Zacks Small-Cap Research

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CytoSorbents Cp (CTSO- NASDAQ)

CTSO: User's Meeting: Outcomes Lend Add'l Support in Cardiac Surgery and Other Indications

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (10/06/15)	$6.62
Target Price	**$12.50**

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. CTSO now also focused in U.S. regulatory approval – either with a cardiac surgery or critical care indication (such as sepsis). Co now investigating EAP route in U.S. to try and speed time to market at lower cost.

Recent restructuring of sales force caused a hiccup in sales but we think this is a short-term issue, is already being resolved with new hires and has no impact on long-term potential of CytoSorb. Interest in and use of CytoSorb from hospitals and physicians continues to increase. Also seeing great interest from distributors and other industry partners.

SUMMARY DATA

52-Week High	**$15.24**
52-Week Low	**$4.40**
One-Year Return (%)	**12.00**
Beta	**-0.56**
Average Daily Volume (sh)	**86,714**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$166**
Short Interest Ratio (days)	**13.85**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**72.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	1062 A	1025 A	1162 A	874 A	4123 A
2015	723 A	964 A	1048 E	1359 E	4094 E
2016					12034 E
2017					19580 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-0.20 A	-0.27 A	-0.22 A	-0.47 A	-1.29 A
2015	-0.19 A	0.06 A	-0.10 E	-0.10 E	-0.34 E
2016					-0.27 E
2017					-0.22 E

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

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2nd Int'l User's Meeting Update: Safety Further Established, Outcomes Lend Add'l Support to REFERSH I U.S. Cardiac Surgery Study…

CytoSorbents announced a summation of their 2nd International User's Meeting, held on Oct 2 in Berlin, Germany. The User's Meeting was held just prior to the 28th European Society of Intensive Care Medicine Conference (ESICM), where CTSO is exhibiting and, with colleagues, will make several presentations covering topics such as CytoSorb's role in controlling deadly cytokine storm and results of users' experience with their flagship device.

CTSO noted that the User's Meeting attracted 100 participants from over 18 countries. Highlights included that CytoSorb has now been used in over 8,000 human treatments – this is up from 5,500+ as of May of this year (a figure that CTSO provided on the Q1 earnings call). And while the press release summarizing the highlights of the meeting did not provide specifics in terms of efficacy data from users' experiences, which included preliminary results from three cardiac surgery trials, it did offer that CytoSorb's safety profile continues to be excellent which is a clear positive for conducting additional and larger trials, including REFRESH I, the company's U.S. cardiac surgery study.

CTSO hopes to be able to make the study presentations publicly available and is seeking permission from the studies' investigators (i.e. CTSO did not sponsor the studies and therefore does not "own" the data) to do so. Of particular interest may be the preliminary data from three cardiac surgery studies, including two randomized and one three-arm study. These are:

- *Reduction of Inflammation Reaction to Extracorporeal Circulation in Cardiac Surgery by Interleukin Dialysis*, being conducted at the University of Hamburg-Eppendorf in Germany. The study is using CytoSorb in the cardiopulmonary circuit in patients undergoing elective coronary bypass and heart valve surgery. Targeted enrollment is 40 patients, which will be randomized 1:1 with and without use of CytoSorb. Primary outcome is change in levels of cytokines during the procedure as compared to baseline. Cytokines measured are IL-6, IL-8, IL-10 and TNF-alpha

- *Effect of Cytokine Removal in Cardiopulmonary Bypass Patients Using the CytoSorb Filter*, being conducted at the Medical University of Vienna. The study is using CytoSorb cardiopulmonary circuit in patients undergoing elective cardiac surgery (which may include valve surgery, CABG or a combination of the two). Targeted enrollment is 46 patients, which will be randomized to CytoSorb installed in the circuit or to a control group where CytoSorb is not used. Primary outcome is evolution of cytokines IL-1β, IL-6, IL-18, TNF-alpha and IL-10.

- *Removal of Cytokine on Cardiopulmonary Bypass with CytoSorb Compared to On- and Off-pump Myocardial Revascularization*, being conducted at the University Hospital of Cologne. This is a three-arm study (with two controls) with targeted enrollment of 300 patients undergoing elective myocardial revascularization. Patients are assigned to one of three cohorts; 1) use of cardiopulmonary bypass with CytoSorb in the circuit , 2) use of cardiopulmonary bypass without CytoSorb in the circuit (control arm) and 3) no pump used (control arm). Primary outcome is evolution of the inflammatory response as measured by change from baseline in cytokine level. Cytokines measured are IL-6, IL-8, TNF-alpha and C3/C4-complement leukocytes CRP

CTSO noted that results of the studies showed that "some cytokines are removed in CytoSorb treat patients" – but qualified that these are shorter studies with relatively 'healthier' patients and that the risk of adverse events and mortality were low in both the CytoSorb and control cohorts. These studies are expected to include more complex cardiac procedures where risk of inflammation is higher – and which might presumably show a more definitive difference in outcomes of CytoSorb versus control patients.

A couple of key takeaways of the results were mentioned in CTSO's press release; that they support feasibility and safety of REFRESH I (patient screening is now underway) and safety, ease of use and feasibility are expected to increase confidence of using CytoSorb in a range of cardiac surgery procedures.

And in addition to cardiac surgery, as well as other conditions such as sepsis, pancreatitis, lung injury (and others), CTSO noted that CytoSorb has now also been used for treatment of certain tropical diseases such as Dengue Fever and Scrub Typhus. So the conditions and illnesses where CytoSorb may have utility continues to grow, which further expands the aggregate size and total value of the device's target markets.

FINANCIAL MODEL

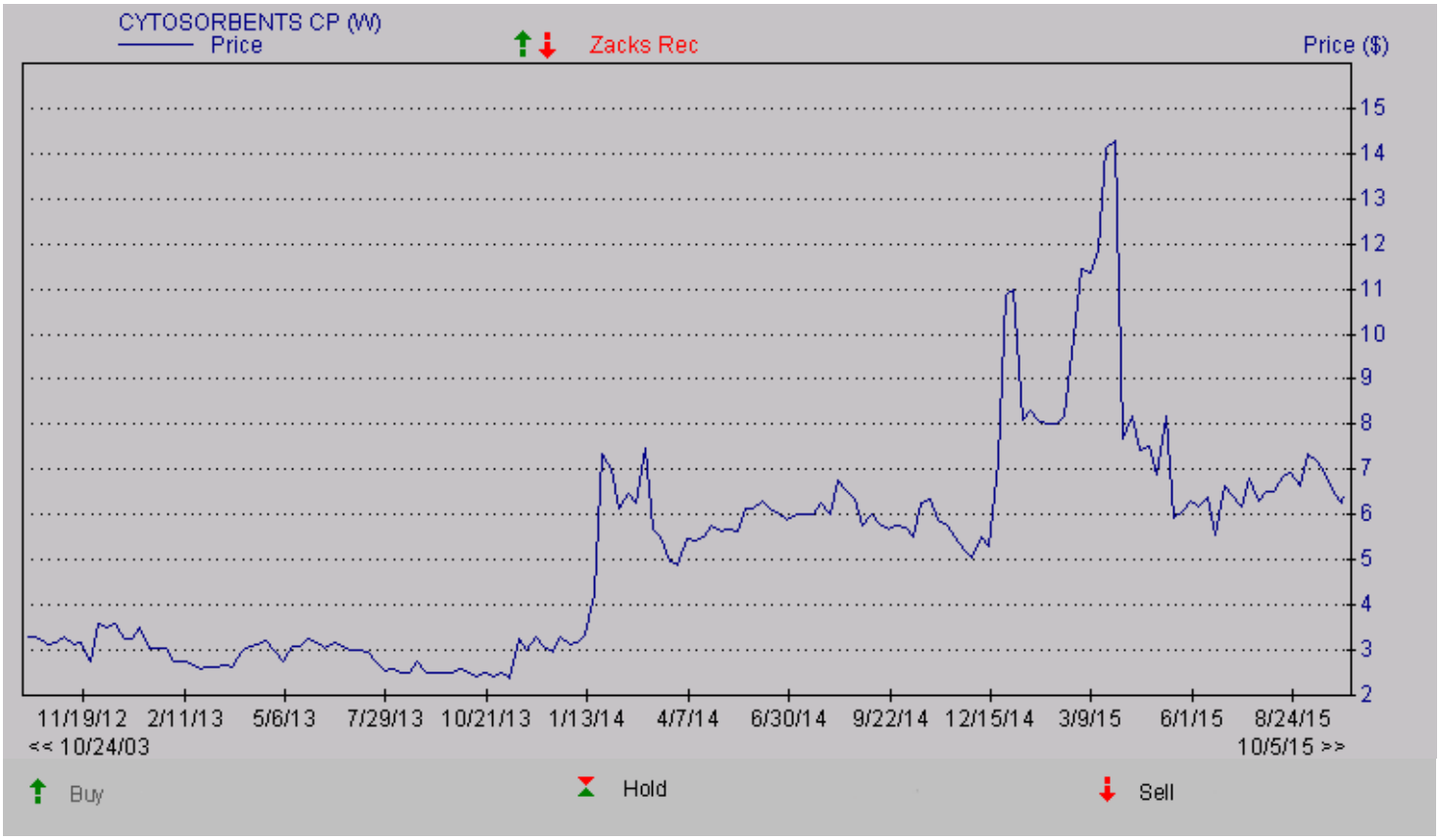
CytoSorbents Inc.

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
CytoSorb Sales	$3,135.4	$703.7	$773.1	$961.4	$1,242.7	$3,680.8	$11,030.0	$19,580.0	$28,010.0
y-o-y growth	*281.5%*	*23.6%*	*16.6%*	*-6.8%*	*42.6%*	*17.4%*	*199.7%*	*77.5%*	*43.1%*
Total Royalties/Grants/Other	$987.5	$19.4	$190.8	$87.0	$116.0	$413.2	$1,004.0	$0.0	$0.0
y-o-y growth	*-38.3%*	*-96.1%*	*-47.2%*	*-33.4%*	*4470.5%*	*-58.2%*	*143.0%*	*-100.0%*	*#DIV/0!*
Revenue	$4,122.9	$723.1	$963.9	$1,048.4	$1,358.7	$4,094.1	$12,034.0	$19,580.0	$28,010.0
YOY Growth	*70.2%*	*-31.9%*	*-5.9%*	*-9.8%*	*55.5%*	*-0.7%*	*193.9%*	*62.7%*	*43.1%*
Cost of Goods Sold	$2,133.9	$304.5	$465.4	$451.5	$586.7	$1,808.1	$5,115.1	$7,440.4	$10,643.8
Gross Income	$1,989.0	$418.6	$498.5	$596.9	$772.0	$2,285.9	$6,918.9	$12,139.6	$17,366.2
Gross Margin	*48.2%*	*57.9%*	*51.7%*	*56.9%*	*56.8%*	*55.8%*	*57.5%*	*62.0%*	*62.0%*
SG&A	$6,836.2	$2,179.2	$1,924.3	$2,225.0	$2,434.0	$8,762.5	$9,654.0	$13,237.0	$14,341.1
% SG&A	*165.8%*	*301.4%*	*199.6%*	*212.2%*	*179.1%*	*214.0%*	*80.2%*	*67.6%*	*51.2%*
R&D	$2,431.7	$951.0	$801.7	$974.0	$1,105.0	$3,831.7	$4,664.0	$4,881.0	$4,915.0
% R&D	*59.0%*	*131.5%*	*83.2%*	*92.9%*	*81.3%*	*93.6%*	*38.8%*	*24.9%*	*17.5%*
Operating Income	($7,278.9)	($2,711.6)	($2,227.5)	($2,602.1)	($2,767.0)	($10,308.3)	($7,399.1)	($5,978.4)	($1,889.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$2,428.5	$2,005.3	($3,661.8)	$0.0	$0.0	($1,656.5)	$0.0	$0.0	$0.0
Pre-Tax Income	($9,707.4)	($4,716.9)	$1,434.3	($2,602.1)	($2,767.0)	($8,651.8)	($7,399.1)	($5,978.4)	($1,889.9)
Taxes (benefit)	($385.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*4.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred Dividend	$9,266.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($18,588.4)	($4,716.9)	$1,434.3	($2,602.1)	($2,767.0)	($8,651.8)	($7,399.1)	($5,978.4)	($1,889.9)
Net Margin	-	*-652.3%*	*148.8%*	*-248.2%*	*-203.7%*	*-211.3%*	*-61.5%*	*-30.5%*	*-6.7%*
EPS	($1.29)	($0.19)	$0.06	($0.10)	($0.11)	($0.34)	($0.27)	($0.22)	($0.07)
YOY Growth	-	-	-	-	-	-			
Diluted Shares O/S	14,441	24,394	24,769	25,200	26,000	25,091	27,000	27,700	28,200

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