

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

**AMENDMENT NO. 6 TO  
FORM S-1**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

**SIGYN THERAPEUTICS, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**3841**

(Primary Standard Industrial Classification Code)

**47-2573116**

(I.R.S. Employer Identification No.)

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(Address and Telephone Number of Registrant's Principal Executive Offices and Principal Place of Business)

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**Approximate date of commencement of proposed sale to the public: As soon as practicable on or after the effective date of this registration statement.**

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, please check the following box:

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.**



**The information in this prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED SEPTEMBER , 2023**

**Sigyn Therapeutics, Inc.**



**1,406,250 Class A Units  
Each Class A Unit Consisting of  
One Share of Common Stock and  
One Series A Warrant to Purchase One Share of Common Stock  
Unit**

This is a firm commitment public offering of 1,406,250 Class A Units (“Class A Units”), with each Class A Unit consisting of one share of our common stock, par value \$0.001 per share (“common stock”), and one Series A Warrant to purchase one share our common stock (and the shares issuable from time to time upon exercise of the Series A Warrants) pursuant to this prospectus based on an assumed offer price of \$6.40 for each Class A Unit. Each Series A Warrant will have an exercise price of \$7.04 (assumed) per share, will be exercisable upon issuance and will expire five years from issuance. We anticipate that the public offering price of our Class A Units will be between \$6.00 and \$8.00, and the number of Class A Units offered hereby is based upon an assumed offering price of \$6.40 per Class A Unit, which is the last reported sale price of our common stock on the OTCQB® Venture Market on September 20, 2023. The actual public offering price of the Class A Units will be determined between the underwriters and us at the time of pricing, considering our historical performance and capital structure, prevailing market conditions, and overall assessment of our business, and may be at a discount to the current market price. Therefore, the assumed public offering price per Class A Unit used throughout this prospectus may not be indicative of the actual public offering price for the Class A Units. See “Determination of Offering Price” for additional information.

Concurrent with the closing of this offering, we are effecting a one for twenty (1-for-20) reverse stock split, and the public offering price and the exercise price of the Class A Warrant, as well as all other references to “per share” and the number of shares, and words to similar effect, have been adjusted on the basis of the reverse split ratio.

The Class A Units have no stand-alone rights, will not be certificated or issued as stand-alone securities and there will be no trading market for the Class A Units. The shares of common stock and the Series A Warrants comprising the Class A Units will separate immediately upon completion of this offering and prior to any trading of the common stock and Series A Warrants.

Our common stock trades on the OTCQB® Venture Market under the symbol “SIGY”. On September 20, 2023, the last reported sale price of our common stock on the OTCQB® Venture Market was \$6.40. Prior to this offering, there has been no public market for our Class A Units, or our Series A Warrants. We plan to apply to have our shares of common stock listed on the Nasdaq Capital Market under the symbol “SIGY”. No assurance can be given that our application will be approved or that the trading price of our common stock on the OTCQB® Venture Market will be indicative of the prices of our common stock if our common stock were traded on the Nasdaq Capital Market. If, for whatever reason, Nasdaq does not approve the listing of our common stock on Nasdaq prior to the pricing of the offering, we will not be able to consummate and will terminate this offering. There is no established trading market for the Series A Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series A Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Series A Warrants will be limited.

**Investing in our securities involves a high degree of risk. See “Risk Factors” beginning on page 6 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	<u>Class A Unit</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discounts and commissions(1)	\$	\$
Proceeds to us, before expenses (2)	\$	\$

- (1) We have also agreed to issue warrants to purchase shares of our common stock to the representative of underwriters and to reimburse the representative of the underwriters for certain expenses. See “Underwriting” for additional information regarding total underwriter compensation.
- (2) The amount of offering proceeds to us presented in this table does not give effect to : (i) the exercise (if any) of the over-allotment option we have granted to the representative of the underwriters as described below, (ii) the exercise of the Class A Warrants issued in connection with this offering, and (iii) the exercise of warrants being issued to the representative of the underwriters in this offering. The public offering price and underwriting discount corresponds to in respect of the Class A Units a public offering price per Unit of \$6.40.

We have granted a 45-day option to the representative of the underwriters, exercisable one or more times in whole or in part, to purchase up to an additional 225,000 shares of common stock and/or additional Series A Warrants (each having the same terms as those securities included in the Class A Units issued in the offering) from us in any combination thereof at: (i) the price per share of common stock equal to the public offering price per Class A Unit minus \$0.01 per share, and (ii) \$0.01 per Series A Warrant, respectively, less the underwriting discounts payable by us, solely to cover over-allotments, if any.

The underwriters expect to deliver the securities to purchasers in the offering on or about , 2023.



The date of this prospectus is , 2023





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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

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## PROSPECTUS SUMMARY

Except as otherwise indicated, as used in this prospectus, references to the “Company,” “we,” “us,” or “our” refer to Sigyn Therapeutics, Inc.

*The following summary highlights selected information contained in this prospectus, and it may not contain all of the information that is important to you. Before making an investment decision, you should read the entire prospectus carefully, including “Risk Factors” and our financial statements and related notes, included elsewhere in this prospectus.*

### Our Company

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 Company

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 United States Patent and Trademark Office (“USPTO”). The provisional patent submission established the priority date of our now patent pending invention and provides us up to one year to submit a non-provisional patent application. On October 13, 2022, we subsequently disclosed that trademark applications to register ChemoPrep™ and ChemoPure™ were 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 United States Patent and Trademark Office (“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. 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.

## Risks and Challenges That We Face

An investment in our securities involves a high degree of risk. You should carefully consider the risks summarized below and the other risks that are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

- Demand and market acceptance of our product offerings may be considerably less than what we currently anticipate.
- We may be unable to increase revenues in the manner in which we anticipate and generate profitability.
- We may face challenges in successfully completing FDA testing requirements.
- We may not be able to meet increased and changing regulatory requirements.
- We believe the FDA will classify our lead product candidate to be a significant risk Class III device, which would require 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.
- We will need to raise additional capital to fully commercialize our products.
- Some of our target products may face an uncertain regulatory environment.
- We may be unable to expand operations and manage growth.
- We may be unable to retain key members of our management and development teams and to recruit additional qualified personnel.
- We face competition from companies that have greater resources than we do and we may not be able to effectively compete against these companies.
- As stated in their audit opinion for our audited financials for the year ended December 31, 2022, our auditors believe that we may not be able to continue as a going concern.
- Since inception, our primary focus has been directed toward the advancement of Sigyn Therapy. As of December 31, 2022, we have an accumulated deficit of \$7,195,576 and a working capital deficit of \$1,978,396. As of June 30, 2023, we have an accumulated deficit of \$9,259,736 and a working capital deficit of \$3,117,142.
- We plan to apply to have our shares of common stock listed on the Nasdaq Capital Market under the symbol “SIGY”. No assurance can be given that our application will be approved. If, for whatever reason, Nasdaq does not approve the listing of our common stock on Nasdaq prior to the pricing of the offering, we will not be able to consummate and will terminate this offering.
- There is no established trading market for the Series B Preferred Stock or Series A Warrants being offered in this offering.
- Holders of Series B Preferred Stock will have limited voting rights.
- The Series A Warrants are speculative.
- The Series A Warrants may not have any value and if an active, liquid trading market for the Series A Warrants does not develop, you may not be able to sell your warrants quickly or at or above the price you paid for them.

## Available Information

We file various reports with the SEC, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, which are available through the SEC’s electronic data gathering, analysis and retrieval system (“EDGAR”) by accessing the SEC’s home page (<http://www.sec.gov>).

## Corporate Information

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. Our mailing address is currently 2468 Historic Decatur Road., Suite 140, San Diego, California, 92106. Our telephone number is (619) 353-0800.

## THE OFFERING

**Class A Units offered by us:**

We are offering Class A Units. Each Class A Unit consists of one share of our common stock and a Series A Warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants). The Class A Units will not be certificated or issued in stand-alone form. The shares of our common stock and the Series A Warrants comprising the Class A Units are immediately separable upon issuance and will be issued separately in this offering.

**Assumed Offering price:**

\$6.40 per Class A Unit

**Number of shares of common stock outstanding after the offering:(1)**

\_\_\_\_\_ shares of common stock

**Market for the common stock:**

Our common stock trades on the OTCQB® Venture Market under the symbol “SIGY”. On September 20, 2023, the last reported sale price for our common stock on the OTCQB® Venture Market was \$6.40 per share. Prior to this offering, there has been a limited market for our common stock. While our common stock trades on the OTCQB® Venture Market, there has been negligible trading volume. We plan to apply to have our shares of common stock listed on the Nasdaq Capital Market under the symbol “SIGY”. No assurance can be given that our application will be approved or that the trading price of our common stock on the OTCQB® Venture Market will be indicative of the prices of our common stock if our common stock were traded on the Nasdaq Capital Market. If, for whatever reason, Nasdaq does not approve the listing of our common stock on Nasdaq prior to the pricing of the offering, we will not be able to consummate and will terminate this offering.

There is no assurance that an active trading market will develop, or, if developed, that it will be sustained. Consequently, purchasers of our common stock may find it difficult to resell the securities offered herein should the purchasers desire to do so when eligible for public resale.

Our officers and directors are not purchasing securities in this offering.

**Use of proceeds:**

We estimate that we will receive approximately \$9 million in gross proceeds if we sell all of the Class A Units in the offering (based on an assumed offering price of \$6.40 per Class A Unit, which was the last reported sales price of our common stock on the OTCQB® Venture Market on September 20, 2023), and we will receive estimated net proceeds (after deducting underwriting discounts and estimated offering expenses) (assuming no exercise of the underwriter’s over-allotment option, the Series A Warrants included in the Class A Units or the Representatives’ Warrants offered hereby).

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund our research and development activities, clinical trials and the regulatory review process, and the remainder for working capital and other general corporate purposes. See “Use of Proceeds” for a more detailed explanation of how the proceeds from the Offering will be used.

**Over-allotment option:** We have granted a 45-day option to the representative of the underwriters, exercisable one or more times in whole or in part, to purchase up to 225,000 additional shares of common stock and/or additional Series A Warrants to purchase up to 225,000 shares of our common stock (each having the same terms as those securities included in the Class A Units issued in the offering) from us in any combination thereof at: (i) the price per share of common stock equal to the public offering price per Class A Unit minus \$0.01 per share, and (ii) \$0.01 per Series A Warrant, respectively, less the underwriting discounts payable by us, solely to cover over-allotments, if any.

**Representative's Warrants:** The registration statement of which this prospectus is a part also registers for sale warrants (the "Representative's Warrants") to purchase shares of our common stock (based on an assumed offering price of \$6.40 per share, which was the last reported sales price of our common stock as quoted on the OTCQB® Venture Market on September 20, 2023) to Univest Securities, LLC (the "Representative"), as the representative of the several underwriters, as a portion of the underwriting compensation payable to the representative in connection with this offering. The representative's warrants will be exercisable at any time, and from time to time, in whole or in part, during the four and one half period commencing 180 days following the commencement of sales of the securities in this offering at an exercise price of \$7.04 (110% of the assumed public offering price of the Class A Units). Please see "Underwriting—Representative's Warrants" for a description of these warrants.

**Risk Factors:** See "Risk Factors" and the other information in this prospectus for a discussion of the factors you should consider before deciding to invest in our securities.

**Trading symbol:** Our common stock currently trades on the OTCQB® Venture Market under the symbol "SIGY". We plan to apply to have our shares of common stock listed on the Nasdaq Capital Market under the symbol "SIGY". No assurance can be given that our application will be approved or that the trading prices of our common stock on the OTCQB® Venture Market will be indicative of the prices of our common stock if our common stock were traded on the Nasdaq Capital Market. If, for whatever reason, Nasdaq does not confirm the listing of our common stock on Nasdaq prior to the pricing of the offering, we will not be able to consummate and will terminate this offering.

There is no established trading market for Series A Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series A Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Series B Preferred Stock and the Series A Warrants will be limited.

**Series A Warrants:** The exercise price of the Series A Warrants shall be 110% of the offering price of the Class A Units. The Series A Warrants have a five-year term. The Series A Warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The Series A Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the Series A Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the Series A Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the Series A Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Series A Warrant. No fractional shares of common stock will be issued in connection with the exercise of a Series A Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price. This offering also relates to the shares of our common stock issuable upon exercise of the Series A Warrants.

(1) The number of shares of our common stock to be outstanding after this offering is based on shares of our common stock outstanding as September \_\_, 2023.

Unless we indicate otherwise or the context otherwise requires, all information in this prospectus:

- assumes a one for twenty (1-for-20) reverse stock split, and the public offering price and the exercise price of the Class A Warrant, as well as all other references to "per share" and the number of shares, and words to similar effect, have been adjusted on the basis of the reverse split ratio.
- assumes no exercise by the underwriters of their option to purchase up to 225,000 additional shares of our common stock and/or Series A Warrants from us to cover over-allotments, if any;
- no exercise of the Series A Warrants included in the Class A Units;
- assumes no exercise of the Representative's Warrants to be issued upon consummation of this offering at an exercise price equal to 110% of the initial offering price of the Class A Units;
- assumes no exercise of outstanding warrants to purchase shares of our common stock or exercise or conversion of any outstanding shares of preferred stock or convertible notes; and
- excludes shares of common stock to be reserved for future issuance under our equity incentive plan, which will be effective upon the completion of this offering.

## SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. The statements of operations data for the years ended December 31, 2022, and 2021 and six months ended June 30, 2023 and 2022 and balance sheet data as of December 31, 2022, December 31, 2021, and June 30, 2023 are derived from our audited and unaudited financial statements included elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements included in this prospectus and include, in our opinion, all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements.

The following summary financial information should be read in connection with, and is qualified by reference to, our financial statements related notes thereto and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus. Our historical results are not necessarily indicative of results to be expected in any future period.

### Statement of Operations Data:

	Year ended December 31, 2022	Year ended December 31, 2021	Six months ended June 30, 2023                      2022	
Operating costs and expenses				
General and administrative	\$ 1,489,151	\$ 1,274,203	\$ 652,981	758,625
Marketing expenses	457	-	284	381
Research and development	657,657	734,014	367,002	383,025
Total operating Expenses	<u>2,147,265</u>	<u>2,008,217</u>	<u>1,095,267</u>	<u>1,142,031</u>
Loss from operations	<u>(2,147,265)</u>	<u>(2,008,217)</u>	<u>(1,095,267)</u>	<u>(1,142,031)</u>
Other expense				
Impairment of assets	-	536,047	-	-
Interest expense	782,552	460,355	1,630	31
Total other expense	<u>782,552</u>	<u>996,402</u>	<u>968,893</u>	<u>202,340</u>
Net loss	<u>(2,929,817)</u>	<u>(3,004,619)</u>	<u>(2,064,160)</u>	<u>(1,344,371)</u>
Net loss per share, basic and diluted	\$ (0.08)	\$ (0.08)	(0.05)	(0.04)
Weighted average number of shares of common stock outstanding, basic and diluted	37,396,591	36,396,585	40,911,801	37,295,813

### Balance Sheet Data

	June 30, 2023	December 31, 2022	December 31, 2021
Cash	\$ 23,633	\$ 8,356	\$ 340,956
Other Current Assets	55,162	61,942	52,075
Total assets	\$ 361,817	\$ 332,879	\$ 710,259
Total liabilities	\$ 3,404,035	\$ 2,236,119	\$ 974,843
Preferred stock	\$ -	\$ -	\$ -
Common stock	4,423	3,826	3,730
Additional paid-in-capital	6,213,095	5,288,510	3,997,445
Accumulated deficit	(9,259,736)	(7,195,576)	(4,265,759)
Total stockholders’ deficit	\$ (3,042,218)	\$ (1,903,240)	\$ (264,584)

## RISK FACTORS

*You should carefully consider the risks described below before investing in our securities. Additional risks not presently known to us or that our management currently deems immaterial also may impair our business operations. If any of the risks described below were to occur, our business, financial condition, operating results, and cash flows could be materially adversely affected. In such an event, the trading price of our common stock could decline, and you could lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Prospectus, including our consolidated financial statements and related notes. The risks discussed below include forward-looking statements, and our actual results may differ substantially from those discussed in these forward-looking statements.*

### **Risks Related to Financial Condition**

*The audit report for our fiscal year ended December 31, 2022 includes a going concern qualification.*

As described in our audited financial statements for the year ended December 31, 2022 contained elsewhere in this prospectus for that same time period, our independent registered public accounting firm included an explanatory paragraph indicating that our current liquidity position raises substantial doubt about our ability to continue as a going concern. It is anticipated that we will continue to operate as a going concern until the completion of this offering; however, there are no assurances that we will be able to continue our operations if this offering is delayed.

*We have incurred significant net losses since inception and do not anticipate that we will generate revenue in the near future. It is expected that we will continue to incur substantial net losses in the foreseeable future and we may never achieve profitability.*

We are a development-stage medical technology company which has no approved products and no revenue. Investment in development-stage therapeutic organizations is speculative based on the need for substantial capital resources and the risk that therapeutic candidates will not receive regulatory approval or become commercially viable if market cleared. We have incurred losses in each year since inception. Our net losses were \$2,929,817 and \$3,004,619 for the years ended December 31, 2022 and 2021, respectively, and \$2,064,160 and \$1,344,371 for the six months ended June 30, 2023 and 2022, respectively. As of December 31, 2022 and June 30, 2023, we had an accumulated deficit of \$7,195,576 and \$9,259,736, respectively. We expect to continue to spend significant resources to fund the clinical progression of Sigyn Therapy and other potential product candidates.

*We have a limited operating history, which may make it difficult to evaluate our business and prospects.*

We are a development-stage company and face the risks associated with businesses in their early stages, with limited operating histories and whose prospects are hard to evaluate. Any evaluation of our business and our prospects must be considered in light of the uncertainties, delays, difficulties and expenses commonly experienced by companies at this stage, which generally include unanticipated problems and additional costs relating to the development and testing of products, product approval or clearance, regulatory compliance, production, product introduction and marketing, and competition. Many of these factors are beyond the control of our management. In addition, our performance will be subject to other factors beyond our control, including general economic conditions and conditions in the healthcare industry.

*Upon the completion of this offering, we may require additional capital in the future to fund the continuance of our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate our clinical development programs.*

We believe that the net proceeds from this offering will be approximately \$9.4 million, based on an assumed public offering price of \$6.40 per Class A Unit, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We believe that such proceeds will fund our operations plan for up to 24 months after the completion of the offering. Accordingly, we acknowledge that there will be a need to raise additional capital to fund future operations, which may include the continued clinical progression of Sigyn Therapy and other potential product candidates. However, our business or operations plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned. However, there is no assurance that we will be able to secure funding when we need it or on favorable terms. Additionally, our ability to raise additional capital could be adversely impacted by market conditions or a worsening global economic climate.

***Purchasers of our stock will experience dilution.***

At June 30, 2023 and December 31, 2022, we had a net tangible book value of approximately \$0.008 and \$0.008 per share of our common stock, respectively. If you purchase our common stock from us in our Offering, you will experience immediate and substantial dilution to the extent of the difference between the public offering price per share of our common stock (assuming a \$6.40 per share public offering price, which is the assumed public offering price set forth on the cover page of this prospectus) and the as adjusted net tangible book value per share of our common stock immediately after the offering of \$6.40 per share (assuming all 1,406,250 shares in the Offering are sold at \$6.40 per share, which is the assumed public offering price set forth on the cover page of this prospectus).

***A small group of Company officers and directors hold a majority of the control of the Company.***

As of September 1, 2023, the Company's executive officers and directors beneficially owned approximately 68.9% of the Company's outstanding common stock. By virtue of such stock ownership, the principal shareholders are able to control the election of the members of the Company's Board of Directors and to generally exercise control over the affairs of the Company. Such concentration of ownership could also have the effect of delaying, deterring or preventing a change in control of the Company that might otherwise be beneficial to stockholders. There can be no assurance that conflicts of interest will not arise with respect to such directors or that such conflicts will be resolved in a manner favorable to the Company.

***We may not be able to protect our intellectual property.***

We currently own the rights to U.S. and foreign patents pending and patent applications and endeavor to continually improve our intellectual property position. We consider the protection of our technology to be vital to our business. While we intend to focus primarily on patentable technology, we may also rely on trade secrets, unpatented property, know-how, regulatory exclusivity, patent extensions and continuing technological innovation to develop our competitive position. We also own rights to the trademarks Sigyn Therapeutics™ and Sigyn Therapy™.

Our success will depend in large part on our ability to protect our proprietary technologies, including Sigyn Therapy, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, and other agreements to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses, or cease sales of products or certain activities.

It is possible that our pending patent applications may not result in issued patents, and that we will not develop additional proprietary products that are patentable, that any patents issued to us may not provide us with competitive advantages or will be challenged by third parties and that the patents of others may prevent the commercialization of products incorporating our technology. Furthermore, others may independently develop similar products, duplicate our products or design around our patents. U.S. patent applications are not immediately made public, so it is possible that a third party may obtain a patent on a technology we are actively using. Additionally, there is a risk that any patent applications that we file or later obtain could be challenged by third parties and declared invalid or unenforceable.

Patent law outside the United States is uncertain and currently undergoing review and revisions in many countries. The laws of some countries may not protect our proprietary rights to the same extent as the laws of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that may be issued or pending in the United States. In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. It is possible that others could independently develop or otherwise acquire substantially equivalent technology or somehow gain access to our trade secrets and proprietary technological expertise.

***We Face Industry and Competition Risks.***

Based on the size of the market opportunity, the industry to treat sepsis and other life-threatening inflammatory conditions is expected to become extremely competitive. As a development-stage device, Sigyn Therapy faces the challenge of establishing medical industry support, which will be driven by treatment data resulting from human clinical studies. Should Sigyn Therapy become market cleared, we are likely to face significant competition. Additionally, we will need to establish large-scale production of Sigyn Therapy in order to be competitive in the marketplace.



In the absence of approved drug agents to treat sepsis and other life-threatening disorders, our competition is likely to come from organizations that develop extracorporeal blood purification therapies. Among these therapies are a cytokine adsorption technology (CytoSorb from Cytosorbents Corporation); a technology that removes circulating endotoxin (Toraymyxn from Toray Industries); and two devices that target the removal of pathogens from the bloodstream (the Hemopurifier from Aethlon Medical) and (the Seraph-100 Microbind Affinity Filter from Exthera Medical).

CytoSorb is a clinical-stage therapeutic candidate in the United States and market cleared in more than 40 countries outside the U.S. CytoSorb was recently cleared to treat severe COVID-19 infections under FDA Emergency-Use Authorization (EUA) based on its ability to adsorb inflammatory cytokines from the bloodstream.

Toraymyxn is a clinical-stage therapeutic candidate in the United States and broadly market cleared outside the U.S. Toraymyxn houses an immobilized antibiotic agent with a high specificity to bind circulating endotoxin, a potent activator of sepsis resulting from gram-negative bacterial infections. In North America, exclusive rights to Toraymyxin are licensed to Spectral Medical, who is conducting FDA approved studies to treat sepsis.

The Aethlon Hemopurifier is a clinical-stage therapeutic candidate in the United States. The Hemopurifier has been cleared to treat severe COVID-19 infections through an FDA IDE supplement and was previously cleared under FDA Emergency-Use Authorization (EUA) to treat Ebola virus. Immobilized within the Hemopurifier is an affinity lectin that has a high specificity to bind a broad-spectrum of viral pathogens from the bloodstream.

The Exthera Seraph-100 Microbind Affinity Filter is a clinical-stage therapeutic candidate in the United States and market cleared outside the U.S. for the removal of bloodstream pathogens. The Seraph-100 was recently cleared and broadly deployed to treat severe COVID-19 infections under FDA Emergency-Use Authorization (EUA). The Seraph-100 incorporates heparin-coated polyethylene beads that bind both viral and bacterial pathogens in the bloodstream.

While preclinical *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, there is no assurance that we will receive market clearance for our product or be able to establish scalable manufacturing that would allow us to compete with these and other emerging therapies.

***We are a development-stage therapeutic organization whose primary focus in the foreseeable future will be the clinical progression of Sigyn Therapy toward market clearance.***

We are a development stage company with no approved medical products. To date, we have devoted substantially all of our resources to support the development of Sigyn Therapy. This includes the completion *in vitro* blood purification validation studies, animal studies, the establishment of initial manufacturing protocols, staffing our organization, establishing our intellectual property portfolio, drafting regulatory documents and raising capital to support these activities. However, there is no assurance that we will obtain the capital resources necessary to continue to advance Sigyn Therapy or other product candidates toward market approval.

***Government Regulation May Cause Us Delays in Ability to Obtain Approval.***

Sigyn Therapy is subject to regulation by numerous regulatory bodies, including the United States Food and Drug Administration (FDA) and comparable international regulatory agencies. These agencies will require that we comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing, storage, distribution, advertising and promotion, and post-marketing surveillance of Sigyn Therapy. As a medical device, the FDA's Center for Devices and Radiological Health (CDRH) will have primary jurisdiction over the premarket development, review, and approval of Sigyn Therapy. Failure to comply with applicable requirements could subject us to a variety of administrative sanctions, such as issuance of warning letters, import detentions, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

***FDA's Pre-market Approval (PMA) Pathway May Take a Long Time for Approval of our Product.***

The FDA is likely to classify our lead product candidate, Sigyn Therapy, as a significant risk Class III device, which would require 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. The commercialization of medical devices in the United States requires either a prior 510(k) clearance, unless it is exempt, or a PMA from the FDA. Medical devices are classified into one of three classes; Class I, Class II or Class III which are determined by the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. A Class III device cannot be marketed in the United States unless the FDA approves the device after submission of a PMA. We believe that Sigyn Therapy will be classified as a Class III device and as such will be subject to a PMA submission and approval.

A pre-market approval application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labelling to demonstrate to the FDA's satisfaction reasonable evidence of safety and effectiveness of the device.

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

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

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

The advancement of Sigyn Therapy will be reliant on substantial funding, of which there is no assurance that we will raise the capital resources necessary to maintain the continuance of our operations and clinically advance Sigyn Therapy. Even if we obtain market clearance from FDA to commercialize Sigyn Therapy, there is no assurance that we can successfully compete with other products in the marketplace. Additionally, competitive technologies could emerge that are more effective in treating life-threatening indications targeted by Sigyn Therapy. Such competitive products may be advanced by larger organizations that have substantially greater capital resources and marketing capabilities. Furthermore, Sigyn Therapy may be deemed obsolete should emerging competitive technologies be commercialized prior to market clearance of Sigyn Therapy. Since inception, our primary focus has been directed toward the advancement of Sigyn Therapy. As of June 30, 2023, we have an accumulated deficit of \$9,259,736 and a working capital deficit of \$3,042,218.

#### ***Clinical Trial Requirements Pose Risk to Obtaining Approval.***

Human clinical trials are required to support pre-market approval. In the United States, human clinical studies require the submission of an Investigational Device Exemption (IDE) to FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. At present, we are preparing an IDE to submit to FDA. Prior to initiating human studies, our IDE will need to be approved in advance by the FDA for a specific number of patients at specified study sites. During the trial, we must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and recordkeeping. Our clinical trial investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and recordkeeping requirements. Clinical trials of Sigyn Therapy will not be allowed to begin until our IDE application has been approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. The FDA or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of Sigyn Therapy or other product candidates.

The success of Sigyn Therapy and other product candidates will depend on several factors, which include:

- the completion of clinical studies that demonstrate the safety and efficacy of our products; the receipt of market approval from applicable regulatory authorities, and the completion of post-market studies that may be required by applicable regulatory authorities;
- the establishment of commercial manufacturing capabilities and launch of product marketing and commercial sales;
- the acceptance of Sigyn Therapy or other product candidates by patients, the medical community and third-party payors;
- obtaining and maintaining healthcare coverage and adequate reimbursement for Sigyn Therapy and other product candidates.

Many of these factors may be beyond our control, including the time that will be required to complete clinical testing, the regulatory submission process, and a change in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition and the results of our operations.

***Our Pre-clinical Outcomes May Not Be Predictive of Clinical Trial Success.***

The results of our pre-clinical *in vitro* validations and animal studies may not be predictive of human clinical study outcomes. Historically, therapeutic candidates that perform satisfactorily in pre-clinical and animal studies may nonetheless fail to obtain marketing approval. If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be required to change the way our product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy.

Additionally, our product candidates could potentially cause adverse events that have not yet been predicted. The inclusion of ill patients in our clinical studies may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products.

***We will depend on enrollment and retention of patients in our clinical trials for our product candidates. Delays or difficulties enrolling or retaining patients in our clinical trials could adversely impact our business operations.***

The successful and timely completion of clinical trials will require that we enroll and retain a sufficient number of patient candidates. Any clinical trials that we conduct could be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. These types of developments could cause us to delay a clinical trial or halt further development. Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease, condition or infection under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- perceived risks and benefits of the product candidate under evaluation;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
  - the availability of competing clinical trials;
  - the availability of candidate patients during pandemic outbreaks, such as COVID-19; and
  - the availability of new therapies that are approved for the indication the clinical trial is investigating.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of our clinical trials may jeopardize our ability to commence product sales and generate revenue. Additionally, factors that delay the commencement or completion of clinical trials may establish a basis for FDA to deny the approval of our therapeutic candidates.

## **Risks Related to our Business and Industry**

### ***We are dependent on our Chief Executive Officer.***

We are dependent on our Chief Executive Officer, James A. Joyce, who is integral to our business operations and the development of our product candidates. The loss of Mr. Joyce's services could have a material adverse effect on our business operations.

### ***We have a limited number of employees.***

We are a small organization that maintains a staff of five employees. The departure of any employee could have a material adverse effect on our business operations.

### ***We may be adversely affected by current and future pandemic outbreaks.***

The COVID-19 ("COVID-19") outbreak and the emergence of future pandemics could have a deleterious impact on our business operations. As demonstrated by COVID-19, pandemic outbreaks can significantly delay or interrupt crucial business operations. Pandemic outbreaks may also reduce the availability of human resources or critical supplies that will be required to carry out our clinical and manufacturing programs. Additionally, stay-at-home and other pandemic outbreak policies could restrict critical personnel from conducting the core activities necessary to advance Sigyn Therapy and other potential product candidates.

### ***Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.***

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, medical technology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund clinical development efforts. There is no certainty that the capital markets will be conducive to raising capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our clinical progression plan would be compromised. Moreover, we rely and intend to rely on third-party vendors, including clinical research organizations, contract manufacturing organizations and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

### ***Our reliance on third-party vendors heightens the risks faced by our business.***

We rely on third-party vendors for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well, which could adversely affect our business, reputation, financial condition or results of operations.

### ***We rely on third party organizations to conduct our pre-clinical testing, research and clinical trials.***

We rely on third-party organizations to conduct preclinical studies, and we expect to continue to rely on third parties, such as contract research organizations ("CROs"), contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and pre-clinical testing. These third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we are required to enter into alternative arrangements, it could delay our product development activities.

*Upon commercialization of our products, we may be dependent on third parties to market, distribute and sell our products.*

Our ability to generate revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so prior to commercialization. If we fail to reach an agreement with any commercialization partner, or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

*We will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.*

We do not have any manufacturing facilities. We expect to rely on third-party manufacturers for the manufacture of our product candidates for clinical trials and for commercial supply of any product candidate for which we obtain marketing approval.

We may be unable to establish agreements with third-party manufacturers for clinical or commercial supply on terms favorable to us, or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with U.S. Current Good Manufacturing Practices (cGMPs) or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

Any product that we develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our manufacturers, including a failure that may not relate specifically to our product candidates or approved products, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If our contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

Our anticipated future dependence upon others for the manufacture of our current and future product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

*Our business could be adversely affected by reliance on sole suppliers.*

Notwithstanding our current multiple supplier approach, certain essential product components may be supplied in the future by sole, or a limited group of, suppliers. Most of our products and components are purchased through purchase orders rather than through long term supply agreements and large volumes of inventory may not be maintained. There may be shortages and delays in obtaining certain product components. Disruption of the supply or inventory of components could result in a significant increase in the costs of these components or could result in an inability to meet the demand for our products. In addition, if a change in the manufacturer of a key component is required, qualification of a new supplier may result in delays and additional expenses in meeting customer demand for products. These factors could adversely affect our revenues and ability to retain our experienced sales force.

*Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported results of operations.*

We are required to prepare our financial statements in accordance with generally accepted accounting principles in the United States of America (“GAAP”), which is periodically revised and/or expanded. From time to time, we are required to adopt new or revised accounting standards issued by recognized authoritative bodies, including the FASB and the SEC. It is possible that future accounting standards we are required to adopt may require additional changes to the current accounting treatment that we apply to our financial statements and may require us to make significant changes to our reporting systems. Such changes could result in a material adverse impact on our business, results of operations and financial condition.

*Market acceptance of Sigyn Therapy and other product candidates will be vital to our future success.*

The commercial success of our products is dependent upon their acceptance by the intended markets. Our product candidates may not gain or maintain any significant degree of market acceptance among consumers, surgeons or healthcare providers, or acceptance by third-party payors, such as health insurance companies, Medicaid and Medicare. We cannot be certain that our products will be used by the medical community, even upon market approval of our product candidates.

Market acceptance will be dependent on numerous factors, many of which are not under our control, including:

- the safety and efficacy of our products and product candidates, as demonstrated in clinical trials and after commercialization;
- favorable regulatory approval and product labeling;
- the ease of use of our product and any related instrumentation that accompany our product;
- our ability to educate and train doctors on the advantages of our product;
- the price of any approved product relative to alternative technologies; and
- the availability of third-party reimbursement.

If our products and product candidates do not achieve significant market acceptance, our potential for revenues and profitability would be adversely affected.

***Our employees, independent contractors, principal investigators, consultants, vendors and clinical research organizations, or CROs, could engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions or other actions stemming from a failure to comply with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, we may have to terminate employees or others involved and the impact of such termination can result in our experiencing delays and additional costs associated with replacing the services being provided. If we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

***U.S. legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of future product candidates and to manufacture, market and distribute our products after approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

#### ***Information Technology Risks***

Our internal information technology (IT) systems could be compromised, damaged, breached or destroyed. IT risks include hardware and software failure, human error, spam, viruses, malicious attacks, industrial espionage, as well as natural disasters such as fires, earthquakes, hurricanes or floods. IT system failures may affect our ability to run our operations. Operational impact of IT failures or breaches may result in loss of productivity and a reduced ability to advance our clinical programs. Failures or breaches of our IT systems could also result in the loss or corruption of confidential data or in the theft of data or critical information.

Additionally, the increased sophistication and activities of perpetrators of cyber-attacks have resulted in an increase in information security risks in recent years. Hackers develop and deploy viruses, worms, and other malicious software programs that attack products and services and gain access to networks and data centers. If we experience difficulties maintaining existing systems or implementing new systems, we could incur significant losses due to disruptions in our operations. Additionally, these systems may contain valuable proprietary and confidential information and may contain personal data of employees, third-party vendors, and collaborators. A security breach could result in disruptions of our internal systems and business applications, harm to our competitive position from the compromise of confidential business information, or subject us to liability under laws that protect personal data. As cyber threats continue to evolve, we may be required to expend additional resources to continue to enhance our information security measures and/or to investigate and remediate any information security vulnerabilities. Any of these consequences could adversely affect business.

#### **Risk Factors Related to Our Common Stock**

***The price of our common stock may be volatile, and a shareholder's investment in our common stock could suffer a decline in value.***

There has been significant volatility in the volume and market price of our common stock, and such volatility may continue in the future. During the 12 months ended September 20, 2023, the market price of our common stock has ranged from a high of \$9.60 per share to a low of \$1.04 per share. Stockholders may not be able to resell their shares at or above the price they paid for them due to fluctuations in the market price of our stock caused by changes in our operating performance or prospects or other factors. In addition, factors such as quarterly variations in our operating results, actions by governmental agencies, national economic and stock market considerations as well as other events and circumstances beyond our control, including the effects of pandemic outbreaks, could have a significant impact on the future market price of our common stock and the relative volatility of such market price.

A prolonged decline in the price of our common stock could result in a reduction in the liquidity of our common stock and a reduction in our ability to raise capital. If we are unable to raise the funds required for all of our planned operations and key initiatives, we may be forced to allocate funds from other planned uses, which may negatively impact our business and operations, including our ability to develop new products and continue our current operations.

***Our common stock is currently traded on the OTCQB® Venture Market, which may have an unfavorable impact on our stock price and liquidity.***

While we plan to submit an application to list our common stock on the Nasdaq Capital Market, our stock currently trades on the OTCQB® Venture Market. The OTCQB® Venture Market is significantly more limited market than the national securities exchanges such as the New York Stock Exchange, or Nasdaq stock exchange, and there are lower financial or qualitative standards that a company must meet to have its stock traded on the OTCQB® Venture Market. OTCQB® Venture Market is an inter-dealer quotation system much less regulated than the major exchanges, and trading in our common stock may be subject to abuses, volatility and shorting, which may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. The Financial Industry Regulatory Authority (“FINRA”) has adopted rules that require a broker-dealer to have reasonable grounds for believing an investment is suitable for that customer when recommending an investment to a customer. FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for some customers and may make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may result in a limited ability to buy and sell our stock. Consummation of this offering is contingent upon our common stock being accepted for listing on Nasdaq.

***Our common shares are currently subject to the “Penny Stock” rules of the SEC, and the trading market in our securities will likely be limited, which makes transactions in our stock cumbersome and may reduce the value of an investment in our stock.***

The Securities and Exchange Commission has adopted Rule 15g-9 which establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- That a broker or dealer approve a person’s account for transactions in penny stocks; and
- The broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quality of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must:

- Obtain financial information and investment experience objectives of the person; and
- Make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- Sets forth the basis on which the broker or dealer made the suitability determination; and
- That the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commission’s payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

***We do not intend to pay any cash dividends on our shares of common stock in the near future, so our shareholders will not be able to receive a return on their shares unless they sell their shares.***

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. There is no assurance that future dividends will be paid, and if dividends are paid, there is no assurance with respect to the amount of any such dividend. Unless we pay dividends, our shareholders will not be able to receive a return on their shares unless they sell such shares.



***Raising additional capital may cause dilution to our existing stockholders and investors in this offering, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.***

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under other types of contracts, or upon the exercise or conversion of outstanding options, warrants, convertible debt or other similar securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, antidilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in terms of the payment of dividends or in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may need to curtail or cease our operations.

***There is no established trading market for the Series A Warrants being offered in this offering.***

There is no established trading market for the Series B Preferred Stock or Series A Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series B Preferred Stock or Series A Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Series B Preferred Stock or Warrants will be limited.

***Holders of Series B Preferred Stock will have limited voting rights.***

Except with respect to certain material changes in the terms of the Series B Preferred Stock and certain other matters and except as may be required by Delaware law, holders of Series B Preferred Stock will have no voting rights. Holders of Series B Preferred Stock will have no right to vote for any members of our board of directors.

***The Series A Warrants are speculative.***

The Series A Warrants offered in this offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the Series A Warrants may exercise their right to acquire the common stock and pay an exercise price of \$ \_\_\_ per share (110% of the public offering price of our Class A Units in this offering), prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the Series A Warrants is uncertain and there can be no assurance that the market value of the Series A Warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Series A Warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the Series A Warrants.

***The Series A Warrants may not have any value and if an active, liquid trading market for the Series A Warrants does not develop, you may not be able to sell your warrants quickly or at or above the price you paid for them.***

The Series A Warrants issued in this offering will be immediately exercisable and expire five years after their issuance. The Series A Warrants will have an initial exercise price equal to \$7.04. In the event that our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

Prior to this offering, there has been no public market for any of our warrants and we do not intend to list the Series A Warrants on the Nasdaq Capital Market or any other exchange. As a result, an active trading market may not develop for the Series A Warrants to be sold in this offering or, if developed, may not be sustained, and the market for the Series A Warrants may be volatile or may decline regardless of our operating performance. The lack of an active market may impair your ability to sell your Series A Warrants at the time you wish to sell them or at a price that you consider reasonable.

***The exercise price of the Series A Warrants offered by this prospectus will not be adjusted for certain dilutive events.***

The exercise price of the Series A Warrants offered by this prospectus is subject to adjustment for certain events, including, but not limited to, the payment of a stock dividend, stock splits, certain issuances of capital stock, options, convertible securities and other securities. However, the exercise prices will not be adjusted for dilutive issuances of securities and there may be transactions or occurrences that may adversely affect the market price of our common stock or the market value of such warrants without resulting in an adjustment of the exercise prices of such warrants.

***There is no assurance that we will fulfill or maintain the listing requirements of the NASDAQ.***

We are applying to list our common stock on the Nasdaq Capital Market, a national securities exchange. An approval of our listing application by NASDAQ will be subject to, among other things, our ability to fulfill all of the listing requirements of NASDAQ. There is no assurance that our securities will become NASDAQ listed and even if our shares become NASDAQ listed, there is no assurance that an active trading market for our securities will develop or be sustained. If our common stock is not accepted for listing on NASDAQ, we will not proceed with the consummation of this offering.

In addition, NASDAQ has rules for continued listing, including, without limitation, minimum market capitalization and other requirements. Failure to maintain our listing, or delisting from NASDAQ, would make it more difficult for shareholders to dispose of our securities and more difficult to obtain accurate price quotations on our securities. This could have an adverse effect on the price of our common shares. Our ability to issue additional securities for financing or other purposes, or otherwise to arrange for any financing we may need in the future, may also be materially and adversely affected if our common shares and/or other securities are not traded on a national securities exchange.

***If we are unable to meet the NASDAQ listing criteria, our common shares may continue to trade on the OTCQB® Venture Market.***

We are applying for our common stock to be listed on NASDAQ, a national securities exchange. The NASDAQ requires companies desiring to list their common stock to meet certain listing criteria including total number of shareholders: minimum stock price (which will necessitate that we effect a reverse split of our issued and outstanding common stock before listing), total value of public float, and in some cases total shareholders' equity and market capitalization. Our failure to meet such applicable listing criteria could prevent us from listing our common stock on NASDAQ, and if we do not list on NASDAQ, we will not proceed with this offering. In the event we are unable to have our shares traded on NASDAQ, our common stock may continue to trade on the OTC Pink Sheets, which is less liquid and more volatile than the NASDAQ. Our failure to have our shares traded on NASDAQ could make it more difficult for you to trade our shares, could prevent our common stock trading on a frequent and liquid basis and could result in the value of our common stock being less than it would be if we were able to list our shares on NASDAQ.

***Our Amended and Restated Certificate of Incorporation provides that the Court of Chancery in the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our Amended and Restated Certificate of Incorporation, or our Certificate of Incorporation, provides that, unless our Board of Directors consents to an alternative forum, the Court of Chancery in the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought by or on our behalf; (ii) any direct action asserting a claim against us or any of our directors or officers pursuant to any of the provisions of the General Corporation Law of the State of Delaware, or our Certificate of Incorporation; (iii) any action asserting a claim of breach of fiduciary duties owed by any of our directors, officers or other employees to our stockholders; or (iv) any action asserting a violation of Delaware decisional law relating to our internal affairs. This provision does not apply to (a) actions in which the Court of Chancery in the State of Delaware concludes that an indispensable party is not subject to the jurisdiction of Delaware courts, or (b) actions in which a federal court has assumed exclusive jurisdiction to a proceeding. This choice of forum provision is not intended to apply to any actions brought under the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act. However, our Certificate of Incorporation does not relieve us of our duties to comply with federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Our Certificate of Incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to this choice of forum provision.

This choice of forum provision may impose additional litigation costs on stockholders in pursuing such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, this choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes, which may discourage the filing of such lawsuits.

***We will have broad discretion in the use of the net proceeds to us from this offering and may not use them effectively.***

We will have broad discretion in the application of the net proceeds to us from this offering, including for any of the purposes described in the section titled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, our ultimate use may vary substantially from our currently intended use. Investors will need to rely upon the judgment of our management with respect to the use of proceeds. Pending use, we may invest the net proceeds from this offering in investment-grade, interest-bearing securities, such as money market accounts, certificates of deposit, commercial paper and guaranteed obligations of the U.S. government that may not generate a high yield for our stockholders. If we do not use the net proceeds that we receive in this offering effectively, our business, financial condition, results of operations and prospects could be harmed, and the market price of our common stock could decline.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim”, “anticipate”, “assume”, “believe”, “contemplate”, “continue”, “could”, “due”, “estimate”, “expect”, “goal”, “intend”, “may”, “objective”, “plan”, “predict”, “potential”, “positioned”, “pioneer”, “seek”, “should”, “target”, “will”, “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our use of net proceeds from this offering;
- the continued development and growth of the demand and markets for our products;
- our ability to raise future capital through debt or equity financing transactions;
- our ability to attract and retain key employees;
- our ability to manage growth in our business; and
- our ability to identify and successfully execute strategic partnerships.

Although we base the forward-looking statements contained in this prospectus on assumptions that we believe are reasonable, we caution you that actual results and developments (including our results of operations, financial condition and liquidity, and the development of the industry in which we operate) may differ materially from those made in or suggested by the forward-looking statements contained in this prospectus. In addition, even if results and developments are consistent with the forward-looking statements contained in this prospectus, those results and developments may not be indicative of results or developments in subsequent periods. Certain assumptions made in preparing the forward-looking statements contained in this prospectus include:

- our ability to implement our business strategies;
- our ability to complete the development of products on time and on budget;
- our competitive advantages;
- our ability to obtain and maintain financing on acceptable terms;
- the impact of competition;
- the changes and trends in the life sciences industry;
- changes in laws, rules and regulations;
- our ability to maintain good business relationships with our exclusive independent operators and strategic partners;
- our ability to keep pace with changing consumer preferences;
- our ability to protect our intellectual property;
- our ability to identify, manage and integrate acquisitions;
- our ability to retain key personnel; and
- the absence of material adverse changes in our industry or the global economy, including as a result of the COVID-19 pandemic.

These forward-looking statements are based on our current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions, and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements. These forward-looking statements speak only as of the date of this prospectus. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC, after the date of this prospectus. See "Where You Can Find More Information".

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our products. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors". These and other factors could cause our future performance to differ materially from our assumptions and estimates.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of 1,406,250 Class A Units will be approximately \$8.1 million, or approximately \$9.4 million if the underwriter exercises in full its option to purchase additional shares of our common stock and/or Series A Warrants, based on an assumed public offering price of \$6.40 per Class A Unit, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed public offering price of \$6.40 per Class A Units would increase (decrease) the net proceeds to us from this offering by approximately \$1.3 million, or approximately \$1.5 million if the underwriter exercises its over-allotment option in full, assuming the number of Class A Units offered by us, as set forth on the cover page of this prospectus, remain the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The expected use of net proceeds of this offering represents our current intentions based upon our present plan and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors. As a result, management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. We have presumed that we will receive aggregate gross proceeds of \$9 million and deducted \$870,000 payable in offering costs, commissions and fees.

We intend to use the net proceeds from this offering as follows:

- Approximately 34% to fund research and the continued development of Sigyn Therapy; and
- The remainder of the net proceeds, approximately 66%, will be used for working capital and other general corporate purposes, including the additional costs with being a public company.

Based on our current business plans, we believe that the net proceeds of this offering, together with our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for approximately the next two years from the date of this prospectus.

We believe the net proceeds will enable us to complete the first-in-human feasibility study of Sigyn Therapy in End-Stage Renal Disease patients suffering from excel inflammation and/or endotoxemia in addition to pursuing additional product advancements. In addition, we will begin development and testing of ChemoPrep™ and ChemoPure™ with a primary objective to enhance tumor site delivery of chemotherapy and reduce its toxicity and secondary objective to reduce treatment dosing without sacrificing patient benefit. The company does not intend to discharge any indebtedness with the proceeds of the transaction.

This expected use of proceeds from this offering represents our intentions based upon current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above.

The amount and timing of our actual expenditures will depend on numerous factors, including the results of our research and development, the anticipated growth out our business and any unforeseen cash needs. As a result, our management will have broad discretion over the use of proceeds from this offering.

The use of the proceeds represents management's estimates based upon current business and economic conditions. We reserve the right to use of the net proceeds we receive in the offering in any manner we consider to be appropriate. Although our Company does not contemplate changes in the proposed use of proceeds, to the extent we find that adjustment is required for other uses by reason of existing business conditions, the use of proceeds may be adjusted. The actual use of the proceeds of this offering could differ materially from those outlined above as a result of several factors including those set forth under "Risk Factors" and elsewhere in this prospectus.

## **DETERMINATION OF OFFERING PRICE**

The offering price of the Class A Units will be negotiated between the underwriters and us considering our historical performance and capital structure, prevailing market conditions, and overall assessment of our business. Our common stock currently trades on the OTCQB® Venture Market under the symbol "SIGY." On September 20, 2023 the last reported sale price of our common stock on the OTCQB® Venture Market was \$6.40 per share.

## **MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS**

Our common stock currently trades on the OTCQB® Venture Market.

As of September 20, 2023, we had approximately 306 shareholders of record of our shares of common stock.

We intend to apply to list our common stock on the Nasdaq Capital Market under the symbol "SIGY." No assurance can be given that such application will be approved or that a trading market will develop. If, for whatever reason, Nasdaq does not confirm the listing of our common stock on Nasdaq prior to the pricing of the offering, we will not be able to consummate and will terminate this offering.

## **DIVIDEND POLICY**

We have never paid any cash dividends on our common shares. We anticipate that we will retain funds and future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future following this offering. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors that our Board of Directors deems relevant. In addition, the terms of any future debt or credit financings may preclude us from paying dividends.

## CAPITALIZATION

The following table sets forth our capitalization and cash as of June 30, 2023:

- on an actual basis;
- on a pro forma basis to reflect the conversion of convertible notes which will be effective on the closing of the offering; and
- on a pro forma as adjusted basis to reflect the sale by us of 1,406,250 Class A Units at the assumed public offering price of \$6.40 per Class A Unit, after deducting the underwriting discounts and commissions and estimated offering costs payable by us; and

The pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

You should read this table together with the section in this prospectus entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this prospectus. Numbers are expressed in thousands (U.S. dollars) except share and per share data.

<b>Capitalization in U.S. Dollars in thousands (except share data)</b>	<b>As of June 30, 2023</b>		
	<b>Actual</b>	<b>Pro Forma Adjustments</b>	<b>Proforma, As Adjusted</b>
Cash	\$ 24	\$ 8,130	\$ 8,154
Notes payable	2,630	(2,630)	-
Common stock, \$0.0001 par value per share, 1,000,000,000 shares authorized; 44,231,402 shares issued and outstanding; 53,694,135 shares issued and outstanding pro forma as adjusted	\$ 4	\$ 1	\$ 5
Additional paid in capital	6,213	12,499	18,712
Accumulated deficit	(9,260)	-	(9,260)
Accumulated other comprehensive income	-	-	-
<b>Total stockholders’ equity</b>	<b>(3,042)</b>	<b>12,500</b>	<b>9,458</b>
<b>Total Capitalization</b>	<b>\$ (412)</b>	<b>\$ 9,870</b>	<b>\$ 9,458</b>

The number of common shares that will be outstanding after this offering set forth above is based on 44,231,402 common shares outstanding as of June 30, 2023.

Unless specifically stated otherwise, all information in this prospectus assumes:

- assumes no exercise by the underwriters of their option to purchase up to additional shares of our common stock and/or Series A Warrants from us to cover over-allotments, if any;
- assumes no exercise of the representative’s warrants or Series A Warrants to be issued upon consummation of this offering at an exercise price equal to 110% of the initial offering price of the common stock;
- assumes no exercise of outstanding warrants to purchase shares of our common stock or exercise or conversion of any outstanding shares of preferred stock or convertible notes; and
- excludes shares of common stock to be reserved for future issuance under our equity incentive plan, which will be effective upon the completion of this offering.

- (1) A \$1.00 increase or decrease in the assumed public offering price per Class A Units would increase or decrease our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total shareholders’ equity and total capitalization by approximately \$1.3 million assuming the number of Class A Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us.

## DILUTION

If you invest in our shares in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per common share of in this offering and the as adjusted net tangible book value per share immediately after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities less debt discounts, by the number of our outstanding common shares as of June 30, 2023. Our historical net tangible book value (deficit) as of June 30, 2023, was approximately \$3 million or \$(0.069) per common share.

After giving effect to the sale of 1,406,250 Class A Units at an assumed shares at \$6.40 per share, after deducting the underwriting discounts and commissions and estimated offering costs payable by us, our as adjusted net tangible book value (deficit) as of June 30, 2023, would have been approximately \$9.5 million, or \$0.11 per common share. This represents an immediate increase in as adjusted net tangible book value of \$0.18 per share to existing shareholders and an immediate dilution of \$6.29 per share to investors purchasing our common shares in this offering at the assumed public offering price.

The following table illustrates per share dilution as of June 30, 2023:

	<b>If 100% of shares are sold</b>	<b>If 75% of shares are sold</b>	<b>If 50% of shares are sold</b>	<b>If 25% of shares are sold</b>
Assumed public offering price per common share	\$ 6.40	6.40	6.40	6.40
Net tangible book value (deficit) per share as of June 30, 2023	(0.069)	(0.069)	(0.069)	(0.069)
Increase in net tangible book value (deficit) per share attributable to this offering	\$ 0.180	0.135	0.090	0.044
Net tangible book value (deficit) per share after this offering	\$ 0.111	0.067	0.021	(0.025)
Dilution per share to investors participating in this offering	\$ 6.289	6.333	6.379	6.425

Each \$1.00 increase (decrease) in the assumed public offering price per Class A Unit would increase (decrease) our as adjusted net tangible book value (deficit) after this offering by approximately \$1.3 million, or approximately \$0.3 per share, and the dilution per share to new investors by approximately \$7.26 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remain the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of Class A Units we are offering. An increase of 500,000 Class A Units in the number of Class A Units offered by us would increase our as adjusted net tangible book value (deficit) after this offering by approximately \$0.180, or \$0.25 per common share, and decrease the dilution per share to new investors by \$6.22 per common share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a decrease of 500,000 Class A Units offered by us would decrease our as adjusted net tangible book value (deficit) after this offering by approximately \$1.3 million, or \$0.3 per common share, and increase the dilution per share to new investors by \$6.36 per common share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing. This table does not take into account further dilution to new investors that could occur upon the exercise of outstanding options and warrants having a per share exercise price less than the public offering price per share in this offering.

If the underwriters exercise in full their option to purchase up to 225,000 additional shares of common stock and Series A Warrants at the assumed initial public offering price of \$6.40 per share, the as adjusted net tangible book value (deficit) after this offering would be \$0.14 per share, representing an increase in net tangible book value (deficit) of \$0.21 per share to existing shareholders and immediate dilution in net tangible book value (deficit) of \$6.26 per share to investors purchasing our common shares in this offering at the assumed public offering price.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FISCAL CONDITION AND RESULTS OF OPERATION

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this filing. This discussion and other parts of this filing contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, intentions, and beliefs. Our actual results may differ materially from those discussed in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and in other parts of this filing, and you should not place undue certain on these forward-looking statements, which apply only as of the date of this filing. See "Disclosure Regarding Forward-Looking Statements".*

### OVERVIEW:

#### Historical Development

#### Our Company

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. Our corporate address is 2468 Historic Decatur Road, Suite 140, San Diego, California 92106.

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 United States Patent and Trademark Office ("USPTO"). The provisional patent submission established the priority date of our now patent pending invention and provides us up to one year to submit a non-provisional patent application. On October 13, 2022, we subsequently disclosed that trademark applications to register ChemoPrep™ and ChemoPure™ were 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 United States Patent and Trademark Office ("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. 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.

## **Financing Transactions**

### *Preferred Stock*

The Company has 10,000,000 shares of par value \$0.0001 preferred stock authorized, of which 1,215 and no preferred shares were issued and outstanding at June 30, 2023 and December 31, 2022, respectively.

### *Common Stock*

The Company has authorized 1,000,000,000 shares of par value \$0.0001 common stock, of which 44,231,402 and 38,263,813 shares were issued and outstanding as of June 30, 2023 and December 31, 2022, respectively.

On November 23, 2022, an investor elected to convert the aggregate principal amount of the Note, \$145,200, into 968,000 common shares.

On October 28, 2021, an investor elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares.

On October 25, 2021, an investor elected to convert the aggregate principal amount of the Note, \$110,000, into 157,143 common shares.

On October 20, 2021, the Company entered into a securities purchase agreement with an accredited investor that resulted in the issuance of 320,000 shares of common stock and warrants to purchase an aggregate of 320,000 shares of the Company's common stock for total proceeds totaling \$400,000. The offering allowed for qualified investors to purchase one share of the Company's common stock at \$1.25. For each share purchased, the investor received a five-year warrant to purchase one share of common stock at \$1.25 per share. No commissions were paid in the offering. This issuance was pursuant to Section 4(a)(2) of the Securities Act in a transaction exempt from registration.

On October 14, 2021, the Company issued a total of 47,000 shares of its common stock valued at \$37,600 (based on the stock price of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry.

On July 14, 2021, the Company issued a total of 47,000 shares of its common stock valued at \$47,000 (based on the stock price of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry.

On May 10, 2021, Brio Capital elected to convert the aggregate principal amount of a \$110,000 convertible note issued on February 10, 2021 into 157,143 shares of the Company's common stock.

In April 2021, the Company initiated an offering of up to \$1.5 million of the Company's restricted common shares. The offering allowed for qualified investors to purchase one share of the Company's common stock \$1.25. For each share purchased, the investor received a five-year warrant to purchase one share of common stock at \$1.75 per share. On May 10, 2021, the Company closed the offering to investors and subsequently disclosed that it had entered into securities purchase agreements with accredited investors that resulted in the issuance of 1,172,000 shares of common stock and warrants to purchase an aggregate of 1,172,000 shares of the Company's common stock for total proceeds totaling \$1,465,000. No commissions were paid in the offering. This issuance was pursuant to Section 4(a)(2) of the Securities Act in a transaction exempt from registration.

On April 14, 2021, the Company issued a total of 47,000 shares of its restricted common stock valued at \$82,250 (based on the stock price of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry. This issuance was pursuant to Section 4(a)(2) of the Securities Act in a transaction exempt from registration.

On February 19, 2021, a previous noteholder exercised the warrants pursuant to the cashless exercise provision of the warrant agreement into 57,147 common shares. The common shares have not been issued as of March 14, 2022.

On January 14, 2021, the Company issued a total of 47,000 shares of its restricted common stock valued at \$82,250 (based on the stock price of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry. This issuance was pursuant to Section 4(a)(2) of the Securities Act in a transaction exempt from registration.

### *Warrants*

On October 22, 2021, the Company and Osher amended convertible debt agreements for the maturity date from October 20, 2021 to October 20, 2022. In exchange for the extension of the Note, the Company issued Osher 450,000 warrants to purchase an aggregate of 450,000 shares of the Company's common stock, valued at \$197,501 (based on the Black Scholes valuation model on the date of grant) (see Note 6). The warrants are exercisable for a period of five years at \$1.00 per share in whole or in part, as either a cash exercise or as a cashless exercise, and fully vest at grant date. The Company accreted the value of the warrants ratably through October 20, 2022. The Company recorded \$147,720 and \$40,041 for the years ended December 31, 2022 and 2021, respectively, and is classified in other expenses in the consolidated Statements of Operations.

In March 2023, the Company offered a short-term inducement to the Company's warrant holders in which the Company will issue one share of the Company's common stock in exchange for each two warrants returned to the Company to be cancelled. All other terms of the original grants remain the same. A total of 8,899,019 warrants were exchanged for 4,449,512 shares of the Company's common stock through March 24, 2023.

*Current Noteholders [To be revised based on potential conversions]*

#### **2023 Convertible Notes**

During the six months ended June 30, 2023, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "2023 Notes") with a third party investors totaling (i) \$970,200 aggregate principal amount of Note due on various dates from January 2024 through March 27, 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 6,468,000 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$882,000 which was issued at a \$88,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On June 2, 2023, a third party investor elected to convert \$181,500 of principal of the Note into 1,210,000 common shares.

#### **Osher – \$110,000**

On December 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") with respect to the sale and issuance to institutional investor Osher Capital Partners LLC ("Osher") of (i) \$110,000 aggregate principal amount of Note due December 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 733,333 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **Osher – \$55,000**

On November 14, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") with respect to the sale and issuance to institutional investor Osher Capital Partners LLC ("Osher") of (i) \$55,000 aggregate principal amount of Note due November 14, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 366,667 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **Brio – \$82,500**

On November 9, 2022, 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) \$82,500 aggregate principal amount of Note due November 9, 2023 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 550,000 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000**

On October 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due October 20, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000**

On September 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due September 20, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$82,500**

On September 9, 2022, 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) \$82,500 aggregate principal amount of Note due September 9, 2023 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 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000**

On August 31, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due August 31, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Other – \$341,000**

In July 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “July 2022 Notes”) totaling (i) \$341,000 aggregate principal amount of Note (total of \$310,000 cash was received) due in various dates in July 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 676,936 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

**Osher – \$82,500**

On June 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$82,500 aggregate principal amount of Note due June 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 165,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$55,000**

On June 1, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due June 1, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 110,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$110,000**

On May 10, 2022, 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) \$110,000 aggregate principal amount of Note due May 10, 2023 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 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000**

On April 28, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due April 28, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

### **Osher – \$110,000**

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

### **Brio – \$110,000**

On March 23, 2022, 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) \$110,000 aggregate principal amount of Note due March 23, 2023 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 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

### **Osher – \$199,650**

On September 17, 2020 (the “Original Issue Date”), 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) \$181,500 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due September 30, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 8,250 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$165,000 which was issued at a \$16,500 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated September 17, 2020, for the number of warrant shares from 8,250 warrant shares to 465,366 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from September 30, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share.

On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares.

**Osher – \$60,500 (as amended on October 20, 2020 to \$55,000)**

On June 23, 2020 (the “Original Issue Date”), 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) \$50,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due June 23, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 10,000 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at a \$0 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Note for the aggregate principal amount from \$50,000 to \$55,000. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at an amended \$4,995 original issue discount from the face value of the Note.
- The parties amended the Warrants dated June 23, 2020, for the number of warrant shares from 10,000 warrant shares to 141,020 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows (see Note 12):

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share.

**Osher – \$457,380**

On January 28, 2020 (the “Original Issue Date”), the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$385,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due January 26, 2021, 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 80,209 shares of the Company’s Common Stock at an exercise price of \$7.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was \$350,005 which was issued at a \$34,995 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.094 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated January 28, 2020, for the number of warrant shares from 80,209 warrant shares to 4,113,083 warrant shares at an exercise price of \$0.14 per share.
- The parties amended the Note to provide for interest at 8% per annum.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

#### **Previous Noteholders**

##### **Other – \$145,200**

On November 21, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") with a third party investor of (i) \$145,200 aggregate principal amount of Note due November 21, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 968,000 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$132,000 which was issued at a \$13,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On November 23, 2022, third party investor elected to convert the aggregate principal amount of the Note, \$145,200, into 968,000 common shares.

All other previous notes were detailed in our Form 10-K filed on March 31, 2022. No changes occurred related to these notes during the period covered by this Form 10-Q.

##### *Impairment of Inventory*

Based on the significant advancement of Sigyn Therapy, the Company decided in the 4<sup>th</sup> quarter of 2021 to assess the value of retail business operations that were a focus of the Company prior to the merger transaction consummated on October 19, 2020.

Related to this assessment, management determined the wholesale liquidation value of its sapphire gem inventory to be 5-10% of the previously reported retail value, based on communications with certified gemologists, the variance between retail and wholesale valuations, and current market conditions. As a result, the Company has valued the inventory at \$50,000 and recorded an impairment of assets of \$536,047 in the year ended December 31, 2021 and is classified in other expenses in the consolidated Statements of Operations.



### **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.

### **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.

### **Reclassifications**

An adjustment has been made to the Consolidated Balance Sheets as of December 31, 2021, to reclass \$1,072 of other current liabilities previously classified in accrued payroll and payroll taxes. These reclassifications had no effect on the reported results of operations.

### **Results of Operations**

#### ***Year Ended December 31, 2022 Compared to Year Ended December 31, 2021***

The following discussion represents a comparison of our results of operations for the years ended December 31, 2022 and 2021. The results of operations for the periods shown in our audited consolidated financial statements are not necessarily indicative of operating results for the entire period. In the opinion of management, the audited 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.

	Year Ended December 31, 2022	Year Ended December 31, 2021
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	2,147,265	2,008,217
Other expense	782,552	996,402
Net loss before income taxes	<u>\$ (2,929,817)</u>	<u>\$ (3,004,619)</u>

#### *Net Revenues*

For the years ended December 31, 2022 and 2021, we had no revenues.

#### *Cost of Sales*

For the years ended December 31, 2022 and 2021, we had no cost of sales.

#### *Operating expenses*

Operating expenses increased by \$139,048, or 6.9%, to \$2,147,265 for the year ended December 31, 2022 from \$2,008,217 for the year ended December 31, 2021 primarily due to increases in professional fees of \$86,093, compensation costs of \$237,983, depreciation costs of \$3,908, insurance costs of \$212,284, rent expenses of \$30,105, and general and administration costs of \$12,804, offset partially by consulting costs of \$79,369, research and development costs of \$76,357, investor relations costs of \$275,798, and amortization costs of \$12,605, as a result of adding administrative infrastructure for our anticipated business development. In 2022, the Company incurred an increase in professional fees (primarily legal and audit fees), incurred a full year of compensation for its CEO and CTO and hired a CFO resulting in increased compensation costs, increased consulting costs (primarily for public relations and brand awareness), has decreased investor relations costs (primarily the fair value of common stock issued for services of \$249,100 in 2021), and incurred a full year of rent from the lease of office space in June 2021. Research and development costs consist of a decrease of \$76,357 attributed to third parties for developmental services of \$100,211 offset partially by an increase in testing in house efforts of \$23,854.

For the year ended December 31, 2022, we had marketing expenses of \$457, research and development costs of \$657,657, and general and administrative expenses of \$1,489,151 primarily due to professional fees of \$209,386, compensation costs of \$689,717, consulting costs of \$206,825, insurance costs of \$215,704, rent of \$76,768, depreciation costs of \$6,854, amortization costs of \$3,600, investor relations costs of \$53,208, and general and administration costs of \$27,546, as a result of adding administrative infrastructure for our anticipated business development. In 2022, the Company has incurred professional fees (primarily legal and audit fees), incurred compensation for its CEO and CTO and hired a CFO, incurred consulting costs (primarily for public relations and brand awareness), had investor relations costs, and had rent through the lease of office space. Research and development costs consist of \$579,977 attributed to in house efforts and \$77,680 to third parties for developmental services and testing.

For the year ended December 31, 2021, we had research and development costs of \$734,014, and general and administrative expenses of \$1,274,203 primarily due to professional fees of \$123,293, compensation costs of \$451,734, consulting costs of \$286,194, rent of \$46,663, depreciation and amortization costs of \$19,151, investor relations costs of \$329,006, and general and administration costs of \$18,162, as a result of adding administrative infrastructure for our anticipated business development. In 2021, the Company has incurred professional fees (primarily legal and audit fees, and consulting costs), had investor relations costs (primarily the fair value of common stock issued for services of \$249,100), and incurred compensation for its CEO and CTO. Research and development costs consist of \$556,123 attributed to in house efforts and \$177,891 to third parties for developmental services and testing.

### Other Expense

Other expense for the year ended December 31, 2022 totaled \$782,552 primarily due interest expense of \$782,114 in conjunction with accretion of debt discount and original issuance discount, and interest expense of \$438, compared to other expense of \$996,402 primarily due to impairment of assets of \$536,047, interest expense of \$429,488 in conjunction with accretion of debt discount and original issuance discount, and interest expense of \$30,867 for the year ended December 31, 2021.

### Net loss before income taxes

Net loss before income taxes for the year ended December 31, 2022 totaled \$2,929,817 primarily due to (increases/decreases) in compensation costs, professional fees, consulting costs, research and development costs, investor relations costs, insurance costs, and general and administration costs compared to a loss of \$3,004,619 primarily due to (increases/decreases) in compensation costs, professional fees, consulting costs, research and development costs, investor relations costs, and general and administration cost for the year ended December 31, 2021 primarily due to professional fees.

### Assets and Liabilities

Assets were \$332,879 as of December 31, 2022. Assets consisted primarily of cash of \$8,356, inventories of \$50,000, other current assets of \$11,942, equipment of \$22,052, intangible assets of \$2,100, and operating lease right-of-use assets of \$217,718, and other assets of \$20,711. Liabilities were \$2,236,119 as of December 31, 2022. Liabilities consisted primarily of accounts payable of \$327,517, accrued payroll and payroll taxes of \$30,124, convertible notes of \$1,636,656, net of \$642,660 of unamortized debt discount, operating lease liabilities of \$240,625, and other current liabilities of \$1,197.

### Six Months Ended June 30, 2023 Compared to Six Months Ended June 30, 2022

The following discussion represents a comparison of our results of operations for the three months ended June 30, 2023 and 2022. 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,	
	2023	2022
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	1,095,267	1,142,031
Other expense	968,893	202,340
Net loss before income taxes and discontinued operations	\$ (2,064,160)	\$ (1,344,371)

### Net Revenues

For the six months ended June 30, 2023 and 2022, we had no revenues.

### Cost of Sales

For the six months ended June 30, 2023 and 2022, we had no cost of sales as we had no revenues.

### Operating expenses

Operating expenses decreased by \$46,980, or 4.1%, to \$1,095,267 for six months ended June 30, 2023 from \$1,142,031 for the six months ended June 30, 2022 primarily due to decreases in research and development costs of \$16,023, investor relations costs of \$15,946, consulting fees of \$7,133, insurance costs of \$10,816, marketing costs of \$97, compensation costs of \$44,700, professional fees of \$25,433, and general and administration costs of \$3,660, offset primarily by increases in depreciation costs of \$7, rent expenses of \$2,037, stock based compensation of \$75,000, 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.

For the six months ended June 30, 2022, we had marketing expenses of \$381, research and development costs of \$383,025, and general and administrative expenses of \$758,625 primarily due to professional fees of \$131,441, compensation costs of \$340,327, rent of \$36,591, depreciation costs of \$3,423, amortization costs of \$1,800, investor relations costs of \$23,991, consulting fees of \$103,125, and general and administration costs of \$117,927, as a result of adding administrative infrastructure for our anticipated business development. In 2022, the Company has incurred professional fees (primarily legal and audit fees), incurred compensation for its CEO and CTO and hired a Director of Operations, incurred consulting costs (primarily for public relations and brand awareness), had investor relations costs (primarily the fair value of common stock issued for services), and had rent through the lease of office space. Research and development costs consist of \$567,748 attributed to in house efforts and \$166,266 to third parties for developmental services and testing.

#### *Other Expense*

Other expense for the six months ended June 30, 2023 totaled \$968,893 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, compared to other expense of \$202,340 for the three months ended June 30, 2022 primarily due to interest expense of \$160,854 in conjunction with accretion of debt discount and interest expense of \$41,455 in conjunction with accretion of original issuance discount.

#### *Net loss before income taxes*

Net loss before income taxes and discontinued operations for the three months ended June 30, 2023 totaled \$2,064,160 primarily due to (increases/decreases) in compensation costs, professional fees, marketing costs, investor relations costs, consulting fees, research and development costs, rent, insurance, stock based compensation, and general and administration costs compared to a loss of \$1,344,371 for the three months ended June 30, 2022 primarily due to (increases/decreases) in compensation costs, professional fees, marketing costs, investor relations costs, consulting fees, research and development costs, rent, insurance, stock based compensation, and general and administration costs.

### **Liquidity and Capital Resources**

#### **Going Concern**

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company had an accumulated deficit of \$7,195,576 at December 31, 2022, had a working capital deficit of approximately \$1,978,396 at December 31, 2022, had net losses of \$2,929,817 and \$3,004,619 for the years ended December 31, 2022 and 2021, respectively, and net cash used in operating activities of \$1,830,242 and \$1,774,182 for the years ended December 31, 2022 and 2021, 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 consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

#### ***Year Ended December 31, 2022 Compared to Year Ended December 31, 2021***

**General** – Overall, we had a decrease in cash flows for the year ended December 31, 2022 of \$332,600 resulting from cash used in operating activities of \$1,830,242 and cash used in investing activities of \$860, offset partially by cash provided by financing activities of \$1,498,502.

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

	Year Ended December 31, 2022	Year Ended December 31, 2021
Net cash provided by (used in):		
Operating activities	\$ (1,830,242)	\$ (1,774,182)
Investing activities	(860)	(29,264)
Financing activities	1,498,502	2,060,000
	<u>\$ (332,600)</u>	<u>\$ 256,554</u>

**Cash Flows from Operating Activities** – For the year ended December 31, 2022, net cash used in operations was \$1,830,242 compared to net cash used in operations of \$1,774,182 for the year ended December 31, 2021. Net cash used in operations was primarily due to a net loss of \$2,929,817 for year ended December 31, 2022 and the changes in operating assets and liabilities of \$307,007, primarily due to the increases in other current assets of \$9,867, accounts payable of \$287,843, and accrued payroll and payroll taxes of \$29,052, offset primarily by decreases in other current liabilities of \$21. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of \$6,854, amortization expense of \$3,600, accretion of original issuance costs of \$135,812, and the accretion of debt discount of \$646,302.

Net cash used in operations was primarily due to a net loss of \$3,004,619 for year ended December 31, 2021 and the changes in operating assets and liabilities of \$34,149, primarily due to the increases in other current assets of \$2,075 and other assets of \$20,711, and a decrease in accrued payroll and payroll taxes of \$58,635, offset primarily by increases in accounts payable of \$23,669 and other current liabilities of \$23,603. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of \$2,946, amortization expense of \$16,205, accretion of original issuance costs of \$61,283, accretion of debt discount of \$368,205, stock issued for services of \$249,100, interest expense converted to notes payable of \$30,800, and impairment of assets of \$536,047.

**Cash Flows from Investing Activities** – For the year ended December 31, 2022, net cash used in investing was \$860 due to the purchase of property and equipment compared to cash flows from investing activities of \$29,264 due to the purchase of property and equipment for the year ended December 31, 2021.

**Cash Flows from Financing Activities** – For the year ended December 31, 2022, net cash provided by financing was \$1,498,502 due to proceeds from short term convertible notes of \$1,567,000 net of fees associated with the filing of the Company's Form S-1 of \$68,498. For the year ended December 31, 2021, net cash provided by financing was \$2,060,000 due to proceeds from short term convertible notes of \$250,000, repayments of short-term convertible notes of \$55,000, and common stock and warrants issued for cash of \$1,865,000.

**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. However, this belief is based upon many assumptions and is subject to numerous risks, and there can be no assurance that we will not require additional funding in the future.

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 shareholders, in the case of equity financing.

### *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 \$453,067 and \$496,125 (including \$18,542 of 2020 payroll paid in 2021), and employee benefits of \$48,811 and \$31,126, for the years ended December 31, 2022 and 2021, respectively.

Sigyn had no employment agreement with its CTO but still incurred compensation on behalf of the CTO. The Company incurred compensation expense of \$233,678 and \$259,000, and employee benefits of \$25,312 and \$21,704, for the years ended December 31, 2022 and 2021, respectively.

### *Bonus*

On July 21, 2021, as a result of achieving certain milestones, the Board of Directors agreed to pay each of the Company's CEO and CTO a performance bonus equal to 5% of their annual salary totaling \$34,750.

### **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 consolidated financial statements for critical accounting policies.

### **Recent Accounting Pronouncements**

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

### **Future Contractual Obligations and Commitments**

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

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

### **Off-Balance Sheet Arrangements**

As of December 31, 2022, 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.

*Six Months Ended June 30, 2023 Compared to Six Months Ended June 30, 2022*

The following discussion represents a comparison of our results of operations for the three months ended June 30, 2023 and 2022. 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,	
	2023	2022
Net revenues	\$ -	\$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	1,095,267	1,142,031
Other expense	968,893	202,340
Net loss before income taxes and discontinued operations	\$ (2,064,160)	\$ (1,344,371)

*Net Revenues*

For the six months ended June 30, 2023 and 2022, we had no revenues.

*Cost of Sales*

For the six months ended June 30, 2023 and 2022, we had no cost of sales as we had no revenues.

### *Operating expenses*

Operating expenses decreased by \$46,980, or 4.1%, to \$1,095,267 for six months ended June 30, 2023 from \$1,142,031 for the six months ended June 30, 2022 primarily due to decreases in research and development costs of \$16,023, investor relations costs of \$15,946, consulting fees of \$7,133, insurance costs of \$10,816, marketing costs of \$97, compensation costs of \$44,700, professional fees of \$25,433, and general and administration costs of \$3,660, offset primarily by increases in depreciation costs of \$7, rent expenses of \$2,037, stock based compensation of \$75,000, 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.

For the six months ended June 30, 2022, we had marketing expenses of \$381, research and development costs of \$383,025, and general and administrative expenses of \$758,625 primarily due to professional fees of \$131,441, compensation costs of \$340,327, rent of \$36,591, depreciation costs of \$3,423, amortization costs of \$1,800, investor relations costs of \$23,991, consulting fees of \$103,125, and general and administration costs of \$117,927, as a result of adding administrative infrastructure for our anticipated business development. In 2022, the Company has incurred professional fees (primarily legal and audit fees), incurred compensation for its CEO and CTO and hired a Director of Operations, incurred consulting costs (primarily for public relations and brand awareness), had investor relations costs (primarily the fair value of common stock issued for services), and had rent through the lease of office space. Research and development costs consist of \$567,748 attributed to in house efforts and \$166,266 to third parties for developmental services and testing.

### *Other Expense*

Other expense for the six months ended June 30, 2023 totaled \$968,893 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, compared to other expense of \$202,340 for the three months ended June 30, 2022 primarily due to interest expense of \$160,854 in conjunction with accretion of debt discount and interest expense of \$41,455 in conjunction with accretion of original issuance discount.

### *Net loss before income taxes*

Net loss before income taxes and discontinued operations for the three months ended June 30, 2023 totaled \$2,064,160 primarily due to (increases/decreases) in compensation costs, professional fees, marketing costs, investor relations costs, consulting fees, research and development costs, rent, insurance, stock based compensation, and general and administration costs compared to a loss of \$1,344,371 for the three months ended June 30, 2022 primarily due to (increases/decreases) in compensation costs, professional fees, marketing costs, investor relations costs, consulting fees, research and development costs, rent, insurance, stock based compensation, and general and administration costs.

### **Inflation**

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



## DESCRIPTION OF BUSINESS

### 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 United States Patent and Trademark Office (“USPTO”). The provisional patent submission established the priority date of our now patent pending invention and provides us up to one year to submit a non-provisional patent application. On October 13, 2022, we subsequently disclosed that trademark applications to register ChemoPrep™ and ChemoPure™ were 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 United States Patent and Trademark Office (“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. 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 totalling \$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.

As of March 31, 2023, we had a total 42,713,325 shares issued and outstanding, of which 17,073,325 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 tumour 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 U.S. Food and Drug Administration (“FDA”) to support the potential initiation of a human feasibility study in End-Stage Renal Disease (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, tumour necrosis factor-alpha (TNF- $\alpha$ ), interleukin-1 $\beta$  (IL-1 $\beta$ ), and interleukin-6 (IL-6) before and after each Sigyn Therapy administration. Endotoxin and excess TNF- $\alpha$ , IL-1 $\beta$ , 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 end-stage renal disease (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 tumour necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-1 $\beta$  (IL-1 $\beta$ ) 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 fuelling further inflammation, endotoxin is 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- $\alpha$ , IL-1 $\beta$ , 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 U.S. Food and Drug Administration (“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, tumour necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-1 $\beta$  (IL-1 $\beta$ ), and interleukin-6 (IL-6) before and after each Sigyn Therapy administration. Endotoxin and excess TNF- $\alpha$ , IL-1 $\beta$ , 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 countermeasures 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 fuelled 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 United States Patent and Trademark Office ("USPTO"). The provisional patent submission established the priority date of our now patent pending invention and provides us up to one year to submit a non-provisional patent application. On October 13, 2022, we subsequently disclosed that trademark applications to register ChemoPrep™ and ChemoPure™ were 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 diminish the efficacy of chemotherapy. As compared to non-cancer subjects, Tumor-EXs are highly concentrated in the bloodstream of those suffering from cancer. Tumor-EXs 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 could establish a novel, yet practical strategy to increase tumor-site saturation of chemotherapy, which in turn may permit for lower doses of chemotherapy to be administered without diminishing patient benefit.

ChemoPrep™ may also improve the performance of ChemoPure™ as a reduced bloodstream presence of Tumor-EXs, which are competitive binding and adsorption factors based on similar size and structural characteristics, would likely increase the efficiency of ChemoPure™ to reduce the presence of off-target chemotherapeutic agents that remain circulating in the bloodstream.

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. 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 United States Patent and Trademark Office (“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. 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.

### **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** - Appointed Jeremy Ferrell, CPA, MBA as Chief Financial Officer.
- **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 United States Patent and Trademark Office (“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 United States Patent and Trademark Office (“USPTO”).
- **May 2023** - Trademark application to register ImmunePrep™ is filed with the USPTO.

### **Marketing and Sales**

At present, our primary focus is the clinical and regulatory advancement of Sigyn Therapy and our pipeline technologies. As such, we do not market or sell any therapeutic products at this time. However, we plan to forge relationships with organizations that have established distribution channels into markets that may have a demand for Sigyn Therapy or our pipeline technologies should any of these product candidates receive market clearance from FDA or other foreign regulatory agencies.

### **Intellectual Property**

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



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

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD - U.S. Application No.: 62/881,740; Filing Date: 2019-08-01 - Inventors: Joyce and Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD - International Patent Application No.: PCT/US2020/044223; Filing Date: 2020-07-30 - Inventors: Joyce and Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD - U.S. Patent Application No.: 16/943,436; Filing Date: 2020-07-30 - Inventors: Joyce and Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD - EP No.: 20757445; Filing Date: 2022-01-24 - Inventors: Joyce and Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD - CA No.: 3148773; Filing Date: 2022-01-25 - Inventors: Joyce and Roberts

DEVICES, SYSTEMS AND METHODS FOR THE BROAD-SPECTRUM REDUCTION OF PRO-INFLAMMATORY CYTOKINES IN BLOOD - JP No.: 2022-506670; Filing Date: 2022-01-31 - Inventors: Joyce and Roberts

EXTRA-LUMEN ADSORPTION OF VIRAL PATHOGENS FROM BLOOD U.S. Patent Application No.: 63/177,520; Filing Date: 2021-04-21 Inventor: James A. Joyce

SYSTEM AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY U.S. Patent Application No.: 63/410,764; Filing Date: 09/28/2022 Inventor: James A. Joyce

DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES Patent Application No.: 63/465,360; Filing Date: 05/10/2023 Inventors: James A. Joyce, Annette M Marleau

### **Government Regulation**

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

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

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

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

#### **The Pre-market Approval Pathway**

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

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

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

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

### **Clinical Trials**

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

### **Manufacturing and Procurement**

We are advancing a manufacturing relationship with an FDA registered Contract Manufacturing Organization (CMO) to establish cGMPs compliant manufacturing to support human clinical studies and potential commercialization should we receive clearance to market Sigyn Therapy. We plan to establish manufacturing procedure specifications that define each stage of our manufacturing, inspection and testing processes and the control parameters or acceptance criteria that apply to each activity that result in the production of our technology.

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

### **Research and Product Development**

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

### **Environmental Laws and Regulations**

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

### **Employees**

As of the date of this filing, we have 4 salaried employees, whose benefits include paid medical, dental, and vision coverage. We also provide our employees with access to a 401(k) plan, and we anticipate the establishment of an employee equity-stock option plan during the 2023 calendar year. To maintain a manageable employee headcount, we utilize non-employee consultants to perform as-needed services and we contract with third party research organizations to perform studies designed to support the potential clinical advancement of Sigyn Therapy.

## DESCRIPTION OF PROPERTY

### Operating Lease

Our corporate address 2468 Historic Decatur Road, Suite 140, San Diego, California, 92106

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.

We believe that our existing facilities are adequate for our current needs and that we will be able to lease suitable additional or alternative space on commercially reasonable terms if and when we need it.

## DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

### Directors and Executive Officers

The following table sets forth the names, ages, and biographical information of each of our current directors and executive officers and the positions with the Company held by each person. Our executive officers are elected annually by the board of directors. The directors serve one-year terms until their successors are elected. The executive officers serve terms of one year or until their death, resignation or removal by the board of directors. Unless described below, there are no family relationships among any of the directors and officers.

<u>Name</u>	<u>Age</u>	<u>Title</u>
Jim Joyce	60	Chief Executive Officer and Chairman of the Board of Directors (“CEO”)
Craig Roberts	69	Chief Technology Officer and Director
Jeremy Ferrell <sup>(1)</sup>	52	Chief Financial Officer
Richa Nand <sup>(2)</sup>	49	Non-Employee Director
Jim Dorst <sup>(2)</sup>	68	Non-Employee Director
Christopher Wetzel <sup>(2)</sup>	47	Non-Employee Director

(1) Mr. Ferrell was hired as the Company’s Chief Financial Officer effective March 9, 2022.

(2) Ms. Nand, Mr. Dorst and Mr. Wetzel were appointed as Non-Executive Directors effective October 10, 2022.

### Executive Officers

**Jim Joyce.** Mr. Joyce is a Co-founder of Sigyn Therapeutics and has served as Chairman and CEO of the Company since it was founded in 2019. He has 30+ years of diverse public market experience, which includes two decades of public company CEO and Corporate Board leadership roles. Previously, Mr. Joyce was the founder of Exosome Sciences, Inc., where he served as Executive Chairman from 2011 to 2018. Mr. Joyce is also the founder, former Chairman and CEO of Aethlon Medical, a therapeutic device company that he navigated from a single shareholder start-up to Nasdaq-traded Company with 8000+ shareholders.

While employed at Aethlon from 1999 to 2018, Mr. Joyce oversaw the development of the Aethlon Hemopurifier, the first therapeutic candidate to receive two “Breakthrough Device” designations from the FDA. Under his leadership, the Hemopurifier received FDA “Emergency Use Authorization” (EUA) approval to treat Ebola virus and additionally was cleared to treat Ebola by the German Government and Health Canada. Time Magazine named the Hemopurifier one of the “11 Most Remarkable Advances in Healthcare” and designated the device to its “Top 25 Best Inventions” award list.

During Mr. Joyce’s tenure, Aethlon won multiple Department of Defense (DOD) contract awards, a National Cancer Institute (NCI) contract award and grants from the National Institutes of Health (NIH). He also led the completion of approximately \$100 million of equity financings and originated preclinical and clinical collaborations with more than twenty government and non-government institutes and organizations.

We believe Mr. Joyce’s service as our Chief Executive Officer, his extensive experience in therapeutic device technologies, his prior board service and his extensive public company background qualifies him to serve on our board of directors.

**Craig Roberts.** Mr. Roberts is an inventor of therapeutic device technologies, which includes a Percutaneous Adult Extracorporeal Membrane Oxygenation (ECMO) system that was licensed and subsequently sold to C.R. Bard. During the ongoing pandemic, ECMO has been broadly deployed to treat critically ill COVID-19 patients. Additionally, Mr. Roberts is the inventor of the IMPACT System, which received CE Mark clearance in the European Union and was subsequently registered in 32 countries and successfully deployed to treat cytokine storm related conditions, including sepsis, acute respiratory distress syndrome (ARDS), acute liver failure, severe pneumonia and H5N1 bird flu virus infection.

Mr. Roberts is a Co-founder of Sigyn Therapeutics and has been our Chief Technical Officer since it was founded in 2019. Prior to joining the Company, Mr. Roberts served as a consultant for Aethlon Medical, Inc. from 2016 to 2019. Prior to Aethlon, Mr. Roberts was a founder, Chief Technology Officer and Board Member of Hemolife Medical, Inc. We believe Mr. Roberts’s service as our Chief Technology Officer, his extensive experience with therapeutic device technologies and his previous service as board of medical device company qualifies him to serve on our board of directors.

**Jeremy Ferrell.** Mr. Ferrell has more than 25 years of finance and operations leadership experience, with expertise in venture capital; mergers and acquisitions; due diligence; initial public offerings; strategic alliance negotiation; and financial planning and reporting. Mr. Ferrell has served as our CFO since March 2022. Prior to joining the Company, Mr. Ferrell served as the CFO at Miku, Inc, from 2018 to 2022. Previously, he founded a Fractional CFO Services firm, where he served as CFO for various life sciences and technology companies, including Singular Genomics, Inc., Aspen Neuroscience, Inc., and Hyduro, Inc. Before that, he served as Corporate Controller for ecoATM, Inc., which was acquired by Outerwall, Inc. in 2013. Earlier in his career, Mr. Ferrell practiced as a certified public accountant. Mr. Ferrell received his Bachelor of Science degree in Accountancy from Liberty University and his Master of Business Administration degree in International Finance from the Thunderbird School of Global Management.

#### **Non-Employee Directors**

**Richa Nand.** Ms. Nand is a senior legal executive with more than 20 years of experience as an intellectual property (“IP”) attorney and strategic business advisor for biotechnology and medical device companies. Ms. Nand is the founder of Insight Patents (for which she has been a principal since 2014), a legal and consulting firm providing IP and transactional corporate services for the life sciences industry. Ms. Nand previously served as Vice President of Corporate Development and Legal at Bird Rock Bio – a Johnson & Johnson-backed biopharmaceutical company in San Diego – and Vice President of Intellectual Property and Licensing; Director of Business Development; and In-House Patent Counsel at Cytori Therapeutics. Prior to law school, she was a biomedical researcher at Cedars Sinai Medical Center in Beverly Hills, California. Ms. Nand received a Bachelor of Science degree in Microbiology and Molecular Genetics from the University of California, Los Angeles, and a Juris Doctor degree from Boston University School of Law. The Company believes Ms. Nand is qualified to sit on its Board due to her experience with medical device companies.

**Jim Dorst.** Mr. Dorst has more than 30 years of senior management experience in finance, operations, planning and business transactions at both private and public companies. He was most recently Director of Corporate Development at SYNnex/Concentrix from July 2013 to January 2021, where he was primarily responsible for mergers and acquisitions. Mr. Dorst was previously Chief Operating Officer (“COO”) and Chief Financial Officer (“CFO”) at SpectraScience, Inc.; CFO of Aethlon Medical, Inc. and Vice President of Finance and Operations for Verdisoft Corporation. In addition, he previously served as Senior Vice President of Finance and Administration at SeeCommerce; CFO and COO of Omnis Technology Corp; and CFO and Senior Vice President of Information Technology at Savoir Technology Group, Inc. Mr. Dorst practiced as a Certified Public Accountant with Coopers & Lybrand (now PricewaterhouseCoopers LLP); and holds a Master of Science degree in Accounting and a Bachelor of Science degree in Finance from the University of Oregon. The Company believes Mr. Dorst is qualified to sit on its Board due to his longstanding involvement with public companies.

**Christopher Wetzel.** Mr. Wetzel has more than 25 years of leadership experience in various aspects of the healthcare delivery system and since 2004, has served as Chief Executive Officer for the Surgery Center at Hamilton in New Jersey. His career has focused on building organizations, increasing operational efficiency, increasing profitability, maximizing revenue, and managing change in the complex and high-growth healthcare environment. Mr. Wetzel applied his broad background in strategy, finance, and operations to guide various entities starting new ventures, entering new markets, and reengineering business processes. He is a long-term investor in the extracorporeal therapy space. Mr. Wetzel received a Master of Business Administration degree in Healthcare Management and a Bachelor of Science degree in Nursing from Thomas Jefferson University (formerly Philadelphia University). The Company believes Mr. Wetzel is qualified to sit on its Board due to his decades of experience in the healthcare delivery system.

#### **Conflicts of Interest**

Certain potential conflicts of interest are inherent in the relationships between our officers and directors and us.

From time to time, one or more of our affiliates may form or hold an ownership interest in and/or manage other businesses both related and unrelated to the type of business that we own and operate. These persons expect to continue to form, hold an ownership interest in and/or manage additional other businesses which may compete with our business with respect to operations, including financing and marketing, management time and services and potential customers. These activities may give rise to conflicts between or among the interests of us and other businesses with which our affiliates are associated. Our affiliates are in no way prohibited from undertaking such activities, and neither we nor our shareholders will have any right to require participation in such other activities.

We may transact business with some of our officers, directors and affiliates, as well as with firms in which some of our officers, directors or affiliates have a material interest, potential conflicts may arise between the respective interests of us and these related persons or entities. We believe that such transactions will be effected on terms at least as favorable to us as those available from unrelated third parties. As of this filing, we have not transacted business with any officer, director, or affiliate.

With respect to transactions involving real or apparent conflicts of interest, we have adopted policies and procedures which require that: (i) the fact of the relationship or interest giving rise to the potential conflict be disclosed or known to the directors who authorize or approve the transaction prior to such authorization or approval, (ii) the transaction be approved by a majority of our disinterested outside directors, and (iii) the transaction be fair and reasonable to us at the time it is authorized or approved by our directors.

Our policies and procedures regarding transactions involving potential conflicts of interest are not in writing. We understand that it will be difficult to enforce our policies and procedures and will rely and trust our officers and directors to follow our policies and procedures. We will implement our policies and procedures by requiring the officer or director who is not in compliance with our policies and procedures to remove himself and the other officers and directors will decide how to implement the policies and procedures, accordingly.

#### **Corporate Governance**

The Company promotes accountability for adherence to honest and ethical conduct; endeavors to provide full, fair, accurate, timely and understandable disclosure in reports and documents that the Company files with the Securities and Exchange Commission (the “SEC”) and in other public communications made by the Company; and strives to be compliant with applicable governmental laws, rules and regulations.

#### **Director Independence**

Our board of directors consists of five members, with three independent directors in accordance with NASDAQ listing rule 5605(a)(2) before we uplist via an amendment to this registration statement of which this prospectus is a part. Because our common stock is not currently listed on a national securities exchange, we have used the definition of “independence” of The NASDAQ Stock Market to make this determination. NASDAQ Listing Rule 5605(a)(2) provides that an “independent director” is a person other than an officer or employee of the company or any other individual having a relationship which, in the opinion of the company’s board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The NASDAQ listing rules provide that a director cannot be considered independent if:

- the director is, or at any time during the past three years was, an employee of the company;
- the director or a family member of the director accepted any compensation from the company in excess of \$120,000 during any period of 12 consecutive months within the three years preceding the independence determination (subject to certain exclusions, including, among other things, compensation for board or board committee service);

- a family member of the director is, or at any time during the past three years was, an executive officer of the company;
- the director or a family member of the director is a partner in, controlling stockholder of, or an executive officer of an entity to which the company made, or from which the company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or \$200,000, whichever is greater (subject to certain exclusions);
- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three years, any of the executive officers of the company served on the compensation committee of such other entity; or
- the director or a family member of the director is a current partner of the company's outside auditor, or at any time during the past three years was a partner or employee of the company's outside auditor, and who worked on the company's audit.

#### **Board Composition**

Our business and affairs are managed under the direction of our board of directors, which consists of five members. Directors serve for a term of one year and until their successors have been duly elected and qualified.

#### **Committees of the Board**

Our Company currently does not have nominating, compensation, or audit committees or committees performing similar functions nor does our Company have a written nominating, compensation or audit committee charter. The Company plans to update its board committees to meet NASDAQ requirements via an amendment to this registration statement of which this prospectus is a part.

In lieu of an audit committee, the Company's board of directors is responsible for reviewing and making recommendations concerning the selection of outside auditors, reviewing the scope, results and effectiveness of the annual audit of the Company's consolidated financial statements and other services provided by the Company's independent public accountants. The board of directors, the Chief Executive Officer and the Chief Financial Officer of the Company review the Company's internal accounting controls, practices and policies.

The Company maintains a Scientific Advisory Board ("SAB") to assist our Board of Directors by reviewing and evaluating our clinical development programs. We intend for our SAB members to receive per meeting fees and also be eligible to receive stock option compensation. However, a formal SAB compensation plan has not yet been approved by our Board of Directors.

#### **Audit Committee Financial Expert**

Mr. Dorst qualifies as an "audit committee financial expert" as defined in Item 407(D)(5) of Regulation S-K, and our three new directors qualify as "independent" as the term is used in Item 7(d)(3)(iv)(B) of Schedule 14A under the Securities Exchange Act of 1934, as amended, and as defined by Rule 4200(a)(14) of the FINRA Rules.

We believe that our directors are capable of analyzing and evaluating our consolidated financial statements and understanding internal controls and procedures for financial reporting. The directors of our Company do not believe that it is necessary to have an audit committee because management believes that the board of directors can adequately perform the functions of an audit committee. In addition, we believe that retaining an independent director who would qualify as an "audit committee financial expert" would be overly costly and burdensome and is not warranted in our circumstances given the stage of our development and the fact that we have not generated any positive cash flows from operations to date.

## **Involvement in Certain Legal Proceedings**

Our directors and our executive officers have not been involved in or a party in any of the following events or actions during the past ten years:

1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; or
4. being found by a court of competent jurisdiction (in a civil action), the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.
5. Such person was found by a court of competent jurisdiction in a civil action or by the Commission to have violated any Federal or State securities law, and the judgment in such civil action or finding by the Commission has not been subsequently reversed, suspended, or vacated;
6. Such person was found by a court of competent jurisdiction in a civil action or by the Commodity Futures Trading Commission to have violated any Federal commodities law, and the judgment in such civil action or finding by the Commodity Futures Trading Commission has not been subsequently reversed, suspended or vacated;
7. Such person was the subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of: (I) Any Federal or State securities or commodities law or regulation; or (ii) Any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order; or (iii) Any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
8. Such person was the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

## **Code of Ethics**

The Company has not formally adopted a written Code of Ethics that governs the Company's employees, officers and directors as the Company is not required to do so. The board of directors evaluated the business of the Company and the number of employees and determined that since the business is operated by a small number of persons, general rules of fiduciary duty and federal and state criminal, business conduct and securities laws are adequate ethical guidelines. In the event our operations, employees and/or directors expand in the future, we may take actions to adopt a formal Code of Ethics.

## **Role of Board of Directors in Risk Oversight**

Our board of directors oversees an enterprise-wide approach to risk management, designed to support the achievement of business objectives, including organizational and strategic objectives, to improve long-term organizational performance and enhance stockholder value. The involvement of our board of directors in setting our business strategy is a key part of its assessment of management's plans for risk management and its determination of what constitutes an appropriate level of risk for our company. The participation of our board of directors in our risk oversight process includes receiving regular reports from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks.

While our board of directors has the ultimate responsibility for the risk management process, senior management and various committees of our board of directors, when formed, will also have responsibility for certain areas of risk management. Our senior management team is responsible for day-to-day risk management and regularly reports on risks to our full board of directors or a relevant committee. Our finance and regulatory personnel serve as the primary monitoring and evaluation function for company-wide policies and procedures, and manage the day-to-day oversight of the risk management strategy for our ongoing business. This oversight includes identifying, evaluating, and addressing potential risks that may exist at the enterprise, strategic, financial, operational, compliance and reporting levels.

## **Director Compensation**

Our Non-Employee directors receive a \$30,000 annual retainer, paid in equal quarterly amounts for which periods the directors have provided service.

The Company does not currently have any equity compensation plans and there are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers. We have no material bonus or profit-sharing plans.

### **Limitation on Liability and Indemnification Matters**

Our Certificate of Incorporation and Bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our Certificate of Incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to the corporation or its shareholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our Certificate of Incorporation does not eliminate a director's duty of care and in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and bylaws may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our shareholders. A shareholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as we may provide indemnification for liabilities arising under the Securities Act to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

### **EXECUTIVE COMPENSATION**

*The following is a discussion and analysis of compensation arrangements of our named executive officers, or NEOs. This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion.*



### Summary Compensation Table

The particulars of the compensation paid to the following persons: (1) our principal executive officer; and (2) each of our two most highly compensated executive officers who were serving as executive officers at the end of the fiscal year ended December 31, 2022, who we will collectively refer to as the “named executive officers” of the Company, are set out in the following summary compensation table:

#### SUMMARY COMPENSATION TABLE

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)</u>	<u>Stock Awards (\$)</u>	<u>Option Awards (\$)</u>	<u>Non-Equity Incentive Plan Compensation (\$)</u>	<u>Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)</u>	<u>All Other Compensation (\$) (1)</u>	<u>Total (\$)</u>
Jim Joyce	2022	453,067	-	-	-	-	-	\$ 48,811	\$ 501,878
Chief Executive Officer	2021	473,375	22,750	-	-	-	-	\$ 31,126	\$ 527,251
Craig Roberts	2022	233,678	-	-	-	-	-	\$ 25,312	\$ 258,990
Chief Technology Officer	2021	247,000	12,000	-	-	-	-	\$ 21,704	\$ 280,704
Jeremy Ferrell	2022	177,083	-	-	-	-	-	\$ 23,205	\$ 200,288
Chief Financial Officer <sup>(2)</sup>	2021	-	-	-	-	-	-	\$ -	\$ -

(1) Amounts include health insurance and employer matched 401(k) costs.

(2) Mr. Ferrell was hired as the Company’s Chief Financial Officer effective March 9, 2022. Mr. Ferrell receives an annual base salary of \$250,000, amended to \$62,500 on December 1, 2022.

Other than as disclosed below, there are no compensatory plans or arrangements with respect to our executive officers resulting from their resignation, retirement or other termination of employment or from a change of control.

### Grants of Plan-Based Awards Table

None of our named executive officers received any grants of stock, option awards or other plan-based awards during the years ended December 31, 2022 and 2021, except as described below in “Equity Compensation Plans and Other Benefit Plans” below.

### Options Exercised and Stock Vested Table

None of our named executive officers exercised any stock options or restricted stock units during the years ended December 31, 2022 and 2021.

### Outstanding Equity Awards at 2022 Year End

Except as described below in “Equity Compensation Plans and Other Benefit Plans”, the Company has not issued any awards to its named executive officers. The Company and its board of directors may grant awards as it sees fit to its employees as well as key consultants. See the discussion of “Equity Compensation Plans and Other Benefit Plans” below.

### Agreements with Executive Officers

#### **Jim Joyce**

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. There is no written employment agreement for Mr. Joyce at this time.

#### **Jeremy Ferrell**

Mr. Ferrell was hired March 9, 2022 as the Company’s Chief Financial Officer. Mr. Ferrell receives an annual base salary of \$250,000, amended to \$62,500 on December 1, 2022, plus discretionary bonus compensation not to exceed 40% of salary. Mr. Ferrell’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. Ferrell will be granted up to 600,000 options to purchase 600,000 of the Company’s common shares upon the implementation of a Company employee option plan.

## Craig Roberts

Mr. Roberts, the Company's Chief Technology Officer (CTO) receives an annual base salary of \$240,000 as well as medical insurance and related benefits.

Mr. Roberts is eligible to receive bonus compensation at the discretion of the Sigyn Therapeutics, Inc. Board of Directors.

### Equity Compensation Plans and Other Benefit Plans

The Company does not currently have any equity compensation plans and there are no arrangements or plans in which we provide pension, retirement or similar benefits for directors or executive officers. We have no material bonus or profit-sharing plans.

### Indebtedness of Directors, Senior Officers, Executive Officers and Other Management

None of our directors or executive officers or any associate or affiliate of the Company during the last two fiscal years, is or has been indebted to the Company by way of guarantee, support agreement, letter of credit or other similar agreement or understanding currently outstanding.

### Outstanding Equity Awards at Fiscal Year-End Table

The following table sets forth certain information concerning outstanding stock awards held by the Named Executive Officers for our year ended December 31, 2022:

Name	Option Awards					Stock Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
None.	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-

## Equity Compensation Plans

The following represents a summary of the Equity Compensation grants and options awards outstanding at December 31, 2022 and 2021 and changes during the years then ended:

Plan category	2022 and 2021			Number of securities remaining available for future issuance under equity compensation plan (excluding securities reflected in column a))
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights		
	(a)	(b)	(c)	
Equity compensation plans approved by security holders	-0-	\$ -0-	-0-	-0-
Equity compensation plans not approved by security holders	-0-	\$ -0-	-0-	-0-
Total	-0-	\$ -0-	-0-	-0-

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information relating to the beneficial ownership our common stock as of September 20, 2023 by (i) each person known to be the beneficial owner of more than 5% of the outstanding shares of common stock and (ii) each of our directors and executive officers. Unless otherwise noted below, we believe that all persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them. For purposes hereof, a person is deemed to be the beneficial owner of securities that can be acquired by such person within 60 days from the date hereof upon the exercise of warrants or options or the conversion of convertible securities. Each beneficial owner's percentage ownership is determined by assuming that any warrants, options or convertible securities that are held by such person (but not those held by any other person) and which are exercisable within 60 days from the date hereof, have been exercised.

[To be updated]

Name and Address <sup>(2)</sup>	Amount of Beneficial Ownership	Percent of Class (1)
Jim Joyce <sup>(3)</sup>	12,820,000	34.4%
Craig Roberts <sup>(4)</sup>	12,820,000	34.4%
Jeremy Ferrell <sup>(5)</sup>	-	-%
All Officers and Directors as a Group (3 Persons)	25,640,000	68.8%
Brio Capital Master Fund Ltd. <sup>(6)</sup>	3,725,850	9.9%
Osher Capital Partners LLC <sup>(7)</sup>	3,050,658	8.2%

(1) Based on 44,231,402 shares of common stock issued and outstanding.

(2) Unless otherwise noted, the address of each beneficial owner is c/o Sigyn Therapeutics, Inc., 2468 Historic Decatur Road, Suite 140, San Diego, CA 92106.

(3) Mr. Joyce is the Company's CEO.

(4) Mr. Roberts is the Company's CTO.

(5) Mr. Ferrell is the Company's CFO.

(6) Consists of 3,725,850 common shares as of the date of this filing. Brio Capital Master Fund Ltd ("Brio") is contractually limited to beneficial ownership of our common stock not to exceed 9.99%. The stockholder of record by the stockholder is held by Shaye Hirsch who is a director of Brio. The business address of Brio is 100 Merrick Road, Suite 401W, Rockville Center, NY 11570.

(7) Consists of 3,050,658 common shares as of the date of this filing. Osher Capital Partners LLC ("Osher") is contractually limited to beneficial ownership of our common stock not to exceed 9.99%. The Stockholder has advised us that voting and dispositive power of all the common shares of the Company owned of record by the stockholder is held by Ari Kluger, who is President of Osher. The business address of Osher is 23 Tammy Lane, Spring Valley NY 10977.

We are not aware of any person who owns of record, or is known to own beneficially, five percent or more of our outstanding securities of any class, other than as set forth above. We do not have an investment advisor. There are no current arrangements which will result in a change in control.

## UNDERWRITING

Univest Securities, LLC is acting as representative of the underwriters. Subject to the terms and conditions of an underwriting agreement between us and the representative, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of Class A Units listed next to its name in the following table:

Underwriter	Number of Class A Units
Univest Securities, LLC	
Total	

The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the securities offered by this prospectus are subject to various conditions and representations and warranties, including the approval of certain legal matters by their counsel and other conditions specified in the underwriting agreement. The securities are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer to the public and to reject orders in whole or in part. The underwriters are obligated to take and pay for all of the Class A Units offered by this prospectus if any such Class A Units are taken, other than those shares of common stock and/or Series A Warrants covered by the over-allotment option described below.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

### Over-Allotment Option

We have granted to the representative of the underwriters an option, exercisable one or more times in whole or in part, not later than 45 days after the date of this prospectus, to purchase from us up to an (i) additional 225,000 shares of our common stock and/or (ii) additional Series A Warrants to purchase up to 225,000 additional shares of common stock, which represents 15% of the shares of common stock, and Series A Warrants included in the Class A Units sold in this offering (each having the same terms as those securities included in the Class A Units issued in the offering) in any combination thereof at: (i) the price per share of common stock equal to the public offering price per Class A Unit minus \$0.01 per share, and (ii) \$0.01 per Series A Warrant, respectively, less the underwriting discounts payable by us, solely to cover over-allotments, if any. To the extent that the representative exercises this option, each of the underwriters will become obligated, subject to conditions, to purchase approximately the same percentage of these additional shares of common stock and/or Series A Warrants as the number of Class A Units to be purchased by it in the above table bears to the total number of Class A Units offered by this prospectus. We will be obligated, pursuant to the option, to sell these additional shares of common stock and/or Series A Warrants to the underwriters to the extent the option is exercised. If any additional shares of common stock and/or Series A Warrants are purchased, the underwriters will offer the additional shares of common stock and/or Series A Warrants on the same terms as those on which the other Class A Units are being offered hereunder. If this option is exercised in full, the total offering price to the public will be \$ and the total net proceeds, before expenses and after the credit to the underwriting commissions described below, to us will be \$ .

### Discounts and Commissions

The underwriters propose initially to offer the Class A Units to the public at the public offering price set forth on the cover page of this prospectus and to dealers at those prices less a concession not in excess of \$ per Class A Unit. If all of the Class A Units

offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a supplement to this prospectus.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise of the over-allotment option we granted to the representative of the underwriters.

	Per Class A Unit	Total Without Over-allotment Option	Total With Over-allotment Option
Public offering price	\$	\$	\$
Underwriting discount (7.0%)	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$
Non-accountable expense allowance (1.0%)	\$	\$	\$

(1) The non-accountable expense allowance will not be payable with respect to representative's exercise of the over-allotment option.

We have agreed to pay a non-accountable expense allowance to the representative of the underwriters equal to 1.0% of the gross proceeds received at the closing of the offering. The non-accountable expense allowance of 1.0% is not payable with respect to any Class A Units sold upon exercise of the underwriters' over-allotment option. In addition, we have agreed to reimburse the representative up to a maximum of \$150,000 for out-of-pocket accountable expenses, including, but not limited to, travel, due diligence expenses, reasonable fees and expenses of its legal counsel, accountable roadshow expenses, and background checks on our principal shareholders, directors and officers.

Our total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately \$ .

## **Representative's Warrants**

Upon completion of this offering, we have agreed to issue to the representative as compensation warrants to purchase up to 70,313 shares of common stock (5.0% of the aggregate number of shares of common stock sold in this offering inclusive of the over-allotment option (the "representative's warrants"). The representative's warrants will be exercisable at a per share exercise price equal to 110% of the public offering price per Class A Unit in this offering. The representative's warrants are exercisable at any time and from time to time, in whole or in part, during the four and one half year period commencing 180 days following the commencement of sales of the securities issued in this offering.

The representative's warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(e)(1)(A) of FINRA. The representative (or permitted assignees under Rule 5110(e)(2)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days following the commencement of sales of the securities issued in this offering. In addition, the representative's warrants provide for registration rights upon request, in certain cases. The sole demand registration right provided will not be greater than five years from the commencement of sales of the securities issued in this offering in compliance with FINRA Rule 5110(g)(8)(C). The piggyback registration rights provided will not be greater than seven years from the commencement of sales of the securities issued in this offering in compliance with FINRA Rule 5110(g)(8)(D). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

## **Right of First Refusal**

We have agreed to grant the representative, for the 9-month period following the closing of this offering, a right of first refusal to provide investment banking services to us on an exclusive basis in all matters for which investment banking services are sought by us (the "Right of First Refusal"), which right is exercisable in the representative's sole discretion. In accordance FINRA Rule 5110(g)(6)(A), such Right of First Refusal does not have a duration of more than three years from the commencement of sales of the public offering or the termination date of the engagement between the us and the underwriters.

## **Lock-Up Agreements**

Pursuant to "lock-up" agreements, we, our executive officers and directors, and certain stockholders, have agreed, without the prior written consent of the representative not to directly or indirectly, offer to sell, sell, pledge or otherwise transfer or dispose of any of shares of (or enter into any transaction or device that is designed to, or could be expected to, result in the transfer or disposition by any person at any time in the future of) our common stock, enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of our common stock, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any other securities of ours or publicly disclose the intention to do any of the foregoing, subject to customary exceptions, for a period of six months after the date of this prospectus in the case of our directors, executive officers, the Company and any successor of the Company and certain stockholders.

## **Discretionary Accounts**

The underwriters do not intend to confirm sales of the shares of common stock offered hereby to any accounts over which they have discretionary authority.

## **Nasdaq Capital Market Listing**

We intend to apply to have our common stock listed on the Nasdaq Capital Market under the symbol "SIGY". No assurance can be given that our application will be approved by Nasdaq, and if not, we will not consummate this offering.

There is no established trading market for the the Series A Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series A Warrants on any national securities exchange or other trading market.

## **Determination of Offering Price**

The public offering price of the Class A Units that we are offering was negotiated between us and the underwriters. Factors considered in determining the public offering price of the Class A Units include the history and prospects of the Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

### **Price Stabilization, Short Positions and Penalty Bids**

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock, the Series A Warrants. Specifically, the underwriters may over-allot in connection with this offering by selling more shares of common stock, shares of Series A Warrants than are set forth on the cover page of this prospectus. This creates a short position in our common stock or Series A Warrants for its own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares of common stock or Series A Warrants over-allotted by the underwriters is not greater than the number of shares of common stock /or Series A Warrants that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock or Series A Warrants involved is greater than the number of securities in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock or Series A Warrants or reduce any short position by bidding for, and purchasing, common stock or Series A Warrants in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing securities in this offering because the underwriter repurchases the securities in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, securities in market making transactions, including “passive” market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock or Series A Warrants at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on the national securities exchange on which our shares of common stock are traded, in the over-the-counter market, or otherwise.

### **Indemnification**

We have agreed to indemnify the underwriters against liabilities relating to this offering arising under the Securities Act and the Exchange Act, liabilities arising from breaches of some or all of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

### **Affiliations**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and their affiliates may from time to time in the future engage with us and perform services for us or in the ordinary course of their business for which they will receive customary fees and expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of us. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of these securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in these securities and instruments.

### **Conflicts of Interest**

We are not under any contractual obligation to engage any of the underwriters to provide any services for us after this offering and have no present intent to do so. However, any of the underwriters may introduce us to potential target businesses or assist us in raising additional capital in the future. If any of the underwriters provide services to us after this offering, we may pay such underwriter fair and reasonable fees that would be determined at that time in an arm’s length negotiation; provided that no agreement will be entered into with any of the underwriters and no fees for such services will be paid to any of the underwriters prior to the date that is 90 days from the date of this prospectus, unless FINRA determines that such payment would not be deemed underwriter’s compensation in connection with this offering and we may pay the underwriters of this offering or any entity with which they are affiliated a finder’s fee or other compensation for services rendered to us in connection with the completion of a business combination.

### **Electronic Distribution**

This prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on any underwriter’s website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

## **Selling Restrictions**

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of our securities, or the possession, circulation or distribution of this prospectus or any other material relating to us or our securities in any jurisdiction where action for that purpose is required. Accordingly, our securities may not be offered or sold, directly or indirectly, and this prospectus or any other offering material or advertisements in connection with our securities may be distributed or published, in or from any country or jurisdiction, except in compliance with any applicable rules and regulations of any such country or jurisdiction.

### ***European Economic Area and United Kingdom***

In relation to each Member State of the European Economic Area and the United Kingdom (each a “Relevant State”), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which have been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- to legal entities which are qualified investors as defined under the Prospectus Regulation;
- by the underwriters to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of securities shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer of securities to the public” in relation to any securities in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for our securities, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

### ***United Kingdom***

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000, or the FSMA) as received in connection with the issue or sale of our securities in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to our securities in, from or otherwise involving the United Kingdom.

### ***Canada***

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts, or NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### ***Hong Kong***

The securities may not be offered or sold by means of this document or any other document other than (i) in circumstances that do not constitute an offer or invitation to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) or the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances that do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), that is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

### ***People’s Republic of China***

This prospectus has not been and will not be circulated or distributed in the PRC, and the securities may not be offered or sold, and will not be offered or sold to any person for re-offering or resale, directly or indirectly, to any resident of the PRC except pursuant to applicable laws and regulations of the PRC.

### ***Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

### ***South Korea***

The securities may not be offered, sold and delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in South Korea or to any resident of South Korea except pursuant to the applicable laws and regulations of South Korea, including the Financial Investment Services and Capital Markets Act and the Foreign Exchange Transaction Law and the decrees and regulations thereunder. The securities have not been registered with the Financial Services Commission of South Korea for public offering in South Korea. Furthermore, the securities may not be re-sold to South Korean residents unless the purchaser of the securities complies with all applicable regulatory requirements (including but not limited to government approval requirements under the Foreign Exchange Transaction Law and its subordinate decrees and regulations) in connection with their purchase.

### ***Taiwan***

The securities have not been and will not be registered or filed with, or approved by, the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be offered or sold in Taiwan through a public offering or in circumstances which constitute an offer within the meaning of the Securities and Exchange Act of Taiwan or relevant laws and regulations that require a registration, filing or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer or sell the securities in Taiwan.



## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Other than compensation arrangements and convertible promissory debentures, we have not entered into any related party transaction with a member of the immediate family or the foregoing persons of any director, executive officer, or holder of more than 5% of our capital stock during the last two completed fiscal years. Compensation arrangements, including employment agreements, for our directors and named executive officers are described elsewhere in “Executive Compensation—Agreements with Executive Officers.” Convertible promissory debentures are described elsewhere in “Management Discussion and Analysis of Financial Condition and Results of Operations – Financing Transactions”.

### Security Purchase Agreements

#### *Osher*

#### **January 28, 2020 – \$457,380**

On January 28, 2020, the Company entered into a Securities Purchase Agreement with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$385,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due January 26, 2021, 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 80,209 shares of the Company’s Common Stock at an exercise price of \$7.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was \$350,005 which was issued at a \$34,995 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.094 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated January 28, 2020, for the number of warrant shares from 80,209 warrant shares to 4,113,083 warrant shares at an exercise price of \$0.14 per share.
- The parties amended the Note to provide for interest at 8% per annum.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share.

#### **June 23, 2020 – \$60,500**

On June 23, 2020, the Company entered into a Securities Purchase Agreement with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$50,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due June 23, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 10,000 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at a \$0 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Note for the aggregate principal amount from \$50,000 to \$55,000. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at an amended \$4,995 original issue discount from the face value of the Note.
- The parties amended the Warrants dated June 23, 2020, for the number of warrant shares from 10,000 warrant shares to 141,020 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows (see Note 12):

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

#### **September 17, 2020 – \$182,936**

On September 17, 2020, the Company entered into a Securities Purchase Agreement with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$181,500 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due September 30, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 8,250 shares of the Company's Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$165,000 which was issued at a \$16,500 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follow on October 20, 2020:

- The parties amended the Warrants dated September 17, 2020, for the number of warrant shares from 8,250 warrant shares to 465,366 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from September 30, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows (see Note 12):

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares.

#### **March 23, 2022 – \$110,000**

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **April 28, 2022 – \$110,000**

On April 28, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due April 28, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **June 1, 2022 – \$55,000**

On June 1, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due June 1, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 110,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **June 22, 2022 – \$82,500**

On June 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$82,500 aggregate principal amount of Note due June 22, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 165,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **August 31, 2022 – \$110,000**

On August 31, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due August 31, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **September 20, 2022 – \$110,000**

On August 31, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due August 31, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **October 20, 2022 - \$110,000**

On October 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due October 20, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

#### **November 14, 2022 - \$55,000**

On November 14, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due November 14, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 366,667 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On September 14, 2023, the Company entered into an Amendment Agreement with Osher to extend the maturity date to August 30, 2024. As a result of this amendment, the parties agreed to increase the principal amount to reflect an implied 12% interest rate from the date of the Amendment Agreement through the rescheduled maturity date. In addition, the Amendment Agreement provides for an automatic conversion of the notes in accordance with their terms upon a listing of the Company's common stock on a national securities exchange such as NASDAQ or any tier of the New York Stock Exchange.

*Brio*

**March 23, 2022 – \$110,000**

On March 23, 2022, 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) \$110,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 220,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**May 10, 2022 – \$110,000**

On May 10, 2022, 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) \$110,000 aggregate principal amount of Note due May 10, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 220,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**September 9, 2022 – \$82,500**

On September 9, 2022, 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) \$82,500 aggregate principal amount of Note due September 9, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 550,000 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**November 9, 2022 - \$82,500**

On November 9, 2022, 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) \$82,500 aggregate principal amount of Note due November 9, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 550,000 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On September 14, 2023, the Company entered into an Amendment Agreement with Brio to extend the maturity date to August 30, 2024. As a result of this amendment, the parties agreed to increase the principal amount to reflect an implied 12% interest rate from the date of the Amendment Agreement through the rescheduled maturity date. In addition, the Amendment Agreement provides for an automatic conversion of the notes in accordance with their terms upon a listing of the Company's common stock on a national securities exchange such as NASDAQ or any tier of the New York Stock Exchange.

## DESCRIPTION OF SECURITIES

The following description of our capital stock is a summary and is qualified in its entirety by the provisions of our Certificate of Incorporation, which has been filed as an exhibit to our registration statement of which this prospectus is a part.

### Common Stock

We are authorized to issue 1,000,000,000 shares of common stock, par value \$0.0001, of which 44,231,402 shares are issued and outstanding as of September 20, 2023. Each holder of shares of our common stock is entitled to one vote for each share held of record on all matters submitted to the vote of stockholders, including the election of Directors. The holders of shares of common stock have no pre-emptive, conversion, subscription or cumulative voting rights. There is no provision in our Certificate of Incorporation or Bylaws that would delay, defer, or prevent a change in control of our Company.

*Choice of Forum.* The Certificate of Incorporation provides that, unless our Board consents to an alternative forum, the Court of Chancery in the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought by or on our behalf; (ii) any direct action asserting a claim against us or any of our directors or officers pursuant to any of the provisions of the DGCL, our Certificate of Incorporation or our Certificate of Incorporation; (iii) any action asserting a claim of breach of fiduciary duties owed by any of our directors, officers or other employees to our stockholders; or (iv) any action asserting a violation of Delaware decisional law relating to our internal affairs. This provision does not apply to (a) actions in which the Court of Chancery in the State of Delaware concludes that an indispensable party is not subject to the jurisdiction of Delaware courts, or (b) actions in which a federal court has assumed exclusive jurisdiction to a proceeding. This provision is not intended to apply to any actions brought under the Securities Act or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. There is uncertainty as to whether a court would enforce this provision with respect to claims under the Securities Act. However, the Certificate of Incorporation does not relieve us of our duties to comply with federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. The Certificate of Incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and consented to this choice of forum provision.

This choice of forum provision may impose additional litigation costs on stockholders in pursuing such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, this choice of forum provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes, which may discourage the filing of such lawsuits.

### Securities Offered in this Offering

We are offering 1,406,250 Class A Units, each unit consisting of one share of our common stock and one Series A Warrant to purchase one share of our common stock. The share of common stock and accompanying Series A Warrants included in each Class A Unit will be issued separately. Class A Units will not be issued or certificated. We are also registering the shares of common stock included in the Class A Units and the shares of common stock issuable from time to time upon exercise of the Series A Warrants included in the Class A Units offered hereby. The description of our common stock is set forth above under the heading “—Common Stock.”

## Series A Warrants

The following summary of certain terms and provisions of the Series A Warrants offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of Series A Warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Series A Warrant. We do not have a price as of yet so we cannot disclose the amounts of warrants outstanding following the offering, and none were available pre-offering. The exercise price is 110% of the offering price per Class A Unit for the Series A Warrants.

*Exercisability.* The Series A Warrants are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The Series A Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the Series A Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the Series A Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Series A Warrant. No fractional shares of common stock will be issued in connection with the exercise of a Series A Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

*Exercise Limitation.* A holder will not have the right to exercise any portion of the Series A Warrant if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series A Warrants.

*Exercise Price.* The exercise price per whole share of common stock purchasable upon exercise of the Series A Warrants is \$7.04 per share or 110% of the public offering price of the Class A Units. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Transferability.* Subject to applicable laws, the Series A Warrants may be offered for sale, sold, transferred or assigned without our consent.

*Exchange Listing.* There is no established trading market for the Series A Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Series A Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Series A Warrants will be limited.

*Warrant Agent.* The Series A Warrants will be issued in registered form under a warrant agency agreement between VStock Transfer, LLC, as warrant agent, and us. The Series A Warrants shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

*Fundamental Transactions.* In the event of a fundamental transaction, as described in the Series A Warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the Series A Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Series A Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Series A Warrant.

*Governing Law.* The Series A Warrants and the warrant agency agreement are governed by New York law.

## **Warrants and Options**

During 2020, in conjunction with the sale and issuance of Original Issue Discount Senior Convertible Debentures (“Notes”), the Company issued warrants to purchase an aggregate of 1,621,730 shares of the Company’s common stock with an exercise price of \$0.59 and vest over a period of five years. On February 19, 2021, a noteholder exercised 70,510 warrants pursuant to the cashless exercise provision of the warrant agreement into 57,147 common shares. In addition, the Company issued warrants to purchase an aggregate of 4,113,083 shares of the Company’s common stock with an exercise price of \$0.14 and vest over a period of five years.

In February and April 2021, in conjunction with the sale and issuance of Notes, the Company issued warrants to purchase an aggregate of 386,255 shares of the Company’s common stock with an exercise price of \$1.20 and vest over a period of five years.

On May 10, 2021, the Company closed a private placement to accredited investors that resulted in the issuance of 1,172,000 warrants to purchase an aggregate of 1,172,000 shares of the Company’s common stock with an exercise price of \$1.75 and vest over a period of five years.

On October 20, 2021, the Company entered into a securities purchase agreement with an accredited investor that resulted in the issuance of 320,000 shares of common stock and warrants to purchase an aggregate of 320,000 shares of the Company’s common stock for total proceeds totaling \$400,000. For each share purchased, the investor received a five-year warrant to purchase one share of common stock at \$1.25 per share.

On October 22, 2021, in exchange for the extension of Notes, the Company issued a noteholder five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share

## **Security Holders**

As of September 20, 2023, there were 44,231,402 common shares issued and outstanding, which were held by approximately 306 stockholders of record. We do not know the number of our beneficial shareholders or shareholders holding shares through their broker(s) in “street name.”

## **Non-cumulative Voting**

Holders of shares of our common stock do not have cumulative voting rights, which means that the holders of more than 50% of the outstanding shares, voting for the election of directors, can elect all of the directors to be elected, if they so choose, and, in such event, the holders of the remaining shares will not be able to elect any of our directors.

## **Transfer Agent**

We have engaged VStock Transfer, LLC as the Company’s transfer agent to serve as agent for shares of our common stock. Our transfer agent’s contact information is as follows:

VStock Transfer, LLC  
18 Lafayette Place  
Woodmere, NY 11598  
Phone: (212) 828-8436

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was a limited public market for our common stock as we trade sporadically on the OTCQB® Venture Market. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock. Sales of substantial amounts of our common stock in the public market could adversely affect the market prices of our common stock and could impair our future ability to raise capital through the sale of our equity securities.

We have an aggregate of 44,231,402 shares of our common stock outstanding as of September 20, 2023 (prior to the Offering). All of the 1,406,250 shares to be registered in this Offering will be freely tradable without restriction or further registration under the Securities Act, unless those shares are purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act.

### Rule 144

Rule 144 allows for the public resale of restricted and control securities if a number of conditions are met. Meeting the conditions includes holding the shares for a certain period of time, having adequate current information, looking into a trading volume formula, and filing a notice of the proposed sale with the SEC.

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, (ii) we are subject to the Exchange Act periodic reporting requirements and have filed all required reports for a least 90 days before the sale, and (iii) we are not and have never been a shell company (a company having no or nominal operations and either (1) no or nominal assets, (2) assets consisting solely of cash and cash equivalents, or (3) assets consisting of any amount of cash and cash equivalents and nominal other assets). If we ever become a shell company, Rule 144 would be unavailable until one year following the date we cease to be a shell company and file Form 10 information with the SEC ceasing to be a shell company, provided that we are then subject to the reporting requirements of section 13 or 15(d) of the Exchange Act and have filed all reports and other materials required to be filed by section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that we were required to file such reports and materials), other than Form 8-K reports.

Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which would equal approximately 388,000 shares, based on the number of shares of our common stock outstanding as of September 20, 2023 (44,231,402), and assuming the 1,406,250 shares being registered in the Offering are issued and sold; or
- The average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

At the expiration of the one-year holding period, a person who was not one of our affiliates at any time during the three months preceding a sale would be entitled to sell an unlimited number of shares of our common stock without restriction. A person who was one of our affiliates at any time during the three months preceding a sale would remain subject to the volume restrictions described above.

Sales under the Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

## LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon by J.P. Galda & Co., Ardmore, Pennsylvania. Blank Rome LLP, New York, New York is acting as counsel for the underwriters in this offering.



## EXPERTS

Except as disclosed herein, no expert or counsel named in this prospectus as having prepared or certified any part of this prospectus or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis or had, or is to receive, in connection with the offering, a substantial interest, directly or indirectly, in the registrant or its subsidiary. Nor was any such person connected with the Company or any of its parents, or subsidiaries, as a promoter, managing or principal underwriter, voting trustee, director, officer or employee.

The financial statements of Sigyn Therapeutics, Inc. as of December 31, 2022 and 2021 and for each of the years then ended, have been included herein in reliance on the reports of Kreit & Chiu, an independent registered public accounting firm, given on the authority of that firm as experts in auditing and accounting.

## CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

During the two most recent fiscal years ended December 31, 2022 and 2021, there have been no changes in or disagreements with our independent registered public accounting firm on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements if not resolved to the satisfaction of the Former Accounting Firm would have caused them to make reference thereto in their report on the financial statements.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 under the Securities Act with the SEC for the securities offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules which are part of the registration statement. For additional information about our securities, and as we refer you to the registration statement and the accompanying exhibits and schedules. Statements contained in this prospectus regarding the contents of any contract or any other documents to which we refer are not necessarily complete. In each instance, reference is made to the copy of the contract or document filed as an exhibit to the registration statement, and each statement is qualified in all respects by that reference. Our filings, including the registration statement, will also be available to you on the Internet web site maintained by the SEC at <http://www.sec.gov>.

## DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITY

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore,

SIGYN THERAPEUTICS, INC.

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
of Sigyn Therapeutics, Inc.

### *Opinion on the Financial Statements*

We have audited the accompanying consolidated balance sheets of Sigyn Therapeutics, Inc. (the Company) as of December 31, 2022 and 2021, and the related consolidated statements of operations, changes in shareholders' deficit, and cash flows for each of the two years ended December 31, 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

### *The Company's Ability to Continue as a Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a net capital deficiency, and negative cash flows from operating activities, therefore, the Company has stated that substantial doubt exists about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### *Basis for Opinion*

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### *Critical Audit Matters*

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

#### Going Concern

As described further in Note 2 to the consolidated financial statements, the Company has incurred losses each year from inception through December 31, 2022 and expects to incur additional losses in the future.

We determined the Company's ability to continue as a going concern is a critical audit matter due to the estimation and uncertainty regarding the Company's future cash flows and the risk of bias in management's judgments and assumptions in estimating these cash flows.

Our audit procedures related to the Company's assertion on its ability to continue as a going concern included the following, among others:

We reviewed the Company's working capital and liquidity ratios and forecasted revenue, operating expenses, and uses and sources of cash used in management's assessment of whether the Company has sufficient liquidity to fund operations for at least one year from the financial statement issuance date. This testing included inquiries with management, comparison of prior period forecasts to actual results, consideration of positive and negative evidence impacting management's forecasts, the Company's financing arrangements in place as of the report date, market and industry factors and consideration of the Company's relationships with its financing partners.

### *Kreit & Chiu CPA LLP*

(formerly known as Paris Kreit & Chiu CPA LLP)

We have served as the Company's auditor since 2021.

New York, NY

March 31, 2023

**SIGYN THERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 8,356	\$ 340,956
Inventories	50,000	50,000
Other current assets	11,942	2,075
<b>Total current assets</b>	<b>70,298</b>	<b>393,031</b>
Property and equipment, net	22,052	28,046
Intangible assets, net	2,100	5,700
Operating lease right-of-use assets, net	217,718	262,771
Other assets	20,711	20,711
<b>Total assets</b>	<b>\$ 332,879</b>	<b>\$ 710,259</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 327,517	\$ 39,674
Accrued payroll and payroll taxes	30,124	1,072
Short-term convertible notes payable, less unamortized debt issuance costs of \$642,660 and \$53,614, respectively	1,636,656	647,202
Current portion of operating lease liabilities	53,200	46,091
Other current liabilities	1,197	179
<b>Total current liabilities</b>	<b>2,048,694</b>	<b>734,218</b>
Long-term liabilities:		
Operating lease liabilities, net of current portion	187,425	240,625
<b>Total long-term liabilities</b>	<b>187,425</b>	<b>240,625</b>
<b>Total liabilities</b>	<b>2,236,119</b>	<b>974,843</b>
Stockholders' deficit:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2022 and 2021, respectively	-	-
Common stock, \$0.0001 par value, 1,000,000,000 shares authorized; 38,263,813 and 37,295,813 shares issued and outstanding at December 31, 2022 and 2021, respectively	3,826	3,730
Additional paid-in capital	5,288,510	3,997,445
Accumulated deficit	(7,195,576)	(4,265,759)
<b>Total stockholders' deficit</b>	<b>(1,903,240)</b>	<b>(264,584)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 332,879</b>	<b>\$ 710,259</b>

See accompanying notes to consolidated financial statements

**SIGYN THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,	
	2022	2021
<b>Net revenues</b>	\$ -	\$ -
Gross Profit	-	-
Operating expenses:		
Marketing expenses	457	-
Research and development	657,657	734,014
General and administrative	1,489,151	1,274,203
Total operating expenses	<u>2,147,265</u>	<u>2,008,217</u>
Loss from operations	<u>(2,147,265)</u>	<u>(2,008,217)</u>
Other expense:		
Impairment of assets	-	536,047
Interest expense	438	30,867
Interest expense - debt discount	646,302	368,205
Interest expense - original issuance costs	135,812	61,283
Total other expense	<u>782,552</u>	<u>996,402</u>
Loss before income taxes	(2,929,817)	(3,004,619)
Income taxes	-	-
<b>Net loss</b>	<u>\$ (2,929,817)</u>	<u>\$ (3,004,619)</u>
Net loss per share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.08)</u>
Weighted average number of shares outstanding		
Basic and diluted	<u>37,396,591</u>	<u>36,396,594</u>

See accompanying notes to consolidated financial statements

**SIGYN THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Deficit</u>
	<u>Shares</u>	<u>Amount</u>			
<b>Balance as of January 1, 2021</b>	<b>35,201,513</b>	<b>\$ 3,520</b>	<b>\$ 1,356,799</b>	<b>\$ (1,261,140)</b>	<b>\$ 99,179</b>
Common stock issued to third party for services	188,000	19	249,081	-	249,100
Warrants issued to third parties in conjunction with debt issuance	-	-	188,069	-	188,069
Beneficial conversion feature in conjunction with debt issuance	-	-	101,972	-	101,972
Common stock and warrants issued for cash	1,492,000	149	1,864,851	-	1,865,000
Common stock issued in conjunction with cashless exercise of warrants	57,157	6	(6)	-	-
Common stock issued to third parties in conjunction with conversion of debt	357,143	36	236,679	-	236,715
Net loss	-	-	-	(3,004,619)	(3,004,619)
<b>Balance as of December 31, 2021</b>	<b>37,295,813</b>	<b>\$ 3,730</b>	<b>\$ 3,997,445</b>	<b>\$ (4,265,759)</b>	<b>\$ (264,584)</b>
Warrants issued to third parties in conjunction with debt issuance	-	-	793,039	-	793,039
Beneficial conversion feature in conjunction with debt issuance	-	-	273,700	-	273,700
Amortization of warrants issued in connection with a debt modification	-	-	147,720	-	147,720
Common stock issued to third parties in conjunction with conversion of debt	968,000	96	145,104	-	145,200
Fees associated with filing of Form S-1	-	-	(68,498)	-	(68,498)
Net loss	-	-	-	(2,929,817)	(2,929,817)
<b>Balance as of December 31, 2022</b>	<b>38,263,813</b>	<b>\$ 3,826</b>	<b>\$ 5,288,510</b>	<b>\$ (7,195,576)</b>	<b>\$ (1,903,240)</b>

See accompanying notes to consolidated financial statements

**SIGYN THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,929,817)	\$ (3,004,619)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation expense	6,854	2,946
Amortization expense	3,600	16,205
Stock issued for services	-	249,100
Accretion of debt discount	646,302	368,205
Accretion of original issuance costs	135,812	61,283
Interest expense converted to notes payable	-	30,800
Impairment of assets	-	536,047
<b>Changes in operating assets and liabilities:</b>		
Other current assets	(9,867)	(2,075)
Other assets	-	(20,711)
Accounts payable	287,843	23,669
Accrued payroll and payroll taxes	29,052	(58,635)
Other current liabilities	(21)	23,603
<b>Net cash used in operating activities</b>	<b>(1,830,242)</b>	<b>(1,774,182)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(860)	(29,264)
<b>Net cash used in investing activities</b>	<b>(860)</b>	<b>(29,264)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from short-term convertible notes	1,567,000	250,000
Advance from shareholder	-	-
Repayment of short-term convertible notes	-	(55,000)
Common stock issued for cash	-	1,865,000
Fees associated with filing of Form S-1	(68,498)	-
<b>Net cash provided by financing activities</b>	<b>1,498,502</b>	<b>2,060,000</b>
<b>Net (decrease) increase in cash</b>	<b>(332,600)</b>	<b>256,554</b>
Cash at beginning of period	\$ 340,956	\$ 84,402
<b>Cash at end of period</b>	<b>\$ 8,356</b>	<b>\$ 340,956</b>
<b>Supplemental disclosures of cash flow information:</b>		
<b>Cash paid during the period for:</b>		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
<b>Non-cash investing and financing activities:</b>		
Beneficial conversion feature in conjunction with debt issuance	\$ 273,700	\$ 101,972
Amortization of warrants issued in connection with a debt modification	\$ 147,720	\$ -
Warrants issued to third parties in conjunction with debt issuance	\$ 793,039	\$ 188,069
Original issue discount issued in conjunction with debt	\$ 156,700	\$ 126,030
Common stock issued to third parties in conjunction with conversion of debt	\$ 145,104	\$ 236,715

See accompanying notes to consolidated financial statements

**SIGYN THERAPEUTICS, INC.**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021**

**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.

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 United States Patent and Trademark Office (“USPTO”). The provisional patent submission established the priority date of our now patent pending invention and provides us up to one year to submit a non-provisional patent application. On October 13, 2022, we subsequently disclosed that trademark applications to register ChemoPrep™ and ChemoPure™ were 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 United States Patent and Trademark Office (“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. 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 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.

As of March 31, 2023, we have a total 42,713,325 shares issued and outstanding, of which 17,073,325 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 \$7,195,576 at December 31, 2022, had a working capital deficit of approximately \$1,978,396 at December 31, 2022, had net losses of \$2,929,817 and \$3,004,619 for the years ended December 31, 2022 and 2021, respectively, and net cash used in operating activities of \$1,830,242 and \$1,774,182 for the years ended December 31, 2022 and 2021, 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.

## **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: common stock valuation, and the recoverability of intangibles. 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 consolidated Statements of Operations.

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

## **Advertising and Marketing Costs**

Advertising expenses are recorded as general and administrative expenses when they are incurred. The Company had \$457 of advertising expenses for the year ended December 31, 2022 and had no advertising expenses for the year ended December 31, 2021.

## **Research and Development**

All research and development costs are expensed as incurred. The Company incurred research and development expense of \$657,657 and \$734,014 for the years ended December 31, 2022 and 2021, 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 December 31, 2022 and 2021, the Company carried primarily loose sapphire jewels, jewelry for sale on our website, 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 December 31, 2022. 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.

Based on the significant advancement of Sigyn Therapy, the Company decided in the 4<sup>th</sup> quarter of 2021 to assess the value of retail business operations that were a focus of the Company prior to the merger transaction consummated on October 19, 2020.

Related to this assessment, management determined the wholesale liquidation value of its sapphire gem inventory to be 5-10% of the previously reported retail value, based on communications with certified gemologists, the variance between retail and wholesale valuations, and current market conditions. As a result, the Company has valued the inventory at \$50,000 and recorded an impairment of assets of \$536,047 in the year ended December 31, 2021.

## 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.

## Intangible Assets

Intangible assets consist primarily of website development costs. Our intangible assets are being amortized on a straight-line basis over a period of three years.

## 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 December 31, 2022 and 2021, 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 December 31, 2022 and 2021, the fair value of cash, accounts payable, accrued expenses, 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 December 31, 2022 and 2021 and no charges or credits to income for the years ended December 31, 2022 and 2021.

### ***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 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 consolidated balance sheets.

If the conversion feature does not qualify for either the derivative treatment or as a BCF, 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 505, *Equity Based Payments to Non-Employees*, issuances of the Company’s common stock or warrants for acquiring goods or services are measured at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. The measurement date for the fair value of the equity instruments issued to consultants or vendors is determined at the earlier of (i) the date at which a commitment for performance to earn the equity instruments is reached (a “performance commitment” which would include a penalty considered to be of a magnitude that is a sufficiently large disincentive for nonperformance) or (ii) the date at which performance is complete. Although situations may arise in which counter performance may be required over a period of time, the equity award granted to the party performing the service is fully vested and non-forfeitable on the date of the agreement. As a result, in this situation in which vesting periods do not exist as the instruments fully vested on the date of agreement, the Company determines such date to be the measurement date and will record the estimated fair market value of the instruments granted as a prepaid expense and amortize such amount to general and administrative expense in the accompanying statement of operations over the contract period. When it is appropriate for the Company to recognize the cost of a transaction during financial reporting periods prior to the measurement date, for purposes of recognition of costs during those periods, the equity instrument is measured at the then-current fair values at each of those interim financial reporting dates.

### **Reclassifications**

An adjustment has been made to the Consolidated Balance Sheets as of December 31, 2021, to reclass \$1,072 of other current liabilities previously classified in accrued payroll and payroll taxes. These reclassifications had no effect on the reported results of operations.

### **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**

In August 2020, the FASB issued ASU No. 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This ASU is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company adopted ASU No. 2020-06 in the first quarter of fiscal 2021, coinciding with the standard’s effective date, and had an immaterial impact from this standard.

Other recently issued accounting updates are not expected to have a material impact on the Company’s consolidated financial statements.

### **NOTE 4 – PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following as of:

	<u>Estimated Life</u>	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Office equipment	5 years	\$ 29,041	\$ 28,181
Computer equipment	3 years	3,157	3,157
Accumulated depreciation		<u>(10,146)</u>	<u>(3,292)</u>
		<u>\$ 22,052</u>	<u>\$ 28,046</u>

Depreciation expense was \$6,854 and \$2,946 for the years ended December 31, 2022 and 2021, respectively, and is classified in general and administrative expenses in the Consolidated Statements of Operations.

## NOTE 5 – INTANGIBLE ASSETS

Intangible assets consisted of the following as of:

	Estimated life	December 31, 2022	December 31, 2021
Website	3 years	\$ 10,799	\$ 10,799
Accumulated amortization		(8,699)	(5,099)
		<u>\$ 2,100</u>	<u>\$ 5,700</u>

As of December 31, 2022, estimated future amortization expenses related to intangible assets were as follows:

	Intangible Assets
2023	\$ 2,100
	<u>\$ 2,100</u>

The Company had amortization expense of \$3,600 and \$16,205 for the years ended December 31, 2022 and 2021, respectively.

On January 8, 2020, James Joyce, the Company's CEO and Craig Roberts, the Company's CTO, assigned to the Company the rights to patent 62/881,740 pertaining to the devices, systems and methods for the broad-spectrum reduction of pro-inflammatory cytokines in blood.

## NOTE 6 – CONVERTIBLE PROMISSORY DEBENTURES

Convertible notes payable consisted of the following:

	December 30, 2022	December 31, 2021
<i>January 28, 2020 (\$457,380) – 0% interest per annum outstanding principal and interest due October 20, 2022 (“Note 1”)</i>	\$ 457,380	\$ 457,380
<i>June 23, 2020 (\$60,500) – 0% interest per annum outstanding principal and interest due October 20, 2022 (“Note 2”)</i>	60,500	60,500
<i>September 17, 2020 (\$199,650) – 0% interest per annum outstanding principal and interest due October 20, 2022. On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares (“Note 3”).</i>	182,936	182,936
<i>March 23, 2022 (\$220,000) – 0% interest per annum outstanding principal and interest due March 23, 2023 (“Note 4”)</i>	220,000	-
<i>April 28, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due April 28, 2023 (“Note 5”)</i>	110,000	-
<i>May 10, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due May 10, 2023 (“Note 6”)</i>	110,000	-
<i>June 1, 2022 (\$55,000) – 0% interest per annum outstanding principal and interest due June 1, 2023 (“Note 7”)</i>	55,000	-
<i>June 22, 2022 (\$82,500) – 0% interest per annum outstanding principal and interest due June 22, 2023 (“Note 8”)</i>	82,500	-
<i>July 2022 (\$341,000) – 0% interest per annum outstanding principal and interest due various dates July 2023 (“Note 9”)</i>	341,000	-
<i>August 31, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due August 31, 2023 (“Note 10”)</i>	110,000	-
<i>September 9, 2022 (\$82,500) – 0% interest per annum outstanding principal and interest due September 9, 2023 (“Note 11”)</i>	82,500	-
<i>September 20, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due September 20, 2023 (“Note 12”)</i>	110,000	-
<i>October 20, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due October 20, 2023 (“Note 13”)</i>	110,000	-
<i>November 9, 2022 (\$82,500) – 0% interest per annum outstanding principal and interest due November 9, 2023 (“Note 14”)</i>	82,500	-
<i>November 14, 2022 (\$55,000) – 0% interest per annum outstanding principal and interest due November 14, 2023 (“Note 15”)</i>	55,000	-
<i>December 22, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due September 9, 2023 (“Note 16”)</i>	110,000	-
<b>Total convertible notes payable</b>	<u>2,279,316</u>	<u>700,816</u>
<b>Original issue discount</b>	<u>(74,502)</u>	<u>(53,614)</u>
<b>Beneficial conversion feature</b>	<u>(175,275)</u>	<u>-</u>
<b>Debt discount</b>	<u>(392,883)</u>	<u>-</u>
<b>Total convertible notes payable</b>	<u>\$ 1,636,656</u>	<u>\$ 647,202</u>



Principal payments on convertible promissory debentures are due as follows:

Year ending December 31,	
2024	\$ 2,279,316
	<u>\$ 2,279,316</u>

Changes in convertible notes were as follows:

	Note 1	Note 2	Note 3	Note 4	Note 5	Note 6	Note 7	Note 8	Note 9	Note 10	Note 11	Note 12	Note 13	Note 14	Note 15	Note 16	Other	Totals
Convertible notes payable as of January 1, 2021	\$ 385,000	\$ 50,000	\$ 181,500	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 616,500
Extension of convertible note payable	72,380	10,500	18,150	-	-	-	-	-	-	-	-	-	-	-	-	-	-	101,030
Exchange of convertible note payable for common stock	-	-	(16,714)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(16,714)
Convertible notes payable, net, as of December 31, 2021	<u>457,380</u>	<u>60,500</u>	<u>182,936</u>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	<u>700,816</u>
Convertible notes payable issued in 2022	-	-	-	220,000	110,000	110,000	55,000	82,500	341,000	110,000	82,500	110,000	110,000	82,500	55,000	110,000	-	1,578,500
Convertible notes payable as of December 31, 2022	<u>\$ 457,380</u>	<u>\$ 60,500</u>	<u>\$ 182,936</u>	<u>\$ 220,000</u>	<u>\$ 110,000</u>	<u>\$ 110,000</u>	<u>\$ 55,000</u>	<u>\$ 82,500</u>	<u>\$ 341,000</u>	<u>\$ 110,000</u>	<u>\$ 82,500</u>	<u>\$ 110,000</u>	<u>\$ 110,000</u>	<u>\$ 82,500</u>	<u>\$ 55,000</u>	<u>\$ 110,000</u>	<u>\$ -</u>	<u>\$ 2,279,316</u>

Changes in note discounts were as follows:

	Note 1	Note 2	Note 3	Note 4	Note 5	Note 6	Note 7	Note 8	Note 9	Note 10	Note 11	Note 12	Note 13	Note 14	Note 15	Note 16	Other	Totals	
Note discounts as of January 1, 2020	\$ 73,418	\$ 5,830	\$ 18,584	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 97,832
Note discounts in conjunction with extension of convertible note	41,580	5,500	18,150	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	65,230
2021 accretion of note discounts	(80,822)	(6,809)	(21,817)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	(109,448)
Note discounts as of December 31, 2021	34,176	4,521	14,917	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	53,614
Note discounts issued in conjunction with debt	-	-	-	113,418	44,786	44,787	22,794	34,861	140,289	64,104	82,500	110,000	110,000	82,500	55,000	110,000	-	-	1,015,039
2022 accretion of note discounts	(34,176)	(4,521)	(14,917)	(87,938)	(30,308)	(28,836)	(13,301)	(18,336)	(70,720)	(32,316)	(39,994)	(49,874)	(23,671)	(12,822)	(7,726)	(6,537)	50,000	-	(425,993)
Note discounts as of December 31, 2022	\$ -	\$ -	\$ -	\$ 25,480	\$ 14,478	\$ 15,951	\$ 9,493	\$ 16,525	\$ 69,569	\$ 31,788	\$ 42,506	\$ 60,126	\$ 86,329	\$ 69,678	\$ 47,274	\$ 103,463	\$ 50,000	\$ -	\$ 592,660
Convertible notes payable, net, as of December 31, 2021	\$423,204	\$55,979	\$168,019	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 647,202
Convertible notes payable, net, as of December 31, 2022	\$457,380	\$60,500	\$182,936	\$194,520	\$ 95,522	\$ 94,049	\$ 45,507	\$ 65,975	\$271,431	\$ 78,212	\$ 39,994	\$ 49,874	\$ 23,671	\$ 12,822	\$ 7,726	\$ 6,537	\$(50,000)	\$ -	\$1,636,656
2021 Effective interest rate	11%	11%	12%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%
2022 Effective interest rate	7%	7%	8%	40%	28%	26%	24%	22%	21%	29%	48%	45%	22%	16%	14%	6%	-%	-%	19%

**Current Noteholders**

**Osher – \$110,000 (Note 16)**

On December 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due December 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$55,000 (Note 15)**

On November 14, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due November 14, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 366,667 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher noteholder for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$82,500 (Note 14)**

On November 9, 2022, 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) \$82,500 aggregate principal amount of Note due November 9, 2023 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 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 13)**

On October 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due October 20, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 12)**

On September 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due September 20, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$82,500 (Note 11)**

On September 9, 2022, 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) \$82,500 aggregate principal amount of Note due September 9, 2023 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 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 10)**

On August 31, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due August 31, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Other – \$341,000 (Note 9)**

In July 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “July 2022 Notes”) totaling (i) \$341,000 aggregate principal amount of Note (total of \$310,000 cash was received) due in various dates in July 2023 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 676,936 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

**Osher – \$82,500 (Note 8)**

On June 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$82,500 aggregate principal amount of Note due June 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 165,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$55,000 (Note 7)**

On June 1, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due June 1, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 110,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$110,000 (Note 6)**

On May 10, 2022, 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) \$110,000 aggregate principal amount of Note due May 10, 2023 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 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 5)**

On April 28, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due April 28, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 4)**

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Brio – \$110,000 (Note 4)**

On March 23, 2022, 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) \$110,000 aggregate principal amount of Note due March 23, 2023 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 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$199,650 (Note 3)**

On September 17, 2020 (the “Original Issue Date”), 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) \$181,500 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due September 30, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 8,250 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$165,000 which was issued at a \$16,500 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated September 17, 2020, for the number of warrant shares from 8,250 warrant shares to 465,366 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from September 30, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$60,500 (as amended on October 20, 2020 to \$55,000) (Note 2)**

On June 23, 2020 (the "Original Issue Date"), 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) \$50,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the "Note") due June 23, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 10,000 shares of the Company's Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at a \$0 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Note for the aggregate principal amount from \$50,000 to \$55,000. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at an amended \$4,995 original issue discount from the face value of the Note.
- The parties amended the Warrants dated June 23, 2020, for the number of warrant shares from 10,000 warrant shares to 141,020 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows (see Note 12):

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

### **Osher – \$457,380 (Note 1)**

On January 28, 2020 (the “Original Issue Date”), the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$385,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due January 26, 2021, 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 80,209 shares of the Company’s Common Stock at an exercise price of \$7.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was \$350,005 which was issued at a \$34,995 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.094 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated January 28, 2020, for the number of warrant shares from 80,209 warrant shares to 4,113,083 warrant shares at an exercise price of \$0.14 per share.
- The parties amended the Note to provide for interest at 8% per annum.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

### **Previous Noteholders**

#### **Other – \$145,200**

On November 21, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with a third party investor of (i) \$145,200 aggregate principal amount of Note due November 21, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 968,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$132,000 which was issued at a \$13,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On November 23, 2022, third party investor elected to convert the aggregate principal amount of the Note, \$145,200, into 968,000 common shares.

All other previous notes were detailed in our Form 10-K filed on March 31, 2022. No changes occurred related to these notes during the period covered by this Form 10-Q.

### **NOTE 7 – STOCKHOLDERS’ DEFICIT**

#### ***Preferred Stock***

The Company authorized 10,000,000 shares of par value \$0.0001 preferred stock, of which none are issued and outstanding at December 31, 2022 and 2021, respectively.

### Common Stock

The Company has authorized 1,000,000,000 shares of par value \$0.0001 common stock, of which 38,263,813 and 37,295,813 shares are outstanding as of December 31, 2022 and 2021, respectively.

### Warrants

On October 22, 2021, the Company and Osher amended convertible debt agreements for the maturity date from October 20, 2021 to October 20, 2022. In exchange for the extension of the Note, the Company issued Osher 450,000 warrants to purchase an aggregate of 450,000 shares of the Company's common stock, valued at \$197,501 (based on the Black Scholes valuation model on the date of grant) (see Note 6). The warrants are exercisable for a period of five years at \$1.00 per share in whole or in part, as either a cash exercise or as a cashless exercise, and fully vest at grant date. The Company accreted the value of the warrants ratably through October 20, 2022. The Company recorded \$147,720 and \$40,041 for the years ended December 31, 2022 and 2021, respectively, and is classified in other expenses in the consolidated Statements of Operations. See Notes 6 for further warrant discussions.

### 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:

	Years ended December 31,	
	2022	2021
Operating lease expense	\$ 71,676	\$ 41,811
Short term lease cost	\$ -	\$ -
Total lease expense	\$ 71,676	\$ 41,811



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

<u>Years ended December 31,</u>	<u>2022</u>	<u>2021</u>
Operating cash flows from operating leases	\$ 72,714	\$ 17,866
Cash paid for amounts included in the measurement of lease liabilities	\$ 72,714	\$ 17,866
Weighted-average remaining lease term—operating leases	3.67 years	4.67 years
Weighted-average discount rate—operating leases	10%	10%

In accordance with ASC 842, maturities of operating lease liabilities as of December 31, 2022 were as follows:

<u>Year ending:</u>	<u>Operating Lease</u>
2023	\$ 74,895
2024	77,142
2025	79,456
2026	54,225
Total undiscounted cash flows	<u>\$ 285,718</u>
Reconciliation of lease liabilities:	
Weighted-average remaining lease terms	3.67 years
Weighted-average discount rate	10%
Present values	<u>\$ 240,625</u>
Lease liabilities—current	53,200
Lease liabilities—long-term	187,425
Lease liabilities—total	<u>\$ 240,625</u>
Difference between undiscounted and discounted cash flows	<u>\$ 45,093</u>

Operating lease cost was \$71,676 and \$41,811 for the years ended December 31, 2022 and 2021, respectively.

#### NOTE 9 – RELATED PARTY TRANSACTIONS

Other than as set forth below, and as disclosed in Notes 5 and 7, there have not been any transaction entered into or been a participant in which a related person had or will have a direct or indirect material interest.

##### Employment Agreements

Mr. Joyce receives an annual base salary of \$455,000, plus bonus compensation not to exceed 50% of salary. Mr. Joyce's employment also provides for medical insurance, disability benefits and one year of severance pay if his employment is terminated without cause or due to a change in control. Additionally, the Company has agreed to maintain a beneficial ownership target of 9% for Mr. Joyce. The Company incurred compensation expense of \$453,067 and \$496,125 (including \$18,542 of 2020 payroll paid in 2021), and employee benefits of \$48,811 and \$31,126, for the years ended December 31, 2022 and 2021, respectively.

Signyn had no employment agreement with its CTO but still incurred compensation on behalf of the CTO. The Company incurred compensation expense of \$233,678 and \$259,000, and employee benefits of \$25,312 and \$21,704, for the years ended December 31, 2022 and 2021, respectively.

#### NOTE 10 – INCOME TAXES

At December 31, 2021, net operating loss carry forwards for Federal and state income tax purposes totaling approximately \$1,408,000 available to reduce future income which under the Tax Cuts and Jobs Act of 2018, allows for an indefinite carryforward period, with carryforwards limited to 80% of each subsequent year's net income. There is no income tax affect due to the recognition of a full valuation allowance on the expected tax benefits of future loss carry forwards based on uncertainty surrounding realization of such assets.

A reconciliation of the statutory income tax rates and the effective tax rate is as follows:

	December 31,	
	2022	2021
Statutory U.S. federal rate	21.0%	21.0%
State income tax, net of federal benefit	7.0%	7.0%
Permanent differences	(7.5)%	(4.0)%
Valuation allowance	(20.5)%	(24.0)%
	<u>0.0%</u>	<u>0.0%</u>
Provision for income taxes	<u>0.0%</u>	<u>0.0%</u>

The tax effects of the temporary differences and carry forwards that give rise to deferred tax assets consist of the following:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carry forwards	\$ 1,674,531	\$ 1,073,527
Valuation allowance	(1,674,531)	(1,073,527)
	<u>\$ -</u>	<u>\$ -</u>

Major tax jurisdictions are the United States and California. All of the tax years will remain open three and four years for examination by the Federal and state tax authorities, respectively, from the date of utilization of the net operating loss. There are no tax audits pending.

#### NOTE 11 – 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 Years Ended December 31,	
	2022	2021
Convertible notes payable	11,726,940	5,489,940
Warrants to purchase shares of common stock	15,192,493	7,992,558
<b>Total potentially dilutive shares</b>	<b>26,919,433</b>	<b>13,482,498</b>

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

	Years Ended December 31,	
	2022	2021
Net loss attributable to the common stockholders	\$ (2,929,817)	\$ (3,004,619)
Basic weighted average outstanding shares of common stock	37,396,591	36,396,594
Dilutive effect of options and warrants	-	-
<b>Diluted weighted average common stock and common stock equivalents</b>	<b>37,396,591</b>	<b>36,396,594</b>
Loss per share:		
Basic and diluted	\$ (0.08)	\$ (0.08)

## NOTE 12 – 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.

### Media Advertising Agreement

On May 13, 2021, the Company mutually terminated the Media Relations Agreement (“Media Agreement”) with a third party for marketing and to promote brand awareness that was entered into on February 10, 2021. The Company agreed to pay \$25,000 due in cash at the execution of the Media Agreement. No shares were issued in conjunction with the Media Agreement.

### 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 13 – SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2022 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 December 31, 2022, except for the following:

### Warrants

In March 2023, the Company offered a short-term inducement to the Company’s warrant holders in which the Company will issue one share of the Company’s common stock in exchange for each two warrants returned to the Company to be cancelled. All other terms of the original grants remain the same. A total of 8,899,019 warrants were exchanged for 4,449,512 shares of the Company’s common stock through March 24, 2023.

### 2023 Convertible Notes

During the three months ended March 31, 2023, the Company entered into an Original Issue Discount Senior Convertible Debentures totaling (i) \$970,200 aggregate principal amount of Note (total of \$882,000 cash was received) due in various dates in January through March 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 6,468,004 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.15 per share.

**SIGYN THERAPEUTICS, INC.**  
**UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>June 30, 2023</b>	<b>December 31, 2022</b>
<b>ASSETS</b>		
Current assets:		
Cash	\$ 23,633	\$ 8,356
Inventories	50,000	50,000
Other current assets	55,162	11,942
Total current assets	128,795	70,298
Property and equipment, net	18,622	22,052
Intangible assets, net	300	2,100
Operating lease right-of-use assets, net	193,389	217,718
Other assets	20,711	20,711
<b>Total assets</b>	<b>\$ 361,817</b>	<b>\$ 332,879</b>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 339,944	\$ 327,517
Accrued payroll and payroll taxes	186,402	30,124
Advance from shareholder	30,000	-
Short-term convertible notes payable, less unamortized debt issuance costs of \$421,235 and \$642,660, respectively	2,630,281	1,636,656
Current portion of operating lease liabilities	57,049	53,200
Other current liabilities	2,261	1,197
Total current liabilities	3,245,937	2,048,694
Long-term liabilities:		
Operating lease liabilities, net of current portion	158,098	187,425
Total long-term liabilities	158,098	187,425
<b>Total liabilities</b>	<b>3,404,035</b>	<b>2,236,119</b>
Stockholders' deficit:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized; 1,215 and none shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	-	-
Common stock, \$0.0001 par value, 1,000,000,000 shares authorized; 44,231,402 and 38,263,813 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	4,423	3,826
Additional paid-in capital	6,213,095	5,288,510
Accumulated deficit	(9,259,736)	(7,195,576)
Total stockholders' deficit	(3,042,218)	(1,903,240)
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 361,817</b>	<b>\$ 332,879</b>

See accompanying notes to unaudited condensed consolidated financial statements.

**SIGYN THERAPEUTICS, INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<u>Six Months Ended June 30,</u>		<u>Three Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
<b>Net revenues</b>	\$ -	\$ -	\$ -	\$ -
Gross Profit	-	-	-	-
Operating expenses:				
Marketing expenses	284	381	100	131
Stock based compensation	75,000	-	37,500	-
Research and development	367,002	383,025	219,159	154,683
General and administrative	652,981	758,625	317,250	377,981
Total operating expenses	<u>1,095,267</u>	<u>1,142,031</u>	<u>574,009</u>	<u>532,795</u>
Loss from operations	<u>(1,095,267)</u>	<u>(1,142,031)</u>	<u>(574,009)</u>	<u>(532,795)</u>
Other expense:				
Modification of warrants	(224,362)	-	(208,556)	-
Interest expense	1,630	31	491	-
Interest expense - debt discount	1,088,849	160,854	297,141	108,597
Interest expense - original issuance costs	102,776	41,455	60,039	24,933
Total other expense	<u>968,893</u>	<u>202,340</u>	<u>149,115</u>	<u>133,530</u>
Loss before income taxes	(2,064,160)	(1,344,371)	(723,124)	(666,325)
Income taxes	-	-	-	-
<b>Net loss</b>	<u>\$ (2,064,160)</u>	<u>\$ (1,344,371)</u>	<u>\$ (723,124)</u>	<u>\$ (666,325)</u>
Net loss per share, basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.04)</u>	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>
Weighted average number of shares outstanding				
Basic and diluted	<u>40,911,801</u>	<u>37,295,813</u>	<u>43,331,086</u>	<u>37,295,813</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balance as of December 31, 2021</b>	-	\$ -	37,295,803	\$ 3,730	\$ 3,997,445	\$ (4,265,759)	\$ (264,584)
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	162,362	-	162,362
Amortization of warrants issued in connection with a debt modification	-	-	-	-	48,699	-	48,699
Net loss	-	-	-	-	-	(678,046)	(678,046)
<b>Balance as of March 31, 2022</b>	-	\$ -	37,295,803	\$ 3,730	\$ 4,208,506	\$ (4,943,805)	\$ (731,569)
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	168,991	-	168,991
Amortization of warrants issued in connection with a debt modification	-	-	-	-	49,240	-	49,240
Fees associated with filing of Form S-1	-	-	-	-	(3,498)	-	(3,498)
Net loss	-	-	-	-	-	(666,325)	(666,325)
<b>Balance as of June 30, 2022</b>	-	\$ -	37,295,803	\$ 3,730	\$ 4,423,239	\$ (5,610,130)	\$ (1,183,161)
<b>Balance as of December 31, 2022</b>	-	\$ -	38,263,813	\$ 3,826	\$ 5,288,510	\$ (7,195,576)	\$ (1,903,240)
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	578,016	-	578,016
Beneficial conversion feature in conjunction with debt issuance	-	-	-	-	303,984	-	303,984
Stock based compensation	-	-	-	-	37,500	-	37,500
Modification of warrants	-	-	4,541,012	455	(16,261)	-	(15,806)
Fees associated with filing of Form S-1	-	-	-	-	(5,456)	-	(5,456)
Net loss	-	-	-	-	-	(1,341,036)	(1,341,036)
<b>Balance as of March 31, 2023</b>	-	\$ -	42,804,825	\$ 4,281	\$ 6,186,293	\$ (8,536,612)	\$ (2,346,038)
Conversion of common stock for Series A preferred stock	1,215	-	(6,105,528)	(611)	611	-	-
Stock based compensation	-	-	-	-	37,500	-	37,500
Modification of warrants	-	-	6,289,105	629	(209,185)	-	(208,556)
Common stock issued to third parties in conjunction with conversion of debt	-	-	1,243,000	124	197,876	-	198,000
Net loss	-	-	-	-	-	(723,124)	(723,124)
<b>Balance as of June 30, 2023</b>	<b>1,215</b>	<b>\$ -</b>	<b>44,231,402</b>	<b>\$ 4,423</b>	<b>\$ 6,213,095</b>	<b>\$ (9,259,736)</b>	<b>\$ (3,042,218)</b>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,064,160)	\$ (1,344,371)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	3,430	3,423
Amortization expense	1,800	1,800
Stock based compensation	75,000	-
Accretion of debt discount	1,088,849	160,854
Accretion of original issuance costs	102,776	41,455
Modification of warrants	(224,362)	-
Changes in operating assets and liabilities:		
Other current assets	(43,220)	(45,631)
Accounts payable	12,427	259,464
Accrued payroll and payroll taxes	156,278	68,698
Other current liabilities	(85)	-
Net cash used in operating activities	<b>(891,267)</b>	<b>(854,308)</b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	-	(859)
Net cash used in investing activities	<b>-</b>	<b>(859)</b>
<b>Cash flows from financing activities:</b>		
Proceeds from short-term convertible notes	882,000	525,000
Advance from shareholder	30,000	-
Fees associated with filing of Form S-1	(5,456)	(3,498)
Net cash provided by financing activities	<b>906,544</b>	<b>521,502</b>
Net (decrease) increase in cash	<b>15,277</b>	<b>(333,665)</b>
Cash at beginning of period	8,356	340,956
Cash at end of period	<b>\$ 23,633</b>	<b>\$ 7,291</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid during the period for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
<b>Non-cash investing and financing activities:</b>		
Beneficial conversion feature in conjunction with debt issuance	\$ 303,984	\$ -
Warrants issued to third parties in conjunction with debt issuance	\$ 578,016	\$ 331,353
Original issue discount issued in conjunction with debt	\$ 88,200	\$ 52,500
Common stock issued to third parties in conjunction with conversion of debt	\$ 198,000	\$ -
Conversion of common stock for Series A preferred stock	\$ 611	\$ -
Amortization of warrants issued in connection with a debt modification	\$ -	\$ 97,939

See accompanying notes to unaudited condensed consolidated financial statements.

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

**NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES**

**Corporate History and Background**

Sigyn Therapeutics, Inc. (“Sigyn”, the “Company”, “we,” “us,” or “our”) is a development-stage company that creates blood purification devices to overcome limitations of drug therapies.

Sigyn Therapy™, our lead product candidate, is a broad-spectrum blood purification technology designed to treat pathogen-associated inflammatory disorders that are not addressed with approved drug therapies. Candidate treatment indications include endotoxemia, sepsis (a leading cause of hospital deaths), community acquired pneumonia (a leading cause of death among infectious diseases), and emerging drug resistant bacterial and pandemic virus threats. We plan to initiate first-in-human feasibility studies of Sigyn Therapy in end-stage renal disease patients suffering from endotoxemia.

Our therapeutic pipeline is comprised of drug-enhancement technologies, including ImmunePrep™ to enhance the delivery of immunotherapeutic antibodies (including checkpoint inhibitors), and ChemoPrep™ and ChemoPure™ to enhance the tumor site delivery of chemotherapy and reduce its toxicity.

**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.

**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 \$9,259,736 at June 30, 2023, had a working capital deficit of approximately \$3,117,142 at June 30, 2023, had net losses of \$723,124 and \$2,064,160, and \$666,325 and \$1,344,371 for the three and six months ended June 30, 2023 and 2022, respectively, and net cash used in operating activities of \$891,267 and \$854,308 for the six months ended June 30, 2023 and 2022, 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 relate to common stock valuation. 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 consolidated Statements of Operations.

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

#### **Advertising and Marketing Costs**

Advertising expenses are recorded as general and administrative expenses when they are incurred. The Company had \$100 and \$284, and \$131 and \$381 of advertising expenses for the three and six months ended June 30, 2023 and 2022, respectively.

#### **Research and Development**

All research and development costs are expensed as incurred. The Company incurred research and development expense of \$219,159 and \$367,002, and \$154,683 and \$383,025 for the three and six months ended June 30, 2023 and 2022, 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, 2023 and December 31, 2022, the Company carried primarily loose sapphire jewels, jewelry for sale on our website, 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, 2023. 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.

#### **Intangible Assets**

Intangible assets consist primarily of website development costs. Our intangible assets are being amortized on a straight-line basis over a period of three years.

#### **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, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, the fair value of cash, accounts payable, accrued expenses, 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, 2023 and December 31, 2022 and no charges or credits to income for the three and six months ended June 30, 2023 and 2022.

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

## **Concentrations, Risks, and Uncertainties**

### Business Risk

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

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

### Interest rate risk

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

### Credit risk

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

### Seasonality

The business is not subject to substantial seasonal fluctuations.

### Major Suppliers

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:

	<u>Estimated Life</u>	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Office equipment	5 years	\$ 29,041	\$ 29,041
Computer equipment	3 years	3,157	3,157
Accumulated depreciation		(13,576)	(10,146)
		<u>\$ 18,622</u>	<u>\$ 22,052</u>

Depreciation expense was \$1,715 and \$3,430, and \$1,719 and \$3,423 for the three and six months ended June 30, 2023 and 2022, respectively, and is classified in general and administrative expenses in the Consolidated Statements of Operations.

**NOTE 5 – INTANGIBLE ASSETS**

Intangible assets consisted of the following as of:

	<u>Estimated life</u>	<u>June 30, 2023</u>	<u>December 31, 2022</u>
Website	3 years	\$ 10,799	\$ 10,799
Accumulated amortization		(10,499)	(8,699)
		<u>\$ 300</u>	<u>\$ 2,100</u>

As of June 30, 2023, estimated future amortization expenses related to intangible assets were as follows:

	<u>Intangible Assets</u>
2023	<u>\$ 300</u>
	<u>\$ 300</u>

The Company had amortization expense of \$900 and \$1,800, and \$900 and \$1,800 for the three and six months ended June 30, 2023 and 2022, respectively.

**NOTE 6 – CONVERTIBLE PROMISSORY DEBENTURES**

Convertible notes payable consisted of the following:

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
<i>January 28, 2020 (\$457,380) – 0% interest per annum outstanding principal and interest due October 20, 2022 (“Note 1”)</i>	\$ 457,380	\$ 457,380
<i>June 23, 2020 (\$60,500) – 0% interest per annum outstanding principal and interest due October 20, 2022 (“Note 2”)</i>	60,500	60,500
<i>September 17, 2020 (\$182,936) – 0% interest per annum outstanding principal and interest due October 20, 2022. On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares (“Note 3”).</i>	182,936	182,936
<i>March 23, 2022 (\$220,000) – 0% interest per annum outstanding principal and interest due March 23, 2023 (“Note 4”)</i>	220,000	220,000
<i>April 28, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due April 28, 2023 (“Note 5”)</i>	110,000	110,000
<i>May 10, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due May 10, 2023 (“Note 6”)</i>	110,000	110,000
<i>June 1, 2022 (\$55,000) – 0% interest per annum outstanding principal and interest due June 1, 2023 (“Note 7”)</i>	55,000	55,000
<i>June 22, 2022 (\$82,500) – 0% interest per annum outstanding principal and interest due June 22, 2023 (“Note 8”)</i>	82,500	82,500
<i>July 2022 (\$341,000) – 0% interest per annum outstanding principal and interest due various dates July 2023. On June 2, 2023, an investor elected to convert \$16,500 of principal of the Note into 33,000 common shares (“Note 9”)</i>	324,500	341,000
<i>August 31, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due August 31, 2023 (“Note 10”)</i>	110,000	110,000
<i>September 9, 2022 (\$82,500) – 0% interest per annum outstanding principal and interest due September 9, 2023 (“Note 11”)</i>	82,500	82,500
<i>September 20, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due September 20, 2023 (“Note 12”)</i>	110,000	110,000
<i>October 20, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due October 20, 2023 (“Note 13”)</i>	110,000	110,000
<i>November 9, 2022 (\$82,500) – 0% interest per annum outstanding principal and interest due November 9, 2023 (“Note 14”)</i>	82,500	82,500
<i>November 14, 2022 (\$55,000) – 0% interest per annum outstanding principal and interest due November 14, 2023 (“Note 15”)</i>	55,000	55,000
<i>December 22, 2022 (\$110,000) – 0% interest per annum outstanding principal and interest due December 22, 2023 (“Note 16”)</i>	110,000	110,000
<i>During the three and six months ended June 30, 2023 (\$970,200) – 0% interest per annum outstanding principal and interest due on various dates from January 2024 through March 27, 2024. On June 2, 2023, an investor elected to convert \$181,500 of principal of the Note into 1,210,000 common shares (“Note 17”)</i>	788,700	-
<b>Total convertible notes payable</b>	<b>3,051,516</b>	<b>2,279,316</b>
<b>Original issue discount</b>	<b>(59,926)</b>	<b>(74,502)</b>
<b>Beneficial conversion feature</b>	<b>(232,663)</b>	<b>(175,275)</b>
<b>Debt discount</b>	<b>(128,646)</b>	<b>(392,883)</b>
<b>Total convertible notes payable</b>	<b>\$ <u>2,630,281</u></b>	<b>\$ <u>1,636,656</u></b>

Principal payments on convertible promissory debentures are due as follows:

Year ending December 31,	
2023 (6 months remaining)	\$ 2,262,816
2024	\$ 788,700
	<u>\$ 3,051,516</u>

Changes in convertible notes were as follows:

	Note 1	Note 2	Note 3	Note 4	Note 5	Note 6	Note 7	Note 8	Note 9	Note 10	Note 11	Note 12	Note 13	Note 14	Note 15	Note 16	Note 17	Other	Totals
Convertible notes payable, net, as of December 31, 2021	457,380	60,500	182,936	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	700,816
Convertible notes payable issued in 2022	-	-	-	220,000	110,000	110,000	55,000	82,500	341,000	110,000	82,500	110,000	110,000	82,500	55,000	110,000	-	-	1,578,500
Convertible notes payable as of December 31, 2022	457,380	60,500	182,936	220,000	110,000	110,000	55,000	82,500	341,000	110,000	82,500	110,000	110,000	82,500	55,000	110,000	-	-	2,279,316
Convertible notes payable issued in 2023	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	970,200	970,200
Conversion of debt for common stock	-	-	-	-	-	-	-	-	(16,500)	-	-	-	-	-	-	-	-	(181,500)	(198,000)
Convertible notes payable as of June 30, 2023	457,380	60,500	182,936	220,000	110,000	110,000	55,000	82,500	324,500	110,000	82,500	110,000	110,000	82,500	55,000	110,000	788,700	-	3,051,516

Changes in note discounts were as follows:

	Note 1	Note 2	Note 3	Note 4	Note 5	Note 6	Note 7	Note 8	Note 9	Note 10	Note 11	Note 12	Note 13	Note 14	Note 15	Note 16	Note 17	Other	Totals
Note discounts as of December 31, 2021	34,176	4,521	14,917	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	53,614
Note discounts issued in conjunction with debt in 2022	-	-	-	113,418	44,786	44,787	22,794	34,861	140,289	64,104	82,500	110,000	110,000	82,500	55,000	110,000	-	-	1,015,039
2022 accretion of note discounts	(34,176)	(4,521)	(14,917)	(87,938)	(30,308)	(28,836)	(13,301)	(18,336)	(70,720)	(32,316)	(39,994)	(49,874)	(23,671)	(12,822)	(7,726)	(6,537)	-	50,000	(425,993)
Note discounts as of December 31, 2022	\$ -	\$ -	\$ -	\$ 25,480	\$ 14,478	\$ 15,951	\$ 9,493	\$ 16,525	\$ 69,569	\$ 31,788	\$ 42,506	\$ 60,126	\$ 86,329	\$ 69,678	\$ 47,274	\$ 103,463	\$ -	\$ 50,000	\$ 642,660
Note discounts issued in conjunction with debt in 2023	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	970,200	970,200
2023 accretion of note discounts	-	-	-	(25,480)	(14,478)	(15,951)	(9,493)	(16,525)	(69,569)	(31,788)	(37,131)	(49,506)	(49,509)	(37,132)	(24,756)	(49,509)	(710,798)	(50,000)	(1,191,625)
Note discounts as of June 30, 2023	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 5,375	\$ 10,620	\$ 36,820	\$ 32,546	\$ 22,518	\$ 53,954	\$ 259,402	\$ -	\$ 421,235
Convertible notes payable, net, as of December 31, 2022	457,380	60,500	182,936	194,520	95,522	94,049	45,507	65,975	271,431	78,212	39,994	49,874	23,671	12,822	7,726	6,537	-	(50,000)	1,636,656
Convertible notes payable, net, as of June 30, 2023	457,380	60,500	182,936	220,000	110,000	110,000	55,000	82,500	324,500	110,000	77,125	99,380	73,180	49,954	32,482	56,046	529,298	-	2,630,281
2021 Effective interest rate	11%	11%	12%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%	-%
2022 Effective interest rate	7%	7%	8%	40%	28%	26%	24%	22%	21%	29%	48%	45%	22%	16%	14%	6%	-%	-%	19%
2023 Effective interest rate	-%	-%	-%	12%	13%	15%	17%	20%	21%	29%	45%	45%	45%	45%	45%	45%	90%	-%	39%



## Current Noteholders

### **2023 Notes – \$970,200 (Note 17)**

During the six months ended June 30, 2023, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “2023 Notes”) with a third party investors totaling (i) \$970,200 aggregate principal amount of Note due on various dates from January 2024 through March 27, 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 6,468,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$882,000 which was issued at a \$88,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On June 2, 2023, a third party investor elected to convert \$181,500 of principal of the Note into 1,210,000 common shares.

### **Osher – \$110,000 (Note 16)**

On December 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due December 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

### **Osher – \$55,000 (Note 15)**

On November 14, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due November 14, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 366,667 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher noteholder for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

### **Brio – \$82,500 (Note 14)**

On November 9, 2022, 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) \$82,500 aggregate principal amount of Note due November 9, 2023 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 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 13)**

On October 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due October 20, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 12)**

On September 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due September 20, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$82,500 (Note 11)**

On September 9, 2022, 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) \$82,500 aggregate principal amount of Note due September 9, 2023 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 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 10)**

On August 31, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due August 31, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Other – \$341,000 (Note 9)**

In July 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “July 2022 Notes”) totaling (i) \$341,000 aggregate principal amount of Note (total of \$310,000 cash was received) due in various dates in July 2023 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 676,936 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

On June 2, 2023, a third party investor elected to convert \$16,500 of principal of the Note into 33,000 common shares.

**Osher – \$82,500 (Note 8)**

On June 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$82,500 aggregate principal amount of Note due June 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 165,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$55,000 (Note 7)**

On June 1, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due June 1, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 110,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Brio – \$110,000 (Note 6)**

On May 10, 2022, 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) \$110,000 aggregate principal amount of Note due May 10, 2023 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 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$110,000 (Note 5)**

On April 28, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due April 28, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$110,000 (Note 4)**

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Brio – \$110,000 (Note 4)**

On March 23, 2022, 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) \$110,000 aggregate principal amount of Note due March 23, 2023 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 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Brio for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$182,936 (Note 3)**

On September 17, 2020 (the “Original Issue Date”), 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) \$181,500 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due September 30, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 8,250 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$165,000 which was issued at a \$16,500 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated September 17, 2020, for the number of warrant shares from 8,250 warrant shares to 465,366 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from September 30, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share.

On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

**Osher – \$60,500 (as amended on October 20, 2020 to \$55,000) (Note 2)**

On June 23, 2020 (the “Original Issue Date”), 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) \$50,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due June 23, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 10,000 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at a \$0 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Note for the aggregate principal amount from \$50,000 to \$55,000. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at an amended \$4,995 original issue discount from the face value of the Note.
- The parties amended the Warrants dated June 23, 2020, for the number of warrant shares from 10,000 warrant shares to 141,020 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows (see Note 12):

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

#### **Osher – \$457,380 (Note 1)**

On January 28, 2020 (the "Original Issue Date"), the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with respect to the sale and issuance to institutional investor Osher Capital Partners LLC ("Osher") of (i) \$385,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due January 26, 2021, 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 80,209 shares of the Company's Common Stock at an exercise price of \$7.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was \$350,005 which was issued at a \$34,995 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.094 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follows on October 20, 2020:

- The parties amended the Warrants dated January 28, 2020, for the number of warrant shares from 80,209 warrant shares to 4,113,083 warrant shares at an exercise price of \$0.14 per share.
- The parties amended the Note to provide for interest at 8% per annum.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

The Company has not repaid this convertible note and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

#### **Previous Noteholders**

##### **Other – \$145,200**

On November 21, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") with a third party investor of (i) \$145,200 aggregate principal amount of Note due November 21, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 968,000 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$132,000 which was issued at a \$13,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On November 23, 2022, third party investor elected to convert the aggregate principal amount of the Note, \$145,200, into 968,000 common shares.

All other previous notes were detailed in our Form 10-K filed on March 31, 2023. No changes occurred related to these notes during the period covered by this Form 10-Q.

#### **NOTE 7 – 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 \$30,000 and \$0 under Advance From Shareholder in the accompanying Balance Sheets at June 30, 2023 and December 31, 2022, respectively. The Company received advances of \$30,000 and \$0 and no repayments for the six months ended June 30, 2023 and 2022. 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 8 – STOCKHOLDERS’ DEFICIT**

##### **Preferred Stock**

The Company authorized 10,000,000 shares of par value \$0.0001 preferred stock, of which 1,215 and none shares are issued and outstanding at June 30, 2023 and December 31, 2022, respectively.

During fiscal 2023, holders of 6,105,528 shares of common stock elected to exchange these shares for an aggregate of 1,215 shares of Series A Convertible Preferred Stock. Each Series A Convertible Preferred Share converts into one thousand (1,000) 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 A preferred stock have various rights and preferences as follows:

*Rights* - The holders of the Series A 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 A 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 A 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 A 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 44,231,402 and 38,263,813 shares are outstanding as of June 30, 2023 and December 31, 2022, respectively.

During the six months ended June 30, 2023, a total of 21,660,227 warrants were exchanged for 10,830,117 shares of the Company’s common stock.

On June 2, 2023, a third party investor elected to convert the aggregate principal amount of a Note of \$198,000, into 1,243,000 common shares.

### **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, 2023, the Company recorded stock based compensation totaling \$37,500 and \$75,000, respectively, in the consolidated Statements of Operations (see Note 12).

### **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 warrant holders in which the Company will issue one share of the Company's common stock in exchange for each two warrants returned to the Company to be cancelled. All other terms of the original grants remain the same. A total of 21,660,227 warrants were exchanged for 10,830,117 shares of the Company's common stock through June 30, 2023. The Company recognized \$224,362 as modification of warrants in the three and six months ended June 30, 2023 as a result of the modification.

On October 22, 2021, the Company and Osher amended convertible debt agreements for the maturity date from October 20, 2021 to October 20, 2022. In exchange for the extension of the Note, the Company issued Osher 450,000 warrants to purchase an aggregate of 450,000 shares of the Company's common stock, valued at \$197,501 (based on the Black Scholes valuation model on the date of grant) (see Note 6). The warrants are exercisable for a period of five years at \$1.00 per share in whole or in part, as either a cash exercise or as a cashless exercise, and fully vest at grant date. The Company accreted the value of the warrants ratably through October 20, 2022. The Company recorded \$0 and \$0, and \$49,240 and \$97,939 for the three and six months ended June 30, 2023 and 2022, respectively, and is classified in other expenses in the consolidated Statements of Operations. See Note 6 for further warrant discussions.

### **NOTE 9 – OPERATING LEASES**

On May 27, 2021, the Company entered into a sixty-three month lease for its corporate office at \$6,134 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 \$287,805 and operating lease liability of \$287,805 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:

	<b>Six Months ended June 30,</b>		<b>Three Months ended June 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
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:

<b>Six Months ended June 30,</b>	<b>2023</b>	<b>2022</b>
Operating cash flows from operating leases	\$ 36,987	\$ 35,910
Cash paid for amounts included in the measurement of lease liabilities	\$ 36,987	\$ 35,910
Weighted-average remaining lease term—operating leases	3.2 years	4.2 years
Weighted-average discount rate—operating leases	10%	10%

In accordance with ASC 842, maturities of operating lease liabilities as of June 30, 2023 were as follows:

<b>Year ending:</b>	<b>Operating Lease</b>
2023 (remaining 6 months)	\$ 37,908
2024	77,142
2025	79,456
2026	54,224
Total undiscounted cash flows	\$ 248,730
Reconciliation of lease liabilities:	
Weighted-average remaining lease terms	3.2 years
Weighted-average discount rate	10%
Present values	\$ 215,147
Lease liabilities—current	57,049
Lease liabilities—long-term	158,098
Lease liabilities—total	\$ 215,147
Difference between undiscounted and discounted cash flows	\$ 33,583

Operating lease cost was \$17,919 and \$35,838, and \$17,919 and \$35,838 for the three and six months ended June 30, 2023 and 2022, respectively.

#### NOTE 10 – RELATED PARTY TRANSACTIONS

Other than as set forth below, and as disclosed in Notes 7 and 8, 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 \$118,085 (including accrued compensation of \$61,210) and \$231,835 (including accrued compensation of \$61,210), and \$123,857 (including accrued compensation of \$31,043) and \$241,176 (including accrued compensation of \$131,043) for the three and six months ended June 30, 2023 and 2022, respectively.

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 \$76,610 (including accrued compensation of \$26,610) and \$76,610 (including accrued compensation of \$26,610), and \$0 and \$0 for the three and six months ended June 30, 2023 and 2022, respectively.

Sigyn had no employment agreement with its CTO but still incurred compensation on behalf of the CTO. The Company incurred compensation expense of \$62,288 (including accrued compensation of \$32,288) and \$123,288 (including accrued compensation of \$43,288), and \$61,306 (including accrued compensation of \$16,305) and \$120,115 (including accrued compensation of \$16,305) for the three and six months ended June 30, 2023 and 2022, respectively.

## NOTE 11 – 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,	
	2023	2022	2023	2022
Convertible notes payable	18,194,940	6,644,940	18,194,940	6,644,940
Restricted stock units	343,512	-	171,756	11,840,890
Warrants to purchase shares of common stock	-	8,432,288	-	11,840,890
Total potentially dilutive shares	<u>18,538,452</u>	<u>15,077,228</u>	<u>18,366,696</u>	<u>18,485,830</u>

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,	
	2023	2022	2023	2022
Net loss attributable to the common stockholders	\$ (2,064,160)	\$ (1,344,371)	\$ (723,124)	\$ (666,325)
Basic weighted average outstanding shares of common stock	40,911,801	37,295,813	43,331,086	37,295,813
Dilutive effect of options and warrants	-	-	-	-
Diluted weighted average common stock and common stock equivalents	40,911,801	37,295,813	43,331,086	37,295,813
Loss per share:				
Basic and diluted	\$ (0.05)	\$ (0.04)	\$ (0.02)	\$ (0.02)

## NOTE 12 – 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, effective January 1, 2023, 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 13 – SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after June 30, 2023 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, 2023, except for the following:

On July 18, 2023, the Company entered into an Original Issue Discount Senior Convertible Debentures totaling (i) \$110,000 aggregate principal amount of Note (total of \$100,000 cash was received) due July 18, 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 733,334 shares of the Company's Common Stock at an exercise price of \$0.25 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.15 per share.



**Class A Units  
Each Class A Unit Consisting of  
One Share of Common Stock and  
One Series A Warrant to Purchase One Share of Common Stock**

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**PROSPECTUS**

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**, 2023**

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**PART II**

**INFORMATION NOT REQUIRED IN THE PROSPECTUS**

**ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION**

Securities and Exchange Commission Registration Fee	\$	1,853
FINRA Filing Fee		3,499
Nasdaq Listing Fee		-
Transfer Agent and Registrar Fees		-
Printing and Engraving Expenses		-
Legal Fees		-
Accounting Fees and Expenses		-
Miscellaneous		-
<b>Total</b>	<b>\$</b>	<b>-</b>

All amounts are estimates other than the Commission's registration fee. We are paying all expenses of the offering listed above.

**ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

As permitted by Section 102 of the Delaware General Corporation Law, we will adopt provisions in our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our Amended and Restated Certificate of Incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our Amended and Restated Bylaws will provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;

As permitted by Section 102 of the Delaware General Corporation Law, we will adopt provisions in our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;

- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our Amended and Restated Certificate of Incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our Amended and Restated Bylaws will provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions.

We plan to enter into an underwriting agreement that provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

## **ITEM 15. RECENT SALE OF UNREGISTERED SECURITIES**

### *Preferred Stock*

The Company has 10,000,000 shares of par value \$0.0001 preferred stock authorized, of which no preferred shares are issued and outstanding at August 15, 2022.

### *Common Stock*

The Company has authorized 1,000,000,000 shares of par value \$0.0001 common stock, of which 37,295,813 shares are outstanding at August 15, 2022.

The Company issued 500,000 restricted common shares to founders, valued at \$500 (based on the par value on the date of grant).

On October 19, 2020, the Company issued 33,686,169 common shares in conjunction with the Acquisition.

During the year ended December 31, 2020, the Company issued 1,015,344 common shares to third parties in conjunction with the exchange of convertible promissory debentures.

On January 14, 2021, the Company issued a total of 47,000 shares of its common stock valued at \$82,250 (based on the estimated fair market value of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry.

On February 19, 2021, a previous noteholder exercised warrants pursuant to the cashless exercise provision of the warrant agreement into 57,147 common shares. The common shares have not been issued as of November 10, 2021.

In April 2021, the Company initiated an offering of up to \$1.5 million of the Company's restricted common shares. The offering allowed for qualified investors to purchase one share of the Company's common stock \$1.25. For each share purchased, the investor received a five-year warrant to purchase one share of common stock at \$1.75 per share. On May 10, 2021, the Company closed the offering to investors and subsequently disclosed that it resulted in the issuance of 1,172,000 shares of common stock and warrants to purchase an aggregate of 1,172,000 shares of the Company's common stock for total proceeds totaling \$1,465,000.

On April 14, 2021, the Company issued a total of 47,000 shares of its common stock valued at \$82,250 (based on the estimated fair market value of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry.

On May 10, 2021, Brio Capital elected to convert the aggregate principal amount of a \$110,000 convertible note issued on February 10, 2021 into 157,143 shares of the Company's common stock.

On July 14, 2021, the Company issued a total of 47,000 shares of its restricted common stock valued at \$47,000 (based on the stock price of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry. This issuance was pursuant to Section 4(a)(2) of the Securities Act in a transaction exempt from registration.

On October 14, 2021, the Company issued a total of 47,000 shares of its restricted common stock valued at \$37,600 (based on the stock price of the Company's common stock on the date of issuance) to a third party, for communications to the financial industry. This issuance was pursuant to Section 4(a)(2) of the Securities Act in a transaction exempt from registration.

On October 20, 2021, the entered into a securities purchase agreement with an accredited investor that resulted in the issuance of 320,000 shares of common stock and warrants to purchase an aggregate of 320,000 shares of the Company's common stock for total proceeds totaling \$400,000. The offering allowed for qualified investors to purchase one share of the Company's common stock at \$1.25. For each share purchased, the investor received a five-year warrant to purchase one share of common stock at \$1.25 per share. No commissions were paid in the offering. This issuance was pursuant to Section 4(a)(2) of the Securities Act of 1933 in a transaction exempt from registration.

On October 22, 2021, the Company and Osher amended the October 20, 2020 convertible debt agreements for the maturity date from October 20, 2021 to October 20, 2022. In exchange for the extension of the Notes, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

On October 25, 2021, Osher elected to convert the aggregate principal amount of the Note, \$110,000, into 157,143 common shares.

On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$385,000, into 42,857 common shares.

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "Note") totaling (i) \$220,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 440,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

On April 28, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "April 2022 Note") totaling (i) \$110,000 aggregate principal amount of April 2022 Note due April 28, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 220,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

On May 10, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "May 2022 Note") totaling (i) \$110,000 aggregate principal amount of Note due May 10, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 220,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

On June 1, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") totaling (i) \$55,000 aggregate principal amount of Note due June 1, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 110,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.50 per share.

On June 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the "Note") totaling (i) \$82,500 aggregate principal amount of Note due June 22, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 165,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.50 per share.

In July 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the "July 2022 Notes") totaling (i) \$313,500 aggregate principal amount of Note (total of \$285,000 cash was received) due in various dates in July 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 627,000 shares of the Company's Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

These issuances have been made pursuant to transactions exempt from registration under Section 4(a)(2) of the Securities Act.

During the year ended December 31, 2020, the Company issued 1,015,344 common shares to third parties in conjunction with the exchange of convertible promissory debentures.

#### *Warrants*

On October 22, 2021, the Company and Osher amended convertible debt agreements for the maturity date from October 20, 2021 to October 20, 2022. In exchange for the extension of the Note, the Company issued Osher 450,000 warrants to purchase an aggregate of 450,000 shares of the Company's common stock, valued at \$197,501 (based on the Black Scholes valuation model on the date of grant) (see Note 6). The warrants are exercisable for a period of five years at \$1.00 per share in whole or in part, as either a cash exercise or as a cashless exercise, and fully vest at grant date. The Company is amortizing the value of the warrants ratably through October 20, 2022. The Company recorded \$40,041 and \$0 for the years ended December 31, 2021 and 2020, respectively, and is classified in other expenses in the consolidated Statements of Operations.

#### *Current Noteholders*

##### Osher – \$457,380

On January 28, 2020 (the "Original Issue Date"), the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with respect to the sale and issuance to institutional investor Osher Capital Partners LLC ("Osher") of (i) \$385,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due January 26, 2021, 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 80,209 shares of the Company's Common Stock at an exercise price of \$7.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was \$350,005 which was issued at a \$34,995 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.094 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follow-on October 20, 2020:

- The parties amended the Warrants dated January 28, 2020, for the number of warrant shares from 80,209 warrant shares to 4,113,083 warrant shares at an exercise price of \$0.14 per share.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.

#### Osher – \$60,500

On June 23, 2020 (the "Original Issue Date"), the Company entered into a (i) \$50,000 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the "Note") due June 23, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 10,000 shares of the Company's Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at a \$0 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follow-on October 20, 2020:

- The parties amended the Note for the aggregate principal amount from \$50,000 to \$55,000. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$50,005 which was issued at an amended \$4,995 original issue discount from the face value of the Note.
- The parties amended the Warrants dated June 23, 2020, for the number of warrant shares from 10,000 warrant shares to 141,020 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from June 23, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company's common stock at an exercise price of \$1.00 per share.



Osher – \$199,650

On September 17, 2020 (the “Original Issue Date”), the Company entered into a (i) \$181,500 aggregate principal amount of Original Issue Discount Senior Convertible Debenture (the “Note”) due September 30, 2021, based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 8,250 shares of the Company’s Common Stock at an exercise price of \$30.00 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$165,000 which was issued at a \$16,500 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 \$0.39 per share, as amended on October 20, 2020, subject to adjustment as provided therein, such as stock splits and stock dividends.

The Company and Osher amended the convertible debt agreement as follow-on October 20, 2020:

- The parties amended the Warrants dated September 17, 2020, for the number of warrant shares from 8,250 warrant shares to 465,366 warrant shares at an exercise price of \$0.59 per share.
- The parties amended the Note for the maturity date from September 30, 2021 to October 20, 2021.

On October 22, 2021, the Company and Osher amended convertible debt agreements as follows:

- The parties amended the October 20, 2020 Notes for the maturity date from October 20, 2021 to October 20, 2022.
- The parties amended the October 20, 2020 Notes for the aggregate principal amount and accrued interest from \$652,300 to \$717,530 which is issued at a \$65,230 original issue discount from the face value of the October 20, 2020 Notes now due October 20, 2022.
- In exchange for the extension of the Note, the Company issued Osher five-year warrants to purchase an aggregate of 450,000 shares of the Company’s common stock at an exercise price of \$1.00 per share.

On October 28, 2021, Osher elected to convert \$16,714 of the aggregate principal amount of the Note of \$199,650, into 42,857 common shares.

**Brio – \$110,000 (Note 4)**

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “Note”) totaling (i) \$220,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 440,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

**Osher – \$110,000 (Note 4)**

On March 23, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due March 23, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$110,000 (Note 5)**

On April 28, 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “Note”) totaling (i) \$220,000 aggregate principal amount of Note due April 28, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 440,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

These issuances have been made pursuant to transactions exempt from registration under Section 4(a)(2) of the Securities Act.

Osher – \$110,000 (Note 12)

On September 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due September 20, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

Brio – \$82,500 (Note 11)

On September 9, 2022, 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) \$82,500 aggregate principal amount of Note due September 9, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

Osher – \$110,000 (Note 10)

On August 31, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due August 31, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

Other – \$341,000 (Note 9)

In July 2022, the Company entered into an Original Issue Discount Senior Convertible Debentures (the “July 2022 Notes”) totaling (i) \$341,000 aggregate principal amount of Note (total of \$310,000 cash was received) due in various dates in July 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 676,936 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.50 per share.

Osher – \$82,500 (Note 8)

On June 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$82,500 aggregate principal amount of Note due June 22, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 165,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

Osher – \$55,000 (Note 7)

On June 1, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due June 1, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 110,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

Brio – \$110,000 (Note 6)

On May 10, 2022, 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) \$110,000 aggregate principal amount of Note due May 10, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 220,000 shares of the Company’s Common Stock at an exercise price of \$0.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.50 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

*Convertible Promissory Debentures*

**Osher – \$110,000**

On October 20, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due October 20, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Brio – \$82,500**

On November 9, 2022, 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) \$82,500 aggregate principal amount of Note due November 9, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 550,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$75,000 which was issued at a \$7,500 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Osher – \$55,000**

On November 14, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$55,000 aggregate principal amount of Note due November 14, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 366,667 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$50,000 which was issued at a \$5,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**Other – \$145,200**

On November 21, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$145,200 aggregate principal amount of Note due November 21, 2023 based on \$1.00 for each \$0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 968,000 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was \$132,000 which was issued at a \$13,200 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

On November 23, 2022, the noteholder elected to convert the aggregate principal amount of the Note, \$145,200, into 968,000 common shares.

**Osher – \$110,000 (Note 16)**

On December 22, 2022, the Company entered into an Original Issue Discount Senior Convertible Debenture (the “Note”) with respect to the sale and issuance to institutional investor Osher Capital Partners LLC (“Osher”) of (i) \$110,000 aggregate principal amount of Note due December 22, 2023 based on \$1.00 for each \$0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants (“Warrants”) to purchase up to an aggregate of 733,333 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the Note and Warrants was \$100,000 which was issued at a \$10,000 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 \$0.15 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

**2023 Convertible Notes**

During the three months ended March 31, 2023, the Company entered into an Original Issue Discount Senior Convertible Debentures totaling (i) \$970,200 aggregate principal amount of Note (total of \$882,000 cash was received) due in various dates in January through March 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 6,468,004 shares of the Company’s Common Stock at an exercise price of \$0.25 per share. The conversion price for the principal in connection with voluntary conversions by the holders of the convertible notes is \$0.15 per share.

**ITEM 16. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
1.1	Form of Underwriting Agreement**
3.1***	<a href="#">Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware</a>
3.2***	<a href="#">Bylaws of the Registrant, as currently in effect (Filed as Exhibit 3.2 to the Registration Statement on Form S-1 filed by the Registrant on May 27, 2015, and incorporated herein by reference).</a>
4.1	Form of Representative's Warrant**
4.2	Form of Series A Warrant**
5.1	Legal opinion of J.P. Galda & Co. **
10.1	<a href="#">Share Exchange Agreement dated August 25, 2020 (Filed as Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on August 31, 2020 and incorporated herein by reference)***</a>
10.2***	<a href="#">Operating Lease</a>
10.3	<a href="#">Employment Agreement for Jeremy Ferrell (Filed as Exhibit 99.1 to the Current Report on Form 8-K filed by the Registrant on March 9, 2022 and incorporated herein by reference)***</a>
10.4***	<a href="#">January 2020 Financing Documents and Extensions</a>
10.5***	<a href="#">June 23, 2020 Financing Documents</a>
10.6***	<a href="#">September 17, 2020 Financing Documents</a>
10.7***	<a href="#">Senior Convertible Debenture dated May 10, 2022</a>
10.8***	<a href="#">Warrant dated May 10, 2022</a>
10.9***	<a href="#">Warrant dated October 18, 2021</a>
10.10***	<a href="#">Senior Convertible Debenture dated March 23, 2022</a>

10.11***	<a href="#">Warrant dated March 23, 2022</a>
10.12***	<a href="#">Senior Convertible Debenture dated March 23, 2022</a>
10.13***	<a href="#">Warrant dated March 23, 2022</a>
10.14***	<a href="#">Senior Convertible Debenture dated April 28, 2022</a>
10.15***	<a href="#">Warrant dated April 28, 2022</a>
10.16***	<a href="#">June 1, 2022 Financing Documents</a>
10.17***	<a href="#">June 22, 2022 Financing Documents</a>
10.18***	<a href="#">Set of Form Documents for July 2022 Financing</a>
10.19***	<a href="#">August 31, 2022 Financing Documents</a>
10.20***	<a href="#">September 9, 2022 Financing Documents</a>
10.21***	<a href="#">October 20, 2022 Financing Documents</a>
10.22***	<a href="#">November 9, 2022 Financing Documents</a>
10.23***	<a href="#">November 14, 2022 Financing Documents</a>
10.24***	<a href="#">November 21, 2022 Financing Documents</a>
21.1***	<a href="#">Subsidiaries of the Registrant</a>
23.1	<a href="#">Consent of Kreit &amp; Chiu CPA LLP*</a>
23.2	Consent of J.P. Galda & Co.. (included in Exhibit 5.1)**
24.1***	<a href="#">Power of Attorney (included in prior filing of the registration statement)</a>
107	<a href="#">Calculation of Filing Fee Table***</a>
*	Filed herewith.
**	To be filed by amendment
***	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

## ITEM 17. UNDERTAKINGS

The undersigned registrant hereby undertakes to:

- (1) File, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:
  - (i) Include any prospectus required by Section 10(a)(3) of the Securities Act;
  - (ii) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement;
  - (iii) Include any additional or changed material information on the plan of distribution.
- (2) For determining liability under the Securities Act, each post-effective amendment shall be deemed to be a new registration statement of the securities offered, and the offering of the securities at that time shall be deemed to be the initial bona fide offering.
- (3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.
- (4) For determining liability of the undersigned registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No.6 to Registration Statement to be signed on its behalf by the undersigned hereunto duly authorized.

**Sigyn Therapeutics, Inc.**

Dated: September 22, 2023

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

Dated: September 22, 2023

By: /s/ Jeremy Ferrell  
Jeremy Ferrell  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 6 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Mr. James Joyce</u> Mr. James Joyce	Chief Executive Officer and Director	September 22, 2023
<u>/s/ Mr. Craig Roberts</u> Mr. Craig Roberts	Chief Technology Officer and Director	September 22, 2023
<u>/s/ Mr. Jeremy Ferrell</u> Mr. Jeremy Ferrell	Chief Financial Officer	September 22, 2023
<u>*</u> Richa Nand	Director	September 22, 2023
<u>*</u> Jim Dorst	Director	September 22, 2023
<u>*</u> Chris Wetzel	Director	September 22, 2023
*By: <u>/s/ James Joyce</u> James Joyce Attorney-in-fact		



CONSENT OF INDEPENDENT AUDITOR

We consent to the inclusion in this Registration Statement of Sigyn Therapeutics, Inc. on Amendment No.6 to Form S-1 to be filed on or about September 22, 2023 of our report dated March 31, 2023, on our audits of the financial statements of Sigyn Therapeutics, Inc. as of December 31, 2022 and 2021 and for the years then ended. Our report includes an explanatory paragraph about the existence of substantial doubt about the Company's ability to continue as a going concern.

We also consent to the reference to us under the heading "Experts" in such Registration Statement.

*/s/ Kreit & Chiu CPA LLP*

(formerly Kreit & Chiu CPA LLP)

New York, NY  
September 22, 2023

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