

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

A Leader in Critical Care Immunotherapy Q4 2019 and Full Year 2019 Earnings Conference Call March 5, 2020

#### Conference Call Participants

Dr. Phillip Chan, MD, PhD Chief Executive Officer and President

Vincent Capponi, MS Chief Operating Officer

Kathleen Bloch, MBA, CPA Chief Financial Officer

Dr. Christian Steiner, MD Senior Vice President Sales and Marketing

Christopher Cramer, MS, MBA Vice President of Business Development

<u>Moderator: Jeremy Feffer – LifeSci Advisors</u>



#### Safe Harbor Statement

Statements in this presentation regarding CytoSorbents Corporation and its operating subsidiaries CytoSorbents Medical, Inc and CytoSorbents Europe GmbH that are not historical facts are forward-looking statements and are subject to risks and uncertainties that could cause actual future events or results to differ materially from such statements. Any such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. It is routine for our internal projections and expectations to change. Although these expectations may change, we are under no obligation to inform you if they do. Actual events or results may differ materially from those contained in the projections or forward-looking statements. The following factors, among others, could cause our actual results to differ materially from those described in a forward-looking statement: our history of losses; potential fluctuations in our quarterly and annual results; competition, inability to achieve regulatory approval for our device, technology systems beyond our control and technology-related defects that could affect the companies' products or reputation; risks related to adverse business conditions; our dependence on key employees; competition for qualified personnel; the possible unavailability of financing as and if needed; and risks related to protecting our intellectual property rights or potential infringement of the intellectual property rights of third parties. This list is intended to identify only certain of the principal factors that could cause actual results to differ from those discussed in the forward-looking statements. Readers are referred to a discussion of important risk factors detailed in the Company's Form 10-K filed with the Securities and Exchange Commission on March 5, 2020 and other reports and documents filed from time to time by us, which are available online at www.sec.gov.



#### 2019 Operational Highlights

- 80,000+ CytoSorb treatments delivered, up from 56,000 a year ago
- 2019 Total Revenue was \$24.9M, including product sales and grant income, versus \$22.5M a year ago
- Product sales growth accelerated in Q4 2019 by 20%, driven by a 30% increase in direct sales
- Achieved blended product gross margin of 80% in Q4 2019
- Renewed CytoSorb CE Mark to May 2024 and ISO 13485:2016 to Sept 2022
- Expanded organization by 50% to approximately 155 employees, with a strong focus on commercialization
- Extended CytoSorb distribution to 58 countries, including 10 direct countries
- Well-capitalized with cash to fund operations and clinical studies to 2H 2021





### CytoSorb and COVID-19



- CytoSorb is in many of the countries where COVID-19 cases are surging, including Italy, Iran, Germany, France, Spain, Hong Kong and others
- Through our partnership with China Medical System Holding Ltd, we donated CytoSorb devices that were made rapidly available to select hospitals in Wuhan, China. We have learned that multiple patients at multiple hospitals are being actively treated with CytoSorb
- Physicians from Peking Union Medical College Hospital who have been treating
  patients in Wuhan hospitals, recently registered a trial entitled, "CytoSorb
  adsorption therapy combined with standard therapy for new coronavirus
  pneumonia in adult severe patients" in order to have a mechanism to collect and
  publish ongoing safety and efficacy data from patients they are treating
- On March 3, 2020, the National Health Commission in China has issued its 7th updated treatment guidance "Diagnosis and Treatment of New Coronavirus Pneumonia" that now includes the recommendation to use blood purification to treat cytokine storm for severe and critically-ill patients



## CytoSorb and COVID-19 (cont)



- Have submitted our documentation to the U.S. joint agency task force that includes the CDC, HHS, FDA, BARDA and others and are awaiting feedback
- Manufacturing of CytoSorb has been ramped to build inventory of devices should there be a need. Given the 3-year shelf-life of our products, this increase in inventory can be easily worked through with low risk

#### Some observations:

- We contend that COVID-19 would not be so concerning if therapies were available to lower the high 2-4% mortality rate. This is what CytoSorb could help do
- Investors should realize that all of the reasons that make our therapy applicable to treat complications of coronavirus, are what CytoSorb treats EVERY DAY around the world. The problem of cytokine storm and organ failure is NOT unique to COVID-19. Sepsis, our core market, accounts for 1 in every 5 deaths worldwide each year. Coronavirus may be why investors buy our stock now, but what we do every day, year in and year out, is why they should stay



# **Clinical Update**



#### Update on REFRESH 2-AKI and CMO

- Working closely with new CRO to close out re-monitoring and scrubbing of clinical data on first 153 patients, all of which remains usable data
- Expect to address the data and data analytical requests of the DMC with the goal of restarting REFRESH 2-AKI by mid-2020
- Provided we are able to regain our momentum in the trial, our goal is to get to the scheduled interim analysis with 200 patients enrolled by Q4 2020 – Q1 2021
- Conducting an active retained search for new CMO and have several highly qualified candidates, with more under evaluation. Expect to conclude the search no later than the next few months



#### Update on UK TISORB and US Strategy

#### **UK TISORB study**

- 6 of 8 centers are active, 1 patient enrolled
- Protocol amendment to enable enrollment of both emergent and urgent cardiac surgery patients was approved by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) at end of February
- Waiting for Regional Ethics Committee (REC) approvals
- Expect 30 patient enrollment to be complete in 2H 2020

#### <u>US Strategy</u>

- In active discussions with the FDA on path forward for removal of ticagrelor during cardiac surgery
- We expect to have clear feedback from the FDA no later than 1H 2020



#### Update on REMOVE

- The REMOVE endocarditis trial completed enrollment at 288 patients in January
- Currently the data is being monitored with the goal of database lock soon
- Data analysis on outcomes are expected by mid-2020
- Recent publication of single center, 58-patient, infective endocarditis
  retrospective case series from University of Essen demonstrating a statistically
  improved hemodynamic stability at ICU admission, as well as lowered incidence
  of postoperative sepsis and death related to sepsis is encouraging



#### Update on HemoDefend

- Manufacturing issue has been resolved, now in validation testing to confirm this
- Manufacturing of new devices to follow
- Expect to complete bench testing on new devices for efficacy parameters by mid-2020
- IDE for US Pivotal trial expected to be filed and approved in Q4 2020



# 2019 Financial Highlights



### Q4 2019 Comparative Revenue Results

	Quarter Ended Dec. 31, 2019	Quarter Ended Dec. 31, 2018	% Incr.
Product sales	\$ 6,610,395	\$ 5,470,784	21%
Grant income	819,916	610,061	34%
Total revenue	\$ 7,430,311	\$ 6,080,845	22%

- Q4 2019 CytoSorb® sales were \$6.6M, a 21% increase over \$5.5M in Q4 2018
- Total revenue in Q4 2019, which includes both product sales and grant revenue, increased 22% to \$7.4M, compared to \$6.1M in Q4 2018
- Q4 2019 gross profit was approximately \$5.3M, an increase of ~\$1.3M as compared to gross profit of \$4.0M for Q4 2018, an increase of ~33.5%
- Gross profit margins on product sales were 80% for Q4 2019, versus 75% for Q4 2018



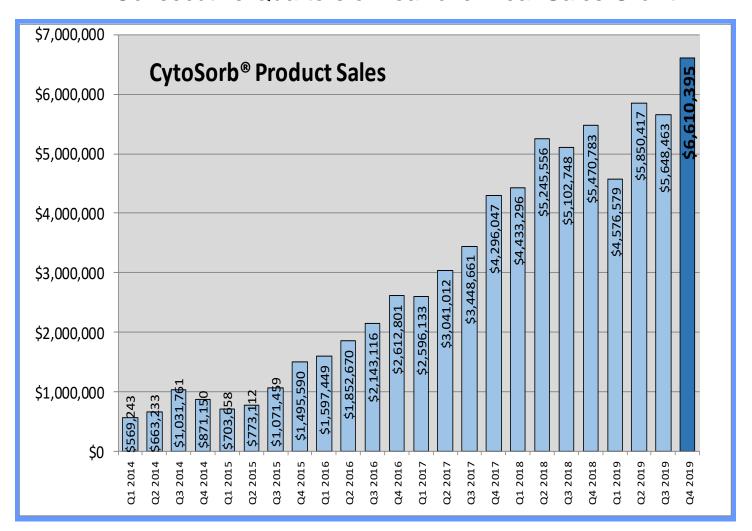
#### Comparative Annual Revenue Results

	Year Ended Dec. 31, 2019	Year Ended Dec. 31, 2018	% Incr.
Product sales	\$22,765,854	\$20,252,383	12%
Grant income	\$2,183,619	\$2,251,525	-3%
Total revenue	\$24,949,473	\$22,503,908	11%

- 2019 Product sales were \$22.8M, a 12% increase over 2018 product sales of \$20.3M
- 2019 Grant revenue was ~\$2.2M, relatively flat compared to 2018 grant revenue of \$2.3M
- Total 2019 revenue, which includes both product sales and grant revenue, was \$24.9M as compared to \$22.5M in 2018, an increase of 11%
- Gross profit was \$17.6M for 2019 versus \$15.0M for 2018, an increase of 17%
- Gross profit margins on product sales were 77% in 2019, as compared to 74% for 2018

### **Quarterly Product Sales**

24 Consecutive Quarters of Year-over-Year Sales Growth





#### Annual Product Sales and Blended Gross Margins





### Working Capital and Cap Table

Working Capital as of											
12,	/31/2019	12,	/31/2018	12/	/31/2017	12/3	31/2016	12,	/31/2015	12/	31/2014
	\$12,232		\$22,369	\$	17,322	\$	5,245	\$	7,509	\$	5,550
	4,467		3,943		2,206		1,433		649		819
	2,114		833		796		834		1,191		538
	2,088		1,119		415		316		512		700
	20,902		28,264		20,739		7,828		9,861		7,607
	2,039		1,486		1,244		1,330		685		698
	5,802		4,386		2,604		2,115		723		825
	1,667		667		4,000		833		-		-
	428		-		-		-		-		-
	-		-		-		-		-		1
	9,936		6,539		7,848		4,278		1,408		1,524
\$	10,965	\$	21,725	\$	12,891	\$	3,550	\$	8,453	\$	6,083
	12	\$12,232 4,467 2,114 2,088 20,902 2,039 5,802 1,667 428 - 9,936	\$12,232 4,467 2,114 2,088 20,902 2,039 5,802 1,667 428 - 9,936	\$12,232 \$22,369 4,467 3,943 2,114 833 2,088 1,119 20,902 28,264 2,039 1,486 5,802 4,386 1,667 667 428 - 9,936 6,539	\$12,232 \$22,369 \$ 4,467 3,943 2,114 833 2,088 1,119 20,902 28,264  2,039 1,486 5,802 4,386 1,667 667 428 - 9,936 6,539	\$12,232 \$22,369 \$ 17,322 4,467 3,943 2,206 2,114 833 796 2,088 1,119 415 20,902 28,264 20,739 2,039 1,486 1,244 5,802 4,386 2,604 1,667 667 4,000 428 9,936 6,539 7,848	12/31/2019         12/31/2018         12/31/2017         12/31/2017           \$12,232         \$22,369         \$ 17,322         \$           4,467         3,943         2,206           2,114         833         796           2,088         1,119         415           20,902         28,264         20,739           2,039         1,486         1,244           5,802         4,386         2,604           1,667         667         4,000           428         -         -           -         -         -           9,936         6,539         7,848	12/31/2019         12/31/2018         12/31/2017         12/31/2016           \$12,232         \$22,369         \$ 17,322         \$ 5,245           4,467         3,943         2,206         1,433           2,114         833         796         834           2,088         1,119         415         316           20,902         28,264         20,739         7,828           2,039         1,486         1,244         1,330           5,802         4,386         2,604         2,115           1,667         667         4,000         833           428         -         -         -           -         -         -         -           9,936         6,539         7,848         4,278	12/31/2019         12/31/2018         12/31/2017         12/31/2016         12/31/2	12/31/2019         12/31/2018         12/31/2017         12/31/2016         12/31/2015           \$12,232         \$22,369         \$ 17,322         \$ 5,245         \$ 7,509           4,467         3,943         2,206         1,433         649           2,114         833         796         834         1,191           2,088         1,119         415         316         512           20,902         28,264         20,739         7,828         9,861           2,039         1,486         1,244         1,330         685           5,802         4,386         2,604         2,115         723           1,667         667         4,000         833         -           428         -         -         -         -           9,936         6,539         7,848         4,278         1,408	12/31/2019         12/31/2018         12/31/2017         12/31/2016         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         12/31/2015         5/509         \$         \$         7,509         \$         \$         44/33         649         44/33         649         44/33         649         41/33         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         649         42/34         41/331         648         42/34         41/331         648         42/34         41/331         648         42/34         41/330         685         42/34         42/34         41/

#### Cap Table 12/31/2019

	Fully Diluted Common Shares
Common Stock	32,616,107
Options	4,218,189
Warrants	30,000
Restricted Stock Unit Awards	167,872
	37,032,168



#### Guidance

- CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed. However:
- We expect Q1 2020 product sales to exceed Q1 2019 product sales driven by strength in direct sales



# **Q&A Session**

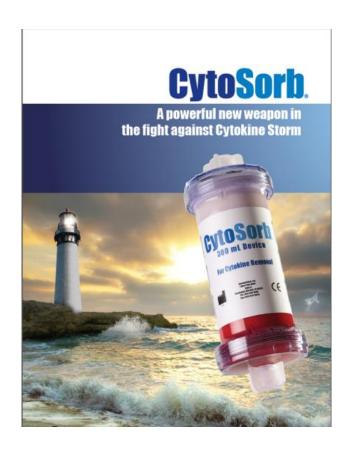
#### **CytoSorbents Corporation**

NASDAQ: CTSO

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A Leader in Critical Care Immunotherapy





