January 12, 2018

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Q4 Preannouncement, Our Thoughts on REFRESH II

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.

Current Price (01/12/18)	$7.60
Valuation	**$12.00**

OUTLOOK

CTSO preannounced expected Q4 revenue of ~$4.6M including product sales of ~$4.2M, implying new records for both. This also implies product sales growth of 58% on a yoy basis and about 20% compared to the $3.5M posted in Q3 – the previous record high. We have since made upward adjustments to our Q4 numbers, as well as to our forecasted product sales in the out-years in our model.
IDE for REFRESH II was approved by FDA in December. The multi-center, randomized, controlled U.S. study is expected to enroll up to 400 patients which are undergoing elective open heart surgery for valve replacement or aortic reconstruction with hypothermic cardiac arrest. As we had hoped, the primary endpoint, reduction of acute kidney injury (AKI) as measured by KDIGO, is outcomes-based. We had a chance to sit down with Dr. Chan earlier this week in San Francisco shortly following his presentation at the Biotech Showcase. Most of our questions revolved around REFRESH II given that it currently represents the potential gateway for CytoSorb to enter the U.S. market. We came away feeling confident in the robustness of the trial design and, by extension, the potential commercial appeal of CytoSorb if the trial is successful.

SUMMARY DATA

52-Week High	**$7.68**
52-Week Low	**$3.30**
One-Year Return (%)	**27.73**
Beta	**-0.54**
Average Daily Volume (sh)	**131,865**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$218**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**55.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 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)
2016	1810 A	2222 A	2412 A	3083 A	9528 A
2017	3114 A	3566 A	3824 A	4536 E	15040 E
2018					21856 E
2019					31690 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	-0.05 A	-0.04 A	-0.07 A	-0.08 E	-0.25 E
2018					-0.35 E
2019					-0.19 E

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

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Q4 / FY2017 Preannouncement: *Product Revenue Crushes Prior Record, Jumping 20% QoQ...*

On Monday (Jan 8th) CytoSorbents preannounced expected Q4 revenue of approximately $4.6M (i.e. between $4.5M and $4.7) including product sales of approximately $4.2M ($4.1 - $4.3M), implying new records for both. This also implies product sales growth of 58% on a yoy basis and about 20% compared to the $3.5M posted in Q3 – the previous record high. It is also well ahead of our estimated $3.4M in product sales and $3.9M in total revenue. We have since made upward adjustments to our Q4 numbers, as well as to our forecasted product sales in the out-years in our model.

CTSO ended 2017 with $17.3M in cash and reiterated their expectation to be cash flow positive (excluding clinical trial costs and non-cash expenses) on a quarterly basis in 2018. Management also continues to expect gross margin to continue to widen – and potentially significantly so with the impending ribbon-cutting on a new manufacturing facility which is expected to drive down production costs.

Clearly uptake and adoption of CytSorb is growing, as evidenced by not only the rapid product sales growth but also by the number of procedures during which the device has been employed. As of the end of 2017, more than 35k CytoSorb treatments were delivered – up from about 20k (i.e. 50% growth) one-year earlier.

While we think the potential for qoq volatility in product sales remains, we also continue to believe product sales will trend higher given several catalysts which we have discussed in prior updates. These include the improved reimbursement picture in Germany, continued robust product sales growth from existing distributors OG (i.e. outside of Germany), recently established distribution in new territories and initial roll-out of the Fresenius co-marketing agreement. Additionally, new product launches, such as the recently-introduced ECMO kit could provide incremental upside. And, with ~60 investigator initiated studies either ongoing or planned as well as recent publication of additional clinical data in a variety of indications (including infective endocarditis and sepsis) and anticipated near-term publication of the REFRESH I data, there should be a regular flow clinical and outcomes data to help further enhance the marketing message.

Publicity (and potentially interim updates) from REFRESH II, an IDE for which FDA approved in late December, could also help drive awareness and adoption of CytSorb overseas. We expect the study to kick off following requisite attainment of IRB approvals at each study site and expect to hear more in the way of anticipated timelines related to site activations and patient enrollment on future update calls.

REFRESH II

As a reminder, REFRESH II is expected to be a pivotal FDA registration study and provide primary support for a U.S. regulatory filing for use of CytoSorb during cardiac surgery.

The multi-center, randomized, controlled U.S. study is expected to enroll up to 400 patients which are undergoing elective open heart surgery for valve replacement or aortic reconstruction with hypothermic cardiac arrest. Patients will be randomized to either standard-of-care (i.e. control) or standard-of-care plus dual CytoSorb cartridges (in parallel in a heart-lung bypass circuit). As we had hoped, the primary endpoint, reduction of acute kidney injury (AKI), is outcomes-based. AKI will be measured by Kidney Disease Improving Global Outcomes (KDIGO) criteria. Secondary endpoints include time on mechanical ventilation, use of vasopressors, days in ICU, reduction of inflammatory mediators and 30-day mortality.

We had a chance to sit down with Dr. Chan earlier this week in San Francisco shortly following his presentation at the Biotech Showcase. While we talked about a variety of topics, most of our questions revolved around REFRESH II given that it currently represents the potential gateway for CytoSorb to enter the U.S. market. We came away feeling confident in the robustness of the trial design and, by extension, the potential commercial appeal of CytoSorb if the trial is successful.

Relative to the KDGIO criteria primary endpoint, this is what we found based on our own research…published in March 2012, KDIGO guidelines are an international initiative for the evaluation and management of AKI. KDIGO guidelines build on already established AKI measures such as RIFLE (Risk, Injury, Failure, Loss of Kidney Function, and End-stage Kidney Disease) and AKIN (Acute Kidney Injury Network) criteria and measure changes in serum creatinine as well as urine output in staging AKI (i.e. 1 – 3 severity scale). Below is the definition and staging of AKI as per KDIGO guidelines (SOURCE: Kidney International Supplements, KDIGO Clinical Practice Guideline for Acute Kidney Injury. Vol 2, Issue 1, March 2012).

KDIGO Definition of AKI

AKI is defined as any of the following (***Not Graded***):

- Increase in SCr by $\geqslant$0.3 mg/dl ($\geqslant$26.5 µmol/l) within 48 hours; or
- Increase in SCr to $\geqslant$1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or
- Urine volume <0.5 ml/kg/h for 6 hours.

KDIGO AKI Staging

Stage	Serum creatinine	Urine output
1	1.5–1.9 times baseline OR $\geqslant$0.3 mg/dl ($\geqslant$26.5 µmol/l) increase	<0.5 ml/kg/h for 6–12 hours
2	2.0–2.9 times baseline	<0.5 ml/kg/h for $\geqslant$12 hours
3	3.0 times baseline OR Increase in serum creatinine to $\geqslant$4.0 mg/dl ($\geqslant$353.6 µmol/l) OR Initiation of renal replacement therapy OR, In patients <18 years, decrease in eGFR to <35 ml/min per 1.73 m^2	<0.3 ml/kg/h for $\geqslant$24 hours OR Anuria for $\geqslant$12 hours

Despite the newness of the KDIGO criteria, our research has found that it appears to be largely widely accepted in the U.S. in defining AKI[1]. In addition, clinical studies[2] have demonstrated a significant positive correlation between KDIGO AKI stage and 30-day mortality, including among subjects undergoing cardiac surgery[3].

Valuation

We expect to see continued strength in product sales growth through 2018, as well as more strides on the operational front. We see several catalysts that begin to make either an initial or a greater impact including dedicated reimbursement in Germany and accelerating adoption in that country, greater contribution from Fresenius (including from co-marketing agreement) as well as from Terumo (which 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.

We have adjusted our model based on the Q4 preannouncement. While most of the revisions relate to Q4 '17, we think the stronger than anticipated product sales growth may be reflective of a greater ramp in initial adoption and/or reordering (i.e. utilization) which has also resulted in a step-up in forecasted product sales in the out-years in our model. We now look for 2017 and 2018 revenue of $15.0M and $21.9M (revised from $14.4M and $21.3M).

We show CTSO nearly reaching GAAP full-year operating profitability in the distant-year (2020) in our model and also believe management's guidance of reaching a level of break-even operating profitability (excluding clinical trial-related and non-cash expenses) on a quarterly basis in 2018 is also achievable.

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.

[1] Palevsky PM, et al. KDOQI US commentary on the 2012 KDIGO clinical practice guideline for acute kidney injury. Am J Kidney Dis. 2013 May;61(5):649-72. doi: 10.1053/j.ajkd.2013.02.349. Epub 2013 Mar 15.

[2] Talito Machado Levi, et al. Comparison of the RIFLE, AKIN and KDIGO criteria to predict mortality in critically ill patients. Rev Bras Ter Intensiva. 2013 Oct-Dec; 25(4): 290–296.

[3] Maurício Nassau Machado, et al. Acute kidney injury based on KDIGO (Kidney Disease Improving Global Outcomes) criteria in patients with elevated baseline serum creatinine undergoing cardiac surgery. Rev Bras Cir Cardiovasc. 2014 Jul-Sep; 29(3): 299–307.

FINANCIAL MODEL

CytoSorbents Inc.

	2016 A	Q1A	Q2A	Q3A	Q4E	2017 E	2018 E	2019 E	2020 E
CytoSorb Sales	$8,206.1	$2,596.1	$3,041.0	$3,448.7	$4,136.0	$13,221.8	$20,210.0	$30,530.0	$42,350.0
y-o-y growth	102.9%	62.5%	64.1%	60.9%	58.3%	61.1%	52.9%	51.1%	38.7%
Total Royalties/Grants/Other	$1,321.8	$517.4	$525.2	$375.6	$400.0	$1,819.0	$1,646.0	$1,160.0	$1,005.0
y-o-y growth	76.8%	143.2%	42.1%	39.9%	-15.0%	37.6%	-9.5%	-	-
Revenue	$9,527.9	$3,113.5	$3,566.2	$3,824.3	$4,536.0	$15,040.0	$21,856.0	$31,690.0	$43,355.0
YOY Growth	98.8%	72.0%	60.5%	58.6%	47.1%	57.9%	45.3%	45.0%	36.8%
Cost of Goods Sold	$3,953.8	$1,254.5	$1,482.0	$1,516.9	$1,846.2	$6,099.6	$7,361.1	$9,534.4	$12,288.8
Gross Income	$5,574.1	$1,859.0	$2,084.2	$2,307.4	$2,689.8	$8,940.4	$14,495.0	$22,155.6	$31,066.3
Gross Margin	58.5%	59.7%	58.4%	60.3%	59.3%	59.4%	66.3%	69.9%	71.7%
SG&A	$12,282.7	$2,947.0	$3,927.5	$3,918.5	$4,087.0	$14,880.0	$17,602.9	$21,126.8	$24,944.2
SG&A % of Prod Sales	149.7%	113.5%	129.2%	113.6%	98.8%	112.5%	87.1%	69.2%	58.9%
R&D	$4,783.5	$469.5	$487.6	$537.9	$622.4	$2,117.5	$7,287.0	$6,956.0	$7,295.0
R&D % Tot Sales	50.2%	15.1%	13.7%	14.1%	13.7%	14.1%	33.3%	22.0%	16.8%
Operating Income	($11,492.1)	($1,557.5)	($2,330.9)	($2,149.0)	($2,019.6)	($8,057.1)	($10,395.0)	($5,927.2)	($1,172.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$765.3	($179.5)	($1,214.5)	($94.8)	$249.6	($1,239.2)	$772.8	$361.1	$44.1
Pre-Tax Income	($12,257.3)	($1,378.0)	($1,116.4)	($2,054.3)	($2,269.2)	($6,817.9)	($11,167.8)	($6,288.3)	($1,217.0)
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)	($1,378.0)	($1,116.4)	($2,054.3)	($2,269.2)	($6,817.9)	($11,167.8)	($6,288.3)	($1,217.0)
Net Margin	-125.3%	-44.3%	-31.3%	-53.7%	-50.0%	-45.3%	-51.1%	-19.8%	-2.8%
EPS	($0.47)	($0.05)	($0.04)	($0.07)	($0.08)	($0.25)	($0.35)	($0.19)	($0.04)
YOY Growth		-	-	-	-				
Diluted Shares O/S	25,433	25,504	27,954	28,206	28,600	27,566	31,500	33,500	34,500

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