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 June 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	**84-4210559**
(State or other jurisdiction of incorporation)	(IRS Employer File Number)
2468 Historic Decatur Road Ste., 140, San Diego, California	**92106**
(Address of principal executive offices)	(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	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging Growth Company	□

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. □

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

As of August 14, 2024, there were 1,263,653 shares of common stock outstanding.

SIGYN THERAPEUTICS, INC.

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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

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash	$ 53,644	$ 11,690
Inventories	50,000	50,000
Other current assets	42,732	56,373
Total current assets	146,376	118,063
Property and equipment, net	12,411	15,296
Operating lease right-of-use assets, net	140,667	167,736
Other assets	20,711	20,711
Total assets	**$ 320,165**	**$ 321,806**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 488,364	$ 461,646
Accrued payroll and payroll taxes	1,493,153	791,754
Advance from shareholder	70,000	80,000
Short-term convertible notes payable, less unamortized debt issuance costs of $229,583 and $297,337, respectively	1,780,444	2,210,299
Current portion of operating lease liabilities	65,409	61,123
Other current liabilities	2,247	3,182
Total current liabilities	3,899,617	3,608,004
Long-term liabilities:		
Operating lease liabilities, net of current portion	92,689	126,302
Total long-term liabilities	92,689	126,302
Total liabilities	**3,992,306**	**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 June 30, 2024 and December 31, 2023, respectively	-	-
Common stock, $0.0001 par value, 1,000,000,000 shares authorized; 1,263,653 and 1,288,415 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	126	129
Additional paid-in capital	9,289,716	7,928,883
Accumulated deficit	(12,961,983)	(11,341,512)
Total stockholders' deficit	(3,672,141)	(3,412,500)
Total liabilities and stockholders' deficit	**$ 320,165**	**$ 321,806**

See accompanying notes to unaudited condensed consolidated financial statements.

SIGYN THERAPEUTICS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Six Months Ended June 30,		Three Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net revenues	$ -	$ -	$ -	$ -
Gross Profit	-	-	-	-
Operating expenses:				
Marketing expenses	346	284	8	100
Stock based compensation	75,000	75,000	37,500	37,500
Research and development	473,022	367,002	240,429	219,159
General and administrative	684,406	652,981	324,868	317,250
Total operating expenses	1,232,774	1,095,267	602,805	574,009
Loss from operations	(1,232,774)	(1,095,267)	(602,805)	(574,009)
Other expense:				
Modification of warrants	-	(224,362	-	(208,556)
Interest expense	2,081	1,630	569	491
Interest expense - debt discount	159,944	1,088,849	116,737	297,141
Interest expense - original issuance costs	225,672	102,776	142,272	60,039
Total other expense	387,697	968,893	259,578	149,115
Loss before income taxes	(1,620,471)	(2,064,160)	(862,383)	(723,124)
Income taxes	-	-	-	-
Net loss	$ (1,620,471)	$ (2,064,160)	$ (862,383)	$ (723,124)
Net loss per share, basic and diluted	$ (1.31)	$ (2.02)	$ (0.70)	$ (0.67)
Weighted average number of shares outstanding				
Basic and diluted	1,234,241	1,022,795	1,238,085	1,083,277

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	in Capital	Deficit	Deficit
Balance as of December 31, 2022	**-**	**$ -**	**956,596**	**$ 96**	**$ 5,292,241**	**$ (7,195,576)**	**$ (1,903,239)**
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**	**$ 6,190,468**	**$ (8,536,612)**	**$ (2,346,037)**
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**	**$ 6,217,408**	**$ (9,259,736)**	**$ (3,042,217)**
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	-	-	-	841,419	-	841,419
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)**

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (1,620,471)	$ (2,064,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,885	3,430
Amortization expense	-	1,800
Stock based compensation	75,000	75,000
Accretion of debt discount	159,943	1,088,849
Accretion of original issuance costs	225,672	102,776
Modification of warrants	-	(224,362)
Changes in operating assets and liabilities:		
Other current assets	13,641	(43,220)
Accounts payable	26,718	12,427
Accrued payroll and payroll taxes	701,399	156,278
Other current liabilities	(3,193)	(85)
Net cash used in operating activities	**(418,406)**	**(891,267)**
Cash flows from financing activities:		
Proceeds from short-term convertible notes	470,360	882,000
Advance from shareholder	35,000	30,000
Repayments of advance from shareholder	(45,000)	-
Fees associated with filing of Form S-1	-	(5,456)
Net cash provided by financing activities	**460,360**	**906,544**
Net (decrease) increase in cash	**41,954**	**15,277**
Cash at beginning of period	11,690	8,356
Cash at end of period	**$ 53,644**	**$ 23,633**
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Beneficial conversion feature in conjunction with debt issuance	$ -	$ 303,984
Warrants issued to third parties in conjunction with debt issuance	$ 211,475	$ 578,016
Original issue discount issued in conjunction with debt	$ 106,386	$ 88,200
Common stock issued to third parties in conjunction with conversion of debt	$ 232,936	$ 198,000
Preferred stock issued to third parties in conjunction with conversion of debt	841,419	-
Cancellation of common stock – related party	7	-
Conversion of common stock for Series A preferred stock	$ -	$ 611

See accompanying notes to unaudited condensed consolidated financial statements.

NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

Corporate History and Background

Sigyn Therapeutics, Inc. ("Sigyn", the "Company" "we," "us," or "our") is a development-stage company that creates blood purification technologies to overcome clearly defined limitations in healthcare.

Sigyn Therapy™, our lead product candidate, is being advanced to treat life-threatening conditions that are not addressed with market-cleared drug agents. Candidate treatment indications include endotoxemia, sepsis (a leading cause of hospital deaths), community acquired pneumonia (a leading cause of infectious disease deaths), drug-resistant bacterial infections, and emerging pandemic viral threats.

Our therapeutic pipeline is comprised of technologies that we have designed to improve the targeted delivery of cancer drug agents. ChemoPrep™ and ChemoPure™ are components of a therapeutic system to improve the delivery of chemotherapy and reduce its toxicity. ImmunePrep™ is a novel platform to enhance the potential efficacy of immunotherapeutic antibodies (including checkpoint inhibitors). At present, we have no market approved medical products and there is no assurance that we will be able to commercialize any of our product candidates.

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"). For accounting purposes, Sigyn is considered to have acquired Reign Resources Corporation as the accounting acquirer because: (i) Sigyn stockholders own 75% of the combined company, on an as-converted basis, immediately following the Closing Date, (ii) Sigyn directors hold a majority of board seats in the combined company and (iii) Sigyn management held all key positions in the management of the combined company. Accordingly, Sigyn's historical results of operations will replace Reign Resources Corporation's historical results of operations for all periods prior to the Acquisition and, for all periods following the Acquisition, the results of operations of the combined company will be included in the Company's financial statements. The Acquisition was treated as a "tax-free exchange" under Section 368 of the Internal Revenue Code of 1986 and resulted in the private Sigyn Therapeutics corporate entity (established on October 29, 2019) to become a wholly owned subsidiary of Reign Resources Corporation. Among the conditions for closing the acquisition, the Reign Resources Corporation extinguished all previously reported liabilities, its preferred class of shares, and all stock purchase options. As a result, the reported liabilities totaling $3,429,516 were converted into a total of 7,907,351 common shares. Additionally, assets held on the books of Reign Resources Corporation, such as Gem inventory, was kept in the Company and therefore recorded as assets on the Share Exchange date. Upon the closing of the Acquisition, we appointed James A. Joyce and Craig P. Roberts to serve as members of our Board of Directors.

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.

As of August 14, 2024, we have a total of 1,263,653 shares issued and outstanding, of which 686,303 shares are held by non-affiliate stockholders.

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 $12,961,983 at June 30, 2024, had a working capital deficit of $3,753,241 at June 30, 2024, had net losses of $862,383 and $1,620,471, and $723,124 and $2,064,160 for the three and six months ended June 30, 2024 and 2023, respectively, and net cash used in operating activities of $418,406 and $891,267 for the six months ended June 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 increase revenues, the Company's cash position may not be significant enough to support the Company's daily operations. Management intends to raise additional funds by way of a public offering or an asset sale transaction. Management believes that the actions presently being taken to further implement its business plan and generate revenues provide the opportunity for the Company to continue as a going concern. While management believes in the viability of its strategy to generate revenues and in its ability to raise additional funds or transact an asset sale, there can be no assurances to that effect or on terms acceptable to the Company. The ability of the Company to continue as a going concern is dependent upon the Company's ability to further implement its business plan and generate revenues.

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

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Use of Estimates

The preparation of these financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of net sales and expenses during the reported periods. Actual results may differ from those estimates and such differences may be material to the financial statements. The more significant estimates and assumptions by management include among others: warrant valuation. 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 $8 and $346, and $100 and $284 of advertising expenses for the three and six months ended June 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 $240,429 and $473,022, and $219,159 and $367,002 for the three and six months ended June 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 June 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 June 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 June 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 June 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 June 30, 2024 and December 31, 2023 and no charges or credits to income for the three and six months ended June 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 Therapy 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 Therapy 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 Therapy.

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:

	Estimated Life	June 30, 2024	December 31, 2023
Office equipment	5 years	$ 29,041	$ 29,041
Computer equipment	3 years	3,157	3,157
Accumulated depreciation		(19,787)	(16,902)
		$ 12,411	$ 15,296

Depreciation expense was $1,364 and $2,885, and $1,715 and $3,430 for the three and six months ended June 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 June 30, 2024	Outstanding Balance as of December 31, 2023
Osher Capital Partners LLC				
January 28, 2020 ("Note 1")	August 30, 2024	$ 350,005	$ 564,138	$ 564,138
June 22, 2022 ("Note 2")	August 30, 2024	75,000	94,314	94,314
August 31, 2022 ("Note 2")	August 30, 2024	100,000	123,200	123,200
September 20, 2022 ("Note 2")	August 30, 2024	100,000	123,200	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")	July 18, 2024	60,000	66,000	66,000
December 7, 2023 ("Note 3")	December 7, 2024	40,000	44,000	44,000
May 13, 2024 ("Note 4")	May 13, 2025	35,000	40,000	-
Brio Capital Master Fund, Ltd.				
March 23, 2022 ("Note 2")	August 30, 2024	100,000	129,964	129,964
November 9, 2022 ("Note 2")	August 30, 2024	75,000	92,400	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")	July 20, 2024	40,000	44,000	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	-
Various third-party noteholders				
Various dates in June 2024 ("Note 4")	Various dates in June 2025	148,600	163,461	-
Notes converted in fiscal 2024			-	841,420
Total convertible notes payable		$ 1,548,605	$ 2,010,027	$ 2,507,636
Original issue discount			(106,549)	(225,835)
Beneficial conversion feature			(7,081)	(22,013)
Debt discount			(115,953)	(49,489)
Total convertible notes payable			$ 1,780,444	$ 2,210,299

Principal payments on convertible promissory debentures are due as follows:

Year ending December 31,	
2024	$ 1,281,216
2025	728,811
	$ 2,010,027

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	-	41,350	15,000	520,397	576,747
Conversion of debt for common stock	(299,998)	(541,422)	-	(232,936)	(1,074,356)
Convertible notes payable as of June 30, 2024	$ 564,138	$ 879,428	$ 279,000	$ 287,461	$ 2,010,027

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	-	41,350	15,000	261,521	317,871
2024 accretion of note discounts	(93,059)	(93,975)	(65,642)	(132,949)	(385,625)
Note discounts as of June 30, 2024	$ 21,936	$ 48,185	$ 30,890	$ 128,572	$ 229,583
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 June 30, 2024	$ 542,202	$ 831,243	$ 248,110	$ 158,889	$ 1,780,444
2023 Effective interest rate	6%	50%	496%	-%	81%
2024 Effective interest rate	16%	11%	24%	46%	19%

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) $520,396 aggregate principal amount of Notes (total of $470,360 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 86,740 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 for the issuance of the Note and Warrants was $470,360 which was issued at a $50,036 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 $6.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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 $10.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was $240,000 which was issued at a $24,000 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 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 $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 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 – $564,138 (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) $564,138 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.

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 $70,000 and $80,000 under Advance from Shareholder in the accompanying the unaudited condensed consolidated balance sheets at June 30, 2024 and December 31, 2023, respectively. The Company received advances of $35,000 and $49,500 and had repayments of $45,000 and $19,500 for the six months ended June 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.

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 June 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 126.53 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 1,263,653 and 1,288,415 shares are outstanding as of June 30, 2024 and December 31, 2023, respectively.

In the six months ended June 30, 2024, the holders of $232,937 of Original Issue Discount Senior Convertible Debentures converted their debentures at a contractual exercise price of $6.00 per share in exchange for the issuance of 38,826 shares of Common Stock to the holders.

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 shall receive an annual grant of restricted stock units of $50,000. During the three and six months ended June 30, 2024 and 2023, respectively, the Company recorded stock-based compensation totaling $37,500 and $75,000, and $37,500 and $75,000, 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

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.

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 maturing September 30, 2026. The Company accounts for this lease in accordance with ASC 842. Adoption of the standard resulted in the initial recognition of operating lease ROU asset of $290,827 and operating lease liability of $290,827 as of June 15, 2021.

Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Generally, the implicit rate of interest in arrangements is not readily determinable and the Company utilizes its incremental borrowing rate in determining the present value of lease payments. The Company's incremental borrowing rate is a hypothetical rate based on its understanding of what its credit rating would be. The operating lease ROU asset includes any lease payments made and excludes lease incentives. Our variable lease payments primarily consist of maintenance and other operating expenses from our real estate 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:

	Six Months ended June 30,		Three Months ended June 30,	
	2024	***2023***	***2024***	***2023***
Operating lease expense	$ 35,838	$ 35,838	$ 17,919	$ 17,919
Short term lease cost	$ -	$ -	$ -	$ -
Total lease expense	$ 35,838	$ 35,838	$ 17,919	$ 17,919

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

Six Months ended June 30,	***2024***	***2023***
Operating cash flows from operating leases	$ 38,097	$ 36,987
Cash paid for amounts included in the measurement of lease liabilities	$ 38,097	$ 36,987
Weighted-average remaining lease term—operating leases	2.2 years	3.2 years
Weighted-average discount rate—operating leases	10%	10%

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

Year ending:		Operating Lease
2024 (remaining 6 months)	$	39,045
2025		79,456
2026		54,225
Total undiscounted cash flows	$	172,726
Reconciliation of lease liabilities:		
Weighted-average remaining lease terms		2.2 years
Weighted-average discount rate		10%
Present values	$	215,147
Lease liabilities—current		65,409
Lease liabilities—long-term		92,689
Lease liabilities—total	$	158,098
Difference between undiscounted and discounted cash flows	$	14,628

NOTE 9 – RELATED PARTY TRANSACTIONS

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

Employment Agreements

Mr. Joyce receives an annual base salary of $455,000, plus bonus compensation not to exceed 50% of salary. Mr. Joyce's employment also provides for medical insurance, disability benefits and one year of severance pay if his employment is terminated without cause or due to a change in control. Additionally, the Company has agreed to maintain a beneficial ownership target of 9% for Mr. Joyce. The Company incurred compensation expense of $113,748 (including accrued compensation of $113,748) and $227,496 (including accrued compensation of $113,748), and $118,085 (including accrued compensation of $61,210) and $231,835 (including accrued compensation of $61,210) for the three and six months ended June 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 up to 17,500 options to purchase 17,500 of the Company's common shares. The Company incurred compensation expense of $31,248 (including accrued compensation of $31,248) and $62,496 (including accrued compensation of $62,496) for the three and six months ended June 30, 2024. 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 $26,575 and $35,242 under Accounts Payable in the accompanying the unaudited condensed consolidated balance sheets as of June 30, 2024 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 $154,500 (including accrued compensation of $141,625), and $76,610 (including accrued compensation of $26,610) and $76,610 (including accrued compensation of $26,610) for the three and six months ended June 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 Six Months Ended June 30,		For the Three Months Ended June 30,	
	2024	2023	2024	2023
Convertible notes payable	391,659	454,874	297,249	454,874
Restricted stock units	24,848	8,589	12,424	4,295
Warrants to purchase shares of common stock	164,740	-	164,740	-
Total potentially dilutive shares	581,247	463,463	474,413	459,169

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

	Six Months Ended June 30,		Three Months Ended June 30,	
	2024	2023	2024	2023
Net loss attributable to the common stockholders	$ (1,620,471)	$ (2,064,160)	$ (862,383)	$ (723,124)
Basic weighted average outstanding shares of common stock	1,234,241	1,022,795	1,238,085	1,083,277
Dilutive effect of options and warrants	-	-	-	-
Diluted weighted average common stock and common stock equivalents	1,234,241	1,022,795	1,238,085	1,083,277
Loss per share:				
Basic and diluted	$ (1.31)	$ (2.02)	$ (0.70)	$ (0.67)

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 June 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 June 30, 2024, except for the following:

Convertible Notes

Subsequent to June 30, 2024, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $29,040 aggregate principal amount of Note (total of $25,900 cash was received) due in July 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 4,837 shares of the Company's Common Stock at an exercise price of $10.00 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is $6.00 per share.

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 June 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 5,025.1 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 1,263,653 and 1,288,415 shares were outstanding as of June 30, 2024 and December 31, 2023, respectively.

In the six months ended June 30, 2024, the holders of $232,937 of Original Issue Discount Senior Convertible Debentures converted their debentures at a contractual exercise price of $6.00 per share in exchange for the issuance of 38,826 shares of Common Stock to the holders.

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 shall receive an annual grant of restricted stock units of $50,000. During the three and six months ended June 30, 2024 and 2023, respectively, the Company recorded stock-based compensation totaling $37,500 and $75,000, and $37,500 and $75,000, respectively, in the unaudited condensed consolidated statements of operations.

Warrants

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

Subsequent to June 30, 2024, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $29,040 aggregate principal amount of Note (total of $25,900 cash was received) due in July 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 4,837 shares of the Company's Common Stock at an exercise price of $10.00 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is $6.00 per share.

During the six months ended June 30, 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $520,396 aggregate principal amount of Notes (total of $470,360 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 86,740 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 for the issuance of the Note and Warrants was $470,360 which was issued at a $50,036 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 $6.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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 $10.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was $240,000 which was issued at a $24,000 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 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 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 – $564,138

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) $564,138 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.

Limited Operating History; Need for Additional Capital

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

Business Overview

Sigyn Therapeutics, Inc. ("Sigyn", the "Company" "we," "us," or "our") is a development-stage company that creates blood purification technologies to overcome clearly defined limitations in healthcare.

Sigyn Therapy™, our lead product candidate, is being advanced to treat life-threatening conditions that are not addressed with market-cleared drug agents. Candidate treatment indications include endotoxemia, sepsis (a leading cause of hospital deaths), community acquired pneumonia (a leading cause of infectious disease deaths), drug-resistant bacterial infections, and emerging pandemic viral threats.

We plan to initiate first-in-human feasibility studies of Sigyn Therapy™ in End-Stage Renal Disease ("ESRD") patients with endotoxemia and concurrent inflammation, whose incidence is elevated among ~550,000 U.S. dialysis patients. To support the initiation of our proposed study, we have drafted an Investigational Device Exemption ("IDE") for submission to the U.S. Food and Drug Administration ("FDA"). Our clinical study plan proposes to enroll 12-15 ESRD subjects to evaluate the safety of Sigyn Therapy at three clinical site locations that have already been identified and evaluated by a contract research organization that specializes in ESRD related clinical studies. Beyond our clinical objective to demonstrate safety, we will also quantify changes in endotoxin levels as well as markers of inflammation as secondary endpoints. However, the clinical plan proposed in our IDE has not yet been communicated to FDA and there is no assurance that FDA will approve the initiation of our proposed feasibility study. Additionally, there is no assurance that we will receive FDA market approval of Sigyn Therapy™ as a Class III medical device.

Our Therapeutic Pipeline

Our therapeutic pipeline is comprised of technologies that we have designed to improve the targeted delivery of cancer drug agents. ChemoPrep™ and ChemoPure™ are components of a therapeutic system to improve the delivery of chemotherapy and reduce its toxicity. ImmunePrep™ is a novel platform to enhance the potential efficacy of immunotherapeutic antibodies (including checkpoint inhibitors). At present, we have no market approved medical products and there is no assurance that we will be able to commercialize any of our product candidates.

ChemoPrep™ and ChemoPure™

On October 6, 2022, we disclosed that a provisional patent application entitled: *"SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY"* had been filed with the USPTO. The provisional patent submission established the priority date for our patent pending invention and provided us up to one year to submit a non-provisional patent application. On October 4, 2023, we subsequently disclosed that a non-provisional Patent Cooperation Treaty ("PCT") submission had been filed to support the continued advancement of this patent. Related to these patent submissions, trademark applications to register ChemoPrep™ and ChemoPure™ have been filed with the USPTO. However, there is no assurance that we will receive a registered trademark for either the ChemoPrep™ or ChemoPure™ name, nor is there any assurance that patent submissions associated with ChemoPrep™ and ChemoPure™ will result in an issued patent.

Chemotherapeutic agents are the most commonly administered drug to treat cancer, which is the second leading cause of death in the United States. Despite therapeutic advances, treatment toxicity, drug resistance and inadequate tumor site delivery restrict the benefit of chemotherapy. To overcome these challenges, our patent submission describes a therapeutic device system whose primary objective is to enhance tumor site delivery of chemotherapy and reduce its toxicity. A secondary objective of the system is to reduce treatment dosing without sacrificing patient benefit.

Our proposed chemotherapy enhancement system is comprised of two blood purification technologies. ChemoPrep™, administered prior to chemotherapy to optimize tumor site delivery with lower chemotherapy doses and ChemoPure™, which is deployed post-chemotherapy to further reduce toxicity through the extraction of circulating chemotherapeutic agents that were not delivered to the target tumor site.

ImmunePrep™

On May 17, 2023, we disclosed that a provisional patent application entitled: *"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"* had been submitted to the USPTO. The provisional patent submission established the priority date of this patent pending invention and provides us up to one year to submit a non-provisional patent application. Associated with this patent submission, we further disclosed that a trademark application to register the name ImmunePrep™ had also been filed with the USPTO. On May 9, 2024, we subsequently submitted a Patent Cooperation Treaty (PCT) application entitled: *"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"*. WO Patent Application No.: PCT/US24/28579. However, there is no assurance that we will receive a registered trademark for the ImmunePrep™ name, nor is there any assurance that patent submissions associated with ImmunePrep™ will result in an issued patent.

We intend for ImmunePrep™ to become a platform that allows for antibody-based immunotherapies to be incorporated within plasma extraction devices to enhance the targeted delivery of therapeutic antibodies without increased drug toxicity.

Therapeutic antibodies are market-cleared to treat a variety of indications, including cancer. However, patient response to these therapies is often suboptimal as just a small portion of infused antibodies reach their intended therapeutic target. In many cases, infused antibodies are bound by drug decoys that display the antibody's antigen binding site on their surface. As a result, these decoys are empowered to bind and sequester antibodies from being delivered to their intended therapeutic targets.

ImmunePrep™ is designed to extract bloodstream decoys that would subsequently block the infused delivery of therapeutic antibodies. The mechanistic objective of this pre-treatment strategy is to increase the availability of antibodies to interact with their intended therapeutic targets. Conversely, the ability of therapeutic targets to evade antibody interactions would be diminished.

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"). For accounting purposes, Sigyn is considered to have acquired Reign Resources Corporation as the accounting acquirer because: (i) Sigyn stockholders own 75% of the combined company, on an as-converted basis, immediately following the Closing Date, (ii) Sigyn directors hold a majority of board seats in the combined company and (iii) Sigyn management held all key positions in the management of the combined company. Accordingly, Sigyn's historical results of operations will replace Reign Resources Corporation's historical results of operations for all periods prior to the Acquisition and, for all periods following the Acquisition, the results of operations of the combined company will be included in the Company's financial statements. The Acquisition was treated as a "tax-free exchange" under Section 368 of the Internal Revenue Code of 1986 and resulted in the private Sigyn Therapeutics corporate entity (established on October 29, 2019) to become a wholly owned subsidiary of Reign Resources Corporation. Among the conditions for closing the acquisition, the Reign Resources Corporation extinguished all previously reported liabilities, its preferred class of shares, and all stock purchase options. As a result, the reported liabilities totaling $3,429,516 were converted into a total of 197,684 common shares. Additionally, assets held on the books of Reign Resources Corporation, such as Gem inventory, was kept in the Company and therefore recorded as assets on the Share Exchange date. Upon the closing of the Acquisition, we appointed James A. Joyce and Craig P. Roberts to serve as members of our Board of Directors.

As of August 14, 2024, we had a total 1,263,653 shares issued and outstanding, of which 686,303 shares are held by non-affiliate shareholders.

Post-Merger Developments

Since the consummation of the merger transaction on October 19, 2020, we have advanced Sigyn Therapy from conceptual design through completion of *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.

Subsequent to these 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 in 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 underly the FDA goal of using the minimum number of animals necessary to generate valid scientific data to demonstrate reasonable feasibility and performance of a medical device prior to human study consideration. A porcine animal model is a generally accepted model for the study of extracorporeal blood purification devices intended to treat infectious disease and inflammatory disorders. Regardless of these factors, FDA may require that we conduct additional animal studies.

The data resulting from our *in vivo and in vitro* studies is being incorporated into an Investigational Device Exemption (IDE) that we are drafting for submission to the FDA to support the potential initiation of a human feasibility study in ESRD patients with endotoxemia and concurrent inflammation. As per the study protocol, Sigyn Therapy is to be administered in combination with the regularly scheduled dialysis treatments of enrolled subjects. The primary study objective will be to evaluate the safety of Sigyn Therapy in health compromised ESRD patients. A secondary objective will be to quantify changes in circulating levels of endotoxin, tumor necrosis factor-αlpha (TNF-α), interleukin-1β (IL-1β), and interleukin-6 (IL-6) before and after each Sigyn Therapy administration. Endotoxin and excess TNF-α, IL-1β, and IL-6 production are commonly associated with each of our candidate treatment indications, including sepsis and community-acquired pneumonia.

Based on our previous experience in developing extracorporeal blood purification therapies, we believe that we have collected sufficient data to support first-in-human studies of Sigyn Therapy. Sigyn Therapy, as a significant risk Class III device, which 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. At present, we are identifying candidate clinical site locations and then plan to submit an IDE application to FDA related to the potential initiation of a human feasibility study to demonstrate the safety of Sigyn Therapy. Our clinical strategy has not yet been communicated to FDA and there is no assurance that FDA will approve the initiation of our feasibility study. Additionally, while we believe the data from our *in vivo and in vitro* studies provides support for our IDE submission, FDA may request that we conduct additional animal or pre-clinical studies prior to approving our IDE. Among our previous experiences in developing extracorporeal blood purification therapies, our CEO oversaw the development of the Aethlon Hemopurifier, a blood purification device that received an FDA "Breakthrough Device" designation for the treatment of life-threatening viruses and was awarded a second FDA "Breakthrough Device" designation related to the treatment of cancer. The Hemopurifier has not yet been approved by FDA and remains in clinical trials.

Sigyn Therapy Mechanism of Action

We designed Sigyn Therapy to be a candidate to treat pathogen-associated inflammatory conditions that are life-threatening. To date, pre-clinical *in vitro* studies have quantified the reduction of viral pathogens, bacterial toxins, and inflammatory mediators from human blood plasma with small-scale versions of Sigyn Therapy. Such capabilities establish Sigyn Therapy as a candidate to treat pathogen-associated conditions that precipitate Sepsis, Community Acquired Pneumonia, Emerging Bioterror and Pandemic threats, and End-Stage Renal Disease patients with endotoxemia and elevated inflammatory cytokine production.

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 hemodialysis machine manufactured by Fresenius Medical Care, the 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 presence of pathogenic and inflammatory targets that precipitate the cytokine storm that underlies sepsis and other life-threatening inflammatory 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 circulating viruses, bacterial toxins, and inflammatory mediators. Beyond a potential capacity to reduce therapeutic targets from human blood plasma, we believe that Sigyn Therapy offers an efficient treatment methodology. Based on targeted blood flow rates of 350ml/min, a patient’s entire bloodstream can pass through Sigyn Therapy more than 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’s 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.

Overview of Candidate Treatment Indications

Based on data resulting from *in vitro* blood purification studies, our candidate treatment indications include, but are not limited to; endotoxemia, sepsis, community acquired pneumonia, drug resistant bacterial infections, and emerging pandemic viral threats. However, there is no assurance that human feasibility and pivotal studies will demonstrate Sigyn Therapy to be a safe and efficacious treatment for these or any other treatment indications.

End-Stage Renal Disease, Endotoxemia and Inflammation

According to the United States Renal Data System (“USRDS”), more than 550,000 individuals suffer from ESRD, which results in approximately 85 million kidney dialysis treatments being administered in the United States each year. Persistent inflammation is a hallmark feature of ESRD as reflected by the excess production of inflammatory cytokines, including tumor necrosis factor-α (TNF-α), interleukin-1β (IL-1β) and interleukin-6 (IL-6), which contribute to increased all-cause mortality. ESRD inflammation also induces intestinal permeability, which allows endotoxin (gram-negative bacterial toxin) to translocate from the gut and into the bloodstream. Beyond fueling further inflammation, endotoxin is a potent activator of sepsis, which can lead to multiple organ failure and ultimately death.

Sigyn Therapy establishes a candidate strategy to improve the health and quality-of-life of ESRD patients. Beyond its potential to reduce endotoxin, TNF-α, IL-1β, and IL-6 from human blood plasma, Sigyn Therapy can be administered in series with regularly scheduled dialysis therapy.

We are currently preparing an Investigational Device Exemption (IDE) for submission to the FDA related to a human feasibility study of Sigyn Therapy in ESRD patients with endotoxemia and concurrent inflammation. As per the study protocol, Sigyn Therapy will be administered in combination with the regularly scheduled dialysis treatments of enrolled subjects. The primary study objective will be to evaluate the safety of Sigyn Therapy in health compromised ESRD patients. A secondary objective is to quantify changes in circulating levels of endotoxin, tumor necrosis factor-α (TNF-α), interleukin-1β (IL-1β), and interleukin-6 (IL-6) before and after each Sigyn Therapy administration. Endotoxin and excess TNF-α, IL-1β, and IL-6 production are commonly associated with each of our candidate treatment indications, including sepsis and community-acquired pneumonia.

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,"* was published in the Journal Lancet. The publication 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 an emerging interest in multi-mechanism therapies that can target both inflammatory and pathogen associated targets. Sigyn Therapy addresses a broad-spectrum of pathogen sources and the resulting dysregulated cytokine production (the cytokine storm) that is the hallmark of sepsis. Additionally, we believe that inflammatory cytokine cargos transported by CytoVesicles may represent a novel, yet important therapeutic target.

Community Acquired Pneumonia

Community Acquired Pneumonia ("CAP") represents a significant opportunity for Sigyn Therapy to reduce the occurrence of sepsis. CAP is a leading cause of death among infectious diseases, the leading cause of death in children under five years of age, and a catalyst for approximately 50% of sepsis and septic shock cases.

In the United States, more than 1.5 million individuals are hospitalized with CAP each year, resulting in an annual financial burden that exceeds $10 billion.

Statistically, a therapeutic strategy that reduced the incidence of CAP related sepsis and septic shock would save thousands of lives each year. In a study of 4,222 patients, the all-cause mortality for adult patients with CAP was reported to be 6.5% during hospitalization. However, the mortality of patients with CAP related sepsis and septic shock rose to 51% during hospitalization.

CAP is further complicated by the fact that the pathogen sources of CAP are identified in only 38% of patients, based on a study of 2,259 subjects whose pneumonia diagnosis was confirmed by chest x-ray. Of the source pathogens identified in the study, ninety seven percent (97%) were either viral or bacterial in origin.

To reduce the occurrence of CAP related sepsis and septic shock, Sigyn Therapy offers a broad-spectrum mechanism to reduce the circulating presence of viral pathogens and bacterial toxins before and if they are identified as the CAP pathogen source. Additionally, Sigyn Therapy may help to control the excess production of inflammatory cytokines (the cytokine storm) that precipitate sepsis and septic shock.

Drug-Resistant Bacterial Infections

According to the U.S. Centers for Disease Control and Prevention ("CDC"), nearly three million individuals are infected with multi-drug 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 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 potential broad-spectrum mechanism to extract bacterial toxins from the bloodstream, Sigyn Therapy may provide a novel strategy to address life-threatening drug-resistant bacterial infections.

Emerging Pandemic Threats

Covid-19 affirmed the use of extracorporeal blood purification as a first-line countermeasure to treat an emerging pandemic threat not addressed with an approved drug or vaccine at the outset of an outbreak. On March 24, 2020, the U.S. Department of Health and Human Services ("HHS") declared that the emergence of COVID-19 justified the Emergency-Use Authorization ("EUA") of drugs, biological products, and medical devices to combat the pandemic. Within a month of this HHS declaration, FDA awarded an EUA to blood purification therapies from Terumo BCT, ExThera Medical Corporation, CytoSorbents, Inc., and Baxter Healthcare Corporation. In connection with these authorizations, 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 the bloodstream.

Consistent with FDA's statement, small-scale versions of Sigyn Therapy have been quantified to reduce the presence of various pathogens, cytokines, and other inflammatory mediators from human blood plasma during *in vitro* studies. As such, we believe that Sigyn Therapy could provide a 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 a majority of infectious human 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. In this regard, we believe Sigyn Therapy aligns with HHS initiatives established through the Public Health Emergency Medical Countermeasure Enterprise ("PHEMCE") that support the development of broad-spectrum medical countermeasures that can mitigate the impact of an emerging pandemic or bioterror threat, yet also have viability in established disease indications.

Our Therapeutic Pipeline

Our therapeutic pipeline is comprised of technologies that we have designed to improve the targeted delivery of cancer drug agents. ChemoPrep™ and ChemoPure™ are components of a therapeutic system to improve the delivery of chemotherapy and reduce its toxicity. ImmunePrep™ is a novel platform to enhance the potential efficacy of immunotherapeutic antibodies (including checkpoint inhibitors). At present, we have no market approved medical products and there is no assurance that we will be able to commercialize any of our product candidates.

ChemoPrep™ and ChemoPure™

On October 6, 2022, we disclosed that a provisional patent application entitled: *"SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY"* had been filed with the USPTO. The provisional patent submission established the priority date for our patent pending invention and provided us up to one year to submit a non-provisional patent application. On October 4, 2023, we subsequently disclosed that a non-provisional Patent Cooperation Treaty ("PCT") submission had been filed to support the continued advancement of this patent. Related to these patent submissions, trademark applications to register ChemoPrep™ and ChemoPure™ have been filed with the USPTO. However, there is no assurance that we will receive a registered trademark for either the ChemoPrep™ or ChemoPure™ name, nor is there any assurance that patent submissions associated with ChemoPrep™ and ChemoPure™ will result in an issued patent.

Chemotherapeutic agents are the most commonly administered drug to treat cancer, which is the second leading cause of death in the United States. Despite therapeutic advances, treatment toxicity, drug resistance and inadequate tumor site delivery restrict the benefit of chemotherapy. To overcome these challenges, our patent submission describes a therapeutic device system whose primary objective is to enhance tumor site delivery of chemotherapy and reduce its toxicity. A secondary objective of the system is to reduce treatment dosing without sacrificing patient benefit.

Our proposed chemotherapy enhancement system is comprised of two blood purification technologies. ChemoPrep™, administered prior to chemotherapy to optimize tumor site delivery with lower chemotherapy doses and ChemoPure™, which is deployed post-chemotherapy to further reduce toxicity through the extraction of circulating chemotherapeutic agents that were not delivered to the target tumor site.

To improve the delivery of chemotherapeutic agents, we designed ChemoPrep™ with an objective to reduce the bloodstream presence of tumor-derived extracellular vesicles or exosomes (Tumor-EXs) that scientific publications report to interfere with chemotherapy delivery. As compared to non-cancer subjects, Tumor-EXs are highly concentrated in the bloodstream of those suffering from cancer. Tumor-EXs can decoy and directly inhibit chemotherapeutic agents from reaching tumor cell targets. Tumor-EXs have also been reported to export chemotherapeutic agents out of cancer cells. Based on these factors, we believe the pre-chemo depletion of circulating Tumor-EXs may establish a novel strategy to increase tumor-site saturation of chemotherapy, which in turn could permit for lower doses of chemotherapy to be administered without diminishing patient benefit.

Unlike Sigyn Therapy™, which is a candidate to treat life-threatening conditions that are not addressed with approved drug therapies, the intent of the ChemoPrep™ and ChemoPure™ is to enhance the delivery of market-cleared chemotherapeutic drugs and reduce their toxicity. Additionally, while Sigyn Therapy™ is a hollow-fiber based device designed for use on dialysis and continuous renal replacement machines, 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 chemotherapy is administered. During treatment, the functionality of the blood processing system allows for patient blood plasma to flow through our devices, which contain formulations of adsorbent and binding components intended to deplete Tumor-EXs and chemotherapeutic agents from the bloodstream.

In an *in vitro* study conducted by researchers at Innovative Biotherapies, we obtained pre-clinical insight that liposomal nanoparticles, commonly used to deliver chemotherapeutic agents, can be reduced from human blood plasma with a formulation of adsorbent components. In the study, liposome concentrations in human blood plasma were reduced by 92.5% after a two-hour interaction with the adsorbent components. Beyond providing initial support for our candidate strategy to remove liposomal drug agents, the study established the possibility that Tumor-EXs may also be reduced from blood plasma as liposomes have previously served as a research model system for isolating extracellular vesicles and exosomes based on a similarity of size and structural characteristics. However, we have yet to conduct other *in vitro* studies to further validate the potential of either ChemoPrep™ or ChemoPure™.

ImmunePrep™

On May 17, 2023, we disclosed that a provisional patent application entitled: *"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"* had been submitted to the USPTO. The provisional patent submission established the priority date of this patent pending invention and provides us up to one year to submit a non-provisional patent application. Associated with this patent submission, we further disclosed that a trademark application to register the name ImmunePrep™ had also been filed with the USPTO. On May 9, 2024, we subsequently submitted a Patent Cooperation Treaty (PCT) application entitled: *"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"*. WO Patent Application No.: PCT/US24/28579. However, there is no assurance that we will receive a registered trademark for the ImmunePrep™ name, nor is there any assurance that patent submissions associated with ImmunePrep™ will result in an issued patent.

We intend for ImmunePrep™ to become a platform that allows for antibody-based immunotherapies to be incorporated within plasma extraction devices to enhance the targeted delivery of therapeutic antibodies without increased drug toxicity.

Therapeutic antibodies are market-cleared to treat a variety of indications, including cancer. However, patient response to these therapies is often suboptimal as just a small portion of infused antibodies reach their intended therapeutic target. In many cases, infused antibodies are bound by drug decoys that display the antibody's antigen binding site on their surface. As a result, these decoys are empowered to bind and sequester antibodies from being delivered to their intended therapeutic targets.

ImmunePrep™ is designed to extract bloodstream decoys that would subsequently block the infused delivery of therapeutic antibodies. The mechanistic objective of this pre-treatment strategy is to increase the availability of antibodies to interact with their intended therapeutic targets. Conversely, the ability of therapeutic targets to evade antibody interactions would be diminished.

Unlike Sigyn Therapy™, which is a candidate to treat life-threatening conditions that are not addressed with approved drug therapies, the intent of our ImmunePrep™ platform is to enhance the infused delivery of therapeutic antibodies. Additionally, while Sigyn Therapy™ is a hollow-fiber based device designed for use on dialysis and continuous renal replacement machines, ImmunePrep™ does not contain hollow-fibers and is intended for use on portable blood processing systems that can be located within the clinical sites where therapeutic antibodies are administered. During treatment, the functionality of the blood processing system allows for patient blood plasma to flow through ImmunePrep™, which selectively extracts circulating drug decoys from the bloodstream prior to antibody infusion.

Candidate Pipeline Product

Beyond our focus to clinically advance Sigyn Therapy, we intend to develop a pipeline of extracorporeal blood purification therapies. In this regard, we have designed a therapeutic system to enhance the benefit of cancer chemotherapy. To support this endeavor, we disclosed on October 6, 2022, that a patent application entitled: *"SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY"* had been filed with the USPTO. On October 13, 2022, we subsequently disclosed that trademark applications to register ChemoPrep™ and ChemoPure™ were filed with the USPTO. On October 4, 2023, we subsequently disclosed the submission of a Patent Cooperation Treaty (PCT) application entitled: *"SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY."* However, there is no assurance that we will receive a registered trademark for the ChemoPrep™ or ChemoPure™ names, nor is there any assurance that patent submissions associated with ChemoPrep™ or ChemoPure™ will result in an issued patent.

Chemotherapeutic agents are the most commonly administered drugs to treat cancer, which is the second leading cause of death in the United States. Despite therapeutic advances, treatment toxicity, drug resistance and inadequate tumor site delivery restrict the benefit of chemotherapy. To overcome these challenges, our patent submission describes a therapeutic device system whose primary objective is to enhance tumor site delivery of chemotherapy and reduce its toxicity. A secondary objective of the system is to reduce treatment dosing without sacrificing patient benefit, or conversely increase chemotherapy dosing without added toxicity. In concert with these objectives, our candidate therapeutic system offers to inhibit the spread of cancer metastasis that can be induced by the administration of chemotherapy.

Our proposed chemotherapy enhancement system is comprised of two blood purification technologies. ChemoPrep™, administered prior to chemotherapy to optimize tumor site delivery and improve the benefit of ChemoPure™, which is deployed post-chemotherapy to reduce treatment toxicity and inhibit the potential spread of cancer metastasis.

To improve the delivery of chemotherapeutic agents, we designed ChemoPrep™ with an objective to reduce the bloodstream presence of tumor-derived extracellular vesicles or exosomes (Tumor-EXs) that scientific publications report to interfere with chemotherapy delivery. As compared to non-cancer subjects, Tumor-EXs are highly concentrated in the bloodstream of those suffering from cancer. Tumor-EXs can decoy and directly inhibit chemotherapeutic agents from reaching tumor cell targets. Tumor-EXs have also been reported to export chemotherapeutic agents out of cancer cells. Based on these factors, we believe the pre-chemo depletion of circulating Tumor-EXs may establish a novel strategy to increase tumor-site saturation of chemotherapy, which in turn could permit for lower doses of chemotherapy to be administered without diminishing patient benefit.

ChemoPure™ was designed to perform two critical functions after chemotherapy administration. To reduce treatment toxicity by lowering the bloodstream presence of chemotherapeutic agents that are not delivered to the target tumor site, and to reduce the circulating presence of chemotherapy-induced Tumor-EXs that may promote the spread of cancer metastases.

Unlike Sigyn Therapy™, which is a candidate to treat life-threatening conditions that are not addressed with approved drug therapies, the intent of the ChemoPrep™ and ChemoPure™ is to enhance the delivery of market-cleared chemotherapeutic drugs and reduce their toxicity. Additionally, while Sigyn Therapy™ is a hollow-fiber based device designed for use on dialysis and continuous renal replacement machines, 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 chemotherapy is administered. During treatment, the functionality of the blood processing system allows for patient blood plasma to flow through our devices, which contain formulations of adsorbent and binding components intended deplete Tumor-EXs and chemotherapeutic agents from the bloodstream.

In an *in vitro* study conducted by researchers at Innovative Biotherapies, we obtained pre-clinical insight that liposomal nanoparticles, commonly used to deliver chemotherapeutic agents, can be reduced from human blood plasma with a formulation of adsorbent components. In the study, liposome concentrations in human blood plasma were reduced by 92.5% after a two-hour interaction with the adsorbent components. Beyond providing initial support for our candidate strategy to remove liposomal drug agents, the study established the possibility that Tumor-EXs may also be reduced from blood plasma as liposomes have previously served as a research model system for isolating extracellular vesicles and exosomes based on a similarity of size and structural characteristics.

Recent Corporate Developments

- **December 2020** – Reported the first *in vitro* study results of Sigyn Therapy. The study reported the simultaneous reduction of endotoxin, a gram-negative bacterial toxin, and relevant pro-inflammatory cytokines from human blood plasma. The cytokines evaluated in the study were Interleukin-1 Beta (IL-1B), Interleukin-6 (IL-6) and Tumor Necrosis Factor alpha (TNF-a).

- **January 2021** - Reported the results of an *in vitro* study that modelled the potential of Sigyn Therapy adsorbent components to reduce the presence of CytoVesicles (extracellular vesicles that transport inflammatory cargos in the bloodstream) from human blood plasma.

- **January 2021** - Appointed industry veteran Eric Lynam as Head of Clinical Affairs, with a mandate to oversee clinical studies of Sigyn Therapy.

- **April 2021** - Disclosed *in vitro* study observations that small-scale versions of Sigyn Therapy were quantified to reduce the presence of viral pathogens, including SARS-CoV-2 (COVID-19) from human blood plasma.

- **April 2021** - Appointed former Aethlon Medical executive Charlene Owen as Director of Operations.

- **July 2021** - Disclosed the completion of *in vitro* studies that quantified the reduction of hepatic toxins (ammonia, bile acid & bilirubin) from human blood plasma with small-scale versions of Sigyn Therapy.

- **July 2021 -** Disclosed the completion of a first-in-mammal pilot animal study of Sigyn Therapy at the University of Michigan.

- **December 2021** - Reported that small-scale versions of Sigyn Therapy reduced the presence of gram-positive bacterial toxins from human blood plasma.

- **February 2022 -** Reported the subsequent completion of an *in vivo* animal study of Sigyn Therapy at the University of Michigan.

- **March 2022** - Announced the appointments of two internationally recognized clinician researchers, Alexander S. Yevzlin, MD, FASN and H. David Humes, MD, to Sigyn Therapeutics' Scientific Advisory Board.

- **March 2022** - Ajay Verma, MD, PhD, a recognized thought leader in the field of neurology joins the Scientific Advisory Board.

- **April 2022** - Donald J. Hillebrand, M.D., a recognized thought leader in the field of Hepatology and Liver Transplantation joins the Scientific Advisory Board.

- **August 2022 –** The Company's common stock commences trading on the OTCQB Venture Market.

- **October 2022** –

  - Announced the appointment of Richa Nand, B.S., J.D.; Jim Dorst, B.S., M.S.; and Christopher Wetzel, B.S., M.B.A. to our Board of Directors.

  - Patent application entitled: *"SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY"* is submitted to the USPTO.

  - Trademark applications to register ChemoPrep™ and ChemoPure™ are filed with the USPTO related to medical device products to enhance cancer therapies.

- **December 2022 –** Eric Stroup, a dialysis industry thought leader joins the Sigyn Therapeutics Science Advisory Board.

- **April 2023** - Annette Marleau, Ph.D. appointed as Chief Scientific Officer (CSO) of Sigyn Therapeutics.

- **May 2023** – Patent application entitled: *"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"* submitted to the USPTO.

- **May 2023** - Trademark application to register ImmunePrep™ is filed with the USPTO.

- **December 2023** - Appointed Gerald DeCiccio, CPA, as Chief Financial Officer.

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 June 30, 2024 Compared to Three Months Ended June 30, 2023

The following discussion represents a comparison of our results of operations for the three months ended June 30, 2024 and 2023. The results of operations for the periods shown in our audited condensed consolidated financial statements are not necessarily indicative of operating results for the entire period. In the opinion of management, the audited 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 June 30,	
	2024	2023
Net revenues	$ -	$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	602,805	574,009
Other expense	259,578	149,115
Net loss before income taxes	$ (862,383)	$ (723,124)

Net Revenues

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

Cost of Sales

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

Operating expenses

Operating expenses increased by $28,796, or 5.0%, to $602,805 for three months ended June 30, 2024 from $574,009 for the three months ended June 30, 2023 primarily due to increases in research and development costs of $21,270, investor relations costs of $5,284, compensation costs of $25,093, and professional fees of $8,059, offset primarily by decreases in consulting fees of $6,850, insurance costs of $18,933, depreciation costs of $351, amortization costs of $900, and general and administration costs of $3,762 as a result of adding administrative infrastructure for our anticipated business development.

For the three months ended June 30, 2024, we had marketing expenses of $8, research and development costs of $240,429, stock based compensation of $37,500, and general and administrative expenses of $324,868 primarily due to professional fees of $33,910, compensation costs of $179,847, rent expense of $19,292, depreciation costs of $1,364, investor relations costs of $9,803, consulting fees of $33,500, insurance expense of $44,601, and general and administration costs of $2,551, as a result of adding administrative infrastructure for our anticipated business development.

For the three months ended June 30, 2023, we had marketing expenses of $100, research and development costs of $219,159, stock based compensation of $37,500, and general and administrative expenses of $317,250 primarily due to professional fees of $25,851, compensation costs of $154,754, rent expense of $19,314, depreciation costs of $1,715, amortization costs of $900, investor relations costs of $4,519, consulting fees of $40,350, insurance expense of $63,534, and general and administration costs of $6,313, as a result of adding administrative infrastructure for our anticipated business development.

Other Expense

Other expense for the three months ended June 30, 2024 totaled $259,578 primarily due to interest expense of $116,737 in conjunction with accretion of debt discount, interest expense of $142,272 in conjunction with accretion of original issuance discount, and interest expense of $569, compared to other expense of $149,115 for the three months ended June 30, 2023 primarily due to interest expense of $297,141 in conjunction with accretion of debt discount, interest expense of $60,039 in conjunction with accretion of original issuance discount, interest expense of $491, and modification of warrants of $208,556.

Net loss before income taxes

Net loss before income taxes for the three months ended June 30, 2024 totaled $862,383 primarily due to increases in compensation costs, professional fees, investor relations costs, and research and development costs, offset primarily by decreases in marketing costs, consulting fees, rent, insurance, depreciation, amortization, and general and administration costs compared to a loss of $723,124 for the three months ended June 30, 2023 primarily due to increases in research and development costs, rent, insurance, and stock based compensation, offset primarily by decreases in compensation costs, professional fees, marketing costs, investor relations costs, consulting fees, and general and administration costs.

Assets and Liabilities

Assets were $320,165 as of June 30, 2024. Assets consisted primarily of cash of $53,644, inventories of $50,000, other current assets of $42,732, equipment of $12,411, operating lease right-of-use assets of $140,667, and other assets of $20,711. Liabilities were $3,992,306 as of June 30, 2024. Liabilities consisted primarily of accounts payable of $488,364, accrued payroll and payroll taxes of $1,493,153, advance from shareholder of $70,000, other current liabilities of $2,247, convertible notes of $1,780,444, net of $229,583 of unamortized debt discount and debt issuance costs, and operating lease liabilities of $158,098.

Six Months Ended June 30, 2024 Compared to Six Months Ended June 30, 2023

The following discussion represents a comparison of our results of operations for the six months ended June 30, 2024 and 2023. The results of operations for the periods shown in our audited condensed consolidated financial statements are not necessarily indicative of operating results for the entire period. In the opinion of management, the audited 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.

	Six Months Ended June 30,	
	2024	2023
Net revenues	$ -	$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	1,232,774	1,095,267
Other expense	387,697	968,893
Net loss before income taxes	$ (1,620,471)	$ (2,064,160)

Net Revenues

For the six months ended June 30, 2024 and 2023, we had no revenues.

Cost of Sales

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

Operating expenses

Operating expenses increased by $137,507, or 12.6%, to $1,232,774 for six months ended June 30, 2024 from $1,095,267 for the six months ended June 30, 2023 primarily due to increases in research and development costs of $106,020, investor relations costs of $14,489, insurance costs of $23,916, marketing costs of $62, and compensation costs of $62,331, offset primarily by decreases in consulting fees of $39,992, depreciation costs of $545, amortization costs of $1,800, professional fees of $26,694, and general and administration costs of $425 as a result of adding administrative infrastructure for our anticipated business development.

For the six months ended June 30, 2024, we had marketing expenses of $346, research and development costs of $473,022, stock based compensation of $75,000, and general and administrative expenses of $684,406 primarily due to professional fees of $79,314, compensation costs of $357,958, rent expense of $38,773, depreciation costs of $2,885, investor relations costs of $22,534, consulting fees of $56,000, insurance expense of $116,938, and general and administration costs of $10,004, as a result of adding administrative infrastructure for our anticipated business development.

For the six months ended June 30, 2023, we had marketing expenses of $284, research and development costs of $367,002, stock based compensation of $75,000, and general and administrative expenses of $652,981 primarily due to professional fees of $106,008, compensation costs of $295,627, rent expense of $38,628, depreciation costs of $3,430, amortization costs of $1,800, investor relations costs of $8,045, consulting fees of $95,992, insurance expense of $93,022, and general and administration costs of $10,429, as a result of adding administrative infrastructure for our anticipated business development.

Other Expense

Other expense for the six months ended June 30, 2024 totaled $387,697 primarily due to interest expense of $159,944 in conjunction with accretion of debt discount, interest expense of 225,672 in conjunction with accretion of original issuance discount, and interest expense of $2,081, compared to other expense of $968,893 for the six months ended June 30, 2023 primarily due to interest expense of $1,088,849 in conjunction with accretion of debt discount, interest expense of $102,776 in conjunction with accretion of original issuance discount, interest expense of $1,630, and modification of warrants of $224,362.

Net loss before income taxes

Net loss before income taxes for the six months ended June 30, 2024 totaled $1,620,471 primarily due to decreases in professional fees, consulting fees, depreciation, amortization, and general and administration costs, offset primarily by compensation costs, marketing costs, investor relations costs, research and development costs, rent, and insurance compared to a loss of $2,064,160 for the six months ended June 30, 2023 primarily due to decreases in compensation costs, professional fees, marketing costs, investor relations costs, consulting fees, research and development costs, insurance, and general and administration costs, offset primarily by increases in rent, and stock based compensation.

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 $12,961,983 at June 30, 2024, had a working capital deficit of $3,753,241 and $3,489,941 at June 30, 2024 and December 31, 2023, respectively, had net losses of $862,383 and $1,620,471, and $723,124 and $2,064,160 for the three and six months ended June 30, 2024 and 2023, respectively, and net cash used in operating activities of $418,406 and $891,267 for the six months ended June 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 increase revenues, the Company's cash position may not be significant enough to support the Company's daily operations. Management intends to raise additional funds by way of a public offering or an asset sale transaction. Management believes that the actions presently being taken to further implement its business plan and generate revenues provide the opportunity for the Company to continue as a going concern. While management believes in the viability of its strategy to generate revenues and in its ability to raise additional funds or transact an asset sale, there can be no assurances to that effect or on terms acceptable to the Company. The ability of the Company to continue as a going concern is dependent upon the Company's ability to further implement its business plan and generate revenues.

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

General – Overall, we had an increase in cash flows for the six months ended June 30, 2024 of $41,954 resulting from cash provided by financing activities of $460,360, offset partially by cash used in operating activities of $418,406.

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

	Six Months Ended June 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	$ (418,406)	$ (891,267)
Investing activities	-	-
Financing activities	460,360	906,544
	$ 41,954	$ 15,277

Cash Flows from Operating Activities – For the six months ended June 30, 2024, net cash used in operations was $418,406 compared to net cash used in operations of $891,267 for the six months ended June 30, 2023. Net cash used in operations was primarily due to a net loss of $1,620,471 for six months ended June 30, 2024 and the changes in operating assets and liabilities of $738,564, primarily due to the changes in accounts payable of $26,718, other current assets of $13,641, accrued payroll and payroll taxes of $701,399, offset partially by the change in other current liabilities of $3,194. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of $2,885, stock based compensation of $75,000, accretion of original issuance costs of $225,672, and the accretion of debt discount of $159,943.

For the six months ended June 30, 2023, net cash used in operations was primarily due to a net loss of $2,064,160 for the six months ended June 30, 2023 and the changes in operating assets and liabilities of $125,400, primarily due to the increase in accounts payable of $12,427 and accrued payroll and payroll taxes of $156,278, offset partially by the decrease in other current liabilities of $85, and other current assets of $43,220. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of $3,430, amortization expense of $1,800, stock based compensation of $75,000, accretion of debt discount of $1,088,849, accretion of original issuance costs of $102,776, and modification of warrants of $224,362.

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

Cash Flows from Financing Activities – For the six months ended June 30, 2024, net cash provided by financing was $460,360, due to proceeds from short term convertible notes of $470,360 and advance from shareholder of $35,000, and repayments of advance from shareholder of $45,000 compared to cash provided by financing activities of $906,544 for the six months ended June 30, 2023 due to proceeds from short term convertible notes of $882,000, advances from shareholder of $30,000, 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 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

From May 2024 through July 2024, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $272,500 aggregate principal amount of Note (total of $244,500 cash was received) due from May 2025 through July 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 45,421 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 for the issuance of the Note and Warrants was $244,500 which was issued at a $28,000 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 $6.00 per share.

In February 2024, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $232,936 aggregate principal amount of Note (total of $211,760 cash was received) due in February 2024 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 38,825 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 for the issuance of the Note and Warrants was $211,760 which was issued at a $21,176 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 $6.00 per share.

On January 8, 2024, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") with respect to the sale and issuance to institutional investor Brio Capital Master Fund Ltd ("Brio") of (i) $44,000 aggregate principal amount of Note due January 8, 2025 based on $1.00 for each $0.90909 paid by Brio and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 7,333 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 Brio for the issuance of the Note and Warrants was $40,000 which was issued at a $4,000 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 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 $70,000 and $80,000 under Advance from Shareholder in the accompanying the unaudited condensed consolidated balance sheets at June 30, 2024 and December 31, 2023, respectively. The Company received advances of $35,000 and $49,500 and had repayments of $45,000 and $19,500 for the six months ended June 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 June 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-l5(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 (June 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-l5(f) of the Securities Exchange Act). Management assessed the effectiveness of the Company's internal control over financial reporting as of June 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 June 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-K, 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 months ended June 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 June 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 PROCEDINGS.

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 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.

From May 2024 through July 2024, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $272,500 aggregate principal amount of Note (total of $244,500 cash was received) due from May 2025 through July 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 45,421 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 for the issuance of the Note and Warrants was $244,500 which was issued at a $28,000 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 $6.00 per share.

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 June 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 June 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
31.1	Certification by Principal Executive Officer pursuant to Rule13a-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.
*	Previously filed.
**	To be filed by amendment
***	Filed herewith
+	
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.
+	Management contract or compensatory plan

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: August 19, 2024

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

Dated: August 19, 2024

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

Dated: August 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.

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

EXHIBIT 31.1

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: August 19, 2024

/s/ James Joyce

James Joyce
Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

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: August 19, 2024

/s/ Gerald DeCiccio

Gerald DeCiccio
Chief Financial Officer (Principal Financial and Accounting Officer)

EXHIBIT 32.1

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 June 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)

August 19, 2024

EXHIBIT 32.2

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 June 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)

August 19, 2024