

# Sigyn Therapeutics Announces Filing of 2021 Annual Report on Form 10-K

SAN DIEGO, CA, March 22, 2022 (GLOBE NEWSWIRE) --

via NewMediaWire --Sigyn Therapeutics, Inc. (OTC Markets: "SIGY") ("Sigyn Therapeutics" or the "Company"), a medical technology company focused on the treatment of pathogen-associated conditions that induce sepsis and other life-threatening disorders, announced today that it has filed its annual report on Form 10-K for the year ended December 31, 2021 with the Securities and Exchange Commission ("SEC") and provided a corporate update. The Company's Sigyn Therapy™ is a novel blood purification technology designed to perform functions that are beyond the reach of drugs and overcome the limitations of current devices to treat life-threatening inflammatory disorders, including sepsis, the leading cause of hospital deaths worldwide.

"2021 was a transformative year, during which we advanced Sigyn Therapy from conceptual design to clinical application and added key members to our clinical and management team," stated Jim Joyce, co-founder and CEO of Sigyn Therapeutics. "During the year, we conducted a series of studies that validated Sigyn Therapy's potential to address an unrivaled breadth of therapeutics targets. Moving forward, we will seek to demonstrate that our expansive capabilities translate into patient benefit through human clinical studies."

Sigyn Therapeutics plans to incorporate results from recent *in vivo* and *in vitro* studies into an Investigational Device Exemption that the Company is drafting for submission to the U.S. Food and Drug Administration to support the advancement of human clinical studies.

## 2021 and Recent Development Program Milestone Achievements

- In January 2021, announced the results of an in vitro pilot study that successfully
  modeled the ability of Sigyn Therapy to address CytoVesicles (extracellular vesicles
  that transport inflammatory cargos in the bloodstream). Prior to this milestone event,
  the Company reported the simultaneous elimination of endotoxin and relevant proinflammatory cytokines from human blood plasma in December 2020.
- In April 2021, disclosed initial *in vitro* study observations that demonstrated the ability of Sigyn Therapy to adsorb viral pathogens, including SARS-CoV-2 (COVID-19).
- In July 2021, announced the completion of an in vitro blood purification study that demonstrated the broad-spectrum ability of Sigyn Therapy to eliminate hepatic toxins (ammonia, bile acid & bilirubin) associated with Hepatic Encephalopathy ("HE"), a lifethreatening neurological disorder that often occurs in individuals suffering from chronic and acute forms of liver failure.
- In July 2021, disclosed the completion of the first-in-mammal pilot animal study that validated the feasibility of a clinical protocol that resulted in the safe administration of Sigyn Therapy during six-hour treatment exposures.
- In December 2021, announced that preclinical in vitro studies had validated the ability

- of Sigyn Therapy to deplete the presence of gram-positive bacterial toxins from human blood plasma.
- In February 2022, reported the successful completion of an *in vivo* animal study conducted at the University of Michigan, which demonstrated Sigyn Therapy to be safe and well tolerated. A video of Sigyn Therapy being administered on January 7, 2022 can be accessed <a href="here">here</a>.

### 2021 and Recent Corporate Developments

- In January 2021, appointed industry veteran Eric Lynam as Head of Clinical Affairs, with a mandate to oversee clinical studies of Sigyn Therapy.
- In April 2021, appointed former Aethlon Medical executive Charlene Owen as Director of Operations.
- In March 2022, appointed accomplished financial executive, Jeremy Ferrell, CPA, MBA as Chief Financial Officer, with overall responsibility for operational finance, budgeting, and financial reporting, as well as helping to manage the Company's relationships and interactions with the investment community.
- In March 2022, announced the appointments of two internationally recognized clinician researchers, Alexander S. Yevzlin, MD, FASN and H. David Humes, MD, to Sigyn Therapeutics' Scientific Advisory Board.

### **Summary 2021 Financial Results**

For the year ended December 31, 2021, the Company had a loss from operations of approximately \$2.0 million, compared to an operating loss of approximately \$916,000 for the comparable period of 2020. The Company's net loss for the year ended December 31, 2021 was approximately \$3.0 million, or approximately \$0.08 per share, compared to a net loss of approximately \$1.3 million, or approximately \$0.17 per share, for the comparable period in 2020. In 2021, net cash used in operating activities was approximately \$1.8 million.

A copy of Sigyn Therapeutics' annual report is available on the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>, and on the Company's website at <a href="https://www.sigyntherapeutics.com">www.sigyntherapeutics.com</a> under "Financial Info" in the Investors section.

## About Sigyn Therapeutics™

Sigyn Therapeutics is a medical technology company focused on the treatment of pathogenassociated conditions that precipitate sepsis, the leading cause of hospital deaths worldwide. Sigyn Therapy™ is a multi-function blood purification technology that extracts pathogen sources of life-threatening inflammation in concert with the broad-spectrum elimination of inflammatory mediators from the bloodstream.

Beyond establishing a novel strategy to combat sepsis, candidate treatment indications for Sigyn Therapy include, but are not limited to; emerging pandemic threats, hepatic encephalopathy, bridge to liver transplant, and community-acquired pneumonia (CAP), which is a leading cause of death among infectious diseases, the leading cause of death in children under five years of age, and a catalyst for approximately 50% of sepsis and septic shock cases.

To learn more, visit 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 forwardlooking statements are based upon Sigvn'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, 2021, 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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