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Zacks Small-Cap Research

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CytoSorbents Corporation (CTSO-NASDAQ)

CTSO: FDA Approves REFRESH-2 Protocol Amendment. HemoDefend Pivotal Study Upcoming? CytoSorb HLH More Evidence

Based on our 10-year DCF model, which uses a 9.5% discount rate and a 2% terminal growth rate, the shares are valued at approximately $16.

Current Price (09/04/18)	$14.85
Valuation	**$16.00**

OUTLOOK

This morning (9/4) CytoSorbents (CTSO) announced that FDA approved the protocol amendment for their REFRESH 2-AKI trial. As a reminder, CTSO mentioned on their Q2 earnings call (8/2) that their clinical advisors recommended the protocol amendment as it would "expand the inclusion criteria, improve operational aspects of the patient screening process, enhance the rate of enrollment, and ultimately increase the applicable market that CytoSorb could address if approved."

HemoDefend development could accelerate with a new (up to) $3M/3-yr award that is expected to fund pivotal FDA trial, starting (maybe) in Q1'19. The significance of continued development progress of HemoDefend and success under these NHBLI-funded programs should not be underestimated. And certain tangible milestones, such as eventual commencement of a pivotal FDA study, if that happens, should be a wake-up call for investors to pay much more attention to HemoDefend – as we think this program has the potential to create meaningful incremental shareholder value.

More (new) evidence supports CytoSorb utility in HLH/CRS/cancer immunotherapy as evidenced by a recent case at Mount Sinai Beth Israel where CytoSorb was successfully used on a patient with poor prognosis and diagnosed with HLH. This could be a harbinger to additional activity and focus on this condition.

SUMMARY DATA

52-Week High	**$14.95**
52-Week Low	**$5.10**
One-Year Return (%)	**181.73**
Beta	**0.15**
Average Daily Volume (sh)	**312,486**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$468**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**54.9**
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	5755 A	5816 E	6363 E	22858 E
2019					33311 E
2020					45280 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	-0.19 A	-0.10 E	-0.11 E	-0.51 E
2019					-0.29 E
2020					-0.14 E

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

FDA Approves REFRESH II Protocol Amendment

This morning (9/4) CytoSorbents (CTSO) announced that FDA approved the protocol amendment for their REFRESH 2-AKI trial. As a reminder, CTSO mentioned on their Q2 earnings call (8/2) that their clinical advisors recommended the protocol amendment as it would "expand the inclusion criteria, improve operational aspects of the patient screening process, enhance the rate of enrollment, and ultimately increase the applicable market that CytoSorb could address if approved."

As we noted in our Q2 update (8/7: *Q2 Product Sales Beat Big. More Upward Estimate Revisions. New Catalysts Come Online. Moving PT to $15/share*), while enrollment-to-date was not disclosed on the Q2 call, clearly the pace was slower than previously anticipated. While we still do not know the complete specifics of this amendment (clinicaltrials.gov was not yet updated as of the time of this writing), management noted on the Q2 call that it includes an increase in the age limit and modifications to baseline renal risk factors. The adjustments are expected to facilitate enrollment and increase the target market (if approved) - with no compromise to any other aspects.

Approval of the amendment from the trial sites' ethics committees is next. CTSO's press release notes that, currently, nine sites are active, seven more are nearing budget and contract finalization and another nine are completing start-up activities. Following the ethics committees' approval, CTSO hopes to have 15 to 20 sites ready to enroll. At that time, the pace of enrollment is anticipated to be approximately one patient per site per month. Which implies full enrollment (n=400) by approximately September 2020.

While not unexpected, FDA approval of the amendment was a significantly positive event as it eliminates any related uncertainty of an alternative, adverse outcome - which, among other possible consequences, could have resulted in costly delays.

HemoDefend Closer to Commercialization with New $3M, 3-Year NHLBI Award

With CytoSorb consuming most of the investor interest in CTSO, the potential incremental value of HemoDefend may be under-realized. This is despite successful progression through a phase 1 program (*Elimination of blood contaminants from pRBCs using HemoDefend™ hemocompatible porous polymer beads*) funded by a $204k grant (awarded Sept 2013) from NHLBI and a follow-on $1.5M phase 2 NHLBI award (*pRBCs Contaminant Removal with Porous Polymer Beads*). As of Q2 '18 ~$140k remains under the ph2 award – which we estimate will be recognized by current year-end.

In August another NHLBI award was announced. p*RBC contaminant removal with hemocompatible porous polymer beads* provides up to $1M per year for up to three years (i.e. up to $3M total) and is matched dollar-for-dollar with CTSO's own funds. CTSO expects this will be used to fund a pivotal FDA clinical trial – and anticipates that that pivotal study will begin (contingent on FDA IDE approval) in Q1 2019 (i.e. less than 7 months from today).

The potential market for HemoDefend could be fairly enormous. An estimated 80M – 100M blood donations happen each year worldwide with each donation generating multiple blood transfusion products such as packed red blood cells (pRBCs), platelets, fresh frozen plasma, and cryoprecipitate. Every year more than 100M RBC units are transfused, including ~30M in the U.S. Blood can become contaminated either from the donor or during storage as the blood ages. If not removed, contaminants can cause health risks, which can range from mild fever and itching, to potentially life-threatening and lethal reactions. The NHLBI-funded development of HemoDefend focuses on use as an RBC filter for removal of contaminants such as antibodies, free hemoglobin, cytokines, and bioactive lipids in packed red blood cells.

Practical and effective ways to purify contaminated blood and reduce risk of transfusion-related adverse reactions is an objective of NHLBI (100+ related projects are listed in NIH's Project Information database) as well as the U.S. military and represents a significant current unmet need. As such, the significance of continued development progress of HemoDefend and success under these NHBLI-funded programs should not be underestimated. And certain tangible milestones, such as eventual commencement of a pivotal FDA study, if that happens, should be a wake-up call for investors to pay much more attention to HemoDefend – as we think this program has the potential to create meaningful incremental shareholder value.

More Evidence Supporting CytoSorb's Utility in HLH

Additional evidence appears to support the potential utility of CytoSorb in the treatment of hemophagocytic lymphohistiocytosis (HLH). 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 cytokine

release syndrome (CRS), can exhibit responses similar to cancer patients treated with certain immunotherapies. Severe CRS (i.e. severe inflammatory response with excessive and harmful levels of cytokines), which can lead to serious complications including organ failure and even death, has been associated with the use cancer immunotherapies, including Novartis' (NVS) Kymriah and Gilead's (GILD) Yescarta which were recently approved by FDA for the treatment of certain blood cancers.

While these immunotherapies have shown extraordinary efficacy, mitigating risk of CRS remains problematic. 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.

Early in 2017 CTSO appeared to be working towards a potential program in HLH / CRS. In Q1 of that year they announced that Dr. Carl June joined their scientific advisory board for the purpose of guiding their strategy in oncology. Dr. June is considered the pioneer of cancer immunotherapy and guided Novartis' Kymriah program. In March 2017 CTSO disclosed that "we have confirmed the interest in the therapy [CytoSorb], once available, as an adjunct to tocilizumab, and before high dose steroids are administered. We plan to continue to pursue applications of our therapy in the treatment of CRS in the United States, Europe, and elsewhere, as cancer immunotherapies continue to expand worldwide."

As we noted in early 2017, the similarity in CRS response in HLH and cancer patients treated with immunotherapies and CytoSorb's apparent early success in treating HLH patients (via reduction in inflammatory markers) was encouraging, particularly as it may relate to the leveraging the massive interest in and growth of the immunotherapy segment. Since then, CTSO had not talked much more about a potential CRS/HLH/cancer focus. But activity has clearly continued as evidenced by a recent case at Mount Sinai Beth Israel where CytoSorb was successfully used on a patient with poor prognosis and diagnosed with HLH. The case, published in Mount Sinai's Division of Nephrology publication earlier this year, indicated CytoSorb was used as a last resort when other therapies failed – the ICU team obtained IRB approval to use CytoSorb, following which the "patient's clinical improvement was immediate and significant, with hemodynamic stabilization during the first treatment, followed by enhanced liver function and mental status."

Valuation

We have updated our model for inclusion of the new NHLBI HemoDefend award. We have also, again, positively adjusted our risk discount to account for FDA approval of the REFRESH-2 protocol amendment. And while we still have yet to model any potential contribution from HemoDefend or from CytoSorb in specific expanded indications, such as for HLH/cancer, we think ongoing product development progress is substantive value-added and also supports favorable adjustments to our risk discount.

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.

As we noted in our Q2 update, the addition of CTSO to the Russell 2000 and Russell 3000 indices in late-June provides more liquidity in the stock -which we also treat as a reduction to our risk discount - which we have moved from 10% to 9.5%. The updates to our model and risk-discount has moved our 10-year DCF-based valuation from $15 to $16/share.

FINANCIAL MODEL

CytoSorbents Inc.

	2017 A	Q1A	Q2A	Q3E	Q4E	2018 E	2019 E	2020 E
CytoSorb Sales	$13,381.9	$4,433.3	$5,245.6	$5,269.0	$5,682.5	$20,630.4	$31,404.0	$43,520.0
y-o-y growth	*63.1%*	*70.8%*	*72.5%*	*52.8%*	*32.3%*	*54.2%*	*52.2%*	*38.6%*
Total Royalties/ Grants/ Other	$1,769.7	$491.4	$509.9	$547.0	$680.0	$2,227.4	$1,907.0	$1,760.0
y-o-y growth	*33.9%*	*-5.0%*	*-2.9%*	*45.6%*	*93.9%*	*25.9%*	*-14.4%*	*-7.7%*
Revenue	$15,150.8	$4,924.7	$5,755.4	$5,816.0	$6,362.5	$22,857.7	$33,311.0	$45,280.0
YOY Growth	*59.0%*	*58.2%*	*61.4%*	*52.1%*	*36.9%*	*50.9%*	*45.7%*	*35.9%*
Cost of Goods Sold	$5,518.4	$1,567.6	$1,785.9	$1,808.5	$1,941.8	$7,103.8	$8,843.9	$11,070.4
Gross Income	$9,632.4	$3,357.0	$3,969.6	$4,007.5	$4,420.7	$15,753.9	$24,467.1	$34,209.6
Gross Margin	*63.6%*	*68.2%*	*69.0%*	*68.9%*	*69.5%*	*68.9%*	*73.5%*	*75.6%*
SG&A	$15,558.7	$4,677.9	$6,581.7	$4,978.0	$5,224.0	$21,461.6	$24,306.7	$28,940.8
SG&A % of Prod Sales	*116.3%*	*105.5%*	*125.5%*	*94.5%*	*91.9%*	*87.1%*	*77.4%*	*66.5%*
R&D	$3,916.3	$1,780.3	$1,575.8	$1,955.0	$2,621.0	$7,932.1	$8,421.0	$8,689.0
R&D % Tot Sales	*25.8%*	*36.2%*	*27.4%*	*33.6%*	*41.2%*	*34.7%*	*25.3%*	*19.2%*
Operating Income	($9,842.6)	($3,101.2)	($4,187.9)	($2,925.5)	($3,424.3)	($13,639.8)	($8,260.6)	($3,420.2)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Expense	($705.1)	($119.1)	$1,633.3	$250.2	$250.2	$2,014.6	$1,506.2	$1,318.6
Pre-Tax Income	($9,137.5)	($2,982.0)	($5,821.2)	($3,175.7)	($3,674.5)	($15,654.4)	($9,766.8)	($4,738.8)
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)	($5,821.2)	($3,175.7)	($3,674.5)	($15,654.4)	($9,766.8)	($4,738.8)
Net Margin	*-58.1%*	*-60.6%*	*-101.1%*	*-54.6%*	*-57.8%*	*-68.5%*	*-29.3%*	*-10.5%*
EPS	($0.32)	($0.10)	($0.19)	($0.10)	($0.11)	($0.51)	($0.29)	($0.14)
YOY Growth		-	-	-	-			
Diluted Shares O/ S	27,614	29,351	30,302	31,500	32,000	30,788	34,000	35,000

Brian Marckx, CFA

HISTORICAL STOCK PRICE

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