



WORKING TO SAVE LIVES

CytoSorbents Corporation Q3 2023 Earnings Conference Call November 9, 2023

Conference Call Participants



Phillip Chan, MD, PhD Chief Executive Officer



Vincent Capponi, MS President and Chief Operating Officer



Kathleen Bloch, MBA, CPA Chief Financial Officer



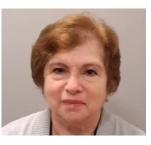
Efthymios "Makis" Deliargyris MD, FACC, FESC, FSCAI Chief Medical Officer



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



Christopher Cramer, MS, MBA Senior VP Business Development



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 <u>www.sec.gov</u>.



Operational Update

Phillip Chan, MD, PhD Chief Executive Officer



Recent Operational Highlights

- Completed the pivotal STAR-T trial in August, following the last patient follow-up. Trial remains blinded with database lock nearing, with completion of data analysis expected before year end
- The International STAR Registry highlighted low rates of CABG-related perioperative bleeding in patients undergoing isolated CABG surgery with CytoSorb within 2 days of discontinuing Brilinta[®]/Brilique[®] in the first and second analyses
- Exceeded 221,000 cumulative human treatments delivered across 75 countries worldwide
- Expanded ANVISA registration of CytoSorb to treat shock in Brazil, Latin America's largest medical device market
- Highlighted how CytoSorb and ECOS-300CY are helping to shape the future of solid organ transplant by reducing inflammation during *ex vivo* organ perfusion a strategy to potentially improve the quality and quantity of donated organs and improve transplant outcomes
- Kathleen Bloch resumed her role as full-time Chief Financial Officer





STAR-T Pivotal Trial Update



Brilinta and the Use Case for DrugSorb





The ultimate goal of DrugSorb-ATR is to allow patients to get the critical surgery they need without delay, while reducing or preventing bleeding complications by actively removing the drug from blood during surgery

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7 CytoSorbents...

U.S. and Canadian STAR-T: What do we know?

- The STAR-T RCT completed in August, with follow-up on 100% of patients, at 30 centers in the U.S. and Canada
- Data monitoring is nearing completion with database lock to follow. The STAR-T study data remain blinded to all partied and will not be unblinded until after database lock, when the final statistical analysis will occur. The results of the study are currently unknown
- As noted previously, there were no device-related safety issues with DrugSorb-ATR raised in the first two scheduled DSMB data reviews, the last one at 80 patients. The final DSMB analysis will take place after database lock
- We expect to complete our initial STAR-T data analysis before year-end. We intend to announce whether we believe the results from STAR-T can support an FDA marketing approval thereafter
- Meanwhile, encouraging initial results from the International STAR Registry demonstrate low rates of serious perioperative bleeding when CytoSorb (which uses an equivalent polymer technology to DrugSorb-ATR) is used in this indication
- With supportive data, our goal is to submit to for U.S. FDA and Health Canada regulatory approval in early-2024 with the potential of a faster review with our FDA Breakthrough Device Designation, targeting potential U.S. FDA marketing approval by late 2024-early 2025
 CytoSorbents

DrugSorb-ATR: A Potential Win-Win-Win

Through many discussions with cardiac surgeons in the U.S., Canada, and abroad, we continue to validate the potential value proposition that DrugSorb-ATR could have if successful – things we are already seeing with CytoSorb in Europe. Some potential benefits:

Patients

• Ability to get definitive surgery - safely and without delay, with low risk of bleeding complications

Surgeons

- Solves the intraoperative and postoperative nightmare of bleeding due to blood thinners
- Reduces the need for costly and time consuming re-exploration surgeries
- Relieves the surgical scheduling logjam due to patients still recovering from bleeding complications in the CT ICU, allowing new patients to be operated on

Hospitals

- Reduces or eliminates the 3-5 day waiting period to washout Brilinta that can cost \$6,000-\$30,000 depending on where they wait
- Reduces longer operative times due to bleeding costs, which can be >\$4,000 per 30 minutes
- Relieves logiam of patients in the ICU who bleed, allowing more revenue generating surgeries
- May improve a hospital's Quality Star Rating as defined by CMS, by reducing serious adverse events like bleeding. This Star rating helps hospitals differentiate themselves based on objective quality criteria, helping to drive patient traffic and procedure revenue



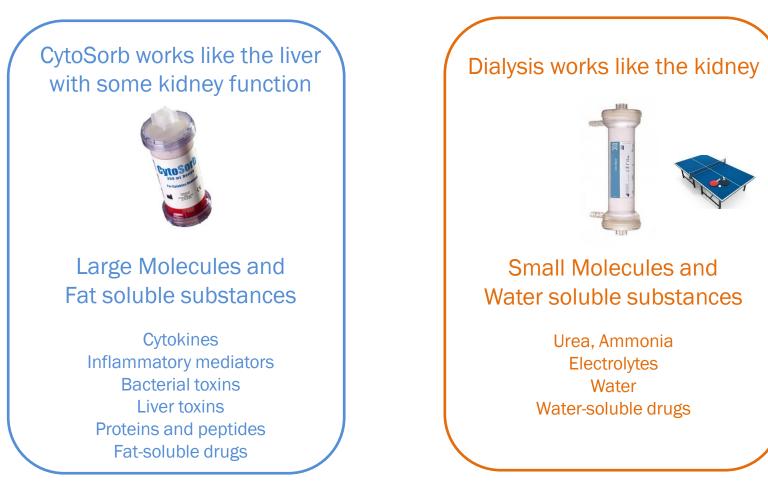


Expanding the Dimension of Blood Purification[®]



Expanding the Dimension of Blood Purification®

CytoSorb is fundamentally different from, but complementary to, dialysis technology, removing a broad range of dissimilar toxins that dialysis does not remove well



CytoSorbents...

Targets Deadly Conditions That Afflict Millions of People

Critical Care

Removes the "fuel to the fire" of massive uncontrolled <u>inflammation</u> that is often associated with organ failure and death

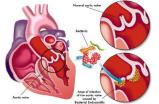


Cardiothoracic Surgery

Reduces <u>inflammation and blood thinners</u>, targeting reduction in complications of cardiac surgery like sepsis, bleeding, shock, and others



Life-threatening bleeding due to anti-thrombotic "blood thinners"



Infective Endocarditis



High Risk Procedures

CytoSorbents...

Global Marketing Agreement with

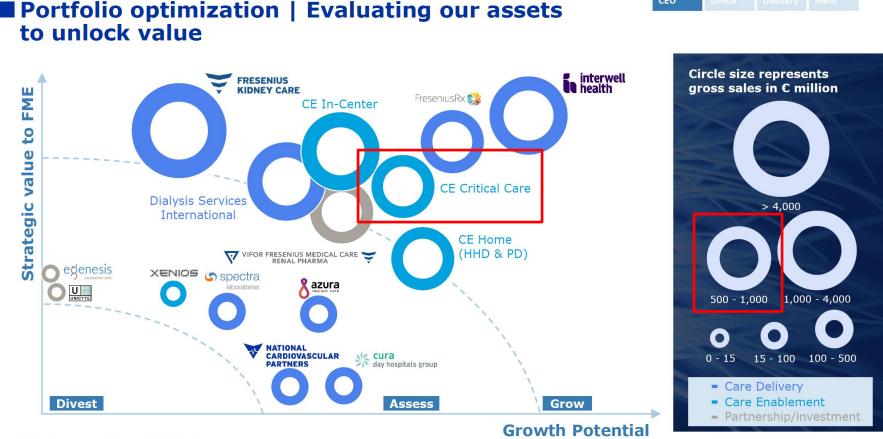
- Last year, we announced a new, expanded global marketing agreement with long-time partner, Fresenius Medical Care, the market leader in dialysis worldwide, with a massive installed base of blood purification machines in ICUs worldwide.
- Fresenius has begun marketing CytoSorb as the "featured technology for cytokine, bilirubin, and myoglobin removal" on its critical care platforms worldwide (excluding the U.S.) but is expected to officially launch a more comprehensive effort next year through its sales force, website, conferences, =literature, social media, & other platforms next year
- The partnership "Expands the Dimension of Blood Purification" with excellent synergy between the two companies
 - Fresenius dominates kidney replacement blood purification technologies where 10-15% of patients in the ICU have failed kidneys
 - CytoSorbents strengthens and broadens the focus on the lucrative critical care segment, as CytoSorb helps to address deadly inflammation and toxin overload that afflicts an estimated 40-50% of patients in the ICU
- CytoSorbents benefits from the global endorsement and push on Fresenius' sales and marketing platform and has agreed to subsidize this effort with a 0.9% royalty to FMC on ex-US CytoSorb sales



FRESENIUS

MEDICAL CARE

Fresenius and CytoSorbents Are Well-Aligned



Note: Axes are non-linear, indicative only

FRESENIUS -

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CEO



Financial Highlights

Kathleen Bloch, MBA, CPA Chief Financial Officer



Comparative Quarterly Revenue Results

	Quarter Ended Sep 30, 2023	Quarter Ended Sep 30, 2022	% Incr.
Product revenue	\$7,754,016	\$6,462,696	20.0%
Grant and other income	1,056,831	1,648,657	-35.9%
Total revenue	\$8,810,847	\$8,111,353	8.6%

- Total revenue, including product sales and grant income, was \$8.8M in Q3 2023, an increase of approximately 8.6% as compared to \$8.1M for Q3 2022
- Product sales for Q3 2023 were approximately \$7.8M as compared to \$6.5M in sales in Q3 2022, an increase of 20% as compared to Q3 of 2022
- Grant income was approximately \$1.1M in Q3 2023 as compared to \$1.6 in Q3 2022
- Q3 2023 product gross margins were 72% as compared to 55% for Q3 2022 **CytoSorbents**

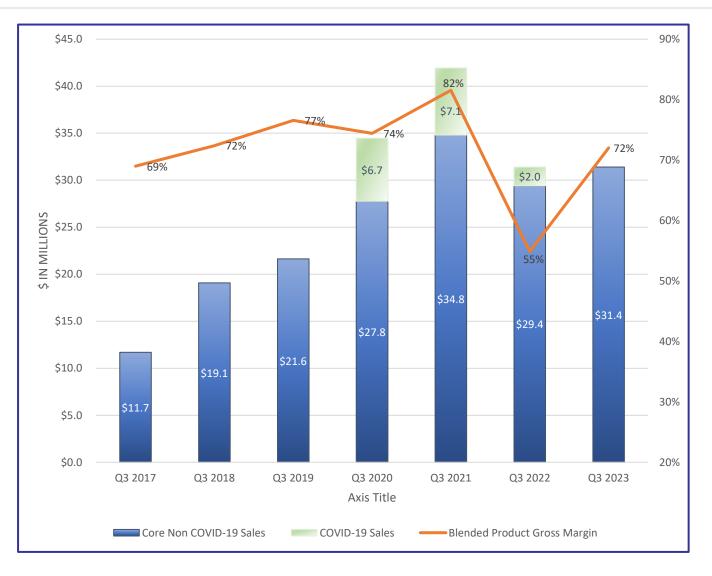
Comparative YTD Revenue Results

	YTD Sep 30, 2023	YTD Sep 30, 2022	Y-Y % Increase
Product revenue	\$23,736,468	\$21,717,888	9.3%
Grant and other income	3,944,696	3,580,447	10.2%
Total revenue	\$27,681,164	\$25,298,335	9.4%

- Total YTD revenue as of September 30, 2023, which includes both product sales and grant revenue, was \$27.7M as compared to \$25.3M for the YTD period ended September 30, 2022, an increase of 9.4%
- YTD product sales as of September 30, 2023 were approximately \$23.7M, a 9.3% increase over product sales of \$21.7M for the same period a year ago
- YTD Grant revenue as of September 30, 2023 was approximately \$3.9M as compared to \$3.6M for the same period a year ago

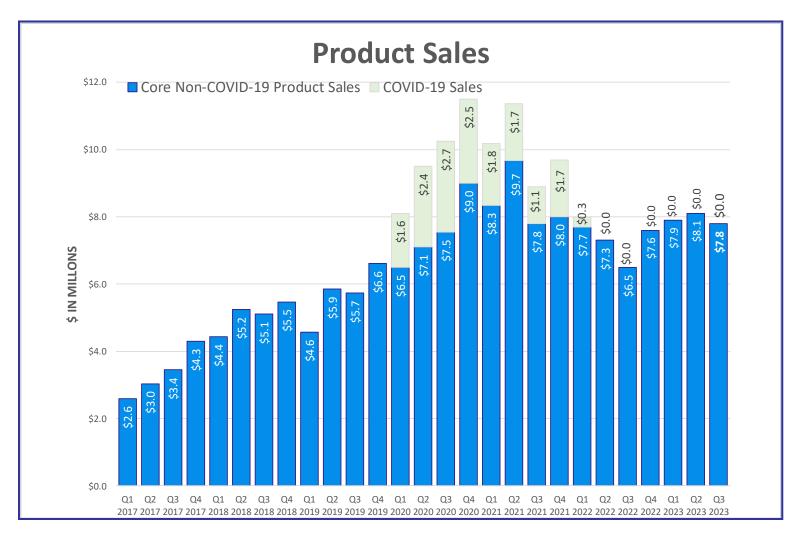


TTM Product Sales & Blended Gross Margin





Historical Quarterly Product Sales





2023 Cash Burn

- Cash balance as of 9/30/2023 was approximately \$10M, which included restricted cash of approximately of \$1.7M.
- Our quarterly cash burn during the nine months in 2023 averaged approximately \$4.6M, down significantly from the average quarterly cash burn in the nine months of 2022 of approximately \$9.9M.
- We are pursuing alternative sources of capital, which may include debt financing, royalty financing, strategic or direct investments, equity financing and/or combinations thereof.
- We continue to maintain tight controls over cash, and we continue to identify and implement cost reduction opportunities in our operations.



Concluding Remarks

Phillip Chan, MD, PhD Chief Executive Officer



Today: CytoSorb Drives our Growth

- CytoSorb forms the Company's foundation
 - E.U. approved and sold around the world
 - Generated ~\$205M in sales since launch
 - High margin razorblade business model with
 historically high blended product gross margins
 - Strong validation by customers, partners, and government agencies
 - Current sales supports near-breakeven, less clinical trial costs, which we believe helps to derisk the Company and the investment opportunity



We believe CytoSorb represents the fuel for future strong anticipated growth targeting the \$20-30B worldwide TAM of major unmet medical needs in critical care, cardiac surgery, as well as liver and kidney disease

We believe this gives CytoSorbents the potential upside of a biotechnology company, with the lower risk profile of a high margin medical device company with sales



Soon: **CytoSorb** & DrugSorb = Dual Growth Engines

- STAR-T has now completed and is heading to database lock with initial data analysis expected this year. International usage and trial safety to date gives us confidence.
- Should STAR-T be successful and DrugSorb-ATR achieves U.S. FDA and Health Canada regulatory approval, we intend to commercialize DrugSorb-ATR in both the U.S. and Canada – a potentially <u>major second engine of growth</u>, working in tandem with CytoSorb to drive sales
- DrugSorb-ATR is expected to have a higher ASP and product gross margin than CytoSorb and would open an expected U.S. and Canadian TAM of \$600-650M for Brilinta[®] alone, where we expect significant penetration, given the major unmet need indicated by our FDA Breakthrough Designation
- With CytoSorb and DrugSorb-ATR driving sales, we expect to drive accelerated sales growth of the Company with the goal of profitability soon thereafter







CytoSorbents Corporation

NASDAQ: CTSO

Company Contact Dr. Phillip Chan pchan@cytosorbents.com







