



# CytoSorbents Corporation

OTCBB: CTSO

Q3 2013 Earnings Review

November 6, 2013

Webcast replay with slides can be accessed at:  
<http://public.viavid.com/player/index.php?id=106521>

A transcript of the earnings call will be available shortly at [www.sec.gov](http://www.sec.gov) or on the Company website



**CytoSorbents**

Working to Save Lives Through Blood Purification

# Safe Harbor Statement

Statements in this presentation regarding CytoSorbents Corporation and its operating subsidiary CytoSorbents, Inc 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 April 3, 2013 and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).



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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: Valter Pinto - Alliance Advisors

# Overview

**CytoSorbents** (OTCBB: CTSO) is a critical care focused company working to save lives by targeting uncontrolled inflammation through blood purification



**CytoSorbents**

Working to Save Lives Through Blood Purification

# Inflammation Plays a Major Role in Nearly Every Known Disease

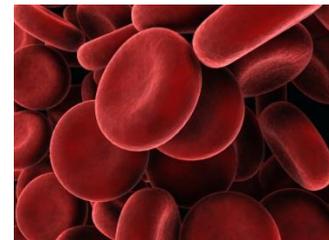
- Life threatening conditions like sepsis & trauma
- Autoimmune diseases like rheumatoid arthritis, inflammatory bowel, psoriasis, and lupus
- Heart disease, peripheral artery disease
- Cancer, cancer cachexia, graft vs host disease
- Neurodegenerative diseases such as Alzheimer's, multiple sclerosis (MS), Parkinson's
- Many, many others



Uncontrolled inflammation wreaks havoc on the body and can be deadly

# Severe Inflammation Drives Organ Failure

Organ failure occurs when vital organs stop working, causing nearly half of all deaths in the ICU, but little can be done to treat or prevent it today



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

CytoSorb<sup>®</sup> is the only specifically approved extracorporeal cytokine filter in the E.U.

Cytokines and other inflammatory mediators are the substances that drive inflammation

Clinically proven to reduce key cytokines in blood by 30-50% in critically ill patients

Approved for use in any situation where cytokines are elevated

Safe: More than 1,100 human treatments with no serious device related adverse events



# CytoSorb Is A Powerful New Strategy to Control Severe Inflammation in the ICU

**Anti-Inflammatory  
(too weak)**

**NSAIDS**

**Aspirin**

**Anti-cytokine  
antibodies**

**Anti-integrin  
antibodies**

**Anti-oxidants**



**Immunosuppressive  
(too strong)**

**Corticosteroids**

**Chemotherapy**

**Organ transplant  
Anti-rejection drugs**

**Radiation**

**Immune system  
ablation**

**Anti-leukocyte  
Antibodies**

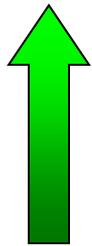
**Immunomodulatory  
("just right")**



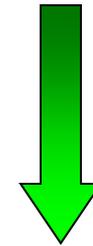
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# The Goal: Actively Prevent or Treat Organ Failure in Many Life-Threatening Conditions

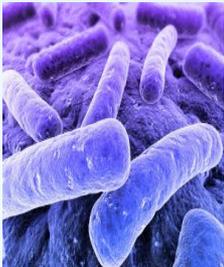


Improve Patient Outcome and Survival

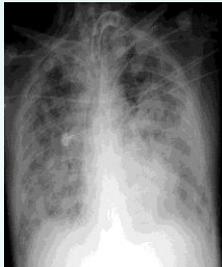


Decrease Costs Of ICU and Patient Care

Sepsis



ARDS



Burn Injury



Trauma



Pancreatitis



Influenza



Surgical



Critical Care: \$10 - 15B Opportunity

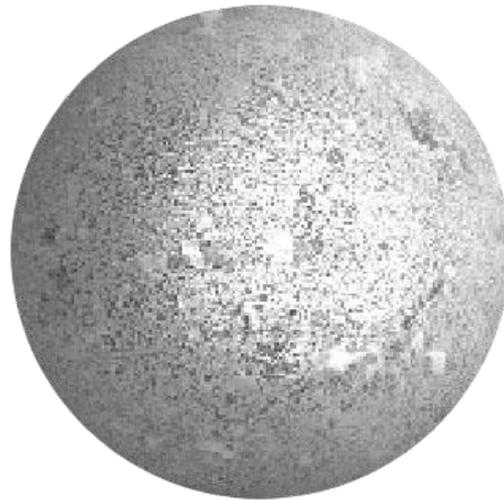


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# The Heart of the Technology

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



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 medical market today



# Our Bead Technology Enables a Versatile Product Portfolio

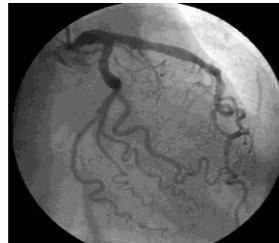


Critical Care, High Risk Surgery



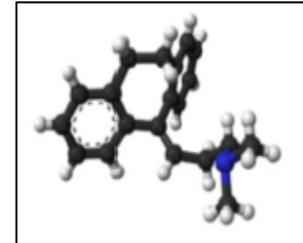
Blood Collection & Transfusion

**ContrastSorb**



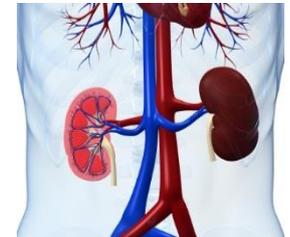
CT Imaging, Interventional Radiology

**DrugSorb**



Drug Overdose, Chemo Removal

**BetaSorb**



Improving Dialysis

CE Mark Approved

Under Development



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# \$15+ Million in US Government Support

- DARPA awarded \$3.8M five year (2012) contract as part of “Dialysis-Like Therapeutics” program to treat sepsis by removing cytokines and pathogen-derived toxins
- U.S. Army awarded \$1.15M SBIR contracts for trauma and burn injury research (2011-13)
- U.S. Air Force is funding a 30 patient human pilot study in trauma valued at \$3M. FDA approved trial to begin this year
- US Dept of Health and Human Services awarded \$0.5M grant (2010) for therapies that can save lives and reduce costs under the QTDP Program
- NIH grant awarded \$7M five year (2006-2010) to University of Pittsburgh and Dr. John Kellum to research CytoSorb bead for treatment of sepsis
- NIH/NHLBI awarded \$0.2M Phase I SBIR to advance the HemoDefend purification technology intended to improve the quality and safety of bloodtransfusions (2013)



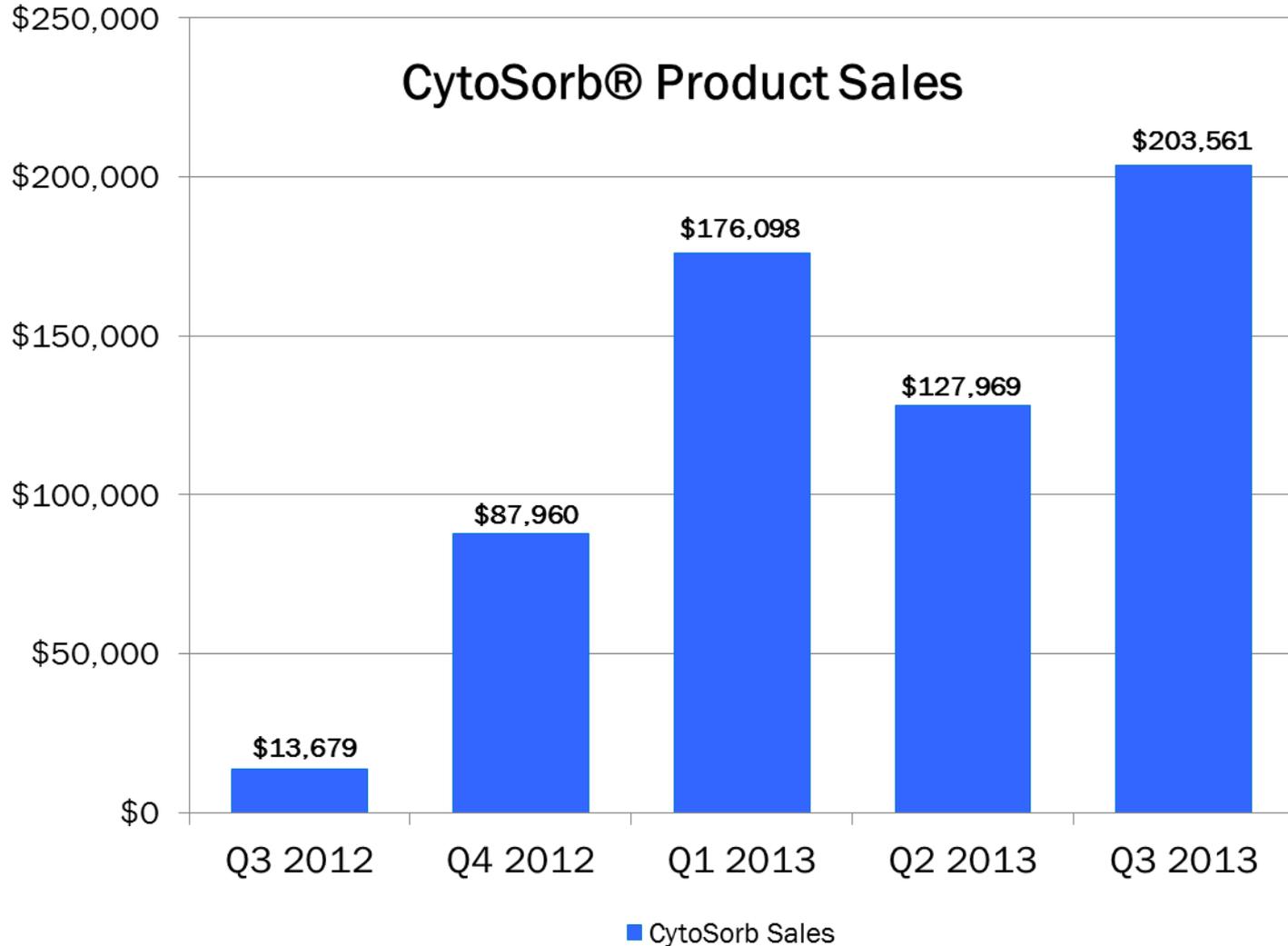
# Q3 2013 Financial Highlights

# Third Quarter Key Financial Info

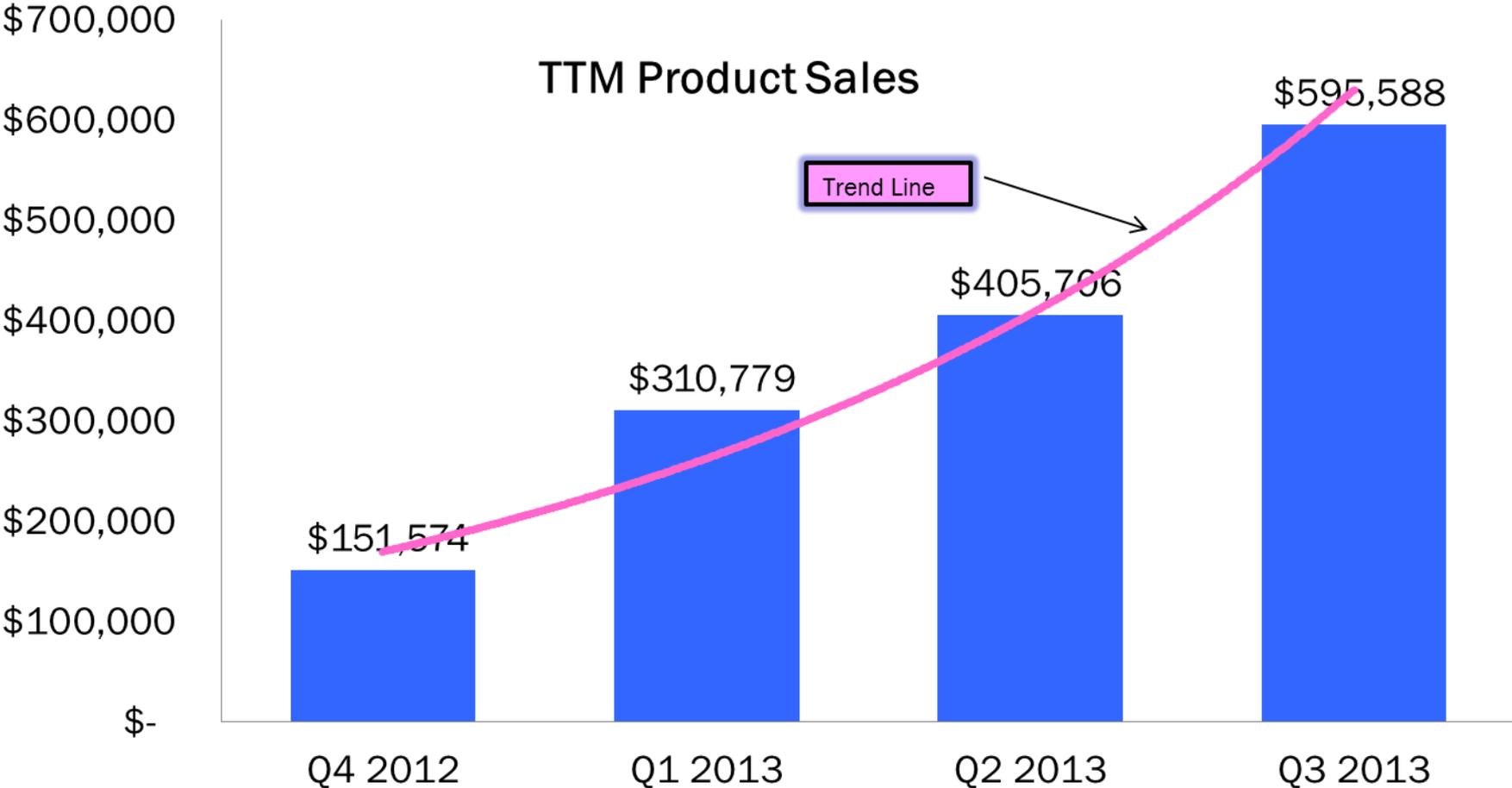
(in thousands of U.S. Dollars)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Product Sales	\$ 204	\$ 14	\$ 508	\$ 64
Grant and other income	677	591	1,036	675
<b>Total revenue</b>	<b>\$ 881</b>	<b>\$ 605</b>	<b>\$1,544</b>	<b>\$ 739</b>
EBITDA	\$(807)	\$(552)	\$(3,433)	\$(2,225)
Operating loss	\$(965)	\$(652)	\$(4,009)	\$(3,125)
EPS	\$(0.01)	\$(0.01)	\$(0.02)	\$(0.03)

# Strong Product Growth in Q3 2013

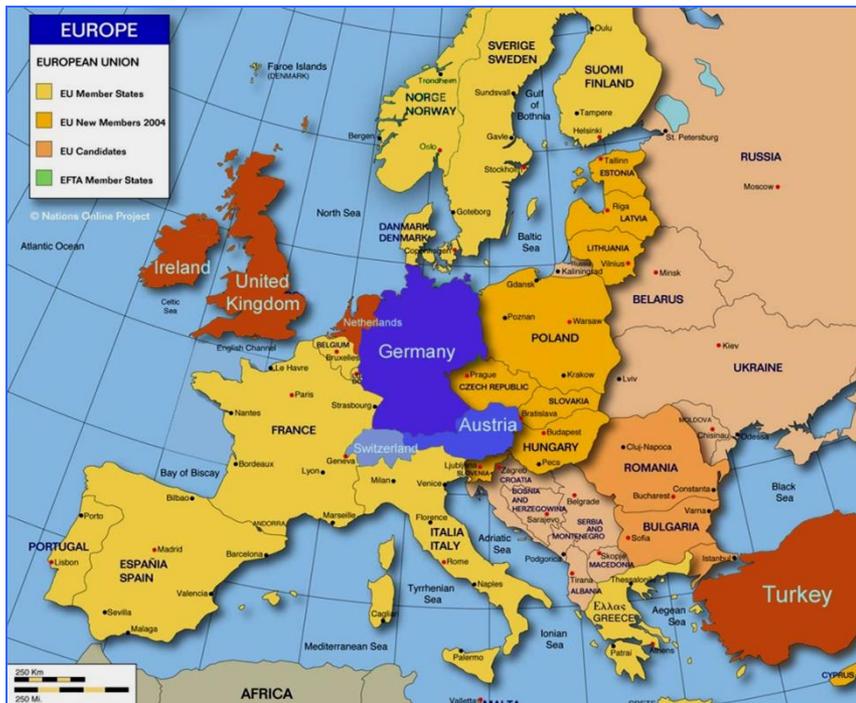


# Product Sales



# Strong Gross Margins

CytoSorbents currently has distributors in the United Kingdom, Ireland, the Netherlands, and Turkey plus a strategic partnership in India

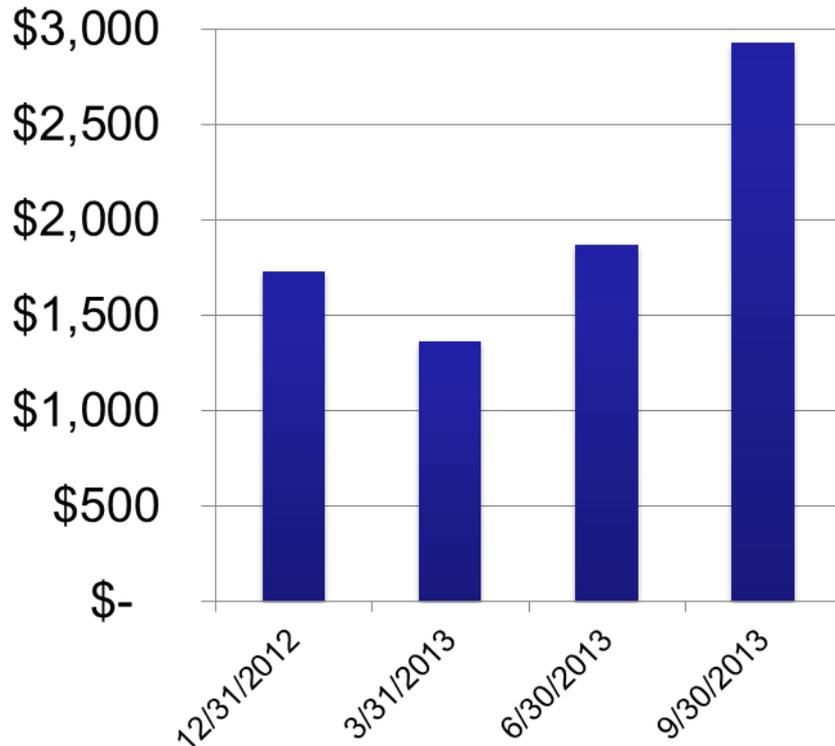


- For the three months ended September 30, 2013 product gross margins were 71%
- Overall 2013 product gross margins were approximately 64%
- Sales prices have remained constant
- Gross margins will vary based on the ratio of direct sales vs. sales to distributors, but are expected to remain very healthy
- As CytoSorb® sales increase, gross margin on our products will help provide working capital



# Working Capital

## Cash on Hand (in thousands of \$)



September 30, 2012 cash balance includes \$580,000 in proceeds received in October 2013 from the sale of convertible notes.

## Multiple Sources of Capital to Fund Growth

- Grant income - continues to provide funding to offset operating costs
- Product Sales – high gross margins and increasing sales will drive us closer to cash flow breakeven
- Potential strategic partnerships
- Raising capital through traditional equity and convertible notes
- Our financing facility with Lincoln Park Capital



# Q3 2013

## Operational Highlights



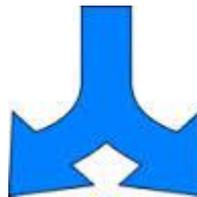
# Focus is on Driving Departmental Usage



Key Opinion Leader



Junior and Senior Physicians



Nursing and Technical Staff

# Will Have A Number of Reference Sites Soon

- We are currently working with KOLs in the largest and most important university and public hospitals in most major cities in Germany and many in Austria and the United Kingdom
- Usage of CytoSorb® at many hospitals is increasing, both in the number of patients being treated, but also in the number of physicians using the therapy and the number of departments using it within a single hospital
  - Surgical ICU
  - Medical ICU
  - Trauma ICU
  - Cardiac and high risk surgery
- We believe these will become reference sites for CytoSorb® in the future



# Actively Expanding our Direct Sales Force

~100  
KOLs

2013 Target  
7 sales reps  
& 1 clinical  
support  
specialist

Many Junior and Senior Physicians

Many Nursing and Technical Staff



\$ Hundreds of thousands in sales



\$ Millions in sales



# Partnership with Biocon

## The Largest Biotech in India

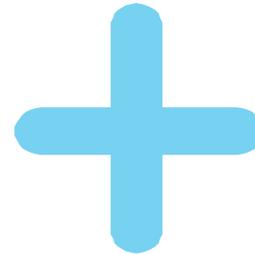
On World Sepsis Day 2013, BioCon and CytoSorbents announced a strategic partnership with initial distribution in India and select emerging markets

Biocon: \$467M in 2013 revenue, targeting \$1B with \$18% CAGR

- An India Centric Business with Global Ambitions
- Front Ending of our vertically integrated API & Biologics pipeline
- Portfolio highlights:
  - Insugen & Basalog: India's largest selling generic insulin & analog
  - BioMAb EGFR: India's 1<sup>st</sup> indigenous novel MAb for head & neck cancer

<b>DIABETOLOGY</b> sustaining life	100IU Insugen <sup>®</sup> 770	BASALOG <sup>™</sup>	INSUPen <sup>®</sup>
<b>CARDIOLOGY</b> enhancing life	In high risk patient with ACS STATIX The Parent Atorvastatin	MYOKINASE <sup>®</sup>	
<b>ONCO THERAPEUTICS</b> transforming life	BIOMAb EGFR <sup>®</sup>	NUFILsafe <sup>®</sup>	Abraxane <sup>®</sup>
<b>IMMUNOTHERAPY</b> empowering life	TBIS <sup>®</sup>	PSORID <sup>™</sup>	PICON <sup>™</sup>
<b>NEPHROLOGY</b> protecting life	ERYPRO safe <sup>®</sup>	RENODAPT <sup>®</sup>	RAPACAN <sup>™</sup> TACROGRAF <sup>™</sup>
<b>COMPREHENSIVE CARE</b> improving life	Biopiper TZ <sup>™</sup>	CELIM TZ <sup>™</sup>	IMICELUM <sup>™</sup> PENMER <sup>™</sup>
<b>BIOPRODUCTS</b> preserving life	Albumin for a better life ALBUBET <sup>®</sup> Safe	Next to Natural Immunity IVNEX <sup>®</sup> Safe	

# Biocon Antibiotics + CytoSorb® The Most Comprehensive Treatment for Sepsis



Treat the Primary Infection

Treat the Massive  
Inflammatory Response

India has 1.2 billion people with one in every 4 patients in the ICU has or develops sepsis in India

Biocon expected to contribute to revenue growth for 2013

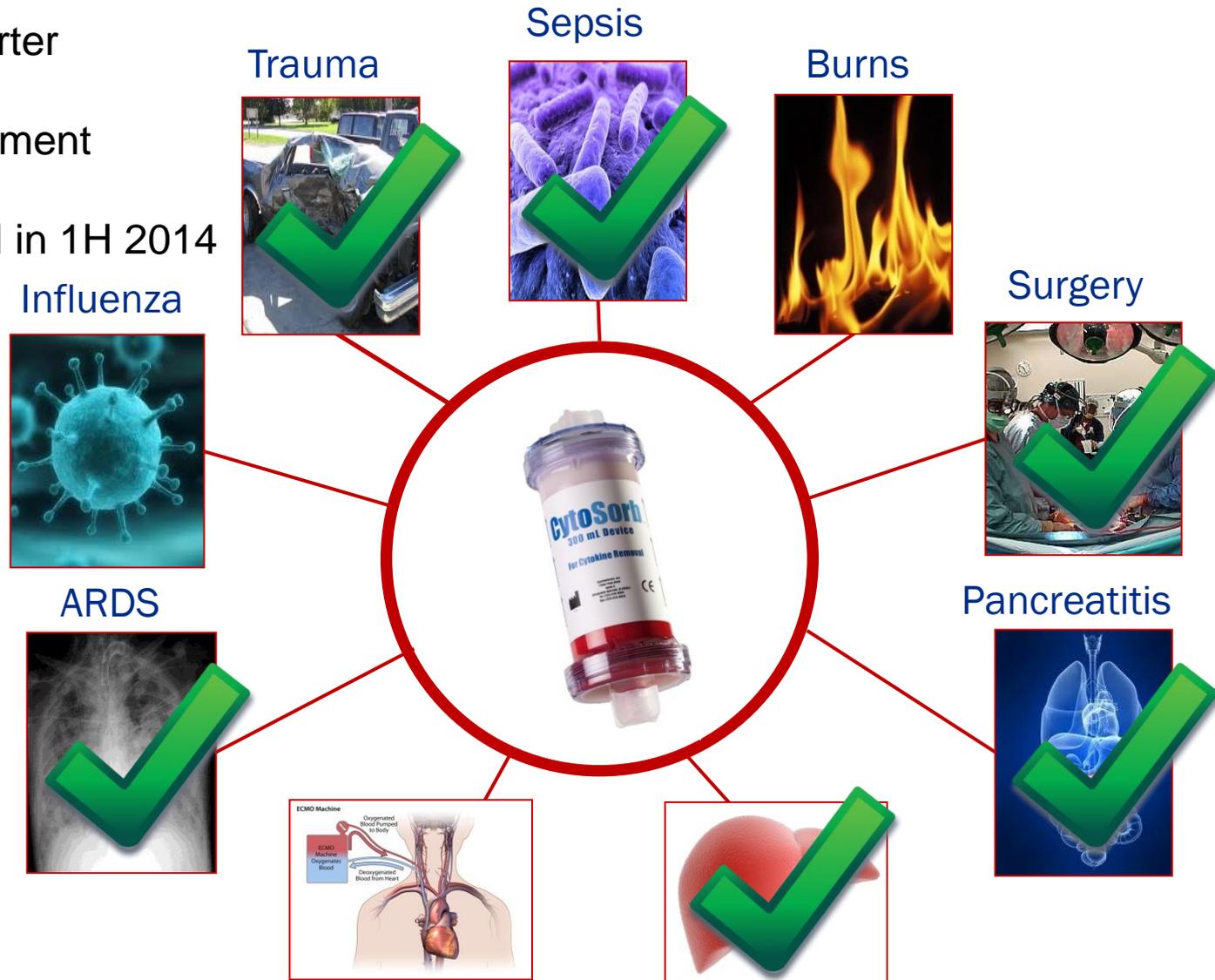


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# 26 Investigator Initiated Studies

- Up from 18 last quarter
- 3 have begun enrollment
- Initial data expected in 1H 2014



# CytoSorbents Case Reports



## Pattern of cytokine removal using an adsorption column CytoSorb® during severe candida albicans induced septic shock

Bracht H, Schneider M, Weiss M, Georgieff M, Barth E  
University Clinic for Anesthesiology, University of Ulm, Germany

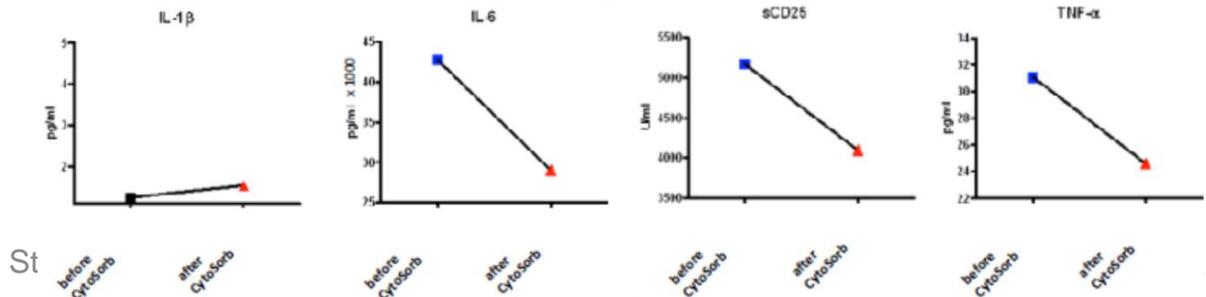
Mortality in patients with septic shock and Candida infection is 64% even with treatment<sup>1</sup>

46 year old woman with septic shock and documented Candida albicans infection of an IV port

- Critically ill with septic shock multiple organ failure
- Increasing vasopressor dependence and instability
- Treated with Anidulafungin, Meropenem, Linezolid
- Initiated CRRT plus CytoSorb for 24 hours with initiation of Levosimendan.
- Hemodynamics significantly improved and norepinephrine was decreased 0.7 to 0.2 ug/kg/min and levosimendan was weaned with continued hemodynamic stability
- The patient went on to survive

	baseline	after Hemoadsorption
Heartrate (bpm)	133	100
MAP (mmHg)	62	81
Cardiac Index (L/min/m <sup>2</sup> )	1.9	2.9
Stroke volume variation (%)	14	7
Core Body Temperature (°C)	36.2	36.3
Base excess (mmol/l)	-14.5	6.0
paO <sub>2</sub> (mmHg)	125	128
paCO <sub>2</sub> (mmHg)	27.1	38.2

Table 1: Hemodynamic, metabolic and gas exchange variables before and after hemoadsorption.



<sup>1</sup>Kollef, M, et al., Clin Infect Dis 2012;54:1739-46



# CytoSorbents Case Reports

Time course of noradrenalin (NA,  $\mu\text{g}/\text{kg}/\text{min}$ ), creatinine (Crea,  $\mu\text{mol}/\text{l}$ ), C-reactive protein (CRP,  $\text{mg}/\text{l}$ ), and interleukin 6 (IL6,  $\text{pg}/\text{ml}$ ) from admission to the ICU until day 6.

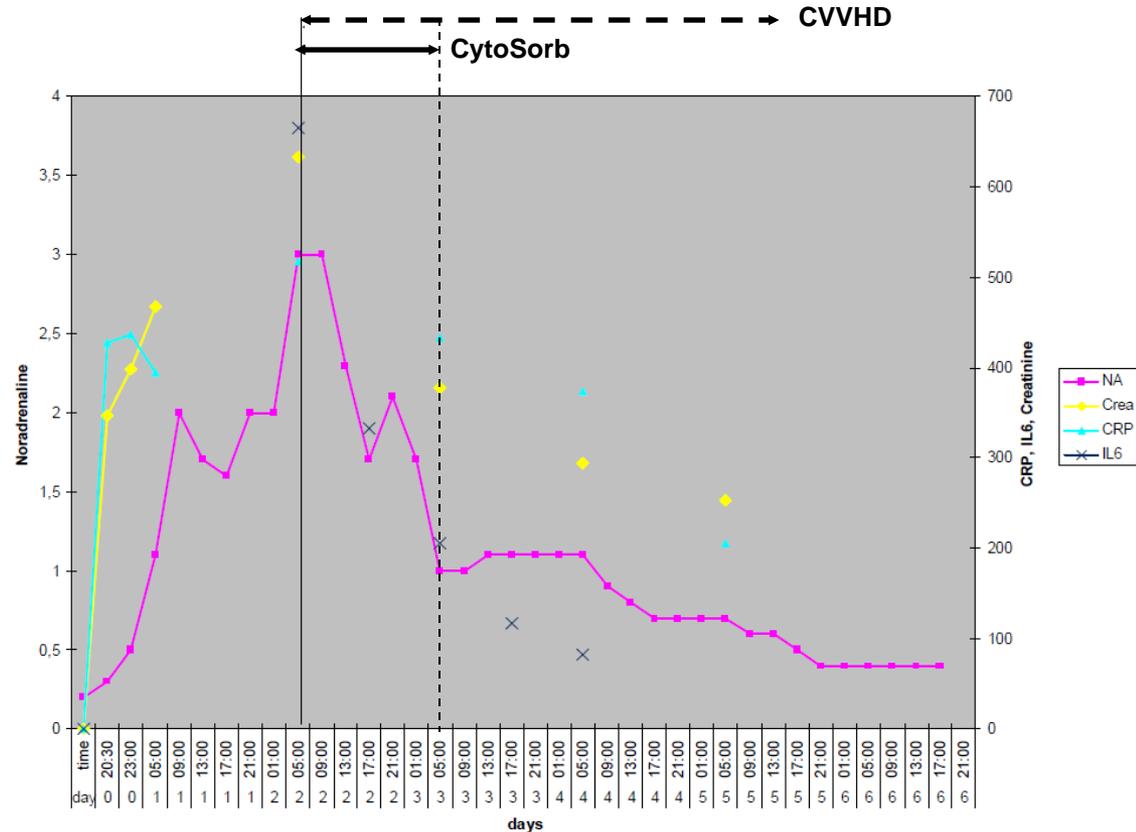
## Improvement of Hemodynamic and Inflammatory Parameters by Combined Hemoadsorption and Hemodiafiltration in Septic Shock: A Case Report

Steffen R. Mitzner<sup>a</sup> Martin Gloger<sup>b</sup> Jörg Henschel<sup>b</sup> Sebastian Koball<sup>a</sup>

Divisions of <sup>a</sup>Nephrology and <sup>b</sup>Pulmonology and Internal Intensive Care, Department of Internal Medicine, University of Rostock, Rostock, Germany

80 year old man with end-stage kidney failure on chronic hemodialysis with Type 2 diabetes

- Septic shock due to *Staphylococcus aureus* pneumonia treated with ceftriaxone and clarithromycin
- Despite antibiotics, continued to deteriorate
- On Day 3, began CytoSorb for 24 hours with hemodiafiltration
  - IL-6: 665  $\text{pg}/\text{mL}$  to 200  $\text{pg}/\text{mL}$
  - Norepinephrine: 3 to 1  $\text{ug}/\text{kg}/\text{min}$
  - Stabilized blood pressure
  - Reduction in the inflammatory marker, C-reactive protein
- The patient went on to survive



# Hemoperfusion using CytoSorb® in a cirrhotic patient with sepsis and multiple organ failure – A case report

Andrea Gruber, F. Firlinger, K. Lenz, M. Clodi

Departement of Internal and Intensive Care Medicine  
Konventhospital Barmherzige Brüeder Linz, Austria



BARMHERZIGE BRÜDER  
KONVENT LINZ

37 year old patient with alcoholic liver cirrhosis admitted to ICU because of multi-organ failure due to bilateral pneumonia with *Staphylococcus aureus* sepsis. Predicted mortality based on CLIF-SOFA score was >90%

Treatment time in in h	-12	-3	0	6	12	30	54
Bilirubin (mg/dl)		8,5			8	5,5	4,7
CRP (mg/dl)	11,8			8,5	12,4	10	6,5
Il- 6 (pg/ml)	27 423			2260	762	151	250
PCT (ng/ml)	27423			6,22		5,24	3,9
paO <sub>2</sub> /FiO <sub>2</sub> (mmHg)		13,2	12	15,3	6,7	15,2	26,4

Underwent 4 consecutive CytoSorb® treatments, with hemodynamic stabilization and reduction of IL-6 from 27,423 pg/mL to 2,260 pg/mL in the first treatment, and back to high normal during the next several days of treatment. The patient was stabilized for partial lung resection surgery and went on to survive

# Increased Presence at Major Conferences



## Exhibited

- European Society of Intensive Care Medicine - ESICM 2013: Paris, France
- 6<sup>th</sup> International Congress of the German Sepsis Society 2013: Weimar, Germany
- American Association of Blood Banks - AABB 2013: Denver, Colorado
- Cytokines 2013: San Francisco, California
- Military Health System Research Symposium – MHSRS 2013: Fort Lauderdale, Florida
- Rodman and Renshaw 2013: New York, New York

## Attended

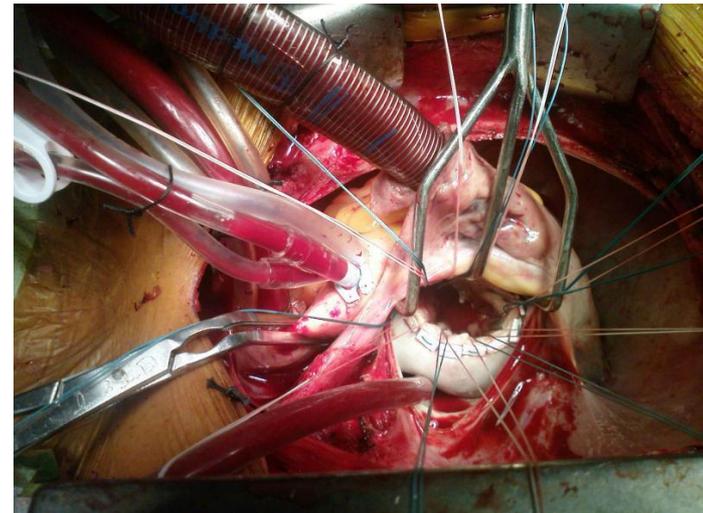
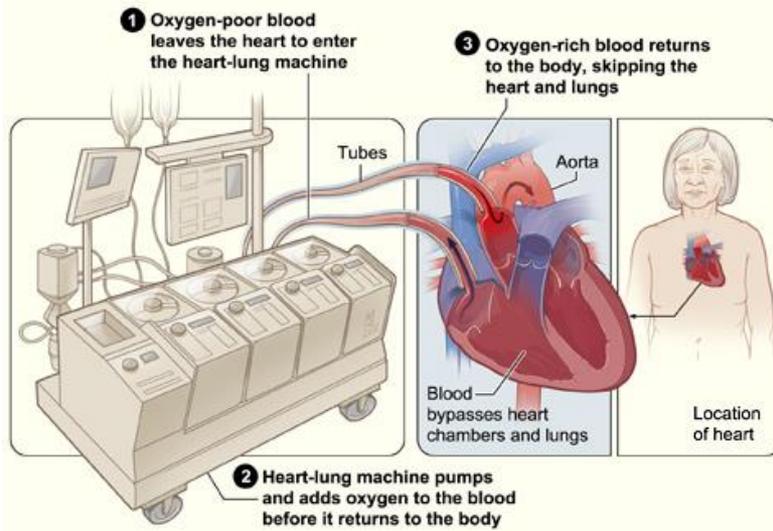
- European Society of Cardiovascular Surgery 2013: Vienna, Austria



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# Prevention or Treatment of Organ Failure in Cardiac Surgery



# Cardiac Surgery Stats

Approximately 1MM Cardiopulmonary Bypass Surgeries in US and EU annually

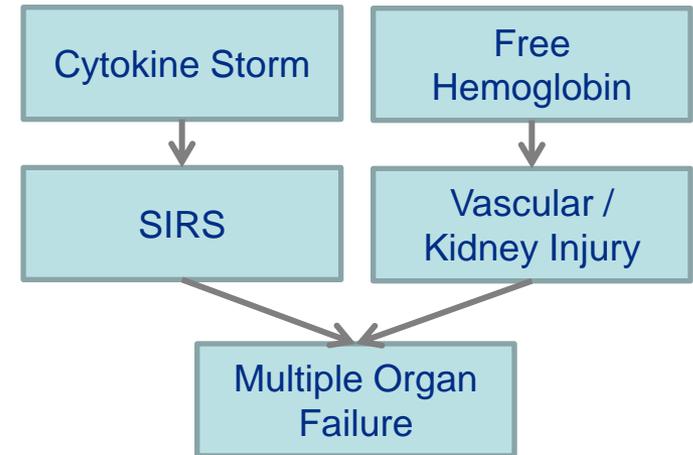
- Coronary artery bypass graft surgery
- Open valve repair
- Heart or lung transplantation
- Cardiac defect repair

Patients often develop inflammation due to cytokine storm and free hemoglobin release during the surgery

Organ dysfunction and failure, particularly lung and kidney failure, frequently result

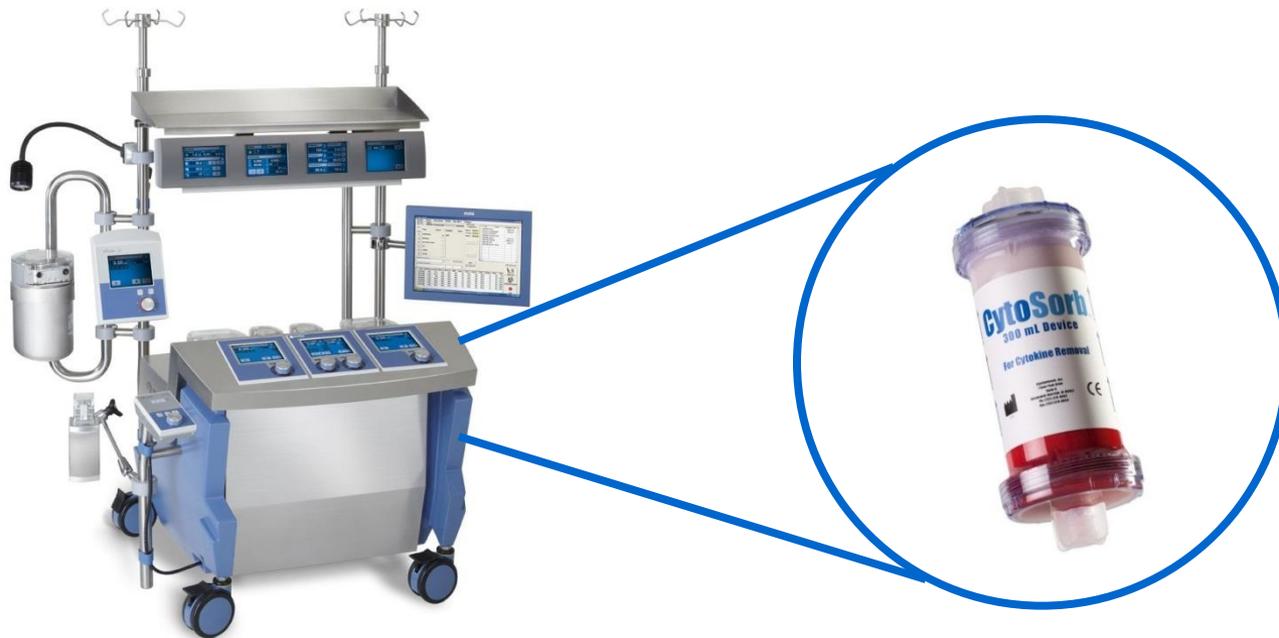
No technology has been able to easily and directly reduce cytokine storm and free hemoglobin

Leukoreduction filters used today to remove cytokine producing white cells, generate millions of dollars in revenue, but do not work and cannot directly remove cytokines



# Simple, Rapid Implementation

CytoSorb is installed on cardiopulmonary bypass equipment within minutes and without needing another machine



# CytoSorb<sup>®</sup> Is Ideally Suited for CPB

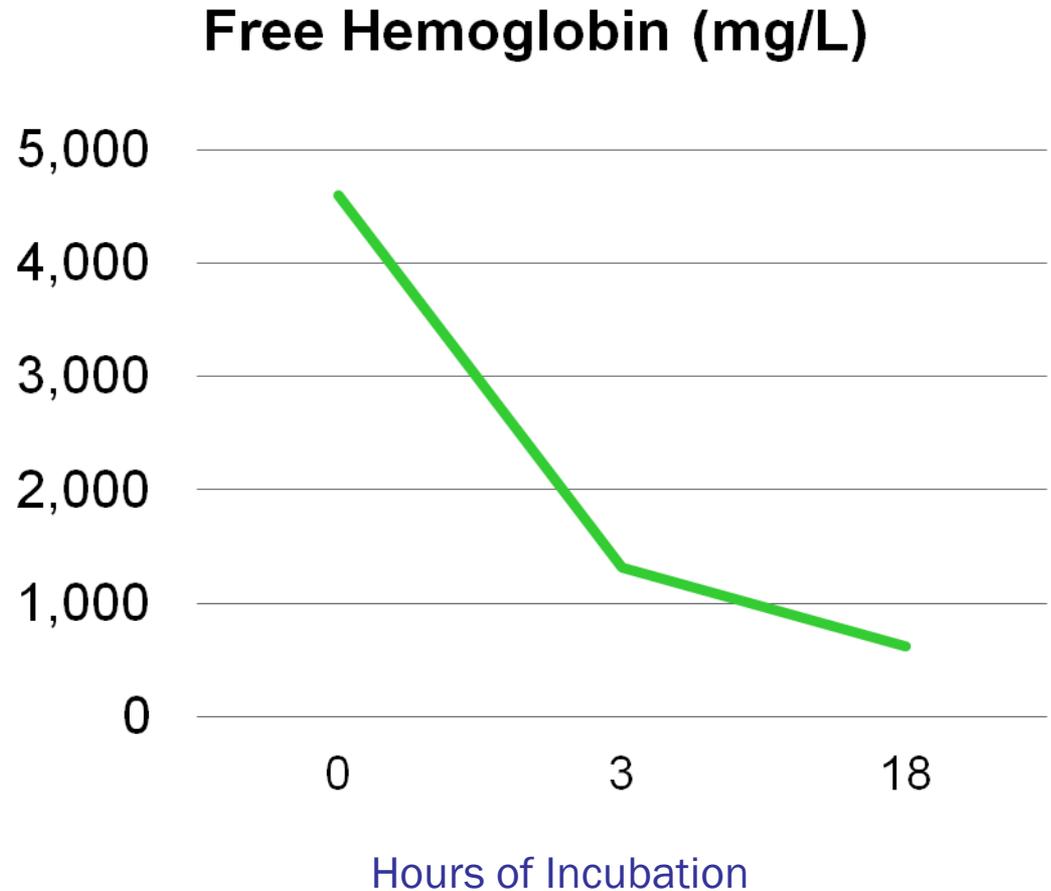
- Effective removal of excess cytokines and free hemoglobin
- Installs into CPB circuit easily and within minutes
- Drop-in replacement for leukoreduction filters
- Utilizes blood flow generated by the CPB circuit. No need for perfusionist to worry about another machine to run
- Blood in, blood out; No dialysate, ultrafiltrate to be concerned about
- High flow, low resistance and can accommodate high blood flow rates at least to 400 mL/min; Has been tested to 1L/min without hemolysis
- 7+ football fields of surface area vs 1-3 m<sup>2</sup> in membrane-based filters
- Compatible with systemic heparin anti-coagulation used during CPB



# Removal of Free Hemoglobin



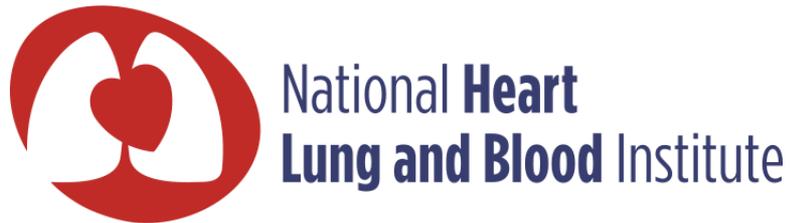
Removal of free hemoglobin from partially hemolyzed whole citrated bovine blood following incubation with 1:8 v/v CytoSorb beads (L to R: T0, 3, 18 h) at 12 rpm. Plasma fractions are shown following centrifugation.



# Cardiac Surgery Is a Major Opportunity

- Cardiac surgeons and patients both want zero complications
- Although early, the initial experience with many cardiac surgery patients is very promising
- Clinical trials can be done rapidly in this space
- Represents a total addressable market >\$500 million in the U.S. and E.U. if we can establish CytoSorb as standard of care
- Is a market that sits separate from critical care, so represents a completely separate market opportunity

# \$200K NHLBI SBIR Award for **HemoDefend™**



- Collaborating with Dr. Larry Dumont, MD, MBA – Director of the Center for Transfusion Medicine Research and Associate Professor of Pathology at the Geisel School of Medicine at Dartmouth
- The goal is to further develop and characterize the HemoDefend technology to reduce contaminants in transfused blood products that can lead to transfusion reactions and adverse outcomes including death
- This award is a major step towards commercialization of both “Beds-in-a-Bag” and the in-line filter



# Progress on Dosing Study

Goal: To determine the safety and preliminary efficacy of extended treatment to help inform the design of a U.S. pivotal sepsis trial

- Enrollment has accelerated with a total of 8 clinical sites including:
  - University of Goettingen
  - Helios Erfurt
  - University of Aachen
  - University of Greifswald
  - University of Jena
  - University of Hamburg-Eppendorf
  - University of Leipzig
  - European Medical School of Oldenburg
- At least an interim data analysis is planned for 2013

# Proud Sponsor of World Sepsis Day and Sepsis Heroes



**In life-threatening conditions such as sepsis, trauma, lung injury or severe burns...**

**A lot depends on you making it out alive.**



## **CytoSorbents**

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For more information,  
please visit  
[www.cytosorbents.com](http://www.cytosorbents.com)



**GSA**  
GLOBAL SEPSIS ALLIANCE

**SEPSIS HEROES**  
Celebrating Champions of Sepsis Awareness



**SEPSIS ALLIANCE**  
*Suspect Sepsis. Save Lives.*



## **CytoSorbents**

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# Comments on Q4 2013

- Seeing continued strong momentum of CytoSorb® sales into early Q4 2013
- Expecting record fiscal performance for all of 2013, our first full year of commercialization

# Why Is CytoSorbents Attractive Now?

We are at the “ground floor” of commercialization, poised to create significant value with an approved product, **CytoSorb**<sup>®</sup>, that may revolutionize critical care medicine, save lives, and reduce costs

**Blockbuster potential:** Massive market with one of the biggest unmet medical needs

**Validation of our company and technology from many fronts:**

- ✓ Biocon, DARPA, US Army, US Air Force, NIH/NHLBI, scientific advisors, analysts

**Unique, highly profitable product and pipeline with little to no competition**

**Led by an experienced and responsible management team**

**Undiscovered at a fully-diluted market cap of ~\$50M, CTSO is trading at a significant discount to biotech/med device peers but with greater opportunity**

**Potential major catalysts in the next 6-9 months** including revenue growth, partnerships, clinical data, up-listing, institutional ownership, and more

# Question and Answer Session

**Working to Save Lives  
Through Blood Purification**

**OTCBB: CTSO**

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