



# **CytoSorbents Corporation** (NASDAQ: CTSO)

A Leader in Critical Care Immunotherapy

Q2 2015 Earnings Conference Call

August 13, 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

# **CytoSorbents** is A Leader in Critical Care Immunotherapy



Leading the Prevention or Treatment of  
**Life-Threatening Inflammation**  
in the ICU and Cardiac Surgery using  
CytoSorb® Blood Purification



# Case Report Video

Please note: Because of different internet speeds of participants on today's call, there may be a slight waiting period after the video plays on your computer as others finish watching the video.

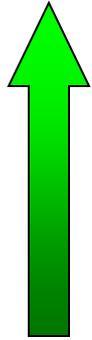
We will promptly get back to the slide presentation

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

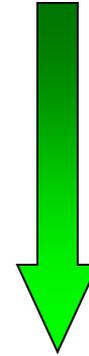
- CytoSorb<sup>®</sup> targets the \$20 billion opportunity in critical care and cardiac surgery
- Approved in the European Union as the only specifically approved cytokine filter
- Clinically proven to remove key cytokines in the blood of critically-ill patients
- Approved for use in any situation where cytokines are elevated
- Safe: More than 6,000 human treatments, safe and well-tolerated



# Goal: To Prevent or Treat Organ Failure

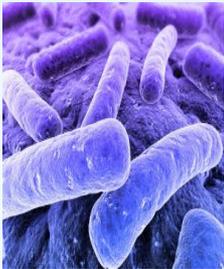


Improve  
Patient  
Outcome  
and  
Survival

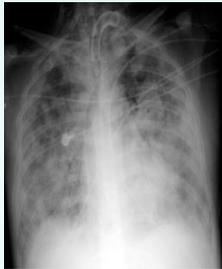


Decrease  
Costs Of  
ICU and  
Patient  
Care

Sepsis



ARDS



Burn Injury



Trauma



Pancreatitis



Influenza



Surgical



The Potential to Revolutionize Critical Care Medicine



**CytoSorbents**

Working to Save Lives Through Blood Purification

# Operating and Financial Highlights



**CytoSorbents**

Working to Save Lives Through Blood Purification

# Q2 2015 Comparative Revenue Results

	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	% Incr.
Product revenue	\$ 773,112	\$ 663,233	17%
Grant and other income	190,827	361,422	(47)%
Total revenue	\$ 963,939	\$ 1,024,655	(6)%

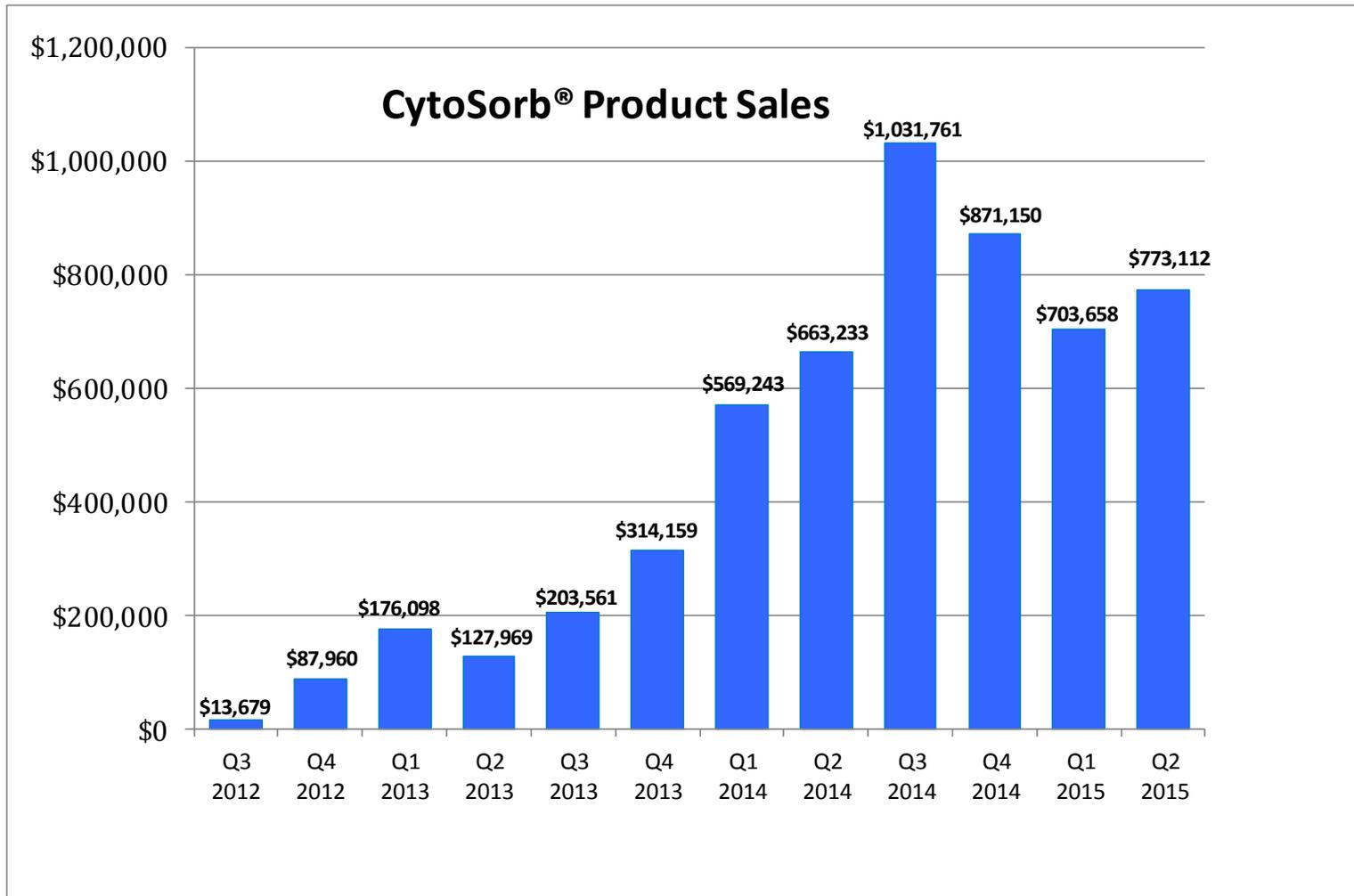
- CytoSorb® product sales were \$773K in Q2 2015, a 17% increase over product sales of \$663K in Q2 2014
- Product sales were negatively impacted by the decline in the exchange rate of the Euro by ~\$147,000 or 19% of product sales for the three months ended June 30, 2015
- Grant and other income was \$191K for the quarter ended June 30, 2015, as compared to \$361K for the quarter ended June 30, 2014 as a result of the conclusion of several significant grants
- Product gross margins were ~63% in Q2 2015, as compared to 65% for Q2 2014

# 6 Months Comparative Revenue Results

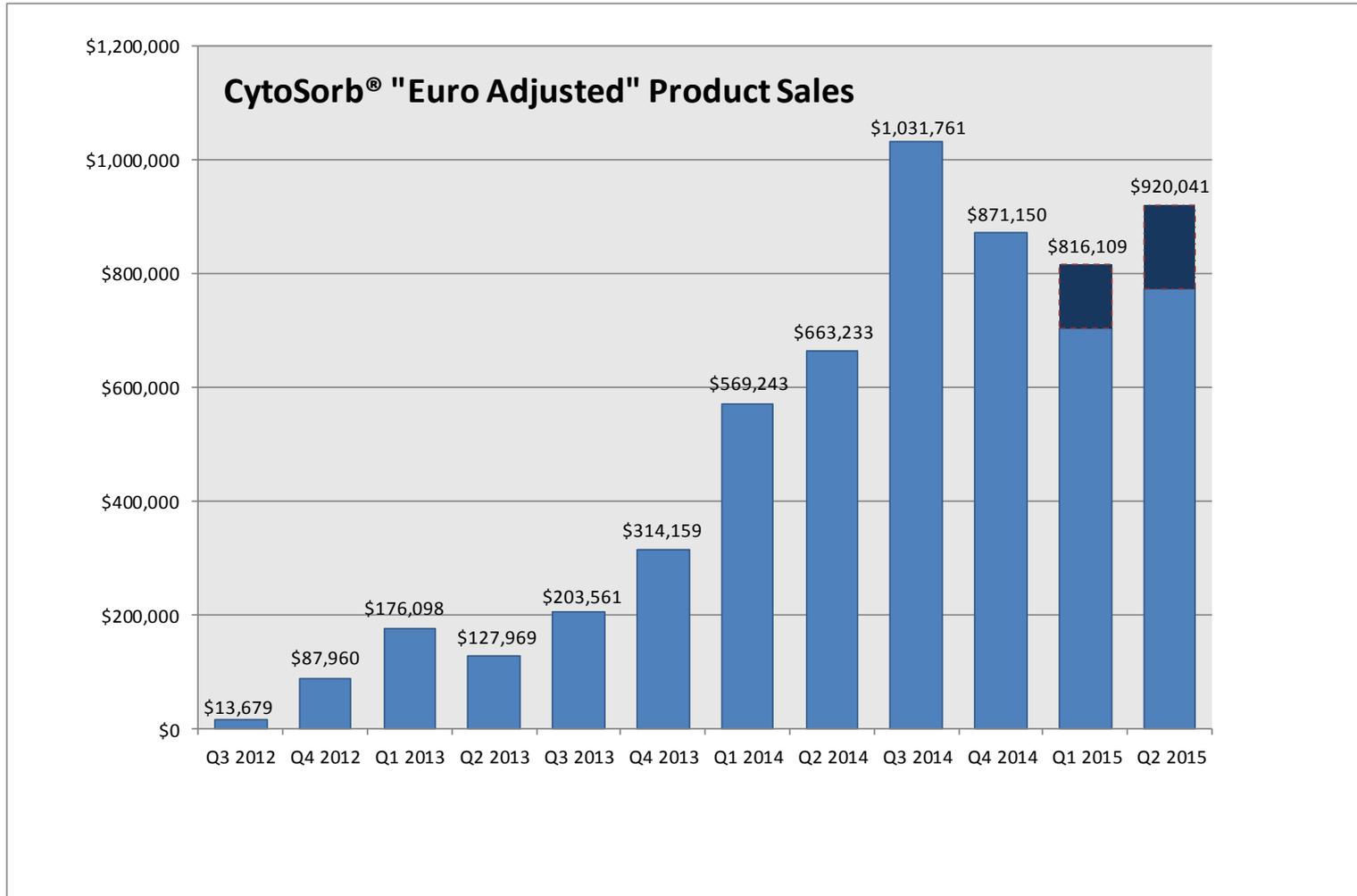
	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014	% Incr.
Product revenue	\$ 1,476,770	\$ 1,232,476	20%
Grant and other income	210,243	854,351	(75)%
Total revenue	\$ 1,687,013	\$ 2,086,827	(19)%

- CytoSorb® product sales were \$1.5M for the six months ended June 30, 2015, a 20% increase over product sales of \$1.2M in Q2 2014
- Product sales were negatively impacted by the decline in the exchange rate of the Euro by ~\$259,000 or 19% of product sales for the six months ended June 30, 2015
- Trailing twelve month product revenue for the period ended June 30, 2015 was ~\$3.4M, as compared to \$1.8M for the twelve month period ended June 30, 2014
- Gross profit margins on product sales were ~61% for the first half of 2015, as compared to 63% for first half of 2014

# Quarterly Product Sales



# Quarterly "Euro-Adjusted" Product Sales



# Working Capital and Cap Table

Working Capital as of					
	6/30/15	3/31/15	12/31/14	12/31/13	12/31/12
<b>Current Assets:</b>					
Cash and short-term investments	\$ 11,205	\$ 13,358	\$ 5,550	\$ 2,183	\$ 1,729
Grants and accounts receivable, net	501	673	819	453	51
Inventories	1,060	703	538	245	682
Prepaid expenses and other current assets	275	148	700	605	476
<b>Total current assets</b>	<b>13,041</b>	<b>14,882</b>	<b>7,607</b>	<b>3,486</b>	<b>2,938</b>
<b>Current Liabilities(1):</b>					
Accounts payable	418	475	698	787	801
Accrued expenses and other current liabilities	718	734	825	362	350
Deferred revenue	-	-	1	272	-
<b>Total current liabilities</b>	<b>1,136</b>	<b>1,209</b>	<b>1,524</b>	<b>1,421</b>	<b>1,151</b>
<b>Net Working Capital</b>	<b>11,905</b>	<b>\$ 13,673</b>	<b>\$ 6,083</b>	<b>\$ 2,065</b>	<b>\$ 1,787</b>
(1) Excludes warrant liability, a current liability that does not have cash implications.					

## CytoSorbents Cap Table (Pro-Forma as of 6/30/2015)

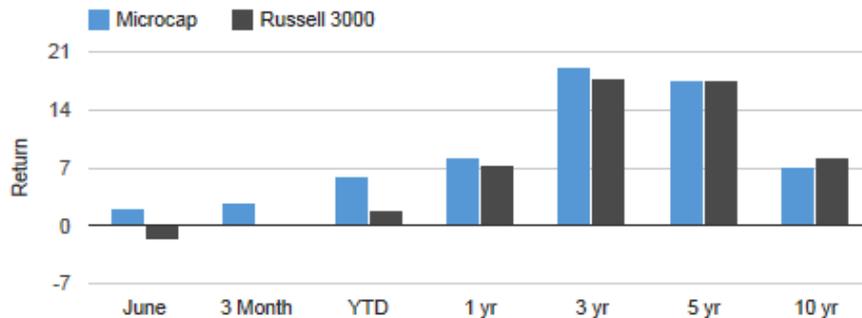
Common stock outstanding	24,890,521
Options	2,639,374
Warrants	1,418,145
<b>Fully-diluted Common shares</b>	<b>28,948,040</b>



# Added to the Russell Microcap Index

## Performance (USD)

		TOTAL RETURNS AS OF JUNE 30, 2015						
		JUNE	3 MONTH	YTD	1 YR	3 YR	5 YR	10 YR
Microcap		2.18	2.80	6.03	8.21	19.25	17.48	7.07
Russell 3000		-1.67	0.14	1.94	7.29	17.73	17.54	8.15



## CytoSorbents Corporation Set to Join Russell Microcap Index

6/19/15

**CytoSorbents Corporation** (NASDAQ: CTSO), a critical care immunotherapy leader commercializing its CytoSorb® blood purification technology to reduce deadly uncontrolled inflammation in hospitalized patients around the world, is set to join the Russell Microcap® Index at the conclusion of the Russell indexes annual reconstitution on June 26, 2015, according to a [preliminary list of additions](#) posted on June 12, 2015.

Membership in the Russell Microcap Index, which remains in place for one year, means automatic inclusion in the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes.

Dr. Phillip Chan, Chief Executive Officer of CytoSorbents stated, "We are pleased to be included in the Russell Microcap Index, a significant corporate achievement that is expected to increase visibility and exposure of our company and life-saving technology to the broader investment community. This complements our continued institutional investor outreach, where the response has been extremely positive to date."

Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. Approximately \$5.7 trillion in assets are benchmarked to the Russell's U.S. indexes. Russell Indexes are part of FTSE Russell, a leading global index provider.

For more information on the Russell 1000 and the Russell indexes reconstitution, go to "Recon Central"

June 2015

## Membership

### Top 10 Holdings

HOLDING
Raptor Pharmaceutical Corp
BioCryst Pharmaceuticals, Inc



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# Second Half 2015 Catalysts



# Strengthening the Direct Sales Team

## Sales



**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



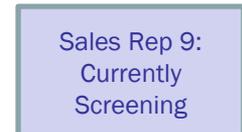
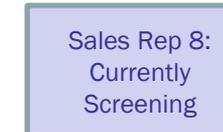
**Uwe Gerks**  
 Regional Sales Manager  
 Northern Germany



**Steffen Martens**  
 Regional Sales Manager  
 North East Germany



**Andreas Pendleler**  
 Regional Sales Manager  
 Western Germany



## 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

# Starting Sales Now in 3 New Countries

## Saudi approval with Medical Device Marketing Authorization



- Enables sales in Saudi Arabia (29M people) via our partner, Techno Orbits
- Tender orders can be substantial
- Potentially opens doors to rest of Middle East

## TekMed

## Signed with TekMed for Australia and New Zealand

- Targets collective population of 28M people
- CytoSorb is registered already, so sales can begin immediately

# Fresenius Medical Care in 2H 2015



multi**Filtrate**<sup>PRO</sup>

- Initial marketing to key opinion leaders in critical care is planned in Q3 2015 in France, Sweden, Norway, Finland, Denmark and Poland (131M people)
- CytoSorb will not only be certified on the existing Fresenius multiFiltrate, but will also be certified on the newly launched multiFiltratePRO



- Sales training and preparation of marketing literature are ongoing
- Both sides are eager to get started

# Sowing the Seeds of Growth

Contributing to Revenue			Not Yet Contributing to Revenue		
#	Country	Population (M)	#	Country	Population (M)
1	Germany	81	16	France	66
2	Austria	9	17	Poland	39
3	Switzerland	8	18	Sweden	10
4	United Kingdom	64	19	Denmark	6
5	Italy	60	20	Norway	5
6	Turkey	75	21	Finland	5
7	India	1,200	22	Russia	144
8	Sri Lanka	21	23	UAE	9
9	Netherlands	17	24	Qatar	2
10	Romania	20	25	Kuwait	3
11	Ireland	5	26	Oman	4
12	Moldova	4	27	Bahrain	1
13	Australia	23	28	Iraq	33
14	New Zealand	5	29	Jordan	7
15	Saudi Arabia	29	30	Yemen	24
			31	Israel	8
Total		1,621	Total		366

**TekMed**   
 Q3 2015 Start  
 57M people

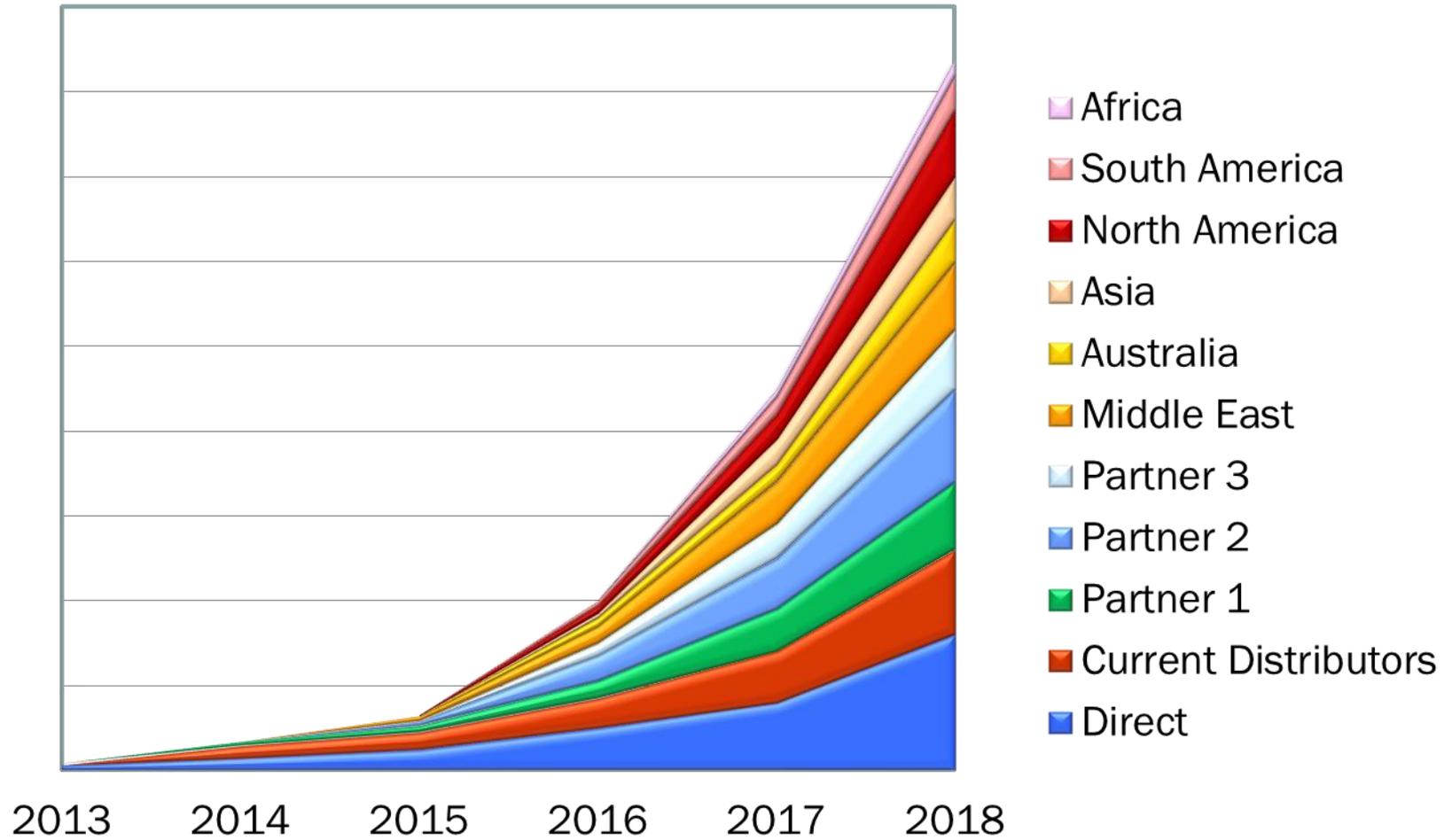
  
 Fresenius Medical Care  
 Q3 2015 Start  
 131M people  
 Estimated  
 2016 Start

We are just tapping into these major markets. We expect Q3 2015 to begin to reflect initiation of selling in new markets covering 188 million people  $\approx$  600,000 cases of severe sepsis/shock per year.

Given \$3,000 - \$5,000 in CytoSorb treatment costs per patient, these new territories enable us to target a \$1.8 - 3.0 billion total addressable market for sepsis alone

# Growth Driven by Direct, Distributor, Partner Sales

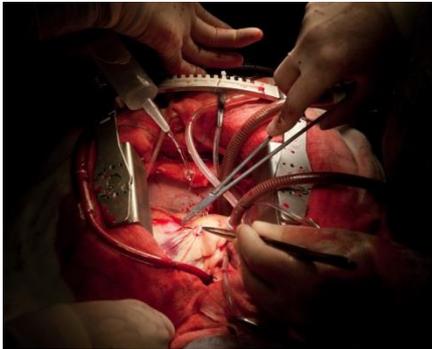
## Theoretical Revenue Growth Based on Layering\*



\* This graph is provided only to demonstrate the concept of revenue layering. It does NOT represent revenue forecasts or guidance

# Cardiac Surgery Partner Update

- The evaluation by our cardiac surgery partner in France, one of the top-4 cardiac surgery companies in the world, continues to go well and, though slower than anticipated, should be completed in the next several months
- Meanwhile, two randomized, controlled studies (University of Hamburg-Eppendorf and Medical University of Vienna, using CytoSorb intra-operatively during cardiac surgery have completed, with data expected this year
- CytoSorb® has been used safely in more than 300 intra-operative cardiac surgery cases to date



# REFRESH Update

## REduction in FREe HEmoglobin

- FDA approved our amendment to expand the trial to a 40-patient randomized controlled study at 8 centers
- Led by our Chief Medical Officer, Dr. Robert Bartlett, we are in the process of negotiating and finalizing clinical trial agreements and obtaining IRB approvals with 8 major cardiac surgery centers in the US
- Central IRB approval has been obtained, which is applicable to some of the sites
- The Data Safety Monitoring Board (DSMB) has been established
- We are on schedule to start enrollment in September 2015 with a goal of completing enrollment in Q4 2015/Q1 2016
- Added Steven Sisk as Director of Clinical Operations, formerly at Medtronic to oversee the day to day operations of the trial
- This trial is expected to support the REFRESH 2 Registration Trial for CytoSorb



# REFRESH Trial Overview

- 40 patient, 8-center randomized controlled feasibility study using CytoSorb intra-operatively in a bypass circuit during complex cardiac surgery lasting more than 180 minutes
  - Standard of care (20 control) vs CytoSorb + Standard of care (20 treatment)
- Primary safety endpoint: Safety
- Primary efficacy endpoint: Reduction in plasma free hemoglobin
- Secondary endpoints:
  - Ventilator time, time in the ICU, days in the hospital, incidence and progression to AKI, 30-day mortality
  - Biomarker reduction: Complement, cytokines and other inflammatory mediators

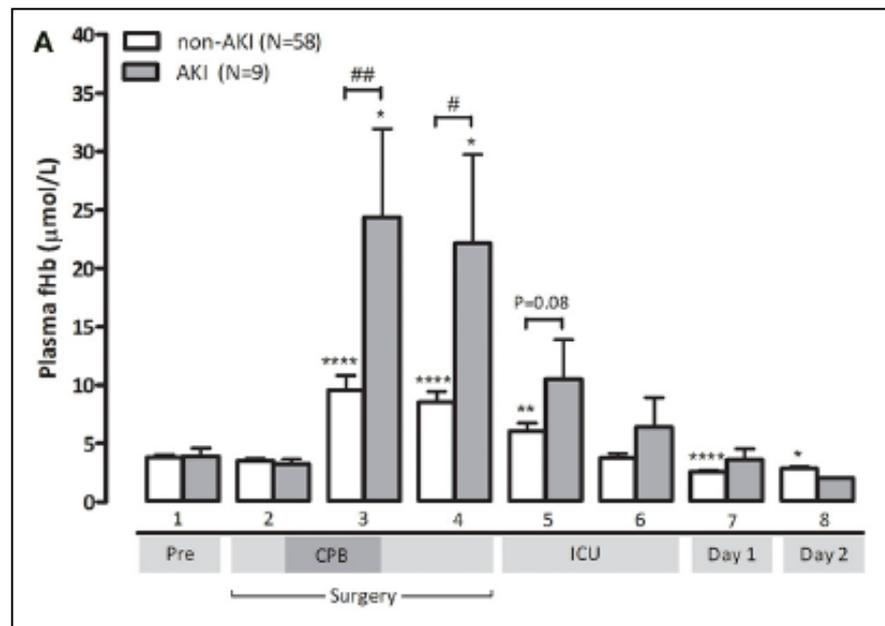
# Dangers of Plasma Free Hemoglobin (PfHb)

Patients undergoing complex cardiac surgery with significant cardiotomy suction are at highest risk of hemolysis, releasing large amounts of PfHb into circulation

Once the haptoglobin scavenging system is overwhelmed, PfHb can cause a direct depletion of plasma nitric oxide (NO), leading to pulmonary hypertension, renal ischemia and AKI, intestinal mucosal injury, organ failure, and other complications.

PfHb also can lead to oxygen radical generation and oxidative injury to tissues

PfHb is correlated to the development of AKI



Source: Windsant et al., Hemolysis during cardiac surgery is associated with increased intravascular nitric oxide consumption and perioperative kidney and intestinal damage, *Frontiers in Physiology*, Sep-2014

# Leading Advisors in Cardiac Surgery

**Dr. Joe Zwischenberger, M.D.**  
- SAB Chair  
University of Kentucky



**Dr. Robert Bartlett, M.D.**  
University of Michigan



**Dr. Paul Checchia, M.D.**  
Texas Children's  
Hospital in Houston



**Dr. Jonathan William Haft, M.D.**  
University of Michigan



**Dr. Nicholas Smedira, M.D.**  
Cleveland Clinic Foundation



**Dr. Craig Smith, M.D.**  
Columbia University



**Dr. Peter Wearden, M.D., Ph.D.**  
U. of Pittsburgh Medical Center



# 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 have no approved alternative treatments



- We believe that CytoSorb® is an excellent candidate for EAP Designation (similar to Breakthrough Designation for drugs and biologics) as it targets the treatment of many life-threatening illnesses such as sepsis, lung injury, pancreatitis, trauma, and other conditions that do not have viable treatment alternatives
- If we obtain EAP Designation, CytoSorb® could potentially get to market with a clinical trial using less stringent endpoint criteria (e.g. NOT 28-day all-cause mortality), provided that it is safe and that the company commits to obtaining the more stringent end-point in the post-market period
- We have been working diligently on the EAP application for sepsis and expect to file it with the FDA in the coming weeks. The application must be very thorough, including a data designation plan that details the clinical trials that will be pursued in the pre-market and post-market periods. FDA response on EAP Designation is expected within 30 days of submission, but could be delayed with questions



# CytoSorb Attacks Sepsis Broadly



Inflammatory cytokines (organ failure) & other factors



Immunosuppressive cytokines & re-establish immune responsiveness



Many bacterial toxins (organ failure)



Re-establish proper leukocyte trafficking to prevent cell-mediated organ injury



Improvement in hemodynamics



Reduction in capillary leak

**No other single therapy has demonstrated this broad range of activity**

# CytoSorb®

## SIRS and Sepsis: Regain Control!



**CytoSorbents**

Working to Save Lives Through Blood Purification

# Case Report: Septic Shock

- 72 year old male patient was admitted with sepsis from a urinary tract infection
- His condition and hemodynamic stability rapidly deteriorated with concurrent elevation in plasma inflammatory markers, despite broad antibiotic coverage
- Developed full-blown multi-organ failure: septic shock, respiratory failure, severely disturbed coagulation, liver dysfunction, and kidney failure.
- Placed on standard CRRT hemofiltration therapy with CytoSorb. Three CytoSorb sessions were run in the following days
- The first and consecutive second session resulted in a reduction of procalcitonin (PCT), C-reactive protein (CRP) and bilirubin and a markedly reduced need for vasopressors with significantly improved hemodynamics and reduced signs of capillary leak
- Due to a recurring inflammatory “second hit” episode, another session with CytoSorb was run, resulting in a marked improvement in organ function and inflammatory status, and stabilization of the patient
- The treatment was well-tolerated and safe, helping to “regain control” of the patient, who survived

# Case Report: ARDS & Multi-organ Failure

- A 45-year-old male patient was admitted with small intestine obstruction due to torsion
- Immediately scheduled for surgical intervention, but aspirated at anesthesia induction
- Rapidly developed one of the worst and most fatal forms of lung failure called acute respiratory distress syndrome (ARDS) requiring ECMO therapy to ensure sufficient oxygen supply
- Developed an overwhelming systemic inflammatory response syndrome (SIRS) with shock and severe capillary leak syndrome, causing severe swelling all over his body, with multiple organ failure
- CytoSorb was initiated and led to a profound decrease of IL-6 and IL-8, paralleled by a marked clinical stabilization of the patient including a significant reduction in vasopressors, and a significant improvement in lung function
- In this patient, CytoSorb therapy helped to “regain control” over the initially dramatic hyper-inflammatory response and helped to stabilize the patient hemodynamically, ultimately leading to a full recovery
- CytoSorb treatment was safe with no serious device related adverse events observed

# Case Report: Rhabdomyolysis

- A 55 year old patient was transferred from an outside hospital with sepsis from pneumonia and ARDS due to complications
- He had developed a complication called “compartment syndrome” where high pressure builds up in a muscle compartment that cannot expand. The muscle tissue was damaged and resulted in a drastic increase in myoglobin levels (rhabdomyolysis) that can cause kidney failure
- In addition, his inflammatory markers were extremely elevated, and he developed acute liver dysfunction
- A total of 4 CytoSorb® consecutive treatments (20 hours each) were performed
- During the course of the treatment, plasma concentrations of IL-6, PCT, and myoglobin decreased significantly, with a simultaneous normalization of blood counts, blood coagulation parameters, and liver enzymes
- With treatment, the patient had a strong improvement of his clinical situation, including stabilization of his respiratory and liver function
- In this patient, CytoSorb resulted in many improvements, including improved organ function, a significant reduction of cytokines including IL-6, and a major additional benefit of treating rhabdomyolysis and preventing kidney failure. The patient went on to a full recovery
- The treatment was safe with no adverse device-related events



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# Much More to Report

CytoSorb® is helping to save lives around the world. More clinical data will be made public in October at three major upcoming events.



Berlin, Germany  
October 2, 2015



European Society of Intensive Care Medicine



29th EACTS  
Annual Meeting  
Amsterdam, The Netherlands  
3-7 October 2015

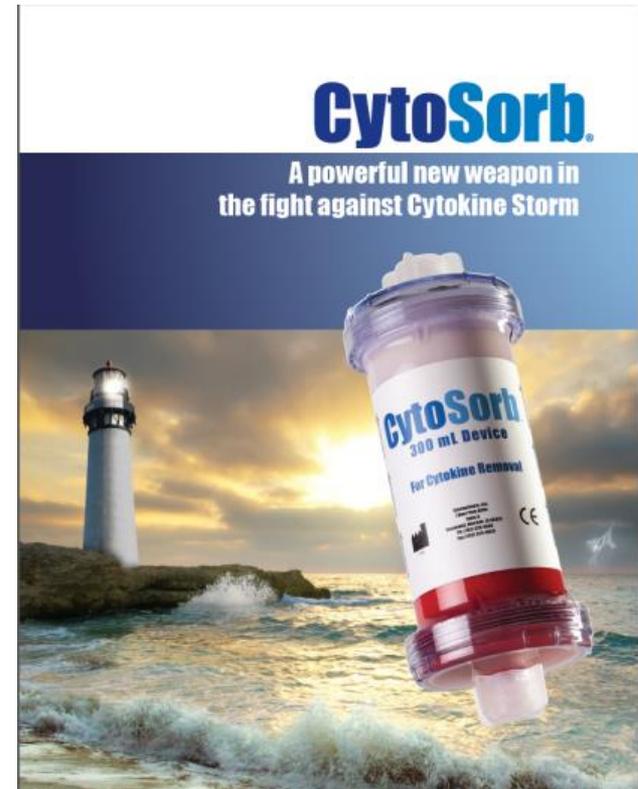


# Q&A Session

## CytoSorbents Corporation

**NASDAQ: CTSO**

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Monmouth Junction, NJ 08852  
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**A Leader in Critical Care Immunotherapy Company**



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