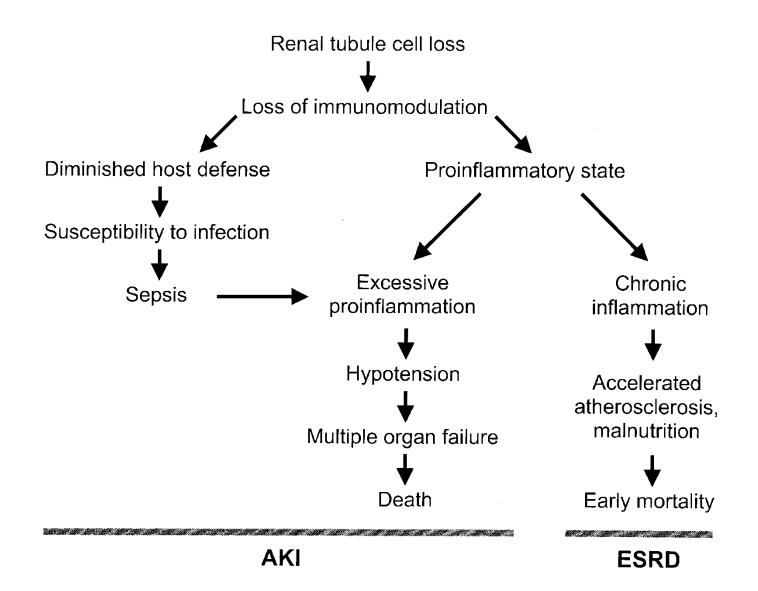
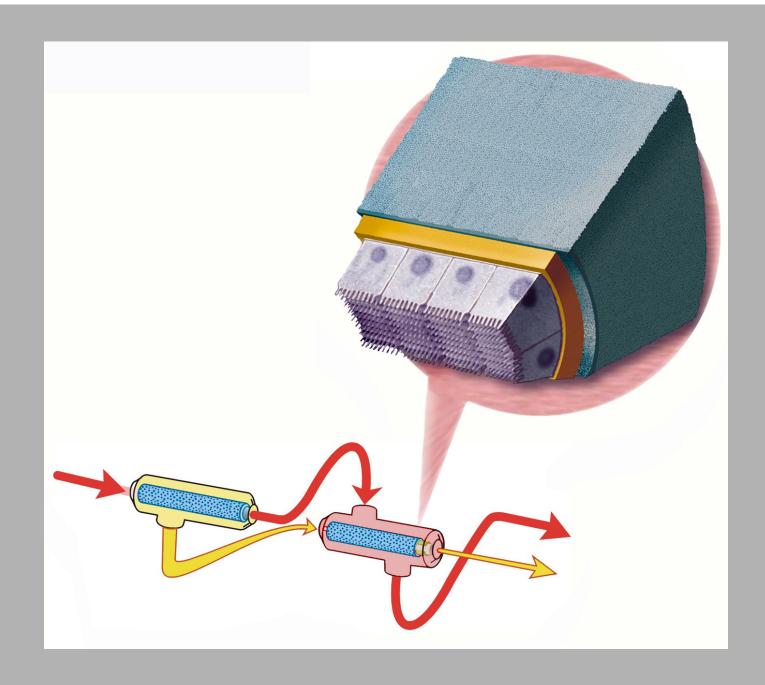
### Innovative Devices to Treat Kidney Failure

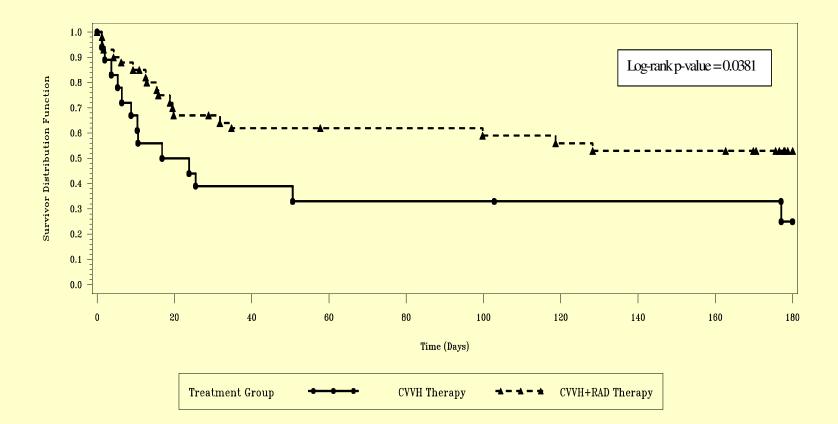
### H. David Humes, M.D. University of Michigan

Disclosures: Innovative BioTherapies, Inc.; CytoPherx, Inc.; Renal Solutions, Inc.



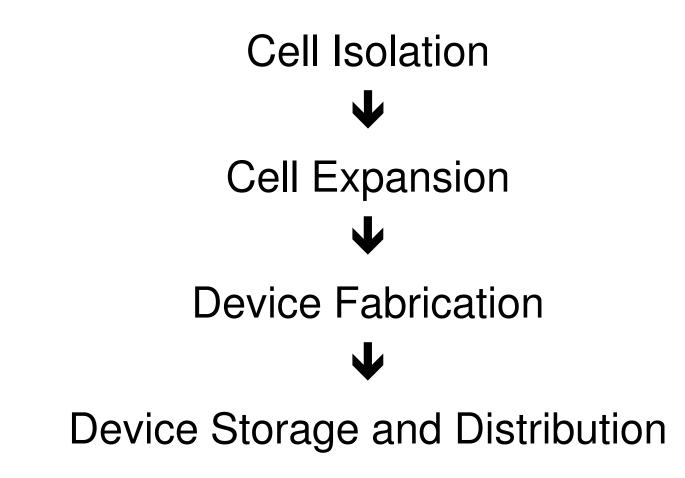


### Kaplan-Meier Survival Curve



The Cox Proportional Hazard ratio was 0.49 indicating that the risk of death for patients in the CVVH + RBT group was ~ 50% of that observed in the CVVH alone group.

# **Cell Therapy Manufacturing**

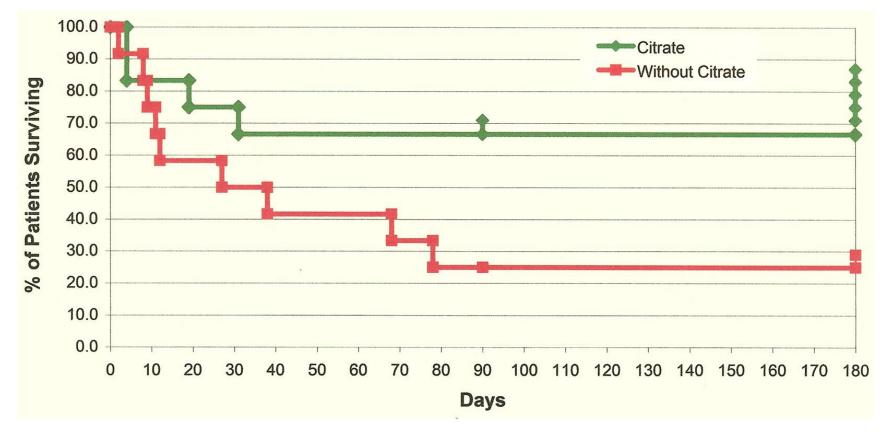


### RAD PHASE IIb CLINICAL STUDY

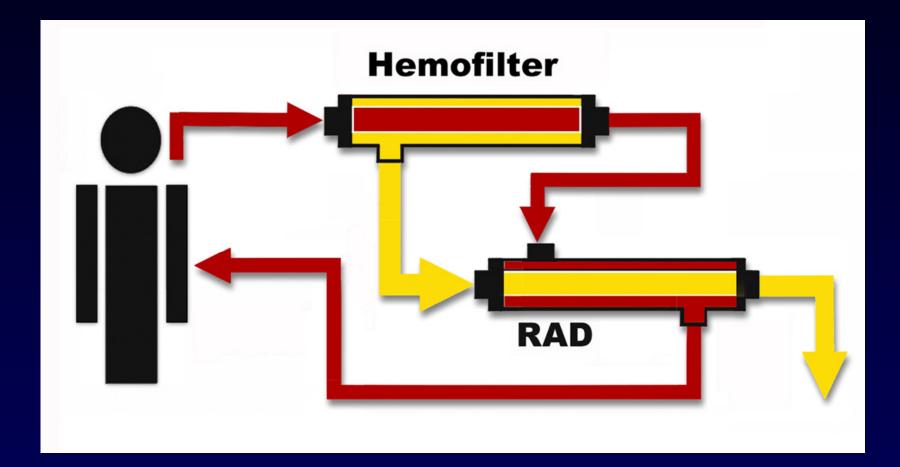
- Interim analysis suspended study
- Predicted improvement in mortality was not achievable due to be higher than expected survival in the control sham group
- Control group had a non-cell second cartridge
- Subgroup analysis demonstrated difference in the sham group between heparin and citrate anticoagulation

Blood Purification 29:183-190,2010

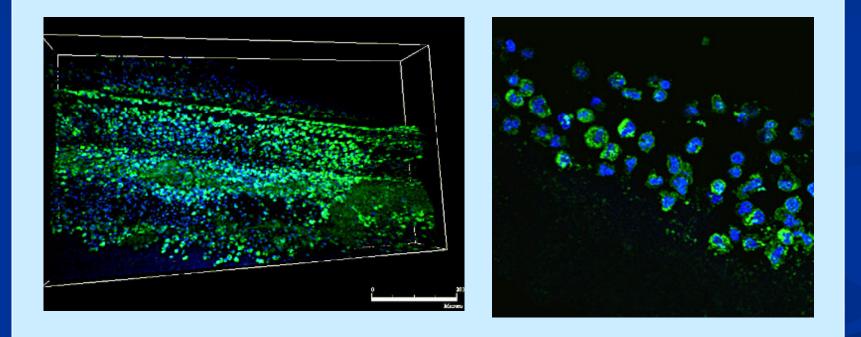
# **ARF CRRT Human Phase IIB**



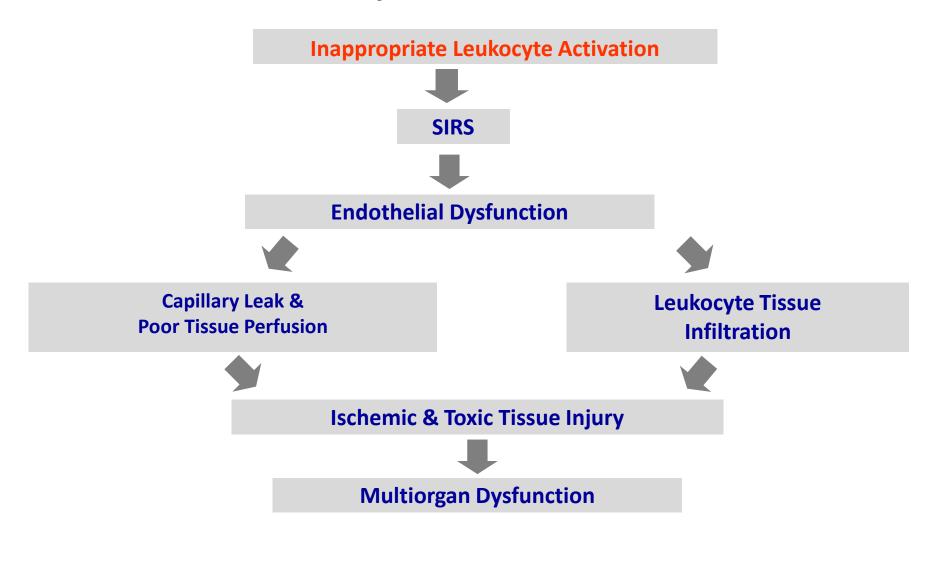
Survival Rates of Patients (n=12 each arm) in Phase II Multicenter, Randomized Clinical Trial



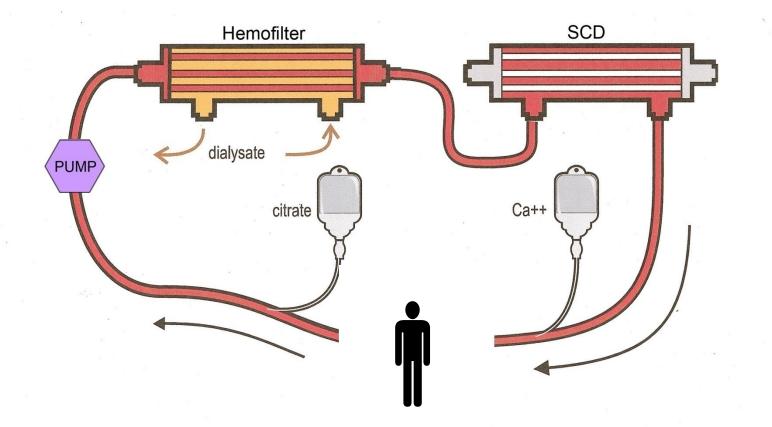
### Leukocytes Adherent To Surface of Fibers In Dialysis Cartridge



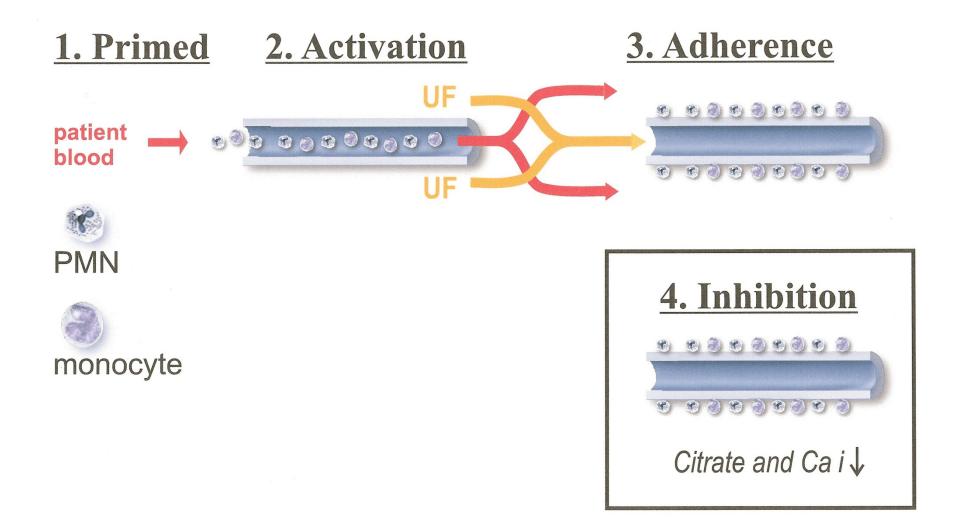
#### Inappropriate Inflammatory Response 58 + % Mortality in Acute Renal Failure



### **One-Pump System**

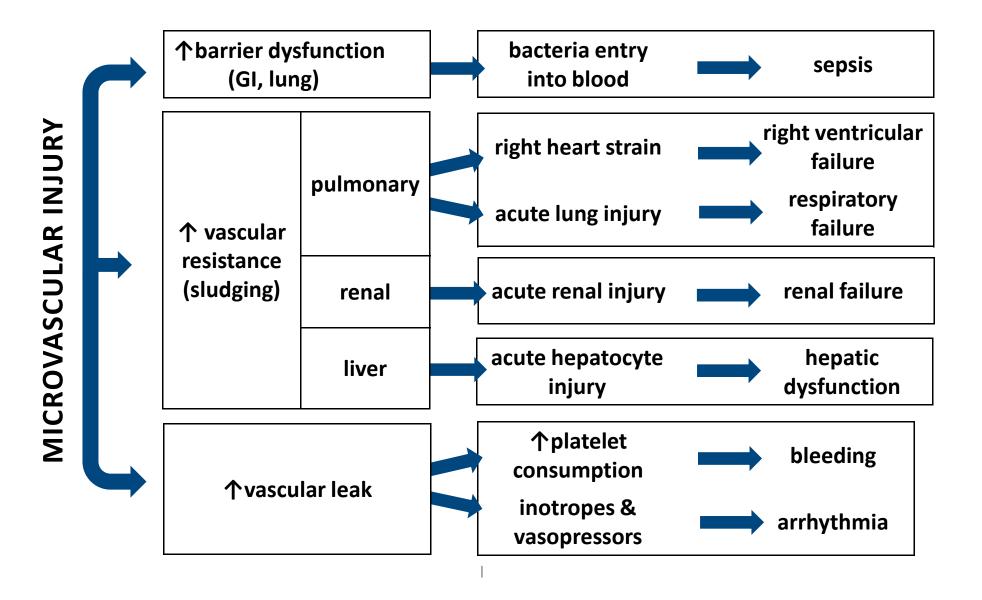


### Working Hypothesis of Mechanism for SCD Influence on SIRS

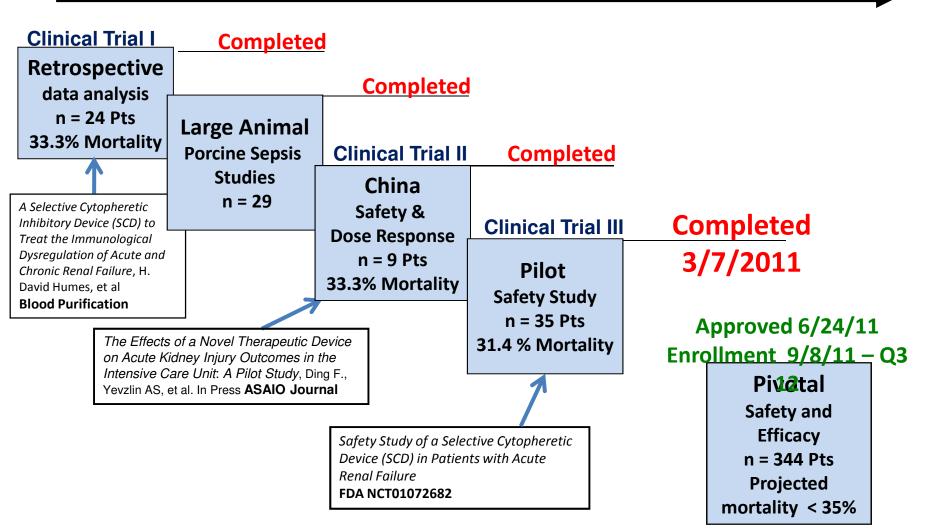


#### **SCD Mechanism of Action**

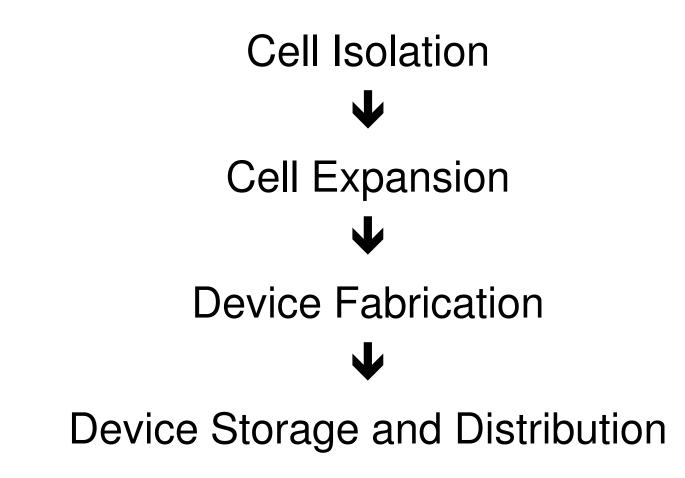
#### **REGULATION AND MODULATION OF NEUTROPHIL KINETICS**

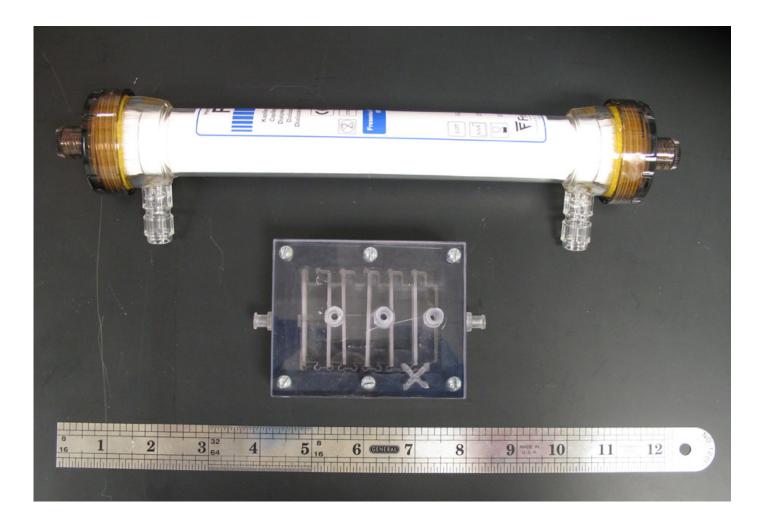


#### **Clinical Studies**



# **Cell Therapy Manufacturing**





# Renal Cell Therapy Development

- Cardiorenal syndrome: BRECS(Bioartificial Renal Epithelial Cell System) testing in a CHF canine model
- ESRD: WEBAK(Weareable Bioartificial Kidney) using recycling peritoneal fluid for dialysate regeneration(sorbent based) and BRECS maintenance testing in a chronic uremic sheep model.
- BRECS improves MOF in pig septic shock model.