Zacks Small-Cap Research

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Cytosorbents Cp (CTSO-OTCBB)

CTSO: *Business Update Call, Dosing Study Details…*

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (08/23/13)	$0.10
Target Price	**$0.50**

OUTLOOK

CytoSorb 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. $4.8MM worth of gov't contracts/grants that CTSO scored since August 2012 should benefit near-term revenue and cash flow as well as 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 has recently accelerated. Early feedback is positive and encouraging. Investigator-initiated studies and ongoing dosing study will provide add'l data points, facilitate increased uptake, and support quest for U.S.-based study. U.S. pilot study recently approved by FDA.

As near-term revenue and contracts/grants 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.

SUMMARY DATA

52-Week High	**$0.15**
52-Week Low	**$0.08**
One-Year Return (%)	**-23.24**
Beta	**0.18**
Average Daily Volume (sh)	**559,048**
Shares Outstanding (mil)	**231**
Market Capitalization ($mil)	**$25**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	17 A	116 A	605 A	604 A	1343 A
2013	371 A	292 A	704 E	858 E	2225 E
2014					6133 E
2015					15490 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-0.01 A	-0.01 A	-0.01 A	-0.01 A	-0.03 A
2013	-0.01 A	-0.01 A	-0.01 E	-0.01 E	-0.03 E
2014					-0.03 E
2015					-0.01 E

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

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Dosing Study Details , Biz Update Call…

Additional details of the ongoing dosing study being conducted in Germany were announced last week, just prior to CytoSorbents' business update call. The dosing study, results of which are expected to be used to initiate a pivotal study to support U.S. approval and provide additional support for ongoing commercialization in Europe, has now been expanded to eight clinical sites in Germany (at least 3 of which also participated in the European sepsis trial) - up from two sites initially. CTSO noted that while it took longer than expected to get the additional sites included in the study, that by expanding to more institutions that this should help to accelerate completion of the study - they expect to have at least interim data by the current year-end. The company noted that all sites are now eligible to begin patient enrollment. Treatment protocol was also released; dosing will be split between two arms - one for 24 hours of treatment over 7 days continuously, the other for 6 hours of treatment every day for up to 14 days or until clinical improvement.

As a reminder, treatment duration in the 47-patient European sepsis trial was for 6 hours per day for 7 days. That trial, performed at 14 sites in Germany showed that CytoSorb significantly reduced cytokines in patients with severe sepsis or septic shock. In two subgroups of patients (classified as being particularly high risk of death), CytoSorb-treated patients showed a statistically significant reduction in mortality. The dosing study was initiated to determine if increasing the treatment duration may yield even better results.

While the dosing study is designed to assess safety and preliminary efficacy only, the results are important for advancing to a U.S. regulatory pathway and could offer relevant insight into effectiveness - which could directly, and potentially very positively, impact demand and utilization in the currently commercialized countries. Depending on the success of this dosing study, results will be used to support initiation of a pivotal U.S.-based study which will be intended to be used to support an FDA filing - CTSO hopes to initiate this study in 2014.

CytoSorbents' business update call was also held last week. While there were no particularly significant revelations revealed, management did offer some additional insight into their near-term commercialization and business development strategies. The tone of the call was clearly positive with management obviously optimistic about the chances for ultimate success of CytoSorb in the commercial marketplace. Reiterated were the themes that the list of key opinion leaders either using the device or interested in doing so continues to grow and that feedback from physicians using it remains highly positive.

Relative to commercialization of CytoSorb, management noted 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 are now also placing a greater emphasis on penetration within the critical departments which have already been introduced to the technology in order to increase adoption and utilization. Management indicated that while their sales efforts have been successful from the standpoint of getting physicians and hospitals interested in CytoSorb, that the next step, that being to drive utilization, has been more drawn out and, perhaps, more difficult than initially anticipated. The goal now is to ramp up efforts relative to utilization and get their message communicated not just to the key opinion leaders and department heads but also to the other senior and junior critical care physicians. To facilitate this, management expects that they may need to add some headcount - although also reiterating that they will continue to use their financial resources wisely.

This deeper-penetration strategy has already commenced and is expected to result in continued y-o-y revenue growth from more re-orders. Management noted that Q3 has already seen "an encouraging level of activity." Also noting that they have a handful of accounts that they expect to be able to talk more about in the future. Increased utilization also presumably means more positive real-world patient outcomes data and experiences - which will be key to further driving awareness and in accelerating the adoption process. Directly related to that, management noted on the call that they plan to establish a patient registry database where they will archive the successes of CytoSorb use in clinical practice - a small handful of which the company reported on previously.

Relative to business development, noteworthy is that CTSO is actively seeking strategic partnership opportunities for not only HemoDefend (which the company had talked about before) but also for CytoSorb. Management indicated that they have identified a number of potential partners for CytoSorb and are in late-stage discussions with about four or five. Specifics relative to the exact nature of the potential partnership or the companies involved in discussions were not offered although it's clear that increasing distribution of CytoSorb is a front-burner goal and management noted that their list of potential partners spans various industries and includes equipment manufacturers related to the ICU, cardiac surgery companies and large pharmaceutical companies. CTSO hopes to have at least one strategic partnership agreement in place by the end of the current year.

European Sepsis Trial refresher…
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.

FINANCIAL MODEL

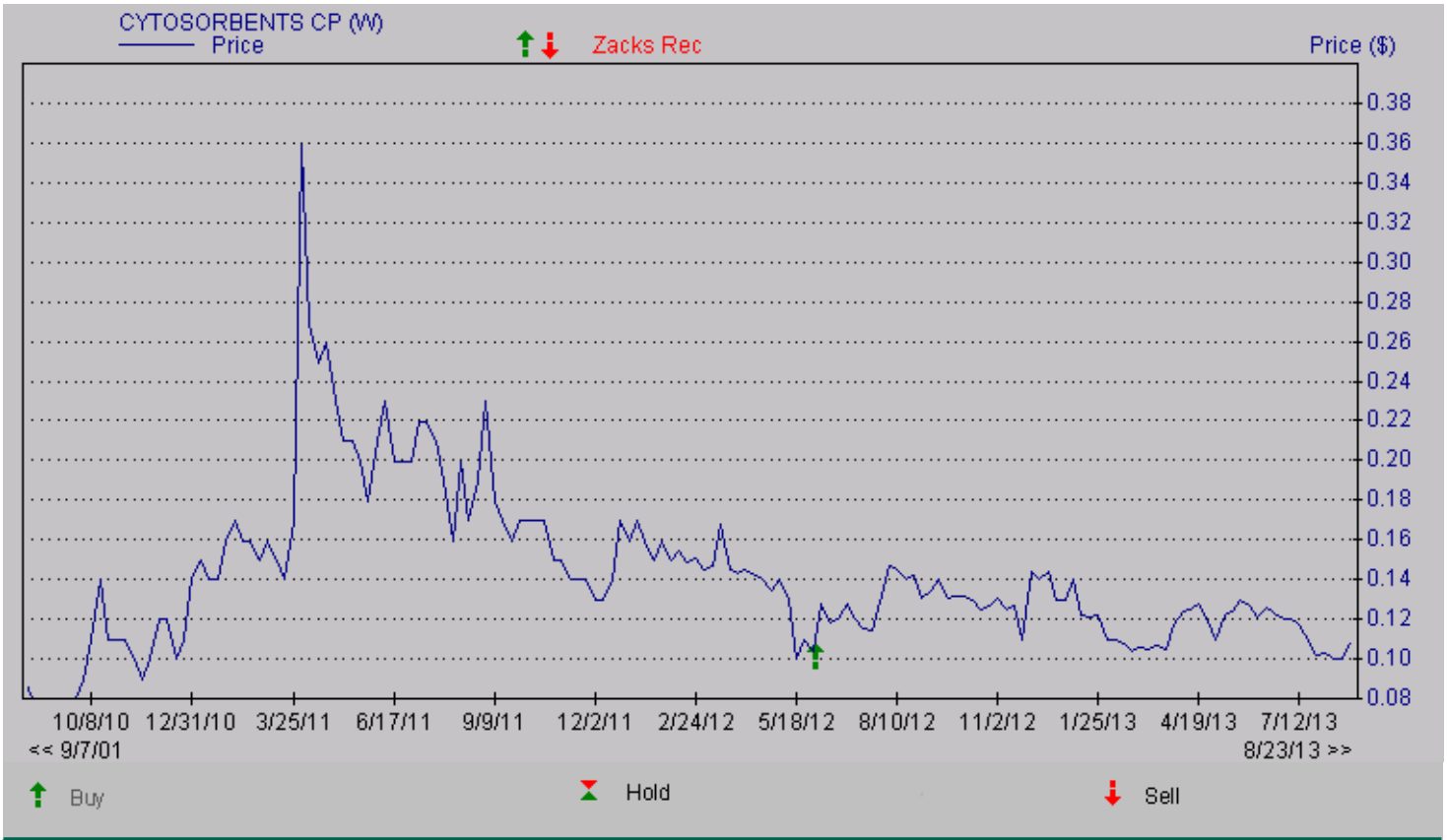
CytoSorbents Inc.

	2012 A	Q1A	Q2A	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
CytoSorb Sales	$151.6	$176.1	$128.0	$175.0	$200.0	$679.1	$4,820.0	$15,190.0	$24,260.0
y-o-y growth	-	*942.4%*	*287.3%*	*1179.3%*	*127.3%*	*348.0%*	*609.8%*	*215.1%*	*59.7%*
Total Royalties/Grants	$1,191.4	$195.2	$163.5	$529.0	$658.0	$1,545.7	$1,313.0	$300.0	$0.0
y-o-y growth	-	-	*96.2%*	*-10.6%*	*27.4%*	*29.7%*	*-15.1%*	*-77.2%*	*-100.0%*
Revenue	$1,342.9	$371.3	$291.5	$704.0	$858.0	$2,224.8	$6,133.0	$15,490.0	$24,260.0
YOY Growth	-	*2098.1%*	*150.5%*	*16.3%*	*42.0%*	*65.7%*	*175.7%*	*152.6%*	*56.6%*
Cost of Goods Sold	$319.3	$253.5	$199.6	$461.4	$516.6	$1,431.0	$2,688.7	$6,036.2	$8,976.2
Gross Income	$1,023.6	$117.8	$91.9	$242.6	$341.5	$793.8	$3,444.4	$9,453.8	$15,283.8
Gross Margin	*76.2%*	*31.7%*	*31.5%*	*34.5%*	*39.8%*	*35.7%*	*56.2%*	*61.0%*	*63.0%*
SG&A	$1,982.0	$835.9	$790.6	$787.0	$813.0	$3,226.5	$6,062.0	$10,327.0	$13,558.0
% SG&A	*147.6%*	*225.1%*	*271.2%*	*111.8%*	*94.8%*	*145.0%*	*98.8%*	*66.7%*	*55.9%*
R&D	$2,532.4	$704.1	$708.2	$660.0	$850.0	$2,922.3	$5,650.0	$5,500.0	$3,800.0
% R&D	*188.6%*	*189.6%*	*243.0%*	*93.8%*	*99.1%*	*131.4%*	*92.1%*	*35.5%*	*15.7%*
Operating Income	($3,490.8)	($1,422.2)	($1,406.8)	($1,204.4)	($1,321.6)	($5,355.0)	($8,267.7)	($6,373.2)	($2,074.2)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$564.4	$206.7	$8.1	$22.0	$22.0	$258.9	$12.0	$0.0	$0.0
Pre-Tax Income	($4,055.2)	($1,628.9)	($1,415.0)	($1,226.4)	($1,343.6)	($5,613.9)	($8,279.7)	($6,373.2)	($2,074.2)
Taxes (benefit)	($391.8)	$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	$2,511.5	$586.4	$616.5	$645.0	$645.0	$2,492.9	$1,500.0	$0.0	$0.0
Net Income	($6,174.9)	($2,215.4)	($2,031.5)	($1,871.4)	($1,988.6)	($8,106.8)	($9,779.7)	($6,373.2)	($2,074.2)
Net Margin	-	*-596.6%*	*-696.9%*	*-265.8%*	*-231.8%*	-	-	*-41.1%*	*-8.5%*
EPS	($0.03)	($0.01)	($0.01)	($0.01)	($0.01)	($0.03)	($0.03)	($0.01)	($0.00)
YOY Growth	-	-	-	-	-	-	-	-	
Diluted Shares O/S	198,228	222,969	231,583	242,000	250,000	236,638	363,000	505,000	535,000

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