

**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): October 4, 2023

SIGYN THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

333-204486
(Commission
File Number)

47-2573116
(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: 619.368.2000

Prior address and phone number:

2468 Historic Decatur Road, Suite 140
San Diego, CA
(Address of principal executive offices)

92106
(Zip Code)

619.353.0800

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 7.01 Regulation FD Disclosure.

On October 4, 2023, Sigyn Therapeutics, Inc. (the “Company”) issued a press release announcing a PCT patent submission to enhance chemotherapy delivery and reduce cancer treatment toxicity. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information included in this Item 7.01 “Regulation FD Disclosure” and Exhibit 99.1 is being furnished and 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 the liabilities of that Section, nor shall it be incorporated by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

ITEM 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated October 4, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 4, 2023

By: /s/ James A. Joyce

James A. Joyce, Chairman and CEO

Sigyn Therapeutics™ Discloses PCT Patent Submission to Enhance Chemotherapy Delivery and Reduce Cancer Treatment Toxicity

OCTOBER 04, 2023 8:30AM EDT SAN DIEGO, CA, Oct. 04, 2023 (GLOBE NEWSWIRE) — via [NewMediaWire](#) — Sigyn Therapeutics, Inc. (“Sigyn” or the “Company”) (OTCQB: SIGY), a development-stage medical technology company, today disclosed the submission of a Patent Cooperation Treaty (PCT) application entitled: “*SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY.*”

The PCT submission is associated with medical technologies being advanced by Sigyn Therapeutics to enhance the clinical benefit of chemotherapeutic drugs administered to cancer patients. Among therapeutic technologies being developed by the Company are ChemoPrep™ and ChemoPure™. Chemotherapy is the most commonly administered drug to treat cancer, the second leading cause of death in the United States. Despite utility across a broad-spectrum of cancers, there remains a critical need to optimize chemotherapy delivery as less than 5% of administered doses reach their tumor-site target.

ChemoPrep™ is being advanced to extract circulating molecules that restrict the tumor-site delivery of chemotherapy and induce an unresponsiveness to therapy (chemoresistance) associated with 90% of metastatic cancer deaths. The clinical intent of ChemoPrep™ is to safely increase the tumor-site saturation of chemotherapeutic agents with reduced doses. Achievement of this objective will likely improve treatment outcomes yet reduce treatment toxicity and long-term health consequences associated with chemotherapy administration. Beyond the potential to increase survival and enhance patient quality of life, reduced dosing of chemotherapeutic agents may alleviate ongoing supply chain issues associated with nationwide shortages of chemotherapy.

Post infusion of chemotherapy, Sigyn Therapeutics designed ChemoPure™ to extract off-target drug agents from the bloodstream as a means to further reduce patient toxicity.

The Patent Cooperation Treaty (PCT) is an international treaty with more than 150 Contracting States. A PCT submission makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single “international” patent application instead of filing multiple national or regional patent applications. However, the granting of patents remains under the control of the national or regional patent offices. Sigyn Therapeutics previously disclosed that a related provisional patent application was filed with the United States Patent and Trademark Office (“USPTO”).

About Sigyn Therapeutics™

Sigyn Therapeutics is a development-stage medical technology company headquartered in San Diego, California. The Company plans to become a clinical-stage organization through first-in-human studies of Sigyn Therapy, a blood purification technology to treat pathogen-induced disorders that are not addressed with FDA approved therapies. Candidate treatment indications include community-acquired pneumonia, drug-resistant virus and bacterial infections, endotoxemia, and sepsis, the leading cause of hospital deaths in the United States.

Sigyn Therapeutics also develops therapeutic technologies to enhance the performance of cancer therapies. Sigyn Therapeutics designed ChemoPrep™ to improve the tumor-site delivery of chemotherapeutic agents and reduce their toxicity. ChemoPure™ extracts off-target chemotherapy from the bloodstream to further reduce treatment toxicity. ImmunePrep™ is a novel commercialization platform to enhance efficacy of monoclonal antibodies (including cancer checkpoint inhibitors) and antibody drug-conjugates (ADCs).

To learn more about Sigyn Therapeutics, 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 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 its therapeutic technologies in human studies required for market clearance, the Company’s ability to manufacture its therapeutic technologies, 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, 2022, 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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