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# CytoSorbents Corporation

Nasdaq: CTSO

Q2 2025 Financial Results and Recent Business Highlights Conference Call  
August 7, 2025

**CytoSorbents**<sup>TM</sup>

# Conference Call Participants



**Phillip Chan, MD, PhD**  
Chief Executive Officer



**Peter J. Mariani, CPA**  
Chief Financial Officer



**Moderator: Adanna Alexander, PhD**  
VP Investor Relations, ICR Healthcare

# 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, the restructuring of our direct sales team and strategy in Germany, our ability to resolve deficiencies in the FDA denial letter and the Health Canada Notice of Refusal and/or successfully appeal the FDA's and Health Canada's decision, competition, inability to achieve regulatory approval for our devices, 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 2024 Form 10-K filed with the Securities and Exchange Commission on March 31, 2025, and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).



# Operational Update

**Phillip Chan, MD, PhD**  
**Chief Executive Officer**

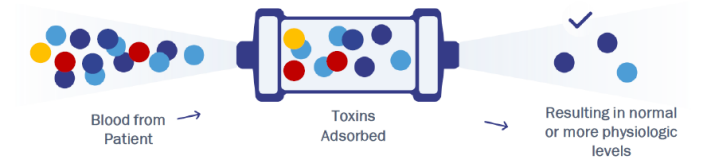
# CytoSorbents at a Glance

- **Platform** blood purification technology for removing toxins and harmful substances from the blood
- **High margin** “razorblade” that is “plug and play” into existing hospital blood pumps
- **Two main products** leveraging the underlying polymer technology

## CytoSorb



- Treatment of life-threatening conditions in the ICU and cardiac surgery
- Record core product sales of **\$35.6 million** in 2024
- E.U. Approved with **nearly 300,000** CytoSorb devices utilized cumulatively to date in 70+ countries



- Investigational device to reduce the severity of perioperative bleeding during CABG surgery due to blood thinners
- **Two FDA Breakthrough Device Designations**
- **Currently navigating appeals with FDA and Health Canada with final regulatory decisions expected in 2025**
- If approved/cleared, we expect to begin commercialization rapidly, targeting a significant unmet need in large U.S. and Canada addressable markets

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# Agenda

- **Q2 2025 Performance Summary**
- **Regulatory/Clinical Update on DrugSorb-ATR**
- **Turning the Tide in Sepsis and Septic Shock with CytoSorb**
- **Financial Results and Cash**

# Q2 2025 Performance Summary

- Q2 2025 Revenue was \$9.6M, a 9% increase vs \$8.8M a year ago, or 4% on a constant currency basis
- Performance led by Germany growth of 22% year-over-year and sequentially following pro-active reorganization initiated in Q1, and continued strength in our other direct EU territories
- Distributor sales were among our best ever, second only to a record Q2 2024
- With Q2 behind us we are pleased with our initial progress of our Germany reorganization and remain confident it will lead to stronger execution, improved performance, and more robust sales growth in our overall business this year and beyond
- Product gross margin was steady at ~71%, consistent with the average from 2024
- Operating expenses were slightly higher in the quarter due to new unique operating and strategic charges, but we remain committed to reducing core business operating costs and drive efficiencies to manage our total core business toward near breakeven as we exit 2025





# DrugSorb™ Update ATR

CytoSorbents™



# Blood Thinners Can Cause Serious Perioperative Bleeding

## DrugSorb-ATR can help

- Acute heart attack patients commonly receive blood thinners like Brilinta® to improve clinical outcomes
- But Brilinta® (ticagrelor) can cause serious and potentially life-threatening bleeding in patients that need to undergo urgent coronary artery bypass graft (CABG) surgery
- Only drug washout for 3-5 days can reduce the risk of serious bleeding. However:
  - Frequently, surgery cannot wait - patients now risk major bleeding
  - Delaying surgery in a patient who is still having a heart attack risks complications like sudden death, and is expensive and an inefficient use of hospital resources
- DrugSorb-ATR is a Breakthrough Designated Device intended to solve this pervasive and serious unmet medical need in the U.S. and Canada that puts tens of thousands of patients at risk each year.
- DrugSorb-ATR addresses an estimated \$300+M initial market opportunity that could exceed \$1B as Brilinta® becomes generic and DrugSorb-ATR expands to additional indications



# Continued Real World Validation

Continue to demonstrate and be recognized for the ability to address the critical global unmet need of reducing serious bleeding in CABG patients on Brilinta®

- At EuroPCR (May 2025), Prof. Robert Storey presented a new comparative analysis of bleeding risk in 150 CABG patients on Brilinta® with CytoSorb (STAR Registry) vs 644 control CABG patients on Brilinta® without CytoSorb\*
  - Key findings: CytoSorb led to highly significant reductions in:
    - Rates of severe CABG-related bleeding (10.7% vs 33% control,  $p < 0.001$ )
    - Large transfusion events ( $\geq 5$  units of blood): 6% vs. 27% control,  $p < 0.001$ )
    - Need for re-operations to control bleeding (4% vs. 9.6% control,  $p = 0.02$ )
- At the 73rd International Congress of the European Society for Cardiovascular and Endovascular Surgery (May 2025), Prof. Matthias Thielmann received the “Best Oral Presentation Award” for his talk “Early CABG with Intraoperative Hemoadsorption in Patients on Ticagrelor: Real World Data from the International Safe and Timely Antithrombotic Removal (STAR) Registry”

2025 | euro  
PCR



# FDA and Health Canada Regulatory Update

- U.S. FDA De Novo submission and Medical Device License application to Health Canada included STAR-T RCT data and STAR registry real world evidence (RWE)
- Interactive review with FDA resolved many issues, however, a denial letter was issued April 25, 2025
- Formal in-person appeal hearing with FDA was conducted in July 2025
  - Comprehensive presentation of our De Novo submission with attendance by FDA senior officials and review team, the Company, our FDA regulatory counsel, and in-person testimony from our external cardiac surgery clinical experts
  - As an FDA Breakthrough Device, we continue to believe we can resolve remaining deficiencies in our De Novo Request
  - Expect appeal conclusion by this month, with three potential outcomes: Reversed, reversed with conditions, or upheld
- Continue to work with Health Canada following receipt of Health Canada's Notice of Refusal on June 26, 2025, citing certain deficiencies in our application
  - Filed a Level 1 "Request for Reconsideration" and with Health Canada agreement, will pursue this reconsideration following completion of the FDA appeal process
- We continue to expect final regulatory decisions in U.S. and Canada in 2025 and continue to prepare for potential North American commercialization



# CytoSorb Update

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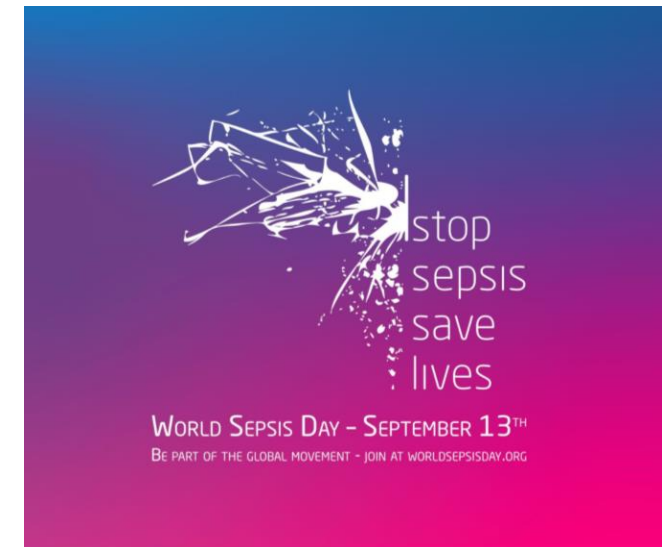
# Turning the Tide of Sepsis and Septic Shock





# Sepsis and Septic Shock are Deadly

- Sepsis is a complex life-threatening condition where the inflammatory response to a serious infection can spiral out of control, fueled by the excessive production of cytokines (cytokine storm), bacterial toxins, and other inflammatory agents
- Unchecked, massive inflammation can lead to Septic Shock – an often fatal complication marked by circulatory collapse and a lethal drop in blood pressure and a host of other problems like capillary leak and fluid overload that can lead to multiple organ failure and death
- Sepsis and septic shock afflict an estimated 49 million people worldwide each year, killing 11 million, and accounts for 1 in 5 deaths globally
- Supportive care treatment has improved, but mortality is still unacceptably high, despite antibiotics, fluids, vasopressors, and mechanical “life support”
- September is Sepsis Awareness Month and September 13<sup>th</sup> is World Sepsis Day, designed to create greater awareness of this pervasive problem



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# CytoSorbents is Leading a New Era in Sepsis Treatment

For more than a decade, CytoSorbents has collaborated with clinicians and scientists around the world to advance the treatment of sepsis and septic shock by complementing traditional antibiotics with the broad-spectrum capability of CytoSorb



Antibiotics treat the infection



CytoSorb treats the deadly inflammatory response by removing the “fuel to the fire” that causes a system crash



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# CytoSorb Enables Multi-Faceted Attack on Septic Shock

A wealth of published, peer-reviewed studies support the broad mechanisms of action of CytoSorb that enable a comprehensive and multi-faceted attack on septic shock – from beginning to end

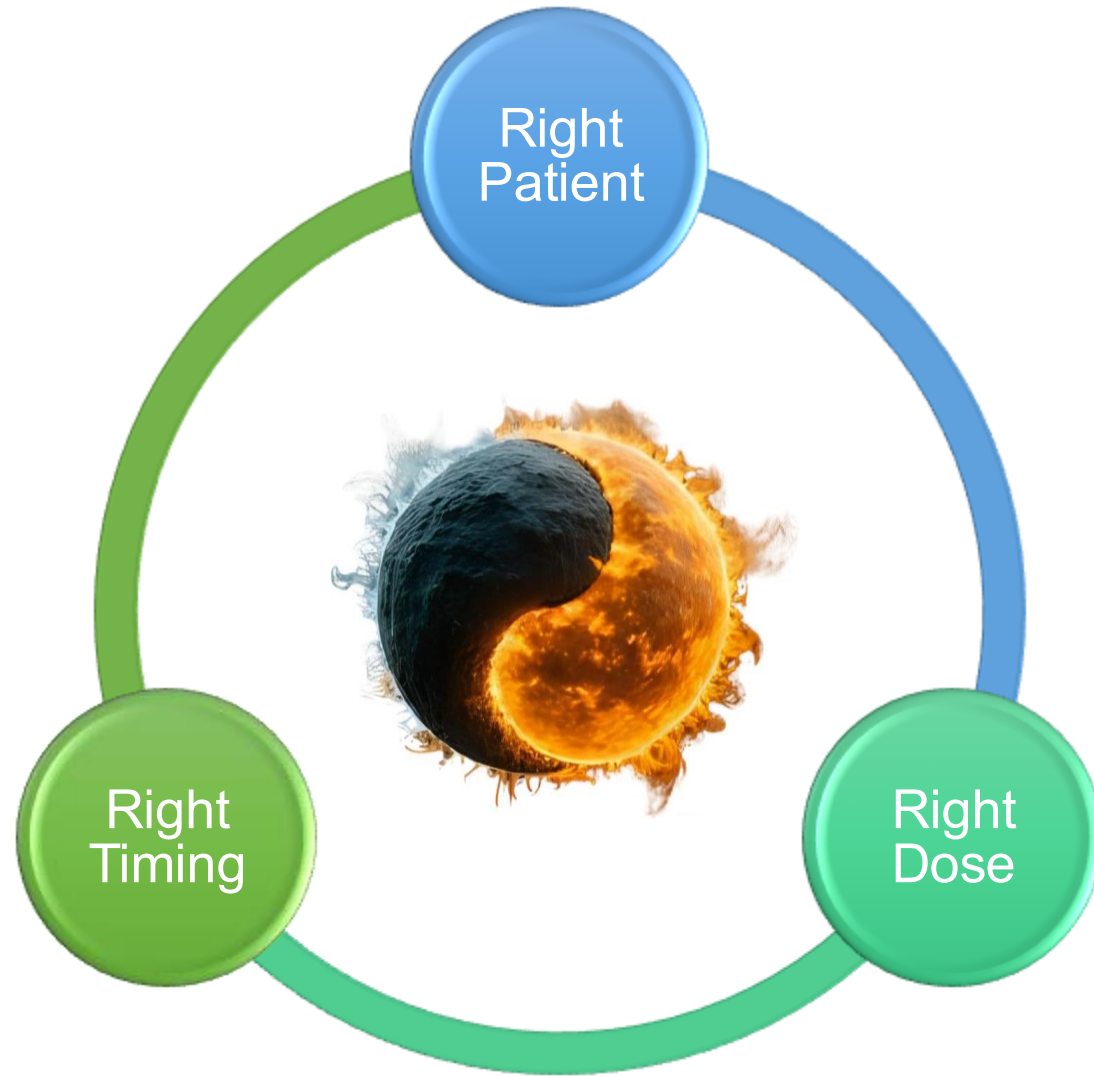
## CytoSorb enables the Core Treatment Goals in Septic Shock to Help Patients Recover

- Break the vicious cycle of uncontrolled inflammation
- Reverse shock and restore oxygenated blood flow
- Promote the repair of leaky blood vessels
- Actively remove excessive fluid and reduce fluid overload in organs
- Prevent or treat multiple organ failure



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# The Key to Success: Right Patient, Right Timing, Right Dosing



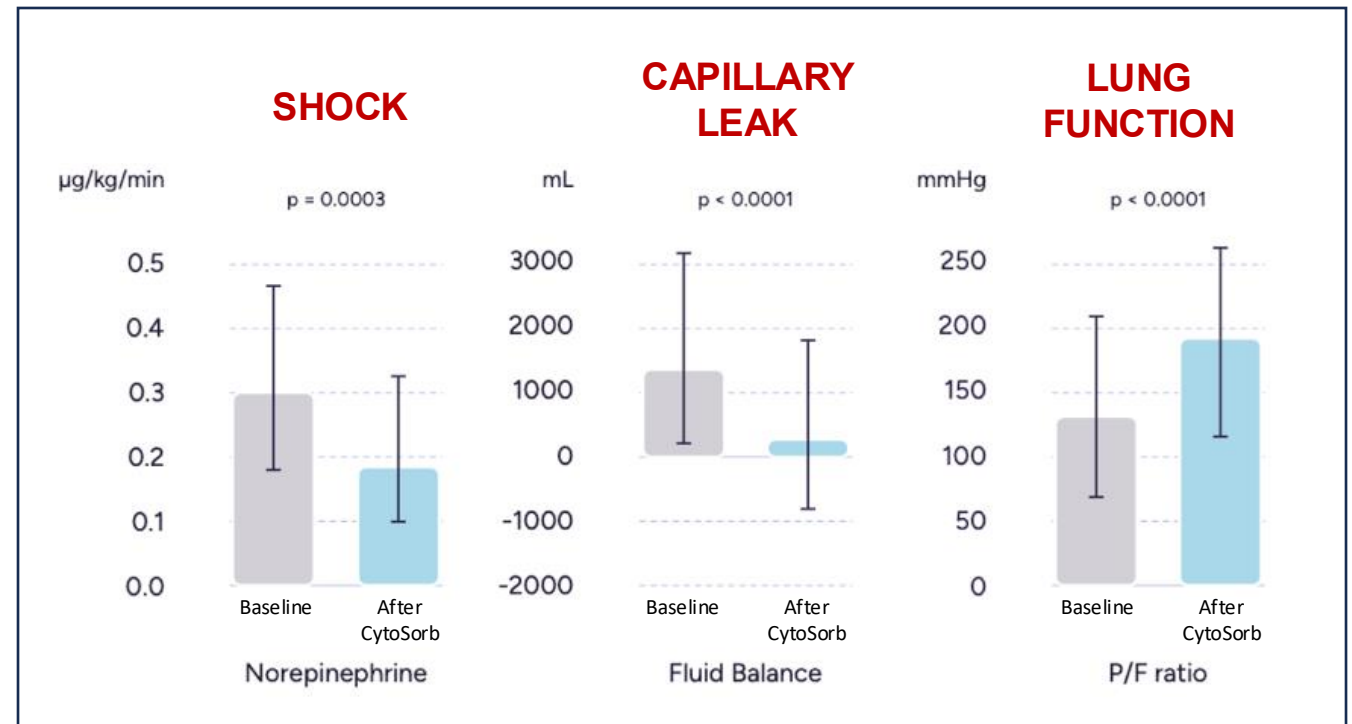
Just like antibiotics, CytoSorb works most effectively when:

- Treat Early
- Treat Intensively
- Complete the Full Course of Treatment

# 2025: COSMOS Registry Highlights Treatment Strategy Success

## COSMOS registry, patient characteristics

- Data from 150 patients analyzed
- Critical care indications:
  - ✦ Septic shock (57.6%)
  - ✦ Cardiogenic shock (12.9%)
  - ✦ Rhabdomyolysis (10.6%)
  - ✦ Acute/acute-on-chronic liver failure (10.6%)
  - ✦ Acute respiratory distress syndrome (6.8%)
  - ✦ Others (9.1%)



## When added to standard therapy, CytoSorb treatment:

- Led to significant improvements in fundamental problems in critical illness: Shock, capillary leak, and lung function
- Observed mortality rates in Registry participants were lower compared with the predicted mortality rates according to standardized and established critical care risk scores

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# 2025: Early & Intensive Treatment with More Blood Treated Works Best



Original Research

## Real-World Outcomes of Hemoadsorption with CytoSorb® in Patients with Septic Shock: Insights from a Single-Center Study

Giorgio Berlot, MD<sup>1</sup> , Paolo Carocci, MD<sup>1</sup>, Valentina Votrico, MD<sup>2</sup>, Barbara Iacoviello, MD<sup>1</sup>, Nicolò Taverna, MD<sup>1</sup>, Ugo Gerini, MD<sup>3</sup>, Vittorio di Maso, MD<sup>4</sup>, and Ariella Tomasini, MD<sup>1</sup>

- Large, retrospective single center study
- 175 patients with septic shock treated with CytoSorb
- Evaluated the impact of early versus late, and low versus high intensity treatment with CytoSorb on mortality compared to predicted mortality based on illness severity scores

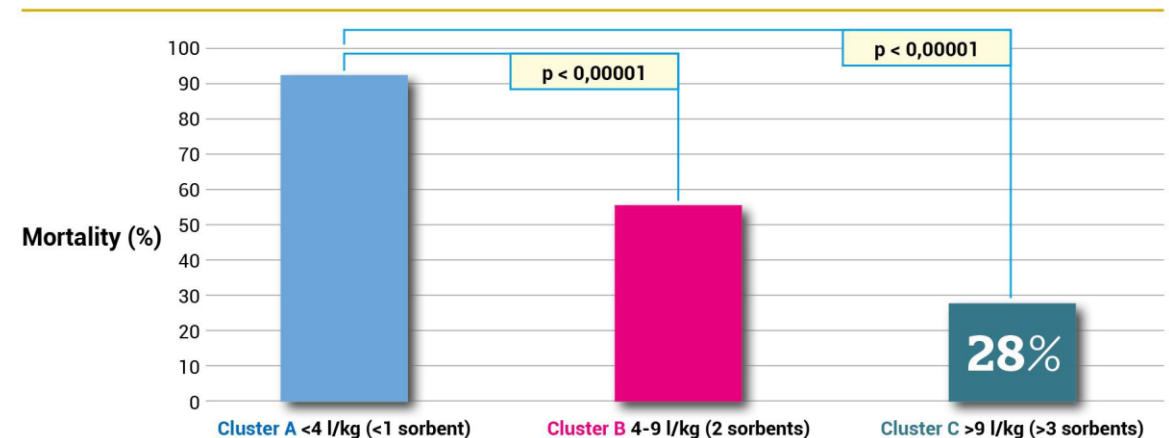
## Early and Intensive Treatment with CytoSorb Doubles Survival Expectation

**Table 3.** Observed Versus Expected Mortality (%).

Categories	Expected mortality (%)	Observed mortality (%)	p-value
All (n = 175)	66	49	0.048
Early starters (n = 102)	66	48	n.s.
Late starters (n = 73)	70	51	n.s.
High intensity (n = 90)	63	30	0.002
Low intensity (n = 85)	71	69	n.s.
Early starters-high intensity (n = 56)	63	30	0.02
Late starters-low intensity (n = 38)	74	68	n.s.

Abbreviations: n.s., nonsignificant.

## The More Blood Purified with CytoSorb, the Higher the Survival. Treatment Intensity is Key



# CytoSorb Septic Shock Meta-Anaysis



Systematic Review

## Hemoadsorption in the Management of Septic Shock: A Systematic Review and Meta-Analysis

David Steindl <sup>1,†</sup>, Tim Schroeder <sup>2,†</sup>, Alexander Krannich <sup>3,\*</sup> and Jens Nee <sup>2</sup>



- Meta-analysis of 744 septic shock patients from 1 RCT and 8 observational studies from 2019-2024, of which 449 patients were treated with CytoSorb
- CytoSorb reduced in-hospital mortality (OR 0.64, p=0.04)
- 28-30-day mortality was also halved with CytoSorb (OR 0.46, p=0.003) than without (p=0.003)
- Significant hemodynamic improvement with reductions in vasopressor need in CytoSorb patients again confirmed

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# World Sepsis Day Global Webinar – September 10, 2025

## Turning the Tide in Sepsis and Septic Shock: Real World Insights with CytoSorb

**Date:** Wednesday, September 10, 2025

**Time:** 11:00 AM EDT

**Hosted by:** Dr. Phillip Chan, MD, PhD

**Webinar registration required:** <https://cyto.news/webinar-sepsis/sep10>



# Financial Highlights

**Peter J. Mariani**  
**Chief Financial Officer**



# Revenue and Gross Margin

	2Q25	2Q24	YoY Change
<b>Revenue</b>	<b>\$9.6m</b>	<b>\$8.8m</b>	<b>+9%</b>
Constant currency growth			+4%
<b>Gross Profit</b>	<b>\$6.8m</b>	<b>\$6.5m</b>	<b>+5%</b>
<b>Gross Margin</b>	<b>70.9%</b>	<b>73.5%</b>	

- Revenue led by 22% growth year-over-year and sequentially in Germany with continued strength in our other direct territories
- Distributor sales were among our best ever, second only to a record Q2 2024
- We are pleased with the initial results of our proactive reorganization of our German commercial team and sales approach
- 2Q25 GM is consistent with 2024 average and 1Q25

# Operating Results

	2Q25	2Q24	YoY Change
Total operating expenses	<b>\$10.4m</b>	\$10.1m	3% increase
Operating loss	<b>\$3.6m</b>	\$3.6m	flat
Net income / (loss)	<b>\$1.9m</b> (\$0.03 / basic and diluted sh)	(\$4.3m) (\$0.08 / basic and diluted sh)	
Adjusted net income / (loss)	<b>(\$3.7m)</b> (\$0.06 / basic sh; \$0.05 / diluted sh)	(\$2.8m) (\$0.05 / basic and diluted sh)	
Adjusted EBITDA loss	<b>\$2.6m</b>	\$2.2m	

\*Non-GAAP measures including EBTIDA, Adjusted, EBITDA, and Adjusted Net Loss, and Adjusted Net Loss per share. We use these non-GAAP financial measures for financial and operational decision-making and to evaluate period-to-period comparisons. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our performance and that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting, and analyzing future periods.

# **Strong Balance Sheet**

## **Driving Core Business toward Cash Flow Breakeven as we exit 2025**

- \$11.7 million in cash, cash equivalents and restricted cash at June 30, 2025
- Includes \$1.7 million received in April from Sale of NOL and R&D credits
- \$5.0 million second tranche available at our option on our debt agreement
  - Requires FDA approval of DrugSorb-ATR prior to December 31, 2025

**We continue to prioritize initiatives to drive revenue growth, improve gross margins, and reduce costs to lead our core business toward cash-flow breakeven as we exit 2025, and allow for investment in our North American commercial launch of DrugSorb-ATR later this year and into 2026.**



# Closing Remarks

**Phillip Chan, MD, PhD**  
**Chief Executive Officer**

# A Clear and Compelling Value Proposition

- ✓ CytoSorb is an established, international core business in critical care and cardiac surgery with \$35M+ in high margin product sales with expectations for growth due to:
  - Significant market opportunity, targeting major unmet medical needs
  - “Right patient at the Right Time with the Right Dose of CytoSorb”
  - Strong growth from Direct sales outside Germany and Distributor/Partner sales
  - Active measures to restore Germany back to growth with encouraging progress
- ✓ Goal is to drive towards near breakeven in this core business and achieve financial independence
- ✓ We remain committed to bringing DrugSorb-ATR to the North American market, and continue to believe that we can successfully work through remaining questions on our application with the FDA and Canada and expect to have final regulatory decisions in 2025
  - Actively preparing as we wait for regulatory decisions from FDA and Health Canada

# Q&A Session

## NASDAQ: CTSO

### Company Contact:

Peter J. Mariani

[pmariani@cytosorbents.com](mailto:pmariani@cytosorbents.com)

### Investor Relations Contact:

Aman Patel, CFA & Adanna Alexander, PhD

ICR Healthcare

[ir@cytosorbents.com](mailto:ir@cytosorbents.com)



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