances from the blood - most notably albumin. CytoSorbents has since improved on the technology and developed newer generations of BetaSorb that are specifically designed for chronic treatment (although further optimization will be necessary). These new polymers are able to more selectively remove B2M while limiting albumin loss. Further clinical development of BetaSorb has been on hold in favor of developing CytoSorb for critical care applications.

We currently do not include any contribution from BetaSorb in our model as there are a number of unknowns relative to further development, regulatory approval strategy, and the commercial opportunity for the device - the most glaring unknown right now is the approvability of the device. Another potentially limiting factor is the relatively small size of the DRA market - which we estimate (roughly) at about 80k people in the U.S. and roughly a similar number in Europe. Although anticipated use of BetaSorb would be 3 times per week for life in this patient population, compared to the 2 million - 3 million patients in the sepsis and other critical care markets (i.e. - CytoSorb's market) in the U.S. and Europe combined, DRA seems like a significantly less attractive patient segment.

Relative to the company's plans for future development of BetaSorb, CytoSorbents notes in their most recent 10-K (ending 12/31/2011) that, "*We currently intend to pursue our BetaSorb product after the commercialization of the CytoSorb product. At such time as we determine to proceed with our proposed BetaSorb product, if ever, we will need to conduct additional clinical studies using the BetaSorb device and obtain separate regulatory approval in Europe and/or the United States*."

FINANCIAL POSITION / SHARE COUNT

Cash

As of their most recent reporting period (ending 6/30/2012) the company had $1.74 million in cash and equivalents. Cash used in operations was approximately $1.15 million in the three months ending 6/30/2012. CapEx has been immaterial.

During Q2 2012 CytoSorbents raised approximately $1.1 million from the sale of 8.9 million common shares under the LPC stock purchase agreement (explained below). The $1.74 million cash balance at the end of Q2 represented approximately 5 months worth of operating funds. However, operating cash needs will likely materially increase as a result of continuing CytoSorb studies and pre-launch, launch, and ongoing sales and marketing activities (i.e. - inventory build, sales team expenses, etc.) of CytoSorb in Europe. Some of this near-term cash draw may be offset by incremental sales of CytoSorb in Europe and future grant payments (i.e. - SBIR Phase II, DARPA).

U.S. clinical trials for CytoSorbents, if and when they commence, will also require substantial cash resources - the extent of which will be at least in part determined by scope and size of the trials (i.e. - smaller trials with targeted, high risk patients or larger trials, with more diverse patient population). At the minimum, we ballpark CytoSorb U.S. trials and related regulatory activities will require $5 million - and substantially more if a 400 - 500 patient study is required. In lieu, or in addition to, funding these studies themselves CytoSorbents may potentially score additional government grants and/or look for a partnership (although we have no insight into any developments towards these ends). We note, however, that the lack of an answer on how to fund these prospective trials is not a near-term concern from a liquidity standpoint and places no incremental stress on the balance sheet. As it is now (which is subject to change), our financial model incorporates the assumption that CytoSorbents funds ongoing operations including U.S. clinical trials (which we assume requires ~$5MM to fund) of CytoSorb with regular sales of common stock - we will update this assumption, along with the other elements of our model depending on news flow and how the future unfolds.

Stock Purchase Agreement
To help fund the European launch and ongoing operations, in December 2011 CytoSorbents signed a stock purchase agreement with an existing institutional investor (Lincoln Park Capital Fund or LPC) which allows the company to sell to the investor up to $8.5 million worth of stock over a 32-month period. CTSO filed an S-1 covering the sale of 39.6 million shares (including 38 million purchase shares) related to this LPC agreement. The timing and quantity of stock purchased is at CytoSorbents' option. The purchase price of the shares related to the agreement will be based on the prevailing market prices of the company's shares at the time of sale without any fixed discount. LPC shall not have the right or the obligation to purchase any shares of CytoSorbents' common stock on any business day that the price of the stock is below $0.10/share (i.e. - the "floor price"). Through Q2 2012, CTSO sold $2.1 million worth of shares under this agreement at an average price of approximately $0.13/share.

While this stock purchase agreement materially reduces any near-term liquidity concerns, it will also likely significantly increase the outstanding share count. If, for example, the average sale per share is made at $0.25 (completely hypothetical) and the entire $8.5 million is sold at this price, this equates to 34 million in additional shares. At the end of Q2 2012 there were approximately 194 million shares outstanding. U.S. clinical studies, assuming CytoSorbents would fund them themselves, would require the company to raise significantly more capital.

Debt
Debt at 6/30/2012 consisted of $1.45 million of principal value of 8% promissory notes due within one year. Terms of the notes call for principal and interest to be repaid in common stock, not cash. Principal is convertible at any time at the option of the holder at $0.10/share or $0.15/share (conversion price per the series of the bonds). Any principal and accrued interest that remains outstanding at maturity will be converted to common stock at $0.10/share or $0.15/share. Warrants were also issued with the notes - which are accounted for as a debt discount.

Preferred Stock
As of 6/30/2012 Preferred stock consists of 1.5 million shares of Series A and 69k shares of Series B. The Series A has a stated value of $1.00, pays a 10% dividend, payable either in cash or in-kind (CTSO has been paying these in-kind and as such, all preferred dividends have been non-cash). The Series B pays a 10% dividend, payable in-kind. The Series B has a stated value of $100 per share and a conversion price of $0.0362 - if fully converted this would be highly dilutive and result in the issuance of ~190 million common shares.

Dilutive Shares Outstanding
An increase to the share count is not necessarily of significant concern, especially if funds are efficiently invested in the business. We only make specific mention of the financing arrangement and CTSO's capital structure in the context of additional share issuance to make investors aware that the share count could significantly increase over the near-to-mid term.

(Per 2011 10-K): *Basic earnings per share and diluted earnings per share for the years ended December 31, 2011 and 2010 have been computed by dividing the net loss for each respective period by the weighted average number of shares outstanding during that period. All outstanding warrants and options representing approximately 61,473,817 and 60,546,634 incremental shares at December 31, 2011 and 2010, respectively, as well as shares issuable upon conversion of Series A & B Convertible Preferred Stock and Preferred Stock Warrants representing 182,041,312 and 185,838,147 incremental shares at December 31, 2011 and 2010, respectively, as well as potential shares issuable upon Promissory Note conversion into Common Stock representing approximately 11,330,000 and 13,352,500 shares at December 31, 2011 and 2010, respectively, and have been excluded from the computation of diluted loss per share as they are anti-dilutive.*

OUTLOOK / RECOMMENDATION / VALUATION

Following its debut introduction at industry conferences in Europe during Q3 2011, the company began an incremental roll-out of CytoSorb in Germany targeting early adopters and looking to build greater awareness through investigator-led studies. While the device is now generating revenue, sales are expected to remain modest over the course of 2012 as CytoSorbents focuses the roll-out with their initial sales team, bringing on distribution partners, and increasing visibility of the device to influential industry leaders. Initial success of CytoSorb in Germany and throughout Europe will hinge on a number of factors, including sufficient reimbursement, the company's ability to drive awareness and, ultimately, interest from hospitals and critical care units.

We model very modest yet sequentially growing sales of CytoSorb in Germany during 2012, reflecting measured progress with implementation of the sales/marketing strategy. The majority of our modeled revenue in 2012 relates to projected DARPA grant income mostly in Q4.

We assume increased awareness and visibility of CytoSorb results in a greater rate of burgeoning interest materializing during 2013. We assume this will facilitate a broader roll-out of CytoSorb in Germany and, coupled with incremental contribution from sales in other European countries, results in CytoSorb revenue of just over $3 million in 2013. We also include ~$2.4 million in grant revenue in 2013 (again, is a best-guess at this point). As we indicated earlier, establishing reimbursement in other European countries will be key for CytoSorbents to generate any meaningful demand for their device outside of the German market. We assume CytoSorbents makes progress on this front on a country-by-country basis.

Our modeled revenue in 2014 and beyond includes mostly sales of CytoSorb (with a relatively small % contribution from contracts/grants). Assuming positive results from company-sponsored and investigator-led studies as well as supportive feedback from hospitals and critical care professionals, we think late-2013 could be an inflection point for CytoSorb and mark the beginning of a significantly greater ramp in commercial sales.

Based on the current ambiguity relative to what the FDA will be looking for to support a potential future PMA submission and the real risk of delays (from a best-case-scenario launch in 2015), we do not incorporate any contribution from sales of CytoSorb in the U.S. until an assumed soft-launch sometime in 2017. We will update our assumptions if appropriate when there is more clarity on the U.S. regulatory strategy and related timelines.

Based on our 10-year DCF model, which uses a 15% discount rate to account for certain risks and uncertainties that CytoSorbents faces (several of which we detail below), the shares are valued at approximately $0.50. Our model and assumptions will be updated commensurate with news flow which could also influence the valuation. As it is now, we value the company at $0.50/share, implying upside to the current share price and reflecting our Outperform rating.

RISK FACTORS

A number of unknowns exist, several of which, depending on the outcomes, could have a materially negative impact on CytoSorbent's future. As such, an investment in CytoSorbents comes with meaningful risk. Factors that should be considered include;

- **Small Clinical Trial:** Although data from the European Sepsis trial showed treatment with CytoSorb was associated with a statistically significant reduction in key cytokines and reduced mortality (in high-risk cohorts), the trial was very small with analysis done on 43 patients. The ongoing dosing study as well as other small trials may help confirm these results but it remains to be seen how influential these small studies will be in regards to both helping drive adoption in Europe and with supporting CytoSorbents' request to modify the IDE.

- **U.S. Commercialization:** The specific regulatory pathway and chances/timing of eventual FDA approval is substantially uncertain at this point. The outcome of near-term discussions with FDA will hopefully shed more light into this but even if these talks do provide answers to a number of important current unknowns, until the device is FDA approved there will remain a meaningful risk that CytoSorb fails to make it to the U.S. market. As our valuation of CytoSorbents is based on our DCF model and our DCF model incorporates several assumptions including launch of CytoSorb in the U.S. sometime in 2017 (which is little more than a rough guess at this point), delays relative to our assumptions or an altogether failure to get the device commercialized in the U.S. could mean our valuation is liberal (although we have included a risk discount in our valuation).

- **European Roll-Out:** Almost all of our modeled revenue through 2016 is coming from sales of CytoSorb in Europe. As it's unlikely the device will make it to the U.S. market prior to 2015 (we assume 2017), the ability of the company to fund regular operations and ongoing development over the next several years may largely depend on the success of CytoSorb in Europe. We model very modest sales of CytoSorb in 2012 but a steeper ramp beginning in late-2013. Underperformance relative to our assumptions in 2014 and beyond could not only effect valuation, it could also effect the company's ability to continue to raise capital and remain a going concern. We note, however, that these risks associated with revenue underperformance (relative to our model) over the near-to-mid term could potentially be mitigated by the occurrence of a number of events including a meaningfully beneficial licensing deal for HemoDefend (as noted we currently do not model any contribution from HemoDefend), additional grants, or (potentially) partnerships for development of CytoSorb for the U.S.

- **Reimbursement:** Germany was chosen as the initial launch territory for CytoSorb in Europe for a handful of reasons, not the least of which is expected reimbursement. However, as the more than 120 regional payers or local sickness funds in Germany negotiate reimbursement rates individually with local hospitals, the ability to get reimbursed will be a risk until there's more sales / reimbursement history. Similar specific reimbursement has yet to be established outside of Germany - in order for there to be meaningful demand for the product in other parts of Europe (and eventually the U.S.), sufficient reimbursement will need to be established.

- **Commercial Manufacturing:** CytoSorbents will commercially manufacture CytoSorb themselves. The company has limited manufacturing experience. Substantially increased demand will also require additional manufacturing capacity.

- **Dilutive Share Count:** As of Q4 2011 there were 181 million basic and approximately 255 million potentially dilutive shares outstanding. Our model assumes the share count increases with regular sales of securities to fund operations.

- **Operating Capital:** CytoSorbents will have to raise capital on an ongoing basis. The stock purchase agreement with LPC will provide meaningful breathing room but we believe CytoSorbents may need up to $20 million or more (assuming they fund U.S. studies themselves) before they reach the point of positive operating cash flow.

FINANCIAL MODEL

CytoSorbents Inc.

	2011 A	Q1A	Q2A	Q3E	Q4E	2012 E	2013 E	2014 E	2015 E
CytoSorb Sales	$36.1	$16.9	$33.0	$96.3	$192.5	$338.7	$3,205.0	$9,550.0	$27,900.0
y-o-y growth	-	-	-	-	-	-	*846.3%*	*198.0%*	*192.1%*
Total Royalties/Grants	$0.0	$0.0	$0.0	$100.0	$525.0	$625.0	$2,375.0	$1,250.0	$300.0
y-o-y growth	-	-	-	-	-	-	*280.0%*	-	-
Revenue	$36.1	$16.9	$33.0	$196.3	$717.5	$963.7	$5,580.0	$10,800.0	$28,200.0
YOY Growth	-					-	*479.0%*	*93.5%*	*161.1%*
Cost of Goods Sold	$11.8	$10.1	$10.8	$72.2	$125.1	$218.2	$1,602.5	$5,011.0	$10,842.0
Gross Income	$24.3	$6.8	$22.2	$124.1	$592.4	$745.5	$3,977.5	$5,789.0	$17,358.0
Gross Margin	*67.4%*	*40.3%*	*67.3%*	*63.2%*	*82.6%*	*77.4%*	*71.3%*	*53.6%*	*61.6%*
SG&A	$1,572.8	$430.8	$366.7	$515.0	$780.0	$2,092.5	$4,292.0	$6,590.0	$14,255.0
% SG&A	-	*2549.9%*	*1109.8%*	*262.4%*	*108.7%*	*217.1%*	*76.9%*	*61.0%*	*50.5%*
R&D	$2,888.2	$643.3	$665.8	$784.0	$884.0	$2,977.0	$5,465.0	$5,170.0	$4,155.0
% R&D	-	*3808.0%*	*2014.9%*	*399.5%*	*123.2%*	*308.9%*	*97.9%*	*47.9%*	*14.7%*
Operating Income	($4,436.8)	($1,067.2)	($1,010.2)	($1,174.9)	($1,071.6)	($4,324.0)	($5,779.5)	($5,971.0)	($1,052.0)
Operating Margin	-					-	-	-	-
Total Other Expense	$1,044.9	$359.4	$37.8	$200.0	$100.0	$697.2	$0.0	$0.0	$0.0
Pre-Tax Income	($5,481.6)	($1,426.6)	($1,048.0)	($1,374.9)	($1,171.6)	($5,021.2)	($5,779.5)	($5,971.0)	($1,052.0)
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividend	$3,087.0	$663.9	$577.2	$625.0	$605.0	$2,471.1	$2,200.0	$1,500.0	$0.0
Net Income	($8,568.7)	($2,090.5)	($1,625.2)	($1,999.9)	($1,776.6)	($7,492.3)	($7,979.5)	($7,471.0)	($1,052.0)
Net Margin	-	*-12375.0%*	*-4918.7%*	*-1019.1%*	*-247.6%*	-	-	-	*-3.7%*
EPS	($0.05)	($0.01)	($0.01)	($0.01)	($0.01)	($0.04)	($0.03)	($0.02)	($0.00)
YOY Growth	-					-	-	-	-
Diluted Shares O/S	160,235	181,151	194,440	225,000	239,000	209,898	315,000	395,000	505,000

Brian Marckx, CFA

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MANAGEMENT / DIRECTORS

Philip P. Chan, MD, PhD
Chief Executive Officer and President
Dr. Phillip Chan is the CEO and President of CytoSorbents Corporation. Prior to CytoSorbents, Dr. Chan led healthcare and life science investments as Partner for NJTC Venture Fund. He was responsible for numerous investments in therapeutics, medical devices and diagnostics. Dr. Chan also co-founded Andrew Technologies, a venture-backed medical device company that is now commercializing its FDA-approved HydraSolve™ advanced lipoplasty device. Dr. Chan is a Board-certified internal medicine physician with a strong background in clinical medicine and research, having completed his residency at Harvard Medical School at the Beth Israel Deaconess Medical Center. Dr. Chan received his MD/PhD from Yale University School of Medicine and his BS in cell and molecular biology from Cornell University.

Vincent Capponi
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 Inc. as our VP of Operations in 2002 until his promotion to Chief Operating Officer in 2005. 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 from 2000 to 2001 he 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.

David Lamadrid, MBA
Chief Financial Officer
Mr. Lamadrid has primary responsibility for managing CytoSorbents′ finance department. His responsibilities include managing all areas of financial management and planning, accounting functions, and the Company′s information systems. He has over 19 years of business experience in finance and management. Prior to joining MedaSorb in 2000, Mr. Lamadrid was a financial analyst at Chase Manhattan Bank working in the Middle Market Division. He also has experience in high growth product distribution companies. Mr. Lamadrid earned his AAS in Accounting from S.U.N.Y. Rockland, a BS in Finance from St. John′s University, and an MBA from New York University.

Robert Bartlett, MD
Chief Medical Officer
Dr. Bartlett is Professor Emeritus of Surgery at the University of Michigan Health System. Prior to becoming Professor Emeritus in 2005, Dr. Bartlett was Director of the Surgical Intensive Care Unit, Chief of the Trauma/Critical Care division and Director of the Extracorporeal Life Support Program at the University of Michigan Medical Center. Dr. Bartlett was the pioneer in the development of the extracorporeal membrane oxygenation machine (ECMO), used to oxygenate blood in critically ill patients worldwide. He received his MD from the University of Michigan Medical School, cum laude. He completed his general surgery residency at Peter Bent Brigham Hospital in Boston, and was Chief resident in thoracic surgery. Dr. Bartlett was also a NIH Trainee in Academic Surgery at Harvard Medical School, and was previously faculty at the University of California, Irvine. Dr. Bartlett is the recipient of 26 separate research grants, 14 from the National Institutes of Health, including an RO1 grant for the development of a totally artificial lung. He has also received numerous national and international awards for his contributions to critical care medicine. Dr. Bartlett brings a wealth of research and clinical experience including management of sepsis, acute respiratory distress syndrome, and mechanical life support systems and continues to be active in lab and clinical research.

Al Kraus
Mr. Kraus has been a director of the Company since 2003 and up until the end of 2008 was the Company′s President and CEO. Mr. Kraus currently serves as Chairman of the Board of Directors. Mr. Kraus has more than twenty-five years′ experience managing companies in the dialysis, medical device products, personal computer and custom software industries. Prior to joining us, from 2001 to 2003, Mr. Kraus was President and CEO of NovoVascular Inc., an early stage company developing coated stent technology. From 1996 to 1998, Mr. Kraus was President and CEO of Althin Healthcare and from 1998 to 2000, of Althin Medical Inc., a manufacturer of products for the treatment of end stage renal disease. While CEO of Althin, he provided strategic direction and management for operations throughout the Americas. From 1979 to 1985, Mr. Kraus was U.S. Subsidiary Manager and Chief Operating Officer of Gambro Inc., a leading medical technology and healthcare company. Mr. Kraus was the Chief Operating Officer of Gambro when it went public in the United States in an offering led by Morgan Stanley.

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Joseph Rubin, Esq.

Mr. Rubin became a director of the Company in 1997. Mr. Rubin is a founder and Senior Partner of, Rubin & Bailin, LLP an international and domestic corporate and commercial law firm in New York City, where he has practiced law since 1986. Mr. Rubin also taught at the Columbia University School of International and Public Affairs, where he is also Executive Director of the International Technical Assistance Program for Transforming Economies (ITAP). Mr. Rubin was Adjunct Professor at the Columbia University Graduate School of Business from 1973 to 1994, and taught at Columbia Law School in 1996. Mr. Rubin received his law degree from Harvard Law School, and his B.A., MIA, and M.Phil degrees in political science and international relations from Columbia University.

Edward R. Jones, MD, MBA

Dr. Jones has been a director of the Company since April 2007. Dr. Jones is an attending physician at the Albert Einstein Medical Center and Chestnut Hill Hospital as well as Clinical Professor of Medicine at Temple University Hospital. Dr. Jones has published or contributed to the publishing of 30 chapters, articles, and abstracts on the subject of treating kidney-related illnesses. He is a sixteen-year member of the Renal Physicians Association, the Philadelphia County Medical Society and a past board member of the National Kidney Foundation of the Delaware Valley. Dr. Jones is a past President of the Renal Physicians Association.

James Gunton

Mr. Gunton became a director of the Company in 2008. He is a cofounder of the NJTC Venture Fund. Mr. Gunton has been investing in privately-held growth technology companies for fifteen years. Before co-founding in 2001 the $80 million NJTC Venture Fund, Jim was a manager at Oracle Corporation in the Silicon Valley. He represents NJTC Venture Fund at nine portfolio companies and is a former Governor of the National Association of Small Business Investment Companies. Jim earned a BS from Stanford University and an MBA with distinction from Duke University.

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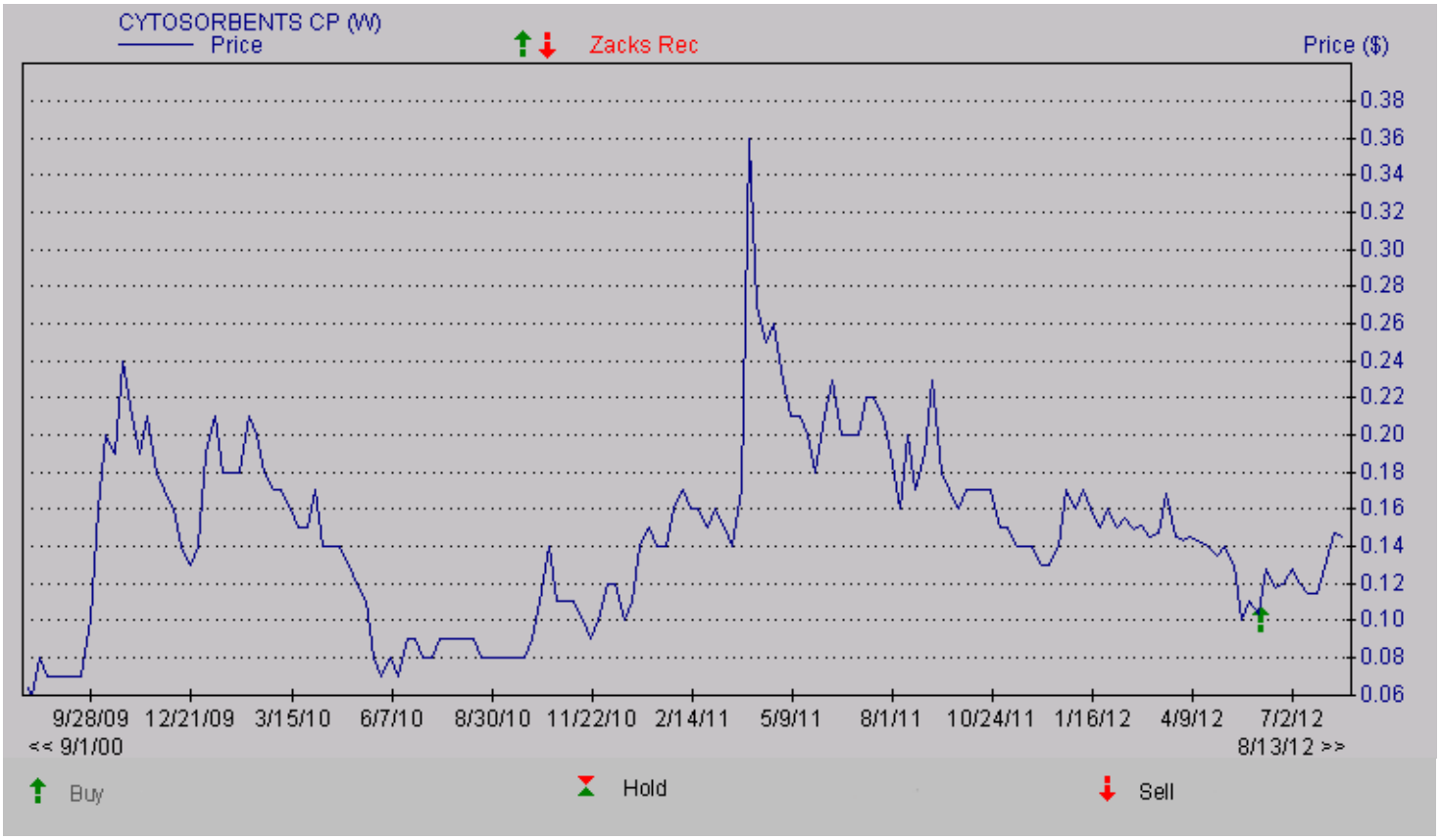

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