Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Several Catalysts Will Extend Record Revenue Streak Into 2017

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 (03/07/17)	$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	**$6.73**
52-Week Low	**$3.85**
One-Year Return (%)	**1.35**
Beta	**-0.07**
Average Daily Volume (sh)	**50,123**
Shares Outstanding (mil)	**26**
Market Capitalization ($mil)	**$134**
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	**Average,**
Type of Stock	**Small-Growth**
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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Q4 Financials / Operating Update: *Product Sales Up 103% in 2016, We See Several Catalysts Extending Record Revenue Into 2017…*

CytoSorbents reported financial results for the fourth quarter ending December 31st and provided a business update. Total revenue and product sales continue to show considerable strength, rising for the seventh straight quarter and catalyzed by CytoSorb cartridge ("razor blade") reorders as well as new customer wins and expansion of the distribution footprint.

Both product sales and total revenue set new records in Q4. Q4 product sales were up 74% yoy and 22% sequentially to $2.6M. Meanwhile, total revenue (which along with product sales includes grant revenue) grew 75% yoy and 28% sequentially to $3.1M. As we have stressed in the past, we are encouraged by the high quality product revenue growth – that is, mostly reorders, no channel stuffing or lumpy distributor stocking – which we believe offers a certain level of validation of burgeoning demand and by extension, clinical utility of CytoSorb.

Financials…

Product revenue came in at $2.6M, midway between the company's $2.5M - $2.7M preannouncement in January and largely inline with our estimate. Meanwhile, grant income, at $471k, was about $141k better than our number – the difference related to earlier than anticipated recognition from some of the outstanding contracts. For the full year, product revenue was $8.2M, up 103% yoy while total revenue was $9.5M, representing yoy growth of 99%.

While it has been clear that Germany has been a significant contributor to both sales and revenue growth, for the first time management disclosed just how important that country has been to their success to-date. As a reminder, Germany was where CytoSorb was initially launched back in 2012 and is detailed by the company's direct sales force. Being the largest medical device market in Europe and already having some established reimbursement, the country was (and remains) particularly attractive.

Germany accounted for approximately $5M, or 61% of product sales in 2016 - which is up approximately 112% from $2.4M in 2015 (~59% of sales). And while Germany has been a significant contributor to revenue, that market may still remain relatively untapped given their significant population and large hospital network. Management has indicated that adoption in that country remains brisk and is aided by strong support by certain KOLs. In 2016, one hospital in Germany accounted for over $1M in product sales. With over 400 mid-to-large hospitals in the country, we think there is considerable near-term upside from that market – particularly now with dedicated reimbursement available.

Management noted that FY2016 product margin was approximately 67%, which implies Q4 product margin was~ 68.5% - these compare with approximately 62% and 64% in FY2015 and Q4 '15, respectively. The 68.5% in Q4 '16 looks to be the widest product margin to-date. While we had (perhaps conservatively) been modeling flattish product margin going forward, we have since updated this assumption and now look for incremental widening through the course of the out-years in our model given what we now think is greater likelihood of some opportunistic pricing power, particularly in reimbursement-favorable territories.

Operating expenses, at $6.4M were up almost 77% sequentially from $3.6M in Q3 '16 but most of the difference was related to $2M in non-cash stock compensation. Management noted on the Q4 call that they believe the fixed portion of SG&A should be largely scalable going forward – as such we expect to see SG&A expense to grow at a significantly lower rate than revenue which should help to improve profitability.

Cash used in operating activities was $1.1M ($2.2M ex-changes in working capital) in Q4 and $6.7M ($8.4M ex-changes in working capital) in FY2016. Cash balance at year-end stood at $5.2M which management believes is sufficient to fund operations through the first half of 2017. While the $5M "B" tranche from the June 2016 debt facility remains untapped, access is conditional on meeting certain financial (cash and revenue) metrics. Management noted on the Q4 call that they are exploring a variety of other potential funding sources as well. We have little concern that CTSO will be able to raise additional capital on reasonable terms. We also think that additional positive clinical data as well continued strong financial results should help to facilitate those efforts.

Operational update…

Going into 2017, we see no reason why product sales do not continue to set new regular records, particularly given some recent catalysts that came online – this includes;

- dedicated reimbursement in Germany which became effective Jan 1, 2017 (more details below)

- accelerating adoption in Germany, the largest (yet still barely tapped) medical device market in Europe
- Fresenius: roll-out began in Q2 ’16. 2017 will benefit from full-year FMS contribution. In addition, co-marketing agreement (details below), expected to kick-off 2H ’17, will greatly expand FMS footprint
- Terumo (cardiac channel): launch just began Dec ’16. 2017 will benefit from full-year contribution. We think Terumo could also be key in eventually accessing (very substantial) Japanese market
- Biocon: CTSO’s large distributor in India recently reorganized CytoSorb into a separate division. Biocon has been a key partner and this restructuring is an indication they are putting even more resources behind CytoSorb
- distribution/geographic expansion: we expect additional territories and distribution agreements will continue to come online on a regular basis
- clinical data: has been and continues to be the driving force behind adoption. In addition to REFRESH I data (at AATC in late April), a fairly regular flow of clinical data from case studies and investigator-initiated trials should be forthcoming
- increasing use in a number of critical care applications where CytoSorb has been associated with positive patient outcomes including sepsis

Obtaining a **dedicated reimbursement procedure code in Germany**, which CTSO announced in early December 2016, has the potential in our opinion to have a significant and almost immediate (the code became effective Jan 1, 2017) positive impact on sales of CytoSorb. Management noted that in the past, a more generic code was used which covered as little as 60% of the cost of the cartridge – but, perhaps more inimical was that the cost of the procedure was not always reimbursed. That caused a headwind to adoption and hampered greater utilization of CytoSorb.

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, should 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 (as noted, Germany currently accounts for 61% of product sales), this could have a meaningfully positive effect on adoption and utilization 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.

Fresenius, while a contributor to CTSO’s record results in 2016, we think the dialysis behemoth will be a much more significant factor during 2017 for several reasons. For one, the FMS official launch happened in late May 2016 - so 2017 will not only include a full five additional months’ worth of contribution but will also benefit from FMS’ experience with CytoSorb including priming of their accounts. In addition, any launch and integration challenges or hurdles should now be a thing of the past. And finally, the co-marketing agreement which was penned in January 2017 will significantly expand FMS’ distribution reach. This is expected to begin making an impact in the second half of this year.

As we mentioned in a recent Investor Note, we think this updated agreement, which was constructed to be a win-win-win for CytoSorbents, for Fresenius and also for all other distributors of CytoSorb, was among the most savvy that we have seen among any small medical device companies. 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.

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

Terumo Cardiovascular similarly will almost certainly be a more meaningful contributor to CTSO in 2017 than in the prior year given that their launch did not happen until December 2016**.** CytoSorbents' 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.

Expansion of the **distribution network** and **geographic footprint** as well as **accelerating sales activity of existing distributors** also figures into the expectation of extending the streak of CTSO's record financial performance. Noteworthy is that most of the company's distribution agreements are still in their relative infancy with only about 12 of their 37 distribution territories having been actively selling for two years or more. As such, just the maturation of the existing distribution network almost certainly holds significant unrealized revenue potential. But in addition, we expect CTSO will continue to look to grow their distribution footprint.

Clinical data and positive patient outcomes has been and continues to be the driving force behind adoption and with REFRESH I efficacy data expected to be announced at AATC in late April (at AATS), 2017 could be include a major milestone in that regard. CytoSorb has now been used in more than 20k treatments, more than double the number from just 12 months ago, and we think additional positive clinical data, particularly from randomized trials such as REFRESH, will have major influence on further adoption and utilization of the device. And in addition to REFRESH, 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.

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. 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).

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 (as well as in other territories), this will be something to stay tuned to.

CTSO had a busy schedule at SepsEast2016, a leading Europe-based sepsis-related conference held in November 2016. 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 in 2016. 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.

Outlook and Valuation

On the Q4 call management reiterated their belief that cash flow break-even is attainable at an annual revenue level of $20M, which they think they will reach within one to two years' time. Along with annual revenue growth of at least 45% (which assumes $20M is reached in 2018), that forecast is also predicated on the expectation that gross margins continue to widen as well as meaningful improvement in operating leverage. For some reference, product sales have increased at a CAGR of 115% from 2013 to 2016 and product margin improved from approximately 61% to 67% over that same period. While this revenue and margin growth did not result in improved profitability, with operating loss growing from $4.7M in 2013 to $11.5M in 2016, management has indicated that much of the reason for that is due to build out of (fixed cost related) operating infrastructure. As the majority of this initial build out is largely complete, expectations are that operating expenses will now grow at a significantly slower rate, resulting in much greater operating leverage and improved profitability.

We have updated our model following reporting of Q4 2016 results. We expect to see continued strength in product sales growth as well as more strides on the operational front. We see several catalysts that begin to make either an initial or a greater impact in 2017 including dedicated reimbursement in Germany and accelerating adoption in that country, greater contribution from Fresenius (i.e. full year impact, additional experience, co-marketing agreement) as well as from Terumo (which just came online in December 2016), maturation of existing distribution relationships and expansion of the overall sales footprint, and the release of additional clinical data supporting the utility of CytoSorb in a several indications.

While we continue to model 2017 revenue of approximately $14M, this is subject to updating and, based on recent top-line performance and the scope and potential of near-term catalysts, believe that our current forecast could prove conservative. Meanwhile, we have moved our 2018 revenue number from $20.8M to $22M. We now have CTSO reaching GAAP operating profitability in our out-year (2020) in our model.

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.

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	27,000	28,000	28,400	27,230	31,200	33,200	34,000

Brian Marckx, CFA

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