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CytoSorbents Corporation (NASDAQ/CTSO)

June 16, 2023

BUY: DSMB Recommends Complete STAR-T – No Modifications Needed

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CytoSorbents reported it has received the recommendation from the independent Data and Safety Monitoring Board (DSMB), following the second scheduled safety review, to complete the pivotal Safe and Timely Antithrombotic Removal – Ticagrelor (STAR-T) trial as planned without any modifications. The goal of the trial - DrugSorb-ATR is to allow patients to get the critical surgery they need without delay, while reducing or preventing bleeding risk by actively removing blood thinners during the surgery. DrugSorb-ATR has received FDA Breakthrough Device Designation for this indication.

Investment Highlights

STAR-T & STAR-D: The Company has initiated two FDA-approved pivotal trials designed to support U.S. marketing approval of DrugSorb-ATR. The first, which is now prioritized, is the 120-patient, 30-center STAR-T (Safe and Timely Antithrombotic Removal-Ticagrelor) randomized, controlled trial evaluating the ability of intraoperative DrugSorb-ATR use to reduce perioperative bleeding risk in patients on ticagrelor undergoing cardiothoracic surgery.

STAR-T Update: (from the quarter's press release): "the rapid pace of enrollment of STAR-T led us to elect to forego a formal interim analysis on the first 80 patients. To fully understand this decision, it is important to clarify that the original intent of this interim analysis was to provide the opportunity to stop the trial early, an important option if enrollment was expected to be slow or delayed. However, the current enrollment pace is brisk and our projections suggest that the trial will likely be completed by the time a formal interim analysis - that requires fully monitored, cleaned, locked, and adjudicated data - would have been completed."

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 derive a \$12.00 price target. If we choose a more aggressive 15%, we arrive at a \$34.00 target. We select 25% to balance risk versus reward to derive a \$16.00 target.

Risks to our price target include: market, regulatory, financial, and commercialization risks.

Current Price \$3.57
Price Target \$16.00



Source: CytoSorbents

Stock Data			
52-Week Range	\$1.03	-	\$4.59
Shares Outstanding (mil.)	44.0		
Market Capitalization (mil.)	\$157		
Enterprise Value (mil.)	\$137		
Debt to Capital	0%		
Book Value/Share	\$0.35		
Price/Book	1.9		
Average Three Months Trading Volume (K)	56		
Insider Ownership	12.0%		
Institutional Ownership	35.0%		
Short interest (mil.)	1.8%		
Dividend / Yield	\$0.00/0.0%		



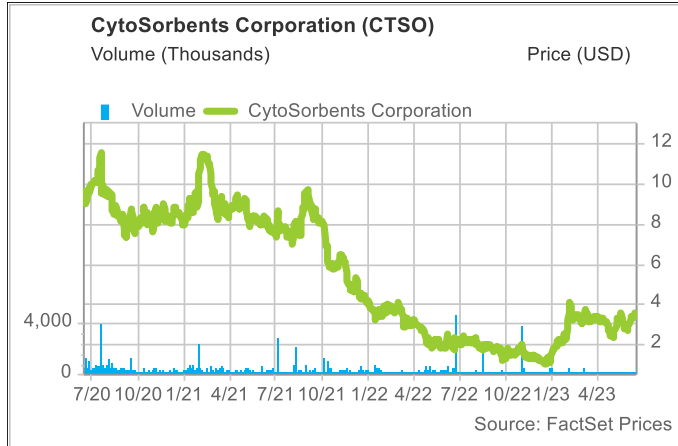
Exhibit 1. Income Statement

CTSO.: Income Statement (\$000)																
YE December 31	2019A	2020A	2021A	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																
CytoSorb Direct Sales (Germany, Austria, Switzerland)	22,766	25,607	29,354	17,573	5,910	7,451	8,072	8,383	31,046	42,620	49,732	58,030	67,713	79,013	92,198	92,198
CytoSorb Distributor (Rest of EU)		10,240	10,498	11,000	1,000	3,276	3,549	3,685	13,649	15,878	18,472	21,490	25,001	29,085	33,837	33,837
CytoSorb (Cardiac surgery EU)		3,420			1,000	2,785	3,017	3,133	11,604	14,022	16,474	16,589	16,705	16,822	16,940	16,940
CytoSorb (Cardiac surgery US)		-	-	-	-	-	-	-	-	21,899	27,593	66,755	67,290	67,829	68,373	68,373
CytoSorb (other US)		-	-	-	-	-	-	-	-	38,459	78,231	190,960	283,238	395,071	602,722	602,722
VetResQ		185	194		-	-	-	-	-	-	-	-	-	-	-	-
Other Sales				787												
Total Product Sales	22,766	39,452	40,047	29,360	7,910	13,512	14,638	15,201	56,299	132,878	190,502	353,824	459,947	587,820	814,070	814,070
Royalty (HemoDefend US)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Grant revenue	2,184	1,552	3,062	5,328	1,539	-	-	-	1,539	-	-	-	-	-	-	-
Other revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	24,950	41,004	43,109	34,689	9,449	13,512	14,638	15,201	57,838	132,878	190,502	353,824	459,947	587,820	814,070	814,070
Expenses:																
Costs of Goods Sold	7,364	11,052	11,047	13,956	3,994	2,702	2,928	3,040	12,664	26,576	38,100	70,765	91,989	117,564	162,814	162,814
	%COGS	25%	28%	32%	48%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
Research and Development	12,092	8,810	16,380	15,119	4,214	3,991	4,324	4,490	16,631	18,294	20,123	22,136	24,349	26,784	29,462	32,409
	%R&D	53%	22%	41%	51%	53%	30%	30%	30%	14%	11%	6%	5%	5%	4%	4%
Selling, General and Administrative	22,006	28,463	35,749	34,288	8,463	8,394	9,093	9,443	34,974	35,673	36,387	37,115	37,857	38,614	39,386	40,174
	%SG&A	97%	72%	89%	117%	107%	62%	62%	62%	27%	19%	10%	8%	7%	5%	5%
Legal, financial and other counseling	2,462	3,048	2,731	2,848	669	683	740	769	2,848	2,848	2,848	2,848	2,848	2,848	2,848	2,848
Total Expenses	43,924	51,373	65,907	66,211	17,340	15,771	17,085	17,742	67,117	83,391	97,458	132,863	157,043	185,810	234,511	238,245
Operating Income (Loss)	(18,974)	(10,369)	(22,799)	(31,522)	(7,891)	(2,259)	(2,448)	(2,542)	(9,279)	49,488	93,044	220,961	302,904	402,010	579,559	575,825
Interest income (expense), net																
Gain (loss) on foreign currency transactions	(1,384)	(1,201)	2	133												
Change in warrant liability		2,607	(2,569)	(2,449)												
Other income (expense), net				(67)												
Total Other Income	(1,384)	1,406	(2,567)	(2,383)	566	-	-	-	-	-	-	-	-	-	-	-
Pretax Income	(20,358)	(8,964)	(25,366)	(33,905)	(7,326)	(2,259)	(2,448)	(2,542)	(9,279)	49,488	93,044	220,961	302,904	402,010	579,559	575,825
Fx				1,804												
Income Tax Benefit (Provision)	1,092	1,127	(2,537)	1,095	-	(339)	(367)	(381)		8,908	19,539	53,031	84,813	132,663	191,255	190,022
Tax Rate	5%	8%	10%	12%	15%	15%	15%	15%	15%	18%	21%	24%	28%	33%	33%	33%
GAAP Net Income (Loss)	(19,266)	(7,837)	(22,829)	(31,009)	(7,326)	(1,920)	(2,080)	(2,160)	(9,279)	40,580	73,505	167,931	218,091	269,347	388,305	385,803
GAAP-EPS	(0.62)	(0.20)	(0.57)	(0.71)	(0.17)	(0.04)	(0.05)	(0.05)	(0.21)	0.92	1.67	3.79	4.91	6.04	8.67	8.58
GAAP-EPS (Dil)	(0.60)	(0.20)	(0.53)	(0.71)	(0.17)	(0.04)	(0.05)	(0.05)	(0.21)	0.92	1.67	3.79	4.91	6.04	8.67	8.58
Wgtd Avg Shrs (Bas) - '000s	32,253	38,819	43,358	43,636	43,676	43,720	43,763	43,807	43,742	43,917	44,093	44,269	44,447	44,625	44,804	44,983
Wgtd Avg Shrs (Dil) - '000s	32,253	38,819	43,358	43,636	43,676	43,720	43,763	43,807	43,742	43,917	44,093	44,269	44,447	44,625	44,804	44,983

Source: Dawson James

Important Disclosures:

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
- Update – Buy – May 6, 2020 – Price Target \$17.00
- Update – Buy – June 9, 2020 – Price Target \$17.00
- Update – Buy – July 31, 2020 – Price Target \$15.00
- Update – Buy – August 12, 2020 – Price Target \$16.00
- Update – Buy – September 16, 2020 – Price Target \$16.00
- Update – Buy – October 14, 2020 – Price Target \$16.00
- Update – Buy – November 5, 2020 – Price Target \$16.00
- Update – Buy – December 2, 2020 – Price Target \$16.00
- Update – Buy – January 12, 2021 – Price Target \$16.00
- Update – Buy – January 19, 2021 – Price Target \$16.00
- Update – Buy – April 20, 2021 – Price Target \$16.00
- Update – Buy – May 6, 2021 – Price Target \$16.00
- Update – Buy – July 6, 2021 – Price Target \$16.00
- Update – Buy – September 1, 2021 – Price Target \$16.00
- Update – Buy – October 15, 2021 – Price Target \$16.00
- Update – Buy – November 9, 2021 – Price Target \$16.00
- Update – Buy – November 22, 2021 – Price Target \$16.00
- Update – Buy – January 18, 2022 – Price Target \$16.00
- Update – Buy – March 9, 2022 – Price Target \$16.00
- Update – Buy – April 29, 2022 – Price Target \$16.00
- Update – Buy – May 4, 2022 – Price Target \$16.00
- Update – Buy – August 3, 2022 – Price Target \$16.00
- Update – Buy – August 17, 2022 – Price Target \$16.00
- Update – Buy – October 6, 2022 – Price Target \$16.00
- Update – Buy – November 4, 2022 – Price Target \$16.00
- Update – Buy – November 15, 2022 – Price Target \$16.00
- Update – Buy – December 29, 2022 – Price Target \$16.00
- Update – Buy – January 24, 2023 – Price Target \$16.00
- Update – Buy – February 1, 2023 – Price Target \$16.00
- Update – Buy – March 10, 2023 – Price Target \$16.00
- Update – Buy – April 20, 2023 – Price Target \$16.00
- Update – Buy – May 3, 2023 – Price Target \$16.00

Update – Buy – June 16, 2023 – Price Target \$16.00

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 25-May-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	26	72%	2	6%
Market Perform (Neutral)	10	28%	1	3%
Market Underperform (Sell)	0	0%	0	0%
Total	36	100%	3	9%

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