

May 7, 2024



# **Sigyn Therapeutics™ Discloses Publication of “Sigyn Therapy™, an Emerging Candidate to Address Endotoxemia, Sepsis, and Drug-Resistant Viral & Bacterial Infections.”**

SAN DIEGO, May 7, 2024 -- Sigyn Therapeutics, Inc. (“Sigyn Therapeutics”, “Sigyn” or the “Company”) (OTCQB: “SIGY”), a development-stage medical technology company, announced today that it has published an article entitled: *“Sigyn Therapy™, an Emerging Candidate to Address Endotoxemia, Sepsis, and Drug-Resistant Viral & Bacterial Infections.”* Please note that this publication is for informational purposes only and does not constitute an offer to sell, nor is a solicitation to acquire shares of Sigyn Therapeutics.

Companies referenced in the paper include Toray Industries, Spectral Medical, Aethlon Medical, Eli Lilly, Fresenius Medical Care, DaVita Kidney Care, and CytoSorbents Corporation.

The full manuscript of the 3,384 word paper (12 minute read) can be accessed at: [https://d1io3yog0oux5.cloudfront.net/\\_bb1813af0e2259d25b277b0e9f6c42b2/sigyntherapeutics/db/927/7595/pdf/Sigyn+Therapy+050724.pdf](https://d1io3yog0oux5.cloudfront.net/_bb1813af0e2259d25b277b0e9f6c42b2/sigyntherapeutics/db/927/7595/pdf/Sigyn+Therapy+050724.pdf)

The introduction of the paper includes the following content:

*When we designed Sigyn Therapy™, we envisioned a medical device that could overcome the limitations of previous blood purification technologies to treat life-threatening conditions that are beyond the reach of drugs. Along with the efforts of our dedicated team, contributions from science advisors, collaborators and shareholders have helped to advance our vision toward reality.*

*Consider that in the midst of the COVID-19 pandemic, we progressed Sigyn Therapy™ from concept through initial product development and then completed a series of five invitro study programs that validated the ability of Sigyn Therapy™ to extract twelve relevant therapeutic targets from human blood plasma. Subsequently, we completed first-in-mammal studies at the University of Michigan and then leveraged dialysis industry relationships to establish the treatment protocol, clinical site locations, and principal investigators for first-in-human studies of Sigyn Therapy™.*

*In parallel with these achievements, we designed ChemoPrep™, a device to improve the delivery of cancer chemotherapy, ChemoPure™ to reduce chemotherapy toxicity, and we then introduced the ImmunePrep™ platform to expand the use and enhance the*

*performance of immunotherapeutic antibodies, which account for 9 of the top 15 selling cancer drugs. While these therapeutic candidates will be the subject of future communications, the focus of this paper is Sigyn Therapy™. Beyond our mission to save lives, I believe we have created a foundation for value creation.*

*Sincerely, Jim*

*Jim Joyce is co-founder and CEO of Sigyn Therapeutics and can be reached at [jj@sigyntherapeutics.com](mailto:jj@sigyntherapeutics.com).*

## **Introduction**

Sigyn Therapy™ is a novel hemoadsorption technology designed to extract pathogen sources of life-threatening inflammation from the bloodstream in concert with dampening down dysregulated immune responses that are pathogen induced. Our candidate treatment indications are not addressed with drug therapies and include endotoxemia, sepsis, and drug-resistant viral and bacterial infections.

Subsequent to our completion of pre-clinical *in vitro* and first-in-mammal studies, we established the treatment protocol and identified clinical site locations to support first-in-human feasibility studies of Sigyn Therapy™ in dialysis dependent end-stage renal disease (ESRD) patients with endotoxemia. Endotoxemia is associated with cardiovascular disease, infection, and sepsis. These are the three leading causes of early death in the ESRD patient population. The successful completion of our feasibility study would set the stage for pivotal efficacy studies to seek potential market clearance for Sigyn Therapy™ to treat endotoxemia and other candidate treatment indications.

## **Sigyn Therapy™ Notable Features**

- Broad-spectrum extraction of viral pathogens, bacterial toxins, hepatic toxins, inflammatory cytokines, and other mediators of inflammation from the bloodstream.
- Highly efficient mechanism. Sigyn Therapy™ processes the entire bloodstream ~15 times during a four-hour treatment.
- Substantial capture capacity. Sigyn Therapy™ incorporates a formulation of adsorbent components with 200,000+ square meters (~50 acres) of surface area on which to capture and remove therapeutic targets from the bloodstream.
- Sigyn Therapy™ is delivered for use on dialysis and continuous renal replacement machines already located in hospitals and clinics around the world.
- To optimize potential scalability, Sigyn Therapy™ is comprised of non-biological components that are readily available from established industry vendors.
- Early clinical opportunities in ESRD as Sigyn Therapy™ can be administered in series with normally scheduled dialysis treatments to conveniently treat conditions that shorten the lives of ESRD patients.

## **About Sigyn Therapeutics™**

Sigyn Therapeutics is a development-stage medical technology company headquartered in San Diego, California. The Company's therapeutic candidates are each designed to overcome a clearly defined limitation in healthcare. These include the ImmunePrep™

platform, ChemoPrep™, ChemoPure™, and Sigyn Therapy™.

ImmunePrep™ is a development-stage commercialization platform to enhance and extend the performance of immunotherapeutic antibodies, which account for nine of the top 15 best-selling cancer treatment drugs. ChemoPrep™ is designed to optimize the delivery of chemotherapy, the most commonly administered drug to treat cancer, while ChemoPure™ extracts off-target chemotherapy from the bloodstream to reduce patient toxicity.

Sigyn Therapy™ is a novel blood purification technology being advanced to treat pathogen-associated conditions that are not addressed with drug therapies. *In vitro* studies have demonstrated the ability of Sigyn Therapy™ to reduce the circulating prevalence of twelve pathogen and inflammatory disease targets from human blood plasma. Based on these outcomes, candidate treatment indications include drug resistant viral and bacterial infections, endotoxemia, and sepsis, the leading cause of hospital deaths in the United States. First-in-human feasibility studies of Sigyn Therapy™ plan to enroll end-stage renal disease (ESRD) patients with endotoxemia and concurrent inflammation, which are highly prevalent and associated with increased mortality in the ESRD population.

To learn more about Sigyn Therapeutics, visit: [www.SigynTherapeutics.com](http://www.SigynTherapeutics.com)

#### Cautionary Note Regarding Forward-Looking Statements

This information in this press release contains forward-looking statements of Sigyn Therapeutics, Inc. ("Sigyn") that involve substantial risks and uncertainties. All statements contained in this summary are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve risks and uncertainties. Statements containing words such as "may," "believe," "anticipate," "expect," "intend," "plan," "project," "will," "projections," "estimate," "potentially" or similar expressions constitute forward-looking statements. Such forward-looking statements are subject to significant risks and uncertainties and actual results may differ materially from the results anticipated in the forward-looking statements. These forward-looking statements are based upon Sigyn's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Factors that may contribute to such differences may include, without limitation, the Company's ability to clinically advance Sigyn Therapy in human studies required for market clearance, the Company's ability to manufacture Sigyn Therapy, the Company's ability to raise capital resources, and other potential risks. The foregoing list of risks and uncertainties is illustrative but is not exhaustive. Additional factors that could cause results to differ materially from those anticipated in forward-looking statements can be found under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and in the Company's other filings with the Securities and Exchange Commission, including its quarterly Reports on Form 10-Q. All forward-looking statements contained in this report speak only as of the date on which they were made. Except as may be required by law, the Company does not intend, nor does it undertake any duty, to update this information to reflect future events or circumstances.

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