Zacks Small-Cap Research

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CytoSorbents Cp (CTSO- NASDAQ)

CTSO: Product Sales Rebounding w/ Sales Force Rebuilding, Add'l Distribution

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/04/2012
Current Price (08/17/15)	$7.42
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	**$4.40**
One-Year Return (%)	**4.33**
Beta	**-0.82**
Average Daily Volume (sh)	**106,997**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$186**
Short Interest Ratio (days)	**10.76**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**72.8**
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	964 A	1048 E	1359 E	4094 E
2016					12034 E
2017					19580 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 A	-0.10 E	-0.10 E	-0.34 E
2016					-0.27 E
2017					-0.22 E

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

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Q2 Financials, Business Update

Q2 Financials: Product Sales Continue to Rebound w/ Sales Force Rebuilding, Additional Distribution

CytoSorbents reported financial results for the second quarter ending June 30. Results remain very much inline with our estimates with only slight variances to revenue – mostly related to higher grant income – as well as lower operating expenses. We have made only small adjustments to our model following Q2 results. With three more reps added in Q3 and another two expected to come onboard (for a total of nine) before year-end, management continues to expect direct product sales to pick up further in the second half of the year. And with distribution just brought on in Australia/New Zealand, regulatory approval granted in Saudi Arabia and the initial Fresenius roll-out slated to begin shortly, third-party sales are also expected to benefit.

And despite the recent reshuffling of the sales force, product sales have remained resilient. Q2 product sales (ex-Fx) were the second highest on record and management noted that the quarter represented the greatest number of devices sold by the direct sales force. Q2 and 1H product sales increased 17% and 20%, respectively – and this is in the face of an Fx headwind that CTSO has been fighting – on a constant currency basis Q2 and 1H product sales would have been up 39% and 41%, respectively. The new reps will likely take several months to get fully productive but with revenue continuing to be driven by a mix of both reorders from existing customers as well as from new accounts and with the new territories that just came online, we continue to think product sales will show a meaningful yoy and sequential increase in 2H.

CTSO also made meaningful progress on the operational side. An amendment to REFRESH, the company's U.S. cardiac surgery feasibility study, was approved by FDA. The amendment consolidates the non-interventional arm directly into the study. So it converts REFRESH from a 20-patient, single-arm, three site study to a 40-patient, eight site, randomized controlled study. CTSO expects REFRESH to begin in September – if all goes well they think it could complete in Q4 of this year or Q1 of next.

Relative to the cardiac surgery pathway, CTSO expects to submit an EAP application in the coming weeks – FDA response (assuming they do not come back with additional questions) is expected in ~30 days – which means CTSO could hear back as soon as early-Q4. And on the theme of cardiac surgery, their large (unnamed) cardiac surgery partner continues to evaluate CytoSorb – while the evaluation was expected to be completed in Q2, CytoSorbents now hopes this will be finalized in the "next several months."

On the clinical data and awareness building efforts, CTSO expects to have data from two randomized, controlled investigator-initiated cardiac surgery-related studies, which are being done at the University of Hamburg-Eppendorf and Medical University of Vienna, later this year. The data is expected to be presented at their second annual International CytoSorb User's Meeting in Berlin in October. In addition to this User's Meeting, CTSO will be attending the European Society of Intensive Care Meeting and European Association for Cardio-Thoracic Surgery meeting in Berlin and Amsterdam, respectively.

Q2 Results

Q2 total revenue was $964k, including $773k in product sales which was largely inline with our $807k estimate. Grant revenue, which benefitted from the conclusion of certain grants, was $191k. Product revenue increased 17% yoy and 10% sequentially. On a constant currency basis product sales increased by about 39%. Excluding the effect of Fx, product sales were the second highest on record.

Product margins continue to hold up well despite the Fx headwind. Product margin was about 63% in the most recent quarter, up from 59% in Q1 and 65% in the prior year comparable period. OpEx at $2.7M was down from about $3.1M in Q1 and lower than our $3.2M estimate – the difference coming from R&D expense as we had allocated additional spend to the REFRESH study in the quarter as well as SG&A – which we allocated additional to for the new hires.

Excluding non-cash change in warrant liability, Q1 net income and EPS were ($2.2)M and ($0.09), compared to our with our ($2.7)M and ($0.11) estimates. CTSO exited Q2 with $11.2 million in cash and equivalents which they believe will provide funding into 2016.

Recent Points-of-Interest

- Distribution of CytoSorb now covers over 30 countries. Recent additions have been Saudi Arabia (distributed by Techno Orbits) where CytoSorb just received regulatory approval and Australia/New Zealand where CytoSorb will be distributed by TekMed, with which CTSO penned a distribution agreement in July. Other territories, including Russia (awaiting regulatory approval) and other areas in the GCC could come onboard over 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. Second international user's meeting will be held in October in Berlin
- 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 and has the potential to increase further
- Fresenius partnership announced in December 2014 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 Q3 of this year – which is a slight delay from earlier expectations of Q2
- 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 had hoped the evaluation would be completed in Q2, although this timeline has slipped – and now they may be looking at later in 2015
- FDA approval to commence U.S. feasibility study of CytoSorb came in early February. The study, named REFRESH (Reduction in FREe Hemoglobin), was original designed as a 20-patient, three center, single arm study which would compare CytoSorb in cardiac surgery to a non-interventional trial. FDA recently approved an amendment to the study converting it to a 40-patient, eight site, randomized controlled study. So the amendment consolidates the non-interventional arm directly into the study. The study 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. The study 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 in September and if all goes well will wrap up in late 2015 or Q1 2016.
- 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-related indications (and/or other critical care illnesses) and allow for much of the pivotal data collection during commercialization (although proof of safety and efficacy on more stringent endpoints would still need to happen following initial approval in order to stay on the market). 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 care 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. CTSO noted on the Q2 call (8/13) that they expect to submit the EAP application in the "coming weeks." The application includes protocol of proposed premarket and postmarket studies. While management did not disclose specifically what they expect to pursue as endpoints in either of the studies, they indicated premarket could be metrics such as days in the intensive care unit, days on the ventilator, hemodynamic stability or use of vasopressors. Standard primary endpoint for a sepsis indication has been 28-day all-cause mortality, which is what was used in CTSO's European Sepsis Trial and which is being used in Spectral Medical's EUPHRATES trial (and which was used by Eli Lily to gain approval of Xigirs – which was removed from the market). So this is presumably the primary endpoint that CTSO would use in a postmarket study.

- 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 additional full-time direct reps and a contract cardiac surgery rep were brought on in Q3. Another two are expected to come onboard (for a total of nine) before year-end. The new reps will likely take several months to get fully productive but with revenue continuing to be driven by a mix of both reorders from existing customers as well as from new accounts and with the new territories that just came online, we continue to think product sales will show a meaningful yoy and sequential increase in 2H. 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 has caused 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 meaningful adjustments following Q1 or Q2 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 sales to show a more substantial recovery in the second half of the year – 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

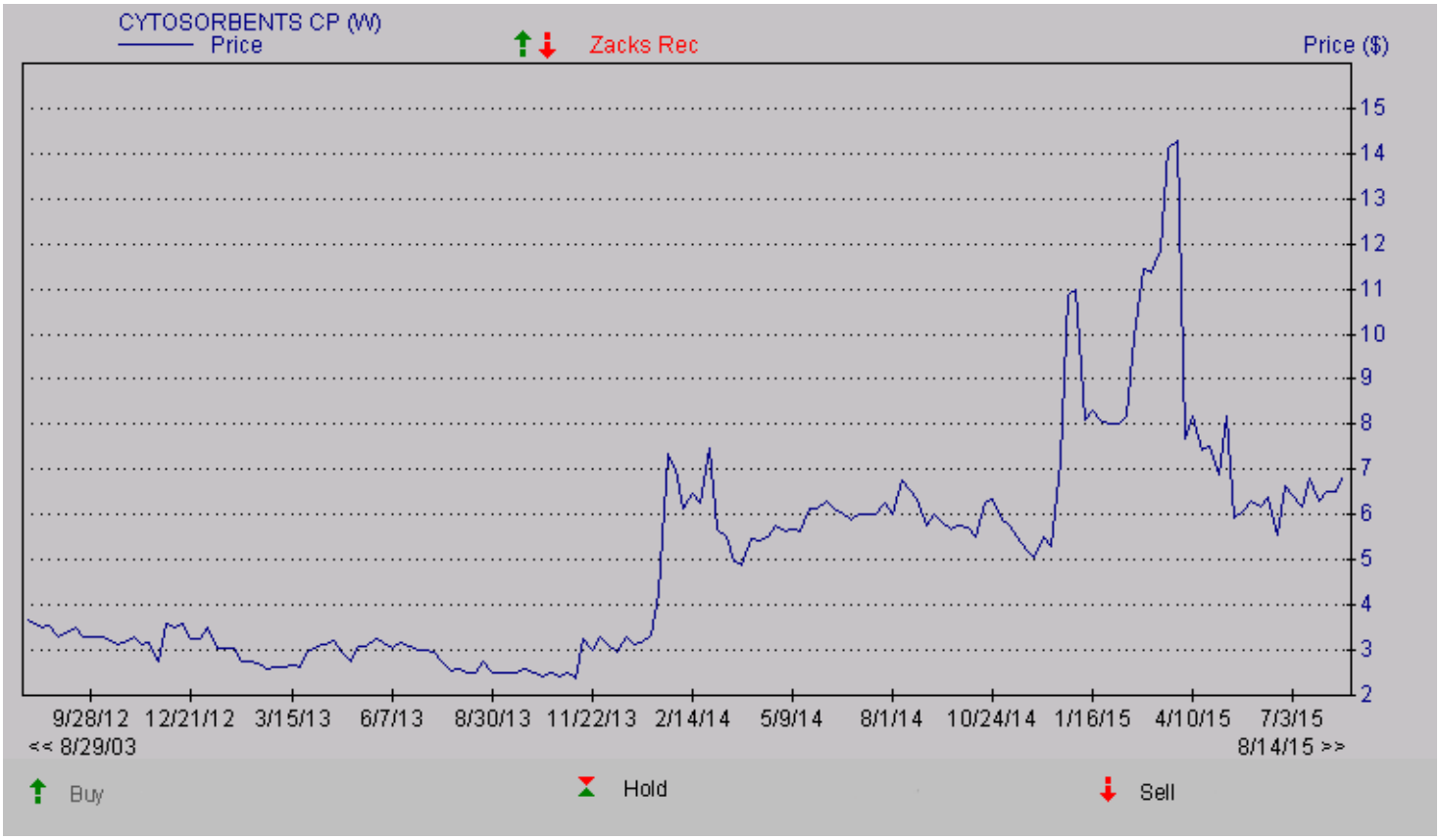
CytoSorbents Inc.

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
CytoSorb Sales	$3,135.4	$703.7	$773.1	$961.4	$1,242.7	$3,680.8	$11,030.0	$19,580.0	$28,010.0
y-o-y growth	*281.5%*	*23.6%*	*16.6%*	*-6.8%*	*42.6%*	*17.4%*	*199.7%*	*77.5%*	*43.1%*
Total Royalties/Grants/Other	$987.5	$19.4	$190.8	$87.0	$116.0	$413.2	$1,004.0	$0.0	$0.0
y-o-y growth	*-38.3%*	*-96.1%*	*-47.2%*	*-33.4%*	*4470.5%*	*-58.2%*	*143.0%*	*-100.0%*	*#DIV/0!*
Revenue	$4,122.9	$723.1	$963.9	$1,048.4	$1,358.7	$4,094.1	$12,034.0	$19,580.0	$28,010.0
YOY Growth	*70.2%*	*-31.9%*	*-5.9%*	*-9.8%*	*55.5%*	*-0.7%*	*193.9%*	*62.7%*	*43.1%*
Cost of Goods Sold	$2,133.9	$304.5	$465.4	$451.5	$586.7	$1,808.1	$5,115.1	$7,440.4	$10,643.8
Gross Income	$1,989.0	$418.6	$498.5	$596.9	$772.0	$2,285.9	$6,918.9	$12,139.6	$17,366.2
Gross Margin	*48.2%*	*57.9%*	*51.7%*	*56.9%*	*56.8%*	*55.8%*	*57.5%*	*62.0%*	*62.0%*
SG&A	$6,836.2	$2,179.2	$1,924.3	$2,225.0	$2,434.0	$8,762.5	$9,654.0	$13,237.0	$14,341.1
% SG&A	*165.8%*	*301.4%*	*199.6%*	*212.2%*	*179.1%*	*214.0%*	*80.2%*	*67.6%*	*51.2%*
R&D	$2,431.7	$951.0	$801.7	$974.0	$1,105.0	$3,831.7	$4,664.0	$4,881.0	$4,915.0
% R&D	*59.0%*	*131.5%*	*83.2%*	*92.9%*	*81.3%*	*93.6%*	*38.8%*	*24.9%*	*17.5%*
Operating Income	($7,278.9)	($2,711.6)	($2,227.5)	($2,602.1)	($2,767.0)	($10,308.3)	($7,399.1)	($5,978.4)	($1,889.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$2,428.5	$2,005.3	($3,661.8)	$0.0	$0.0	($1,656.5)	$0.0	$0.0	$0.0
Pre-Tax Income	($9,707.4)	($4,716.9)	$1,434.3	($2,602.1)	($2,767.0)	($8,651.8)	($7,399.1)	($5,978.4)	($1,889.9)
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)	$1,434.3	($2,602.1)	($2,767.0)	($8,651.8)	($7,399.1)	($5,978.4)	($1,889.9)
Net Margin	-	*-652.3%*	*148.8%*	*-248.2%*	*-203.7%*	*-211.3%*	*-61.5%*	*-30.5%*	*-6.7%*
EPS	($1.29)	($0.19)	$0.06	($0.10)	($0.11)	($0.34)	($0.27)	($0.22)	($0.07)
YOY Growth	-	-	-	-	-	-			
Diluted Shares O/S	14,441	24,394	24,769	25,200	26,000	25,091	27,000	27,700	28,200

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