

# CytoSorbents Corporation

NASDAQ: CTSO

An Emerging Leader in  
Critical Care Immunotherapy

Q1 2015 Review – May 11, 2015



# 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 Form 10-K filed with the Securities and Exchange Commission on March 31, 2015 and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).



**CytoSorbents**

Working to Save Lives Through Blood Purification

# Conference Call Participants

Dr. Phillip Chan, MD, PhD

Chief Executive Officer and President

Vincent Capponi, MS

Chief Operating Officer

Kathleen Bloch, MBA, CPA

Chief Financial Officer

Dr. Christian Steiner, MD

Vice President of Sales and Marketing

Christopher Cramer, MS, MBA

Vice President of Business Development

Moderator: Lee Roth – The Ruth Group

# CytoSorbents is An Emerging Leader in Critical Care Immunotherapy



Leading the Prevention or Treatment of  
Life-Threatening Inflammation in the ICU using  
CytoSorb<sup>®</sup> Blood Purification



# \$20 Billion Opportunity in Critical Care

Millions of people are admitted to the intensive care unit in hospitals in the U.S. and the European Union each year with deadly inflammatory conditions



- In these conditions, massive inflammation driven by a “cytokine storm” causes cell death and organ failure. Nearly half of all deaths in the ICU is due to organ failure with no effective therapies
- Because of the lack of effective therapies, approximately 1 in every 3 patients dies
- The costs can be staggering: Lack of “active” therapies lead to patients lingering days to weeks in the ICU at \$2,000-3,000 per day in the ICU\* on average
- Not surprising that we spend nearly 1% of our GDP on critical care\*\*

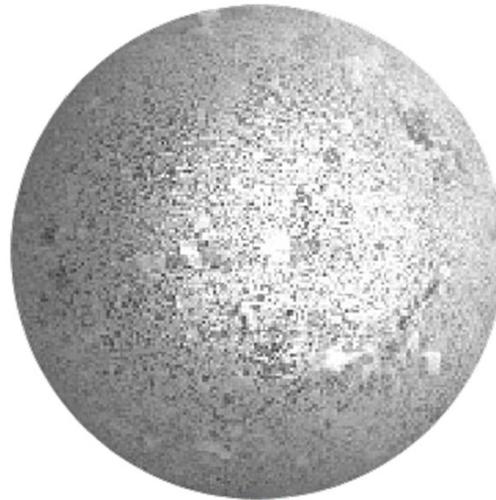
# CytoSorb<sup>®</sup> Removes the Fuel to the Fire

- CytoSorb<sup>®</sup> represents a powerful immunotherapy to control inflammation
- Approved in the European Union as the only specifically approved cytokine filter
- Clinically proven to remove key cytokines in the blood of critically-ill patients
- Approved for use in any situation where cytokines are elevated
- Safe: More than 5,500 human treatments, safe and well-tolerated



# The Heart of the Technology

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



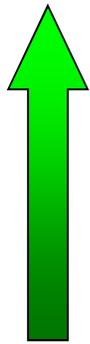
Each bead is about the size of a grain of salt



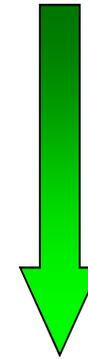
- Protected by 32 issued US patents and multiple applications pending
- Manufactured at our ISO 13485 certified facility in New Jersey
- One of the highest grade medical sorbents on the medical market today



# Goal: To Prevent or Treat Organ Failure

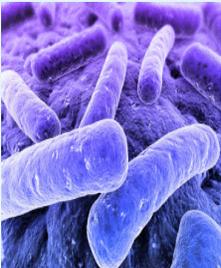


Improve  
Patient  
Outcome  
and  
Survival



Decrease  
Costs Of  
ICU and  
Patient  
Care

Sepsis



ARDS



Burn Injury



Trauma



Pancreatitis



Influenza



Surgical



The Potential to Revolutionize Critical Care Medicine



# Case Report: Drug Resistant Pneumonia

- A 46 year old man was hospitalized with fatigue, cough and breathing difficulty to a small hospital in Northern Germany
- Patient was diagnosed with pneumonia and severe sepsis, and placed on broad spectrum antibiotics. Blood cultures grew out multi-drug resistant *Acinetobacter baumannii*
- The patient developed complications of rhabdomyolysis, leading to kidney failure with no urine output. In the meantime, he rapidly developed acute respiratory distress syndrome requiring mechanical ventilation. Sputum samples grew out both *Staph aureus* and *Strep pyogenes*
- Despite aggressive management and 5 days of dialysis, patient had little improvement in myoglobin levels and was transferred to major hospital
- Patient underwent the first CytoSorb® treatment which reduced plasma levels of myoglobin by 50%
- A total of 4 treatments were conducted. After 3 treatments, organ failure stabilized, myoglobin levels were significantly reduced, and renal function and urine production returned. Control of the infection was also achieved
- Patient was discharged from ICU on day 10.

# Operating and Financial Highlights



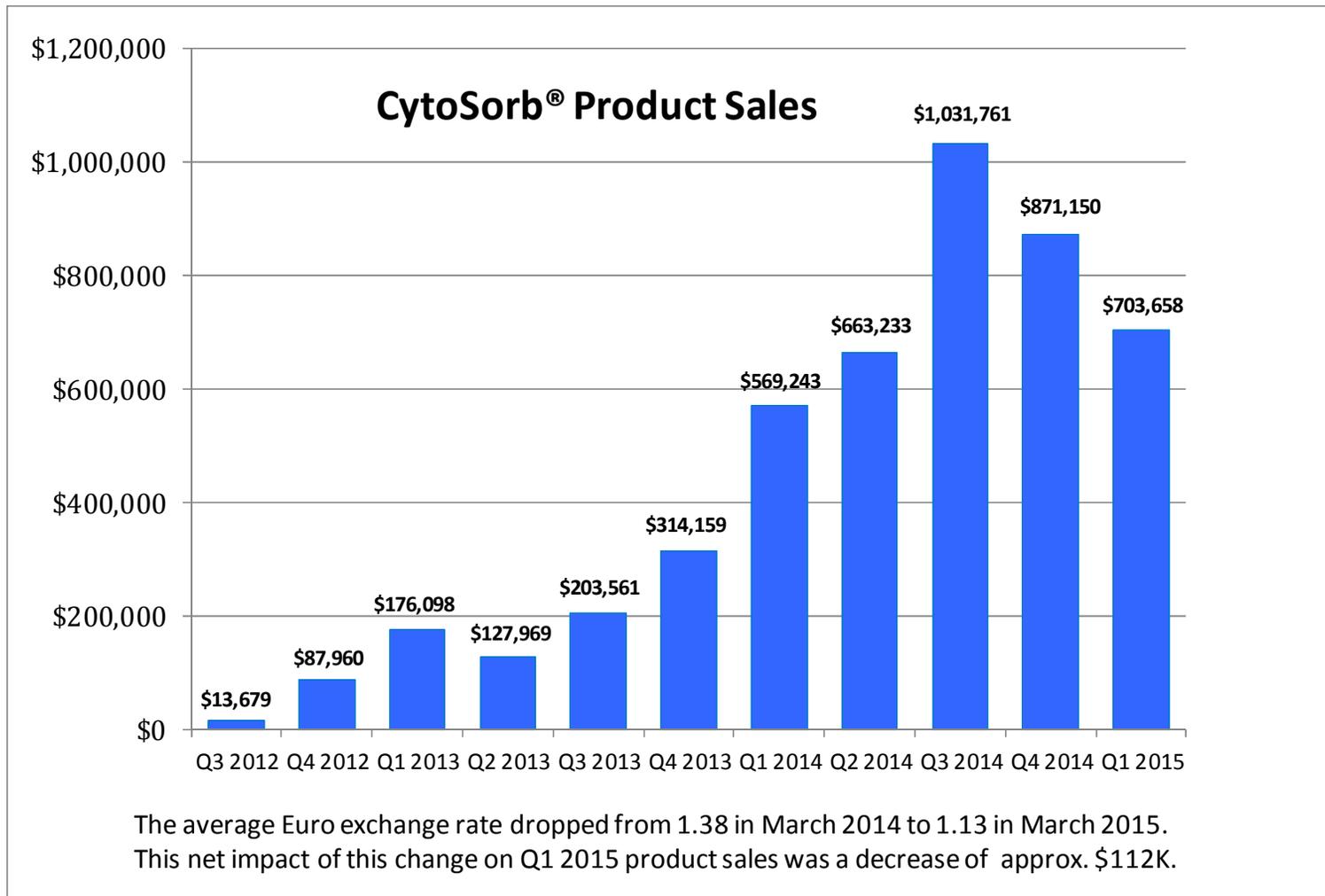
**CytoSorbents**  
Working to Save Lives Through Blood Purification

# Comparative Revenue Results

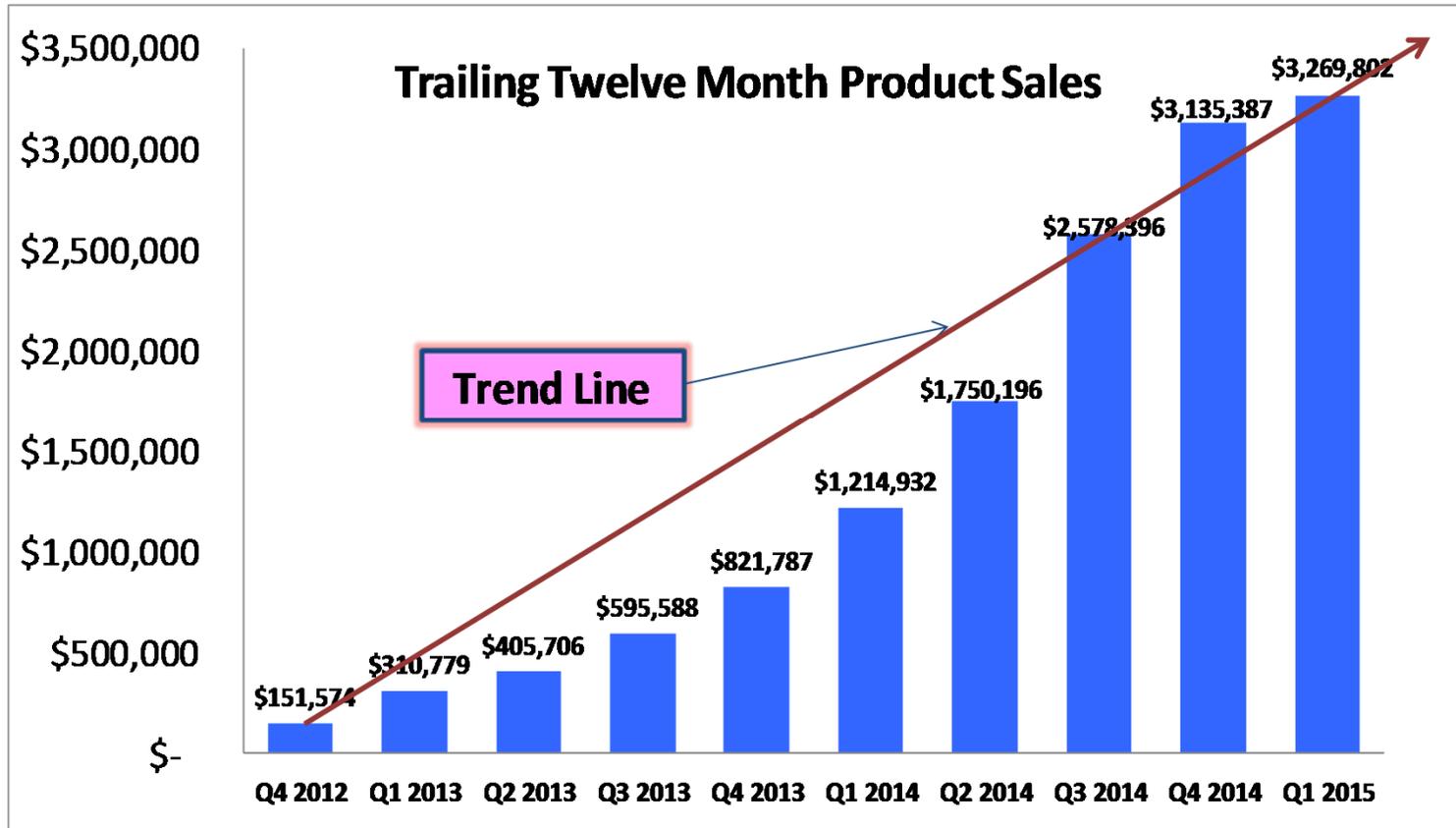
	2015	2014	% Incr.
Product revenue	\$ 703,658	\$ 569,243	24%
Grant and other income	19,416	492,929	(96)%
Total revenue	\$ 723,074	\$ 1,062,172	(32)%

- CytoSorb® product sales were \$703K in Q1 2015, a 24% increase over product sales of \$569K in Q1 2014
- Product sales were impacted by the decline in the exchange rate of the Euro by approximately \$112,000 or 16% of product sales for Q1 2015
- Grant income was nominal in the first quarter of 2015, as a result of the conclusion of several significant grants
- Gross profit margins on product sales were approximately 59% in Q1 2015, as compared to 61% for Q1 2014, also impacted by the weakness of the Euro

# Quarterly Product Sales



# Product Sales Growth



# Working Capital and Cap Table

	3/31/15	12/31/14	12/31/13	12/31/12
Current Assets:				
Cash and short-term investments	\$ 13,358	\$ 5,550	\$ 2,183	\$ 1,729
Grants and accounts receivable, net	673	819	453	51
Inventories	703	538	245	682
Prepaid expenses and other current assets	148	700	605	476
Total current assets	14,882	7,607	3,486	2,938
Current Liabilities(1):				
Accounts payable	475	698	787	801
Accrued expenses and other current liabilities	734	825	362	350
Deferred revenue	-	1	272	-
Total current liabilities	1,209	1,524	1,421	1,151
Net Working Capital	\$ 13,673	\$ 6,083	\$ 2,065	\$ 1,787
(1) Excludes warrant liability, a current liability that does not have cash implications.				

## CytoSorbents Cap Table (Pro-Forma as of 3/31/2015)

Common stock outstanding	24,678,415
Options	2,195,171
Warrants	1,521,479
Fully-diluted Common shares	<u>28,395,065</u>



# Catalysts of Growth



# #1: Core Focus on **CytoSorb**® Sales



Working with KOLs worldwide



Driving Departmental Adoption targeting Junior & Senior physicians



50+ Company Sponsored and Post-Market Studies



Reference Hospitals with Expansion to MICU, SICU, CICU, Trauma ICU



Strong Direct Sales Team with Distributor Support



Reimbursement and Expansion of Distributor Network is Key



# Targeting Significant Revenue Acceleration

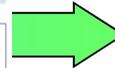
\$M: 2015 Sales and Beyond

2014 Sales



## Revenue Multiplying Effect

 Working with NCLs worldwide	 Strong Direct Sales Team with Distributor Support	 Reference Hospitals with Expertise to MICU, SICU, DDU, Trauma ICU
 Driving Departmental Adoption targeting Junior and Senior Physicians	 50+ Post Market Studies Generate Clinical Data in Many Applications	 Orders from Existing Distributors, Further International Expansion and Reimbursement Focus



\* Number of cartridges used only to graphically demonstrate the multiplier effect concept. This does not reflect revenue guidance for 2015.

# Strong Direct Sales Infrastructure



**Dr. Christian Steiner**  
 Managing Director



**Stefan M. Baudis**  
 Sales Director International



**Alexandru Bojan**  
 Business Manager Export



**Hans-Jürgen Kraus**  
 Regional Sales Manager  
 Southern Germany



**Matthias Höldtke**  
 Regional Sales Manager  
 South-East Germany



**Martin Scherer**  
 Regional Sales Manager  
 Southwest Germany



**Uwe Gerks**  
 Regional Sales Manager  
 Northern Germany

Sales Rep 5:  
 Signed to start  
 early Q3

Sales Rep 6:  
 Signed to start  
 early Q3

Regional Sales Manager  
 Northeast Germany

Regional Sales Manager  
 Northwest Germany

Sales Rep 7:  
 Currently  
 Screening

Sales Rep 8:  
 Currently  
 Screening

## Support



**Dr. Jörg Scheier**  
 Medical Director Europe



**Dr. Rainer Kosanke**  
 Head of Scientific Marketing



**Dominik Gutzler**  
 Head of Product  
 Management



**Eva Wechsler**  
 Application Specialist



**Ilona Otto**  
 Sales Assistant / Customer  
 Support national



**Petra Hoffmann**  
 Sales Assistant / Customer  
 Support international

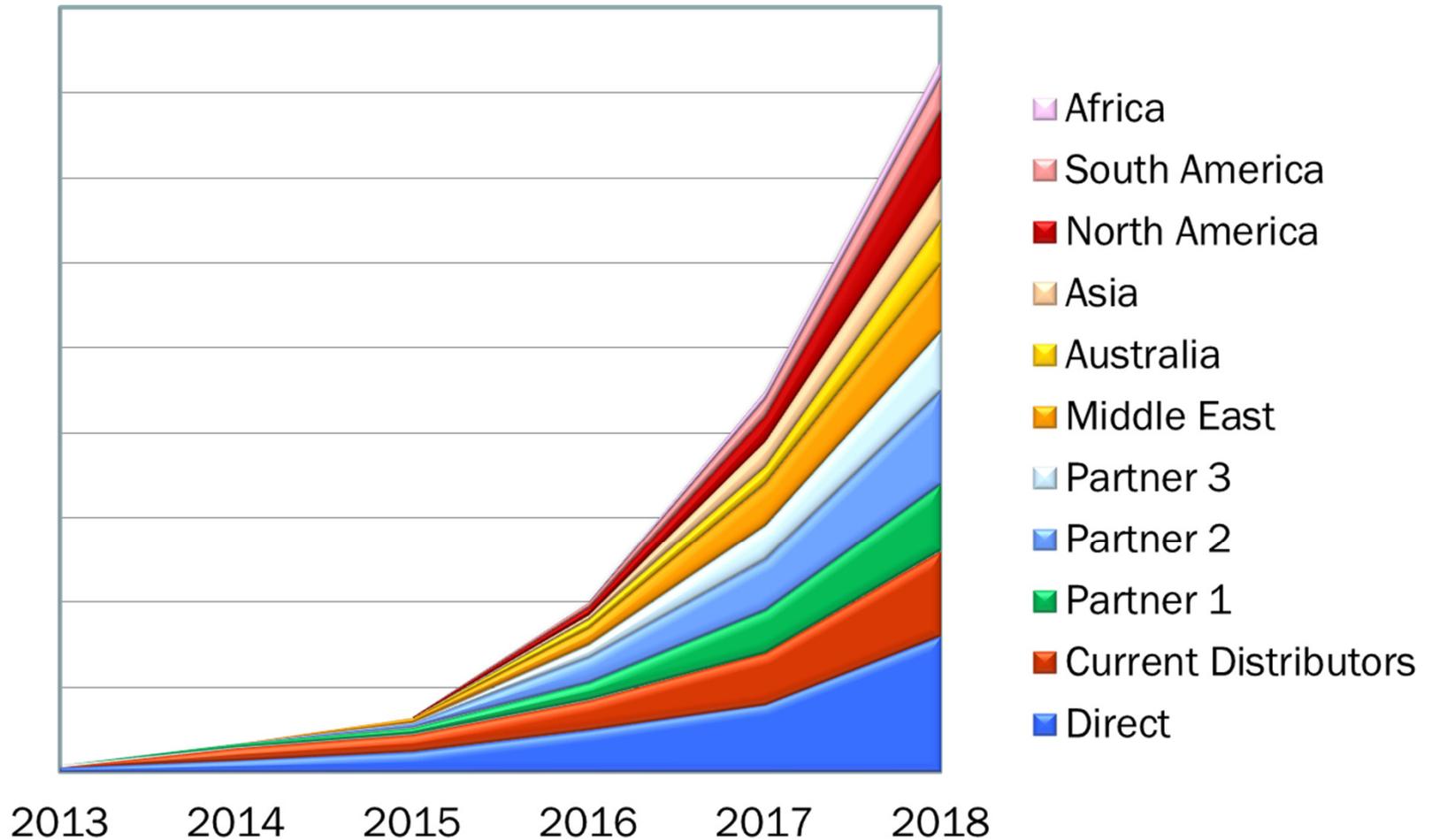


# Progress on Registration

- Actively selling product in the E.U. in Germany, Italy, the U.K., Austria, Switzerland, Romania, and the Netherlands, as well as in Turkey and India
- Now registered in France, the second largest medical device market in the E.U.
  - Paves the way for both Fresenius and our cardiac surgery partner
- Currently registered in Saudi Arabia, and are waiting for Saudi FDA approval that can be leveraged rapidly across all seven countries of the Gulf Cooperation Council (GCC) including the United Arab Emirates, Kuwait, Qatar, and others
- Registered in Australia through the Therapeutic Goods Administration (TGA).
  - In final stages of negotiations with our distribution partner there.
- In the final stages of registration in Russia, expected in Q1 2016, if not sooner
- Have met the requirements to add Canadian registration to our ISO 13485 certification. This will allow CytoSorb® to be registered in Canada once all Health Canada requirements have been met
- Currently working establishing distribution in a number of other countries

# Growth Driven by Direct, Distributor, Partner Sales

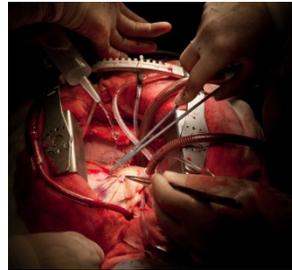
## Theoretical Revenue Growth Based on Layering\*



# #2: Target US FDA Approval

## Cardiac Surgery

One million open heart surgeries performed in the US and EU each year, representing a \$500M-1 billion market



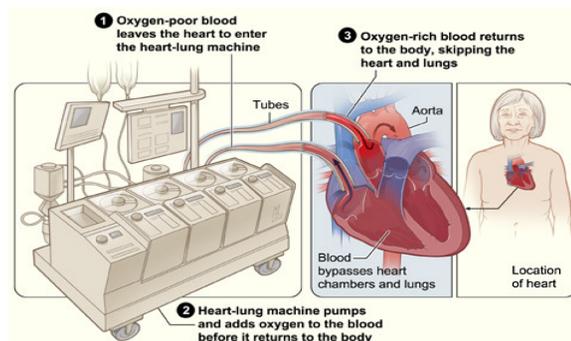
Reduce free hemoglobin



Reduce cytokines, activated complement

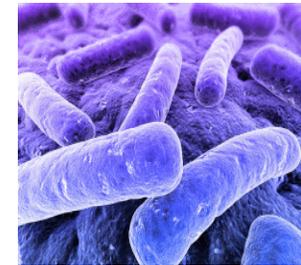


Reduction or treatment of post-operative SIRS



## Sepsis and Critical Illness

Sepsis alone afflicts 2.5 million people in the US and EU annually without an approved therapy. Critical care illnesses represents a \$20 billion market overall



Inflammatory cytokines (organ failure)



Immunosuppressive cytokines (infection)



Many bacterial toxins (organ failure)



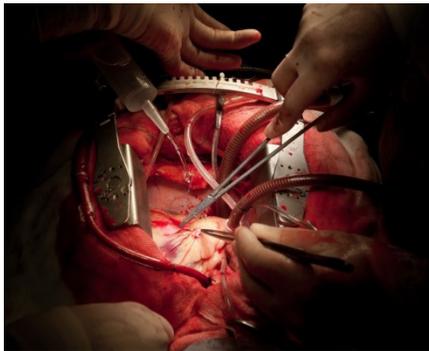
Directs immune system where to go and where not to go (organ failure)

No other single therapy has demonstrated this broad range of activity



# FDA Approval of IDE for REFRESH Study

- **REFRESH** (Reduction in FRee Hemoglobin) Trial is a 20-patient multi-center feasibility study evaluating the safety of CytoSorb® use intra-operatively in a bypass circuit in a heart-lung machine during complex cardiac surgery. The goal is the safe reduction of plasma-free hemoglobin and other inflammatory mediators that can cause post-operative complications
- The trial is on target to commence mid-year and is expected to be completed before year-end. Following discussions with the FDA, we plan to file a pivotal trial IDE shortly thereafter designed to support US regulatory approval



# FDA Expedited Access Pathway (EAP)

The FDA has issued formal guidance on the EAP program that will facilitate the approval of medical devices that treat life-threatening conditions and fulfill the following criteria:



- ✓ 1) The medical device is intended to treat a life-threatening or irreversibly debilitating disease **AND**
- ✓ 2) Meets at least one of the following:
  - ***No approved alternative treatment exists, or***
  - A breakthrough technology that provides a clinically meaningful advantage over existing technology, or
  - Offers a significant, clinically meaningful advantage over existing approved alternatives, or
  - ***Availability is in the patient's best interest***
- 3) And Sponsor submits an acceptable Data Development Plan draft outlining pre-market and post-market data collection

CytoSorb® targets the treatment of many life-threatening conditions such as sepsis, acute respiratory distress syndrome, severe acute pancreatitis, trauma and many others that do not have viable treatment alternatives

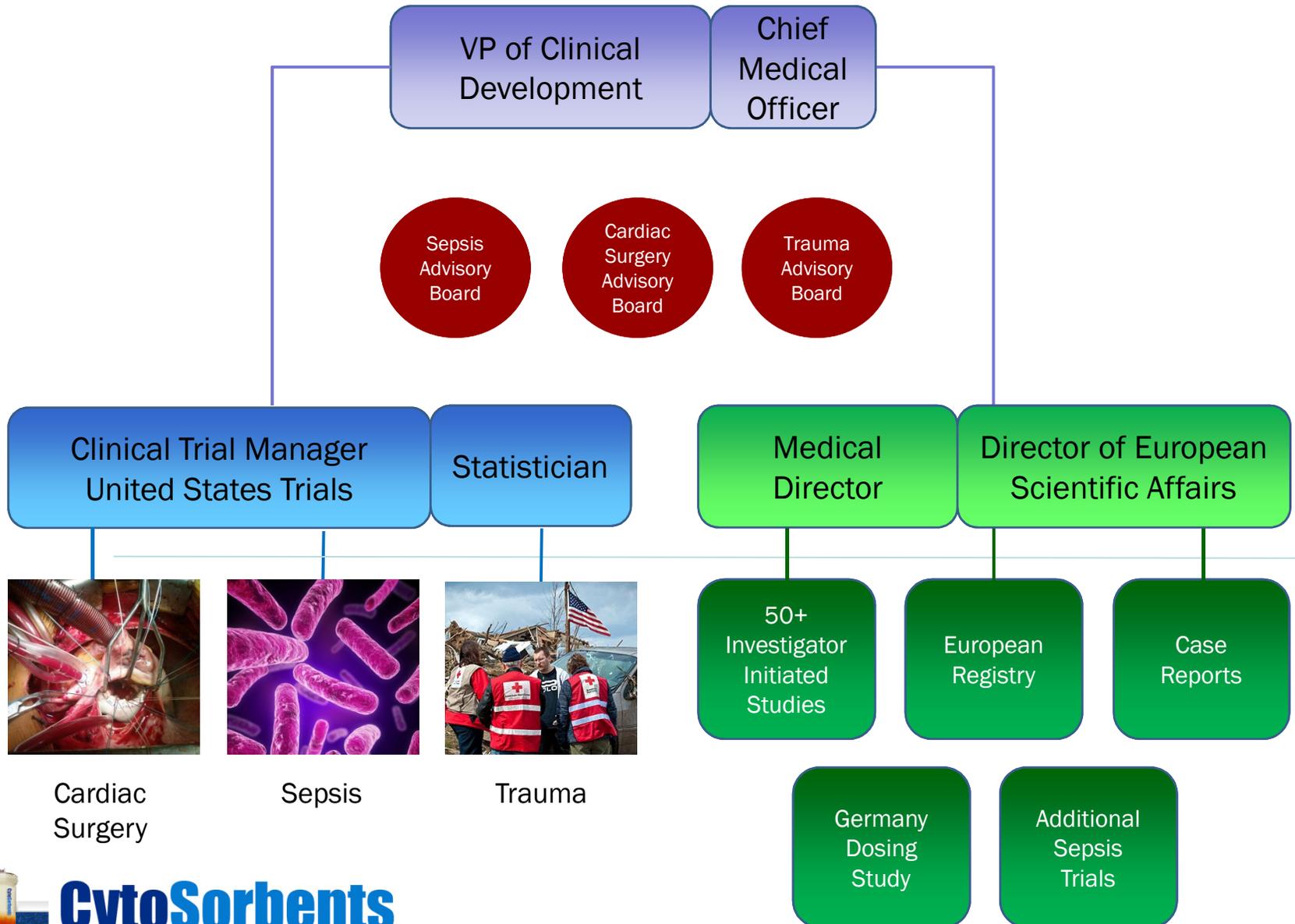
# Advantages of EAP Designation

The first step is to submit an application to the FDA to request EAP Designation. If successful, this has a number of advantages:

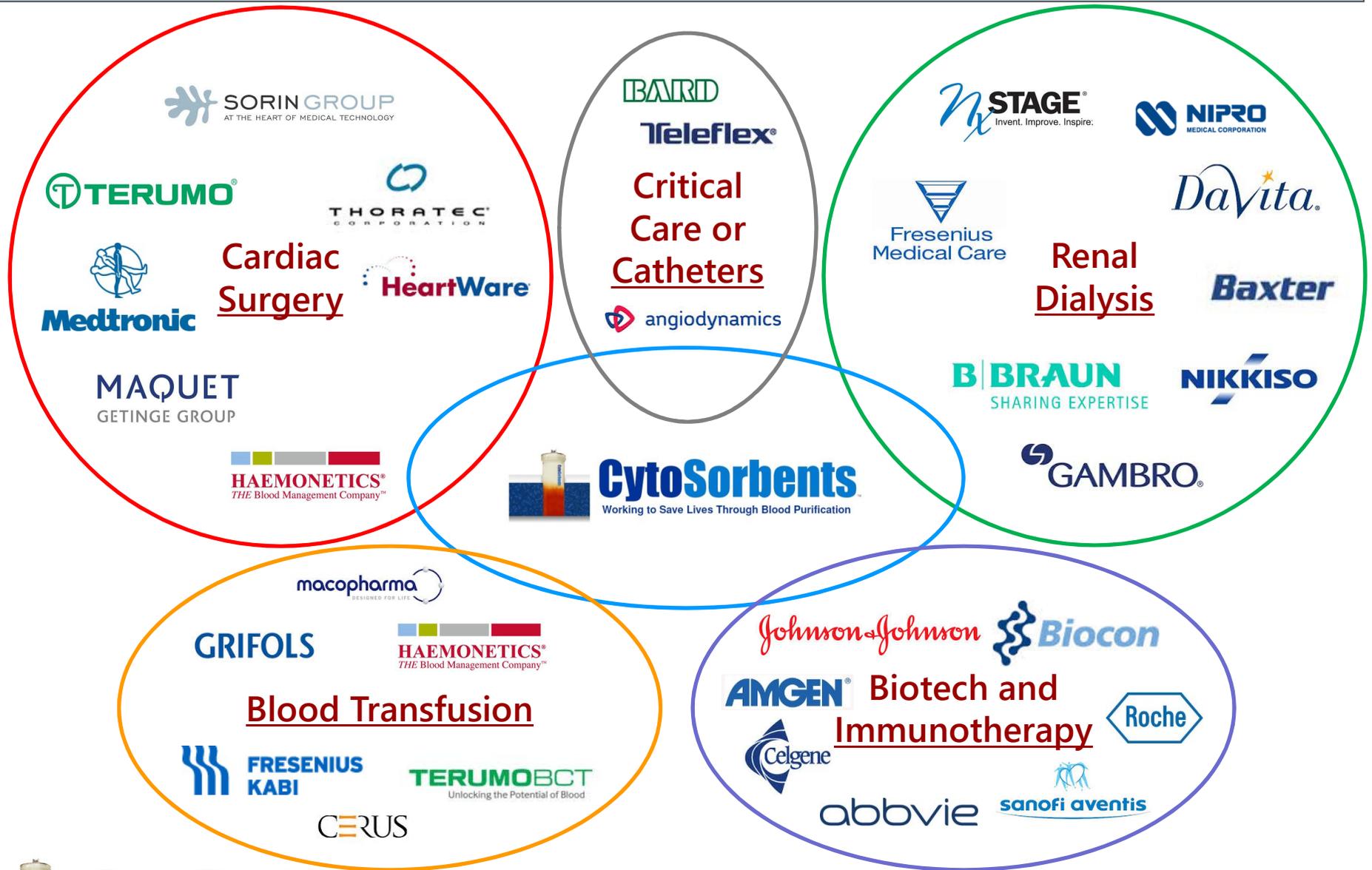
- CytoSorb® would be given priority status and be assigned an FDA case manager which would facilitate future discussions with the FDA
- Valid for both PMA and De Novo 510(k) paths
- Shifts Premarket data collection to the post-market setting with the appropriate safeguards for safety
- May allow for the potential acceptance of softer clinical endpoints to justify approval, in anticipation of more conclusive post-market data on endpoints such as mortality
- 30-day review of the application

This program is designed to facilitate early and faster US regulatory approval of potentially life-saving medical devices. We believe this squarely applies to the core of our critical care strategy at CytoSorbents. As we move forward with our cardiac surgery trial, we plan to pursue this EAP opportunity in critical care applications and foster open discussions and collaboration with the FDA.

# #3: Generation of Clinical Data



# #4: Advance Strategic Partnerships\*



\*Companies listed here are used simply as examples of companies in these respective verticals. We make no other representations to our relationship with any of these companies.

# Strategic Partner Update

- In collaboration with CytoSorbents, Biocon is moving forward with the design and funding of 4 investigator initiated or proof of concept studies and a focused effort to collect and publish clinical data from the field. Biocon is also planning to expand to Sri Lanka, a country of 20 million
- Fresenius is working to complete the necessary start-up activities and training needed to launch CytoSorb® in France, Norway, Sweden, Finland, Denmark and Poland. We are very close to a launch and hope to have more information soon
- We are currently in process of the market evaluation with our Cardiac Surgery partner with a leading cardiac surgery center in France, including an initial order of CytoSorb® devices to support this process. We expect this process to go quickly. A successful outcome could pave the way for a broader partnership



**Cardiac Surgery  
Partner**



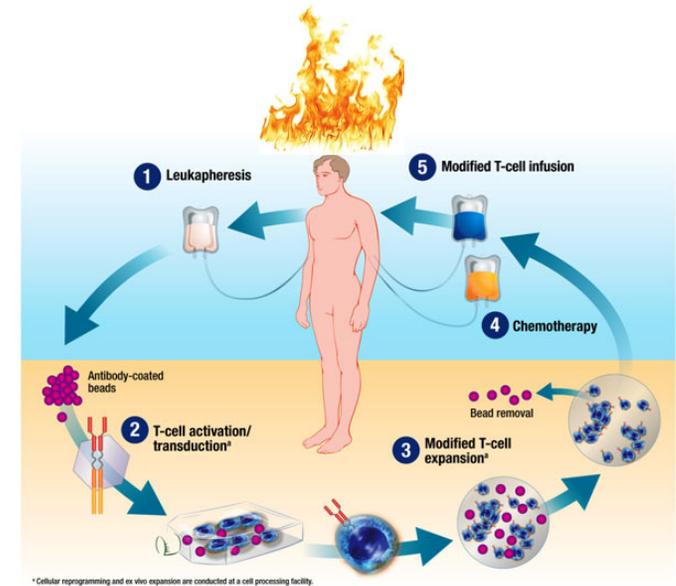
# #5: New Opportunities



# Cytokine Release Syndrome in Cancer Immunotherapy

One of the most promising and exciting areas of cancer research is where:

- 1) A patient's own white blood cells (T-cells) are removed from the body
- 2) Modified with a gene for a chimeric antigen receptor (CAR) that enables it to recognize, proliferate, and now kill cancer cells



- This experimental CAR T-cell immunotherapy has now led to the “cure” of many refractory leukemias in ongoing studies
- It potently stimulates the inflammatory response, leading to an expected “flu-like” syndrome in patients, characterized by high levels of cytokines. This “cytokine release syndrome”, or CRS, can spiral out of control, despite the use of tocilizumab and other prophylactic measures, leading rapidly to multiple organ failure and death

# A Lucrative Market for Deals and Values



## CAR T-CELL DEALS

Institution/Company	Date	Partner	Terms
University of Pennsylvania	August 2012	Novartis	Undisclosed
Celgene	March 2013	Bluebird Bio, Baylor College of Medicine	Unspecified upfront payment plus up to \$225 million per product in option fees and milestone payments
Collectis	June 2014	Pfizer	\$80 million upfront plus up to \$185 million per product and royalties
Collectis	January 2015	Ohio State University	Undisclosed
Kite Pharma	January 2015	Amgen	\$60 million upfront and up to \$525 million per product in milestone payments, plus royalties on sales and IP licensing
Md Anderson	January 2015	Ziopharm, Intrexon	\$100 million in stock and \$15-20 million/year for 3 years

As of 5/8/15

Market Cap

Juno

\$4.2 billion

Bluebird Bio

\$5.3 billion

Kite Pharma

\$2.4 billion

Intrexon

\$4.5 billion

Collectis

\$1.1 billion

April 2015



# Ensuring Safety is A Major Concern

**TheScientist**  
EXPLORING LIFE, INSPIRING INNOVATION

## **SAFETY CONCERNS**

Despite the growing number and length of remissions using CAR T-cell therapy to treat leukemias and lymphomas, key challenges remain—first and foremost, safety. There have been a half-dozen treatment-related deaths in the University of Pennsylvania and Juno trials in the past few years that involve a major side-effect of CAR T-cell therapy called cytokine-release syndrome (CRS). T-cell activation causes the release of inflammatory cytokines, producing symptoms including high fevers, aches, hypotension, and, more rarely, pulmonary edema and neurologic effects such as delirium.

Researchers tie the severity of what they call a “cytokine storm” to tumor burden—a patient’s total mass of cancer tissue or quantity of malignant cells. One hypothesis for this is that higher tumor burden seems to incite a stronger immune reaction. Moreover, the deaths have all occurred in adults, some of whom had serious underlying medical issues, and others who had undiagnosed infections. Interestingly, children seem relatively resistant to severe CRS and, when they get it, are more easily managed, says Michel Sadelain of Memorial Sloan Kettering and Juno. “Adults do not tolerate the treatment as well as children, in whom the cells differ in speed of action and persistence,” Sadelain says. Treatment with an anti-IL6 antibody, or in severe cases, corticosteroids, can mitigate a cytokine storm’s severity, as can dosing with lower numbers of CAR T cells.

“In our trial [on diffuse large B-cell lymphoma], we saw that toxicity was reduced in patients who received low-dose chemotherapy rather than high-dose [prior to CAR T-cell treatment], and lower numbers of engineered T cells [than given previously],” says James Kochenderfer of the National Cancer Institute (NCI).

Bellicum is partnering with the University of Leiden in the Netherlands and the NCI, among others, to develop “suicide switches,” or safety on-and-off switches that are incorporated into CAR T-cell candidates to control T-cell activation and proliferation. And Juno’s second-generation “armored” CAR technologies include mechanisms to dampen T-cell activation. “It will be important to find new ways to overcome toxicity of CAR T cells,” says the Weizmann Institute’s Zelig Eshhar.



**CytoSorbents**  
Working to Save Lives Through Blood Purification

April 2015



and



Fate Therapeutics

Juno recently announced a strategic partnership with Fate Therapeutics, for the screening and development of small molecules that can modulate the biologic activities of activated T-cells. The goal of this program is to develop a pharmacologic “switch” to turn activated T-cells on or off.

- Small molecules developed in this pre-clinical program will be specific to Juno’s CAR T-cell constructs
- It is unclear whether or not “turning off” these activated T-cells will reduce cytokine release syndrome, because at this point, the broader immune system (not just CAR T-cells) has been activated

### Terms of the deal

- \$5M upfront payment to Fate
- Purchase of 1 million shares at \$8 per share (75% premium)
- Up to a four year research term where Juno pays all development costs
- For each Juno CAR T-cell program that is developed incorporating Fate’s technology, the company may receive \$50 million in milestones plus low single-digit royalties on net sales
- Ability to extend the term by 2 years with a \$10M stock purchase



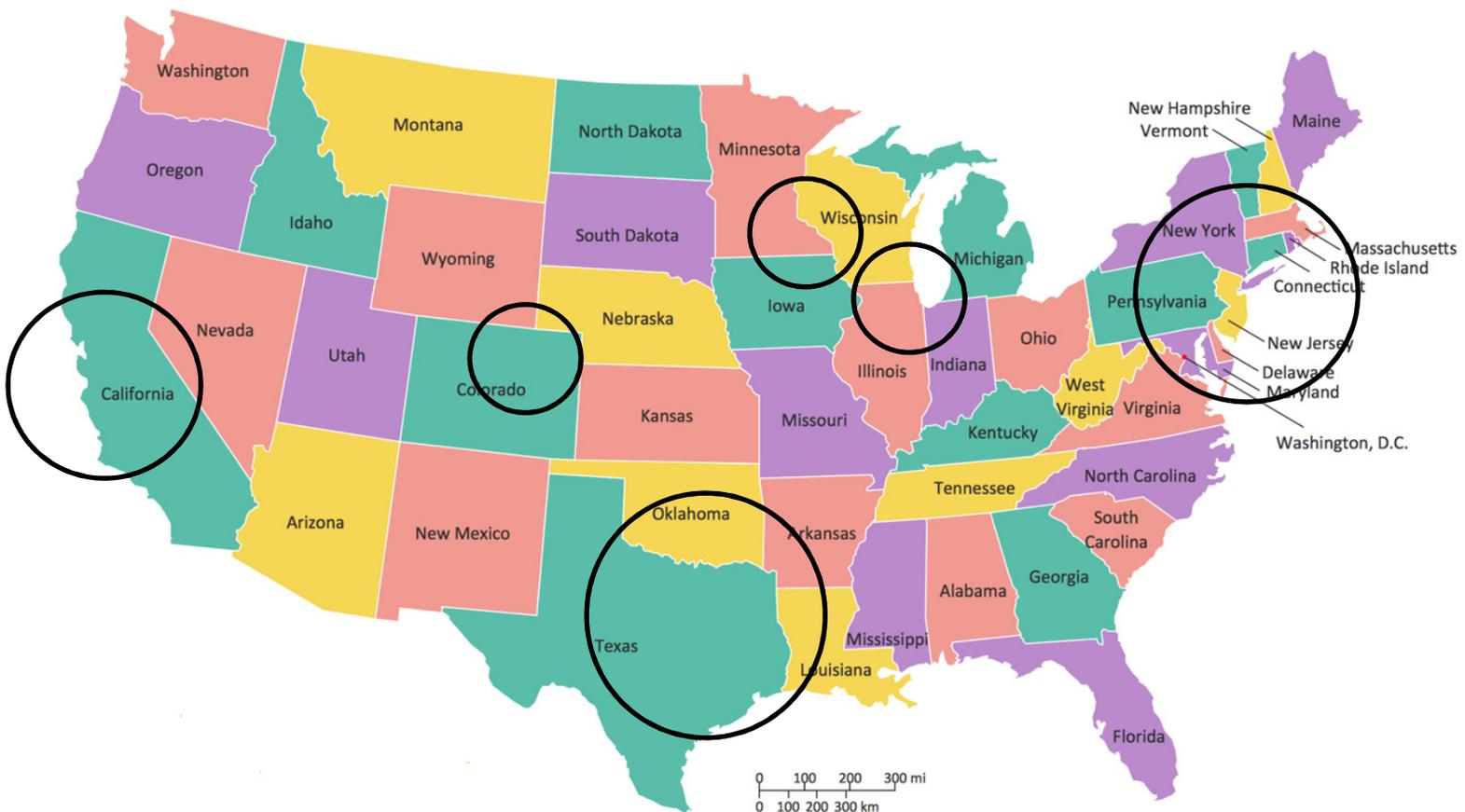
**CytoSorbents**  
Working to Save Lives Through Blood Purification

# CytoSorb<sup>®</sup> Was Designed to Control CRS

- CytoSorb<sup>®</sup> was specifically designed to control cytokine storm and cytokine release syndrome (CRS) by reducing the broad range of inflammatory mediators that are driving the systemic inflammatory response syndrome
- We believe that CytoSorb<sup>®</sup> represents a unique and easy to administer rescue therapy for CAR T-cell immunotherapies and for other activated T-cell therapies
- It is agnostic to the CAR T-cell approach and could potentially be used as a broad spectrum solution across the technologies of all companies in this space
- We currently have multiple initiatives in this area that we are exploring

# #5: Increased Investor Awareness

In the near future, we will be meeting with institutional investors in many major cities across the country to increase awareness of our company and technology



# Continued Positive Analyst Coverage and Investor Outreach

## Current Analyst Coverage:

- Brean Capital
- H.C. Wainwright
- MLV & Co
- Merriman Capital
- WBB Securities
- Zacks

# Increased Media Coverage

**+ MASS DEVICE**

CytoSorbents inks deal with Fresenius Medical Care ([link](#))  
 By Mark Hollmer  
 Mass Device  
 December 16, 2014

Fresenius Medical Care is slated to distribute CytoSorbents' cytokine blood purification filters in several countries as part of a new strategic partnership.

CytoSorbents (OTC:CTSOD) said yesterday that it scored an international strategic partnership with Fresenius (NYSE:FMS) that will boost access to international markets for its cytokine blood purification technology.

**MEDICAL DEVICE DAILY™**  
 THE DAILY MEDICAL TECHNOLOGY NEWS SOURCE  
 WEDNESDAY, DECEMBER 24, 2014

People in the News  
 Medical Device Daily  
 December 24, 2014

CytoSorbents (Monmouth Junction, New Jersey), a critical care focused immunotherapy company marketing its CytoSorb blood purification technology to help fight deadly inflammation in critically-ill and cardiac surgery patients, reported the appointment of Gregory Di Russo, as its Senior Vice President of Clinical Development, effective Jan. 5, 2015. Di Russo is an accomplished pediatric cardiothoracic surgeon specializing in congenital cardiac surgery and was Vice Chairman of Cardiothoracic Surgery at

**Cardiovascular News**

CytoSorbents submits IDE application for US CytoSorb cardiac surgery trial ([link](#))  
 By Dawn Powell  
 Cardiovascular News  
 January 2, 2014

CytoSorbents has submitted an Investigational Device Exemption (IDE) application to the US Food and Drug Administration (FDA) to conduct its proposed clinical trial using CytoSorb intra-operatively in patients undergoing complex cardiac surgery requiring the use of a heart-lung machine.

**FDANEWS**  
 Simplifying Global Compliance

CytoSorbents Files IDE for CytoSorb Cardiac Surgery Trial ([link](#))  
 By Kellen Owings  
 FDANews  
 January 2, 2015

**FierceDrugDelivery**

Cytosorbents no longer an OTC stock, uplists to Nasdaq ([link](#))  
 By Varun Saxena  
 FierceDrugDelivery  
 December 24, 2014

Starting today, CytoSorbents, maker of the CytoSorb extracorporeal cytokine adsorber to reduce

**BioCentury®**

CytoSorbents Corp. (OTCQB:CTSOD), Monmouth Junction, N.J.  
 By Staff Writer  
 BioCentury  
 December 15, 2014

**MICROCAP DAILY**

Cytosorbents Corp (NASDAQ:CTSOD) Rebounding on a Stronger Note ([link](#))  
 By James Elliot  
 MicroCap Daily  
 December 30, 2014

Cytosorbents Corp (NASDAQ:CTSOD) is coming back strong after a smack to just over \$9 a share. The stock has been upwards on huge strength in recent days hitting a high of \$12.86. The ticker symbol has changed back to CTSOD from CTSOD after the 1 for 25 reverse split of the stock. The Company announced on December 15 that its common stock has been approved for listing on The NASDAQ Capital Market. Shares are expected to begin trading on The NASDAQ Capital Market on Tuesday, December 30, 2014 under the ticker symbol "CTSOD".

**FierceMedicalDevices**

Fresenius adds blood purification tech to its dialysis offerings via partnership ([link](#))  
 By Varun Saxena  
 FierceMedicalDevice  
 December 16, 2014

Dialysis magnate Fresenius Medical Care, a leading provider of hemodialysis machines, has entered into a partnership to help commercialize the cytokine adsorber CytoSorb to combat sepsis and other infections that can lead to organ failure. The financial terms of the pact with product developer CytoSorbents were not disclosed.

The blood purification therapy CytoSorb complements Fresenius' extensive




# CytoSorbents Has Tremendous Potential

**CytoSorb<sup>®</sup>** may help revolutionize critical care medicine,  
saving lives, and reducing costs

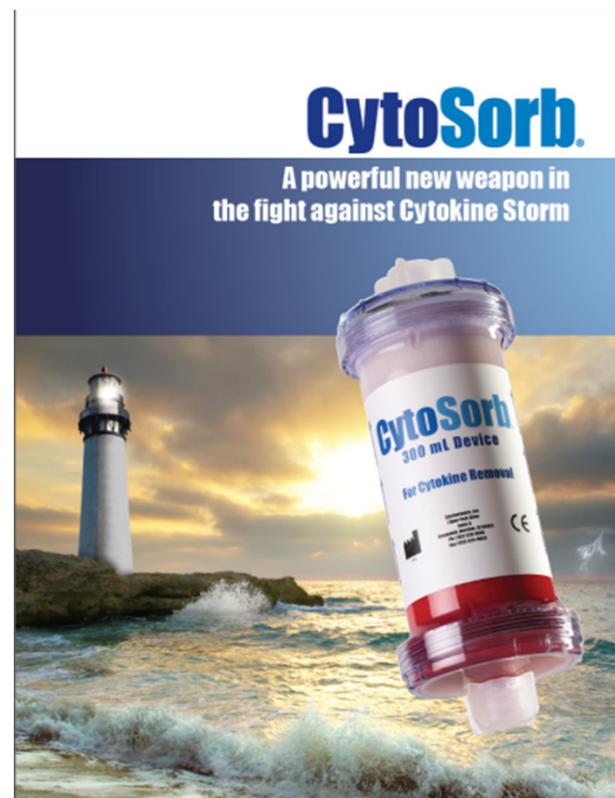
- Massive untapped \$20 billion unmet medical need in critical care
- CytoSorb<sup>®</sup> sales are generating significant growth with attractive 60+% gross margins
- Continued geographic expansion throughout the world
- Two pathways to US FDA approval for CytoSorb<sup>®</sup>: Cardiac Surgery and EAP Designation for critical illnesses such as sepsis
- Expansion of existing strategic partnerships and potential new ones
- NASDAQ Capital Market up-listing and clean cap structure dramatically changes profile of company and ability for institutional and retail investors to invest

# Q&A Session

## CytoSorbents Corporation

NASDAQ: CTSO

Phillip P. Chan, MD, PhD - CEO  
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Monmouth Junction, NJ 08852  
pchan@cytosorbents.com



The Rise of An Emerging Critical Care Immunotherapy Company