

CytoSorbents Corporation (NASDAQ: CTSO)

A Leader in Critical Care Immunotherapy Q3 2015 Earnings Conference Call November 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 <u>www.sec.gov</u>.



CytoSorbents is A Leader in Critical Care Immunotherapy

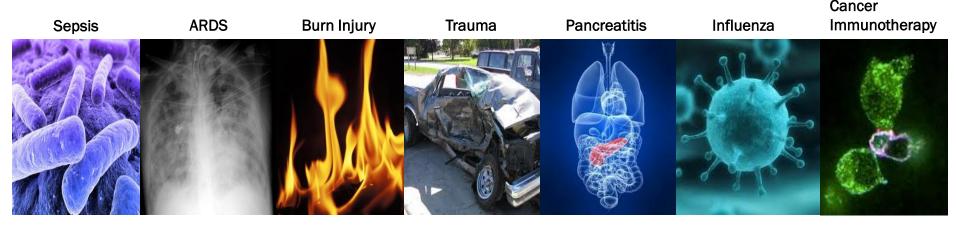


Leading the Prevention or Treatment of Life-Threatening Inflammation in the ICU and Cardiac Surgery using CytoSorb[®] Blood Purification



Severe Inflammation is Deadly in the ICU

Millions of people are admitted to the intensive care unit in hospitals worldwide each year with deadly inflammatory conditions



- In these conditions, massive inflammation driven by a "cytokine storm" causes cell death and organ failure. Nearly half of all deaths in the ICU are due to organ failure with <u>no effective therapies</u>
- Because of the lack of effective therapies, approximately 1 in every 3 patients dies
- The costs can be staggering: Lack of "active" therapies lead to patients lingering days to weeks in the ICU at \$2,000-3,000 per day in the ICU* on average
- Not surprising that we spend nearly 1% of our GDP on critical care**



Severe Inflammation is Dangerous in Open Heart Surgery

~1 million Open Heart Surgeries in US and EU annually

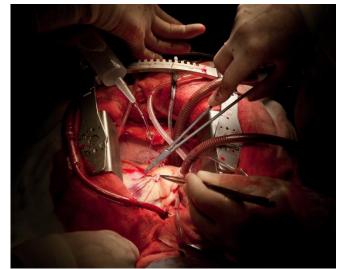
- Coronary artery bypass graft surgery
- Valve repair or replacement
- Heart or lung transplantation
- Congenital defect repair
- Aortic reconstruction

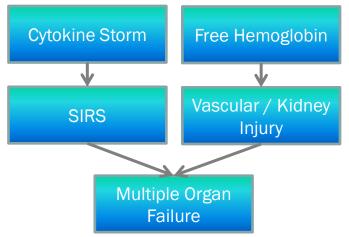
In complex cardiac surgeries, patients are on the heart-lung machine and operating table for a long time which can cause destruction of blood cells and can trigger a cytokine storm and severe inflammation

Organ dysfunction and failure, particularly lung and kidney failure, frequently result

Before now, there were no effective ways to prevent this from happening







CytoSorb® Removes the Fuel to the Fire

- CytoSorb[®] targets the \$20+ billion opportunity in critical care and cardiac surgery
- Approved in the European Union as the only specifically approved extracorporeal 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
- Removes many other inflammatory mediators such as free hemoglobin, bacterial toxins, and complement
- Safe and well-tolerated: In 8,000+ human treatments, mainly in critically-ill patients, including 1,000+ cardiac surgeries





Goal: To Prevent or Treat Organ Failure

Improve Patient Outcome and Survival



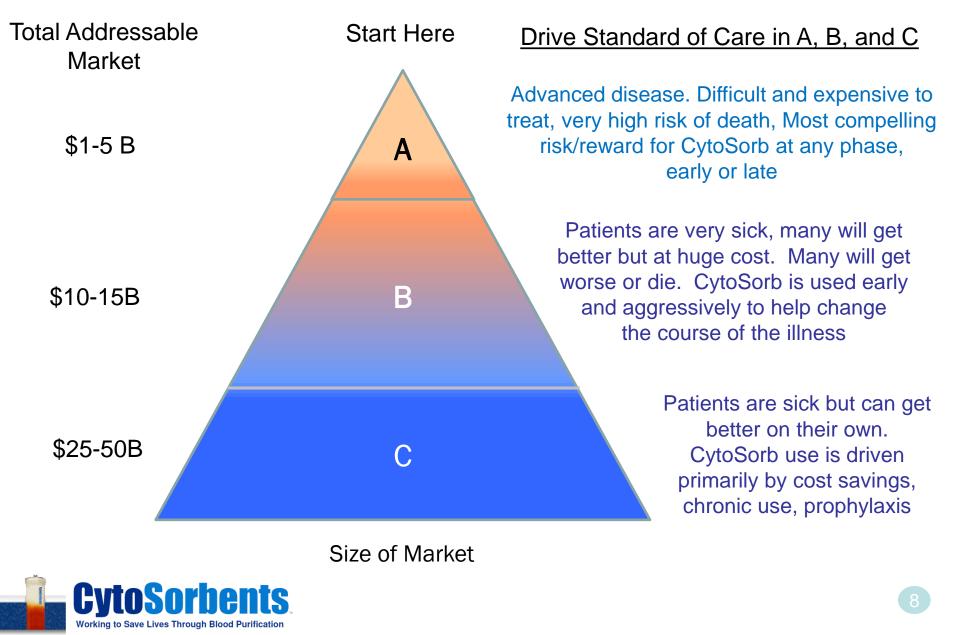
Decrease Costs Of ICU and Patient Care



The Potential to Revolutionize Critical Care Medicine



Evolution of the CytoSorb Market



Financial Highlights



Q3 2015 Comparative Revenue Results

	Three Months Ended Sept 30, 2015	Three Months Ended Sept 30, 2014	% Incr.
Product revenue	\$ 1,071,459	\$ 1,031,761	4%
Grant and other income	272,166	130,586	108%
Total revenue	\$1,343,625	\$ 1,162,347	16%

- CytoSorb® product sales were approximately \$1.1M in Q3 2015, the highest quarterly product sales in our history
- Product sales were negatively impacted by the decline in the exchange rate of the Euro, which amounted to approximately \$150K or 14% of product sales for the three months ended September 30, 2015
- Product sales increased by \$298K, or 39%, over the previous quarter of 2015
- Grant and other income was \$272K for the quarter ended September 30, 2015, compared to \$131K for the quarter ended September 30, 2014
- Product gross margins were approximately 62% in Q3 2015



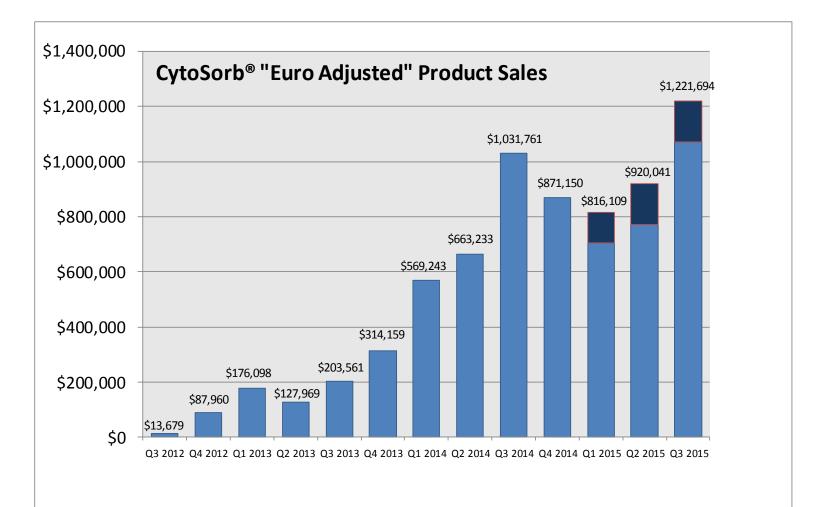
9 Months Comparative Revenue Results

	Nine Months Ended Sept 30, 2015	Nine Months Ended Sept 30, 2014	% Incr.
Product revenue	\$ 2,548,229	\$ 2,264,237	13%
Grant and other income	482,393	984,937	(51)%
Total revenue	\$ 3,030,622	\$ 3,249,174	(7)%

- CytoSorb® product sales were \$2.5M for the nine months ended September 30, 2015, a 13% increase over product sales of \$2.3M for the same period of 2014
- Product sales were negatively impacted by the decline in the exchange rate of the Euro, which amounted to approximately \$410K or 16% of product sales for the nine months ended September 30, 2015
- Trailing twelve month product revenue for the period ended September 30, 2015 was approximately \$3.4M, compared to \$2.6M for the twelve month period ended September 30, 2014
- Gross profit margins on product sales were approximately 62% for the nine months ended September 30, 2015

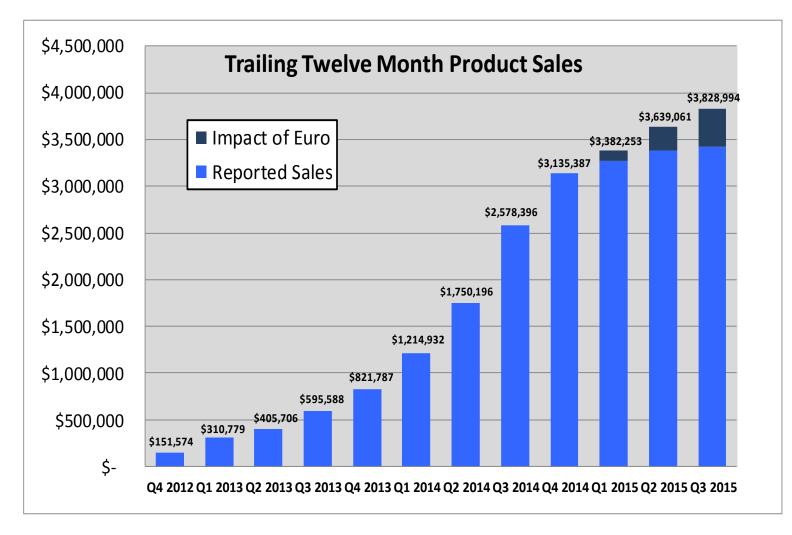


Quarterly "Euro-Adjusted" Product Sales





Product Sales Growth, "Euro Adjusted"





Working Capital and Cap Table

Working Capital as of										
	9/	30/2015	6	/30/15	3	/31/15	12	/31/14	12	2/31/13
Current Assets:										
Cash and short-term investments	\$	9,329	\$	11,205	\$	13,358	\$	5,550	\$	2,183
Grants and accounts receivable, net		553		501		673		819		453
Inventories		1,337		1,060		703		538		245
Prepaid expenses and other current assets		372		275		148		700		605
Total current assets		11,591		13,041		14,882		7,607		3,486
Current Liabilities(1):	_									
Accounts payable		527		418		475		698		787
Accrued expenses and other current liabilities		756		718		734		825		362
Deferred revenue				-		-		1		272
Total current liabilities		1,283		1,136		1,209		1,524		1,421
Net Working Capital	\$	10,308	\$	11,905	\$	13,673	\$	6,083	\$	2,065
(1) Excludes warrant liability, a current liability that does not have cash implications.					ns.					

CAP TABLE AS OF SEPTEMBER 30, 2015				
	Fully Diluted			
(unaudited)	Common Shares			
Common Stock	25,177,005			
Options	2,522,486			
Warrants	1,256,809			
	28,956,300			



Operating Highlights



Submitted for Expedited Access Pathway

The FDA has established the Expedited Access Pathway (EAP) program that is intended to facilitate the approval of medical devices that treat life-threatening conditions and have no approved alternative treatments

- We have submitted our EAP Application to request EAP Designation. EAP Designation is the equivalent of "Breakthrough Designation" for drugs and biologics but for medical devices
- Given that the application is under review, it would not be appropriate for us to discuss it at this time
- We will have an update at the appropriate time



Cardiac Surgery Partner Update

- The evaluation by our cardiac surgery partner in France, one of the top 4 cardiac surgery companies in the world, is now successfully completed. We are currently in discussions with the cardiac surgery partner and will have an update at the appropriate time
- CytoSorb[®] has been used safely in more than 1,000 intra-operative cardiac surgery cases to date in Europe









Cardiac Surgery IIT Updates

At the 2nd International CytoSorb Users Meeting, preliminary results were presented from three safety and inflammatory mediator biomarker studies using CytoSorb[®] intra-operatively in a heart-lung machine in low risk cardiac surgery patients:

- <u>University of Hamburg-Eppendorf</u>: 20 patient RCT pilot study Complete
- Medical University of Vienna: 37 patient RCT pilot study Complete
- <u>University of Cologne</u>: Interim data from 142 of 300 patients comparing off-pump surgery (n=21), on-pump surgery without CytoSorb (n=61), and on-pump surgery with CytoSorb (N=60)
 - Therapy was well-tolerated and safe without device-related issues, including no removal of heparin, no bleeding or coagulation issues, no device set-up concerns
 - Preliminary initial cytokine data show that some cytokines are removed in CytoSorb® treated patients compared to control, but overall inflammation in these shorter, lower risk surgeries, was not high. Cytokine and other inflammatory mediator analysis is continuing. Similarly, the risk of adverse events and mortality were low in both treatment and control groups
 - Now that safety has been determined, all three trial sites are interested in extending their treatment experience to complex cardiac surgery, where the risk of inflammation and adverse events are much higher
 - The completed studies are in the process of being prepared for journal submission



REFRESH Update REduction in FREe Hemoglobin Trial



- 40-patient RCT safety and feasibility study using CytoSorb intra-operatively in a heart-lung machine bypass circuit on patients undergoing complex cardiac surgery
- Endpoints include safety and free hemoglobin removal from blood
- Working with major cardiac surgery centers in this trial
 - Baylor College of Medicine
 - Baystate Medical Center
 - Columbia University
 - Cooper University Hospital
 - University of Kentucky
 - University of Maryland
 - University of Pennsylvania
 - University of Pittsburgh Medical Center
- The study has started with one site screening to enroll patients. A total of 6 out of 8 sites will be in a similar position at the end of November



Fresenius Medical Care by Q1 2016

- We are currently working with Fresenius in the initial marketing to critical care key opinion leaders in multiple countries
- CytoSorb will not only be certified on the existing Fresenius multiFiltrate, but will also be certified on the newly launched multiFiltratePRO



- Expecting a formal roll-out of CytoSorb in the next several months
- Q3 2015 product sales were based on broad organic growth with no contribution yet from Fresenius



multiFiltrate



Fresenius Medical Care

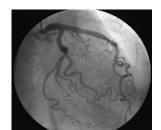


Beads Enable a Broad and Valuable Pipeline

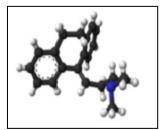




ContrastSorb



DrugSorb



BetaSorb



Critical Care, HighBloodCT Imaging,
InterventionalDrug Overdose,
Chemo RemovalImproving
DialysisRisk SurgeryCollection &
TransfusionInterventional
RadiologyChemo RemovalDialysis

CE Mark Approved

Under Development



Blood Transfusion Carries Risks

- 85M pRBCs transfused WW each year with 15M in the US alone
- While blood transfusion is considered safe, in the US alone there were over 65,000 transfusion reactions as per the National Blood Collection and Utilization Survey Report
- Exact cause is unknown, but linked to accumulation of many substances during storage and degradation of blood cells, as well as donor factors
 - Antibodies (anti-HLA, IgA, anti-A, anti-B)
 - Cytokines and other inflammatory mediators
 - Free hemoglobin, bioactive lipids
 - Drugs, Foreign antigens

· When they occur, transfusion reactions drive increased healthcare utilization and cost

- Reactions can cause costly patient complications, expensive ICU care, and death
- Millions of less severe reactions require extensive and costly testing and documentation
- Free hemoglobin and cytokines can increase risk of adverse outcomes, complications, and death in high risk patients
- Antibody screening of pRBC units to be transfused into sensitized patients, are expensive and time consuming
- Driving goal across the industry: Improve safety and quality of the blood supply at reasonable cost





The **HemoDefend**[™] Solution



HemoDefend[™] is a small, in-line, point-of-transfusion filter

- Contains hemocompatible, porous polymer beads that can improve the quality and safety of blood by broadly reducing contaminants in packed red blood cells (pRBCs) that can cause transfusion reactions
- Designed for broad removal of substances from <1 kDa to >150 kDa
- High flow, low resistance filter works by gravity within 20 min without the need for special equipment
- No expensive or leachable antibodies, ligands or other affinity agents are used
- Sterilization is simple with long shelf life at room temperature

CytoSorbents...

HemoDefend[™] "Washes Blood" Without Washing

HemoDefend[™] aims to improve blood quality and reduce transfusion reactions by effectively "washing blood" but without the time, expense and equipment required to do so

The in-line filter targets the removal of broad range of blood contaminants including:

- Potassium
- Free Hemoglobin
- Antibodies
- Cytokines
- Inflammatory Mediators
- Bioactive Lipids

This project was supported by contract # HHSN268201300044C from NHLBI



Target	% Reduction from 42 day old pRBCs	P value
Potassium	96.9	< 0.01
Free Hemoglobin	70.1	< 0.01
IL-7	98.9	< 0.01
lgG	73.8	<0.01
IgA	72.7	< 0.01
Phospholipase	83.2	< 0.01
Lysophosphatidyl choline	64.4	<0.01

Government Validation of HemoDefend Technology





Awarded \$1.7M in a Phase I and II SBIR Contract by National Heart, Lung, and Blood Institute (NHLBI), a division of NIH

Overall goal is to reduce contaminants in packed red blood cells that can that can cause transfusion reactions

Key Collaborator

• Dr. Larry Dumont – Director for Transfusion Medicine Research, Dartmouth Geisel School of Medicine

\$1.5M Phase 2 SBIR Grant funding will advance HemoDefend[™] In-line filter towards human treatment trials and commercialization, particularly in surgery and critical care



This project has been funded in whole or in part with Federal funds from the National Heart, Lung, and Blood Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN268201600006C.



CytoSorb® SIRS and Sepsis: Regain Control!



CytoSorbents KOL 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.

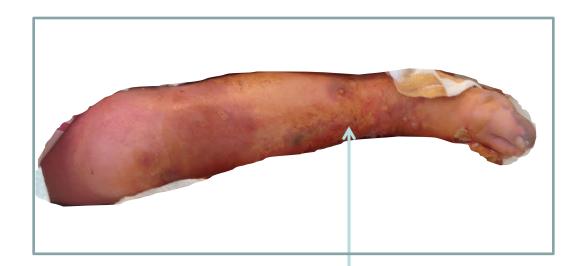
We will promptly get back to the slide presentation



Case Report: Toxic Shock Syndrome

- A 4-year, 38 pound girl was stung by an insect on her right leg which became infected
- She was admitted to Medical Center of University of Debrecen, Hungary, (Fresenius Medical Center Hungary affiliated with the university) in August 2015
- She was diagnosed with Staph. aureus infection and was positive for toxic shock syndrome toxin and treated with antibiotics





Site of insect sting



Case Report: Toxic Shock Syndrome

- Despite antibiotics, her condition rapidly worsened and developed a systemic inflammatory response syndrome with the onset of multiple organ failure
- Required mechanical ventilation for acute respiratory distress syndrome, vasopressors for shock, and acute kidney failure
- Extensive capillary leak syndrome, broad drop in her blood cell levels with hemorrhage, and progression towards scalded skin syndrome







Case Report: Toxic Shock Syndrome



- She was stabilized with 72 hours with CytoSorb accompanied with CVVHD (continuous hemodialysis) using regional citrate anticoagulation (CiCa), and then continued on CVVHD for 5 days afterwards
- She made a complete recovery after 3 weeks. CytoSorb was credited with helping to save her life and helping to prevent an amputation of her leg
- This case was presented at the Hungarian Pediatric Congress

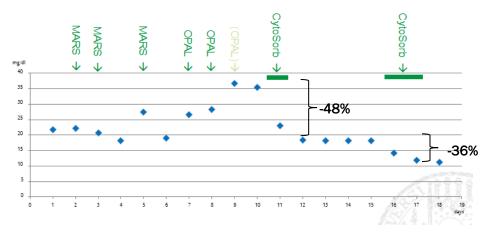


Many thanks to Prof. Jozsef Balla for this information



Case Report: CytoSorb and Liver Support

- A 36 year-old male patient with ulcerative colitis treated with prednisolone and azathioprine developed Pneumocystis and Cytomegalovirus opportunistic infections
- Patient developed severe multiple organ failure with septic shock, severe acute respiratory distress syndrome, kidney failure requiring continuous renal replacement therapy, and acute liver dysfunction with hyperbilirubinemia (attributed to CMV viral hepatitis)
- Treated with 6 cycles of albumin-liver dialysis (MARS[®] Molecular Adsorbent Recirculating System) and OPAL[®] - Open Albumin Dialysis) but little effect on serum bilirubin levels
- Subsequently was treated with CytoSorb x 2 which helped stabilize him with an immediate drop in bilirubin
 Serum Bilirubin Level

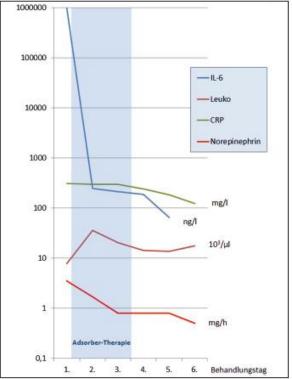






Case Report: Pyelonephritis

- 56 year old patient was admitted and diagnosed with urosepsis, caused by obstruction of his right kidney
- A ureteral stent was placed, but the patient decompensated and went into shock with a sharp rise in the need for vasopressors
- IL-6 was 1,000,000 pg/mL. Normal IL-6 levels are < 10 pg/mL. Patients with serious septic shock are in the 500-10,000 pg/ml range
- CytoSorb® with CVVHD was implemented with citrate anti-coagulation
- Within 24 hours, his IL-6 dropped to from 1,000,000 pg/mL to 234 pg/mL with norepinephrine decreasing from 3.5 vs 1.7 mg/h)
- The patient made a swift recovery







32

Case Report: Helping in a Tragedy

On October 30, 2015, a night club in Bucharest, Romania caught on fire from pyrotechnics from an inside concert. 27 people died in the blaze, with another 146 people hospitalized with serious burn, smoke inhalation and trauma related injuries. 80-90 of the survivors were in serious or critical condition. 29 of those hospitalized were so badly burned that they could not be immediately identified.

Many of the critically-ill patients were treated with CytoSorb at local hospitals. Our thoughts and prayers are with the victims and families of this terrible tragedy.



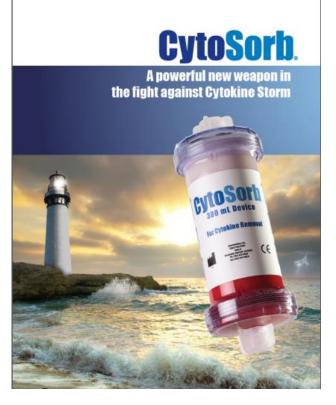


Q&A Session

CytoSorbents Corporation

NASDAQ: CTSO

Phillip P. Chan, MD, PhD - CEO 7 Deer Park Drive, Suite K Monmouth Junction, NJ 08852 pchan@cytosorbents.com



A Leader in Critical Care Immunotherapy Company

