UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **February 26, 2025**

SIGYN THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**000-55575**	**84-4210559**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2468 Historic Decatur Road Suite 140 San Diego, California (Address of principal executive offices)	92106 (Zip Code)

Registrant's telephone number, including area code: 619.353.0800

Prior address and phone number:

(Address of principal executive offices) (Zip Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
None	None	None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On February 26, 2025, our Chief Financial Officer, Mr. Gerald DeCiccio provided us a notice of retirement, effective immediately. In Mr. DeCiccio's notice of retirement, Mr. DeCiccio indicated his retirement was not the result of any disagreements with us. We provided Mr. DeCiccio with a copy of this disclosure in Item 5.02, and Mr. DeCiccio informed us he agrees with the statements made by us in this Item 5.02.

As a result of Mr. DeCiccio's retirement, Mr. James Joyce, our Chief Executive Officer, will serve as our interim Chief Financial Officer.

Subsequently, we entered into a Consulting Agreement with Mr. DeCiccio, to provide financial support services similar to what he provided to the Company prior to his appointment as the Company's CFO.

Item 7.01 Regulation FD Disclosure.

On March 5, 2025, we released a letter authored by our CEO entitled "Combating the Rising Threat of a New Pandemic." The letter included information regarding the emergence of new viral pathogens that are infectious to humans and reviewed our potential clinical and business opportunities to advance Sigyn Therapy as a candidate countermeasure to treat these emerging viral threats. A copy of the letter is attached hereto as Exhibit 99.1.

On February 26, 2025, our CEO participated in a Fireside Chat with a Zacks Healthcare Analyst, which can be viewed here:https://www.youtube.com/watch?v=KHSzDEh8HMU

On February 19, 2025, we released an investor presentation (the "Investor Presentation") which includes information regarding our business, and operations that our management intends to use from time to time in investor communications and conferences. A copy the Investor Presentation is attached hereto as Exhibit 99.2.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under such section, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Title
99.1	Letter from CEO re "Combating the Rising Threat of a New Pandemic"
99.2	Investor Presentation
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SIGYN THERAPEUTICS, INC.

Date: March 6, 2025

By: */s/ James A. Joyce*
James A. Joyce, Chairman and CEO

Exhibit 99.1

Sigyn CEO Note: Combating the Rising Threat of New Pandemic Viruses

SAN DIEGO, March 05, 2025 — Sigyn Therapeutics, Inc. ("Sigyn" or the "Company") (OTCQB: SIGY), today released the following note authored by its Chairman and CEO, Jim Joyce.

Dear Readers,

Aside from ongoing COVID infections and one of the deadliest influenza seasons in a quarter century, the range of life-threatening viruses endangering humans continues to expand. Failure to contain these threats could severely impact already fragile economies.

As was the case with COVID-19, blood purification therapies are a critical first line of defense to treat emerging viral pathogens. In the United States, the FDA first granted Emergency Use Authorization (EUA) to four COVID-19 treatments, all of which were extracorporeal blood purification technologies. Three of these devices were designed to reduce excessive inflammatory cytokine production (the cytokine storm), while the mechanism of the fourth device was primarily directed toward pathogen removal.

With an ability to target viral pathogens, inflammatory cytokines, and other relevant factors, Sigyn Therapy™ establishes a next-generation strategy to address both known and newly emerging viral threats. Amid their increasing prevalence, consider recent viral outbreak reports:

- Mpox, previously known as monkeypox, has been declared a public health emergency of international concern. To date, infections have been reported in 127 countries, including the United States. In the past week, a new mpox variant has emerged, potentially enhancing the virus's ability to spread among humans.
- In January, a Marburg virus outbreak in Tanzania resulted in an alarming 89% case fatality rate.
- Last month, an Ebola virus outbreak was declared in Kampala, the capital of Uganda.
- The World Health Organization has reported that nearly half of the 950 recorded human cases of H5N1 bird flu infections have been fatal.
- A measles virus outbreak in the United States has now spread across 11 states, with the death of a young child occurring last week.
- In the Democratic Republic of Congo, a yet-to-be-named virus has infected over 400 individuals since February 9th, leading to 53 deaths—most occurring within just 48 hours of first symptoms.
- Meanwhile, global warming continues to accelerate the spread of mosquito-borne viruses, including Dengue, Zika, Chikungunya, and West Nile virus.

Given the scope of viral threats around the globe, Sigyn Therapy targets multiple mechanisms that contribute to life-threatening viral infections.

Removal of Infectious Viruses from the Bloodstream

Sigyn Therapy clears viral pathogens from the bloodstream before they can infect healthy cells. Why is this important? Because a single virus can replicate thousands of new viruses from just one infected cell. Disrupting viral replication gives the immune system a critical advantage in combating infection.

Previously, I oversaw the development a virus reduction device that played a critical role in saving the life of an Ebola-infected physician who was comatose with multiple organ failure. During a six-hour treatment, the device extracted 242 million Ebola viruses from the doctor's bloodstream. Now consider that each of those viruses had the potential to replicate thousands of new viruses, which would continue to produce progeny viruses had the infection not been brought under control.

Nonetheless, we designed Sigyn Therapy to target a broader range of relevant therapeutic targets with increased efficiency. Incorporated within Sigyn Therapy is a formulation of adsorbent components with more than 200,000 square meters of surface area on which to remove circulating targets. In regard to increased efficiency, the entire bloodstream of an average size individual can be processed through our device ~15 times during a four-hour treatment. Also note that we designed Sigyn Therapy for use on dialysis and CRRT machines that are already located in hospitals around the world. To date, Sigyn Therapy has been demonstrated to reduce the circulating presence of COVID-19 and other tested viruses from human blood plasma.

Removal of Bacterial Toxins from the Bloodstream

The inflammatory response to a viral infection can increase intestinal permeability, which allows bacterial toxins that reside in the gut to leak into the bloodstream. This phenomenon can induce cytokine storm syndrome, a life-threatening immune response in which the body releases excessive inflammatory cytokines in an uncontrolled manner. To date, Sigyn Therapy has been demonstrated to reduce the circulating presence of both gram-positive and gram-negative bacterial toxins, including endotoxin from human blood plasma.

At present, the targeted removal of endotoxin from the bloodstream has emerged to become a leading strategy to treat sepsis, the #1 cause of death in U.S. hospitals. Additionally, the treatment of endotoxemia in dialysis patients is an early clinical and business opportunity for Sigyn Therapy as most U.S. dialysis patients suffer from this disorder.

Removal of Inflammatory Cytokines from the Bloodstream

Cytokines regulate the immune response during a viral infection. They play a crucial role in virus detection, immune cell activation, inflammation, and viral clearance. However, uncontrolled cytokine responses can lead to excessive inflammation, tissue damage, and organ failure. These are defining features of sepsis.

In severe infections, dampening down the excessive production of inflammatory cytokines is critical for patient survival. To date, Sigyn Therapy has been demonstrated to reduce the circulating presence of IL-6, TNF-a, and IL-1b from human blood plasma. These are among the most relevant cytokines involved in life-threatening inflammation.

Removal of Viral Exosomes from the Bloodstream

Viral exosomes are released from virus-infected cells and contribute to virus proliferation, immune evasion, and excessive inflammation. Reducing the presence of viral exosomes in the bloodstream may help to reduce disease severity and complications. To date, the adsorbent components housed in Sigyn Therapy have been demonstrated to rapidly reduce the presence of 104nm liposomes from human blood plasma. Based on their similar size and surface characteristics, liposomes have long been a model for exosome studies.

Removal of Viral Toxins from the Bloodstream

Beyond addressing viruses and other relevant targets, we believe Sigyn Therapy can reduce the circulating presence of glycoproteins (viral toxins) that shed from the surface of viral pathogens and interfere with the immune response. Nonetheless, we need to conduct confirmatory *in vitro* studies. Our rationale for targeting viral toxins? They are highly concentrated in the bloodstream of infected individuals and act as decoys that sequester antibodies from being delivered to intended viral targets. As a result, viruses can evade the immune response and continue to persist within the infected host.

Augmenting the Benefit of Antiviral Drugs

Sigyn Therapy is a first-line countermeasure to treat infectious viruses for which there is no approved antiviral drug. Note that the vast majority of viruses that infect humans are not addressed with corresponding antiviral drugs. However, should an antiviral drug be available to combat an emerging viral threat, Sigyn Therapy can be deployed synergistically to reduce baseline viral load as a means to enhance the potential effectiveness of the drug.

By lowering viral load, Sigyn Therapy may augment a drug's ability to control and eliminate infection and simultaneously may reduce the risk that a mutation evolves to cause drug resistance. Furthermore, a reduced viral load may enable an antiviral drug to act more quickly, potentially shortening the severity and duration of illness.

Sigyn Therapy Clinical Strategy

In regard to clinical strategy, we have established the protocol of a human feasibility study that will enroll end-stage renal disease (ESRD) subjects with endotoxemia and concurrent inflammation (excess inflammatory cytokine production), which are prevalent, yet untreatable conditions that shorten the lives of dialysis patients. At this point, you may recall that endotoxin and inflammatory cytokines are also critically important targets that underly sepsis and life-threatening viral infections.

While the primary endpoint of our feasibility study safety, its successful completion establishes potential opportunities to advance Sigyn Therapy as a countermeasure to treat emerging viral threats under compassionate-use and emergency-use programs in the United States and abroad. I say this from personal experience as the same device referenced earlier in the treatment of the Ebola was also approved by FDA under Emergency-Use Authorization based on safety data and pre-clinical *in vitro* studies. The device was also approved under similar provisions in Germany and Canada.

The successful completion of our feasibility study also sets-the-stage for pivotal studies required for market clearance to treat endotoxemia and concurrent inflammation in ESRD patients. This is a compelling opportunity as endotoxemia impacts a majority of the 550,000 individuals on dialysis in the United States. A value of therapeutic strategy that helped to extend the lives of ESRD patients is quantifiable to the dialysis industry, dominated by Fresenius Medical Care and DaVita, Inc. in North America. Based on the number of ESRD patients treated in their networks, each month of extended life would equate to approximately $1 billion in added revenues for each company. Based on these factors, we can leverage our ESRD opportunity to build a strong business foundation.

When evaluating our opportunities in infectious disease, the question isn't whether new pandemic viruses will emerge, but when the next outbreaks will occur?

Thank you for taking the time to read my note.

Sincerely, Jim

About Sigyn Therapeutics™

Sigyn Therapeutics is developing next-generation blood purification therapies to address life-threatening infectious disease disorders. Sigyn Therapy™ has been demonstrated to reduce the presence of viral pathogens, bacterial toxins, inflammatory cytokines, and other relevant therapeutic targets from human blood plasma. Based on these capabilities, Sigyn Therapy™ is a candidate to treat life-threatening viruses, endotoxemia, and sepsis, the leading cause of death in U.S. hospitals. The clinical protocol of first-in-human studies incorporates Sigyn Therapy into regularly scheduled dialysis treatments to address endotoxemia and concurrent inflammation, which are highly prevalent disorders that shorten the lives of end-stage renal disease (ESRD) patients. The value of extending ESRD patient lives is quantifiable based its potential impact on dialysis industry revenues.

The Company also has an oncology pipeline comprised of ImmunePrep™, a platform to enhance the delivery of immunotherapeutic antibodies; ChemoPrep™ to improve the delivery of chemotherapeutic agents; and ChemoPure™ to reduce chemotherapy toxicity. If successfully advanced, the Company's therapies offer to provide strategic value to the dialysis and biopharmaceutical industries.

To learn more about Sigyn Therapeutics, visit:www.SigynTherapeutics.com

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CONTACTS:

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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, 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.


February 19, 2025
SIGYN
THERAPEUTICS
Emerging Growth Conference
Jim Joyce
CEO, Inventor
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FORWARD-LOOKING STATEMENTS
The following presentation is for informational purposes only and is not an offer to sell or a solicitation of an offer to buy any securities of Sigyn Therapeutics, Inc. ("Sigyn"). All statements in this presentation, other than statements of historical fact, are forward-looking statements within the meaning of federal securities laws. In some cases, you can identify forward-looking statements by terms such as "may," "will," "expect," "plan," "anticipate," "strategy," "designed," "intend," "believe," "estimate," "target," or "potential" and other similar expressions. Forward-looking statements involve risks, uncertainties and assumptions that may cause Sigyn's actual results, performance, or achievements to be materially different from those expressed or implied by the forward-looking statements in this presentation, including risks and uncertainties inherent in Sigyn's business and other risks described in Sigyn's filings with the Securities and Exchange Commission (SEC). Sigyn's forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Further information regarding these and other risks is included under the heading "Risk Factors" in Sigyn's periodic reports filed with the SEC, which are available on the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Sigyn undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.
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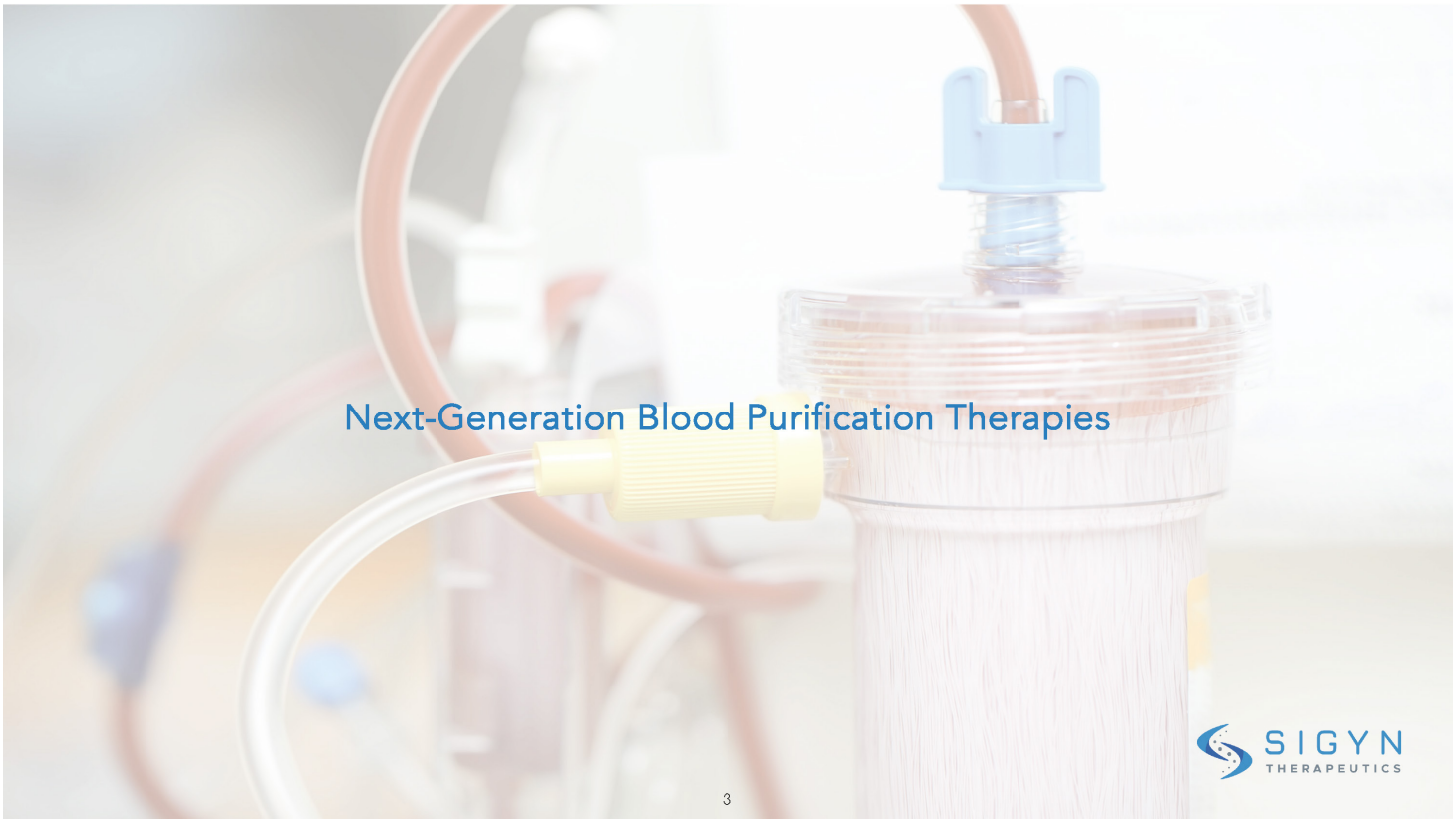
Next-Generation Blood Purification Therapies
SIGYN
THERAPEUTICS


Investment Considerations
➢ Sigyn Therapy™ addresses untreatable infectious disease disorders
- Clinical-stage market comp to treat sepsis ~20x current Sigyn value
- CEO's previous company peaked at ~30x current Sigyn value
- Notable first-in-industry achievements
➢ Pipeline of device candidates to enhance performance of cancer therapies
- ImmunePrep™, ChemoPrep™ & ChemoPure™
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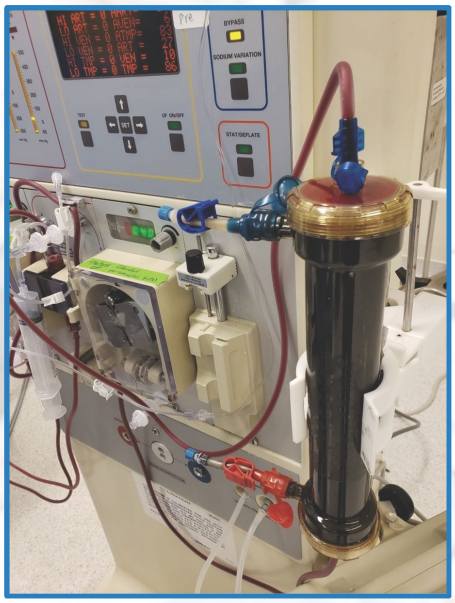


First-in-Mammal Studies at University of Michigan

Sigyn Therapy™

To Address Life-Threatening Infections

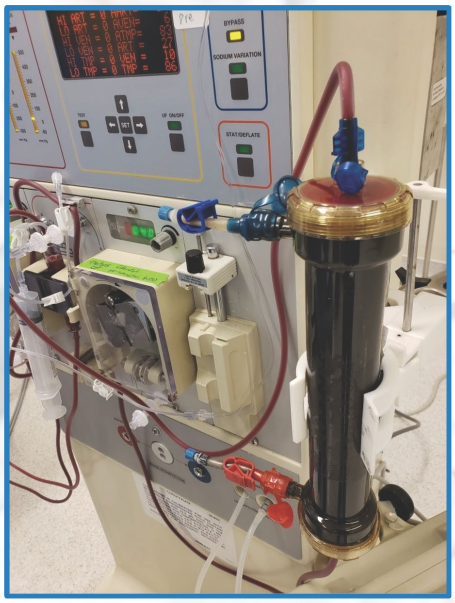
1. Broadly Deployable
2. Highly Efficient
3. Immense Capacity
4. Broad Spectrum Mechanism

SIGYN THERAPEUTICS

Sigyn Therapy™

Broadly Deployable

SIGYN THERAPEUTICS



Sigyn Therapy™

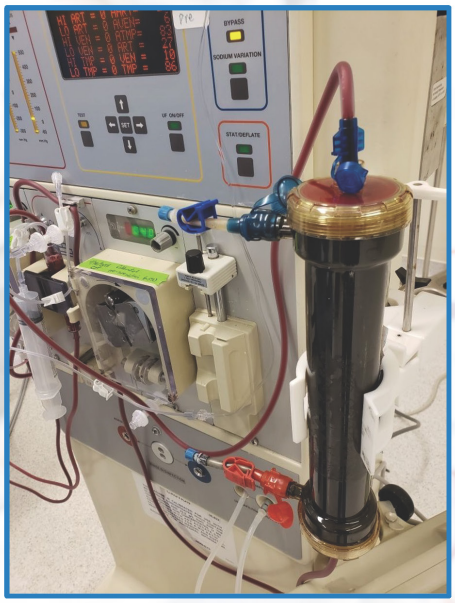
Highly Efficient

SIGYN THERAPEUTICS

Sigyn Therapy™

Immense Capacity

SIGYN THERAPEUTICS



Sigyn Therapy™

Broad-Spectrum Mechanism

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Unmet Needs in Global Health

Sepsis
Leading Cause of Hospital Deaths

ESRD Endotoxemia
Early Clinical Opportunity in Dialysis Patients

Untreatable Viral Pathogens
Most Viruses are not treatable w/ Drugs

Antibiotic-Resistant Bacteria
Emerging Global Health Threat

SIGYN THERAPEUTICS

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EARLY CLINICAL & COMMERCIALIZATION OPPORTUNITY

End-Stage Renal Disease (ESRD) Endotoxemia

- 550,000+ dialysis dependent ESRD patients in the United States
- ~20% annual mortality rate
- Endotoxemia and concurrent inflammation underly early causes of death
- Incidence of endotoxemia is 60-90% (>330,000) in ESRD patients

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Potential Value of Sigyn Therapy to the Dialysis Industry

- Extending ESRD patient lives increases revenues
- Provides pathway into non-ESRD markets

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The Dialysis Industry is Dominated By Two Organizations in North America

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- ~200,000 ESRD patients in North American Network
- Average annual revenue per patient is ~$58,000
- **$960 million** of increased revenue per month of extended ESRD patient life
- **$240 million** in recouped revenues per week of reduced hospitalization

- **~208,000 ESRD patients in North American Network**
- Average annual revenue per patient is ~$70,000
- **$1.2 billion** of increased revenue per month of extended ESRD patient life
- **$300 million** in recouped revenues per week of reduced hospitalization

End-Stage Renal Disease (ESRD) Clinical Plan

- Investigation Device Exemption (IDE) drafted for FDA submission
- Enrollment of 12-15 ESRD subjects with endotoxemia and concurrent inflammation at three site locations (Hartford, San Antonio, Las Vegas)
- Sigyn Therapy administered during regularly scheduled dialysis sessions
- Primary endpoint is safety / secondary endpoints includes endotoxin and inflammatory cytokine reduction
- Successful completion sets stage for ESRD pivotal studies and establishes pathway to pursue Sepsis* studies in non-ESRD subjects (Modular Clinical Design)

** ESRD study therapeutic targets underly sepsis and other life-threatening infections*

About Sepsis

- Leading cause of death in U.S. hospitals*
- $38 billion annual cost to the U.S. healthcare system*
- A dysregulated immune response most often induced by a bacterial or viral infection
- An excessive production of pro-inflammatory cytokines ("the cytokine storm")
- Bacterial toxins that leak from the gut into the bloodstream are potent activators of sepsis

** Source: U.S. National Institutes of Health (NIH)*

Sigyn Therapy™ Sepsis Related Studies*

- A dysregulated immune response most often induced by a bacterial or viral infection
  The clearance of viral pathogens from human blood plasma has been validated
- An excessive production of pro-inflammatory cytokines ("the cytokine storm")
  *The clearance of **TNF alpha, IL-1b and IL-6** has been validated*
- Bacterial toxins that leak from the gut into the bloodstream are potent activators of sepsis
  *The clearance of **peptidoglycan, lipoteichoic acid and endotoxin** has been validated*

** All studies conducted with pediatric versions of Sigyn Therapy™*

Clinical-Stage Market Comparable to Treat Sepsis

- Spectral Medical holds the North American rights to the Polymyxin B ("PMX") endotoxin removal device
- PMX is being evaluated in a study of adults with endotoxemia and septic shock
- As a model for clinical progression-based value, Spectral Medical has a market cap ~20x the current value of Sigyn Therapeutics

Oncology

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

Chemotherapy

- Most common class of drug to treat cancer
- < 3.5% is delivered to tumor-cell targets
- Off-target chemotherapy contributes to toxicity
- Cancer cells release exosomes that interfere with chemotherapy delivery (chemosomes)

Sigyn Solution

Associated with a pending patent entitled: "SYSTEMS AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY"

ChemoPrep™

- Pre-treatment depletion of chemosomes to improve delivery of chemotherapy to cancer cell targets
- Therapeutic objective to maintain chemotherapy effectiveness with lower doses (toxicity reduction)

ChemoPure™

- Post-treatment clearance of off-target chemotherapy to further mitigate treatment toxicity

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Immunotherapeutic Antibodies

- Top selling drugs to treat cancer
- Most valued assets in global medicine based on 2023 & 2024 M&A activity
- Over 1000 human studies, yet no effective strategy to improve delivery

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Limitation of Immunotherapeutic Antibodies

- ~2% of doses reach intended cancer cell target
- Delivery intercepted by circulating decoys that display the binding site receptor of the antibody
- Most patients don't respond to therapy

Sigyn Solution

*Associated with a pending patent entitled: **"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"***

ImmunePrep™

- Platform to incorporate a therapeutic antibody to sweep decoys from circulation prior to the infusion of the antibody into a cancer patient
- Simultaneous clearance of the antibody's therapeutic target to further enhance patient benefit without added drug toxicity
- Expanding the use of therapeutic antibodies and enhancing their benefit would provide strategic value to the drug industry

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Conclusion

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Next-Generation Blood Purification Therapies

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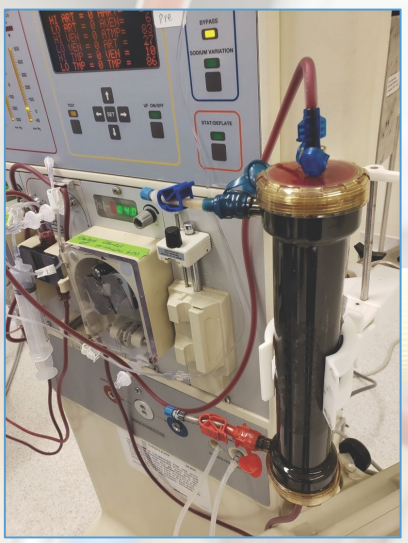

"Sigyn Therapy in Action"

Summary

- Lead product targets infectious disease disorders not treatable with drugs
- Pipeline comprised of first-in-industry devices to improve delivery of leading cancer therapies

SIGYN THERAPEUTICS

Public Market Data

- OTCQB: SIGY
- 52-Week Range: $3.15 - $6.34
- Shares Outstanding: 1,605,377
- >90% of Shares Outstanding are held by management, two funds, and one investment group

SIGYN THERAPEUTICS

Reg-D Offering Memorandum Contact: Johan Louw
(281) 660-1815 or jlouw@SigynTherapeutics.com

Finance Plan

- **2025 Q1**: $3.75 million Reg D 506c offering of 10% convertible notes[1] (offering documents now available)
- **2025 Q2**: Initiation of $20 million Regulation A+ uplist to Nasdaq[2] offering

[1]The Company previously raised ~$5 million through 10% convertible notes whose average conversion price was $6.75 per share

[2]The Company has submitted listing application to Nasdaq, but there is no assurance the Company will achieve the listing requirements for its shares to trade on Nasdaq

SIGYN THERAPEUTICS

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