CytoSorbents Corporation

Nasdaq: CTSO

Q1 2025 Financial Results and Recent Business Highlights

Conference Call

May 14, 2025

CytoSorbents™

Conference Call Participants

Phillip Chan, MD, PhD
Chief Executive Officer

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

Efthymios “Makis” Deliargyris
MD, FACC, FESC, FSCAI
Chief Medical Officer

Peter J. Mariani, CPA
Chief Financial Officer

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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 through a successfully appeal the FDA'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.

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Operational Update

Phillip Chan, MD, PhD
Chief Executive Officer

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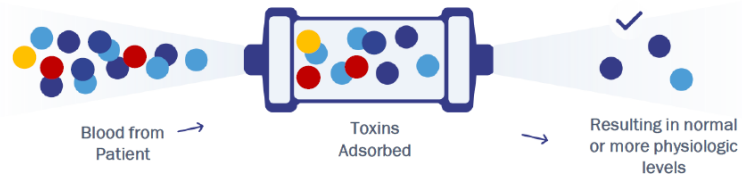
CytoSorbents at a Glance



- **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 **> 270,000** CytoSorb devices utilized cumulatively to date in 70+ countries

DrugSorb ATR

- Investigational device to reduce the severity of perioperative bleeding during CABG surgery due to blood thinners
- **Two FDA Breakthrough Device Designations**
- **Submitted to FDA (9/2024)** and **Health Canada (11/2024)** 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

* CytoSorb and DrugSorb-ATR are not yet cleared or approved in the U.S. or Canada

Agenda

- **Core CytoSorb Sales**
- **Regulatory/Clinical Update on DrugSorb-ATR**
- **Operating metrics and cash**

CytoSorb Update

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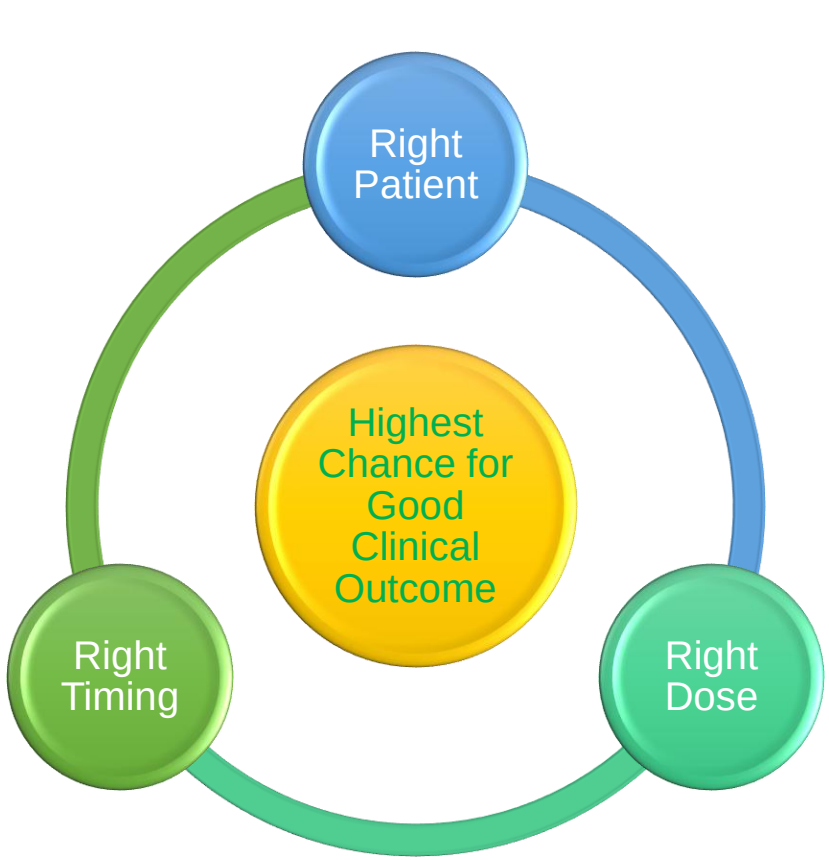
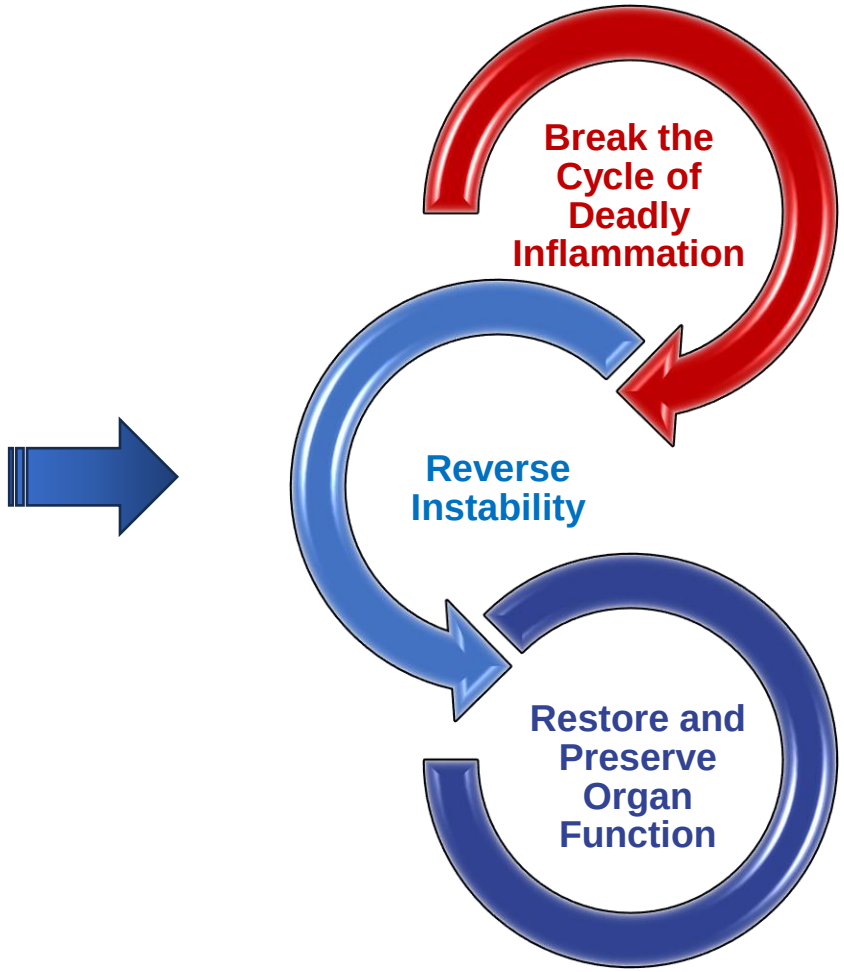
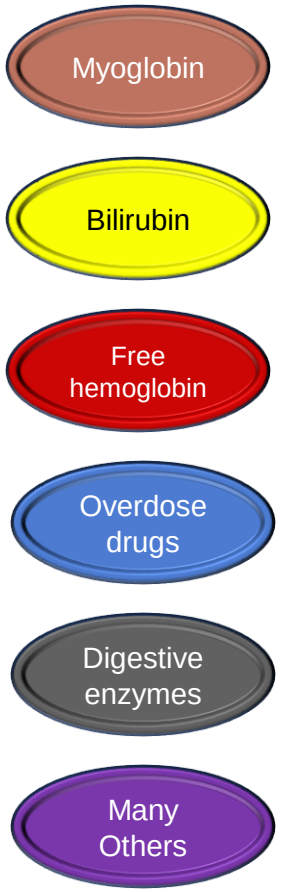
Q1 2025 Sales Overview

- Q1 2025 Product Sales were $8.7M, a 3% decrease y-o-y. On a constant currency basis, sales were flat
- Strong performance from International Distribution and Other Direct Sales countries significantly offset disruption in German Direct Sales caused by our proactive reorganization and strategic realignment of the German sales team and strategy during the quarter
- Goal of these changes is to return Germany back to growth in 2H 2025, after flat sales for two consecutive years
- Product gross margin was steady at 71% from the average from 2024
- Meanwhile, we continue to make significant operational progress as we manage our total core business toward near breakeven in 2H 2025

CytoSorb Integrated Approach for Critical Care







Right Patient, Right Timing, Right Dose of CytoSorb

resonates well with users and is corroborated by new clinical data

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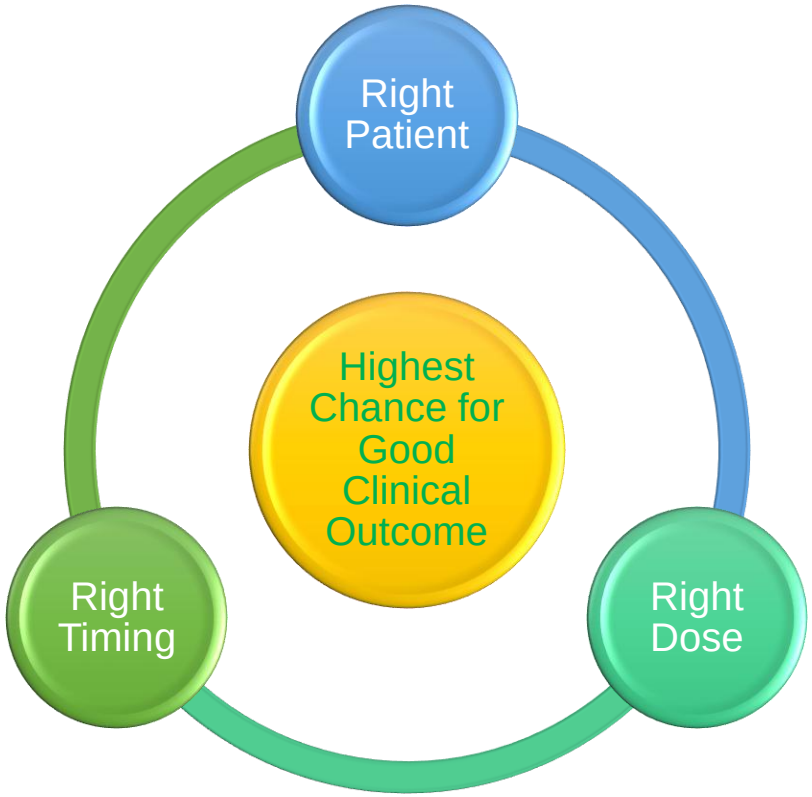
CytoSorb - The Antibiotic Analogy



- **Treat Early**
- **Treat Aggressively**
- **Compete the full course of treatment**

Key Catalysts for Future Growth

- Compelling new data in core applications
- New, simplified and impactful messaging to customers
- Return Germany to growth through optimization of German commercial team and sales approach
- Geographic expansion with Dubai, UAE subsidiary – Gateway to Middle East and Africa

Dr. Phillip Chan
Chief Executive Officer

Dr. Efthymios Deliargyris
Chief Medical Officer

DrugSorb™ ATR Update

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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 and addresses a $300+M initial market opportunity which could exceed $1 billion as Brilinta® becomes generic and DrugSorb-ATR expands to additional indications

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DrugSorb-ATR is an investigational medical device in the U.S. and Canada and is not yet cleared or approved.
Brilinta® is a trademark of AstraZeneca

FDA and Health Canada Regulatory Update

- 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
- Subsequent meeting with FDA provided clarity on remaining issues
- We continue to believe that our submission package is strong and that remaining issues can be resolved
- We plan to file a formal appeal within 60 days from the FDA letter as the most expedited path forward
  - Prescribed process includes a formal hearing with the Company, our regulatory counsel DuVal & Associates, the FDA review team, FDA senior officials, and testimony from external clinical experts (e.g. cardiac surgeons)
  - Appeal decision estimated at ~ 60 days after filing
  - Three potential outcomes: Decision can be upheld, reversed, or reversed with conditions
- Meanwhile, our Health Canada submission is in advanced review
  - While Health Canada has indicated that application reviews are currently delayed beyond target deadlines, they reaffirmed their commitment to issue a decision as soon as possible
- We continue to expect final regulatory decisions in U.S. and Canada in 2025

DrugSorb-ATR is an investigational medical device in the U.S. and Canada and is not yet cleared or approved.

Real World Evidence

- STAR Registry now in 6 countries (GER, UK, BEL, AUT, SWE, CH) with 600+ subjects enrolled in different cardiac surgeries
- Ticagrelor removal in 102 CABG patients now published
- Ticagrelor removal in 150 CABG patients to be presented in Paris at EuroPCR next week
- First report on DOAC removal in 62 CABG patients now published
- Results consistently show significant reductions in severe bleeding
- Excellent safety: Zero device-related adverse events reported to date
- Device is increasingly used in the routine care of patients on blood thinners undergoing cardiac surgery at heart centers around the world
- Based on our experience, we believe our technology represents a compelling value to patients, surgeons, and hospitals in this application

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

journal homepage: www.sciencedirect.com/journal/cardiovascular-revascularization-medicine

Early CABG with intraoperative hemoadsorption in patients on ticagrelor: Real world data from the international Safe and Timely Antithrombotic Removal (STAR) registry

Robert F. Storey[a,b,*,1], Kambiz Hassan[c,1], Anna L. Meyer[d,1], Thomas Eberle[e,1], Nikolaas deNeve[f,1], Matthias Thielmann[g,1], Martin H. Bernardi[h,1], Nandor Marczin[i,j], Ulf Guenther[k,1], Bernd Panholzer[l,1], Heinrich Maechler[m,1], Steven Hunte[n,1], Michael Schmoeckel[r,1]

Schmoeckel et al. Journal of Cardiothoracic Surgery (2025) 20:74 https://doi.org/10.1186/s13019-024-03326-1

Journal of Cardiothoracic Surgery

RESEARCH Open Access

Direct-acting oral anticoagulant removal by intraoperative hemoadsorption in CABG and/or single valve surgery: interim analysis of the International Safe and Timely Antithrombotic Removal (STAR) registry

Michael Schmoeckel[1,15*], Matthias Thielmann[2], Keti Vitanova[3], Thomas Eberle[4], Nandor Marczin[5], Kambiz Hassan[6], Andreas Liebold[7], Sandra Lindstedt[8], Georg Mächler[9], Marijana Matejic-Spasic[10], Daniel Wendt[10,11], Efthymios N. Deliargyris[12] and Robert F. Storey[13,14]

Abstract

Objective Patients on direct-acting oral anticoagulants (DOACs) are at high risk of perioperative bleeding complications. Intraoperative hemoadsorption is a novel strategy to reduce perioperative bleeding in patients on DOACs undergoing non-deferable cardiac surgery. The international STAR-registry reports real-world clinical outcomes associated with this application.

Methods The hemoadsorption device was incorporated into the cardiopulmonary bypass (CPB) circuit and active for the duration of the pump run. Patients on DOACs undergoing CABG and/or single valve surgery before completing the recommended washout were included. Outcome measurements included bleeding events according to standardized definitions and 24-hour chest-tube-drainage (CTD).

Results A total of 62 patients were included from 7 institutions in Austria, Germany, Sweden, and the UK (mean age 69.9 ± 7.5years, 71% male). Approximately half were on apixaban and the other half was split between rivaroxaban and edoxaban with 21% of patients also on aspirin. Surgery occurred at a median time of 28.9 h since the last DOAC dose with single valve surgery accounting for 2/3 of cases. Mean CPB duration was 118.6 ± 46.4 min. Severe bleeding (UDPB ≥ 3) occurred in 4.8%, and BARC-4 bleeding occurred in 3.2% of the patients. Only one patient (1.6%) required reoperation for bleeding control. The mean 24-hour CTD was 771.3 ± 482.79mL. No device-related adverse events were reported.

Presented at the 38th EACTS Annual Meeting in Lisbon, Portugal, Oct 9–12, 2024.

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Full list of author information is available at the end of the article

BMC

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DrugSorb-ATR and CytoSorb are investigational medical devices in the U.S. and Canada and are not yet cleared or approved.

Preparing for Potential Launch

- Preparing for a controlled market release as we wait for FDA and Health Canada decisions
  - Get real-world feedback
  - Validate assumptions
  - Refine our commercialization strategy

- DrugSorb-ATR Launch Team is undertaking a number pre-launch activities
  - Engaging with leading U.S. and Canadian KOLs
  - Recruiting essential talent
  - Managing numerous market access activities
  - Developing a clear value proposition for patients surgeons and hospitals.
  - Visibility within the cardiovascular community with data presentations at conferences
    - American College of Cardiology
    - Society of Cardiovascular Anesthesiologists
    - EuroPCR
    - Canadian Society of Cardiac Surgery
    - European Society of Cardiology Heart Failure

DrugSorb-ATR and CytoSorb are investigational medical devices in the U.S. and Canada and are not yet cleared or approved.

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Introducing Tom Shannon – VP Marketing, North America

Tom Shannon
Vice President Marketing, North America

- Genesee Biomedical - VP of Sales and Marketing, an innovator in cardiac heart valve repair
- Fresenius Medical Care - Director of Marketing. Launched the first FDA-cleared ECMO machine
- Getinge (formerly Maquet) - commercialized 20 new products across the Americas, including the successful launch of the market-leading CardioHelp® ECMO platform, and managed a $450 million cardiac and vascular surgery portfolio
- Medtronic - Led initiatives in sales, therapy development and marketing, and product launches including anti-coagulation monitoring devices, blood pumps, and auto-transfusion technologies
- Prior to industry, spent 17 years as a healthcare practitioner, including 12 years as a cardiovascular perfusionist, supporting complex cardiothoracic surgeries

Financial Highlights

Peter J. Mariani
Chief Financial Officer

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Revenue and Gross Margin

	1Q25	1Q24	YoY Change
Revenue	**$8.7m**	**$9.0m**	**-3%**
Constant currency growth			**0%**
Gross Profit	**$6.2m**	**$6.9m**	**-10%**
Gross Margin	**71%**	**77%**	

- Strength in other our Distributor and other EU Direct Markets offset by declines in Germany
- We are pleased with the progress of our initiative to realign our commercial team and sales approach in Germany and expect improved execution and results in the second half of the year.
- Q125 GM is consistent with 2024 average
- YOY GM decrease due to 23% reduction in units produced, slightly offset by an 11% decrease in total costs

Improved Operating Leverage

	1Q25	1Q24	YoY Change
Total operating expenses	**$10.1m**	$11.5m	12% decrease
Operating loss	**$3.9m**	$4.7m	17% improvement
Net loss	**$1.5m / $0.02/sh**	$6.1 m / $0.11/sh	
Adjusted net loss	**$3.7m / $0.06/sh**	$3.7m / $0.07/sh	
Adjusted EBITDA loss	**$2.7m**	$3.3m	17% improvement

*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.

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Strengthened balance sheet
Driving core business to cash flow break-even in 2H 2025

- **$6.8 million received from successful Rights Offering**
  - Provided $6.8 million, net of fees, to date
  - Released $5.0 million of restricted cash
  - Together increased net liquidity of $11.8 million
  - 60-day extension of the Series B Right Warrant to June 10, 2025
- **$13.1 million in cash, cash equivalents and restricted cash at March 31, 2025**
  - $3.7 million cash used in Q1, inclusive of $0.9 million of disbursements unique to Q1
- **$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

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Introducing Melanie Grossman– VP and Controller

Melanie Grossman, CPA

Vice President and Controller

- Over 25 years of accomplished finance and accounting leadership in global, publicly-traded, and private companies
- SEC reporting, financial systems, processes and internal controls
- Financial planning, analysis and strategy
- Former Ernst & Young (EY) auditor
- Healthcare experience with Stryker, Byram Healthcare and Vaxxinity

Closing Remarks

Phillip Chan, MD, PhD
Chief Executive Officer

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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
- ✓ 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

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