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Sigyn Therapeutics (SIGY) CEO Note: Overcoming the Limitations of Previous Cytokine Storm Treatment Strategies

SAN DIEGO, Jan. 12, 2021 (GLOBE NEWSWIRE) -- via [NewMediaWire](#) -- Sigyn Therapeutics, Inc. (OTCMarkets: SIGY), today released the following note authored by its Chairman and CEO, Jim Joyce.

Dear Current and Candidate Shareholders,

We created Sigyn Therapy to address a significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome (the Cytokine Storm). An annual market opportunity that exceeds \$20 billion.

Based on our cumulative experience in developing first-in-industry medical technologies, we designed Sigyn Therapy to overcome the limitations of previous strategies to treat cytokine storm related conditions, yet still optimize patient safety and support widespread deployment.

As anti-cytokine drug mechanisms are limited to single cytokine targets, our focus was directed toward overcoming the limitations of two industry pioneering devices that are market cleared and broadly deployed to treat life-threatening inflammatory conditions outside of the U.S. At present, both of these devices are being evaluated in the U.S. as candidates to treat severe COVID-19 infection.

The first device incorporates an adsorbent bead to address inflammatory cytokines that circulate freely in the blood. However, this device does not address endotoxin, which is a potent activator of cytokine storm syndrome. Conversely, the second device depletes the presence of circulating endotoxin, but does not address inflammatory cytokines. The cytokine device underlies a Nasdaq traded company whose market value is ~\$385 million. The endotoxin device is among a family of products marketed by an OTC traded company valued at almost \$10 billion.

Since establishing ourselves as a public company on October 19, 2020, we have made considerable progress in collecting relevant data that reinforces the prospect of Sigyn Therapy overcoming the limitations of these products.

On November 2, 2020, I authored my first CEO note entitled: "*Rethinking the Treatment of Sepsis and Other Life-Threatening Inflammatory Conditions.*" The note disclosed that we had initiated an *in vitro* study to validate whether Sigyn Therapy could reduce the presence of inflammatory cytokines and endotoxin from human blood plasma.

On December 1, 2020, we reported *in vitro* study results that validated the ability of Sigyn

Therapy to simultaneously clear both inflammatory cytokines and endotoxin from human blood plasma. Beyond reporting this milestone achievement, we disclosed our intent to further evaluate the ability of Sigyn Therapy to address CytoVesicles (extracellular vesicles) that transport inflammatory cytokine cargos throughout the bloodstream.

On January 6, 2021, we reported the results of an *in vitro* pilot study that successfully modeled the ability of Sigyn Therapy to address inflammatory CytoVesicles, which have been elusive targets for previous therapeutic candidates. As a result, we now have pre-clinical insight that Sigyn Therapy can address a broad-spectrum of inflammatory targets, including inflammatory cytokines, endotoxin and CytoVesicles that participate in concert with freely circulating cytokines to escalate Cytokine Storm Syndrome.

The data resulting from these and a series of forthcoming studies will be incorporated into an Investigational Device Exemption (IDE) that we plan to submit to the United States Food and Drug Administration (FDA) in 2021.

Beyond the continued advancement of our clinical endeavors, we also recognize the need to establish a market for our securities, which are thinly traded at present. I am not naïve to this challenge as I previously navigated Aethlon Medical from single-shareholder start-up to Nasdaq-traded Company with 8000+ shareholders and a peak-market value that reached \$200 million during my tenure as Chairman and CEO.

Similar to our pathway to the public markets, Aethlon established itself as a public company through a merger with an OTC-traded entity.

I look forward to keeping you updated on our endeavors to advance Sigyn Therapy.

Sincerely,

Jim Joyce

Co-founder, Chairman and CEO

Sigyn Therapeutics, Inc.

About Sigyn Therapeutics

Sigyn Therapeutics is a development-stage therapeutic technology company headquartered in San Diego, California USA. Our focus is directed toward a significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome and not addressed with an approved therapy. Our mission is to save lives.

Sigyn Therapy™ is a novel blood purification technology designed to mitigate cytokine storm syndrome through the broad-spectrum depletion of inflammatory targets from the bloodstream. Cytokine storm syndrome is the hallmark of sepsis, which is the most common cause of in-hospital deaths and claims more lives each year than all forms of cancer combined. Virus induced cytokine storm (VICS) is associated with high mortality and is a leading cause of SARS-CoV-2 (COVID-19) deaths. Other therapeutic opportunities include, but are not limited to bacteria induced cytokine storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure, such as hepatic encephalopathy.

To learn more, visit www.SigynTherapeutics.com or www.SigynTherapy.com

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of Sigyn Therapeutics, Inc. (“Sigyn”) that involve substantial risks and uncertainties. All statements contained in this press release are forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words “could,” “will,” “plan,” “intend,” “anticipate,” “approximate,” “expect,” “potential,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about Sigyn’s future financial performance, the impact of management changes, any proposed organizational restructuring, results of operations, capital resources to fund operations; statements about Sigyn’s expectations regarding the capitalization, resources and ownership structure of the combined company; statements about the potential benefits of the transaction; the expected completion and timing of the transaction and other information relating to the transaction; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that Sigyn makes due to a number of important factors, including (i) the risk that the transaction may not be completed in a timely manner or at all, which may adversely affect Sigyn’s business and the price of the common stock of Sigyn, (ii) the failure to satisfy of the conditions to the consummation of the transaction, (iii) the occurrence of any event, change or other circumstance that could give rise to the termination of the merger agreement, (iv) risks related to the ability to realize the anticipated benefits of the transaction, including the risk that the businesses will not be integrated successfully, (v) the effect of the announcement or pendency of the transaction on Sigyn’s business relationships, operating results and business generally, (vi) risks that the proposed transaction disrupts current plans and operations, (vii) risks related to the combined entity’s ability to up-list to a national securities exchange, (viii) risks related to the combined entity’s access to existing capital and fundraising prospects to fund its ongoing operations, (ix) risks related to diverting management’s attention from Sigyn’s ongoing business operations, (x) other business effects, including the effects of industry, market, economic, political or regulatory conditions, future exchange and interest rates, and changes in tax and other laws, regulations, rates and policies, and (xi) the outcome of any legal proceedings that may be instituted against Sigyn related to the merger agreement or the transaction. Further risks that could cause actual results to differ materially from those matters expressed in or implied by such forward-looking statements are discussed in “Risk Factors” and elsewhere in the previous Reign Resources Corporation Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 and other reports filed with the SEC. The forward-looking statements in this press release represent Sigyn’s views as of the date of this press release. Sigyn anticipates that subsequent events and developments may cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing Sigyn’s views as of any date subsequent to the date of this press release.

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