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CytoSorbents Corporation (NASDAQ/CTSO)

April 13, 2020

BUY: Emergency Use Authorization for COVID19

The FDA has granted an Emergency Use Authorization (EUA) for the CytoSorb device to treat COVID patients admitted to the ICU with confirmed or imminent respiratory failure to reduce pro-inflammatory cytokine levels.

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Emergency Use Authorization Granted. Based on bench performance testing and reported clinical experience, the FDA has concluded that the CytoSorb device may be effective at treating certain patients with confirmed COVID-19 by removing various pro-inflammatory cytokines from their blood. The letter states that **the FDA believes, based on the totality of scientific evidence available, that the removal of pro-inflammatory cytokines may ameliorate cytokine storm due to the overabundance of pro-inflammatory cytokines and, in turn, provide clinical benefit.**

FDA Letter: <https://www.fda.gov/media/136867/download>

Patients Being Treated in China. The CytoSorb filter is being used across multiple patients with respiratory failure, shock, and or kidney failure in multiple hospitals in China and Italy and Iran, and likely other EU nations too.

ARDS and the Cytokine Storm Can kill you. As we wrote in our Feb.11th note for Athersys (ATHX-Buy Rated), Acute Respiratory Distress Syndrome, or ARDS, occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. Severe pneumonia, and the new Coronavirus too, can result in an infection in the lobes of the lungs, triggering an inflammatory cascade that causes death. CytoSorb can mechanically assist in slowing down the storm (vs. Athersys Multistem, which uses cell therapy to slow down – normalize immune system modulation). The two together could curb the mortality rate associated with this virus, and what's very positive for both companies is that the therapy is agnostic of the cause, i.e., It's not viral-specific, so it should work on all patients (flu and or Coronavirus).

Valuation. We use a series of therapeutic models across the various indications and geographies and project product revenues for the company out to the year 2030. In our U.S. therapeutic models, we apply a 30% risk cut (70% success probability) that both U.S. approvals and our market share forecasts can be realized. For us, valuation becomes an interesting question when we discuss the appropriate "r" risk-rate to use in our three model metrics, free cash flow to the firm (FCFF), Discounted EPS and Sum-Of-The-Parts (SOP) models, which are equal-weighted, averaged and rounded to the nearest whole number. Typically for early-stage companies with no revenues, we use 30%, and for companies with established products and revenues, we use a lower 15%. CytoSorbents arguably is somewhere in the middle, as products are approved and selling in Europe but not yet in the U.S. If we select a conservative 30%, we drive a \$9.00 price target. If we select a more aggressive 15%, we arrive at a \$28.00 target. If we select a mid-point (22.5%), we derive a \$17.00 target.

Risk. Market risks, Regulatory risks, Financial risks, and Commercialization risks.

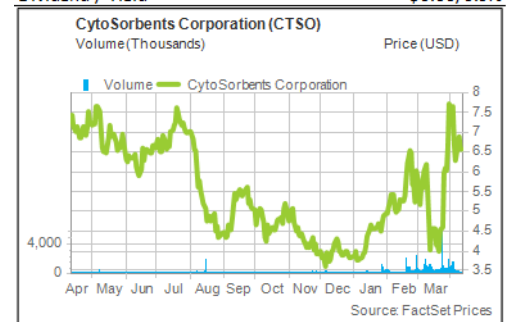
Current Price **\$6.59**
 Price Target **\$17.00**

Estimates	F2019E	F2020E	F2021E
Expenses (\$000s)	\$ 43,924	\$ 47,921	\$ 60,071
1Q March	\$ 9,475	\$ 11,022	\$ 13,816
2Q June	\$ 9,862	\$ 11,501	\$ 14,417
3Q September	\$ 11,723	\$ 12,459	\$ 15,618
4Q December	\$ 12,864	\$ 12,939	\$ 16,219

	F2019E	F2020E	F2021E
EPS (diluted)	\$ (0.62)	\$ (0.39)	\$ 0.26
1Q March	\$ (0.15)	\$ (0.09)	\$ 0.06
2Q June	\$ (0.11)	\$ (0.09)	\$ 0.06
3Q September	\$ (0.21)	\$ (0.10)	\$ 0.07
4Q December	\$ (0.14)	\$ (0.10)	\$ 0.07

EBITDA/Share	(\$0.63)	(\$0.42)	\$0.28
EV/EBITDA (x)	0.0	0.0	0.0

Stock Data		
52-Week Range	\$3.49	\$8.10
Shares Outstanding (mil.)	35.1	
Market Capitalization (mil.)	\$231	
Enterprise Value (mil.)	\$211	
Debt to Capital	0%	
Book Value/Share	\$0.35	
Price/Book	36.7	
Average Three Months Trading Volume (K)	138	
Insider Ownership	5.3%	
Institutional Ownership	25.8%	
Short interest (mil.)	8.8%	
Dividend / Yield	\$0.00/0.0%	



Please find Important Disclosures beginning on Page 7.

Adapted from the company's February press release: *"The clinical features of the COVID-19 coronavirus and its causal relationship to the "cytokine storm" create a potential role for CytoSorb in treating patients suffering from severe coronavirus infection. "CytoSorb, the Wuhan Coronavirus, and Cytokine Storm." This was highlighted in a recent publication in Lancet Respiratory Medicine by Drs. Claudio Ronco, Paolo Navalesi, and Jean Louis Vincent entitled, "Coronavirus epidemic: preparing for extracorporeal organ support in intensive care." Notably, the authors state, "A sepsis-like syndrome might occur frequently due to the virus itself or to a superimposed bacterial infection and in this case, since pharmacological approaches have shown poor results, new extracorporeal organ support therapies including haemoadsorption and haemoperfusion, with new sorbent cartridges designed to remove cytokines and other circulating mediators, should be considered." These publications provide the rationale to potentially use CytoSorb, the first specifically-approved extracorporeal cytokine adsorber in the European Union, in this setting. CytoSorb is distributed in 58 countries worldwide, and is available in Hong Kong, Vietnam, Malaysia, Germany, United Kingdom, Italy France, Spain, Belgium, United Arab Emirates, India, Russia, Finland, Sri Lanka, and Australia where patients infected with the virus have been reported"*.

We have not factored in China to our model, so any sales to China represent upside. We can recall other products and companies such as Sciclone (private), which has an immune modulator product that was utilized during the SARS outbreak in China and became a significant product afterward. **CytoSorb could build an important foothold in China as awareness grows of the technology and its ease of use and its ability to treat any virus related severe complication independent of the specific pathogen.**

Multiple Catalysts Ahead:

- The **"Remove Endocarditis"** trial in Germany. The trial has now enrolled 250 patients (and plans to add another 15 to account for any drop-outs). We should see data this year.
- Advancement of the **U.S. pivotal REFRESH 2-AKI** trial. An interim analysis is planned at N=200, estimated to occur by 1H20.
- **UK TISORB study** (company-sponsored) is evaluating the use of CytoSorb to remove anti-platelet drugs (ticagrelor) in emergency cardiac surgery patients. We note this is a global \$20B market.
- **HemoDefend IDE.** We need to check on the status suffice to say we believe a 2020 approval is possible as this is expected to be a DeNovo 510-K (two-site, n=20 person trial), to support the filing.
- **HemoDefend background.** Recall that there has been ongoing controversy on whether there is a difference between "old" blood and "new" blood or blood that has been stored for some time in a refrigerated compartment versus blood that has been freshly donated by a person. Although current studies show contradicting results (independent studies were highly varied in approach), it is undisputed that biological changes occur during RBC storage, although unknown if they are beneficial/harmless or detrimental changes. Whether or not aged blood is bad, HemoDefend is still advantageous when storing donated blood. Not only will it keep donated blood fresh and extend the shelf-life of blood, but it will also remove the many contaminants that may be present in donated blood, or from the changes, RBCs undergo while in storage. This is to minimize the current 1-5% risk chance patients have of developing a transfusion reaction, which could be as mild as a fever to as severe as death.
- **The HemoDefend technology** can be implemented in two ways; as an in-line filter between the blood bag and the patient during transfusion, or in an approach called "Beads in a Bag." Beads in a Bag is CytoSorbents' innovative, patent-pending technology that will purify blood during the entire refrigerated storage period. CytoSorbents' biocompatible beads are perfect for this use for several reasons: the beads can have extended contact with blood without causing damage to the RBCs, they are neutrally buoyant and will suspend in blood so that the blood storage bag does not need to be mixed, and during transfusion, an integrated filter will keep the beads in the bag. HemoDefend won't require any extra machine, electricity, energy source, or any other manipulation to be used, so it won't cost much to possibly save a life.

approvals and our market share forecasts can be realized. For us, valuation becomes an interesting question when we discuss the appropriate "r" risk-rate to use in our three model metrics, free cash flow to the firm (FCFF), Discounted EPS and Sum-Of-The-Parts (SOP) models, which are equal-weighted, averaged and rounded to the nearest whole number. Typically for early-stage companies with no revenues, we use 30%, and for companies with established products and revenues, we use a lower 15%. CytoSorbents arguably is somewhere in the middle, as products are approved and selling in Europe but not yet in the U.S. If we select a conservative 30%, we drive a \$9.00 price target. If we select a more aggressive 15%, we arrive at a \$28.00 target. If we select a mid-point (22.5%), we derive a \$17.00 target. Given their unique position of approval in Europe, established proof of concept, and a product that works, we select the mid-point of 22.5% and set our target for CytoSorbents at \$17.00.

Exhibit 6. FCFF Model

Average \$	17
Price Target \$	18
Year	2020

DCF Valuation Using FCF (min):

units ('000)	2018A	2019A	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(17,830)	(20,358)	(13,669)	9,301	32,034	83,013	147,875	252,067	315,248	356,152	386,456	405,408	401,536
Tax Rate	0%	5%	8%	10%	12%	15%	18%	21%	24%	28%	33%	33%	33%
EBIT (1-t)	(17,830)	(19,340)	(12,575)	8,371	28,190	70,561	121,257	199,133	239,589	256,429	258,926	271,623	269,029
CapEx	(493)	(698)	(768)	(845)	(929)	(1,022)	(1,124)	(1,237)	(1,361)	(1,497)	(1,646)	(1,811)	(1,992)
Depreciation	391	582	-	-	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(17,932)	(19,457)	(13,343)	7,526	27,261	69,539	120,133	197,896	238,228	254,933	257,279	269,812	267,037
PV of FCF	(26,910)	(23,834)	(13,343)	6,144	18,166	37,828	53,348	71,739	70,498	61,585	50,736	43,435	35,092
Discount Rate	22.5%												
Long Term Growth Rate	1%												
Terminal Cash Flow	1,254,453												
Terminal Value YE2030	164,852												
NPV	600,080												
NPV-Debt	33,858												
Shares out ('000)	2030E												
NPV Per Share	18												

Source: Dawson James estimates

Exhibit 7. Discounted EPS Model

Current Year	2020
Year of EPS	2030
Earnings Multiple	15
Discount Factor	22.5%
Selected Year EPS	7.95
NPV	15.66

Source: Dawson James estimates

Discount Rate and Earnings Multiple Varies, Year is Constant							
Earnings Multiple	15.66	5%	10%	15%	20%	25%	30%
	0	0.00	0.00	0.00	0.00	0.00	0.00
5	24.39	15.32	9.82	6.42	4.27	2.88	2.88
10	48.78	30.63	19.64	12.83	8.53	5.76	5.76
15	73.17	45.95	29.46	19.25	12.80	8.65	8.65
20	97.56	61.27	39.28	25.67	17.06	11.53	11.53
25	121.95	76.59	49.10	32.08	21.33	14.41	14.41
30	146.34	91.90	58.92	38.50	25.60	17.29	17.29
35	170.73	107.22	68.74	44.91	29.86	20.17	20.17

Source: Dawson James estimates

Exhibit 8. Sum of the Parts Model

CytoSorbents	LT Gr	Discount Rate	Yrs to Mkt	% Success	Peak Sales (MMs)	Term Val
CytoSorb - Sepsis Direct Sales(EU)	1%	22.5%	0	70%	\$151	\$701
NPV						\$7
CytoSorb - Sepsis Distributor (EU)	1%	22.5%	0	70%	\$88	\$408
NPV						\$4
CytoSorb (Cardiac surgery US)	1%	22.5%	2	50%	\$68	\$318
NPV						\$1.41
CytoSorb (Cardiac surgery EU)	1%	22.5%	0	70%	\$17	\$79
NPV						\$0.7
CytoSorb (Sepsis US)	1%	22.5%	4	50%	\$271	\$1,262
NPV						\$3.7
Net Margin						45%
MM Shrs OS (2030E)						34
Total						\$16

Source: Dawson James estimates

Risk Analysis

Market Share Risk: CytoSorbents' potential inability to further grow product sales in the EU will hinder its profitability as more capital is invested in clinical trials to bring CytoSorb to the U.S. market. The company's product represents a new treatment for critical care patients that may take longer for adoption than predicted.

Regulatory Risk: There may be certain regulatory risks related to CytoSorb approval in the U.S.

Commercial Risk: There is no guarantee that the company will be able to develop and expand sales operations to offset research and development costs. Delays in U.S. commercialization will be negatively reflected in its valuation.

Financial Risk: The company should be expected to raise capital in the near term. We assume a raise and dilution, but there is no guarantee that market conditions will be favorable.

Exhibit 9. Income Statement

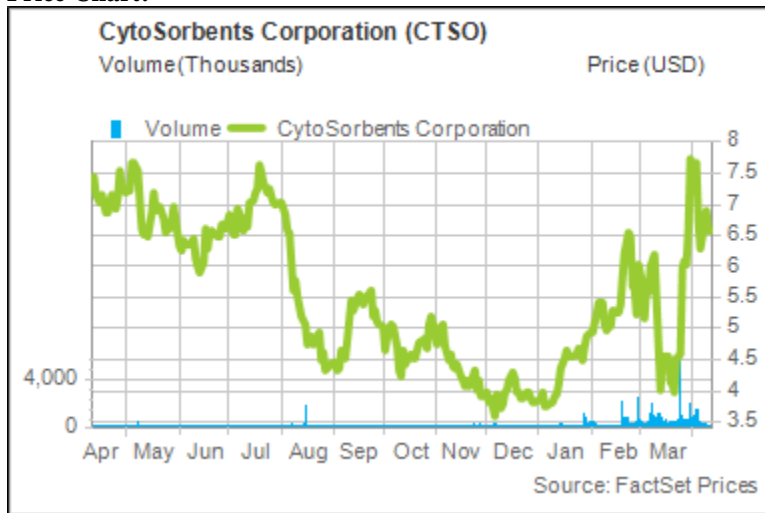
CTSO: Income Statement (\$000)																					
:YE December 31																					
	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	1Q21E	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	
Revenue:																					
CytoSorb Direct Sales (Germany, Austria, Switzerland)	22,766	4,945	5,160	5,590	5,805	21,500	9,255	9,657	10,462	10,865	40,239	54,439	69,046	84,070	99,520	115,405	131,735	148,520	150,699	150,699	
CytoSorb Distributor (Rest of EU)		2,208	2,304	2,497	2,593	9,602	3,067	3,201	3,467	3,601	13,336	21,587	27,297	41,422	55,871	70,651	85,766	86,763	87,771	87,771	
CytoSorb (Cardiac surgery EU)		690	720	780	810	3,000	1,579	1,648	1,785	1,854	6,866	9,218	11,604	14,022	16,474	16,589	16,705	16,822	16,940	16,940	
CytoSorb (Cardiac surgery US)		-	-	-	-	-	-	-	-	-	-	-	16,294	21,899	27,593	66,755	67,290	67,829	68,373	68,373	
CytoSorb (sepsis US)		-	-	-	-	-	2,018	2,106	2,281	2,369	8,773	17,846	45,376	92,302	187,755	200,508	223,353	246,919	271,225	271,225	
VetResQ		35	36	39	41	150	36	38	41	43	158	165	174	182	191						
Other Sales		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total Product Sales	22,766	7,878	8,220	8,906	9,248	34,252	15,956	16,649	18,037	18,730	69,372	103,255	169,790	253,897	387,404	469,908	524,849	566,853	595,008	595,008	
Royalty (HemoDefend US)		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Grant revenue	2,184	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Other revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Total Revenue	24,950	7,878	8,220	8,906	9,248	34,252	15,956	16,649	18,037	18,730	69,372	103,255	169,790	253,897	387,404	469,908	524,849	566,853	595,008	595,008	
Expenses:																					
Costs of Goods Sold	7,364	1,576	1,644	1,781	1,850	6,850	3,191	3,330	3,607	3,746	13,874	20,651	33,958	50,779	77,481	93,982	104,970	113,371	119,002	119,002	
	25%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Research and Development	12,092	3,059	3,192	3,458	3,591	13,301	3,365	3,512	3,804	3,950	14,631	16,094	17,704	19,474	21,422	23,564	25,920	28,512	31,364	34,500	
	53%	39%	39%	39%	39%	39%	21%	21%	21%	21%	21%	16%	10%	6%	5%	5%	5%	5%	5%	6%	6%
Selling, General and Administrative	22,006	5,821	6,074	6,580	6,833	25,307	6,694	6,985	7,567	7,858	29,103	32,013	32,653	33,307	33,973	34,652	35,345	36,052	36,773	37,509	
	97%	74%	74%	74%	74%	74%	42%	42%	42%	42%	42%	31%	19%	13%	9%	7%	7%	6%	6%	6%	6%
Legal, financial and other counseling	2,462	566	591	640	665	2,462	566	591	640	665	2,462	2,462	2,462	2,462	2,462	2,462	2,462	2,462	2,462	2,462	
Total Expenses	43,924	11,022	11,501	12,459	12,939	47,921	13,816	14,417	15,618	16,219	60,071	71,221	86,777	106,022	135,337	154,660	168,697	180,397	189,600	193,472	
Operating Income (Loss)	(18,974)	(3,144)	(3,280)	(3,554)	(3,690)	(13,669)	2,139	2,232	2,418	2,511	9,301	32,034	83,013	147,875	252,067	315,248	356,152	386,456	405,408	401,536	
Interest income (expense), net																					
Gain (loss) on foreign currency transactions	(1,384)																				
Change in warrant liability																					
Other income (expense), net																					
Total Other Income	(1,384)																				
Pretax Income	(20,358)	(3,144)	(3,280)	(3,554)	(3,690)	(13,669)	2,139	2,232	2,418	2,511	9,301	32,034	83,013	147,875	252,067	315,248	356,152	386,456	405,408	401,536	
Income Tax Benefit (Provision)	1,092	(252)	(262)	(284)	(295)	(1,093)	214	223	242	251	930	3,844	12,452	26,617	52,934	75,660	99,723	127,531	133,784	132,507	
Tax Rate	5%	8%	8%	8%	8%	8%	10%	10%	10%	10%	10%	12%	15%	18%	21%	24%	28%	33%	33%	33%	
GAAP Net Income (Loss)	(19,266)	(2,892)	(3,018)	(3,270)	(3,395)	(12,575)	1,925	2,009	2,176	2,260	8,371	28,190	70,561	121,257	199,133	239,589	256,429	258,926	271,623	269,029	
GAAP-EPS	(0.60)	(0.09)	(0.09)	(0.10)	(0.10)	(0.39)	0.06	0.06	0.07	0.07	0.26	0.86	2.14	3.67	6.00	7.19	7.67	7.71	8.05	7.95	
GAAP-EPS (Dil)	(0.60)	(0.09)	(0.09)	(0.10)	(0.10)	(0.39)	0.06	0.06	0.07	0.07	0.26	0.86	2.14	3.67	6.00	7.19	7.67	7.71	8.05	7.95	
Wgtd Avg Shrs (Bas) - '000s	32,253	32,482	32,515	32,547	32,580	32,531	32,613	32,645	32,678	32,711	32,662	32,792	32,924	33,056	33,188	33,321	33,454	33,589	33,723	33,858	
Wgtd Avg Shrs (Dil) - '000s	32,253	32,482	32,515	32,547	32,580	32,531	32,613	32,645	32,678	32,711	32,662	32,792	32,924	33,056	33,188	33,321	33,454	33,589	33,723	33,858	

Source: Dawson James estimates

Important Disclosures:

Companies mentioned in this report include:
Athersys (ATHX) Buy rated

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – July 11, 2019 – Price Target \$15.00
- Update – Buy – August 12, 2019 – Price Target \$15.00
- Update – Buy – August 15, 2019 – Price Target \$15.00
- Update – Buy – August 19, 2019 – Price Target \$15.00
- Update – Buy – November 6, 2019 – Price Target \$15.00
- Update – Buy – February 19, 2020 – Price Target \$15.00
- Price Target Increase – Buy – March 9, 2020 – Price Target \$17.00
- Update – Buy – March 25, 2020 – Price Target \$17.00
- Update – Buy – April 13, 2020 – Price Target \$17.00

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	22	85%	3	14%
Market Perform (Neutral)	4	15%	1	25%
Market Underperform (Sell)	0	0%	0	0%
Total	26	100%	4	15%

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