Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Equity Raise, Cancer Applications, REFRESH I Data Upcoming

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 $12.50.

Current Price (04/13/17)	$5.30
Valuation	**$12.50**

OUTLOOK

CTSO coming off record year with product sales growth of 103% in 2016. We see several catalysts which will extend these record sales. We expect to see accelerating product sales growth as well as more strides on the operational front. Terumo is a key addition to exploit cardiac surgery channel and indications are that they are off to strong start. We think Terumo channel could be particular highlight in 2017. New co-marketing deal with Fresenius is savvy, win-win-win and significantly expands CTSO's distribution capabilities and reach – another potential major catalyst for 2017. Dedicated reimbursement in Germany coming online should further benefit uptake in CTSO's most important and single largest sales territory. Expect regular flow of clinical data, including REFRESH I efficacy read-out, as well as publications in near term to provide additional evidence of clinical benefits including improved patient outcomes.

SUMMARY DATA

52-Week High	**$6.90**
52-Week Low	**$4.00**
One-Year Return (%)	**6.65**
Beta	**0.00**
Average Daily Volume (sh)	**127,285**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$130**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**58.8**
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	**High,**
Type of Stock	**N/A**
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	3117 E	3414 E	3627 E	3846 E	14004 E
2018					22072 E
2019					32896 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	-0.11 E	-0.11 E	-0.10 E	-0.11 E	-0.42 E
2018					-0.25 E
2019					-0.12 E

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

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Restocked Cash Balance, Upcoming REFRESH I Data, Cancer Shows Additional Promise:

CytoSorbents has been busy the last several weeks which included an equity financing which raised $11.5M (gross) and should provide a healthy runway towards furthering their U.S. regulatory program(s), adding a cancer immunotherapy expert to their scientific advisory board and announcing additional validation of CytoSorb's potential utility in several indications, including in cancer.

Relative to the financing, CTSO sold 2.56M common shares (including 333k optional underwriter's overallotment) at $4.50/share (~18% discount to prior-day close) for gross (and approximate net proceeds) of $11.5M ($10.4M). Pro forma for this equity raise, cash balance at 2016 year-end would be approximately $15.6M. Cash burn averaged approximately $2.1M per quarter in 2016 – at that rate the pro forma cash balance represents an approximate runway through roughly Q3 2018. While additional R&D activities including the U.S. clinical program could steepen cash needs, we think at least some (and potentially all) of that increase will be offset by an increase in cash generation via our expectation of continued significant revenue growth. We also note that the additional share count from the raise has no effect on our modeled EPS or target share price given that we had already included an expected near-term equity raise in our model. We reiterate our $12.50/share price target.

On the operational front….

- We look forward to the upcoming **REFRESH I efficacy data** presentation on May 1st at AATS. As we have noted in the past, we think additional positive clinical data, particularly from randomized trials such as REFRESH, will have major influence on further adoption and utilization of CytoSorb.

  As a reminder, REFRESH I is a multi-site 40+-patient randomized study comparing CytoSorb plus standard-of-care (SOC) to SOC alone (1:1) in the reduction of free hemoglobin in patients undergoing elective complex cardiac surgery requiring cardiopulmonary bypass with anticipated duration of more than 180 minutes. In October 2016 CTSO announced positive safety-related information.

  Management has indicated that they are confident the data will show that CytoSorb was effective in lowering plasma free hemoglobin. And perhaps just as encouraging was their comments on the Q4 call (Feb 26, 2017), indicating that they have identified certain cardiac surgeries which are associated with particularly high levels of plasma free hemoglobin – more than 50% of REFRESH I patients fell into this category. These procedures/patients could be the low-hanging fruit in terms of demonstrating efficacy and also help to power REFRESH II, which could commence later this year (following discussions with FDA and requisite IDE approval).

- And while the U.S. strategy is currently focused on a cardiac surgery indication, it's important to remember that CytoSorb could have effective utility in a number of different indications. One of which is sepsis and another is in cancer applications. While sepsis has been a significant topic of CTSO in the past, cancer has not received nearly as much attention (although CytoSorb has shown some utility in oncological applications). That could soon change, however. A few weeks ago CTSO announced that Dr, Carl June, an expert in CAR T-cell cancer immunotherapy, joined the company's scientific advisory board for the purpose of guiding the **strategy in oncology.**

  Just days prior to the Dr. June announcement, CTSO revealed that CytoSorb had been used successfully in several patients with a condition called hemophagocytic lymphohistiocytosis (HLH) – one of these was the subject of a case report published in early March in the Journal of Clinical Immunology. Studies have shown that subjects with secondary HLH, which is often caused by virologic infection and characterized by a strong and sometimes uncontrollable immune response – including cytokine release syndrome (CRS), can exhibit responses similar to cancer patients treated with certain immunotherapies. Specifically, severe CRS (i.e. severe inflammatory response with excessive and harmful levels of cytokines) which can lead to serious complications including organ failure and even death, has been associated with the use cancer immunotherapies such as CART-19 and blinatumomab as well as with secondary HLH. While corticosteroids and tocilizumab have been used with some success in controlling CRS, there are drawbacks. This includes that corticosteroids are suspected of potentially comprising immunotherapy efficacy. Relative to tocilizumab, researchers have noted that its use should be avoided if macrophage activating syndrome (MAS) is suspected.[1] The similarity in CRS response in HLH and cancer patients treated with immunotherapies and CytoSorb's apparent early success in treating HLH patients (via reduction in inflammatory markers) is encouraging, particularly as it may relate to the leveraging the massive interest in and growth of the immunotherapy segment.

[1] Shannon L. Maude, MD, PhD,* David Barrett, MD, PhD,* David T. Teachey, MD,* and Stephan A. Grupp, MD, PhD. Managing Cytokine Release Syndrome Associated With Novel T Cell-Engaging Therapies. Cancer J. 2014 Mar-Apr; 20(2): 119–122.

CTSO notes in their March 20, 2017 press release that “we have confirmed the interest in the therapy, once available, as an adjunct to tocilizumab, and before high dose steroids are administered. We plan to continue to pursue applications of our therapy in the treatment of CRS in the United States, Europe, and elsewhere, as cancer immunotherapies continue to expand worldwide.”
So while cancer has been what we would characterize as a back-burner application – that could soon change given the recent hiring of Dr. June and the additional recent clinical work indicating CytoSorb’s potential utility in oncology-related areas.

FINANCIAL MODEL

CytoSorbents Inc.

	2016 A	Q1E	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E	2020 E
CytoSorb Sales	$8,206.1	$2,738.8	$3,072.3	$3,360.0	$3,652.5	$12,823.5	$21,822.0	$32,116.0	$44,300.0
y-o-y growth	*102.9%*	*71.4%*	*65.8%*	*56.8%*	*39.8%*	*56.3%*	*70.2%*	*47.2%*	*37.9%*
Total Royalties/Grants/Other	$1,321.8	$378.0	$342.0	$267.0	$193.0	$1,180.0	$250.0	$780.0	$825.0
y-o-y growth	*76.8%*	*77.7%*	*-7.5%*	*-0.6%*	*-59.0%*	*-10.7%*	*-78.8%*	-	-
Revenue	$9,527.9	$3,116.8	$3,414.3	$3,627.0	$3,845.5	$14,003.5	$22,072.0	$32,896.0	$45,125.0
YOY Growth	*98.8%*	*72.2%*	*53.6%*	*50.4%*	*24.7%*	*47.0%*	*57.6%*	*49.0%*	*37.2%*
Cost of Goods Sold	$3,953.8	$1,254.4	$1,309.8	$1,308.6	$1,307.0	$5,179.8	$6,565.9	$9,733.5	$12,744.8
Gross Income	$5,574.1	$1,862.4	$2,104.5	$2,318.4	$2,538.5	$8,823.7	$15,506.1	$23,162.5	$32,380.3
Gross Margin	*58.5%*	*59.8%*	*61.6%*	*63.9%*	*66.0%*	*63.0%*	*70.3%*	*70.4%*	*71.8%*
SG&A	$12,282.7	$3,246.0	$3,505.0	$3,570.0	$3,725.0	$14,046.0	$16,759.3	$20,040.4	$24,143.5
SG&A % of Prod Sales	*149.7%*	*118.5%*	*114.1%*	*106.3%*	*102.0%*	*109.5%*	*76.8%*	*62.4%*	*54.5%*
R&D	$4,783.5	$1,227.0	$1,368.0	$1,440.0	$1,647.0	$5,682.0	$5,987.0	$6,849.0	$7,295.0
R&D % Tot Sales	*50.2%*	*39.4%*	*40.1%*	*39.7%*	*42.8%*	*40.6%*	*27.1%*	*20.8%*	*16.2%*
Operating Income	($11,492.1)	($2,610.7)	($2,768.5)	($2,691.6)	($2,833.5)	($10,904.3)	($7,240.2)	($3,726.9)	$941.8
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$765.3	$102.5	$168.9	$187.9	$170.8	$630.2	$546.5	$276.0	$5.3
Pre-Tax Income	($12,257.3)	($2,713.1)	($2,937.4)	($2,879.5)	($3,004.3)	($11,534.4)	($7,786.6)	($4,002.8)	$936.5
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)	($2,713.1)	($2,937.4)	($2,879.5)	($3,004.3)	($11,534.4)	($7,786.6)	($4,002.8)	$936.5
Net Margin	*-125.3%*	*-87.1%*	*-86.0%*	*-79.4%*	*-78.1%*	*-82.4%*	*-35.3%*	*-12.2%*	*2.1%*
EPS	($0.47)	($0.11)	($0.11)	($0.10)	($0.11)	($0.42)	($0.25)	($0.12)	$0.03
YOY Growth		-	-	-	-				
Diluted Shares O/S	25,433	25,520	27,970	28,000	28,400	27,473	31,200	33,200	34,000

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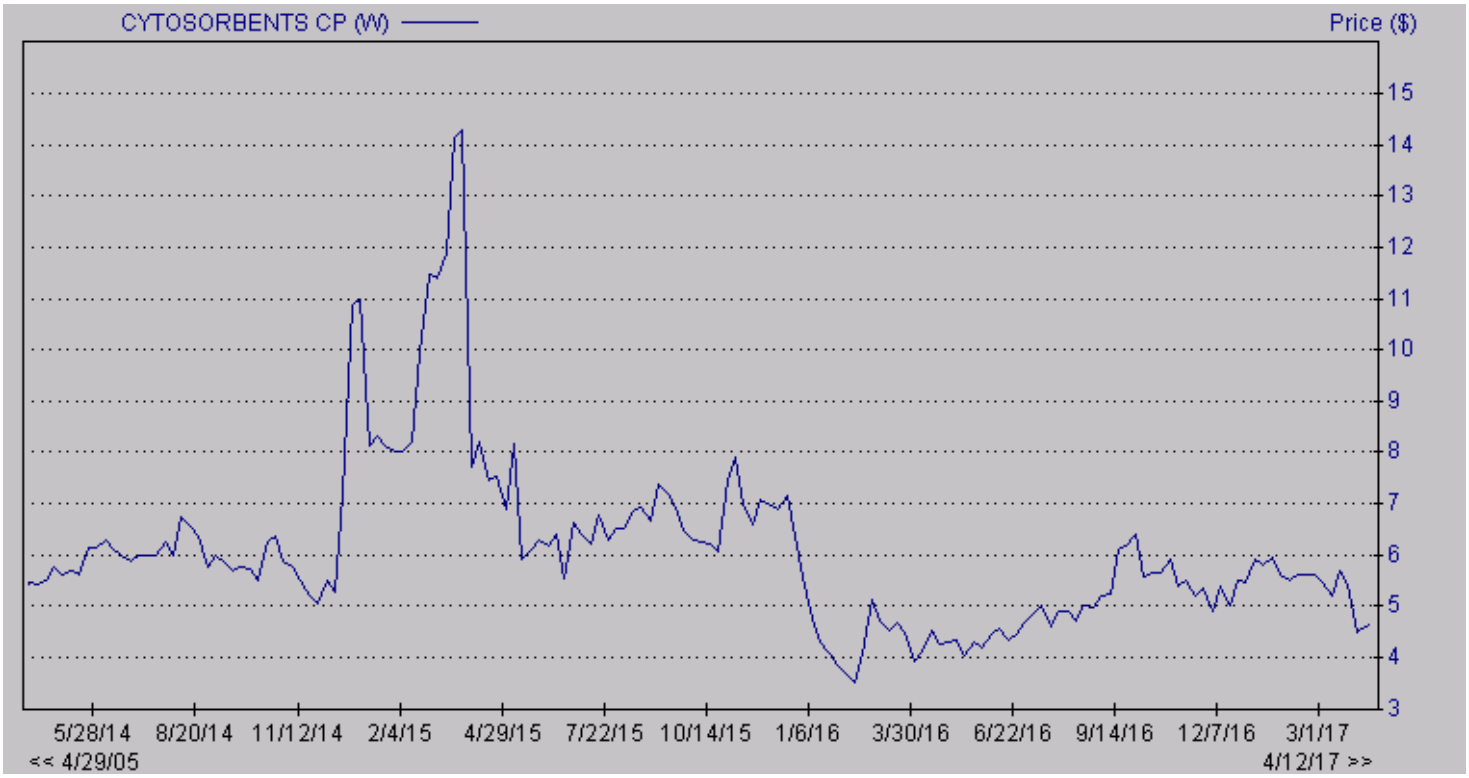

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