

CytoSorbentsTM



HELPING REDUCE DEADLY UNCONTROLLED INFLAMMATION IN HOSPITALIZED PATIENTS WORLDWIDE

NASDAQ: CTSO

MicroCap Rodeo Investor Conference

October 15, 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 \$4.50)

- CytoSorb® is E.U. approved as an extracorporeal cytokine adsorber with 67,000+ cumulative treatments (up from 46,000 a year ago) delivered and distributed in 58 countries
- Trailing 12-month performance (as of 6/30/19)

	2018	2019	Increase
Total Revenue	\$19.1M	\$23.2M	+22%
Product Revenue	\$17.4M	\$21.0M	+21%
Blended Product Gross Margin	74%	76%	-

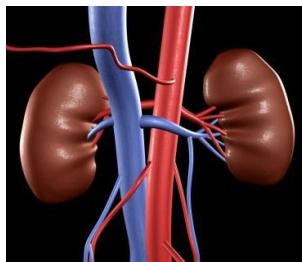
- Healthy cash balance of ~\$20M (7/31/19)
- Two key RCTs underway: 250 patient **REMOVE** endocarditis trial nearly complete and 400 patient pivotal **REFRESH 2-AKI** cardiac surgery trial designed to support US FDA approval
- 155 employees with international footprint across two wholly-owned subsidiaries
 - 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 ~\$29M in grants, contracts, other non-dilutive funds
- Russell 2000 & 3000 listed. Coverage by Cowen, B Riley, HCW, Maxim, Dawson James, 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

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

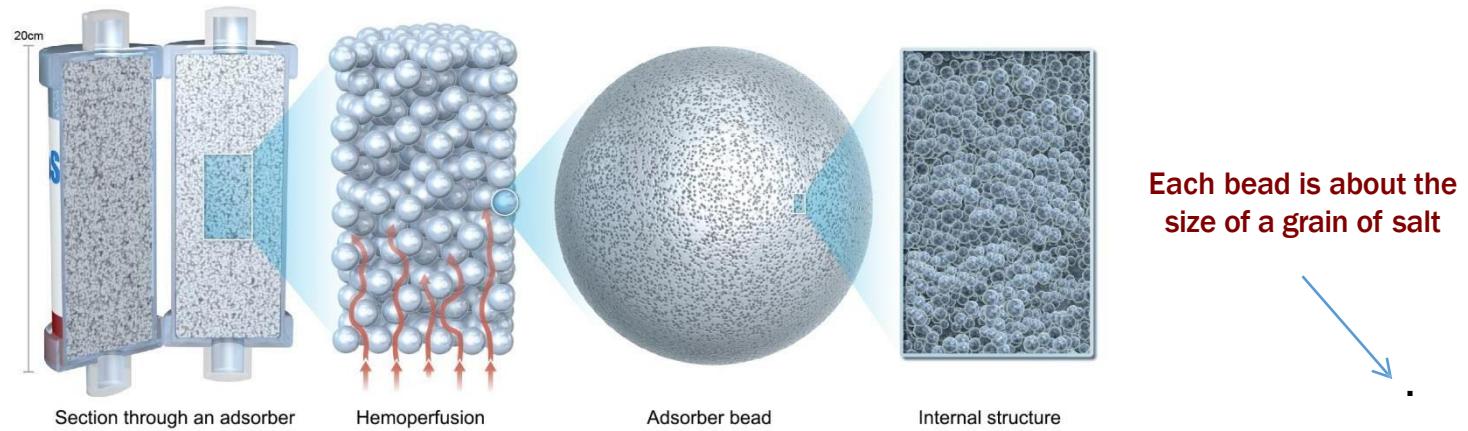
- CytoSorb® targets the \$20+ billion opportunity in critical care and cardiac surgery
- Approved in the European Union as the first specifically approved extracorporeal cytokine adsorber
- Broad indication for use where cytokines are elevated
- Removes cytokines and many other inflammatory mediators such as free hemoglobin, bacterial toxins, myoglobin, and activated complement
- Safe and well-tolerated: 67,000+ cumulative treatments delivered, up from 46,000 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

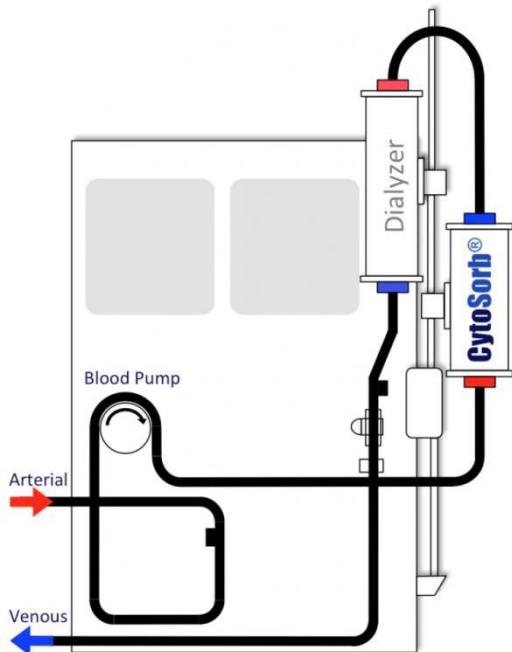


- Proprietary patented technology with multiple patents pending worldwide
- Manufactured at our ISO 13485 certified facility in New Jersey
- One of the highest grade medical sorbents on medical market today

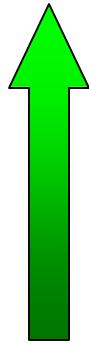
CytoSorb is “Plug and Play”

Compatible with Existing Dialysis and Heart-Lung Machines

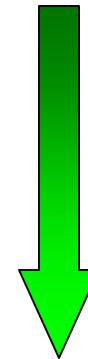
- Place a temporary dialysis catheter in a major vein
- Connect the device to a standard dialysis, ECMO, or heart-lung machine found in hospitals worldwide
- Pump blood out of the body and through the cartridge
- The polymer beads directly contact blood and remove unwanted or toxic substances
- “Purified”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



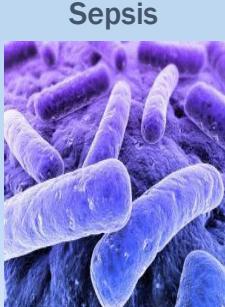
Goal: To Prevent or Treat Organ Failure



Improve
Patient
Outcome
and
Survival



Decrease
Costs Of
ICU and
Patient
Care



Sepsis



ARDS



Burn Injury



Trauma



Pancreatitis



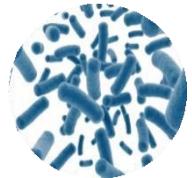
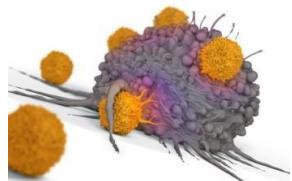
Influenza



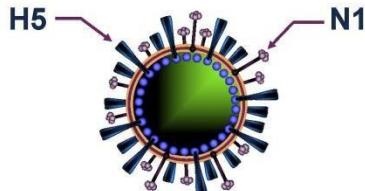
Surgical

The Potential to Revolutionize Critical Care Medicine

The World Needs CytoSorb®



H1N1



Hospital Stays for Sepsis Appear to Be Rising Dramatically
Experts say cases of sepsis may have been undercounted for years

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

Konrad Reinhart, M.D., Ron Daniels, M.D., Nirajan Kissack, M.D., Flavia R. Machado, M.D., Ph.D., Raymond D. Schachter, L.L.B., and Simon Finer, M.D.

"...one very important clinical issue, some of whom 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 drives 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

Bloomberg



America Has a \$27 Billion Sepsis Crisis

Bloomberg

Refractory Septic Shock

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 ± 4 mmol/L, and 75% requiring renal replacement therapy had a mortality of 100% at 28 days.*

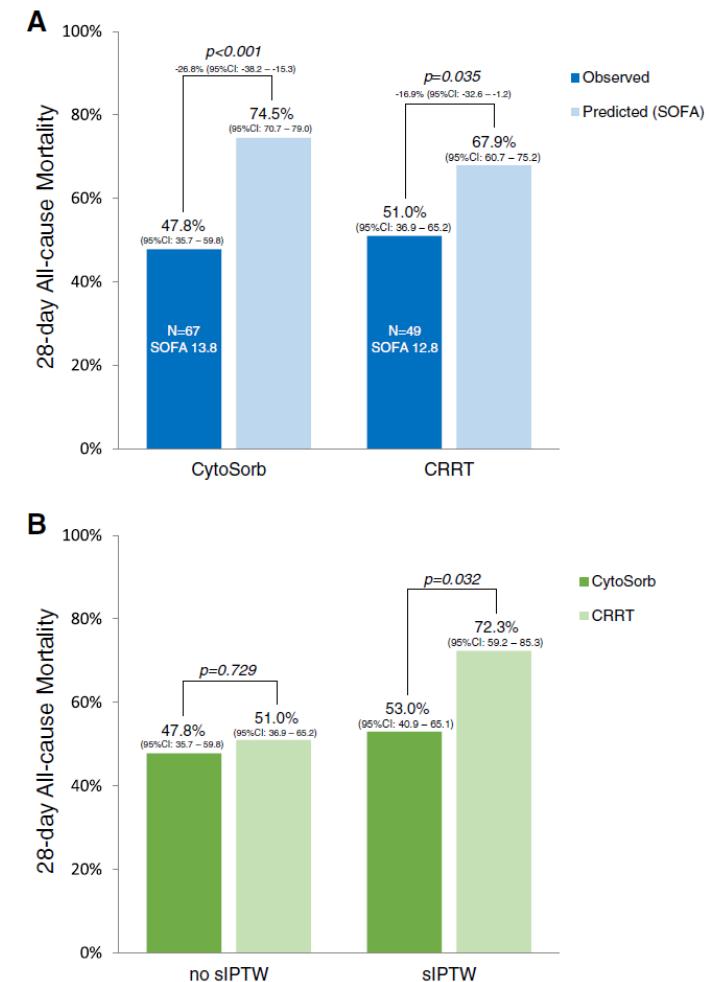
- Conrad, M., et. al., "Early prediction of norepinephrine dependency and refractory septic shock with a multimodal approach of vascular failure", J Crit Care, 2015; 30:739-743.
- Friesecke, S, et.al., "Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single center study", J Artif Organs 2017 Sep; 20(3):252-259.



CytoSorb Survival Benefit in Septic Shock

Retrospective study evaluating primary endpoint of 28-day mortality in 116 septic shock patients

- Continuous renal replacement (CRRT) alone (n=49)
- CRRT with CytoSorb (n=67)
- At baseline, patients treated with CytoSorb were more sick
 - SOFA score: 13.8 Treatment vs 12.8 control
 - Predicted mortality: 75% vs 68% control
- Patients were weighted for stabilized inverse probability of treatment weights (sIPTW), commonly used in observational studies to adjust for differences in baseline characteristics
- CytoSorb treatment showed decreased mortality of 53% vs 72% control by sIPTW analysis
- Brouwer, WP., et. al., "Hemoadsorption with CytoSorb shows a decreased observed versus expected 28-day all-cause mortality in ICU patients with septic shock: a propensity-score-weighted retrospective study", Crit Care, 2019; 23:317.



CytoSorb® Has a Hybrid Sales Model

58 Countries Worldwide and 67,000+ treatments

Critical Care and Cardiac Surgery

Direct Sales



Direct sales in 10 countries:

Germany, Austria, Switzerland, Belgium,
Poland, Netherlands, Denmark, Norway,
Sweden, Luxembourg



Distributor and Partner Sales



Distributor and Partner sales in 48 countries

Recently added Mexico and South Korea

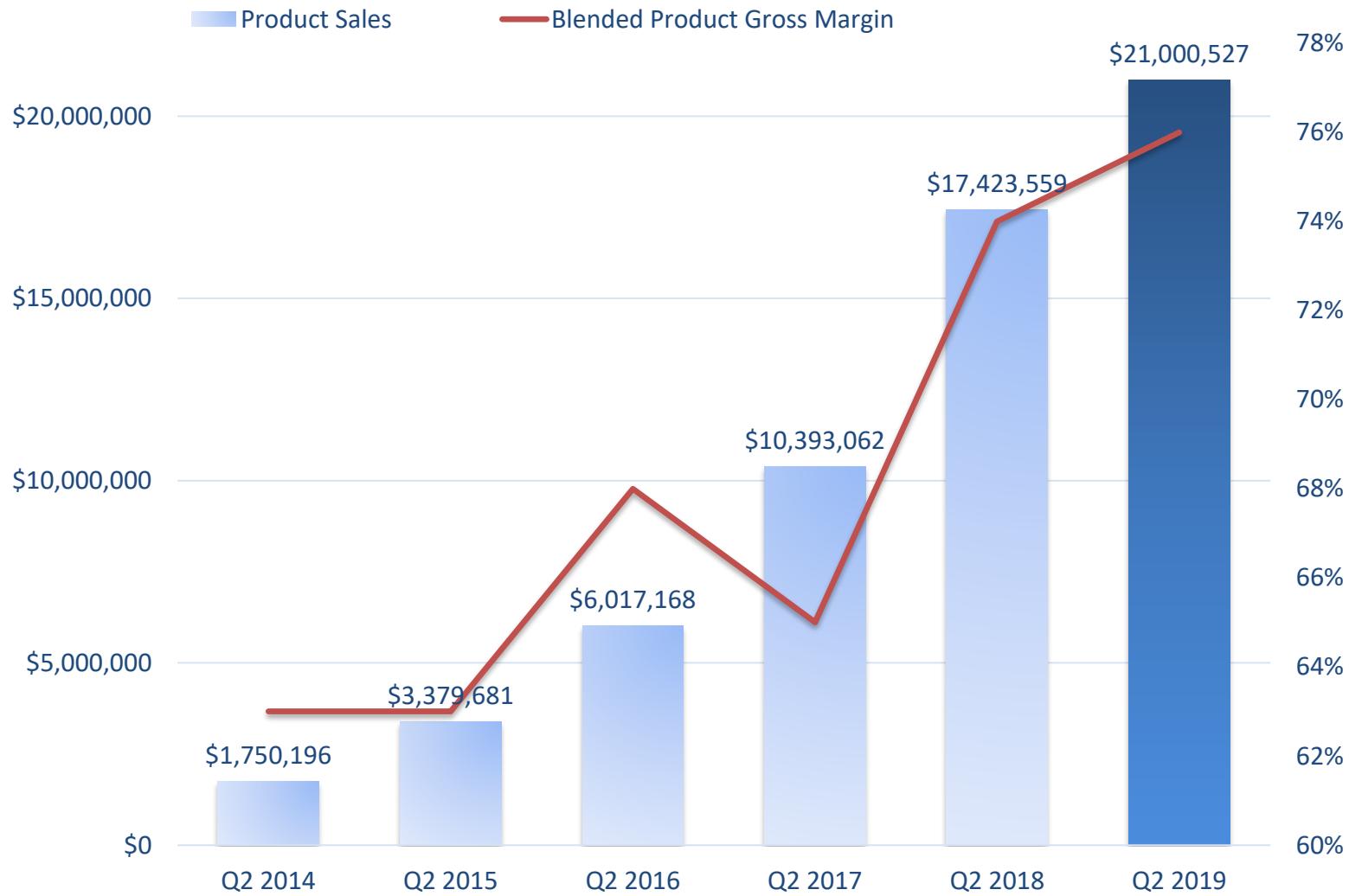
with partner, Fresenius Medical Care

Also added Brazil, Colombia, and Costa Rica

CytoSorb® Is a High Margin “Razorblade”

- 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 76%, 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

Product Sales (TTM) and Blended Gross Margins



Forecast CytoSorbents 2020: Faster Growth Ahead

Investing Heavily for Growth

- Direct sales are ~75% of our product sales, with higher product gross margins
- Doubled the number direct sales countries from 5 to 10 in 2019, adding Poland, Sweden, Netherlands, Norway and Denmark, to Germany, Austria, Switzerland, Belgium and Luxembourg with a combined population of 190M
- Expanded countries to 58, with registration pending at major countries including Brazil, Mexico, South Korea and Colombia that add more than 440M people
- Since September 2018, added 50 people or a 48% increase in headcount to 155, with many key hires in the past 3-6 months. Expansion was lengthy and challenging due to insistence of quality people, tight labor market, and labor laws
- Significantly strengthened the commercial organization
 - Doubled customer facing sales reps and specialists, particularly in Germany
 - Subdivided management of direct sales
 - New leadership and expansion of distributor and partner sales
 - New head of marketing who will report to Christian Steiner, SVP of Sales and Marketing
 - Bolstered manufacturing, quality, clinical, and reimbursement personnel
- Manpower will enable more focused targeting of key accounts, with modest impact this year, but is expected to be a major catalyst for strong growth in 2020

Demand for CytoSorb Continues to Grow

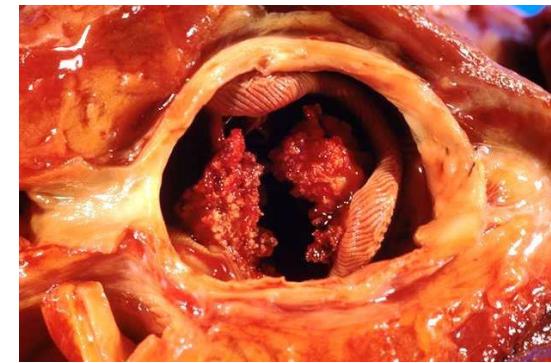
- CytoSorb sales are driven primarily by re-orders with ~85% of our invoices from repeat customers
- The number of CytoSorb cartridges per invoice continues to rise, demonstrating increased usage and adoption at many accounts
- Usage is increasing because CytoSorb is helping physicians “regain control” of their very sick patients, particularly in controlling complications of inflammation
- Clinical data generation continues to be robust with more than 120 publications in peer-reviewed scientific and medical journals
- Clinicians have honed in on key areas where CytoSorb works well such as sepsis, cardiac surgery, and liver failure
- New applications and new data are expected to drive more rapid adoption and broader based usage

Antithrombotic Drug Removal As A Major Catalyst

- Anti-thrombotic drugs, such as Eliquis®, Xarelto®, Pradaxa®, Brilinta®, Plavix® and others are blockbuster products with collective sales of more than \$20 billion
 - Used extensively to reduce stroke and cardiac risk in patients following a heart attack or stent placement, patients with atrial fibrillation, those with peripheral artery disease, etc.
 - However, approximately 4% of patients will have an acute cardiac event due to their underlying disease that will require either urgent or emergency cardiac surgery
 - Because these drugs reduce the ability to clot, approximately 30% of patients that undergo emergency surgery will suffer severe or massive bleeding peri-operatively
 - A recent study from St. Georg Hospital in Hamburg, Germany, evaluated 55 patients on either ticagrelor (Brilinta®) and rivaroxaban (Xarelto®) that underwent emergency cardiac surgery. Of these, 39 were treated with CytoSorb intra-operatively
 - Patients not using CytoSorb had significant bleeding complications
 - CytoSorb significantly:
 - Reduced need for red blood cell ($p=0.01$) and platelet ($p=0.05$) transfusions
 - Reduced surgical drainage ($p=0.004$)
 - Reduced the need for rethoracotomy (0% vs 37.5% control, $p<0.001$)
 - Reduced length of operation ($p=0.004$)
 - Reduced time in ICU ($p=0.01$) and hospital stay ($p=0.02$)
 - A separate cost-effectiveness analysis concluded a savings of approximately \$5,000 per case due to these clinical benefits
- Hassan, K., et. al., "CytoSorb Adsorption During Emergency Cardiac Operations in Patients at High Risk of Bleeding," Ann Thoracic Surg, 108:45-51.

REMOVE Endocarditis Trial Data Read in Mid-2020

- 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
- Outcomes are generally poor with hemodynamic instability, high mortality (~15%), many adverse events, and high cost (\$150-250,000 per case). 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
- Expected completion of trial in 2019 with 240 of 250 patients currently enrolled. Data analysis is expected in 1H 2020, with data release in mid-2020



REFRESH 2-AKI Interim Analysis Target in 1H 2020

- 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 the incidence or severity of AKI in high risk cardiac surgery
 - Up to 400 patient from 25 centers
 - Primary endpoint: incidence or severity of AKI at 48 hours after surgery
- Trial has achieved more than a third of targeted enrollment
 - 135 patients enrolled at 25 initiated sites
 - Expect to complete enrollment by end of 2020 with 2021 PMA submission to seek U.S. FDA approval



First CRS Trial Initiated in CAR-T Cell Immunotherapy

- CAR-T cell cancer immunotherapy is a blood cancer treatment breakthrough.
- However, ~40-50% of patients can develop severe, high grade cytokine release syndrome (CRS), a cytokine storm that can lead to rapid organ failure and potentially death
- CytoSorb® was specifically designed to control cytokine storm and CRS and has already successfully treated a dozen cases of the closely related disease hemophagocytic lymphohistiocytosis (HLH)
- With FDA and E.U. approvals of Kymriah (Novartis) and Yescarta (Gilead), we are positioning CytoSorb® to be used as an alternative to, or in conjunction with, tocilizumab and steroids
- In 2017, the pioneer of CAR T-cell immunotherapy, Dr. Carl June at University of Pennsylvania, joined our Scientific Advisory Board
- In September 2019, University of Hannover, Germany announced the launch of the first trial to evaluate CytoSorb for CRS and CRES



HemoDefend Could Be Approved in US in 2020

- Point-of-care filter rapidly and efficiently removes non-infectious contaminants from transfused pRBCs that can cause transfusion reactions
- Funded up to \$4.7M by NHLBI (NIH) and USSOCOM
- Compatible with pathogen reduction technologies
- 100M pRBC transfusions administered annually worldwide
 - Initially intended for patients receiving multiple units of blood including trauma, gastrointestinal bleed, high risk surgery, cancer, blood disorders
- Pivotal trial design
 - Post-transfusion recovery and survival assay for autologous blood
 - Goal of FDA IDE submission this year following requisite bench testing for efficacy
 - Meanwhile, CRO and clinical trial sites have been selected
 - Following IDE approval, clinical trial is expected to be complete within 3 - 6 months
 - If successful, HemoDefend could achieve U.S. FDA approval in 2020



Investment Summary

- We believe we are a unique company in the medical device space with a high margin razorblade in another company's razor business model
- We are helping to treat some of the biggest unmet medical needs in modern medicine and are riding the wave of multiple macro trends
 - Aging baby boomer generation and risk of sepsis, structural heart disease, and trauma
 - The pandemic of liver failure
 - The rise of cancer immunotherapy (CART-cell)
 - The opiate crisis
 - Many others
- We have extensive validation from physicians around the world, leading strategic partners, US government agencies, and the media
- We believe 2020 will be a year of strong growth and are confident in the future, with management purchasing 100,000+ shares recently



TheStreet



FORTUNE

Bloomberg



WSJ

The New York Times

CytoSorbents™



Providing Hope in a helpless situation

HELPING PATIENTS SURVIVE CRITICAL ILLNESSES WORLDWIDE

CytoSorbents™



Working to Save Lives Through Blood Purification

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