Zacks Small-Cap Research

August 12, 2016

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Reorders Fuel Record Product Sales. New Territories Coming Online Will Complement This

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 (08/12/16)	$4.74
Valuation	**$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 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	**$8.10**
52-Week Low	**$3.11**
One-Year Return (%)	**-23.46**
Beta	**0.00**
Average Daily Volume (sh)	**63,812**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$120**
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 (%)	**58.0**
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	1810 A	2222 A	2615 E	3006 E	9653 E
2017					15974 E
2018					22334 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 E	-0.10 E	-0.40 E
2017					-0.31 E
2018					-0.19 E

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

Q2 Financials / Operating Update: *Reorders Fuel Record Product Sales, New Territories Coming Online…*

CytoSorbents (CTSO) reported financial results for the second quarter ending June 30th. It was another very solid quarter with product revenue setting a new record, up 16% from its previous high, fueled by increasing reorders from existing accounts and, to a lesser degree, initial contribution from new customers. This marks the fifth consecutive period of sequential product sales growth which, coupled with the high quality of the growth drivers (i.e. mostly reorders, no channel stuffing or lumpy distributor stocking), provides further validation of increasing demand and by extension, clinical utility of CytoSorb.

Q2 total revenue, product sales and grant income were all just about dead-on with our estimates. Total revenue of $2.22M ($2.22M E) was also a new record and up 131% yoy and 23% sequentially. Product sales were $1.85M ($1.87M E), an increase of 140% from $773k in Q2 2015 (as a reminder 1H 2015 sales were negatively impacted by sales force restructuring) and up 16% from $1.60M in Q1 2016. Grant income was $370k ($350k E).

Product margin, at approximately 68%, was nearly a record (only bested by 71% in Q3 2013) - although we expect there to be some variability in this particularly as third-party sales make a greater contribution. Operating expenses, at $4.0M were on the higher side, up from about $3.1M in Q1 of this year but the difference mostly relates to non-cash stock-based compensation.

Cash balance at quarter end, recently bolstered by a new debt facility ($5M term loan with another $5M available upon meeting certain financial metrics), was approximately $8.9M which management expects to be sufficient to fund operations for at least the next 12 months. The other $5M, assuming borrowing conditions are met, could extend this another ~6 months.

Contribution from new territories, distributors will begin to make impact…
Management noted that reorders from existing customers has fueled 80% - 90% of recent revenue growth. With several new territories having either recently come online or expected to do so in the very near future, this strong reorder growth should be complemented with steepening third party distributor sales.

There are now 28 countries where CytoSorb is approved for sale and distribution is in place - this is up from just 15 at the beginning of 2016. The recent additions include Fresenius which is now commencing roll-out with 30 reps detailing CytoSorb at the ICU level in Poland, France, Sweden, Denmark, Finland and Norway. Fresenius is also actively involved in promoting CytoSorb at critical care conferences where feedback has been positive. Russia, where CytoSorb received product registration in May and is being actively promoted by INTENSIVEMED (including exhibiting at clinical conferences), could also be meaningful territory for CTSO.

Fresenius' booth exhibiting dialysis machine with CytoSorb cartridge

Management noted on the call that initial orders were received during Q2 from their distributors covering Vietnam, Spain and Portugal. The current quarter (Q3) will benefit from initial contribution from orders in Hungary, the Czech Republic and Slovakia.

And the list of countries where CytoSorb is being sold should grow following gaining requisite marketing clearance. CTSO has distribution partnerships covering another nine countries, all in the Middle East, which could come online in the near future. The Middle East could present a new opportunity for CTSO given the unique flu strains in that part of the world. As a reminder, management had previously talked about the potential utility of CytoSorb for the treatment of Middle East Respiratory Syndrome Coronavirus, or MERS, which is an aggressive and often deadly virus thought to be linked to camels and/or bats.

Clinical Data, Positive Outcomes Driving Awareness, Interest and Demand…

CytoSorb has now been used in more than 1,400 human treatments. CTSO recently noted 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 is being driven by positive patient outcomes and clinical evidence which has been and continues to be the basis for increasing demand. And more and more of the clinical evidence is starting to be published – which should be a catalyst to broadening both awareness of the technology as well as providing greater validation of its effectiveness.

The clinical database continues to grow as does evidence of CytoSorb's efficacy in treating various conditions and diseases. Management noted that while much of the early validation was in the form of small case studies involving one or only a few patients that that has more recently migrated towards case series and small clinical trials – providing a much more robust efficacy assessment. Earlier this year CTSO announced highly positive outcomes from a recent investigator-initiated sepsis study (detailed below) where CytoSorb was introduced with very ill patients after standard of care had failed. More outcomes data from case studies and investigator initiated studies have been released since with use of CytoSorb in sepsis, cardiac surgery, liver failure and other applications. Presentations at the third annual international user's meeting (link http://bit.ly/1TPL4jg) and ISICEM conference, including five poster presentations, further supported efficacy of the device in areas such as sepsis, cardiac surgery and liver failure. This included an evaluation in cardiac surgery with a 10-patient population similar to those treated in CTSO's REFRESH I study which showed CytoSorb helped to stabilize two patients and reduced the need for vasopressors and extracorporeal life support.

CytoSorb's ability to remove toxic levels of bilirubin in patients with severely compromised liver function is an application which CTSO has not talked about much in the past but was another of the poster presentations at ISICEM. This may be an area where the device sees more use and something which CTSO may be reporting more on the future.

Cardiac surgery (as well as sepsis) is the application with perhaps the bulk of the clinical history and evidence continues to support CytoSorb's utility in this area. In addition to the aforementioned positive 10-patient data, a three-arm randomized open heart surgery study conducted in Cologne, France showed positive results. Late last year CTSO announced data from 142 patients, more recently data from 165 (of an expected 300) was presented showing a statistically significant reduction in sternal wound infections. Sternal wounds are potentially lethal complications following cardiac surgery and associated with high morbidity and mortality.

And case reports also continue to provide growing evidence of CtyoSorb's life-saving efficacy. On the Q2 call management highlighted two cases where their device was introduced in critically ill individuals after their condition continued to deteriorate when standard care failed to stabilize the patients. While these case studies do not provide the breadth of scientific data of randomized clinical studies, we think as the number of case reports similar to these (i.e. critically ill patients make full recovery after CytoSorb is introduced when standard care failed) grows it will be increasingly difficult to ignore the association between CytoSorb and its utility in saving lives.

REFRESH I Close to Fully Enrolled…

As use in cardiac surgery applications is expected to form the basis for the initial indication in the U.S., ongoing positive data in this area is obviously encouraging. Relative to REFRESH I, in May CTSO announced that, based on an evaluation of safety data of the first 24 patients, that the data safety monitoring board (DSMB) recommended continuation of REFRESH I given no concerns about safety. Management noted on the Q2 call that 40 off 44 patients have completed the study protocol and they expect the final patient to run through "within the next couple of weeks". Management continues to expect to announce top-line data at the European Association of Cardio-thoracic Surgery Conference (EACS) in Barcelona in early October and, assuming positive results, to complete final

analysis and meet with FDA later this year regarding design of REFRESH II, a larger pivotal study to form the basis for support of U.S. regulatory clearance.

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.

Relative to potential plans of a U.S. pivotal sepsis study – management has previosuly 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.

We expect to see continued acceleration in product sales growth as well as more strides on the operational front. 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 promise. Consummation of a partnering agreement could further this opportunity.

CTSO also continues to see significant interest in its technology from government agencies in the form of grants and contracts. This includes recent award of $650k in new SBIR grants focused on potassium binding polymers, which is a new area for CytoSorb and highlights its versatility and breadth of the number and different kinds of toxins that it can remove.

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.

	2015 A	Q1A	Q2A	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
CytoSorb Sales	$4,043.8	$1,597.4	$1,852.7	$2,199.8	$2,580.8	$8,230.6	$14,848.0	$22,134.0	$27,252.0
y-o-y growth	*29.0%*	*127.0%*	*139.6%*	*105.3%*	*72.6%*	*103.5%*	*80.4%*	*49.1%*	*23.1%*
Total Royalties/Grants/Other	$747.8	$212.7	$369.7	$415.0	$425.0	$1,422.4	$1,126.0	$200.0	$0.0
y-o-y growth	*-24.3%*	*995.7%*	*93.7%*	*52.5%*	*60.1%*	*90.2%*	*-20.8%*	*-82.2%*	-
Revenue	$4,791.7	$1,810.2	$2,222.3	$2,614.8	$3,005.8	$9,653.0	$15,974.0	$22,334.0	$27,252.0
YOY Growth	*16.2%*	*150.3%*	*130.5%*	*94.6%*	*70.7%*	*101.5%*	*65.5%*	*39.8%*	*22.0%*
Cost of Goods Sold	$2,212.6	$819.5	$873.3	$1,206.9	$1,354.1	$4,253.7	$6,471.3	$8,047.6	$9,538.2
Gross Income	$2,579.1	$990.7	$1,349.1	$1,407.8	$1,651.7	$5,399.3	$9,502.7	$14,286.4	$17,713.8
Gross Margin	*53.8%*	*54.7%*	*60.7%*	*53.8%*	*55.0%*	*55.9%*	*59.5%*	*64.0%*	*65.0%*
SG&A	$8,011.9	$2,224.7	$2,944.4	$2,963.0	$3,105.6	$11,237.6	$13,078.4	$14,497.8	$16,187.7
SG&A % of Prod Sales	*198.1%*	*139.3%*	*158.9%*	*134.7%*	*120.3%*	*136.5%*	*88.1%*	*65.5%*	*59.4%*
R&D	$3,871.1	$856.1	$1,092.1	$1,218.0	$1,308.0	$4,474.2	$5,751.0	$5,866.0	$6,120.0
R&D % Tot Sales	*80.8%*	*47.3%*	*49.1%*	*46.6%*	*43.5%*	*46.4%*	*36.0%*	*26.3%*	*22.5%*
Operating Income	($9,303.9)	($2,090.1)	($2,687.4)	($2,773.2)	($2,761.9)	($10,312.5)	($9,326.7)	($6,077.3)	($4,593.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	($847.3)	($253.8)	$317.9	($90.0)	($92.5)	($118.4)	($612.2)	($526.5)	($266.0)
Pre-Tax Income	($8,456.6)	($1,836.3)	($3,005.2)	($2,683.2)	($2,669.4)	($10,194.1)	($8,714.5)	($5,550.9)	($4,327.9)
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)	($2,683.2)	($2,669.4)	($10,194.1)	($8,714.5)	($5,550.9)	($4,327.9)
Net Margin	*-169.7%*	*-101.4%*	*-135.2%*	*-102.6%*	*-88.8%*	*-105.6%*	*-54.6%*	*-24.9%*	*-15.9%*
EPS	($0.33)	($0.08)	($0.12)	($0.11)	($0.10)	($0.40)	($0.31)	($0.19)	($0.14)
YOY Growth	-	-	-	-	-				
Diluted Shares O/S	24,886	24,401	25,416	25,430	25,500	25,187	28,200	29,400	29,900

Brian Marckx, CFA

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