Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Large, Randomized Clinical Study Aims to Further Validate CytoSorb Efficacy in Infective Endocarditis

Based on our 10-year DCF model, which uses a 13% discount rate to account for certain risks and uncertainties that CytoSorbents faces, and a 2% terminal growth rate, the shares are valued at approximately $12.

Current Price (12/19/17)	$6.00
Valuation	**$12.00**

OUTLOOK

CytoSorbents hopes to further validate efficacy CytoSorb in infective endocarditis, announcing last week that a new, large, randomized clinical study is expected to begin early next year in Germany. The multi-center study, dubbed REMOVE, is expected to enroll 250 subjects and will evaluate CytoSorb in patients with infective endocarditis undergoing valve replacement surgery. This study could be a win-win for CytoSorbents – potentially providing robust evidence of CytoSorb's utility in a large and growing patient population – and doing so at (presumably) little cost to the company as the study is being fully funded by the German government. Primary endpoint is change in SOFA score, which is based on six different measures - many of which were assessed (with favorable results) in a prior 39-patient case study. Mortality was also much lower than predicted in the 39-patient case series. We also note that another recently published study also showed that CytoSorb treatment was associated with significant reduction in vasopressor requirements, hemodynamic stability, pro-inflammatory mediators and mortality. We provide this as background as we think it offers context in terms of the potential for eventual success of REMOVE.

SUMMARY DATA

52-Week High	**$7.05**
52-Week Low	**$3.305**
One-Year Return (%)	**19.00**
Beta	**-0.53**
Average Daily Volume (sh)	**154,799**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$172**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**11**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**55.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 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)
2016	1810 A	2222 A	2412 A	3083 A	9528 A
2017	3114 A	3566 A	3824 A	3850 E	14354 E
2018					21253 E
2019					30676 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-0.08 A	-0.12 A	-0.11 A	-0.17 A	-0.47 A
2017	-0.05 A	-0.04 A	-0.07 A	-0.09 E	-0.26 E
2018					-0.36 E
2019					-0.19 E

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

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Large, Randomized Clinical Study Aims to Further Validate CytoSorb Efficacy in Infective Endocarditis..

As a reminder, a manuscript of a retrospective case series involving 39 patients with infective endocarditis undergoing valve replacement surgery using CytoSorb was published in May in the International Journal of Artificial Organs. The study (which was the largest study to-date using CytoSorb for patients with infective endocarditis undergoing valve replacement surgery) showed that intraoperative use of CytoSorb was associated with lower mortality as compared to historical data (without CytoSorb use) as well as a meaningful reduction in certain inflammatory mediators (including IL-6 and IL-8), hemodynamic stabilization and reduction in vasopressor requirements. (See our Nov 20th update for our discussion of this case report

Infective endocarditis, as the name implies, is an infection of the endocardial surface of the heart – which includes one or more heart valves. It is a result of certain bacteria and other pathogens that enter the bloodstream, which can be highly and rapidly destructive to heart valves and spread to systemic sepsis and septic shock. Septic shock occurs when infection leads to critically low blood pressure and organ failure. Rates of infective endocarditis have been on the rise as a result of the recent dramatic growth of intravenous (i.e. dirty needles) heroin use in the U.S.).

CytoSorbents hopes to further validate use of CytoSorb in this patient population and last week announced that a new, large, randomized clinical study is expected to begin early next year in Germany and is aimed at doing just that. The multi-center study, dubbed REMOVE (REvealing Mechanisms and Investigating Efficacy Of Hemoadsorption for Prevention of Vasodilatory Shock in Cardiac Surgery Patients With Infective Endocarditis), is expected to enroll 250 subjects and will evaluate safety and efficacy of CytoSorb in patients with infective endocarditis undergoing valve replacement surgery. Primary endpoint will be 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 – and doing so at (presumably) little 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.

REMOVE incorporates inclusion criteria of EuroSCORE II ≥ 4. Higher EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) scores are associated with higher risk of mortality. For reference, mean and median EuroSCORE II scores among the 39 patients from the earlier case study was 12.8 and 26.0, respectively, - so those were relatively very sick individuals. While a specific organ function-related measure was not part of that case study, certain parameters associated with organ function and clinical outcomes, were. The case study showed that CytoSorb-treated patients experienced marked reduction in IL-6 and IL-8, "normalization of lactate and base excess back to preoperative baseline levels within 3 days and hemodynamic stability before, during, and after the operation accompanied by a rapid decrease in need for vasopressors."

Primary endpoint of REMOVE is change in SOFA score – which is a widely accepted clinical measure of organ function as well as of mortality. SOFA is based on six different measures; respiratory, cardiovascular, hepatic, coagulation, renal and neurological – many of which were assessed (with favorable results) in the 39-patient case study. Mortality was also much lower than predicted in the 39-patient case series – also suggesting a CytoSorb-related mortality benefit. We also note that another recently published study ("Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single-center study", *Journal of Artificial Organs*, Sept 2017) also showed that CytoSorb treatment was associated with significant reduction in vasopressor requirements, hemodynamic stability, pro-inflammatory mediators and mortality. We provide this as background as we think it offers context in terms of the potential for eventual success of REMOVE.

REMOVE will be conducted in parallel with REFRESH II (i.e. their U.S.-based valve replacement surgery study), the latter which specifically excludes subjects with infective endocarditis. As such and assuming success of both studies, CytoSorbents envisions that their device could one day be considered standard of care for the majority of open heart valve replacement surgeries ("hundreds of thousands of procedures worldwide").

In terms of the co-collaborators, it appears (based on our Google search) that both B.R.A.H.M.S. and the Fraunhofer Institute for Interfacial Engineering and Biotechnology are involved in (among many other projects) the

development of diagnostics for the early detection of sepsis. B.R.A.H.M.S.'s Procalcitonin (PCT)-detection assays determine whether an infection is bacterial and helps clinicians in deciding on best therapeutic care. Fraunhofer Institute for Interfacial Engineering and Biotechnology is using next-generation sequencing to facilitate earlier and more accurate diagnosis of sepsis through identification of specific bacteria, fungi and viruses.

While it is too early for us to opine on the possibility of any future direct working relationships between CTSO and these co-collaborators in REMOVE, the fact that CytoSorb has shown utility in removing PCT as well as certain fungal toxins piques our interest – particularly in the context of the possibility that CTSO may eventually move towards a specific FDA sepsis program – but that is purely conjecture on our part.

FINANCIAL MODEL

CytoSorbents Inc.

	2016 A	Q1A	Q2A	Q3A	Q4E	2017 E	2018 E	2019 E	2020 E
CytoSorb Sales	$8,206.1	$2,596.1	$3,041.0	$3,448.7	$3,366.5	$12,452.3	$19,690.0	$29,516.0	$41,700.0
y-o-y growth	102.9%	62.5%	64.1%	60.9%	28.8%	51.7%	58.1%	49.9%	41.3%
Total Royalties/Grants/Other	$1,321.8	$517.4	$525.2	$375.6	$483.0	$1,902.0	$1,563.0	$1,160.0	$1,005.0
y-o-y growth	76.8%	143.2%	42.1%	39.9%	2.6%	43.9%	-17.8%	-	-
Revenue	$9,527.9	$3,113.5	$3,566.2	$3,824.3	$3,849.5	$14,353.5	$21,253.0	$30,676.0	$42,705.0
YOY Growth	98.8%	72.0%	60.5%	58.6%	24.8%	50.6%	48.1%	44.3%	39.2%
Cost of Goods Sold	$3,953.8	$1,254.5	$1,482.0	$1,516.9	$1,574.9	$5,828.3	$7,038.7	$9,102.9	$11,904.8
Gross Income	$5,574.1	$1,859.0	$2,084.2	$2,307.4	$2,274.6	$8,525.3	$14,214.4	$21,573.1	$30,800.3
Gross Margin	58.5%	59.7%	58.4%	60.3%	59.1%	59.4%	66.9%	70.3%	72.1%
SG&A	$12,282.7	$2,947.0	$3,927.5	$3,918.5	$3,961.0	$14,754.0	$17,445.3	$20,690.7	$24,728.1
SG&A % of Prod Sales	149.7%	113.5%	129.2%	113.6%	117.7%	118.5%	88.6%	70.1%	59.3%
R&D	$4,783.5	$469.5	$487.6	$537.9	$622.4	$2,117.5	$7,287.0	$6,956.0	$7,295.0
R&D % Tot Sales	50.2%	15.1%	13.7%	14.1%	16.2%	14.8%	34.3%	22.7%	17.1%
Operating Income	($11,492.1)	($1,557.5)	($2,330.9)	($2,149.0)	($2,308.8)	($8,346.2)	($10,518.0)	($6,073.6)	($1,222.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$765.3	($179.5)	($1,214.5)	($94.8)	$249.6	($1,239.2)	$772.8	$361.1	$44.1
Pre-Tax Income	($12,257.3)	($1,378.0)	($1,116.4)	($2,054.3)	($2,558.4)	($7,107.1)	($11,290.8)	($6,434.7)	($1,267.0)
Taxes (benefit)	($318.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	2.6%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Preferred Dividend	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($11,938.8)	($1,378.0)	($1,116.4)	($2,054.3)	($2,558.4)	($7,107.1)	($11,290.8)	($6,434.7)	($1,267.0)
Net Margin	-125.3%	-44.3%	-31.3%	-53.7%	-66.5%	-49.5%	-53.1%	-21.0%	-3.0%
EPS	($0.47)	($0.05)	($0.04)	($0.07)	($0.09)	($0.26)	($0.36)	($0.19)	($0.04)
YOY Growth		-	-	-	-				
Diluted Shares O/S	25,433	25,504	27,954	28,206	28,600	27,566	31,500	33,500	34,500

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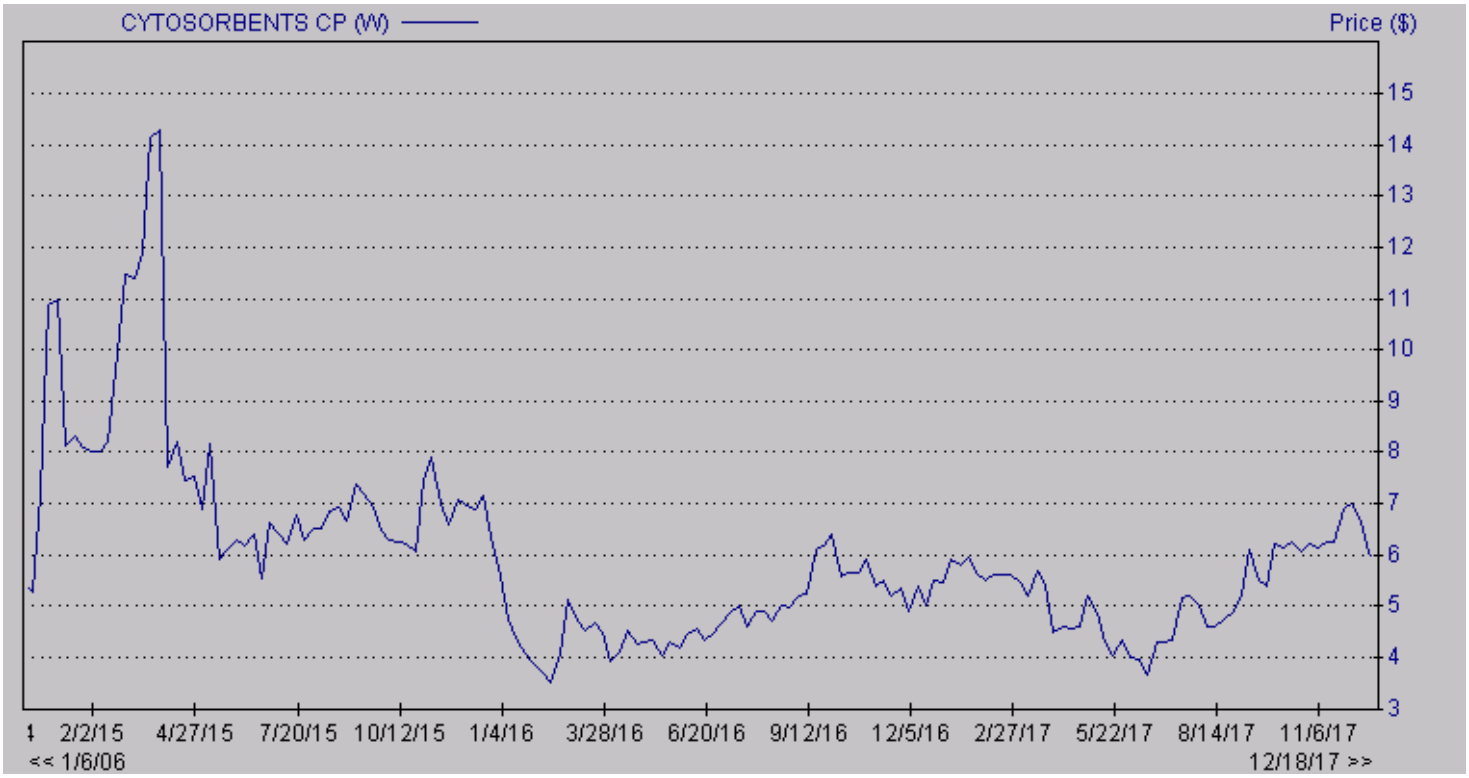

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