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

FORM 10-K

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

For the fiscal year ended December 31, 2024

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

For the transition period from _____ to _____

Commission File Number **000-55575**

SIGYN THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**84-4210559**
(State or other jurisdiction of incorporation)	(IRS Employer File Number)
2468 Historic Decatur Road Ste., 140, San Diego, California	**92106**
(Address of principal executive offices)	(zip code)

(619) 353-0800
(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.0001 Par Value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging Growth Company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the issued and outstanding common stock held by non-affiliates of the registrant was $3,605,453. For purposes of the above statement only, all directors, executive officers and 10% shareholders are assumed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

As of April 11, 2025, there were 1,605,377 shares of common stock outstanding.

SIGYN THERAPEUTICS, INC.
2024 ANNUAL REPORT ON FORM 10-K

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DISCLOSURE REGARDING FORWARD LOOKING STATEMENTS

This report contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Description of Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "seeks," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. These risks and uncertainties include, but are not limited to, the factors described in the section captioned "Risk Factors" below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Such statements may include, but are not limited to, information related to: anticipated operating results; licensing arrangements; relationships with our customers; consumer demand; financial resources and condition; changes in revenues; changes in profitability; changes in accounting treatment; cost of sales; selling, general and administrative expenses; interest expense; the ability to secure materials and subcontractors; the ability to produce the liquidity or enter into agreements to acquire the capital necessary to continue our operations and take advantage of opportunities; legal proceedings and claims.

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

USE OF CERTAIN DEFINED TERMS

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

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

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

PART I

Item 1. Business

Background

Business Overview

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

Infectious Disease Disorders

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

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

Previous Infectious Disease Industry Achievements

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

Sigyn Therapy™ Human Studies

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

Emerging Opportunity in Xenotransplantation

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

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

1. Gene-edited donor pigs to reduce pathogen accumulation in donor kidneys prior to their extraction for human transplantation. The feasibility of Sigyn Therapy™ administration has been demonstrated in eight (8) porcine subjects to date.

2. Human transplant recipients during and after transplantation to reduce the bloodstream presence of pathogen, inflammatory and other circulating factors that may cause severe illness or induce the rejection of a transplanted organ, whose source may be either a human or animal donor.

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

Devices to Optimize the Benefit of Cancer Therapies

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

ImmunePrep™ to Optimize Immunotherapeutic Antibodies

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

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

ChemoPrep™ to Optimize Chemotherapy Delivery

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

ChemoPure™ to Reduce Chemotherapy Toxicity

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

About Sigyn Therapy - Our Lead Therapeutic Candidate

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

Sigyn Therapy™ Pre-Clinical Studies

Since the inception of our Company, we have advanced Sigyn Therapy from conceptual design through completion of pre-clinical *in vitro* studies that have quantified the reduction of relevant therapeutic targets from human blood plasma with small-scale versions of Sigyn Therapy. These include endotoxin (gram-negative bacterial toxin); peptidoglycan and lipoteichoic acid (gram-positive bacterial toxins); viral pathogens (including SARS-CoV-2); hepatic toxins (ammonia, bile acid, and bilirubin); and tumor necrosis factor alpha (TNF alpha), interleukin-1 beta (IL-1b), and interleukin 6 (IL-6), which are pro-inflammatory cytokines whose dysregulated production (the cytokine storm) precipitate sepsis and play a prominent role in each of our therapeutic opportunities.

Sigyn Therapy™ Animal Studies

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

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

The animal studies were conducted to correspond with FDA's best practice guidance. The number of animals enrolled in our study and the amount of data collected was based on the ethical and least burdensome principles that 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.

Sigyn Therapy™ Clinical Plan

The data resulting from our *in vivo* animal and pre-clinical *in vitro* studies has been incorporated in an Investigational Device Exemption (IDE) that we have drafted for submission to the U.S. Food and Drug Administration ("FDA") to support first-in-human feasibility studies of Sigyn Therapy. The clinical plan of our IDE proposes to enroll 12-15 End-Stage Renal Disease ("ESRD") patients with endotoxemia and concurrent inflammation at three clinical site locations that have been identified and evaluated by a contract research organization that specializes in ESRD related clinical studies. The primary study objective is to demonstrate that Sigyn Therapy can be safely administered to health compromised ESRD subjects. Additionally, we plan to quantify changes in endotoxin levels as well as markers of inflammation as secondary endpoints. The clinical plan proposed in our draft IDE has not yet been provided to FDA and there is no assurance that FDA will approve the initiation of our proposed feasibility study, nor is there any assurance that we will receive FDA market approval of Sigyn Therapy™.

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

Sigyn Therapy Mechanism of Action

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

To support widespread implementation, Sigyn Therapy is a single-use disposable device that is deployable on the global infrastructure of hemodialysis and continuous renal replacement therapy (CRRT) machines already located in hospitals and clinics. To reduce the risk of blood clotting and hemolysis, the anticoagulant heparin is administered, which is the standard-of-care drug administered in dialysis and CRRT therapies. During animal studies conducted at the University of Michigan, Sigyn Therapy was deployed for use on a dialysis machine manufactured by Fresenius Medical Care, a global leader in the dialysis industry.

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

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

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

From a technical perspective, Sigyn Therapy is a 325mm long polycarbonate column that internally contains polyethersulphone hollow fibers that have porous walls with a median pore size of ~200 nanometers (nm). As blood flows into Sigyn Therapy, plasma and therapeutic targets below 200nm travel through the porous walls as a result of blood-side pressure. As the hollow fiber bundle within Sigyn Therapy creates a resistance to the flow of blood, a pressure drop is created along the length of the device such that the blood-side pressure is higher at the blood inlet and lower at the blood outlet. This allows for plasma and therapeutic targets to flow away from the blood and into the extra-lumen space (inside the polycarbonate shell, yet outside the hollow-fiber bundle) to interact with Sigyn Therapy’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.

Opportunities to Address Unmet Needs in Global Health

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

Untreatable Viral Pathogens

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

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

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

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

Antibiotic-Resistant Bacterial Infections

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

Endotoxemia

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

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

Sepsis

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

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

Emerging Opportunity for Sigyn Therapy in Xenotransplantation

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

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

1. Gene-edited donor pigs to reduce pathogen accumulation in donor kidneys prior to their extraction for human transplantation. The feasibility of Sigyn Therapy™ administration has been demonstrated in eight (8) porcine subjects to date.

2. Human transplant recipients during and after transplantation to reduce the bloodstream presence of pathogen, inflammatory and other circulating factors that may cause severe illness or induce the rejection of a transplanted organ, whose source may be either a human or animal donor.

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

Devices to Optimize the Benefit of Cancer Therapies

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

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

ImmunePrep™ to Optimize Immunotherapeutic Antibodies

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

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

ChemoPrep^{TM} to Optimize Chemotherapy Delivery

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

ChemoPure^{TM} to Reduce Chemotherapy Toxicity

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

Marketing and Sales

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

Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Government Regulation

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

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

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

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

The Pre-market Approval Pathway

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

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

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

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

Clinical Trials

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

Manufacturing and Procurement

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

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

Research and Product Development

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

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 2025 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.

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). The documents are also available to be read or copied at the SEC's Public Reference Room located at 100 F Street, NE, Washington, D.C., 20549. Information on the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

Item 1A. Risk Factors

This item is not applicable because we are a "smaller reporting company" as defined in Exchange Act Rule 12b-2.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Our board of directors and senior management recognize the critical importance of maintaining the trust and confidence of our clients, business partners and employees. Our management, led by our Chief Executive Officer, are actively involved in oversight of our risk management efforts, and cybersecurity represents an important component of the Company's overall approach to enterprise risk management ("ERM"). Our cybersecurity processes and practices are fully integrated into the Company's ERM efforts. In general, we seek to address cybersecurity risks through a cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Risk Management and Strategy

As one of the critical elements of our overall ERM approach, our cybersecurity efforts are focused on the following key areas:

- **Governance:** Management oversees cybersecurity risk mitigation and reports to the board of directors any cybersecurity incidents.
- **Collaborative Approach:** We have implemented a cross-functional approach to identifying, preventing and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by management in a timely manner.
- **Technical Safeguards**: We deploy technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.

We have not engaged third-party service providers to conduct evaluations of our security controls, independent audits or consulting on best practices to address new challenges.

While we have not experienced any cybersecurity threats in the past in the normal course of business, in the future, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us.

Item 2. Properties

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

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.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Pursuant to Section 1503(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, issuers that are operators, or that have a subsidiary that is an operator, of a coal or other mine in the United States are required to disclose in their periodic reports filed with the SEC information regarding specified health and safety violations, orders and citations, related assessments and legal actions, and mining-related fatalities from the Federal Mine Safety and Health Administration, or MSHA, under the Federal Mine Safety and Health Act of 1977, or the Mine Act. During the year ended December 31, 2024, we did not have any projects that were in production and as such, were not subject to regulation by MSHA under the Mine Act.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

(a) Market Information

Our stock is quoted on the OTC markets under the symbol "SIGY." There are 1,605,377 shares outstanding as of April 11, 2025.

(b) Transfer Agent

The transfer agent and registrar for our common stock is VStock Transfer, LLC located at 18 Lafayette Place, Woodmere, New York.

(c) Shareholders of Record

The number of beneficial holders of record of our common stock as of the close of business on December 31, 2024 was 118.

(d) Dividends

We do not expect to pay cash dividends in the next term. We intend to retain future earnings, if any, to provide funds for operation of our business. We currently have no restrictions affecting our ability to pay cash dividends.

(e) Equity Compensation Plans

The Company does not have an equity compensation plan.

Recent Sales of Unregistered Securities

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of $5,000 per unit with each Unit consisting of one (1) $5,500 principal amount convertible debenture (convertible at Four dollars ($4.00) per share) and a Warrant to purchase 1,250 shares of common stock at $6.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at $4.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of $6.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of April 15, 2025, a total of 69 Units were sold to accredited investors at a price of $5,000 per Unit totaling $345,197.

On November 19, 2024, the Company entered into Original Issue Discount Senior Convertible totaling (i) $26,400 aggregate principal amount of Notes (total of $24,000 cash was received) due November 19, 2025 based on $1.00 for each $0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 6,600 shares of the Company's Common Stock at an exercise price of $6.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was $24,000 which was issued at a $2,400 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is $4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

Item 6. Selected Financial Data

Because we are a smaller reporting company, this Item 6 is not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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".

We are an emerging growth company as defined in Section 2(a) (19) of the Securities Act. Pursuant to Section 107 of the Jumpstart Our Business Startups Act, we may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards, meaning that we can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have chosen to take advantage of the extended transition period for complying with new or revised accounting standards applicable to public companies to delay adoption of such standards until such standards are made applicable to private companies. Accordingly, our consolidated financial statements may not be comparable to the financial statements of public companies that comply with such new or revised accounting standards.

OVERVIEW:

Historical Development

Our Company

Sigyn Therapeutics, Inc. ("Sigyn", the "Company", "we," "us," or "our") is a development-stage company focused on creating therapeutic solutions that address unmet needs in global healthcare. Our corporate address is 2468 Historic Decatur Road, Suite 140, San Diego, California, 92106.

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 and inflammation in end-stage renal disease (dialysis) patients, sepsis (a leading cause of hospital deaths), community acquired pneumonia (a leading cause of death among infectious diseases), and emerging pandemic threats.

Our development pipeline includes a cancer treatment system comprised of ChemoPrep™ to enhance the tumor site delivery of chemotherapy, and ChemoPure™ to reduce treatment toxicity and inhibit the spread of cancer metastasis.

Reverse Stock Split

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

Financing Transactions

Preferred Stock

The Company has 10,000,000 shares of par value $0.0001 preferred stock authorized, of which 2,403 and 1,287 shares preferred shares are issued and outstanding at December, 31, 2024 and 2023, respectively.

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

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

During fiscal 2023, holders of 161,684 shares of common stock elected to exchange these shares for an aggregate of 1,287 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.53 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio in the Warrant Exchange Agreement.

Common Stock

On December 30, 2024, the Company filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the State of Delaware, which went effective immediately upon filing. The Certificate of Amendment decreased our authorized common stock to One Hundred Million (100,000,000) shares, par value $0.0001, of which 1,605,377 and 1,288,415 shares are outstanding as of December 31, 2024 and 2023, respectively.

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

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

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

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

Shares Cancelled

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

Restricted Stock Units

Effective October 10, 2022, the Company's Board of Directors appointed Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel and on January 11, 2025, appointed Mr. Michael Ryan as non-executive members to the Company's Board of Directors ("Director"). Each Director shall receive an annual grant of restricted stock units of $50,000. During the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation totaling $150,000 and $150,000, respectively, in the consolidated Statements of Operations.

Warrants

On August 24, 2024, the Company issued 2,617 warrants valued at $15,703 (based on the fair value of the options using the Black-Scholes option-pricing method on the date of grant), for services rendered.

On October 8, 2024, the Company offered a short-term inducement to the Company's warrant holders in which the Company will issue ¾ of a share of the Company's common stock in exchange for each warrant. In response to this offer, 246,257 warrants were exchanged for 184,700 shares of the Company's common stock. The Company recognized a gain of $63,715 due to the modification of the warrants in October 2024.

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

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

Promissory Notes

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

Regulation D

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of $5,000 per unit with each Unit consisting of one (1) $5,500 principal amount convertible debenture (convertible at Four dollars ($4.00) per share) and a Warrant to purchase 1,250 shares of common stock at $6.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at $4.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of $6.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of April 15, 2025, a total of 69 Units were sold to accredited investors at a price of $5,000 per Unit totaling $345,197.

Convertible Notes

Between January 2020 and November 2024, the Company received cash of $4,849,885 through the issuance of 10% Original Issue Discount Senior Convertible Debentures with third party investors. Between June 2023 and September 2024, $3,069,348 in aggregate principal amount of the notes were converted into 371,110 common shares and 1,116.29 shares of Series B Convertible Preferred Stock. Each share of Series B Convertible Preferred Stock converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for the issuances of additional shares at an issue price of less than the conversion ratio.

The remaining outstanding Notes are as follows:

Note Holder/Original Issuance Date	Maturity Date	Cash Received	Outstanding Balance as of December 31, 2024 [1]	Outstanding Balance as of December 31, 2023 [1]
Osher Capital Partners LLC				
January 28, 2020 ("Note 1")	August 31, 2025	$ 350,005	$ 620,553	$ 564,138
June 22, 2022 ("Note 2")	August 31, 2025	75,000	103,745	94,314
August 31, 2022 ("Note 2")	August 31, 2025	100,000	135,520	123,200
September 20, 2022 ("Note 2")	August 31, 2025	100,000	135,520	123,200
October 20, 2022 ("Note 2")	March 31, 2025	100,000	127,000	110,000
November 14, 2022 ("Note 2")	March 31, 2025	50,000	64,350	55,000
December 22, 2022 ("Note 2")	March 31, 2025	100,000	125,000	110,000
July 18, 2023 ("Note 3")	August 31, 2025	60,000	72,600	66,000
December 7, 2023 ("Note 3")	August 31, 2025	40,000	48,400	44,000
May 13, 2024 ("Note 4")	May 13, 2025	35,000	40,000	-
August 19, 2024 ("Note 4")	August 19, 2025	7,500	8,250	-
November 19, 2024 ("Note 4")	November 19, 2025	8,000	8,800	-
Brio Capital Master Fund, Ltd.				
March 23, 2022 ("Note 2")	August 31, 2025	100,000	142,960	129,964
November 9, 2022 ("Note 2")	August 31, 2025	75,000	101,640	92,400
January 20, 2023 ("Note 3")	March 31, 2025	50,000	62,500	55,000
February 9, 2023 ("Note 3")	March 31, 2025	50,000	62,500	55,000
July 20, 2023 ("Note 3")	August 31, 2025	40,000	48,400	44,000
January 8, 2024 ("Note 4")	January 8, 2025	40,000	44,000	-
May 13, 2024 ("Note 4")	May 13, 2025	35,000	40,000	-
August 20, 2024 ("Note 4")	August 20, 2025	11,500	12,650	-
November 19, 2024 ("Note 4")	November 19, 2025	8,000	8,800	-
Various third-party noteholders				
Various dates in fiscal 2024 ("Note 4")	None outstanding	650,890	8,800	-
Previous fiscal 2021, 2022, and 2023 Osher and Brio Notes converted in fiscal 2024			-	841,420
Total convertible notes payable		$ 2,085,895	$ 2,021,988	$ 2,507,636

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

The outstanding Osher and Brio Notes can convert into a total of 4,092 shares of Series B Convertible Preferred Stock, with each share of Series B Convertible Preferred Stock convertible into 125.63 shares of the Company's common stock, subject to adjustment as provided therein, such as stock splits and stock dividends. In addition, the remaining Notes provide for an automatic conversion into Series B Convertible Preferred Stock in accordance with their terms upon a listing of the Company's common stock on a national securities exchange such as Nasdaq Capital Market.

The Company has not repaid the Brio January 8, 2024 convertible note of $44,000 that matured on January 8, 2025 and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

The Company has not repaid two Brio convertible notes totaling $125,000 that matured on March 31, 2025 and the convertible notes are now in default. The Company is currently in discussions to restructure the terms of these notes.

The Company has not repaid three Osher convertible notes totaling $316,350 that matured on March 31, 2025 and the convertible notes are now in default. The Company is currently in discussions to restructure the terms of these notes.

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
- Off-Balance Sheet Arrangements
- Critical Accounting Policies

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

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

Results of Operations

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

The following discussion represents a comparison of our results of operations for the years ended December 31, 2024 and 2023. 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, 2024	Year Ended December 31, 2023
Net revenues	$ -	$ -
Cost of sales	-	-
Gross Profit	-	-
Operating expenses	2,519,242	2,455,317
Other expense	820,970	1,690,619
Net loss before income taxes	$ (3,340,212)	$ (4,145,936)

Net Revenues

For the years ended December 31, 2024 and 2023, we had no revenues.

Cost of Sales

For the years ended December 31, 2024 and 2023, we had no cost of sales.

Operating expenses

Operating expenses increased by $63,925, or 2.6%, to $2,519,242 for the year ended December 31, 2024 from $2,455,317 for the year ended December 31, 2023 primarily due to increases in professional fees of $64,973, investor relations costs of $206,862, offset partially by research and development costs of $24,886, compensation costs of $8,624, insurance costs of $31,808, rent expenses of $573, travel costs of $2,170, stock based compensation of $65,558, consulting costs of $67,739, depreciation costs of $1,145, amortization costs of $2,100, and general and administration costs of $3,307, as a result of administrative infrastructure for our anticipated business development. In 2024 and 2023, the Company incurred stock-based compensation as a result adding members to our board of directors, research and development costs attributed to in house efforts, and increased professional fees, primarily investor relations, for brand awareness.

For the year ended December 31, 2024, we had marketing expenses of $1,130, research and development costs of $773,279, and general and administrative expenses of $1,744,833 primarily due to professional fees of $239,218, compensation costs of $671,984, consulting costs of $136,153, insurance costs of $203,944, stock based compensation of $150,000, rent of $77,732, depreciation costs of $5,611, investor relations costs of $243,390, and general and administration costs of $16,801, as a result of administrative infrastructure for our anticipated business development. In 2024 and 2023, the Company incurred stock-based compensation as a result adding members to our board of directors, research and development costs attributed to in house efforts, and professional fees, primarily investor relations, for brand awareness.

For the year ended December 31, 2023, we had marketing expenses of $392, research and development costs of $798,165, and general and administrative expenses of $1,656,760 primarily due to professional fees of $174,245, compensation costs of $680,608, consulting costs of $203,892, insurance costs of $235,752, stock based compensation of $215,558, rent of $78,305, depreciation costs of $6,756, amortization costs of $2,100, investor relations costs of $36,528, travel costs of $2,170, and general and administration costs of $20,846, as a result of administrative infrastructure for our anticipated business development. In 2023, the Company incurred stock-based compensation as a result adding members to our board of directors, research and development costs attributed to in house efforts, and professional fees, primarily investor relations.

Other Expense

Other expense for the year ended December 31, 2024 totaled $820,970 primarily due interest expense of $856,533 in conjunction with accretion of debt discount and original issuance discount, and interest expense of $3,382, and the gain on modification of warrants of $38,945, compared to other expense of $1,690,619 primarily due interest expense of $2,041,182 in conjunction with accretion of debt discount and original issuance discount, and interest expense of $2,402, and the modification of warrants of $352,965 for the year ended December 31, 2023.

Net loss before income taxes

Net loss before income taxes for the year ended December 31, 2024 totaled $3,340,212 primarily due to increases/decreases in compensation costs, professional fees, consulting costs, research and development costs, investor relations costs, insurance costs, stock based compensation, rent, and general and administration costs compared to a loss of $4,145,936 primarily due to increases/decreases in compensation costs, professional fees, consulting costs, research and development costs, investor relations costs, insurance costs, stock based compensation, rent, and general and administration costs.

Assets and Liabilities

Assets were $213,719 as of December 31, 2024. Assets consisted primarily of cash of $12,144, other current assets of $9,100, equipment of $9,685, operating lease right-of-use assets of $112,079, and other assets of $70,711. Liabilities were $4,671,343 as of December 31, 2024. Liabilities consisted primarily of accounts payable of $608,384, accrued payroll and payroll taxes of $1,868,973, short-term promissory notes of $174,206, net of $139,794 of unamortized debt issuance costs, convertible notes of $1,891,736, net of $130,252 of unamortized debt issuance costs, operating lease liabilities of $126,302, and other current liabilities of $1,742.

Liquidity and Capital Resources

Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company had an accumulated deficit of $14,681,724 at December 31, 2024, had a working capital deficit of $4,593,743 at December 31, 2024, had net losses of $3,340,212 and $4,145,936 for the years ended December 31, 2024 and 2023, respectively, and net cash used in operating activities of $872,436 and $1,383,210 for the years ended December 31, 2024 and 2023, respectively, with no revenue earned since inception, and a lack of operational history. These matters raise substantial doubt about the Company's ability to continue as a going concern.

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

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

General – Overall, we had an increase in cash flows for the year ended December 31, 2024 of $454 resulting from cash provided by financing activities of $872,890, offset partially by cash used in operating activities of $872,436.

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, 2024	Year Ended December 31, 2023
Net cash provided by (used in):		
Operating activities	$ (872,436)	$ (1,383,210)
Investing activities	-	-
Financing activities	872,890	1,386,544
	$ 454	$ 3,334

Year Ended December 31, 2024 Compared to Year Ended December 31, 2023

Cash Flows from Operating Activities – For the year ended December 31, 2024, net cash used in operations was $872,436 compared to net cash used in operations of $1,383,210 for the year ended December 31, 2023. Net cash used in operations was primarily due to a net loss of $3,340,212 for year ended December 31, 2024 and the changes in operating assets and liabilities of $1,264,324, primarily due to the increases in other current assets of $47,273, accounts payable of $146,738, and accrued payroll and payroll taxes of $1,077,219, offset primarily by a decrease in other current liabilities of $6,906. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of $5,611, stock issued for services of $214,550, warrants issued for services of $15,703, accretion of original issuance costs of $392,783, the accretion of debt discount of $463,750, stock-based compensation of $150,000, and the gain on modification of warrants of $38,945.

For the year ended December 31, 2023, net cash used in operations was primarily due to a net loss of $4,145,936 and the changes in operating assets and liabilities of $850,095, primarily due to the increases in other current assets of $44,431, accounts payable of $196,629, and accrued payroll and payroll taxes of $699,130, offset primarily by decreases in other current liabilities of $1,233. In addition, net cash used in operating activities includes adjustments to reconcile net profit from depreciation expense of $6,756, amortization expense of $2,100, accretion of original issuance costs of $285,187, the accretion of debt discount of $1,755,995, stock-based compensation of $215,558, and the modification of warrants of $352,965.

Cash Flows from Investing Activities – For the years ended December 31, 2024 and 2023, the Company had no cash flows from investing activities.

Cash Flows from Financing Activities – For the year ended December 31, 2024, net cash provided by financing was $872,890 due to proceeds from short term convertible notes of $795,890, proceeds from short term promissory notes of $157,000, advance from shareholder of $35,000, partially offset by repayments of advance from shareholder of $115,000. For the year ended December 31, 2023, net cash provided by financing was $1,386,544 due to proceeds from short term convertible notes of $1,312,000 net of fees associated with the filing of the Company's Form S-1 of $5,456 and advance from shareholder of $80,000.

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.

Regulation D

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of $5,000 per unit with each Unit consisting of one (1) $5,500 principal amount convertible debenture (convertible at Four dollars ($4.00) per share) and a Warrant to purchase 1,250 shares of common stock at $6.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at $4.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of $6.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of April 15, 2025, a total of 69 Units were sold to accredited investors at a price of $5,000 per Unit totaling $345,197.

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 $0 and $80,000 under Advance From Shareholder in the accompanying Balance Sheets at December 31, 2024 and 2023, respectively. The Company received advances of $35,000 and $80,000 and had repayments of $115,000 and $0 for the years ended December 31, 2024 and 2023, respectively. The advance from our CEO was not made pursuant to any loan agreements or promissory notes, is non-interest bearing and due on demand.

Convertible Notes Payable

During fiscal 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $852,630 aggregate principal amount of Notes (total of $771,891 cash was received) due between January and June 2025 based on $1.00 for each $0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 213,164 shares of the Company's Common Stock at an exercise price of $7.50 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was $771,891 which was issued at a $80,738 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is $4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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

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

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

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

In October 2023, the holders of $997,700 of Original Issue Discount Senior Convertible Debentures converted their debentures at a contractual exercise price of $10.00 per share in exchange for the issuance of 166,284 shares of Common Stock to the holders.

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.

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.

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.

Off-Balance Sheet Arrangements

As of December 31, 2024, we have not entered into any transaction, agreement or other contractual arrangement with an entity unconsolidated under which it has:

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

Inflation

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

Critical Accounting Policies

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

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

Use of Estimates

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

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

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

Item 8. Financial Statements and Supplementary Data

The financial statements and supplementary financial information which are required to be filed under this item are presented under Item 15. Exhibits, Financial Statement Schedules and Reports on Form 10-K in this document, and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rule 13a-l5(e) under the Exchange Act) that are designed to ensure that information that would be required to be disclosed in Exchange Act reports is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including to our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

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

Management's Report on Internal Controls over Financial Reporting

The Company's management is responsible for establishing and maintaining effective internal control over financial reporting (as defined in Rule 13a-l5(f) of the Securities Exchange Act). Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") (2013). Based on that assessment, management believes that, as of December 31, 2024, the Company's internal control over financial reporting was ineffective based on the COSO criteria, due to the following material weaknesses listed below.

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

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

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

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

Management's Remediation Plan

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

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

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

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

Management believes that despite our material weaknesses set forth above, our consolidated financial statements for the year ended December 31, 2024 are fairly stated, in all material respects, in accordance with GAAP.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal year ending December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

There have been no events required to be reported under this Item.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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.

Name	Age	Title	Full Time/Part Time
Jim Joyce [1]	63	Chief Executive Officer, Interim Chief Financial Officer, and Chairman of the Board of Directors ("CEO")	Full Time
Craig Roberts	72	Chief Technology Officer and Director	Part Time
Richa Nand [2]	51	Non-Employee Director	Not applicable
Jim Dorst [2]	70	Non-Employee Director	Not applicable
Christopher Wetzel [2]	49	Non-Employee Director	Not applicable
Michael Ryan [3]	67	Non-Employee Director	Not applicable

(1) Mr. Joyce was hired as the Company's Interim Chief Financial Officer effective February 26, 2025.
(2) Ms. Nand, Mr. Dorst and Mr. Wetzel were appointed as Non-Executive Directors effective October 10, 2022.
(3) Mr. Ryan was appointed as a Non-Executive Director effective January 11, 2025.

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, and the Company's interim Chief Financial Officer since February 2025. 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" (EAU) 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.

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.

Michael Ryan. Mr. Ryan is a seasoned executive, entrepreneur and investor within the early-stage technology and life science industry. Mr. Ryan is one of the Founder Directors of Irrus Investments, Ltd., a role he has held since 2011. Irrus Investments is the largest angel investment syndicate in Ireland with an emphasis on life science companies. To date, Irrus has invested over €40million in 35 early-stage life science and technology companies in Ireland, UK, Sweden and USA. Mr. Ryan previously served as Chief Executive Officer and Board Member of Sedana Medical, from 2011 until shortly before the Company launched on the Nasdaq owned First North stock exchange in Stockholm in 2017. Prior to this, he was the main shareholder and Chief Executive Officer of Artema Medical AB, where he helped orchestrate the Company's acquisition by Datascope Corporation. Mr. Ryan holds a B.Eng in Mechanical Engineering and a Masters in Industrial Engineering from University College Dublin.

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 six members, with four independent directors in accordance with Nasdaq Capital Market 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 Capital Market to make this determination. with Nasdaq Capital Market 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 Capital Market 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 six members. Directors serve for a term of one year and until their successors have been duly elected and qualified.

Committees of the Board

On October 26, 2023, the Company established an audit, nominating, and compensation committee.

Our Audit Committee is primarily responsible for overseeing our risk management processes on behalf of our Board of Directors. The Audit Committee receives and reviews periodic reports from management, auditors, legal counsel, and others, as considered appropriate regarding our company's assessment of risks. In addition, the Audit Committee reports regularly to the full Board of Directors, which also considers our risk profile. The Audit Committee and the full Board of Directors focus on the most significant risks facing our Company and our Company's general risk management strategy, and also ensure that risks undertaken by our Company are consistent with the Board's appetite for risk. While the Board oversees our company's risk management, management is responsible for day-to-day risk management processes. We believe this division of responsibilities is the most effective approach for addressing the risks facing our company and that our Board leadership structure supports this approach.

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.

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

On October 25, 2023, we adopted a Code of Ethics for our principal executive officers and senior management. The Code is designed to deter wrongdoing and promote honest and ethical conduct; full and fair disclosure in reports and documents submitted to the SEC; compliance with applicable governmental laws, rules and regulations; and the prompt internal reporting of violations of the code to appropriate persons by our senior management. A copy of our Code of Ethics can be accessed at https://www.sigyntherapeutics.com/investors/corporate-governance/governance-documents.

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

Effective October 10, 2022, the Company's Board of Directors appointed Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel and on January 11, 2025, appointed Mr. Michael Ryan 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. During the years ended December 31, 2024 and 2023, respectively, each Director received a total of 10,840 and 5,728 restricted stock units.

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.

Item 11. 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. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

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, 2024, 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

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($) [1]	Total ($)
Jim Joyce	2024	455,000	-	-	-	-	-	$ 52,655	$ 507,655
Chief Executive Officer, Interim Chief Financial Officer [2]	2023	455,000	-	-	-	-	-	$ 31,037	$ 486,037
	2022	453,067	-	-	-	-	-	$ 48,811	$ 501,878
Craig Roberts	2024	160,000	-	-	-	-	-	$ 11,589	$ 171,589
Chief Technology Officer [3]	2023	240,000	-	-	-	-	-	$ 16,460	$ 256,460
	2022	233,678	-	-	-	-	-	$ 25,312	$ 258,990
Gerald DeCiccio	2024	125,000	-	-	-	-	-	$ 21,379	$ 146,379
Forner Chief Financial Officer [4]	2023	9,000	-	-	-	-	-	$ -	$ 9,000
	2022	-	-	-	-	-	-	$ -	$ -
Jeremy Ferrell	2024	-	-	-	-	-	-	$ -	$ -
Former Chief Financial Officer [5]	2023	57,288	-	-	-	-	-	$ 4,263	$ 61,551
	2022	177,083	-	-	-	-	-	$ 23,205	$ 200,288

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

(2) Mr. Joyce's 2024 and 2023 salary includes $412,814 and $284,375 of accrued salary, respectively. Mr. Joyce was appointed as our interim Chief Financial Officer on February 26, 2025. He is not receiving any additional compensation for assuming this role.

(3) Mr. Roberts 2024 and 2023 salary includes $160,000 and $160,000 of accrued salary, respectively.

(4) Mr. DeCiccio was hired as the Company's Chief Financial Officer effective December 6, 2023 and he retired on February 26, 2025. Mr. DeCiccio received an annual salary of $250,000 at a pro-rated amount of $125,000 until transition to full-time employment at the completion of a financing that underlies an S-1 registration statement. Mr. DeCiccio's 2024 and 2023 salary includes $125,000 and $9,000 of accrued salary, respectively.

(5) Mr. Ferrell was hired as the Company's Chief Financial Officer effective March 9, 2022. Mr. Ferrell received an annual base salary of $250,000, amended to $62,500 on December 1, 2022. Mr. Ferrell's employment was terminated on December 6, 2023. Mr. Ferrell's 2023 salary includes $24,479 of accrued salary.

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, 2024 and 2023, 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, 2024 and 2023.

Outstanding Equity Awards at 2024 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.

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, 2024:

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned 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 ($)
Jim Joyce.	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Craig Roberts	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-
Gerald DeCiccio	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-	-0-

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information relating to the beneficial ownership our common stock as of April 11, 2025 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.

Name and Address [2]	Amount of Beneficial Ownership	Percent of Class [1]
Jim Joyce [3]	320,500	20.0%
Craig Roberts [4]	256,400	16.0%
Gerald DeCiccio [5]	13,125	0.8%
Chris Wetzel[8]	19,693	1.2%
Jim Dorst[8]	16,568	1.0%
Richa Nand[8]	16,568	1.0%
Michael Ryan[8]	82,249	5.1%
Brio Capital Master Fund Ltd. [6]	93,146	5.8%
Osher Capital Partners LLC [7]	88,261	5.5%
Gerard Ryan	208,940	13.0%
Colin McMahon	112,188	7.0%
All Officers and Directors as a Group (6 Persons)	642,854	40.0%

(1) Based on 1,605,377 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. DeCiccio was hired as the Company's Chief Financial Officer effective December 6, 2023 and he retired on February 26, 2025.
(6) Consists of 93,146 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 76,266 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.
(8) Mr. Wetzel, Mr. Dorst, Ms. Nand, and Mr. Ryan are directors of the Company. Each director receives an annual grant of $50,000 worth of restricted stock units.

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.

Equity Compensation Plans

The following represents a summary of the Equity Compensation grants and options awards outstanding at December 31, 2024 and 2023 and changes during the years then ended:

2024 and 2023

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

Item 13. Certain Relationships and Related Transactions, and Director Independence

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2023 (i.e., the last two completed fiscal years), to which we were a party or will be a party, in which the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and any of our directors, executive officers, or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest. Compensation arrangements, including employment agreements, for our directors and named executive officers are described elsewhere in "Executive Compensation - Agreements with Executive Officers."

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 $455,000 (of which $42,416 was paid and $412,584 is unpaid and accrued) and $455,000 (of which $170,625 was paid and $284,375 is unpaid and accrued) for the years ended December 31, 2024 and 2023, respectively. The cumulative amount accrued at December 31, 2024 related to Mr. Joyce's salary was $715,210.

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 $309,000 (of which $83,688 was paid and $225,313 is unpaid and accrued) and $225,000 (of which $125,000 was paid and $100,000 is unpaid and accrued) for the years ended December 31, 2024 and 2023, respectively. The cumulative amount accrued at December 31, 2024 related to Dr. Marleau's salary was $325,313.

Convertible Notes

Between January 2020 and September 2024, the Company received cash of $5,249,885 through the issuance of 10% Original Issue Discount Senior Convertible Debentures with third party investors. Between June 2023 and September 2024, $3,069,348 in aggregate principal amount of the notes were converted into 371,110 common shares and 1,116.29 shares of Series B Convertible Preferred Stock. Each share of Series B Convertible Preferred Stock converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for the issuances of additional shares at an issue price of less than the conversion ratio.

The remaining outstanding Notes are as follows:

Note Holder/Original Issuance Date	Maturity Date	Cash Received	Outstanding Balance as of December 31, 2024 [1]	Outstanding Balance as of December 31, 2023 [1]
Osher Capital Partners LLC				
January 28, 2020 ("Note 1")	August 31, 2025	$ 350,005	$ 620,553	$ 564,138
June 22, 2022 ("Note 2")	August 31, 2025	75,000	103,745	94,314
August 31, 2022 ("Note 2")	August 31, 2025	100,000	135,520	123,200
September 20, 2022 ("Note 2")	August 31, 2025	100,000	135,520	123,200
October 20, 2022 ("Note 2")	March 31, 2025	100,000	127,000	110,000
November 14, 2022 ("Note 2")	March 31, 2025	50,000	64,350	55,000
December 22, 2022 ("Note 2")	March 31, 2025	100,000	125,000	110,000
July 18, 2023 ("Note 3")	August 31, 2025	60,000	72,600	66,000
December 7, 2023 ("Note 3")	August 31, 2025	40,000	48,400	44,000
May 13, 2024 ("Note 4")	May 13, 2025	35,000	40,000	-
August 19, 2024 ("Note 4")	August 19, 2025	7,500	8,250	-
November 19, 2024 ("Note 4")	November 19, 2025	8,000	8,800	-
Brio Capital Master Fund, Ltd.				
March 23, 2022 ("Note 2")	August 31, 2025	100,000	142,960	129,964
November 9, 2022 ("Note 2")	August 31, 2025	75,000	101,640	92,400
January 20, 2023 ("Note 3")	March 31, 2025	50,000	62,500	55,000
February 9, 2023 ("Note 3")	March 31, 2025	50,000	62,500	55,000
July 20, 2023 ("Note 3")	August 31, 2025	40,000	48,400	44,000
January 8, 2024 ("Note 4")	January 8, 2025	40,000	44,000	-
May 13, 2024 ("Note 4")	May 13, 2025	35,000	40,000	-
August 20, 2024 ("Note 4")	August 20, 2025	11,500	12,650	-
November 19, 2024 ("Note 4")	November 19, 2025	8,000	8,800	-
Various third-party noteholders				
Various dates in fiscal 2024 ("Note 4")	None outstanding	650,890	8,800	-
Previous fiscal 2021, 2022, and 2023 Osher and Brio Notes converted in fiscal 2024			-	841,420
Total convertible notes payable		$ 2,085,895	$ 2,021,988	$ 2,507,636

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

The outstanding Osher and Brio Notes can convert into a total of 4,092 shares of Series B Convertible Preferred Stock, with each share of Series B Convertible Preferred Stock convertible into 125.63 shares of the Company's common stock, subject to adjustment as provided therein, such as stock splits and stock dividends. In addition, the remaining Notes provide for an automatic conversion into Series B Convertible Preferred Stock in accordance with their terms upon a listing of the Company's common stock on a national securities exchange such as Nasdaq Capital Market.

The Company has not repaid the Brio January 8, 2024 convertible note of $44,000 that matured on January 8, 2025 and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

The Company has not repaid two Brio convertible notes totaling $125,000 that matured on March 31, 2025 and the convertible notes are now in default. The Company is currently in discussions to restructure the terms of these notes.

The Company has not repaid three Osher convertible notes totaling $316,350 that matured on March 31, 2025 and the convertible notes are now in default. The Company is currently in discussions to restructure the terms of these notes.

Indemnification Agreements

We have entered or intend to enter into indemnification agreements with each of our directors and executive officers. These agreements, among other things, will require us to indemnify each individual to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the individual in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director, officer or other employee.

Policies and Procedures for Related Party Transactions

Given our small size and limited financial resources, we have not adopted formal policies and procedures for the review, approval or ratification of transactions with our executive officer(s), director(s) and significant shareholders. We rely on our board to review related party transactions on an ongoing basis to prevent conflicts of interest. Our board reviews a transaction in light of the affiliations of the director, officer or employee and the affiliations of such person's immediate family. Transactions are presented to our board for approval before they are entered into or, if this is not possible, for ratification after the transaction has occurred. If our board finds that a conflict of interest exists, then it will determine the appropriate remedial action, if any. Our board approves or ratifies a transaction if it determines that the transaction is consistent with the best interests of the Company. We intend to establish formal policies and procedures in the future, once we have sufficient resources and have appointed additional directors, so that such transactions will be subject to the review, approval or ratification of our board of directors, or an appropriate committee thereof.

Item 14. Principal Accounting Fees and Services

The aggregate fees billed for the most recently completed fiscal period for the audit of our annual financial statements and services normally provided by the independent registered public accounting firm for this fiscal period were as follows:

	FY 2024	FY 2023
Audit Fees	$ 103,395	$ 46,350
Total Fees	$ 103,395	$ 46,350

In the above table, "audit fees" are fees billed by our external auditor for services provided in auditing our annual financial statements for the subject year. The fees set forth on the foregoing table relate to the audit as of and for the years ended December 31, 2024 and 2023 which were performed by Kreit & Chiu CPA LLP (formerly Paris, Kreit & Chiu CPA LLP). All of the services described above were approved in advance by the Board of Directors or the Company's Audit Committee.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as a part of this Annual Report:

1. Financial Statements. The following consolidated financial statements of the Company are included below:

2. Financial Statement Schedule(s):

All schedules are omitted for the reason that the information is included in the consolidated financial statements or the notes thereto or that they are not required or are not applicable.

Exhibit Number	Description
1.1	Form of Underwriting Agreement**
3.1*	Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware
3.2*	Bylaws of the Registrant, as currently in effect (Filed as Exhibit 3.2 to the Registration Statement on Form S-1 filed by the Registrant on May 27, 2015, and incorporated herein by reference).
10.1	Share Exchange Agreement dated August 25, 2020 (Filed as Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on August 31, 2020 and incorporated herein by reference)*
10.2	Operating Lease*
10.3	Employment Agreement for Jeremy Ferrell (Filed as Exhibit 99.1 to the Current Report on Form 8-K filed by the Registrant on March 9, 2022 and incorporated herein by reference)*
10.4	January 2020 Financing Documents and Extensions*
10.5	June 23, 2020 Financing Documents*
10.6	September 17, 2020 Financing Documents*
10.7	Senior Convertible Debenture dated May 10, 2022*
10.8	Warrant dated May 10, 2022*
10.9	Warrant dated October 18, 2021*
10.10	Senior Convertible Debenture dated March 23, 2022*
10.11	Warrant dated March 23, 2022*
10.12	Senior Convertible Debenture dated March 23, 2022*
10.13	Warrant dated March 23, 2022*
10.14	Senior Convertible Debenture dated April 28, 2022*
10.15	Warrant dated April 28, 2022*
10.16	June 1, 2022 Financing Documents*
10.17	June 22, 2022 Financing Documents*
10.18	Set of Form Documents for July 2022 Financing*

Exhibit Number	Description
10.19	August 31, 2022 Financing Documents*
10.20	September 9, 2022 Financing Documents*
10.21	October 20, 2022 Financing Documents*
10.22	November 9, 2022 Financing Documents*
10.23	November 14, 2022 Financing Documents*
10.24	November 21, 2022 Financing Documents*
21.1	Subsidiaries of the Registrant*
31.1	Certification by Principal Executive Officer pursuant to Rule 13a-14(a)
32.1	Certification by Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
*	Previously filed.
**	To be filed by amendment
***	Filed herewith

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Sigyn Therapeutics, Inc.
a Delaware corporation

Dated: April 15, 2025

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

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

Name	Title	Date
/s/ Mr. James Joyce *Mr. James Joyce*	Chief Executive Officer, Interim Chief Financial Officer, and Director	April 15, 2025
/s/ Mr. Craig Roberts *Mr. Craig Roberts*	Chief Technology Officer and Director	April 15, 2025
/s/ Richa Nand Richa Nand	Director	April 15, 2025
/s/ Jim Dorst Jim Dorst	Director	April 15, 2025
/s/ Chris Wetzel Chris Wetzel	Director	April 15, 2025
/s/ Michael Ryan Michael Ryan	Director	April 15, 2025

SIGYN THERAPEUTICS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
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, 2024 and 2023, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the two years ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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 entity'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 Sigyn Therapeutics, Inc. 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. Sigyn Therapeutics, Inc. is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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

Critical audit matters 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. We determined that there are no critical audit matters.

/s/ Kreit & Chiu CPA LLP

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

Los Angeles, California
April 15, 2025

SIGYN THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash	$ 12,144	$ 11,690
Inventories	-	50,000
Other current assets	9,100	56,373
Total current assets	21,244	118,063
Property and equipment, net	9,685	15,296
Operating lease right-of-use assets, net	112,079	167,736
Other assets	70,711	20,711
Total assets	**$ 213,719**	**$ 321,806**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 608,384	$ 461,646
Accrued payroll and payroll taxes	1,868,973	791,754
Advance from shareholder	-	80,000
Short-term promissory notes, less unamortized debt issuance costs of $139,794 and $0, respectively	174,206	-
Short-term convertible notes payable, less unamortized debt issuance costs of $130,252 and $297,337, respectively	1,891,736	2,210,299
Current portion of operating lease liabilities	69,946	61,123
Other current liabilities	1,742	3,182
Total current liabilities	4,614,987	3,608,004
Long-term liabilities:		
Operating lease liabilities, net of current portion	56,356	126,302
Total long-term liabilities	56,356	126,302
Total liabilities	**4,671,343**	**3,734,306**
Stockholders' deficit:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized; 2,403 and 1,287 shares issued and outstanding at December 31, 2024 and 2023, respectively	-	-
Common stock, $0.0001 par value, 100,000,000 shares authorized; 1,605,377 and 1,288,415 shares issued and outstanding at December 31, 2024 and 2023, respectively	161	129
Additional paid-in capital	10,223,939	7,928,883
Accumulated deficit	(14,681,724)	(11,341,512)
Total stockholders' deficit	(4,457,624)	(3,412,500)
Total liabilities and stockholders' deficit	**$ 213,719**	**$ 321,806**

See accompanying notes to consolidated financial statements

SIGYN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2024	**2023**
Net revenues	$ -	$ -
Gross Profit	-	-
Operating expenses:		
Marketing expenses	1,130	392
Research and development	773,279	798,165
General and administrative	1,744,833	1,656,760
Total operating expenses	2,519,242	2,455,317
Loss from operations	(2,519,242)	(2,455,317)
Other expense (income):		
Modification of warrants	(38,945)	(352,965)
Interest expense	3,382	2,402
Interest expense - debt discount	463,750	1,755,995
Interest expense - original issuance costs	392,783	285,187
Total other expense	820,970	1,690,619
Loss before income taxes	(3,340,212)	(4,145,936)
Income taxes	-	-
Net loss	$ (3,340,212)	$ (4,145,936)
Net loss per share, basic and diluted	$ (2.51)	$ (3.77)
Weighted average number of shares outstanding		
Basic and diluted	1,332,449	1,100,372

See accompanying notes to consolidated financial statements

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

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of December 31, 2022	**-**	**$ -**	**956,595**	**$ 96**	**$ 5,292,240**	**$ (7,195,576)**	**$ (1,903,240)**
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	858,276	-	858,276
Beneficial conversion feature in conjunction with debt issuance	-	-	-	-	401,063	-	401,063
Stock-based compensation	-	-	-	-	215,558	-	215,558
Common stock issued to third parties in conjunction with conversion of debt	-	-	213,584	21	1,520,179		1,520,200
Modification of warrants	-	-	279,920	28	(352,993)	-	(352,965
Conversion of common stock for Series A preferred stock	1,287	-	(161,684)	(16)	16		-
Fees associated with filing of Form S-1	-	-	-	-	(5,456)	-	(5,456)
Net loss	-	-	-	-	-	(4,145,936)	(4,145,936)
Balance as of December 31, 2023	**1,287**	**$ -**	**1,288,415**	**$ 129**	**$ 7,928,883**	**$ (11,341,512)**	**$ (3,412,500)**
Warrants issued to third parties in conjunction with debt issuance	-	-	-	-	404,632	-	404,632
Cancellation of common stock - related party	-	-	(64,100)	(6)	6	-	-
Stock-based compensation	-	-	-	-	150,000	-	150,000
Common stock issued to third parties in conjunction with conversion of debt	-	-	157,526	16	707,714		707,730
Preferred stock issued to third parties in conjunction with conversion of debt	1,116	-	-	-	841,418	-	841,418
Common stock issued to third party for services	-	-	38,325	4	214,546	-	214,550
Warrants issued to third parties for services	-	-	-	-	15,703	-	15,703
Modification of warrants	-	-	184,699	18	(38,963)	-	(38,945)
Post split rounding of common shares	-	-	512	-	-	-	-
Net loss	-	-	-	-	-	(3,340,212)	(3,340,212)
Balance as of December 31, 2024	**2,403**	**$ -**	**1,605,377**	**$ 161**	**$ 10,223,939**	**$ (14,681,724)**	**$ (4,457,624)**

See accompanying notes to consolidated financial statements

SIGYN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (3,340,212)	$ (4,145,936)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	5,611	6,756
Amortization expense	-	2,100
Stock issued for services	214,550	-
Warrants issued for services	15,703	-
Stock based compensation	150,000	215,558
Accretion of debt discount	463,750	1,755,995
Accretion of original issuance costs	392,783	285,187
Modification of warrants	(38,945)	(352,965)
Changes in operating assets and liabilities:		
Other current assets	47,273	(44,431)
Accounts payable	146,738	196,629
Accrued payroll and payroll taxes	1,077,219	699,130
Other current liabilities	(6,906)	(1,233)
Net cash used in operating activities	**(872,436)**	**(1,383,210)**
Cash flows from financing activities:		
Proceeds from short-term convertible notes	795,890	1,312,000
Proceeds from short-term promissory notes	157,000	-
Advance from shareholder	35,000	80,000
Repayments of advance from shareholder	(115,000)	-
Fees associated with filing of Form S-1	-	(5,456)
Net cash provided by financing activities	**872,890**	**1,386,544**
Net (decrease) increase in cash	454	3,334
Cash at beginning of period	$ 11,690	$ 8,356
Cash at end of period	**$ 12,144**	**$ 11,690**
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Warrants issued to third parties in conjunction with debt issuance	$ 404,632	$ 858,276
Original issue discount issued in conjunction with debt	$ 83,139	$ 131,200
Original issue discount issued in conjunction with extension of debt	$ 184,471	$ 305,320
Preferred stock issued to third parties in conjunction with conversion of debt	$ 841,418	$ -
Common stock issued to third parties in conjunction with conversion of debt	$ 707,730	$ 1,520,200
Common stock issued for Series A preferred stock	$ -	$ 16
Cancellation of common stock - related party	$ 6	$ -
Beneficial conversion feature in conjunction with debt issuance	$ -	$ 401,063

See accompanying notes to consolidated financial statements

NOTE 1 – ORGANIZATION AND PRINCIPAL ACTIVITIES

Corporate History and Background

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

Infectious Disease Disorders

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

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

Previous Infectious Disease Industry Achievements

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

Sigyn Therapy™ Human Studies

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

Emerging Opportunity in Xenotransplantation

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

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

1. Gene-edited donor pigs to reduce pathogen accumulation in donor kidneys prior to their extraction for human transplantation. The feasibility of Sigyn Therapy™ administration has been demonstrated in eight (8) porcine subjects to date.

2. Human transplant recipients during and after transplantation to reduce the bloodstream presence of pathogen, inflammatory and other circulating factors that may cause severe illness or induce the rejection of a transplanted organ, whose source may be either a human or animal donor.

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

Devices to Optimize the Benefit of Cancer Therapies

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

ImmunePrep™ to Optimize Immunotherapeutic Antibodies

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

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

ChemoPrep™ to Optimize Chemotherapy Delivery

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

ChemoPure™ to Reduce Chemotherapy Toxicity

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

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

Merger Transaction

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

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

Reverse Stock Split

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

NOTE 2 – BASIS OF PRESENTATION

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

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

Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The Company had an accumulated deficit of $14,681,724 at December 31, 2024, had a working capital deficit of $4,593,743 at December 31, 2024, had net losses of $3,340,212 and $4,145,936 for the years ended December 31, 2024 and 2023, respectively, and net cash used in operating activities of $872,436 and $1,383,210 for the years ended December 31, 2024 and 2023, respectively, with no revenue earned since inception, and a lack of operational history. These matters raise substantial doubt about the Company's ability to continue as a going concern.

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

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

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Use of Estimates

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

Cash

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

Income Taxes

Income taxes are accounted for under an asset and liability approach. This process involves calculating the temporary and permanent differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The temporary differences result in deferred tax assets and liabilities, which would be recorded on the Consolidated 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 or any uncertain income tax positions.

Advertising and Marketing Costs

Advertising expenses are recorded as general and administrative expenses when they are incurred. The Company had $1,130 and $392 of advertising expenses for the years ended December 31, 2024 and 2023, respectively.

Research and Development

All research and development costs are expensed as incurred. The Company incurred research and development expense of $773,279 and $798,165 for the years ended December 31, 2024 and 2023, respectively.

Inventories

In conjunction with the October 19, 2020 Share Exchange Agreement, the Company kept the gem inventory of Reign Resources Corporation. Inventories are stated at the lower of cost or market (net realizable value) on a lot basis each quarter. A lot is determined by the cut, clarity, size, and weight of the sapphires. Inventory consists of sapphire jewels that meet rigorous grading criteria and are of cuts and sizes most commonly used in the jewelry industry. As of December 31, 2024 and 2023, the Company carried primarily loose sapphire jewels, jewelry for sale, and jewelry held as samples. Samples are used to show potential customers what the jewelry would look like. Promotional items given to customers that are not expected to be returned will be removed from inventory and expensed. There have been no promotional items given to customers as of December 31, 2024. The Company performs its own in-house assessment based on gem guide and the current market price for metals to value its inventory on an annual basis or if circumstances dictate sooner to determine if the estimated fair value is greater or less than cost. In addition, the inventory is reviewed each quarter by the Company against industry prices from gem-guide and if there is a potential impairment, the Company would appraise the inventory. The estimated fair value is subject to significant change due to changes in popularity of cut, perceived grade of the clarity of the sapphires, the number, type and size of inclusions, the availability of other similar quality and size sapphires, and other factors. As a result, the internal assessed value of the sapphires could be significantly lower from the current estimated fair value. Loose sapphire jewels do not degrade in quality over time. As the Company does not have any current plans to dispose of the inventory, the Company included the inventory in Other Assets in the Consolidated Balance Sheets as of December 31, 2024.

Property and Equipment

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

Impairment of Long-lived Assets

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

Our impairment analyses require management to apply judgment in estimating future cash flows as well as asset fair values, including forecasting useful lives of the assets, assessing the probability of different outcomes, and selecting the discount rate that reflects the risk inherent in future cash flows. If the carrying value is not recoverable, we assess the fair value of long-lived assets using commonly accepted techniques, and may use more than one method, including, but not limited to, recent third-party comparable sales and discounted cash flow models. If actual results are not consistent with our assumptions and estimates, or our assumptions and estimates change due to new information, we may be exposed to an impairment charge in the future. As of December 31, 2024 and 2023, the Company had not experienced impairment losses on its long-lived assets.

Fair Value of Financial Instruments

The provisions of accounting guidance, FASB Topic ASC 825 requires all entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet, for which it is practicable to estimate fair value, and defines fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties. As of December 31, 2024 and 2023, the fair value of cash, accounts payable, accrued expenses, advance from shareholder, and notes payable approximated carrying value due to the short maturity of the instruments, quoted market prices or interest rates which fluctuate with market rates.

Fair Value Measurements

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

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

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

Debt

The Company issues debt that may have separate warrants, conversion features, or no equity-linked attributes.

Embedded Conversion Features

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

Derivative Financial Instruments

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

For option-based simple derivative financial instruments, the Company uses the Monte Carlo simulations to value the derivative instruments at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period. There were no derivative financial instruments as of December 31, 2024 and 2023 and no charges or credits to income for the years ended December 31, 2024 and 2023.

Debt Issue Costs and Debt Discount

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

Original Issue Discount

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

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

Basic and diluted earnings per share

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

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

Stock Based Compensation

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

Non-Employee Stock-Based Compensation

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

Concentrations, Risks, and Uncertainties

Business Risk

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

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

Interest rate risk

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

Credit risk

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

Seasonality

The business is not subject to substantial seasonal fluctuations.

Major Suppliers

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

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

Recent Accounting Pronouncements

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

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

NOTE 4 – PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of:

	Estimated Life	December 31, 2024	December 31, 2023
Office equipment	5 years	$ 29,041	$ 29,041
Computer equipment	3 years	3,157	3,157
Accumulated depreciation		(22,513)	(16,902)
		$ 9,685	$ 15,296

Depreciation expense was $5,611 and $6,756 for the years ended December 31, 2024 and 2023, respectively, and is classified in general and administrative expenses in the Consolidated Statements of Operations.

NOTE 5 – CONVERTIBLE PROMISSORY DEBENTURES

Convertible notes payable consisted of the following:

Note Holder/Original Issuance Date	Maturity Date	Cash Received	Outstanding Balance as of December 31, 2024	Outstanding Balance as of December 31, 2023
Osher Capital Partners LLC				
January 28, 2020 (“Note 1”)	August 31, 2025	$ 350,005	$ 620,553	$ 564,138
June 22, 2022 (“Note 2”)	August 31, 2025	75,000	103,745	94,314
August 31, 2022 (“Note 2”)	August 31, 2025	100,000	135,520	123,200
September 20, 2022 (“Note 2”)	August 31, 2025	100,000	135,520	123,200
October 20, 2022 (“Note 2”)	March 31, 2025	100,000	127,000	110,000
November 14, 2022 (“Note 2”)	March 31, 2025	50,000	64,350	55,000
December 22, 2022 (“Note 2”)	March 31, 2025	100,000	125,000	110,000
July 18, 2023 (“Note 3”)	August 31, 2025	60,000	72,600	66,000
December 7, 2023 (“Note 3”)	August 31, 2025	40,000	48,400	44,000
May 13, 2024 (“Note 4”)	May 13, 2025	35,000	40,000	-
August 19, 2024 (“Note 4”)	August 19, 2025	7,500	8,250	-
November 19, 2024 (“Note 4”)	November 19, 2025	8,000	8,800	-
Brio Capital Master Fund, Ltd.				
March 23, 2022 (“Note 2”)	August 31, 2025	100,000	142,960	129,964
November 9, 2022 (“Note 2”)	August 31, 2025	75,000	101,640	92,400
January 20, 2023 (“Note 3”)	March 31, 2025	50,000	62,500	55,000
February 9, 2023 (“Note 3”)	March 31, 2025	50,000	62,500	55,000
July 20, 2023 (“Note 3”)	August 31, 2025	40,000	48,400	44,000
January 8, 2024 (“Note 4”)	January 8, 2025	40,000	44,000	-
May 13, 2024 (“Note 4”)	May 13, 2025	35,000	40,000	-
August 20, 2024 (“Note 4”)	August 20, 2025	11,500	12,650	-
November 19, 2024 (“Note 4”)	November 19, 2025	8,000	8,800	-
Various third-party noteholders				
Various dates in fiscal 2024 (“Note 4”)	None outstanding	650,890	8,800	-
Previous fiscal 2021, 2022, and 2023 Osher and Brio Notes converted in fiscal 2024			-	841,420
Total convertible notes payable		$ 2,085,895	$ 2,021,988	$ 2,507,636
Original issue discount			(117,868)	(225,835)
Beneficial conversion feature			-	(22,013)
Debt discount			(12,384)	(49,489)
Total convertible notes payable			$ 1,891,736	$ 2,210,299

Principal payments on convertible promissory debentures are due as follows:

Year ending December 31,	
2025	$ 2,021,988
	$ 2,021,988

Changes in convertible notes were as follows:

	Note 1	Note 2	Note 3	Note 4	Totals
Convertible notes payable as of December 31, 2022	$ 700,816	$ 1,578,500	$ -	$ -	$ 2,279,316
Convertible notes payable issued in 2023	163,320	142,000	1,443,200	-	1,748,520
Conversion of debt for common stock	-	(341,000)	(1,179,200)	-	(1,520,200)
Convertible notes payable as of December 31, 2023	$ 864,136	$ 1,379,500	$ 264,000	$ -	$ 2,507,636
Convertible notes payable issued in 2024	56,416	97,655	30,400	879,029	1,063,500
Conversion of debt for common stock	(299,999)	(541,419)	-	(707,730)	(1,549,148)
Convertible notes payable as of December 31, 2024	$ 620,553	$ 935,736	$ 294,400	$ 171,299	$ 2,021,988

Changes in note discounts were as follows:

	Note 1	Note 2	Note 3	Note 4	Totals
Note discounts as of December 31, 2022	$ -	$ 642,660	$ -	$ -	$ 642,660
Note discounts issued in conjunction with debt in 2023	163,320	142,000	1,390,535	-	1,695,855
2023 accretion of note discounts	(48,325)	(683,850)	(1,309,003)	-	(2,041,178)
Note discounts as of December 31, 2023	$ 114,995	$ 100,810	$ 81,532	$ -	$ 297,337
Note discounts issued in conjunction with debt in 2024	56,414	97,657	30,400	487,771	672,242
2024 accretion of note discounts	(129,214)	(145,792)	(95,981)	(468,340)	(839,327)
Note discounts as of December 31, 2024	$ 42,195	$ 52,675	$ 15,951	$ 19,431	$ 130,252
Convertible notes payable, net, as of December 31, 2023	$ 749,141	$ 1,278,690	$ 182,468	$ -	$ 2,210,299
Convertible notes payable, net, as of December 31, 2024	$ 578,358	$ 883,060	$ 278,449	$ 151,869	$ 1,891,736
2023 Effective interest rate	6%	50%	496%	-%	81%
2024 Effective interest rate	21%	16%	33%	273%	41%

Current Noteholders

2024 Convertible Notes (Note 4)

During fiscal 2024, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2024 Notes") totaling (i) $879,029 aggregate principal amount of Notes (total of $795,890 cash was received) due between January and June 2025 based on $1.00 for each $0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 219,758 shares of the Company's Common Stock at an exercise price of $6.00 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was $795,890 which was issued at a $83,139 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is $4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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

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

The Company has not repaid the Brio January 8, 2024 convertible note of $44,000 that matured on January 8, 2025 and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note.

2023 Convertible Notes (Note 3)

During fiscal 2023, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2023 Notes") totaling (i) $294,400 aggregate principal amount of Notes (total of $240,000 cash was received) due in various dates from July 2024 through March 2025 based on $1.00 for each $0.90909 paid by the noteholders and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 66,000 shares of the Company's Common Stock at an exercise price of $7.50 per share. The aggregate cash subscription amount received by the Company for the issuance of the Note and Warrants was $240,000 which was issued at a $54,400 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is $4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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

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

2022 Convertible Notes (Note 2)

During fiscal 2022, the Company entered into Original Issue Discount Senior Convertible Debentures (the "2022 Notes") totaling (i) $935,735 aggregate principal amount of Notes (total of $700,000 cash was received) due on various dates from January 2024 through December 7, 2024 based on $1.00 for each $0.90909 paid by the previous noteholder and (ii) five-year Common Stock Purchase Warrants ("Warrants") to purchase up to an aggregate of 192,500 shares of the Company's Common Stock at an exercise price of $7.50 per share. The aggregate cash subscription amount received by the Company from the previous noteholder for the issuance of the Note and Warrants was $770,000 which was issued at a $70,000 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is $4.00 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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

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

Osher – $620,553 (Note 1)

On January 28, 2020, as subsequently amended, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with respect to the sale and issuance to institutional investor Osher Capital Partners LLC ("Osher") of (i) $620,553 aggregate principal amount of Original Issue Discount Senior Convertible Debenture due August 30, 2024, based on $1.00 for each $0.90909 paid by Osher and (ii) five-year Common Stock Purchase Warrants to purchase up to an aggregate of 102,827 shares of the Company's Common Stock at an exercise price of $5.60 per share. The aggregate cash subscription amount received by the Company from Osher for the issuance of the note and warrants was $350,005 with a total of $270,548 original issue discount from the face value of the Note. The conversion price for the principal in connection with voluntary conversions by a holder of the convertible notes is $3.76 per share, subject to adjustment as provided therein, such as stock splits and stock dividends.

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

NOTE 6 –PROMISSORY NOTES

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

NOTE 7 – 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 $0 and $80,000 under Advance From Shareholder in the accompanying Balance Sheets at December 31, 2024 and 2023, respectively. The Company received advances of $35,000 and $80,000 and had repayments of $115,000 and $0 for the years ended December 31, 2024 and 2023, respectively. The advance from our CEO was not made pursuant to any loan agreements or promissory notes, is 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 2,403 and 1,287 shares are issued and outstanding at December 31, 2024 and 2023, respectively.

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

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

During fiscal 2023, holders of 161,684 shares of common stock elected to exchange these shares for an aggregate of 1,287 shares of Series B Convertible Preferred Stock. Each Series B Convertible Preferred Share converts into 125.63 shares of the Company's common stock, subject to antidilution adjustments for any stock splits and recapitalizations, and for issuances of additional shares at an issue price of less than the conversion ratio in the Warrant Exchange Agreement.

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

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

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

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

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

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

Common Stock

On December 30, 2024, the Company filed a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the State of Delaware, which went effective immediately upon filing. The Certificate of Amendment decreased our authorized common stock to One Hundred Million (100,000,000) shares, par value $0.0001, of which 1,605,377 and 1,288,415 shares are outstanding as of December 31, 2024 and 2023, respectively.

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

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

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

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

Shares Cancelled

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

Restricted Stock Units

Effective October 10, 2022, the Company's Board of Directors appointed Ms. Richa Nand, Mr. Jim Dorst, and Mr. Chris Wetzel as non-executive members to the Company's Board of Directors ("Director"). Each Director shall receive an annual grant of restricted stock units of $50,000. During the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation totaling $150,000 and $150,000, respectively, in the consolidated Statements of Operations.

Reverse Stock Split

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

Warrants

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

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

On October 8, 2024, the Company offered a short-term inducement to the Company's warrant holders in which the Company will issue ¾ of a share of the Company's common stock in exchange for each warrant. In response to this offer, 246,257 warrants were exchanged for 184,700 shares of the Company's common stock. The Company recognized a gain of $63,715 due to the modification of the warrants in October 2024.

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

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

NOTE 9 – 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 a lease agreement 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,	
	2024	***2023***
Operating lease expense	$ 71,676	$ 71,676
Short term lease cost	$ -	$ -
Total lease expense	$ 71,676	$ 71,676

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

Years ended December 31,	*2024*	*2023*
Operating cash flows from operating leases	$ 77,142	$ 54,263
Cash paid for amounts included in the measurement of lease liabilities	$ 77,142	$ 54,263
Weighted-average remaining lease term—operating leases	1.67 years	2.67 years
Weighted-average discount rate—operating leases	10%	10%

In accordance with ASC 842, maturities of operating lease liabilities as of December 31, 2024 were as follows:

Year ending:	**Operating Lease**
2025	$ 79,456
2026	54,225
Total undiscounted cash flows	$ 133,681
Reconciliation of lease liabilities:	
Weighted-average remaining lease terms	1.67 years
Weighted-average discount rate	10%
Present values	$ 126,302
Lease liabilities—current	69,946
Lease liabilities—long-term	56,356
Lease liabilities—total	$ 126,302
Difference between undiscounted and discounted cash flows	$ 7,379

Operating lease cost was $71,676 and $71,676 for the years ended December 31, 2024 and 2023, respectively.

NOTE 10 – RELATED PARTY TRANSACTIONS

Other than as set forth below, and as disclosed in Notes 7, 8, and 13, 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 $455,000 (of which $42,416 was paid and $412,584 is unpaid and accrued) and $455,000 (of which $170,625 was paid and $284,375 is unpaid and accrued) for the years ended December 31, 2024 and 2023, respectively. The cumulative amount accrued at December 31, 2024 related to Mr. Joyce's salary was $715,210.

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 $309,000 (of which $83,688 was paid and $225,313 is unpaid and accrued) and $225,000 (of which $125,000 was paid and $100,000 is unpaid and accrued) for the years ended December 31, 2024 and 2023, respectively. The cumulative amount accrued at December 31, 2024 related to Dr. Marleau's salary was $325,313.

NOTE 11 – INCOME TAXES

At December 31, 2024, net operating loss carry forwards for Federal and state income tax purposes totaling approximately $3,340,000 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,	
	2024	2023
Statutory U.S. federal rate	21.0%	21.0%
State income tax, net of federal benefit	7.0%	7.0%
Permanent differences	-%	-%
Valuation allowance	(28.0)%	(28.0)%
Provision for income taxes	0.0%	0.0%

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

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carry forwards	$ 4,008,548	$ 3,059,299
Depreciation and amortization	(50,078)	(35,541)
Valuation allowance	(3,958,470)	(3,023,758)
	$ -	$ -

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 12 – 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:

	Years Ended December 31,	
	2024	2023
Convertible notes payable	516,105	365,274
Preferred shares	301,900	-
Restricted stock units	49,704	17,178
Warrants to purchase shares of common stock	1,100	78,000
Total potentially dilutive shares	868,809	460,452

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

	Years Ended December 31,	
	2024	2023
Net loss attributable to the common stockholders	$ (3,340,212)	$ (4,145,936)
Basic weighted average outstanding shares of common stock	1,332,449	1,100,372
Dilutive effect of options and warrants	-	-
Diluted weighted average common stock and common stock equivalents	1,332,449	1,100,372
Loss per share:		
Basic and diluted	$ (2.51)	$ (3.77)

NOTE 13 – 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 and on January 11, 2025, appointed Mr. Michael Ryan 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 14 – SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2024 up through the date the financial statements were available to be issued. During this period, the Company did not have any material recognizable subsequent events required to be disclosed as of and for the period ended December 31, 2024, except for the following:

Regulation D

On January 9, 2025, the Company initiated a Regulation D offering to sell up to 750,000 Units at a price of $5,000 per unit with each Unit consisting of one (1) $5,500 principal amount convertible debenture (convertible at Four dollars ($4.00) per share) and a Warrant to purchase 1,250 shares of common stock at $6.00 per share. The Debentures have a principal amount equal to 110% of such Purchaser's subscription amount, convertible at $4.00 per share and maturing one (1) year from the date the subscription amount is accepted by the Company. The Warrants for a number of shares equal to the subscription amount divided by the conversion price with an exercise price of $6.00 per share, exercisable upon issuance and will expire five years from issuance. The Debentures will not be redeemable but contain an automatic conversion feature, which will cause all principal and interest due under the Debenture to automatically convert if our common stock is listed for trading on a national securities exchange, such as NASDAQ or the NYSE. As of April 15, 2025, a total of 69 Units were sold to accredited investors at a price of $5,000 per Unit totaling $345,197.

Convertible Notes

The Company has not repaid the Brio January 8, 2024 convertible note of $44,000 that matured on January 8, 2025 and the convertible note is now in default. The Company is currently in discussions to restructure the terms of the note (see Note 5).

The Company has not repaid two Brio convertible notes totaling $125,000 that matured on March 31, 2025 and the convertible notes are now in default. The Company is currently in discussions to restructure the terms of these notes.

The Company has not repaid three Osher convertible notes totaling $316,350 that matured on March 31, 2025 and the convertible notes are now in default. The Company is currently in discussions to restructure the terms of these notes.

EXHIBIT 31.1

SECTION 302 CERTIFICATION

I, James Joyce, certify that:

1. I have reviewed this annual report on Form 10-K of Sigyn Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2025

/s/ James Joyce

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

EXHIBIT 32.1

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

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

In connection with the Annual Report of Sigyn Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Joyce, Chief Executive Officer and Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the dates and periods covered by the Report.

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

/s/ James Joyce
James Joyce
Chief Executive Officer and Interim Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer)

April 15, 2025