Zacks Small-Cap Research

May 20, 2015

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CytoSorbents Cp (CTSO- NASDAQ)

CTSO: Correction to our May 15th report re: plans for U.S. regulatory pathway

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (05/19/15)	$6.16
Target Price	**$12.50**

OUTLOOK

CytoSorb was CE Marked in March 2011 and subsequently commenced its initial commercialization. Initial focus on building awareness appears to be paying off. CTSO now generating clinical outcomes data which is just starting to be used to accelerate adoption and utilization. CTSO now also focused in U.S. regulatory approval – either with a cardiac surgery or critical care indication (such as sepsis). Co now investigating EAP route in U.S. to try and speed time to market at lower cost.

Recent restructuring of sales force caused a hiccup in sales but we think this is a short-term issue, is already being resolved with new hires and has no impact on long-term potential of CytoSorb. Interest in and use of CytoSorb from hospitals and physicians continues to increase. Also seeing great interest from distributors and other industry partners.

SUMMARY DATA

52-Week High	**$15.24**
52-Week Low	**$4.40**
One-Year Return (%)	**5.30**
Beta	**-0.94**
Average Daily Volume (sh)	**347,015**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$153**
Short Interest Ratio (days)	**0.97**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**85.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
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	825 E	1218 E	1578 E	4344 E
2016					13074 E
2017					26620 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 E	-0.10 E	-0.10 E	-0.45 E
2016					-0.25 E
2017					-0.19 E

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

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Q1 Financials, Business Update

NOTE: Our May 15th report indicated that if FDA approved an EAP pathway then CTSO would discontinue their U.S. regulatory-related cardiac surgery program. This was an incorrect interpretation of the company's plans which was confirmed via communication with management following publishing of the report. The correct interpretation is that CTSO will still pursue FDA approval in a cardiac surgery indication even if the EAP pathway is deemed viable. This May 20th report includes language which is consistent with management's plans and our May 15th report should be disregarded. The correction has no effect on our investment recommendation.

Q1 Financials: In-Line, Model Remains Intact w/ Expectations of Accelerating Growth in 2H

CytoSorbents reported financial results for the first quarter ending March 31. There were no meaningful surprises with revenue, product margin and OpEx all coming in very close to our numbers. Our model, which we made significant revisions to after CTSO reported during Q4 earnings and noted that direct sales would suffer over the near-term as they reshuffled their sales force, remains intact following Q1 results. Management noted on the Q1 call that timelines for rebuilding the direct sales force remain within initial expectations with two new hires expected to be onboard in Q2 and on the ground detailing in early Q3. And with two other positions expected to be filled shortly afterwards, this would bring the team back to full strength.

We continue to look for relative softness in product sales to persist through the remainder of the first half of the year but for sales to begin to recover in Q3 and, particularly Q4 – reflecting contribution from newly hired reps, related productivity gains and incremental additional ordering from distributors. Importantly, revenue continues to be driven by a mix of both reorders from existing customers as well as from new accounts. And fuel for future growth, including new distribution agreements, regulatory approvals in additional territories (many of which could come in fairly short order and which CTSO already has distribution lined up) and further build-out of the direct team all remain very viable to make a more substantial impact later this or early next. Gathering additional clinical data from investigator-initiated and case studies remains at the forefront of the company's marketing efforts.

On the operational side, REFRESH, the company's 20-patient U.S. cardiac feasibility study, an IDE for which was approved by FDA in February, is expected to begin by the middle of the year and wrap up before year-end. There is an update to the game-plan in seeking regulatory approval for the U.S. market, however. Until recently, the singular focus was to go directly from the small cardiac feasibility study to a larger pivotal study, results from which (assuming positive) would be used to support a cardiac surgery indication in the U.S. CTSO would then look to expand the indications through additional clinical studies to critical care illnesses such as sepsis.

Now, however, in an effort to speed the time to the U.S. market for critical care indications, CTSO is investigating the Expedited Access Pathway (EAP) while they still pursue their U.S. cardiac surgery program. If the EAP pathway is approved by FDA it would afford a quicker time to market for sepsis (and/or other critical care illnesses) and allow for much of the pivotal data collection during commercialization (although proof of safety and efficacy would still need to happen prior to marketing approval). So the cardiac feasibility study will happen and in the meantime CTSO will pursue the EAP pathway. If FDA greenlights EAP, CTSO can go directly to pursuing U.S. approval in critical illnesses while, in parallel, pursuing a cardiac surgery indication. If EAP is not viable, the prior strategy will be followed – that being seeking FDA approval via a cardiac surgery study and then looking to expand the label once FDA approved to include critical care illnesses such as sepsis. There are clear benefits of the EAP route – not only potentially quicker time to market for bread-and-butter critical care applications, but also less expensive and would potentially allow for the major efficacy hurdle of the study to not have to be met until after already on the market. Management did not provide an expected timeline for filing for EAP approval but this is presumably on their hot-list.

Q1 Results

Q1 total revenue was $723k, including $704k in product revenue which were in line with our respective $720k and $715k estimates. On a constant-currency basis product sales increased by approximately 43% yoy and were roughly flat on a sequential basis.

Product margins continue to hold up well despite the recent slip in product volumes and lower direct sales (which carry higher margins). Product margin was about 61% in the most recent quarter which is flat yoy. OpEx at $3.1M was down from about $3.6M in Q4 2014 and was mostly inline with our $3.0M estimate.

Excluding non-cash change in warrant liability, Q1 net income and EPS were ($2.7)M and ($0.11), inline with our ($2.5)M and ($0.10) estimates.

As noted, we have made no meaningful changes to our model following Q1 results. We are maintaining our Buy recommendation and $12.50/share price target.

Recent Points-of-Interest

- Distribution of CytoSorb now covers 34 countries. Company expects to add several new distributors by the end of 1H 2015. Many of these countries are working towards regulatory approval of CytoSorb – some of which could come online in the near-term.
- International CytoSorb registry went live in Q4 2014. Sponsored by Jena University Hospital (Germany), the registry will collect data from users of CytoSorb. CTSO noted on the Q4 call that as many as 1,000 patients may be included in the registry by current year-end. The registry is listed on clinicaltrials.gov (https://clinicaltrials.gov/ct2/show/NCT02312024)
- CytoSorb.com website also recently launched – which includes list of investigator initiated studies which are underway or in the planning phase. Website also includes case reports, many of which have been published in peer-reviewed journals. We expect the clinical experience documented in case reports, studies and through the registry to be key components of driving awareness and facilitating marketing efforts
- First international users meeting held in March 2015 at the International Symposium on Intensive Care and Emergency Medicine in Belgium. These user meetings are another significant part of CTSO's marketing and awareness efforts and are expected to provide valuable feedback from early adopters. The company noted on the Q4 call that the meeting was very well attended with standing room only
- Agreement with Biocon, CTSO's distributor in India, was expanded whereby Biocon agreed to increase the minimum purchase agreement and will be funding and publishing results from their own investigator initiated and patients case studies. Biocon now also has distribution rights of CytoSorb for all critical care illnesses in India and certain emerging countries. As we have noted in the recent past, Biocon has been a key ally of CTSO and, while CTSO does not disclose sales per revenue channel, we think Biocon has been a material contributor to product sales growth
- Fresenius partnership announced in December whereby Fresenius has distribution rights of CytoSorb for critical care applications in France, Sweden, Norway, Finland, Denmark and Poland. As we noted in a recent investor note we think this deal with Fresenius, which is the world leader in dialysis, provides not only substantial distribution reach, it also provides a significant vote of credibility to CytoSorb and CytoSorbents. Fresenius-related sales are expected to commence in Q2 of this year
- Recently announced partnership with "top four" (unnamed) medical device company for use of CytoSorb in France for cardiac surgery. Assuming all goes well, following the evaluation period the parties will collaborate on a broader marketing message and promote the product - initially at the KOL level and then drive down into hospitals and individual physicians levels. CTSO noted on the Q4 call that the initial six month evaluation period is expected to be completed in Q2 of this year.
- FDA approval to commence U.S. feasibility study of CytoSorb came in early February. The study, named REFRESH (Reduction in FREe Hemoglobin), is expected to enroll 20 patients undergoing cardiac surgery across three U.S. sites and, along with safety, will evaluate CytoSorb s ability to actively remove plasma free hemoglobin and cytokines, among other inflammatory markers. These toxic substances, which are produced during cardiac surgery, can lead to serious complications including kidney injury / failure. While this is a single-arm study, CTSO will also conduct a parallel, non-interventional study across several U.S. cardiac surgery centers. This study will use similar enrollment criteria as the interventional study and collect similar data related to adverse events, such as kidney injury / failure, and inflammatory markers, such as plasma free hemoglobin and cytokines from a broad population of patients undergoing cardiac surgery. The two studies will provide a comparison of how well CytoSorb was able to reduce toxic substances and related adverse events between the active study patient population and those undergoing cardiac surgery where CytoSorb was not used. REFRESH is expected to begin by mid-2015 and wrap up by year-end.
- In April 2015 CTSO announced they would investigate the Expedited Access Pathway for U.S. regulatory approval. Prior to this, the singular plan was to go directly from the small cardiac feasibility study to a larger pivotal study, results from which (assuming positive) would be used to support a cardiac surgery indication in the U.S. CTSO would then look to expand the indications through additional clinical studies to critical care

illnesses such as sepsis. If the EAP pathway is approved by FDA it would afford a quicker time to market for sepsis (and/or other critical care illnesses) and allow for much of the pivotal data collection during commercialization (although proof of safety and efficacy would still need to happen prior to marketing approval). So the cardiac feasibility study will happen and in the meantime CTSO will pursue the EAP pathway. If FDA greenlights EAP, CTSO can go directly to pursuing U.S. approval in critical illnesses while, in parallel, pursuing a cardiac surgery indication. If EAP is not viable, the prior strategy will be followed – that being seeking FDA approval via a cardiac surgery study and then looking to expand the label once FDA approved to include critical care illnesses such as sepsis. There are clear benefits of the EAP route – not only potentially quicker time to market for bread-and-butter critical care applications, but also less expensive and would potentially allow for the major efficacy hurdle of the study to not have to be met until after already on the market. Management did not provide an expected timeline for filing for EAP approval but this is presumably on their hot-list.

- German dosing study progressing well with over 100 of the planned 300 patients currently enrolled.
- Recently restructured direct sales team, with four of the ten reps fired in Q1 2015. Two replacements have already been identified and will begin detailing in Germany in Q3. Two other positions expected to be filled shortly afterwards, this would bring the team back to full strength. As we noted following the announcement with Q4 earnings of the disruption in the direct sales force, while disappointing, we view it as a short-term speed bump, not a traffic jam and certainly not a dead-end. While restructuring of the sales force in order to improve productivity is causing a near-term hiccup, it in no way negatively affects the fundamental long-term potential of the company or CytoSorb.

Outlook and Model Update

As noted we have made some adjustments to our model following Q4 results and management's recent guidance. Also as noted, we think the hiccup to revenue has no bearing on the long-term prospects of the company or CytoSorb. So the changes we made to our model following Q4 results mostly reflected our estimates being pushed back by about one-year with our long-term outlook remaining intact. We view 2015 as somewhat of a re-grouping year on the income statement but, on the positive side, we expect CTSO to continue to make major strides on the operational front and think recent developments such as the Fresenius deal and expanded agreement with Biocon can begin to add incrementally as soon as the back half of the year.

The changes to our model were significant (we reiterate that we have not made adjustments following Q1 results as these were inline with our expectations) in the near term, given that we had forecast a steep ramp in the revenue curve to materialize in 2015 – we have delayed this until next year which we think is reasonable given the continued expected expansion of the direct sales force, productivity gains from the new hires, expanded third-party distribution network, growing list of KOL's using CytoSorb as well as investigator initiated studies utilizing the device, and fruits from awareness efforts materializing in a greater rate of adoption.

We continue to look for relative softness in product sales to persist through the remainder of the first half of the year but for sales to begin to recover in Q3 and, particularly Q4 – reflecting contribution from newly hired reps, related productivity gains and incremental additional ordering from distributors. Importantly, revenue continues to be driven by a mix of both reorders from existing customers as well as from new accounts. And fuel for future growth, including new distribution agreements, regulatory approvals in additional territories (many of which could come in fairly short order and which CTSO already has distribution lined up) and further build-out of the direct team all remain very viable to make a more substantial impact later this or early next.

Important to recognize and the reason we continue to reiterate this, is that we believe management is wisely navigating and executing the roll-out of CytoSorb. Unlike a shotgun approach and "just trust us that our novel product works" followed by many inexperienced med-tech start-ups, CTSO is following a game plan that puts clinical experience and positive outcomes first in order to drive demand and is targeting KOL's (i.e. those who have the most influence). While this strategy can take time, we already see early successes with growth in product sales, a growing list of KOLs using or interested in using CytoSorb as well an increasing number of investigator initiated studies coming online. Many of the user experiences are also being documented in peer-reviewed journal articles which, now with the patient registry live, may expand further and facilitate even greater awareness and resultant adoption. As such our long-term outlook and positive recommendation remain unchanged as our fundamental investment view is unaffected by the short-term revenue disruption attributed to a restructuring of the direct sales force.

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

FINANCIAL MODEL

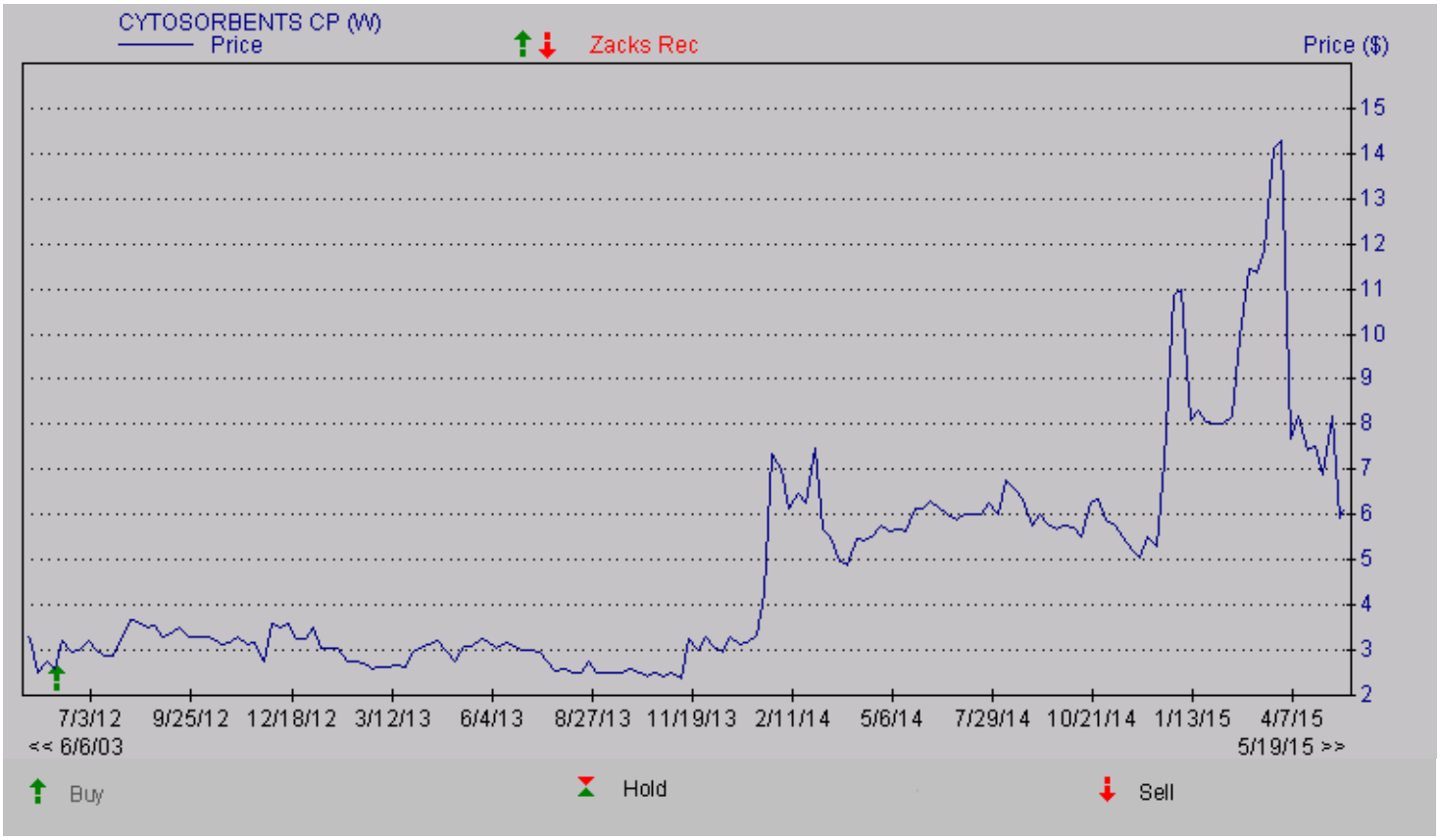
CytoSorbents Inc.

	2014 A	Q1A	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
CytoSorb Sales	$3,135.4	$703.7	$807.0	$1,131.0	$1,462.0	$4,103.7	$12,070.0	$20,620.0	$29,050.0
y-o-y growth	*281.5%*	*23.6%*	*21.7%*	*9.6%*	*67.8%*	*30.9%*	*194.1%*	*70.8%*	*40.9%*
Total Royalties/Grants/Other	$987.5	$19.4	$18.0	$87.0	$116.0	$240.4	$1,004.0	$0.0	$0.0
y-o-y growth	*-38.3%*	*-96.1%*	*-95.0%*	*-33.4%*	*4470.5%*	*-75.7%*	*317.6%*	*-100.0%*	*#DIV/0!*
Revenue	$4,122.9	$723.1	$825.0	$1,218.0	$1,578.0	$4,344.1	$13,074.0	$20,620.0	$29,050.0
YOY Growth	*70.2%*	*-31.9%*	*-19.5%*	*4.8%*	*80.6%*	*5.4%*	*201.0%*	*57.7%*	*40.9%*
Cost of Goods Sold	$2,133.9	$304.5	$318.7	$495.0	$643.0	$1,761.3	$5,510.3	$7,835.6	$11,039.0
Gross Income	$1,989.0	$418.6	$506.3	$723.0	$935.0	$2,582.8	$7,563.7	$12,784.4	$18,011.0
Gross Margin	*48.2%*	*57.9%*	*61.4%*	*59.4%*	*59.3%*	*59.5%*	*57.9%*	*62.0%*	*62.0%*
SG&A	$6,836.2	$2,179.2	$2,252.0	$2,225.0	$2,434.0	$9,090.2	$9,654.0	$13,237.0	$14,873.6
% SG&A	*165.8%*	*301.4%*	*273.0%*	*182.7%*	*154.2%*	*209.3%*	*73.8%*	*64.2%*	*51.2%*
R&D	$2,431.7	$951.0	$961.0	$1,010.0	$1,105.0	$4,027.0	$4,664.0	$4,881.0	$4,915.0
% R&D	*59.0%*	*131.5%*	*116.5%*	*82.9%*	*70.0%*	*92.7%*	*35.7%*	*23.7%*	*16.9%*
Operating Income	($7,278.9)	($2,711.6)	($2,706.7)	($2,512.0)	($2,604.0)	($10,534.4)	($6,754.3)	($5,333.6)	($1,777.6)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$2,428.5	$2,005.3	($1,218.0)	$0.0	$0.0	$787.3	$0.0	$0.0	$0.0
Pre-Tax Income	($9,707.4)	($4,716.9)	($1,488.7)	($2,512.0)	($2,604.0)	($11,321.7)	($6,754.3)	($5,333.6)	($1,777.6)
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)	($1,488.7)	($2,512.0)	($2,604.0)	($11,321.7)	($6,754.3)	($5,333.6)	($1,777.6)
Net Margin	-	*-652.3%*	*-180.5%*	*-206.2%*	*-165.0%*	*-260.6%*	*-51.7%*	*-25.9%*	*-6.1%*
EPS	($1.29)	($0.19)	($0.06)	($0.10)	($0.10)	($0.45)	($0.25)	($0.19)	($0.06)
YOY Growth	-	-	-	-	-	-			
Diluted Shares O/S	14,441	24,394	24,750	25,200	26,000	25,086	26,800	27,500	28,000

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