

**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, 2024

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)

2468 Historic Decatur Road Ste., 140, San Diego, California

(Address of principal executive offices)

92106

(zip code)

(619) 353-0800

(Registrant's telephone number, including area code)

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging Growth Company	<input type="checkbox"/>

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 19, 2024, there were 1,605,378 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, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash	\$ 164,788	\$ 11,690
Inventories	50,000	50,000
Other current assets	54,320	56,373
Total current assets	269,108	118,063
Property and equipment, net	11,048	15,296
Operating lease right-of-use assets, net	126,571	167,736
Other assets	20,711	20,711
Total assets	\$ 427,438	\$ 321,806
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 611,643	\$ 461,646
Accrued payroll and payroll taxes	1,761,644	791,754
Advance from shareholder	43,426	80,000
Short-term convertible notes payable, less unamortized debt issuance costs of \$204,723 and \$297,337, respectively	1,790,865	2,210,299
Current portion of operating lease liabilities	67,650	61,123
Other current liabilities	48	3,182
Total current liabilities	4,275,276	3,608,004
Long-term liabilities:		
Operating lease liabilities, net of current portion	74,748	126,302
Total long-term liabilities	74,748	126,302
Total liabilities	4,350,024	3,734,306
Stockholders' deficit:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; 1,148 and 32 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	-	-
Common stock, \$0.0001 par value, 1,000,000,000 shares authorized; 1,420,678 and 1,288,415 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	142	129
Additional paid-in capital	10,236,178	7,928,883
Accumulated deficit	(14,158,906)	(11,341,512)
Total stockholders' deficit	(3,922,586)	(3,412,500)
Total liabilities and stockholders' deficit	\$ 427,438	\$ 321,806

See accompanying notes to unaudited condensed consolidated financial statements.

SIGYN THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Nine Months Ended September 30,</u>		<u>Three Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Net revenues	\$ -	\$ -	\$ -	\$ -
Gross Profit	-	-	-	-
Operating expenses:				
Marketing expenses	460	335	114	51
Stock based compensation	112,500	112,500	37,500	37,500
Research and development	679,183	582,232	206,161	215,230
General and administrative	1,249,089	1,043,014	564,683	390,033
Total operating expenses	<u>2,041,232</u>	<u>1,738,081</u>	<u>808,458</u>	<u>642,814</u>
Loss from operations	<u>(2,041,232)</u>	<u>(1,738,081)</u>	<u>(808,458)</u>	<u>(642,814)</u>
Other expense:				
Modification of warrants	24,770	(226,929)	24,770	(2,567)
Interest expense	2,931	2,300	850	670
Interest expense - debt discount	423,663	1,309,703	263,719	220,854
Interest expense - original issuance costs	324,798	146,731	99,126	43,955
Total other expense	<u>776,162</u>	<u>1,231,805</u>	<u>388,465</u>	<u>262,912</u>
Loss before income taxes	(2,817,394)	(2,969,886)	(1,196,923)	(905,726)
Income taxes	-	-	-	-
Net loss	<u>\$ (2,817,394)</u>	<u>\$ (2,969,886)</u>	<u>\$ (1,196,923)</u>	<u>\$ (905,726)</u>
Net loss per share, basic and diluted	<u>\$ (2.26)</u>	<u>\$ (2.83)</u>	<u>\$ (0.94)</u>	<u>\$ (0.82)</u>
Weighted average number of shares outstanding				
Basic and diluted	<u>1,245,885</u>	<u>1,050,782</u>	<u>1,268,795</u>	<u>1,105,844</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, 2022	-	\$ -	956,596	\$ 96	\$ 5,292,240	\$ (7,195,576)	\$ (1,903,240)
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	578,016	-	578,016
Beneficial conversion feature in conjunction with debt issuance	-	-	-	-	303,984	-	303,984
Stock based compensation	-	-	-	-	37,500	-	37,500
Modification of warrants	-	-	113,525	11	(15,817)	-	(15,806)
Fees associated with filing of Form S-1	-	-	-	-	(5,456)	-	(5,456)
Net loss	-	-	-	-	-	(1,341,036)	(1,341,036)
Balance as of March 31, 2023	-	\$ -	1,070,121	\$ 107	\$ 6,190,467	\$ (8,536,612)	\$ (2,346,038)
Conversion of common stock for Series A preferred stock	30	-	(152,638)	(15)	15	-	-
Stock based compensation	-	-	-	-	37,500	-	37,500
Modification of warrants	-	-	157,228	16	(208,572)	-	(208,556)
Common stock issued to third parties in conjunction with conversion of debt	-	-	31,075	3	197,997	-	198,000
Net loss	-	-	-	-	-	(723,124)	(723,124)
Balance as of June 30, 2023	30	\$ -	1,105,786	\$ 111	\$ 6,217,407	\$ (9,259,736)	\$ (3,042,218)
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	255,692	-	255,692
Beneficial conversion feature in conjunction with debt issuance	-	-	-	-	81,647	-	81,647
Conversion of common stock for Series A preferred stock	72	-	(9,045)	(1)	1	-	-
Stock based compensation	-	-	-	-	37,500	-	37,500
Modification of warrants	-	-	9,167	1	(2,567)	-	(2,566)
Net loss	-	-	-	-	-	(905,726)	(905,726)
Balance as of September 30, 2023	102	\$ -	1,105,907	\$ 111	\$ 6,589,680	\$ (10,165,462)	\$ (3,575,671)
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)

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (2,817,394)	\$ (2,969,886)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	4,248	5,146
Amortization expense	-	2,100
Stock issued for services	214,550	-
Warrants issued for services	15,703	-
Stock based compensation	112,500	112,500
Accretion of debt discount	423,663	1,309,703
Accretion of original issuance costs	324,798	146,731
Modification of warrants	24,770	(226,929)
Changes in operating assets and liabilities:		
Other current assets	2,053	(42,345)
Accounts payable	149,997	34,112
Accrued payroll and payroll taxes	969,890	375,124
Other current liabilities	(6,996)	(1,572)
Net cash used in operating activities	(582,218)	(1,255,316)
Cash flows from financing activities:		
Proceeds from short-term convertible notes	771,890	1,272,000
Advance from shareholder	35,000	45,000
Repayments of advance from shareholder	(71,574)	-
Fees associated with filing of Form S-1	-	(5,456)
Net cash provided by financing activities	735,316	1,311,544
Net (decrease) increase in cash	153,098	56,228
Cash at beginning of period	11,690	8,356
Cash at end of period	\$ 164,788	\$ 64,584
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	\$ 390,637	\$ 833,708
Original issue discount issued in conjunction with debt	\$ 80,739	\$ 127,200
Original issue discount issued in conjunction with extension of debt	\$ 184,471	\$ 305,319
Preferred stock issued to third parties in conjunction with conversion of debt	\$ 841,418	\$ -
Common stock issued to third parties in conjunction with conversion of debt	\$ 707,730	\$ 198,000
Cancellation of common stock – related party	\$ 7	\$ -
Beneficial conversion feature in conjunction with debt issuance	\$ -	\$ 385,631
Conversion of common stock for Series A preferred stock	\$ -	\$ 647

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”) develops medical devices to treat cancer and infectious disease disorders. We believe our lineup of therapeutic candidates is among the most expansive in the field of extracorporeal blood purification. To optimize the benefit of drugs to treat cancer, we invented the **ImmunePrep™** platform to enhance the performance of immunotherapeutic antibodies; **ChemoPrep™** to improve the delivery of chemotherapy; and **ChemoPure™** to reduce chemotherapy toxicity. Our lead therapeutic candidate is **Sigyn Therapy™**, which if successful, will address infectious disease disorders that are not treatable with drugs. If successfully advanced, our therapies may provide strategic value to the pharmaceutical, dialysis, and organ transplant industries.

Infectious Disease Disorders

To address infectious disease disorders that are not treatable with drugs, we designed Sigyn Therapy™ to extract deadly pathogens and toxins from a patient’s bloodstream, while simultaneously providing a mechanism to dampen down excessive immune responses that are associated with life-threatening infections. Sigyn Therapy™ has been validated to extract viral pathogens, bacterial toxins (including endotoxin), hepatic toxins and inflammatory cytokines from human blood plasma. These expansive capabilities establish Sigyn Therapy™ as a novel strategy to address several unmet needs in global health:

1. **Untreatable viral pathogens** (most of the 200+ viruses that infect humans are not treatable with drugs)
2. **Antibiotic-resistant bacterial infections** (an increasingly prevalent global health threat)
3. **Endotoxemia** (bacterial toxin whose bloodstream presence commonly induces sepsis)
4. **Sepsis** (leading cause of hospital deaths in the United States)

Previous Infectious Disease Industry Achievements

The Company’s management has relevant experience in developing blood purification technologies to treat infectious disease disorders. Most members of our team previously worked alongside our CEO while overseeing development of the first medical device to receive FDA “Emergency Use Authorization” approval to treat an infectious viral pathogen (Ebola) and the first to receive two “Breakthrough Device” designation awards from FDA. As a result of these achievements, in 2015, TIME Magazine named the device to its list of “Top Inventions” and “Top Medical Breakthroughs.”

Sigyn Therapy™ Human Studies

First-in-human clinical studies of Sigyn Therapy™ plan to enroll end-stage renal disease (ESRD) subjects with endotoxemia and concurrent inflammation, which are prevalent, yet untreatable conditions that shorten the lives of dialysis patients. Approximately 550,000 individuals suffer from ESRD in the United States. A therapeutic strategy that helps to extend the lives of ESRD patients may have quantifiable value to the dialysis industry, which is dominated by Fresenius Medical Care and DaVita, Inc. in North America. Based on the number of ESRD patients treated in their networks, every month of extended life would equate to approximately \$1 billion in added revenues for each company.

Emerging Opportunity in Xenotransplantation

Beyond the post-exposure treatment of infectious disease disorders, Sigyn Therapy™ offers a potential preventative strategy to reduce the spread of infection in organ transplantations, including xenotransplantation, an emerging field related to the transplantation of an organ from a donor animal species into a human recipient. The advancement of xenotransplantation is being fueled by a global shortage of transplantable human organs and the recent emergence of gene-editing technologies that have increased the compatibility of porcine-derived (pig) kidneys for human transplantation. In the United States, approximately 90,000 individuals are on the waitlist for a kidney transplant, yet fewer than 30,000 kidney transplants are performed each year.

To optimize xenotransplantation outcomes, Sigyn Therapy™ is proposed for administration to:

1. Gene-edited donor pigs to reduce pathogen accumulation in donor kidneys prior to their extraction for human transplantation. The feasibility of Sigyn Therapy™ administration has been demonstrated in eight (8) porcine subjects to date.
2. Human transplant recipients during and after transplantation to reduce the bloodstream presence of pathogen, inflammatory and other circulating factors that may cause severe illness or induce the rejection of a transplanted organ, whose source may be either a human or animal donor.

This use of Sigyn Therapy™ in these applications corresponds with published FDA™ guidance on the need for strategies to mitigate the risk of a known or unknown pathogen being transmitted from a porcine-derived organ to a human transplant recipient.

Devices to Optimize the Benefit of Cancer Therapies

We are not a developer of drugs to treat cancer. We are a developer of medical devices to optimize the benefit of drugs to treat cancer, the 2nd leading cause of death in the United States. Our therapeutic candidates include the ImmunePrep™ platform to enhance the performance of immunotherapeutic antibodies, ChemoPrep™ to improve the delivery of chemotherapy, and ChemoPure™ to extract off-target chemotherapy from the bloodstream to reduce treatment toxicity.

ImmunePrep™ to Optimize Immunotherapeutic Antibodies

Immunotherapeutic antibodies (monoclonal antibodies, therapeutic antibodies, checkpoint inhibitors, antibody drug conjugates) generate more revenues than any other class of drug to treat cancer and are the most valued assets in global medicine based on 2023 and 2024 M&A transactions. However, therapeutic antibodies are poorly delivered to their intended cancer targets and as a result, most patients don't respond to therapy. In many cases, less than 2% of an antibody dose will reach its cancer target, yet a significant portion of same dose can be intercepted by high concentrations of circulating decoys that display the antigen binding site of the antibody.

In response, we invented the ImmunePrep™ platform to allow for a therapeutic antibody to be immobilized within an extracorporeal circuit to sweep antibody decoys out of the bloodstream prior to the subsequent infusion of the antibody to a patient. We believe this reverse decoy mechanism will improve targeted antibody delivery and simultaneously reduce the circulating presence of the antibody's cancer targets to further enhance patient benefit. As a platform technology, ImmunePrep™ allows for the potential development of products that may incorporate a development-stage, clinical-stage or market-approved antibody. Based on previous FDA interactions, we believe ImmunePrep™ products that incorporate market-approved antibodies may have an accelerated pathway to potential market clearance.

ChemoPrep™ to Optimize Chemotherapy Delivery

Chemotherapeutic agents are the most commonly administered class of drug to treat cancer, yet only a small fraction of infused doses reach their cancer cell targets. Contributing to inadequate delivery are high concentrations of tumor-derived exosomes, whose bloodstream presence disrupts chemotherapy delivery and corresponds with treatment resistance. We designed ChemoPrep™ to reduce the circulating presence of tumor-derived exosomes prior chemotherapy administration. Our clinical goal is to maintain or improve the efficacy of chemotherapy with lower doses, which would reduce treatment toxicity. In this regard, ChemoPrep™ aligns with the FDA "Project Optimus" initiative to minimize the toxicity of cancer drugs while maximizing patient benefit.

ChemoPure™ to Reduce Chemotherapy Toxicity

Once chemotherapy has been administered, residual off-target chemotherapy that is left to circulate in the bloodstream is more likely to cause patient harm versus benefit. In response, we designed ChemoPure™ to extract off-target chemotherapy from the bloodstream to further reduce treatment toxicity.

To learn more, visit: www.SigynTherapeutics.com.

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”).

Reverse Stock Split

Effective January 19, 2024, 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.

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 \$14,158,906 at September 30, 2024, had a working capital deficit of \$4,006,168 at September 30, 2024, had net losses of \$1,196,923 and \$2,817,394, and \$905,726 and \$2,969,886 for the three and nine months ended September 30, 2024 and 2023, respectively, and net cash used in operating activities of \$582,218 and \$1,255,316 for the nine months ended September 30, 2024 and 2023, 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 generate revenues, the Company’s cash position will not be significant enough to support the Company’s daily operations for the foreseeable future. Management intends to raise additional funds by way of a private offering, 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. The Company calculates the fair value of warrants using the Black-Scholes option-pricing method. The Black-Scholes option-pricing method 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 or any uncertain income tax positions.

Advertising and Marketing Costs

Advertising expenses are recorded as general and administrative expenses when they are incurred. The Company had \$114 and \$460, and \$51 and \$335 of advertising expenses for the three and nine months ended September 30, 2024 and 2023, respectively.

Research and Development

All research and development costs are expensed as incurred. The Company incurred research and development expense of \$206,161 and \$679,183, and \$215,230 and \$582,232 for the three and nine months ended September 30, 2024 and 2023, 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, 2024 and December 31, 2023, 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, 2024. 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.

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, 2024 and December 31, 2023, 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, 2024 and December 31, 2023, 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 no 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 no derivative financial instruments as of September 30, 2024 and December 31, 2023 and no charges or credits to income for the three and nine months ended September 30, 2024 and 2023.

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 either the derivative treatment or as a beneficial conversion feature, 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 unaudited condensed consolidated statements 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

Sigyn TherapyTM 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 Sigyn TherapyTM 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 Sigyn TherapyTM.

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.

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of:

	<u>Estimated Life</u>	<u>September 30, 2024</u>	<u>December 31, 2023</u>
Office equipment	5 years	\$ 29,041	\$ 29,041
Computer equipment	3 years	3,157	3,157
Accumulated depreciation		(21,150)	(16,902)
		<u>\$ 11,048</u>	<u>\$ 15,296</u>

Depreciation expense was \$1,363 and \$4,248, and \$1,716 and \$5,146 for the three and nine months ended September 30, 2024 and 2023, 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, 2024	Outstanding Balance as of December 31, 2023
<i>Osher Capital Partners LLC</i>				
January 28, 2020 (“Note 1”)	August 31, 2025	\$ 350,005	\$ 620,553	\$ 564,138
June 22, 2022 (“Note 2”)	August 31, 2025	75,000	103,745	94,314
August 31, 2022 (“Note 2”)	August 31, 2025	100,000	135,520	123,200
September 20, 2022 (“Note 2”)	August 31, 2025	100,000	135,520	123,200
October 20, 2022 (“Note 2”)	March 31, 2025	100,000	127,000	110,000
November 14, 2022 (“Note 2”)	March 31, 2025	50,000	64,350	55,000
December 22, 2022 (“Note 2”)	March 31, 2025	100,000	125,000	110,000
July 18, 2023 (“Note 3”)	August 31, 2025	60,000	72,600	66,000
December 7, 2023 (“Note 3”)	August 31, 2025	40,000	48,400	44,000
May 13, 2024 (“Note 4”)	May 13, 2025	35,000	40,000	-
August 19, 2024 (“Note 4”)	August 19, 2025	7,500	8,250	-
<i>Brio Capital Master Fund, Ltd.</i>				
March 23, 2022 (“Note 2”)	August 31, 2025	100,000	142,960	129,964
November 9, 2022 (“Note 2”)	August 31, 2025	75,000	101,640	92,400
January 20, 2023 (“Note 3”)	March 31, 2025	50,000	62,500	55,000
February 9, 2023 (“Note 3”)	March 31, 2025	50,000	62,500	55,000
July 20, 2023 (“Note 3”)	August 31, 2025	40,000	48,400	44,000
January 8, 2024 (“Note 4”)	January 8, 2025	40,000	44,000	-
May 13, 2024 (“Note 4”)	May 13, 2025	35,000	40,000	-
August 20, 2024 (“Note 4”)	August 20, 2025	11,500	12,650	-
<i>Various third-party noteholders</i>				
Various dates in fiscal 2024 (“Note 4”)	None outstanding	642,890	-	-
<i>Previous fiscal 2021, 2022, and 2023 Osher and Brio Notes converted in fiscal 2024</i>				
			-	841,420
Total convertible notes payable		\$ 2,061,895	\$ 1,995,588	\$ 2,507,636
Original issue discount			(166,247)	(225,835)
Beneficial conversion feature			-	(22,013)
Debt discount			(38,476)	(49,489)
Total convertible notes payable			\$ 1,790,865	\$ 2,210,299

Principal payments on convertible promissory debentures are due as follows:

Year ending December 31, 2025	\$ 1,995,588
	\$ 1,995,588

Changes in convertible notes were as follows:

	Note 1	Note 2	Note 3	Note 4	Totals
Convertible notes payable as of December 31, 2022	\$ 700,816	\$ 1,578,500	\$ -	\$ -	\$ 2,279,316
Convertible notes payable issued in 2023	163,320	142,000	1,443,200	-	1,748,520
Conversion of debt for common stock	-	(341,000)	(1,179,200)	-	(1,520,200)
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	852,630	1,037,101
Conversion of debt for common stock	(299,999)	(541,420)	-	(707,730)	(1,549,149)
Convertible notes payable as of September 30, 2024	\$ 620,553	\$ 935,735	\$ 294,400	\$ 144,900	\$ 1,995,588

Changes in note discounts were as follows:

	Note 1	Note 2	Note 3	Note 4	Totals
Note discounts as of December 31, 2022	\$ -	\$ 642,660	\$ -	\$ -	\$ 642,660
Note discounts issued in conjunction with debt in 2023	163,320	142,000	1,390,535	-	1,695,855
2023 accretion of note discounts	(48,325)	(683,850)	(1,309,003)	-	(2,041,178)
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	470,826	665,297
2024 accretion of note discounts	(114,995)	(116,489)	(88,501)	(427,926)	(747,911)
Note discounts as of September 30, 2024	\$ 56,414	\$ 81,978	\$ 23,431	\$ 42,900	\$ 204,723
Convertible notes payable, net, as of December 31, 2023	\$ 749,141	\$ 1,278,690	\$ 182,468	\$ -	\$ 2,210,299
Convertible notes payable, net, as of September 30, 2024	\$ 564,139	\$ 853,757	\$ 270,969	\$ 102,000	\$ 1,790,865
2023 Effective interest rate	6%	50%	496%	-%	81%
2024 Effective interest rate	19%	12%	30%	295%	37%

Current Noteholders

2024 Convertible Notes (Note 4)

During fiscal 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the “2024 Notes”) totaling (i) \$852,630 aggregate principal amount of Notes (total of \$771,890 cash was received) due between January and June 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 213,164 shares of the Company’s Common Stock at an exercise price of \$7.50 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$771,891 which was issued at a \$80,739 original issue discount from the face value of the Note.

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

In May 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) \$264,000 aggregate principal amount of Notes (total of \$240,000 cash was received) due in various dates from July 2024 through March 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 44,002 shares of the Company’s Common Stock at an exercise price of \$7.50 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 \$24,000 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 \$4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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) \$879,428 aggregate principal amount of Notes (total of \$700,000 cash was received) due on various dates from January 2024 through December 7, 2024 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 240,534 shares of the Company’s Common Stock at an exercise price of \$7.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$770,000 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 \$4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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 between August 2024 and March 2025 for original issue discount totaling \$41,350.

Osher – \$564,139 (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) \$564,139 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 \$5.60 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 \$214,133 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 \$3.76 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On September 30, 2024, a noteholder agreed to extend the note to August 31, 2025 for original issue discount totaling \$56,414.

NOTE 6 – ADVANCE FROM SHAREHOLDER

The Company borrows funds from the Company’s CEO for working capital purposes from time to time. The Company has recorded the principal balance due of \$43,426 and \$80,000 under Advance from Shareholder in the accompanying the unaudited condensed consolidated balance sheets at September 30, 2024 and December 31, 2023, respectively. The Company received advances of \$35,000 and \$64,500 and had repayments of \$71,574 and \$19,500 for the nine months ended September 30, 2024 and 2023. The advances from our CEO were not made pursuant to any loan agreements or promissory notes, are non-interest bearing and due on demand.

NOTE 7 – STOCKHOLDERS’ DEFICIT

Preferred Stock

The Company authorized 10,000,000 shares of par value \$0.0001 preferred stock, of which 1,148 and 32 shares are issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.

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.

During fiscal 2023, holders of 161,684 shares of common stock elected to exchange these shares for an aggregate of 32 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 126.63 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 the Warrant Exchange Agreement.

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

The Company has authorized 1,000,000,000 shares of par value \$0.0001 common stock, of which 1,420,678 and 1,288,415 shares are outstanding as of September 30, 2024 and December 31, 2023, respectively.

In the nine months ended September 30, 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 nine months ended September 30, 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.

During the year ended December 31, 2023, a total of 559,839 warrants were exchanged for 279,920 shares of the Company’s common stock.

On June 2, 2023, a third-party investor elected to convert the aggregate principal amount of two Notes of \$198,000, into 31,075 common shares.

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

Reverse Stock Split

Effective January 19, 2024, 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

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 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).

In March 2023, the Company offered a short-term inducement to the Company's third party warrant holders in which the Company will issue one share of the Company's common stock in exchange for each two warrants were exchanged for 279,920 shares of the Company's common stock through December 31, 2023. The Company recognized a gain of \$352,965 due to the modification of the warrants in the year ended December 31, 2023, as a result of the modification.

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 and ending on 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 leases. 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.

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,	
	2024	2023	2024	2023
Operating lease expense	\$ 53,757	\$ 53,757	\$ 17,919	\$ 17,919
Short term lease cost	\$ -	\$ -	\$ -	\$ -
Total lease expense	\$ 53,757	\$ 53,757	\$ 17,919	\$ 17,919

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

<i>Nine Months ended September 30,</i>	2024	2023
Operating cash flows from operating leases	\$ 57,619	\$ 55,941
Cash paid for amounts included in the measurement of lease liabilities	\$ 57,619	\$ 55,941
Weighted-average remaining lease term—operating leases	1.92 years	2.92 years
Weighted-average discount rate—operating leases	10%	10%

In accordance with ASC 842, maturities of operating lease liabilities as of September 30, 2024 were as follows:

<i>Year ending:</i>	Operating Lease
2024 (remaining 3 months)	\$ 19,522
2025	79,456
2026	54,225
Total undiscounted cash flows	\$ 153,203
Reconciliation of lease liabilities:	
Weighted-average remaining lease terms	1.92 years
Weighted-average discount rate	10%
Present values	\$ 142,398
Lease liabilities—current	67,650
Lease liabilities—long-term	74,748
Lease liabilities—total	\$ 142,398
Difference between undiscounted and discounted cash flows	\$ 10,805

NOTE 9 – RELATED PARTY TRANSACTIONS

Other than as set forth below, and as disclosed in Notes 6 and 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 (including accrued compensation of \$113,750) and \$341,250 (including accrued compensation of \$341,250), and \$113,750 (including accrued compensation of \$113,750) and \$345,585 (including accrued compensation of \$174,960) for the three and nine months ended September 30, 2024 and 2023, respectively.

Mr. DeCiccio was hired December 6, 2023 as the Company's Chief Financial Officer ("CFO"). Mr. DeCiccio receives an annual base salary of \$250,000, plus discretionary bonus compensation not to exceed 40% of salary. Mr. DeCiccio's employment also provides for medical insurance, disability benefits and three months of severance pay if his employment is terminated without cause or due to a change in control. Additionally, Mr. DeCiccio was granted stock options to purchase 17,500 shares of the Company's common shares. The Company incurred compensation expense of \$31,248 (including accrued compensation of \$31,248) and \$93,744 (including accrued compensation of \$93,744) for the three and nine months ended September 30, 2024, respectively. Prior to Mr. DeCiccio being hired as the CFO, he was a consultant to the Company. The Company has recorded a balance due to Mr. DeCiccio of \$21,575 and \$35,242 under Accounts Payable in the accompanying the condensed consolidated balance sheets as of September 30, 2024 (unaudited) and December 31, 2023, respectively, for services rendered.

On April 1, 2023, the Company entered into an Employment Agreement with Dr. Annette Marleau whereby Dr. Marleau became the Company's Chief Scientific Officer. Dr. Marleau receives an annual base salary of \$300,000, with automatic 3% annual increases plus bonus compensation not to exceed 40% of salary. Dr. Marleau's employment also provides for medical insurance, disability benefits and up to six months of severance pay if her employment is terminated by the Company. The Company incurred compensation expense of \$77,250 (including accrued compensation of \$64,375) and \$231,750 (including accrued compensation of \$193,125), and \$75,000 (including accrued compensation of \$37,500) and \$151,610 (including accrued compensation of \$37,500) for the three and nine months ended September 30, 2024 and 2023, 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,	
	2024	2023	2024	2023
Convertible notes payable	509,504	546,185	509,504	546,185
Restricted stock units	41,566	12,885	12,424	4,295
Warrants to purchase shares of common stock	251,125	53,167	251,125	53,167
Total potentially dilutive shares	<u>802,195</u>	<u>612,237</u>	<u>773,053</u>	<u>603,647</u>

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

	Nine Months Ended September 30,		Three Months Ended September 30,	
	2024	2023	2024	2023
Net loss attributable to the common stockholders	<u>\$ (2,817,394)</u>	<u>\$ (2,969,886)</u>	<u>\$ (1,196,923)</u>	<u>\$ (905,726)</u>
Basic weighted average outstanding shares of common stock	1,245,885	1,050,782	1,268,795	1,105,844
Dilutive effect of options and warrants	-	-	-	-
Diluted weighted average common stock and common stock equivalents	<u>1,245,885</u>	<u>1,050,782</u>	<u>1,268,795</u>	<u>1,105,844</u>
Loss per share:				
Basic and diluted	<u>\$ (2.26)</u>	<u>\$ (2.83)</u>	<u>\$ (0.94)</u>	<u>\$ (0.82)</u>

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 October 10, 2022, the Company's Board of Directors appointed Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel 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.

NOTE 12 – SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after September 30, 2024 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, 2024, except for the following:

Warrants

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 loss of \$29,971 due to the modification of the warrants in October 2024.

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, 2023 particularly under the "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements and Risk Factors Summary" sections.

Recent Developments

Reverse Stock Split

Effective January 19, 2024, 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 1,148 and 32 shares preferred shares are issued and outstanding as of September 30, 2024 and December, 31, 2023, respectively.

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.

During fiscal 2023, holders of 161,684 shares of common stock elected to exchange these shares for an aggregate of 32 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 126.63 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 the Warrant Exchange Agreement.

Common Stock

The Company has authorized 1,000,000,000 shares of par value \$0.0001 common stock, of which 1,420,678 and 1,288,415 shares were outstanding as of September 30, 2024 and December 31, 2023, respectively.

In the nine months ended September 30, 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 nine months ended September 30, 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.

During the year ended December 31, 2023, a total of 559,839 warrants were exchanged for 279,920 shares of the Company's common stock.

On June 2, 2023, a third-party investor elected to convert the aggregate principal amount of two Notes of \$198,000, into 31,075 common shares.

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

Warrants

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 loss of \$29,971 due to the modification of the warrants in October 2024.

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 March 2023, the Company offered a short-term inducement to the Company's third party warrant holders in which the Company will issue one share of the Company's common stock in exchange for each two warrants were exchanged for 279,920 shares of the Company's common stock through December 31, 2023. The Company recognized a gain of \$352,965 due to the modification of the warrants in the year ended December 31, 2023 as a result of the modification.

Current Noteholders

2024 Convertible Notes

During fiscal 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) \$852,630 aggregate principal amount of Notes (total of \$771,891 cash was received) due between January and June 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 213,164 shares of the Company's Common Stock at an exercise price of \$7.50 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$771,891 which was issued at a \$80,738 original issue discount from the face value of the Note. In connection with voluntary conversions by the holders of the convertible notes, the conversion price for principal of \$619,692 is \$4.00 per share and principal of \$232,937 is \$6.00 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 2024, holders converted \$232,937 in exchange for the issuance of 38,826 shares of Common Stock to the holders.

2023 Convertible Notes

During fiscal 2023, the Company entered into Original Issue Discount Senior Convertible Debentures (the “2023 Notes”) totaling (i) \$264,000 aggregate principal amount of Notes (total of \$240,000 cash was received) due in various dates from July 2024 through March 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 44,002 shares of the Company’s Common Stock at an exercise price of \$7.50 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 \$24,000 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 \$4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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

During fiscal 2022, the Company entered into Original Issue Discount Senior Convertible Debentures (the “2022 Notes”) totaling (i) \$879,428 aggregate principal amount of Notes (total of \$700,000 cash was received) due on various dates from January 2024 through December 7, 2024 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 240,534 shares of the Company’s Common Stock at an exercise price of \$10.00 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$770,000 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 \$6.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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 between August 2024 and March 2025 for original issue discount totaling \$41,350.

Osher – \$564,139

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) \$564,139 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 \$5.60 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 \$214,133 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 \$3.76 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On September 30, 2024, a noteholder agreed to extend the note to August 31, 2025 for original issue discount totaling \$56,414.

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”) develops medical devices to treat cancer and infectious disease disorders. We believe our lineup of therapeutic candidates is among the most expansive in the field of extracorporeal blood purification. To optimize the benefit of drugs to treat cancer, we invented the **ImmunePrep™** platform to enhance the performance of immunotherapeutic antibodies; **ChemoPrep™** to improve the delivery of chemotherapy; and **ChemoPure™** to reduce chemotherapy toxicity. Our lead therapeutic candidate is **Sigyn Therapy™** designed to address infectious disease disorders that are not treatable with drugs. If successfully advanced, our therapies may provide strategic value to the pharmaceutical, dialysis, and organ transplant industry.

Infectious Disease Disorders

To address infectious disease disorders that are not treatable with drugs, we designed Sigyn Therapy™ to extract deadly pathogens and toxins from a patient’s bloodstream, while simultaneously providing a mechanism to dampen down excessive immune responses that are associated with life-threatening infections. Sigyn Therapy™ has been validated to extract viral pathogens, bacterial toxins (including endotoxin), hepatic toxins and inflammatory cytokines from human blood plasma. These expansive capabilities establish Sigyn Therapy™ as a novel strategy to address several unmet needs in global health:

1. **Untreatable viral pathogens** (most of the 200+ viruses that infect humans are not treatable with drugs)
2. **Antibiotic-resistant bacterial infections** (an increasingly prevalent global health threat)
3. **Endotoxemia** (bacterial toxin whose bloodstream presence commonly induces sepsis)
4. **Sepsis** (leading cause of hospital deaths in the United States)

Previous Infectious Disease Industry Achievements

The Company’s management has relevant experience in developing blood purification technologies to treat infectious disease disorders. Most members of our team previously worked alongside our CEO while overseeing development of the first medical device to receive FDA “Emergency Use Authorization” approval to treat an infectious viral pathogen (Ebola) and the first to receive two “Breakthrough Device” designation awards from FDA. As a result of these achievements, TIME Magazine named the device to its list of “Top Inventions” and “Top Medical Breakthroughs.”

Sigyn Therapy™ Human Studies

First-in-human clinical studies of Sigyn Therapy™ plan to enroll end-stage renal disease (ESRD) subjects with endotoxemia and concurrent inflammation, which are prevalent, yet untreatable conditions that shorten the lives of dialysis patients. Approximately 550,000 individuals suffer from ESRD in the United States. A therapeutic strategy that helps to extend the lives of ESRD patients may have quantifiable value to the dialysis industry, which is dominated by Fresenius Medical Care and DaVita, Inc. in North America. Based on the number of ESRD patients treated in their networks, every month of extended life would equate to approximately \$1 billion in added revenues for each company.

Emerging Opportunity in Xenotransplantation

Beyond the post-exposure treatment of infectious disease disorders, Sigyn Therapy™ offers a potential preventative strategy to reduce the spread of infection in organ transplantations, including xenotransplantation, an emerging field related to the transplantation of an organ from a donor animal species into a human recipient. The advancement of xenotransplantation is being fueled by a global shortage of transplantable human organs and the recent emergence of gene-editing technologies that have increased the compatibility of porcine-derived (pig) kidneys for human transplantation. In the United States, approximately 90,000 individuals are on the waitlist for a kidney transplant, yet fewer than 30,000 kidney transplants are performed each year.

To optimize xenotransplantation outcomes, Sigyn Therapy™ is proposed for administration to:

1. Gene-edited donor pigs to reduce pathogen accumulation in donor kidneys prior to their extraction for human transplantation. The feasibility of Sigyn Therapy™ administration has been demonstrated in eight (8) porcine subjects to date.
2. Human transplant recipients during and after transplantation to reduce the bloodstream presence of pathogen, inflammatory and other circulating factors that may cause severe illness or induce the rejection of a transplanted organ, whose source may be either a human or animal donor.

This use of Sigyn Therapy™ in these applications corresponds with published FDA guidance on the need for strategies to mitigate the risk of a known or unknown pathogen being transmitted from a porcine-derived organ to a human transplant recipient.

Devices to Optimize the Benefit of Cancer Therapies

We are not a developer of drugs to treat cancer. We are a developer of medical devices to optimize the benefit of drugs to treat cancer, the 2nd leading cause of death in the United States. Our therapeutic candidates include the ImmunePrep™ platform to enhance the performance of immunotherapeutic antibodies, ChemoPrep™ to improve the delivery of chemotherapy, and ChemoPure™ to extract off-target chemotherapy from the bloodstream to reduce treatment toxicity.

ImmunePrep™ to Optimize Immunotherapeutic Antibodies

Immunotherapeutic antibodies (monoclonal antibodies, therapeutic antibodies, checkpoint inhibitors, antibody drug conjugates) generate more revenues than any other class of drug to treat cancer and are the most valued assets in global medicine based on 2023 and 2024 M&A transactions. However, therapeutic antibodies are poorly delivered to their intended cancer targets and, as a result, most patients don't respond to therapy. In many cases, less than 2% of an antibody dose will reach its cancer target, yet a significant portion of same dose can be intercepted by high concentrations of circulating decoys that display the antigen binding site of the antibody.

In response, we invented the ImmunePrep™ platform to allow for a therapeutic antibody to be immobilized within an extracorporeal circuit to sweep antibody decoys out of the bloodstream prior to the subsequent infusion of the antibody to a patient. We believe this reverse decoy mechanism will improve targeted antibody delivery and simultaneously reduce the circulating presence of the antibody's cancer targets to further enhance patient benefit. As a platform technology, ImmunePrep™ allows for the potential development of products that may incorporate a development-stage, clinical-stage or market-approved antibody. Based on previous FDA interactions, we believe ImmunePrep™ products that incorporate market-approved antibodies may have an accelerated pathway to potential market clearance.

ChemoPrep™ to Optimize Chemotherapy Delivery

Chemotherapeutic agents are the most commonly administered class of drug to treat cancer, yet only a small fraction of infused doses reach their cancer cell targets. Contributing to inadequate delivery are high concentrations of tumor-derived exosomes, whose bloodstream presence disrupts chemotherapy delivery and corresponds with treatment resistance. We designed ChemoPrep™ to reduce the circulating presence of tumor-derived exosomes prior chemotherapy administration. Our clinical goal is to maintain or improve the efficacy of chemotherapy with lower doses, which would reduce treatment toxicity. In this regard, ChemoPrep™ aligns with the FDA "Project Optimus" initiative to minimize the toxicity of cancer drugs while maximizing patient benefit.

ChemoPure™ to Reduce Chemotherapy Toxicity

Once chemotherapy has been administered, residual off-target chemotherapy that is left to circulate in the bloodstream is more likely to cause patient harm versus benefit. In response, we designed ChemoPure™ to extract off-target chemotherapy from the bloodstream to further reduce treatment toxicity.

About Sigyn Therapy™ - Our Lead Therapeutic Candidate

To address infectious disease disorders that are not treatable with drugs, we designed Sigyn Therapy™ to extract deadly pathogens and toxins from a patient's bloodstream, while simultaneously providing a mechanism to dampen down excessive immune responses that are associated with life-threatening infections. Sigyn Therapy™ has been validated to extract viral pathogens, bacterial toxins (including endotoxin), hepatic toxins and inflammatory cytokines from human blood plasma. These expansive capabilities establish Sigyn Therapy™ as a novel strategy to address several unmet needs in global health, including untreatable viral pathogens, antibiotic-resistant bacterial infections, endotoxemia, and sepsis.

Sigyn Therapy™ Pre-Clinical Studies

Since the inception of our Company, we have advanced 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 Sigyn Therapy™. 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 dysregulated production (the cytokine storm) precipitate sepsis and play a prominent role in each of our therapeutic opportunities.

Sigyn Therapy™ Animal Studies

Subsequent to our pre-clinical *in vitro* studies, we disclosed the completion of *in vivo* animal studies. In these studies, 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 Sigyn Therapy™, 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 underlie 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.

Sigyn Therapy™ Clinical Plan

The data resulting from our *in vivo* animal and pre-clinical *in vitro* studies has been incorporated in an Investigational Device Exemption (IDE) that we have drafted for submission to the U.S. Food and Drug Administration (“FDA”) to support first-in-human feasibility studies of Sigyn Therapy™. The clinical plan of our IDE proposes to enroll 12-15 End-Stage Renal Disease (“ESRD”) patients with endotoxemia and concurrent inflammation 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 Sigyn Therapy™ can be safely administered to health compromised ESRD subjects. Additionally, we plan to quantify changes in endotoxin levels as well as markers of inflammation as secondary endpoints. 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 Sigyn Therapy™.

Based on our previous experience in developing extracorporeal blood purification therapies, we believe we have collected sufficient data to support first-in-human studies of Sigyn Therapy™. However, Sigyn Therapy™ is a Class III device that requires extensive pre-clinical and clinical studies to be conducted along with the submission of a Pre-Market Approval (PMA) application prior to market clearance consideration by FDA.

Sigyn Therapy™ Mechanism of Action

We designed Sigyn Therapy™ to treat life-threatening infectious disease disorders that are not addressed with drug therapies. Based on its ability to extract viral pathogens, bacterial toxins (including endotoxin), hepatic toxins and inflammatory cytokines from human blood plasma, Sigyn Therapy™ establishes a novel strategy to address several unmet needs in global health. These include untreatable viral pathogens, antibiotic resistant bacterial infections, endotoxemia, and sepsis.

To support widespread implementation, Sigyn Therapy™ is a single-use disposable device that is deployable on the global infrastructure of hemodialysis and continuous renal replacement therapy (CRRT) 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 in dialysis and CRRT therapies. During animal studies conducted at the University of Michigan, Sigyn Therapy™ was deployed for use on a dialysis machine manufactured by Fresenius Medical Care, a global leader in the dialysis industry.

Incorporated within Sigyn Therapy™ is a “cocktail” of adsorbent components formulated to optimize the broad-spectrum reduction of therapeutic targets from the bloodstream. In the medical field, the term “cocktail” is a reference to the simultaneous administration of multiple drugs (a drug cocktail) with differing mechanisms of actions. While drug cocktails are emerging as potential mechanisms to treat cancer, they are life-saving countermeasures to treat HIV and Hepatitis-C viral infections. However, dosing of multi-drug agent cocktails is limited by toxicity and adverse events that can result from deleterious drug interactions.

Sigyn Therapy™ is not constrained by such limitations as active adsorbent components are maintained within Sigyn Therapy™ and not introduced into the body. As a result, we are able to incorporate a substantial quantity of adsorbent components to capture therapeutic targets outside of the body as they circulate through Sigyn Therapy™. Each adsorbent component has differing capture characteristics that contribute to optimizing the potential of Sigyn Therapy™ to reduce the circulating presence of both pathogen and inflammatory targets that underly sepsis and other life-threatening infectious disease disorders.

The adsorbent components incorporated within Sigyn Therapy™ 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 Sigyn Therapy™ to be a highly efficient treatment methodology. Based on targeted blood flow rates of 350ml/min, the entire bloodstream of an average size person can be processed through Sigyn Therapy™ approximately fifteen times during a single four-hour treatment period.

From a technical perspective, Sigyn Therapy™ 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 Sigyn Therapy™, plasma and therapeutic targets below 200nm travel through the porous walls as a result of blood-side pressure. As the hollow fiber bundle within Sigyn Therapy™ 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 Sigyn Therapy™ 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 Sigyn Therapy™.

Opportunities to Address Unmet Needs in Global Health

Based on data obtained during pre-clinical *in vitro* validation studies, we are advancing Sigyn Therapy™ to address several unmet needs in global health. These include untreatable viral pathogen, antibiotic resistant bacterial infections, endotoxemia, and sepsis.

Untreatable Viral Pathogens

A majority of 200+ viruses that are known to be infectious to humans are not treatable with drug therapies. Furthermore, newly emerging viruses will remain drug-resistant until a corresponding drug is developed and demonstrated to be safe and effective in human studies. As a result, extracorporeal blood purification therapies are increasingly being deployed as first-line treatment countermeasures.

The first blood purification device to receive FDA Emergency-Use Authorization approval to treat a pandemic virus was the Hemopurifier to treat Ebola, which occurred under the leadership of our CEO at a previous company. Subsequently, the first therapies to receive FDA Emergency-Use Authorization to treat Covid-19 were blood purification therapies from Terumo BCT, ExThera Medical Corporation, CytoSorbents, Inc., and Baxter Healthcare Corporation. In connection with these approvals, FDA published a statement that blood purification devices may be effective at treating patients with confirmed COVID-19 by reducing various pathogens, cytokines, and other inflammatory mediators from their bloodstream.

Consistent with FDA's statement, pediatric versions of Sigyn Therapy™ have demonstrated an ability to reduce the presence of various pathogens, cytokines, and other inflammatory mediators from human blood plasma. As such, we believe Sigyn Therapy™ offers an important candidate strategy to treat future pandemic outbreaks, which are increasingly being fueled by a confluence of global warming, urban crowding, and intercontinental travel.

Additionally, as many infectious viruses are not addressed with a corresponding drug or vaccine, there may be an ongoing need for blood purification technologies that offer to reduce the severity of infection and mitigate the excess production of inflammatory cytokines (the cytokine storm) associated with high mortality in non-pandemic viral infections. Sigyn Therapy™ also aligns with government initiatives to support the development of broad-spectrum medical countermeasures that could help mitigate the impact of an emerging pandemic or bioterror threat yet may also have viability in established disease indications.

Antibiotic-Resistant Bacterial Infections

According to the U.S. Centers for Disease Control and Prevention ("CDC"), nearly three million individuals are infected with antibiotic resistant bacterial infections in the U.S. each year, which results in more than 35,000 deaths. The United Nations reported approximately 5 million deaths worldwide in 2019 were associated with antimicrobial drug resistance and projects the annual death toll could increase to 10 million by 2050 in the absence of new therapeutic advances. Based on its broad-spectrum mechanism to extract bacterial toxins and inflammatory mediators from the bloodstream, Sigyn Therapy™ may provide a novel strategy to assist in the treatment of antibiotic-resistant bacterial infections.

Endotoxemia

Endotoxin is a gram-negative bacterial toxin whose bloodstream presence commonly induces sepsis, the leading cause of death in U.S. hospitals. Our initial clinical focus is directed toward the treatment of end-stage renal disease (ESRD) patients who suffer from endotoxemia and concurrent inflammation, which are prevalent, yet untreatable conditions that shorten the lives of dialysis patients.

According to the United States Renal Data System ("USRDS"), more than 550,000 individuals have ESRD, which results in approximately 85 million kidney dialysis treatments being administered in the United States each year. A therapy that could help extend the lives of these patients may have a quantifiable value to the dialysis industry, which is dominated by Fresenius Medical Care and DaVita, Inc. in North America. Based on the number of ESRD patients treated in their networks, every month of extended life would equate to approximately \$1 billion in added revenues for each company.

Sepsis

Sepsis is defined as a life-threatening organ dysfunction caused by a dysregulated host response to infection. In January of 2020, a report entitled; "*Global, Regional, and National Sepsis Incidence and Mortality, 1990-2017: Analysis for the Global Burden of Disease Study*," reported 48.9 million cases of sepsis and 11 million deaths in 2017. In that same year, an estimated 20.3 million sepsis cases and 2.9 million deaths were among children younger than 5-years old. The report included a reference that sepsis kills more people around the world than all forms of cancer combined. In the United States, sepsis was reported to be the most common cause of hospital deaths with an annual financial burden that exceeds \$24 billion.

To date, more than 100 human studies have been conducted to evaluate the safety and efficacy of candidate drugs to treat sepsis. With one brief exception (Xigris, Eli Lilly), none of these studies resulted in a market cleared therapy. As sepsis remains beyond the reach of single-target drugs, there is a growing interest in multi-mechanism therapies that can simultaneously address both inflammatory and pathogen associated targets. Sigyn Therapy™ offers to address a broad-spectrum of pathogen sources and the resulting dysregulated cytokine production (the cytokine storm) that is a hallmark of sepsis.

Emerging Opportunity for Sigyn Therapy™ in Xenotransplantation

Beyond the post-exposure treatment of infectious disease disorders, Sigyn Therapy™ offers a potential preventative strategy to reduce the spread of infection in organ transplantation, including xenotransplantation, an emerging field related to the transplantation of an organ from a donor animal species into a human recipient. The advancement of xenotransplantation is being fueled by a global shortage of transplantable human organs and the recent emergence of gene-editing technologies that have increased the compatibility of porcine-derived (pig) kidneys for human transplantation. In the United States, approximately 90,000 individuals are on the waitlist for a kidney transplant, yet fewer than 30,000 kidney transplants are performed each year.

To optimize xenotransplantation outcomes, Sigyn Therapy™ is proposed for administration to:

1. Gene-edited donor pigs to reduce pathogen accumulation in donor kidneys prior to their extraction for human transplantation. The feasibility of Sigyn Therapy™ administration has been demonstrated in eight (8) porcine subjects to date.
2. Human transplant recipients during and after transplantation to reduce the bloodstream presence of pathogen, inflammatory and other circulating factors that may cause severe illness or induce the rejection of a transplanted organ, whose source may be either a human or animal donor.

This use of Sigyn Therapy™ in these applications corresponds with published FDA guidance on the need for strategies to mitigate the risk of a known or unknown pathogen being transmitted from a porcine-derived organ to a human transplant recipient.

Devices to Optimize the Benefit of Cancer Therapies

We are not a developer of drugs to treat cancer. We are a developer of medical devices to optimize the benefit of drugs to treat cancer, the 2nd leading cause of death in the United States. Our therapeutic candidates include the ImmunePrep™ platform to enhance the performance of immunotherapeutic antibodies, ChemoPrep™ to improve the delivery of chemotherapy, and ChemoPure™ to extract off-target chemotherapy from the bloodstream to reduce treatment toxicity. At present, we do not have any market approved products to treat cancer and there is no assurance that we will commercialize any of our proposed cancer therapies.

Unlike Sigyn Therapy™ to treat infectious disease disorders, the intent of ImmunePrep™ and ChemoPrep™ is to optimize the delivery of leading drugs to treat cancer, while ChemoPure™ introduces a strategy to reduce chemotherapy toxicity. Additionally, Sigyn Therapy™ is a hollow fiber-based device deployed for use on dialysis and continuous renal replacement machines. Whereas ImmunePrep™, ChemoPrep™ and ChemoPure™ do not contain hollow-fibers and are intended for use on portable blood processing systems that can be located within the clinical sites where cancer therapies are infused to patients. During treatment, the functionality of the blood processing system allows for patient blood plasma to flow through our devices, which in the case of ImmunePrep™ products, therapeutic antibodies are immobilized for selective elimination of drug decoys and antibody therapeutic targets from the bloodstream. ChemoPrep™ and ChemoPure™ incorporate adsorbent components to reduce the circulating presence of particles that interfere with chemotherapy delivery and to extract off-target chemotherapy from the bloodstream as a means to reduce toxicity.

ImmunePrep™ to Optimize Immunotherapeutic Antibodies

Immunotherapeutic antibodies (monoclonal antibodies, therapeutic antibodies, checkpoint inhibitors, antibody drug conjugates) generate more revenues than any other class of drug to treat cancer and are the most valued assets in global medicine based on 2023 and 2024 M&A transactions. However, therapeutic antibodies are poorly delivered to their intended cancer targets and as a result, most patients don't respond to therapy. In many cases, less than 2% of an antibody dose will reach its cancer target, yet a significant portion of same dose can be intercepted by high concentrations of circulating decoys that display the antigen binding site of the antibody.

In response, we invented the ImmunePrep™ platform to allow for a therapeutic antibody to be immobilized within an extracorporeal circuit to sweep antibody decoys out of the bloodstream prior to the subsequent infusion of the antibody to a patient. We believe this reverse decoy mechanism will improve targeted antibody delivery and simultaneously reduce the circulating presence of the antibody's cancer targets to further enhance patient benefit. As a platform technology, ImmunePrep™ allows for the potential development of products that may incorporate a development-stage, clinical-stage or market-approved antibody. Based on previous FDA interactions, we believe ImmunePrep™ products that incorporate market-approved antibodies may have an accelerated pathway to potential market clearance.

ChemoPrep™ to Optimize Chemotherapy Delivery

Chemotherapeutic agents are the most commonly administered class of drug to treat cancer, yet only a small fraction of infused doses reach their cancer cell targets. Contributing to inadequate delivery are high concentrations of tumor-derived exosomes, whose bloodstream presence disrupts chemotherapy delivery and corresponds with treatment resistance. We designed ChemoPrep™ to reduce the circulating presence of tumor-derived exosomes prior chemotherapy administration. Our clinical goal is to maintain or improve the efficacy of chemotherapy with lower doses, which would reduce treatment toxicity. In this regard, ChemoPrep™ aligns with the FDA “Project Optimus” initiative to minimize the toxicity of cancer drugs while maximizing patient benefit.

ChemoPure™ to Reduce Chemotherapy Toxicity

Once chemotherapy has been administered, residual off-target chemotherapy that is left to circulate in the bloodstream is more likely to cause patient harm versus benefit. In response, we designed ChemoPure™ to extract off-target chemotherapy from the bloodstream to further reduce treatment toxicity.

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, Sigyn Therapy™, 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 Sigyn TherapyTM 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 Sigyn TherapyTM or other pipeline devices.

Manufacturing and Procurement

At present, we plan to manufacture Sigyn Therapy™ 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 Sigyn Therapy™. 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 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 and staff our own research and product development facility.

Competition

Our therapeutic candidates provide a novel approach and are not similar to other products in the marketplace. However, there are there may be medical device or pharmaceuticals companies that may develop products that could compete directly with our therapeutic candidates. If these companies develop competing products, they have far greater resources to support the clinical advancement and post approval marketing of their products within the medical industry than we do.

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, 2024 Compared to Three Months Ended September 30, 2023

The following discussion represents a comparison of our results of operations for the three months ended September 30, 2024 and 2023. 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,	
	2024	2023
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	808,458	642,814
Other expense	388,465	262,912
Net loss before income taxes	<u>\$ (1,196,923)</u>	<u>\$ (905,726)</u>

Net Revenues

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

Cost of Sales

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

Operating expenses

Operating expenses increased by \$165,644, or 25.8%, to \$808,458 for three months ended September 30, 2024 from \$642,814 for the three months ended September 30, 2023 primarily due to increases in investor relations costs of \$192,886, compensation costs of \$17,522, and professional fees of \$17,051, offset primarily by decreases in consulting fees of \$18,197, research and development costs of \$9,069, insurance costs of \$21,114, depreciation costs of \$353, amortization costs of \$300, and general and administration costs of \$12,782 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.

For the three months ended September 30, 2023, we had marketing expenses of \$51, research and development costs of \$215,230, stock based compensation of \$37,500, and general and administrative expenses of \$390,033 primarily due to professional fees of \$40,485, compensation costs of \$158,941, rent expense of \$20,146, depreciation costs of \$1,716, amortization costs of \$300, investor relations costs of \$18,974, consulting fees of \$69,700, insurance expense of \$64,783, travel costs of \$2,170, and general and administration costs of \$12,818, as a result of adding administrative infrastructure for our anticipated business development.

Other Expense

Other expense for the three months ended September 30, 2024 totaled \$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, compared to other expense of \$262,912 for the three months ended September 30, 2023 primarily due to interest expense of \$220,854 in conjunction with accretion of debt discount, interest expense of \$43,955 in conjunction with accretion of original issuance discount, interest expense of \$670, and modification of warrants of \$2,567.

Net loss before income taxes

Net loss before income taxes for the three months ended September 30, 2024 totaled \$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 compared to a loss of \$905,726 for the three months ended September 30, 2023 primarily due to increases in consulting fees, research and development costs, rent, stock based compensation, travel costs, and general and administration costs, offset primarily by decreases in compensation costs, professional fees, marketing costs, investor relations costs, insurance, and amortization costs.

Assets and Liabilities

Assets were \$427,438 as of September 30, 2024. Assets consisted primarily of cash of \$164,788, inventories of \$50,000, other current assets of \$54,320, equipment of \$11,048, operating lease right-of-use assets of \$126,571, and other assets of \$20,711. Liabilities were \$4,350,024 as of September 30, 2024. Liabilities consisted primarily of accounts payable of \$611,643, accrued payroll and payroll taxes of \$1,761,644, advance from shareholder of \$43,426, other current liabilities of \$48, convertible notes of \$1,790,865, net of \$204,723 of unamortized debt discount and debt issuance costs, and operating lease liabilities of \$142,398.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

The following discussion represents a comparison of our results of operations for the nine months ended September 30, 2024 and 2023. 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,	
	2024	2023
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	2,041,232	1,738,081
Other expense	776,162	1,231,805
Net loss before income taxes	\$ (2,817,394)	\$ (2,969,886)

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 increased by \$303,151, or 17.4%, to \$2,041,232 for nine months ended September 30, 2024 from \$1,738,081 for the nine months ended September 30, 2023 primarily due to increases in research and development costs of \$96,951, investor relations costs of \$207,374, insurance costs of \$2,802, marketing costs of \$125, and compensation costs of \$79,853, offset primarily by decreases in consulting fees of \$58,189, depreciation costs of \$898, amortization costs of \$2,100, professional fees of \$4,331, travel costs of \$2,170, rent of \$523, and general and administration costs of \$15,743 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.

For the nine months ended September 30, 2023, we had marketing expenses of \$335, research and development costs of \$582,232, stock based compensation of \$112,500, and general and administrative expenses of \$1,043,014 primarily due to professional fees of \$141,181, compensation costs of \$454,568, rent expense of \$58,775, depreciation costs of \$5,146, amortization costs of \$2,100, investor relations costs of \$27,019, consulting fees of \$165,692, insurance expense of \$157,805, travel costs of \$2,170, and general and administration costs of \$28,558, as a result of adding administrative infrastructure for our anticipated business development.

Other Expense

Other expense for the nine months ended September 30, 2024 totaled \$776,162 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, compared to other expense of \$1,231,805 for the nine months ended September 30, 2023 primarily due to interest expense of \$1,309,703 in conjunction with accretion of debt discount, interest expense of \$146,731 in conjunction with accretion of original issuance discount, interest expense of \$2,300, and modification of warrants of \$226,929.

Net loss before income taxes

Net loss before income taxes for the nine months ended September 30, 2024 totaled \$2,817,394 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, compared to a loss of \$2,969,886 for the nine months ended September 30, 2023 primarily due to increases in consulting fees, research and development costs, rent, travel costs, stock based compensation, and general and administration costs, offset primarily by decreases in compensation costs, professional fees, marketing costs, investor relations costs, insurance, and amortization 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 \$14,158,906 at September 30, 2024, had a working capital deficit of \$4,006,168 and \$3,489,941 at September 30, 2024 and December 31, 2023, respectively, had net losses of \$1,196,923 and \$2,817,394, and \$905,726 and \$2,969,886 for the three and nine months ended September 30, 2024 and 2023, respectively, and net cash used in operating activities of \$582,218 and \$1,255,316 for the nine months ended September 30, 2024 and 2023, 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 generate 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, 2024 of \$153,098 resulting from cash provided by financing activities of \$735,316, offset partially by cash used in operating activities of \$582,218.

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,	
	2024	2023
Net cash provided by (used in):		
Operating activities	\$ (582,218)	\$ (1,255,316)
Investing activities	-	-
Financing activities	735,316	1,311,544
	<u>\$ 153,098</u>	<u>\$ 56,228</u>

Cash Flows from Operating Activities – For the nine months ended September 30, 2024, net cash used in operations was \$582,218 compared to net cash used in operations of \$1,255,316 for the nine months ended September 30, 2023. Net cash used in operations was primarily due to a net loss of \$2,817,394 for nine months ended September 30, 2024 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.

For the nine months ended September 30, 2023, net cash used in operations was primarily due to a net loss of \$2,969,886 and the changes in operating assets and liabilities of \$365,319, primarily due to the increase in accounts payable of \$34,112 and accrued payroll and payroll taxes of \$375,124, offset partially by the decrease in other current liabilities of \$1,572, and other current assets of \$42,345. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of \$5,146, amortization expense of \$2,100, stock based compensation of \$112,500, accretion of debt discount of \$1,309,703, accretion of original issuance costs of \$146,731, and modification of warrants of \$226,929.

Cash Flows from Investing Activities – For the nine months ended September 30, 2024 and 2023, the Company had no cash flows from investing activities.

Cash Flows from Financing Activities – For the nine months ended September 30, 2024, net cash provided by financing was \$735,316, 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 compared to cash provided by financing activities of \$1,311,544 for the nine months ended September 30, 2023 due to proceeds from short term convertible notes of \$1,272,000, advances from shareholder of \$45,000, and fees associated with the filing of the Company’s Form S-1 of \$5,456.

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 private offering, 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.

Convertible Notes Payable

During fiscal 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the “2024 Notes”) totaling (i) \$852,630 aggregate principal amount of Notes (total of \$771,891 cash was received) due between January and June 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 213,164 shares of the Company’s Common Stock at an exercise price of \$7.50 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$771,891 which was issued at a \$80,738 original issue discount from the face value of the Note. In connection with voluntary conversions by the holders of the convertible notes, the conversion price for principal of \$619,692 is \$4.00 per share and principal of \$232,937 is \$6.00 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 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 October 2023, the holders of \$997,700 of Original Issue Discount Senior Convertible Debentures converted their debentures at a contractual exercise price of \$10.00 per share in exchange for the issuance of 166,284 shares of Common Stock to the holders.

Advance from Shareholder

The Company borrows funds from the Company’s CEO for working capital purposes from time to time. The Company has recorded the principal balance due of \$43,426 and \$80,000 under Advance from Shareholder in the accompanying the unaudited condensed consolidated balance sheets at September 30, 2024 and December 31, 2023, respectively. The Company received advances of \$35,000 and \$64,500 and had repayments of \$71,574 and \$19,500 for the nine months ended September 30, 2024 and 2023. The advance from our CEO was not made pursuant to any loan agreements or promissory notes, are non-interest bearing and due on demand.

Capital Expenditures

We expect to purchase approximately \$30,000 of equipment in connection with the expansion of our business during the next twelve months.

Fiscal year end

Our fiscal year end is December 31.

Critical Accounting Policies

Refer to Note 3 in the accompanying notes to the unaudited condensed consolidated financial statements for critical accounting policies.

Recent Accounting Pronouncements

Refer to Note 3 in the accompanying notes to the condensed consolidated financial statements.

Off-Balance Sheet Arrangements

As of September 30, 2024, 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.

As of the end of the period covered by this report (September 30, 2024), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)). Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q our disclosure controls and procedures were not effective to enable us to accurately record, process, summarize and report certain information required to be included in the Company's periodic SEC filings within the required time periods, and to accumulate and communicate to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

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, 2024. 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, 2024, 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 2024 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, 2024 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, 2024 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 August 2024 and September 2024, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “2024 Notes”) totaling (i) \$303,193 aggregate principal amount of Note (total of \$275,630 cash was received) due from August 2025 through September 2025 based on \$1.00 for each \$0.90909 paid by the noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 75,800 shares of the Company’s Common Stock at an exercise price of \$7.50 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was \$275,630 which was issued at a \$27,563 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$4.00 per share. In September 2024, holders converted \$282,293 in exchange for the issuance of 70,574 shares of Common Stock to the holders. All of the securities discussed in this Item 2 were all issued in reliance on the exemption under Section 4(a)(2) of the Securities Act since the investors were sophisticated investors and familiar with our management and operations.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

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, 2024, 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, 2024, 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.

Item 6. Exhibits.

Exhibit Number	Description
3.1 ⁽¹⁾	Second Amended and Restated Certificate of Incorporation*
3.2 ⁽²⁾	Certificate of Amendment to Certificate of Incorporation*
3.3 ⁽³⁾	Certificate of Amendment to Certificate of Incorporation*
10.1	Form of Notice of Conversion for September 2024 Conversion of Convertible Debentures**
10.2	Form of Warrant Exchange for October 2024 Exchange of Warrants for Common Stock**
31.1	Certification by Principal Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification by Principal Financial and Accounting Officer pursuant to Rule 13a-14(a).
32.1	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.
32.2	Certification by Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.
**	Filed herewith.
+	Management contract or compensatory plan
(1)	Filed as Exhibit 3.1 to Company’s Current Report on Form 8-K filed with the Commission on December 24, 2015
(2)	Filed as Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the Commission on October 23, 2020

(3) Filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Commission on January 30, 2024

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 19, 2024

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

Dated: November 19, 2024

By: /s/ Gerald DeCiccio
Gerald DeCiccio
Chief Financial Officer (Principal Financial and Accounting Officer)

Dated: November 19, 2024

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ James Joyce</u> James Joyce	<u>Chief Executive Officer and Director</u> (Principal Executive Officer)	November 19, 2024
<u>/s/ Gerald DeCiccio</u> Gerald DeCiccio	<u>Chief Financial Officer</u> (Principal Financial and Accounting Officer)	November 19, 2024
<u>/s/ Craig Roberts</u> Craig Roberts	<u>CTO and Director</u>	November 19, 2024
<u>/s/ Richa Nand</u> Richa Nand	<u>Director</u>	November 19, 2024
<u>/s/ Jim Dorst</u> Jim Dorst	<u>Director</u>	November 19, 2024
<u>/s/ Chris Wetzel</u> Chris Wetzel	<u>Director</u>	November 19, 2024

ANNEX A

NOTICE OF CONVERSION

The undersigned hereby elects to convert principal under the Senior Convertible Debenture due [] of **SIGYN THERAPEUTICS INC.** (the "Company"), into shares of common stock (the "Common Stock"), of the Company according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto and is delivering herewith such certificates and opinions as reasonably requested by the Company in accordance therewith. No fee will be charged to the holder for any conversion, except for such transfer taxes, if any.

By the delivery of this Notice of Conversion the undersigned represents and warrants to the Company that its ownership of the Common Stock does not exceed the amounts specified under Section 4 of this Debenture, as determined in accordance with Section 13(d) of the Exchange Act.

The undersigned agrees to comply with the prospectus delivery requirements under the applicable securities laws in connection with any transfer of the aforesaid shares of Common Stock.

Conversion calculations:

Date to Effect Conversion:

Principal Amount of Debenture to be Converted: \$[]

Number of shares of Common Stock to be issued:

Signature:

Name:

Address for Delivery of Common Stock Certificates:

Or

DWAC Instructions:

Broker No: _____

Account No: _____

SHARE FOR WARRANT EXCHANGE AGREEMENT

THIS WARRANT EXCHANGE AGREEMENT (the “**Agreement**”) is made as of the **XX**th day of October 2024, by and between Sigyn Therapeutics, Inc., a Delaware corporation (the “**Company**”) located at 2468 Historic Decatur Road, Suite 140, San Diego, CA. 92106, and XXXXX (the “**Holder**”).

RECITALS

WHEREAS, the Holder currently holds a warrant or warrants to purchase [] shares of the Company’s Common Stock (the “**Existing Warrant**”);

WHEREAS, the Existing Warrant is comprised in its entirety of;

(a.) [] warrants that the Company issued to the Holder on [].

WHEREAS, on September 10, 2024, the Company’s Board of Directors approved the issuance of three quarters (3/4) of a restricted common share (the “**Common Stock**”) of the Company in exchange for every one (1) warrant that is returned to the Company by the Holder to be cancelled;

WHEREAS, the Holder wishes to exchange their Existing Warrant for Common Stock of the Company;

THE PARTIES HEREBY AGREE AS FOLLOWS:

1. Exchange of Existing Warrant. The Holder shall surrender the Existing Warrant for, and the Company shall cancel the Existing Warrant and shall issue to Holder, [] shares of Common Stock (adjusted for any stock dividends, combinations or splits after the date hereof) (the “**Shares**”).

2. Cancellation and Surrender of Existing Warrant. Holder agrees that the Existing Warrant shall be deemed canceled and have no further force or effect.

3. Representations and Warranties of Holder. Holder hereby represents and warrants that:

(a) The Holder is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

(b) The Holder has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby and such execution, delivery and consummation have been duly authorized by all necessary action. This Agreement has been duly executed and delivered by the Holder and constitutes the valid and binding obligation of such party, enforceable against it in accordance with its terms. The Holder is the owner, beneficially and of record, of the Existing Warrant, free and clear of any encumbrances.

(c) This Agreement is made with the Holder in reliance upon the Holder's representation, which by the Holder's execution of this Agreement the Holder hereby confirms, that the Shares to be received by the Holder are and will be acquired for investment for its own account and not with a view to the distribution of any part thereof, and that the Holder has no present intention of selling, granting any participation in, or otherwise distributing the same.

(d) The Holder has had the opportunity to ask questions of and receive answers from the Company regarding the Company and to obtain additional information necessary to verify the accuracy of the information supplied or to which it had access.

(e) The Holder acknowledges that an investment in the Shares is a speculative risk and is able to bear the economic risk of its investment (including possible complete loss of such investment) for an indefinite period of time and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares.

(f) The Holder understands that the Shares to be acquired hereunder are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances and in accordance with the terms and conditions set forth in the legend described in Section 3(g) below. The Holder represents that it is familiar with SEC Rule 144, as presently in effect, and understands the resale limitations imposed thereby and by the Securities Act.

(g) The Holder understands that each of the certificates evidencing the Shares to be acquired hereunder may bear the following legend:

"THE SECURITIES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY APPLICABLE STATE SECURITIES LAW, AND NO INTEREST THEREIN MAY BE SOLD, DISTRIBUTED, ASSIGNED, OFFERED, PLEDGED OR OTHERWISE TRANSFERRED UNLESS (i) THERE IS AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT AND APPLICABLE STATE SECURITIES LAWS COVERING ANY SUCH TRANSACTION INVOLVING SAID SECURITIES, (ii) THIS COMPANY RECEIVES AN OPINION OF LEGAL COUNSEL FOR THE HOLDER OF THESE SECURITIES SATISFACTORY TO THIS COMPANY STATING THAT SUCH TRANSACTION IS EXEMPT FROM REGISTRATION, OR (iii) THE COMPANY OTHERWISE SATISFIES ITSELF THAT SUCH TRANSACTION IS EXEMPT FROM REGISTRATION."

4. Representations and Warranties of the Company

(a) The Company is duly organized, validly existing and in good standing under the laws of Delaware.

(b) The Company has the requisite power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby and such execution, delivery and consummation have been duly authorized by all necessary action. This Agreement has been duly executed and delivered by the Holder and constitutes the valid and binding obligation of such party, enforceable against it in accordance with its terms.

(c) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) conflict with, or result in a breach or violation of, any provision of the Company's organizational documents, (ii) constitute, with or without notice or the passage of time or both, a breach violation or default under any law, rule, regulation, permit, license, agreement or other instrument of the Company or to which the Company or the Company's property is subject, or (iii) require any consent, approval or authorization of, or notification to, or filing with, any federal, state, local or foreign court, governmental agency or regulatory or administrative authority on the part of the Company.

(d) The Shares to be issued to the Holder hereunder, when issued, sold and delivered in accordance with the terms of this Agreement, will be duly and validly issued, fully paid, and nonassessable.

5. Miscellaneous.

5.1 Entire Agreement. This Agreement constitutes the entire agreement between the Company and Holder with respect to the subject matter hereof and no party shall be liable or bound to any other party in any manner by any warranties, representations or covenants except as specifically set forth herein or therein.

5.2 Survival of Warranties. The warranties and representations of the parties contained in or made pursuant to this Agreement shall survive the execution and delivery of this Agreement.

5.3 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware without regard to principles regarding conflicts of law.

5.4 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and Holder.

5.5 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

5.6 Electronic Signatures. This Agreement may be executed by electronic signatures, and that each electronic signature has the same validity, enforceability, and admissibility as a handwritten signature.

5.7 Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

5.8 Transfer of Existing Warrant. If the Holder transfers the Existing Warrant, in whole or in part, in accordance with the terms thereof, then the Holder shall also assign to the transferee the Holder's rights and obligations under this Agreement with respect to the portion of the Existing Warrant so transferred. As conditions to any transfer of the Existing Warrant, such transferee and the Company and, if the Existing Warrant is transferred in part, the Holder and the Company, shall execute and deliver new Warrant Exchange Agreements substantially in the form of this Agreement, with the Holder's new Warrant Exchange Agreement covering the portion of the Existing Warrant retained by the Holder. In no event shall the Company be obligated to issue to the Holder and any transferee(s) of the Existing Warrant a number of Shares greater than the number of Shares set forth in Section 1 above. Any assignment of this Agreement shall be subject to the same requirements for compliance with applicable federal and state securities laws and agreements among stockholders as are applicable to a transfer of the Existing Warrant under the terms thereof.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

COMPANY:

SIGYN THERAPEUTICS, INC.

By: _____
Name: James A. Joyce
Title: Chief Executive Officer

HOLDER

By: _____
Name: XXXXXX XXXXXXXXXXXX
Title:

HOLDER ADDRESS

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, including its consolidated subsidiaries, 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 19, 2024

/s/ James Joyce

James Joyce

Chief Executive Officer (Principal Executive Officer)

SECTION 302 CERTIFICATION

I, Gerald DeCiccio, 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-15I 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, including its consolidated subsidiaries, 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 19, 2024

/s/ Gerald DeCiccio

Gerald DeCiccio

Chief Financial Officer (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 three months ended September 30, 2024 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)

November 19, 2024

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 three months ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerald DeCiccio, Chief Financial 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 Financial 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/ Gerald DeCiccio

Gerald DeCiccio

Chief Financial Officer (Principal Financial and Accounting Officer)

November 19, 2024
