



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

**A Leader in Critical Care Immunotherapy**

Q2 2017 Earnings Conference Call

August 7, 2017

# 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. Eric Mortensen, MD, PhD

Chief Medical Officer

Dr. Christian Steiner, MD

Vice President of Sales and Marketing

Christopher Cramer, MS, MBA

Vice President of Business Development

**Moderator: Bob Yedid – LifeSci Advisors**

# 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 3, 2017 and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).

# Operational Highlights

- Achieved total revenue of \$3.6M, and the first \$3M quarter in CytoSorb sales, on record direct and distributor sales
- More than 27,000 CytoSorb treatments delivered, an increase from 14,000 a year ago with continued strong reorder rates
- Excellent progress on German CytoSorb reimbursement rates in many key accounts that covers device and procedure costs
- Extended partnership with Aferetica in Italy through 2021 with cumulative sales expected to exceed \$10M during this period
- Fresenius co-marketing effort will soon begin in 5 major countries and the launch of our ECMO kit is also expected to catalyze sales
- Expecting that 2H 2017 sales of CytoSorb will exceed 1H 2017
- Reiterate guidance on achieving operating profitability in 2018



# Operational Highlights

- We thank Dr. Robert Bartlett, our former CMO who has retired, for his many years of support, guidance, and camaraderie
- Dr. Eric Mortensen, started as the new CMO in June, and has focused on optimizing the REFRESH 2 trial design (expected to start later this year), and refining the clinical trial and data strategy
- Our goal is to prioritize company-sponsored clinical trials and invest to make clinical development a core competency
- Data publication has been accelerating
  - Two dozen peer-reviewed journal articles have been published highlighting clinical usage in the past ~12 months, with ~60 investigator-initiated studies in various stages of progress or planning with more data to come
  - An interim analysis on nearly 200 patients in the CytoSorb International Registry has been accepted for publication
  - “Case of the Week” reports, presentations at major conferences highlight ongoing treatment successes



# Operational Highlights

- New opportunities, such as cancer immunotherapy with the likely approval of the first CAR T-cell immunotherapy by Novartis expected later this year, open up potential new fast track paths to U.S. approval
- Our new manufacturing facility is in build out and on schedule to come online in Q1 2018, increasing manufacturing capacity to ~\$80M in sales
- Engaged with LifeSci Advisors as our IR firm to expand our investor network and shareholder base in both in the U.S. and abroad
- We plan to be visible at multiple investor and industry conferences, such as the European Society of Intensive Care Medicine (ESICM) and the European Association of Cardiothoracic Surgery (EACTS) in Vienna, Austria, and the Military Health System Research Symposium (MHSRS) later this month in Florida

# Financial Highlights

# Q2 2017 Comparative Revenue Results

	3 Months Ended June 30, 2017		3 Months Ended June 30, 2016		% Incr.
Product revenue	\$ 3,041,012		\$ 1,852,670		64%
Grant and other income	525,214		369,668		42%
Total revenue	\$ 3,566,226		\$ 2,222,338		60%

- Total Q2 2017 revenue was \$3.6M, including both product sales and grant revenue, compared to \$2.2K for Q2 2016, an increase of 60%
- CytoSorb sales were a record \$3.0M for Q2 2017, a 64% increase over \$1.9M in Q2 2016
- Annualized CytoSorb sales run rate was ~\$12.2M (Q2 2017) vs. ~\$7.4M (Q2 2016)
- Q2 2017 gross margins rose to ~\$2.1M compared to gross margins of ~\$1.3 million for Q2 2016, an increase of \$735K
- Gross profit margins on product sales were ~65% for Q2 2017, as compared to 68% for Q2 2016, primarily as a result of the mix of direct and distributor sales

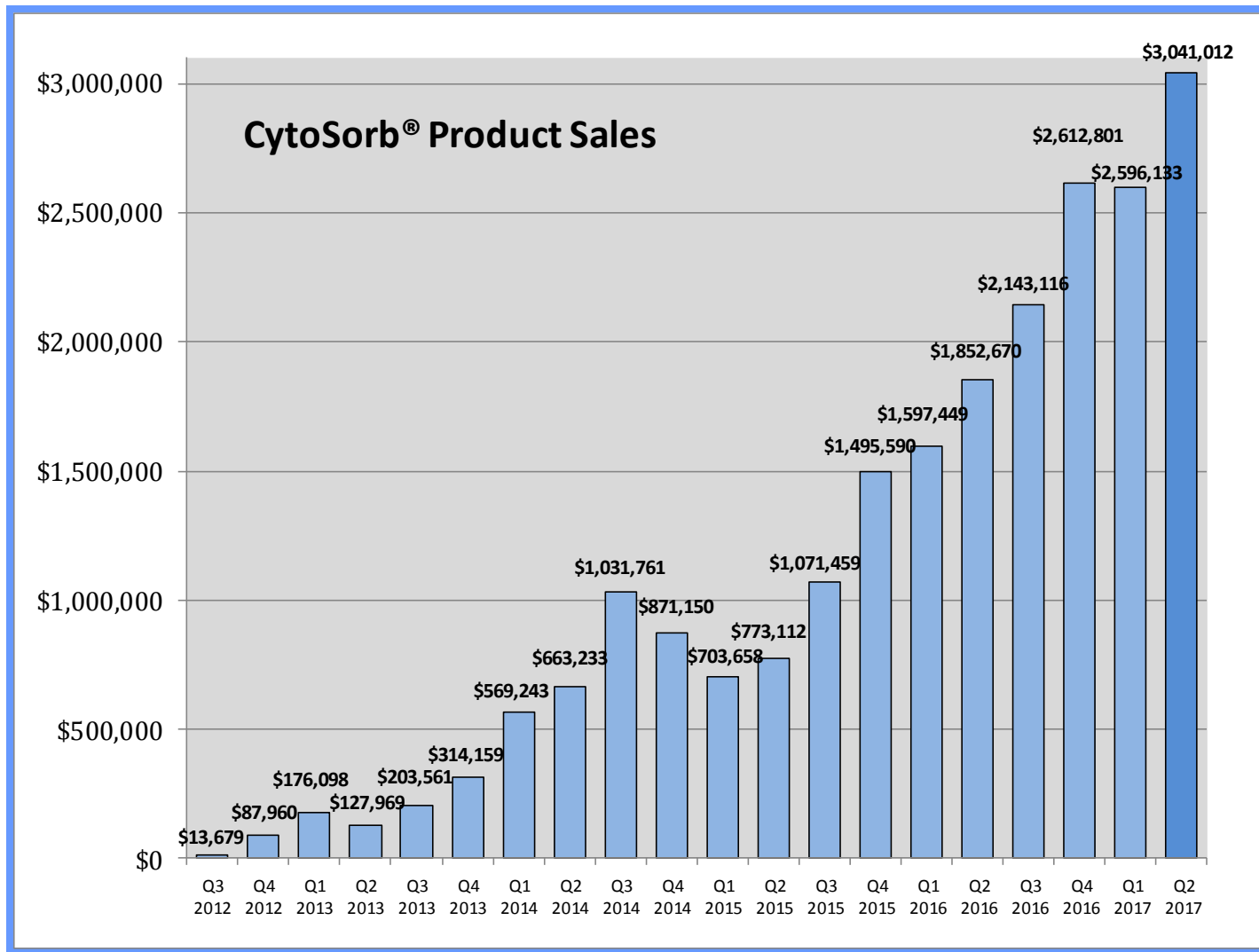


# Comparative 6-Month Revenue Results

	6 Months Ended June 30, 2017		6 Months Ended June 30, 2016		% Incr.
Product revenue	\$ 5,637,145		\$ 3,450,119		63%
Grant and other income	1,042,599		582,401		79%
Total revenue	\$ 6,679,744		\$ 4,032,520		66%

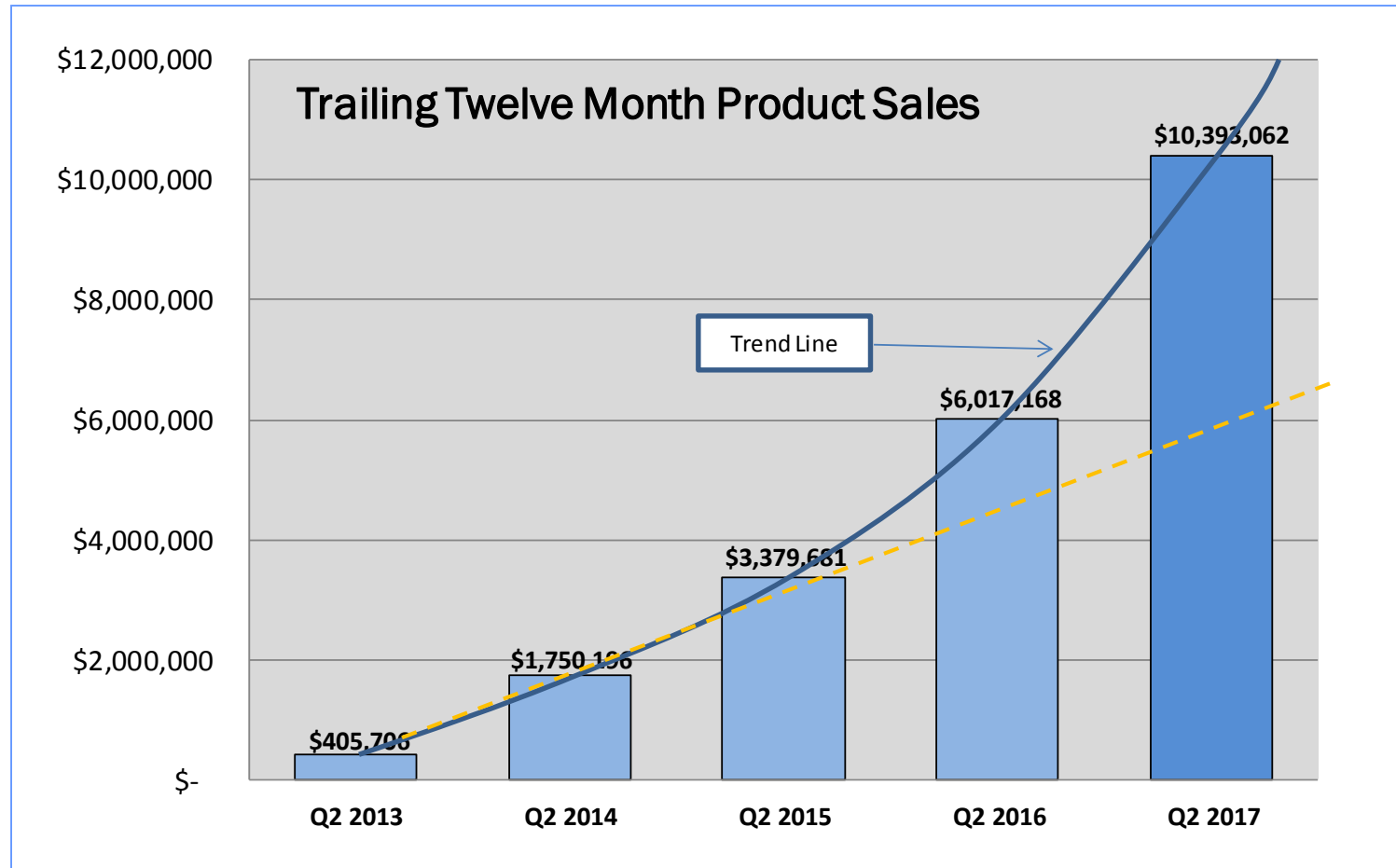
- CytoSorb® product sales for 1H 2017 were \$5.6M, a 63% increase over product sales of \$3.5M for the same period a year ago
- Grant revenue grew 79% from \$582K for 1H 2016 to \$1.0 million for 1H 2017
- Total revenue for 1H 2017, which includes both product sales and grant revenue, was \$6.7M as compared to \$4.0M for 1H 2016, an increase of 66%

# Quarterly Product Sales



# Trailing Twelve Months Product Sales

Over the past three years, the compound growth rate of return (“CAGR”) on product sales was 81%



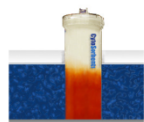
# Working Capital and Cap Table

Working Capital as of					
	6/30/17	3/31/17	12/31/16	12/31/15	12/31/14
Current Assets:					
Cash and short-term investments	\$ 16,402	\$ 3,240	\$ 5,245	\$ 7,509	\$ 5,550
Grants and accounts receivable, net	2,059	1,732	1,433	649	819
Inventories	890	858	834	1,191	538
Prepaid expenses and other current assets	390	451	316	512	700
Total current assets	19,741	6,281	7,828	9,861	7,607
Current Liabilities(1):					
Accounts payable	1,581	1,660	1,330	685	698
Accrued expenses and other current liabilities	1,602	1,608	2,115	723	825
Current maturities of long-term debt	2,000	1,250	833		
Deferred revenue				-	1
Total current liabilities	5,183	4,518	4,278	1,408	1,524
Net Working Capital	\$ 14,558	\$ 1,763	\$ 3,550	\$ 8,453	\$ 6,083

(1) Excludes warrant liability, a current liability that does not have cash implications.

## Cap Table 6/30/2017

	Fully Diluted Common Shares
Common Stock	28,133,986
Options	3,868,407
Warrants	1,038,560
Restricted Stock Unit Awards	110,003
	33,150,956

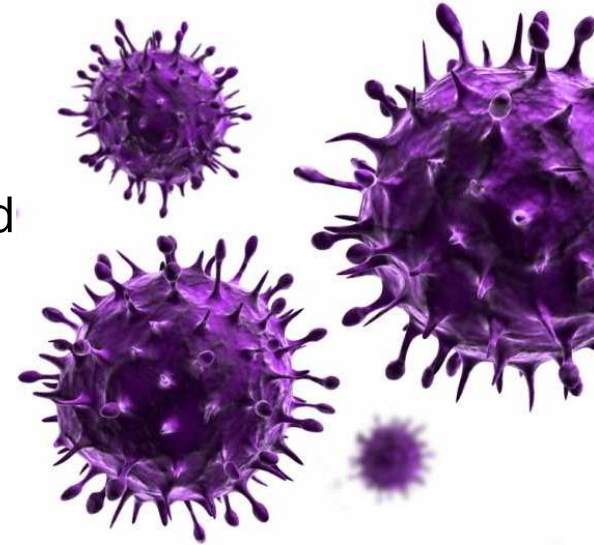


# Sepsis



# Sepsis: A Top Ten Killer Worldwide

- Sepsis is the result of an overzealous immune response to an infection and is driven by “cytokine storm”
- Afflicts ~30 million people worldwide every year and growing due to the aging baby boomer population and drug resistant bacteria
- Severe sepsis kills 1 in every 3 despite the best medical treatment that includes antibiotics
- Kills more people in the U.S. than either heart attacks, strokes, or any single type of cancer
- No approved therapies to treat it with virtually no drugs, biologics, and devices in Phase III clinical trials
- At an average cost > \$45,000 to treat, hospitals lose billions annually



# The Sepsis Crisis is NOW

- In May 2017, the World Health Organization (WHO) mandated sepsis as a “Global Health Priority”
- In July 2017, Bloomberg declared “America has a \$27 Billion Sepsis Crisis”

Sepsis is an equal opportunity killer.  
It is not going away



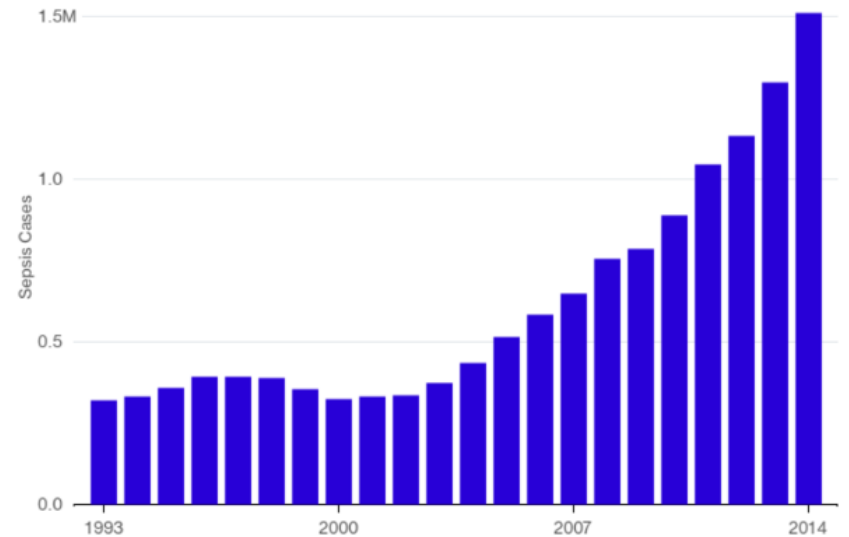
## Recognizing Sepsis as a Global Health Priority — A WHO Resolution

Konrad Reinhart, M.D., Ron Daniels, M.D., Niranjana Kissoon, M.D., Flavia R. Machado, M.D., Ph.D.,  
Raymond D. Schachter, L.L.B., and Simon Finfer, M.D.

“Some very important clinical issues, some of them affecting life and death, stay largely in a backwater which is inhabited by academics and professionals the world have died prematurely or faced long-term disability. This toll of unnecessary suffering drove Germany, with the unanimous support of the WHO executive code” in the Global Burden of Disease statistics, where most deaths due to sepsis are classified as being caused by the underlying infection. Improving the coding

## Hospital Stays for Sepsis Appear to Be Rising Dramatically

Experts say cases of sepsis may have been undercounted for years



AHRQ Healthcare Cost and Utilization Project

Bloomberg



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

# Sepsis Has Defied Any Solution

- There have been more than 100 Phase II and Phase III clinical trials exploring the potential of different interventional strategies on sepsis
- All of these included the use of standard of care including antibiotics
- With the exception of the PROWESS Xigris trial, all have failed. Xigris was subsequently taken off the market after a failed PROWESS SHOCK Trial
- Currently, there are no approved therapies to treat sepsis and **NO ONE** has pivotal data demonstrating efficacy of any therapy

Table 1. Clinical trials of biologic response modifiers in sepsis

Target	Strategies
Endotoxin (LPS)	Monoclonal antibodies
	LPS: HA-1A, E5
	Enterobacterial common antigen
	Toll-like receptor 4 (TLR4) antagonists
	Eritoran
	TAK-242
	Anti-CD14
	Bactericidal permeability increasing protein
	Taurolidine
	Alkaline phosphatase
	Polymyxin B
	Conjugate
	Extracorporeal column
	Lipid emulsion
Tumor necrosis factor (TNF)	Monoclonal or polyclonal antibodies
	Soluble receptor constructs
Interleukin-1 (IL-1)	Recombinant IL-1 receptor antagonist
Platelet activating factor (PAF)	Small molecule inhibitors
	PAF acetylhydrolase
Eicosanoids	Ibuprofen
	Soluble phospholipase A2 (sPLA2) inhibitor
Nitric oxide	L-NMMA
	Methylene blue
Hypercoagulability/disseminated intravascular coagulation (DIC)	APC, Protein C concentrate
	TFPI
	Antithrombin
	Anti-tissue factor antibody
	Heparin
	Thrombomodulin
	Intravenous immunoglobulin
	G-CSF, GM-CSF
	Interferon $\gamma$
	Corticosteroids
Endocrinopathy	Vasopressin
	Selenium
Others	Lactoferrin
	Bradykinin antagonists
	Statins
	Extracorporeal hemoperfusion



# Caution of Promising Early Studies

## Early Goal Directed Therapy (EGDT):

- Very promising 263 patient single center randomized, controlled trial (RCT) between severe sepsis or septic shock patients with either: Protocol-based hemodynamic resuscitation vs standard therapy. Mortality was 46.5% in the control arm, and 30.5% in the treatment ( $p < 0.01$ )
- However, multiple large scale multi-center studies including ProCESS, ARISE, ProMISe, showed now benefit, and the PRISM metanalysis studying 3,723 patients from 138 countries showed no benefit in 90-day mortality

## Talactoferrin:

- Promising 190 patient Phase II RCT demonstrating that orally-administered talactoferrin vs placebo led to a reduction in mortality in patients without shock from 22.6% to 2.6% ( $p = 0.03$ ), and all patients from 26.6% to 14.6% ( $p = 0.04$ )
- Subsequent Phase II/III RCT in 77 centers in 10 countries was terminated after 305 patients because of futility and safety concerns

Rivers, et al. NEJM 2001; 345:1368-77  
ProCESS: NEJM 2014; 370:1683-1693  
ARISE: NEJM 2014; 371:1496-1506  
PRISM: NEJM 2017; 376:2223-2234  
ProMISe: NEJM 2015; 372:1301-1311  
Vincent JL, et al, Crit Care Med 2015; 43:1832-1838

# Steroids in Sepsis

- **HYPRESS (2016):** RCT with 380 patient with severe sepsis, no shock. Given 50 mg hydrocortisone IV bolus, followed by 200 mg/d for 5 days then tapered to Day 11. No effect in 14 days on progression to shock, or 28- or 90-day mortality. 28-day mortality was 8.8% treatment vs 8.2% control
- **CORTICUS:** RCT with 499 patients with septic shock. 200 mg/day hydrocortisone x 5 days, then tapered to Day 11. Shorter time to reversal of shock. No change in 28-day mortality (34.3% vs 31.5% control) but treatment had more new incidences of sepsis and superinfection

# Vitamin C, Hydrocortisone, Thiamine trial

## Vitamin C, Hydrocortisone, Thiamine (2017)

- Retrospective single center 47 consecutive patient trial in severe sepsis or septic shock patients given daily treatment with 6g IV Vitamin C, 200 mg hydrocortisone IV for 7 days, and 400 mg IV thiamine each day. Compared against a same center 47 consecutive patient historical control. Hospital mortality was 40.4% in the control vs 8.5% in the treated
- Interesting data supported by real mechanism of action but limited by:
  - Single center, non-randomized controlled study
  - Low relative severity of illness, with:
    - 22% in each group in septic shock requiring vasopressors and short duration of use (2 days) even in control
    - 22% vs 26% control requiring mechanical ventilation
    - Modest perfusion deficits, with lactate 2.7 vs 3.1 mmol/L in control
    - Short ICU stay (mean 4 days in both groups)
  - APACHE 2 scores are unusually high, given the above

Conclusion: A larger multi-center RCT is needed

# CytoSorb Attacks Sepsis Broadly



Inflammatory cytokines (organ failure) & other factors



Immunosuppressive cytokines & re-establish immune responsiveness



Many bacterial toxins (organ failure), PAMPs and DAMPs



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 Sepsis Strategy – Playing Smart

We are pleased to have Dr. Eric Mortensen lead our clinical trial program. The goals of development will be to:

- Avoid the heterogeneity inherent to most large scale pivotal trials in sepsis
- Take advantage of the unique mechanistic aspects of CytoSorb
- Benefit from the ever expanding clinical usage of CytoSorb and focus on subgroups where CytoSorb works well and reproducibly
- Conduct focused validating RCTs where the effect of CytoSorb can be seen with a smaller number of patients

**We believe these studies will add to the widening body of clinical evidence of CytoSorb and help drive the therapy as standard of care**

# Q&A Session

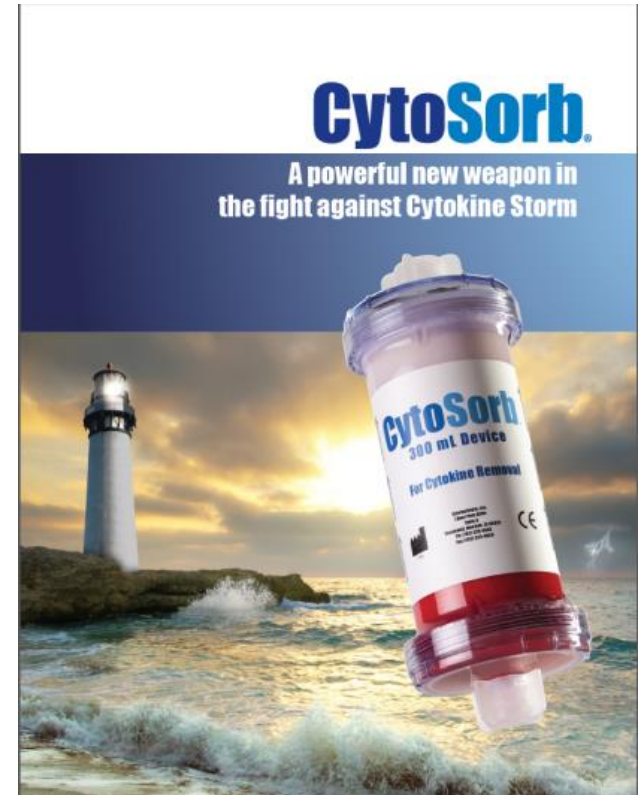
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