Zacks Small-Cap Research

February 3, 2015

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CytoSorbents Cp (CTSO- NASDAQ)

CTSOD: FDA Approves U.S. Study

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	02/02/2015
Current Price (02/02/15)	$8.11
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 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 hospitals and physicians continues to increase. Also seeing great interest from distributors and other industry partners.

SUMMARY DATA

52-Week High	**$12.87**
52-Week Low	**$4.40**
One-Year Return (%)	**106.25**
Beta	**-1.65**
Average Daily Volume (sh)	**32,605**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$154**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**24**
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	**Above Avg.,**
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	1162 A	1587 E	4836 E
2015					14210 E
2016					22380 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-0.25 A	-0.22 A	-0.15 A	-0.18 A	-0.75 A
2014	-0.20 A	-0.27 A	-0.22 A	-0.11 E	-0.73 E
2015					-0.24 E
2016					-0.14 E

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

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FDA Approves Cardiac Surgery Feasibility Study

FDA's approval for CytoSorbents to conduct a feasibility study comes about one month after the company submitted its investigational device exemption. This morning's press release provides some details on the study design. The study is expected to enroll 20 patients undergoing cardiac surgery across three (unnamed) U.S. sites and, along with safety, will evaluate CytoSorb's ability to actively remove plasma free hemoglobin and cytokines, among other inflammatory markers. These toxic substances, which are produced during cardiac surgery, can lead to serious complications including kidney injury / failure.

While this is a single-arm study, CTSO will also conduct a parallel, non-interventional study across several U.S. cardiac surgery centers. This study will use similar enrollment criteria as the interventional study and collect similar data related to adverse events, such as kidney injury / failure, and inflammatory markers, such as plasma free hemoglobin and cytokines from a broad population of patients undergoing cardiac surgery.

The two studies will provide a comparison of how well CytoSorb was able to reduce toxic substances and related adverse events between the active study patient population and those undergoing cardiac surgery where CytoSorb was not used. This data, assuming positive, will then be used as support for regulatory approval to initiate a larger, pivotal study for support of FDA approval. CTSO expects to commence this feasibility study shortly after receiving requisite institutional review board approvals at the selected study sites.

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. In addition to this study, CTSO has 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, data from which is expected to be forthcoming. A larger 200-patient (100 treatment / 100 control) cardiac surgery study recently 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 and, along with data from the feasibility study, provide additional insight into the approvability of the device in the U.S.

We are reiterating our Outperform rating on CTSO as well as our $12.50/share price target.

FINANCIAL MODEL

CytoSorbents Inc.

	2013 A	Q1A	Q2A	Q3A	Q4E	2014 E	2015 E	2016 E	2017 E
CytoSorb Sales	$821.8	$569.2	$663.2	$1,031.8	$1,180.0	$3,444.2	$13,110.0	$22,180.0	$30,090.0
y-o-y growth	*442.1%*	*223.3%*	*418.3%*	*406.9%*	*275.6%*	*319.1%*	*280.6%*	*69.2%*	*35.7%*
Total Royalties/Grants/Other	$1,600.9	$492.9	$361.4	$130.6	$407.0	$1,391.9	$1,100.0	$200.0	$0.0
y-o-y growth	*34.4%*	*152.5%*	*121.0%*	*-80.7%*	*-28.0%*	*-13.1%*	*-21.0%*	*-81.8%*	*-100.0%*
Revenue	$2,422.7	$1,062.2	$1,024.7	$1,162.3	$1,587.0	$4,836.2	$14,210.0	$22,380.0	$30,090.0
YOY Growth	*80.4%*	*186.0%*	*251.5%*	*32.0%*	*80.5%*	*99.6%*	*193.8%*	*57.5%*	*34.5%*
Cost of Goods Sold	$1,911.6	$662.5	$666.2	$475.9	$847.6	$2,652.2	$6,154.8	$8,658.4	$11,434.2
Gross Income	$511.1	$399.6	$358.5	$686.5	$739.4	$2,184.0	$8,055.2	$13,721.6	$18,655.8
Gross Margin	*21.1%*	*37.6%*	*35.0%*	*59.1%*	*46.6%*	*45.2%*	*56.7%*	*61.3%*	*62.0%*
SG&A	$3,485.4	$1,317.1	$1,394.6	$1,492.5	$1,664.0	$5,868.2	$9,654.0	$13,236.0	$15,616.7
% SG&A	*143.9%*	*124.0%*	*136.1%*	*128.4%*	*104.9%*	*121.3%*	*67.9%*	*59.1%*	*51.9%*
R&D	$1,738.9	$236.8	$347.0	$880.3	$862.0	$2,326.1	$4,500.0	$4,200.0	$3,287.0
% R&D	*71.8%*	*22.3%*	*33.9%*	*75.7%*	*54.3%*	*48.1%*	*31.7%*	*18.8%*	*10.9%*
Operating Income	($4,713.2)	($1,154.2)	($1,383.1)	($1,686.4)	($1,786.6)	($6,010.2)	($6,098.8)	($3,714.4)	($247.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$422.8	($179.1)	$470.5	($188.0)	($47.0)	$56.4	$0.0	$0.0	$0.0
Pre-Tax Income	($5,136.1)	($975.1)	($1,853.6)	($1,498.4)	($1,739.6)	($6,066.6)	($6,098.8)	($3,714.4)	($247.9)
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	$1,281.1	$701.0	$4,470.8	$0.0	$0.0	$0.0
Net Income	($7,073.3)	($2,089.6)	($3,227.8)	($2,779.4)	($2,440.6)	($10,537.4)	($6,098.8)	($3,714.4)	($247.9)
Net Margin	-	*-196.7%*	*-315.0%*	*-239.1%*	*-153.8%*	-	*-42.9%*	*-16.6%*	*-0.8%*
EPS	($0.75)	($0.20)	($0.27)	($0.22)	($0.11)	($0.73)	($0.24)	($0.14)	($0.01)
YOY Growth	-	-	-	-	-	-	-		
Diluted Shares O/S	9,441	10,619	12,048	12,496	22,600	14,441	25,000	25,900	26,800

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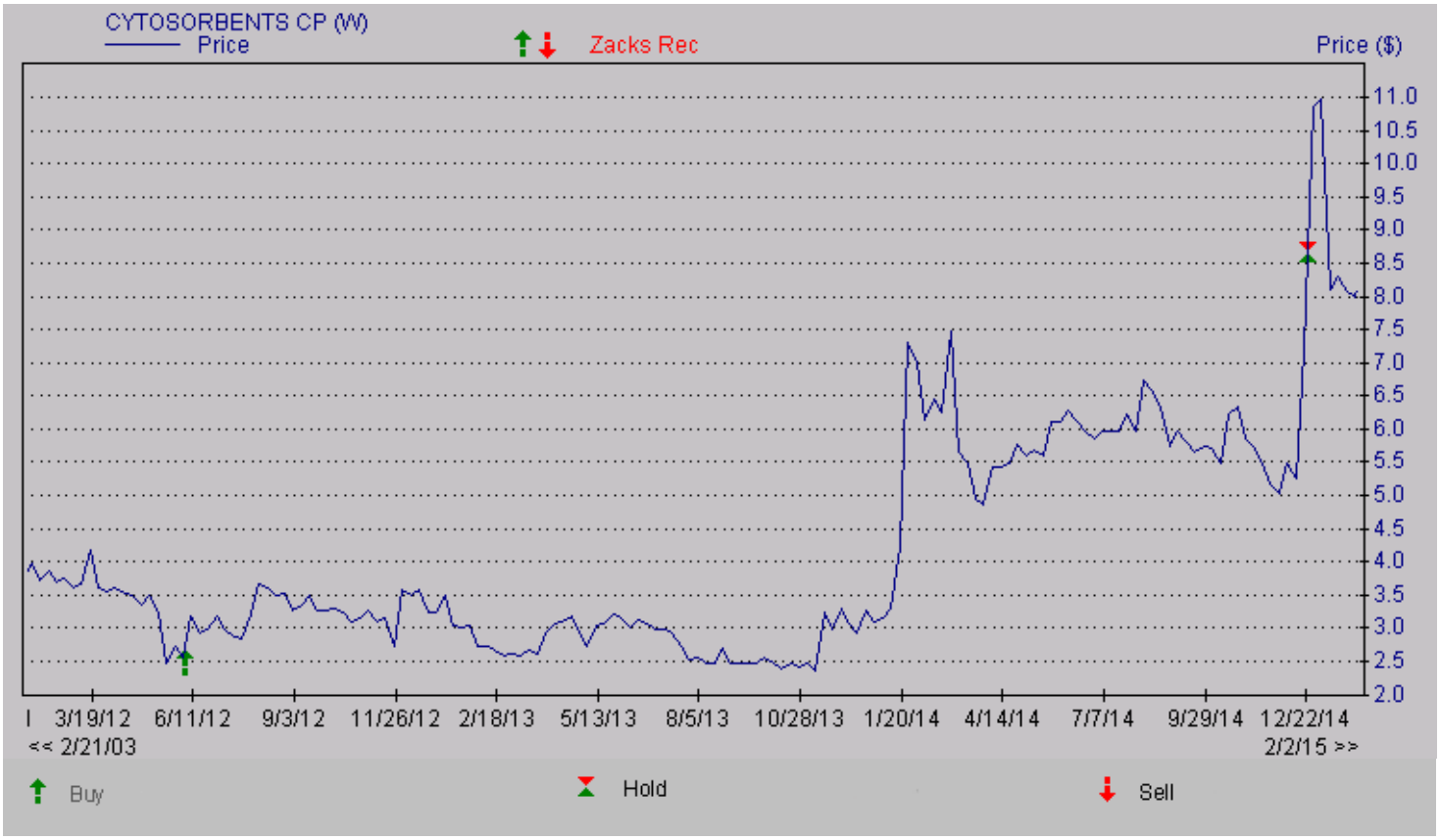

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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