Zacks Small-Cap Research

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CytoSorbents Cp (CTSO- NASDAQ)

CTSO: Record Product Sales. Expect Growth Curve To Further Steepen in 2016, Fueled By Several Catalysts

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (03/10/16)	$4.47
Target Price	**$12.50**

OUTLOOK

We view 2015 as somewhat of a re-grouping year on the income statement - although "regrouping" should be put into context given that product sales grew 29% – and which would have been almost 50% growth if not for an Fx headwind. And if not for the sales force disruption earlier in the year, product sales growth would likely have been even significantly stronger.

We expect to see accelerating product sales growth as well as more strides on the operational front in 2016. In addition to Fresenius coming online, expansion into other geographic territories (in addition to those detailed by Fresenius), an expected continued regular flow of clinical data (including that from the patient registry as well as REFRESH I), potential additional production gains from the direct sales force, sales through Biocon could also accelerate further. And the cardiac-surgery channel also holds significantly potential. Consummation of a partnering agreement could further this opportunity.

SUMMARY DATA

52-Week High	**$15.24**
52-Week Low	**$3.11**
One-Year Return (%)	**-55.33**
Beta	**0.35**
Average Daily Volume (sh)	**99,074**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$114**
Short Interest Ratio (days)	**N/A**
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)
2015	723 A	964 A	1344 A	1761 A	4792 A
2016	1850 E	2543 E	3051 E	3634 E	11078 E
2017					18505 E
2018					26450 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-0.19 A	0.06 A	-0.11 A	-0.08 A	-0.33 A
2016	-0.08 E	-0.08 E	-0.08 E	-0.07 E	-0.32 E
2017					-0.23 E
2018					-0.06 E

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

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Q4 Financials / Operating Update: *Product Sales Set New Record. Several Catalysts Should Further Steepen Sales Growth Throughout 2016….*

CytoSorbents reported financial results for the fourth quarter ending December 31st. They turned in another very strong quarter with product sales jumping 40% from Q3 and 72% yoy. The sequential growth is particularly impressive given that much of the disruption caused by the sales force restructuring had already been mended by end of Q2 of this year. Both product sales and total revenue were at all-time records. And the fundamentals behind the growth continue to suggest stickiness in the customer base and ongoing re-ordering. Management indicated on the call that they are seeing a greater shift from hospitals employing CytoSorb in somewhat of a one-off use to more regularly reliance on the device for certain diseases and conditions including some hospitals where CytoSorb "has been used almost as a standard of care."

This has been, and continues to be an important part of our thesis for expectations of continued product sales growth. The driving force remains positive clinical outcomes data from company sponsored and investigator initiated studies. An example being the highly positive outcomes from a recent investigator-initiated sepsis study where CytoSorb was introduced with very ill patients after standard of care had failed (study summarized below). CTSO's clinical data registry is a key piece of the awareness and validation effort and by all accounts appears to be successful in that regard. CTSO expects upcoming interim data from the registry, announcement of which could be another catalyst to driving interest in CytoSorb.

Other pieces of the growth story include expansion into new geographic territories (such as Russia, Saudi Arabia, Israel, Canada and others which could come online in 2016) and additional distribution. Fresenius, in particular, could be meaningful part of this. While the official Fresenius launch has been delayed, CTSO noted on the call that this will kick off at ISICEM conference in Brussels next week. CytoSorb will be featured in Fresenius' booth. The launch is expected to physically begin shortly afterwards in France, Poland, Denmark, Norway, Finland and Sweden.

And expanding use for other indications is another area which has and will almost certainly continue to be a tailwind to adoption. Cardiac surgery is one where adoption has been growing (CytoSorb has now been used in more than 1,000 cardiac surgeries) and could accelerate further when results of the REFRESH I study are available. The study is now (per the Q4 call) ~35% enrolled and expected to complete enrollment around mid-year. Data could be available shortly afterwards. And, assuming positive results, CTSO will look to move into the larger REFRESH II study. The company also continues to have discussions with potential cardiac-surgery partners – if and when consummated, this could further fuel use in related indications.

And in addition to the fundamentally sound product sales growth, product margin is also trending in a positive direction, inching up on higher volume. Product margin widened by about 100 basis points throughout 2015 and we think it continues to incrementally expand through 2016 – mostly as a result of greater sales volume, as opposed to any pricing increases.

Q4 Results

Q4 total revenue was $1,766, up 102% yoy and +16% sequentially. Product sales grew 72% yoy to $1.5M, representing 40% sequential growth. For the full-year product sales increased 29% - while a solid rate of growth, had it not been for the sales force disruption in the beginning of the year, this could have been significantly stronger. And there was also an Fx headwind which shaved off ~$637k in 2015 – so on a constant currency basis and even with the sales force disruption, product sales would have shown growth of ~49% in 2015. The number of growth catalysts (above) and an expectation that turnover of the sales force does not reoccur, should bode well for 2016 product sales dwarfing those of 2015.

Grant revenue fell slightly from $978k in 2014 to $736k in 2015. Going into 2016 we expect initial contribution from the recently awarded $1.5M Phase II SBIR contract by NHLBI. In addition ~$300k remains under the DARPA sepsis grant.

As noted, product margins remain very healthy - which was approximately 62% for the full year. This was ~64% in Q4, the peak of all of 2015. Operating expenses ticked up in Q4 to $3.2M with R&D reflecting additional clinical trial activities – but OpEx still came in lower than our $3.4M estimate.

Excluding non-cash items and income tax benefit, EPS was ($0.09), slightly ahead of our ($0.10) estimate. Cash balance (inc liquid investments) was $7.5M at year-end. Subsequently CTSO received another $325k. CTSO expects this to be sufficient to fund operations through the end of 2016.

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 we believe the study is too small to draw any concrete 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.

Management noted on the Q4 call that they are very encouraged by the results. Also noting that this is an example of a patient population (i.e. refractory septic shock) that could potentially represent one which a formal, and potentially relatively small, sepsis study could be designed around.

Relative to potential plans of a U.S. pivotal sepsis study – management indicated that they are approaching this idea very systematically. Indicating that they will continue to conduct OUS sepsis-related studies to help flesh out potential patient populations in which CytoSorb appears to be most effective and which may afford a relatively small (potentially) pivotal sepsis study. We fully support that strategy given the potential black hole that a large, long and drawn out and expensive pivotal sepsis study could create given the difficulty in enrolling from a relatively heterogeneous population.

Outlook and Model Update

We view 2015 as somewhat of a re-grouping year on the income statement - although "regrouping" should be put into context given that product sales grew 29% – and which would have been almost 50% if not for an Fx headwind. And if not for the sales force disruption earlier in the year, product sales growth would likely have been even significantly stronger.

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We are maintaining our Buy recommendation as well as our $12.50/share price target.

FINANCIAL MODEL

CytoSorbents Inc.

	2015 A	Q1A	Q2A	Q3A	Q4A	2016 E	2017 E	2018 E	2019 E
CytoSorb Sales	$4,043.8	$1,725.0	$2,242.5	$2,726.3	$3,308.8	$10,002.5	$17,760.0	$26,450.0	$32,400.0
y-o-y growth	*29.0%*	*145.1%*	*190.1%*	*154.4%*	*121.2%*	*147.4%*	*77.6%*	*48.9%*	*22.5%*
Total Royalties/Grants/Other	$747.8	$125.0	$300.0	$325.0	$325.0	$1,075.0	$745.0	$0.0	$0.0
y-o-y growth	*-24.3%*	*543.8%*	*57.2%*	*19.4%*	*22.5%*	*43.8%*	*-30.7%*	*-100.0%*	*#DIV/0!*
Revenue	$4,791.7	$1,850.0	$2,542.5	$3,051.3	$3,633.8	$11,077.5	$18,505.0	$26,450.0	$32,400.0
YOY Growth	*16.2%*	*155.9%*	*163.8%*	*127.1%*	*106.3%*	*131.2%*	*67.1%*	*42.9%*	*22.5%*
Cost of Goods Sold	$2,212.6	$746.0	$1,107.3	$1,306.5	$1,516.2	$4,675.9	$7,138.6	$9,389.8	$11,340.0
Gross Income	$2,579.1	$1,104.0	$1,435.2	$1,744.8	$2,117.6	$6,401.6	$11,366.4	$17,060.3	$21,060.0
Gross Margin	*53.8%*	*59.7%*	*56.4%*	*57.2%*	*58.3%*	*57.8%*	*61.4%*	*64.5%*	*65.0%*
SG&A	$8,011.9	$2,241.0	$2,171.0	$2,397.0	$2,466.0	$9,275.0	$11,894.0	$12,881.2	$13,770.0
% SG&A	*167.2%*	*121.1%*	*85.4%*	*78.6%*	*67.9%*	*83.7%*	*64.3%*	*48.7%*	*42.5%*
R&D	$3,871.1	$1,142.0	$1,274.0	$1,441.0	$1,550.0	$5,407.0	$5,751.0	$5,866.0	$6,120.0
% R&D	*80.8%*	*61.7%*	*50.1%*	*47.2%*	*42.7%*	*48.8%*	*31.1%*	*22.2%*	*18.9%*
Operating Income	($9,303.9)	($2,279.0)	($2,009.8)	($2,093.2)	($1,898.4)	($8,280.4)	($6,278.6)	($1,686.9)	$1,170.0
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	($847.3)	($2.0)	($2.0)	($2.0)	($2.0)	($8.0)	$0.0	$0.0	$0.0
Pre-Tax Income	($8,456.6)	($2,277.0)	($2,007.8)	($2,091.2)	($1,896.4)	($8,272.4)	($6,278.6)	($1,686.9)	$1,170.0
Taxes (benefit)	($324.6)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*3.8%*	*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	($8,132.0)	($2,277.0)	($2,007.8)	($2,091.2)	($1,896.4)	($8,272.4)	($6,278.6)	($1,686.9)	$1,170.0
Net Margin	*-169.7%*	*-123.1%*	*-79.0%*	*-68.5%*	*-52.2%*	*-74.7%*	*-33.9%*	*-6.4%*	*3.6%*
EPS	($0.33)	($0.09)	($0.08)	($0.08)	($0.07)	($0.32)	($0.23)	($0.06)	$0.04
YOY Growth	-	-	-	-	-				
Diluted Shares O/S	24,886	25,400	25,625	25,720	26,500	25,811	27,700	28,700	29,500

Brian Marckx, CFA

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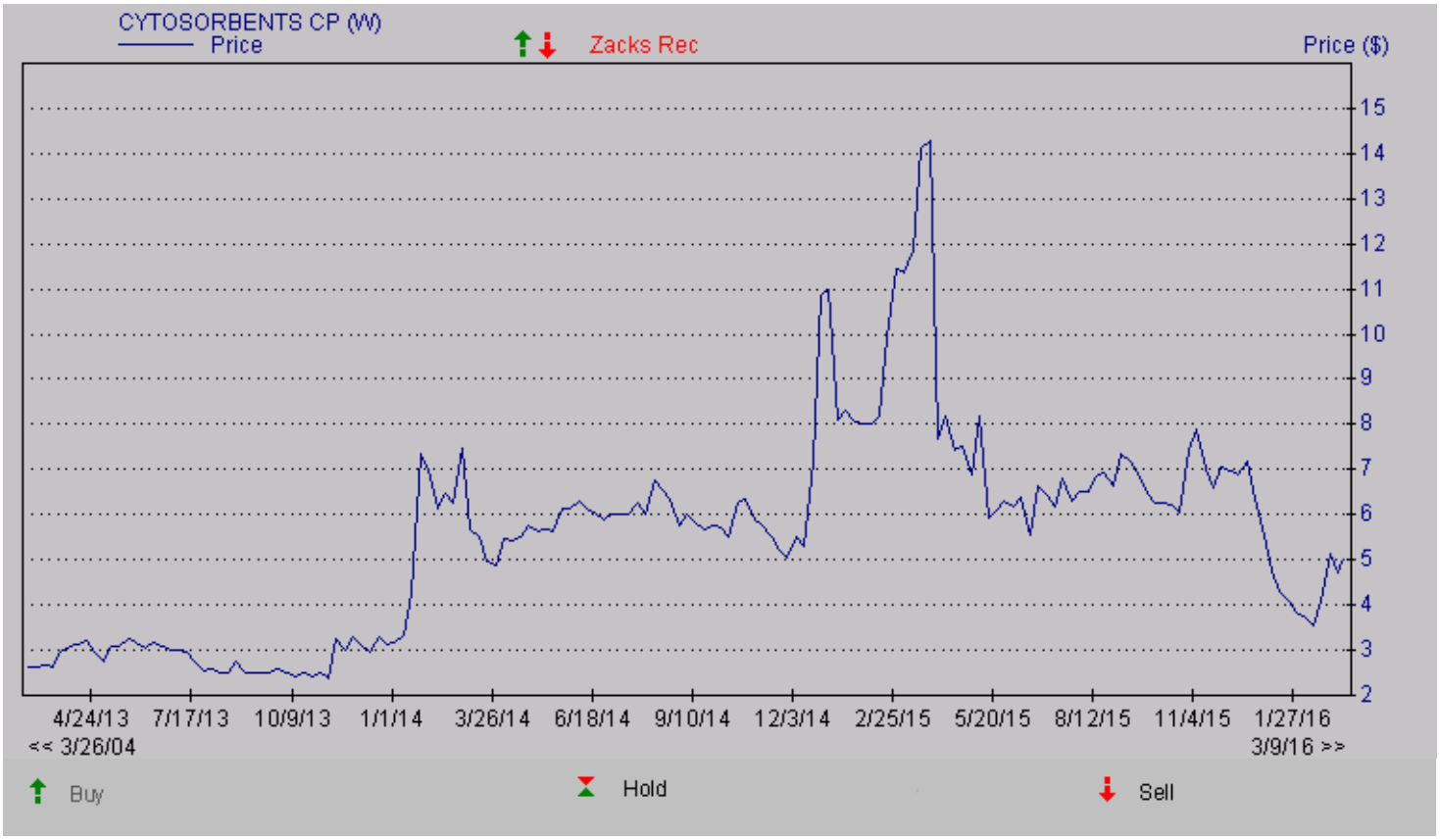

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
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