Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Q1 Slight Miss But Acceleration Expected 2H. REFRESH Efficacy Compelling.

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 (05/15/17)	$4.35
Valuation	**$12.00**

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 as well as publications in near term to provide additional evidence of clinical benefits including improved patient outcomes. REFRESH I safety and efficacy data is compelling. REFRESH II design in the works – could include acute kidney injury clinical endpoint.

SUMMARY DATA

52-Week High	**$6.90**
52-Week Low	**$4.00**
One-Year Return (%)	**6.17**
Beta	**-0.05**
Average Daily Volume (sh)	**160,065**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$125**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**6**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**59.3**
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	**N/A**
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	3190 E	3480 E	3685 E	13468 E
2018					20445 E
2019					30296 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	-0.07 E	-0.07 E	-0.08 E	-0.28 E
2018					-0.38 E
2019					-0.15 E

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

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Q1 Financials / Operating Update: *Slight Miss But Revenue Remains Robust. Expect Acceleration 2H …*

CytoSorbents (CTSO) reported financial results for the first quarter ending March 31st and provided a business update. Product sales again posted very strong double-digit yoy growth, although dipped very slightly from Q4 – breaking the streak of sequential revenue growth which had endured for the last seven consecutive quarters. And while mildly disappointing and about 5% shy of our forecast, product sales still managed to come in at the second highest in company history. Management pointed to the likelihood of some German hospitals delaying purchasing as they awaited notification regarding reimbursement amounts under the new reimbursement code as a headwind. Importantly, this issue is expected to dissipate given that, per management's comments on the call, many of the hospitals in Germany have now received this information.

And while product sales just barely missed hitting a new high, total product sales, aided by initial contribution from the recently (January 2017) scored phase II (follow-on) mycotoxin grant ($1M over two years), did manage to set a new record. While product sales garner almost all of the attention as it relates to the top-line, government grants have been an important and non-dilutive funding source for CTSO over the last several years – helping to reduce cash burn and at the same time broaden development programs as well as potential applications for CytoSorb.

And there were other highlights in the financials – including 68% gross margin, which is near the all-time high, and an almost 50% drop in operating expenses – partly due to lower stock comp but also from a big decline in R&D, the latter related to the lull between REFRESH I & II.

Financials…

Total revenue was $3.1M, up 72% yoy, up about 1% sequentially and dead-on with our $3.1M estimate. Product revenue came in at $2.6M, up 63% yoy and down less than 1% sequentially. Grant income was $517k – which is the highest of any quarter since Q4 2013 (i.e. when the DARPA grant was highly active).

While Germany continues to account for the majority of product sales, that company's proportional contribution slipped slightly to 58.9% in the most recent quarter – that compares to 61.5% in Q1 2016 and 61% for the full year 2016. This may be explained by the aforementioned reimbursement-related headwind. 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 has been brisk and is aided by strong support by certain KOLs. One hospital in Germany already generates over $1M in product sales for CTSO. With over 400 mid-to-large hospitals in the country, we think there is considerable near-term upside from that market.

So, as Germany represents what we believe to be CTSO's single-most important territory as it relates to both near-term sales as well as opportunity for growth, it will be important that any issues from the establishment of the new reimbursement code do not result in a long-term hangover. Based on management's comments on the call indicating that they expect sales to pick up (particularly in 2H), this may have been just a short-term and very mild case of heartburn.

Gross margin: Product margin, at 68%, remained relatively very healthy in Q1. This compares to 62% in the comparable prior-year period and approximately 67% for the full year 2016. We continue to model incremental widening through the course of the out-years in our model from a combination of opportunistic pricing power and volume-related production efficiencies.

Operating expenses, at $3.4M were up slightly from $3.1M in Q1 2016 but down about 46% from Q4. The $2.9M sequential drop mostly related to ~$1.8M lower stock compensation and $1.1M decrease in R&D expense. At $470k, R&D expense was at the lowest level since Q2 2014 and reflects reduced activity related to the conclusion of REFRESH I. Preparations for REFRESH II could begin before year-end – significant expenses related to which will likely not be incurred until following a pretrial meeting with FDA. As it relates to SG&A – we continue to model this line to grow at a lower than historical rate as compared to revenue given leverage of certain fixed costs which should also help to improve profitability.

Cash used in operating activities was $2.0M ($1.5M ex-changes in working capital) in Q1. Pro forma for the $11.5M gross ($10.3M net) equity raise (2.56M shares @ $4.50/share, no warrants) in early April, cash balance at Q1 quarter-end was approximately $13.5M. Along with $5M available under their existing debt facility, management believes their cash needs are satisfied into 2H 2018.

Operational Update: REFRESH I Efficacy Data, Thoughts on REFRESH II Design Including Endpoints…

Given the importance of the REFRESH studies/program in terms of CTSO's most near-term opportunity to enter the U.S. market, the outsized significance of the U.S. market relative to opportunity for growth and the recent read-out of REFRESH I and management's comments on the Q1 call as it relates to their additional thoughts on design of REFRESH II, this is where the bulk of our operational update is focused.

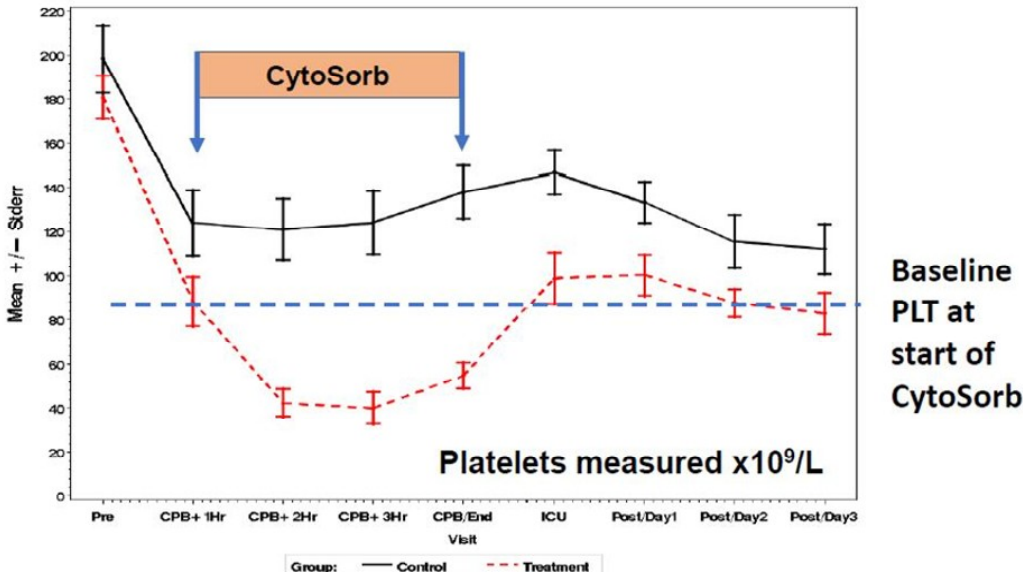
As a reminder, REFRESH I was a multi-site 40+-patient randomized study comparing CytoSorb plus standard-of-care (SOC) to SOC alone (1:1) in the reduction of free hemoglobin in patients undergoing elective complex cardiac surgery requiring cardiopulmonary bypass with anticipated duration of more than 180 minutes. 46 patients (23 each arm) were assessed in the safety population while 38 (18 CytoSorb, 20 control) were assessed in the efficacy population.

In October 2016 CTSO announced positive **safety-related information** and released additional information on the Q1 call. Both the number of total adverse events as well as number of serious adverse events was similar between the treatment and control arms. While there were two deaths in the CytoSorb group (8.7%), this was not statistically different than the one (4.3%) in the control group. Of the 121 adverse events in the CytoSorb arm, two were related to the device – with both related to a drop in platelets.

	Control (N = 23)	CytoSorb (N = 23)
Total Number AEs	137	121
Total Number SAEs	43	44
Mortality	1 (4.3%)	2 (8.7%)
Device Related AEs		2

SOURCE CytoSorbents

Of the 121 adverse events in the CytoSorb arm, two were related to the device – with both related to a drop in platelets. As management explained on the Q1 call, decrease in platelets (i.e. cells that help blood clot) is not unexpected given that patients undergoing these procedures must be highly anticoagulated and CPB in itself causes a drop in platelets. The chart below illustrates a drop in platelets in both cohorts even prior to introduction of the CytoSorb therapy in the treatment group. Nonetheless, the platelet level in the CytoSorb arm continues to drop with introduction of that therapy while the control group exhibits more of a leveling off. While the decrease in platelets, per management, was not associated with any serious device-related events and post-op coagulation and bleeding parameters as well as transfusions were not different between the two groups, the greater decrease in platelets among the treatment cohort is something that investigators will look at in more detail.



SOURCE CytoSorbents

REFRESH I Efficacy: CytoSorb More Effectively Reduces PfHB Which Is Associated With Kidney Injury….
A clinical study by Windsant, et al. indicated that hemolysis (including plasma free hemoglobin) during cardiac surgery is a contributor to postoperative kidney injury.[1] Plasma free hemoglobin can be dangerous, particularly at relatively high levels. While levels at or below 60 mg/dL have been found to be generally safe, levels over 120 mg/dL have been associated with acute kidney injury (AKI). As it relates to efficacy, there appears to be an association between the type of cardiac surgery and how much plasma free hemoglobin is generated. Specifically, valve replacement surgery (either in isolation or in combination with other cardiac surgery procedures) appears to be associated with higher levels of plasma free hemoglobin.

The average peak plasma free hemoglobin level of the nine patients in the control group (efficacy population) in REFRESH I that underwent valve replacement surgery was 121 mg/dL (median was 123 mg/dL) – or, at potentially dangerously-high levels.

Control group only: Peak PfHb in Different Surgical Procedures (mg/dL)

Procedure	N	Mean	Std	Median	Min	Max
All	20	104.0	58.54	101	23	245
Valve Replacement	9	121.0	46.57	123	57	204
Non-valve Replacement	11	90.1	65.60	61	23	246

CPB Length (median control): 2.8h (Valve) vs 4.0h (Non-valve), p=0.03

SOURCE CytoSorbents

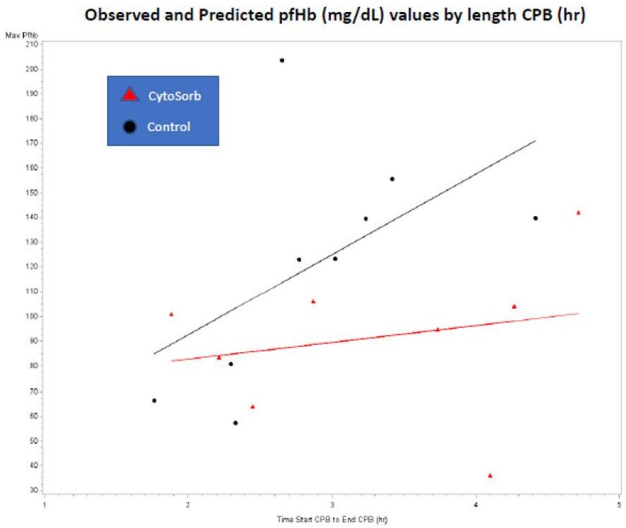
Valve replacement patients in the CytoSorb group fared better as it relates to PfHb levels. Among those patients in REFRESH I that underwent valve replacement surgery that lasted between 3 and 4.5 hours, CytoSorb demonstrated a statistically significant reduction in plasma free hemoglobin as compared to control.

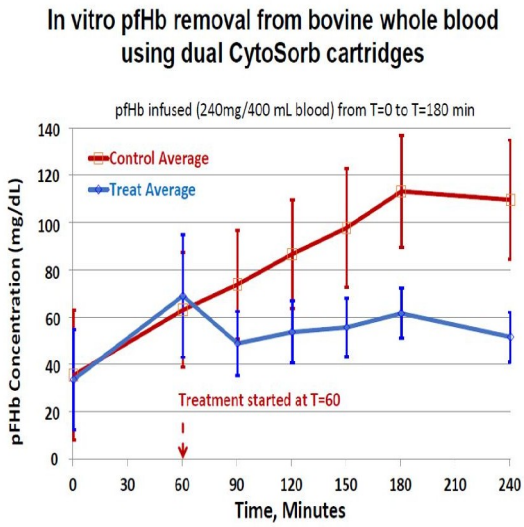
CPB Length	Mean Reduction of pfHb (mg/dL)	P-value
3.0	35 mg/dL	0.09
3.5	48 mg/dL	0.05
4.0	61 mg/dL	0.05
4.5	74 mg/dL	0.07

SOURCE CytoSorbents

[1] Iris C. Vermeulen Windsant, et al. Hemolysis during cardiac surgery is associated with increased intravascular nitric oxide consumption and perioperative kidney and intestinal tissue damage. Front Physiol. 2014; 5: 340. Published online 2014 Sep 8. doi: 10.3389/fphys.2014.00340

Interestingly, these findings are similar to an earlier pre-clinical study which found CytoSorb was more effective than standard bypass circuit in reducing free hemoglobin from bovine blood. In fact, the charts from REFRESH (left) and the in vitro bovine-blood study (right) have very similar patterns.





C3a / C5a:
In addition to plasma free hemoglobin, significant reductions in the activated complements C3a and C5a, high levels of which are associated with poor outcomes, were also observed.

In Summary:
Evidence to date has shown;

- high levels of PfHb generated during cardiac surgery with valve replacement surgery associated with particularly high levels
- an association between high levels (i.e. > 120 mg/dL) of PfHb and AKI
- CytoSorb's ability to significantly reduce PfHb vs. control in valve replacement procedures (3hr – 4.5hrs)

REFRESH II…
REFRESH II is expected to build on those findings. While CTSO still needs to meet with FDA regarding finalization of design of REFRESH II, management provided their current thoughts related to that topic in the Q1 call. Included is;

- N = 300-500
- enriching for procedures associated with high PfHb – such as valve replacement surgery
- primary endpoint: acute kidney injury or possibly a composite endpoint

Near-term Outlook

We continue to see no reason why product sales do not continue to set new regular records, particularly given some recent catalysts that came online. These include;

- **dedicated reimbursement in Germany** which became effective Jan 1, 2017. While the new code may have actually been an impediment to Q1 sales growth given that some hospitals in Germany may have delayed purchasing as they still awaited reimbursement amounts, we expect this to reverse and product sales to benefit as this headwind dissipates
- **accelerating adoption in Germany**, the largest (yet still barely tapped) medical device market in Europe
- **Fresenius**: roll-out began in Q2 2016. 2017 will benefit from full-year FMS contribution. In addition, co-marketing agreement, expected to kick-off 2H 17, will greatly expand FMS footprint
- **Terumo** (cardiac channel): launch began December 2016. 2017 should 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, 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

Valuation

We have updated our model following reporting of Q1 2017 results. We expect to see continued strength in product sales growth, particularly in 2H, 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.

Incorporating the slight top-line miss in Q1, coupled with the potential that there's a hangover into Q2 from the reimbursement-code item, our modeled 2017 revenue has moved from $14M to $13.5M. We show CTSO nearly 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.

FINANCIAL MODEL

CytoSorbents Inc.

	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E	2020 E
Cyto Sorb Sales	$8,206.1	$2,596.1	$2,786.3	$3,074.0	$3,366.5	$11,822.9	$19,690.0	$29,516.0	$41,700.0
y-o-y growth	*102.9%*	*62.5%*	*50.4%*	*43.4%*	*28.8%*	*44.1%*	*66.5%*	*49.9%*	*41.3%*
Total Royalties/Grants/Other	$1,321.8	$517.4	$404.0	$406.0	$318.0	$1,645.0	$755.0	$780.0	$825.0
y-o-y growth	*76.8%*	*143.2%*	*9.3%*	*51.2%*	*-32.5%*	*24.5%*	*-54.1%*	-	-
Revenue	$9,527.9	$3,113.5	$3,190.3	$3,480.0	$3,684.5	$13,468.3	$20,445.0	$30,296.0	$42,525.0
YOY Growth	*98.8%*	*72.0%*	*43.6%*	*44.3%*	*19.5%*	*41.4%*	*51.8%*	*48.2%*	*40.4%*
Cost of Goods Sold	$3,953.8	$1,254.5	$1,281.7	$1,358.9	$1,344.8	$5,239.9	$6,465.1	$9,044.5	$12,084.0
Gross Income	$5,574.1	$1,859.0	$1,908.6	$2,121.1	$2,339.7	$8,228.4	$13,979.9	$21,251.5	$30,441.0
Gross Margin	*58.5%*	*59.7%*	*59.8%*	*61.0%*	*63.5%*	*61.1%*	*68.4%*	*70.1%*	*71.6%*
SG&A	$12,282.7	$2,947.0	$3,240.0	$3,410.0	$3,725.0	$13,322.0	$15,574.8	$19,037.8	$23,643.9
SG&A %of Prod Sales	*149.7%*	*113.5%*	*116.3%*	*110.9%*	*110.6%*	*112.7%*	*79.1%*	*64.5%*	*56.7%*
R&D	$4,783.5	$469.5	$521.0	$667.0	$812.0	$2,469.5	$7,247.0	$6,849.0	$7,295.0
R&D %Tot Sales	*50.2%*	*15.1%*	*16.3%*	*19.2%*	*22.0%*	*18.3%*	*35.4%*	*22.6%*	*17.2%*
Operating Income	($11,492.1)	($1,557.5)	($1,852.4)	($1,955.9)	($2,197.3)	($7,563.1)	($8,841.9)	($4,635.3)	($497.9)
Operating Margin	-	-	-	-	-	-	-	-	-
Total Other Expense	$765.3	($179.5)	$125.0	$131.2	$170.8	$247.6	$546.5	$276.0	$5.3
Pre-Tax Income	($12,257.3)	($1,378.0)	($1,977.4)	($2,087.1)	($2,368.1)	($7,810.7)	($9,388.4)	($4,911.3)	($503.2)
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)	($1,977.4)	($2,087.1)	($2,368.1)	($7,810.7)	($9,388.4)	($4,911.3)	($503.2)
Net Margin	*-125.3%*	*-44.3%*	*-62.0%*	*-60.0%*	*-64.3%*	*-58.0%*	*-45.9%*	*-16.2%*	*-1.2%*
EPS	($0.47)	($0.05)	($0.07)	($0.07)	($0.08)	($0.28)	($0.30)	($0.15)	($0.01)
YOY Growth		-	-	-	-				
Diluted Shares O/S	25,433	25,504	27,970	28,200	28,400	27,518	31,200	33,200	34,000

Brian Marckx, CFA

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