

# INSTITUTIONAL RESEARCH

# Medical Technology UPDATE REPORT

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## **CytoSorbents Corporation (NASDAQ/CTSO)**

July 6, 2021

## **BUY: CytoSorbents STAR Shines Bright**

CytoSorbents Receives Full FDA Approval of Investigational Device Exemption (IDE) for U.S. STAR-T Trial on Ticagrelor Removal During Cardiothoracic Surgery

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## **Investment Highlights**

A STAR is Born. CytoSorbents announces the full approval of its Investigational Device Exemption (IDE) application to conduct the pivotal STAR-T (Safe and Timely Antithrombotic Removal – Ticagrelor) double-blind, randomized, controlled trial (RCT) in the U.S. to support FDA regulatory clearance. This study is being performed under the previously announced Breakthrough Designation granted for the removal of ticagrelor in a cardiopulmonary bypass circuit during urgent and emergent cardiothoracic surgery with CytoSorbents's proprietary polymer adsorption technology. The company has already identified and pre-screened many high-quality U.S. clinical centers that have indicated strong interest in participating in the STAR-T trial.

Breakthrough Device Designation. Last year, the FDA granted the breakthrough designation to remove ticagrelor during cardiothoracic surgery, recognizing the unmet medical need. Each year, ticagrelor is prescribed to millions of cardiovascular patients worldwide to reduce the risk of recurrent heart attack, stroke, or cardiovascular death. Ticagrelor is frequently preferred as first-line therapy in patients presenting to hospitals with an acute coronary syndrome in preparation of percutaneous coronary intervention (PCI) and stent placement. As many as ten percent of patients will require coronary artery bypass graft (CABG) open heart surgery. As several clinical studies, such as the PLATO trial, have shown, they face a very high risk of severe or life-threatening perioperative bleeding.

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 \$9.00 price target. If we select a more aggressive 15%, we arrive at a \$26.00 target. We select a mid-point (22.5%) to derive a \$16.00 target, which reflects the revised share count from the recent capital raise.

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



Source. Cytosorbents			
Stock Data			
52-Week Range	\$7.13	-	\$11.74
Shares Outstanding (mil.)			43.3
Market Capitalization (mil.)			\$318
Enterprise Value (mil.)			\$299
Debt to Capital			0%
Book Value/Share			\$0.35
Price/Book			4.3
Average Three Months Trac	ling Volume	(K)	220
Insider Ownership			11.7%
Institutional Ownership			43.3%
Short interest (mil.)			4.9%
Dividend / Yield			\$0.00/0.0%





### **Exhibit 1. Income Statement**

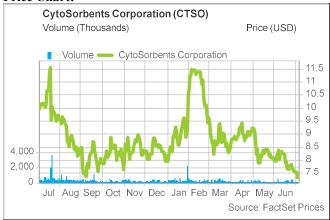
September 3	CTSO.: Income Statement (\$000)																
Consideration   Consideratio	.: YE December 31	2019A	2020A	1Q21A	2Q21E	3Q21E	4Q21E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Cyclosing Charter (Rest of EU)	Revenue:																
Cost	CytoSorb Direct Sales (Germany, Austria, Switzerland)	22,766	25,607	7,000	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
Cyclosfor (Cardinac surgery US)   2,106   2,281   2,399   8,773   17,864   64,5376   62,720   62,755   67,720   69,775	CytoSorb Distributor (Rest of EU)		10,240	3,098	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
CkoSoft (Claridia curriger) US)	CytoSorb (Cardiac surgery EU)		3,420		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
CysoSort (separe US)			-	_	· -	· -				16.294	21.899	27.593	66.755		67.829	68.373	68.373
WeRes O     185   45   47   51   52   194   204   214   225   236					2.106	2.281	2.369	8.773	17.846	45.376		187,755	200.508	223.353	246.919		271.225
Cher Sales    Control Product Sales   2,2768   39,452   10,143   16,558   18,046   18,740   69,409   103,293   169,231   25,393   37,440   469,908   524,549   566,853   595,008   595,008   695,008			185	45	47	51		194	204				,	.,	.,.	, ,	, -
Total Product Sales  2.766																	
Grant revenue 0 2,184 1,552 455		22,766	39,452	10,143	16,658	18,046	18,740	69,409	103,293	169,831	253,939	387,449	469,908	524,849	566,853	595,008	595,008
Grant revenue 0 2,184 1,552 455	Describe (Users a Defendation)																
Other revenue 2.4.950 41,004 10.598 16,659 18,046 18,740 69,864 103,263 169,881 253,939 387,449 469,908 524,649 566,853 595,008 Expenses:  Costs of Goods Sold 7,364 11,052 25,751 4,519 4,895 5,084 17,250 20,659 20% 20% 20% 20% 20% 20% 12,000 20% 20% 20% 20% 20% 20% 20% 20% 20%	* * * * * * * * * * * * * * * * * * * *				-	-	-	_	-	-		-	-	-	-	-	-
Total Revenue 24,950 41,004 10,598 16,658 18,046 18,740 69,864 103,293 169,831 253,939 37,449 469,908 524,849 566,855 595,008 559,008 529,008		2,184	1,552				Ĭ		-	-	-	-	-	-	-	-	-
Expenses   7,364   11,052   2,751   4,519   4,895   5,084   17,250   20,59   20,59   20,59   20,50	Other revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Costs of Goods Sold  \$4,000\$ \$4,000\$ \$5,000\$ \$2,554 \$2,854 \$2,2754 \$2,754 \$2,755 \$2,75	Total Revenue	24,950	41,004	10,598	16,658	18,046	18,740	69,864	103,293	169,831	253,939	387,449	469,908	524,849	566,853	595,008	595,008
Research and Development									_	L	L	L	L	L I	_	_	
Research and Development    Research and Development   12,092   8,810   2,282   2,326   2,520   2,617   9,691   10,680   11,726   12,898   14,188   15,607   17,168   18,885   20,773   22,850   22%   14%	Costs of Goods Sold						5,084	17,250	20,659	33,966	50,788	77,490		104,970	113,371		
Selling, General and Administrative 22,066 28,423 7,710 7,866 8,510 8,838 32,733 36,006 38,424 37,61 38,210 38,746 38,746 38,210 38,746 38,746 38,210 38,746 38,746 38,210 38,746 38,746 38,210 38,746	%COG		28%			27%											
Selling, General and Administrative	Research and Development						2,617	9,691	10,660	11,726	12,898	14,188	15,607	17,168	18,885	20,773	22,850
SGRA   97%   72%   76%   77%   77%   77%   77%   77%   35%   22%   15%   10%   8%   8%   7%   7%   7%   7%   7%   7	%R8	D 53%	22%	22%	14%	14%	14%	14%	10%	7%	5%	4%	3%	3%	3%	3%	4%
Legal, financial and other counseling 2,462 3,048 708 732 792 823 3,048	Selling, General and Administrative	22,006	28,463				8,838	32,733	36,006		37,461	38,210	38,974	39,753	40,549	41,360	42,187
Total Expenses (18,974) (10,369) (2,853) 1,226 1,328 1,379 6,902 32,921 84,365 149,745 254,513 318,297 359,910 391,002 410,826 407,921 (10,369) (1,384) (1,201) (10) (1,369) (2,853) 1,226 1,328 1,379 6,902 32,921 84,365 149,745 254,513 318,297 359,910 391,002 410,826 407,921 (1,366) (1,	%SG8	A 97%	72%	76%	47%	47%	47%	47%	35%	22%	15%	10%	8%	8%	7%	7%	7%
Common   Class   Cla	Legal, financial and other counseling	2,462	3,048	708	732	792	823	3,048	3,048	3,048	3,048	3,048	3,048	3,048	3,048	3,048	3,048
Interest income (expense), net Gain (loss) on foreign currency transactions (1,384) (1,201) (10) Change in warrant liability Other income (expense), net  Total Other Income (20,358) (8,964) (4,168) 1,226 1,328 1,379 6,902 32,921 84,365 149,745 254,513 318,297 359,910 391,002 410,826 407,921  Income Tax Benefit (Provision) 1,092 1,127 - 123 133 138 690 3,951 12,655 26,954 53,448 76,391 100,775 129,031 135,573 134,614 Tax Rate 5% 8% 10% 10% 10% 10% 10% 10% 15% 15% 18% 21% 24% 28% 33% 33% 33% 33% 33% 33% 33% 33% 33% 3	Total Expenses	43,924	51,373	13,451	15,432	16,718	17,361	62,962	70,372	85,466	104,195	132,936	151,611	164,939	175,852	184,182	187,086
Gain (loss) on foreign currency transactions (1,384) (1,201) (1,306) (1,384) (1,384) (1,201) (1,306) (1,384) (	Operating Income (Loss)	(18,974)	(10,369)	(2,853)	1,226	1,328	1,379	6,902	32,921	84,365	149,745	254,513	318,297	359,910	391,002	410,826	407,921
Change in warrant liability Other income (expense), net  Total Other Income  (1,384) 1,406 (1,316)	Interest income (expense), net	, ,	, ,														
Other income (expense), net         (1,384)         1,406         (1,316)         - <td>Gain (loss) on foreign currency transactions</td> <td>(1,384)</td> <td>(1,201)</td> <td>(10)</td> <td></td>	Gain (loss) on foreign currency transactions	(1,384)	(1,201)	(10)													
Total Other Income  (1,384) 1,406 (1,316)	Change in warrant liability		2,607	(1,306)													
Pretax Income         (20,358)         (8,964)         (4,168)         1,226         1,328         1,379         6,902         32,921         84,365         149,745         254,513         318,297         359,910         391,002         410,826         407,921           Income Tax Benefit (Provision)         1,092         1,127         -         123         133         138         690         3,951         12,655         26,954         53,448         76,391         100,775         129,031         135,573         134,614           Tax Rate         5%         8%         10%         10%         10%         12%         15%         18%         21%         24%         28%         33%         24,00         41,00         41,00         41,0	Other income (expense), net																
Pretax Income         (20,358)         (8,964)         (4,168)         1,226         1,328         1,379         6,902         32,921         84,365         149,745         254,513         318,297         359,910         391,002         410,826         407,921           Income Tax Benefit (Provision)         1,092         1,127         -         123         133         138         690         3,951         12,655         26,954         53,448         76,391         100,775         129,031         135,573         134,614           Tax Rate         5%         8%         10%         10%         10%         12%         15%         18%         21%         24%         28%         33%         24,00         41,00         41,00         41,0	Total Other Income	(1 384)	1 406	(1.316)			_						_				
Tax Rate         5%         8%         10%         10%         10%         10%         12%         15%         18%         21%         24%         28%         33%         34%         34%<					1,226	1,328	1,379	6,902	32,921	84,365	149,745	254,513	318,297	359,910	391,002	410,826	407,921
Tax Rate         5%         8%         10%         10%         10%         10%         12%         15%         18%         21%         24%         28%         33%         34%         34%<	Income Tay Renefit (Provision)	1 002	1 127		123	133	138	600	3 051	12 655	26 954	53.449	76 301	100 775	120 031	135 573	134 614
GAAP Net Income (Loss) (19,266) (7,837) (4,168) 1,103 1,195 1,241 6,212 28,970 71,710 122,791 201,066 241,906 259,135 261,971 275,253 273,307   GAAP-EPS (0,62) (0,20) (0,10) 0,03 0,03 (0,01) 0,67 1,64 2,80 4,57 5,48 5,84 5,88 6,16 6,09 (3,44) (4,162) (4,162) (4,163) (4,163) (4,164) (4,162) (4,164) (4,164) (4,165) (4,164) (4,165) (4,164) (4,165) (4,																	
GAAP-EPS (0.62) (0.20) (0.10) 0.03 0.03 (0.01) 0.67 1.64 2.80 4.57 5.48 5.84 5.88 6.16 6.09 (0.64) (0.67) (0.60) (0.20) (0.10) 0.03 0.03 0.03 0.14 0.67 1.64 2.80 4.57 5.48 5.84 5.88 6.16 6.09 (0.60) (0.60) (0.60) (0.20) (0.10) 0.03 0.03 0.14 0.67 1.64 2.80 4.57 5.48 5.84 5.88 6.16 6.09 (0.60) (0																	
GAAP-EPS (Dil) (0.60) (0.20) (0.10) 0.03 0.03 0.03 0.14 0.67 1.64 2.80 4.57 5.48 5.84 5.88 6.16 6.09 Wgtd Avg Shrs (Bas) - '000s 32,253 38,819 43,243 43,286 43,329 43,373 43,308 43,481 43,655 43,830 44,006 44,182 44,359 44,537 44,715 44,894		(10,200)	(1,001)	(1,100)	.,,,,,	.,,100	,	0,212	20,010		122,101	201,000	211,000	1200,100	201,071	210,200	210,001
GAAP-EPS (Dil) (0.60) (0.20) (0.10) 0.03 0.03 0.03 0.14 0.67 1.64 2.80 4.57 5.48 5.84 5.88 6.16 6.09 Wgtd Avg Shrs (Bas) - '000s 32,253 38,819 43,243 43,286 43,329 43,373 43,308 43,481 43,655 43,830 44,006 44,182 44,359 44,537 44,715 44,894	GAAP-EPS	(0.62)	(0.20)	(0.10)	0.03	0.03	0.03	(0.01)	0.67	1.64	2.80	4.57	5.48	5.84	5.88	6.16	6.09
Wgtd Avg Shrs (Bas) - '000s 32,253 38,819 43,243 43,286 43,329 43,373 43,308 43,481 43,655 43,830 44,006 44,182 44,359 44,537 44,715 44,894																	

Source: Dawson James estimates and company reports



#### **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

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#### **Rating Definitions:**

- 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.

As of: 30-Jun-21

	Company Co	overage	Investment Banking			
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals		
Market Outperform (Buy)	24	71%	4	17%		
Market Perform (Neutral)	10	29%	0	0%		
Market Underperform (Sell)	0	0%	0	0%		
Total	34	100%	4	12%		

#### **Analyst Certification:**

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