



WORKING TO SAVE LIVES

CytoSorbents Corporation Q4 2023 and FY 2023 Earnings Conference Call March 14, 2024

## **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



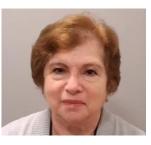
Efthymios "Makis" Deliargyris MD, FACC, FESC, FSCAI Chief Medical Officer



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 14, 2024, 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**

- >228,000 cumulative CytoSorb® treatments delivered as of end-2023, up 17% from end-2022
- Our European Union CE Mark for CytoSorb was extended under the Medical Devices Directive (MDD) to the earlier of either December 2028 or when we achieve E.U. Medical Device Regulation (MDR) certification, which effort is currently ongoing
- Entered new strategic partnership and temporary distribution agreement in India for CytoSorb with the publicly-traded Indian pharmaceutical company, Eris Lifesciences, following its <u>definitive agreement</u> with Biocon Biologics to acquire Biocon's Nephrology branded formulations business unit, and with it, Biocon's key leadership and field force of these businesses, including the personnel commercializing CytoSorb in India





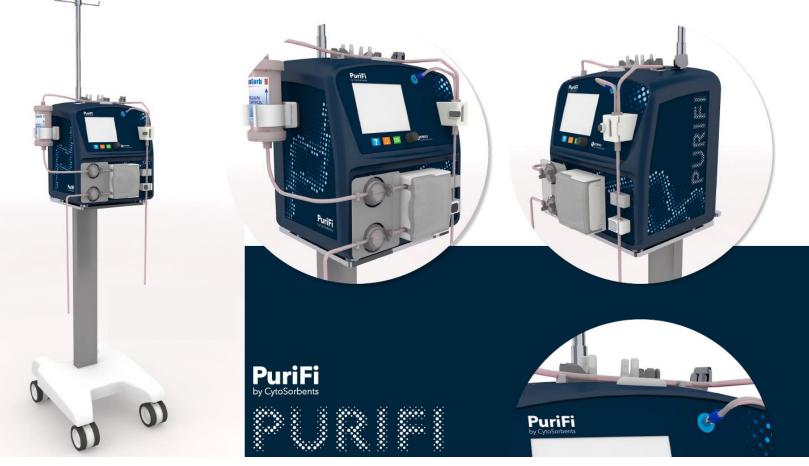




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### **Stand-Alone Hemoperfusion Pump Initiative**

- Our Stand-alone pump initiative is expected to bring our next generation blood purification capability to countries that do not have a strong dialysis infrastructure
- Expecting to launch our new PuriFi pump later this year following the expiration of our distribution agreement with Nikkiso Europe GmbH for its PureAdjust® pump in September 2023



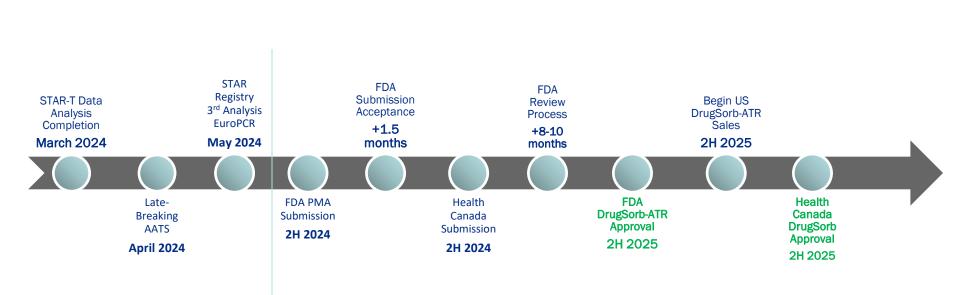
#### **STAR-T** Update

- The pivotal STAR-T RCT was selected for a Breakout Presentation at the American Association of Thoracic Surgery (AATS) Annual Meeting being held April 27-30, 2024 in Toronto, Canada
- We plan to have a subsequent Analyst and Investor Day and provide a review of the data by an esteemed thought leader panel
- Plan to submit for regulatory approval of DrugSorb®-ATR to U.S. FDA and Health Canada in the second half of 2024 to reduce the severity of bleeding in patients undergoing isolated CABG surgery on the blood thinner, Brilinta<sup>®</sup>



#### **Estimated STAR-T Timeline\***







\* These are targeted milestones with projected timing, but there can be no assurance that

8 any or all of these milestones will be met, or met in an acceptable timeframe

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- We believe that focusing our approval request on the isolated CABG population will not significantly change our U.S. and Canadian total addressable market opportunity given that patients on ticagrelor needing isolated CABG represent the overwhelming majority facing this clinical unmet need



#### **United States & Canada TAM for Brilinta Removal**

#### ~65,000 patients on Brilinta needing emergent/urgent CABG surgery annually

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\$5,000 per device

#### \$325M Initial U.S. & Canada Total Addressable Market



#### Brilinta market share expected to grow

- DrugSorb-ATR would make Brilinta the only reversible platelet inhibitor
- Brilinta goes off patent in 2024 leading to a likely drop in prices



#### \$650M U.S. & Canada Total Addressable Market Potential

\* CytoSorb price assumption = \$5,000 based on Javanbakht, M, et al. Pharmacoecon Open. 2020 Jun; 4(2):307-319. Pricing of the U.S. market has not yet been established

#### **CytoSorbents**...

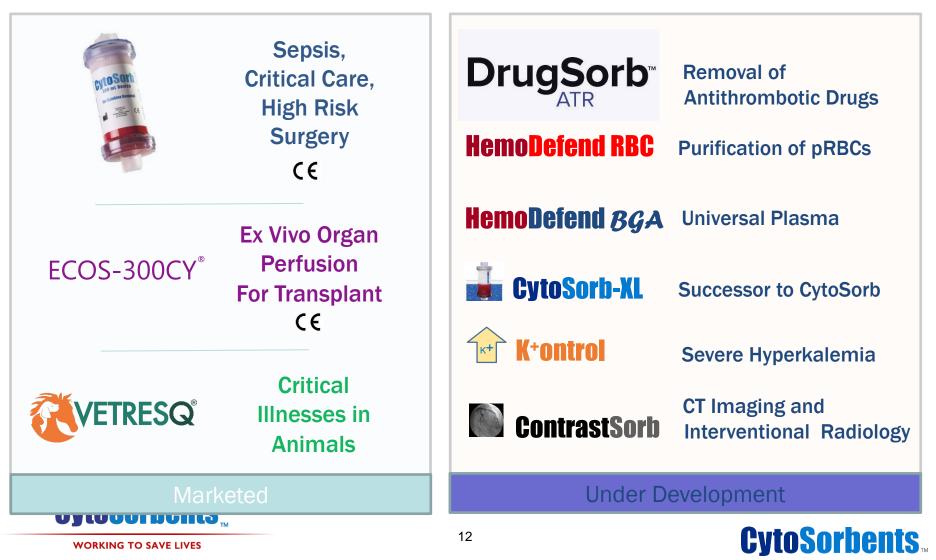
#### 2023 Sales Update

- Core CytoSorb sales grew 10% year over year
  - Strong performance from International Direct: 27% sales growth to \$6M (19% product sales)
  - Distributor/Partner sales: 18% growth in Q1-Q3 2024 vs same period 2022 (not including US distributor sales)
    - Impacted by change in stand-alone pump strategy and delay of distributor orders
    - Overall sales growth for year was 9% (not including US distributor sales) (39% product sales)
  - Direct Sales Germany: 3% growth hospitals still feeling the weight of the aftermath of COVID-19 but improved outlook for 2024 (42% product sales)

#### **CytoSorbents**...

#### Marketed Products and Product Pipeline

Internal development supplemented by strong government support with ~\$50M in grants, contracts, other non-dilutive funds awarded since 2003 for our technology from DARPA, NIH, NHLBI, U.S. Army, U.S. Air Force, HHS, and others



#### ECOS-300CY<sup>®</sup> in Ex Vivo Perfusion and Solid Organ Transplant

- Solid organ transplant is the main treatment option in advanced organ failure but is limited by the availability of suitable and healthy organs
- Ex vivo organ perfusion (EVOP) with temperature controlled, oxygenated, nutrient rich fluid or blood is being increasingly used as an alternative to transporting the organ on ice, to improve functioning of transplant organs and to salvage substandard ones that would otherwise be discarded.
- However, it does not directly control inflammation within the organ that is core to dysfunction
- ECOS-300CY is specifically E.U. approved to reduce inflammatory mediators during EVOP



Goals and cited benefits of ECOS-300CY in early data

- Reduces inflammatory mediators
- Helps to recondition poorly functioning organs that would normally be discarded, increasing the donor pool of organs
- Reduces rates of primary graft dysfunction, improving clinical outcomes



# **VETRESQ** For Companion Animals

- The COVID pandemic has driven companion animal ownership, with 45% of U.S. households owning a dog, and 26% owning a cat, according to the American Veterinarian Medical Society
- Companion animals are prone to a wide variety of medical emergencies ranging from:
  - Drug intoxication
  - Heat Stroke
  - Infections such as leptospirosis
  - Sepsis and septic shock
  - Trauma
  - Others
- VetResQ brings the power of CytoSorb to veterinary medicine with three sizes of cartridges, intended to treat the full size range of companion animals
- In 2023, we had a limited, but successful launch of VetResQ to a number of regional veterinary centers and in 2024, we will debut our integrated all-in-one solution that includes a hemoperfusion pump for vets
  CytoSorbents



Treat severe inflammation | Trauma injuries | Accidental drug overdose and poisoning





#### The Promise of Universal Plasma **HemoDefend** BGA

- HemoDefend-BGA was developed to create "universal plasma" - plasma that does not need blood-typing and can be given off the shelf to anyone in need regardless of blood type - by removing anti-A and anti-B antibodies that make plasma blood-type specific
- Many applications of life-saving plasma include trauma resuscitation, treatment of critically ill patients, and component purification (e.g. clotting factors, albumin, IVIG)
- In the U.S. alone, >10,000 units of fresh frozen plasma are administered daily, or >3.6M units per year
- With more than \$17M in funding from the U.S. Dept of Defense, CytoSorbents has successfully developed and demonstrated a prototype HemoDefend-BGA adsorber that removes anti-A and anti-B antibodies from human plasma, with the goal of having our off-the-shelf, one-size-fits-all blood-type independent "universal plasma" in every ambulance and emergency room around the world

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We have now recently met with FDA in preliminary discussions, with the goal of advancing ٠ HemoDefend-BGA to a human clinical trial and commercialization



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**CytoSorbents** 



Simplifies to

# **Financial Highlights**

Kathleen Bloch, MBA, CPA Chief Financial Officer



#### 2023 Comparative Revenue Results

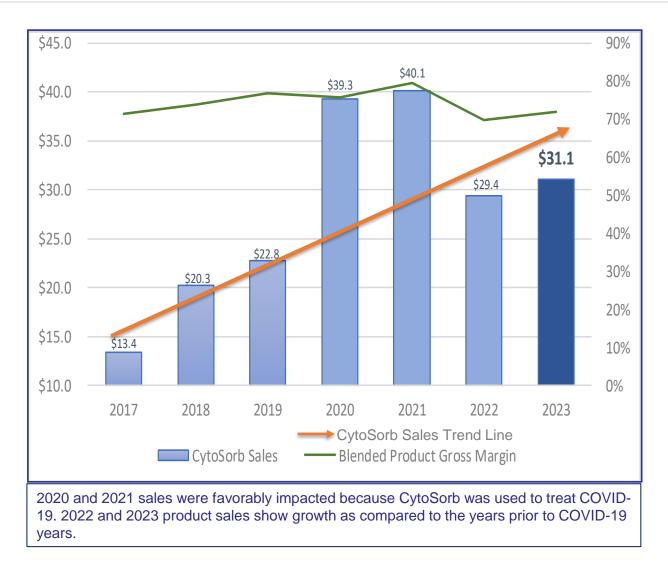
	Year Ended Dec. 31, 2023	Year Ended Dec. 31, 2022	% Incr.
CytoSorb Sales	\$31,015,268	\$28,572,709	9%
Other Sales	69,685	787,201	-91%
Total Product Sales	31,084,953	29,359,910	6%
Grant Income	5,264,426	5,328,899	-1%
Total Revenue	\$36,349,379	\$34,688,809	5%

- Total 2023 revenue, which includes both product sales and grant revenue, was \$36.3M as compared to \$34.7M in 2022, an increase of 5%
- CytoSorb product sales were \$31.0M in 2023, compared to \$28.6M in 2022, an increase of approximately \$2.4M or 9%. There was an increase in the average exchange rate of the Euro to the US Dollar, which favorably impacted 2023 CytoSorb product sales by approximately \$780K
- Other product revenue was \$70K for 2023, compared to \$787K for 2022, due to the discontinuation of orders from a customer who no longer required a specialized polymer
- Product gross margin was 72% in 2023 compared to 70% in 2022. Gross margins are expected to continue to improve in 2024 as we realize economies of scale at our new manufacturing facility
- 2023 Grant revenue was \$5.3M, approximately the same as 2022 grant revenue



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#### **Annual Product Sales**





#### Q4 2023 Comparative Revenue Results

	Quarter Ended Dec. 31, 2023	Quarter Ended Dec. 31, 2022	% Incr.
CytoSorb sales	\$7,334,085	\$ 7,396,515	-1%
Other Sales	14,400	245,507	-94%
Total Product Sales	7,348,485	7,642,022	-4%
Grant Income	1,319,730	1,748,453	-25%
Total Revenue	\$ 8,668,215	\$ 9,390,475	-8%

• Total revenue in Q4 2023, which includes both product sales and grant revenue, decreased 8% to approximately \$8.7M, compared to approximately \$9.4M in Q4 2022

- CytoSorb product sales were 7.3M in Q4 2023, compared to \$7.4M in Q4 2022, a decrease of 1% The increase in the average exchange rate of the Euro to the US dollar favorably impacted Q4 2023 CytoSorb product sales by approximately \$369K
- Other product revenue was \$14.4K in 2023, compared to \$246K in 2022, due to the discontinuation of orders from a customer who no longer required a specialized polymer
- Grant revenue in Q4 2023 was \$1.3M, compared to \$1.7M in Q4 2022



#### Preserving the Cash Runway

- We have \$15.6M (includes \$1.5M of restricted cash) in cash as of December 31, 2023. This includes net proceeds of \$9.8M from our equity raise in December 2023 and approximately \$4.5M raised in 2023 utilizing the ATM facility. We believe that cash on hand is sufficient to fund the Company's operations into the fourth quarter of 2024.
- Cash conservation is a corporate priority. We have adjusted our operating budget and taken measures to reduce our quarterly cash burn in 2024. We have instituted and continue to maintain tight controls over our spending. These actions are expected to preserve our cash runway.
- We will need to raise additional capital to support our ongoing operations in the future, and the Company is actively pursuing sources of capital, including less or non-dilutive debt financing, royalty financing, strategic or direct investments, equity financing, and/or combinations thereof.



# **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 ~\$200M in sales since launch
  - High margin razorblade business model with historically ~80% blended product gross margins
  - Strong validation by customers, partners, and government agencies



CytoSorb is designed to address 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

- 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 potential <u>second engine of growth</u>, working in tandem with CytoSorb to drive sales
- At this stage, we believe our Company represents an exceptional value proposition







### **CytoSorbents Corporation**

#### NASDAQ: CTSO

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