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Sigyn Therapeutics Issues Shareholder Update Highlighting the Advancement of CardioDialysis(TM) and New Corporate Initiatives

SAN DIEGO, CA - January 15, 2026 (NEWMEDIAWIRE) - Sigyn Therapeutics, Inc. ("Sigyn" or the "Company") (OTCQB: SIGY), a developer of dialysis-like therapies to address cardiovascular disease and cancer, today released the following shareholder update authored by Chief Executive Officer, Jim Joyce.

Dear Shareholders and Interested Parties,

Cardiovascular disease is the #1 cause of death worldwide. The primary aim of treatment is to reduce major adverse cardiovascular events (MACE).

The leading class of drugs to treat cardiovascular disease are statins, which reduce the incidence of MACE by approximately 25%. In contrast, blood purification therapies (lipoprotein apheresis) can achieve 75-95% reductions in MACE (American Heart Association), but access to therapy is limited to specialized apheresis centers.

As compared to lipoprotein apheresis, CardioDialysis addresses a broader range of cardiovascular disease targets, and is designed for use on dialysis machines located at approximately 50,000 dialysis clinics around the world.

The purpose of this update is to:

1. Clarify our FDA clinical pathway to commercialize CardioDialysis
2. Disclose our investigation of Nasdaq merger opportunities.
3. Disclose a strategy to advance our therapies with less shareholder dilution.

Clinical pathway to commercialize CardioDialysis through FDA

The commercialization pathway for CardioDialysis through FDA requires the completion of a feasibility (safety) study and a subsequent pivotal efficacy study. The basis of our feasibility study protocol was developed in collaboration with the clinical research division of a leading dialysis company, who offered three clinical site locations and principal investigators to support a 12-15 subject study. The cost to conduct this feasibility study is estimated at $1.25 million. The successful completion of this study would set the stage for a pivotal efficacy study necessary to obtain FDA market clearance.

Our recent introduction of **CardioDialysis** (formerly known as Sigyn Therapy) is a critically important inflection point as it unlocked a clinical pathway that allows us to conduct both

feasibility and pivotal efficacy studies in a dialysis clinic setting. By doing so, we overcome the historic challenge of conducting studies of blood purification therapies in a hospital intensive care unit (ICU) setting.

Prior to advancing CardioDialysis to treat cardiovascular disease, our proposed treatment indications (all supported by an expansive collection of *in vitro* study validations) included hepatic encephalopathy, sepsis, life-threatening virus and drug-resistant bacterial infections. At a minimum, pivotal efficacy studies for each of these indications would need to have been conducted in an ICU setting, which is logistical challenge that can drag on for years. In this regard, I am aware of just one blood purification company that completed the full enrollment of ICU-based efficacy studies and that took more than a decade.

In contrast, the treatment of cardiovascular disease allows for feasibility and pivotal efficacy studies of CardioDialysis to be conducted in end-stage renal disease (ESRD) patients during regularly scheduled dialysis sessions at their dialysis clinic.

As compared to clinical studies of other devices, we anticipate an efficient clinical study enrollment as a vast majority of the approximately 550,000 ESRD patients in the U.S. have cardiovascular disease and two thirds are expected to die from the condition.

If commercialized, the treatment of just 1% of the U.S. ESRD population provides for a $700+ million annual revenue model based on one treatment per week at a reimbursement of $2500 per treatment. Extending the lives of U.S. ESRD patients by just one month would boost topline dialysis industry revenues by approximately $2.8 billion.

To learn more about CardioDialysis, the following link provides access to the articles listed below:

https://www.sigyntherapeutics.com/ceo-notes

"Introducing CardioDialysis(TM)" (11/6/25), *"Nature Review Article Reinforces Clinical Rationale of CardioDialysis to Address Cardiovascular Disease in Dialysis Patients"* (12/4/25), "*First-in-Industry Attributes of CardioDialysis to Treat Cardiovascular Disease"* (12/12/25), and *"The Emergence of Blood Purification Devices to Treat Cardiovascular Disease"* (1/6/26).

Pursuit of Nasdaq Merger Opportunities

As an OTC listed company, we recognize the need to identify potential opportunities that could elevate the trading of our shares to a major exchange such as Nasdaq. Based on two plus decades of public company CEO experience, I know that a Nasdaq listing would expand our access to the capital markets, improve share liquidity, and increase our visibility among the U.S. investment community and beyond.

However, Nasdaq's initial listing requirements have become increasingly prohibitive in recent years. A reality that we experienced firsthand. Now, the requirements for companies to maintain their continued listing on Nasdaq are about to become more daunting as well.

In September 2025, Nasdaq announced plans to increase their minimum "Market Value of Listed Securities" (MVLS) requirement to maintain continued listing from $1 million to $5 million for Nasdaq Capital Market companies. At the time, approximately 235 companies

were reported to be non-compliant with Nasdaq's continued listing requirements.

This new MVLS requirement was expected to be formalized in mid-December and awaits final SEC clearance. Once enacted, we believe there will be a widespread push for non-compliant Nasdaq companies to identify merger candidates that are willing to accept the issuance of shares as a basis to complete a merger transaction. Especially, if the resulting share issuance allows the Nasdaq-traded entity to maintain compliance with the new $5 million MVLS requirement.

In anticipation of this rule change, we have initiated discussions with a Nasdaq company at risk of being below the $5 million MVLS requirement and are exploring other potential merger opportunities with investment banking houses on a non-exclusive basis. While these activities are potentially material to our business, there is no assurance that we will complete a merger transaction once Nasdaq's increased MVLS requirement is implemented.

Strategy to fund clinical progression with reduced shareholder dilution

Independent of our pursuit of a merger transaction, we plan to establish a Sigyn owned private subsidiary to fund the clinical progression of CardioDialysis at valuations potentially more favorable as compared to our current public market value. This action would also provide access to investment funds that are restricted from investing in OTC listed securities.

While the completion of a Nasdaq merger may enhance market liquidity and visibility, we can't assume that market value will increase accordingly. In this regard, the following assessment reinforces our rationale to establish a private entity.

Excluding mainstream dialysis providers, three Nasdaq-listed companies are focused on the advancement of blood purification therapies. One is clinical-stage and the other two are considered commercial-stage organizations. In the past year, the share prices of these organizations have declined approximately 95%, 85%, and 34%, respectively. In recent years, the company with the smallest share price decline saw its market capitalization descend from a peak of approximately $800 million to a present value of approximately $44 million.

Historically, public companies are often valued at a premium to comparable private organizations. That is not necessarily the case at present. At present, a private pre-clinical stage blood purification company is raising capital at a $59 million valuation, which exceeds the combined market capitalization of the three Nasdaq-listed companies referenced above.

This variance in valuation raises the question to what extent we can reduce shareholder dilution if capital can be raised at higher valuations through a private entity? It is certainly not hard to envision CardioDialysis being funded at more favorable valuations through a private subsidiary.

As CardioDialysis offers potential strategic value to the dialysis industry, we also recognize that a private subsidiary may be a more attractive acquisition candidate as an acquirer could avoid inheriting legacy liabilities, public disclosure obligations, and the non-core assets of a public parent company. To be clear, we are not currently in acquisition discussions with a dialysis company.

With respect to our oncology assets, they are not contributing quantifiable value at present. While these are early-stage programs, we plan to assess the rationale to advance ImmunePrep(TM) (optimization of immunotherapeutic antibodies), ChemoPrep(TM) (enhanced delivery of chemotherapy), and ChemoPure(TM) (reduction of chemotherapy-related toxicity) within a private subsidiary that might evolve to become a valued asset on the balance sheet of Sigyn Therapeutics.

In closing, we appreciate your support and look forward to providing continued updates as we advance our therapeutic and corporate endeavors. If you have questions or comments, I can be reached at *jj@sigyntherapeutics.com*.

Sincerely, Jim

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

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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.