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

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2024

or

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

Commission file number: 001-41512

SILO PHARMA, INC
(Name of Registrant as Specified in Its Charter)

Nevada	**27-3046338**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
677 N. Washington Boulevard Sarasota, FL	**34236**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code**: (718) 400-9031**

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**SILO**	**The Nasdaq Stock Market LLC**

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 check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) 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 definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒

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 provided 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 by Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

The aggregate market value of the voting stock and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2024 was approximately $3,431,092 based upon the closing price of the registrant's common stock of $0.9705 on the NASDAQ as of that date.

Number of shares of common stock outstanding as of March 26, 2025 was 4,484,456.

Documents incorporated by reference: None.

SILO PHARMA, INC.
FORM 10-K
DECEMBER 31, 2024

TABLE OF CONTENTS

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "could," "will," "would," "should," "expect," "plan,", "anticipate," "believe," "estimate," "intend," "predict," "seek," "contemplate," "project," "continue," "potential," "ongoing" or the negative of these terms or other comparable terminology.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report on Form 10-K. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include, but are not limited to:

- our ability to obtain additional funds for our operations;
- our financial performance;
- risks relating to the timing and costs of clinical trials and the timing and costs of other expenses;
- risks related to market acceptance of products;
- intellectual property risks;
- the impact of government regulation and developments relating to our competitors or our industry;
- our competitive position;
- our industry environment;
- our anticipated financial and operating results, including anticipated sources of revenues;
- assumptions regarding the size of the available market, benefits of our products, product pricing and timing of product launches;

- our estimates of our expenses, losses, future revenue and capital requirements, including our needs for additional financing;
- our ability to attract and retain qualified key management and technical personnel;
- statements regarding our goals, intensions, plans and expectations, including the introduction of new products and markets; and
- our cash needs and financing plans.

These statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this report.

Any forward-looking statement in this report reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our business, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this report completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

This report also contains estimates, projections and other information concerning our industry, our business and our markets, including data regarding the estimated size of those markets and their projected growth rates. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, and general publications, government data and similar sources. While we believe that the reports, research surveys, studies and similar data prepared by third parties are reliable, we have not independently verified the data contained in them.

You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report. Except as required by law, we do not undertake any obligation to update or release any revisions to these forward-looking statements to reflect any events or circumstances, whether as a result of new information, future events, changes in assumptions or otherwise, after the date hereof. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this Annual Report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to our Financial Position and Need for Capital

- We have only a limited history upon which an evaluation of our prospects and future performance can be made and have no history of profitable operations.
- We will require additional financing in the future to fund our operations; and
- Raising additional capital may cause dilution to holders of our stockholders, restrict our operations or require us to relinquish certain rights

Risks Related to our Therapeutics Business

- Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of any future therapeutic candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals, and therefore we will be unable to commercialize our future therapeutic candidates on a timely basis or at all, which will adversely affect our business.
- Any therapeutic candidates we may develop in the future may be subject to controlled substance laws and regulations in the territories where the product will be marketed, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations governing controlled substances, may adversely affect the results of our business operations and our financial condition.
- Any significant breaches in our compliance with U.S. and foreign laws and regulations governing controlled substances, or changes in the laws and regulations may result in interruptions to our development activity or business continuity.
- Our product candidates may contain controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding psilocybin or our current or future investigational therapies using psilocybin may negatively influence the success of these therapies.
- Even if any of our future therapeutic candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any such therapeutic candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any of our future therapeutic candidates.
- We will depend on enrollment of patients in our clinical trials for our future therapeutic candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.
- We have never commercialized a therapeutic candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our therapies on our own or with suitable collaborators.
- The future commercial success of our future therapeutic candidates will depend on the degree of market access and acceptance of our potential therapies among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large.

- We may become exposed to costly and damaging liability claims, either when testing our future therapeutic candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claim.

- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any of our future therapeutic candidates and could have a material adverse effect on our business.

- Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to U.S. federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, other healthcare laws and regulations and other foreign privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Risks Relating to Our Intellectual Property Rights

- The failure to obtain or maintain patents, licensing agreements and other intellectual property could materially impact our ability to compete effectively.

- If we are unable to obtain and maintain patent protection for our products, or if the scope of the patent protection obtained is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products could be impaired.

- If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

Risks Related to Our Securities

- We have never paid cash dividends and have no plans to pay cash dividends in the future.

- If we fail to remain current in our reporting requirements, we could be removed from the NASDAQ which would limit the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

- Our common stock could be subject to extreme volatility. Market and economic conditions may negatively impact our business, financial condition and share price.

- Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

- The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in non-interest-bearing and interest-bearing operating accounts may exceed the Federal Deposit Insurance Corporation ("**FDIC**") insurance limits. If such banking institutions were to fail, we could lose all or a portion of those amounts held in excess of such insurance limitations. Any material loss that we may experience in the future could have an adverse effect on our ability to pay our operational expenses or make other payments. To mitigate our risk, in March 2023 we began transferring our cash to other banks to ensure that our exposure is limited or reduced to the FDIC protection limits.

PART I

Throughout this Annual Report on Form 10-K, the "Company," "Silo," "we," "us," and "our" refers to Silo Pharma, Inc. and its subsidiary.

ITEM 1. BUSINESS

Overview

We are a developmental stage biopharmaceutical company developing novel therapeutics that address underserved conditions including PTSD, stress-induced anxiety disorders, fibromyalgia, and central nervous system (CNS) diseases. We are focused on developing novel therapies that include conventional drugs and psychedelic formulations. The Company's lead program, SPC-15, is an intranasal drug targeting PTSD and stress-induced anxiety disorders. SP-26 is a time-release ketamine-based loaded implant for fibromyalgia and chronic pain relief. Silo's two preclinical programs are SPC-14, an intranasal compound for the treatment of Alzheimer's disease, and SPU-16, a CNS-homing peptide targeting the central nervous system with initial research indication in multiple sclerosis (MS).

Therapeutics

We seek to acquire and/or develop intellectual property or technology rights from leading universities and researchers to treat rare diseases, including the use of psychedelic drugs, such as psilocybin, ketamine, and the potential benefits they may have in certain cases involving depression, mental health issues and neurological disorders. We are focused on developing traditional therapeutics and psychedelic medicine. The company concentrates on the development and commercialization of therapies for unmet needs from indications such as depression, post-traumatic stress disorder ("PTSD"), and other rare neurological disorders. Our mission is to identify assets to license and fund the research which we believe will be transformative to the well-being of patients and the health care industry.

Psilocybin is considered a serotonergic hallucinogen and is an active ingredient in some species of mushrooms. Recent industry studies using psychedelics, such as psilocybin, have been promising, and we believe there is a large unmet need with many people suffering from depression, mental health issues and neurological disorders. While classified as a Schedule I substance under the Controlled Substances Act ("CSA"), there is an accumulating body of evidence that psilocybin may have beneficial effects on depression and other mental health conditions. Therefore, the U.S. Food and Drug Administration ("FDA") and U.S. Drug Enforcement Agency ("DEA") have permitted the use of psilocybin in clinical studies for the treatment of a range of psychiatric conditions.

The potential of psilocybin therapy in mental health conditions has been demonstrated in a number of academic-sponsored studies over the last decade. In these early studies, it was observed that psilocybin therapy provided rapid reductions in depression symptoms after a single high dose, with antidepressant effects lasting for up to at least six months for a number of patients. These studies assessed symptoms related to depression and anxiety through a number of widely used and validated scales. The data generated by these studies suggest that psilocybin is generally well-tolerated and may have the potential to treat depression when administered with psychological support.

We have engaged in discussions with a number of world-renowned educational institutions and advisors regarding potential opportunities and have formed a scientific advisory board that is intended to help advise management regarding potential acquisition and development of products.

In addition, as more fully described below, we have entered into a license agreement with the University of Maryland, Baltimore, and are developing a Ketamine polymer implant. In addition, we entered into a sponsored research agreement with Columbia University for the study of ketamine in combination with other drugs for treatment of Alzheimer's and depression disorders and we have also entered into an exclusive license agreement with Columbia under which we have rights to certain patents and inventions relating to the treatment of Alzheimer's disease and stress-induced affective disorders using Ketamine in combination with certain other compounds.

We plan to actively pursue the acquisition and/or development of intellectual property or technology rights to treat rare diseases, and to ultimately expand our business to focus on this new line of business.

Product Candidates

We are currently focusing on four product candidates:

1. SPC-15 for stress-indued psychiatric disorders, including PTSD and anxiety;
2. SP-26 for treatments of fibromyalgia and chronic pain;
3. SPC-14 for treatment of Alzheimer's disease; and
4. SPU-16 for CNS disorders, initially targeting multiple sclerosis.

SPC-15: Intranasal Treatment for PTSD and Anxiety Disorders

Our lead product candidate, SPC-15, is designed as a novel serotonin 4 (5-HT4) receptor agonist that utilizes biomarkers for treatment of stress-induced psychiatric disorders such as PTSD and anxiety disorders. This innovative treatment is administered via an intranasal formulation, potentially qualifying for the FDA's streamlined 505(b)(2) regulatory pathway, which could expedite its approval process. We are actively collaborating with Columbia University, holding exclusive global rights to develop and commercialize SPC-15, pursuant to the exclusive license agreement entered into with Columbia on July 1, 2024. See "---License Agreements between the Company and Vendor—Exclusive License Agreement with Columbia University."

On November 15, 2023, we entered into an exclusive license agreement with Medspray Pharma BV for its proprietary patented soft mist nasal spray technology, as the delivery mechanism for SPC-15, which agreement has an effective date of October 31, 2023. Preclinical and formulation studies were completed in the first half of 2024 and on June 4, 2024 the Company submitted a pre-Investigational New Drug (pre-IND) briefing package and meeting request to the U.S. Food and Drug Administration (FDA) for SPC-15, Silo's intranasal prophylactic treatment for post-traumatic stress disorder (PTSD) and stress-induced anxiety disorder. In September 2024, we had a pre-IND meeting with the FDA to align on the 505(b)(2) regulatory pathway for approval of SPC-15 and review our proposed plan to support opening an IND.

Currently, we are conducting GLP-compliant pharmacokinetic and pharmacodynamic studies and in March 2025 we completed first dosing in an IND-enabling GLP-compliant toxicology and toxicokinetics, and we are aiming for an IND submission in 2025. The preclinical data suggests additional applications for eating disorders and anorexia, as well as enhanced efficacy when combined with an NMDA receptor antagonist for major depressive disorder and other severe stress-related conditions.

We believe our patented intranasal nose-to-brain drug dispersion technology provides a competitive advantage by increasing brain drug concentration, ensuring a faster onset of therapeutic effects with optimized safety.

SP-26: Ketamine Implant for Fibromyalgia

SP-26 represents a novel approach to treating chronic pain and fibromyalgia through a ketamine-based injectable dissolvable polymer implant. Designed for subcutaneous insertion, SP-26 focuses on regulating dosage and time release to provide sustained relief from chronic pain, offering a potentially safer alternative to opioids. Presently, our SP-26 product is in preclinical research. Initial animal studies, which began in early 2025, are evaluating the implant's dosage, time release, and absorption.

In March 2023, we filed a provisional patent application with the USPTO to use SP-26 for treatment of chronic pain, including fibromyalgia. We intend to develop SP-26 following the Section 505(b)(2) regulatory pathway of the FDA rules. Section 505(b)(2) of the FDCA was enacted to enable sponsors to seek NDA approval for novel repurposed drugs without the need for such sponsors to undertake time consuming and expensive pre-clinical safety studies and Phase 1 safety studies. Proceeding under this regulatory pathway, we will be able to rely upon publicly available data with respect to our active ingredient in our NDA submission to the FDA for marketing approval.

Fibromyalgia affects approximately 4 million U.S. adults (2% of the population). We believe SP-26's implant design provides a compelling non-opioid alternative to traditional pain management, improving dosage control compared to intravenous delivery.

SPC-14: Treatment for Alzheimer's Disease

SPC-14 targets glutamate receptor NDMAR and serotonin 5-HT4 to address cognitive and neuropsychiatric symptoms in Alzheimer's disease. Given the global Alzheimer's therapeutics market is projected to exceed $30.8 billion by 2033, SPC-14 presents a promising opportunity. SPC-14 was developed under a sponsored research agreement with Columbia University See "---Investigator-Sponsored Study Agreements between the Company and Vendors---Sponsored Research Agreement with Columbia University for the Study of Ketamine in Combination with Other Drugs for Treatment of Alzheimer's and Depression Disorders," and we have exclusive global rights to develop and commercialize SPC-14, pursuant to that certain exclusive license agreement entered into with Columbia on July 1, 2024. See "---License Agreements between the Company and Vendor—Exclusive License Agreement with Columbia University.". On October 13, 2022, we extended the term of the sponsored research agreement with Columbia to conduct further research studies into the mechanism of action of SPC-14 in the treatment of Alzheimer's disease. In addition, we have been granted an option to license certain assets currently under development, including SPC-14 for the treatment of Alzheimer's disease.

We believe our SPC-14 product has shown efficacy against luteinizing hormone (LH) in attenuating learned helplessness, preservative behavior and hyponeophagia (a measure of anxiety).

SPU-16: Treatment for CNS Disorders, Initial Indication for Multiple Sclerosis

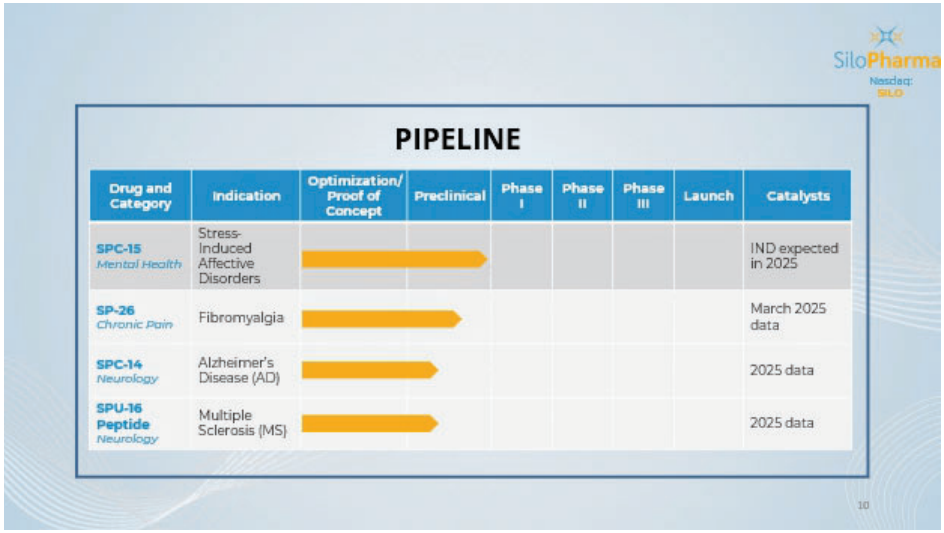
SPU-16 is a promising candidate targeting central nervous system (CNS) disorders, with an initial indication for multiple sclerosis. On February 12, 2021, we entered into a Master License Agreement (the "UMB License Agreement") with the University of Maryland, Baltimore ("UMB") pursuant to which UMB granted us an exclusive, worldwide, sublicensable, royalty-bearing license to certain intellectual property (i) to make, have made, use, sell, offer to sell, and import certain licensed products and (ii) to use the invention titled "Central nervous system-homing peptides in vivo and their use for the investigation and treatment of multiple sclerosis and other neuroinflammatory pathology," or SPU-16. See "---License Agreements between the Company and Vendors--Vendor License Agreement with the University of Maryland, Baltimore for CNS Homing Peptide" for additional details.

On April 11, 2023 certain intellectual property under the UMB License Agreement described above were issued a patent from the U.S. Patent & Trademark Office (USPTO) for "Peptide-Targeted Liposomal Delivery For Treatment, Diagnosis, and Imaging of Diseases and Disorders" (US 11,766,403, B2).

We believe SPU-16 provides a competitive advantage by using homing peptides to reduce toxicity while enhancing therapeutic payload delivery.

Product Development Pipeline

The following table summarizes our product development pipeline.



License Agreements between the Company and Vendor

Vendor License Agreement with the University of Maryland, Baltimore for CNS Homing Peptide

On February 12, 2021, we entered into a Master License Agreement (the "UMB License Agreement") with the University of Maryland, Baltimore ("UMB") pursuant to which UMB granted us an exclusive, worldwide, sublicensable, royalty-bearing license to certain intellectual property (i) to make, have made, use, sell, offer to sell, and import certain licensed products and (ii) to use the invention titled, "Central nervous system-homing peptides in vivo and their use for the investigation and treatment of multiple sclerosis and other neuroinflammatory pathology" (the "Invention") and UMB's confidential information to develop and perform certain licensed processes for the therapeutic treatment of neuroinflammatory disease. The term of the License Agreement shall commence on the UMB Effective Date and shall continue until the latest of (i) ten years from the date of First Commercial Sale (as defined in the Sublicense Agreement) of the Licensed Product in such country and (ii) the date of expiration of the last to expire claim of the Patent Rights (as defined in the UMB License Agreement) covering such Licensed Product in such country, or (iii) the expiration of data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity, or other legally enforceable market exclusivity, if applicable, unless terminated earlier pursuant to the terms of the agreement. Pursuant to the UMB License Agreement, we agreed to pay UMB (i) a license fee of $75,000, (ii) certain event-based milestone payments, (iii) royalty payments, depending on net revenues, (iv) minimum royalty payments, and (v) a tiered percentage of sublicense income. The UMB License Agreement will remain in effect until the later of: (a) the last patent covered under the UMB License Agreement expires, (b) the expiration of data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity, or other legally enforceable market exclusivity, if applicable, or (c) ten years after the first commercial sale of a licensed product in that country, unless earlier terminated in accordance with the provisions of the UMB License Agreement. The term of the UMB License Agreement shall expire 15 years after the effective date in which (a) there were never any patent rights, (b) there was never any data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity, or other legally enforceable market exclusivity or (c) there was never a first commercial sale of a licensed product.

As described below, we have entered into an investigator sponsored research agreement with UMB related to a clinical study to examine a novel peptide-guided drug delivery approach for the treatment of Multiple Sclerosis.

Commercial Evaluation License and Option Agreement with UMB for Joint Homing Peptide

Effective as of February 26, 2021, we, through our wholly-subsidiary, Silo Pharma, Inc., a Florida corporation, and University of Maryland, Baltimore ("UMB"), entered into a commercial evaluation license and option agreement ("License Agreement"), which we were granted an exclusive, non-sublicensable, non-transferable license to with respect to the exploration of the potential use of joint-homing peptides for use in the investigation and treatment of arthritogenic processes. The License Agreement also granted us an exclusive option to negotiate and obtain an exclusive, sublicensable, royalty-bearing license ("Exclusive Option") to with respect to the subject technology. The License Agreement had a term of six months from the effective date. Both parties could have terminated the License Agreement within thirty days by giving a written notice.

On July 6, 2021, we entered into a First Amendment Agreement ("Amended License Agreement") with UMB to extend the term of the original License Agreement by an additional six months such that the Amended License Agreement was effective until February 25, 2022 however, if we exercise the Exclusive Option, the License Agreement shall expire at the end of the negotiation period (as defined in the License Agreement) or upon execution of a master license agreement, whichever occurs first. We paid a license fee of $10,000 to UMB in March 2021 pursuant to the License Agreement, which was expensed, since we could not conclude that such costs would be recoverable for this early-stage venture.

On January 28, 2022, we entered into a second amendment to the License Agreement with UMB dated February 26, 2021 ("Second Amendment"). The Second Amendment extended the term of the License Agreement until December 31, 2022. However, if we exercise the Exclusive Option, the License Agreement shall expire at the end of the negotiation period (as defined in the License Agreement) or upon execution of a master license agreement, whichever occurs first.

On June 22, 2022, we entered into a third amendment to the License Agreement with UMB dated February 26, 2021 under which UMB agreed, to expand the scope of the license granted in the CELA to add additional Patent Rights with respect to an invention generally known as "Peptide-Targeted Liposomal Delivery for Treatment Diagnosis, and Imaging of Diseases and Disorders." On December 16, 2022, we entered into a fourth amendment to License Agreement with UMB (the "Fourth Amendment") dated February 26, 2021 to extend the term of the License Agreement until March 31, 2023. In addition, the parties agreed in the Fourth Amendment to allow us to extend the term of the License Agreement to June 30, 2023 by paying UMB a fee of $1,000 on or before February 28, 2023. This fee was paid and thus the term of the License Agreement was extended to June 30, 2023. We let this license expire by its terms on December 31, 2023.

Exclusive License Agreement between Medspray Pharma BV and the Company

On November 15, 2023, we entered into an Exclusive License Agreement (the "Medspray License Agreement") with Medspray Pharma BV ("Medspray") pursuant to which Medspray granted us an exclusive, non-revocable, worldwide royalty bearing license for Medspray's proprietary patented soft mist nasal spray technology for marketing, promotion, sale and distribution of the products licensed by Medspray to us under the Medspray License Agreement. The Medspray License Agreement has an effective date of October 31, 2023 and expires on the earlier of (i) termination of the Medspray License Agreement or expiry of all Medspray license rights in the United States, Germany, United Kingdom, Spain, Italy and France. In consideration of the exclusive rights granted by Medspray to us, we agreed to pay Medspray a royalty on a quarterly basis equal to 5% of net sales. The term of the agreement commences on the effective date and continues until the earlier of (i) expiration of the last to expire of Medspray's patent rights or (ii) December 31, 2023 (the "Initial Term") at which time, the Medspray License Agreement will automatically renew for a successive period of three (3) years, unless terminated by either party upon one year prior written notice prior to the end of any term; provided, however, the Medspray may terminate the Medspray License Agreement immediately if fail to have any licensed product under the Medspray License Agreement registered with the FDA or EMA by July 1, 2028 or has filed to reach the point of first sale of any licensed product under the Medspray License Agreement by July 1, 2028.

Exclusive License Agreement with Columbia University

On July 1, 2024, we entered into an exclusive license agreement (the "Columbia License Agreement") with Columbia University ("Columbia") effective as of June 28, 2024 (the "Effective Date") and pursuant to which we have been granted exclusive rights to certain patents and technical information to develop, manufacture and commercialize Products related to our SPC-15 (as defined in the Columbia License Agreement), including therapies for stress-induced affective disorders and other conditions.

The term of the Columbia License Agreement shall commence on the Effective Date and shall continue on a country-by-country and product-by-product basis until the latest of: (a) the date of expiration of the last to expire of the issued Patents (as defined in the Columbia License Agreement), (b) twenty (20) years after the first bona fide commercial sale of the Product in the country in question, or (c) expiration of any market exclusivity period granted by a regulatory agency for a Product in the country in question. Pursuant to the Columbia License Agreement, we agreed to pay Columbia (i) initial and annual license fees ranging from the low five figures to mid five figures that are creditable to earned royalties and milestone payments due to Columbia in the same calendar year, (ii) certain development-based and other milestone payments, (iii) royalty payments, depending on net revenues, (iv) minimum royalty payments, and (v) certain non-royalty sublicense income. Royalties on each particular Product are payable on a country-by-country and product-by-product basis until the later of (i) twenty (20) years after the first bona fide commercial sale of such particular Technology Product in each country and (ii) expiration of any market exclusivity period granted by a regulatory agency of such particular Product in such country.

Investigator-Sponsored Study Agreements between the Company and Vendors

Sponsored Research Agreement with Columbia University for the Study of Ketamine in Combination with Other Drugs for Treatment of Alzheimer's and Depression Disorders

On October 1, 2021, we entered into a sponsored research agreement with Columbia University ("Columbia") pursuant to which Columbia shall conduct two different studies related to all uses of Ketamine or its metabolites in combination with Prucalopride, one of which is related to Alzheimer's and the other of which is related to Depression, PTSD and Stress Projects. In addition, Company has been granted an option to license certain assets currently under development, including Alzheimer's disease. The term of the option will commence on the effective date of this agreement and will expire upon the earlier of (i) 90 days after the date of the Company's receipt of a final research report for each specific research proposal as defined in the agreement or (ii) termination of the research. If we elect to exercise the option, both parties will commence negotiation of a license agreement and will execute a license agreement no later than 3 months after the dated of the exercise of the option. We exercised our option for an exclusive license agreement for SPC-15, a prophylactic treatment for stress-induced affective disorders including anxiety and PTSD pursuant to which we were granted an exclusive license to further develop, manufacture, and commercialize SPC-15 worldwide. See "---License Agreements between the Company and Vendor – Exclusive License Agreement with Columbia University." Columbia University and the Company will work towards developing a therapeutic treatment for patients suffering from Alzheimer's disease to posttraumatic stress disorder. During a one-year period from the date of this agreement, we shall pay a total of $1,436,082 to Columbia University for the support of the research according to the payment schedule as follows: (i) 30% at signing, (ii) 30% at four and half months after the start of the project, (iii) 30% at nine months after the start of the project and (iv)10% at completion of the project. On October 13, 2022, we entered into an amendment of the sponsored research agreement pursuant to which the parties agreed to extend the payment schedule until March 31, 2024, which as of the date of this report has not been paid, pending final completion of the research agreement. We paid the first payment of $430,825 in November 2021 and the second payment of $430,825 in July 2022.

Sponsored Research Agreement with University of Maryland, Baltimore for the Study of Targeted liposomal drug delivery for rheumatoid arthritis

On July 6, 2021, we entered into a sponsored research agreement (the "July 2021 Sponsored Research Agreement") with UMB pursuant to which UMB shall evaluate the pharmacokinetics of dexamethasone delivered to arthritic rats via liposome. The research pursuant to the July 2021 Sponsored Research Agreement commenced on September 1, 2021 and will continue until the substantial completion thereof, subject to renewal upon written consent of the parties with a project timeline of twelve months. The July 2021 Sponsored Research Agreement may be terminated by either party upon 30 days' prior written notice to the other party. In addition, if either party commits any material breach of or defaults with respect to any terms or conditions of the July 2021 Sponsored Research Agreement and fails to remedy such default or breach within 10 business days after written notice from the other party, the party giving notice may terminate the July 2021 Sponsored Research Agreement as of the date of receipt of such notice by the other party. If we terminate the July 2021 Sponsored Research Agreement for any reason other than an uncured material breach by UMB, we shall relinquish any and all rights it may have in the Results (as defined in the July 2021 Sponsored Research Agreement) to UMB. In addition, if the July 2021 Sponsored Research Agreement is terminated early, we, among other things, will pay all costs incurred and accrued by UMB as of the date of termination. Pursuant to the terms of the July 2021 Sponsored Research Agreement, UMB granted us an option (the "Option") to negotiate and obtain an exclusive license to any UMB Arising IP (as defined in the July 2021 Sponsored Research Agreement) and UMB's rights in any Joint Arising IP (as defined in the July 2021 Sponsored Research Agreement) (collectively, the "UMB IP"). We may exercise the Option by giving UMB written notice within 60 days after it receives notice from UMB of the UMB IP. We shall pay total fees of $276,285 as set forth in the July 2021 Sponsored Research Agreement. We paid the first payment of $92,095 on September 1, 2021 and on August 31, 2022, we paid the second payment of $92,095. As of the date of this report, the final payment of $92,095 is yet to be paid and has been partially paid in 2025, with the remaining payment pending completion of the July 2021 Sponsored Research Agreement.

Sponsored Research Agreement with The Regents of the University of California for the Effect of Psilocybin on Inflammation in the Blood

On June 1, 2021, we entered into a sponsored research agreement ("Sponsored Research Agreement") with The Regents of the University of California, on behalf of its San Francisco Campus ("UCSF") pursuant to which UCSF shall conduct a study to examine psilocybin's effect on inflammatory activity in humans to accelerate its implementation as a potential treatment for Parkinson's Disease, chronic pain, and bipolar disorder. The purpose of this is to show what effect psilocybin has on inflammation in the blood. We believe that this study will help support the UMB homing peptide study. Pursuant to the Agreement, we shall pay UCSF a total fee of $342,850 to conduct the research over the two-year period. The Agreement shall be effective for a period of two years from the effective date, subject to renewal or earlier termination as set forth in the Sponsored Research Agreement. During the years ended December 31, 2022 and 2021, pursuant to the Sponsored Research Agreement, we paid UCSF $181,710 and $100,570, respectively. We have notified UCSF we do not plan to continue this study.

COVID-19

The outbreak of the novel Coronavirus (COVID-19) evolved into a global pandemic. The Coronavirus has spread to many regions of the world. The extent to which the Coronavirus impacts the Company's business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the Coronavirus and the actions to contain the Coronavirus or treat its impact, among others.

As a result of the continuing spread of the Coronavirus, certain aspects of the Company's business operations may be delayed or subject to interruptions. Specifically, as a result of the shelter-in-place orders and other mandated local travel restrictions, among other things, the research and development activities of certain of the Company's partners may be affected, which may result in delays to the Company's clinical trials, and the Company can provide no assurance as to when such trials, if delayed, will resume at this time or the revised timeline to complete trials once resumed.

Furthermore, site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the Coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and the Company may be unable to conduct its clinical trials.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from or materially delay U.S. Food and Drug Administration review and/or approval with respect to the Company's clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of the Company's clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of the Company's product candidates.

The spread of the Coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on the Company's business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may negatively impact the Company's ability to access capital on favorable terms, if at all. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the Coronavirus could materially and adversely affect the Company's business and the value of its common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, its clinical trials, its research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's operations, and the Company will continue to monitor the situation closely.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection relating to our products (including formulations, processes, and methods) and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties. Our policy is to actively seek the broadest intellectual property protection possible for our products, proprietary information and proprietary technology through a combination of contractual arrangements and patents. Specifically, we try to ensure that we own intellectual property created for us by signing agreements with employees, independent contractors, consultants, companies, and any other third party that create intellectual property for us or that assign any intellectual property rights to us. In addition, we have established business procedures designed to maintain the confidentiality of our proprietary information, including the use of confidentiality agreements with employees, independent contractors, consultants and entities with which we conduct business.

To date, the intellectual property owned and licensed by us includes 5 issued patents and 20 pending patent applications in 14 patent families in the U.S. and abroad. Our own intellectual property includes five pending U.S. patent applications related to the use of the central nervous system-homing peptides covered by the License Agreement with the University Maryland, Baltimore ("UMB") to deliver certain compounds, including a nonsteroidal anti-inflammatory drug and/or psilocybin, for the treatment of diseases such as arthritis, central nervous system diseases, neurological diseases as well as cancer. Among the intellectual property that we license from UMB, there is one issued U.S. patent covering certain central nervous system homing peptides and uses thereof, and one issued U.S. patent covering certain peptides capable of selectively targeting inflamed synovial tissue and uses thereof. Among the intellectual property that we license from Columbia University, there are three issued U.S. patents related to the treatment or prevention of stress-induced affective disorders or stress-induced psychopathology.

Concentrations

Customer Concentration

For the years ended December 31, 2024 and 2023, one licensee, Aikido Pharma, Inc. accounted for 100% of our total revenues from customer license fees.

Vendor Concentrations

For the years ended December 31, 2024 and 2023, two licensors, UMB and Columbia, accounted for 100% of the Company's vendor license agreements.

Competition

With respect to the rare disease therapeutics segment of our business, our industry is characterized by many newly emerging and innovative technologies, intense competition and a strong emphasis on proprietary product rights. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and medical research organizations. Any product candidates that we may successfully develop and commercialize will compete with the standard of care and new therapies that may become available in the future.

Many of the pharmaceutical, biopharmaceutical and biotechnology companies with whom we may compete have established markets for their therapies and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or therapies. In addition, many of these potential competitors have significantly greater experience than we have in undertaking non-clinical studies and human clinical trials of new therapeutic substances and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining regulatory approvals for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. An increasing number of companies are increasing their efforts in discovery of new psychedelic compounds.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with any potential vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the U.S. Food and Drug Administration (FDA) regulates drug products under the Federal Food, Drug, and Cosmetic Act (FDCA), its implementing regulations and other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before any product candidates are approved as drugs for therapeutic indications and may be marketed in the United States generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice requirements;
- Completion of the manufacture, under current good manufacturing practice (cGMP) requirements, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- Submission to the FDA of an investigational new drug (IND) application which must become effective before clinical trials may begin;
- Approval by an institutional review board or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice (GCP) requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a New Drug Application (NDA);
- Payment of user fees for FDA review of the NDA;
- A determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;

- Satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- Potentially, satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Controlled Substances

The federal Controlled Substances Act (CSA) and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s).

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Employees

As of March 26, 2025, we employed a total of three full-time employees. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

Corporate History

We were incorporated as Gold Swap, Inc. ("Gold Swap") under the laws of the State of New York on July 13, 2010.

On December 11, 2012, stockholders approved changing our state of incorporation from New York to Delaware via the merger of Gold Swap with and into our wholly-owned subsidiary, Point Capital, Inc., and to change our name from "Gold Swap Inc." to "Point Capital, Inc". The merger was effective on January 24, 2013.

On May 21, 2019, we amended our Certificate of Incorporation to change our name to "Uppercut Brands, Inc," and on September 24, 2020, we amended our Certificate of Incorporation to change our name to "Silo Pharma, Inc.".

Through September 28, 2018, we were a closed-end, non-diversified investment company that had elected to be regulated as a business development company under the Investment Company Act of 1940 (the "Investment Company Act"). As a business development company, we were required to comply with certain regulatory requirements. For instance, we generally had to invest at least 70% of our total assets in "qualifying assets", including securities of private U.S. companies, cash, cash equivalents, U.S. government securities and high-quality debt investments that mature in one year or less.

On September 29, 2018, we filed Form N-54C, Notification of Withdrawal of election to be Subject to Section 55 through 65 of the Investment Company Act, because we changed the nature of our business so as to cease to be a business development company. Accordingly, as of December 31, 2018, our consolidated financial statements of have been prepared in accordance with accounting principles generally accepted in the United States of America.

As a result of this change in status, we discontinued applying the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 946 - Financial Services – Investment Company and account for the change in our status prospectively by accounting for our equity investments in accordance with ASC Topics 320 - Investments—Debt and Equity Securities as of the date of the change in status. In addition, the presentation of the financial statements are that of a commercial company rather than that of an investment company.

In accordance with ASC 946, we made this change to our financial reporting prospectively, and did not restate periods prior to our change in status to a non-investment company effective September 29, 2018. Accordingly, we may refer to both accounting in accordance with U.S. generally accepted accounting principles applicable to corporations ("Corporation Accounting"), which applied commencing September 29, 2018 and to that applicable to investment companies under the Investment Company Act ("Investment Company Accounting") which applied to prior periods. We determined that there is no cumulative effect of the change from Investment Company Accounting to Corporation Accounting on periods prior to those presented, and that there is no effect on our financial position or results of operations as a result of this change.

In order to maintain our status as a non-investment company, we will continue to operate so as to fall outside the definition of an "investment company" or within an applicable exception. We expect to continue to operate outside the definition of an "investment company" as a developmental stage company primarily engaged in merging traditional therapeutics with psychedelic research.

Through March 31, 2017, we elected to be treated as a regulated investment company ("RIC") under Subchapter M of the Internal Revenue Code of 1986, as amended, and operated in a manner so as to qualify for the tax treatment applicable to RICs. At March 31, 2017, we failed the diversification test since our investment in Ipsidy Inc. accounted for over 25% of our total assets. We did not cure our failure to retain our status as a RIC and we will not seek to obtain RIC status again. Accordingly, beginning in 2017, we became subject to income taxes at corporate tax rates. The loss of our status as a RIC did not have any impact on our financial position or results of operations.

Currently, we are not making any new equity investments.

On April 8, 2020, we incorporated a wholly-owned subsidiary, Silo Pharma Inc., in the State of Florida.

On December 19, 2023, we changed our state of incorporation from Delaware to Nevada.

Our Corporate Information

We were incorporated as in the State of New York on July 13, 2010. On January 24, 2013, the Company changed its state of incorporation from New York to Delaware. On December 19, 2023, the Company changed its state of incorporation from Delaware to Nevada. Our principal executive offices are located at 677 N Washington Blvd Sarasota Fl 34236 and our telephone number is (718) 400-9031.

Available Information

Our website address is *www.silopharma.com*. The contents of, or information accessible through, our website is not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We have only a limited history upon which an evaluation of our prospects and future performance can be made and have no history of profitable operations.

We were incorporated in 2010 but started operating under our current business plan in September 2020 and have a limited history upon which an evaluation of our prospects and future performance can be made and have no history of profitable operations. We may sustain losses in the future as we implement our business plan. We have not yet achieved positive cash flow on a monthly basis during any fiscal year including the fiscal year ended December 31, 2024, and there can be no assurance that we will ever generate revenues or operate profitably.

We will require additional financing in the future to fund our operations.

We will need additional capital in the future to continue to execute our business plan. Therefore, we will be dependent upon additional capital in the form of either debt or equity to continue our operations. At the present time, we do not have arrangements to raise all of the needed additional capital, and we will need to identify potential investors and negotiate appropriate arrangements with them. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue our operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish certain rights.

We may seek additional capital through a combination of equity offerings, debt financings, strategic collaborations and alliances or licensing arrangements. To the extent that we raise additional capital through the sale of equity, convertible debt securities or other equity-based derivative securities, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Any indebtedness we incur could involve restrictive covenants, such as limitations on our ability to incur additional debt, acquire or license intellectual property rights, declare dividends, make capital expenditures and other operating restrictions that could adversely impact our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights including to future therapeutic candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our future therapeutic candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Therapeutics Businesses

Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of any future therapeutic candidates are prolonged or delayed, we or our current or future collaborators may be unable to obtain required regulatory approvals, and therefore we will be unable to commercialize our future therapeutic candidates on a timely basis or at all, which will adversely affect our business.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may experience delays in initiating or completing our clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any future therapeutic candidates.

We cannot provide any assurance that any product candidates will successfully complete clinical trials or receive regulatory approval, which is necessary before they can be commercialized.

We currently have no therapies that are approved for commercial sale and may never be able to develop marketable therapies. We entered into license agreements with numerous companies and universities, including the University of Maryland, Baltimore and Columbia University. See "---License Agreements between the Company and Vendor." Accordingly, our business may depend on the successful regulatory approval of potential in-licensed product candidates. We cannot be certain that any of our product candidates will receive regulatory approval or that our therapies will be successfully commercialized even if we receive regulatory approval.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of any in-licensed product is, and will remain, subject to comprehensive regulation by the FDA, the DEA, the European Medicines Agency ("EMA"), the Medicines and Healthcare Products Regulatory Agency ("MHRA") and foreign regulatory authorities.

Any therapeutic candidates we may develop in the future may be subject to controlled substance laws and regulations in the territories where the product will be marketed, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations and our financial condition.

In the United States, psilocybin and its active metabolite, psilocin, are listed by the DEA as a Schedule I substance and ketamine is listed by the DEA as a Schedule III substance, under the CSA. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II substances are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II substances is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Further, most, if not all, state laws in the United States classify psilocybin and psilocin as Schedule I controlled substances. For any product containing psilocybin to be available for commercial marketing in the United States, psilocybin and psilocin must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Commercial marketing in the United States will also require scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while psilocybin and psilocin are Schedule I controlled substances, products approved by the FDA for medical use in the United States that contain psilocybin or psilocin should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If one of our product candidates receives FDA approval, we anticipate that the DEA may make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may introduce a delay into the approval and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will require DEA to conduct notice and comment rule making including issuing an interim final rule. Such action will be subject to public comment and requests for hearing which could affect the scheduling of the substance. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), at the federal level, such substance would also require scheduling determinations under state laws and regulations.

In addition, therapeutic candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures, including:

- **DEA registration and inspection of facilities.** Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of product candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

- **State-controlled substances laws.** Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule product candidates. While some states automatically schedule a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or any partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

- **Clinical trials.** Because our product candidates may contain psilocybin, to conduct clinical trials in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense such product candidates and to obtain the product from our importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites.

- **Importation.** If any of our product candidates is approved and classified as a Schedule II, III or IV substance, an importer can import it for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of our product candidates and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration.

- **Manufacture.** If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements.

- **Distribution.** If any of our product candidates is scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute any future therapeutic candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations.

The potential reclassification of psilocybin and psilocin in the United States could create additional regulatory burdens on our operations and negatively affect our results of operations.

If psilocybin and/or psilocin, other than the FDA-approved formulation, is rescheduled under the CSA as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), the ability to conduct research on psilocybin and psilocin would most likely be improved. However, rescheduling psilocybin and psilocin may materially alter enforcement policies across many federal agencies, primarily the FDA and DEA. The FDA is responsible for ensuring public health and safety through regulation of food, drugs, supplements, and cosmetics, among other products, through its enforcement authority pursuant to the FDCA. The FDA's responsibilities include but are not limited to regulating the ingredients as well as the marketing and labeling of drugs sold in interstate commerce. Because it is currently illegal under federal law to produce and sell psilocybin and psilocin, and because there are no federally recognized medical uses, the FDA has historically deferred enforcement related to psilocybin and psilocin to the DEA. If psilocybin and psilocin were to be rescheduled to a federally controlled, yet legal, substance, the FDA would likely play a more active regulatory role. The DEA would continue to be active in regulating manufacturing, distribution and dispensing of such substances. The potential for multi-agency enforcement post-rescheduling could threaten or have a materially adverse effect on our business.

Any significant breaches in our compliance with U.S. and foreign laws and regulations governing controlled substances, or changes in the laws and regulations may result in interruptions to our development activity or business continuity.

Psilocybin and psilocin are categorized as Schedule I controlled substances under the CSA, and are similarly categorized by most states and foreign governments. Even assuming any future therapeutic candidates containing psilocybin or psilocin are approved and scheduled by regulatory authorities to allow their commercial marketing, the ingredients in such therapeutic candidates would likely continue to be Schedule I, or the state or foreign equivalent.

Despite the current status of psilocybin and psilocin as Schedule I controlled substances in the United States, there may be changes in the status of psilocybin or psilocin under the laws of certain U.S. cities or states. For instance, the city of Denver voted to decriminalize the possession of psilocybin in 2019 and a few other cities have decriminalized psilocybin since (including Oakland, California; Santa Cruz, California; Ann Arbor, Michigan; Cambridge, Massachusetts; and Somerville, Massachusetts). Moreover, in the November 2020 election, Oregon passed Measure 109 which legalizes medical use of "psilocybin products," including magic mushrooms, to treat mental health conditions in licensed facilities with registered therapists.

The legalization of psilocybin without regulatory oversight may lead to the setup of clinics without proper therapeutic infrastructure or adequate clinical research, which could put patients at risk and bring reputational and regulatory risk to the entire industry, making it harder for us to achieve regulatory approval.

Violations of any federal, state or foreign laws and regulations relating to controlled substances (including Psilocybin and psilocin which are categorized as Schedule I controlled substances under the CSA in the U.S.) could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, seizure of product, cessation of business activities, divestiture or prison time. This could have a material adverse effect on us, including on our reputation and ability to conduct business, our financial position, operating results, profitability or liquidity, the potential listing of our shares or the market price of our shares. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or defense of any such matters or our final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

Various federal, state, provincial and local laws govern our business in any jurisdictions in which we may operate, and to which we may export our products, including laws relating to health and safety, the conduct of our operations, and the production, storage, sale and distribution of our products. Complying with these laws requires that we comply concurrently with complex federal, state, provincial and/or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure our compliance with these laws, we will need to invest significant financial and managerial resources. It is impossible for us to predict the cost of complying with such laws or the effect they may have on our future operations. A failure to comply with these laws could negatively affect our business and harm our reputation. Changes to these laws could negatively affect our competitive position and the markets in which we operate, and there is no assurance that various levels of government in the jurisdictions in which we operate will not pass legislation or regulation that adversely impacts our business.

In addition, even if we or third parties were to conduct activities in compliance with U.S. state or local laws or the laws of other countries and regions in which we conduct activities, potential enforcement proceedings could involve significant restrictions being imposed upon us or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on our business, revenue, operating results and financial condition as well as on our reputation and prospects, even if such proceedings conclude successfully in our favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of our key executives, the seizure of corporate assets, and consequently, our inability to continue business operations. Strict compliance with state and local laws with respect to psilocybin and psilocin does not absolve us of potential liability under U.S. federal law or EU law, nor provide a defense to any proceeding which may be brought against us. Any such proceedings brought against us may adversely affect our operations and financial performance.

The psychedelics industry and market are relatively new, and the industry may not succeed in the long term.

We operate our business in a relatively new industry and market. The use of psychedelics for medicinal purposes has shown promise in various studies and we believe that both regulators and the public have an increasing awareness and acceptance of this promising field. Nevertheless, psychedelics remain a controlled substance in the United States and most other jurisdictions and their use for research and therapeutic purposes remains highly regulated and narrow in scope. There is no assurance that the industry and market will continue to grow as currently estimated or anticipated or function and evolve in the manner consistent with management's expectations and assumptions. Any event or circumstance that adversely affects the psychedelic manufacturing and medicines industry and market could have a material adverse effect on our business, financial condition and results of operations. We have committed and expect to continue committing significant resources and capital to the development of psychedelic products for therapeutic uses. As a category of products, medical-grade psychedelics raw materials and psychedelic-derived APIs, and research into such substances, represent relatively untested offerings in the marketplace, and we cannot provide assurance that psychedelics as a category, or that our prospective products, in particular, will achieve market acceptance. Moreover, as a relatively new industry, there are not many established players in the psychedelic-based medicines industry whose business model we can emulate.

Our product candidates may contain controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding psilocybin or our current or future investigational therapies using psilocybin may negatively influence the success of these therapies.

Our ability to establish and grow our business is substantially dependent on the success of the emerging market for psychedelics-based medicines, which will depend upon, among other matters, pronounced and rapidly changing public preferences, factors which are difficult to predict and over which we have little, if any, control. We and our clients will be highly dependent upon consumer perception of psychedelic-based therapies and other products.

Therapies containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for any future therapeutic candidates we may develop. Opponents of these therapies may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these therapies. For example, we may face media-communicated criticism directed at our clinical development program. Adverse publicity from psilocybin misuse may adversely affect the commercial success or market penetration achievable by our product candidates. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of any future therapeutic candidates.

Our clinical trials may fail to demonstrate substantial evidence of the safety and effectiveness of future product candidates that we may identify and pursue, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of future therapeutic candidates, we must demonstrate through lengthy, complex and expensive nonclinical studies, preclinical studies and clinical trials that the applicable therapeutic candidate is both safe and effective for use in each target indication. A therapeutic candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

We cannot be certain that any clinical trials will be successful. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants.

Even if any of our future therapeutic candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any such therapeutic candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any of our future therapeutic candidates.

If the FDA, the EMA, the MHRA or a comparable foreign regulatory authority approves any of our future therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the therapy and underlying therapeutic substance will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice ("cGMP") and with good clinical practice ("GCP") for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such therapies. The FDA may also place other conditions on approvals, including the requirement for a risk evaluation and mitigation strategy ("REMS"), to assure the safe use of the drug. Later discovery of previously unknown problems with any approved therapeutic candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of our future therapeutic candidates, withdrawal of the product from the market or product recalls;
- untitled and warning letters or holds on clinical trials;
- refusal by the FDA, the EMA, the MHRA or other foreign regulatory body to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- product seizure or detention or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

In addition, any regulatory approvals that we receive for our future therapeutic candidates may also be subject to limitations on the approved indicated uses for which the therapy may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of such therapeutic candidates.

If there are changes in the application of legislation, regulations or regulatory policies or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the therapeutic or its manufacture and requiring us to recall or remove the therapeutic from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our therapeutic labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such therapy may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

Research and development of drugs targeting the central nervous system is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others.

Discovery and development of new drugs targeting central nervous system disorders are particularly difficult and time-consuming, evidenced by the higher failure rate for new drugs for central nervous system disorders compared with most other areas of drug discovery. For example, in 2019, both rapastinel and SAGE-217, two new drugs targeting major depressive disorder ("MDD"), failed to meet their primary endpoints in Phase III trials. ALKS 5461, another new drug targeting MDD, was rejected by FDA in 2019 after its Phase III trials as FDA required additional clinical data to provide substantial evidence of effectiveness. Any such setbacks in our clinical development could have a material adverse effect on our business and operating results. In addition, our later stage clinical trials may present challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in trials given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects. Due to the complexity of the human brain and the central nervous system, it can be difficult to predict and understand why a drug may have a positive effect on some patients but not others and why some individuals may react to the drug differently from others.

The results of preclinical studies and early-stage clinical trials of our future therapeutic candidates may not be predictive of the results of later stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our future therapeutic candidates. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

We will depend on enrollment of patients in our clinical trials for our future therapeutic candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Identifying and qualifying patients to participate in our clinical trials will be critical to our success. Patient enrollment depends on many factors, including:

- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;

- safety profile, to date, of the therapeutic candidate under study;
- the willingness or availability of patients to participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance;
- perceived risks and benefits of our approach to treatment of indication;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

In addition, any negative results we may report in clinical trials may make it difficult or impossible to recruit and retain patients in other clinical trials of that same therapeutic candidate. Delays in the enrollment for any clinical trial will likely increase our costs, slow down the approval process and delay or potentially jeopardize our ability to commence sales of our future therapeutic candidates and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of any future therapeutic candidates.

We have never commercialized a therapeutic candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our therapies on our own or with suitable collaborators.

We have limited organizational experience in the sale or marketing of therapeutic candidates. To achieve commercial success for any approved therapy, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships.

If we enter into arrangements with third parties to perform market access and commercial services for any approved therapies, the revenue or the profitability of these revenue to us could be lower than if we were to commercialize any therapies that we develop ourselves. Such collaborative arrangements may place the commercialization of any approved therapies outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our therapies or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. We may not be successful in entering into arrangements with third parties to commercialize our therapies or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to commercialize our therapies effectively, to set up sufficient number of treatment centers in third-party therapy sites, or to recruit, train and retain adequate number of therapists to administer our therapies.

If we do not establish commercial capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our therapies, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations.

The future commercial success of our future therapeutic candidates will depend on the degree of market access and acceptance of our potential therapies among healthcare professionals, patients, healthcare payors, health technology assessment bodies and the medical community at large.

We may never have a therapy that is commercially successful. To date, we have no therapy authorized for marketing. Furthermore, if approved, our future therapies may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large, and we may not become profitable. The level of acceptance we ultimately achieve may be affected by negative public perceptions and historic media coverage of psychedelic substances, including psilocybin. Because of this history, efforts to educate the medical community and third-party payors and health technologies assessment bodies on the benefits of our future therapies may require significant resources and may never be successful, which would prevent us from generating significant revenue or becoming profitable. Market acceptance of our future therapies by healthcare professionals, patients, healthcare payors and health technology assessment bodies will depend on a number of factors, many of which are beyond our control, including, but not limited to, the following:

- acceptance by healthcare professionals, patients and healthcare payors of each therapy as safe, effective and cost-effective;
- changes in the standard of care for the targeted indications for any therapeutic candidate;
- the strength of sales, marketing and distribution support;
- potential product liability claims;
- the therapeutic candidate's relative convenience, ease of use, ease of administration and other perceived advantages over alternative therapies;
- the prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of therapeutic characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with our therapy in relation to alternative treatments;
- the ability to manufacture our product in sufficient quantities and yields;
- the steps that prescribers and dispensers must take, given that our therapeutic candidates include a controlled substance, as well as the perceived risks based upon their controlled substance status;
- the availability and amount of coverage and reimbursement from healthcare payors, and the willingness of patients to pay out of pocket in the absence of healthcare payor coverage or adequate reimbursement;
- the willingness of the target patient population to try, and of healthcare professionals to prescribe, the therapy;
- any potential unfavorable publicity, including negative publicity associated with recreational use or abuse of psilocybin;
- the extent to which therapies are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether our therapies are designated under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line therapy.

If our future therapeutic candidates fail to gain market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some therapies achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue.

Changes in methods of therapeutic candidate manufacturing or formulation may result in additional costs or delay.

As therapeutic candidates are developed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. Any of these changes could cause any of our future therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of any of our future therapeutic candidates and jeopardize our ability to commence product sales and generate revenue.

We may become exposed to costly and damaging liability claims, either when testing our future therapeutic candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We will be exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of therapeutic substances. Currently, we have no therapies that have been approved for commercial sale; however, any future therapeutic candidates by us and our corporate collaborators in clinical trials, and the potential sale of any approved therapies in the future, may expose us to liability claims. These claims might be made by patients who use our therapies, healthcare providers, pharmaceutical companies, our corporate collaborators or other third parties that sell our therapies. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our future therapeutic candidates or any prospects for commercialization of our future therapeutic candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our future therapeutic candidates causes adverse side effects during clinical trials or after regulatory approval, we may be exposed to substantial liabilities.

Physicians and patients may not comply with warnings that identify known potential adverse effects and describe which patients should not use any of our future therapeutic candidates. Regardless of the merits or eventual outcome, liability claims may cause, among other things, the following:

- decreased demand for our therapies due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from therapeutic sales; and
- our inability to commercialize any of our future therapeutic candidates, if approved.

In addition, we may not be able to obtain or maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business, financial condition and results of operations could be materially adversely affected. Liability claims resulting from any of the events described above could have a material adverse effect on our business, financial condition and results of operations.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any of our future therapeutic candidates and could have a material adverse effect on our business.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "ACA"), substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry.

Among the provisions of the ACA of importance to our potential therapeutic candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs, a Federal and state program which extends healthcare to low-income individuals and other groups, by, among other things, allowing states to offer Medicaid coverage to certain individuals and adding new eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program, which requires that drug manufacturers provide rebates to states in exchange for state Medicaid coverage for most of the manufacturers' drugs by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans (i.e., a type of Medicare healthcare plan offered by private companies);

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

- expansion of the types of entities eligible for the 340B drug discount program, which requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices;

- establishment of the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 1, 2019) off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;

- creation of a new non-profit, nongovernmental institute, called the Patient-Centered Outcomes Research Institute, to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and

- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business. This uncertainty is heightened by President Biden's January 28, 2021 Executive Order on Strengthening Medicaid and the Affordable Care Act which indicated that the Biden Administration may significantly modify the ACA and potentially revoke any changes implemented by the Trump Administration. It is also possible that President Biden will further reform the ACA and other federal programs in manner that may impact our operations. The Biden Administration has indicated that a goal of its administration is to expand and support Medicaid and the ACA and to make high-quality healthcare accessible and affordable. The potential increase in patients covered by government funded insurance may impact our pricing. Further, it is possible that the Biden Administration may further increase the scrutiny on drug pricing. The ACA continues to be challenged in court and it is unclear how any future litigation and the healthcare reform measures of the Biden administration will impact the ACA. In August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for pharmaceutical manufacturers and Medicare beneficiaries, including allowing the federal government to negotiate drug prices for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring drug companies to pay rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, capping out-of-pocket spending for Medicare Part D enrollees and making additional changes to Medicare Part D to further reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The Biden administration released an additional executive order on October 14, 2022, requiring the U.S. Department of Health & Human Services ("HHS") to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product or product candidates to be medically necessary or cost-effective compared to other available therapies.

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. For example, the Biden Administration, including his nominee for Secretary of DHHS, has indicated that lowering prescription drug prices is a priority, but we do not yet know what steps the administration will take or whether such steps will be successful. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products or product candidates if approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates once approved or additional pricing pressures.

In addition, new laws and additional health reform measures may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our future therapeutic candidates and, accordingly, the results of our financial operations.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to U.S. federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, other healthcare laws and regulations and other foreign privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any therapies on the market, our current and future operations may be directly, or indirectly through our relationships with investigators, health care professionals, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute or the federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any therapies for which we obtain marketing approval. These laws impact, among other things, our research activities and proposed sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in our clinical research program, healthcare professionals and others who recommend, purchase, or provide our approved therapies, and other parties through which we market, sell and distribute our therapies for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business, along with foreign regulators (including European data protection authorities). Finally, our current and future operations will be subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. These laws include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act ("FCA"). The definition of the "remuneration" under the federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- the federal civil and criminal false claims laws, such as the FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH Act") and their implementing regulations (collectively referred to as "HIPAA") as well as numerous other federal and state laws and regulations, govern the collection, dissemination, use, privacy, security, confidentiality, integrity and availability of personally identifiable information ("PII"), including protected health information ("PHI"). HIPAA applies national privacy and security standards for PHI to covered entities, including certain types of health care entities and their service providers that access PHI, known as business associates. HIPAA requires covered entities and business associates to maintain policies and procedures governing PHI that is used or disclosed, and to implement administrative, physical and technical safeguards to protect PHI, including PHI maintained, used and disclosed in electronic form. These safeguards include employee training, identifying business associates with whom covered entities need to enter into HIPAA-compliant contractual arrangements and various other measures. While we shall undertake substantial efforts to secure the PHI we maintain, use and disclose in electronic form, a cyber-attack or other intrusion that bypasses our information security systems causing an information security breach, loss of PHI, PII or other data subject to privacy laws or a material disruption of our operational systems could result in a material adverse impact on our business, along with potentially substantial fines and penalties. Ongoing implementation and oversight of these security measures involves significant time, effort and expense. HIPAA requires covered entities and their business associates to report breaches of unsecured PHI to affected individuals without unreasonable delay and in no case later than 60 days after the discovery of the breach by the covered entity or its agents. Notification must also be made to the U.S. Department of Health and Human Services ("HHS") and, in certain situations involving large breaches, to the media. The HIPAA rules created a presumption that all non-permitted uses or disclosures of unsecured PHI are breaches unless the covered entity establishes that there is a low probability the information has been compromised. A data breach affecting sensitive personal information, including health information, also could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

- the FDCA, which governs the production, sale, distribution and promotion of drugs, biologics and medical devices and prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners; and

- analogous state laws and regulations, including the following: state anti-kickback and false claims laws, which may be broader in scope than their federal equivalents, and which may apply to our business practices, including research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including licensing, extensive record-keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, their ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Of note, in response to the global COVID-19 pandemic, the FDA adopted a risk-based system for the conduct of inspections of manufacturing facilities and began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities inside and outside the United States may adopt similar restrictions or other policy measures in response to any future pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Failure to comply with health and data protection laws and regulations could lead to U.S. federal and state government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to U.S. federal and state data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, which are subject to privacy and security requirements under HIPAA, as amended by HITECH. To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and foreign privacy and data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

The successful commercialization of any of our future therapeutic candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for any of our future therapeutic candidates, if approved, could limit our ability to market those therapies and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford therapies. As Schedule I substances under the CSA, psilocybin and psilocin are deemed to have no accepted medical use and therapies that use psilocybin or psilocin are precluded from reimbursement in the United States. Our products that include psilocybin or psilocin must be scheduled as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) before they can be commercially marketed. Our ability to achieve acceptable levels of coverage and reimbursement for therapies by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of our future therapeutic candidates. Even if we obtain coverage for a given therapy by third-party payors, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients may find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any therapy that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Furthermore, third-party payors are increasingly challenging prices charged for therapeutic substances and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our future therapeutic candidates as substitutable and only offer to reimburse patients for the less expensive therapy. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed therapies at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our future therapeutic candidates, and may not be able to obtain a satisfactory financial return on therapeutic candidates that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved therapies. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our future therapeutic candidates.

Furthermore, obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug therapies exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug therapies can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our therapies to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations. Negotiating coverage and reimbursement with governmental authorities can delay commercialization. Coverage and reimbursement policies may adversely affect our ability to sell our products on a profitable basis. Some countries allow companies to fix their own prices for medical therapies, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our future therapeutic candidates. Accordingly, in markets outside the United States, the reimbursement for our therapies may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

We will be subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.

Our operations, including our research, development, testing and manufacturing activities, will be subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, manufacture, handling, release and disposal of and the maintenance of a registry for, hazardous materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens.

We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. Furthermore, if we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

Risks Relating to Our Intellectual Property Rights

The failure to obtain or maintain patents, licensing agreements and other intellectual property could materially impact our ability to compete effectively.

In order for our business to be viable and to compete effectively, we need to develop and maintain, and we will heavily rely on, a proprietary position with respect to our intellectual property. However, there are significant risks associated with our actual or proposed intellectual property. The risks and uncertainties that we face with respect to our rights principally include the following:

- pending patent applications we have filed or will file may not result in issued patents or may take longer than we expect to result in issued patents;
- we may be involved in reexamination proceedings;
- we may be subject to post grant review proceedings;
- we may be subject to *inter partes* review proceedings;
- we may be subject to derivation proceedings;

- we may be subject to opposition proceedings in foreign countries;
- any patents that are issued or licensed to us may not provide us with any competitive advantages or meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us;
- other companies may have independently developed and patented (or may in the future independently develop and patent) similar or alternative technologies, or duplicate our technologies;
- other companies may design around technologies we have licensed or developed;
- enforcement of patents is complex, uncertain and very expensive and we may not be able to secure, enforce and defend our patents;
- in the event that we were to ever seek to enforce our patents in ligation, there is some risk that they could be deemed invalid, not infringed, or unenforceable; and
- the patents of others may have an adverse effect on our business.

We cannot be certain that any patents will be issued as a result of any pending or future applications, or that any patents, once issued, will provide us with adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we or our licensors were the first to invent or to file patent applications covering them.

It is also possible that others may have or may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. There is no guarantee that such licenses will be available, or available based on commercially reasonable terms. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

If we are unable to obtain and maintain patent protection for our products, or if the scope of the patent protection obtained is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products could be impaired.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our development output before it is too late to obtain patent protection.

The patent position of life science companies generally is highly uncertain, involves complex legal and factual questions and has in past years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States and we may fail to seek or obtain patent protection in all major markets. For example, unlike the U.S., European patent law restricts the patentability of methods of treatment of the human body. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection, even post-grant. For example, the federal courts of the United States have taken an increasingly negative view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain uses of such subject matter, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had been considered important for the biotechnology and biopharmaceutical industry to protect their discoveries, is now many times considered ineligible in the first instance for protection under the patent laws of the United States. We cannot definitively predict the types or breadth of claims that may be allowable or enforceable in our patent rights (whether licensed or otherwise held).

Patent reform legislation has increased the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. Under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review challenging our patent rights (whether licensed or otherwise held). An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights (whether licensed or otherwise held), allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications (whether licensed or otherwise held) is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications (whether licensed or otherwise held) result in the issuance of patents, they may not be in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our licensed or owned patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products. Given the amount of time required for the development, testing and regulatory review of new life science product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property rights portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe our intellectual property. To counter infringement or unauthorized use, we may be required to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our product; and
- restructuring our Company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or to assert that our intellectual property is invalid or unenforceable. The result of these challenges may narrow the scope or claims of or invalidate or find unenforceable patents that are integral to our product or product candidate. In addition, in a patent infringement proceeding, a court may decide that a licensed or owned patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover that technology. Moreover, lawsuits to protect or enforce our intellectual property rights could be expensive, time-consuming and ultimately unsuccessful.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

Our commercial success depends upon our ability to develop, manufacture, market and sell our products without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the life sciences industry. We cannot guarantee that our products and candidates will not infringe third-party patents or other proprietary rights. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including *inter partes* review, post-grant review, or derivation proceedings before the USPTO and similar proceeding before similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our own patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees and annuities on any issued patent or pending application may be due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent or pending application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter our markets, which could have a material adverse effect on our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

We may retain employees and contractors that were previously employed at universities or other companies, including potential competitors. Although we will try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims, and any such litigation could have an unfavorable outcome.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and adverse results, and be a distraction to management.

If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We have licensed and may enter into or may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone, payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various universities and research institutions, we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part, increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to the third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

Disputes over intellectual property that we have licensed may prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, and we may be unable to successfully develop and commercialize our product candidate.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock. Such litigation or proceedings could increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may spend considerable resources developing and maintaining patents, license agreements and other intellectual property that may later be abandoned or may otherwise never result in products brought to market.

Not all technologies and product candidates that initially show potential as the basis for future products will ultimately meet the rigors of our development process and as a result may be abandoned and/or never otherwise result in products brought to market. In some cases, prior to abandonment we may be required to incur significant costs developing and maintaining intellectual property and/or maintaining license agreements and our business could be harmed by such costs.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We rely on information technology, and if we are unable to protect against service interruptions, data corruption, cyber-based attacks or network security breaches, our operations could be disrupted, and our business could be negatively affected.

We rely on information technology networks and systems to process, transmit and store electronic and financial information; to coordinate our business; and to communicate within our Company and with customers, suppliers, partners and other third-parties. These information technology systems may be susceptible to damage, disruptions or shutdowns, hardware or software failures, power outages, computer viruses, cyber-attacks, telecommunication failures, user errors or catastrophic events. If our information technology systems suffer severe damage, disruption or shutdown, and our business continuity plans do not effectively resolve the issues in a timely manner, our operations could be disrupted, and our business could be negatively affected. In addition, cyber-attacks could lead to potential unauthorized access and disclosure of confidential information, and data loss and corruption. There is no assurance that we will not experience these service interruptions or cyber-attacks in the future.

Other Risks Related to Our Business

We may not be successful in hiring and retaining key employees, including executive officers.

Our success materially depends upon the expertise, experience and continued service of our management and other key personnel, including, but not limited to, Eric Weisblum, our Chief Executive Officer. If we lose the services of Mr. Weisblum or any of other member of management, our business would be materially and adversely affected.

Our future success also depends upon our ability to attract and retain highly qualified management personnel and other employees. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

Unfavorable global economic, business or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including conditions that are outside of our control, including the impact of health and safety concerns, such as those relating to the current COVID-19 outbreak. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our domestic and international customers, possibly resulting in delays in customer payments. Any of the foregoing could harm our business and we cannot anticipate all the ways in which the current economic climate and financial market conditions could adversely impact our business.

Risks Relating to Our Securities

Our Articles of Incorporation grants our board of directors, without any action or approval by our stockholders, the power to designate and issue preferred stock with rights, preferences and privileges that may be adverse to the rights of the holders of our common stock.

The total number of preferred stock that we are authorized to issue is 5,000,000 shares, none of which are issued and outstanding as of March 26, 2025. Pursuant to authority granted by our Articles of Incorporation, our board of directors, without any action or approval by our stockholders, may issue preferred stock in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The rights of holders of other classes or series of capital stock, including preferred stock that may be issued could be superior to the rights of the holders of shares of our common stock. The designation and issuance of shares of capital stock having preferential rights could materially adversely affect the rights of the holders of our common stock. In addition, any issuances of additional capital stock (common or preferred) will dilute the percentage of ownership interest of our stockholders.

We have never paid cash dividends and have no plans to pay cash dividends in the future.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our capital stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our capital stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock.

We have issued options and warrants and may continue to issue additional securities in the future. The exercise of these securities and the sale of the common stock issuable thereunder may dilute your percentage ownership interest and may also result in downward pressure on the price of our common shares.

As of March 26, 2025, we have issued and outstanding options to purchase 22,850 common stock with a weighted average exercise price of $9.19 per share and warrants to purchase 2,211,730 shares of common stock with a weighted average exercise price of $4.55 per share. In addition, we have 447,150 shares of common stock available for future issuance under our Amended and Restated 2020 Omnibus Equity Incentive Plan. Because the market for our common stock may be thinly traded, the sales and/or the perception that those sales may occur, could adversely affect the market price of our common stock. Furthermore, the mere existence of a significant number of shares of common stock issuable upon exercise of our outstanding securities may be perceived by the market as having a potential dilutive effect, which could lead to a decrease in the price of our common stock.

Our compliance with complicated U.S. regulations concerning corporate governance and public disclosure is expensive and diverts management's attention from our core business, which could adversely affect our business, results of operations, and financial condition.

As a publicly reporting company, we are faced with expensive, complicated and evolving disclosure, governance and compliance laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the Dodd-Frank Act, and Nasdaq rules. As a result of the complexity involved in complying with the applicable rules and regulations, our management's attention may be diverted from other business concerns, which could harm our business, results of operations and financial condition. We may need to hire more personnel in the future or engage outside consultants, which will increase our operating expenses, to assist us in complying with these requirements.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest substantial resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business operations to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Our common stock could be subject to extreme volatility.

The trading price of our common stock may be affected by a number of factors, including events described in the risk factors set forth herein and in our other reports filed with the SEC from time to time, as well as our operating results, financial condition and other events or factors. In addition to the uncertainties relating to future operating performance and the profitability of operations, factors such as variations in interim financial results or various, and unpredictable, factors, many of which are beyond our control, may have a negative effect on the market price of our common stock. In recent years, broad stock market indices, in general, and smaller capitalization companies, in particular, have experienced substantial price fluctuations. In a volatile market, we may experience wide fluctuations in the market price of our common stock and wide bid-ask spreads. These fluctuations may have a negative effect on the market price of our common stock. In addition, the securities market has, from time to time, experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may have a material adverse effect the market price of our common stock.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and places significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley") and the Dodd-Frank Wall Street Reform and Consumer Protection Act. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation among other potential problems.

Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could cause our financial reports to be inaccurate.

We are required pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. If we fail to implement any required improvements to our disclosure controls and procedures, we may be obligated to report control deficiencies and our independent registered public accounting firm may not be able to certify the effectiveness of our internal controls over financial reporting. In either case, we could become subject to regulatory sanction or investigation. Further, these outcomes could damage investor confidence in the accuracy and reliability of our financial statements.

Our management has concluded that our internal controls over financial reporting were, and continue to be, ineffective, as December 31, 2022 as a result of the following: (i) we lack segregation of duties within accounting functions duties as a result of our limited financial resources to support hiring of personnel, and; (ii) we not have not implemented adequate system and manual controls. While management intends to remediate the material weakness, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

Nasdaq Capital Market may subsequently delist our common stock if we fail to comply with ongoing listing standards.

Nasdaq Capital Market will require us to meet certain financial, public float, bid price and liquidity standards on an ongoing basis in order to continue the listing of our common stock. If we fail to meet these continued listing requirements, our common stock may be subject to delisting. If our common stock are delisted and we are not able to list such common stock or warrants on another national securities exchange, we expect our securities would be quoted on an over-the-counter market; However, if this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. In addition, in the event of such delisting, we could experience a decreased ability to issue additional securities and obtain additional financing in the future. Even if our common stock is listed on the Nasdaq Capital Market, there can be no assurance that an active trading market for our common stock will develop or be sustained after our initial listing.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We believe cybersecurity is critical to advancing our technological advancements. As a biopharmaceutical company, we face a multitude of cybersecurity threats that range from common attacks to most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our operations, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Our Board of Directors oversees management's processes for identifying and mitigating risks, including cybersecurity risks, to help align our risk exposure with our strategic objectives. Senior leadership, including our cybersecurity consultant, regularly briefs the Board of Directors on our cybersecurity and information security posture and the Board of Directors is apprised of cybersecurity incidents deemed to have a moderate or higher business impact, even if immaterial to us. The full Board retains oversight of cybersecurity because of its importance. In the event of an incident, any incident will be reported to our Board of Directors who will then formulate a plan for mitigation, recovery, and notification. Our Cybersecurity consultant has extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks.

As a biopharmaceutical company, we must comply with extensive regulations, including requirements imposed by the Federal Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. We work with our cybersecurity consultant on assessing cybersecurity risk and on policies and practices aimed at mitigating these risks. We believe we are positioned to meet the requirements of the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Third parties also play a role in our cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach.

We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a supplier, subcontractor or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to us so that we can assess the impact of the incident on us. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See “Risk Factors” for a discussion of cybersecurity risks.

ITEM 2. PROPERTIES

Our principal executive offices are located at 677 N. Washington Boulevard Sarasota, FL. We pay approximately $80 per month to rent such space on a month-to-month basis. We believe that our current office space will be adequate for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. 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 such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

On September 27, 2022 our common stock began trading on The Nasdaq Capital Market under the symbol "SILO." Prior to that time, our common stock was quoted on the OTCQB.

Security Holders

As of March 26, 2025, there were 95 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividends

Common Stock

We have not declared or paid dividends on our common stock since our formation. Declaration or payment of dividends, if any, in the future, will be at the discretion of our Board of Directors and will depend on our then-current financial condition, results of operations, capital requirements and other factors deemed relevant by the board of directors. There are no contractual restrictions on our ability to declare or pay dividends.

Stock Repurchase Program

On January 26, 2023, our Board of Directors authorized a stock repurchase plan to repurchase up to $1.0 million of the Company's issued and outstanding common stock, from time to time, with such plan to be in place until December 31, 2023. On January 9, 2024, the Board of Directors of the Company approved an extension of the previously announced stock repurchase program authorizing the purchase of up to $1 million of the Company's common stock until March 31, 2024. On April 4, 2024, the Board of Directors of Silo Pharma, Inc. (the "Company") approved an extension of the previously announced stock repurchase program authorizing the purchase of up to $1.0 million of the Company's common stock until April 30, 2024. In aggregate, during the years ended December 31, 2024 and 2023, the Company repurchased a total of 355,710 shares of its common stock for a total cost of $644,234 pursuant to its Stock Repurchase Program. During the year ended December 31, 2024, 355,710 shares treasury shares for a cost of $644,234 were cancelled.

Recent Sales of Unregistered Securities

None.

ITEM 6. [RESERVED]

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 plan of operations together with and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

We are a developmental stage biopharmaceutical company developing novel therapeutics that address underserved conditions including PTSD, stress-induced anxiety disorders, fibromyalgia, and central nervous system (CNS) diseases. We are focused on developing novel therapies that include conventional drugs and psychedelic formulations. The Company's lead program, SPC-15, is an intranasal drug targeting PTSD and stress-induced anxiety disorders. SP-26 is a time-release ketamine-based loaded implant for fibromyalgia and chronic pain relief. Silo's two preclinical programs are SPC-14, an intranasal compound for the treatment of Alzheimer's disease, and SPU-16, a CNS-homing peptide targeting the central nervous system with initial research indication in multiple sclerosis (MS).

Therapeutics

We seek to acquire and/or develop intellectual property or technology rights from leading universities and researchers to treat rare diseases, including the use of psychedelic drugs, such as psilocybin, ketamine, and the potential benefits they may have in certain cases involving depression, mental health issues and neurological disorders. We are focused on developing traditional therapeutics and psychedelic medicine. The company concentrates on the development and commercialization of therapies for unmet needs from indications such as depression, post-traumatic stress disorder ("PTSD"), and other rare neurological disorders. Our mission is to identify assets to license and fund the research which we believe will be transformative to the well-being of patients and the health care industry.

Psilocybin is considered a serotonergic hallucinogen and is an active ingredient in some species of mushrooms. Recent industry studies using psychedelics, such as psilocybin, have been promising, and we believe there is a large unmet need with many people suffering from depression, mental health issues and neurological disorders. While classified as a Schedule I substance under the Controlled Substances Act ("CSA"), there is an accumulating body of evidence that psilocybin may have beneficial effects on depression and other mental health conditions. Therefore, the U.S. Food and Drug Administration ("FDA") and U.S. Drug Enforcement Agency ("DEA") have permitted the use of psilocybin in clinical studies for the treatment of a range of psychiatric conditions.

The potential of psilocybin therapy in mental health conditions has been demonstrated in a number of academic-sponsored studies over the last decade. In these early studies, it was observed that psilocybin therapy provided rapid reductions in depression symptoms after a single high dose, with antidepressant effects lasting for up to at least six months for a number of patients. These studies assessed symptoms related to depression and anxiety through a number of widely used and validated scales. The data generated by these studies suggest that psilocybin is generally well-tolerated and may have the potential to treat depression when administered with psychological support.

We have engaged in discussions with a number of world-renowned educational institutions and advisors regarding potential opportunities and have formed a scientific advisory board that is intended to help advise management regarding potential acquisition and development of products.

In addition, as more fully described below, we have entered into a license agreement with the University of Maryland, Baltimore, and developing a Ketamine polymer implant. In addition, we into a sponsored research agreement with Columbia University for the study of ketamine in combination with other drugs for treatment of Alzheimer's and depression disorders and we have also entered into an exclusive license agreement with Columbia under which we have rights to certain patents and inventions relating to the treatment of Alzheimer's disease and stress-induced affective disorders using Ketamine in combination with certain other compounds.

We plan to actively pursue the acquisition and/or development of intellectual property or technology rights to treat rare diseases, and to ultimately expand our business to focus on this new line of business.

Product Candidates

We are currently focusing on four product candidates:

1. SPC-15 for stress-induced psychiatric disorders, including PTSD and anxiety;
2. SP-26 for treatments of fibromyalgia and chronic pain;
3. SPC-14 for treatment of Alzheimer's disease; and
4. SPU-16 for CNS disorders, initially targeting multiple sclerosis.

SPC-15: Intranasal Treatment for PTSD and Anxiety Disorders

Our lead product candidate, SPC-15, is designed as a novel serotonin 4 (5-HT4) receptor agonist that utilizes biomarkers for treatment of stress-induced psychiatric disorders such as PTSD and anxiety disorders. This innovative treatment is administered via an intranasal formulation, potentially qualifying for the FDA's streamlined 505(b)(2) regulatory pathway, which could expedite its approval process. We are actively collaborating with Columbia University, holding exclusive global rights to develop and commercialize SPC-15, pursuant to and the exclusive license agreement entered into with Columbia on July 1, 2024. See "Item 1 Business --License Agreements between the Company and Vendor—Exclusive License Agreement with Columbia University."

On November 15, 2023, we entered into an exclusive license agreement with Medspray Pharma BV for its proprietary patented soft mist nasal spray technology, as the delivery mechanism for SPC-15, which agreement has an effective date of October 31, 2023. Preclinical and formulation studies were completed in the first half of 2024 and on June 4, 2024 the Company submitted a pre-Investigational New Drug (pre-IND) briefing package and meeting request to the U.S. Food and Drug Administration (FDA) for SPC-15, Silo's intranasal prophylactic treatment for post-traumatic stress disorder (PTSD) and stress-induced anxiety disorder. In September 2024, we had a pre-IND meeting with the FDA to align on the 505(b)(2) regulatory pathway for approval of SPC-15 and review our proposed plan to support opening an IND.

Currently, we are conducting GLP-compliant pharmacokinetic and pharmacodynamic studies and in early March 2025 we completed first dosing in an IND-enabling GLP-compliant toxicology and toxicokinetics, and we are aiming for an IND submission in 2025. The preclinical data suggests additional applications for eating disorders and anorexia, as well as enhanced efficacy when combined with an NMDA receptor antagonist for major depressive disorder and other severe stress-related conditions.

We believe our patented intranasal nose-to-brain drug dispersion technology provides a competitive advantage by increasing brain drug concentration, ensuring a faster onset of therapeutic effects with optimized safety.

SP-26: Ketamine Implant for Fibromyalgia

SP-26 represents a novel approach to treating chronic pain and fibromyalgia through a ketamine-based injectable dissolvable polymer implant. Designed for subcutaneous insertion, SP-26 focuses on regulating dosage and time release to provide sustained relief from chronic pain, offering a potentially safer alternative to opioids. Presently, our SP-26 product is in preclinical research. Initial animal studies, which began in early 2025, are evaluating the implant's dosage, time release, and absorption.

In March 2023, we filed a provisional patent application with the USPTO to use SP-26 for treatment of chronic pain, including fibromyalgia. We intend to develop SP-26 following the Section 505(b)(2) regulatory pathway of the FDA rules. Section 505(b)(2) of the FDCA was enacted to enable sponsors to seek NDA approval for novel repurposed drugs without the need for such sponsors to undertake time consuming and expensive pre-clinical safety studies and Phase 1 safety studies. Proceeding under this regulatory pathway, we will be able to rely upon publicly available data with respect to our active ingredient in our NDA submission to the FDA for marketing approval.

Fibromyalgia affects approximately 4 million U.S. adults (2% of the population). We believe SP-26's implant design provides a compelling non-opioid alternative to traditional pain management, improving dosage control compared to intravenous delivery.

SPC-14: Treatment for Alzheimer's Disease

SPC-14 targets glutamate receptor NDMAR and serotonin 5-HT4 to address cognitive and neuropsychiatric symptoms in Alzheimer's disease. Given the global Alzheimer's therapeutics market is projected to exceed $30.8 billion by 2033, SPC-14 presents a promising opportunity. SPC-14 was developed under a sponsored research agreement with Columbia University See "Item 1 Business--Investigator-Sponsored Study Agreements between the Company and Vendors---Sponsored Research Agreement with Columbia University for the Study of Ketamine in Combination with Other Drugs for Treatment of Alzheimer's and Depression Disorders," and we have exclusive global rights to develop and commercialize SPC-14, pursuant to and that certain exclusive license agreement entered into with Columbia on July 1, 2024. See "Item 1 Business--License Agreements between the Company and Vendor—Exclusive License Agreement with Columbia University.". On October 13, 2022, we extended the term of the sponsored research agreement with Columbia to conduct further research studies into the mechanism of action of SPC-14 in the treatment of Alzheimer's disease. In addition, we have been granted an option to license certain assets currently under development, including SPC-14 for the treatment of Alzheimer's disease.

We believe our SPC-14 product has shown efficacy against luteinizing hormone (LH) in attenuating learned helplessness, preservative behavior and hyponeophagia (a measure of anxiety).

SPU-16: Treatment for CNS Disorders, Initial Indication for Multiple Sclerosis

SPU-16 is a promising candidate targeting central nervous system (CNS) disorders, with an initial indication for multiple sclerosis. On February 12, 2021, we entered into a Master License Agreement (the "UMB License Agreement") with the University of Maryland, Baltimore ("UMB") pursuant to which UMB granted us an exclusive, worldwide, sublicensable, royalty-bearing license to certain intellectual property (i) to make, have made, use, sell, offer to sell, and import certain licensed products and (ii) to use the invention titled "Central nervous system-homing peptides in vivo and their use for the investigation and treatment of multiple sclerosis and other neuroinflammatory pathology," or SPU-16. See "License Agreements between the Company and Vendors--Vendor License Agreement with the University of Maryland, Baltimore for CNS Homing Peptide" for additional details.

On April 11, 2023 certain intellectual property under the UMB License Agreement described above were issued a patent from the U.S. Patent & Trademark Office (USPTO) for "Peptide-Targeted Liposomal Delivery For Treatment, Diagnosis, and Imaging of Diseases and Disorders" (US 11,766,403, B2).

We believe SPU-16 provides a competitive advantage by using homing peptides to reduce toxicity while enhancing therapeutic payload delivery.

Stock Repurchase Plan

On January 26, 2023, the Company's Board of Directors authorized a stock repurchase plan to repurchase up to $1 million of the Company's issued and outstanding common stock, from time to time, with such plan to be in place until December 31, 2023. On January 9, 2024, the Board of Directors of the Company approved an extension of the previously announced stock repurchase program authorizing the purchase of up to $1 million of the Company's common stock until March 31, 2024 and on April 4, 2024, the Stock Repurchase Plan was extended to April 30, 2024. During the year ended December 31, 2023, the Company purchased 252,855 shares of common stock for a cost of $471,121, which is reflected in treasury stock on the accompanying consolidated balance sheet. During the year ended December 31, 2024, the Company purchased 102,855 shares of common stock for a cost of $173,113. In aggregate, during the years ended December 31, 2024 and 2023, the Company repurchased a total of 355,710 shares of its common stock for a total cost of $644,234 pursuant to its Stock Repurchase Program. During the year ended December 31, 2024, all 355,710 shares treasury shares with a cost of $644,234 were cancelled.

Results of Operations

Comparison of Our Results of Operations for the Years Ended December 31, 2024 and 2023

The following table summarizes the results of operations for the years ending December 31, 2024 and 2023 and were based primarily on the comparative audited financial statements, footnotes and related information for the periods identified and should be read in conjunction with the consolidated financial statements and the notes to those consolidated financial statements that are included elsewhere in this report.

	Years Ended December 31,	
	2024	2023
Revenues	$ 72,102	$ 72,102
Cost of revenues	5,838	5,838
Gross profit	66,264	66,264
Operating expenses	4,771,958	3,921,856
Operating loss from continuing operations	(4,705,694)	(3,855,592)
Other income, net	312,814	224,509
Provision for income taxes	-	-
Loss from discontinued operations, net of tax	-	(69,600)
Net loss	$ (4,392,880)	$ (3,700,683)

Revenues

During the years ended December 31, 2024 and 2023, we generated minimal revenues from operations. For the years ended December 31, 2024 and 2023, revenues amounted to $72,102 and $72,102, respectively. Such revenues are related to the Aikido License and Sublicense Agreement and are recognized over the estimated 15-year term of the related UMB license agreement.

Cost of Revenues

During the years ended December 31, 2024 and 2023, cost of revenues amounted to $5,838 and $5,838, respectively, and consisted of license fees related to the UMB License and Sublicense Agreement, which are being amortized into cost of revenues over the estimated 15-year terms of their respective agreements with Akido and UMB.

Operating Expenses

For the years ended December 31, 2024 and 2023, total operating expenses consisted of the following:

	For the Years Ended December 31,	
	2024	2023
Compensation expense	$ 906,773	$ 871,625
Professional fees	1,198,745	1,726,061
Research and development	2,368,156	845,092
Selling, general and administrative expenses	298,284	479,078
Total	$ 4,771,958	$ 3,921,856

- Compensation Expense:

  For the years ended December 31, 2024 and 2023, compensation expense was $906,773 and $871,625, respectively, an increase of $35,148, or 4.0%. This increase primarily resulted from an increase in health insurance expense of $22,051 and an increase in executive bonus pay of $25,000, offset by a decrease in stock-based compensation of $14,125.

- Professional Fees:

  For the years ended December 31, 2024 and 2023, professional fees were $1,198,745 and $1,726,061, respectively, a decrease of $527,316, or 30.6%. The decrease was primarily attributable to a decrease in other consulting fees of $487,125, a decrease in legal fees of $188,110, and a decrease in stock-based consulting fees of $90,067 related to the amortization of prepaid expense on previously issued shares to consultants for business advisory and strategic planning services, offset by an increase in investor relations fees of $219,072, and an increase in accounting and auditing fees of $18,914.

- Research and Development:

  For the year ended December 31, 2024 and 2023, we incurred research and development expense of $2,368,156 and $845,092, respectively, an increase of $1,523,064, or 180.2%. The increase was a result of an increase in research and development costs in connection with our key Investigator-sponsored Study Agreements and other research projects with third party vendors and universities. We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

  - fees related to in-licensed products and technology;
  - expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our pre-clinical activities;
  - the cost of acquiring and manufacturing clinical trial materials; and
  - costs associated with non-clinical activities and regulatory approvals.

- Other Selling, General and Administrative Expenses:

  Selling, general and administrative expenses include advertising and promotion, patent related expenses, public company expenses, custodian fees, bank service charges, travel, and other office expenses.

  For the years ended December 31, 2024 and 2023, selling, general and administrative expenses were $298,284 and $479,078, respectively, a decrease of $180,794, or 37.7%. The decrease was primarily attributed to a decrease in Delaware franchise taxes of $228,814 resulting from the change in our state of incorporation from the State of Delaware to the State of Nevada. This decrease was offset by a net increase in other general and administrative expenses of $48,020 primarily consisting of an increase in proxy meeting fees of $15,974 and an increase in SEC filing fees of $16,095.

Operating Loss from Continuing Operations

For the years ended December 31, 2024 and 2023, loss from continuing operations amounted to $4,705,694 and $3,855,592 respectively, an increase of $850,102, or 22.1%. The increase was primarily a result of the changes in operating expenses discussed above.

Other Income (Expenses), net

For the year ended December 31, 2024 and 2023, other income, net amounted to $312,814 and $224,509, respectively, an increase of $88,305, or 39.3%. The increase in other income, net was primarily due to a decrease in penalty expense of $166,034 which was incurred during the 2023 period due to the early termination of a certificate of deposit and a decrease in net unrealized loss on equity investment of $3,118, offset by an increase in foreign currency transaction loss of $14,242, a decrease in interest and dividend income of $65,365, an increase in realized loss of short-term debt investments of $1,025, and an increase in interest expense of $215.

Loss from Discontinued Operations

For the year ended December 31, 2024 and 2023, loss from discontinued operations amounted to $0 and $69,600, respectively, a decrease of $69,600. As of December 31, 2023, we recognized an allowance for loss on the NFID. LLC note receivable and accrued interest receivable in an amount equal to the estimated probable losses, and accordingly, we recorded bad debt expense of $69,600.

Net Loss

For the year ended December 31, 2024, net loss amounted to $4,392,880 or $1.19 per common share (basic and diluted), as compared to net loss amounted to $3,700,683 or $1.20 per common share (basic and diluted) for the year ended December 31, 2023, an increase of $692,197, or 18.7%. The change was primarily a result of the changes discussed above.

Liquidity and Capital Resources

Liquidity is the ability of an enterprise to generate adequate amounts of cash to meet its needs for cash requirements. We had a working capital of $5,455,483, $3,174,724 in short-term investments, and $3,905,799 in cash and cash equivalents as of December 31, 2024, and working capital of $6,905,568, short-term investments of $4,140,880 and $3,524,308 in cash and cash equivalents as of December 31, 2023, respectively.

	December 31, 2024	December 31, 2023	Working Capital Change	Percentage Change
Working capital:				
Total current assets	$ 7,111,480	$ 7,681,158	$ (569,678)	(7)%
Total current liabilities	(1,655,997)	(775,590)	(880,407)	(114)%
Working capital	$ 5,455,483	$ 6,905,568	$ (1,450,085)	(21)%

The decrease in working capital of $1,450,085 was primarily attributable to a decrease in current assets of $569,678 primarily due to a decrease in short-term investments of approximately $966,000, offset by an increase in cash and cash equivalents of approximately $381,000 and an increase in prepaid expenses and other current assets of $15,000, and an increase in current liabilities of approximately $880,000.

Cash Flows

A summary of cash flow activities is summarized as follows:

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (3,833,914)	$ (3,224,498)
Net cash provided by (used in) investing activities	973,777	(4,147,107)
Net cash provided by (used in) financing activities	3,241,628	(471,121)
Net increase (decrease) in cash and cash equivalents	$ 381,491	$ (7,842,726)

Net Cash Used in Operating Activities

Net cash used in operating activities for the years ended December 31, 2024 and 2023 were $3,833,914 and $3,224,498, respectively, an increase of $609,416, or 18.9%.

- Net cash used in operating activities for the year ended December 31, 2024 primarily reflected a net loss of $4,392,880, adjusted for the add-back of non-cash items such as amortization expense of $6,185 and net realized loss on short-term investments of $1,025, and changes in operating asset and liabilities primarily consisting of an increase in prepaid expenses and other current assets of $9,149, an increase in accounts payable and accrued expenses of $633,007, and a decrease in deferred revenue of $72,102.

- Net cash used in operating activities for the year ended December 31, 2023 primarily reflected a net loss of $3,700,683, adjusted for the add-back of non-cash items such as net realized and unrealized loss on equity investments of $3,118, bad debt expense of $69,600, stock-based compensation of $14,125, and amortization of prepaid stock-based professional fees of $90,067, and changes in operating asset and liabilities primarily consisting of a decrease in prepaid expenses and other current assets of $35,695, an increase of interest receivable of $3,590, an increase in accounts payable and accrued expenses of $339,272, and a decrease in deferred revenue of $72,102.

Net Cash Provided by (Used in) by Investing Activities

Net cash provided by (used in) investing activities for the years ended December 31, 2024 and 2023 were $973,777 and $(4,147,107), respectively, a positive change of $5,120,884, or 123.5%.

- Net cash provided by investing activities for the year ended December 31, 2024 was $973,777 which consisted of proceeds from the sale of short-term investments of $1,149,320, offset by aggregate payments for the purchase of short-term investments of $175,543.

- Net cash used in investing activities for the year ended December 31, 2023 was $4,147,107 which consisted of aggregate payments for the purchase of short-term investments of $4,147,107.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by (used in) financing activities for the years ended December 31, 2024 and 2023 were $3,241,628 and $(471,121), respectively, a positive change of $3,712,749, or 788%.

- Net cash provided by financing activities for the year ended December 31, 2024 was $3,241,628 which consisted of net proceeds from sale of common stock and pre-funded warrants of $1,673,216, net proceeds from sale of common stock and warrants of $1,741,522 and proceeds from the exercise of pre-funded warrants of $3, offset by the purchase of treasury stock of $173,113.

- Net cash used in financing activities for the year ended December 31, 2023 was $471,121, which consisted of the purchase of treasury stock.

Cash Requirements

We believe that our current cash and cash equivalent amount and short-term investment amount will provide sufficient cash required to meet our obligations for a minimum of twelve months from the date of this filing.

Other than cash requirements pursuant to research and development agreements, we currently have no other material commitments for any capital expenditures.

Liquidity

As reflected in the accompanying consolidated financial statements, we generated a net loss of $4,392,880 and used cash in operations of $3,833,914 during the year ended December 31, 2024. Additionally, we have an accumulated deficit of $15,264,691 on December 31, 2024. As of December 31, 2024, we had working capital of $5,455,483.

The positive working capital serves to mitigate the conditions that historically raised substantial doubt about our ability to continue as a going concern. We believe that the Company has sufficient cash to meet its obligations for a minimum of twelve months from the date of this filing.

Off-Balance Sheet Arrangements

None.

Critical Accounting Estimates

Research and Development

In accordance with ASC 730-10, *"Research and Development-Overall,"* research and development costs are expensed when incurred.

Recent Accounting Pronouncements

Management does not believe that any other recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the Company's consolidated financial statements. In certain research and development projects, we estimate the percentage of completion of the research and development projects to recognize research and development expense.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and the reports of our independent registered public accounting firm required pursuant to this Item are included in Item 15 of this report and are presented beginning on page F-1.

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

Our principal executive officer and principal financial officer evaluated the effectiveness of our "disclosure controls and procedures" as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is accumulated and communicated to a company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and our Chief Financial Officer determined that we maintained effective internal control over financial reporting as of December 31, 2024.

Management's Report on Internal Control Over Financial Reporting

As of December 31, 2024, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

This Annual Report on Form 10-K 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 the Company's registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Status of Remediation of Material Weaknesses in Internal Control over Financial Reporting

As previously disclosed, as of December 31, 2023, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was not effective because management identified a material weakness. A material weakness is a significant deficiency or a combination of significant deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses which we identified in our internal control over financial reporting:

- We lack segregation of duties within accounting functions duties as a result of our limited financial resources to support hiring of personnel.
- We have not implemented adequate system and manual controls.

To address the material weakness described above, during the fourth quarter of 2024,

- We have enhanced controls within our business process controls to establish and maintain appropriate segregation of duties.
- We have enhanced our monitoring level controls to detect material and unusual variances in accounts payable.
- We have enhanced the design of the bank reconciliation controls to standardize the review and enhanced our cash disbursement and treasury controls.

In addition, we are taking steps to review and enhance business policies, procedures and related internal controls to standardize business processes.

Limitations on Effectiveness of Controls

Our principal executive officer and principal financial officer does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, 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 a simple error or mistake. Additional controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation and presentation and may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

Other than the remedial actions we implemented during the fourth quarter of 2024 as discussed above under "Status of Remediation of Material Weaknesses in Internal Controls over Financial Reporting". There were no other changes in the Company's internal control over financial reporting that occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

During our last fiscal quarter ended December 31, 2024, none of our directors or executive officers adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" as such terms are defined under Item 408 of Regulation

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the names, positions and ages of our directors and executive officers as of the date of this annual report.

All directors shall serve until the 2025 annual meeting of stockholders.

Name	Age	Position
Eric Weisblum	55	Chairman, Chief Executive Officer, President, and Director
Daniel Ryweck	60	Chief Financial Officer
Wayne D. Linsley	68	Director
Dr. Kevin Muñoz	46	Director
Jeff Pavell	58	Director

The business background and certain other information about our directors and executive officers is set forth below.

Eric Weisblum

Eric Weisblum is the founder and Chief Executive Officer of Silo Pharma Inc. Prior to Silo Pharma Mr. Weisblum was a private investor, board member, and advisor to several companies. Mr. Weisblum has experience in both licensing therapeutic assets and assisting in their development. As a result, Mr. Weisblum brings with him nearly 20 years of experience in structuring and trading financial instruments. Mr. Weisblum was a registered representative with Domestic Securities, a New Jersey-based broker-dealer. While with Domestic Securities, Mr. Weisblum held the Series 7 - General Securities Representative, the Series 63 – Uniform Securities Agent State Law Examination, and the Series 55 – Registered Equity Trader securities registrations. From 1993 to 2002, Mr. Weisblum originated, structured, traded, and placed structured financing transactions at M.H. Meyerson & Co. Inc., a publicly-traded registered investment bank. He holds a B.A. from the University of Hartford's Barney School of Business.

Daniel Ryweck

Mr. Ryweck has served as Chief Financial Officer of the Company since September 27, 2022. Since January 2020, Mr. Ryweck has served as Controller at Mill City Ventures III Ltd. (NASDAQ: MCVT), a non-bank lender and specialty finance company. From. June 2014 to December 2019, he served as Chief Compliance Officer of Mill City Ventures III Ltd. Mr. Ryweck holds a Bachelor of Science degree in Accounting from the Carlson School of Management at the University of Minnesota.

Wayne D. Linsley

Wayne D. Linsley has served as a director of the Company since January 2020. Mr. Linsley has over 40 years of experience in business management. Since April 2020, Mr. Linsley has served as a member of the board of directors of Hoth Therapeutics, Inc. (NASDAQ: HOTH), a clinical-stage biopharmaceutical company. Since August 2021, Mr. Linsley has served as a member of the board of directors of DatChat, Inc. (NASDAQ: DATS), a communication software company. From 2014 to September 2021, Mr. Linsley served as the Vice President of Operations at CFO Oncall, Inc., a company that provides financial reporting and controller services on an outsourced basis and previously, from 2012 to 2014, Mr. Linsley worked at CFO Oncall, Inc. as an independent contractor. Mr. Linsley holds Bachelor of Science degree in Business Administration from Siena College. We believe that Mr. Linsley is qualified to serve as a member of our board of directors because of his experience as a director of public companies and background in financial reporting.

Dr. Kevin Muñoz

Dr. Kevin Muñoz has served as a director of the Company since October 2020. Since December 2021, Dr. Muñoz has taught Biomedical Science and Medical Intervention at Passaic County Technical Institute. Since June 2008, Dr. Muñoz has served as the Director of Operations and Medical Assistant at The Physical Medicine and Rehabilitation Center, P.A., a diagnostic and treatment facility that specializes in treating sports, spine, orthopedic and neuromuscular conditions. Dr. Muñoz holds Doctor of Medicine degree from Xavier University School of Medicine and a Bachelor of Science degree in Kinesiology from the University of Michigan. We believe that Dr. Muñoz is qualified to serve as a member of our board of directors because of his medical background and experience in business operations.

Dr. Jeff Pavell – Director

Dr. Pavell has served as our director since September 27, 2022. Dr. Pavell has over 20 years of medical experience. Since January 2021, Dr. Pavell has served as a director of FoxWayne Enterprises Acquisition Corp. (NASDAQ: FOXW), a blank check company incorporated for the purpose of effecting a business combination. Since October 1999, Dr. Pavell has served as an Attending Physician at the Physical Medicine and Rehabilitation Center, P.A., a diagnostic and treatment facility that specializes in treating sports, spine, orthopedic and neuromuscular conditions. Since January 2000, Dr. Pavell has served as the Chief of Rehabilitation Medicine at Englewood Hospital and Medical Center. Since April 2002, Dr. Pavell has served as the Associate Director of Pain Medicine at the Center for Advanced Surgery in Paramus, New Jersey. Since April 2002, Dr. Pavell has been an Instructor in Clinical Rehabilitation at Columbia University's College of Physicians & Surgeons. Dr. Pavell holds a Doctor of Medicine degree from the New York College of Osteopathic Medicine and a Bachelor of Art degree in Political Science from John Hopkins University. We believe that Dr. Pavell is qualified to serve as a member of our board of directors due to his medical background and experience practicing in the healthcare industry.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Arrangements between Officers and Directors

Except as set forth herein, to our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person pursuant to which the officer or director was selected to serve as an officer or director.

Involvement in Certain Legal Proceedings

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

Board Composition

Our board of directors currently consists of four members, all of whom are members pursuant to the board composition provisions of our current articles of incorporation and agreements with our stockholders, and who will remain members pursuant to the board composition provisions of our articles of incorporation.

Our nominating and corporate governance committee and our board of directors may consider a broad range of factors relating to the qualifications and background of board nominees, which may include diversity, which is not only limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. Our articles of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of the holders of 2/3 of the votes that all our stockholders would be entitled to cast in an election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office and not by the stockholders, unless the board determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders.

Director Independence. Our board of directors has determined that all members of our board of directors are independent directors, with the exception of Eric Weisblum, including for purposes of Nasdaq Listing Rule 5605(a)(2) and relevant federal securities laws and regulations.

The board of directors held a total of nine meetings and took action by written consent or electronically on eight occasions during the year ended December 31, 2024. All directors attended all of the meetings of the Board of Directors, except for the meeting held on December 3, 2024 where a majority of directors were in attendance. No annual meeting was held during the year ended December 31, 2024, and all relevant matters were approved by stockholder consent. Our policy is to encourage all directors to attend our annual meetings of stockholders.

Committees of Our Board of Directors

Our board of directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board of directors and its standing committees. We have a standing audit committee and compensation committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

Our board of directors has determined that all of the members of the audit committee and the compensation committee are independent as defined under the applicable rules of The Nasdaq Capital Market, including, in the case of all of the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act. In making such determination, the board of directors considered the relationships that each director has with our Company and all other facts and circumstances that the board of directors deemed relevant in determining director independence, including the beneficial ownership of our capital stock by each director.

Audit Committee

Our audit committee is responsible for, among other things:

- approving and retaining the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approval of audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent registered public accounting firm and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Our audit committee consists of Wayne D. Linsley, Jeff Pavel and Dr. Kevin Muñoz, with Mr. Linsley serving as chair. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that Mr. Linsley qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K.

Our audit committee held five meetings and took action by written consent or electronically on five occasions during the year ended December 31, 2024. All members of the audit committee attended all of the meetings while they were members of the audit committee. The Audit Committee Charter is available on the Company's website.

REPORT OF THE AUDIT COMMITTEE[(1)]

The role of the Audit Committee is to assist the board of directors in its oversight of the Company's financial reporting process. As set forth in the Audit Committee Charter, management of the Company is responsible for the preparation, presentation and integrity of the Company's consolidated financial statements, accounting and financial reporting policies, principles and practices, and internal controls and procedures designed to assure compliance with accounting standards and applicable laws and regulations. The independent auditors are responsible for auditing the Company's consolidated financial statements and expressing an opinion as to their conformity with accounting principles generally accepted in the United States of America ("generally accepted accounting principles" or "GAAP").

In the performance of this oversight function, the Audit Committee has reviewed and discussed the audited financial statements for the fiscal Year Ended December 31, 2024 with management, and has discussed with the independent auditors the matters required to be discussed by Public Company Accounting Oversight Board ("PCAOB") Auditing Standard, AS 1301, Communication with Audit Committee, as currently in effect. The Audit Committee has received the written disclosures and the letter from the independent auditors required by Independence Standards Board Standard No. 1, Independence Discussions with Audit Committees, as currently in effect, and has discussed with the independent auditors the independent auditors' independence; and based on its review, discussions, and related deliberations, the Audit Committee recommended to the board of directors that the audited consolidated financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 for filing with the SEC.

(1) The material in the Audit Committee report is not soliciting material, is not deemed filed with the SEC and is not incorporated by reference in any filing of the Company under the Securities Act of 1933, or the Securities Exchange Act of 1934, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in such filing.

The members of the Audit Committee are not professionally engaged in the practice of auditing or accounting, are not experts in the fields of accounting or auditing, including in respect of auditor independence. Members of the Audit Committee rely without independent verification on the information provided to them and on the representations made by management and the independent auditors. Accordingly, the Audit Committee's oversight does not provide an independent basis to determine that management has maintained appropriate accounting and financial reporting principles, or appropriate internal control and procedures designed to assure compliance with accounting standards and applicable laws and regulations. Furthermore, the Audit Committee's consideration and discussions referred to above do not assure that the audit of the Company's consolidated financial statements has been carried out in accordance with the auditing standards established by the PCAOB, or that the Company's auditors are in fact independent, as required under professional auditing standards.

Based upon the reports, review and discussions described in this report, and subject to the limitations on the role and responsibilities of the Audit Committee referred to above and in the Audit Committee Charter, the Audit Committee recommended to the Board that the audited consolidated financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission.

THE AUDIT COMMITTEE

Wayne D. Linsley (Chair of the Audit Committee)

Jeff Pavel

Dr. Kevin Muñoz

Compensation Committee

Our compensation committee is responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Our compensation committee consists of Wayne D. Linsley, Jeff Pavell and Dr. Kevin Muñoz, with Mr. Linsley serving as chair.

Our board of directors has assessed the risks that could arise from our employee compensation policies and does not believe that such policies are reasonably likely to have a materially adverse effect on the Company.

Our compensation committee held two meetings and took action by written consent or electronically on two occasions during the year ended December 31, 2024. All members of the compensation committee attended all of the meetings while they were members of the compensation committee. The Compensation Committee Charter is available on the Company's website.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee, among other things, will be responsible for:

- reviewing and assessing the development of the executive officers and considering and making recommendations to the Board regarding promotion and succession issues;
- evaluating and reporting to the Board on the performance and effectiveness of the directors, committees and the Board as a whole;
- working with the Board to determine the appropriate and desirable mix of characteristics, skills, expertise and experience, including diversity considerations, for the full Board and each committee;
- annually presenting to the Board a list of individuals recommended to be nominated for election to the Board;
- reviewing, evaluating, and recommending changes to the Company's Corporate Governance Principles and Committee Charters;
- recommending to the Board individuals to be elected to fill vacancies and newly created directorships;
- overseeing the Company's compliance program, including the Code of Conduct; and
- overseeing and evaluating how the Company's corporate governance and legal and regulatory compliance policies and practices, including leadership, structure, and succession planning, may affect the Company's major risk exposures.

Our nominating and corporate governance committee consists of Wayne Linsley, Kevin Munoz and Jeff Pavell, with Mr. Linsley serving as chair.

Our nominating and corporate governance committee held one meeting and took action by written consent or electronically on no occasion during the year ended December 31, 2024. All members of the nominating and corporate governance committee attended all of the meetings while they were members of the nominating and corporate governance committee. The board of directors has adopted a written charter for the nominating and governance committee. The Nominating and Corporate Governance Committee Charter is available on the Company's website.

Compensation Committee Interlocks and Insider Participation

None of the Company's executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of the Company's board of directors or its compensation committee. None of the members of the Company's compensation committee is, or has ever been, an officer or employee of the company.

Scientific Advisory Board

We have formed a scientific advisory board that is intended to help advise management regarding potential acquisition and development of products. The members of such board are as follows: Dr. Josh Woolley MD/Ph.D.; and Dr. Charles Nemeroff.

Dr. Josh Woolley MD/Ph.D. is an Associate Professor in the Department of Psychiatry and Behavioral Sciences at the University of California, San Francisco ("UCSF"). He is also a licensed psychiatrist on staff at the San Francisco Veterans Affairs Medical Center. He received both his MD and his Ph.D. in Neuroscience from UCSF and completed his psychiatry residency training at UCSF. Dr. Woolley is the director and founder of the Bonding and Attunement in Neuropsychiatric Disorders ("BAND") Laboratory. The mission of the BAND Lab is to understand why people with mental illnesses, including schizophrenia, posttraumatic stress disorder, mood disorders, and substance use disorders, have trouble with social connection, and to develop and test novel treatments for these deficits. His laboratory is actively investigating psilocybin therapy for multiple disorders including major depressive disorder, bipolar depression, chronic pain, and mood symptoms associated with Parkinson's Disease.

Dr. Charles Nemeroff is chair and professor with the Department of Psychiatry and Behavioral Sciences. He also directs the Institute for Early Life Adversity Research within the Department of Psychiatry and Behavioral Sciences as part of the Mulva Clinic for the Neurosciences. Prior to joining Dell Med, Dr. Nemeroff was chair of the Department of Psychiatry and Behavioral Sciences and clinical director of the Center on Aging at the University of Miami Miller School of Medicine in Miami, Florida. He received his medical degree and doctorate degrees in neurobiology from the University of North Carolina ("UNC") School of Medicine. After psychiatry residency training at UNC and Duke University, he held faculty positions at Duke University Medical Center and at Emory University School of Medicine before relocating to the University of Miami in 2009. He has served as president of the American College of Psychiatrists and the American College of Neuropsychopharmacology and sits on the Scientific Advisory Board of the Brain and Behavior Research Foundation. He is President-elect of the Anxiety and Depression Association of America and a member of the National Academy of Medicine.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities.

To our knowledge, based solely upon a review of Forms 3, 4, and 5 filed with the SEC during the fiscal year ended December 31, 2024, we believe that our directors, executive officers, and greater than 10% beneficial owners have complied with all applicable filing requirements during the fiscal year ended December 31, 2024.

Insider Trading Policy and Anti-hedging

We have adopted an Insider Trading Policy that applies to our officers, directors and all other employees (including temporary employees) of, or consultants to, the Company or its subsidiaries, as well as family members of such persons. As part of our Insider Trading Policy, all of our officers, directors, employees and consultants and family members or others sharing a household with any of the foregoing or that may have access to material non-public information regarding our Company are prohibited from engaging in short sales of our securities, any hedging or monetization transactions involving our securities and in transactions involving puts, calls or other derivative securities based on our securities. Our Insider Trading Policy further prohibits such persons from purchasing our securities on margin, borrowing against any account in which our securities are held or pledging our securities as collateral for a loan unless pre-cleared by our Insider Trading Compliance Officer. As of December 31, 2024, none of our directors or executive officers had pledged any shares of our common stock.

Code of Ethics

We have adopted a Code of Business Ethics that applies to all of our directors, officers and employees. A copy of the Code of Business Ethics is incorporated by reference as an exhibit. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be posted on our website at *www.silopharma.com* or will be included in a Current Report on Form 8-K, which we will file within four business days following the date of the amendment or waiver.

Changes in Nominating Procedures

None.

ITEM 11. EXECUTIVE COMPENSATION

The following table provides certain information regarding compensation awarded to, earned by or paid to persons serving as our principal executive officer and our principal financial officer during the year ended December 31, 2024 and 2023 (each a "named executive officer").

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Eric Weisblum, Chief Executive Officer (1)	2024	350,000(3)	200,000	—	—	—	—	80,051(3)	630,051
	2023	350,151(3)	200,000	—	—	—	—	18,858(3)	569,009
Daniel Ryweck, Chief Financial Officer (2)	2024	60,000(4)	25,000	—	—	—	—	3,600(4)	88,600
	2023	59,923(4)	—	—	—	—	—	2,769(4)	62,692

(1) On October 12, 2022, the Company entered into an employment agreement with Eric Weisblum (the "Weisblum Employment Agreement") pursuant to which Mr. Weisblum's (i) base salary will be $350,000 per year, and (ii) Mr. Weisblum shall be entitled to receive an annual bonus of up to $350,000, subject to the sole discretion of the Compensation Committee of the Board of Directors of the Company.

(2) On September 28, 2022, the Company entered into an employment agreement (the "Ryweck Employment Agreement") with Mr. Ryweck. Pursuant to the terms of the Ryweck Employment Agreement, which was amended on October 12, 2022 and on November 11, 2024, Mr. Ryweck will (i) receive a base salary at an annual rate of $60,000, and (ii) be eligible to receive an annual discretionary bonus of up to $60,000.

(3) During 2024 and 2023, the Company contributed funds for the executive to the Company's 401(k) plan. Additionally, the Company paid for the Executive's health insurance premiums.

(4) During 2024 and 2023, the Company contributed funds for each executive to the Company's 401(k) plan.

Narrative Disclosure to Summary Compensation Table

Except as otherwise described below, there are no compensatory plans or arrangements, including payments to be received from the Company with respect to any named executive officer that would result in payments to such person because of his or her resignation, retirement or other termination of employment with the Company, or our subsidiaries, any change in control, or a change in the person's responsibilities following a change in control of the Company.

Employment Agreements

Eric Weisblum

On October 12, 2022, the Company entered into an employment agreement with Eric Weisblum (the "Weisblum Employment Agreement") pursuant to which Mr. Weisblum's (i) base salary will be $350,000 per year, (ii) Mr. Weisblum will be paid a one-time signing bonus of $100,000, and (iii) Mr. Weisblum shall be entitled to receive an annual bonus of up to $350,000, subject to the sole discretion of the Compensation Committee of the Board of Directors of the Company (the "Compensation Committee"), and upon the achievement of additional criteria established by the Compensation Committee from time to time (the "Annual Bonus"). In addition, pursuant to the Weisblum Employment Agreement, upon termination of Mr. Weisblum's employment for death or Total Disability (as defined in the Weisblum Employment Agreement), in addition to any accrued but unpaid compensation and vacation pay through the date of his termination and any other benefits accrued to him under any Benefit Plans (as defined in the Weisblum Employment Agreement) outstanding at such time and the reimbursement of documented, unreimbursed expenses incurred prior to such termination date (collectively, the "Weisblum Payments"), Mr. Weisblum shall also be entitled to the following severance benefits: (i) 24 months of his then base salary; (ii) if Mr. Weisblum elects continuation coverage for group health coverage pursuant to COBRA Rights (as defined in the Weisblum Employment Agreement), then for a period of 24 months following Mr. Weisblum's termination he will be obligated to pay only the portion of the full COBRA Rights cost of the coverage equal to an active employee's share of premiums (if any) for coverage for the respective plan year; and (iii) payment on a pro-rated basis of any Annual Bonus or other payments earned in connection with any bonus plan to which Mr. Weisblum was a participant as of the date of his termination (together with the Weisblum Payments, the "Weisblum Severance"). Furthermore, pursuant to the Weisblum Employment Agreement, upon Mr. Weisblum's termination (i) at his option (A) upon 90 days prior written notice to the Company or (B) for Good Reason (as defined in the Weisblum Employment Agreement), (ii) termination by the Company without Cause (as defined in the Weisblum Employment Agreement) or (iii) termination of Mr. Weisblum's employment within 40 days of the consummation of a Change in Control Transaction (as defined in the Weisblum Employment Agreement), Mr. Weisblum shall receive the Weisblum Severance; provided, however, Mr. Weisblum shall be entitled to a pro-rated Annual Bonus of at least $200,000. In addition, any equity grants issued to Mr. Weisblum shall immediately vest upon termination of Mr. Weisblum's employment by him for Good Reason or by the Company at its option upon 90 days prior written notice to Mr. Weisblum, without Cause.

Daniel Ryweck

On September 27, 2022, the Board appointed Daniel Ryweck as Chief Financial Officer of the Company. On September 28, 2022, the Company entered into an employment agreement (the "Ryweck Employment Agreement") with Mr. Ryweck. Pursuant to the terms of the Ryweck Employment Agreement, which was amended on October 12, 2022, Mr. Ryweck will (i) receive a base salary at an annual rate of $60,000 (the "Base Compensation") payable in equal monthly installments, and (ii) be eligible to receive an annual discretionary bonus. The term of Mr. Ryweck's engagement under the Ryweck Employment Agreement commenced on September 28, 2022 and continued until September 28, 2023, unless earlier terminated in accordance with the terms of the Ryweck Employment Agreement. The term of Mr. Ryweck's Employment Agreement was automatically renewed until September 28, 2025 and will automatically renew for successive one-year periods until terminated by Mr. Ryweck or the Company. On November 11, 2024, the Company entered into a Second Amendment to Employment Agreement with Daniel Ryweck (the "Second Amendment"). The Second Amendment amended the Employment Agreement to provide that Mr. Ryweck is entitled to receive an annual cash bonus in an amount up to $60,000 if the Company meets or exceeds criteria adopted by the Compensation Committee of the Board for earning bonuses.

Potential Payment Upon Termination

If Mr. Weisblum dies or has a total disability, resigns, is terminated for good reason (as defined in the agreement), without cause (as defined in the agreement) or within 40 days of a change of control (as defined in the agreement, then he is entitled to 24 months' severance.

The following table sets forth quantitative information with respect to potential payments to be made to Mr. Weisblum upon termination in various circumstances. The potential payments are based on the terms of Mr. Weisblum's employment agreement discussed above. For a more detailed description of Mr. Weisblum's employment agreement, see the "Employment Agreements" section above:

Name	Potential Payment Upon Termination
Eric Weisblum	$ 700,000(1)

(1) Mr. Weisblum is entitled to 24 months' severance at the applicable base salary rate. Mr. Weisblum's current base salary is $350,000 per annum.

Outstanding Equity Awards at Fiscal Year-End Table

There were no stock awards or other equity awards outstanding as of December 31, 2024 held by named executive officers

Amended and Restated 2020 Omnibus Equity Incentive Plan

The following is a summary of the material features of the Amended and Restated 2020 Omnibus Equity Incentive Plan (the "Amended and Restated 2020 Plan"). This summary is qualified in its entirety by the full text of the Amended and Restated 2020 Plan, a copy of which was filed as an Appendix to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on October 23, 2023.

Types of Awards. The Amended and Restated 2020 Plan provides for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights ("SARs"), restricted stock, restricted stock units ("RSUs"), and other stock-based awards. Items described above in the Section called "Shares Available; Certain Limitations" are incorporated herein by reference.

Administration. The Amended and Restated 2020 Plan will be administered by the Board, or if the Board does not administer the Amended and Restated 2020 Plan, any committee of the Board or any other committee or subcommittee of the Board that complies with the applicable requirements of Section 16 of the Exchange Act, as amended from time to time, and any other applicable legal or stock exchange listing requirements (each of the Board, or such committee or such subcommittee, the "plan administrator"). The plan administrator may interpret the Amended and Restated 2020 Plan and may prescribe, amend and rescind rules and make all other determinations necessary or desirable for the administration of the Amended and Restated 2020 Plan.

The Amended and Restated 2020 Plan permits the plan administrator to select the eligible recipients who will receive awards, to determine the terms and conditions of those awards, including, but not limited to, the exercise price or other purchase price of an award, the number of shares of common stock or cash or other property subject to an award, the term of an award and the vesting schedule applicable to an award, and to amend the terms and conditions of outstanding awards.

Restricted Stock and Restricted Stock Units. Restricted stock and RSUs may be granted under the Amended and Restated 2020 Plan. The plan administrator will determine the purchase price, vesting schedule and performance goals, if any, and any other conditions that apply to a grant of restricted stock and RSUs. If the restrictions, performance goals or other conditions determined by the plan administrator are not satisfied, the restricted stock and RSUs will be forfeited. Subject to the provisions of the Amended and Restated 2020 Plan and the applicable award agreement, the plan administrator has the sole discretion to provide for the lapse of restrictions in installments.

Unless the applicable award agreement provides otherwise, participants with restricted stock will generally have all of the rights of a shareholder; provided that dividends will only be paid if and when the underlying restricted stock vests. RSUs will not be entitled to dividends prior to vesting, but may be entitled to receive dividend equivalents if the award agreement provides for them. The rights of participants granted restricted stock or RSUs upon the termination of employment or service to us will be set forth in the award agreement.

Options. Incentive stock options and non-statutory stock options may be granted under the Amended and Restated 2020 Plan. An "incentive stock option" means an option intended to qualify for tax treatment applicable to incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended ("Code"). A "non-statutory stock option" is an option that is not subject to statutory requirements and limitations required for certain tax advantages that are allowed under specific provisions of the Code. A non-statutory stock option under the Amended and Restated 2020 Plan is referred to for federal income tax purposes as a "non-qualified" stock option. Each option granted under the Amended and Restated 2020 Plan will be designated as a non-qualified stock option or an incentive stock option. At the discretion of the plan administrator, incentive stock options may be granted only to our employees, employees of our "parent corporation" (as such term is defined in Section 424I of the Code) or employees of our subsidiaries.

The exercise period of an option may not exceed ten years from the date of grant and the exercise price may not be less than 100% of the fair market value of a share of common stock on the date the option is granted (110% of fair market value in the case of incentive stock options granted to 10% stockholders). The exercise price for shares of common stock subject to an option may be paid in cash, or as determined by the plan administrator in its sole discretion, (i) through any cashless exercise procedure approved by the plan administrator (including the withholding of shares of common stock otherwise issuable upon exercise), (ii) by tendering unrestricted shares of common stock owned by the participant, (iii) with any other form of consideration approved by the plan administrator and permitted by applicable law or (iv) by any combination of these methods. The option holder will have no rights to dividends or distributions or other rights of a shareholder with respect to the shares of the Company's common stock subject to an option until the option holder has given written notice of exercise and paid the exercise price and applicable withholding taxes.

In the event of a participant's termination of employment or service, the participant may exercise his or her option (to the extent vested as of such date of termination) for such period of time as specified in his or her option agreement.

Stock Appreciation Rights.

SARs may be granted either alone (a "Free-Standing SAR") or in conjunction with all or part of any option granted under the Amended and Restated 2020 Plan (a "Related Right"). A Free-Standing SAR will entitle its holder to receive, at the time of exercise, an amount per share up to the excess of the fair market value (at the date of exercise) of a share of common stock over the base price of the Free-Standing SAR (which shall be no less than 100% of the fair market value of the related shares of common stock on the date of grant) multiplied by the number of shares in respect of which the SAR is being exercised. A Related Right will entitle its holder to receive, at the time of exercise of the SAR and surrender of the applicable portion of the related option, an amount per share up to the excess of the fair market value (at the date of exercise) of a share of common stock over the exercise price of the related option multiplied by the number of shares in respect of which the SAR is being exercised. The exercise period of a Free-Standing SAR may not exceed ten years from the date of grant. The exercise period of a Related Right will also expire upon the expiration of its related option.

The holder of a SAR will have no rights to dividends or any other rights of a shareholder with respect to the shares of the Company's common stock subject to the SAR until the holder has given written notice of exercise and paid the exercise price and applicable withholding taxes

In the event of a participant's termination of employment or service, the holder of a SAR may exercise his or her SAR (to the extent vested as of such date of termination) for such period of time as specified in his or her SAR agreement.

Other Stock-Based Awards. The plan administrator may grant other stock-based awards under the Amended and Restated 2020 Plan, valued in whole or in part by reference to, or otherwise based on, shares of common stock. The plan administrator will determine the terms and conditions of these awards, including the number of shares of common stock to be granted pursuant to each award, the manner in which the award will be settled, and the conditions to the vesting and payment of the award (including the achievement of performance goals). The rights of participants granted other stock-based awards upon the termination of employment or service to us will be set forth in the applicable award agreement. In the event that a bonus is granted in the form of shares of common stock, the shares of common stock constituting such bonus shall, as determined by the plan administrator, be evidenced in uncertificated form or by a book entry record or a certificate issued in the name of the participant to whom such grant was made and delivered to such participant as soon as practicable after the date on which such bonus is payable. Any dividend or dividend equivalent award issued under the Amended and Restated 2020 Plan shall be subject to the same restrictions, conditions and risks of forfeiture as apply to the underlying award.

Equitable Adjustment and Treatment of Outstanding Awards Upon a Change in Control

Equitable Adjustments. In the event of a merger, consolidation, reclassification, recapitalization, spin-off, spin-out, repurchase, reorganization, special or extraordinary dividend or other extraordinary distribution (whether in the form of common shares, cash or other property), combination, exchange of shares, or other change in corporate structure affecting our common stock, an equitable substitution or proportionate adjustment shall be made in (i) the aggregate number and kind of securities reserved for issuance under the Amended and Restated 2020 Plan, (ii) the kind and number of securities subject to, and the exercise price of, any outstanding options and SARs granted under the Amended and Restated 2020 Plan, (iii) the kind, number and purchase price of shares of common stock, or the amount of cash or amount or type of property, subject to outstanding restricted stock, RSUs and other stock-based awards granted under the Amended and Restated 2020 Plan and (iv) the terms and conditions of any outstanding awards (including any applicable performance targets). Equitable substitutions or adjustments other than those listed above may also be made as determined by the plan administrator. In addition, the plan administrator may terminate all outstanding awards for the payment of cash or in-kind consideration having an aggregate fair market value equal to the excess of the fair market value of the shares of common stock, cash or other property covered by such awards over the aggregate exercise price, if any, of such awards, but if the exercise price of any outstanding award is equal to or greater than the fair market value of the shares of common stock, cash or other property covered by such award, the plan administrator may cancel the award without the payment of any consideration to the participant. With respect to awards subject to foreign laws, adjustments will be made in compliance with applicable requirements. Except to the extent determined by the plan administrator, adjustments to incentive stock options will be made only to the extent not constituting a "modification" within the meaning of Section 424(h)(3) of the Code.

Change in Control. The Amended and Restated 2020 Plan provides that, unless otherwise determined by the plan administrator and evidenced in an award agreement, employment, services or other agreement, if a "change in control" (as defined below) occurs and a participant is employed by, or otherwise providing services to the Company or any of its affiliates immediately prior to the consummation of the change in control, then the plan administrator, in its sole and absolute discretion, may (i) provide that any unvested or unexercisable portion of an award carrying a right to exercise will become fully vested and exercisable; and (ii) cause the restrictions, deferral limitations, payment conditions and forfeiture conditions applicable to any award granted under the Amended and Restated 2020 Plan to lapse, and the awards will be deemed fully vested and any performance conditions imposed with respect to such awards will be deemed to be fully achieved at target performance levels. The plan administrator shall have discretion in connection with such change in control to provide that all outstanding and unexercised options and SARs shall expire upon the consummation of such change in control.

For purposes of the Amended and Restated 2020 Plan, a "change in control" means, in summary, the occurrence of any of the following events: (i) a person or entity becomes the beneficial owner of more than 50% of our voting power; (ii) an unapproved change in the majority membership of our Board; (iii) a merger or consolidation of us or any of our subsidiaries, other than (A) a merger or consolidation that results in our voting securities continuing to represent 50% or more of the combined voting power of the surviving entity or its parent and our Board immediately prior to the merger or consolidation continuing to represent at least a majority of the Board of the surviving entity or its parent or (B) a merger or consolidation effected to implement a recapitalization in which no person is or becomes the beneficial owner of our voting securities representing more than 50% of our combined voting power; or (iv) shareholder approval of a plan of our complete liquidation or dissolution or the consummation of an agreement for the sale or disposition of substantially all of our assets, other than (A) a sale or disposition to an entity, more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of us immediately prior to such sale or (B) a sale or disposition to an entity controlled by our Board. However, a change in control will not be deemed to have occurred as a result of any transaction or series of integrated transactions following which our stockholders, immediately prior thereto, hold immediately afterward the same proportionate equity interests in the entity that owns all or substantially all of our assets.

Tax Withholding

Each participant will be required to make arrangements satisfactory to the plan administrator regarding payment of up to the maximum statutory tax rates in the participant's applicable jurisdiction with respect to any award granted under the Amended and Restated 2020 Plan, as determined by us. We have the right, to the extent permitted by applicable law, to deduct any such taxes from any payment of any kind otherwise due to the participant. With the approval of the plan administrator, the participant may satisfy the foregoing requirement by either electing to have us withhold from delivery of shares of common stock, cash or other property, as applicable, or by delivering already owned unrestricted shares of common stock, in each case, having a value not exceeding the applicable taxes to be withheld and applied to the tax obligations. We may also use any other method of obtaining the necessary payment or proceeds, as permitted by applicable law, to satisfy our withholding obligation with respect to any award.

Amendment and Termination of the Amended and Restated 2020 Plan

The Amended and Restated 2020 Plan provides our Board with authority to amend, alter or terminate the Amended and Restated 2020 Plan, but no such action may impair the rights of any participant with respect to outstanding awards without the participant's consent. The plan administrator may amend an award, prospectively or retroactively, but no such amendment may materially impair the rights of any participant without the participant's consent. Shareholder approval of any such action will be obtained if required to comply with applicable law. The Amended and Restated 2020 Plan will terminate on the tenth anniversary of the Effective Date (although awards granted before that time will remain outstanding in accordance with their terms).

Clawback

If the Company is required to prepare a financial restatement due to the Company's material non-compliance with any financial reporting requirement under the securities law, then the plan administrator may require any Section 10D-1(d) of the Exchange Act "executive officer" to repay or forfeit to us that part of the cash or equity incentive compensation received by that Section 10D-1(d) executive officer during the preceding three completed fiscal years that the plan administrator determines was in excess of the amount that such Section 10D-1(d) executive officer would have received had such cash or equity incentive compensation been calculated based on the restated amounts reported in the restated financial statement. The plan administrator may take into account any factors it deems reasonable in determining whether to seek recoupment of previously paid cash or equity incentive compensation and how much of such compensation to recoup from each Section 10D-1(d) executive officer (which shall be made irrespective of any fault, misconduct or responsibility of each Section 10D-1(d) executive officer). The amount and form of the incentive compensation to be recouped shall be determined by the plan administrator in its sole and absolute discretion, and calculated on a pre-tax basis.

Disclosure of Equity Awards Based on Material Nonpublic Information: None

Pay Versus Performance Disclosure

In accordance with the SEC's disclosure requirements regarding pay versus performance, or PVP, this section presents the SEC-defined "Compensation Actually Paid," or CAP of our NEOs for each of the fiscal years ended December 31, 2024, 2023 and 2022, and our financial performance. Also required by the SEC, this section compares CAP to various measures used to gauge performance at the Company for each such fiscal year.

Pay versus Performance Table - Compensation Definitions

Salary, Bonus, Stock Awards, and All Other Compensation are each calculated in the same manner for purposes of both CAP and Summary Compensation Table, or SCT values. The primary difference between the calculation of CAP and SCT total compensation is the calculation of the value of "Stock Awards," with the table below describing the differences in how these awards are valued for purposes of SCT total and CAP:

Pay Versus Performance Table

Year (1)	Summary Compensation Table Total for PEO	Compensation Actually Paid to PEO (2)	Average Summary Compensation Table Total for Non-PEO NEOs	Average Compensation Actually Paid to Non-PEO NEOs (2)	Value of Initial Fixed $100 Investment Based On Total Shareholder Return	Net Income (Loss)
2024	$ 630,051	$ 630,051	$ 88,600	$ 88,600	6.19	$ (4,392,880)
2023	$ 569,009	$ 569,009	$ 62,692	$ 62,692	6.79	$ (3,700,683)
2022	$ 352,500	$ 352,500	$ 15,000	$ 15,000	15.83	$ (3,908,551)

(1) The PEO (CEO) in the 2024, 2023 and 2022 reporting year is Eric Weisblum. The non-PEO NEOs in the 2024, 2023 and 2022 reporting year is Dan Ryweck.

(2) The CAP was calculated beginning with the PEO's SCT total. No amounts were deducted from or added to the applicable SCT total compensation. Since all equity awards were fully vested prior to 2021, no reconciliation to with respect to equity awards for summary compensation numbers was required.

Non-Employee Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2024. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2024.

Director Compensation

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Wayne Linsley	$ 45,000	—	$ -	—	—	-	$ 45,000
Dr. Kevin Muñoz	$ 25,000	—	$ -	—	—	-	$ 25,000
Jeff Pavel	$ 25,000	—	-	—	—		$ 25,000

Director Compensation Program

Our current director compensation program is designed to align our director compensation program with the long-term interests of our stockholders by implementing a program comprised of cash and equity compensation.

In setting director compensation, we consider the amount of time that directors expend in fulfilling their duties to the Company as well as the skill level and experience required by our board of directors. We also consider board compensation practices at similarly situated companies, while keeping in mind the compensation philosophy of us and the stockholders' interests. The directors also receive reimbursement for expenses, including reasonable travel expenses to attend board and committee meetings, reasonable outside seminar expenses, and other special board related expenses.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 26, 2025 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers and (iv) all of our directors and named executive officers as a group.

The percentage ownership information is based on 4,484,456 issued outstanding. Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules attribute beneficial ownership of securities as of a particular date to persons who hold convertible preferred stock, options or warrants to purchase shares of common stock and that are exercisable within 60 days of such date. These shares are deemed to be outstanding and beneficially owned by the person holding those convertible preferred stock, options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Silo Pharma, Inc., 677 N. Washington Boulevard Sarasota, FL 34236.

Name and Address of Beneficial Owner	Number of shares beneficially owned	Percentage of shares beneficially owned
Directors and Named Executive Officers:		
Eric Weisblum	187,932	4.19%
Wayne D. Linsley	3,425(1)	*
Kevin Munoz	3,425(1)	*
Daniel Ryweck	5,000	*
Jeff Pavell	-	-
All executive officers and directors as a group (5 persons)	199,782	4.44%

* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) Includes options to purchase 3,425 shares of common stock, all of which are presently exercisable.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table shows information regarding our equity compensation plans as of December 31, 2024.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column
Equity compensation plans approved by security holders (1)	22,850	$ 9.19	447,150
Equity compensation plans not approved by security holders	—	—	—
Total	22,850	$ 9.19	447,150

(1) **Amended and Restated 2020 Omnibus Equity Incentive Plan**. On January 18, 2021, the board of directors of the Company approved the Silo Pharma, Inc. 2020 Omnibus Equity Incentive Plan (the "2020 Plan") to incentivize employees, officers, directors and consultants of the Company and its affiliates. The number of shares of common stock that are reserved and available for issuance under the 2020 Plan shall be equal to 170,000 shares provided that with respect to exempt awards as defined in the 2020 Plan, shall not count against such share limit. The 2020 Plan provides for the grant, from time to time, at the discretion of the Board or a committee thereof, of cash, stock options, including incentive stock options and nonqualified stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation units and other stock or cash-based awards. The Plan shall terminate on the tenth anniversary of the date of adoption by the Board of Directors. Subject to certain restrictions, the Board of Directors may amend or terminate the Plan at any time and for any reason. An amendment of the Plan shall be subject to the approval of the Company's stockholders only to the extent required by applicable laws, rules or regulations. On March 10, 2021, the stockholders of the Company approved the Plan. On September 15, 2023, our Board of Directors adopted the Silo Pharma, Inc. Amended and Restated 2020 Omnibus Equity Incentive Plan, which was approved by the Company's stockholders on December, 2023. The Amended and Restated 2020 Omnibus Equity Incentive Plan (i) increases the number of shares of common stock that may be issued under such Plan by 300,000 shares and (ii) includes clawback provisions to comply with recent developments of applicable law.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Except as set forth below, there were no transactions during our fiscal years ended December 31, 2024 and 2023 to which we were a party, including transactions in which the amount involved in the transaction exceeds 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 in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this registration statement. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds 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 in which a related person had or will have a direct or indirect material interest.

Director Independence

Our board of directors has determined that a majority of the board consists of members who are currently "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). The Board considers Wayne D. Linsley, Jeff Pavell and Dr. Kevin Muñoz to be "independent."

The board of directors as a whole carries out the function of a nominating and corporate governance committee.

Except as may be provided in our bylaws, we do not currently have specified procedures in place pursuant to which whereby security holders may recommend nominees to the board of directors.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table shows the fees for services provided by Salberg & Company, P.A. for the years ended December 31, 2024 and 2023.

	2024	2023
Audit Fees	$ 72,000	$ 64,000
Audit Related Fees	12,000	–
Tax Fees	-	–
All Other Fees	-	–
Total	$ 84,000	$ 64,000

Audit Fees: Audit fees consist of fees billed for professional services performed by Salberg & Company, P.A. for the audit of our annual consolidated financial statements, and the review of interim consolidated financial statements.

Audit-Related Fees: Audit-related fees may consist of fees billed by our independent registered public accounting firm for audit-related consulting services related to registration statements.

Tax Fees: Tax fees may consist of fees for professional services, including tax compliance. There were no such fees paid by the Company to Salberg & Company, P.A. in the fiscal years ended December 31, 2024 and 2023.

All Other Fees: There were no such fees incurred by the Company in the fiscal years ended December 31, 2024 and 2023.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements
The financial statements and Report of Independent Registered Public Accounting Firm are listed in the "Index to Financial Statements and Schedules" on page F-1 and included on pages F-2 thereon.

2. Financial Statement Schedules
All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission (the "Commission") are either not required under the related instructions, are not applicable (and therefore have been omitted), or the required disclosures are contained in the financial statements included herein.

3. Exhibits (including those incorporated by reference).

Exhibits	Description
2.1	Plan of Conversion dated December 19, 2023, filed as Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on December 20, 2023 and incorporated herein by reference
3.1	Articles of Incorporation of Silo Pharma, Inc., a Nevada corporation, filed as an Exhibit 3.3 to the Company's Current Report on Form 8-K, filed with the Commission on December 20, 2023 and incorporated herein by reference.
3.2	Bylaws of Silo Pharma, Inc., a Nevada corporation, filed as an Exhibit 3.4 to the Company's Current Report on Form 8-K, filed with the Commission on December 20, 2023 and incorporated herein by reference.
3.3	Articles of Conversion filed with the Nevada Secretary of State on December 19, 2023, filed as an Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on December 20, 2023 and incorporated herein by reference.
3.4	Certificate of Conversion filed with the Delaware Secretary of State on December 19, 2023, filed as an Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on December 20, 2023 and incorporated herein by reference.
4.1*	Description of the Registrant's Securities.
4.2	Form of Representative's Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on September 30, 2022 and incorporated herein by reference.
4.3	Form of Warrant, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on June 6, 2024 and incorporated herein by reference.
4.4	Form of Placement Agent Warrant, filed as Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on June 6, 2024 and incorporated herein by reference.
4.5	Form of Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2024 and incorporated herein by reference.
4.6	Form of Placement Agent Warrant, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2024 and incorporated herein by reference.
10.1	Stock Purchase Agreement dated April 24, 2013 between Point Capital, Inc. and Alpha Capital Anstalt, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on April 30, 2013 and incorporated herein by reference.
10.2	Corrected Asset Purchase Agreement with Blind Faith Concepts Holdings, Inc. dated September 28, 2018, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 20, 2018 and incorporated herein by reference.
10.3	Form of Return to Treasury Agreement, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on December 20, 2018 and incorporated herein by reference.
10.4	Form of Securities Purchase Agreement, dated October 2019, between Uppercut Brands, Inc., and Investors, filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on March 20, 2020 and incorporated herein by reference.
10.5	Form of convertible note agreement with Investors dated October 2019, filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on March 20, 2020 and incorporated herein by reference.
10.6	Form of Warrant, dated October 2019, filed as an exhibit to the Quarterly Report on Form 10-Q filed with the Commission on November 13, 2019 and incorporated herein by reference.

10.7	Form of Securities Purchase Agreement for the purchase of Series B preferred shares, dated November 2019, between Uppercut Brands, Inc., and Investors, filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on March 20, 2020 and incorporated herein by reference.
10.8	Form of Warrant related to Series B preferred shares, dated November 2019, between Uppercut Brands, Inc., and Investors, filed as an exhibit to the Annual Report on Form 10-K, filed with the Commission on March 20, 2020 and incorporated herein by reference.
10.9	Form of registration rights agreement related to Series B preferred shares, dated November 2019, between Uppercut Brands, Inc., and Investors, filed as an exhibit to the Annual Report on Form 10-K filed with the Commission on March 20, 2020 and incorporated herein by reference.
10.10	Form of Exchange Agreement for Convertible Notes, dated as of April 15, 2020, filed as an exhibit to the Current Report on Form 8-K/A, filed with the Commission on April 22, 2020 and incorporated herein by reference.
10.11	Form of Exchange Agreement for Series B Preferred Stock, dated as of April 15, 2020, filed as an exhibit to the Current Report on Form 8-K/A, filed with the Commission on April 22, 2020 and incorporated herein by reference.
10.12	Form of Subscription Agreement, dated as of April 17, 2020, filed as an exhibit to the Current Report on Form 8-K/A, filed with the Commission on April 22, 2020 and incorporated herein by reference.
10.13	Form of Consulting Agreement, dated as of April 17, 2020, filed as an exhibit to the Current Report on Form 8-K/A, filed with the Commission on April 22, 2020 and incorporated herein by reference.
10.14	Form of Advisory Agreement, dated as of April 17, 2020, filed as an exhibit to the Current Report on Form 8-K/A, filed with the Commission on April 22, 2020 and incorporated herein by reference.
10.15	Form of Securities Purchase Agreement, dated as of April 28, 2020, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on April 28, 2020 and incorporated herein by reference.
10.16	Form of Registration Rights Agreement, dated as of April 28, 2020, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on April 28, 2020 and incorporated herein by reference.
10.17	Form of Lock-Up Agreement, dated as of April 28, 2020, filed as an exhibit to the Current Report on Form 8-K, filed with the Commission on April 28, 2020 and incorporated herein by reference.
10.18	Patent License Agreement by and among the Company and Silo Pharma, Inc., a Florida corporation and their affiliates and subsidiaries and AIkido Pharma Inc., filed as an exhibit to the Current Report on Form 8-K filed with the Commission on January 11, 2021 and incorporated herein by reference.
10.19	Sponsored Research Agreement by and between the Company and the University of Maryland, Baltimore, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on January 11, 2021 and incorporated herein by reference.
10.20+	Silo Pharma, Inc. 2020 Omnibus Equity Incentive Plan, filed as an exhibit to the Current Report on Form 8-K filed with the Commission on January 28, 2021 and incorporated herein by reference.
10.21	Form of Securities Purchase Agreement, dated as of February 9, 2021, between Silo Pharma, Inc. and the signatories thereto (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 10, 2021)
10.22	Form of Warrant (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 10, 2021)
10.23	Form of Registration Rights Agreement, dated as of February 9, 2021, between Silo Pharma, Inc. and the signatories thereto (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on February 10, 2021)
10.24	Form of Lock-Up Agreement, dated as of February 9, 2021 (Incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on February 10, 2021)
10.25	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K/A filed on February 12, 2021)
10.26#	Master License Agreement, dated February 12, 2021, by and between the Company and the University of Maryland, Baltimore (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 16, 2021)
10.27#	Letter of Intent, dated February 12, 2021, by and between the Company and Aikido Pharma, Inc. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 16, 2021)
10.28	Patent License Agreement by and among the Company and Silo Pharma, Inc., a Florida corporation and their affiliates and subsidiaries and Aikido Pharma Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 11, 2021).

10.29	Sponsored Research Agreement by and between the Company and the University of Maryland, Baltimore (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 11, 2021).
10.30	Underwriting Agreement by and between the Company and Laidlaw & Company (UK) Ltd., as representative of the several underwriters named therein, dated September 26, 2022. (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on September 30, 2022.)
10.31	Representative's Warrant, dated as of September 29, 2022. (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 30, 2022.)
10.32	Ryweck Employment Agreement, dated September 28, 2022. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 30, 2022.)
10.33	Form of First Amendment to Sponsored Research Agreement by and between the Company and Columbia University. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report om Form 8-K filed with the SEC on October 18, 2022).
10.34	Employment Agreement by and between the Company and Eric Weisblum, dated October 12, 2022. (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on October 18, 2022).
10.35+	First Amendment to Employment Agreement by and between the Company and Daniel Ryweck, dated October 12, 2022. (Incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on October 18, 2022).
10.36	Silo Pharma, Inc. Amended and Restated 2020 Omnibus Equity Incentive Plan, filed as Appendix A to the Company Definitive Proxy Statement on Schedule 14A filed with the SEC on October 23, 2023 and incorporated herein by reference.
10.37	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 6, 2024 and incorporated herein by reference.
10.38	Form of Lock-Up Agreement, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on June 6, 2024 and incorporated herein by reference.
10.39	Exclusive License Agreement dated June 28, 2024 with Columbia University, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 8, 2024 and incorporated herein by reference.
10.40	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2024 and incorporated herein by reference.
10.41	Form of Lock-Up Agreement, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2024 and incorporated by reference herein.
10.42+	Second Amendment to Employment Agreement dated November 11, 2024 between the Company and Daniel Ryweck, filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q for the period ended September 30, 2024 and incorporated herein by reference.
19.1*	Insider Trading Policy
21.1	Subsidiaries, filed as Exhibit 21.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Commission on March 25, 2024 and incorporated herein by reference.
23.1*	Consent of Salberg & Company, P.A.
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Silo Pharma, Inc. Clawback Policy, filed as Exhibit 97.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2024 and incorporated herein by reference.
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 (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
\+ Indicates a management contract or any compensatory plan, contract or arrangement.
\# Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SILO PHARMA, INC.

Date: March 28, 2025

By: */s/ Eric Weisblum*
Eric Weisblum
Chairman, Chief Executive Officer
(Principal Executive 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/ Eric Weisblum Eric Weisblum	Chairman, Chief Executive Officer, President, and Director (Principal Executive Officer)	March 28, 2025
/s/ Daniel Ryweck Daniel Ryweck	Chief Financial Officer, (Principal Accounting and Financial Officer)	March 28, 2025
/s/ Wayne D. Linsley Wayne D. Linsley	Director	March 28, 2025
/s/ Dr. Kevin Muñoz Dr. Kevin Muñoz	Director	March 28, 2025
/s/ Jeff Pavell Jeff Pavell	Director	March 28, 2025

SILO PHARMA, INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2024 AND 2023

SALBERG & COMPANY, P.A.
Certified Public Accountants and Consultants

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of:
Silo Pharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SILO Pharma, Inc. (the "Company") as of December 31, 2024, and 2023, the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024, and 2023, and the consolidated 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.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company'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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters are matters arising from the current period audit of the consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Salberg & Company, P.A.

SALBERG & COMPANY, P.A.
We have served as the Company's auditor since 2019.
Boca Raton, Florida
March 28, 2025

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SILO PHARMA, INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 3,905,799	$ 3,524,308
Short-term investments	3,174,724	4,140,880
Prepaid expenses and other current assets	30,957	15,970
Total Current Assets	7,111,480	7,681,158
LONG-TERM ASSETS:		
Prepaid expenses and other assets - non-current	59,145	64,983
Intangible assets, net	241,215	-
Total Long-Term Assets	300,360	64,983
Total Assets	$ 7,411,840	$ 7,746,141
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 1,583,895	$ 703,488
Deferred revenue - current portion	72,102	72,102
Total Current Liabilities	1,655,997	775,590
LONG TERM LIABILITIES:		
Deferred revenue - long-term portion	721,578	793,680
Total Long Term Liabilities	721,578	793,680
Total Liabilities	2,377,575	1,569,270
Commitment and Contingencies (see Note 7)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized: none designated as of December 31, 2024 and 2023		
Common stock, $0.0001 par value, 100,000,000 shares authorized; 4,484,456 and 3,159,096 shares issued and 4,484,456 and 2,906,241 shares outstanding at December 31, 2024 and 2023, respectively	449	316
Additional paid-in capital	20,296,088	17,525,714
Treasury stock, at cost (0 and 252,855 shares on December 31, 2024 and 2023, respectively)	-	(471,121)
Accumulated other comprehensive income (loss)	2,419	(6,227)
Accumulated deficit	(15,264,691)	(10,871,811)
Total Stockholders' Equity	5,034,265	6,176,871
Total Liabilities and Stockholders' Equity	$ 7,411,840	$ 7,746,141

See accompanying notes to consolidated financial statements.

SILO PHARMA, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Year Ended December 31,	
	2024	**2023**
LICENSE FEE REVENUE	$ 72,102	$ 72,102
COST OF REVENUES	5,838	5,838
GROSS PROFIT	66,264	66,264
OPERATING EXPENSES:		
Compensation expense	906,773	871,625
Professional fees	1,198,745	1,726,061
Research and development	2,368,156	845,092
Other selling, general and administrative expenses	298,284	479,078
Total operating expenses	4,771,958	3,921,856
LOSS FROM OPERATIONS	(4,705,694)	(3,855,592)
OTHER INCOME (EXPENSE):		
Interest and dividend income, net	333,165	398,530
Interest expense	(5,084)	(4,869)
Net realized loss on short-term debt investments	(1,025)	-
Penalty from early termination of certificate of deposit	-	(166,034)
Net unrealized loss on equity investments	-	(3,118)
Foreign currency transaction loss	(14,242)	-
Total other income, net	312,814	224,509
LOSS BEFORE PROVISION FOR INCOME TAXES	(4,392,880)	(3,631,083)
Provision for income taxes	-	-
LOSS FROM CONTINUING OPERATIONS	(4,392,880)	(3,631,083)
DISCONTINUED OPERATIONS:		
Loss from discontinued operations, net of tax	-	(69,600)
LOSS FROM DISCONTINUED OPERATIONS	-	(69,600)
NET LOSS	$ (4,392,880)	$ (3,700,683)
COMPREHENSIVE LOSS:		
Net loss	$ (4,392,880)	$ (3,700,683)
Other comprehensive income (loss):		
Unrealized gain (loss) on short-term debt investments	8,646	(6,227)
Total comprehensive loss	$ (4,384,234)	$ (3,706,910)
NET LOSS PER COMMON SHARE:		
Continuing operations - basic and diluted	$ (1.19)	$ (1.18)
Discontinued operations - basic and diluted	-	(0.02)
Net loss per common share - basic and diluted	$ (1.19)	$ (1.20)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and diluted	3,680,389	3,079,874

See accompanying notes to consolidated financial statements.

SILO PHARMA, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Common Stock		Additional Paid In	Treasury Stock		Accumulated Other Comprehensive	Accumulated	Total Stockholder'
	Shares	Amount	Capital	Shares	Amount	Income (Loss)	Deficit	Equity
Balance, December 31, 2022	3,159,096	$ 316	$ 17,511,589	-	$ -	$ -	$ (7,171,128)	$ 10,340,777
Accretion of stock options expense to stock based compensation	-	-	14,125	-	-	-	-	14,125
Purchase of treasury stock	-	-	-	252,855	(471,121)	-	-	(471,121)
Unrealized loss on short-term debt investments	-	-	-	-	-	(6,227)	-	(6,227)
Net loss	-	-	-	-	-	-	(3,700,683)	(3,700,683)
Balance, December 31, 2023	3,159,096	316	17,525,714	252,855	(471,121)	(6,227)	(10,871,811)	6,176,871
Accretion of stock options expense to stock based compensation	-	-	-	-	-	-	-	-
Purchase of treasury stock	-	-	-	102,855	(173,113)	-	-	(173,113)
Sale of common stock and pre-funded warrants	883,395	89	1,673,127	-	-	-	-	1,673,216
Exercise of pre-funded warrants	34,037	3	-	-	-	-	-	3
Sale of common stock and warrants, net of issuance costs	763,638	76	1,741,446	-	-	-	-	1,741,522
Cancellation of treasury stock	(355,710)	(35)	(644,199)	(355,710)	644,234	-	-	-
Unrealized gain on short-term debt investments	-	-	-	-	-	8,646	-	8,646
Net loss	-	-	-	-	-	-	(4,392,880)	(4,392,880)
Balance, December 31, 2024	4,484,456	$ 449	$ 20,296,088	-	$ -	$ 2,419	$ (15,264,691)	$ 5,034,265

See accompanying notes to consolidated financial statements.

SILO PHARMA, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,392,880)	$ (3,700,683)
Adjustments to reconcile net loss to net cash used in operating activities		
Bad debt expense - discontinued operations		69,600
Stock-based compensation and professional fees	-	14,125
Amortization of prepaid stock-based professional fees	-	90,067
Amortization expense	6,185	-
Net realized loss on short-term investments	1,025	-
Net unrealized loss on equity investments	-	3,118
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(9,149)	35,695
Interest receivable	-	(3,590)
Accounts payable and accrued expenses	633,007	339,272
Deferred revenue	(72,102)	(72,102)
NET CASH USED IN OPERATING ACTIVITIES	(3,833,914)	(3,224,498)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of short-term debt investments	1,149,320	-
Purchase of short-term investments	(175,543)	(4,147,107)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	973,777	(4,147,107)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock and pre-funded warrants	1,673,216	-
Proceeds from sale of common stock and warrants	1,741,522	-
Proceeds from exercise of pre-funded warrants	3	-
Purchase of treasury stock	(173,113)	(471,121)
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	3,241,628	(471,121)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	381,491	(7,842,726)
CASH AND CASH EQUIVALENTS - beginning of the year	3,524,308	11,367,034
CASH AND CASH EQUIVALENTS - end of the year	$ 3,905,799	$ 3,524,308
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during the period for:		
Interest	$ 5,084	$ 4,869
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Change in accumulated other comprehensive income (loss)	$ 8,646	$ (6,227)
Increase in intangible assets and accounts payable and accrued expenses	$ 247,400	$ -
Cancellation of treasury stock	$ 644,234	$ -

See accompanying notes to consolidated financial statements.

NOTE 1 – ORGANIZATION AND BUSINESS

Silo Pharma, Inc. (the "Company") was incorporated in the State of New York on July 13, 2010, under the name Gold Swap, Inc. On May 21, 2019, the Company filed an amendment to its Certificate of Incorporation with the State of Delaware to change its name from Point Capital, Inc. to Uppercut Brands, Inc. Thereafter, on September 24, 2020, the Company filed an amendment to its Certificate of Incorporation with the State of Delaware to change its name from Uppercut Brands, Inc. to Silo Pharma, Inc.

On January 24, 2013, the Company changed its state of incorporation from New York to Delaware. On December 19, 2023, the Company changed its state of incorporation from the State of Delaware to the State of Nevada.

On April 8, 2020, the Company incorporated a new wholly-owned subsidiary, Silo Pharma Inc., in the State of Florida.

The Company is a developmental stage biopharmaceutical company developing novel therapeutics that address under-served conditions using therapies that include conventional drugs and psychedelic formulations. The Company is focused on developing (i) an intranasal drug targeting PTSD and stress-induced anxiety disorders (SPC-15); (ii) a time-release ketamine-based loaded implant for fibromyalgia and chronic pain relief (SP-26); (iii) an intranasal compound for the treatment of Alzheimer's disease (SPC-14); and (iv) a CNS-homing peptide targeting the central nervous system in multiple sclerosis (SPU-16).

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), the instructions to Form 10-K, and the rules and regulations of the United States Securities and Exchange Commission (the "SEC") for financial information. The Company's consolidated financial statements include financial statements for Silo Pharma, Inc. and its inactive wholly-owned subsidiary with the same name as the parent entity, Silo Pharma, Inc. All intercompany transactions and balances have been eliminated in consolidation.

In accordance with, Accounting Standard Codification ("ASC") 205-20 "Discontinued Operations" establishes that the disposal or abandonment of a component of an entity or a group of components of an entity should be reported in discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. As a result, the results of operations related to the Company's previous business operations in the development of a streetwear apparel brand, NFID, have been classified as discontinued operations on a retrospective basis for all periods presented. Accordingly, the results of operations of this business, for all periods, are separately reported as "discontinued operations" on the consolidated statements of operations.

Liquidity

As reflected in the accompanying consolidated financial statements, the Company generated a net loss of $4,392,880 and used cash in operations of $3,833,914 during the year ended December 31, 2024. Additionally, the Company has an accumulated deficit of $15,264,691 on December 31, 2024. As of December 31, 2024, the Company had working capital of $5,455,483.

The positive working capital serves to mitigate the conditions that historically raised substantial doubt about the Company's ability to continue as a going concern. The Company believes that the Company has sufficient cash and liquid short-term investments to meet its obligations for a minimum of twelve months from the date of this filing.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate could change in the near term due to one or more future events. Accordingly, the actual results could differ significantly from estimates. Significant estimates during the years ended December 31, 2024 and 2023 include the collectability of notes receivable, the percentage of completion of research and development projects, valuation of equity investments, valuation allowances for deferred tax assets, and the fair value of shares and stock options issued for services.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when acquired to be cash equivalents. The Company places its cash with high credit quality financial institutions. The Company's accounts at these institutions are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 or by the Securities Investor Protection Corporation up to $250,000. To reduce its risk associated with the failure of such financial institutions, the Company evaluates at least annually the rating of the financial institutions in which it holds deposits. On December 31, 2024 and 2023, the Company had cash in excess of FDIC limits of approximately $3,406,000 and $2,805,000, respectively. In connection with the early termination of a certificate of deposit, during the year ended December 31, 2023, the Company paid a penalty of $166,034, which is reflected on the accompanying consolidated statements of operations and comprehensive loss. Any material loss that we may experience in the future could have an adverse effect on our ability to pay our operational expenses or make other payments.

Short-Term Investments

The Company's portfolio of short-term investments consists of marketable debt securities which are comprised solely of highly rated U.S. government securities with maturities of more than three months, but less than one year. The Company classifies these as available-for-sale at purchase date and will reevaluate such designation at each period end date. The Company may sell these marketable debt securities prior to their stated maturities depending upon changing liquidity requirements. These debt securities are classified as current assets in the consolidated balance sheet and recorded at fair value, with unrealized gains or losses included in accumulated other comprehensive income and as a component of the consolidated statements of comprehensive loss. Gains and losses are recognized when realized. Gains and losses are determined using the specific identification method and are reported in other income (expense), net in the consolidated statements of operations and comprehensive loss.

An impairment loss may be recognized when the decline in fair value of the debt securities is determined to be other-than-temporary. The Company evaluates its investments for other-than-temporary declines in fair value below the cost basis each quarter, or whenever events or changes in circumstances indicate that the cost basis of the short-term investments may not be recoverable. The evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below the cost basis, as well as adverse conditions related specifically to the security, such as any changes to the credit rating of the security and the intent to sell or whether the Company will more likely than not be required to sell the security before recovery of its amortized cost basis.

The Company recorded $8,646 and $(6,227) of unrealized gain (loss) on short-term investments as a component of accumulated other comprehensive income (loss) for the years ended December 31, 2024 and 2023, respectively.

Equity Investments, at Fair Value

Realized gain or loss is recognized when an investment is disposed of and is computed as the difference between the Company's carrying value and the net proceeds received from such disposition. Realized gains and losses on investment transactions are determined by specific identification. Net unrealized gains or losses are computed as the difference between the fair value of the investment and the cost basis of such investment. Net unrealized gains or losses for equity investments are recognized in operations as the difference between the carrying value at the beginning of the period and the fair value at the end of the period. As of December 31, 2024 and 2023, the Company had no such investments.

Note Receivable

The Company recognizes an allowance for losses on notes receivable in an amount equal to the estimated probable losses net of recoveries. The allowance is based on an analysis of historical bad debt experience, current note receivable aging, and expected future write-offs, as well as an assessment of specific identifiable accounts considered at risk or uncollectible. As of December 31, 2023, the Company recognized an allowance for loss on the note receivable and accrued interest receivable in an amount equal to the estimated probable losses, and accordingly, the Company recorded bad debt expense of $69,600, which represents the note receivable principal balance of $60,000 and accrued interest receivable of $9,600. In 2023, the expense associated with the allowance for loss is recorded as part of general and administrative expenses. As of December 31, 2024, there were no subsequent collections of previously written-off notes receivable.

Prepaid Expenses

Prepaid expenses and other current assets of $30,957 and $15,970 on December 31, 2024 and 2023, respectively, consist primarily of costs paid for future services which will occur within a year. On December 31, 2024 and 2023, prepaid expenses and other assets – non-current amounted to $59,145 and $64,983, respectively, and consist primarily of costs paid for future services which will occur after a year. Prepaid expenses may include prepayments in cash and equity instruments for consulting, research and development, license fees, public relations and business advisory services, and legal fees which are being amortized over the terms of their respective agreements, which may exceed a year of service.

Intangible Assets

Intangible assets, consisting of an exclusive license agreement, are carried at cost less accumulated amortization, computed using the straight-line method over the estimated useful life of 20 years, less any impairment charges. The Company examines the possibility of decreases in the value of these assets when events or changes in circumstances reflect the fact that their recorded value may not be recoverable.

Revenue Recognition

The Company applies ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). ASC 606 establishes a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most of the existing revenue recognition guidance. This standard requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services and also requires certain additional disclosures.

For the license and royalty income, revenue is recognized when the Company satisfies the performance obligation based on the related license agreement. Payments received from the licensee that are related to future periods are recorded as deferred revenue to be recognized as revenues over the term of the related license agreement (see Note 8).

Cost of Revenues

The primary components of cost of revenues on license fees includes the cost of the license fees. Payments made to the licensor that are related to future periods are recorded as prepaid expense to be amortized over the term of the related license agreement (see Note 8).

Stock-Based Compensation

Stock-based compensation is accounted for based on the requirements of ASC 718 – "Compensation – Stock Compensation", which requires recognition in the financial statements of the cost of employee, director, and non-employee services received in exchange for an award of equity instruments over the period the employee, director, or non-employee is required to perform the services in exchange for the award (presumptively, the vesting period). The ASC also requires measurement of the cost of employee, director, and non-employee services received in exchange for an award based on the grant-date fair value of the award. The Company has elected to recognize forfeitures as they occur as permitted under Accounting Standards Update ("ASU") 2016-09 Improvements to Employee Share-Based Payment.

Income Taxes

Deferred income tax assets and liabilities arise from temporary differences between the financial statements and tax basis of assets and liabilities, as measured by the enacted tax rates, which are expected to be in effect when these differences reverse. Deferred tax assets and liabilities are classified as current or non-current, depending upon the classification of the asset or liabilities to which they relate. Deferred tax assets and liabilities not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") ASC 740-10, "Uncertainty in Income Taxes". Certain recognition thresholds must be met before a tax position is recognized in the financial statements. An entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. The Company does not believe it has any uncertain tax positions as of December 31, 2024 and 2023 that would require either recognition or disclosure in the accompanying consolidated financial statements.

Research and Development

In accordance with ASC 730-10, *"Research and Development-Overall,"* research and development costs are expensed when incurred. During the years ended December 31, 2024 and 2023, research and development costs were $2,368,156 and $845,092, respectively.

Leases

Leases are accounted for using ASU 2016-02, "*Leases (Topic 842)"*. ASU 2016-02 sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to recognize a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. As of December 31, 2024 and 2023, the Company has no leases. The Company will analyze any lease to determine if it would be required to record a lease liability and a right of use asset on its consolidated balance sheets at fair value upon adoption of ASU 2016-02. The Company has elected not to recognize right-of-use assets and lease liabilities for short-term leases that have a term of 12 months or less.

Net Loss per Common Share

Basic loss per share is computed by dividing net loss allocable to common shareholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share is computed by dividing net loss available to common shareholders by the weighted average number of shares of common stock, common stock equivalents and potentially dilutive securities outstanding during the period using the as-if converted method. Potentially dilutive securities which include stock options and stock warrants are excluded from the computation of diluted shares outstanding if they would have an anti-dilutive impact on the Company's net losses.

The following potentially dilutive shares have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive for the years ended December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
Stock options	22,850	28,850
Warrants	2,211,730	404,580
	2,234,580	433,430

Segment Reporting

The Company operates as a single operating segment as a clinical-stage biopharmaceutical company focused on developing new generation therapies for unmet medical needs. In accordance with ASC 280 – "*Segment Reporting*", the Company's chief operating decision maker has been identified as the Chief Executive Officer, who reviews operating results to make decisions about allocating resources and assessing performance for the entire Company. Existing guidance, which is based on a management approach to segment reporting, establishes requirements to report selected segment information quarterly and to report annually entity-wide disclosures about products and services, major customers, and the countries in which the entity holds material assets and reports revenue. All material operating units qualify for aggregation under "Segment Reporting" due to their similarities in economic characteristics such as nature of services; and procurement processes. Since the Company operates in one segment, all financial information required by "Segment Reporting" can be found in the accompanying notes to consolidated financial statements.

Recent Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material effect on the Company's consolidated financial statements.

NOTE 3 – FAIR VALUE OF FINANCIAL INSTRUMENTS AND FAIR VALUE MEASUREMENTS

Fair Value Measurements and Fair Value of Financial Instruments

FASB ASC 820 - *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to the Company on December 31, 2024 and 2023. Accordingly, the estimates presented in these consolidated financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments. FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

Level 1 - Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.

Level 2 - Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.

Level 3 - Inputs are unobservable inputs which reflect the reporting entity's own assumptions on what assumptions the market participants would use in pricing the asset or liability based on the best available information.

The carrying value of certain financial instruments, including cash and cash equivalents, prepaid expenses and other current assets, notes receivable, and accounts payable and accrued expenses are carried at historical cost basis, which approximates their fair values because of the short-term nature of these instruments.

The Company analyzes all financial instruments with features of both liabilities and equity under the Financial Accounting Standard Board's (the "FASB") accounting standard for such instruments. Under this standard, financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The following table represents the Company's fair value hierarchy of its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2024 and 2023.

	December 31, 2024			December 31, 2023		
Description	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Short-term investments	$ 3,174,724	$ -	$ -	$ 4,140,880	$ -	$ -

The Company's short-term investments and equity investments are level 1 measurements and are based on redemption value at each date.

Short-Term Investments – Debt Securities, at Fair Value

The following table summarizes activity in the Company's short-term investments, at fair value for the periods presented:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Balance, beginning of period	$ 4,140,880	$ -
Additions	175,543	4,147,107
Sales of short-term debt investments	(1,149,320)	-
Net realized loss on the sale of short-term investments	(1,025)	-
Unrealized gain (loss)	8,646	(6,227)
Balance, end of period	$ 3,174,724	$ 4,140,880

Equity Investments, at Fair Value

The following table summarizes activity in the Company's equity investments, at fair value for the periods presented:

	December 31, 2024	December 31, 2023
Balance, beginning of year	$ -	$ 3,118
Unrealized loss	-	(3,118)
Balance, end of year	$ -	$ -

Equity investments are carried at fair value with unrealized gains or losses which are recorded as net unrealized gain (loss) on equity investments in the accompanying consolidated statement of operations and comprehensive loss. Realized gains and losses are determined on a specific identification basis which is recorded as net realized gain (loss) on equity investments in the consolidated statement of operations and comprehensive loss. The Company reviews equity investments, at fair value, for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recovered.

ASC 825-10 "Financial Instruments" allows entities to voluntarily choose to measure certain financial assets and liabilities at fair value (fair value option). The fair value option may be elected on an instrument-by-instrument basis and is irrevocable, unless a new election date occurs. If the fair value option is elected for an instrument, unrealized gains and losses for that instrument should be reported in earnings at each subsequent reporting date. The Company did not elect to apply the fair value option to any outstanding equity instruments.

NOTE 4 – INTANGIBLE ASSETS

On July 1, 2024, the Company entered into an exclusive license agreement (the "Columbia License Agreement") with Columbia University ("Columbia") with an effective date of June 28, 2024 (the "Effective Date") pursuant to which the Company has been granted exclusive rights to certain patents and technical information to develop, manufacture and commercialize Products (as defined in the Columbia License Agreement), including therapies for stress-induced affective disorders and other conditions, for a cost of $247,400, which consisted of i) an initial license fee of $50,000 paid in October 2024, and ii) the reimburse to Columbia of $197,400 for patent and legal expenses that Columbia incurred before September 30, 2021 (See Note 8). The term of the Columbia License Agreement shall commence on the Effective Date and shall continue on a country-by-country and product-by-product basis until the latest of: (a) the date of expiration of the last to expire of the issued Patents (as defined in the Columbia License Agreement), (b) 20 years after the first bona fide commercial sale of the Product in the country in question, or (c) expiration of any market exclusivity period granted by a regulatory agency for a Product in the country in question (See Note 8).

On December 31, 2024 and 2023, intangible assets consisted of the following:

	Useful life	December 31, 2024	December 31, 2023
License	20 years	$ 247,400	$ -
Less: accumulated amortization		(6,185)	-
		$ 241,215	$ -

For the years ended December 31, 2024 and 2023, amortization expense amounted to $6,185 and $0, respectively.

Amortization of intangible assets with finite lives attributable to future periods is as follows:

Year ending December 31:	Amount
2025	$ 12,370
2026	12,370
2027	12,370
2028	12,370
2029	12,370
Thereafter	179,365
Total	$ 241,215

NOTE 5 – DISPOSAL OF THE DISCONTINUED OPERATIONS OF THE NFID BUSINESS

On September 30, 2021, the Company entered into and closed on an Asset Purchase Agreement with NFID, LLC, an unrelated party, a Florida limited liability company, whereby the Company sold certain assets, properties, and rights in connection with its NFID trademark name, logos, domain, and apparel clothing and accessories for a purchase price of $60,000 in the form of a promissory note amounting to $60,000. The promissory note bore 8% interest per annum and matured on October 1, 2023. On November 8, 2023 and effective on October 1, 2023, the Company and the Buyer entered into a First Amendment Promissory Note which increased the interest rate to 9% per annum and extended the maturity date to December 30, 2023 for no consideration. As of December 31, 2023, the Company recognized an allowance for loss on the note receivable and accrued interest receivable in an amount equal to the estimated probable losses, and accordingly, the Company recorded bad debt expense of $69,600, which represents the note receivable principal balance of $60,000 and accrued interest receivable of $9,600, which is recorded in loss from discontinued operations on the accompanying consolidated statement of operations.

ASC 205-20 “Discontinued Operations” establishes that the disposal or abandonment of a component of an entity or a group of components of an entity should be reported in discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity’s operations and financial results. As a result, the component’s results of operations have been classified as discontinued operations on a retrospective basis for all periods presented. Accordingly, the results of operations of this component, for all periods, are separately reported as “discontinued operations” on the consolidated statements of operations.

The summarized operating result of discontinued operations of the NFID Business included in the Company’s consolidated statements of operations for the years ended December 31, 2024 and 2023 is as follows:

	For the Year Ended December 31,	
	2024	2023
Product sales, net	$ -	$ -
Cost of sales	-	-
Gross loss	-	-
Total operating and other non-operating expenses	-	(69,600)
Loss from discontinued operations	$ -	$ (69,600)

NOTE 6 – STOCKHOLDERS’ EQUITY

Shares Authorized

On December 19, 2023, the Company reincorporated as a Nevada corporation and filed Articles of Incorporation with the Nevada Secretary of State on such date. The Company has 105,000,000 shares authorized which consist of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock.

Common Stock Issued for Services

On August 29, 2022, the Company entered into a one-year consulting agreement with an entity for investor relations services. In connection with this consulting agreement, the Company issued 20,000 restricted common shares of the Company to the consultant. These shares vest immediately. These shares were valued at $135,100, or $6.755 per common share, based on contemporaneous common share sales by the Company. In connection with this consulting agreement, during the years ended December 31, 2024 and 2023, the Company recorded stock-based professional fees of $0 and $90,067, respectively. which was amortized into stock-based professional fees over the term of the agreement.

Sale of Common Stock and Warrants

June 2024

On June 4, 2024, the Company entered into a securities purchase agreement (the "June 2024 Purchase Agreement") with certain institutional investors, pursuant to which the Company agreed to sell to such investors 883,395 shares (the "Shares") of common stock of the Company (the "Common Stock") at a purchase price of $2.18 per share of Common Stock, and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 34,037 shares of Common Stock of the Company (the "Pre-Funded Warrant Shares"), having an exercise price of $0.0001 per share, and a purchase price of $2.1799 per Pre-Funded Warrant (the "Offering"). The shares of Common Stock and Pre-Funded Warrants (and shares of common stock underlying the Pre-Funded Warrants) were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-276658), which was declared effective by the Securities and Exchange Commission on January 30, 2024.

Concurrently with the sale of Common Stock and/or the Pre-Funded Warrants, pursuant to the June 2024 Purchase Agreement in a private placement, for each share of Common Stock and/or Pre-Funded Warrant purchased by the investors, such investors received from the Company an unregistered warrant (the "June 2024 Common Warrant") to purchase one share of Common Stock (the "June 2024 Common Warrant Shares"). Accordingly, the Company issued an aggregate of 917,432 June 2024 Common Warrants to the Investors. The June 2024 Common Warrants have an exercise price of $2.06 per share and are exercisable immediately upon issuance for a five-year period.

On April 23, 2024, the Company entered into an engagement agreement with H.C. Wainwright & Co., LLC, as exclusive placement agent (the "Placement Agent"), pursuant to which the Placement Agent agreed to act as placement agent on a reasonable "best efforts" basis in connection with the Offering. The Company agreed to pay the Placement Agent an aggregate cash fee equal to 7.5% of the gross proceeds from the sale of securities in the Offering and a management fee equal to 1.0% of the gross proceeds raised in the Offering. The Company also agreed to issue the Placement Agent (or its designees) a warrant (the "June 2024 Placement Agent Warrant") to purchase up to 7.5% of the aggregate number of shares of Common Stock and/or Pre-Funded Warrants sold in the offering, In connection with the June 2024 Purchase Agreement, the Company paid the Placement Agent a cash fee and management fee of $170,000 and the Placement Agent received the June 2024 Placement Agent Warrants to purchase up to 68,807 shares of Common Stock, at an exercise price equal to 125.0% of the offering price per share of Common Stock, or $2.725 per share. The June 2024 Placement Agent Warrants are exercisable immediately upon issuance for a period of five years following the commencement of the sales pursuant to the Offering. In addition, the Company paid the Placement Agent $25,000 for non-accountable expenses, $50,000 for legal expenses and other out-of-pocket expenses and $15,950 for clearing fees.

The closing of the sales of these securities under the June 2024 Purchase Agreement took place on June 6, 2024. The public offering price for each share of Common Stock was $2.18 for aggregate gross proceeds of $1,925,801, and public offering price for the Pre-Funded Warrants was $2.1799 for each Pre-Funded Warrant for aggregate gross proceeds of $74,201. In connection with this Offering, the Company raised aggregate gross proceeds of $2,000,002 and received net proceeds of $1,673,216, net of Underwriters discounts and offering costs of $260,950 and legal fees of $65,833. The Company is using the net proceeds from the offering for working capital and other general corporate purposes.

The per share exercise price for the Pre-Funded Warrants was $0.0001 and the Pre-Funded Warrants were exercisable immediately. The Underwriters immediately exercised the 34,037 Pre-Funded Warrants and the Underwriters received 34,037 shares of Common Stock for cash proceeds of $3. The Pre-Funded Warrants are not and will not be listed for trading on any national securities exchange or other nationally recognized trading system.

The June 2024 Common Warrants and the Common Warrant Shares were sold without registration under the Securities Act of 1933 (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

Pursuant to the terms of the June 2024 Purchase Agreement and subject to certain exceptions as set forth in the June 2024 Purchase Agreement, from the date of the June 2024 Purchase Agreement until fifteen (15) days after the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents. In addition, until the one year from the Closing Date, the Company is prohibited from entering into a Variable Rate Transaction (as defined in the Purchase Agreement), subject to certain limited exceptions.

The Company agreed to file a registration statement on Form S-3 (or other appropriate form if the Company is not then S-3 eligible) providing for the resale of the Common Warrant Shares (the "Resale Registration Statement") within 45 calendar days of the date of the Purchase Agreement (the "Filing Date"), and to use commercially reasonable efforts to cause the Resale Registration Statement to be declared effective by the SEC within 60 calendar days following the date of the Filing Date and to keep the Resale Registration Statement effective at all times until the Holders no longer own any June 2024 Common Warrants or Common Warrant Shares. On July 25, 2024, the Company filed an S-1 registration statement related to the June 2024 Common Warrant Shares and June 2024 Placement Agent Warrant, which was declared effective on July 30, 2024.

July 2024

On July 18, 2024, the Company entered into a securities purchase agreement (the "July 2024 Purchase Agreement") with certain institutional investors, pursuant to which the Company agreed to sell to such investors 763,638 shares (the "Shares") of common stock of the Company (the "Common Stock"), at a purchase price of $2.75 per share of Common Stock (the "Offering"). The shares of Common Stock were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-276658), which was declared effective by the Securities and Exchange Commission on January 30, 2024.

Concurrently with the sale of Common Stock, pursuant to the July 2024 Purchase Agreement in a private placement, for each share of Common Stock purchased by the investors, such investors received from the Company an unregistered warrant (the "July 2024 Common Warrants") to purchase one share of common stock for an aggregate of 763,638 July 2024 Common Warrants. The July 2024 Common Warrants have an exercise price of $2.75 per share and are exercisable immediately upon issuance for a five-year period.

The closing of the sales of these securities under the July 2024 Purchase Agreement took place on July 22, 2024. The gross proceeds from the offering were $2,100,005, prior to deducting placement agent's fees and other offering expenses payable by the Company, and the Company received net proceeds of $1,741,522, net of Underwriters discounts and offering costs of $269,450 and legal fees and other fees of $89,033. The Company is using the net proceeds from the offering for working capital and other general corporate purposes.

In connection with the April 23, 2024 engagement agreement with the Placement Agent discussed above, in connection with the July 2024 Purchase Agreement, the Placement Agent received warrants to purchase up to 57,273 shares of Common Stock, at an exercise price equal to 125.0% of the offering price per share of Common Stock, or $3.4375 per share (the "July 2024 Placement Agent Warrant").

The July 2024 Common Warrants were sold without registration under the Securities Act of 1933 (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

The July 2024 Placement Agent Warrants are exercisable immediately upon issuance for a period of five years following the commencement of the sales pursuant to the Offering. In addition, the Company paid to pay the Placement Agent $25,000 for non-accountable expenses, $50,000 for legal expenses and other out-of-pocket expenses and $15,950 for clearing fees.

Pursuant to the terms of the July 2024 Purchase Agreement and subject to certain exceptions as set forth in the July 2024 Purchase Agreement, from the date of the Purchase Agreement until fifteen days after the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents. In addition, until the one year from the Closing Date, the Company is prohibited from entering into a Variable Rate Transaction (as defined in the Purchase Agreement), subject to certain limited exceptions.

Each of our executive officers and directors have agreed, subject to certain exceptions, not to dispose of or hedge any shares of Common Stock or securities convertible into or exchangeable for shares of Common Stock during the period from the date of the lock-up agreement continuing through the fifteen (15) days after the closing of this offering.

The Company agreed to file a registration statement on Form S-3 (or other appropriate form if the Company is not then S-3 eligible) providing for the resale of the Common Warrant Shares (the "Resale Registration Statement") within 45 calendar days of the date of the Purchase Agreement (the "Filing Date"), and to use commercially reasonable efforts to cause the Resale Registration Statement to be declared effective by the SEC within 75 calendar days following the date of the Filing Date and to keep the Resale Registration Statement effective at all times until the Holders no longer own any July 2024 Common Warrants or Common Warrant Shares. On August 21, 2024, the Company filed an S-1 registration statement related to the July 2024 Common Warrant Shares and July 2024 Placement Agent Warrant, which was declared effective on September 3, 2024.

Stock Repurchase Plan

On January 26, 2023, the Company's Board of Directors authorized a stock repurchase plan to repurchase up to $1 million of the Company's issued and outstanding common stock, from time to time, with such plan to be in place until December 31, 2023. On January 9, 2024, the Board of Directors of the Company approved an extension of the previously announced stock repurchase program authorizing the purchase of up to $1 million of the Company's common stock until March 31, 2024 and on April 4, 2024, the Stock Repurchase Plan was extended to April 30. During the year ended December 31, 2023, the Company purchased 252,855 shares of common stock for a cost of $471,121, which is reflected in treasury stock on the accompanying consolidated balance sheet. During the year ended December 31, 2024, the Company purchased 102,855 shares of common stock for a cost of $173,113. In aggregate, during the years ended December 31, 2024 and 2023, the Company repurchased a total of 355,710 shares of its common stock for a total cost of $644,234 pursuant to its Stock Repurchase Program. During the year ended December 31, 2024, 355,710 shares treasury shares for a cost of $644,234 were cancelled.

Stock Options

On January 18, 2021, the Company's board of directors ("Board") approved the Silo Pharma, Inc. 2020 Omnibus Equity Incentive Plan (the "2020 Plan") to incentivize employees, officers, directors and consultants of the Company and its affiliates. 170,000 shares of common stock are reserved and available for issuance under the 2020 Plan, provided that certain exempt awards (as defined in the 2020 Plan), shall not count against such share limit. The 2020 Plan provides for the grant, from time to time, at the discretion of the Board or a committee thereof, of cash, stock options, including incentive stock options and nonqualified stock options, restricted stock, dividend equivalents, restricted stock units, stock appreciation units and other stock or cash-based awards. The 2020 Plan shall terminate on the tenth anniversary of the date of adoption by the Board. Subject to certain restrictions, the Board may amend or terminate the Plan at any time and for any reason. An amendment of the 2020 Plan shall be subject to the approval of the Company's stockholders only to the extent required by applicable laws, rules or regulations. On March 10, 2021, the 2020 Plan was approved by the stockholders. On September 15, 2023, our Board of Directors adopted the Silo Pharma, Inc. Amended and Restated 2020 Omnibus Equity Incentive Plan which was approved by the Company's stockholders on December 4, 2023. The Amended and Restated Omnibus Equity Incentive Plan (i) increases the number of shares of common stock that may be issued under such plan by 300,000 shares to 470,000 shares and (ii) includes clawback provisions to comply with recent developments of applicable law.

During the years ended December 31, 2024 and 2023, the Company amortized $0 and $14,125 of the deferred compensation which was recorded as compensation expenses in the accompanying consolidated statement of operations and comprehensive loss. As of December 31, 2024 and 2023, there was no remaining deferred compensation related to these issuances.

Stock option activities for the years ended December 31, 2024 and 2023 are summarized as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance Outstanding, December 31, 2022	28,850	$ 7.28	6.31	$ 20,130
Granted	-	-	-	-
Balance Outstanding, December 31, 2023	28,850	7.28	5.31	8,610
Expired	(6,000)	0.005	-	-
Balance Outstanding, December 31, 2024	22,850	$ 9.19	5.56	$ -
Exercisable, December 31, 2024	22,850	$ 9.19	5.56	$ -

Stock Warrants

As discussed above under Sale of Common Stock and Warrants, on June 4, 2024, the Company Pre-Funded Warrants to purchase up to 34,037 shares of Common Stock of the Company, having an exercise price of $0.0001 per share, and a purchase price of $2.1799 per Pre-Funded Warrant, The per share exercise price for the Pre-Funded Warrants was $0.0001 and the Pre-Funded Warrants were exercisable immediately. The Underwriters immediately exercised the 34,037 Pre-Funded Warrants and the Underwriters received 34,037 shares of Common Stock for cash proceeds of $3.

On June 4, 2024, concurrently with the sale of Common Stock and/or the Pre-Funded Warrants, pursuant to the June 2024 Purchase Agreement in a private placement as discussed above, the Company issued an aggregate of 917,432 June 2024 Common Warrants to the Investors. The June 2024 Common Warrants have an exercise price of $2.06 per share and are exercisable immediately upon issuance for a five-year period. Additionally, the Placement Agent received the June 2024 Placement Agent Warrant to purchase up to 68,807 shares of Common Stock, at an exercise price equal to 125.0% of the offering price per share of Common Stock, or $2.725 per share. The June 2024 Placement Agent Warrants are exercisable immediately upon issuance for a period of five years.

On July 18, 2024, concurrently with the sale of Common Stock, pursuant to the July 2024 Purchase Agreement in a private placement as discussed above, the Company issued an aggregate of 763,638 July 2024 Common Warrants to the Investors. The July 2024 Common Warrants have an exercise price of $2.75 per share and are exercisable immediately upon issuance for a five-year period. Additionally, the Placement Agent received the July 2024 Placement Agent Warrants to purchase up to 57,275 shares of Common Stock, at an exercise price equal to 125.0% of the offering price per share of Common Stock, or $3.4375 per share. The July 2024 Placement Agent Warrants are exercisable immediately upon issuance for a period of five years.

Warrant activities for the years ended December 31, 2024 and 2023 are summarized as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance Outstanding, December 31, 2022	404,580	$ 14.05	3.3	$ -
Granted	-	-	-	-
Balance Outstanding, December 31, 2023	404,580	14.05	2.3	-
Granted	1,841,187	2.38	-	-
Exercised	(34,037)	0.0001	-	-
Balance Outstanding, December 31, 2024	2,211,730	$ 4.55	3.9	$ -
Exercisable, December 31, 2024	2,211,730	$ 4.55	3.9	$ -

NOTE 7 – CONCENTRATIONS

Customer concentration

For the years ended December 31, 2024 and 2023, one licensee accounted for 100% total revenues from customer license fees.

Vendor concentrations

For the years ended December 31, 2024 and 2023, one licensor accounted for 100% of the Company's vendor license agreements (see below) related to the Company's biopharmaceutical operations.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

Employment Agreements

Eric Weisblum

On October 12, 2022, the Company entered into an employment agreement with Eric Weisblum (the "2022 Weisblum Employment Agreement") pursuant to which Mr. Weisblum's (i) base salary will be $350,000 per year, (ii) Mr. Weisblum was paid a one-time signing bonus of $100,000, and (iii) Mr. Weisblum shall be entitled to receive an annual bonus of up to $350,000, subject to the sole discretion of the Compensation Committee of the Board of Directors of the Company (the "Compensation Committee"), and upon the achievement of additional criteria established by the Compensation Committee from time to time (the "Annual Bonus"). In addition, pursuant to the 2022 Weisblum Employment Agreement, upon termination of Mr. Weisblum's employment for death or Total Disability (as defined in the 2022 Weisblum Employment Agreement), in addition to any accrued but unpaid compensation and vacation pay through the date of his termination and any other benefits accrued to him under any Benefit Plans (as defined in the 2022 Weisblum Employment Agreement) outstanding at such time and the reimbursement of documented, unreimbursed expenses incurred prior to such termination date (collectively, the "Weisblum Payments"), Mr. Weisblum shall also be entitled to the following severance benefits: (i) 24 months of his then base salary; (ii) if Mr. Weisblum elects continuation coverage for group health coverage pursuant to COBRA Rights (as defined in the 2022 Weisblum Employment Agreement), then for a period of 24 months following Mr. Weisblum's termination he will be obligated to pay only the portion of the full COBRA Rights cost of the coverage equal to an active employee's share of premiums (if any) for coverage for the respective plan year; and (iii) payment on a pro-rated basis of any Annual Bonus or other payments earned in connection with any bonus plan to which Mr. Weisblum was a participant as of the date of his termination (together with the Weisblum Payments, the "Weisblum Severance"). Furthermore, pursuant to the 2022 Weisblum Employment Agreement, upon Mr. Weisblum's termination (i) at his option (A) upon 90 days prior written notice to the Company or (B) for Good Reason (as defined in the 2022 Weisblum Employment Agreement), (ii) termination by the Company without Cause (as defined in the 2022 Weisblum Employment Agreement) or (iii) termination of Mr. Weisblum's employment within 40 days of the consummation of a Change in Control Transaction (as defined in the Weisblum Employment Agreement), Mr. Weisblum shall receive the Weisblum Severance; provided, however, Mr. Weisblum shall be entitled to a pro-rated Annual Bonus of at least $200,000. In addition, any equity grants issued to Mr. Weisblum shall immediately vest upon termination of Mr. Weisblum's employment by him for Good Reason or by the Company at its option upon 90 days prior written notice to Mr. Weisblum, without Cause. In October 2024 and September 2023, the Company paid a bonus of $200,000 and $200,000 to Mr. Weisblum, respectively.

Daniel Ryweck

On September 27, 2022, the Board appointed Daniel Ryweck as Chief Financial Officer of the Company. On September 28, 2022, the Company entered into an employment agreement (the "Ryweck Employment Agreement") with Mr. Ryweck. Pursuant to the terms of the Ryweck Employment Agreement, which was amended on October 12, 2022, Mr. Ryweck will (i) receive a base salary at an annual rate of $60,000 (the "Base Compensation") payable in equal monthly installments, and (ii) be eligible to receive an annual discretionary bonus. The term of Mr. Ryweck's engagement under the Ryweck Employment Agreement commenced on September 28, 2022 and continued until September 28, 2023, unless earlier terminated in accordance with the terms of the Ryweck Employment Agreement. The term of Mr. Ryweck's Employment Agreement was automatically renewed until September 28, 2025 and will automatically renew for successive one-year periods until terminated by Mr. Ryweck or the Company. On November 11, 2024, the Company entered into a Second Amendment to Employment Agreement with Daniel Ryweck (the "Second Amendment"). The Second Amendment amends the Employment Agreement to provide that Mr. Ryweck will be entitled to receive an annual cash bonus in an amount up to $60,000 if the Company meets or exceeds criteria adopted by the Compensation Committee of the Board for earning bonuses. In December 2024, the Company paid a bonus of $25,000 to Mr. Ryweck.

Dr. James Kuo

On January 27, 2022, the Company and Dr. James Kuo entered into an employment agreement ("Kuo Employment Agreement") for Dr. Kuo to serve as the Vice President of Research & Development. The Kuo Employment Agreement shall be effective as of the date of the agreement and shall automatically renew for a period of one year at every anniversary of the effective date, with the same terms and conditions, unless either party provides written notice of its intention not to extend the term of the Kuo Employment Agreement at least thirty days prior to the applicable renewal date. Dr. Kuo shall be paid an annual base salary of $30,000. For each twelve-month period of his employment, Dr. Kuo shall be entitled to a bonus whereby amount and terms shall be in the sole and absolute discretion of the Board of Directors ("Board") and shall be payable at the Company's sole option in stock or in cash. In addition, an aggregate of 16,000 incentive stock options were granted under the 2020 Plan to Dr. Kou, exercisable at $10.00 per share and expires on January 31, 2032. The stock options vest as follows: (i) 6,000 stock options upon issuance; (ii) 5,000 vests on October 31, 2022 and; (iii) 5,000 vests on October 31, 2023. The 16,000 stock options had a fair value of $94,915 which valued at grant date using Binomial Lattice option pricing model with the following assumptions: risk-free interest rate of 1.18%, expected dividend yield of 0%, expected term of 2 years using the simplified method and expected volatility of 117% based on calculated volatility. The Company recorded the fair value of the stock options, in the amount of $94,915, as deferred compensation which is being amortized over the vesting period. During the years ended December 31, 2024 and 2023, the Company amortized $0 and $14,125 of the deferred compensation which was recorded as compensation expenses in the consolidated statement of operations and comprehensive loss, respectively. As of December 31, 2024 and 2023, the deferred compensation had a balance of $0 (See Note 6).

License Agreements between the Company and Vendors

Master License Agreement with the University of Maryland, Baltimore

Effective as of February 12, 2021, the Company and University of Maryland, Baltimore ("UMB"), entered into the Master License Agreement ("Master License Agreement") which grants the Company an exclusive, worldwide, sublicensable, royalty-bearing license to certain intellectual property: (i) to make, have made, use, sell, offer to sell, and import certain licensed products and: (ii) to use the invention titled, "Central nervous system-homing peptides in vivo and their use for the investigation and treatment of multiple sclerosis and other neuroinflammatory pathology" and UMB's confidential information to develop and perform certain licensed processes for the therapeutic treatment of neuroinflammatory disease.

The Master License Agreement will remain in effect on a Licensed Product-by-Licensed Product basis and country-by-country basis until the later of: (a) the last patent covered under the Master License Agreement expires, (b) the expiration of data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity, or other legally enforceable market exclusivity, if applicable, or (c) 10 years after the first commercial sale of a Licensed Product in that country, unless earlier terminated in accordance with the provisions of the Master License Agreement. The term of the Master License Agreement shall expire 15 years after the Master License Agreement Effective Date in which (a) there were never any patent rights, (b) there was never any data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity, or other legally enforceable market exclusivity or (c) there was never a first commercial sale of a Licensed Product.

The Company may assign, sublicense, grant, or otherwise convey any rights or obligations under the Master License Agreement to a Company affiliate, without obtaining prior written consent from UMB provided that it meets the terms defined in the Master License Agreement. The Company may grant sublicenses of some or all of the rights granted by the Master License Agreement, provided that there is no uncured default or breach of any material term or condition under the Master License Agreement, by Company, at the time of the grant, and that the grant complies with the terms and conditions of the Master License Agreement. The Company shall be and shall remain responsible for the performance by each of the Company's sublicensee. Any sublicense shall be consistent with and subject to the terms and conditions of the Master License Agreement and shall incorporate terms and conditions sufficient to enable the Company to comply with the Master License Agreement. The Company or Company affiliates shall pay to UMB a percentage of all income received from its sublicensee as follows: (i) 25% of the Company's sublicense income which is receivable with respect to any sublicense that is executed before the filing of an NDA (or foreign equivalent) for the first licensed product; and (b) 15% of the Company's sublicense income which is receivable with respect to any sublicense that is executed after the filing of an NDA (or foreign equivalent) for the first licensed product.

Pursuant to the Master License Agreement, the Company shall pay UMB; (i) a license fee, (ii) certain event-based milestone payments (see below for payment terms), (iii) royalty payments depending on net revenues (see below for payment terms), and (iv) a tiered percentage of sublicense income. In 2022 and 2021, the Company paid UMB a license fee of $75,000. The license fee is non-refundable and is not creditable against any other fee, royalty or payment. The Company shall be responsible for payment of all patent expenses in connection with preparing, filing, prosecution and maintenance of patents or patent applications relating to the patent rights. The license fee paid of $75,000 was recorded as prepaid expense and is being amortized over the 15-year term. During the years ended December 31, 2024 and 2023, the Company recognized license fees of $5,000 and $5,000, respectively, from the amortization of prepaid license fees, which is included in costs of revenues on the accompanying consolidated statements of operations. On December 31, 2024, prepaid expense and other current assets – current amounted to $5,000 and prepaid expense – non-current amounted to $50,625. On December 31, 2023, prepaid expense and other current assets – current amounted to $5,000 and prepaid expense – non-current amounted to $55,625.

Milestone		Payment
Filing of an Investigational New Drug (or any foreign equivalent) for a Licensed Product	$	50,000
Dosing of first patient in a Phase 1 Clinical Trial of a Licensed Product	$	100,000
Dosing of first patient in a Phase 2 Clinical Trial of a Licensed Product	$	250,000
Receipt of New Drug Application ("NDA") (or foreign equivalent) approval for a Licensed Product	$	500,000
Achievement of First Commercial Sale of Licensed Product	$	1,000,000

Royalty Payments Terms:

(i) 3% on sales of licensed products (as defined in the Master License Agreement) during the applicable calendar year for sales less than $50,000,000; and

(ii) 5% on sales of licensed products during the applicable calendar year for sales greater than $50,000,000; and

(iii) minimum annual royalty payments, as follows:

Years		Minimum Annual Royalty
Prior to First Commercial Sale	$	N/A
Year of First Commercial Sale	$	N/A
First calendar year following the First Commercial Sale	$	25,000
Second calendar year following the First Commercial Sale	$	25,000
Third calendar year following the First Commercial Sale	$	100,000

On November 10, 2023, the Company entered into a Third Amendment to Master License Agreement (the "Third Amendment") with UMB, pursuant to which the parties agreed to an amended and restated schedule of diligence milestones for the Master License Agreement.

In April 2021, in connection with the Company's Sublicense Agreement with Aikido Pharma Inc. (see below - *Patent License Agreement with Aikido Pharma Inc.*), the Company paid 25% of its sublicense income to UMB, pursuant to the Master License Agreement, which amounted to $12,500. During the years ended December 31, 2024 and 2023, the Company recognized license fees of $838 and $838, respectively, from the amortization of the sublicense fee. On December 31, 2024, prepaid expense and other current assets – current amounted to $838 and prepaid expenses – non-current amounted to $8,520. On December 31, 2023, prepaid expense and other current assets – current amounted to $838 and prepaid expenses – non-current amounted to $9,358.

Exclusive License Agreement with the Trustees of Columbia University in the City of New York

On July 1, 2024, the Company entered into an exclusive license agreement (the "Columbia License Agreement") with Columbia University ("Columbia") with an effective date of June 28, 2024 (the "Effective Date") and pursuant to which the Company has been granted exclusive rights to certain patents and technical information to develop, manufacture and commercialize Products (as defined in the Columbia License Agreement), including therapies for stress-induced affective disorders and other conditions. The term of the Columbia License Agreement commenced on the Effective Date and shall continue on a country-by-country and product-by-product basis until the latest of: (a) the date of expiration of the last to expire of the issued Patents (as defined in the Columbia License Agreement), (b) 20 years after the first bona fide commercial sale of the Product in the country in question, or (c) expiration of any market exclusivity period granted by a regulatory agency for a Product in the country in question. Pursuant to the Columbia License Agreement, the Company agreed to pay Columbia:

(i) an initial license fee of $50,000 paid in October 2024 and included in intangible assets on the accompanying consolidated balance sheet as of December 31, 2024 (See Note 4).

(ii) an annual license fee of $25,000 payable on the 1st and 2nd anniversary of the Effective Date and an annual license fee of $50,000 payable on the third and subsequent anniversary of the Effective Date.

(iii) Royalties as follows:

(A) Concerning sales of Products by the Company, its Designees, or their Affiliates in the Territory, a non-refundable and non-recoverable royalty of the following on a country-by-country and Product-by-Product basis:

(1) 4% of Net Sales of Patent Products; and

(2) 2% of Net Sales of Technology Products.

(B) No later than 30 days following the second (2nd) anniversary of the first bona fide commercial sale of a Product by the Company, a Sublicensee, a Designee, or any of their Affiliates to a Third-Party customer, and the first business day of each January after that, the Company shall pay Columbia a non-refundable and non-recoverable minimum royalty payment in the amount of $500,000. The Company may credit each minimum royalty payment against earned royalties accrued during the same calendar year in which the minimum royalty payment is due and payable. To the extent minimum royalty payments exceed the earned royalties accrued during the same calendar year, the Company may not carry over this excess amount to any other year, either to decrease the earned royalties due in that year or to decrease the minimum royalty payments due in that year; and

(iv) Trigger Event Fee: The Company shall pay Columbia a Trigger Event Fee within 30 days after the Initial Date or, if later, within 10 days following the date upon which the Trigger Event Fee. A Trigger Event means any Assignment of the Columbia License Agreement or Change of Control and a Trigger Event Fee shall mean an additional cash license fee equal to 5% of the Business Valuation, as defined in the agreement.

(v) The Company shall reimburse Columbia for patent expenses as follows:

(i) The Company shall reimburse Columbia for the actual fees, costs, and expenses Columbia has incurred before, on, and after the Effective Date in preparing, filing, prosecuting, and maintaining the Patents (and those patents and patent applications to which Patents claim priority) (collectively "Patent Expenses"). Patent Expenses include, without limitation, legal fees, the costs of any interference proceedings, oppositions, re-examinations, or any other ex parte or inter partes administrative proceeding before patent offices, taxes, annuities, issue fees, working fees, maintenance fees, and renewal charges, plus a five percent processing fee.

(ii) Unreimbursed Patent Expenses that Columbia incurred for legal activities occurring before September 30, 2021 are "Past Patent Expenses**."**

(iii) Columbia, using reasonable efforts, estimated that unreimbursed Patent Expenses for legal activities occurring before September 30, 2021 were $197,400 ("Estimated Past Patent Expenses"). The Company shall reimburse Columbia in full no later than thirty (30) days after the Effective Date. On June 28, 2024, the Company considered the Estimated Past Patents Expenses due of $197,400 as part of the cost of entering into the Columbia License Agreement license and accordingly, increased intangible assets and accounts payable by $197,400. In November 2024, the Company paid $50,000 of this amount and as of December 31, 2024, the balance of $147,400 is included in accounts payable on the accompanying consolidated balance sheet (See Note 4).

(iv) The Company will pay any additional unreimbursed Past Patent Expenses within thirty (30) days after receiving an invoice from Columbia for the additional Past Patent Expenses.

(v) The Company will reimburse Columbia for unreimbursed Patent Expenses incurred by Columbia after the Past Patent Expenses ("Ongoing Patent Expenses") no later than thirty (30) days after receiving Columbia's invoice.

(vi) At Columbia's election, Columbia may require advance payment of a reasonable estimate of Ongoing Patent Expenses ("Estimated Ongoing Patent Expenses"). Columbia shall give at least thirty (30) days' notice to the Company before the date the advance payment is due, which payment Columbia may make due up to three months before the date Columbia has chosen for the legal work to be completed. Columbia may credit any unused balance towards future Patent Expenses, or upon the Company's written request, Columbia shall return the unused balance to the Company. No later than thirty (30) days after receiving an invoice from Columbia for any Patent Expenses incurred over the reasonable estimate, the Company shall reimburse Columbia for the excess amount.

License Agreements between the Company and Customer

Customer Patent License Agreement with Aikido Pharma Inc.

On January 5, 2021, the Company and its subsidiary Silo Pharma, Inc., entered into a patent license agreement ("License Agreement") (collectively, the "Licensor") with Aikido Pharma Inc. ("Aikido" or the "Customer"), as amended on April 12, 2021, pursuant to which the Licensor granted Aikido an exclusive, worldwide ("Territory"), sublicensable, royalty-bearing license to certain intellectual property: (i) to make, have made, use, provide, import, export, lease, distribute, sell, offer for sale, develop and advertise certain licensed products and (ii) to develop and perform certain licensed processes for the treatment of cancer and symptoms caused by cancer ("Field of Use").

The License Agreement also provided that, if the Licensor exercised the option granted to it pursuant to its commercial evaluation license and option agreement with UMB, effective as of July 15, 2020, it would grant Aikido a non-exclusive sublicense ("Right") to certain UMB patent rights in the field of neuroinflammatory diseases occurring in patients diagnosed with cancer ("Field"). Pursuant to the License Agreement, Aikido agreed to pay the Licensor, among other things, (i) a one-time non-refundable cash payment of $500,000 and (ii) royalty payments equal to 2% of net sales (as defined in the License Agreement) in the Field of Use in the Territory. In addition, Aikido agreed to issue the Licensor 500 shares of Aikido's newly designated Series M Convertible Preferred Stock which were to be converted into an aggregate of 625,000 shares of Aikido's common stock. On April 12, 2021, the Company entered into an amendment to the License Agreement ("Amended License Agreement") with Aikido dated January 5, 2021 whereby Aikido issued an aggregate of 625,000 restricted shares of Aikido's common stock instead of the 500 shares of the Series M Convertible Preferred Stock.

Pursuant to the License Agreement, the Company is required to prepare, file, prosecute, and maintain the licensed patents. Unless earlier terminated, the term of the license to the licensed patents will continue until the expiration or abandonment of all issued patents and filed patent applications within the licensed patents. The Company may terminate the License Agreement upon 30 day written notice if Aikido fails to pay any amounts due and payable to the Company or if Aikido or any of its affiliates brings a patent challenge against the Company, assists others in bringing a legal or administrative challenge to the validity, scope, or enforceability of or opposes any of the licensed patents ("Patent Challenge") against the Company (except as required under a court order or subpoena). Aikido may terminate the Agreement at any time without cause, and without incurring any additional penalty, (i) by providing at least 30 days' prior written notice and paying the Company all amounts due to it through such termination effective date. Either party may terminate the Agreement for material breaches that have failed to be cured within 60 days after receiving written notice. The Company collected the non-refundable cash payment of $500,000 on January 5, 2021 which was recorded as deferred revenue to be recognized as revenues over 15 years, the estimated term of the UMB Master License Agreement.

Prior to the April 12, 2021, issuance of the common stock in lieu of the Series M Convertible Preferred Stock as discussed above, the Company valued the 500 Series M Convertible Preferred stock which was equivalent into Aikido's 625,000 shares of common stock at a fair value of $0.85 per common share or $531,250 based quoted trading price of Aikido's common stock on the date of grant. The Company recorded an equity investment of $531,250 and deferred revenue of $531,250 to be recognized as revenues over the estimated term of the UMB Master License. Accordingly, the Company recorded a total deferred revenue of $1,031,250 ($500,000 cash received and $531,250 value of equity securities received) to be recognized as revenues over the 15-year term.

During the years ended December 31, 2024 and 2023, the Company recognized license fee revenues of $68,750 and $68,750, respectively. On December 31, 2024, deferred revenue – current portion amounted to $68,750 and deferred revenue – long-term portion amounted to $687,500. On December 31, 2023, deferred revenue – current portion amounted to $68,750 and deferred revenue – long-term portion amounted to $756,250.

The Right shall be, to the full extent permitted by and on terms and conditions required by UMB, for a term consistent with the term of patent and technology licenses that UMB normally grants. In the event that the Company exercises its option and executes a license with UMB to the UMB patent rights within 40 days after the execution of such UMB license, for consideration to be agreed upon and paid by Aikido, which consideration shall in no event exceed 110% of any fee payable by the Company to UMB for the right to sublicense the UMB patent rights. The Company shall grant Aikido a nonexclusive sublicense in the United States to the UMB patent rights in the Field, subject to the terms of any UMB license Licensor obtains, including any royalty obligations on sublicensees required under any such sublicense. The option was exercised on January 13, 2021. Accordingly, on April 6, 2021, the Company entered into the Sublicense Agreement with Aikido pursuant to which it granted Aikido a worldwide exclusive sublicense to its licensed patents under the Master License Agreement.

Customer Sublicense Agreement with Aikido Pharma Inc.

On April 6, 2021 (the "Sublicense Agreement Effective Date"), the Company entered into the Sublicense Agreement with Aikido pursuant to which the Company granted Aikido an exclusive worldwide sublicense to (i) make, have made, use, sell, offer to sell and import the Licensed Products (as defined below) and (ii) in connection therewith to (A) use an invention known as "Central nervous system-homing peptides in vivo and their use for the investigation and treatment of multiple sclerosis and other neuroinflammatory pathology" which was sublicensed to the Company pursuant to the Master License Agreement and (B) practice certain patent rights ("Patent Rights") for the therapeutic treatment of neuroinflammatory disease in cancer patients. "Licensed Products" means any product, service, or process, the development, making, use, offer for sale, sale, importation, or providing of which: (i) is covered by one or more claims of the Patent Rights; or (ii) contains, comprises, utilizes, incorporates, or is derived from the Invention or any technology disclosed in the Patent Rights.

Pursuant to the Sublicense Agreement, Aikido agreed to pay the Company (i) an upfront license fee of $50,000, (ii) the same sales-based royalty payments that the Company is subject to under the Master License Agreement and (iii) total milestone payments of up to $1.9 million. The Sublicense Agreement shall continue on a Licensed Product-by-Licensed Product and country-by-country basis until the later of (i) the date of expiration of the last to expire claim of the Patent Rights covering such Licensed Product in such country, (ii) the expiration of data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity or other legally enforceable market exclusivity, if applicable and (iii) 10 years after the first commercial sale of a Licensed Product in that country, unless terminated earlier pursuant to the terms of the Sublicense Agreement. Furthermore, the Sublicense Agreement shall expire 15 years after the Sublicense Agreement Effective Date with respect to any country in which (i) there were never any Patent Rights, (ii) there was never any data protection, new chemical entity, orphan drug exclusivity, regulatory exclusivity or other legally enforceable market exclusivity with respect to a Licensed Product and (ii) there was never a commercial sale of a Licensed Product, unless such agreement is earlier terminated pursuant to its terms. The Company collected the upfront license fee of $50,000 in April 2021. During the years ended December 31, 2024 and 2023, the Company recognized revenue of $3,352 and $3,352, respectively. On December 31, 2024, deferred revenue – current portion amounted to $3,352 and deferred revenue – long-term portion amounted to $34,078, and on December 31, 2023, deferred revenue – current portion amounted to $3,352 and deferred revenue – long-term portion amounted to $37,430 as reflected in the consolidated balance sheets.

Sponsored Study and Research Agreements between the Company and Vendors

During the years ended December 31, 2024 and 2023, the Company recorded research and development expense of $2,368,156 and $845,092, respectively, which was incurred in connection with sponsored study and research agreements between the Company and various vendors.

On December 31, 2024, future amounts due under sponsored study and research agreements between the Company and vendors is as follows:

Year ended December 31,	Amount
2025	$ 3,310,736
Total	$ 3,310,736

NOTE 9 – INCOME TAXES

The Company maintains deferred tax assets and liabilities that reflect the net tax effects of temporary differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The deferred tax assets on December 31, 2024 and 2023 consist of net operating loss carry-forwards. The net deferred tax asset has been fully offset by a valuation allowance because of the uncertainty of the attainment of future taxable income. As of December 31, 2024 and 2023, the Company had not recorded a liability for any unrecognized tax positions.

The items accounting for the difference between income taxes at the effective statutory rate and the provision for income taxes for the years ended December 31, 2024 and 2023 was as follows:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Income tax benefit at U.S. statutory rate	$ (488,227)	$ (777,143)
Income tax benefit – state	(151,118)	(240,544)
Permanent differences	2,328	29,510
Deferred tax true-up	33,552	-
Change in valuation allowance	603,465	988,177
Total provision for income tax	$ -	$ -

The Company's approximate net deferred tax asset as of December 31, 2024 and 2023 is as follows:

	December 31, 2024	December 31, 2023
Deferred Tax Asset:		
Net operating loss carryforward	$ 2,958,758	$ 2,355,293
Capitalized research and development costs	751,967	183,272
Total deferred tax asset before valuation allowance	3,710,726	2,538,565
Valuation allowance	(3,710,726)	(2,538,565)
Net deferred tax asset	$ -	$ -

The net operating loss carryforward was approximately $13,494,000 on December 31, 2024. Future utilization of the net operating loss carryforward to offset future taxable income is subject to an annual limitation as a result of ownership changes that may occur in the future. The net operating loss carry forwards may be available to reduce future years' taxable income. Net loss carryforwards in the amount of $13,494,000 from 2018 onwards can be carried over indefinitely, subject to annual usage limits. Management believes that it appears more likely than not that the Company will not realize these tax benefits due to the Company's continuing losses for income taxes purposes. Accordingly, the Company has provided a 100% valuation allowance on the deferred tax asset benefit related to the U.S. net operating loss carry forwards to reduce the asset to zero. Management will review this valuation allowance periodically and will make adjustments as necessary. In 2024, the valuation allowance increased by $1,172,161.