

HELPING PATIENTS SURVIVE THE RAVAGES OF DEADLY INFLAMMATION WORLDWIDE



# CytoSorbents™

Working to Save Lives Through Blood Purification

NASDAQ: CTSO  
BIO CEO & Investor Presentation  
February 14, 2017

# 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 9, 2016 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** 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



# CytoSorbents At a Glance

- NASDAQ-traded (CTSO): \$5.55 per share
- International footprint across two wholly-owned operating subsidiaries
  - CytoSorbents Medical, Inc - Monmouth Junction, NJ
    - Headquarters, ISO 13485 manufacturing, QA/QC, R&D
  - CytoSorbents Europe GmbH: International sales office - Berlin, Germany
- Flagship product, CytoSorb<sup>®</sup>, is E.U. approved, with 20,000+ treatments and distributed in 42 countries
- Strategic Partnerships with Fresenius Medical Care, Terumo, and Biocon
- Strong government support with \$18M+ in grants, contracts, other funding
- ~70 employees and consultants worldwide
- Pursuing U.S. approval of CytoSorb<sup>®</sup> in cardiac surgery
- Doubled 2016 CytoSorb sales to \$8.2M vs \$4.0M in 2015 with blended gross margins > 65%
- Accelerated growth expected in 2017 with numerous potential catalysts

Sepsis



Trauma



Burn Injury



Influenza



Millions Die  
Of Uncontrolled Deadly  
Inflammation  
Each Year



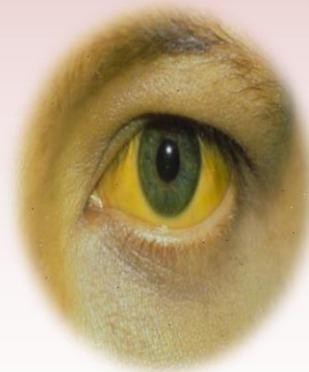
Lung Injury



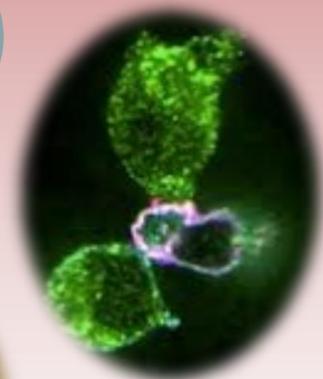
Pancreatitis



Surgical  
Complications



Liver Failure



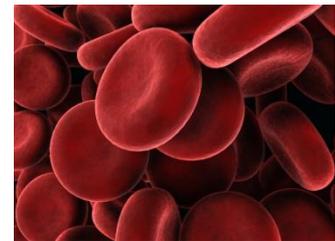
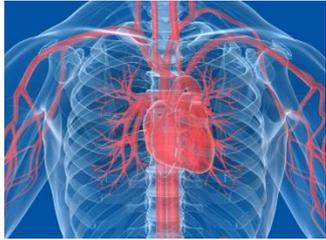
Cytokine  
Release  
Syndrome



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# Massive Inflammation Causes Organ Failure

Organ failure occurs when vital organs stop working, causing nearly half of all deaths in the ICU.



Little can be done to prevent or treat it today



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# No Ideal Options to Treat Severe Inflammation

## 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 Abs



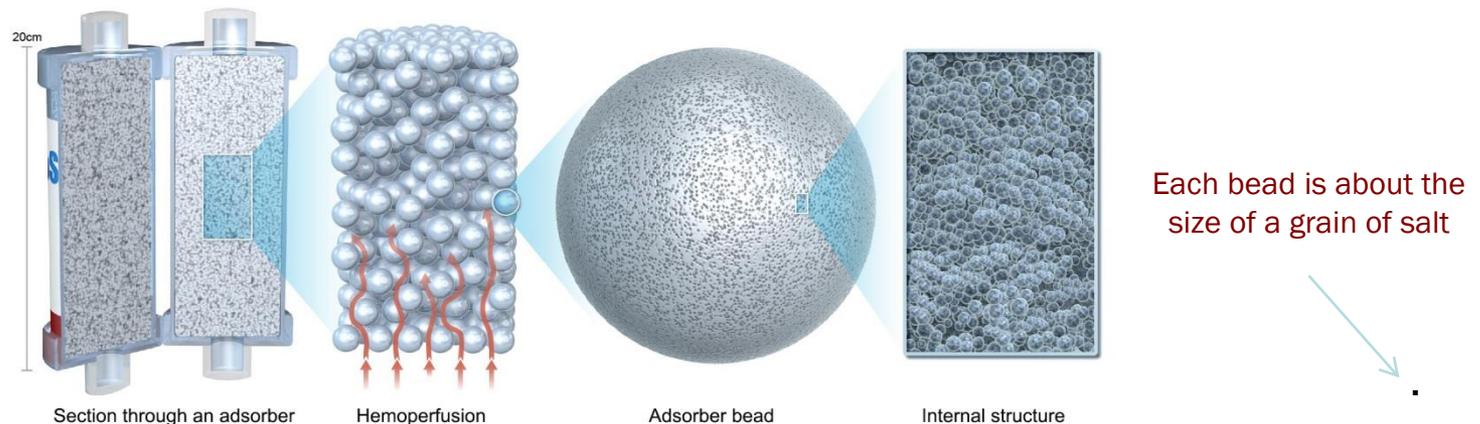
# CytoSorb<sup>®</sup> Removes the Fuel to the Fire

- CytoSorb<sup>®</sup> targets the \$20+ billion opportunity in critical care and cardiac surgery
- Approved in the European Union as the only specifically approved extracorporeal cytokine filter
- Approved for use in any situation where cytokines are elevated
- Removes cytokines and many other inflammatory mediators such as free hemoglobin, bacterial toxins, myoglobin, and activated complement
- Works with standard dialysis and heart-lung machines
- Safe and well-tolerated: In ~20,000 human treatments, up from 9,000 a year ago



# Powerful Blood Purification Technology

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

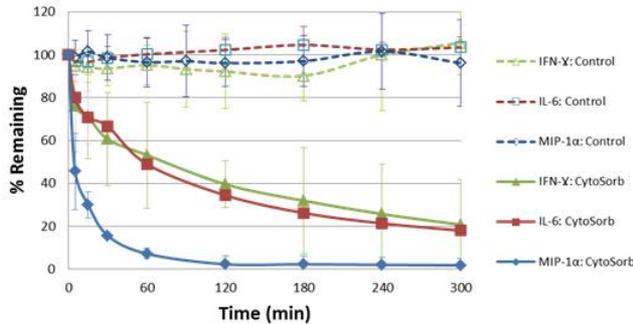


- Protected by 31 issued US patents and multiple applications pending
- Manufactured at our ISO 13485 certified facility in New Jersey
- One of the highest grade medical sorbents on medical market today

# Broadly Reduces Inflammatory Mediators

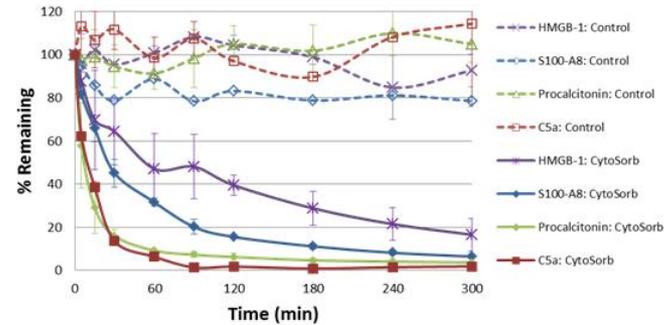
## CYTOKINES

*In Vitro* Adsorption of Cytokines from Blood with CytoSorb® or Control Device



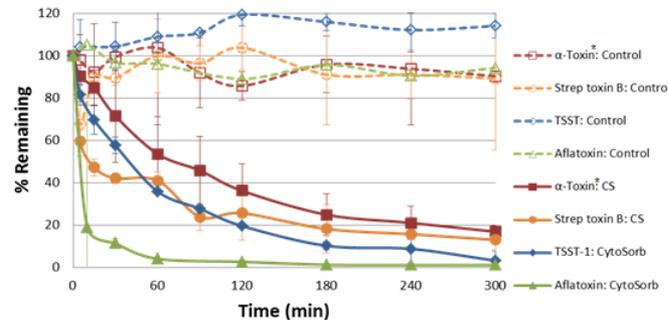
## DAMPS

*In Vitro* Adsorption of DAMPS from Blood with CytoSorb® or Control Device

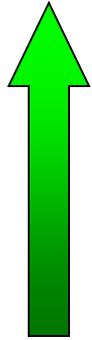


## PAMPS

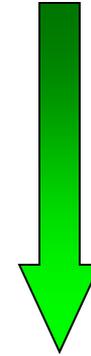
*In Vitro* Adsorption of PAMPS from Blood with CytoSorb® or Control Device



# Goal: To Prevent or Treat Organ Failure

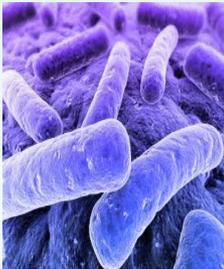


Improve  
Patient  
Outcome  
and  
Survival

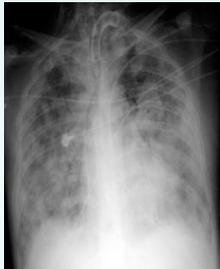


Decrease  
Costs Of  
ICU and  
Patient  
Care

Sepsis



ARDS



Burn Injury



Trauma



Pancreatitis



Influenza



Surgical



The Potential to Revolutionize Critical Care Medicine



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# Refractory Septic Shock

At the 26<sup>th</sup> Symposium for Intensive Medicine + Critical Care in Bremen, Germany, Dr. Sigrun Friesecke, Senior Intensivist in the Greifswald University Hospital MICU reported on a prospective, single arm study in 22 patients with refractory late-stage septic shock

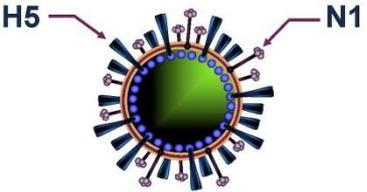
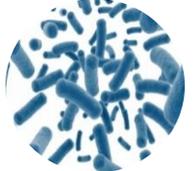
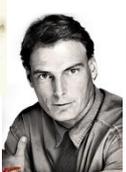
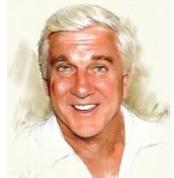
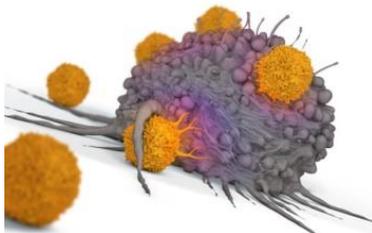
- Patients had refractory shock despite high doses of vasopressors, respiratory failure requiring mechanical ventilation or ECMO, anuric kidney failure requiring dialysis, and lactate > 8 mmol/L
- A similar population (n=16) receiving standard of care, where shock could not be reversed, also on mechanical ventilation with an initial lactate level of  $6.1 \pm 4$  mmol/L, and 75% requiring renal replacement therapy had a mortality of 100% at 28 days.\*
- Results from the CytoSorb Greifswald Study
  - 28-day survival was 41%, a 30-40% absolute improvement over expected (0-10%)
  - Resolution of shock in 68% of patients treated with CytoSorb
  - Reduction of IL-6 from an initial average of 87,000 pg/mL to below 10,000 pg/mL after 24 hours of treatment

\* Conrad, M., et. al., "Early prediction of norepinephrine dependency and refractory septic shock with a multimodal approach of vascular failure", J Crit Care, 2015; 30:739-743.

# The World Needs **CytoSorb®**



## H1N1



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# \$18+ Million in U.S. Government Support

- DARPA awarded \$3.8M five year (2012-present) contract as part of “Dialysis-Like Therapeutics” program to treat sepsis by removing cytokines and pathogen-derived toxins
- U.S. Army awarded ~\$1.7M SBIR contracts for trauma and burn injury research and hyperkalemia (2011-present)
- JPEO-CBD awarded \$150K Phase I SBIR contract for fungal mycotoxin removal (2016-present)
- U.S. 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 beads for treatment of sepsis
- NIH/NHLBI and SOCOM awarded \$1.7M Phase I & II SBIR contracts for HemoDefend blood purification technology to improve the quality/safety of blood transfusions (2013- present)
- Defense Health Agency awarded a \$150K Phase I SBIR contract to treat hyperkalemia
- More than \$2M in New Jersey funding for research-related net operating losses



# Product Pipeline

Critical Care,  
High Risk  
Surgery



**HemoDefend**



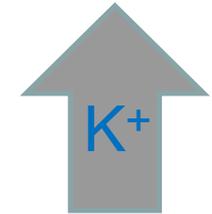
Blood  
Collection &  
Transfusion

**CytoSorb-XL**



Sepsis,  
Critical Care,  
High Risk  
Surgery

**Potassium  
Sorbent**



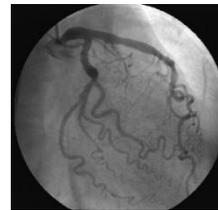
Severe  
Hyperkalemia

CE Mark Approved



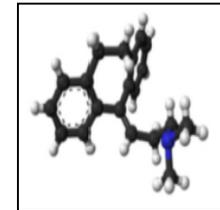
U.S. Animal Health Market

**ContrastSorb**



CT Imaging,  
Interventional  
Radiology

**DrugSorb**



Drug  
Overdose,  
Chemo  
Removal

**BetaSorb**



Improving  
Dialysis

Under Development

We Expect to Achieve  
Operating Profitability  
Within 2 Years



# CytoSorb® Is a High Margin Razorblade

- CytoSorbents is pure play high margin disposables business where CytoSorb is the “razorblade” that is fully compatible with the existing installed base of “Razor” ICU dialysis and ECMO machines, and heart-lung machines in the OR
- Blended gross margins are >65%, but with economies of scale and manufacturing efficiencies, this is expected to be closer to 80%
- Average Selling Price is approximately \$1,000 per cartridge
- Approximately 1 - 10 cartridges are typically used per patient. Open heart surgery uses 1-2 cartridges, treatment of sepsis uses 3-5 cartridges. An entire course of treatment for sepsis is roughly the cost of 1 day in the ICU
- In Germany, 400 hospitals have >400 beds. Each of these hospitals will see 300-600 sepsis patients per year. At 3-5 cartridges per patient:
  - Revenue per patient = ~\$3,000-5,000
  - Potential revenue per hospital = \$1-3M for sepsis alone



# Direct Sales: Expanded to 5 Countries

CytoSorbents' direct sales force focused on most major university and public hospitals in Germany, Austria, Switzerland, Belgium and Luxembourg. German market alone is \$1.0-1.5 billion



**Dr. Christian Steiner, MD**  
Vice President – Sales and Marketing and General Manager  
CytoSorbents Europe GmbH



**Stefan M. Baudis**  
International Sales Director



**Dr. Joerg Scheier, MD**  
Senior Medical Director Europe



**Dr. Volker Humbert, MD**  
Senior Manager - Clinical Affairs



**Dominik Gutzler**  
Head of Product Management



**Dr. Rainer Kosanke, PhD**  
Director Scientific Affairs Europe



**Alexandru Bojan**  
Regional Sales Director



**Adrian Thomas**  
Regional Sales Director



**Linus Khoo**  
Regional Sales Director



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



**Matthias Hoeldtke**  
Regional Sales Manager  
Southeast Germany



**Uwe Gerks**  
Regional Sales Manager  
Northern Germany



**Andreas Gassmann**  
Sales Representative  
Southern Germany



**Christian Koptik**  
Regional Sales Manager  
Austria



**Martin Scherer**  
Regional Sales Manager  
Southwest Germany



**Andreas Pendleler**  
Regional Sales Manager  
Western Germany



**Steffen Martens**  
Regional Sales Manager  
Northeast Germany



**Oliver Lupoli**  
Country Sales Manager  
Switzerland



**Brigitta Waldmueller**  
Application Specialist  
Austria



**Eva Wechsler**  
Application Specialist



**Fernanda Goncalves Zawieja**  
Sales Assistant/Customer Support



**Petra Hoffmann**  
Sales Assistant/Customer Support



**Anke Applehoff**  
Application Specialist



**Franziska Preissing**  
Senior Manager – Reimbursement & Health Economics



**Kristin von Hammerstein**  
Marketing Manager



**Harriet Adamson**  
Clinical Research Manager



# CytoSorb® Distributed in 42 Countries



HOANG LONG PHARMA

IntensivMed



TekMed

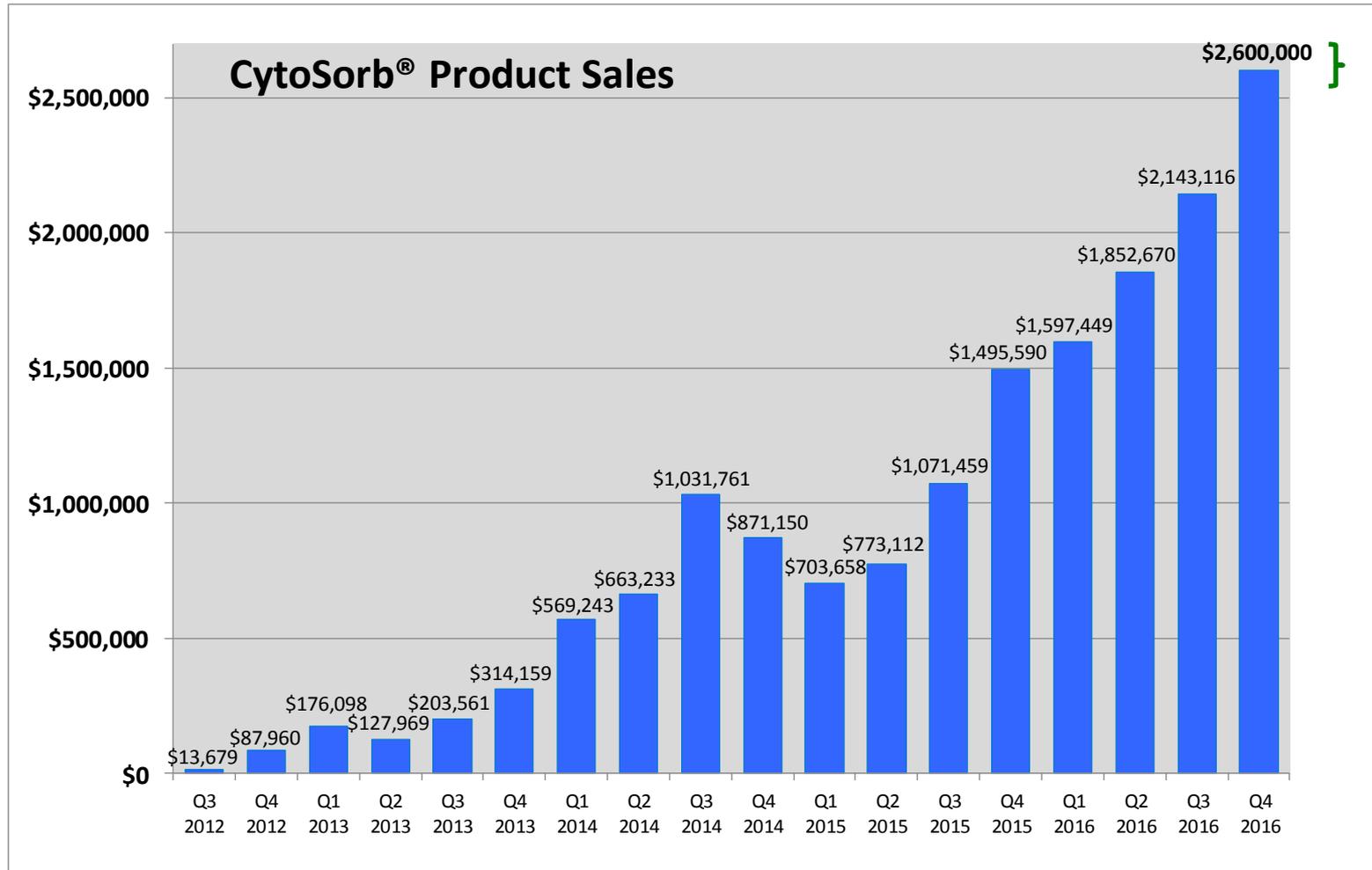


WMC



# Quarterly Product Sales

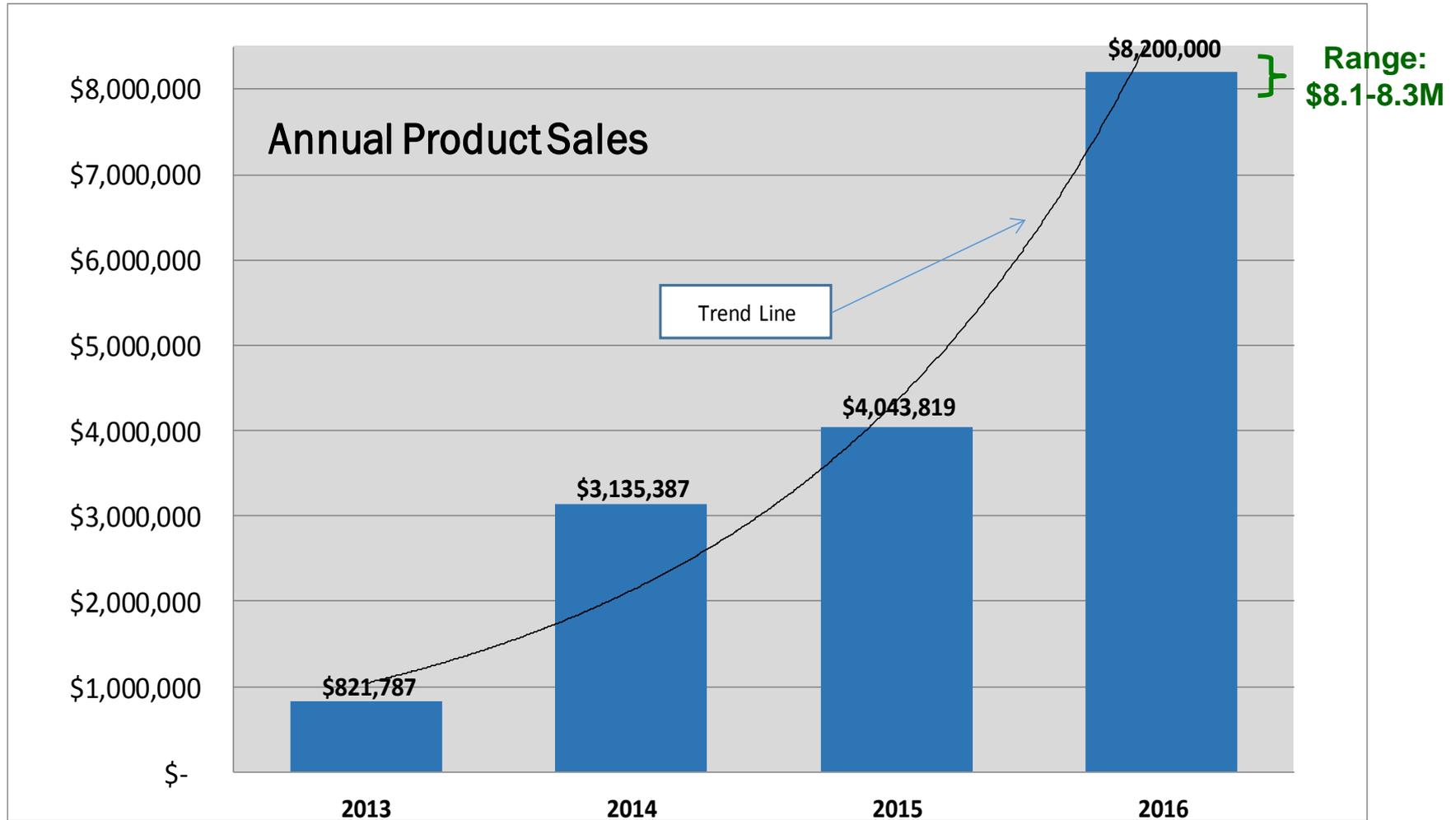
Seventh consecutive quarter of product sales growth  
Sixth consecutive quarter of record sales



Range:  
\$2.5-2.7M



# Annual Product Sales



# Dedicated Reimbursement In Germany

- CytoSorb has achieved a permanent, dedicated reimbursement code in Germany – our most important market and the largest medical device market in the European Union
- Validates the importance of our therapy to physicians in the country
- Was achieved very rapidly by the initiative and strong support of several major medical societies across different medical specialties
- Effective January 1, 2017, the new code is expected to result in much higher reimbursement compared to the more generic code we have used, which in many cases led to inadequate reimbursement, impeding usage and sales
- Expected to catalyze major increases in usage and CytoSorb sales in Germany, and positively impact reimbursement in other countries



# Expanded Fresenius Partnership

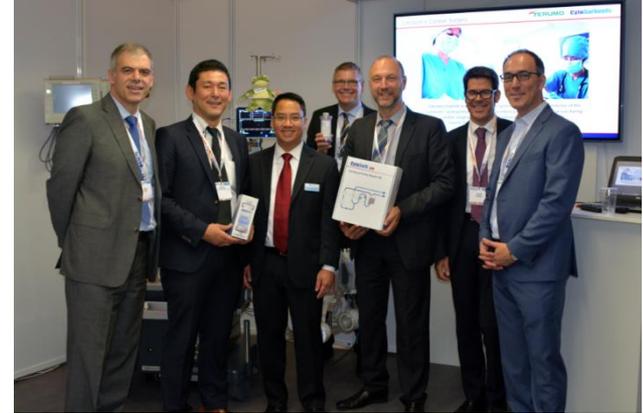
CytoSorbents renewed its partnership with Fresenius Medical Care in January 2017



- 1) 3 year extension on exclusive distribution of CytoSorb for ICU applications in France, Poland, Norway, Sweden, and Finland
- 2) Increased commitment with guaranteed quarterly orders of CytoSorb evaluable every 1.5 years
- 3) Co-marketing agreement across all of the countries where CytoSorb is sold, where possible
  - Increases the “effective” sales force by 2-3x in each country
  - Fresenius to provide written endorsement of CytoSorb for the multiFiltrate platform including the inclusion of CytoSorb as a programmed option on the multiFiltrate PRO
  - Jointly developed marketing materials



- Entered into a multi-year partnership with Terumo Cardiovascular Group, a global leader in medical devices for cardiac and vascular surgery
- Initial exclusive distribution of CytoSorb® in France, Denmark, Norway, Sweden, Finland, and Iceland
- Launched December 2016
- Strong validation of our technology and opens door to potential expansion to other countries, such as Japan – the second largest medical device market in the world



# Biocon Has Renewed Focus on CytoSorb



Treat Primary Infection with  
Antibiotics



Treat Massive Inflammatory  
Response with CytoSorb

- Biocon is the largest biopharmaceutical company in India
- Significant growth in India with expansion into Sri Lanka
- They have renewed their commitment to CytoSorb with its own division, sales force, and funding for small clinical studies

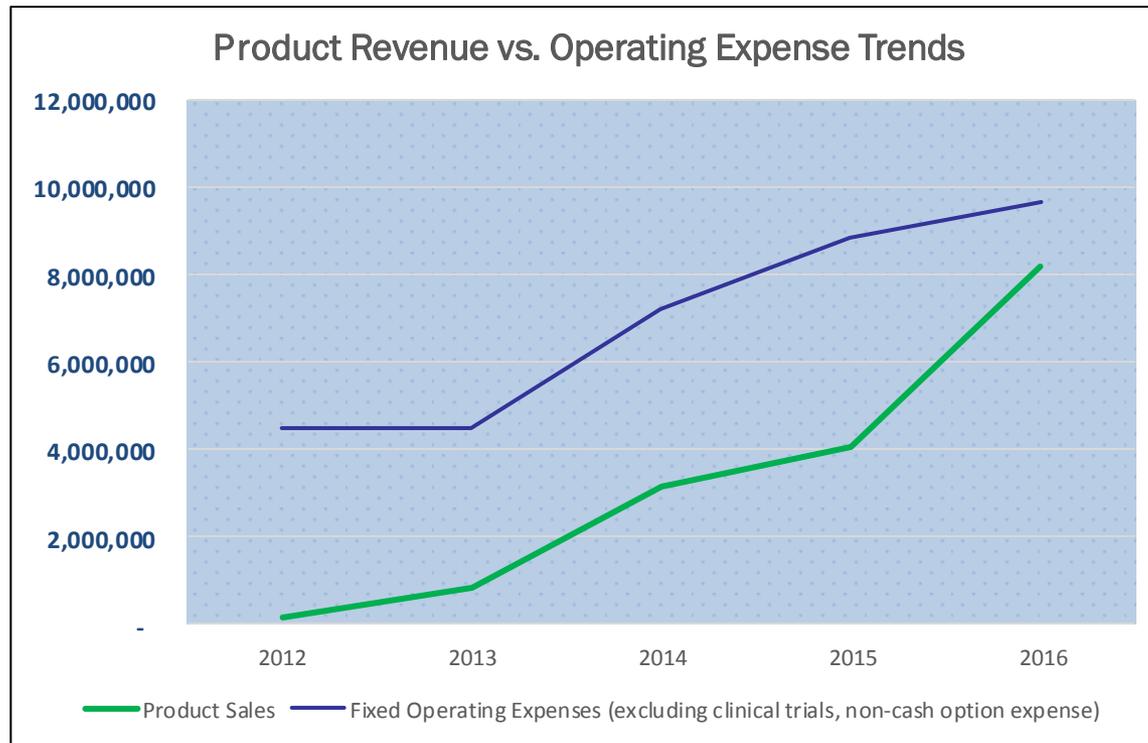


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Working to Save Lives Through Blood Purification

# Operating Profitability Expected in 2 Years

Operating profitability is expected within 2 years at ~\$20M in sales, at which point an estimated 40-50 cents on every dollar drops to the bottom line



Product sales continue to grow rapidly while increases in fixed non-clinical, non-cash expenses taper off

We expect to begin the path  
to U.S. approval later this  
year with initiation of a  
U.S. cardiac surgery  
REFRESH II Trial



# U.S. REFRESH I Trial – Safety Confirmed

## REduction in FREe Hemoglobin

- 40-patient, eight-center study evaluating the safety and efficacy of intra-operative use of CytoSorb® in a heart-lung machine during complex cardiac surgery in elective, non-emergent cardiac surgery > 3 hours
  - Aortic reconstruction, CABG redos, multiple valve replacements, etc
- Working with major cardiac surgery centers
  - Baylor College of Medicine and Texas Heart Institute
  - Baystate Medical Center
  - Columbia University
  - Cooper University Hospital
  - University of Kentucky
  - University of Maryland
  - University of Pennsylvania
  - University of Pittsburgh Medical Center
- Primary endpoints were safety and reduction in free hemoglobin



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# REFRESH I Trial – Safety

## REduction in FREe Hemoglobin Trial



- In this first RCT using CytoSorb in high risk cardiac surgery, we have:
  - Demonstrated safety of the therapy
  - Identified surgical procedures where patients have the highest levels of plasma free hemoglobin and can be used to enrich future studies for those at greatest risk of organ injury
  - Demonstrated that CytoSorb reduces key inflammatory mediators during the treatment period
- An abstract of the REFRESH I Trial has been submitted for the AATS conference
- Meanwhile we plan to confirm the clinical trial strategy with the FDA and expect to begin a registration trial later this year, designed to seek approval of CytoSorb in the U.S. for the application of cardiac surgery
- Depending on the clinical path, approval could occur in the 2018-20 timeframe.



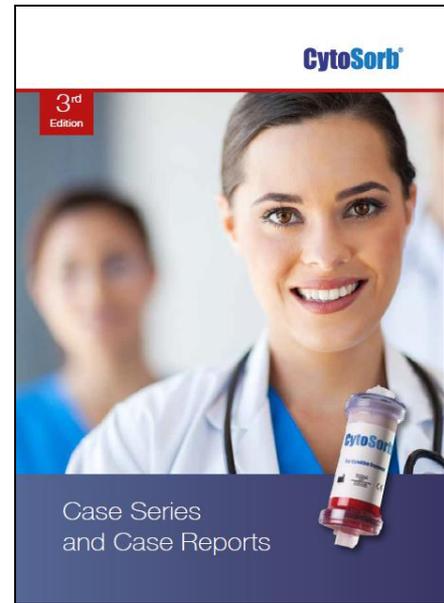
**CytoSorbents**

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Further detail will be forthcoming soon.

# Focus on Clinical Data

- Broad clinical program in Europe with 58 investigator-initiated studies in various stages, including several that have completed and nearly half have started and/or are enrolling
- These studies run the gamut from sepsis, cardiac surgery, post-operative inflammation, liver failure, trauma, and many other applications
- In addition, we have a number of company sponsored trials in cardiac surgery and sepsis that will start this year, in both Europe and the U.S.
- There are more than two dozen publications ranging from case reports, case series, and small randomized controlled studies that have been submitted or are being prepared for submission
- These data will be extremely helpful in driving continued usage and adoption, as well as reimbursement of CytoSorb in many different markets



We see strong, high  
quality, institutional  
interest in our story



# CytoSorbents Is A Unique “De-risked” Hybrid

Combines greater visibility and lower risk of a medtech company with a “razorblade”, high margin business model and strong technology validation

- \$8.2M in 2016 sales
- 70+% Direct Margins
- 20,000 human treatments and growing

**\$18M in Grant  
and Contract  
Funding**



And the upside profile of a biotechnology company with a \$20B worldwide market opportunity in critical care and cardiac surgery

# Our Progress is Resonating with Investors

In 2017, we plan to continue achieving multiple value creating milestones and expect to meet, for the first time, the investment criteria for a wide range of high quality, fundamental institutional investors

- As of Q4 2016, we have already exceeded a \$10M in sales run-rate, a key revenue threshold for many fundamental institutional investors
- We expect to achieve operating profitability, with expanding sales and gross margins, within the next 1 - 2 years, completely changing our investment profile
- Following discussions with the FDA, we plan to initiate a pivotal, registration trial for CytoSorb in the U.S., putting a time-line, for the first time, on a potential U.S. approval

We expect 2017 to be a major year of visibility and progress for our company, to the benefit of all of our shareholders



***Providing Hope  
in a helpless situation***



HELPING PATIENTS SURVIVE CRITICAL ILLNESSES WORLDWIDE



**CytoSorbents™**

Working to Save Lives Through Blood Purification

NASDAQ: CTSO

Dr. Phillip Chan, MD, PhD – CEO

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