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Sigyn Therapeutics Reports Third Quarter Financial Results and Subsequent Introduction of CardioDialysis(TM)

SAN DIEGO, CA - November 14, 2025 (NEWMEDIAWIRE) - Sigyn Therapeutics, Inc. ("Sigyn" or the "Company") (OTCQB: SIGY), a developer of dialysis-like therapies to address cardiovascular disease and cancer, today reported financial results for the third quarter of 2025 and disclosed details related to its subsequent introduction of CardioDialysisTM to treat cardiovascular disease.

During the quarter, the Company reported a loss from operations of $386,529 as compared to an operating loss of $808,458 for the comparable period in 2024. The Company's net loss for Q3 2025 was $578,503 or $0.36 per share, as compared to a net loss of $1,196,923 or $0.94 per share, during Q3 2024.

For complete financial results, please see Sigyn Therapeutics' filings atwww.sec.gov, or access them on the Company's website at www.SigynTherapeutics.com.

Subsequent to the close of the third quarter on September 30, the Company disclosed in a shareholder letter authored by CEO Jim Joyce on November 6, that it had filed a trademark application with the U.S. Patent and Trademark Office to protect the name CardioDialysisTM. The filing reflects the Company's strategic decision to shift the prior therapeutic focus of Sigyn TherapyTM toward cardiovascular disease, the leading cause of death worldwide.

Beyond providing a pathway into a larger market opportunity, the Company believes it can leverage an existing FDA-approved device precedent that demonstrates the ability of blood purification to reduce Major Adverse Cardiovascular Disease Events (MACE). As compared to previously proposed treatment indications, the Company anticipates the enrollment of cardiovascular disease subjects into pivotal efficacy studies required for FDA market approval will be less burdensome.

The strategic shift may also enhance the potential value of Company's endeavors to the dialysis industry, as CardioDialysisTM is deployed for use on dialysis machines and a majority of dialysis patients ultimately die from cardiovascular-related events.

About CardioDialysisTM

CardioDialysis(TM) is an emerging candidate to treat cardiovascular disease, the leading cause of death worldwide. CardioDialysis(TM) aims to reduce the circulating presence of inflammatory molecules that fuel cardiovascular disease progression while simultaneously lowering levels of cholesterol-transporting lipoproteins that contribute to heart attacks, strokes, and other Major Adverse Cardiovascular Events (MACE).

Based on its broad-spectrum mechanism, CardioDialysis(TM) offers to reduce the incidence of MACE by overcoming the inherent limitations of single-target drugs. The annual market for MACE-reducing therapies is reported to exceed $100 billion.

Initial Clinical and Commercialization Focus

The initial clinical and commercialization focus of CardioDialysisTM is directed toward the treatment of cardiovascular disease in end-stage renal disease (ESRD) patients. According to the U.S. Renal Data System (USRDS), cardiovascular disease is attributed to 67% of ESRD patient deaths and its incidence is 20 times higher in dialysis patients as compared to the general population. Whereas the USRDS reports that infections account for 10.1% of ESRD patient deaths. The Company's previous treatment indications, which included sepsis, drug-resistant bacterial infections and life-threatening viral infections, are all included within the 10.1% calculation.

Beyond high mortality rates, cardiovascular disease is a well-defined, yet substantial market opportunity, given an estimated 550,000 ESRD patients receive ~85 million dialysis treatments in the U.S. each year. To optimize market penetration within the dialysis industry, CardioDialysis(TM) can be administered to patients during regularly scheduled dialysis treatments.

A Medical Device Precedent to Treat Cardiovascular Disease

CardioDialysis(TM) targets multiple key therapeutic pathways, including cholesterol-transporting lipoproteins that play a central role in the development and progression of cardiovascular disease.

Lipoprotein Apheresis (LA) is an FDA-approved precedent that has proven the ability of medical devices to significantly reduce Major Adverse Cardiovascular Events (MACE) by lowering levels of lipoprotein(a) and low-density lipoprotein cholesterol (LDL-C) in the bloodstream. In a recent review article published by the American Heart Association, Lipoprotein Apheresis was reported to lower the incidence of MACE by 59% to 95% across 11 studies encompassing 1,387 treated patients. In contrast, pharmaceutical statins (Lipitor, Crestor, and Zocor) to reduce LDL-C levels are reported to reduce MACE by 20% to 45%.

However, the clinical adoption of Lipoprotein Apheresis has been constrained by a limited delivery infrastructure, with fewer than 60 specialized apheresis centers providing access to the therapy in the United States.

Leveraging the Global Infrastructure of Dialysis Machines

CardioDialysis(TM) is not constrained by delivery infrastructure as it can be deployed on dialysis machines already located in hospitals and clinics around the world. An estimated 150,000 dialysis machines are located in more than 7,500 kidney dialysis clinics in the U.S. alone. By leveraging this infrastructure, the Company envisions a possibility to transform current kidney dialysis clinics into future Renal and CardioDialysis(TM) treatment centers.

Potential Value of CardioDialysis(TM) to the Dialysis Industry

If successfully advanced, CardioDialysis(TM) could improve and extend the quality of life of ESRD patients who rely on dialysis for survival. Beyond introducing a potential new revenue

source to the dialysis industry, CardioDialysis(TM) may offer a pathway to treat cardiovascular disease in the general population, which is a commercialization focus of Lipoprotein Apheresis.

Extending ESRD patient lives and reducing their hospitalizations may also provide quantifiable value to the dialysis industry. When ESRD patients are hospitalized, dialysis companies lose revenues as in-clinic dialysis treatments are instead administered at out-of-network hospitals. Based on average dialysis revenues of $400 per treatment, the U.S. dialysis industry could recoup up to $654 million in lost revenues for each week of reduced ESRD patient hospitalizations. More importantly, the U.S. dialysis industry could also increase top-line revenues by ~$2.8 billion for each month the lives of their patients are extended.

Addressing Unique Cardiovascular Disease Challenges of Dialysis Patients

ESRD patients face unique cardiovascular disease challenges that are not addressed with drug therapies. Once they become dialysis dependent, the median length of ESRD patient survival is typically 3-5 years. Unlike the general population, clinical studies indicate that ESRD patients receive limited if any clinical benefit from LDL-C reducing statins, the leading class of drug to treat cardiovascular disease. Additionally, circulating levels of cholesterol-transporting lipoprotein(a) are reported to be two to four times higher in ESRD dialysis patients.

Compounding these treatment challenges is the unfortunate reality that dialysis treatments induce inflammatory responses that further contribute to cardiovascular disease progression. More specifically, circulating levels of endotoxin and inflammatory cytokines are often elevated in response to dialysis treatment.

At present, there are no market-cleared pharmaceutical products to address Lipoprotein(a), endotoxemia, or the broad-spectrum of inflammatory cytokines observed to be elevated in dialysis patients.

In response, CardioDialysis(TM) provides a strategy to reduce circulating LDL-C and Lipoprotein(a) levels, which is clinically proven to reduce major adverse cardiovascular events (MACE). Simultaneously, CardioDialysis(TM) aims to control dialysis-induced inflammation that further contributes to cardiovascular disease progression.

Rationale to Enroll ESRD Patients into Dialysis Clinic Studies

The Company anticipates it will be far less burdensome to clinically advance CardioDialysis(TM) as both feasibility (safety) and pivotal efficacy studies can enroll ESRD subjects in a dialysis clinic setting. Whereas pivotal efficacy studies of previously proposed indications to treat sepsis, drug-resistant bacterial infections and life-threatening viruses would have been limited to enrolling subjects in a hospital intensive care unit (ICU) setting.

The enrollment of ICU patients to evaluate the benefit of extracorporeal blood purification therapies has been a historic challenge. As an example, the first four therapies to receive FDA Emergency-Use Authorization to treat COVID-19 were blood purification devices. While this provided an unprecedented opportunity to collect clinical data in an ICU setting, sufficient data to support formal FDA approval was never obtained for any of these

devices. Also related to the Company's previously proposed treatment indications, clinical efficacy studies of a blood purification device advanced to treat endotoxin-induced sepsis stretched out for more than a decade.

Further supporting the Company's initial clinical plan to treat cardiovascular disease, ESRD patients already have blood access and CardioDialysis(TM) can be administered during regularly scheduled dialysis sessions at their dialysis clinic. When considering cardiovascular disease prevalence, a reasonable percentage of ESRD patients are likely to meet the inclusion criteria to participate in the Company's studies. Dialysis clinic staffs are also experienced in administering blood purification therapies and can help identify candidate enrollment subjects among the ESRD patients they already know and treat on a regular basis. Although ESRD patients are health compromised, their condition is considerably more stable as compared to ICU admitted subjects. Thus, reducing the potential for unexplained in-study adverse events that can arise in ICU-based studies.

Forthcoming FDA Regulatory Steps to Advance CardioDialysisTM

The Company previously collaborated with the clinical research division of a leading dialysis company to design a clinical feasibility study protocol to demonstrate safety of its technology in 12-15 ESRD subjects at three dialysis clinic site locations. The protocol was then incorporated into an Investigational Device Exemption (IDE) that the Company drafted for FDA submission. The protocol and IDE are now being edited to reflect the Company's decision to enroll ESRD subjects as a means to evaluate the use of CardioDialysis(TM) to treat cardiovascular disease. This action will fulfill the FDA requirement to clearly define the disease condition the Company intends to treat in its IDE submission.

About Sigyn Therapeutics(TM)

Sigyn Therapeutics is developing dialysis-like therapies to address cardiovascular disease and cancer. The Company's therapeutic candidates are designed to improve and extend the quality of patient lives, and their successful clinical advancement offers to provide strategic value to the dialysis and biopharmaceutical industry.

Sigyn CardioDialysis(TM) is a first-in-industry medical device to treat cardiovascular disease, the leading cause of death globally. CardioDialysis(TM) aims to reduce the circulating presence of inflammatory molecules that fuel cardiovascular disease progression while simultaneously lowing levels of cholesterol-transporting lipoproteins that contribute to heart attacks, strokes, and other Major Adverse Cardiovascular Events (MACE). Based on its broad-spectrum mechanism, CardioDialysis(TM) offers to reduce the incidence of MACE by overcoming the inherent limitations of single-target drugs.

The Company's development pipeline is comprised of ImmunePrep(TM) to optimize the delivery of immunotherapeutic antibodies to treat cancer; ChemoPrep(TM) to enhance the targeted delivery of chemotherapy; and ChemoPure(TM) to reduce the toxicity of chemotherapy.

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

CONTACT:

Sigyn Therapeutics, Inc.
Jim Joyce
CEO, Inventor
Email: jj@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, 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.