May 9, 2018

Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: Product Sales New Record. REFRESH 2 Enrollment Should Pick Up Steam. REMOVE Already Ramping

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 (05/09/18)	$8.02
Valuation	**$12.00**

OUTLOOK

Product sales, while a hair below our estimate, continue to climb with Q1 marking the 11th consecutive quarter of setting a new high. Product sales growth is broad based – with both direct (i.e. via CTSO's sales force) and distributor sales posting very strong double-digit yoy growth. Meanwhile, product margin, at 74%, was second highest on record. Importantly, these trends are expected to continue. CTSO is guiding for product sales to increase sequentially (i.e. Q1 to Q2), product margin to benefit from higher production volumes (facilitated by on-lining of a new manufacturing facility) and for operating income (ex non-cash and clinical trial expenses) to move into the black (for the first time) on a quarterly basis during 2018.

REFRESH 2 enrolled first patient in April but study site onboarding has been slower than anticipated – fortunately it appears these are mostly administrative delays which are expected to clear. Meanwhile REMOVE (German infective endocarditis RCT, n=250) enrollment is off to very strong start with 22 patients already in.

Maintaining $12/share price target.

SUMMARY DATA

52-Week High	**$8.25**
52-Week Low	**$3.45**
One-Year Return (%)	**69.47**
Beta	**-0.08**
Average Daily Volume (sh)	**156,126**
Shares Outstanding (mil)	**30**
Market Capitalization ($mil)	**$241**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**11**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**54.4**
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)
2017	3114 A	3566 A	3824 A	4647 A	15151 A
2018	4925 A	5330 E	5630 E	5824 E	21708 E
2019					31724 E
2020					43155 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-0.05 A	-0.04 A	-0.07 A	-0.11 A	-0.32 A
2018	-0.10 A	-0.11 E	-0.10 E	-0.12 E	-0.43 E
2019					-0.28 E
2020					-0.13 E

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

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Q1 2018 Update: *Product Sales New Record. REFRESH 2 Enrollment Should Pick Up Steam. REMOVE Already Ramping…*

CytoSorbents reported financial results for their first quarter ending March 31st and provided a business update. Product sales, while a hair below our estimate, continue to climb with Q1 marking the 11th consecutive quarter of setting a new high. Product sales growth is broad based – with both direct (i.e. via CTSO's sales force) and distributor sales posting very strong double-digit yoy growth. Meanwhile, product margin, at 74%, was second highest on record.

Importantly, these trends are expected to continue. CTSO is guiding for product sales to increase sequentially (i.e. Q1 to Q2), product margin to benefit from higher production volumes (facilitated by on-lining of a new manufacturing facility) and for operating income (ex non-cash and clinical trial expenses) to move into the black (for the first time) on a quarterly basis during 2018. Management has noted that they estimate this is achievable at a quarterly product revenue run-rate of approximately $5.5M – which is about $200k more than what we model for product sales in Q4 of this year – that may suggest that our model may prove conservative.

Growth of the direct sales force, onboarding of additional third-party distribution and increased activity from CTSO's partners have all contributed to adoption and utilization of CytoSorb and the resultant product sales growth. CytoSorbents has now been used in more than 40k human treatments, up (74%) from 23k one year prior.

Much of the growth is coming from CTSO direct sales efforts. Headcount of the direct sales team increased by more than 50% over the last 12 months and resulted in direct product sales growing 80% yoy. Direct sales accounted for 76% of product sales in Q1, up from 72% in the prior year – the proportional increase in direct sales likely contributed to the ~600 basis point widening in product margin over the same period.

As we have stated in recent prior updates, while we reiterate the potential for short-term volatility in product sales, we think the additional history of regular growth should provide ever-increasing confidence of the robustness of the fundamentals of the source and 'quality' of these revenues in the context of long-term prospects. Re-orders from existing customers, initial orders from new customers, accounts and territories, use of CytoSorb for additional indications and ramping utilization numbers are all common themes that management cites in relation to the source of product sales growth. Bulk orders and inventory-stocking are not. We continue to like near and long-term prospects for product sales growth, the latter particularly so in the context of potential eventual entry into the U.S. market.

Financials…

Q1 total revenue was $4.9M, up 58% yoy and 6% sequentially. Product revenue was $4.4M (vs. $4.6M E), up 71% yoy and +3% from Q4 '17. Grant income remains robust and was $491k (vs $420k E) in Q1. While we expect additional (and near-term) opportunities to score future grants, the yet-to-be billed portion of CTSO's current grant contracts is still significant. Of the remaining ~$2.9M available under their current roster, we model ~$1.6M to be billed during this year (and most of the remainder in 2019).

Relative to product sales, much of the recent growth has been attributed to improved reimbursement in Germany. 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 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.

Expansion of the geographic and distribution footprint as well as increasing commercial use in a growing number of 'indications' have also benefitted product revenue. Most recently, distribution was expanded to Malaysia – a territory that will be handled through CTSO's partnership with Biocon, which is also actively engaged in promoting use in investigator-initiated studies. CytoSorb is now distributed in 45 countries and has been used for a host of conditions in commercial clinical practice and clinical studies, including more than 60 investigator-initiated studies. Publicity (and potentially interim updates) from REFRESH II, enrollment which kicked-off earlier this year (following FDA IDE approval in December '17), as well as from REMOVE (i.e. large, Germany-based RCT in infective endocarditis) which is already rapidly enrolling, could also help drive awareness and adoption of CytSorb overseas.

Meanwhile, grant income continues to help subsidize R&D as well as providing additional validation of CTSO's technology (particularly given the list of contracts has continually grown). These also may presumably result in new

technology that could provide some optionality in terms of commercial programs that CTSO could pursue – a frontrunner in that regard may relate to HemoDefend.

The last three most recent grant awards are funded by the United States Army Medical Research Acquisition Activity (USAMRAA), including two in May and one in September 2017. This includes funding of up to $999k over two years ($400k of which has been paid to-date) for a phase II contract related to the development of HemoDefend in enabling universal plasma. The other one awarded in May is a phase I contract which will pay up to $719k over four years ($108k of which has been paid to-date) and relates to novel hemoadsorptive therapies for severe burn injuries. Then in September '17 a phase II SBIR contract worth up to $1M over 29 months ($32k paid to-date) was awarded – this relates to the development of potassium binding sorbents to be used in the treatment of traumatic injury and acute kidney injury – this contract follows the related phase I grant that CTSO scored in July 2016.

Product margin, at 74% was second best in history and up from 68% in Q1 '17. While product margin fell from (the record) 78% in Q4 '17, we had anticipated short-term variability as a result of sales mix and order sizes. Q1 product margin was well ahead of our 70% estimate. While production volumes have already contributed to widening of product margins (which have expanded 1,200 basis points over the last two years), the impending opening of a new manufacturing facility is expected to create even greater economies of scale. Management expects the facility to come online in Q2 and is guiding for product margins to eventually eclipse 80%.

Operating expenses were $6.5M in the most recent quarter, compared to $3.4M in Q1 '17 and $7.2M in Q4 '17. On a yoy basis, R&D has nearly quadrupled, largely as a result of REFRESH II activities. We model R&D expense to show flat-to-incremental growth over the next 3 – 6 months but then to steepen again with anticipation of ramping REFRESH 2 enrollment. Meanwhile, SG&A expense was largely flat on a sequential basis and up about $1.7M yoy – much of the increase we attribute to growth of the sales force and ramping product sales. But while on an aggregate basis SG&A has significantly climbed, CTSO is already generating some operating leverage as SG&A as a percentage of product sales has fallen from 114% in Q1 '17 to 106% in Q1 '18. As noted, management is guiding for operating income (ex non-cash and clinical trial expenses) to land in the black on a quarterly run-rate basis this year – increasing leverage in SG&A/product sales indicates that they are well on their way to getting there.

Cash used in operating activities was $2.2M ($2.7M, ex-changes in working capital) in Q1 '18, compared to $2.0M and $410k ($1.5M and $1.8M, ex-changes in working capital) during Q1 and Q4, respectively, of last year. Cash balance was $21M at Q1 '18 quarter end. In March CTSO restructured terms of their $10M loan (principal of which would have begun to amortize), which is now interest-only for 18 months (or for 24 months upon drawing the available $5M "B" tranche) – this will provide a little bit more runway and, per our estimates, get CTSO to at (or nearly at) a point of GAAP operating profitability by the time principal begins payback.

Operational Update: REFRESH 2 Starts, German Endocarditis RCT Ramping Enrollment, HemoDefend FDA Program?...

REFRESH 2 enrollment commences, although slower than expected

As a reminder, REFRESH 2 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. In December 2017 FDA approved the IDE. CMS approval was also required and obtained, as was central ethics committee approval. Per comments on the Q4 call (March 8, 2018) many or most of the REFRESH 1 (see Appendix for REFRESH 1 refresher) clinical sites will be participating in REFRESH 2, with some having already begun screening patients. In April CTSO announced that the first patient was enrolled.

While, based on management's comments on the Q1 call (May 8th), it appears that the pace of onboarding additional study sites has been slower than anticipated, CTSO expects the rate to pick up steam. Per comments, part of the headwind relates to many (all?) legacy REFRESH I sites requesting the full IDE protocol – given the similarities in the studies, the extent of the administrative boxes that needed to be checked for these sites was underestimated. And while management was hesitant to offer specifics in terms of their expectations for site onboarding, the message is clearly that it should begin to accelerate.

The multi-center, randomized, controlled U.S. study is expected to enroll up to 400 patients (over two years) 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). 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.

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 ≥ 0.3 mg/dl (≥ 26.5 µmol/l) within 48 hours; or
- Increase in SCr to ≥ 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 ≥ 0.3 mg/dl (≥ 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 ≥ 12 hours
3	3.0 times baseline OR Increase in serum creatinine to ≥ 4.0 mg/dl (≥ 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 ≥ 24 hours OR Anuria for ≥ 12 hours

Despite the newness of the KDIGO criteria, it appears to be largely widely accepted in the U.S. for 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].

Based on feedback and comments from management, REFRESH 2 was designed in such a way to increase odds of reaching statistical significance on the primary endpoint. Specifically, by enriching with a population at already relatively high risk of AKI (i.e. those already predisposed to known risk factors), it heightens odds that valve replacement surgery (which is well documented as a cause of AKI) will result in AKI. Obviously, the goal is to demonstrate significantly fewer CytoSorb patients develop AKI versus control (i.e. SOC).

And while enriching with a narrower patient population may similarly narrow the label if and when FDA cleared, we think that the main focus should first be on hitting singles – that is, get CytoSorb approved for marketing in the U.S. for a "usable" indication (such as this) and expand the label thereafter. The initial indication would also be another significant step towards demonstrating safety (and build on that from REFRESH I as well as from the 40k+ human uses overseas) – which could help in facilitating off-label use as well as provide support for approval of future FDA studies in other indications (potentially such as for sepsis or infective endocarditis – below). And in the meantime, OUS product sales may immediately benefit as a result of implied or presumed clinical legitimacy associated with FDA approving the IDE – which can sometimes result in a halo effect and prompt use in the related indication.

22 Pts Already Enrolled in German Infective Endocarditis RCT. Follows Recent Published Study Demonstrating CytoSorb's Utility in I.E.

As a reminder, a manuscript of a retrospective case series involving 39 patients with infective endocarditis undergoing valve replacement surgery using CytoSorb was published in May 2017 in the International Journal of

[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.

Artificial Organs. The study (which was the largest study to-date using CytoSorb for patients with infective endocarditis undergoing valve replacement surgery) showed that intraoperative use of CytoSorb was associated with lower mortality as compared to historical data (without CytoSorb use) as well as a meaningful reduction in certain inflammatory mediators (including IL-6 and IL-8), hemodynamic stabilization and reduction in vasopressor requirements. (See our Appendix for our discussion of this case report).

Infective endocarditis, as the name implies, is an infection of the endocardial surface of the heart – which includes one or more heart valves. It is a result of certain bacteria and other pathogens that enter the bloodstream, which can be highly and rapidly destructive to heart valves and spread to systemic sepsis and septic shock. Septic shock occurs when infection leads to critically low blood pressure and organ failure. Rates of infective endocarditis have been on the rise as a result of the recent dramatic growth of intravenous (i.e. dirty needles) heroin use in the U.S.).

CTSO hopes to further validate use of CytoSorb in this patient population and in December 2017 announced that a new, large, randomized clinical study, conducted in Germany, is aimed at doing just that. The multi-center study, dubbed **REMOVE (REvealing Mechanisms and Investigating Efficacy Of Hemoadsorption for Prevention of Vasodilatory Shock in Cardiac Surgery Patients With Infective Endocarditis) has already enrolled 22 patients (of an expected 250 total).** REMOVE will evaluate safety and efficacy of CytoSorb in patients with infective endocarditis undergoing valve replacement surgery. Primary endpoint is the difference in mean SOFA (Sequential Organ Failure Assessment) scores between experimental and control arms. Secondary endpoints include 30-day mortality, changes in cytokine levels, need for supportive care therapies such as vasopressors, mechanical ventilation, and dialysis, incidence of stroke, and the length of intensive care unit and in-hospital stay.

This study could be a win-win for CytoSorbents – potentially providing robust evidence of CytoSorb's utility in a large and growing patient population – and doing so at little or no cost to the company as the study is being fully funded by the German government. Jena University Hospital is primary sponsor - Jena has been an important partner of CTSO's over the years and manages the company's International CytoSorb registry. B.R.A.H.M.S. (a division of Thermo Fisher Scientific) and the Fraunhofer Institute for Interfacial Engineering and Biotechnology are co-collaborators.

REMOVE incorporates inclusion criteria of EuroSCORE II ≥ 4. Higher EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) scores are associated with higher risk of mortality. For reference, mean and median EuroSCORE II scores among the 39 patients from the earlier case study was 12.8 and 26.0, respectively, - so those were relatively very sick individuals. While a specific organ function-related measure was not part of that case study, certain parameters associated with organ function and clinical outcomes, were. The case study showed that CytoSorb-treated patients experienced marked reduction in IL-6 and IL-8, "normalization of lactate and base excess back to preoperative baseline levels within 3 days and hemodynamic stability before, during, and after the operation accompanied by a rapid decrease in need for vasopressors."

Primary endpoint of REMOVE is change in SOFA score – which is a widely accepted clinical measure of organ function as well as of mortality. SOFA is based on six different measures; respiratory, cardiovascular, hepatic, coagulation, renal and neurological – many of which were assessed (with favorable results) in the 39-patient case study (see Appendix). Mortality was also much lower than predicted in the 39-patient case series – also suggesting a CytoSorb-related mortality benefit. We also note that another recently published study ("Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single-center study", *Journal of Artificial Organs*, Sept 2017) also showed that CytoSorb treatment was associated with significant reduction in vasopressor requirements, hemodynamic stability, pro-inflammatory mediators and mortality. We provide this as background as we think it offers context in terms of the potential for eventual success of REMOVE.

REMOVE is being conducted in parallel with REFRESH II, which specifically excludes subjects with infective endocarditis. As such and assuming success of both studies, CytoSorbents envisions that their device could one day be considered standard of care for the majority of open heart valve replacement surgeries ("hundreds of thousands of procedures worldwide"). Management recently noted that, given the robustness of the trial design, that it might be possible to use it as primary support (assuming positive results) for a future FDA filing for an infective endocarditis indication.

While it is way too early to guess the chances of that happening, positive results from this German study would certainly lend significant veracity to the likelihood of an eventual FDA approval for a similar indication – whether it requires a U.S study or not. But, it's probably no coincidence that the anticipated timelines for REMOVE and REFRESH II are similar – both of which are commencing now and with expected durations of two years.

HemoDefend
Since 2015, HemoDefend has been the subject of a $1.52M phase II SBIR grant funded by NHLBI (part of NIH) and U.S. Special Operations Command. The focus of the work (per CTSO's PR) is to, "help advance the Company's HemoDefend™ blood purification technology towards commercialization for the purification of packed red blood cell (pRBC) transfusions. That contract followed the successful completion of a phase I SBIR contract which was, "designed to bring the HemoDefend™ in-line blood filter to human testing, a required major step towards commercialization. In addition, the contract will also fund development of new polymers that could enable safer whole blood transfusions, a potentially life-saving advance in the treatment of trauma and military combat casualty victims."

Approximately $464k remains under the phase II contract but CTSO is wasting no time in readying for the subsequent steps towards a goal of commercialization. Management noted on the Q4 call (March 2018) that they have (informally) met with FDA and, with anticipated support of NHLBI, they expect to commence a pivotal FDA registration study within 12 months.

The anticipated use of HemoDefend for this application is, per CTSO's description on the call, "a point of transfusion inline filter focused on reducing non-infectious contaminants that can cause transfusion reactions ranging from relatively mild fever and allergic reactions to very severe transfusion related acute lung injury which is the leading reported cause of transfusion related deaths that occurs in roughly 1 in 1k to 1 in 5k transfusions."

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 sales in early 2017, indications (including rates increasing by as much as 100% in some locations as well as feedback from some of CTSO's key German accounts) are that the reimbursement issue is proving to be just a short-term hiccup. Certainly the fact that product revenue grew more than 70% from Q1 '17 to Q1 '18 and was up 63% for the full year in 2017, also supports that theme. If reimbursement expands to other parts of Europe, that would likely provide additional upside
- **accelerating adoption in Germany**, the largest (yet still barely tapped) medical device market in Europe. One hospital in Germany already generates over $1M in product sales for CTSO. With over 400 mid-to-large hospitals in the country and strong support from KOLs, we think there is considerable near-term upside from that market.
- **Fresenius**: roll-out began in Q2 2016, expect this to continue to expand over time. In addition, co-marketing agreement, which began initial roll-out in Q3 2017 (in 1st 6 countries) continues to expand. This will greatly expand FMS's footprint
- **Terumo** (cardiac channel): launch began December 2016. 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. In February 2018 CTSO announced that Biocon will also handle distribution in Malaysia. Biocon could be key in driving additional adoption and use in investigator initiated studies.
- **direct sales force**: growth in size of the direct sales force has benefitted product sales growth and product margins. Headcount of the direct sales team increased by more than 50% over the last 12 months and resulted in direct product sales growing 80% yoy. Over the same period product margins increased by 600 basis points.
- **distribution/geographic expansion**: we expect additional territories and distribution agreements will continue to come online on a regular basis. Agreement with Aferetica for distribution in Italy was just extended through 2021 - CTSO believes this could generate $10M or more in sales through that time. In March 2017 Dr. Reddy's came onboard as distributor for S. Africa – look for this relationship to expand to additional territories
- **clinical data / validation**: has been and continues to be the driving force behind adoption. In addition to REFRESH I and valve replacement surgery (including infective endocarditis) a fairly regular flow of clinical data from case studies and investigator-initiated trials should continue. FDA IDE approval can sometimes have somewhat of a halo effect – prompting use in the related indication overseas. CytoSorb has now been used in more than 40k human treatments – up from 23k ~12 months ago
- **increasing use in a number of critical care applications** where CytoSorb has been associated with positive patient outcomes including sepsis. Management has indicated that sepsis remains on their radar
- **ECMO kit launch**: provides seamless and rapid connection of CytoSorb to extracorporeal membrane oxygenation
- **increased capacity**: a new manufacturing facility, which is expected to increase capacity to support up to $80M in sales, is expected to come online in Q2 2018

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 made only minor adjustments to our model following Q4 2017 results. We now look for 2018 and 2019 product and total revenue of $19.6M (+47%) / $21.7M (+43%) and $30.5M (+56%) / $31.7M (46%) – all of which represent immaterial changes from our prior estimates.

We continue to show CTSO nearly reaching GAAP full-year operating profitability in our out-year (2020). And while our model may be slightly conservative, we also continue to 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.**

FINANCIAL MODEL

CytoSorbents Inc.

	2017 A	Q1A	Q2E	Q3E	Q4E	2018 E	2019 E	2020 E
CytoSorb Sales	$13,381.9	$4,433.3	$4,801.0	$5,100.0	$5,292.5	$19,626.8	$30,530.0	$42,350.0
y-o-y growth	*63.1%*	*70.6%*	*57.5%*	*47.5%*	*33.2%*	*46.7%*	*55.6%*	*38.7%*
Total Rogalties/Grants/Other	$1,769.7	$491.4	$529.0	$530.0	$531.0	$2,081.4	$1,200.0	$771.0
y-o-y growth	*33.3%*	*-5.0%*	*0.7%*	*41.1%*	*51.4%*	*17.6%*	*-42.3%*	*-35.8%*
Revenue	$15,150.8	$4,924.7	$5,330.0	$5,630.0	$5,823.5	$21,708.2	$31,730.0	$43,121.0
YOY Growth	*59.0%*	*58.2%*	*49.5%*	*47.2%*	*25.3%*	*43.3%*	*46.2%*	*35.9%*
Cost of Goods Sold	$5,518.4	$1,567.6	$1,849.3	$1,830.5	$1,801.2	$7,048.6	$8,347.2	$10,607.6
Gross Income	$9,632.4	$3,357.0	$3,480.7	$3,799.5	$4,022.3	$14,659.5	$23,382.8	$32,513.4
Gross Margin	*63.6%*	*68.2%*	*65.3%*	*67.5%*	*69.1%*	*67.5%*	*73.7%*	*75.4%*
SG&A	$15,558.7	$4,677.9	$4,516.0	$4,712.0	$4,995.0	$18,900.9	$22,928.0	$27,188.7
SG&A % of Prod Sales	*116.3%*	*105.5%*	*94.1%*	*92.4%*	*94.4%*	*87.1%*	*75.1%*	*64.2%*
R&D	$3,916.3	$1,780.3	$1,887.0	$1,955.0	$2,555.0	$8,177.3	$8,327.0	$8,518.0
R&D % Tot Sales	*25.8%*	*36.2%*	*35.4%*	*34.7%*	*43.9%*	*37.7%*	*26.2%*	*19.8%*
Operating Income	($9,842.6)	($3,101.2)	($2,922.3)	($2,867.5)	($3,527.7)	($12,418.6)	($7,872.2)	($3,193.3)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Expense	($705.1)	($119.1)	$250.2	$250.2	$250.2	$631.5	$1,506.2	$1,318.6
Pre-Tax Income	($9,137.5)	($2,982.0)	($3,172.5)	($3,117.7)	($3,777.9)	($13,050.1)	($9,378.4)	($4,511.9)
Taxes (benefit)	($676.7)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*7.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Preferred/Othr Dividend	$335.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($8,796.5)	($2,982.0)	($3,172.5)	($3,117.7)	($3,777.9)	($13,050.1)	($9,378.4)	($4,511.9)
Net Margin	*-58.1%*	*-60.6%*	*-59.5%*	*-55.4%*	*-64.9%*	*-60.1%*	*-29.6%*	*-10.5%*
EPS	($0.32)	($0.10)	($0.11)	($0.10)	($0.12)	($0.43)	($0.28)	($0.13)
YOY Growth		-	-	-	-			
Diluted Shares O/S	27,614	29,351	30,000	30,500	31,000	30,213	33,500	34,500

Brian Marckx, CFA

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Appendix: Summary of Recent Clinical Studies in Various Indications

Infective Endocarditis 30-Patient Case Series Published in Journal of Artificial Organs

A manuscript of a retrospective case series involving 39 patients with infective endocarditis undergoing valve replacement surgery using CytoSorb was published in May 2017 in the International Journal of Artificial Organs. *Hemoadsorption treatment of patients with acute infective endocarditis during surgery with cardiopulmonary bypass - a case series*, was the largest study to-date using CytoSorb for this patient population in valve replacement surgery.

Infective endocarditis, as the name implies, is an infection of the endocardial surface of the heart – which includes one or more heart valves. Rates of infective endocarditis have been on the rise as a result of the recent dramatic growth of intravenous (i.e. dirty needles) heroin use in the U.S. These infections, from certain bacteria and other pathogens that enter the bloodstream, can be highly and rapidly destructive to heart valves and spread to systemic sepsis and septic shock. In the absence of antibiotic therapy or surgical intervention, infective endocarditis is almost always fatal.

Besides the often-rapid deterioration of the heart (and, possibly, other organs), an additional difficulty in managing these patients during surgery is the complex nature and length of the procedure. As was evidenced by results of REFRESH I, procedural length and relative complexity are positively correlated to higher levels of (toxic) plasma free hemoglobin (PfHb). Evidence also indicates that hemolysis (including plasma free hemoglobin) during cardiac surgery is a contributor to postoperative kidney injury. Results of REFRESH I showed that among those patients that underwent valve replacement surgery that lasted between 3 and 4.5 hours (i.e. procedures that were relatively long in duration), there was a statistically significant reduction in plasma free hemoglobin when CytoSorb was used as compared to control (i.e. patients in which CytoSorb was not used).

Relative to this 39-patient case series….many of these patients were in very poor condition; 59% (n=23) were considered 'medical emergencies', while the remaining 41% (n=16) were characterized as 'urgent'. Median and mean EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) of the entire cohort was 12.8 and 26.0, respectively. Higher EuroSCORE II scores are associated with higher risk of mortality, with EuroSCORE II scores of 20 to 40 considered to be at very high risk of death. Among these patients evaluated to be at very high risk of death, only one of the six (17%) died. Meanwhile, among the larger cohort with EuroSCORE II $\leq$ 40, 7% (3 of 29) died.

These mortality rates were compared to a (unrelated) case study involving 149 patients with infective endocarditis undergoing valve replacement surgery. These patients were in relatively better health than those in the CytoSorb cases – with 34% considered 'medical emergencies' (vs. 59% with CytoSorb), 42% 'urgent' (vs. 41% with CytoSorb) and 24% 'elective' (vs. 0% with CytoSorb). Median and mean EuroSCORE II scores were 9.8 (vs. 12.8 with CytoSorb) and 15.8 (vs. 26.0 with CytoSorb). But, despite the predicted lower mortality, 42.9% of EuroSCORE II 20 – 40 patients died, compared to 17% with CytoSorb, and 18.0% of EuroSCORE II $\leq$ 40 patients died, versus 7% with CytoSorb.

The lead investigator of the CytoSorb case series noted meaningful reductions in certain inflammatory mediators, including IL-6 and IL-8, as well as "normalization of lactate and base excess back to preoperative baseline levels within 3 days and hemodynamic stability before, during, and after the operation accompanied by a rapid decrease in need for vasopressors." This (i.e. reduction vasopressor requirements and levels of inflammatory and other risk-related markers) is similar to what was observed in the (unrelated) refractory septic shock study. Interestingly, septic shock is one of the factors most closely associated with risk of mortality in patients with infective endocarditis.[4]

REFRESH I Refresher

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.

[4] Olmos C., et al. Contemporary epidemiology and prognosis of septic shock in infective endocarditis. European Heart Journal (2013) 34, 1999–2006

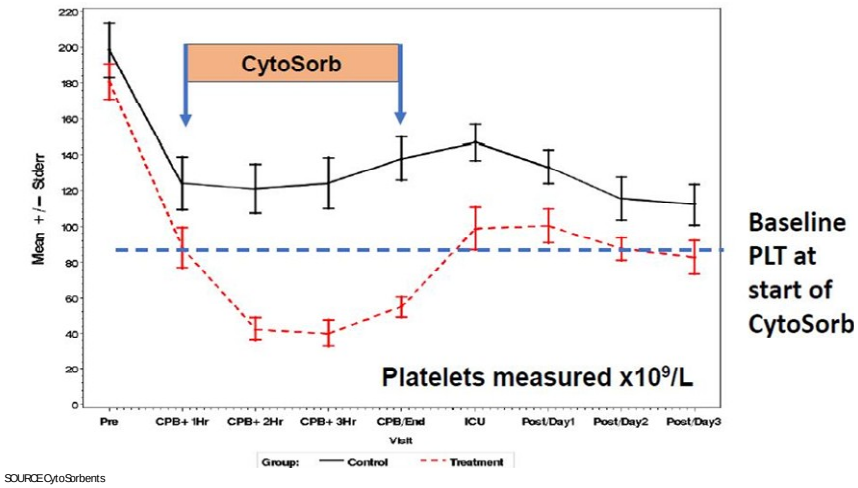
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In October 2016 CTSO announced positive **safety-related information** and released additional information on the Q1 call. Both the number of total adverse events as well as number of serious adverse events was similar between the treatment and control 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. A 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.[5] 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.

[5] 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

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

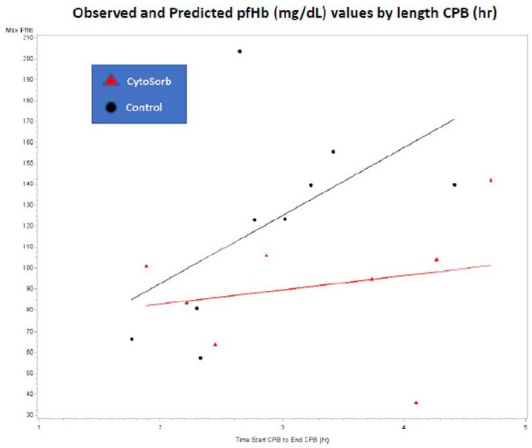
SOURCE CytoSorbents

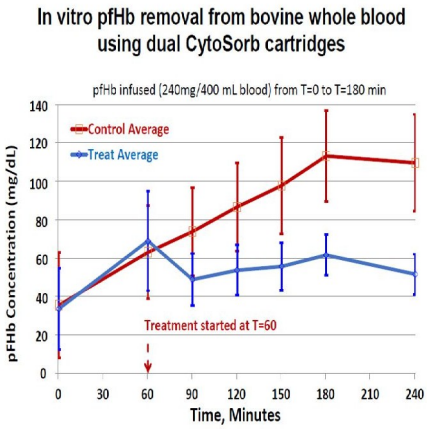
Valve replacement patients in the CytoSorb group fared better as it relates to PfHb levels. Among those patients in REFRESH I that underwent valve replacement surgery that lasted between 3 and 4.5 hours, CytoSorb demonstrated a statistically significant reduction in plasma free hemoglobin as compared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

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 are generated during cardiac surgery and valve replacement surgery is 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)

Refractory Septic Shock Study

Published in September 2017 in the Journal of Artificial Organs, *Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single-center study*[6] (Germany) evaluated the use of CytoSorb

[6] Friesecke S. et al. Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single-center study. J Artif Organs DOI 10.1007/s10047-017-0967-4

treatment in 20 patients with refractory septic shock. The study assessed the ability of CytoSorb to reduce vasopressor requirements (i.e. life-saving drugs) and improve outcomes (based on organ function, reversal of shock and lower mortality) among a group of critically-ill patients.

Septic shock occurs when infection leads to critically low blood pressure and organ failure. It often results in death. Vasopressors, such as noradrenaline (norepinephrine), dopamine, vasopressin and epinephrine are used to increase blood pressure through methods such as increasing the heart rate and vasoconstriction. Refractory (i.e. critically-ill) septic shock is characterized as persistently-low blood pressure despite vasopressor therapy and adequate fluid resuscitation. As persistently-low blood pressure can lead to multiple organ failure, refractory septic shock patients are at particularly high risk of death.

Patients with refractory shock after six hours of standard treatment were included in the study to receive CytoSorb therapy. Certain criteria related to venous oxygen saturation, fluid administration, cardiac output and organ function were used to determine when standard therapy was no longer effective (at which point CytoSorb therapy was introduced). Patients that received CytoSorb therapy were critically ill, all of which had kidney failure, little or no urine output, respiratory failure (requiring mechanical ventilation) and were on high doses of vasopressors. Based on high severity of organ dysfunction and overall severity of disease (based on SAPS II score), predicted mortality among this cohort was greater than 80%.

Prior to the start of CytoSorb therapy;

- lactate clearance in all patients was very low (<25%) and was zero or negative in 16 of the 20. Lactate level is a marker for cellular hypoxia (increasing clearance indicates increasing oxygen saturation) and is positively correlated to the risk of mortality. Studies have shown that lactate clearance is an independent predictor of death[7] in sepsis patients and lactate clearance of less than 33% over 12 hours is associated with a mortality rate of 97%
- average Simplified Acute Physiology Score (SAPS II) implied risk of death of at least 80%
- vasopressor (noradrenaline) demand was increasing in all 20 patients in the two hours prior to commencement of CytoSorb therapy
- IL-6 levels were very high. Average IL-6 among all patients was 25,523 pg/mL, indicative of cytokine storm

Primary endpoint was the change in noradrenaline requirement after six hours and after twelve hours of CytoSorb treatment as compared to baseline (i.e. just prior to the introduction of CytoSorb therapy). Secondary endpoints included resolution of shock and lactate clearance. Change in IL-6 was used as the determinant as to whether CytoSorb would be discontinued. If no further change in IL-6 was expected, then CytoSorb treatment was ended.

Results;

- Primary endpoint: noradrenaline requirements were significantly reduced after both six ($p=0.03$) and twelve ($p=0.001$) hours of CytoSorb treatment versus baseline. The decrease continued after 24 ($p<0.001$) and 36 hours ($p<0.001$). (see chart below)
- Secondary endpoints:
    - as compared to the six hours prior to the commencement of CytoSorb treatment, lactate clearance increased significantly with CytoSorb treatment during three (i.e. hour 6–12, hour 12-18 and hour 18-24) of the four (hour 0-6 was also measured but not statistically significant) timepoints measured (see chart below)
    - shock reversal was achieved in 13 patients, although four of these patients died later of other causes. Nine patients survived 28 days (i.e. standard, accepted primary endpoint in pivotal sepsis studies). This 45% survival compares very favorably to the 20% or less survival rate as predicted by SOFA, SAPS III and lactate clearance metrics of the patients prior to the start of CytoSorb therapy
- In fourteen patients IL-6 levels were either reduced by 90% (or more) or IL-6 concentration was reduced to less than 500 pg/ml

[7] Philippe M. et al. Lactate clearance for death prediction in severe sepsis or septic shock patients during the first 24 hours in Intensive Care Unit: an observational study. Ann Intensive Care. 2013; 3: 3.

Primary Endpoint: Significant Reduction in Vasopressors

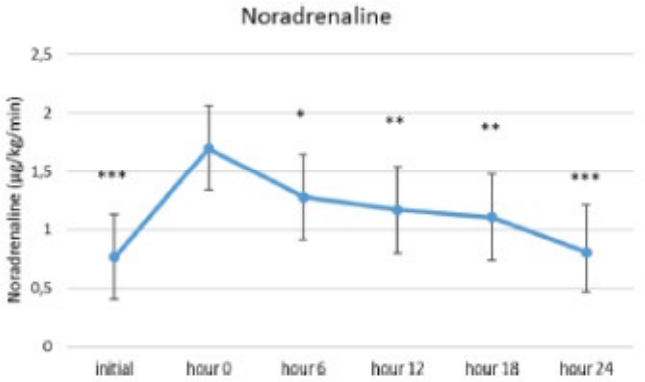


Fig. 1 Noradrenaline dose before and during treatment with CytoSorb®. Values are shown as means with 95% CIs. Difference vs. "hour 0" (CytoSorb® start): $*p < 0.05$, $**p < 0.01$, $***p < 0.001$. Initial and start $n = 20$, hour 6, 12 and 18 $n = 19$, hour 24 $n = 18$

SOURCE: Frisecke S., et al

Secondary Endpt: Significant Increase in Lactate Clearance

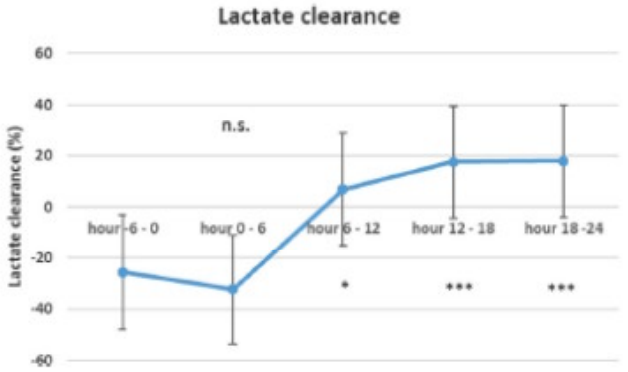


Fig. 2 Lactate clearance before and during treatment with CytoSorb®. Values are shown as means with 95% CIs. Difference vs. "hour -6 - 0" (6 h before CytoSorb® start): $*p < 0.05$, $***p < 0.001$, *n.s.* not significant

SOURCE: Frisecke S., et al.

While this study is too small and not designed or powered to evaluate efficacy on clinical outcomes, we do think it adds to the growing evidence supporting the relationship between the reduction of certain inflammatory mediators, such as IL-6, and improved biological functioning. The study further supports the association between controlling cytokine levels and pared risk of cellular hypoxia, organ failure, hypotension and other signs of hemodynamic instability associated with sepsis and mortality. But it takes this relationship another important step forward, demonstrating that cytokine elimination (via CytoSorb) may provide significant incremental benefit to outcomes and survival in patients with refractory septic shock in which the benefits of vasopressor therapy have been exhausted and predicted mortality may otherwise be near 100%.

Sepsis is a complex condition, the pathogenesis of which is influenced by a number of factors but is still not fully understood. Compounding the difficulty in treating the condition is that even slight patient-to-patient differences (age, health, co-morbidities, etc) may play a significant role in the body's response and in clinical outcomes. This heterogeneity makes trial design a major challenge and means pursuit of a sepsis indication is a risky endeavor (as evidenced by the high failure rate of various other sepsis therapy candidates) and possibly a costly mistake.

Given these challenges, CytoSorbents has been methodical in evaluating possible options as it relates to designing a clinical program around sepsis. Chipping away at the heterogeneity through narrowing of patient and/or condition-related differences and which will help power response to CytoSorb therapy is clearly a goal and one that should improve the chances of success (or at least reduce risk of failure). Results of this refractory sepsis study, like ones that came before and others that will certainly come in the future, should help the company in making informed decisions relative to how best to proceed relative to a pivotal sepsis clinical program.

Cytokine Release Syndrome Associated With CAR-T Cell Cancer Therapies

The feasibility of CytoSorb as a treatment for cytokine release syndrome (CRS) could soon become more clear given the recent FDA approvals of two CAR-T immunotherapies; Novartis' Kymriah (tisagenlecleucel-T) and Gilead/Kite's Yescarta (axicabtagene ciloleucel). These novel CAR-T therapies have shown extraordinary efficacy in the treatment of certain cancers but have also been associated with certain severe side effects in some patients. Specifically, clinical studies have shown that severe CRS (i.e. severe inflammatory response with excessive and harmful levels of cytokines) effects about 47% of patients treated with these therapies. CRS can result in serious complications and lead to organ failure and death.

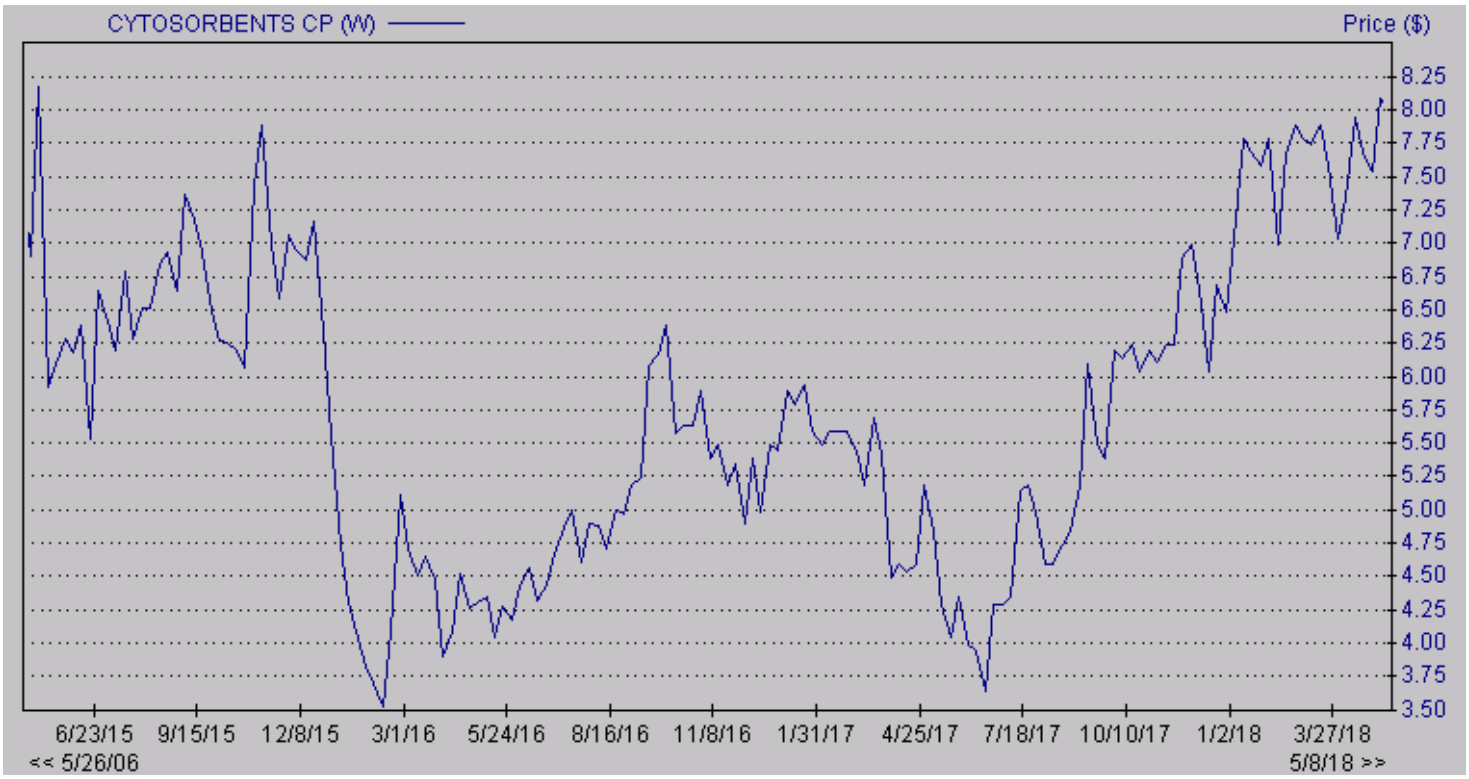
While corticosteroids and tocilizumab have been used with some success in controlling CRS, there are drawbacks. This includes that corticosteroids are suspected of potentially comprising immunotherapy efficacy. Relative to tocilizumab, researchers have noted that its use should be avoided if macrophage activating syndrome (MAS) is suspected.[8] Interestingly, CytoSorb has been used successfully in several patients with a condition called

[8] Shannon L. Maude, MD, PhD,* David Barrett, MD, PhD,* David T. Teachey, MD,* and Stephan A. Grupp, MD, PhD. Managing Cytokine Release Syndrome Associated With Novel T Cell-Engaging Therapies. Cancer J. 2014 Mar-Apr; 20(2): 119 122.

hemophagocytic lymphohistiocytosis (HLH) - one of these was the subject of a case report published in early March 2017 in the Journal of Clinical Immunology. Studies have shown that subjects with secondary HLH, which is often caused by virologic infection and characterized by a strong and sometimes uncontrollable immune response including CRS, can exhibit responses similar to cancer patients treated with certain immunotherapies. The similarity in CRS response in HLH and cancer patients treated with immunotherapies and CytoSorb's early success in treating HLH patients (via reduction in inflammatory markers) is encouraging, particularly as it may relate to mitigating the toxicity of CAR-T therapies. Another factor that could play in CTSO's favor is the fact that Dr. June Carter, who recently joined CytoSorbents' scientific advisory board, also led the CTL019 (i.e. Kymriah) program at the University of Pennsylvania.

Novartis and Gilead are also seeking approval in Europe, which could come in short-order. At that point, CytoSorb could be employed to treat CRS. CTSO would likely pursue investigator-initiated studies overseas, as they have done with other indications, in order to build the experience database – which, assuming positive results, could drive adoption of CytoSorb for CRS. Given the extraordinary efficacy already seen with these two initial therapies and the recent and growing massive inflow of investment dollars targeting immunotherapy development, this is an application that we

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