

# CytoSorbents™



HELPING REDUCE DEADLY UNCONTROLLED INFLAMMATION IN HOSPITALIZED PATIENTS WORLDWIDE

**NASDAQ: CTSO**

**B Riley FBR Institutional Investor Conference**

**May 22, 2019**

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# 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: CTSO \$7)

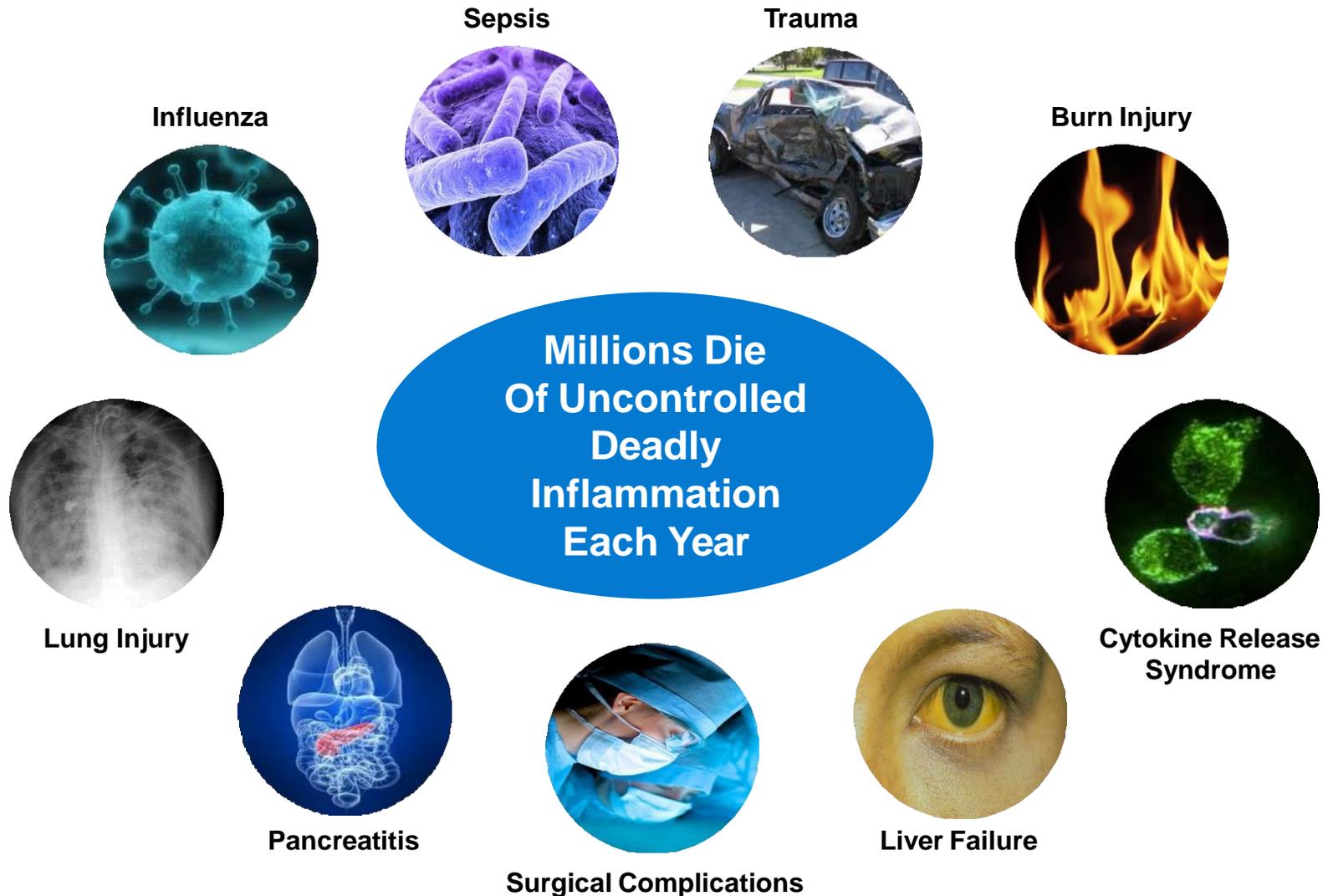
- CytoSorb® is E.U. approved as an extracorporeal cytokine adsorber with 61,000+ cumulative treatments (up from 40,000 a year ago) delivered and distributed in 55 countries

- Record 2018 Financial Performance:

	2017	2018	Increase
<b>Total Revenue</b>	<b>\$15.1M</b>	<b>\$22.5M</b>	<b>+49%</b>
<b>Product Revenue</b>	<b>\$13.4M</b>	<b>\$20.3M</b>	<b>+51%</b>
<b>Blended Product Gross Margin</b>	<b>71%</b>	<b>74%</b>	<b>-</b>

- Healthy cash balance of \$19.6M (3/31/19)
- 135 employees with international footprint across two wholly-owned subsidiaries
  - CytoSorbents Medical, Inc: Headquarters - New Jersey, USA
  - CytoSorbents Europe GmbH: International sales office - Berlin, Germany
- Strategic Partnerships with Fresenius Medical Care, Terumo, Biocon, Dr. Reddy's
- Strong government support with ~\$26M in grants, contracts, other non-dilutive funds
- Russell 2000 & 3000 listed with coverage by Cowen, B Riley, HCW, Maxim, Zacks

# Uncontrolled Inflammation is Deadly



# 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 organ failure today

# No Ideal Options to Treat Severe Inflammation

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## **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 Bridges the Gap

## 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® Reduces the Fuel to the Fire

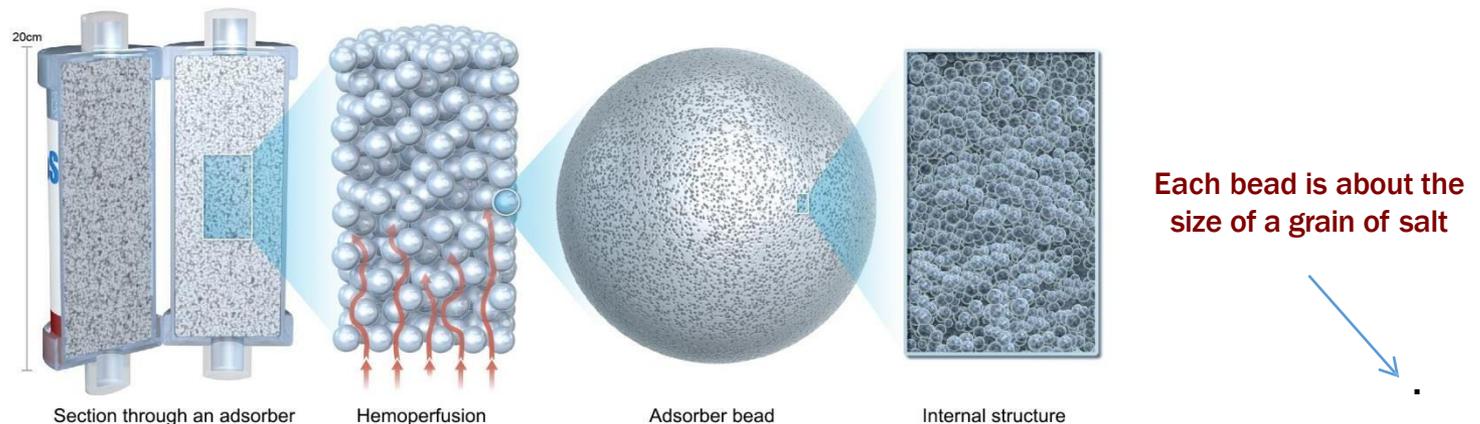
- CytoSorb® targets the \$20+ billion opportunity in critical care and cardiac surgery
- Approved in the European Union as the first specifically approved extracorporeal cytokine adsorber
- Broad indication for use where cytokines are elevated
- Removes cytokines and many other inflammatory mediators such as free hemoglobin, bacterial toxins, myoglobin, and activated complement
- Safe and well-tolerated: 61,000+ cumulative treatments delivered, up from 40,000 a year ago



\*CytoSorb is not yet approved in the U.S.

# Patented Blood Purification Technology

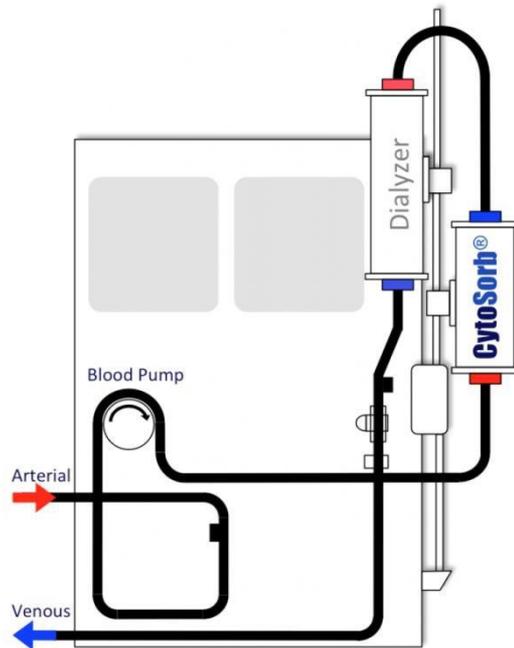
The underlying blood purification technology is based on biocompatible, highly porous polymer beads that act like tiny sponges to remove harmful substances from blood



- Proprietary patented technology with multiple patents pending worldwide
- Manufactured at our ISO 13485 certified facility in New Jersey
- One of the highest grade medical sorbents on medical market today

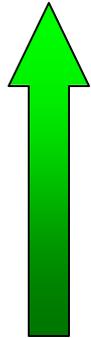
# CytoSorb is “Plug and Play”

## Compatible with Existing Dialysis and Heart-Lung Machines

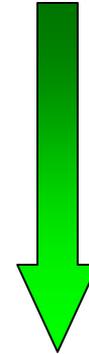


- Place a temporary dialysis catheter in a major vein
- Connect the device to a standard dialysis, ECMO, or heart-lung machine found in hospitals worldwide
- Pump blood out of the body and through the cartridge
- The polymer beads directly contact blood and remove unwanted or toxic substances
- “Purified” blood is pumped back into the patient
- Can treat 70+ total blood volumes per 24 hour treatment
- Each treatment uses a new cartridge

# Goal: To Prevent or Treat Organ Failure

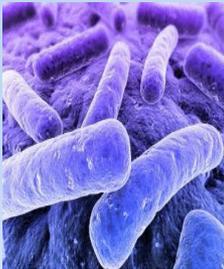


Improve  
Patient  
Outcome  
and  
Survival

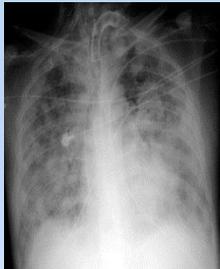


Decrease  
Costs Of  
ICU and  
Patient  
Care

Sepsis



ARDS



Burn Injury



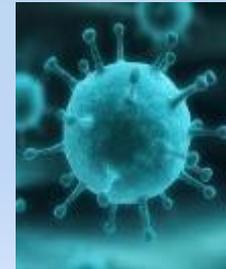
Trauma



Pancreatitis



Influenza



Surgical



The Potential to Revolutionize Critical Care Medicine

# Refractory Septic Shock

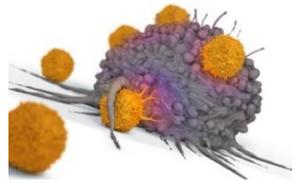
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Prospective, single arm study in 20 patients with refractory late-stage septic shock using CytoSorb aggressively every 12 hours with a new cartridge

- Patients had refractory shock despite high doses of vasopressors, respiratory failure requiring mechanical ventilation, oligo-anuric kidney failure requiring dialysis, and lactate > 8 mmol/L
- Results from the CytoSorb Greifswald Study
  - Resolution of shock in 65% of patients treated with CytoSorb
  - 28-day survival was 45%, a 30-40% absolute improvement over expected (0-10%)
  - Reduction of IL-6 from an initial average of 87,000 pg/mL to below 10,000 pg/mL after 24 hours of treatment
- A similar population (n=16) receiving standard of care but no CytoSorb therapy, 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.\*
- 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.
- Friesecke, S, et.al., "Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single center study", J Artif Organs 2017 Sep; 20(3):252-259.



# The World Needs CytoSorb®

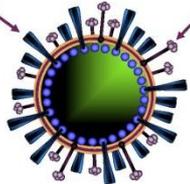


**H1N1**



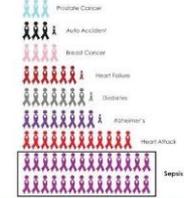
H5

N1



**SEPSIS** THE UK SEPSIS TRUST  
**THE HIDDEN KILLER**

LEADING CAUSES OF DEATH

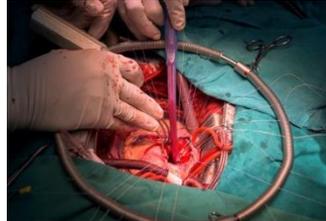


Sepsis Kills More People Than Any Other Medical Condition



Recognizing Sepsis as a Global Health Priority — A WHO Resolution

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



# CytoSorb

61,000+ Treatments

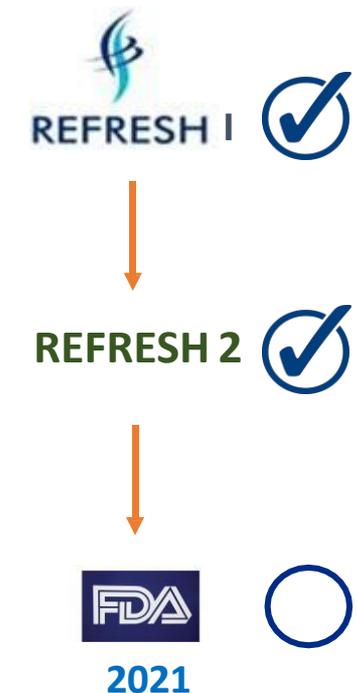
55 Countries Worldwide with E.U.

Critical Care

Cardiac Surgery

United States

Cardiac Surgery



Recently added Mexico and South Korea with partner, Fresenius Medical Care

# CytoSorb® Is a High Margin “Razorblade”

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- High margin “razorblade” fully compatible with existing installed base of “razor” blood pumps: Dialysis/CRRT, ECMO machines (ICU), heart-lung machines (OR)
- Blended gross margins are 74%, expected to rise to ~80% on a quarterly basis in 2019, driven by volume production from our new manufacturing facility
- Average Direct Selling Price is approximately \$1,000 per cartridge
- Approximately 1 - 10 cartridges are typically used per patient
  - Open heart surgery: 1-2 cartridges
  - Sepsis: 3-5 cartridges or roughly 1 day in the ICU
  - Severe acute pancreatitis: 5-10 cartridges
- In Germany, 400 hospitals have >400 beds. Each hospital typically sees 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
- Previously disclosed one German hospital has already achieved sales >\$1M, validating revenue model

# Direct Sales: Focused on 10 Countries



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

CytoSorbents' direct sales force focused on most major university and public hospitals in Germany, Austria, Switzerland, Belgium, Luxembourg, Poland, Norway, Sweden, Denmark, and the Netherlands with full reimbursement in Germany. German market alone is \$1.0-1.5 B.



# CytoSorb® Distributed in 55 Countries



Dr. Reddy's



HOANG LONG PHARMA

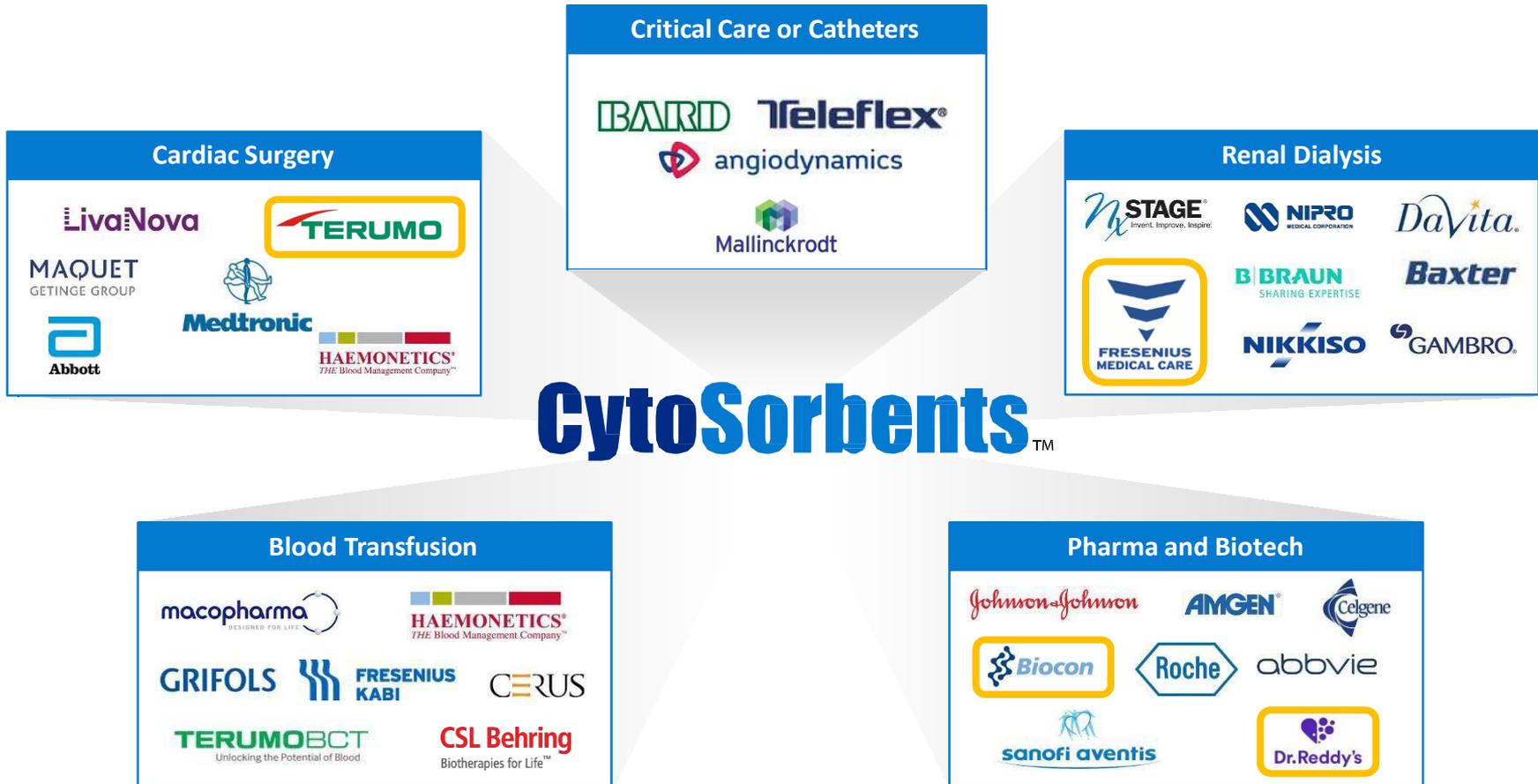
IntensivMed



TekMed



# Four Major Partnerships, Potential for More



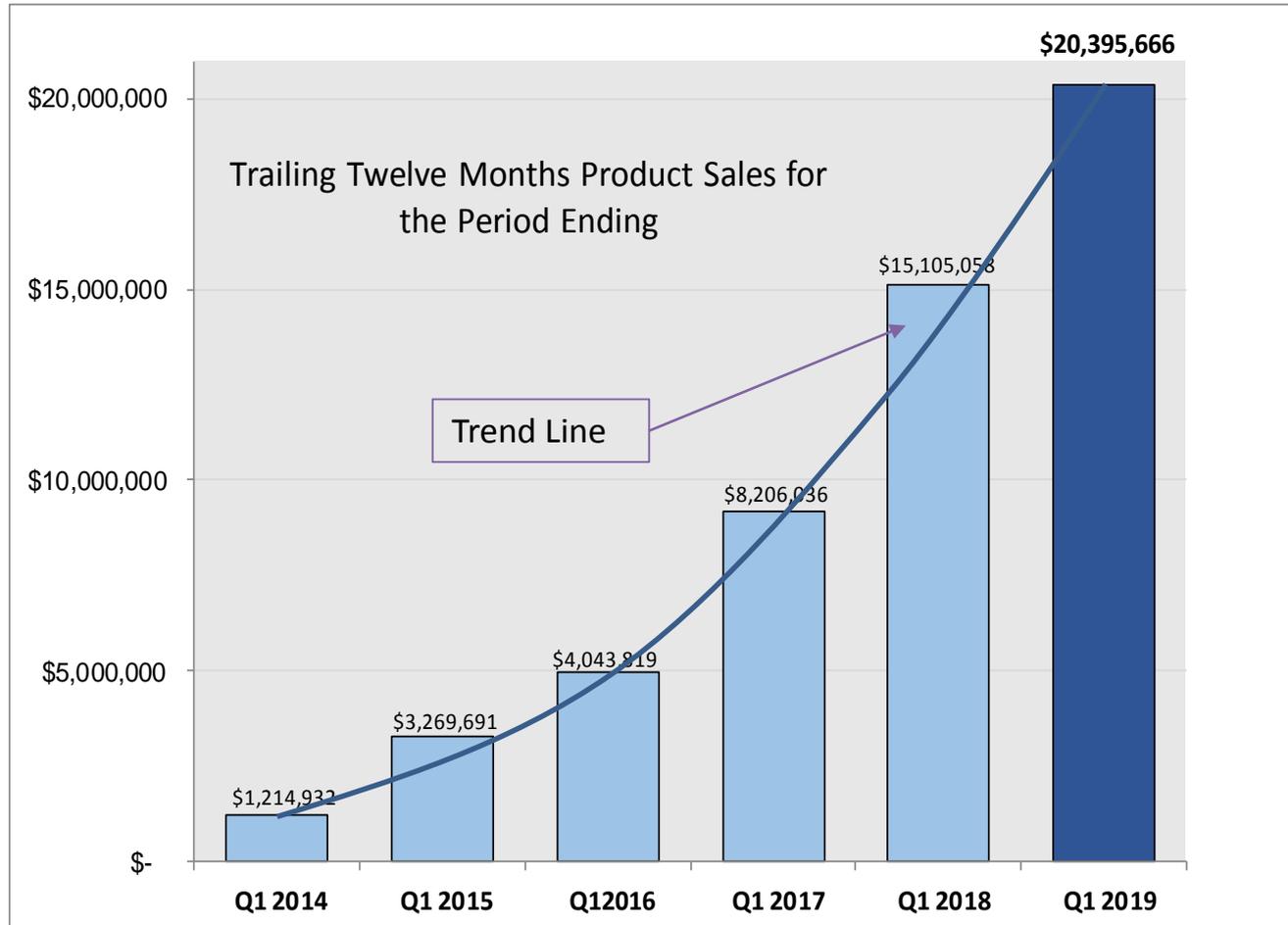
Partnered with leading multinational corporations:

**Fresenius Medical Care, Terumo Cardiovascular, Biocon Ltd, and Dr. Reddy's Laboratories**

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

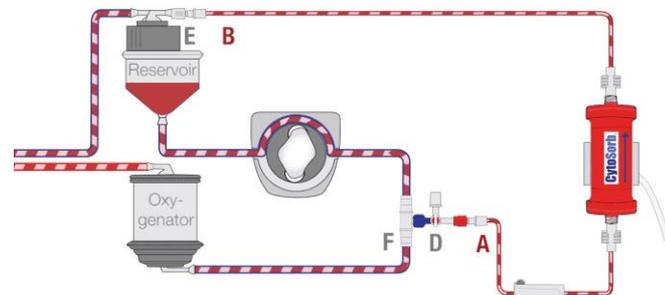
# Trailing Twelve Months Product Sales

The annual product sales growth trajectory remains strong.



# REFRESH 2-AKI Pivotal Trial Targets U.S. Approval

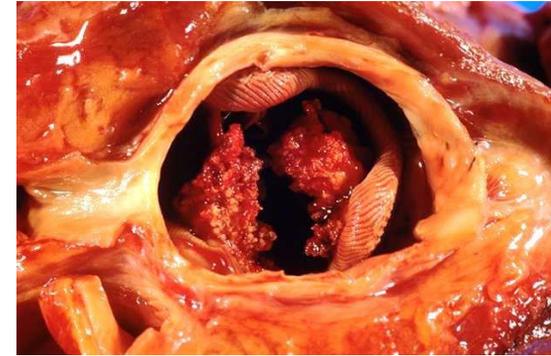
- Heart disease is the leading killer worldwide, driving 1.5M open heart surgeries each year and fueled by the aging baby boomer generation
- High risk invasive cardiac surgery generates inflammatory toxins (e.g. free hemoglobin and activated complement) that can cause post-operative inflammation and organ injury such as acute kidney injury (AKI)  
**CytoSorb reduces these toxins**
- The development of even mild AKI after surgery predicts 1 and 5 year mortality and progression to chronic kidney disease
- REFRESH 2-AKI is a pivotal, multi-center RCT using CytoSorb intraoperatively to reduce AKI in high risk cardiac surgery
  - Up to 400 patient from 25 centers
  - Primary endpoint: Reduction in the incidence and severity of AKI 48 hours post-surgery
  - Expected study completion: 2020 with potential 2021 FDA approval



**Enrollment is at 86 patients, at 23 initiated sites**

# German Govt Funding REMOVE Endocarditis Trial

- Infective endocarditis (heart valve infection) occurs when bacteria seeds a heart valve from IV drug abuse and dirty needles, or from dental procedures
- The incidence of endocarditis is rising due to the opiate crisis
- Patients often require open heart surgery valve replacement but are very hemodynamically unstable before, during, and after surgery due to a combination of sepsis and heart valve destruction
- Intraoperative CytoSorb has been used to help stabilize such patients peri-operatively with good success
- The German Federal Ministry of Education and Research is funding a 250 patient, multi-center, randomized, controlled study (REMOVE) using CytoSorb during valve replacement open heart surgery in patients with infective endocarditis
- Primary endpoint is improvement of SOFA score



**191 patients enrolled, 15 sites**

# Unmet Need Drives Potential in Many Major Areas

- **Cytokine Release Syndrome in Cancer Immunotherapies**
  - Cancer immunotherapies, including new CAR-T cell therapies like Kymriah and Yescarta, can trigger life-threatening inflammation
  - Dr. Carl June, pioneer of CAR T-cell immunotherapy, is on our SAB
- **Liver disease**
  - 1 in 11 people in the world have chronic liver disease
    - Hepatitis, Alcoholism, NASH (fatty liver)
  - Millions are admitted to hospitals every year for acute exacerbations where liver toxins, cytokines, and inflammation plays a major role
  - CytoSorb can remove all of these as a next-gen liver dialysis therapy
- **Trauma**
  - 56 million trauma patients hospitalized, 5 million die, many from uncontrolled inflammation, rhabdomyolysis, and organ failure
  - A number of hospitals have already adopted CytoSorb as standard of care for severe trauma



# Near-Term Potential Catalysts

- Key Sales Drivers
  - Clinical data in more applications
  - Specific reimbursement in key territories
  - Investments in infrastructure and human capital to support our direct, distributor, and partner sales
- 2019 blended product gross margin expansion to 80% on a quarterly basis
- Potential new partnerships and expansion of existing partnerships
- Ramping of pivotal REFRESH 2-AKI and REMOVE studies
- Start of HemoDefend pivotal US Trial in second half
- Publications of clinical and research data
- Expanded institutional ownership and analyst coverage





***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

[pchan@cytosorbents.com](mailto:pchan@cytosorbents.com)