

HELPING REDUCE DEADLY UNCONTROLLED INFLAMMATION IN HOSPITALIZED PATIENTS WORLDWIDE

## **NASDAQ: CTSO**

Cowen 41<sup>st</sup> Annual Healthcare Conference
March 3, 2021

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# CytoSorbents



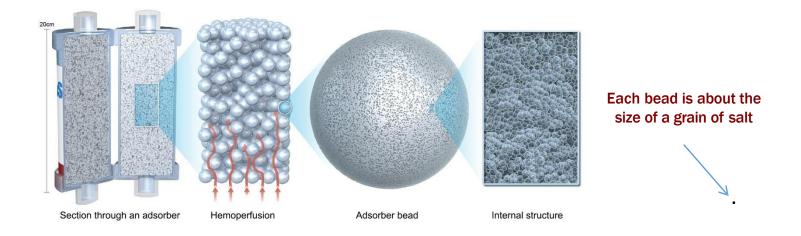
Leading the Prevention or Treatment of

Life-Threatening Inflammation and Cytokine Storm
in the ICU and Cardiac Surgery using

CytoSorb® Blood Purification

### Patented Blood Purification Technology

The underlying blood purification technology is based on biocompatible, highly porous polymer beads that act like tiny sponges to remove harmful substances from blood



- Proprietary patented technology with 16 issued U.S. patents and multiple patents issued and pending worldwide
- Manufactured at our ISO 13485 certified facility in New Jersey

### **Products and Product Pipeline**

Internal development supplemented by strong government support with ~\$38M in grants, contracts, other non-dilutive funds awarded to our technology from DARPA, NIH, NHLBI, US Army, US Air Force, HHS, and others, to date



Sepsis, **Critical Care**, High Risk Surgery CE

ECOS-300CY®

**Ex Vivo Organ Perfusion For Transplant** CE



**Critical** Illnesses in **Animals** 

Marketed

**HemoDefend RBC** 

**Purifcation of pRBCs** 

HemoDefend BGA

**Universal Plasma** 



**CytoSorb-XL** 

Successor to CytoSorb



K+ K+ontrol

Severe Hyperkalemia



**ContrastSorb** 

**CT** Imaging and **Interventional Radiology** 



**DrugSorb** 

**Drug Overdose** 

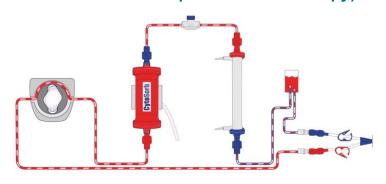
**Under Development** 

## CytoSorb is "Plug and Play" High Margin Razorblade

#### Compatible with Existing Blood Pump Infrastructure In Hospitals Today

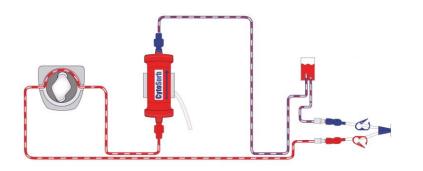
#### **Dialysis or CRRT**

(Continuous Renal Replacement Therapy)



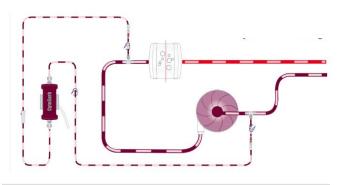
### Hemoperfusion

(Standalone Treatment)



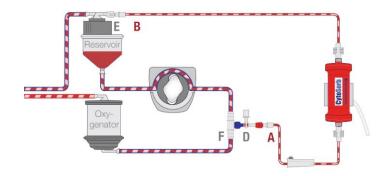
#### **ECMO**

(Extracorporeal Membrane Oxygenation)



#### **CPB**

(Cardiopulmonary Bypass)



## **CytoSorbents** At a Glance (NASDAQ: CTSO)

- CytoSorbents is a rapidly growing NJ-based NASDAQ-traded medical device company
- CytoSorb® is E.U. approved and commercialized in 67 countries as an extracorporeal cytokine adsorber to help treat deadly inflammation where cytokines are elevated (e.g. "cytokine storm").
- Overall, we have shipped more than 121,000 devices to date. Also, treated >5,000 COVID-19 patients in 30+ countries, including in the U.S. under FDA Emergency Use Authorization for use in critically-ill, adult COVID-19+ patients with respiratory failure
- CytoSorb is also E.U. approved to remove bilirubin (liver dialysis), myoglobin (trauma), and blood thinners Brilinta® (ticagrelor) and Xarelto® (rivaroxaban) during cardiothoracic surgery
- CytoSorb is on a dual path to potential U.S. FDA approval
  - FDA Breakthrough Designation to remove Brilinta (ticagrelor) during emergent and urgent cardiothoracic surgery targeting a \$250M total addressable market in the U.S.
  - U.S. REFRESH 2-AKI Trial 400 patient pivotal study using CytoSorb intraoperatively to reduce post-op AKI
- Partnered with leading companies:













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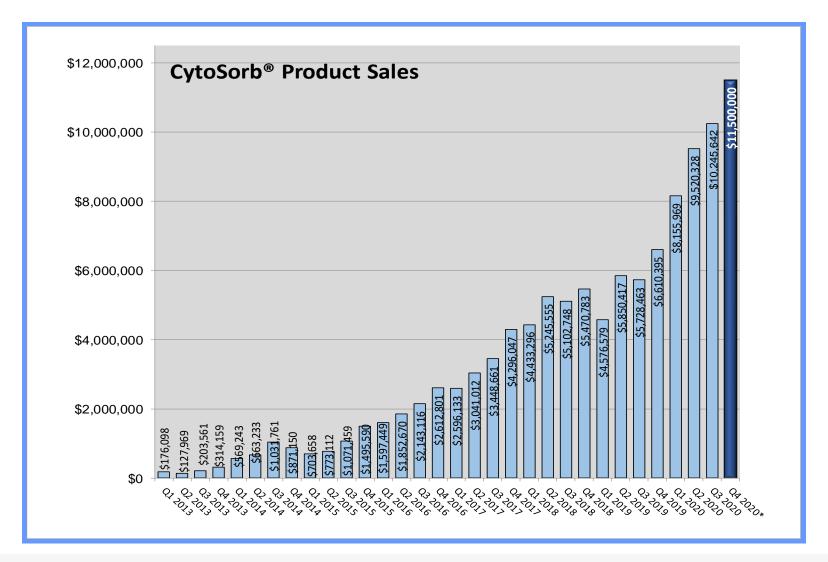
# Pre-Announcement of Q4 2020 and Full Year 2020 Preliminary Unaudited Financials

CytoSorbents sells through a hybrid sales model, with ~65% of sales from direct sales in 10 countries in Europe, including Germany, and the rest from distributors/partners in 57 other countries

- Cumulative CytoSorb treatments delivered surpassed 121,000, from 80,000 at end of 2019
- 2020 Total Revenue (product sales and grant income) was ~40.8M versus \$24.9M in 2019
- 2020 Total Product Sales accelerated to ~\$39.5M versus \$22.8M in 2019, a 73% increase
- Q4 2019 Product Sales growth increased to ~\$11.5M, a 74% increase vs \$6.6M in 2019
- Preliminary blended product gross margins are expected to approach 80% for Q4 2020
- Cash balance at 2020 year end was in excess of \$71M, with no long term debt

## **Quarterly Product Sales**

Q4 2020 product sales were a record high of ~\$11.5M



# Continued Annual Sales Growth and Blended Product Margin Expansion





# What is the U.S. Opportunity?

## EU Approval to Remove Ticagrelor and Rivaroxaban "Blood Thinners" During Cardiothoracic Surgery

CytoSorb has received E.U. approval to remove two well-known blockbuster "blood thinners" during cardiothoracic surgery, used in millions of patients to reduce risk of stroke and heart attacks



**Ticagrelor (Brilinta®, Brilique® - Astra-Zeneca)** is a blockbuster P2Y<sub>12</sub> anti-platelet agent ("blood thinner") with more than \$1.6 billion in worldwide sales, used in patients with acute coronary syndrome



Rivaroxaban (Xarelto® – Bayer, Jansenn/J&J) is a blockbuster Factor Xa inhibitor anti-coagulant ("blood thinner") with ~\$7 billion in 2019 global sales used as lifelong therapy in patients with atrial fibrillation

**Problem:** Patients that require emergent or urgent cardiothoracic surgery on these blood thinners can develop serious bleeding complications

CytoSorb installs easily into a heart-lung machine or cardiopulmonary bypass machine and as blood flows through the cartridge, removes these drugs rapidly during surgery and >90% from whole blood in CPB simulations to reverse their anti-coagulant effect

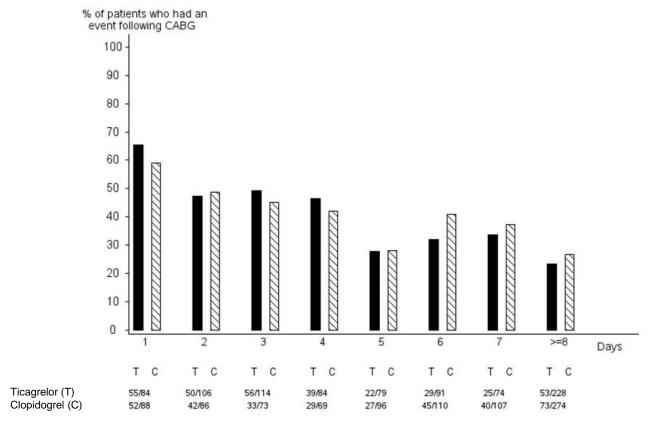
We believe CytoSorb can quickly become a cost-effective standard of care to prevent bleeding due to anti-thrombotics, helping to drive sales growth



### Risk of Bleeding Is High in CABG Patients on Ticagrelor

In the ticagrelor registration PLATO (PLAeleT inhibition and patient Outcomes) trial, 1584 patients underwent CABG surgery, randomized between those who received either ticagrelor or clopidogrel. Those patients (%) with life-threatening bleeding are shown. Bleeding risk is high despite waiting up to 7 days off the drug prior to surgery

Figure 2 – 'Major fatal/life-threatening' CABG-related bleeding by days from last dose of study drug to CABG procedure (PLATO)

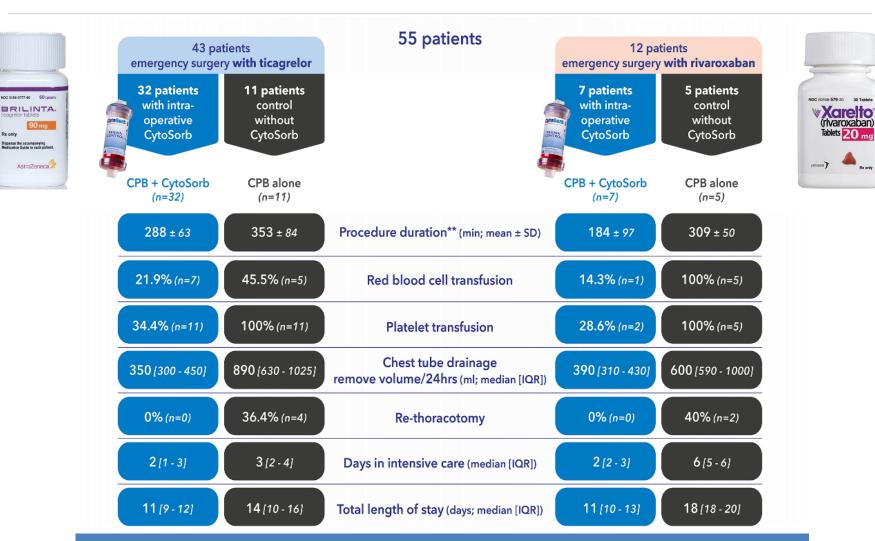


**PLATO Major bleed, fatal/life-threatening:** any major bleed as described above and associated with a decrease in Hb of more than 5 g/dL (or a fall in hematocrit (Hct) of at least 15%); transfusion of 4 or more units. **Fatal:** A bleeding event that directly led to death within 7 days.



<sup>\*</sup> Astra Zeneca Prescribing Information for Ticagrelor PLATO Trial: Wallentin, L. et al. Ticagrelor versus clopidogrel in patients with acute coronary syndromes, NEJM 2009 Sep 10; 361(11):1045-57.

### By Removing Drug, CytoSorb Reduces Bleeding Complications



In a separate analysis done in the U.K., this has translated into a projected cost savings to the hospital of approximately \$5,000 per patient, including the cost of CytoSorb



Hassan K, et al. Ann Thor Surg. 2019; 1:45-51.

Javanbakht, M, et al. Pharmacoecon Open. 2020 Jun; 4(2):307-319.

### **United States TAM for Ticagrelor Removal**

50,000 patients on ticagrelor needing emergent/urgent open heart surgery annually in US

X

\$5,000 per device

### \$250 M Initial U.S. Total Addressable Market



#### Ticagrelor market share expected to grow

- CytoSorb makes ticagrelor the only reversible platelet inhibitor
- Ticagrelor goes off patent in 2024 leading to drop in prices



\$500 M U.S. Total Addressable Market



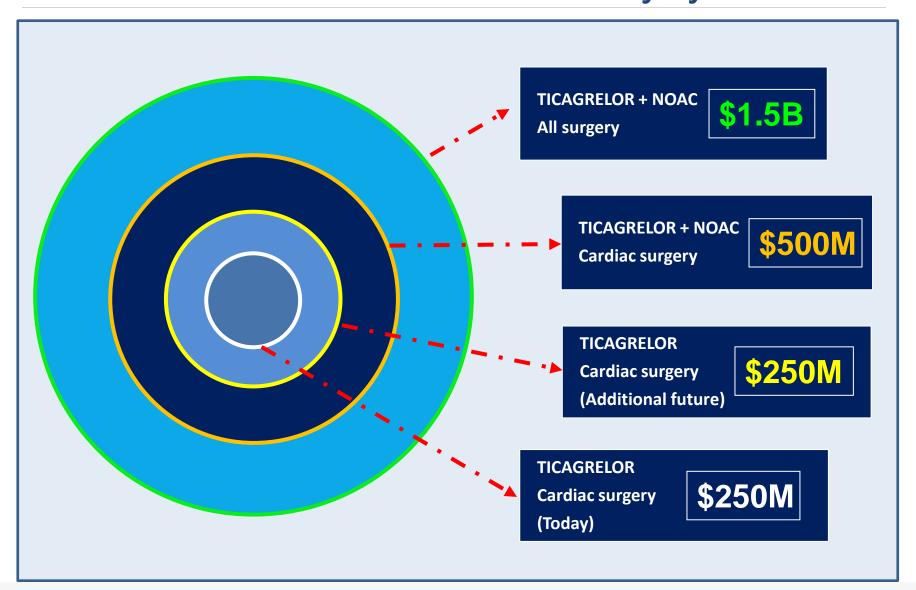
# FDA Breakthrough Designation Sets Stage for Potential Expedited U.S. Regulatory Path



- In April 2020, the FDA granted Breakthrough Designation to CytoSorb to remove ticagrelor during cardiopulmonary bypass in emergent or urgent cardiothoracic surgery – a "fast track" for a major unmet medical need
- We will have more clarity soon on U.S. regulatory path forward that is consistent with Breakthrough Designation status
- Recently hired David Cox as Vice President of Global Regulatory Affairs to help drive approval
  - Former Vice President of Regulatory Affairs for Tissue and Regenerative Technologies at Integra LifeSciences
- Also, recently hired James Komsa as Vice President of US Sales and Marketing to initially manage U.S. COVID-19 sales, but to begin commercialization strategy and build-out ahead of potential U.S. ticagrelor approval.
  - Former Vice President at Medtronic of the Restorative Therapy Group (RTG) and Pain, and former VP of Northeast Region, Cardiac and Vascular Group (CVG)
- New CMS approval of Medicare Coverage of Innovative Technology establishes automatic national Medicare coverage for Breakthrough Devices for 4 years



# Addressable U.S. Market For Current and Potential Future Indications for Antithrombotic Removal by CytoSorb



### **Investment Summary**

CytoSorbents has the potential to become a highly profitable elite performer in the therapeutics space with industry leading operating profit margins

- High margin razorblade business model with excellent operating leverage and a solid track record of ex-US growth
- Strong foundation and well-funded for potential future growth, with new and existing clinical applications that address major unmet medical needs
- Working to drive U.S. FDA approval by leveraging FDA Breakthrough Designation of CytoSorb for ticagrelor (Brilinta®) removal. Believe CytoSorb can rapidly become standard of care and capture an initial \$250M opportunity
- We have extensive validation from physicians around the world, leading strategic partners, U.S. government agencies, and the media
- Additional near-term catalysts could include new clinical data, clarity on U.S.
   regulatory path under Breakthrough Designation, sales progress, and many others

