Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Poised For Strong 2017. Fresenius Deal A Win-Win-Win…

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 (01/13/17)	$5.80
Valuation	**$12.50**

OUTLOOK

CTSO coming off record year with product sales growth of 100%+ 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	**$3.11**
One-Year Return (%)	**36.47**
Beta	**-0.06**
Average Daily Volume (sh)	**65,977**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$148**
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 (%)	**58.3**
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)
2015	723 A	964 A	1344 A	1761 A	4792 A
2016	1810 A	2222 A	2412 A	2888 E	9332 E
2017					14086 E
2018					20824 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 A	-0.12 A	-0.11 A	-0.10 E	-0.40 E
2017					-0.35 E
2018					-0.21 E

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

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Poised for Strong 2017 With Catalysts Such As Terumo, Fresenius Co-Marketing, Dedicated Reimbursement in Germany, REFRESH I Read-Out…

CytoSorbents has had a busy last couple of months leading up to the annual JP Morgan, Biotech Showcase and Medtech Showcase conferences which were held earlier this week in San Francisco and where management took some time to talk to us. Just prior to the company's presentation at the Biotech Showcase they announced an expanded agreement with Fresenius and preannounced expected Q4 and FY2016 product sales.

Record product sales for 6th straight quarter…
Per the January 10th preannouncement, CTSO expects Q4 product sales of ~$2.6M, implying sequential and yoy growth of approximately 21% and 74%, respectively, and marking the sixth straight quarter of record product sales. Product sales of $2.6M is also almost 16% higher than what we had forecast ($2.2M).

For the full year, product sales are expected to be approximately $8.2M, more than double the $4.0M generated in 2015. Similarly, CytoSorb usage more than doubled – from approximately 9k treatments as of the end of 2015 to 20k currently. Product margin is expected to be better than 65% in 2016 - which compares to ~62% for the full year 2015.

We continue to see several catalysts that will continue to drive strong double-digit revenue growth in 2017 including a broadened geographic commercial footprint, additional clinical data and new key distribution relationships.

- **Footprint**: Relative to CTSO's geographic footprint, they now have distribution in 42 countries, 31 of which are now contributing to revenue – this compares to just 15 countries that were contributing to revenue one year ago. We also expect additional countries to come online during the year.
- **Clinical data**: along with the eagerly awaited free hemoglobin data from the REFRESH I U.S. cardiac surgery study which is expected to be announced at AATS in late April, we expect a fairly regular flow of results from ongoing studies in Europe in various indications as well as those that have already been submitted for publication
- **Recent distribution agreements**: most importantly, Terumo Cardiovascular and the updated agreement with Fresenius (more about Fresenius below). The record product sales in 2016 included little to no contribution from Terumo, which has exclusive rights to distribute CytoSorb in France, Sweden, Denmark, Norway, Finland and Iceland for cardiac surgery applications. Indications are that this relationship is off to a strong start with Terumo hitting the ground running and already lining up customer accounts. We think the Terumo channel could be a particular highlight in 2017. And, as we noted in a recent update, Terumo Cardiovascular, which is a division of Terumo Corp., a major Japan-based medical device company with $5B+ in annual revenue, could provide seamless access to the Japanese market. Japan is the second largest medical device market in the world.

CytoSorbent's recently updated agreement with Fresenius Medical Care (FMC) was among the most savvy that we have seen among any small medical device companies. The deal, which includes a co-marketing agreement, was constructed as to be a win-win-win for CytoSorbents, for Fresenius and also for all other distributors of CytoSorb. As a reminder, Fresenius has exclusive distribution rights of CytoSorb in critical care in France, Poland, Denmark, Norway, Sweden and Finland. The initial agreement between CTSO and Fresenius required Fresenius to make minimum annual purchases of CytoSorb in order to maintain exclusivity. Key points of the updated agreement include;

- Agreement is extended through 2019
- FMC is required to make "hard" minimum quarterly purchases (i.e. regardless of maintaining exclusivity)
- FMC will develop a kit containing their CytoSorb-compatible tubing and CytoSorb cartridge
- FMC and CTSO will jointly market the kit in CTSO's direct territories (such as Germany)
- In territories assigned to other distributors, FMC will market their tubing set as well as CytoSorb to critical care customers. FMC will book sales of its tubing set in these territories (i.e. "win" for FMC) while existing distributors will book sale of CytoSorb (i.e. "win" for existing distributors)
- FMC will develop marketing literature and other materials to support the program and will also provide a written endorsement of CytoSorb for use with their acute care dialysis machines
- Endorsement, joint marketing materials and co-marketing program are expected to commence in 2H 2017

We think the potential benefits to CytoSorbents are significant, particularly given that there appears to be no compromise to any party. Both CytoSorbents and their distributors will benefit from FMC's vast distribution

resources, from their existing acute care dialysis machine installed base and the endorsement for using CytoSorb on their machines. This essentially adds significant distribution reach, depth, experience and an installed base of customers in territories where FMC had previously been excluded. FMC benefits as they can now sell their plug-and-play CytoSorb tubing sets in these territories, while CTSO and distributors benefit from the sale of the CytoSorb cartridge. The additional sweetener of guaranteed minimum purchases to CTSO is icing on the top.

Progress Towards Broader Adoption, Improved Reimbursement and Acceptance as Standard of Care…
CytoSorbents has already made additional progress towards not only the roll-out of CytSorb across Europe but also in fortifying the fundamentals which have the potential to broaden adoption and use as standard of care. Among the recent highlights include gaining dedicated reimbursement in Germany and progress towards the same in the U.K., additional positive outcomes data which was presented at SepsEast 2016 and initial successful use in a patient with Dengue Fever.

Obtaining a **dedicated reimbursement procedure code in Germany**, which CTSO announced in early December, has the potential in our opinion to have a significant and almost immediate (the code is effective Jan 1, 2017) positive impact on sales of CytoSorb. Management expects the dedicated, permanent reimbursement code, which should eliminate any ambiguity in terms of payment rates and risk that hospitals are not paid for using the device, to result in much higher reimbursement. With Germany being the largest medical device country in Europe and where CTSO has dedicated much of its early commercialization efforts, this could have a meaningful positive effect on uptake and adoption of CytoSorb and related revenue. As reimbursement, or the lack thereof, can play a significant role in a clinician's/hospital's decision regarding whether they will use a particular therapy, dedicated and reliable reimbursement should provide another impetus towards driving CytoSorb towards standard-of-care status for at least those indications which have already borne out a history of treatment successes.

Also, as it relates to reimbursement, use of CytoSorb in sepsis was the subject of a recent **MedTech Innovation Briefing** (MIB). MIB's are reviews by the U.K.'s National Institute for Health and Care Excellence (NICE) to evaluate new medical device technologies for potential inclusion in and reimbursement for use of the device in the U.K.'s national healthcare system. MIB's include an assessment of the technology, supporting clinical evidence, its intended use and general comments by the evaluators. The CytoSorb MIB can be found here (http://bit.ly/2iolggz).

Among the "specialist commentators" comments were that while the technology showed promise, further studies are warranted including those demonstrating outcomes such as length of stay in the ICU, the need for vasopressors or renal replacement therapy. We note that several of the case and investigator studies using CytoSorb in critically ill patients have indicated/suggested that the device has benefits in all of these areas and with more specifics related to the ability to reduce the use of vasopressors. In fact the commentators noted that, "it is still unclear whether removing cytokines can affect mortality and outcomes in a beneficial way, although **they felt it was clear that it can reduce the dose of vasopressor drugs needed**, which is beneficial because these drugs can have harmful effects." And while cost was noted as a possible issue (as cost of CytoSorb would be in addition to current sepsis standard of care), if CytoSorb is able to reduce length of stay and/or use of vasopressors, it was noted that that could potentially reduce overall treatment costs.

MIB's are regularly updated with new information, including new clinical data. So as additional supporting evidence becomes available (such as data from several ongoing studies, including those highlighted at SepsEast2016, below), it should help strengthen the case for use of CtyoSorb for sepsis, as well as for other critical care indications. As this could eventually result in widespread adoption of CytoSorb in the U.K. healthcare system, this will be something to stay tuned to.

CTSO had a busy schedule at SepsEast2016, a leading Europe-based sepsis-related conference held in mid-November. CytoSorb was the subject of several presentations and lectures, content which included some of the most recent evidence from clinical studies and case reports supporting CytoSorb's utility in the treatment of sepsis. Additionally, a panel of physicians which are active users of CytoSorb provided the first consensus statement on its use which, among the recommendations, was for CytoSorb therapy to be initiated within the first 24 hours of the onset of septic shock and for frequent changes of the CytoSorb adsorber.

Among the presentations were;

- **Interim data from ACESS** (Adsorption of Cytokines Early in Septic Shock), a ~20-patient study being conducted at University of Szeged in Hungary, indicates improvement in certain sepsis-related biomarkers and measures including SOFA (Sepsis-related Organ Failure Assessment) among patients treated with CytoSorb. ACESS is evaluating CytoSorb treatment within the first 48 hours of septic shock on certain parameters including organ dysfunction, circulation and cytokine storm. Patients are randomized to either CytoSorb treatment and standard of care or standard of care alone.

- **Early versus late intervention with CytoSorb in septic shock**. Data from septic shock and SIRS case series indicating that when CytoSorb is used within the first 24 hours. As a reminder, data from a case series of 14 critically-ill patients with multi-organ failure showed that overall survival was 36% but increased to 67% when CytoSorb therapy was initiated within 24 hours. Additionally, data showed that after CytoSorb therapy was started, there was **a 10-fold decrease in catecholamine vasopressor** and a ~50% reduction in lactate levels (lactate level is a marker for cellulary hypoxia, which is positively correlated with mortality).

As we have recently noted in our ongoing coverage of CTSO, the growing amount of evidence indicating CytoSorb therapy is associated with improved patient outcomes makes it increasingly difficult to ignore the association between its use and utility in saving lives. As it relates to sepsis, the SepsEast2016 presentations follow positive results from an investigator initiated septic shock study (n=22) conducted in Germany which were presented at the Symposium for Intensive Medicine + Intensive Care in Bremen, Germany earlier this year. Ongoing and planned studies, along with case series and a very active and rapidly growing user's registry should provide a fairly regular flow of data and offer additional insight into CytoSorb's place in sepsis treatment (as well as a host of other applications).

While animal-borne viral infections have not been a significant focus of CTSO's, CytoSorb has been successfully used in the past for conditions such as swine flu and been investigated for treatment of MERS. And with the November 2016 announcement that **a patient with Dengue virus infection recovered after treatment with CytoSorb therapy** at a hospital in India, this could open up a relatively new area of focus for CytSorb. Per the case report, recently published in the Journal of Evidence Based Medicine Healthcare, the patient went into septic shock, had multiple organ failure and continued to deteriorate. CytoSorb along with renal replacement therapy was given for 6 hours on days 2, 4 and 6. His APACHE II score of 27 (i.e. measure of acute health, higher = worse) when CytoSorb therapy was initiated, fell to 12 after the third CytoSorb therapy. The patient was removed from the ICU on day 13 and subsequently discharged. The author of the manuscript, Dr. Zafir A. Khan, Director of the Department of Internal Medicine at Noble Hospital in Pune, India, credited CytoSorb with helping to stabilize the patient.

FINANCIAL MODEL

CytoSorbents Inc.

	2015 A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E	2019 E
CytoSorb Sales	$4,043.8	$1,597.4	$1,852.7	$2,143.1	$2,557.5	$8,150.7	$12,820.0	$20,574.0	$26,706.0
y-o-y growth	*29.0%*	*127.0%*	*139.6%*	*100.0%*	*71.0%*	*101.6%*	*57.3%*	*60.5%*	*29.8%*
Total Royalties/Grants/Other	$747.8	$212.7	$369.7	$268.6	$330.0	$1,181.0	$1,266.0	$250.0	$0.0
y-o-y growth	*-24.3%*	*995.7%*	*93.7%*	*-1.3%*	*24.3%*	*57.9%*	*7.2%*	*-80.3%*	-
Revenue	$4,791.7	$1,810.2	$2,222.3	$2,411.7	$2,887.5	$9,331.7	$14,086.0	$20,824.0	$26,706.0
YOY Growth	*16.2%*	*150.3%*	*130.5%*	*79.5%*	*64.0%*	*94.7%*	*50.9%*	*47.8%*	*28.2%*
Cost of Goods Sold	$2,212.6	$819.5	$873.3	$963.9	$1,199.6	$3,856.2	$5,496.6	$7,026.9	$8,813.0
Gross Income	$2,579.1	$990.7	$1,349.1	$1,447.8	$1,688.0	$5,475.5	$8,589.4	$13,797.1	$17,893.0
Gross Margin	*53.8%*	*54.7%*	*60.7%*	*60.0%*	*58.5%*	*58.7%*	*61.0%*	*66.3%*	*67.0%*
SG&A	$8,011.9	$2,224.7	$2,944.4	$2,419.9	$2,805.6	$10,394.5	$12,141.6	$13,558.3	$16,050.3
SG&A % of Prod Sales	*198.1%*	*139.3%*	*158.9%*	*112.9%*	*109.7%*	*127.5%*	*94.7%*	*65.9%*	*60.1%*
R&D	$3,871.1	$856.1	$1,092.1	$1,172.1	$1,223.0	$4,343.3	$5,751.0	$5,866.0	$6,120.0
R&D % Tot Sales	*80.8%*	*47.3%*	*49.1%*	*48.6%*	*42.4%*	*46.5%*	*40.8%*	*28.2%*	*22.9%*
Operating Income	($9,303.9)	($2,090.1)	($2,687.4)	($2,144.2)	($2,340.7)	($9,262.3)	($9,303.2)	($5,627.2)	($4,277.3)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	($847.3)	($253.8)	$317.9	$538.5	$135.0	$737.6	$648.2	$546.5	$276.0
Pre-Tax Income	($8,456.6)	($1,836.3)	($3,005.2)	($2,682.7)	($2,475.7)	($9,999.9)	($9,951.4)	($6,173.6)	($4,553.3)
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)	($1,836.3)	($3,005.2)	($2,682.7)	($2,475.7)	($9,999.9)	($9,951.4)	($6,173.6)	($4,553.3)
Net Margin	*-169.7%*	*-101.4%*	*-135.2%*	*-111.2%*	*-85.7%*	*-107.2%*	*-70.6%*	*-29.6%*	*-17.0%*
EPS	($0.33)	($0.08)	($0.12)	($0.11)	($0.10)	($0.40)	($0.35)	($0.21)	($0.15)
YOY Growth	-	-	-	-	-				
Diluted Shares O/S	24,886	24,401	25,416	25,445	25,500	25,190	28,200	29,400	29,900

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