Zacks Small-Cap Research

February 26, 2016

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CytoSorbents Cp (CTSO- NASDAQ)

CTSO: Additional Support in Sepsis

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (02/26/16)	$5.03
Target Price	**$11.50**

OUTLOOK

CTSO continues to generate clinical outcomes data which is being used to accelerate adoption and utilization. CTSO now also focused in U.S. regulatory approval – either with a cardiac surgery and/or sepsis indication. Just received notice from FDA that EAP for critical care illness in U.S. not feasible. CTSO now looking at IDE/PMA study for U.S. approval for sepsis.

Recent restructuring of sales force caused a hiccup in sales but looks like was only a short-term issue. Product sales grew 39% from Q2 to Q3. CTSO already made replacements to sales force with 2 add'l hires expected by current year-end. Add'l distributors, including Fresenius and add'l geographic territories to come online shortly should further accelerate product sales. Interest in and use of CytoSorb from hospitals and physicians continues to increase.

SUMMARY DATA

52-Week High	**$15.24**
52-Week Low	**$3.11**
One-Year Return (%)	**-59.07**
Beta	**0.43**
Average Daily Volume (sh)	**70,837**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$118**
Short Interest Ratio (days)	**4.56**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**63.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
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	1344 A	1454 E	4484 E
2016					12212 E
2017					20245 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	-0.11 A	-0.10 E	-0.35 E
2016					-0.27 E
2017					-0.21 E

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

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Further Support for Sepsis Pursuit

CytoSorbents presented initial results from an investigator initiated septic shock study (n=22) conducted in Germany at the Symposium for Intensive Medicine + Intensive Care in Bremen, Germany. The single-arm study included 22 very ill patients with refractory late-stage septic shock and multiple organ failure. All standard intervention (i.e. vasopressors, artificial ventilation, dialysis, etc) had failed prior to initiating CytoSorb therapy for twelve-hours over "several days".

Initial results showed;

- 28-day survival of 41% of the patients. 28-day all-cause mortality is FDA's accepted primary endpoint in sepsis therapy studies to-date. This 41%, as CytoSorbents notes in today's PR, compares favorably to the 0% survival (100% mortality) observed in the Conrad, et al study (published in Journal of Critical Care, Aug 2015) among the group of patients (n=16) that failed to respond to standard intervention (i.e. vasopressors, artificial ventilation, dialysis, etc).
- Shock was reversed in 68% of patients
- IL-6 (high levels of which have been associated with septic shock and mortality) fell from an average mean of 87,000 pg/mL, to below 10,000 pg/mL after 24 hours of treatment. As a reminder, CytoSorbents' European sepsis study also demonstrated the ability of CytoSorb to significantly reduce IL-6 as well as a statistically significant reduction in 28-day mortality in a subgroup of patients which had very high cytokine levels (IL-6 1,000 pg/mL and/or IL-1ra 16,000 pg/mL)

While the study is too small to draw any conclusions, particularly as sepsis is a complex condition affecting heterogeneous populations making homogenous enrollment difficult, we characterize the results as positive in that it provides additional credence to the idea that CytoSorb may be effective in reducing sepsis mortality. CTSO expects to complete the full analysis and submit additional data for publication in the future. And we expect CTSO and clinicians will be conducting more sepsis-related studies which may provide more insight into the effectiveness of CytoSorb for this disease – these studies may also help narrow enrollment criteria for a pivotal U.S. study in a sepsis indication.

FINANCIAL MODEL

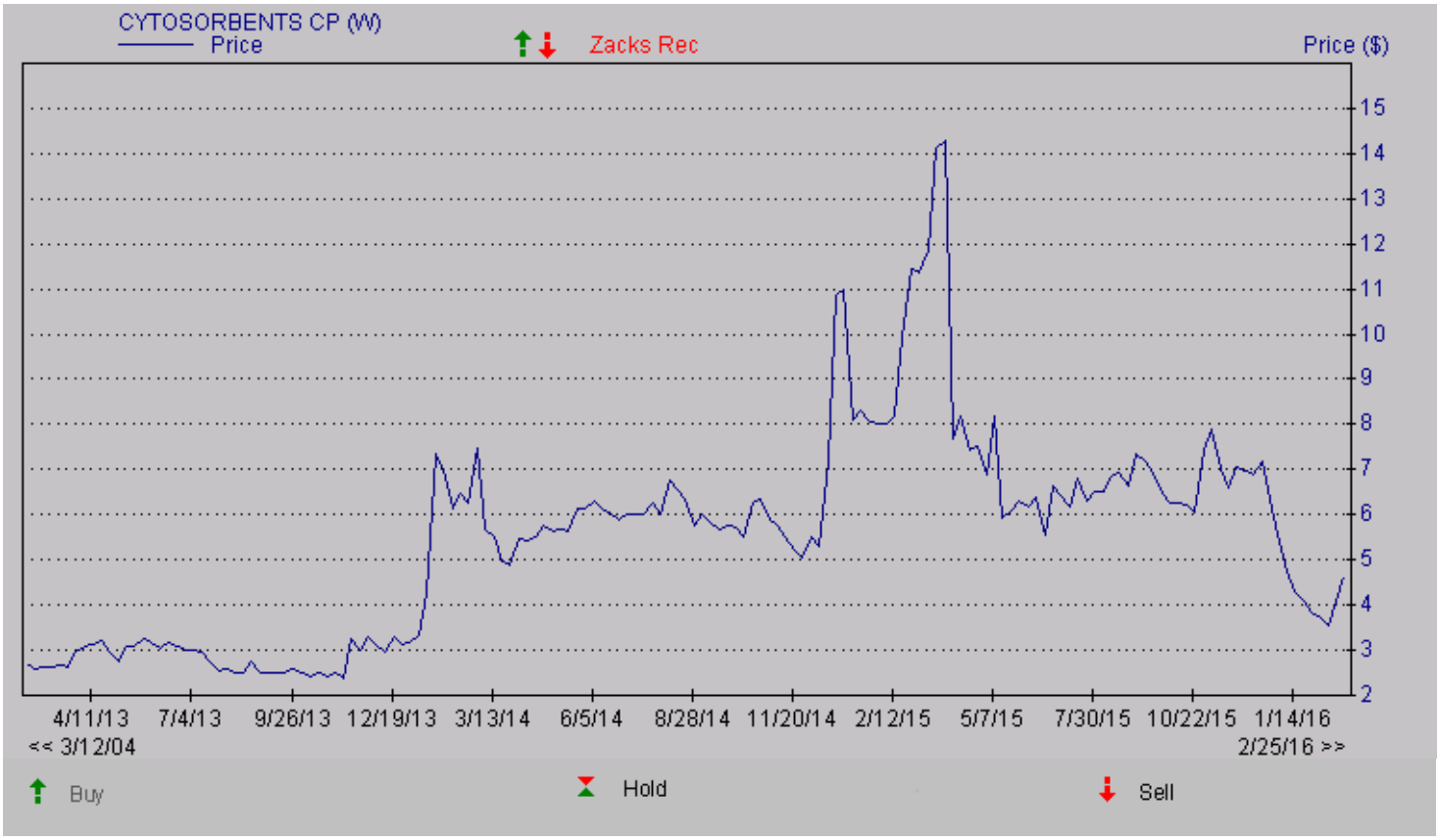
CytoSorbents Inc.

	2014 A	Q1A	Q2A	Q3A	Q4E	2015 E	2016 E	2017 E	2018 E
CytoSorb Sales	$3,135.4	$703.7	$773.1	$1,071.5	$1,242.7	$3,790.9	$11,030.0	$19,580.0	$28,010.0
y-o-y growth	*281.5%*	*23.6%*	*16.6%*	*3.8%*	*42.6%*	*20.9%*	*191.0%*	*77.5%*	*43.1%*
Total Royalties/Grants/Other	$987.5	$19.4	$190.8	$272.2	$211.1	$693.5	$1,181.8	$665.0	$0.0
y-o-y growth	*-38.3%*	*-96.1%*	*-47.2%*	*108.4%*	*8217.6%*	*-29.8%*	*70.4%*	*-43.7%*	*-100.0%*
Revenue	$4,122.9	$723.1	$963.9	$1,343.6	$1,453.8	$4,484.4	$12,211.8	$20,245.0	$28,010.0
YOY Growth	*70.2%*	*-31.9%*	*-5.9%*	*15.6%*	*66.4%*	*8.8%*	*172.3%*	*65.8%*	*38.4%*
Cost of Goods Sold	$2,133.9	$304.5	$465.4	$638.8	$667.6	$2,076.3	$5,225.4	$8,005.7	$10,643.8
Gross Income	$1,989.0	$418.6	$498.5	$704.8	$786.2	$2,408.1	$6,986.4	$12,239.4	$17,366.2
Gross Margin	*48.2%*	*57.9%*	*51.7%*	*52.5%*	*54.1%*	*53.7%*	*57.2%*	*60.5%*	*62.0%*
SG&A	$6,836.2	$2,179.2	$1,924.3	$1,988.8	$2,334.0	$8,426.3	$9,654.0	$13,237.0	$14,341.1
% SG&A	*165.8%*	*301.4%*	*199.6%*	*148.0%*	*160.5%*	*187.9%*	*79.1%*	*65.4%*	*51.2%*
R&D	$2,431.7	$951.0	$801.7	$866.3	$1,035.0	$3,654.0	$4,694.0	$4,902.0	$4,915.0
% R&D	*59.0%*	*131.5%*	*83.2%*	*64.5%*	*71.2%*	*81.5%*	*38.4%*	*24.2%*	*17.5%*
Operating Income	($7,278.9)	($2,711.6)	($2,227.5)	($2,150.3)	($2,582.8)	($9,672.2)	($7,361.6)	($5,899.7)	($1,889.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$2,428.5	$2,005.3	($3,661.8)	$697.1	($3.0)	($962.3)	$0.0	$0.0	$0.0
Pre-Tax Income	($9,707.4)	($4,716.9)	$1,434.3	($2,847.4)	($2,579.8)	($8,709.8)	($7,361.6)	($5,899.7)	($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	($2,847.4)	($2,579.8)	($8,709.8)	($7,361.6)	($5,899.7)	($1,889.9)
Net Margin	-	*-652.3%*	*148.8%*	*-211.9%*	*-177.4%*	*-194.2%*	*-60.3%*	*-29.1%*	*-6.7%*
EPS	($1.29)	($0.19)	$0.06	($0.11)	($0.10)	($0.35)	($0.27)	($0.21)	($0.07)
YOY Growth	-	-	-	-	-	-			
Diluted Shares O/S	14,441	24,394	24,769	25,038	25,350	24,888	27,000	27,700	28,200

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