



The Emergence of

**DrugSorb**<sup>TM</sup>  
ATR

**CytoSorbents Corporation**

Nasdaq: CTSO

Q3 2024 Earnings

Conference Call

November 7, 2024

DrugSorb-ATR is an investigational device currently under U.S. FDA and Health Canada review.  
It is not yet approved or cleared in any country.

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

# Conference Call Participants



Moderator: Adanna Alexander, PhD  
ICR Healthcare



Phillip Chan, MD, PhD  
Chief Executive Officer



Vincent Capponi, MS  
President and Chief Operating Officer



Peter Mariani, CPA  
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

# 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 2022 Form 10-K filed with the Securities and Exchange Commission on March 14, 2024, 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

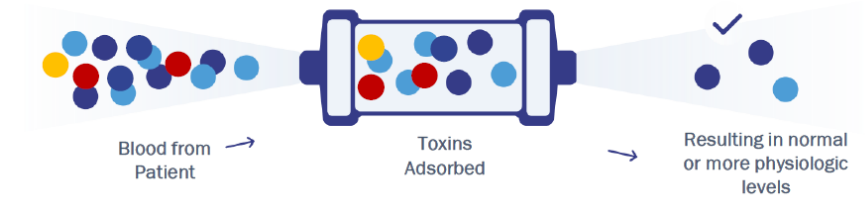
- **Platform** blood purification technology for removing harmful substances from the blood
- **High margin** “razorblade” that is “plug and play” into existing hospital blood pumps
- **Two main products** leveraging the underlying polymer technology

- **CytoSorb**

- Treatment of life-threatening conditions in the ICU and cardiac surgery
- Legacy \$30-35 million product revenue base business (100% OUS)
- >250,000 CytoSorb devices utilized cumulatively to date

- **DrugSorb<sup>™</sup>**  
ATR

- Investigational device to remove “blood thinners” / antithrombotic drugs during urgent cardiovascular surgery
- Two FDA Breakthrough Device Designations
- Submitted to FDA and Health Canada in 2024 with regulatory decisions expected in 2025
- Significant unmet need for DrugSorb-ATR in large US and Canada addressable market



# Third Quarter 2024 Highlights

- ✦ Solid top line performance of our core international critical care business
- ✦ Improvements in operating efficiencies
- ✦ Continued development of real-world clinical evidence supporting our therapies
- ✦ Key regulatory milestones achieved for DrugSorb-ATR in North America



# Solid Progress in Third Quarter 2024

Metric	Performance
Product revenue	\$8.6M, 11% year-over-year growth
Gross margin	61% (planned slowdown and short-term manufacturing issue that was resolved in the quarter)
Operating expenses	25% year-over-year decrease
Operating loss	40% year-over-year reduction
Cash burn	\$2.7 million, down from \$5 million in 2Q24

**With the exception of CytoSorb in the E.U., there are no approved reversal agents for Brilinta in the U.S., E.U., or Canada**



- ✦ Cardiac surgeons frequently encounter patients on anti-thrombotics needing urgent surgery
- ✦ Guidelines recommend that such patients wait for 3-5 days for these drugs to “washout” to avoid bleeding complications
- ✦ Frequently, surgery cannot wait, and patients are operated at a very high risk for major bleeding complications
- ✦ Delaying surgery for washout is also not optimal
  - ✦ Patient’s coronary artery is still blocked, exposing them to risk for complications while waiting
  - ✦ Significant cost, particularly depending on where the patient is waiting to wash out
  - ✦ Hospital efficiency is reduced when beds are occupied with patients waiting

**Room and Board – Per Day Charges** as of January 1, 2023.

Coronary care	\$ 6,156	Chemical Dependency/Detox	\$ 1,998
Intensive care	\$ 6,156	Neonatal Intensive Care	\$ 6,156
Medical/Surgical	\$ 2,420	Skilled Nursing	\$ 1,998
Step Down	\$ 4,070	Rehabilitation	\$ 1,998
Psychiatry	\$ 1,998		





# STAR-T RCT: Conclusions

In the U.S. & Canadian 140-patient pivotal STAR-T RCT evaluating the safety and efficacy of DrugSorb-ATR to reduce the severity of perioperative bleeding in cardiac surgery patients when used within 2 days of Brilinta (ticagrelor, AstraZeneca) discontinuation, the Principal Investigators of the study concluded:

- Primary safety endpoint was met
- Primary efficacy endpoint was not met in the all-comer surgery population
- However, the severe bleeding efficacy endpoint was met in the isolated CABG PP population (>90%)
- In isolated CABG patients, the intraoperative use of DrugSorb-ATR was associated with:
  - Reduced bleeding severity by either Universal Definition of Perioperative bleeding (UDPB) grade or 24-hour Chest Tube Drainage (CTD) volume
  - NNT (Number Needed to Treat) of 6 to prevent a major bleed (UDPB  $\geq$  3 event, or >1L 24-hour CTD bleed)
  - Overall favorable benefit-to-risk profile

**A replay of the KOL and Analyst/Investor Day event where these data were presented can be found at:**

**<https://lifescievents.com/event/cytosorbents/>**

## U.S. FDA

- ✦ Submitted De Novo medical device marketing application to the FDA – Sept 27, 2024 and accepted by FDA in October 2024, initiating substantive review
- ✦ FDA Breakthrough Device Designation makes DrugSorb-ATR eligible for priority review

## Health Canada

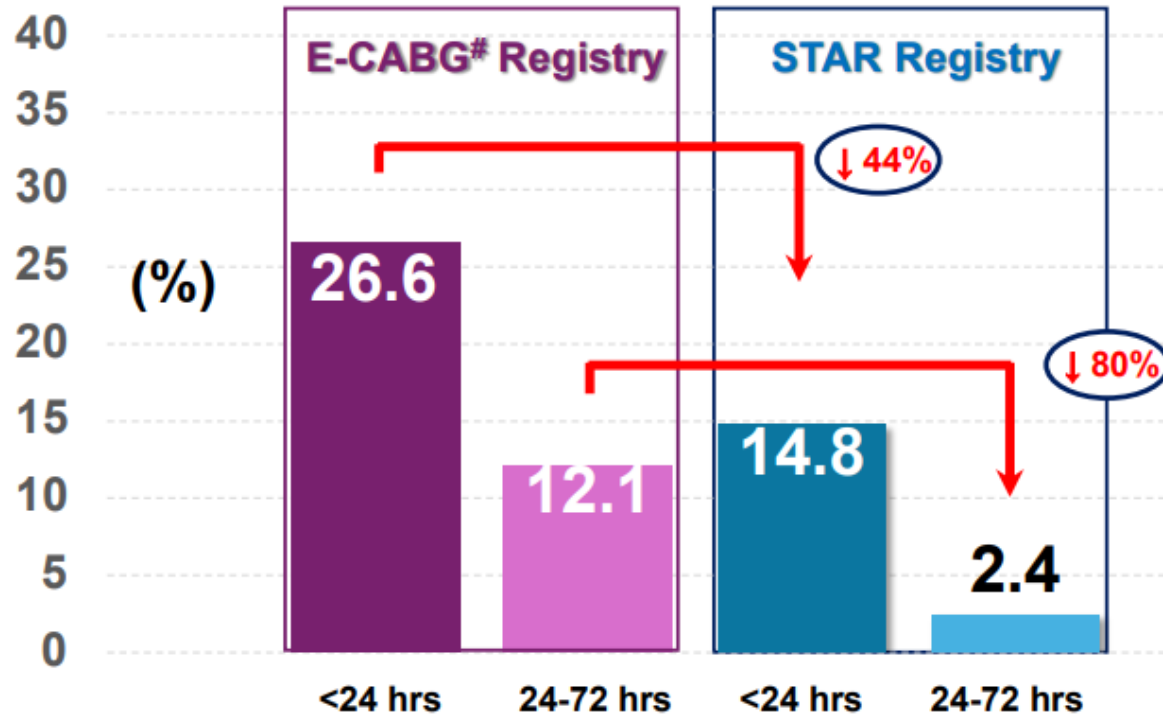
- ✦ Received Medical Device Single Audit Program (MDSAP) certification
  - ✦ Pre-requisite for filing Medical Device License (MDL) Application
  - ✦ MDSAP certifies the compliance of our quality management system with the standard and regulatory requirements of Canada, the United States, Brazil, Japan, and Australia.
  - ✦ FDA accepts MDSAP certification and audit reports as a substitute for routine Agency inspections, if required
- ✦ Submitted MDL Application to Health Canada



Regulatory  
decisions expected  
in 2025



Submitted real-world evidence from an additional 102 CABG patients on Brilinta to support FDA and Health Canada submissions. Suggests guideline-recommended washout period of a minimum of 72 hours may be substantially shortened with CytoSorb and DrugSorb-ATR



#Holm et al., Ann Thorac Surg. 2019;107:1690-1698

## STAR Registry (vs. Real World E-CABG Registry Benchmark)

- ✦ STAR (with CytoSorb) and E-CABG (no CytoSorb) Registries report bleeding outcomes in CABG patients on Brilinta
- ✦ Time from last dose (TLD) < 24h had higher bleeding rates in both registries
- ✦ STAR has lower rates of severe bleeding at any TLD
  - ✦ 44% lower with TLD <24h
  - ✦ 80% lower with TLD 24-72h

- ✦ If approved/cleared, DrugSorb-ATR has potential to improve the standard of care in heart attack patients requiring CABG surgery by enabling safe and timely surgery while reducing treatment delays that expose patients to additional risk and consume valuable hospital resources

## Patients

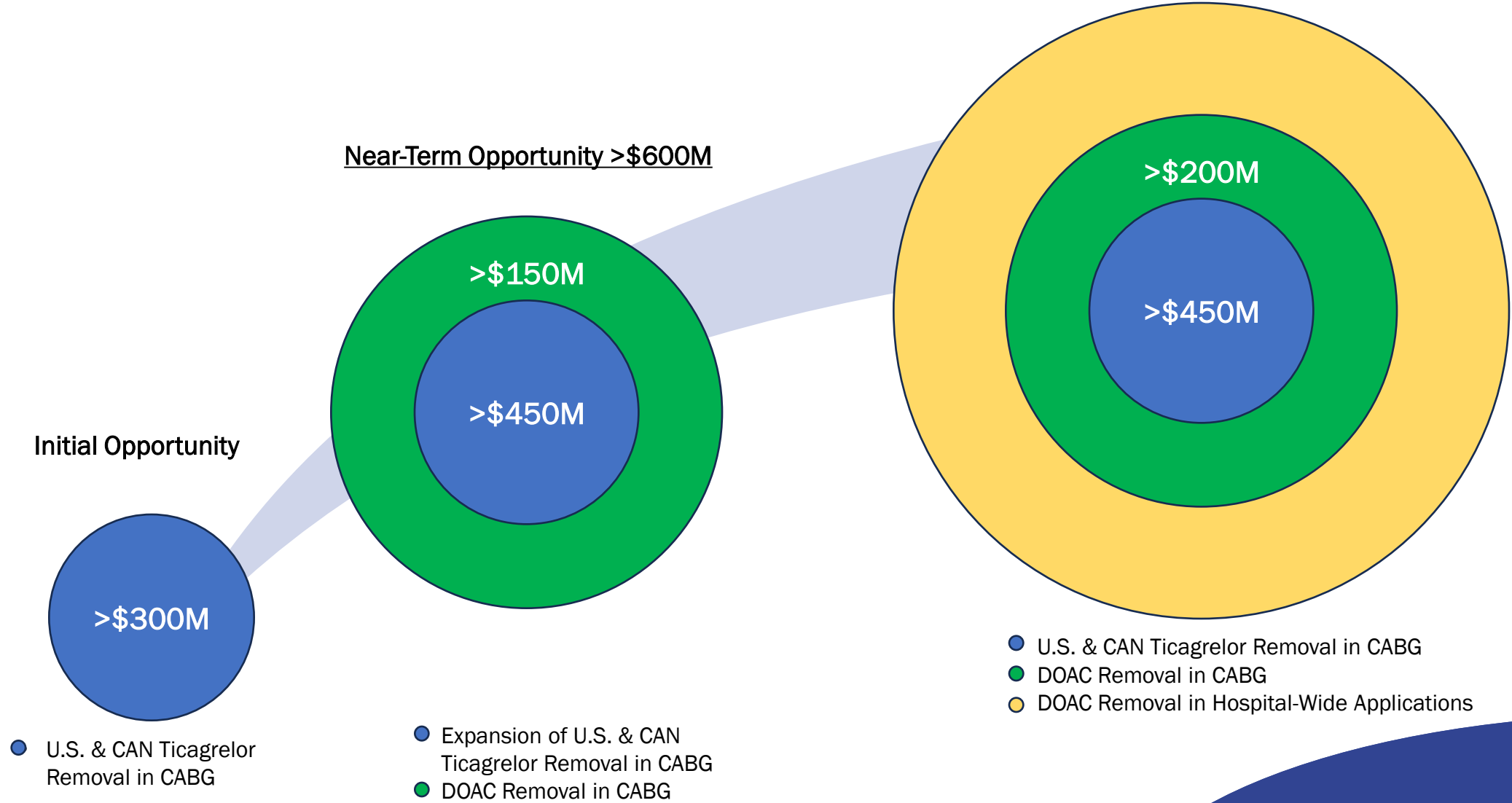
- Potential to reduce serious bleeding complications
- May minimize delays to definitive surgery and avoid complications of waiting

## Surgeons

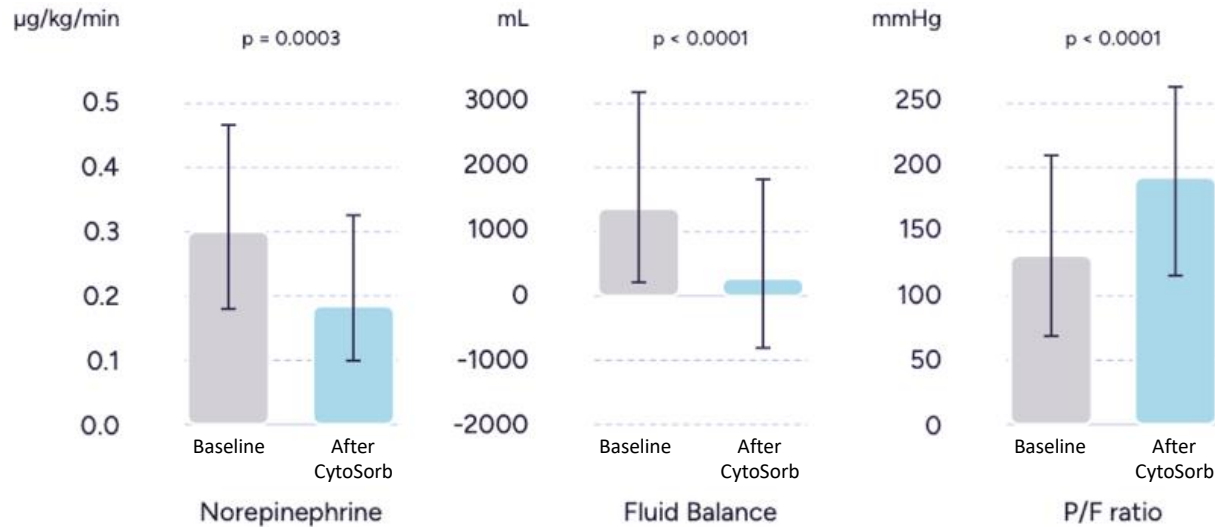
- No major change in workflow, seamless integration into CPB machine
- Protect surgical outcomes and a surgeon's quality rating by reducing complications that are not in the surgeon's direct control

## Hospital Administrators

- Reduces hospital resource utilization for patients who need to wash out the drug
- By reducing serious bleeding complications, it can streamline the scheduling and revenue generation of profitable cardiac surgeries



# CytoSorb Benefits Inflammation-Driven Critical Care Indications



## 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 key clinical markers and outcomes
- ✦ Led to observed mortality rates in Registry participants that were lower compared with the predicted mortality rates according to standardized and established critical care risk scores

# PuriFi<sup>®</sup> - Easy-to-Use Pump Expected to Drive CytoSorb Growth

- Easy-to-use pump supports earlier treatment of patients with CytoSorb without the complex set-up and maintenance of a full dialysis or CRRT machine
- Approximately 60 units received through 9/30;
- Many are placed or in evaluation with customers, with others in process
- Very well-received by users
- Expect to facilitate future Cytosorb revenue growth



# A Simple and Compelling Value Proposition

- ✓ Solid top line performance of our core international critical care and cardiac surgery business
- ✓ Improvements in operating efficiencies, margin expansion, with the goal of cash flow breakeven
- ✓ Key regulatory milestones achieved for DrugSorb-ATR in North America with regulatory decisions in 2025 that could be catalytic to the company, allowing us to enter the large and important U.S. and Canadian markets, which we believe will position us well for our next phase of growth





# Financial Highlights

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

# Solid Product Revenue

	Performance		
Metric	3Q24	3Q23	YoY Change
Product revenue	\$8.6 million	\$7.8 million	+11%
Grant revenue	\$0.8 million	\$1.1 million	-27%
Total revenue	\$9.4 million	\$8.8 million	+7%

# Product Gross Margin to Normalize Through 4Q24

	Performance	
Metric	3Q24	3Q23
Product gross margin	61%	72%

# Improved Operating Leverage

	Performance		
Metric	3Q24	3Q23	YoY Change
Total operating expenses	\$9.7 million	\$13.0 million	25% decrease
Operating loss	\$4.4 million	\$7.4 million	40% improvement

# Additional Performance Metrics\*

	Performance	
Metric	3Q24	3Q23
EBITDA loss	\$1.4 million	\$8.8 million
Adjusted EBITDA loss	\$3.6 million	\$5.6 million
Net loss	\$2.3 million or \$0.04 per share	\$9.2 million or \$0.21 per share
Adjusted net loss	\$4.5 million or \$0.08 per share	\$6.0 million or \$0.14 per share

\*We are introducing additional, non-GAAP measures including EBITDA, Adjusted, EBITDA, and Adjusted Net Loss, and 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.

# Cash Conservation – A Top Corporate Priority

## Reduced cash burn during the quarter

- ✦ Cash burn was approximately \$2.7 million during the quarter versus approximately \$5.0 million in Q2 2024

## Cash balance as of September 30, 2024

- ✦ \$12.2 million in cash
- ✦ Includes \$6.5 million of restricted cash and \$5.7 million in unrestricted cash

## Optionality with current loan and security agreement

- ✦ Secured a \$20 million loan facility in June 2024, with \$10 million immediately accessible and \$5 million held as restricted cash, contingent on FDA acceptance of our DrugSorb-ATR marketing application which was recently received, and receipt of \$3-5 million in equity proceeds by March 31, 2025.
- ✦ A remaining tranche of \$5 million is available at the Company's option between July and December 2025, conditioned on FDA marketing approval of DrugSorb-ATR

# Q&A Session

## NASDAQ: CTSO

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