

OTCQB: "SIGY"



*Jim Joyce
Chairman, CEO, Inventor*

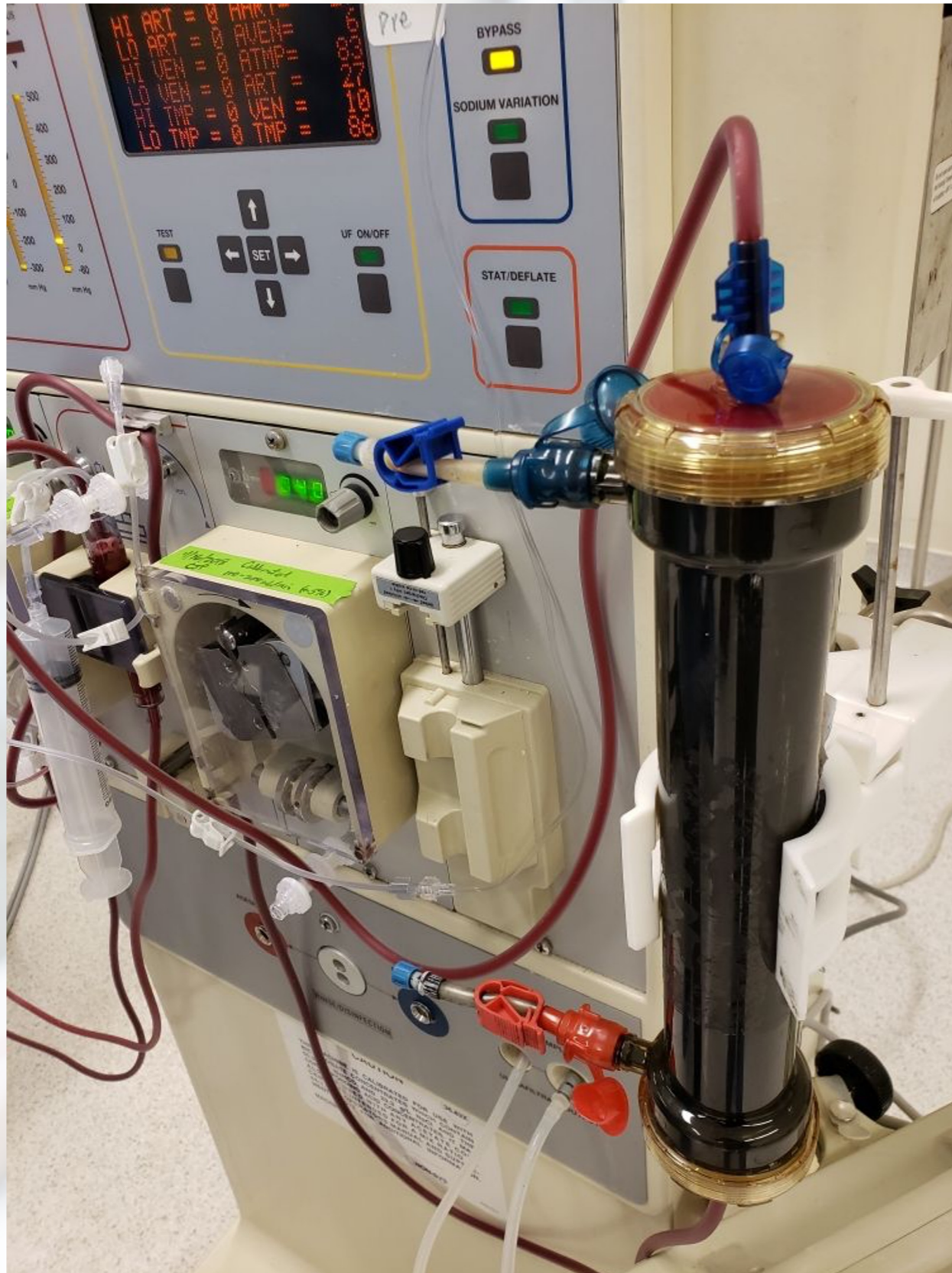
*NIBA Conference
September 7, 2023*

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“We create blood purification therapies to perform functions beyond the reach of drugs”

Sigyn Therapy™



University of Michigan Animal Studies

Sigyn Therapy™ in Action



In Vitro Human Blood Plasma Validations

Inflammatory Cytokines

Bacterial Toxins, including Endotoxin

Viral Pathogens, including COVID-19

Hepatic Toxins

CytoVesicles (model study)

Leading Cause of Hospital Deaths

Sepsis

Leading Cause of Infectious Disease Deaths

**Community
Acquired
Pneumonia**

Induces Hyperinflammation / Sepsis

Endotoxemia

**Market
Opportunities**

The Silent Pandemic

**Drug Resistant
Bacterial
Infections**

Increasing Prevalence of Drug-Resistant Viruses

**Pandemic
Viruses**

Next: FDA IDE Submission (Modular Strategy)

Enrollment of 12-15 dialysis-dependent end-stage renal disease (ESRD) subjects with endotoxemia and concurrent inflammation

>550,000 ESRD patients receive ~85 million dialysis treatments in the U.S. each year

ESRD – Things To Know!

30% of ESRD patients die within a year of dialysis initiation

Cardiovascular disease (CVD), followed by sepsis are leading causes of ESRD deaths

Endotoxemia and concurrent inflammation are hallmark contributors to these indications

North American Dialysis Market Dominated By Two Organizations



“FMS” Market Cap: \$14.2 Billion



“DVA” Market Cap: \$9.4 Billion

Potential Value to the Dialysis Industry

Sigyn Therapy™ would establish new revenue channel

Provides pathway into non-dialysis markets

Reduced ESRD patient hospitalizations = Recouped Revenues

Revenues gains from extended life of ESRD patients

Value for Each Month of Extended Life - DaVita

\$11.6 Billion
2022 Revenues
North America

199.4K ESRD Patients

**30 Million Dialysis
Treatments**

**\$58.2K Per Patient
Revenue**

+ \$960 Million
per month of extended life

Value for Each Month of Extended Life - Fresenius

\$14.5 Billion
2022 Revenues
North America

208.3K ESRD Patients

31.8 Million Dialysis
Treatments

\$69.6K Per Patient
Revenue

+ \$1.2 Billion
per month of extended life



Therapeutic Pipeline

Therapeutic Pipeline

Comprised of technologies to optimize chemotherapy and therapeutic antibodies

Our technologies extract circulating decoys that obstruct drugs from reaching their target

Clinical objective: Improve therapeutic responses and reduce toxicity

Chemotherapy – Things to Know

Most common class of drug administered to cancer patients

Beyond toxicity, just .05% to 3.5% of dose is delivered to target tumor site

Cancer-released exosomes obstruct delivery

Cancer-Released Exosomes



JCI The Journal of Clinical Investigation
Published by The American Society for Clinical Investigation | Founded 1908

[J Clin Invest.](#) 2016 Apr 1; 126(4): 1208–1215.
Published online 2016 Apr 1. doi: [10.1172/JCI81135](https://doi.org/10.1172/JCI81135)

PMCID: PMC4811149
PMID: [27035812](https://pubmed.ncbi.nlm.nih.gov/27035812/)

The biology and function of exosomes in cancer

[Raghu Kalluri](#)

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Department of Cancer Biology, Metastasis Research Center, University of Texas MD Anderson Cancer Center, Houston, Texas, USA.

"the blood of cancer patients is estimated to contain about 4,000 trillion exosomes"

➤ **~248,000 Miles of Chemotherapy Interference**

* Based on average size of 100 nanometers



Rationale to Deplete Cancer-Released Exosomes

- **They Block & Sequester Chemotherapy Delivery**
- **Export Chemotherapy from Tumor Cells**
- **Prime Contributor to Treatment Resistance**

OUR SOLUTION

ChemoPrep™ & ChemoPure™

***“SYSTEMS AND METHODS TO
ENHANCE CHEMOTHERAPY DELIVERY
AND REDUCE TOXICITY”***

Patent Filed: October 2022

OUR SOLUTION



ChemoPrep™

Administered prior to chemotherapy infusion

Pre-treatment sweep of cancer-released exosomes out of the bloodstream

Treatment Goal: Improve chemo delivery w/ 1/2 dose = 50% reduction in toxicity

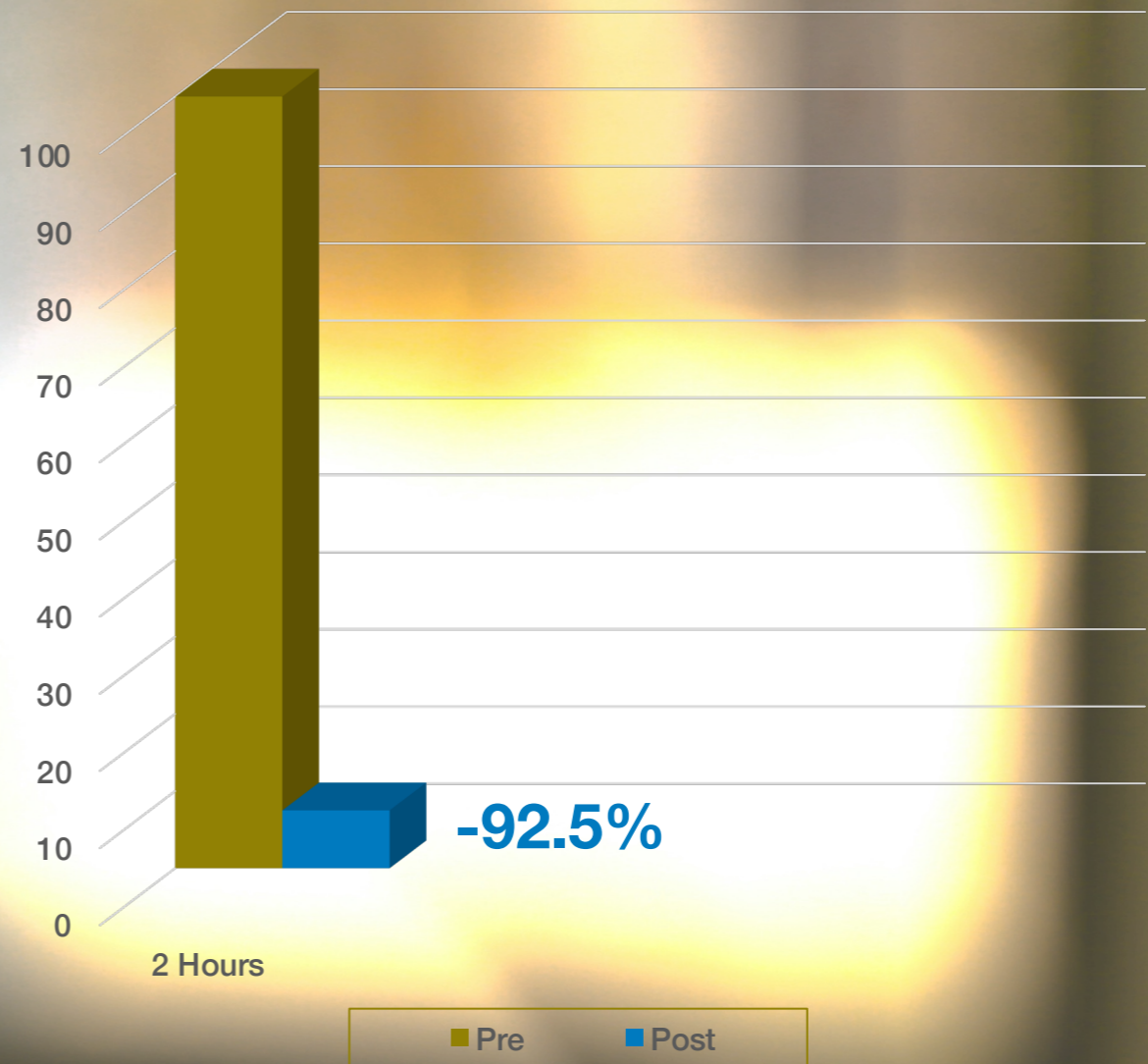
OUR SOLUTION

ChemoPure™

Post-treatment sweep of off-target chemotherapy to further reduce toxicity

OUR SOLUTION

SIGYN LIPOSOME REMOVAL *Pre-Clinical Data*



** Note: Liposomes also serve as a model for exosome depletion*

Therapeutic Antibodies – Things to Know

165 antibodies generated \$188 billion in 2022

Less than 5% of doses are reported to be delivered to target binding site

Anti-drug antibodies, soluble proteins, and cancer-released exosomes intercept delivery

CANCER-RELEASED EXOSOMES



[Proc Natl Acad Sci U S A](#). 2011 Sep 13; 108(37): 15336–15341.

Published online 2011 Aug 25. doi: [10.1073/pnas.1102855108](https://doi.org/10.1073/pnas.1102855108)

PMCID: PMC3174603

PMID: [21873242](https://pubmed.ncbi.nlm.nih.gov/21873242/)

Exosomal evasion of humoral immunotherapy in aggressive B-cell lymphoma modulated by ATP-binding cassette transporter A3

[Thiha Aung](#),^{a,1} [Bjoern Chapuy](#),^{a,b,1} [Daniel Vogel](#),^a [Dirk Wenzel](#),^c [Martin Oppermann](#),^d [Marlen Lahmann](#),^a [Toni Weinhage](#),^a [Kerstin Menck](#),^a [Timo Hupfeld](#),^a [Raphael Koch](#),^a [Lorenz Trümper](#),^a and [Gerald G. Wulf](#)^{a,2}

"Approximately half of all of the plasma rituximab was found to be fixed to exosomes 3 hours after the end of the rituximab infusion"

OUR SOLUTION

ImmunePrep™

*“DEVICES FOR ENHANCING THE ACTIVITY
OF THERAPEUTIC ANTIBODIES”*

Patent Filed: May 2023

OUR SOLUTION

ImmunePrep™

Administered prior to antibody infusion

Incorporates market-cleared antibody to sweep drug decoys out of the bloodstream

Reverse decoy mechanism increases availability of infused antibody to bind targets

“We create blood purification therapies to perform functions beyond the reach of drugs”

Conclusion

Sigyn Therapy™ addresses life-threatening conditions without an approved therapy

Expansive pipeline of technologies to optimize chemotherapy and therapeutic antibodies

Proven team with multiple first-in-industry achievements

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