



CytoSorbents Corporation Q1 2023 Earnings Conference Call May 2, 2023

Conference Call Participants



Phillip Chan, MD, PhD Chief Executive Officer



Vincent Capponi, MS
President and
Chief Operating Officer



Kathleen Bloch, MBA, CPA
Interim Chief Financial Officer



Efthymios "Makis" Deliargyris MD, FACC, FESC, FSCAI Chief Medical Officer



Christian Steiner, MD
Executive VP Sales & Marketing
Managing Director
CytoSorbents Europe GmbH



Christopher Cramer, MS, MBA Senior VP Business Development



Irina Kulinets, PhD
Senior VP
Global Regulatory Affairs



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 forwardlooking 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 2022 Form 10-K filed with the Securities and Exchange Commission on March 9, 2023, and other reports and documents filed from time to time by us, which are available online at www.sec.gov.



WORKING TO SAVE LIVES

Operational Update

Phillip Chan, MD, PhD Chief Executive Officer

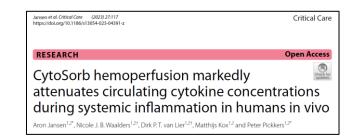


Recent Operational Highlights

 Surpassed 200,000 cumulative CytoSorb treatments across 75 countries (203K+ as of 3/31/23), after achieving the 100,000 treatment milestone less than 3 years ago

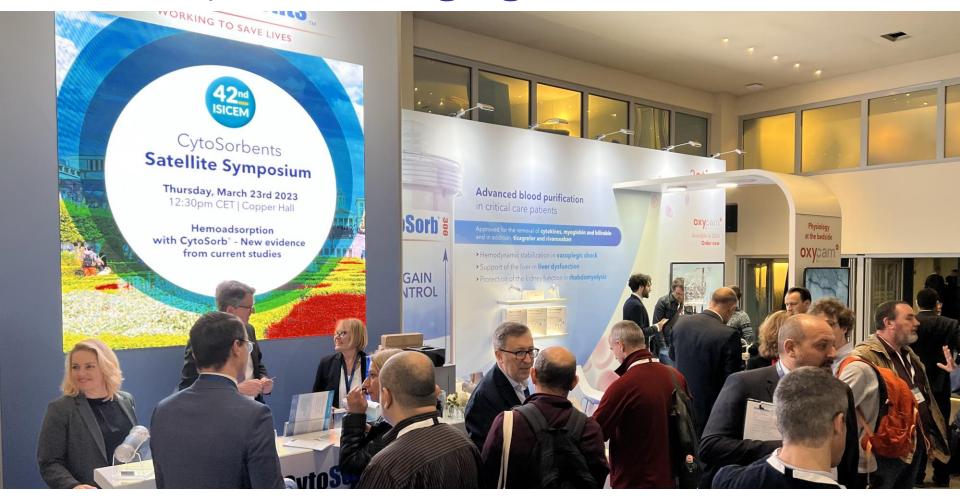


- Pivotal STAR-T trial achieved second milestone of 80 patients enrolled on schedule, after achieving the first milestone of 40 patients enrolled in November 2022, triggering a second independent Data & Safety Monitoring Board (DSMB) that is expected to initiate shortly and be complete in the next 2-3 months
- Q1 2023 total revenue of \$9.4M, including product sales of \$7.9M, was a solid quarter, representing sequential growth from both Q4 2021 and from a year ago on a currency adjusted core basis. First time in the past 5 years that Q1 > Q4. Ended Q1 2023 with \$20.7M in cash
- Al Kraus, Chairman of the Board, announced his retirement at the end of his term next month after 20 years of leadership with the Company. Current Board Director, Michael Bator, will succeed him as Board Chairman, pending the results of the upcoming Annual Meeting
- Highlighted a key publication in Critical Care, underscoring the power of CytoSorb to reduce cytokine storm during systemic hyperinflammation caused by a key toxin in half of sepsis cases, in a well-controlled human study





Recent Operational Highlights



Hosted a successful and highly attended research symposium at the International Symposium of Intensive Care and Emergency Medicine (ISICEM 2023), highlighting data using CytoSorb to treat cytokine storm and inflammation in diseases such as sepsis, shock, and ARDS



2023: Eyes on the Prize

We are focused on three major objectives for 2023:



Opening the U.S. and Canadian markets with DrugSorb-ATR



Return to Sales Growth



Reduced Cash Burn and Tight Control Over Expenses





Opening the U.S. and Canadian markets with DrugSorb-ATR

- DrugSorb-ATR and STAR-T remains the core focus of our clinical efforts, and the vehicle expected to open the U.S. and Canadian markets. We have received 2 FDA Breakthrough Device Designations for DrugSorb-ATR to remove blood thinning medications that can increase the risk of perioperative bleeding in patients undergoing cardiothoracic surgery
- STAR-T enrollment is now in the last third of the trial. Enrollment has been brisk and has recently outpaced our own internal projections. Since recently announcing the achievement of 80 patients enrolled, the study continues to enroll well
 - Nearly all trial sites are enrolling, with strong contribution by both U.S. and Canadian centers
 - High enthusiasm for the study by trial centers
- We are pushing to complete STAR-T enrollment by this summer with topline data expected as soon as possible and before the end of the year. If positive, this would trigger regulatory submissions to both U.S. FDA and Health Canada
- In parallel to the clinical program, we are also executing on our regulatory strategy, that at this stage includes strengthening the regulatory team, planning for future regulatory submissions to both U.S. FDA and Health Canada, and driving interdepartmental alignment and responsibilities to meet our regulatory objectives and timelines
- Waiting on an update from CMS on their Transitional Coverage of Emerging Technologies (TCET) proposal that could provide 4 years of coverage to relevant approved Breakthrough Devices





Opening the U.S. and Canadian markets with DrugSorb-ATR

<u>Decision to Forego Interim Analysis at 80 Patients</u>

- As discussed recently, 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
- Accordingly, a trial that is fully enrolled cannot be stopped early, making an interim analysis of no value, and as such we are now focusing our efforts on the final analysis
- We believe it is also important to emphasize that there are no other considerations or information underlying this decision and that the STAR-T study data remain fully-blinded
- The next milestone for STAR-T is the second independent Data and Safety Monitoring Board (DSMB) safety evaluation after the first 80 patients which we expect to be completed in the next 2-3 months. As previously disclosed, the DSMB recommendation after the safety evaluation of the first 40 patients was to continue the study as planned without any modifications





Return to Sales Growth

- Sequential growth in Q1 2023 product sales from Q4 2022 and 8% quarterly core product sales growth year over year is an encouraging sign
- Seeing strong customer engagement, excellent feedback on our most recent clinical and scientific data, and a trend of improvement in our hospital markets in core countries – though healthcare worker staffing remains an issue
- In Germany, the numbers of ICUs reporting "normal operating conditions" is now higher than those under full restrictions, which has fallen by about 25%. Meanwhile, COVID-19 admissions to the ICU have dropped significantly, raising the prospect that ICU beds reserved for COVID-19 patients will be released, adding to ICU capacity. This is expected to translate into the ability to admit more non-COVID patients to the ICU and to do more surgical operations where patients need to recover in the ICU → all drivers of our business
- Among our many growth initiatives, we have increased the number of accounts in German private hospital networks by 50% in 2022 compared to 2021, based on our preferred supplier agreements
- Q1 2023 demand for CytoSorb was brisk, working down our finished goods inventory. Ramping
 production out of the new manufacturing facility, which is now in full production mode, with the
 goal of meeting demand and replenishing inventory



Financial Highlights

Kathleen Bloch, MBA, CPA
Interim Chief Financial Officer



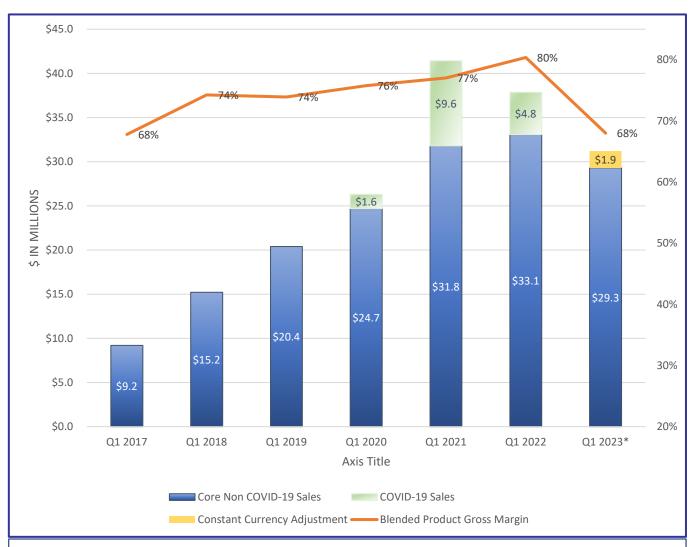
Comparative Quarterly Revenue Results

| | Quarter Ended Mar 31, 2023 | Quarter Ended Mar 31, 2022 | % Incr. |
|------------------------|-------------------------------|-------------------------------|---------|
| Product revenue | \$7,910,039 | \$7,924,457 | (0.2)% |
| Grant and other income | 1,539,457 | 766,967 | 100.7% |
| Total revenue | \$9,449,496 | \$8,691,424 | 8.7% |

- Total revenue, including product sales and grant income was \$9.4M in Q1 2023 compared to \$8.7M for Q1 2022
- Product sales for Q1 2023 were \$7.9M compared to approximately the same product sales in Q1 2022
- COVID-19 product sales were -0- vs. \$300K in Q1 2022
- FX negatively impacted Q1 2023 sales by \$349K. Constant currency product sales were \$8.3M up 8.3% Y-Y excluding COVID-19 sales
- Q1 2023 product gross margins were 68% compared to 80% for Q1 2022, due to start up activities at our new manufacturing facility
- Grant revenue was \$1.5M in Q1 2023 compared to \$767K in Q1 2022



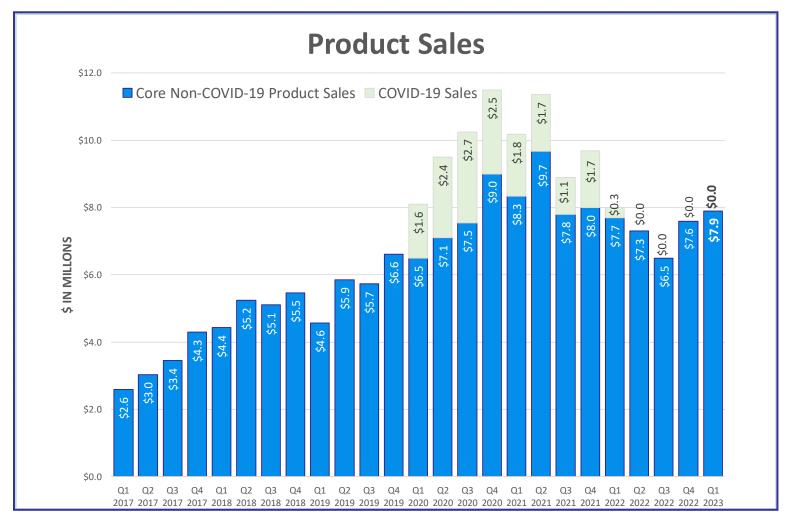
TTM Product Sales & Blended Gross Margin



*Q1 2023 GM decreased primarily due to start-up activities of the new manufacturing facility



Total Quarterly Product Sales



Quarter over quarter sales have been increasing over the past two quarters.



Reduced Cash Burn and Tight Control Over Expenses

- We have \$20.7M (includes \$1.7M of restricted cash) in cash as of March 31, 2023. This
 includes \$5M of loan proceeds received from our debt facility in December 2022. Cash on
 hand provides a runway of more than one year of operating cash flow
- We have taken strong actions to reduce our quarterly cash burn. Cash burn in Q1 2023 was \$3.1M, as compared to a quarterly cash burn of \$9.1M in Q1 2022. Reductions in the cash burn included:
 - Reduced staffing by 10% worldwide last year and implemented a Company-wide hiring freeze, excluding essential hires
 - De minimis cap ex needs having completed our new facility buildout
 - Reductions in non-grant R&D spend
 - Strict 2023 budget, prioritizing spend in key programs and pipeline projects
- While cash burn may increase slightly as we build additional inventory to support sales; however, our product gross margins should improve with scaled-up of production with the expectation of returning to quarterly 75-80%+ product gross margins this year
- Our spend is fully aligned with our strategic priorities, in particular our STAR-T clinical trial designed to obtain US FDA marketing approval



Concluding Remarks

Phillip Chan, MD, PhD Chief Executive Officer



CytoSorbents 2023 – Eyes on the Prize

CytoSorbents 2023 is a rapidly evolving story making progress on these three key objectives:

- Opening the U.S. and Canadian markets with DrugSorb-ATR
- Return to Sales Growth
- Reduced Cash Burn and Tight Control Over Expenses
- We have a strong management team to lead, a fantastic employee base to drive, and a solid cash balance to fund, the timely execution of these key objectives
- We have an excellent high margin razorblade business model with a 10-year history of successful commercialization with more than 200,000 CytoSorb treatments delivered cumulatively across 75 countries worldwide, riding major trends in healthcare
- We believe the story will look very different soon, with our "eyes on the prize" on executing these three key milestones that are expected to drive our current and future success



Many Thanks and a Fond Farewell!



Al Kraus
Chairman of the BOD (2009-2023)
CEO (2003-2008)



Kathy Bloch Chief Financial Officer (2013-2023) Interim CFO (present)



Q&A Session

CytoSorbents Corporation

NASDAQ: CTSO

Investor Contact
Kathy Bloch
Interim Chief Financial Officer
kbloch@cytosorbents.com





WORKING TO SAVE LIVES



