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Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

DSMB Recommends Continuance of REMOVE Study: has several important implications

Based on our 10-year DCF model, which uses a 10% discount rate and a 2% terminal growth rate, the shares are valued at approximately \$15.

Current Price (02/04/19) **\$7.56**
Valuation **\$15.00**

OUTLOOK

CytoSorbents announced this morning that the Data Safety Monitoring Board overseeing REMOVE recommended that the study continue. The DSMB's recommendation was based on an evaluation of the first 50 patients. The assessment, which included 28 patients in the CytoSorb cohort and 22 in the control group, analyzed cytokine and vasoactive mediator levels as "an indicator of the mechanistic mode of action" and found no device-associated adverse events in the CytoSorb group.

This DSMB 50-patient evaluation was a critical milestone as not only does it indicate there are no serious safety concerns, but its success was also a prerequisite for the German government to continue funding the study. And it holds potentially even greater importance when considering that success of REMOVE could eventually inform or even help dictate the company's U.S. regulatory and commercialization decision-making.

SUMMARY DATA

52-Week High **\$14.95**
52-Week Low **\$6.60**
One-Year Return (%) **-4.62**
Beta **1.59**
Average Daily Volume (sh) **203,008**

Shares Outstanding (mil) **32**
Market Capitalization (\$mil) **\$239**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **26**
Insider Ownership (%) **7**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **55.4**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2019 Estimate **N/A**
P/E using 2020 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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	3114 A	3566 A	3824 A	4647 A	15151 A
2018	4925 A	5755 A	5743 A	5889 E	22311 E
2019					32586 E
2020					44780 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	-0.05 A	-0.04 A	-0.07 A	-0.11 A	-0.32 A
2018	-0.10 A	-0.19 A	-0.10 A	-0.12 E	-0.51 E
2019					-0.35 E
2020					-0.12 E

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

DSMB Recommends Continuance of REMOVE Study: *has several important implications...*

CytoSorbents announced this morning that the Data Safety Monitoring Board overseeing REMOVE, the company's Germany-based study funded by the German government and which is evaluating safety and efficacy of CytoSorb in patients with infective endocarditis undergoing valve replacement surgery, recommended that the study continue.

The DSMB's recommendation was based on an evaluation of the first 50 patients. The assessment, which included 28 patients in the CytoSorb cohort and 22 in the control group, analyzed cytokine and vasoactive mediator levels as "an indicator of the mechanistic mode of action" and found no device-associated adverse events in the CytoSorb group.

As a reminder, REMOVE is evaluating safety and efficacy of CytoSorb in patients with infective endocarditis undergoing valve replacement surgery. Primary endpoint is the difference in mean SOFA (Sequential Organ Failure Assessment) scores between experimental and control arms. Secondary endpoints include 30-day mortality, changes in cytokine levels, need for supportive care therapies such as vasopressors, mechanical ventilation, and dialysis, incidence of stroke, and the length of intensive care unit and in-hospital stay.

This study could be a win-win for CytoSorbents – potentially providing robust evidence of CytoSorb's utility in a large and growing patient population (an already-completed 39-patient case study already indicated potential utility of CytoSorb in infective endocarditis, a growing problem among IV drug users which share dirty needles) – and doing so at little or no cost to the company as the study is being fully funded by the German government. Jena University Hospital is primary sponsor - Jena has been an important partner of CTSO's over the years and manages the company's International CytoSorb registry. B.R.A.H.M.S. (a division of Thermo Fisher Scientific) and the Fraunhofer Institute for Interfacial Engineering and Biotechnology are co-collaborators.

This DSMB 50-patient evaluation was a critical milestone as not only does it indicate there are no serious safety concerns, but its success was also a prerequisite for the German government to continue funding the study. And it holds potentially even greater importance when considering that success of REMOVE could eventually inform or even help dictate the company's U.S. regulatory and commercialization decision-making.

Management recently noted that, given the robustness of the trial design, that it might be possible to use REMOVE as primary support (assuming positive results) for a future FDA filing for an infective endocarditis indication. As we noted in our recent update on CTSO, while it is way too early to guess the chances of that happening, positive results from this German study would certainly lend significant veracity to the likelihood of an eventual FDA approval for a similar indication whether it requires a U.S study or not.

As of CTSO's Q3 earnings call on November 6th, 62 patients had enrolled in the study, which is expected to include a total of 250. While this morning's press release does not disclose the number of patients that have been enrolled, it does note that enrollment "is inline with our goals, and we are confident in being able to advance this trial to completion."

FINANCIAL MODEL

CytoSorbents Inc.

	2017 A	Q1A	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E
CytoSorb Sales	\$13,381.9	\$4,433.3	\$5,245.6	\$5,102.7	\$5,396.0	\$20,177.6	\$30,390.0	\$43,006.8
y-o-y growth	63.1%	70.8%	72.5%	48.0%	25.6%	50.8%	50.6%	41.5%
Total Royalties/Grants/Other	\$1,769.7	\$491.4	\$509.9	\$640.2	\$493.0	\$2,133.6	\$2,196.0	\$1,773.0
y-o-y growth	33.9%	-5.0%	-2.9%	70.4%	40.6%	20.6%	2.9%	-19.3%
Revenue	\$15,150.8	\$4,924.7	\$5,755.4	\$5,743.0	\$5,889.0	\$22,311.2	\$32,586.0	\$44,779.8
YOY Growth	59.0%	58.2%	61.4%	50.2%	26.7%	47.3%	46.1%	37.4%
Cost of Goods Sold	\$5,518.4	\$1,567.6	\$1,785.9	\$2,052.7	\$2,100.7	\$7,506.9	\$9,464.1	\$10,108.4
Gross Income	\$9,632.4	\$3,357.0	\$3,969.6	\$3,690.3	\$3,788.3	\$14,804.2	\$23,121.9	\$34,671.4
Gross Margin	63.6%	68.2%	69.0%	64.3%	64.3%	66.4%	71.0%	77.4%
SG&A	\$15,558.7	\$4,677.9	\$6,581.7	\$4,457.5	\$4,866.5	\$20,583.5	\$25,193.3	\$28,986.6
SG&A % of Prod Sales	116.3%	105.5%	125.5%	87.4%	90.2%	87.1%	82.9%	67.4%
R&D	\$3,916.3	\$1,780.3	\$1,575.8	\$1,943.4	\$2,621.0	\$7,920.5	\$8,448.0	\$8,689.0
R&D % Tot Sales	25.8%	36.2%	27.4%	33.8%	44.5%	35.5%	25.9%	19.4%
Operating Income	(\$9,842.6)	(\$3,101.2)	(\$4,187.9)	(\$2,710.6)	(\$3,699.2)	(\$13,699.8)	(\$10,519.4)	(\$3,004.2)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Expense	(\$705.1)	(\$119.1)	\$1,633.3	\$294.1	\$220.6	\$2,028.9	\$1,506.2	\$1,318.6
Pre-Tax Income	(\$9,137.5)	(\$2,982.0)	(\$5,821.2)	(\$3,004.8)	(\$3,919.8)	(\$15,728.7)	(\$12,025.6)	(\$4,322.7)
Taxes (benefit)	(\$676.7)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Tax Rate	7.4%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Preferred/Othr Dividend	\$335.7	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net Income	(\$8,796.5)	(\$2,982.0)	(\$5,821.2)	(\$3,004.8)	(\$3,919.8)	(\$15,728.7)	(\$12,025.6)	(\$4,322.7)
Net Margin	-58.1%	-60.6%	-101.1%	-52.3%	-66.6%	-70.5%	-36.9%	-9.7%
EPS	(\$0.32)	(\$0.10)	(\$0.19)	(\$0.10)	(\$0.12)	(\$0.51)	(\$0.35)	(\$0.12)
YOY Growth		-	-	-	-			
Diluted Shares O/S	27,614	29,351	30,302	31,306	31,850	30,702	34,000	35,000

Brian Marckx, CFA

HISTORICAL STOCK PRICE



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