Zacks Small-Cap Research

August 13, 2014

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CytoSorbents Cp (CTSO-OTCBB)

CTSO: Record Product Sales, Again. Data Supports Cardiac Surgery…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (08/13/14)	$0.26
Target Price	**$0.50**

OUTLOOK

CytoSorb was CE Marked in March 2011 and subsequently commenced its initial commercialization. Initial focus on building awareness appears to be paying off. CTSO now generating clinical outcomes data which is just starting to be used to accelerate adoption and utilization. Mgmt outlined a multi-point plan on Q4 call to use recent cash raise to further accelerate sales as well as generate additional clinical data and build awareness. CTSO now expects to pursue cardiac surgery indication in the U.S. as this may provide the lowest cost, easiest and fastest route to the U.S. market. Cardiac surgery indication has driven substantial interest overseas with successful outcomes. Gov't contracts/grants that CTSO continues to score should benefit near-term revenue and cash flow as well as also aid their awareness-building efforts, further increase visibility and credibility of the technology, and potentially expand the menu of potential applications of the device. Interest in and use of CytoSorb from key opinion leaders continues to increase.

SUMMARY DATA

52-Week High	**$0.35**
52-Week Low	**$0.08**
One-Year Return (%)	**191.16**
Beta	**-1.62**
Average Daily Volume (sh)	**651,164**
Shares Outstanding (mil)	**301**
Market Capitalization ($mil)	**$77**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	371 A	292 A	881 A	879 A	2423 A
2014	1062 A	1025 A	1171 E	1349 E	4617 E
2015					14210 E
2016					22380 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-0.01 A	-0.01 A	-0.01 A	-0.01 A	-0.03 A
2014	-0.01 A	-0.01 A	-0.01 E	-0.01 E	-0.04 E
2015					-0.01 E
2016					-0.01 E

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

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Q2 Financials, Business Update

Q2 Financials: Record Product Sales On Increased Utilization. Add'l Studies/Data Support Efficacy of CytoSorb …

CytoSorbents reported results for the second quarter ending June 3, 2014. Product sales set a new all-time record and have now increased on a sequential basis every quarter except one since Q3 2012 (i.e. - 6 of the last 7 quarters). The fuel behind the growth in product sales has remained consistent, that being increasing re-order volumes and expansion of the customer base. Particularly noteworthy was management's comment on the call that in certain hospitals CytoSorb is being used for specific indications - implying that confidence in the utility and efficacy of CytoSorb for at least certain critically ill applications is taking root. As management pointed out, this is the first important step for the device to be deemed standard of care - which, if that occurs, would likely substantially steepen the demand curve for CytoSorb.

And while there's still potential to see some quarterly volatility, we think it is now clear that follow-on orders from existing customers (where the majority of orders are coming from – which we view as particularly positive), use of CytoSorb in an expanded number of critical care applications and in broadening of the geographic commercialization footprint are all contributing to the consistent sequential revenue growth. Awareness-building, clinical data and case studies outlining successful interventions with CytoSorb has been at the heart of CTSO's sales efforts, the fruits of which are being seen in the consistent product revenue growth. CTSO will continue to build on this throughout 2014 and with the launch of the patient registry documenting real-world successful interventions with CytoSorb, the bulk of clinical evidence will continue to grow which should further enable the marketing message.

On the Q2 call Dr. Chan shared more success stories when CytoSorb was introduced with critical ill patients. The results of these case studies continue to drive a compelling message to the potential utility of the device. These success stories, combined with awareness building via attendance and presentations at industry conferences, complementary efforts of the company's distributors (Biocon is now hiring a dedicated sales force for CytoSorb and going on an awareness-building tour in India), and the patient registry (which is expected to officially launch next month) should further disseminate the utility and efficacy of CytoSorb.

Also important to recognize in the context of the streak of record product revenue is that the majority of sales to date have been from just three countries in Europe; Germany, Austria and Switzerland. CTSO's distribution footprint expands to 20+ countries, most of which distribution is still in more latent stages. And, as noted, the company expects to further broaden their geographic footprint, including expectations of bringing on additional distribution agreements by the end of this year as well as adding direct sales reps, which should result in further expansion of their customer base.

Q2 total revenue was $1.02M, up 252% yoy and down 4% sequentially. Product sales of $663k represented yoy and sequential growth of 418% and 17%, respectively. Grant revenue was $361k in Q2, compared to $164k in Q2 2013 and $493k in Q1 2014. We expect additional grant revenue to be booked during the year from the CTSO's various grants including the DAPRA grant, Phase II SBIR contract and potentially the USAF funded rhabdomyolysis study. CTSO also expects to apply for a Phase II SBIR contract related to HemoDefend - the company is now finishing up the Phase I portion.

Importantly the record product revenue is not coming at the expense of margins. Management noted that Q2 product gross margin was approximately 65% (better than our 61% estimate), compared to product gross margin which "exceeded 60%" in Q1 and product gross margin of 61% in Q4 2013. Total gross margin, which is less reflective of the core business and is impacted by grant-related R&D expenses being captured in COGS, was 35% in Q2, just slightly below our 36.8% estimate. Q2 operating expenses were $1.7M, mostly in-line with our $1.8M estimate.

Q2 net income and EPS were ($3.2) million and ($0.01), compared to our ($2.5) million and ($0.01) estimates. The ~$700 difference in net income is the result of an increase in non-cash preferred stock dividends (paid in-kind) - the increase a result of the recent significant increase in the value of the preferred shares as well as non-cash change in warrant liability. Cash used in operating activities was $1.5M in Q2. Cash balance, including short-term investments, stood at $9.6M at Q2 quarter end.

U.S. Trial for Cardiac Surgery Looking More Promising …
On the Q2 call management provided an update on their potential plans to conduct a U.S. trial of CytoSorb in cardiac surgery. Instead of pursuing an endpoint such as reduction in organ dysfunction, which they were initially exploring, the company is now contemplating reduction of certain inflammatory biomarkers as the clinical endpoint. The inflammatory biomarker endpoint, management noted, has the advantages of a shorter and less costly trial and could potentially follow a 510(k) regulatory pathway, whereas an organ dysfunction trial would likely require the much more involved, time consuming and costly PMA pathway.

CytoSorbents already has early data on efficacy of CytoSorb in reduction of inflammatory biomarkers, which includes that from the study done in Germany and published in the journal Kardiotechnik - results of which showed CytoSorb effectively reduced levels of certain inflammatory biomarkers - we discuss the study and the results in greater detail below. Management noted that in addition to this study, they have had successful results with in vitro studies as well. CytoSorb has also been used successfully by clinicians in Europe in certain cardiac surgery settings and is now being used in a cardiac surgery study in Austria which management noted could have data available by current year-end or early 2015. A larger 200-patient (100 treatment / 100 control) cardiac surgery study just commenced in Germany. Management expects data from these various sources to be available in the coming quarters which could very well provide even more support for use of CytoSorb in this indication.

So CTSO's current game plan relative to a U.S. study is to meet with FDA with their intended protocol for a cardiac surgery inflammatory biomarker study and if all goes well, to submit for an IDE by the current year-end. This potentially means a study could commence in 1H 2015.

Additional Data Supporting Use of CytoSorb in Cardiac Surgery…
A retrospective study done in Germany using CytoSorb in cardiac surgery patients was published in the journal Kardiotechnik in February of this year. The study, titled, *Systemic Inflammatory Response Syndrome in Heart Surgery: New possibilities for treatment through the use of a cytokine adsorber during ECC?* compared inflammatory response after cardiac surgery in 20 patients utilizing CytoSorb versus 20 patients without CytoSorb.

The study was done at the Ludwig Maximilian University of Munich Hospital in Germany. It looked at whether the use of CytoSorb could better control post-surgery inflammation (based on five distinct inflammatory markers) which is associated with the use of heart-lung machines (HLM) during surgery. The inflammatory complications from which can range from temporary organ function limitations to full blown multiple organ failure and death.

Systemic inflammatory response syndrome (SIRS) is a significant complication after surgery when a HLM is used and while a variety of methods have been used to try to control SIRS, the authors note that these have "resulted in only moderate success in the past."

The study included 20 patients where CytoSorb was included in the bypass circuit and 20 patients where CytoSorb was not used. The two groups were considered comparable and followed similar preparatory and procedural protocol. Blood samples were taken from each patient immediately following the operation and 1 - 3 days after the operation. The following inflammatory markers were analyzed; C-reactive protein, procalcitonin, leukocytes, fibrinogen and interleukin-6 (IL-6).

Results showed a significant difference in IL-6 as well as procalcitonin at all time points. Significant differences in fibrinogen and C-reactive protein were also observed but not at every time point.

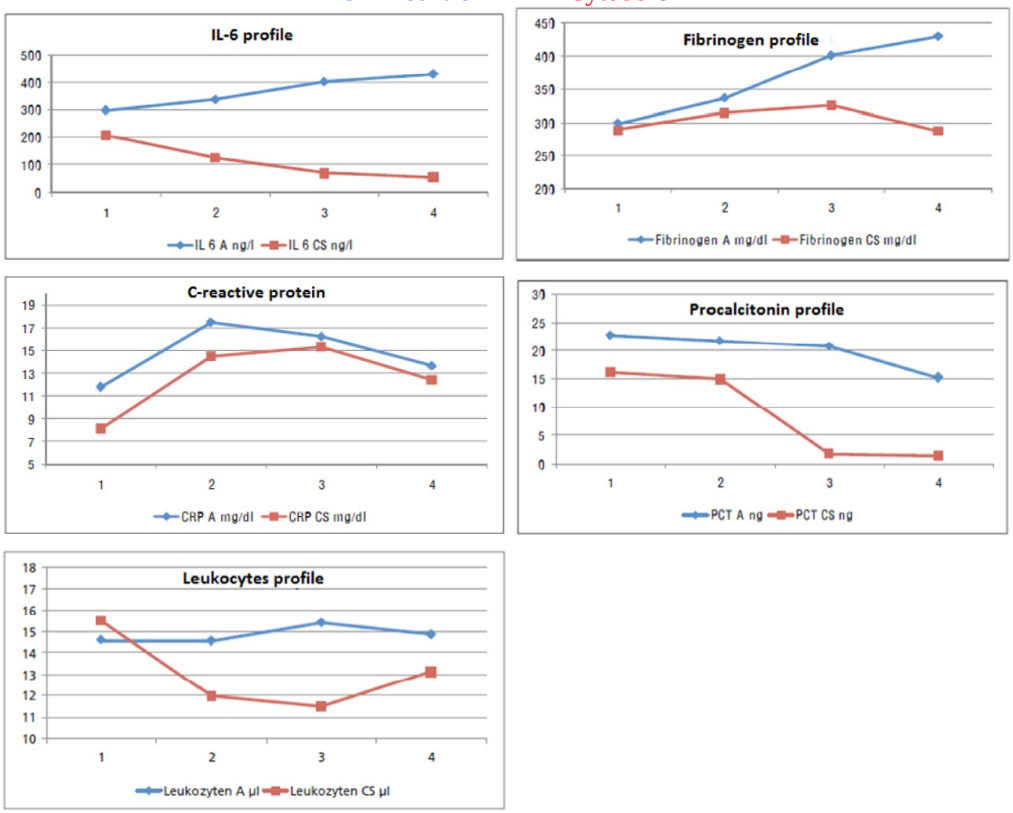
CS group vs. A group	post-OP (1)	1st day (2)	2nd day (3)	3rd day (4)
IL-6	s. p = 0,033	s. p = 0,031	h.s. p = 0,004	h.s. p = 0,005
Fib	n.s. p = 0,657	n.s. p = 0,550	n.s. p = 0,151	s. p = 0,019
Leu	n.s. p = 0,788	n.s. p = 0,652	n.s. p = 0,536	n.s. p = 0,234
CRP	s. p = 0,028	n.s. p = 0,079	n.s. p = 0,747	n.s. p = 0,516
PCT	h.s. p = 0,008	h.s. p < 0,002	h.s. p < 0,001	h.s. p < 0,001

Table 2: Statistical evaluation of the post-operative profile of the inflammation parameters in both groups (s. = significant; n.s. = not significant; h.s. = highly significant)

SOURCE: Footnote [1]

Importantly, investigators found that every marker showed a positive trend in favor of the CytoSorb group even at time points where the difference was not considered statistically significant.

BLUE = control RED = CytoSorb



SOURCE: Footnote 1

Relative to IL-6, reduction in levels of this cytokine was also a primary endpoint in CytoSorbents' European sepsis trial which was also successfully met - we expect this may also be an endpoint in the U.S. cardiac surgery trial.

Among the investigators' conclusions were that use of CytoSorb during cardiac surgery "can significantly attenuate an excessive inflammatory reaction", that it "may lead to a reduction in the development of SIRS" and that if results of this study are confirmed in a controlled clinical study that "CytoSorb could establish itself as a routine measure in cardiac surgery."

CTSO Expects a Busy 2014…

- **Beefed-up distribution:** as of the end of Q2 2014 CTSO had seven distributors (covering parts of the UK, Ireland, The Netherlands, Turkey, Russia, the Middle East and Taiwan) plus the partnership with Biocon covering India. The most recent agreement was signed in early August with Hemoscien Corporation for the Taiwanese market. CTSO expects sign additional distribution agreements in the remainder of 2014 to further broaden their geographic footprint.

  CTSO will also look for other partnership arrangements similar to the one with Biocon, a relationship that appears to be mutually beneficial. In fact Biocon noted on their Q3 2013 earnings call (Jan. 23, 2014) that, "Our recent launches Alzumab and CytoSorb have done extremely well, with strong uptake from both doctors and patients." Biocon appears to be solidly behind promoting CytoSorb, both from the clinical evidence side as well as feet on the ground. CTSO noted that Biocon will create a dedicated sales force for CytoSorb which will be focused on building awareness and educating physicians on use of the device. Biocon will also be setting up a

[1] F. Born, et al. *Systemic Inflammatory Response Syndrome in Heart Surgery: New possibilities for treatment through the use of a cytokine adsorber during ECC?* Kardiotechnik. 2/2014

patient registry and use case studies in promotion of the device and to develop manuscripts. We think additional partnerships similar to the one with Biocon can add meaningfully to CTSO's results.

- **Beefed-up sales force:** as of the end of 2013 CTSO had four sales people selling direct in Germany, Austria and Switzerland. With just this skeleton crew, CTSO was able to ramp product sales to more than $800k in 2013 and established a presence with more than 100 key opinion leaders. CTSO added three more reps (for a total of seven) through mid-May and expects to increase the sales force to 10 reps by the end of 2014. Management noted that the majority of sales have been direct sales - indicating that growth in the sales force is having a direct benefit on growth in product revenue. The direct sales force will continue to have a majority focus on Germany. And with cardiac surgery now a major focus (as is sepsis), CTSO has recently hired reps with contacts specifically in the cardiac surgery space.

- **Drive utilization:** CTSO first outlined their general plans to increase adoption and drive utilization last summer. Noting that while their initial sales strategy had focused almost exclusively on "cast(ing) a wide net" to broaden awareness and get hospitals and doctors interested in the device, that they would now also place a greater emphasis on penetration within the critical departments which have already been introduced to the technology in order to increase adoption and utilization. CTSO has indicated that they have already had successes in this regard – where CytoSorb may have been introduced to a particular hospital by a KOL and used in his or her intensive care specialty, but is now being used by other intensive care units within the same hospital. In addition, they continue to see growth in re-orders, indicating that adoption has been "sticky." And importantly, management noted that in certain hospitals CytoSorb is being used for specific indications - implying that confidence in the utility and efficacy of CytoSorb for at least certain critically ill applications is taking root. As management further noted, this is the first important step for the device to be deemed standard of care - which, if that occurs, would likely substantially steepen the demand curve for CytoSorb.

- **Expanded Indications:** CytoSorbents continues to look to expand the application of CytoSorb to additional indications. It has already been used successfully in sepsis, cardiac surgery, trauma, burn injuries, aggressive flu strains, trauma and others. The company is now investigating use in MERS, an aggressive and often fatal virus, most common in the Middle East. CytoSorbents also sees severe liver disease as a potentially attractive opportunity. And with the recent outbreak of Ebola in West Africa - this potentially presents another opportunity. As the more indications that the device is successful in treating, the potential applicable total target markets will continue to expand.

- **Clinical data:** clinical outcomes data has been a driving force in accelerating product sales. CTSO will dedicate more resources towards additional studies and expects to have a regular flow of outcomes data coming from the various investigator initiated studies. A patient registry, case studies (Dr. Chan has highlighted several successful outcomes when CytoSorb was introduced with critically ill patients) and additional support personnel to help communicate the successes of CytoSorb along with presentations and publications will all be major focuses throughout the rest of 2014 to build awareness, drive adoption, increase sales and to support reimbursement.

  Approximately 30 investigator initiated studies are ongoing as is the sepsis dosing study. In late December CTSO announced preliminary results from the dosing study. Results showed no serious device-related adverse events and demonstrated removal of cytokines throughout the 24hr treatment period in the 28 patients enrolled in the 24hrs/7days treatment arm. The other treatment arm (6hrs/up to 14 days) is currently enrolling patients. Assuming positive results, CTSO game plan now is to move to a larger study in sepsis in Germany.

  Among the 30 investigator initiated studies, several relate to cardiac surgery with results to-date already looking highly promising. Six other studies are using the device in septic shock, severe sepsis and lung injury – one of which should also complete this year. The other studies include patients with liver disease, trauma, burn injuries and acute pancreatitis. Data from these studies offer potential catalysts that can positively impact the marketing message and rate of adoption and utilization of CytoSorb.

  Specific to cardiac surgery, CytoSorbents already has early data on efficacy of CytoSorb in reduction of inflammatory biomarkers, which is the clinical endpoint that company now expects to pursue in a U.S. cardiac surgery study. This early data includes that from the study done in Germany and published in the journal Kardiotechnik - results of which showed CytoSorb effectively reduced levels of certain inflammatory biomarkers. Management noted that in addition to this study, they have had successful results with in vitro studies as well. CytoSorb has also been used successfully by clinicians in Europe in certain cardiac surgery settings and is now being used in a cardiac surgery study in Austria which management noted could have data available by current year-end or early 2015. A larger 200-patient (100 treatment / 100 control) cardiac surgery study just

commenced in Germany. Management expects data from these various sources to be available in the coming quarters which could very well provide even more support for use of CytoSorb in this indication.

- **Presentations, conferences, user-meetings:** another key to CTSO's awareness-building efforts have been attendance and presentations at industry conferences. This will be an ongoing focus. Recently CTSO held its first Users Meeting at the DIVI conference in Germany which allows attendees to hear success stories directly from users the device. Comments at the Users Meeting included that physicians could "see the therapy turning the patient around". CTSO noted that they have had impressive attendance at presentations at recent industry conferences and recently exhibited/attended at eight major international healthcare conferences.

- **U.S. study:** CTSO previous game-plan relative to the U.S. market was to use the European sepsis dosing trial data as support for FDA approval to run a sepsis trial in the U.S. On the Q4 2013 call, however, CTSO said that they are now focused on running a pivotal trial in the U.S. for cardiac surgery. The reasons for focusing on cardiac surgery include the demand (and clinical successes) that CytoSorb has had in that application in Europe and CTSO believes cardiac surgery represents a faster regulatory approval timeline and will be lower cost and have less risk of failure than a sepsis related trial. For one, CTSO noted that outcomes are more predictable with cardiac surgery than with sepsis. Also, mortality will not be an endpoint in cardiac surgery – whereby it is with sepsis and is a relatively high hurdle. The cardiac surgery focus for the U.S. makes sense in that it is a relatively lower-risk endeavor and can get CytoSorb's foot in the domestic door – the company can then focus on expanding the label to encompass additional indications. It also likely puts the device on the U.S. market and generating revenue here earlier than would have been the case if CTSO had pursued sepsis as the initial indication.

  In addition, while there are currently blood-filtration products on the market that are used during cardiac surgery to reduce inflammatory substances, they do not target cytokines – which offers CytoSorb a wide-open market opportunity. While cardiac surgery was barely mentioned just 18 months ago, this seems to have quickly become a major driver of demand and interest in CytoSorb – with CTSO noting that 22 cardiac surgery centers have either used the device or expressed interest in doing so – this is up from just 10 in 2013. CTSO also indicated that based on interest that they've seen for the cardiac surgery application that specifically changed some of their sales efforts to dedicate more focus on cardiac surgery.

  On the Q2 call management provided an update on their potential plans to conduct a U.S. trial of CytoSorb in cardiac surgery. Instead of pursuing an endpoint such as reduction in organ dysfunction, which they were initially exploring, the company is now contemplating reduction of certain inflammatory biomarkers as the clinical endpoint. The inflammatory biomarker endpoint, management noted, has the advantages of a shorter and less costly trial and could potentially follow a 510(k) regulatory pathway, whereas an organ dysfunction trial would likely require the much more involved, time consuming and costly PMA pathway. In addition, as we explained above, data from initial studies including the 40-patient study published in Kardiotechnik in early 2014, lend support for the efficacy of CytoSorb in the reduction of inflammatory biomarkers.

  CTSO's current game plan relative to a U.S. study is to meet with FDA with their intended protocol for a cardiac surgery inflammatory biomarker study and if all goes well, to submit for an IDE by the current year-end. This potentially means a study could commence in 1H 2015.

- **Partnering for other products:** CTSO had mentioned on prior calls that they would look for partners for commercialization of some of their other products – these include HemoDefend (blood purification and storage), ContrastSorb (prevention of CIN), and DrugSorb,(drug detox and overdose) as well as four or five other products that are in the pipeline. This will be an ongoing focus in 2014. CTSO is focused on what they termed "de-risking" these products to make them even more attractive to potential commercialization partners – which includes making enhancements to the products. Further de-risking of HemoDefend may also come from the ABLE (Canada) and RECESS (U.S.) pivotal studies. The studies are attempting to determine whether aged blood may be potentially more toxic than new blood – data from these could be available during the year – and could potentially provide support for use HemoDefend to keep blood fresh. CTSO recently noted that they have confirmed the regulatory pathway in both the U.S. and E.U. (although mgmt. did not elaborate) for the in-line filter HemoDefend product.

Recent operational highlights include;

COMMERCIALIZATION

- Direct sales of CytoSorb commenced in Germany, Austria and Switzerland
- CTSO posted record product sales in Q2 2014 of $663k. Product sales have now increased on a sequential basis every quarter except one since Q3 2012 (i.e. - 6 of the last 7 quarters). Guidance continues to indicate continued yoy growth. Seeing more hospitals as well as more departments within hospitals using CytoSorb. Direct reps continue to score more accounts. As sales force has grown, so have product sales.
- Distribution agreement signed with Hemoscien Corporation for Taiwan - CTSO's first step in expanding to much of Asia
- Distribution agreement signed with Techno Orbits in April 2014 for Middle East. Could have real opportunity with CytoSorb in MERS following requisite product registration in Middle East
- Distribution agreement with Biocon, Ltd signed in Q3 2013. Biocon is largest biotech in India. Affords potential to market Biocon's antibiotics with CytoSorb as a total treatment for sepsis (sort of a one-two punch) in that country. Revenue contribution from Biocon started in Q4 2013. Biocon appears strongly behind CytoSorb and noted on their Q3 2013 call that CytoSorb sales have been very strong.
- CTSO beefed up their internal sales force from 4 (at end of 2013) to 7 currently. Will look to add 3 more by year-end 2014. Both cardiac surgery and sepsis are major focus points as its driving adoption and utilization to different depts within a hospital.
- Distribution agreement with WMC Medical for Netherlands signed in October 2013
- Agreement penned in May 2013 with L.IN.C Medical Systems to distribute CytoSorb in the U.K. and Ireland. In June 2013 CTSO signed agreement with Hiti Medical Systems for distribution in Turkey. In November 2013 signed agreement with INTENSIVMED for distribution in Russia
- International expansion via additional distribution agreements is a major focus for 2014 - looking to add a total of 5 distributors in 2014
- $10M capital raise in early 2014 being used to beef-up distribution and the direct sales force, increase the amount of clinical data and case study reports, increase overall awareness building, build out the patient registry and initiate plans for a U.S.-based cardiac surgery study as well as move forward with a sepsis study in Germany

VALIDATION / REGULATORY

- In June 2013 the FDA approved the first U.S. based human study of CytoSorb in critically ill patients - a significant milestone in our opinion
- CTSO recently noted that about 150 (up from 100 in just the last few months) key opinion leaders (KOL) are either using CytoSorb, want to use it or are planning to use it in clinical trials. As of May 2014 there were 30 investigator initiated studies, some of which are expected to complete in 2014. These studies run a wide gamut of medical complications including cardiac surgery, sepsis, trauma, surgery, pancreatitis, organ failure and acute respiratory failure.
- Relative to cardiac surgery, this has quickly become a high-potential indication. 11 of the investigator initiated studies relate to cardiac surgery. Demand is coming specifically for this indication. Positive patient outcomes in cardiac surgery should further catalyze this opportunity. Data from 40-patient study conducted in Germany showed efficacy in reduction of key inflammatory markers. More data from other studies expected in near term. CTSO announced in March 2014 that instead of pursuing a pivotal study in sepsis in the U.S., that they will now pursue cardiac surgery. Cardiac surgery study could commence in 1H 2015.
- Dosing study (Europe) ongoing with more patients being enrolled. CytoSorb has been used for up to 24 hours over 7 days with no serious device related events reported and showed reduction in cytokines over the full 24-hour treatment period. Other arm (6hrs/up to 14 days) is now enrolling. We could see add'l data from this study in 2014. CTSO will expand the study to ten leading hospitals in Germany (currently 8). Data from the study is expected to be used to further supplement the data from the European Sepsis trial. CTSO expects to initiate a larger sepsis trial in Germany.
- CTSO recently noted that a number of case study reports have been borne from ongoing studies. The first published in Blood Purification in July 2013. Another, published in April 2014 in International Journal of Artificial Organs, detailed successful use of CytoSorb in near fatal case of necrotizing fasciitis. Others are being prepared and expected to be published in near-term. CTSO just established a patient registry where case studies and clinical outcomes data will be kept - this is expected to go live in September of this year
- Initial feedback from physicians using CytoSorb in clinical practice with critically ill patients, including those with septic shock, cardiac surgery and multiple organ failure (which includes the initial indications addressed by CytoSorb), have been encouraging with outcomes including a dramatic reduction in IL-6 levels (which was also an endpoint in the European Sepsis Trial), stabilized organ failure, and patient recovery. Feedback at first Users Meeting held in December 2013 offered further evidence of efficacy - comments included that physicians could "see the therapy turning the patient around".

- Initiation of work under the Phase II Small Business Innovation Research grant from the U.S. Army, worth up to $1 million. Initial revenue recorded for this grant in 2013
- Awarded Phase I grant from NHLBI for HemoDefend worth $203k in September 2013. CTSO also expects to apply for a Phase II SBIR contract related to HemoDefend - the company is now finishing up the Phase I portion.

AWARENESS-BUILDING

- Presentations, exhibitions and research talks at several scientific meetings. Anticipate this will continue and will also be supplemented by presentations by key opinion leaders which are using CytoSorb
- The company attended and presented at several key industry conferences in 2013 and through 1H 2014 in both the U.S. and throughout Europe (including Germany, France and Austria). The company held its first ever Users Meeting at the DIVI conference in Germany in December 2013. Feedback was positive. CTSO also presented at the DIVI meeting, noting strong attendance and significant interest in CytoSorb. CTSO also recently sponsored a research symposium at the International Symposium on Intensive Care and Emergency Medicine where doctors discussed intervention with CytoSorb in various critical care illnesses. CytoSorb was most recently presented at the International Liver Transplant Society meeting in London
- Two abstracts were accepted for presentation at the German Sepsis Society meeting in September. One, from the University of Ulm, Germany related to the first successful fungal sepsis case treated and, the other, from Trauma Hospital in Linz, Austria for the treatment of a septic shock patient with liver cirrhosis. The patient registry and ongoing investigator studies are expected to begin to produce data for a regular flow of manuscripts and publications. This is expected to be a facilitator in increasing adoption and utilization

- **PIPELINE**
  - HemoDefend: refined the filter which now allows a unit of blood to flow through in under a half-hour, within the requirements for blood transfusions. CTSO now working to reduce unit production costs including optimizing packaging. CTSO noted on the Q4 2013 call that they have confirmed the regulatory pathway in both the U.S. and E.U. (although mgmt. did not elaborate) for the in-line filter HemoDefend product
  - In August 2013 Dr. Chan made a presentation on HemoDefend at the Military Health System Research Symposium
  - Beads in a Bag: progress continues towards eventual commercialization. Beads in a Bag technology was the subject of CTSO's poster presentation at the 2012 American Association of Blood Banks conference
  - NHLBI grant provides add'l funding to progress development of HemoDefend and also provides add'l validation of the technology
  - CTSO indicated there is real interest in HemoDefend from potential partners, for both the Beads in a Bag as well as in-line filter configuration
  - ContrastSorb: CTSO's most recent pipeline candidate is being designed to prevent contrast-induced nephropathy (CIN), a condition that patients with compromised kidney function are susceptible to when undergoing procedures that require use of a contrast agent such as image-guided cardiology and certain radiology procedures. CIN has been estimated to be a ~$500 million/yr market. Current standard of care to address CIN, which is essentially indiscriminately flushes the contrast agent from the body, is often times ineffective. CTSO believes their ContrastSorb technology may be a more effective option to remove contrast agents from these high risk patients

OUTLOOK / RECOMMENDATION / VALUATION

We model a sequential uptick in revenue throughout 2014 as near-term catalysts, including several of those that management outlined on the recent conference calls, make an increasing contribution over time. And while there's still potential to see some quarterly volatility, we think it is now clear that follow-on orders from existing customers (where the majority of orders are coming from – which we view as particularly positive), use of CytoSorb in an expanded number of critical care applications and in broadening of the geographic commercialization footprint are all contributing to the consistent sequential revenue growth. Awareness-building, clinical data and case studies outlining successful interventions with CytoSorb has been at the heart of CTSO's sales efforts, the fruits of which are being seen in the consistent product revenue growth. CTSO will continue to build on this in 2014 and with the

launch of the patient registry documenting real-world successful interventions with CytoSorb, the bulk of clinical evidence will continue to grow which should further enable the marketing message.

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 2014 could be more of an inflection point for CytoSorb and mark the beginning of a significantly greater ramp in commercial sales.

Management's recent decision to focus on a cardiac surgery indication instead of the previously expected sepsis indication, may provide an easier, lower cost and quicker time to FDA approval. We look forward to hearing more about CTSO's plans for initiating a U.S.-based pivotal study. We will update our assumptions relative to the U.S. market if and when we feel there is enough clarity to make an informed opinion relative to the regulatory pathway requirements and general launch timelines. As it is now, we are maintaining our assumption that meaningful U.S. sales do not materialize prior to 2018.

Based on our 10-year DCF model, which uses a 13% discount rate to account for certain risks and uncertainties that CytoSorbents faces (several of which we detailed in our initiation report), 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.

FINANCIAL MODEL

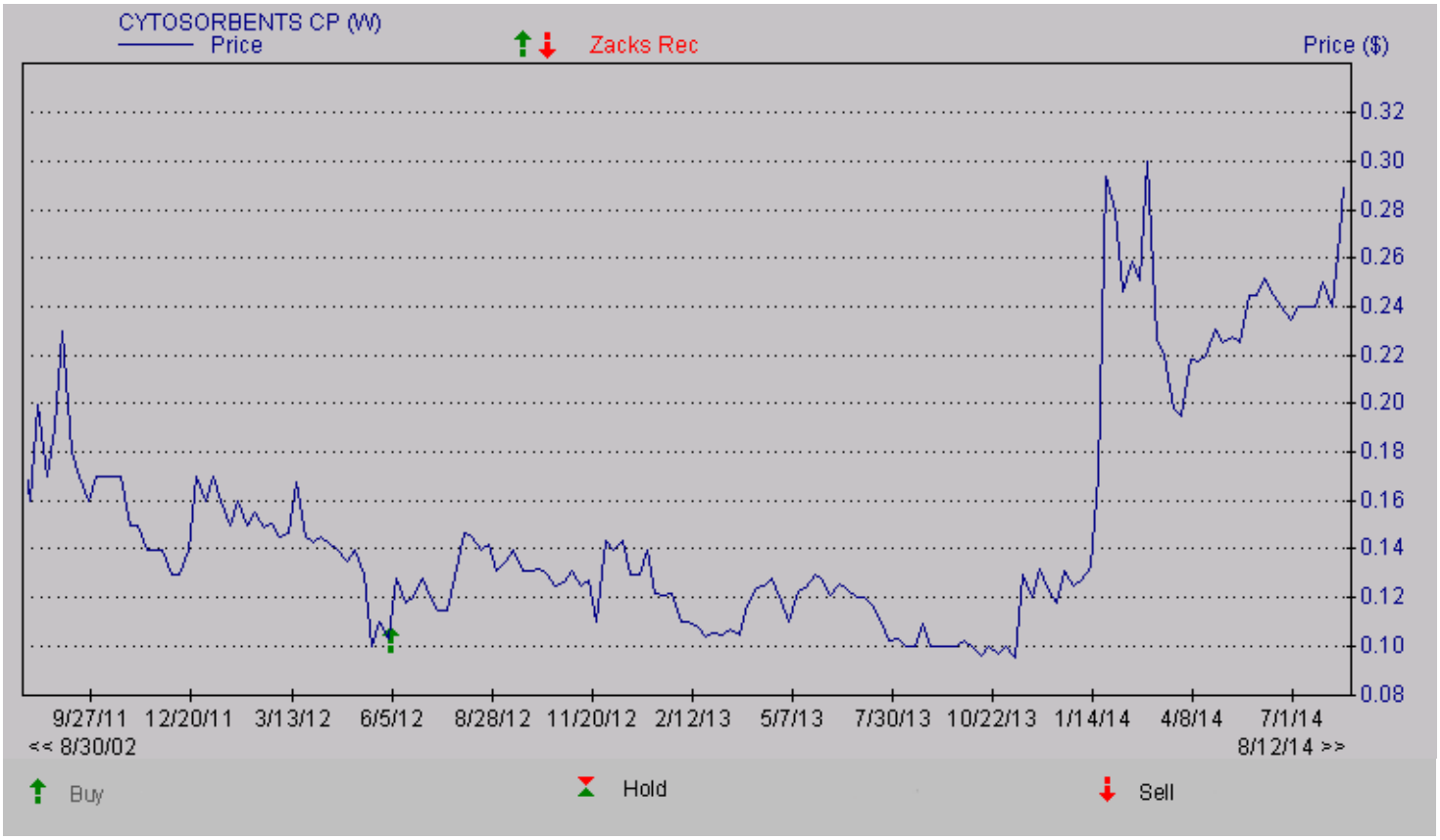
CytoSorbents Inc.

	2013 A	Q1A	Q2A	Q3E	Q4E	2014 E	2015 E	2016 E	2017 E
CytoSorb Sales	$821.8	$569.2	$663.2	$765.0	$942.0	$2,939.5	$13,110.0	$22,180.0	$30,090.0
y-o-y growth	*442.1%*	*223.3%*	*418.3%*	*275.8%*	*199.8%*	*257.7%*	*346.0%*	*69.2%*	*35.7%*
Total Royalties/Grants/Other	$1,600.9	$492.9	$361.4	$406.0	$407.0	$1,667.4	$1,100.0	$200.0	$0.0
y-o-y growth	*34.4%*	*152.5%*	*121.0%*	*-40.0%*	*-28.0%*	*4.2%*	*-34.0%*	*-81.8%*	*-100.0%*
Revenue	$2,422.7	$1,062.2	$1,024.7	$1,171.0	$1,349.0	$4,606.8	$14,210.0	$22,380.0	$30,090.0
YOY Growth	*80.4%*	*186.0%*	*251.5%*	*33.0%*	*53.4%*	*90.2%*	*208.5%*	*57.5%*	*34.5%*
Cost of Goods Sold	$1,911.6	$662.5	$666.2	$707.1	$771.3	$2,807.1	$6,285.9	$8,880.2	$11,735.1
Gross Income	$511.1	$399.6	$358.5	$463.9	$577.7	$1,799.8	$7,924.1	$13,499.8	$18,354.9
Gross Margin	*21.1%*	*37.6%*	*35.0%*	*39.6%*	*42.8%*	*39.1%*	*55.8%*	*60.3%*	*61.0%*
SG&A	$3,485.4	$1,317.1	$1,394.6	$1,522.0	$1,664.0	$5,897.7	$9,532.0	$13,070.0	$15,496.4
% SG&A	*143.9%*	*124.0%*	*136.1%*	*130.0%*	*123.4%*	*128.0%*	*67.1%*	*58.4%*	*51.5%*
R&D	$1,738.9	$236.8	$347.0	$518.0	$667.0	$1,768.8	$4,500.0	$4,200.0	$3,100.0
% R&D	*71.8%*	*22.3%*	*33.9%*	*44.2%*	*49.4%*	*38.4%*	*31.7%*	*18.8%*	*10.3%*
Operating Income	($4,713.2)	($1,154.2)	($1,383.1)	($1,576.1)	($1,753.3)	($5,866.7)	($6,107.9)	($3,770.2)	($241.4)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$422.8	($179.1)	$470.5	$39.0	($47.0)	$283.4	$0.0	$0.0	$0.0
Pre-Tax Income	($5,136.1)	($975.1)	($1,853.6)	($1,615.1)	($1,706.3)	($6,150.1)	($6,107.9)	($3,770.2)	($241.4)
Taxes (benefit)	($458.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*8.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividend	$2,395.5	$1,114.5	$1,374.2	$1,250.0	$1,250.0	$4,988.8	$0.0	$0.0	$0.0
Net Income	($7,073.3)	($2,089.6)	($3,227.8)	($2,865.1)	($2,956.3)	($11,138.8)	($6,107.9)	($3,770.2)	($241.4)
Net Margin	-	*-196.7%*	*-315.0%*	*-244.7%*	*-219.1%*	-	*-43.0%*	*-16.8%*	*-0.8%*
EPS	($0.03)	($0.01)	($0.01)	($0.01)	($0.01)	($0.04)	($0.01)	($0.01)	($0.00)
YOY Growth	-	-	-	-	-	-	-		
Diluted Shares O/S	236,019	265,480	301,196	314,000	327,000	301,919	575,000	590,000	610,000

Brian Marckx, CFA

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