





FORWARD-LOOKING STATEMENTS

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Next-Generation Blood Purification Therapies





Focus is the Creation of Value Through Clinical Progression

➤ Sigyn TherapyTM addresses life-threatening inflammatory disorders - including sepsis, the #1 cause of hospital deaths - \$62 billion annual cost to U.S. Healthcare system

Joint Venture Initiatives to Optimize the Benefit of Cancer Therapies

- ➤ ChemoPrepTM to improve chemotherapy delivery and reduce toxicity most widely administered drug to treat cancer (<1% currently delivered to intended cancer targets)
- ➤ ImmunePrepTM to improve delivery of immunotherapeutic antibodies top selling class of cancer drugs 2024 revenues ~\$125 billion (<1% currently delivered to intended targets)

5-year objective to be acquired





- Includes extracorporeal industry thought leaders across Management, the Company's Board of Directors and Science Advisory Board
- Management oversaw development of first blood purification device to receive two FDA Breakthrough Designations and the first device to receive FDA market clearance to treat a pandemic virus (Ebola). TIME magazine named the device a "Top 25 Invention" & "Top 11 Medical Breakthrough." Also included among management is the inventor of a hemoadsorption system that received CE Mark clearance and was subsequently registered in 32 countries to treat inflammatory related conditions.







First-in-Mammal Studies at University of Michigan

Designed to address life-threatening inflammatory disorders with no FDA-approved treatments



Notable Blood Purification Therapies Being Advanced by Public Companies

- CytoSorb <u>Cytokine Clearance</u> Device (CytoSorbents Corporation)
- > PMX Endotoxin Clearance Device (Spectral Medical) Current Market Cap ~\$250m
- > The Hemopurifier Broad-Spectrum Clearance of Viral Pathogens (Aethlon Medical)

"Wouldn't it be nice if there was one device that could address all these targets?"





One Device Able to Address

- Inflammatory Cytokines
- Bacterial Toxins (including endotoxin)
- Viral Pathogens





First-In-Industry Attributes

- Deployed on dialysis and CRRT machines already
 located in hospitals and clinics
- Highly Efficient bloodstream processed ~15 times during a four-hour treatment
- Immense Capacity incorporates an adsorbent formulation with ~200,000 M² of surface area (50 acres)





FDA Breakthrough Device Initiatives

Target Treatment Indications:

- Sepsis
- Endotoxemia w/ concurrent inflammation in
 End-Stage Renal Disease (ESRD) patients



Criterion for a FDA Breakthrough Device Designation

- ✓ Offers a treatment for a life-threatening or irreversibly debilitating human disease or condition
- √ No approved or cleared alternatives exist
- ✓ Device availability is in the best interest of patients



End-Stage Renal Disease (ESRD) Endotoxemia & Inflammation

- > 550,000+ ESRD patients receive ~85 million dialysis treatments in the U.S. each year
- Annual mortality rate is ~20%
- Cardiovascular Disease & Sepsis are leading causes of early death (~70%)
- > Endotoxemia and concurrent inflammation drive these conditions



Potential Value to the Dialysis Industry?



Two Organizations Dominate The U.S. Dialysis Industry







- > ~200,000 U.S. ESRD patients
- > Average annual revenue per-patient is ~\$60,000
- > **~\$1 Billion** of increased revenue per-month of extended ESRD patient life
- > **~\$250 million** in recouped revenues per-week of reduced hospitalization





- > ~280,000 U.S. ESRD patients
- > Average annual revenue per-patient is ~\$62,000
- ~\$1.45 Billion in increased revenue per-month of extended ESRD patient life
- ~\$362 million in recouped revenues per-week of reduced hospitalization





Clinical Plan

- Investigation Device Exemption (IDE) drafted for FDA submission
- Feasibility study protocol to enroll 12-15 ESRD subjects at three site locations
- > Sigyn Therapy to be administered in series with regular dialysis treatments
- Primary endpoint is safety / Secondary endpoints change in endotoxin and inflammatory cytokine levels
- Value inflection point study completion sets stage for ESRD subject pivotal study and provides a pathway into non-ESRD indications

Modular Feasibility Study Provides Potential Pathway into Market Enabling Studies

ESRD

Endotoxemia & Inflammation

Post Feasibility Study Clinical Opportunities

Multiple Commercialization Opportunities to Treat Rare Disease Disorders Humanitarian-Use Device Indications

Sepsis

~\$250M - The Market Cap of a Company Advancing an Endotoxin Depletion Device





Oncology

"We don't develop drugs to treat cancer. We develop devices to improve the benefit of drugs to treat cancer"





Joint Venture Initiatives to Optimize the Benefit of Cancer Therapies

ChemoPrep[™]

- ➤ ChemoPrepTM is designed to improve delivery and reduce toxicity of chemotherapy, the most widely administered drug to treat cancer (<1% of chemotherapy doses are delivered to intended cancer targets)
- ➤ ChemoPrepTM is an adsorption technology to reduce the circulating presence of tumorderived exosomes that interfere with chemotherapy delivery, extract chemotherapy out of tumor cells, and promote treatment resistance.
- Therapeutic goal is to maintain treatment effectiveness with lower doses. Thus, reducing treatment toxicity





Joint Venture Initiatives to Optimize the Benefit of Cancer Therapies

ImmunePrep[™]

- ➤ ImmunePrepTM is a platform technology to improve the delivery of immunotherapeutic antibodies, the top selling class of cancer drugs with revenues of ~\$125 billion in 2024 (<1% of immunotherapeutic antibody doses are delivered to intended targets)
- Delivery is limited by high concentrations of circulating decoys that display the antigen binding site of the antibody. As a result, most patients don't respond to therapy.
- ImmunePrep[™] products incorporate a therapeutic antibody to sweep circulating decoys from the bloodstream prior to the subsequent infusion of the antibody into the cancer patient. A "REVERSE DECOY" mechanism of action.





> OTCQB: SIGY

Recent Price: \$2.75

> 52-Week Range: \$2.49 - \$5.75

> Shares Outstanding: 1,605,377

>90% of Shares Outstanding held by management, two funds, and one angel investment group



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