

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

A Leader in Critical Care Immunotherapy Q1 2019 Earnings Conference Call May 7, 2019

#### **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. Eric Mortensen, MD, PhD Chief Medical Officer

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

Christopher Cramer, MS, MBA Vice President of Business Development

Moderator: Jeremy Feffer - LifeSci Advisors



#### 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 7, 2019 and other reports and documents filed from time to time by us, which are available online at www.sec.gov.



#### Operational Highlights

- 61,000+ CytoSorb treatments delivered, up from 40,000 a year ago
- Trailing 12-month total revenue, which includes product sales and grant income, increased to \$22.8M, versus \$17.0M a year ago
- Well-capitalized with a healthy cash balance of \$19.6M (3/31/19)
- Q1 2019 product sales were \$4.6M compared to \$4.4M a year ago
  - Adjusted Q1 2019 sales would have been approximately \$4.9M, after reflecting a decrease in the average exchange rate of the Euro to the dollar which was \$1.14 in Q1 2019 vs. \$1.23 for Q1 2018
  - Direct sales achieved new highs, reflecting 18% quarterly growth year-over-year, and 4% sequential growth compared to Q4 2018
  - Distributor sales were affected by anticipated short-term issues from 3 distributors
    - Fresenius Medical Care is transitioning to new exclusive sales territories (Mexico, South Korea, Czech Republic) and did not order in Q1 2019 as it sells through non-transferable European inventory. Once we achieve registration of CytoSorb in Mexico and South Korea, or once European inventories are sold through, we expect new CytoSorb orders
    - Two other distributors temporarily paused from ordering to rebalance inventory but have strong and growing end-user demand for CytoSorb





#### Operational Highlights

- We believe the factors impacting distributor sales in Q1 2019 are shortterm and specific to these 3 distributors and expect a resumption of ordering from all three over the next several quarters
- Each of these distributors/partners has increased their commitment to selling CytoSorb
  - Aggressively pursuing new indications
  - Increasing resource allocation
  - Collaborating on a number of fronts (e.g. clinical studies, marketing, conferences) to help drive success
- We see end-user usage and demand increasing in these territories
- We expect Q2 2019 product sales to return to our historical growth trajectory and are anticipated to be the highest quarterly product sales reported in our history. We are not relying on orders from these distributors to achieve this guidance



## CytoSorb Sales Are Expected to Increase

#### We continue to forecast strong 2019 revenue growth driven by:

- Organic sales growth driven by continued clinical success
- ROI from a larger, more focused direct sales team particularly in Germany
- Increase in international sales infrastructure to better support distributors and strategic partners
- Reimbursement progress
- Contributions from new direct sales territories
- Impact of new clinical data, including the potential completion of the REMOVE endocarditis study
- New applications such as liver disease, trauma, and new cardiac surgery applications
- Other catalysts



### Clinical Trial Update

- U.S. REFRESH 2-AKI Pivotal Trial
  - 400 patient RCT PMA multi-center adaptive trial targeting reduction of post-op AKI using CytoSorb during complex cardiac surgery
  - Approximately 20% complete with 79 patients enrolled. 23 initiated clinical trial sites, with 6 additional sites in process
  - Enrollment rates have been increasing, as new sites have ramped their activity
  - Targeting enrollment of 200 patients in the next 11 months and interim analysis
- REMOVE Endocarditis Trial (funded by German government)
  - 250 patient RCT: Safety and efficacy of CytoSorb to improve organ dysfunction when used intraoperatively during valve replacement for infective endocarditis
  - SAB and DSMB recommended continuation of trial following an interim analysis on the first 50 patients focused on inflammatory mediators (e.g. cytokines)
  - Trial is nearly 75% complete, with 180 patients enrolled at 15 active centers
- HemoDefend Pivotal Trial

Working to Save Lives Through Blood Purification

- Point-of-care filter removes non-infectious contaminants from transfused pRBCs
- Pivotal trial for U.S. FDA approval back on track for 2H 2019 IDE submission.
  Clinical trial devices are being assembled. CRO selected and conducting clinical site negotiations



# Financial Highlights



### Comparative Quarterly Revenue Results

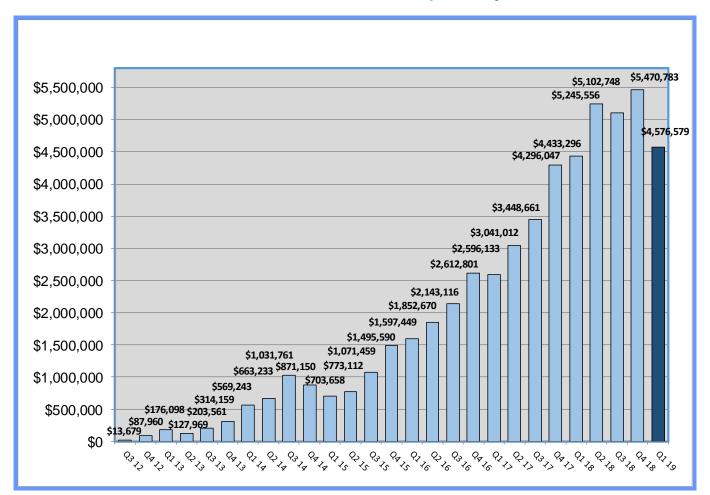
	Quarter Ended Mar 31, 2019	Quarter Ended Mar 31, 2018	% Incr.
Product revenue	\$4,576,579	\$4,433,296	3.2%
Grant and other income	615,050	491,355	25.2%
Total revenue	\$5,191,629	\$4,924,651	5.4%

- Product sales for Q1 2019 increased by \$143K, or 3.2%, to \$4.6M as compared to Q1 2018 product sales of \$4.4M
- Grant revenue was \$615K in Q1 2019, an increase of \$124K, or 25.2% compared to grant revenue of \$491K in Q1 2018
- Total revenue, which includes both product sales and grant revenue, increased by 5.4% to \$5.2M in Q1 2019 as compared to \$4.9M for Q1 2018
- Q1 2019 Product gross margins were 74% for 2019, which was same as Q1 2018



## **Quarterly Product Sales**

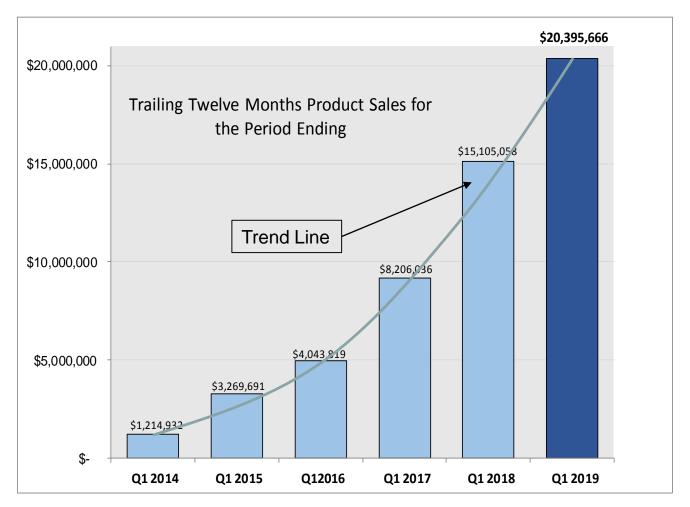
Q2 2019 Product Sales are Expected to Return to Our Historical Growth Trajectory





# Trailing Twelve Months Product Sales

The annual product sales growth trajectory remains strong.





## Working Capital and Cap Table

	Working Capital as of							
	3/31/19	12/31/18	12/31/17	12/31/16	12/31/15	12/31/14	12/31/13	12/31/12
Current Assets:								
Cash and short-term investments	\$19,647	\$22,369	\$ 17,322	\$ 5,245	\$ 7,509	\$ 5,550	\$ 2,183	\$ 1,729
Grants and accounts receivable, net	3,267	3,943	2,206	1,433	649	819	453	51
Inventories	1,214	833	796	834	1,191	538	245	682
Prepaid expenses and other current assets	700	1,119	415	316	512	700	605	476
Total current assets	24,828	28,264	20,739	7,828	9,861	7,607	3,486	2,938
Current Liabilities:								
Accounts payable	1,841	1,486	1,244	1,330	685	698	787	801
Accrued expenses and other current liabilities	2,815	4,386	2,604	2,115	723	825	362	350
Current maturities of long-term debt	1,666	667	4,000	833	-	-	-	-
Lease liability - current portion	389	-	-	-	-	-	-	-
Deferred revenue	-	-	-	-	-	1	272	-
Total current liabilities	6,711	6,539	7,848	4,278	1,408	1,524	1,421	1,151
Net Working Capital	\$ 18,117	\$ 21,725	\$ 12,891	\$ 3,550	\$ 8,453	\$ 6,083	\$ 2,065	\$ 1,787

#### Cap Table 3/31/2019

	Fully Diluted Common Shares
Common Stock	32,243,044
Options	3,624,803
Warrants	30,000
Restricted Stock Unit Awards	63,552
	35,961,399



#### Guidance

- CytoSorbents has not historically given specific financial guidance on quarterly results until the quarter has been completed
- However, we expect Q2 2019 product sales to return to our historical growth trajectory and are anticipated to be the highest quarterly product sales reported in our history
- We reiterate our guidance that we expect to achieve blended product gross margins of 80% on a quarterly basis this year



# **Q&A Session**

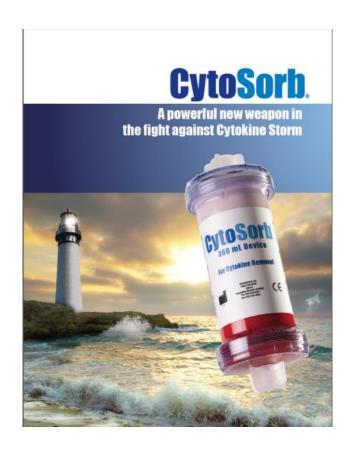
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