The Unrecognized Faces of Critical Illness

CytoSorbents Corporation
Nasdaq: CTSO
Q1 2024 Earnings Conference Call
May 9, 2024

CytoSorbents™

Conference Call Participants

Moderator: Eric Ribner
LifeSci Advisors

Phillip Chan, MD, PhD
Chief Executive Officer

Vincent Capponi, MS
President and Chief Operating Officer

Kathleen Bloch, MBA, 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

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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; 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.

Operational Update

Phillip Chan, MD, PhD
Chief Executive Officer

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Recent Operational Highlights

- $9.0M in product sales in Q1 2024
  - +14% from $7.9M a year ago
  - +22% sequentially from $7.3M in Q4 2023
- Product gross margins were 76%, up 800 bp from 68% a year ago*
- STAR-T Data was presented for the first time by PI Dr. Michael Mack at the 104th Annual Meeting of the American Association for Thoracic Surgery (AATS) in Toronto
- Hosted a Virtual KOL and Analyst-Investor Day earlier this week featuring a review of the STAR-T Pivotal Trial Results and real world experience with blood thinner removal in Europe with a replay available here
- On track to submit marketing applications in parallel for the investigational DrugSorb-ATR system to FDA as a De Novo application and Health Canada in Q3 2024

* Excluding a one-time, non-recurring inventory adjustment recorded in Q1 2024

Recent Operational Highlights (cont)

- Cumulative CytoSorb treatments delivered exceeded 237K (3/31/24) and are expected to reach a quarter million this year

- Expect to take delivery of and launch our easy-to-use PuriFi™ hemoperfusion pump in Q2 2024 in select international countries – a key 2024 growth initiative
  - Expected to spur usage of CytoSorb in countries without well-established dialysis infrastructures
  - Designed to encourage earlier use of CytoSorb therapy everywhere

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Many New Publications

biomedicines

MDPI

Systematic Review

Hemoadsorption Therapy for Critically Ill Patients with Acute Liver Dysfunction: A Meta-Analysis and Systematic Review

Caner Turan [1,2], Csenge Erzsébet Szigetváry [1,2], Tamás Kói [2,3], Marie Anne Engh [2], Işıl Atakan [2], László Zubek [2], Tamás Terebessy [2,4], Péter Hegyi [2,5,6] and Zsolt Molnár [1,2,7,*]

ESC HEART FAILURE
ESC Heart Failure 2024; **11**: 772–782
Published online 19 December 2023 in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/ehf2.14632

ORIGINAL ARTICLE

Use of intraoperative haemoadsorption in patients undergoing heart transplantation: a proof-of-concept randomized trial

Endre Nemeth[1,2]*, Adam
Hajna Katona[1,2], Kristof Racz
Csilla Tamas[1], Beata Nagy[3],

frontiers | Frontiers in Anesthesiology

TYPE Case Report
PUBLISHED 18 January 2024
DOI 10.3389/fanes.2023.1323180

Check for updates

OPEN ACCESS

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PUBLISHED 18 January 2024

Case Report: The management of hemorrhagic shock of different origins by target-controlled coagulation and extracorporeal organ support (continuous renal replacement therapy)

Ákos Pertich and András Lovas*

Department of Anesthesiology and Intensive Care, Kiskunhalas Semmelweis Hospital, The Teaching Hospital of University of Szeged, Kiskunhalas, Hungary

Journal of *Clinical Medicine*

MDPI

Article

Impact of CytoSorb Hemoadsorption Therapy on Fluid Balance in Patients with Septic Shock

Klaus Kogelmann [1,*], Tobias Hübner [2], Matthias Drüner [3] and Dominik Jarczak [4]

CytoSorb® in burn patients with septic shock and Acute Kidney Injury on Continuous Kidney Replacement Therapy is associated with improved clinical outcome and survival

Filippo Mariano [a,b,], Domenico Greco' [a], Nadia Depetris [c], Alberto Mella [a,b], Alberto Sciarrillo [d], Maurizio Stella [d], Maurizio Berardino [c], Daniela Risso [d], Roberto Gambino [b,e], Luigi Biancone [a,b]*

Review

IJAO The International Journal of Artificial Organs

The potential role of extracorporeal cytokine removal with CytoSorb® as an adjuvant therapy in Acute Respiratory Distress Syndrome

The International Journal of Artificial Organs
2023, Vol. 46(12) 605–617

DOI: 10.1177/03913988231211740
journals.sagepub.com/home/jao
Sage

Dana Tomescu[1,2,*], Mihai Popescu[1,2,*], Ali Akil[3], Amir Ahmad Nassiri[4], Florian Wunderlich-Sperl[5], Klaus Kogelmann[6], Zsolt Molnar[7,8,9], Abdulrahman Alha and Dimitrios Karakitsos[10,11]

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Financial Highlights

Kathleen Bloch, MBA, CPA
Chief Financial Officer

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Comparative Quarterly Revenue Results

	Quarter Ended Mar 31, 2024		Quarter Ended Mar 31, 2023		% Incr.
Product revenue	$8,989,520		$7,910,039		14%
Grant and other income	796,772		1,539,457		-48%
Total revenue	$9,786,292		$9,449,496		4%

- Product sales for Q1 2024 were approximately $9.0M compared to $7.9M product sales in Q1 2023
- Grant revenue was $797K in Q1 2024 compared to $1.5M in Q1 2023
- Total revenue, including product sales and grant income was $9.8M in Q1 2024 compared to $9.4M for Q1 2023
- Q1 2024 product gross margin was 76% (excluding the impact of a one-time, non-recurring inventory adjustment), an 800 basis point increase from product gross margin of 68% in Q1 2023

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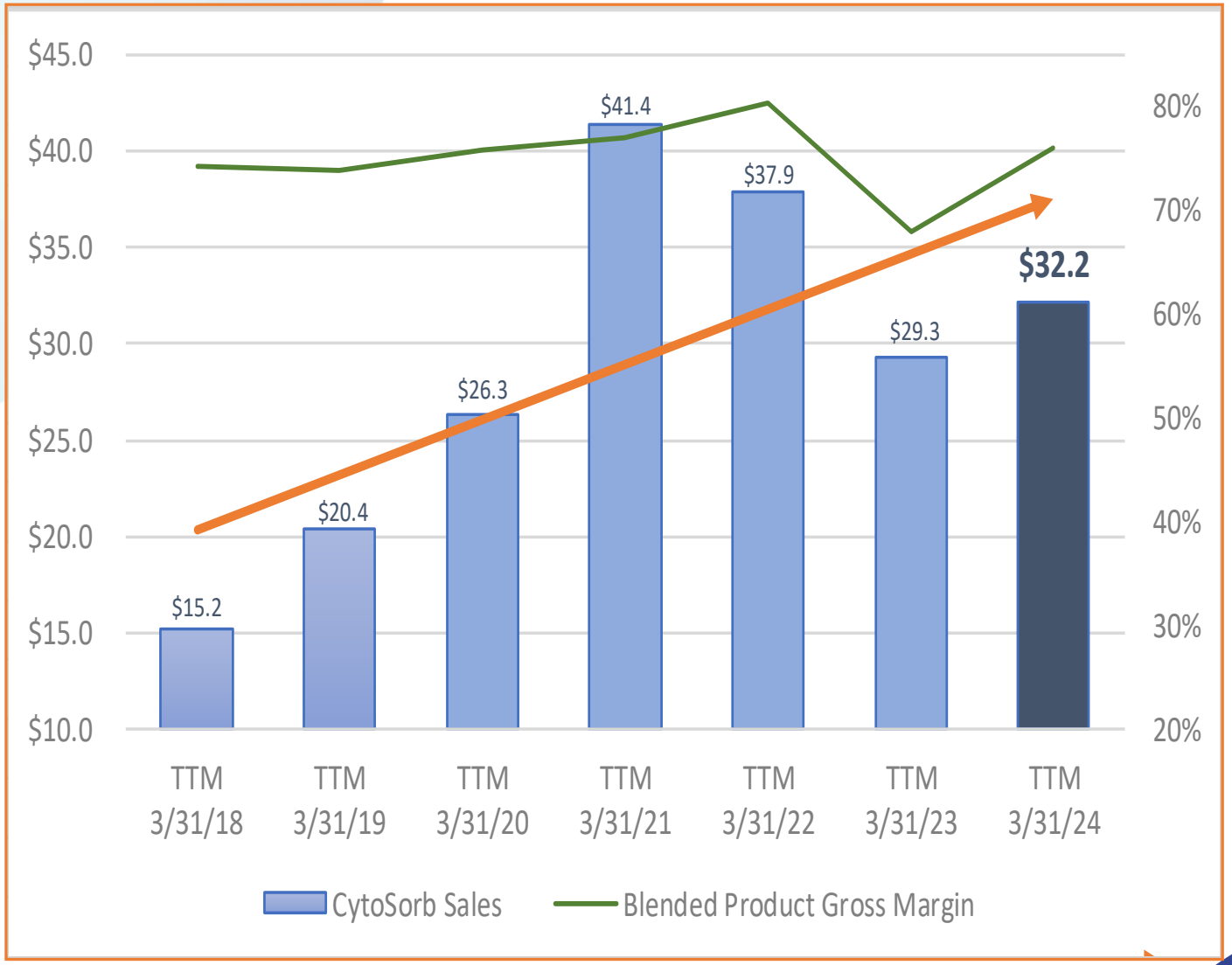
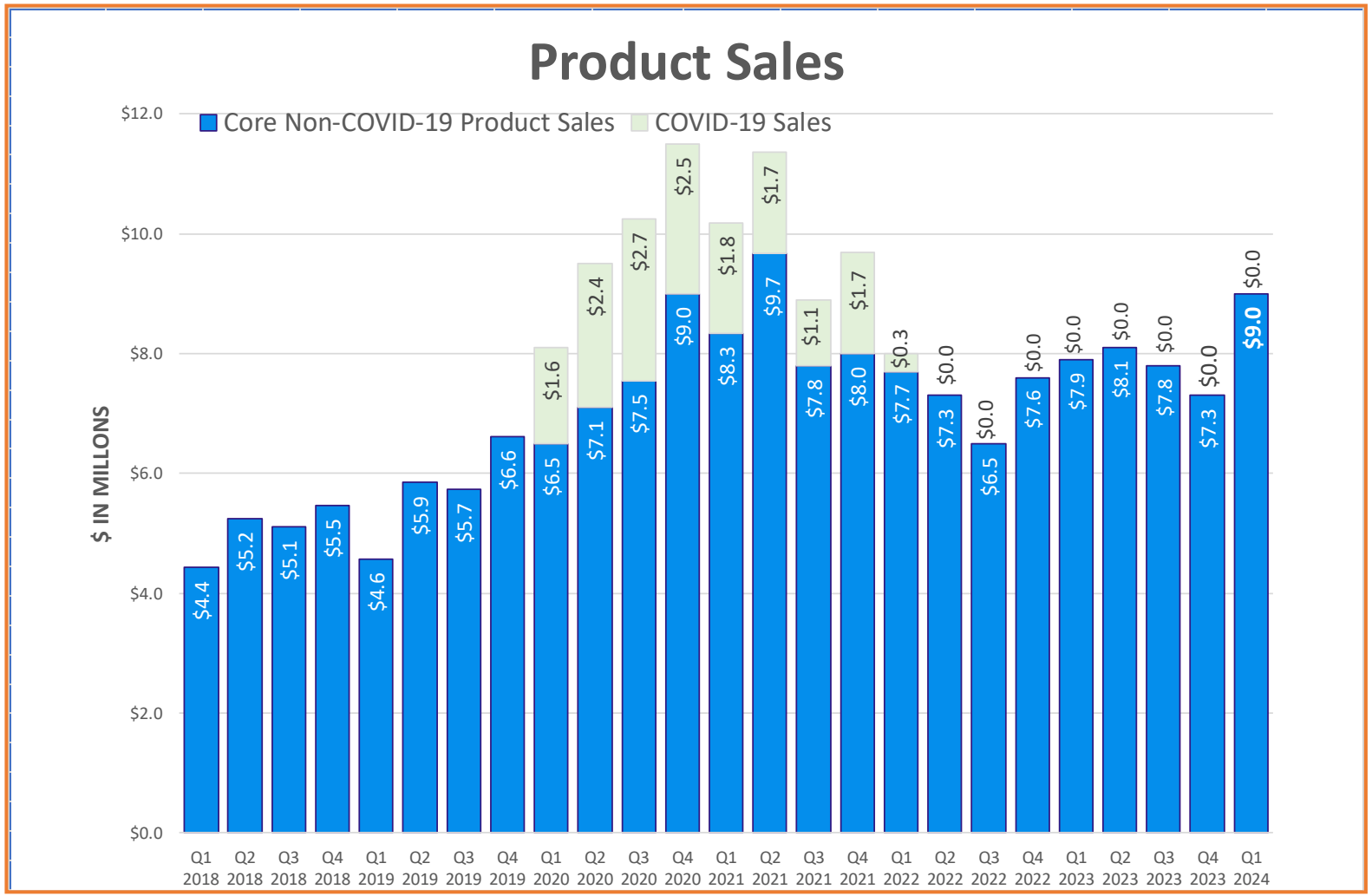
TTM Product Sales & Blended Gross Margin



Total Quarterly Product Sales



Q1 2024 is a record high core product sales following COVID-19 periods.

Cash Flow

- As of March 31, 2024, we had $10.1M in cash, which includes $1.5M of restricted cash. We believe that cash on hand is sufficient to fund the Company's operations into the fourth quarter of 2024.

- We continue to work to strengthen our balance sheet and reduce operating expenses through tight working capital controls on accounts receivable and inventory.

- Cash conservation remains a top corporate priority. We have adjusted our operating budget and taken measures to reduce our quarterly cash burn. We have instituted tight controls over our spending. These actions are expected to preserve our cash runway.

- The Company is actively pursuing alternative sources of capital, with an immediate focus on non-dilutive debt financing. We are currently in active discussions with multiple potential debt lenders.

Clinical Highlights

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

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DrugSorb-ATR is a Breakthrough Device

- FDA has granted 2 Breakthrough Device Designations (BDD) for DrugSorb-ATR*
  - 2020: Removal of ticagrelor (Brilinta®, AstraZeneca) in emergent or urgent cardiothoracic surgery
  - 2021: Removal of DOACs, apixaban (Eliquis®, Pfizer, BMS) and rivaroxaban (Xarelto®, Bayer, Janssen) for same
- BDD Program provides timely access to medical devices by speeding up development, assessment and review for premarket approval, 510(k), and De Novo marketing authorization

1st Criterion:

Device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions

2nd Criterion - Device must meet at least one:

- Represents Breakthrough Technology
- No approved or cleared alternatives exist
- Offers significant advantages over existing approved or cleared alternatives
- Device availability is in the best interest of patients

- Since 2015, FDA has granted BDD to 192 CV and 83 GI/Urology devices and diagnostics
- Breakthrough Devices must meet the FDA's rigorous standards for device safety and effectiveness to be authorized for marketing
- BDD marketing submissions receive priority review

https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s1

*** The DrugSorb-ATR system is an investigational device that is not yet cleared/approved by FDA, Health Canada, or by any other Global Regulatory Agency and is not commercially available for sale**

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Highlights from STAR-T Presentation @AATS

STUDY METRICS

140 Randomized – 8 no study device = 132 (Overall)
92% Isolated CABG and 8% “Other surgeries”
Enrollment breakdown 66% US, 34% Canada
11 Major protocol deviations (<10%)
0 Patients lost to follow-up (100% complete)

SAFETY: Overall population

3 DSMB reviews (40, 80, 140) = no concerns
Balanced AEs between device and control
0 Device related serious AE (SAE)
0 Unanticipated device AE (UADE)
0 Device AE leading to study discontinuation

EFFICACY: Assessment of bleeding

2 composite endpoints UDPB and CTD (prespecified)
Exploratory assessment of Major Bleeding (post-hoc)

Primary composite endpoint not met (Overall)

Isolated CABG Per Protocol (no deviations):

Prespecified	WIN Ratio	p value
Mod/Severe	1.33	0.202
Severe	**1.59**	**0.041**
PI Sensitivity	**WIN Ratio**	**p value**
Mod/Severe	**1.65**	**0.026**
Severe	**1.59**	**0.041**

Exploratory “Major Bleeding”:

Type	DrugSorb	Control
Major UDPB	3	9
Major CTD*	0	4
Total	**3**	**13**

6% vs. 22%
p=0.028
NNT: 6

**Among those without UDPB*

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Regulatory Path: De Novo Pathway

"We have been working with CytoSorbents on the development of their regulatory strategy for the DrugSorb-ATR device. Based on the data the company has shared with us and the extensive experience we have in the preparation of De Novo submissions, it is our opinion this device is appropriate for the De Novo pathway."

Mark DuVal, J.D., FRAPS, President and CEO, DuVal & Associates, P.A.

- De Novo is for low-to-moderate risk devices for which special controls (e.g. clinical data) provide reasonable assurance of safety and effectiveness, but there is no approved predicate device
- Heavy emphasis on the probable benefit and risk of the device in the intended application
- Breakthrough devices receive priority review on device marketing submissions and in a recent analysis, led to a more rapid review of De Novo device applications by 25%
- We are targeting parallel De Novo submission to FDA and Health Canada in Q3 '24
- FDA timeline for De Novo review is 150 days, but post-COVID it's been closer to a year

https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request
https://www.fda.gov/media/99769/download?attachment
https://medicaldeviceacademy.com/breakthrough-device-designation/

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Summary

- Ticagrelor is an FDA approved drug widely used as standard of care in U.S. and Canada, but confers increased risk of severe perioperative bleeding for patients who require urgent surgical treatment

- DrugSorb-ATR is an investigational device that has FDA Breakthrough status for this application, highlighting the large unmet medical need and the lack of available alternatives

- We believe STAR-T data inform the regulatory pathway by providing:
  - Necessary safety information
  - Proposed target intended population (CABG surgery)
  - Proposed indication for use (reduction of bleeding severity)

- Based on the benefit-to-risk profile observed in STAR-T, regulatory experts recommend FDA submission for DrugSorb-ATR use in CABG surgery under the De Novo pathway

- Pending FDA agreement of the De Novo pathway, BDD is expected to facilitate a priority review with a potential FDA decision between 6-12 months following Q3 submission – Health Canada submission in parallel

Closing Statement

Phillip Chan, MD, PhD
Chief Executive Officer

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The Path Forward

- We see tremendous opportunity fueled by important demographic trends such as:
  - Aging baby boomer generation who are prone to critical illness
  - Expanding global use of blood thinners by millions for stroke and heart attack prophylaxis
  - The chronic liver disease epidemic in 20% of people due to alcoholism, hepatitis, and fatty liver
- We are at the forefront in helping to fill the substantial treatment gaps that exist across a spectrum of critical conditions such as:
  - Sepsis, shock, liver failure, acute respiratory distress syndrome, infective endocarditis, serious bleeding due to blood thinners, and organ transplant
- And in the future, with products in advanced development like HemoDefend-BGA for universal plasma, our contribution could be even greater
- We are excited by our near-term progress with sales, product gross margins, potential catalysts like PuriFi, Fresenius, debt financing, new data, and the greatly increased visibility on DrugSorb-ATR
- By continually pushing boundaries and driving innovation, we are committed to "Expanding the Dimension of Blood Purification®", setting the stage for lasting transformation within the industry

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Q&A Session

NASDAQ: CTSO

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