

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2025

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number **000-55575**

SIGYN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

84-4210559

(IRS Employer
File Number)

**2305 Historic Decatur Road Ste., 100, San Diego,
California**

(Address of principal executive offices)

92106

(zip code)

(619) 353-0800

(Registrant's telephone number, including area code)

**2468 Historic Decatur Road, Suite 140
San Diego, California 92106**

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None		

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.0001 Par Value

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by checkmark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 14, 2025, there were 1,605,377 shares of common stock outstanding.

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DISCLOSURE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Description of Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “seeks,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “would” and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. The following factors, among others, could cause actual results to differ materially from those described in these forward-looking statements: the ability of Sigyn to meet its financial and strategic goals, due to, among other things, competition; the ability of Sigyn to grow and manage growth profitability and retain its key employees; the possibility that the Sigyn may be adversely affected by other economic, business, and/or competitive factors; risks relating to the successful development of Sigyn’s product candidates; the ability to successfully complete planned clinical studies of its product candidates; the risk that we may not fully enroll our clinical studies or enrollment will take longer than expected; risks relating to the occurrence of adverse safety events and/or unexpected concerns that may arise from data or analysis from our clinical studies; changes in applicable laws or regulations; expected initiation of the clinical studies, the timing of clinical data; the outcome of the clinical data, including whether the results of such study is positive or whether it can be replicated; the outcome of data collected, including whether the results of such data and/or correlation can be replicated; the timing, costs, conduct and outcome of our other clinical studies; the anticipated treatment of future clinical data by the FDA, the EMA or other regulatory authorities, including whether such data will be sufficient for approval; the success of future development activities for its product candidates; potential indications for which product candidates may be developed; the expected duration over which Sigyn’s balances will fund its operations; and other risks and uncertainties described herein, as well as those risks and uncertainties discussed from time to time in other reports and other public filings with the SEC by Sigyn.

Also, forward-looking statements represent our estimates and assumptions only as of the date of this report. You should read this report and the documents that we reference and filed as exhibits to this report completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

USE OF CERTAIN DEFINED TERMS

Except as otherwise indicated by the context, references in this report to “we,” “us,” “our,” “our Company,” or “the Company” is of Sigyn Therapeutics, Inc.

In addition, unless the context otherwise requires and for the purposes of this report only:

- “Sigyn” refers to Sigyn Therapeutics, Inc., a Delaware corporation;
- “Commission” refers to the Securities and Exchange Commission;
- “Exchange Act” refers to the Securities Exchange Act of 1934, as amended; and
- “Securities Act” refers to the Securities Act of 1933, as amended.

PART 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SIGYN THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash	\$ 85,571	\$ 12,144
Other current assets	-	9,100
Total current assets	85,571	21,244
Property and equipment, net	-	9,685
Operating lease right-of-use assets, net	-	112,079
Other assets	50,000	70,711
Total assets	\$ 135,571	\$ 213,719
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 773,604	\$ 608,384
Accrued payroll and payroll taxes	2,279,731	1,868,973
Short-term promissory notes, less unamortized debt issuance costs of \$22,363 and \$139,794, respectively	304,637	174,206
Convertible notes payable, less unamortized debt issuance costs of \$319,593 and \$130,252, respectively	446,225	1,891,736
Derivative liability	181,362	-
Current portion of operating lease liabilities	-	69,946
Other current liabilities	3,932	1,742
Total current liabilities	3,989,491	4,614,987
Long-term liabilities:		
Long-term convertible notes payable, less unamortized debt issuance costs of \$720,687 and \$0, respectively, net of current	2,063,289	-
Operating lease liabilities, net of current portion	-	56,356
Total long-term liabilities	2,063,289	56,356
Total liabilities	6,052,780	4,671,343
Stockholders' deficit:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; 5,107 and 2,403 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	-	-
Common stock, \$0.0001 par value, 100,000,000 shares authorized; 1,605,377 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	161	161
Additional paid-in capital	11,462,608	10,223,939
Accumulated deficit	(17,379,978)	(14,681,724)
Total stockholders' deficit	(5,917,209)	(4,457,624)
Total liabilities and stockholders' deficit	\$ 135,571	\$ 213,719

See accompanying notes to unaudited condensed consolidated financial statements.

SIGYN THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2025	2024	2025	2024
Net revenues	\$ -	\$ -	\$ -	\$ -
Gross Profit	-	-	-	-
Operating expenses:				
Marketing expenses	236	460	52	114
Stock based compensation	150,000	112,500	50,000	37,500
Research and development	46,004	679,183	29,681	206,161
General and administrative	1,205,861	1,249,089	306,796	564,683
Total operating expenses	1,402,101	2,041,232	386,529	808,458
Loss from operations	(1,402,101)	(2,041,232)	(386,529)	(808,458)
Other expense:				
Other income	(5,797)	-	-	-
Modification of warrants	17,505	24,770	-	24,770
Inducement of preferred shares	845,901	-	-	-
Interest expense	3,345	2,931	2,024	850
Interest expense - debt discount	140,090	423,663	70,211	263,719
Interest expense - original issuance costs	295,109	324,798	119,739	99,126
Total other expense	1,296,153	776,162	191,974	388,465
Loss before income taxes	(2,698,254)	(2,817,394)	(578,503)	(1,196,923)
Income taxes	-	-	-	-
Net loss	\$ (2,698,254)	\$ (2,817,394)	\$ (578,503)	\$ (1,196,923)
Net loss per share, basic and diluted	<u><u>\$ (1.68)</u></u>	<u><u>\$ (2.26)</u></u>	<u><u>\$ (0.36)</u></u>	<u><u>\$ (0.94)</u></u>
Weighted average number of shares outstanding				
Basic and diluted	<u>1,605,377</u>	<u>1,245,885</u>	<u>1,605,377</u>	<u>1,268,795</u>

See accompanying notes to unaudited condensed consolidated financial statements.

SIGYN THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2023	32	\$ -	1,288,415	\$ 129	\$ 7,928,883	\$ (11,341,512)	\$ (3,412,500)
Cancellation of common stock - related party	-	-	(64,100)	(7)	7	-	-
Post split rounding of shares	-	-	512	-	-	-	-
Stock based compensation	-	-	-	-	37,500	-	37,500
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	111,834	-	111,834
Net loss	-	-	-	-	-	(758,088)	(758,088)
Balance as of March 31, 2024	32	\$ -	1,224,827	\$ 122	\$ 8,078,224	\$ (12,099,600)	\$ (4,021,254)
Common stock issued to third parties in conjunction with conversion of debt	-	-	38,826	4	232,933	-	232,937
Preferred stock issued to third parties in conjunction with conversion of debt	1,116	-	-	-	841,418	-	841,418
Stock based compensation	-	-	-	-	37,500	-	37,500
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	99,641	-	99,641
Net loss	-	-	-	-	-	(862,383)	(862,383)
Balance as of June 30, 2024	1,148	\$ -	1,263,653	\$ 126	\$ 9,289,716	\$ (12,961,983)	\$ (3,672,141)
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	179,161	-	179,161
Common stock issued to third parties in conjunction with conversion of debt	-	-	118,700	12	474,782	-	474,794
Common stock issued to third party for services	-	-	38,325	4	214,546	-	214,550
Stock based compensation	-	-	-	-	37,500	-	37,500
Warrants issued to third parties for services	-	-	-	-	15,703	-	15,703
Modification of warrants	-	-	-	-	24,770	-	24,770
Net loss	-	-	-	-	-	(1,196,923)	(1,196,923)
Balance as of September 30, 2024	1,148	\$ -	1,420,678	\$ 142	\$ 10,236,178	\$ (14,158,906)	\$ (3,922,586)
Balance as of December 31, 2024	2,403	-	1,605,377	161	10,223,939	14,681,724	(4,457,624)
Stock based compensation	-	-	-	-	50,000	-	50,000
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	130,981	-	130,981
Net loss	-	-	-	-	-	(668,564)	(668,564)
Balance as of March 31, 2025	2,403	\$ -	1,605,377	\$ 161	\$ 10,404,920	\$ (15,350,288)	\$ (4,945,207)
Stock based compensation	-	-	-	-	50,000	-	50,000
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	45,359	-	45,359
Modification of warrants	-	-	-	-	17,505	-	17,505
Inducement of preferred shares	2,704	-	-	-	845,901	-	845,901
Net loss	-	-	-	-	-	(1,451,187)	(1,451,187)
Balance as of June 30, 2025	5,107	\$ -	1,605,377	\$ 161	\$ 11,363,685	\$ (16,801,475)	\$ (5,437,629)
Stock based compensation	-	-	-	-	50,000	-	50,000
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	48,923	-	48,923
Net loss	-	-	-	-	-	(578,503)	(578,503)
Balance as of September 30, 2025	5,107	\$ -	1,605,377	\$ 161	\$ 11,462,608	\$ (17,379,978)	\$ (5,917,209)

See accompanying notes to unaudited condensed consolidated financial statements.

SIGYN THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (2,698,254)	\$ (2,817,394)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,363	4,248
Stock based compensation	150,000	112,500
Accretion of debt discount	140,090	423,663
Accretion of original issuance costs	295,109	324,798
Modification of warrants	17,505	24,770
Inducement of preferred shares	845,901	-
Settlement of lease	(5,798)	-
Stock issued for services	-	214,550
Warrants issued for services	-	15,703
Changes in operating assets and liabilities:		
Other current assets	8,997	2,053
Other assets	20,711	-
Accounts payable	165,220	149,997
Accrued payroll and payroll taxes	410,758	969,890
Other current liabilities	2,190	(6,996)
Net cash used in operating activities	(646,208)	(582,218)
Cash flows from financing activities:		
Proceeds from short-term convertible notes	706,635	771,890
Proceeds from short-term promissory notes	13,000	-
Advance from shareholder	-	35,000
Repayments of advance from shareholder	-	(71,574)
Net cash provided by financing activities	719,635	735,316
Net increase in cash	73,427	153,098
Cash at beginning of period	12,144	11,690
Cash at end of period	\$ 85,571	\$ 164,788
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
Non-cash investing and financing activities:		
Warrants issued to third parties in conjunction with debt issuance	\$ 414,687	\$ 390,637
Derivative liability in conjunction with debt issuance	\$ 181,362	\$ -
Original issue discount issued in conjunction with debt	\$ 75,320	\$ 80,739
Original issue discount issued in conjunction with extension of debt	\$ 737,788	\$ 184,471
Common stock issued to third parties in conjunction with conversion of debt	\$ -	\$ 707,730
Preferred stock issued to third parties in conjunction with conversion of debt	\$ -	\$ 841,419
Cancellation of common stock – related party	\$ -	\$ 7

See accompanying notes to unaudited condensed consolidated financial statements.

SIGYN THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

Corporate History and Background

Sigyn Therapeutics, Inc. (“Sigyn”, the “Company” “we,” “us,” or “our”) is a development-stage Company advancing dialysis-like therapies to address cardiovascular disease and cancer. Sigyn CardioDialysis™ (previously known as Sigyn Therapy™) is a novel blood purification technology to treat cardiovascular disease, the leading cause of death globally. CardioDialysis™ 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™ offers to reduce the incidence of MACE by overcoming the inherent limitations of single-target drugs.

Our development pipeline of cancer therapies is comprised of ImmunePrep™ to optimize the delivery of immunotherapeutic antibodies; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy.

Recent Event

On November 6, 2025, we disclosed in a letter to shareholders the filing of a trademark application with the United States Patent and Trademark Office to protect the name CardioDialysis™. The action reflects our intent to shift the previous therapeutic focus of Sigyn Therapy™ toward cardiovascular disease.

This action provides us a pathway into a larger market opportunity, for which there is an FDA-approved device precedent that clinically demonstrates the ability of blood purification to reduce Major Adverse Cardiovascular Disease Events (MACE). As compared to our previously proposed treatment indications, we believe it will be significantly less burdensome to enroll cardiovascular disease subjects into pivotal efficacy studies that will be required for FDA market approval. Furthermore, we consider our potential value to the dialysis industry as a majority of their patients die from cardiovascular disease related events. Our previously proposed indications, which included the treatment of sepsis, drug-resistant bacterial infections, and life-threatening viruses will become downstream therapeutics opportunities.

Merger Transaction

On October 19, 2020, Sigyn Therapeutics, Inc, a Delaware corporation (the “Registrant”) formerly known as Reign Resources Corporation, completed a Share Exchange Agreement (the “Agreement”) with Sigyn Therapeutics, Inc., a private entity incorporated in the State of Delaware on October 19, 2019.

In the Share Exchange Agreement, we acquired 100% of the issued and outstanding shares of privately held Sigyn Therapeutics common stock in exchange for 75% of the fully paid and nonassessable shares of our common stock outstanding (the “Acquisition”). In conjunction with the transaction, we changed our name from Reign Resources Corporation to Sigyn Therapeutics, Inc. pursuant to an amendment to our articles of incorporation that was filed with the State of Delaware. Subsequently, our trading symbol was changed to SIGY. The Acquisition was treated by the Company as a reverse merger in accordance with accounting principles generally accepted in the United States of America (“GAAP”).

NOTE 2 – BASIS OF PRESENTATION

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and include all adjustments necessary for the fair presentation of the Company’s financial position and results of operations for the periods presented.

The Company currently operates in one business segment. The Company is not organized by market and is managed and operated as one business. A single management team reports to the chief operating decision maker, the Chief Executive Officer, who comprehensively manages the entire business. The Company does not currently operate any separate lines of businesses or separate business entities.

Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company had an accumulated deficit of \$17,379,978 at September 30, 2025, had a working capital deficit of \$3,903,920 at September 30, 2025, had net losses of \$578,503 and \$2,698,254, and \$1,196,923 and \$2,817,394 for the three and nine months ended September 30, 2025 and 2024, respectively, and net cash used in operating activities of \$646,208 and \$582,218 for the nine months ended September 30, 2025 and 2024, respectively, with no revenue earned since inception, and a lack of operational history. These matters raise substantial doubt about the Company's ability to continue as a going concern.

While the Company is attempting to expand operations and increase revenues, the Company's cash position may not be significant enough to support the Company's daily operations. Management intends to raise additional funds by way of a public offering or an asset sale transaction. Management believes that the actions presently being taken to further implement its business plan and generate revenues provide the opportunity for the Company to continue as a going concern. While management believes in the viability of its strategy to generate revenues and in its ability to raise additional funds or transact an asset sale, there can be no assurances to that effect or on terms acceptable to the Company. The ability of the Company to continue as a going concern is dependent upon the Company's ability to further implement its business plan and generate revenues.

The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern for a year from the date of issuance.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This summary of significant accounting policies of the Company is presented to assist in understanding the Company's financial statements. The financial statements and notes are representations of the Company's management, which is responsible for their integrity and objectivity. These accounting policies conform to GAAP and have been consistently applied in the preparation of the financial statements.

Use of Estimates

The preparation of these financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of net sales and expenses during the reported periods. Actual results may differ from those estimates, and such differences may be material to the financial statements. The more significant estimates and assumptions by management include among others: warrant valuation and the derivative liability embedded in the convertible note. The Company calculates the fair value of warrants using the Black-Scholes option-pricing method and calculates the fair value of the derivative liability using the binomial option-pricing method. The Black-Scholes and the binomial option-pricing methods requires the use of subjective assumptions, including stock price volatility, the expected life of stock options, risk free interest rate and the fair value of the underlying common stock on the date of grant. The current economic environment has increased the degree of uncertainty inherent in these estimates and assumptions.

Cash

The Company's cash is held in bank accounts in the United States and is insured by the Federal Deposit Insurance Corporation (FDIC) up to \$250,000. The Company has not experienced any cash losses.

Income Taxes

Income taxes are accounted for under an asset and liability approach. This process involves calculating the temporary and permanent differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The temporary differences result in deferred tax assets and liabilities, which would be recorded on the Balance Sheets in accordance with ASC 740, which established financial accounting and reporting standards for the effect of income taxes. The likelihood that its deferred tax assets will be recovered from future taxable income must be assessed and, to the extent that recovery is not likely, a valuation allowance is established. Changes in the valuation allowance in a period are recorded through the income tax provision in the unaudited condensed consolidated Statements of Operations.

ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in an entity's consolidated financial statements and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under ASC 740-10, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, ASC 740-10 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. As a result of the implementation of ASC 740-10 and currently, the Company does not have a liability for unrecognized income tax benefits.

Advertising and Marketing Costs

Advertising expenses are recorded as general and administrative expenses when they are incurred. The Company had \$52 and \$236, and \$114 and \$460 of advertising expenses for the three and nine months ended September 30, 2025 and 2024, respectively.

Research and Development

All research and development costs are expensed as incurred. The Company incurred research and development expense of \$29,681 and \$46,004, and \$206,161 and \$679,183 for the three and nine months ended September 30, 2025 and 2024, respectively.

Inventories

In conjunction with the October 19, 2020 Share Exchange Agreement, the Company kept the gem inventory of Reign Resources Corporation. Inventories are stated at the lower of cost or market (net realizable value) on a lot basis each quarter. A lot is determined by the cut, clarity, size, and weight of the sapphires. Inventory consists of sapphire jewels that meet rigorous grading criteria and are of cuts and sizes most commonly used in the jewelry industry. As of September 30, 2025 and December 31, 2024, the Company carried primarily loose sapphire jewels, jewelry for sale, and jewelry held as samples. Samples are used to show potential customers what the jewelry would look like. Promotional items given to customers that are not expected to be returned will be removed from inventory and expensed. There have been no promotional items given to customers as of September 30, 2025. The Company performs its own in-house assessment based on gem guide and the current market price for metals to value its inventory on an annual basis or if circumstances dictate sooner to determine if the estimated fair value is greater or less than cost. In addition, the inventory is reviewed each quarter by the Company against industry prices from gem-guide and if there is a potential impairment, the Company would appraise the inventory. The estimated fair value is subject to significant change due to changes in popularity of cut, perceived grade of the clarity of the sapphires, the number, type and size of inclusions, the availability of other similar quality and size sapphires, and other factors. As a result, the internal assessed value of the sapphires could be significantly lower from the current estimated fair value. Loose sapphire jewels do not degrade in quality over time. As the Company does not have any current plans to dispose of the inventory, the Company included the inventory in Other Assets in the unaudited condensed consolidated balance sheets as of September 30, 2025 and December 31, 2024.

Property and Equipment

Property and equipment are carried at cost and are depreciated on a straight-line basis over the estimated useful lives of the assets, generally five years. The cost of repairs and maintenance is expensed as incurred; major replacements and improvements are capitalized. When assets are retired or disposed of, the cost and accumulated depreciation are removed from the accounts, and any resulting gains or losses are included in income in the year of disposition.

Impairment of Long-lived Assets

We periodically evaluate whether the carrying value of property, equipment and intangible assets has been impaired when circumstances indicate the carrying value of those assets may not be recoverable. The carrying amount is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. If the carrying value is not recoverable, the impairment loss is measured as the excess of the asset's carrying value over its fair value.

Our impairment analyses require management to apply judgment in estimating future cash flows as well as asset fair values, including forecasting useful lives of the assets, assessing the probability of different outcomes, and selecting the discount rate that reflects the risk inherent in future cash flows. If the carrying value is not recoverable, we assess the fair value of long-lived assets using commonly accepted techniques, and may use more than one method, including, but not limited to, recent third-party comparable sales and discounted cash flow models. If actual results are not consistent with our assumptions and estimates, or our assumptions and estimates change due to new information, we may be exposed to an impairment charge in the future. As of September 30, 2025 and December 31, 2024, the Company had not experienced impairment losses on its long-lived assets.

Fair Value of Financial Instruments

The provisions of accounting guidance, FASB Topic ASC 825 requires all entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet, for which it is practicable to estimate fair value, and defines fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties. As of September 30, 2025 and December 31, 2024, the fair value of cash, accounts payable, accrued expenses, advance from shareholder, and notes payable approximated carrying value due to the short maturity of the instruments, quoted market prices or interest rates which fluctuate with market rates.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability, in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs, of which the first two are considered observable and the last unobservable, as follows:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities

The carrying value of financial assets and liabilities recorded at fair value are measured on a recurring or nonrecurring basis. Financial assets and liabilities measured on a non-recurring basis are those that are adjusted to fair value when a significant event occurs. There were no financial assets or liabilities carried and measured on a nonrecurring basis during the reporting periods. Financial assets and liabilities measured on a recurring basis are those that are adjusted to fair value each time a financial statement is prepared. There have been no transfers between levels.

Debt

The Company issues debt that may have separate warrants, conversion features, or equity-linked attributes.

Embedded Conversion Features

The Company evaluates embedded conversion features within convertible debt under ASC 815, *Derivatives and Hedging*, to determine whether the embedded conversion feature(s) should be bifurcated from the host instrument and accounted for as a derivative at fair value with changes in fair value recorded in earnings. If the conversion feature does not require derivative treatment under ASC 815, the instrument is evaluated under ASC 470-20, *Debt with Conversion and Other Options*, for consideration of any beneficial conversion feature.

Derivative Financial Instruments

The Company evaluates all of its financial instruments, including stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported as charges or credits to income.

For option-based simple derivative financial instruments, the Company uses the Monte Carlo simulations to value the derivative instruments at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. There were derivative financial instruments of \$181,362 and \$0 as of September 30, 2025 and December 31, 2024, respectively, and no charges or credits to income for the three and nine months ended September 30, 2025 and 2024.

Debt Issue Costs and Debt Discount

The Company may record debt issue costs and/or debt discounts in connection with raising funds through the issuance of debt. These costs may be paid in the form of cash or equity (such as warrants). These costs are amortized to interest expense through the maturity of the debt. If a conversion of the underlying debt occurs prior to maturity a proportionate share of the unamortized amounts is immediately expensed. Any unamortized debt issue costs and debt discount are presented net of the related debt on the unaudited condensed consolidated balance sheets.

Original Issue Discount

For certain convertible debt issued, the Company may provide the debt holder with an original issue discount. The original issue discount would be recorded to debt discount, reducing the face amount of the note and is amortized to interest expense through the maturity of the debt. If a conversion of the underlying debt occurs prior to maturity a proportionate share of the unamortized amounts is immediately expensed. Any unamortized original issue discounts are presented net of the related debt on the unaudited condensed consolidated balance sheets.

If the conversion feature does not qualify for derivative treatment, the convertible debt is treated as traditional debt.

Basic and diluted earnings per share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted earnings (loss) per share are computed on the basis of the weighted average number of common shares (including common stock subject to redemption) plus dilutive potential common shares outstanding for the reporting period. In periods where losses are reported, the weighted-average number of common stock outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive.

Basic and diluted earnings (loss) per share are the same since net losses for all periods presented and including the additional potential common shares would have an anti-dilutive effect.

Stock Based Compensation

In accordance with ASC No. 718, *Compensation – Stock Compensation* (“ASC 718”), we measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees are required to provide services. Share-based compensation arrangements include stock options, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. As such, compensation cost is measured on the date of grant at their fair value. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

Non-Employee Stock-Based Compensation

In accordance with ASC 718, issuances of the Company's common stock or warrants for acquiring goods or services are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The measurement date for the fair value of the equity instruments issued to consultants or vendors is determined at the earlier of (i) the date at which a commitment for performance to earn the equity instruments is reached (a "performance commitment" which would include a penalty considered to be of a magnitude that is a sufficiently large disincentive for nonperformance) or (ii) the date at which performance is complete. Although situations may arise in which counter performance may be required over a period of time, the equity award granted to the party performing the service is fully vested and non-forfeitable on the date of the agreement. As a result, in this situation in which vesting periods do not exist as the instruments fully vested on the date of agreement, the Company determines such date to be the measurement date and will record the estimated fair market value of the instruments granted as a prepaid expense and amortize such amount to general and administrative expense in the accompanying statement of operations over the contract period. When it is appropriate for the Company to recognize the cost of a transaction during financial reporting periods prior to the measurement date, for purposes of recognition of costs during those periods, the equity instrument is measured at the then-current fair values at each of those interim financial reporting dates.

Concentrations, Risks, and Uncertainties

Business Risk

Substantial business risks and uncertainties are inherent to an entity, including the potential risk of business failure.

The Company is headquartered and operates in the United States. To date, the Company has generated no revenues from operations. There can be no assurance that the Company will be able to raise additional capital and failure to do so would have a material adverse effect on the Company's financial position, results of operations and cash flows. Also, the success of the Company's operations is subject to numerous contingencies, some of which are beyond management's control. Currently, these contingencies include general economic conditions, price of components, competition, and governmental and political conditions.

Interest rate risk

Financial assets and liabilities do not have material interest rate risk.

Credit risk

The Company is exposed to credit risk from its cash in banks. The credit risk on cash in banks is limited because the counterparties are recognized financial institutions.

Seasonality

The business is not subject to substantial seasonal fluctuations.

Major Suppliers

CardioDialysis™ is comprised of components that are supplied by various industry vendors. Additionally, the Company is reliant on third-party organizations to conduct clinical development studies that are necessary to advance CardioDialysis™ toward the marketplace.

Should the relationship with an industry vendor or third-party clinical development organization be interrupted or discontinued, it is believed that alternate component suppliers and third-party clinical development organizations could be identified to support the continued advancement of CardioDialysis™.

Recent Accounting Pronouncements

There are no recently issued accounting updates that are expected to have a material impact on the Company's consolidated financial statements except for:

In November 2024, the FASB issued ASU 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which is intended to improve disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses in commonly presented expense captions. Such information should allow investors to better understand an entity's performance, assess future cash flows, and compare performance over time and with other entities. The amendments will require public business entities to disclose in the notes to the financial statements, at each interim and annual reporting period, specific information about certain costs and expenses, including purchases of inventory, employee compensation, depreciation, and intangible asset amortization included in each expense caption presented on the face of the income statement, and the total amount of an entity's selling expenses. The amendments are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, and may be applied either prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on the consolidated financial statements.

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of:

	Estimated Life	September 30, 2025	December 31, 2024
Office equipment	5 years	\$ -	\$ 29,041
Computer equipment	3 years	-	3,157
Accumulated depreciation		-	(22,513)
		<u>\$ -</u>	<u>\$ 9,685</u>

Depreciation expense was \$0 and \$1,363, and \$1,363 and \$4,248 for the three and nine months ended September 30, 2025 and 2024, respectively, and is classified in general and administrative expenses in the unaudited condensed consolidated statements of operations.

NOTE 5 – CONVERTIBLE PROMISSORY DEBENTURES

Convertible notes payable consisted of the following:

Note Holder/Original Issuance Date	Maturity Date	Cash Received	Outstanding Balance as of September 30, 2025	Outstanding Balance as of December 31, 2024
<i>Osher Capital Partners LLC</i>				
January 28, 2020 ("Note 1")	December 31, 2027	\$ 350,005	\$ 834,771	\$ 620,553
June 22, 2022 ("Note 2")	December 31, 2027	75,000	139,559	103,745
August 31, 2022 ("Note 2")	December 31, 2027	100,000	182,302	135,520
September 20, 2022 ("Note 2")	December 31, 2027	100,000	182,302	135,520
October 20, 2022 ("Note 2")	December 31, 2027	100,000	178,670	127,000
November 14, 2022 ("Note 2")	December 31, 2027	50,000	90,531	64,350
December 22, 2022 ("Note 2")	December 31, 2027	100,000	175,856	125,000
July 18, 2023 ("Note 3")	December 31, 2027	60,000	97,662	72,600
December 7, 2023 ("Note 3")	December 31, 2027	40,000	65,108	48,400
May 13, 2024 ("Note 4")	December 31, 2027	35,000	55,584	40,000
August 19, 2024 ("Note 4")	December 31, 2027	7,500	11,139	8,250
November 19, 2024 ("Note 4")	December 31, 2027	8,000	11,556	8,800
April 15, 2025	December 31, 2027	20,000	27,570	-
<i>Brio Capital Master Fund, Ltd.</i>				
March 23, 2022 ("Note 2")	December 31, 2027	100,000	192,311	142,960
November 9, 2022 ("Note 2")	December 31, 2027	75,000	136,727	101,640
January 20, 2023 ("Note 3")	December 31, 2027	50,000	87,928	62,500
February 9, 2023 ("Note 3")	December 31, 2027	50,000	87,928	62,500
July 20, 2023 ("Note 3")	December 31, 2027	40,000	65,108	48,400
January 8, 2024 ("Note 4")	December 31, 2027	40,000	63,402	44,000
May 13, 2024 ("Note 4")	December 31, 2027	35,000	55,584	40,000
August 20, 2024 ("Note 4")	December 31, 2027	11,500	17,074	12,650
November 19, 2024 ("Note 4")	December 31, 2027	8,000	11,556	8,800
April 23, 2025	December 31, 2027	10,000	13,748	-
July 21, 2025	July 21, 2026	5,000	5,500	-
<i>Various third-party noteholders</i>				
Various dates in fiscal 2024 ("Note 4")	November 19, 2025	8,000	8,800	8,800
	Due on various dates from April 15, 2026 through September 12, 2026			
Various dates in fiscal 2025 ("Note 5")		334,500	371,800	-
FY 2025 Regulation D	Primarily January 9, 2026	345,197	379,717	-
Total convertible notes payable		<u>\$ 2,157,702</u>	<u>\$ 3,549,793</u>	<u>\$ 2,021,988</u>
Original issue discount			(753,298)	(117,868)
Debt discount			<u>(286,981)</u>	<u>(12,384)</u>

Total convertible notes payable	\$ 2,509,514	\$ 1,891,736

Principal payments on convertible promissory debentures are due as follows:

Year ending December 31,	
2025 (excluding the nine months ended September 30, 2025)	\$ 8,800
2026	757,018
2027	2,783,975
	<u>\$ 3,549,793</u>

Changes in convertible notes were as follows:

	Note 1	Note 2	Note 3	Note 4	Reg D	Note 5	Totals
Convertible notes payable as of December 31, 2023	\$ 864,136	\$ 1,379,500	\$ 264,000	\$ -	\$ -	\$ -	\$ 2,507,636
Convertible notes payable issued in 2024	56,416	97,655	30,400	879,029	-	-	1,063,500
Conversion of debt for common stock	(299,999)	(541,419)	-	(707,730)	-	-	(1,549,148)
Convertible notes payable as of December 31, 2024	\$ 620,553	\$ 935,736	\$ 294,400	\$ 171,299	\$ -	\$ -	\$ 2,021,988
Convertible notes payable issued in 2025	-	-	-	-	379,717	410,300	790,017
Extension of convertible notes payable	214,218	342,522	109,334	63,396	-	8,318	737,788
Convertible notes payable as of September 30, 2025	\$ 834,771	\$ 1,278,258	\$ 403,734	\$ 234,695	\$ 379,717	\$ 418,618	\$ 3,549,793

Changes in note discounts were as follows:

	Note 1	Note 2	Note 3	Note 4	Reg D	Note 5	Totals
Note discounts as of December 31, 2023	\$ 114,995	\$ 100,810	\$ 81,532	\$ -	\$ -	\$ -	\$ 297,337
Note discounts issued in conjunction with debt in 2024	56,414	97,657	30,400	487,771	-	-	672,242
2024 accretion of note discounts	(129,214)	(145,792)	(95,981)	(468,340)	-	-	(839,327)
Note discounts as of Dec 31, 2024	\$ 42,195	\$ 52,675	\$ 15,951	\$ 19,431	\$ -	\$ -	\$ 130,252
Note discounts issued in conjunction with debt in 2025	214,219	342,522	109,334	63,395	165,500	332,825	1,227,795
2025 accretion of note discounts	(50,783)	(65,545)	(20,059)	(19,790)	(113,776)	(47,815)	(317,768)
Note discounts as of September 30, 2025	\$ 205,631	\$ 329,652	\$ 105,226	\$ 63,036	\$ 51,724	\$ 285,010	\$ 1,040,279
Convertible notes payable, net, as of Dec 31, 2024	\$ 578,358	\$ 883,061	\$ 278,449	\$ 151,868	\$ -	\$ -	\$ 1,891,736
Convertible notes payable, net, as of September 30, 2025	\$ 629,140	\$ 948,606	\$ 298,508	\$ 171,659	\$ 327,993	\$ 133,608	\$ 2,509,514
2024 Effective interest rate	21%	16%	33%	273%	-%	-%	42%
2025 Effective interest rate	6%	5%	5%	8%	30%	11%	9%

Current Noteholders

Extension of Notes

On August 29, 2025, noteholders Osher and Brio agreed to extend all of their outstanding notes to December 31, 2027 for original issue discount totaling \$737,786. ASC 470-50-40-10, *Modifications and Extinguishments*, provides guidance on whether a modification or exchange of a term loan or debt security should be accounted for as a modification or an extinguishment. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is less than 10 percent, the debt instruments are not considered to be substantially different and deemed to be a modification of the debt instrument. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is greater than 10 percent, the debt instruments are considered to be substantially different and deemed to be an extinguishment of the debt instrument. The Company accounted for the extension of the notes as a modification with no gain or loss recognized since there were no notes where the cash flow effect on present value basis was greater than 10%.

Regulation D

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of \$5,000 per unit with each Unit consisting of one (1) \$5,500 principal amount convertible debenture (convertible at two dollars (\$2.00) per share into the Company's common stock) and a Warrant to purchase 1,250 shares of common stock at \$4.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at \$2.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of \$4.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of September 30, 2025, a total of 69 Units were sold to accredited investors at a price of \$5,500 per Unit totaling \$379,717 (total of \$345,197 cash was received).

2025 Convertible Notes (Note 5)

During fiscal 2025, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2025 Notes") totaling (i) \$178,200 aggregate principal amount of Notes (total of \$162,000 cash was received) due between April and June 2026 based on \$1.00 for each \$0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 80,851 shares of the Company's Common Stock at an exercise price of \$4.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$178,200 which was issued at a \$16,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

In addition, in August and September 2025, the Company entered into two Notes totaling \$232,100 (total of \$207,500 cash was received) that provide for a variable conversion price. The Notes provide for a variable conversion rate per share equal to 65% and 75%, respectively, of the lowest trading price for the proceeding 10 trading days prior to a conversion, are due in one year and provide for interest of 7% to 8% per annum. The Company determined that in accordance with ASC 815-15, *Embedded Derivatives*, it should bifurcate and separately recognize the variable conversion rate at its fair value and at each subsequent measurement date, remeasure its fair value with such changes in fair value recorded in earnings. The Company recognized a total value of \$181,362 as a derivative on the grant dates (based on the Binomial valuation model on the date of grant). During the three and nine months ended September 30, 2025 and 2024, the Company did not recognize a remeasurement to fair value as it was deemed immaterial. The issuances of the foregoing securities are exempt from registration pursuant to Section 4(a)(2) of the Securities Act promulgated thereunder as the Sellers are sophisticated investors and familiar with the Company's operations. No stock purchase warrants were issued as part of the agreement.

On August 29, 2025, two noteholders agreed to extend their notes to December 31, 2027 for original issue discount totaling \$8,316.

2024 Convertible Notes (Note 4)

During fiscal 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) \$171,300 aggregate principal amount of Notes (total of \$153,000 cash was received) due between January and November 2025 based on \$1.00 for each \$0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 80,426 shares of the Company's Common Stock at an exercise price of \$4.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$153,000 which was issued at a \$18,300 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On August 29, 2025, the noteholders agreed to extend the notes to December 31, 2027 for original issue discount totaling \$63,395.

In September 2024, holders converted \$474,794 in exchange for the issuance of 118,700 shares of Common Stock to the holders.

In May and June 2024, holders converted \$232,937 in exchange for the issuance of 38,826 shares of Common Stock to the holders.

2023 Convertible Notes (Note 3)

During fiscal 2023, the Company entered into Original Issue Discount Senior Convertible Debentures (the “2023 Notes”) totaling (i) \$264,400 aggregate principal amount of Notes (total of \$240,000 cash was received) due between January and December 2024 based on \$1.00 for each \$0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 139,500 shares of the Company’s Common Stock at an exercise price of \$4.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$240,000 which was issued at a \$24,400 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On August 29, 2025, the noteholders agreed to extend the notes to December 31, 2027 for original issue discount totaling \$109,334.

On September 30, 2024, a noteholder agreed to extend the note to August 31, 2025 for original issue discount totaling \$15,400.

On April 9, 2024, a noteholder agreed to extend the note to March 31, 2025 for original issue discount totaling \$15,000.

2022 Convertible Notes (Note 2)

During fiscal 2022, the Company entered into Original Issue Discount Senior Convertible Debentures (the “2022 Notes”) totaling (i) \$770,000 aggregate principal amount of Notes (total of \$700,000 cash was received) due between January and December 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 192,500 shares of the Company’s Common Stock at an exercise price of \$4.00 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$700,000 which was issued at a \$70,000 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On August 29, 2025, the noteholders agreed to extend the notes to December 31, 2027 for original issue discount totaling \$342,522.

On September 30, 2024, a noteholder agreed to extend the note to August 31, 2025 for original issue discount totaling \$56,306.

On April 10, 2024, a noteholder agreed to extend the notes to March 2025 for original issue discount totaling \$41,350. During 2023, the noteholders agreed to extend the notes to between August 2024 and March 2025 for original issue discount totaling \$68,078.

Osher – \$620,553 (Note 1)

On January 28, 2020, as subsequently amended, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$385,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due August 30, 2024, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants to purchase up to an aggregate of 102,827 shares of the Company’s Common Stock at an exercise price of \$3.76 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was \$350,005 with a total of \$34,995 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

At various dates from October 2021 through September 2024, the noteholder agreed to extend the note for original issue discount totaling \$235,552 which were due August 31, 2025.

On August 29, 2025, the noteholder agreed to extend the note to December 31, 2027 for original issue discount totaling \$214,219. The note totals \$834,771 as of September 30, 2025 and is included in long term convertible notes payable in the unaudited condensed consolidated balance sheets as of September 30, 2025.

NOTE 6 –PROMISSORY NOTES

On July 3, 2025, the Company entered into a promissory note of \$3,000 due August 15, 2025 and is non-interest bearing. On October 23, 2025, the note was repaid.

On June 9, 2025, the Company entered into a promissory note of \$10,000 due July 31, 2025 and is non-interest bearing. On November 3, 2025, the noteholder agreed to extend the note to January 15, 2026 of original issue discount of \$1,000.

On November 26, 2024, the Company entered into promissory notes totaling \$314,000 aggregate principal amount of promissory notes (total of \$157,000 cash was received) due November 26, 2025 based on \$1.00 for each \$0.50 paid by the noteholders which were issued at a \$157,000 original issue discount from the face value of the promissory notes.

NOTE 7 – STOCKHOLDERS’ DEFICIT

Preferred Stock

The Company authorized 10,000,000 shares of par value \$0.0001 preferred stock, of which 5,107 and 2,403 shares are issued and outstanding as of September 30, 2025 and December 31, 2024, respectively.

On June 5, 2025, as a means to induce further investment from established or candidate shareholders, the Company issued four (4) Series B preferred shares for each \$5,000 of shares previously converted by a Convertible Debenture noteholder. The Company recorded a total inducement of 2,704 Series B preferred shares, valued at \$845,901 (based on the estimated fair value of the stock on the date of grant) in the unaudited condensed consolidated statements of operations.

On April 10, 2024, Osher elected to exchange \$621,000 of Notes for an aggregate of 823.86 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company’s common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio.

On April 9, 2024, Brio elected to exchange \$220,420 of Notes for an aggregate of 292.4 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company’s common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio.

Rights and Privileges - The holders of Series B preferred stock have various rights and preferences as follows:

Rights - The holders of the Series B preferred stock have the same rights as the Common Stock, on an “as-if” converted basis, with respect to any dividends, distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily.

Voting Rights - Shares of Series B preferred stock have no voting rights except on matters adversely affecting the rights of the holders of the Preferred Stock.

Rank - With respect to payment of dividends and distribution of assets upon liquidation or dissolution or winding up of the Corporation, whether voluntary or involuntary, the Series B Preferred Stock shall rank equal to the Common Stock on an as converted basis.

Conversion Rights - The holders of the preferred stock have certain conversion rights of such preferred stock into shares of common stock of the Company. Each share of preferred stock is convertible at the option of the holder at any time into the number of shares of common stock at the quotient of the stated value divided by the conversion price, subject to customary adjustments to protect against dilution.

Redemption Rights – The Series B preferred stock is not subject to any redemption rights.

Common Stock

On December 30, 2024, the Company filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the State of Delaware, which went effective immediately upon filing. The Certificate of Amendment decreased our authorized common stock to One Hundred Million (100,000,000) shares, par value \$0.0001, of which 1,605,377 shares are outstanding as of September 30, 2025 and December 31, 2024.

During the year ended December 31, 2024, the holders of \$707,730 of Original Issue Discount Senior Convertible Debentures converted their debentures in exchange for the issuance of 157,526 shares of Common Stock to the holders.

During the year ended December 31, 2024, the Company issued 38,325 common shares valued at \$214,550 (based on the estimated fair value of the stock on the date of grant), respectively, for services rendered.

Shares Cancelled

On January 9, 2024, the Company's CTO agreed to surrender 64,100 common shares held by him and were cancelled by the Company.

Restricted Stock Units

Effective January 11, 2025 and October 10, 2022, the Company's Board of Directors appointed Mr. Michael Ryan, and Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel, respectively, as non-executive members to the Company's Board of Directors ("Director"). Effective January 1, 2023, each Director shall receive an annual grant of restricted stock units ("RSU's") of \$50,000. During the three and nine months ended September 30, 2025 and 2024, respectively, the Company recorded stock-based compensation totaling \$50,000 and \$150,000, and \$37,500 and \$112,500, respectively, in the unaudited condensed consolidated statements of operations.

On August 8, 2025, Richa Nand and Michael Ryan notified the Company of their decision to resign from the Company's Board of Directors, effective August 8, 2025. On August 7, 2025, Christopher Wetzel (collectively, the "Resigning Directors") notified the Company of his decision to resign from the Board of Directors, effective August 7, 2025. The resignations were based on the Company's discontinuation of directors' and officers' liability insurance coverage which expired on August 4, 2025. The Resigning Directors will vest in previously granted RSU's and beginning October 1, 2025, will no longer receive RSU's as board compensation.

Reverse Stock Split

Effective January 19, 2024, the Board of Directors declared a one-for-forty reverse stock split to shareholders of record on or before January 31, 2024 of the Company's issued and outstanding shares of common stock, outstanding warrants and options, and the Series B Convertible Preferred Stock. The number of shares of common stock and convertible preferred shares obtainable upon exercise or conversion and the exercise prices and conversion rate have been equitably adjusted. As such, all share and per share amounts have been retroactively adjusted to reflect the reverse stock split.

Warrants

During the three months ended September 30, 2025, the Company entered into notes totaling \$90,200 along with 45,100 warrants to purchase up to an aggregate of 45,100 shares of the Company's Common Stock at an exercise price of \$4.00 per share (see Note 5).

On June 5, 2025, as a means to induce further investment from established shareholders, the Company adjusted the conversion price of the Company's outstanding warrants from \$6.00 per share to \$4.00 per share. The Company recognized a loss of \$17,505 due to the modification of the warrants in June 2025 in the unaudited condensed consolidated statements of operations.

On August 24, 2024, the Company issued 3,325 warrants valued at \$15,703 (based on the fair value of the options using the Black-Scholes option-pricing method on the date of grant), for services rendered.

In accordance with ASC 718-20, *Compensation – Stock Compensation*, a modification of a stock award is treated as an exchange of the original award for a new award incurring additional compensation cost for any incremental value resulting from the modification. Incremental compensation cost shall be measured as the excess of the fair value of the modified award over the fair value of the original award immediately before its terms are modified and recognized over the vesting period. A short-term inducement shall be accounted for as a modification of the terms of only those that accept the inducement.

On October 8, 2024, the Company offered a short-term inducement to the Company's warrant holders in which the Company will issue $\frac{3}{4}$ of a share of the Company's common stock in exchange for each warrant. In response to this offer, 246,257 warrants were exchanged for 184,700 shares of the Company's common stock. The Company recognized a gain of \$63,715 due to the modification of the warrants in October 2024.

On September 5, 2024, the Company entered into the 2024 Notes that included warrants at an exercise price of \$7.50 (see Note 5) resulting in a modification of the warrants valued at \$24,770 (based on the Black Scholes options pricing method on the modification date).

NOTE 8 – OPERATING LEASES

On May 27, 2021, the Company entered into a sixty-three month lease for its corporate office at \$5,955 per month commencing June 15, 2021 maturing September 30, 2026. The Company accounts for this lease in accordance with ASC 842. Adoption of the standard resulted in the initial recognition of operating lease ROU asset of \$290,827 and operating lease liability of \$290,827 as of June 15, 2021.

Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Generally, the implicit rate of interest in arrangements is not readily determinable and the Company utilizes its incremental borrowing rate in determining the present value of lease payments. The Company's incremental borrowing rate is a hypothetical rate based on its understanding of what its credit rating would be. The operating lease ROU asset includes any lease payments made and excludes lease incentives. Our variable lease payments primarily consist of maintenance and other operating expenses from our real estate lease. Variable lease payments are excluded from the ROU assets and lease liabilities and are recognized in the period in which the obligation for those payments is incurred. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

We have lease agreements with lease and non-lease components. We have elected to account for these lease and non-lease components as a single lease component. We are also electing not to apply the recognition requirements to short-term leases of twelve months or less and instead will recognize lease payments as expense on a straight-line basis over the lease term.

On May 15, 2025, the Company entered into a lease termination agreement ("Termination Agreement") with HGIT Historic Decatur LP to terminate the Company's San Diego, California office space. The Termination Agreement allows HGIT Historic Decatur LP to retain the security deposit of \$20,711 (recorded as operating lease expense) and to be paid \$12,000 within twelve (12) months from the termination date. The Company was released from any other obligations.

The components of lease expense and supplemental cash flow information related to leases for the period are as follows:

In accordance with ASC 842, the components of lease expense were as follows:

	Nine Months ended September 30,		Three Months ended September 30,	
	2025	2024	2025	2024
Operating lease expense	\$ 24,751	\$ 53,757	\$ -	\$ 17,919
Short term lease cost	\$ -	\$ -	\$ -	\$ -
Total lease expense	\$ 24,751	\$ 53,757	\$ -	\$ 17,919

In accordance with ASC 842, other information related to leases was as follows:

Nine Months ended September 30,	2025	2024
Operating cash flows from operating leases	\$ 32,537	\$ 57,619
Cash paid for amounts included in the measurement of lease liabilities	\$ 32,537	\$ 57,619
Weighted-average remaining lease term—operating leases	no years	1.92 years
Weighted-average discount rate—operating leases	10%	10%

Operating lease cost was \$0 and \$24,751, and \$17,919 and \$53,757 for the three and nine months ended September 30, 2025 and 2024, respectively.

NOTE 9 – RELATED PARTY TRANSACTIONS

Other than as set forth below, and as disclosed in Note 7, there have not been any transaction entered into or been a participant in which a related person had or will have a direct or indirect material interest.

Employment Agreements

Mr. Joyce receives an annual base salary of \$455,000, plus bonus compensation not to exceed 50% of salary. Mr. Joyce's employment also provides for medical insurance, disability benefits and one year of severance pay if his employment is terminated without cause or due to a change in control. Additionally, the Company has agreed to maintain a beneficial ownership target of 9% for Mr. Joyce. The Company incurred compensation expense of \$113,750 (of which \$79,135 was paid and \$34,615 is unpaid and accrued) and \$341,250 (of which \$208,816 was paid and \$132,434 is unpaid and accrued) and \$113,750 (of which \$0 was paid and \$113,750 is unpaid and accrued) and \$341,250 (of which \$0 was paid and \$341,250 is unpaid and accrued), for the three and nine months ended September 30, 2025 and 2024, respectively.

NOTE 10 – EARNINGS PER SHARE

FASB ASC Topic 260, *Earnings Per Share*, requires a reconciliation of the numerator and denominator of the basic and diluted earnings (loss) per share (EPS) computations.

Basic earnings (loss) per share are computed by dividing net earnings available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed similar to basic earnings per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. In periods where losses are reported, the weighted-average number of common stock outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive.

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because the effects were anti-dilutive based on the application of the treasury stock method and because the Company incurred net losses during the period:

	For the Nine Months Ended September 30,		For the Three Months Ended September 30,	
	2025	2024	2025	2024
Convertible notes payable	1,774,896	509,504	1,774,896	509,504
Preferred stock	641,577	301,900	641,577	301,900
Restricted stock units	90,473	41,566	90,473	12,424
Warrants to purchase shares of common stock	43,438	251,125	43,438	251,125
Total potentially dilutive shares	2,550,383	1,104,095	2,550,383	1,074,953

The following table sets forth the computation of basic and diluted net loss per share:

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2025	2024	2025	2024
Net loss attributable to the common stockholders	\$ (2,698,254)	\$ (2,817,394)	\$ (578,503)	\$ (1,196,923)
Basic weighted average outstanding shares of common stock	1,605,377	1,245,885	1,605,377	1,268,795
Dilutive effect of options and warrants	-	-	-	-
Diluted weighted average common stock and common stock equivalents	1,605,377	1,245,885	1,605,377	1,268,795
Loss per share:				
Basic and diluted	\$ (1.68)	\$ (2.26)	\$ (0.36)	\$ (0.94)

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Legal

From time to time, various lawsuits and legal proceedings may arise in the ordinary course of business. However, litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any legal proceedings or claims that it believes will have a material adverse effect on its business, financial condition or operating results.

Board of Directors Compensation

Effective January 11, 2025 and October 10, 2022, the Company's Board of Directors appointed Mr. Michael Ryan and Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel, respectively, as non-executive members to the Company's Board of Directors ("Director"). Each Director shall receive an annual retainer of \$30,000 paid in equal quarterly amounts at the end of each quarter. In addition, each Director shall receive a grant of restricted stock units of \$50,000, or at the discretion of the Board of Directors, options to acquire shares of common stock. Restricted stock units will be valued based on the average of the five trading days preceding and including the date of grant and will vest at a rate determined by the Board of Directors over one year. If options are granted, the options will be valued at the exercise price based on the average of the five trading days preceding and including the date of grant, have a ten year term, and will vest at a rate determined by the Board of Directors.

On August 8, 2025, Richa Nand and Michael Ryan notified the Company of their decision to resign from the Company's Board of Directors, effective August 8, 2025. On August 7, 2025, Christopher Wetzel (collectively, the "Resigning Directors") notified the Company of his decision to resign from the Board of Directors, effective August 7, 2025. The resignations were based on the Company's discontinuation of directors' and officers' liability insurance coverage which expired on August 4, 2025. The Resigning Directors will vest in previously granted RSU's and beginning October 1, 2025, will no longer receive RSU's as board compensation.

NOTE 12 – SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after September 30, 2025 up through the date the financial statements were available to be issued. During this period, the Company did not have any material recognizable subsequent events required to be disclosed as of and for the period ended September 30, 2025, except for the following:

Convertible Redeemable Note

On November 5, 2025, the Company entered into a Securities Purchase Agreement ("Redeemable Note") with respect to the sale and issuance to institutional investor CFI Capital LLC ("CFI Capital") of \$150,000 aggregate principal amount of Redeemable Note (total of \$130,000 cash was received) due November 6, 2026, based on \$1.00 for each \$0.90909 paid by CFI. The Note provides for a variable conversion rate per share equal to 70% of the lowest trading price for the proceeding 20 trading days prior to a conversion (including the day upon which a notice of conversion is received by the Company), are due in one year, and provide for interest of 6% per annum. The issuances of the foregoing securities are exempt from registration pursuant to Section 4(a)(2) of the Securities Act promulgated thereunder as the Sellers are sophisticated investors and familiar with the Company's operations. No stock purchase warrants were issued as part of the agreement. Upon an event of default, the conversion price discount shall increase by 15%.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and the notes included elsewhere in this Form 10-Q. The following discussion contains forward-looking statements that involve certain risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2024 particularly under the “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements and Risk Factors Summary” sections.

Our Company

We are a development-stage Company advancing dialysis-like therapies to address cardiovascular disease and cancer. Sigyn CardioDialysis™ (previously known as Sigyn Therapy™) is a novel blood purification technology to treat cardiovascular disease, the leading cause of death globally. CardioDialysis™ 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™ offers to reduce the incidence of MACE by overcoming the inherent limitations of single-target drugs.

Our development pipeline of cancer therapies is comprised of ImmunePrep™ to optimize the delivery of immunotherapeutic antibodies; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy.

Recent Developments

On November 6, 2025, we disclosed the filing of a trademark application with the United States Patent and Trademark Office to protect the name CardioDialysis™. The action reflects our intent to shift the previous therapeutic focus of Sigyn Therapy™ toward cardiovascular disease.

This action provides us a pathway into a larger market opportunity, for which there is an FDA-approved device precedent that clinically demonstrates the ability of blood purification to reduce Major Adverse Cardiovascular Disease Events (MACE). As compared to our previously proposed treatment indications, we believe it will be significantly less burdensome to enroll cardiovascular disease subjects into pivotal efficacy studies that will be required for FDA market approval. Furthermore, we consider our potential value to the dialysis industry as a majority of their patients die from cardiovascular disease related events. Our previously proposed indications, which included the treatment of sepsis, drug-resistant bacterial infections, and life-threatening viruses will become downstream therapeutics opportunities.

Reverse Stock Split

Effective January 19, 2024, the Board of Directors declared a one-for-forty reverse stock split to shareholders of record on or before January 31, 2024 of the Company’s issued and outstanding shares of common stock, outstanding warrants and options, and the Series B Convertible Preferred Stock. The number of shares of common stock and convertible preferred shares obtainable upon exercise or conversion and the exercise prices and conversion rate have been equitably adjusted. As such, all share and per share amounts have been retroactively adjusted to reflect the reverse stock split.

Financing Transactions

Preferred Stock

The Company has 10,000,000 shares of par value \$0.0001 preferred stock authorized, of which 5,107 and 2,403 shares preferred shares are issued and outstanding at September 30, 2025 and December, 31, 2024, respectively.

On June 5, 2025, as a means to induce further investment from established or candidate shareholders, the Company issued four (4) Series B preferred shares for each \$5,000 of shares previously converted by a Convertible Debenture noteholder. The Company recorded a total inducement of 2,704 Series B preferred shares, valued at \$845,901 (based on the estimated fair value of the stock on the date of grant) in the unaudited condensed consolidated statements of operations.

On April 10, 2024, Osher elected to exchange \$621,000 of Notes for an aggregate of 823.86 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio.

On April 9, 2024, Brio elected to exchange \$220,420 of Notes for an aggregate of 292.4 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio.

Common Stock

On December 30, 2024, the Company filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the State of Delaware, which went effective immediately upon filing. The Certificate of Amendment decreased our authorized common stock to One Hundred Million (100,000,000) shares, par value \$0.0001, of which 1,605,377 and 1,605,377 shares are outstanding as of September 30, 2025 and December 31, 2024, respectively.

During the year ended December 31, 2024, the holders of \$707,730 of Original Issue Discount Senior Convertible Debentures converted their debentures in exchange for the issuance of 157,526 shares of Common Stock to the holders.

During the year ended December 31, 2024, the Company issued 38,325 common shares valued at \$214,550 (based on the estimated fair value of the stock on the date of grant), respectively, for services rendered.

Shares Cancelled

On January 9, 2024, the Company's CTO agreed to surrender 64,100 common shares held by him and were cancelled by the Company.

Restricted Stock Units

Effective January 11, 2025 and October 10, 2022, the Company's Board of Directors appointed Mr. Michael Ryan and Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel, respectively, as non-executive members to the Company's Board of Directors ("Director"). Effective January 1, 2023, each Director shall receive an annual grant of restricted stock units of \$50,000. During the three and nine months ended September 30, 2025 and 2024, respectively, the Company recorded stock-based compensation totaling \$50,000 and \$150,000, and \$37,500 and \$112,500, respectively, in the unaudited condensed consolidated statements of operations.

Warrants

On June 5, 2025, as a means to induce further investment from established shareholders, the Company adjusted the conversion price of the Company's outstanding warrants from \$6.00 per share to \$4.00 per share. The Company recognized a loss of \$17,505 due to the modification of the warrants in June 2025 in the unaudited condensed consolidated statements of operations.

On August 24, 2024, the Company issued 3,325 warrants valued at \$15,703 (based on the fair value of the options using the Black-Scholes option-pricing method on the date of grant), for services rendered.

In accordance with ASC 718-20, *Compensation – Stock Compensation*, a modification of a stock award is treated as an exchange of the original award for a new award incurring additional compensation cost for any incremental value resulting from the modification. Incremental compensation cost shall be measured as the excess of the fair value of the modified award over the fair value of the original award immediately before its terms are modified and recognized over the vesting period. A short-term inducement shall be accounted for as a modification of the terms of only those that accept the inducement.

On October 8, 2024, the Company offered a short-term inducement to the Company's warrant holders in which the Company will issue $\frac{3}{4}$ of a share of the Company's common stock in exchange for each warrant. In response to this offer, 246,257 warrants were exchanged for 184,700 shares of the Company's common stock. The Company recognized a gain of \$63,715 due to the modification of the warrants in October 2024.

On September 5, 2024, the Company entered into the 2024 Notes that included warrants at an exercise price of \$7.50 (see Note 5) resulting in a modification of the warrants valued at \$24,770 (based on the Black Scholes options pricing method on the modification date).

Promissory Notes

On July 3, 2025, the Company entered into a promissory note of \$3,000 due August 15, 2025 and is non-interest bearing. On October 23, 2025, the note was repaid.

On June 9, 2025, the Company entered into a promissory note of \$10,000 due July 31, 2025 and is non-interest bearing. On November 3, 2025, the noteholder agreed to extend the note to January 15, 2026 of original issue discount of \$1,000.

On November 26, 2024, the Company entered into promissory notes totaling \$314,000 aggregate principal amount of promissory notes (total of \$157,000 cash was received) due November 26, 2025 based on \$1.00 for each \$0.50 paid by the noteholders which were issued at a \$157,000 original issue discount from the face value of the promissory notes.

Regulation D

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of \$5,000 per unit with each Unit consisting of one (1) \$5,500 principal amount convertible debenture (convertible at two dollars (\$2.00) per share into the Company's common stock) and a Warrant to purchase 1,250 shares of common stock at \$4.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at \$2.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of \$4.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of September 30, 2025, a total of 69 Units were sold to accredited investors at a price of \$5,500 per Unit totaling \$379,717 (total of \$345,197 cash was received).

Convertible Notes

Between January 2020 and September 2025, the Company received cash of \$5,224,385 through the issuance of 10% Original Issue Discount Senior Convertible Debentures with third party investors. Between June 2023 and September 2024, \$3,069,348 in aggregate principal amount of the notes were converted into 371,110 common shares and 1,116.29 shares of Series B Convertible Preferred Stock. Each share of Series B Convertible Preferred Stock converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for the issuances of additional shares at an issue price of less than the conversion ratio.

In addition, in August and September 2025, the Company entered into two Notes totaling \$232,100 (total of \$207,500 cash was received) that provide for a variable conversion price. The Notes provide for a variable conversion rate per share equal to 65% and 75%, respectively, of the lowest trading price for the proceeding 10 trading days prior to a conversion, are due in one year and provide for interest of 7% to 8% per annum. The Company determined that in accordance with ASC 815-15, *Embedded Derivatives*, it should bifurcate and separately recognize the variable conversion rate at its fair value and at each subsequent measurement date, remeasure its fair value with such changes in fair value recorded in earnings. The Company recognized a total value of \$181,362 as a derivative on the grant dates (based on the Binomial valuation model on the date of grant). During the three and nine months ended September 30, 2025 and 2024, the Company did not recognize a remeasurement to fair value as it was deemed immaterial. The issuances of the foregoing securities are exempt from registration pursuant to Section 4(a)(2) of the Securities Act promulgated thereunder as the Sellers are sophisticated investors and familiar with the Company's operations. No stock purchase warrants were issued as part of the agreement.

Convertible Redeemable Note

On November 5, 2025, the Company entered into a Securities Purchase Agreement (“Redeemable Note”) with respect to the sale and issuance to institutional investor CFI Capital LLC (“CFI Capital”) of \$150,000 aggregate principal amount of Redeemable Note (total of \$130,000 cash was received) due November 6, 2026, based on \$1.00 for each \$0.90909 paid by CFI. The Note provides for a variable conversion rate per share equal to 70% of the lowest trading price for the proceeding 20 trading days prior to a conversion (including the day upon which a notice of conversion is received by the Company), are due in one year, and provide for interest of 6% per annum. The issuances of the foregoing securities are exempt from registration pursuant to Section 4(a)(2) of the Securities Act promulgated thereunder as the Sellers are sophisticated investors and familiar with the Company’s operations. No stock purchase warrants were issued as part of the agreement. Upon an event of default, the conversion price discount shall increase by 15%.

The remaining outstanding Notes are as follows:

Note Holder/Original Issuance Date	Maturity Date	Cash Received	Outstanding Balance as of September 30, 2025	Outstanding Balance as of December 31, 2024
<i>Osher Capital Partners LLC</i>				
January 28, 2020 (“Note 1”)	December 31, 2027	\$ 350,005	\$ 834,771	\$ 620,553
June 22, 2022 (“Note 2”)	December 31, 2027	75,000	139,559	103,745
August 31, 2022 (“Note 2”)	December 31, 2027	100,000	182,302	135,520
September 20, 2022 (“Note 2”)	December 31, 2027	100,000	182,302	135,520
October 20, 2022 (“Note 2”)	December 31, 2027	100,000	178,670	127,000
November 14, 2022 (“Note 2”)	December 31, 2027	50,000	90,531	64,350
December 22, 2022 (“Note 2”)	December 31, 2027	100,000	175,856	125,000
July 18, 2023 (“Note 3”)	December 31, 2027	60,000	97,662	72,600
December 7, 2023 (“Note 3”)	December 31, 2027	40,000	65,108	48,400
May 13, 2024 (“Note 4”)	December 31, 2027	35,000	55,584	40,000
August 19, 2024 (“Note 4”)	December 31, 2027	7,500	11,139	8,250
November 19, 2024 (“Note 4”)	December 31, 2027	8,000	11,556	8,800
April 15, 2025	December 31, 2027	20,000	27,570	-
<i>Brio Capital Master Fund, Ltd.</i>				
March 23, 2022 (“Note 2”)	December 31, 2027	100,000	192,311	142,960
November 9, 2022 (“Note 2”)	December 31, 2027	75,000	136,727	101,640
January 20, 2023 (“Note 3”)	December 31, 2027	50,000	87,928	62,500
February 9, 2023 (“Note 3”)	December 31, 2027	50,000	87,928	62,500
July 20, 2023 (“Note 3”)	December 31, 2027	40,000	65,108	48,400
January 8, 2024 (“Note 4”)	December 31, 2027	40,000	63,402	44,000
May 13, 2024 (“Note 4”)	December 31, 2027	35,000	55,584	40,000
August 20, 2024 (“Note 4”)	December 31, 2027	11,500	17,074	12,650
November 19, 2024 (“Note 4”)	December 31, 2027	8,000	11,556	8,800
April 23, 2025	December 31, 2027	10,000	13,748	-
July 21, 2025	July 21, 2026	5,000	5,500	-
<i>Various third-party noteholders</i>				
Various dates in fiscal 2024 (“Note 4”)	November 19, 2025	8,000	8,800	8,800
	Due on various dates from April 15, 2026 through September 12, 2026			
Various dates in fiscal 2025 (“Note 5”)	Primarily January 9, 2026	334,500	371,800	-
<i>FY 2025 Regulation D</i>		345,197	379,717	-
Total convertible notes payable		\$ 2,157,702	\$ 3,549,793	\$ 2,021,988

(1) includes amounts for original issue discounts and implied interest for subsequent note extensions at between 10% and 12%.

The outstanding Osher and Brio Notes can convert into a total of 4,153 shares of Series B Convertible Preferred Stock, with each share of Series B Convertible Preferred Stock convertible into 125.63 shares of the Company's common stock, subject to adjustment as provided therein, such as stock splits and stock dividends. In addition, the remaining Notes provide for an automatic conversion into Series B Convertible Preferred Stock in accordance with their terms upon a listing of the Company's common stock on a national securities exchange such as Nasdaq Capital Market.

Extension of Notes

On August 29, 2025, noteholders Osher and Brio agreed to extend all of their outstanding notes to December 31, 2027 for original issue discount totaling \$737,786. ASC 470-50-40-10, *Modifications and Extinguishments*, provides guidance on whether a modification or exchange of a term loan or debt security should be accounted for as a modification or an extinguishment. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is less than 10 percent, the debt instruments are not considered to be substantially different and deemed to be a modification of the debt instrument. If the terms of a debt instrument are changed or modified and the cash flow effect on a present value basis is greater than 10 percent, the debt instruments are considered to be substantially different and deemed to be an extinguishment of the debt instrument. The Company accounted for the extension of the notes as a modification with no gain or loss recognized since there were no notes where the cash flow effect on present value basis was greater than 10%.

Lease Termination

On May 15, 2025, the Company entered into a lease termination agreement ("Termination Agreement") with HGIT Historic Decatur LP to terminate the Company's San Diego, California office space. The Termination Agreement allows HGIT Historic Decatur LP to retain the security deposit of \$20,711 (recorded as operating lease expense) and to be paid \$12,000 within twelve (12) months from the termination date. The Company was released from any other obligations.

Limited Operating History; Need for Additional Capital

There is limited historical financial information about us on which to base an evaluation of our performance. We cannot guarantee we will be successful in our business operations. Our business is subject to risks inherent in the establishment of a new business enterprise, including limited capital resources, and possible cost overruns due to increases in the cost of services. To become profitable and competitive, we must receive additional capital. We have no assurance that future financing will materialize. If that financing is not available, we may be unable to continue operations.

Business Overview

Sigyn Therapeutics, Inc. ("Sigyn", the "Company" "we," "us," or "our") is a development-stage Company advancing dialysis-like therapies to address cardiovascular disease and cancer. Sigyn CardioDialysis™ is a novel blood purification technology to treat cardiovascular disease, the leading cause of death globally. CardioDialysis™ 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™ offers to reduce the incidence of MACE by overcoming the inherent limitations of single-target drugs.

Our development pipeline of cancer therapies is comprised of ImmunePrep™ to optimize the delivery of immunotherapeutic antibodies; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy.

Recent Development

On November 6, 2025, we disclosed the filing of a trademark application with the United States Patent and Trademark Office to protect the name CardioDialysis™, which reflects our intent to shift the previous therapeutic focus of Sigyn Therapy™ toward cardiovascular disease.

This action provides us a pathway into a larger market opportunity, for which there is an FDA-approved device precedent that clinically demonstrates the ability of blood purification to reduce Major Adverse Cardiovascular Disease Events (MACE). As compared to our previously proposed treatment indications, we believe it will be significantly less burdensome to enroll cardiovascular disease subjects into pivotal efficacy studies that will be required for FDA market approval. Furthermore, we consider our potential value to the dialysis industry as a majority of their patients die from cardiovascular disease related events. Our previously proposed indications, which included the treatment of sepsis, drug-resistant bacterial infections, and life-threatening viruses will become downstream therapeutics opportunities.

About CardioDialysis™

We are advancing CardioDialysis™ to treat cardiovascular disease, the leading cause of death globally. CardioDialysis™ 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™ 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.

Our Initial Clinical and Commercialization Focus to Treat ESRD Dialysis Patients

Our initial clinical and commercialization focus of CardioDialysis™ 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.

Beyond high mortality rates, we believe 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 potential market penetration within the dialysis industry, CardioDialysis™ can be conveniently integrated with regularly scheduled dialysis treatments.

A Medical Device Precedent to Treat Cardiovascular Disease

CardioDialysis™ 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 device precedent that demonstrates blood purification can 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 remained constrained by a limited delivery infrastructure, with fewer than 60 specialized apheresis centers able to provide access to the therapy in the United States.

Opportunity to Leverage the Global Dialysis Machine Infrastructure

CardioDialysis™ 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 United States alone. By leveraging this infrastructure, we envision a future possibility to transform current kidney dialysis clinics into Renal and CardioDialysis™ treatment centers.

Potential Value of CardioDialysis™ to the Dialysis Industry

If successfully advanced, we believe CardioDialysis™ 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™ may offer a potential pathway to treat cardiovascular disease in the general population, which is the current 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 suddenly 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. The U.S. dialysis industry could also increase top-line revenues by ~\$2.8 billion for each month of extending ESRD patient lives.

Addressing the 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 reveal that ESRD patients receive limited if any clinical benefit from LDL-C reducing statins, the leading class of drugs 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 an unfortunate reality. 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, we believe CardioDialysis™ could provide a strategy to reduce circulating LDL-C and Lipoprotein(a) levels, which is clinically proven to reduce major adverse cardiovascular events (MACE). Simultaneously, CardioDialysis™ offers to control dialysis-induced spikes of endotoxin and inflammatory cytokines that contribute to cardiovascular disease progression.

The Enrollment of ESRD Dialysis Patients in Clinic Studies

To obtain potential FDA market approval, we need to demonstrate the safety of CardioDialysis™ in a human feasibility (safety) study and then subsequently conduct pivotal studies to demonstrate treatment efficacy of CardioDialysis™.

Pivotal efficacy studies of our previously proposed indications (including sepsis, drug-resistant bacterial infections and life-threatening viruses) would have been limited to enrolling treatment subjects in a hospital intensive care unit (ICU) setting. Enrolling ICU subjects is a daunting challenge that can restrict the clinical advancement of extracorporeal blood purification technologies.

Whereas we plan to advance feasibility and pivotal efficacy studies of CardioDialysis™ in dialysis clinics, which we believe all reduce the challenge and cost of conducting studies. As per our treatment protocol, ESRD subjects will receive CardioDialysis™ during their regularly scheduled dialysis treatments, which is anticipated to further increase the efficiency of conducting clinical studies.

We plan to conduct first-human feasibility studies of CardioDialysis™ in 12-15 ESRD subjects at three dialysis clinic site locations. The protocol of this study has been incorporated into an Investigational Device Exemption (IDE) that we drafted for FDA submission. Based on our decision to advance CardioDialysis™ to address cardiovascular disease, we can now fulfill FDA's requirement to clearly define the disease condition we intend to treat in our IDE submission.

Development-Stage Cancer Therapy Pipeline

Our development pipeline of cancer therapies is comprised of ImmunePrep™ to optimize the delivery of immunotherapeutic antibodies; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy

Pre-Clinical Study Validations

Since the inception of our Company, we have advanced CardioDialysis™ (formerly known as Sigyn Therapy) from conceptual design through completion of pre-clinical *in vitro* studies that have quantified the reduction of relevant therapeutic targets from human blood plasma with small-scale versions of our device. These include endotoxin (gram-negative bacterial toxin); peptidoglycan and lipoteichoic acid (gram-positive bacterial toxins); viral pathogens (including SARS-CoV-2); hepatic toxins (ammonia, bile acid, and bilirubin); and tumor necrosis factor alpha (TNF alpha), interleukin-1 beta (IL-1b), and interleukin 6 (IL-6), which are pro-inflammatory cytokines whose chronic dysregulated production contributes to accelerate cardiovascular disease progression. Additionally, we demonstrated the adsorbents in our device are able to reduce the circulating presence of liposomes from blood plasma, which serve as a model to validate the potential to address cholesterol-transporting lipoproteins.

Completion of Animal Studies

Subsequent to our pre-clinical *in vitro* studies, we disclosed the completion of *in vivo* animal studies. In these studies, CardioDialysis™ (formerly known as Sigyn Therapy) was administered via standard dialysis machines utilizing conventional blood-tubing sets, for periods of up to six hours to eight (8) porcine (pig) subjects, each weighing approximately 40-45 kilograms. The studies were comprised of a pilot phase (two subjects), which evaluated the feasibility of the study protocol in the first-in-mammal use of our technology; and an expansion phase (six subjects) to further assess treatment feasibility and refine pre-treatment set-up and operating procedures. There were no serious adverse events reported in any of the treated animal subjects. Of the eight treatments, seven were administered for the entire six-hour treatment period. One treatment was halted early due to the observation of a clot in the device, which was believed to be the result of a procedural deviation in the pre-treatment set-up. Important criteria for treatment feasibility – including hemodynamic parameters, serum chemistries and hematologic measurements – were stable across all subjects.

The studies were conducted by a clinical team at Innovative BioTherapies, Inc. ("IBT"), under a contract with the University of Michigan to utilize animal care, associated institutional review oversight, as well as surgical suite facilities located within the North Campus Research Complex. The treatment protocol of the study was reviewed and approved by the University of Michigan Institutional Animal Care and Use Committee ("IACUC").

The animal studies were conducted to correspond with FDA's best practice guidance. The number of animals enrolled in our study and the amount of data collected was based on the ethical and least burdensome principles that underly the FDA goal of using the minimum number of animals necessary to generate valid scientific data to demonstrate reasonable feasibility and performance of a medical device prior to human study consideration. A porcine animal model is a generally accepted model for the study of extracorporeal blood purification devices intended to treat infectious disease and inflammatory disorders. Regardless of these factors, FDA may require that we conduct additional animal studies.

First-in-Human Feasibility Study

The data resulting from our *in vivo* animal and pre-clinical *in vitro* studies is being incorporated into an Investigational Device Exemption (IDE) that we are drafting for submission to the U.S. Food and Drug Administration (“FDA”) to support first-in-human feasibility studies of CardioDialysis™. The clinical plan of our IDE proposes to enroll 12-15 End-Stage Renal Disease (“ESRD”) patients at three clinical site locations that have been identified and evaluated by a contract research organization that specializes in ESRD related clinical studies. The primary study objective is to demonstrate that our device can be safely administered to health compromised ESRD subjects. Additionally, we plan to quantify changes in cholesterol-transporting lipoprotein levels, as well endotoxin and inflammatory cytokine levels during treatment. The clinical plan proposed in our draft IDE has not yet been provided to FDA and there is no assurance that FDA will approve the initiation of our proposed feasibility study, nor is there any assurance that we will receive FDA market approval of CardioDialysis™. Based on our previous experience in developing extracorporeal blood purification therapies, we believe we have collected sufficient data to support the initiation of a CardioDialysis™ human feasibility study.

CardioDialysis™ Mechanism of Action

We are advancing CardioDialysis™ (formerly known as Sigyn Therapy) to treat cardiovascular disease. To support potential widespread implementation, CardioDialysis is a single-use disposable device that is deployable on the global infrastructure of hemodialysis machines already located in hospitals and clinics. To reduce the risk of blood clotting and hemolysis, the anticoagulant heparin is administered, which is the standard-of-care drug administered during dialysis treatments. During animal studies conducted at the University of Michigan, CardioDialysis was deployed for use on a dialysis machine manufactured by Fresenius Medical Care, a global leader in the dialysis industry.

Incorporated within our device is a “cocktail” of adsorbent components formulated to optimize the broad-spectrum reduction of therapeutic targets from the bloodstream. Each adsorbent component has differing capture and adsorption characteristics that contribute to optimizing the potential of CardioDialysis to reduce the circulating presence of therapeutic targets that contribute to the progression of cardiovascular disease.

The CardioDialysis adsorbent components provide more than 200,000 square meters (~50 acres) of surface area on which to adsorb and remove therapeutic targets from the bloodstream. Beyond its capacity to reduce the circulating presence of therapeutic targets we believe CardioDialysis to be a highly efficient blood processing technology. Based on targeted blood flow rates of 350ml/min, the entire bloodstream of an average size person can be processed through our device approximately fifteen times during a single four-hour treatment period.

From a technical perspective, CardioDialysis is a 325mm long polycarbonate column that internally contains polyethersulphone hollow fibers that have porous walls with a median pore size of ~200 nanometers (nm). As blood flows into our device, plasma and therapeutic targets below 200nm travel through the porous walls as a result of blood-side pressure. As the hollow fiber bundle within CardioDialysis creates a resistance to the flow of blood, a pressure drop is created along the length of the device such that the blood-side pressure is higher at the blood inlet and lower at the blood outlet. This allows for plasma and therapeutic targets to flow away from the blood and into the extra-lumen space (inside the polycarbonate shell, yet outside the hollow-fiber bundle) to interact with our adsorbent components in a low shear force environment. In the distal third of the fiber bundle, the pressure gradient is reversed, which allows for plasma to flow back through the fiber walls to be reconvened into the bloodstream without the presence of therapeutic targets that were captured or bound by adsorbent components housed in the extra-lumen space of CardioDialysis.

Development-Stage Cancer Therapy Pipeline

Our development pipeline of cancer therapies is comprised of ImmunePrep™ to optimize the delivery of immunotherapeutic antibodies; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy.

Marketing and Sales

Our primary focus is the regulatory and clinical advancement of Sigyn Therapy and the continued development of our cancer treatment technologies. We do not market or sell any therapeutic products at this time. However, we may choose to forge relationships with organizations that have established distribution channels into markets that may have a demand for our therapies should they receive market clearance from FDA or other foreign regulatory agencies.

Intellectual Property

We own the intellectual property rights to pending royalty-free patents that have been assigned to us by our CEO and other employee inventors. We have also received a “Notice of Allowance” from the USPTO related to the use of Sigyn Therapeutics and the protection of our corporate logo. We plan to continually expand our intellectual property portfolio and protect trade secrets that are not the subject of patent submissions. However, there is no assurance that the claims of current pending and future patent applications will result in issued patents. Pending changes in patent law, it is anticipated that each patent that becomes issued will have an enforceable life that will extend for a period of 20 years from the initial patent filing date (i.e., the priority date) and will expire at the end of such 20-year terms.

At present, we own the rights to the following patents pending.

EXTRACORPOREAL THERAPIES FOR XENOTRANSPLANTATION – U.S. Patent Application No.: 63/707,507; Priority Date: 10/15/2024 - Inventors: James A. Joyce and Annette M. Marleau

DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES – International Patent Application No.: PCT/US2024/028579; Priority Date: 05/10/2023 - Inventors: James A. Joyce and Annette M. Marleau

SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY – U.S. Patent Application No.: 18/373,829; Priority Date: 09/28/2022 - Inventor: James A. Joyce

SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY – International Patent Application No.: PCT/US2023/033878; Priority Date: 09/28/2022 - Inventor: James A. Joyce

EXTRA-LUMEN ADSORPTION OF VIRAL PATHOGENS FROM BLOOD – U.S. Patent Application No.: 18/802,722; Priority Date: 2021-04-21- Inventor: James A. Joyce

EXTRA-LUMEN ADSORPTION OF VIRAL PATHOGENS FROM BLOOD – EP No.: 22722028.2; Priority Date: 2021-04-21 - Inventor: James A. Joyce

EXTRA-LUMEN ADSORPTION OF VIRAL PATHOGENS FROM BLOOD – CA No.: 3,214,888; Priority Date: 2021-04-21 - Inventor: James A. Joyce

EXTRA-LUMEN ADSORPTION OF VIRAL PATHOGENS FROM BLOOD – International Patent Application No.: PCT/US2022/025495; Priority Date: 2021-04-01 - Inventor: James A. Joyce

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD – International Patent Application No.: PCT/US2020/044223; Priority Date: 2019-08-01 - Inventors: James Joyce and Craig P. Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD – U.S. Patent Application No.: 16/943,436; Priority Date: 2019-08-01 - Inventors: James A. Joyce and Craig P. Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD – EP No.: 20757445.0; Priority Date: 2019-08-01 - Inventors: James A. Joyce and Craig P. Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD – CA No.: 3,148,773; Priority Date: 2019-08-01 - Inventors: James A. Joyce and Craig P. Roberts

Government Regulation

In the United States, our medical devices are subject to regulation by the FDA. Should we seek to commercialize our products outside the United States, we expect to face comparable international regulatory oversight. The U.S. regulatory jurisdiction for extracorporeal blood purification therapies is the Center for Devices and Radiological Health (“CDRH”), the FDA branch that oversees the market approval of medical devices.

Based on published CDRH guidance, we believe that each of our therapeutic candidates will be classified as Class III medical devices that are subject to a Pre-Market Approval (“PMA”) submission pathway. A PMA pathway requires extensive data, including but not limited to technical documents, preclinical studies, animal studies, human clinical trials, the establishment of Current Good Manufacturing Practices (“cGMPs”) standards and labelling that fulfils FDA’s requirement to demonstrate reasonable evidence of safety and effectiveness of a medical device product. However, as our therapeutic candidates do not emit electronic product radiation, they will not be subject to regulatory challenges associated with medical devices that emit electronic radiation.

The commercialization of medical devices in the United States requires either a prior 510(k) clearance, unless it is exempt, or a PMA from the FDA. Generally, if a new device has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; otherwise, a premarket approval, or PMA, is required. Medical devices are classified into one of three classes; Class I, Class II or Class III which are determined by the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the general controls of the Federal Food, Drug and Cosmetic Act, such as provisions that relate to: adulteration; misbranding; registration and listing; notification, including repair, replacement, or refund; records and reports; and good manufacturing practices. Most Class I devices are classified as exempt from pre-market notification under section 510(k) of the FD&C Act, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls include performance standards, post market surveillance, patient registries and guidance documents. A manufacturer may be required to submit to the FDA a pre-market notification requesting permission to commercially distribute some Class II devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA. We believe that all of our therapeutic candidates will be classified as a Class III device and as such will be subject to a PMA submission and approval.

Should CardioDialysis™ or any of our other therapeutic candidates receive market clearance from FDA, we would need to comply with applicable laws and regulations that govern the development, testing, manufacturing, labeling, marketing, storage, distribution, advertising and promotion, and post-marketing surveillance reporting for medical devices. Failure to comply with these applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning letters, import detentions, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution. Our failure to comply with any of these laws and regulations could have a material adverse effect on our operations.

The Pre-market Approval Pathway

A pre-market approval (“PMA”) application must be submitted to FDA for Class III devices requiring a PMA. The PMA application process is more demanding than the 510(k)-pre-market notification process. A PMA application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA’s satisfaction reasonable evidence of safety and effectiveness of the device.

After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device.

Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA decision making process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with the Quality System Regulation, or QSR. The agency also may inspect one or more clinical sites to assure compliance with FDA's regulations.

Upon completion of the PMA review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Clinical Trials

Clinical trials are almost always required to support PMA market clearance and are sometimes required for 510(k) clearance. In the United States, for significant risk Class III devices, these trials require submission of an Investigational Device Exemption (IDE) application to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients at specified study sites. During the trial, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record keeping requirements. Clinical trials for Class III devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. The FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, there is no assurance that clinical testing will demonstrate the safety and effectiveness of CardioDialysis™ or any of our other pipeline therapies.

Manufacturing and Procurement

At present, we plan to manufacture CardioDialysis™ and other candidate products through contracts with FDA registered Contract Manufacturing Organizations (CMO) to establish cGMPs compliant manufacturing to support human clinical studies and potential commercialization should we receive clearance from FDA to market one or more of our products. We plan to establish manufacturing procedure specifications that define each stage of our manufacturing, inspection and testing processes and the control parameters or acceptance criteria that apply to each activity that result in the production of our technologies.

We have also established relationships with industry vendors that provide components necessary to manufacture CardioDialysis™. Should the relationship with an industry vendor be interrupted or discontinued, we believe that alternate component suppliers can be identified to support continued manufacturing. However, delays related to interrupted or discontinued vendor relationships could adversely impact our business.

Research and Product Development

To date, we have outsourced much of our research and product development activities, which include the performance of *in vitro* blood plasma validation studies, animal studies, pre-cGMPs product assembly and manufacturing through third party organizations with experience in advancing extracorporeal blood purification technologies. Our pre-clinical *in vitro* blood plasma studies we each performed under an agreement with Innovative BioTherapies, Inc. (IBT) and our animal clinical studies were conducted by IBT team members through a contract with the University of Michigan to utilize animal care, associated institutional review oversight, as well as surgical suite facilities located within the North Campus Research Complex. While we maintain ownership rights to all study data collected by IBT, we do permit for IBT to publish or present the results of our contracted studies. At present, we do not have plans to build our own research and product development facility.

Competition

Our primary competition includes Lipoprotein Apheresis devices that are market-approved and proven to reduce Major Adverse Cardiovascular Events (MACE) in cardiovascular disease patients. Lipoprotein Apheresis devices primarily target the reduction of cholesterol-transporting lipoprotein(a) and LDL-C from the bloodstream. We believe CardioDialysis can target these lipoproteins and additionally address a broad-spectrum of inflammatory targets that also contribute to cardiovascular disease progression. Furthermore, we believe CardioDialysis has an advantage of being deployed for use on dialysis machines already located in hospitals and clinics around the world. Whereas the administration of Lipoprotein Apheresis is mostly limited to specialized apheresis centers. However, medical device or pharmaceutical companies may develop products that compete with CardioDialysis and our other product candidates. Should these companies develop competing products, they are likely to have access to greater resources to support the clinical advancement and post-approval marketing of their products within the medical industry.

Environmental Laws and Regulations

At present, our operations are not subject to any environmental laws or regulations

Overview of Presentation

The following Management's Discussion and Analysis ("MD&A") or Plan of Operations includes the following sections:

- Results of Operations
- Liquidity and Capital Resources
- Capital Expenditures
- Going Concern
- Critical Accounting Policies
- Off-Balance Sheet Arrangements

General and administrative expenses consist primarily of personnel costs and professional fees required to support our operations and growth.

Depending on the extent of our future growth, we may experience significant strain on our management, personnel, and information systems. We will need to implement and improve operational, financial, and management information systems. In addition, we are implementing new information systems that will provide better record-keeping, customer service and billing. However, there can be no assurance that our management resources or information systems will be sufficient to manage any future growth in our business, and the failure to do so could have a material adverse effect on our business, results of operations and financial condition.

Results of Operations

Three Months Ended September 30, 2025 Compared to Three Months Ended September 30, 2024

The following discussion represents a comparison of our results of operations for the three months ended September 30, 2025 and 2024. The results of operations for the periods shown in our unaudited condensed consolidated financial statements are not necessarily indicative of operating results for the entire period. In the opinion of management, the unaudited condensed consolidated financial statements recognize all adjustments of a normal recurring nature considered necessary to fairly state our financial position, results of operations and cash flows for the periods presented.

	Three Months Ended September 30,	
	2025	2024
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	386,529	808,458
Other expense	191,974	388,465
Net loss before income taxes	\$ (578,503)	\$ (1,196,923)

Net Revenues

For the three months ended September 30, 2025 and 2024, we had no revenues.

Cost of Sales

For the three months ended September 30, 2025 and 2024, we had no cost of sales as we had no revenues.

Operating expenses

Operating expenses decreased by \$421,930, or 52.2%, to \$386,528 for three months ended September 30, 2025 from \$808,458 for the three months ended September 30, 2024 primarily due to decreases in research and development costs of \$176,480, depreciation costs of \$1,363, rent expense of \$18,651, professional fees of \$35,184, investor relations costs of \$184,196, compensation costs of \$8,497, consulting fees of \$2,590, insurance costs of \$5,686, and general and administration costs of \$1,783, offset primarily by increases in stock based compensation of \$12,500, as a result of adding administrative infrastructure for our anticipated business development.

For the three months ended September 30, 2025, we had marketing expenses of \$52, research and development costs of \$29,681, stock based compensation of \$50,000, and general and administrative expenses of \$306,796 primarily due to professional fees of \$22,352, compensation costs of \$167,966, rent expense of \$829, investor relations costs of \$27,664, consulting fees of \$48,913, insurance expense of \$37,983, and general and administration costs of \$1,089, as a result of adding administrative infrastructure for our anticipated business development.

For the three months ended September 30, 2024, we had marketing expenses of \$114, research and development costs of \$206,161, stock based compensation of \$37,500, and general and administrative expenses of \$564,683 primarily due to professional fees of \$57,536, compensation costs of \$176,463, rent expense of \$19,480, depreciation costs of \$1,363, investor relations costs of \$211,860, consulting fees of \$51,503, insurance expense of \$43,669, and general and administration costs of \$2,809, as a result of adding administrative infrastructure for our anticipated business development.

Other Expense

Other expense for the three months ended September 30, 2025 totaled \$191,974 primarily due to interest expense of \$70,211 in conjunction with accretion of debt discount, interest expense of \$119,739 in conjunction with accretion of original issuance discount, and interest expense of \$2,024, compared to other expense for the three months ended September 30, 2024 of \$388,465 primarily due to interest expense of \$263,719 in conjunction with accretion of debt discount, interest expense of \$99,126 in conjunction with accretion of original issuance discount, interest expense of \$850, and modification of warrants of \$24,770.

Net loss before income taxes

Net loss before income taxes for the three months ended September 30, 2025 totaled \$578,503 primarily due to decreases in research and development costs, investor relations costs, professional fees, rent, depreciation, compensation costs, insurance expense, consulting fees, and general and administration costs, primarily offset by increases in stock based compensation, compared to a loss of \$1,196,923 primarily due to increases in compensation costs, professional fees, investor relations costs, and research and development costs, offset primarily by decreases in consulting fees, rent, insurance, depreciation, amortization, and general and administration costs.

Assets and Liabilities

Assets were \$135,571 as of September 30, 2025. Assets consisted primarily of cash of \$85,571 and other assets of \$50,000. Liabilities were \$6,052,780 as of September 30, 2025. Liabilities consisted primarily of accounts payable of \$773,604, accrued payroll and payroll taxes of \$2,279,731, other current liabilities of \$3,932, convertible notes of \$2,509,514, net of \$1,040,279 of unamortized debt discount and debt issuance costs, short term promissory notes of \$304,637, net of \$22,363 of unamortized debt discount and debt issuance costs, and derivative liability of \$181,362.

Nine Months Ended September 30, 2025 Compared to Nine Months Ended September 30, 2024

The following discussion represents a comparison of our results of operations for the nine months ended September 30, 2025 and 2024. The results of operations for the periods shown in our unaudited condensed consolidated financial statements are not necessarily indicative of operating results for the entire period. In the opinion of management, the unaudited condensed consolidated financial statements recognize all adjustments of a normal recurring nature considered necessary to fairly state our financial position, results of operations and cash flows for the periods presented.

	Nine Months Ended September 30,	
	2025	2024
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	1,402,101	2,041,232
Other expense	1,296,153	776,162
Net loss before income taxes	\$ (2,698,254)	\$ (2,817,394)

Net Revenues

For the nine months ended September 30, 2024 and 2023, we had no revenues.

Cost of Sales

For the nine months ended September 30, 2024 and 2023, we had no cost of sales as we had no revenues.

Operating expenses

Operating expenses decreased by \$639,132, or 31.3%, to \$1,402,100 for nine months ended September 30, 2025 from \$2,041,232 for the nine months ended September 30, 2024 primarily due to decreases in research and development costs of \$633,179, investor relations costs of \$186,920, insurance costs of \$45,842, marketing costs of \$224, rent of \$31,111, professional fees of \$47,454, depreciation costs of \$2,885, and general and administration costs of \$5,892, offset primarily by increases in consulting fees of \$41,785, compensation costs of \$234,145, stock based compensation of \$37,500, and travel costs of \$945, as a result of adding administrative infrastructure for our anticipated business development.

For the nine months ended September 30, 2025, we had marketing expenses of \$236, research and development costs of \$46,004, stock based compensation of \$150,000, and general and administrative expenses of \$1,205,861 primarily due to professional fees of \$89,396, compensation costs of \$768,566, rent expense of \$27,141, depreciation costs of \$1,363, investor relations costs of \$47,473, consulting fees of \$149,288, insurance expense of \$114,765, travel costs of \$945, and general and administration costs of \$6,924, as a result of adding administrative infrastructure for our anticipated business development.

For the nine months ended September 30, 2024, we had marketing expenses of \$460, research and development costs of \$679,183, stock based compensation of \$112,500, and general and administrative expenses of \$1,249,089 primarily due to professional fees of \$136,850, compensation costs of \$534,421, rent expense of \$58,252, depreciation costs of \$4,248, investor relations costs of \$234,393, consulting fees of \$107,503, insurance expense of \$160,607, and general and administration costs of \$12,815, as a result of adding administrative infrastructure for our anticipated business development.

Other Expense

Other expense for the nine months ended September 30, 2025 totaled \$1,296,153 primarily due to interest expense of \$140,090 in conjunction with accretion of debt discount, interest expense of \$295,109 in conjunction with accretion of original issuance discount, and interest expense of \$3,345, modification of warrants of \$17,505, inducement of preferred shares of \$845,901, and other income of \$5,797, compared to other expense of \$776,162 for the nine months ended September 30, 2024 primarily due to interest expense of \$423,663 in conjunction with accretion of debt discount, interest expense of \$324,798 in conjunction with accretion of original issuance discount, interest expense of \$2,931, and modification of warrants of \$24,770.

Net loss before income taxes

Net loss before income taxes for the nine months ended September 30, 2025 totaled \$2,698,254 primarily due to decreases in professional fees, depreciation, insurance costs, rent, research and development costs, investor relations costs, and general and administration costs, offset primarily by stock based compensation, consulting fees, travel costs, and compensation costs, compared to a loss of \$2,817,394 for the nine months ended September 30, 2024 primarily due to increases in insurance, marketing costs, investor relations costs, research and development costs, and compensation costs, offset primarily by decreases in professional fees, consulting fees, depreciation, amortization, and general and administration costs compensation costs.

Liquidity and Capital Resources

Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company had an accumulated deficit of \$17,379,978 at September 30, 2025, had a working capital deficit of \$3,903,920 at September 30, 2025, had net losses of \$578,503 and \$2,698,254, and \$1,196,923 and \$2,817,394 for the three and nine months ended September 30, 2025 and 2024, respectively, and net cash used in operating activities of \$646,208 and \$582,218 for the nine months ended September 30, 2025 and 2024, respectively, with no revenue earned since inception, and a lack of operational history. These matters raise substantial doubt about the Company's ability to continue as a going concern.

While the Company is attempting to expand operations and increase revenues, the Company's cash position may not be significant enough to support the Company's daily operations. Management intends to raise additional funds by way of a public offering or an asset sale transaction. Management believes that the actions presently being taken to further implement its business plan and generate revenues provide the opportunity for the Company to continue as a going concern. While management believes in the viability of its strategy to generate revenues and in its ability to raise additional funds or transact an asset sale, there can be no assurances to that effect or on terms acceptable to the Company. The ability of the Company to continue as a going concern is dependent upon the Company's ability to further implement its business plan and generate revenues.

The condensed consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

General – Overall, we had an increase in cash flows for the nine months ended September 30, 2025 of \$73,427 resulting from cash provided by financing activities of \$719,635, offset partially by cash used in operating activities of \$646,208.

The following is a summary of our cash flows provided by (used in) operating, investing, and financing activities during the periods indicated:

	Nine Months Ended September 30,	
	2025	2024
Net cash provided by (used in):		
Operating activities	\$ (646,208)	\$ (582,218)
Investing activities	-	-
Financing activities	719,635	735,316
	<u>\$ 73,427</u>	<u>\$ 153,098</u>

Cash Flows from Operating Activities – For the nine months ended September 30, 2025, net cash used in operations was \$646,208 compared to net cash used in operations of \$582,218 for the nine months ended September 30, 2024. Net cash used in operations was primarily due to a net loss of \$2,698,254 for nine months ended September 30, 2025 and the changes in operating assets and liabilities of \$607,76, primarily due to the changes in other current assets of \$8,997, other assets of \$20,711, accounts payable of \$165,220, accrued payroll and payroll taxes of \$410,758, and other current liabilities of \$2,190. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of \$1,363, stock based compensation of \$150,000, accretion of original issuance costs of \$295,109, the accretion of debt discount of \$140,090, modification of warrants of \$17,505, and the inducement of preferred shares of \$845,901, offset partially by the settlement of lease of \$5,798.

For the nine months ended September 30, 2024, net cash used in operations was primarily due to a net loss of \$2,817,394 and the changes in operating assets and liabilities of \$1,114,944, primarily due to the changes in accounts payable of \$149,997, other current assets of \$2,053, accrued payroll and payroll taxes of \$969,890, offset partially by the change in other current liabilities of \$6,996. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of \$4,248, stock issued for services of \$214,550, warrants issued for services of \$15,703, stock-based compensation of \$112,500, accretion of original issuance costs of \$324,798, the accretion of debt discount of \$423,663, and modification of warrants of \$24,770.

Cash Flows from Investing Activities – For the nine months ended September 30, 2025 and 2024, the Company had no cash flows from investing activities.

Cash Flows from Financing Activities – For the nine months ended September 30, 2025, net cash provided by financing was \$719,635, due to proceeds from short term convertible notes of \$706,635 and proceeds from short-term promissory notes of \$13,000, compared to cash provided by financing activities of \$735,316 for the nine months ended September 30, 2024, due to proceeds from short term convertible notes of \$771,890 and advance from shareholder of \$35,000, offset primarily by repayments of advance from shareholder of \$71,574.

Financing – We expect that our current working capital position, together with our expected future cash flows from operations will be insufficient to fund our operations in the ordinary course of business, anticipated capital expenditures, debt payment requirements and other contractual obligations for at least the next twelve months. As stated above, Management intends to raise additional funds by way of a public offering or an asset sale transaction, however there can be no assurance that we will be successful in completing such transactions.

We have no present agreements or commitments with respect to any material acquisitions of other businesses, products, product rights or technologies or any other material capital expenditures. However, we will continue to evaluate acquisitions of and/or investments in products, technologies, capital equipment or improvements or companies that complement our business and may make such acquisitions and/or investments in the future. Accordingly, we may need to obtain additional sources of capital in the future to finance any such acquisitions and/or investments. We may not be able to obtain such financing on commercially reasonable terms, if at all. Due to the ongoing global economic crisis, we believe it may be difficult to obtain additional financing if needed. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

Regulation D

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of \$5,000 per unit with each Unit consisting of one (1) \$5,500 principal amount convertible debenture (convertible at two dollars (\$2.00) per share into the Company's common stock) and a Warrant to purchase 1,250 shares of common stock at \$4.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at \$2.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of \$4.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of September 30, 2025, a total of 69 Units were sold to accredited investors at a price of \$5,500 per Unit totaling \$379,717 (total of \$345,197 cash was received).

Convertible Notes Payable

In fiscal year 2024 and through September 30, 2025, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) \$1,289,329 aggregate principal amount of Notes (total of \$1,165,390 cash was received) due between January and November 2025 based on \$1.00 for each \$0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 255,708 shares of the Company's Common Stock at an exercise price of \$4.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$1,165,390 which was issued at a \$123,939 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

In September 2024, holders converted \$474,793 in exchange for the issuance of 118,700 shares of Common Stock to the holders.

In May and June 2024, holders converted \$232,937 in exchange for the issuance of 38,826 shares of Common Stock to the holders.

On April 10, 2024, Osher elected to exchange \$621,000 of Notes for an aggregate of 823.86 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio.

On April 9, 2024, Brio elected to exchange \$220,420 of Notes for an aggregate of 292.4 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio.

In addition, in August and September 2025, the Company entered into two Notes totaling \$232,100 (total of \$207,500 cash was received) that provide for a variable conversion price. The Notes provide for a variable conversion rate per share equal to 65% and 75%, respectively, of the lowest trading price for the proceeding 10 trading days prior to a conversion, are due in one year and provide for interest of 7% to 8% per annum. The Company determined that in accordance with ASC 815-15, *Embedded Derivatives*, it should bifurcate and separately recognize the variable conversion rate at its fair value and at each subsequent measurement date, remeasure its fair value with such changes in fair value recorded in earnings. The Company recognized a total value of \$181,362 as a derivative on the grant dates (based on the Binomial valuation model on the date of grant). During the three and nine months ended September 30, 2025 and 2024, the Company did not recognize a remeasurement to fair value as it was deemed immaterial.

Convertible Redeemable Note

On November 5, 2025, the Company entered into a Securities Purchase Agreement (“Redeemable Note”) with respect to the sale and issuance to institutional investor CFI Capital LLC (“CFI Capital”) of \$150,000 aggregate principal amount of Redeemable Note (total of \$130,000 cash was received) due November 6, 2026, based on \$1.00 for each \$0.90909 paid by CFI. The Note provides for a variable conversion rate per share equal to 70% of the lowest trading price for the proceeding 20 trading days prior to a conversion (including the day upon which a notice of conversion is received by the Company), are due in one year, and provide for interest of 6% per annum. The issuances of the foregoing securities are exempt from registration pursuant to Section 4(a)(2) of the Securities Act promulgated thereunder as the Sellers are sophisticated investors and familiar with the Company’s operations. No stock purchase warrants were issued as part of the agreement. Upon an event of default, the conversion price discount shall increase by 15%.

Capital Expenditures

We expect to have limited capital expenditures during the next twelve months.

Lease Termination

On May 15, 2025, the Company entered into a lease termination agreement (“Termination Agreement”) with HGIT Historic Decatur LP to terminate the Company’s San Diego, California office space. The Termination Agreement allows HGIT Historic Decatur LP to retain the security deposit of \$20,711 (recorded as operating lease expense) and to be paid \$12,000 within twelve (12) months from the termination date. The Company was released from any other obligations.

Fiscal year end

Our fiscal year end is December 31.

Critical Accounting Policies

The SEC has defined a company’s critical accounting policies as the ones that are most important to the portrayal of the Company’s financial condition and results of operations and which require the Company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified the critical accounting policies and judgments addressed below.

The following are deemed to be the most critical accounting policies affecting the Company.

Use of Estimates

The preparation of these financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of net sales and expenses during the reported periods. Actual results may differ from those estimates and such differences may be material to the financial statements. The more significant estimates and assumptions by management include among others: warrant valuation and the derivative liability embedded in the convertible note. The Company calculates the fair value of warrants using the Black-Scholes option-pricing method and calculates the fair value of the derivative liability using the binomial option-pricing method. The Black-Scholes and the binomial option-pricing methods requires the use of subjective assumptions, including stock price volatility, the expected life of stock options, risk free interest rate and the fair value of the underlying common stock on the date of grant. The current economic environment has increased the degree of uncertainty inherent in these estimates and assumptions.

Recent Accounting Pronouncements

There are no recently issued accounting updates that are expected to have a material impact on the Company's consolidated financial statements except for:

In November 2024, the FASB issued ASU 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which is intended to improve disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses in commonly presented expense captions. Such information should allow investors to better understand an entity's performance, assess future cash flows, and compare performance over time and with other entities. The amendments will require public business entities to disclose in the notes to the financial statements, at each interim and annual reporting period, specific information about certain costs and expenses, including purchases of inventory, employee compensation, depreciation, and intangible asset amortization included in each expense caption presented on the face of the income statement, and the total amount of an entity's selling expenses. The amendments are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, and may be applied either prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on the consolidated financial statements.

Future Contractual Obligations and Commitments

Refer to Note 3 in the accompanying notes to the consolidated financial statements for future contractual obligations and commitments. Future contractual obligations and commitments are based on the terms of the relevant agreements and appropriate classification of items under GAAP as currently in effect. Future events could cause actual payments to differ from these amounts.

We incur contractual obligations and financial commitments in the normal course of our operations and financing activities. Contractual obligations include future cash payments required under existing contracts, such as debt and lease agreements. These obligations may result from both general financing activities and from commercial arrangements that are directly supported by related operating activities. Details on these obligations are set forth below.

Off-Balance Sheet Arrangements

As of September 30, 2025, we have not entered into any transaction, agreement or other contractual arrangement with an entity unconsolidated under which it has:

- a retained or contingent interest in assets transferred to the unconsolidated entity or similar arrangement that serves as credit;
- liquidity or market risk support to such entity for such assets;
- an obligation, including a contingent obligation, under a contract that would be accounted for as a derivative instrument; or
- an obligation, including a contingent obligation, arising out of a variable interest in an unconsolidated entity that is held by, and material to us, where such entity provides financing, liquidity, market risk or credit risk support to or engages in leasing, hedging, or research and development services with us.

Inflation

We do not believe that inflation has had a material effect on our results of operations.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) that are designed to ensure that information that would be required to be disclosed in Exchange Act reports is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including to our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our CEO and Chief Financial Officer ("CFO"), has evaluated the effectiveness of our disclosure controls and procedures as defined in SEC Rules 13a-15(e) and 15d-15(e) as of the end of the period covered by this report. Based on such evaluation, management identified deficiencies that were determined to be a material weakness.

Management's Report on Internal Controls over Financial Reporting

The Company's management is responsible for establishing and maintaining effective internal control over financial reporting (as defined in Rule 13a-15(f) of the Securities Exchange Act). Management assessed the effectiveness of the Company's internal control over financial reporting as of September 30, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2013). Based on that assessment, management believes that, as of September 30, 2025, the Company's internal control over financial reporting was ineffective based on the COSO criteria, due to the following material weaknesses listed below.

The specific material weaknesses identified by the company's management as of end of the period covered by this report include the following:

- we have not performed a risk assessment and mapped our processes to control objectives;
- we have not implemented comprehensive entity-level internal controls;
- we have not implemented adequate system and manual controls; and
- we do not have sufficient segregation of duties. As such, the officers approve their own related business expense reimbursements

Despite the material weaknesses reported above, our management believes that our condensed consolidated financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented and that this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

This report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the Commission that permit us to provide only management's report in this report.

Management's Remediation Plan

The weaknesses and their related risks are not uncommon in a company of our size because of the limitations in the size and number of staff. Due to our size and nature, segregation of all conflicting duties has not always been possible and may not be economically feasible.

However, we plan to take steps to enhance and improve the design of our internal control over financial reporting. During the period covered by this quarterly report on Form 10-Q, we have not been able to remediate the material weaknesses identified above. To remediate such weaknesses, we plan to implement the following changes in the current fiscal year as resources allow:

- (i) Appoint additional qualified personnel to address inadequate segregation of duties and implement modifications to our financial controls to address such inadequacies;

The remediation efforts set out herein will be implemented in the 2025 fiscal year. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake.

Management believes that despite our material weaknesses set forth above, our condensed consolidated financial statements for the three and nine months ended September 30, 2025 are fairly stated, in all material respects, in accordance with U.S. GAAP.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ending September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in legal proceedings that could reasonably be expected to have a material adverse effect on our business, prospects, financial condition or results of operations. We may become involved in material legal proceedings in the future. To the best of our knowledge, none of our directors, officers or affiliates is involved in a legal proceeding adverse to our business or has a material interest adverse to our business.

ITEM 1A. RISK FACTORS.

We are a Smaller Reporting Company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

In fiscal year 2025, the Company entered into Original Issue Discount Senior Convertible Debentures totaling (i) \$410,300 aggregate principal amount of Notes (total of \$369,500 cash was received) due on various dates from April 15, 2026 through September 12, 2026 based on \$1.00 for each \$0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 80,851 shares of the Company’s Common Stock at an exercise price of \$4.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$369,500 which was issued at a \$40,800 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$2.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

On August 29, 2025, noteholders Osher and Brio agreed to extend all of their outstanding notes to December 31, 2027 for original issue discount totaling \$737,786.

ITEM 4. MINE SAFETY DISCLOSURE.

Pursuant to Section 1503(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, issuers that are operators, or that have a subsidiary that is an operator, of a coal or other mine in the United States are required to disclose in their periodic reports filed with the SEC information regarding specified health and safety violations, orders and citations, related assessments and legal actions, and mining-related fatalities from the Federal Mine Safety and Health Administration, or MSHA, under the Federal Mine Safety and Health Act of 1977, or the Mine Act. During the quarter ended September 30, 2025, we did not have any projects that were in production and as such, were not subject to regulation by MSHA under the Mine Act.

ITEM 5. OTHER INFORMATION.

During the quarter ended September 30, 2025, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Board of Directors and Officer Resignations

On July 31, 2025 Dr. Annette Marleau resigned as Chief Scientific Officer of the Company.

On August 8, 2025, Richa Nand and Michael Ryan notified the Company of their decision to resign from the Company’s Board of Directors, effective August 8, 2025. On August 7, 2025, Christopher Wetzel (collectively, the “Resigning Directors”) notified the Company of his decision to resign from the Board of Directors, effective August 7, 2025. The resignations were based on the Company’s discontinuation of directors’ and officers’ liability insurance coverage which expired on August 4, 2025. The Resigning Directors will vest in previously granted RSU’s and beginning October 1, 2025, will no longer receive RSU’s as board compensation.

Item 6. Exhibits.

Exhibit Number	Description
1.1	Form of Underwriting Agreement**
3.1*	Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware
3.2*	Bylaws of the Registrant, as currently in effect (Filed as Exhibit 3.2 to the Registration Statement on Form S-1 filed by the Registrant on May 27, 2015, and incorporated herein by reference).
10.1*	Share Exchange Agreement dated August 25, 2020 (Filed as Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on August 31, 2020 and incorporated herein by reference)
10.2*	Operating Lease (Filed as Exhibit 10.2 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).
10.3*	Employment Agreement for Jeremy Ferrell (Filed as Exhibit 99.1 to the Current Report on Form 8-K filed by the Registrant on March 9, 2022 and incorporated herein by reference)
10.4*	January 2020 Financing Documents and Extensions (Filed as Exhibit 10.4 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).
10.5*	June 23, 2020 Financing Documents (Filed as Exhibit 10.5 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).
10.6*	September 17, 2020 Financing Documents (Filed as Exhibit 10.6 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).
10.7*	Senior Convertible Debenture dated May 10, 2022 (Filed as Exhibit 10.7 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).

10.8*	<u>Warrant dated May 10, 2022 (Filed as Exhibit 10.8 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.9*	<u>Warrant dated October 18, 2021 (Filed as Exhibit 10.9 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.10*	<u>Senior Convertible Debenture dated March 23, 2022 (Filed as Exhibit 10.10 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.11*	<u>Warrant dated March 23, 2022 (Filed as Exhibit 10.11 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.12*	<u>Senior Convertible Debenture dated March 23, 2022 (Filed as Exhibit 10.12 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.13*	<u>Warrant dated March 23, 2022 (Filed as Exhibit 10.13 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.14*	<u>Senior Convertible Debenture dated April 28, 2022 (Filed as Exhibit 10.14 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.15*	<u>Warrant dated April 28, 2022 (Filed as Exhibit 10.15 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.16*	<u>June 1, 2022 Financing Documents (Filed as Exhibit 10.16 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.17*	<u>June 22, 2022 Financing Documents (Filed as Exhibit 10.17 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.18*	<u>Set of Form Documents for July 2022 Financing (Filed as Exhibit 10.18 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.19*	<u>August 31, 2022 Financing Documents (Filed as Exhibit 10.19 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.20*	<u>September 9, 2022 Financing Documents (Filed as Exhibit 10.20 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.21*	<u>October 20, 2022 Financing Documents (Filed as Exhibit 10.21 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.22*	<u>November 9, 2022 Financing Documents (Filed as Exhibit 10.22 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.23*	<u>November 14, 2022 Financing Documents (Filed as Exhibit 10.23 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.24*	<u>November 21, 2022 Financing Documents (Filed as Exhibit 10.24 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.25*	<u>December 22, 2022 Financing Documents (Filed as Exhibit 10.25 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
10.26*	<u>September 14, 2023 Financing Documents (Filed as Exhibit 10.26 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>

21.1*	<u>Subsidiaries of the Registrant (Filed as Exhibit 21.1 to the Registration Statement on Form S-1 filed by the Registrant on April 10, 2024, and incorporated herein by reference).</u>
31.1***	<u>Certification by Principal Executive Officer pursuant to Rule 13a-14(a).</u>
32.1***	<u>Certification by Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
*	Previously filed.
**	To be filed by amendment
***	Filed herewith

All references to Registrant's Forms 8-K, 10-K and 10-Q include reference to File No. 000-55575

SIGNATURES

Pursuant to the requirements of the Securities 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.
a Delaware corporation

Dated: November 14, 2025

By: /s/ James Joyce
James Joyce
Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)

Dated: November 14, 2025

By: /s/ Craig Roberts
Craig Roberts
Chief Technology Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ James Joyce</u> James Joyce	<u>Chief Executive Officer and Director</u> (Principal Executive Officer and Principal Financial and Accounting Officer)	November 14, 2025
<u>/s/ Craig Roberts</u> Craig Roberts	<u>CTO and Director</u>	November 14, 2025
<u>/s/ Jim Dorst</u> Jim Dorst	<u>Director</u>	November 14, 2025

SECTION 302 CERTIFICATION

I, James Joyce, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sigyn Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2025

/s/ James Joyce

James Joyce

Chief Executive Officer (Principal Executive Officer and Principal Financial and Accounting Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Sigyn Therapeutics, Inc. (the “Company”) on Form 10-Q for the nine months ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, James Joyce, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the dates and periods covered by the Report.

This certificate is being made for the exclusive purpose of compliance by the Chief Executive Officer of the Company with the requirements of Section 906 of the Sarbanes-Oxley Act of 2002, and may not be disclosed, distributed or used by any person or for any reason other than as specifically required by law.

/s/ James Joyce

James Joyce
Chief Executive Officer (Principal Executive Officer and Principal Financial and
Accounting Officer)

November 14, 2025
