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

FORM 10-K

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

For the fiscal year ended **December 31, 2024**

OR

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

For the transition period from _____ to _____

Commission File Number: **001-39126**

CNS Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Nevada	**82-2318545**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

2100 West Loop South, Suite 900
Houston, Texas 77027
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, including Area Code: **800-946-9185**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CNSP	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 periods as 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards 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 in Rule 12b-2 of the Act). YES ☐ NO ☒

The aggregate market value of the registrant's voting equity held by non-affiliates of the registrant, computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter, was $8.78 million. In determining the market value of the voting equity held by non-affiliates, securities of the registrant beneficially owned by directors, officers and 10% or greater shareholders of the registrant have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant's common stock outstanding as of March 31, 2025 was 2,944,381.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the end of the registrant's fiscal year are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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References in this Form 10-K to “we”, “us”, “its”, “our” or the “Company” are to CNS Pharmaceuticals, Inc., as appropriate to the context.

Cautionary Statement About Forward-Looking Statements

We make forward-looking statements under the “Risk Factors,” “Business,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in other sections of this report. In some cases, you can identify these statements by forward-looking words such as “may,” “might,” “should,” “would,” “could,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “potential” or “continue,” and the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to known and unknown risks, uncertainties and assumptions about us, may include projections of our future financial performance based on our growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the numerous risks and uncertainties described under “Risk Factors”.

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this report may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors 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.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of any of these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We are under no duty to update any of these forward-looking statements after the date of this report to conform our prior statements to actual results or revised expectations, and we do not intend to do so.

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

- our ability to obtain additional funding to develop our product candidates;
- the need to obtain regulatory approval of our product candidates;
- the success of our clinical trials through all phases of clinical development;
- compliance with obligations under intellectual property licenses with third parties;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to commercialize our product candidates;
- market acceptance of our product candidates;
- competition from existing products or new products that may emerge;
- potential product liability claims;

- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- our ability to adequately support future growth; and
- our ability to attract and retain key personnel to manage our business effectively.

We caution you not to place undue reliance on the forward-looking statements, which speak only as of the date of this report in the case of forward-looking statements contained in this report.

You should not rely upon forward-looking statements as predictions of future events. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Although we believe that the expectations reflected in the forward looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Therefore, you should not rely on any of the forward-looking statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I

Item 1. Business.

Overview

We are a clinical pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anti-cancer drug candidates for the treatment of brain and central nervous system tumors, based on intellectual property that we license under license agreements with Cortice Biosciences, Inc. ("Cortice") and own pursuant to a collaboration and asset purchase agreement with Reata Pharmaceuticals, Inc. ("Reata").

We believe our drug candidates, TPI 287 and Berubicin, may be significant developments in the treatment of Glioblastoma and other CNS malignancies, and if approved by the U.S. Food and Drug Administration ("FDA"), could give Glioblastoma patients important new therapeutic alternatives to the current standard of care. Glioblastomas are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful and extensively used chemotherapy drugs known. TPI 287 is an abeotaxane, and is related to the family of common chemotherapy drugs known as taxanes. Based on limited clinical and preclinical data, we believe TPI 287 is the first taxane that appears to cross the blood brain barrier ("BBB") in significant concentrations targeting brain cancer cells. Based on clinical and preclinical data, Berubicin is the first anthracycline that appears to cross the BBB in significant concentrations targeting brain cancer cells. While our focus is currently on the development of TPI 287 and Berubicin, we are also in the process of attempting to secure intellectual property rights to additional compounds that we plan to develop into drugs to treat CNS and other cancers.

TPI 287 had previously been granted Orphan Drug Designation ("ODD") status by the FDA. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a New Drug Application ("NDA") in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD strengthens our intellectual property protections although the Company is exploring if there are other patents that could be filed related to TPI 287 to extend additional protections.

TPI 287 is an abeotaxane and is an investigational chemotherapy agent classified as a third-generation taxane derivative. It was developed to address some of the limitations of earlier taxanes like paclitaxel (Taxol) and docetaxel (Taxotere), particularly issues related to drug resistance and poor penetration of the BBB. As a synthetic, lipophilic compound, TPI 287 is designed to be brain-penetrant, potentially allowing it to reach CNS tumors more effectively than its predecessors. Like other taxanes, TPI 287's mechanism of action is to stabilize microtubules, which disrupts cell division and induces apoptosis. However, one of its notable advantages is its reduced susceptibility to drug efflux pumps such as P-glycoprotein (P-gp), a common mechanism by which cancer cells develop resistance to chemotherapy. This feature gives TPI 287 potential utility in treating drug-resistant cancers in the CNS.

TPI 287 has been studied in early-phase clinical trials (Phase I and II) in over 300 patients for several indications, including Glioblastoma, metastatic breast cancer with brain metastases, non-small cell lung cancer ("NSCLC"), castration-resistant prostate cancer, and neuroblastoma. TPI 287 represents a promising candidate for treating cancers involving the CNS, as well as those that have become resistant to traditional taxane therapies. While it has shown promise in limited clinical trials, further clinical development is necessary to determine its future in neuro-oncology.

Berubicin was discovered at The University of Texas M.D. Anderson Cancer Center ("UTMDACC") by Dr. Waldemar Priebe, the founder of the Company. Through a series of transactions, Berubicin was initially licensed to Reata. Reata initiated several Phase I clinical trials with Berubicin for CNS malignancies, one of which was for malignant gliomas, but subsequently allowed their Investigational New Drug ("IND") with the FDA to lapse for strategic reasons. This required us to obtain a new IND for Berubicin before beginning further clinical trials. On December 17, 2020, we announced that our IND application with the FDA for Berubicin for the treatment of Glioblastoma Multiforme was in effect. We initiated this trial for patient enrollment during the second quarter of 2021 with the first patient dosed during the third quarter of 2021 to investigate the efficacy of Berubicin in adults with Glioblastoma Multiforme who have failed first-line therapy. The first patient on the trial was treated during the third quarter of 2021. Correspondence between the Company and the FDA resulted in modifications to our initial trial design, including designating overall survival (OS) as the primary endpoint of the study. OS is a rigorous endpoint that the FDA has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.

On March 25, 2025, CNS released topline data from a primary analysis of a clinical trial being conducted to evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their disease. The trial, compares the efficacy of Berubicin to that of Lomustine, a current standard of care in this setting, with a 2 to 1 randomization of the 252 patients to Berubicin or Lomustine. Patients receiving Berubicin were administered a 2-hour IV infusion of 7.5 mg/m2 berubicin hydrochloride daily for three consecutive days followed by 18 days off (a 21-day cycle). Lomustine is administered orally once every six weeks. The trial design included a pre-planned, non-binding interim futility analysis. We reached the criteria required by the study protocol to conduct this interim futility analysis, which an independent Data Safety Monitoring Board ("DSMB") was responsible for conducting. The DSMB's charter mandated that they review the primary endpoint, Overall Survival, as well as secondary endpoints and safety data to determine whether the efficacy data for the risk-benefit profile warrants modification or discontinuation of the study. On December 18, 2023, we released the DSMB's recommendation which was to continue the study without modification. The recently released topline data showed that although Berubicin produced clinically relevant outcomes that appear to be comparable (although the trial was not powered to determine non-inferiority) to Lomustine across multiple endpoints, it did not demonstrate a statistically significant difference in overall survival, the primary endpoint. Nevertheless, given the dearth of alternative approved therapies for GBM, we believe Berubicin has demonstrated potential value as a possible treatment for Glioblastoma. As such we are currently evaluating whether any potential paths forward exist for the program. Any such path will be planned and executed in consultation with the FDA. Even if Berubicin is approved, there is no assurance that patients will choose an infusion treatment, as compared to the current standard of care, which requires oral administration.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization.

On November 21, 2017, we entered into a Collaboration and Asset Purchase Agreement with Reata (the "Reata Agreement"). Pursuant to the Reata Agreement we purchased all of Reata's intellectual property and development data regarding Berubicin, including all trade secrets, knowhow, confidential information and other intellectual property rights.

On December 28, 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from HPI in an agreement we refer to as the HPI License. HPI is affiliated with our founder, Dr. Priebe. Under the HPI License we obtained the exclusive right to develop certain chemical compounds for use in the treatment of cancer anywhere in the world. In the HPI License we agreed to pay HPI: (i) development fees of $750,000 over a three-year period beginning November 2019; (ii) a 2% royalty on net sales; (iii) a $50,000 per year license fee; (iv) milestone payments of $100,000 upon the commencement of a Phase II trial and $1.0 million upon the approval of a New Drug Application ("NDA") for Berubicin; and (v) 3 shares of our common stock. The patents we licensed from HPI expired in March 2020. On March 23, 2025, the Company terminated the HPI License.

On June 10, 2020, the FDA granted Orphan Drug Designation for Berubicin for the treatment of malignant gliomas. The ODD now constitutes our primary intellectual property protections related to Berubicin although the Company is exploring other patents that could be filed related to Berubicin to extend additional protections. We believe we have all rights and intellectual property necessary to develop Berubicin. As stated earlier, it is our plan to obtain additional intellectual property covering other compounds which, subject to the receipt of additional financing, may be developed into drugs for brain and other cancers.

On July 29, 2024, we entered into an Exclusive License Agreement and Stock Purchase Agreement (collectively, the "Cortice Agreements") with Cortice Biosciences, Inc. ("Cortice") pursuant to which Cortice granted us an exclusive license to the intellectual property rights related to certain patents around the compound TPI 287 in the United States, Canada, Mexico and Japan. The term of the license will expire, other than due to a breach of the Cortice Agreements, at the end of the royalty term with respect to any licensed product in any of the included territories, which begins upon the first commercial sale in such territory and ends on the latest of (i) ten years after such sale, (ii) the expiration of regulatory or marketing exclusivity for such licensed product in such country, or (c) the expiration of the last to expire valid patent claim in such country covering such licensed product.

Market for Cancer Drugs

Cancer is the second leading cause of death in the United States behind heart disease. In 2019, there were an estimated 16.9 million cancer survivors in the United States. In 2022, the American Cancer Society estimated that nearly 1.9 million new cases would be diagnosed and over 600,000 Americans would die from cancer.

Digestive, reproductive, breast and respiratory cancers comprise 69% of expected cancer diagnoses in 2022, while cancers like leukemia and brain tumors are considered "rare diseases."

The worldwide cancer drug business has been estimated to represent nearly $100 billion in annual sales. Our drug candidate, Berubicin, is in a class of drugs referred to as anthracyclines, which are chemotherapy drugs designed to destroy the DNA of targeted cancer cells. The most common approved anthracyclines are daunorubicin and doxorubicin and, prior to the expansion of their generic equivalents, annual revenues generated from anthracyclines have been estimated in the range of $600 million. Many cancers are currently treated with anthracyclines; however, primary and metastatic brain cancers have not been among them because heretofore no anthracyclines have been able to sufficiently penetrate the BBB. We believe that based on clinical and preclinical data, Berubicin appears to cross the BBB despite not showing a statistically significant superiority to Lomustine, the current standard of care in refractory and recurrent GBM.

Brain cancer in general is considered a rare disease for which there are few available treatments. The leading brain tumor drug is temozolomide ("TMZ"), a drug introduced under the brand name Temodar®. In 2012, one industry source reported annual revenues of approximately $882 million for Temodar before the expiration of its patent protection, at which point generic versions of the drug began to enter the market and reduce prices. TMZ extends overall survival when used in combination with radiation after preliminary surgery, followed by maintenance therapy as a single agent thereafter.

The Orphan Drug Act and other legislative initiatives provide incentives, including market exclusivity and accelerated approval pathways, for companies that pursue the development of treatments for rare diseases and serious diseases for which there are few or no acceptable available treatment alternatives. Orphan Drug exclusivity prevents for seven years the approval of another product with the same active moiety for the same rare disease. If a product is a new chemical entity (i.e., generally that the moiety has not previously been approved), it may receive five years of exclusivity, during which period FDA may not accept for review certain NDAs for another product with the same moiety. If approval of a product required new clinical data, it may convey three years of exclusivity against approval of certain NDAs for similar products. Over the last 10 years, an increasing number of companies have begun using these designations to obtain new drug approvals for drugs where patent coverage has expired and/or where accelerated approval appears possible. An IMS Health report estimated that, in 2013, the sale of drugs with full or partial Orphan Drug exclusivity represented approximately $29 billion in revenue. We consider the receipt of Orphan Drug exclusivity and expedited pathways to approval or further development to be an important part of our development strategy for our drug candidates.

The Clinical Therapeutic Opportunity

The Company was created to specialize in the discovery and development of novel treatments for brain tumors. Our main focus is currently the development and testing of TPI 287 and Berubicin. We believe TPI 287 is the first taxane and Berubicin is the first anthracycline that appears to cross the BBB and target cancer cells based upon preclinical animal models and limited clinical data derived from Phase 1 human clinical trials, and in the case of Berubicin, based on Phase 2 clinical data. Currently, there are no curative therapies for glioblastoma.

TPI 287 has been investigated in neuro-oncology for its potential to treat brain tumors due to its apparent ability to cross the blood-brain barrier. A Phase 1/2 clinical trial evaluated TPI 287 in combination with bevacizumab in patients with recurrent glioblastoma multiforme (GBM). The study reported an objective response rate of 54%, including two complete responses, and a disease control rate of 92%. The combination therapy was generally well-tolerated, with no dose-limiting toxicities observed up to doses of 170 mg/m². These early trials suggest that TPI 287 shows potential in neuro-oncology.

In 2009, Reata, the prior developer of Berubicin, completed its Phase 1 clinical trial in patients diagnosed with brain cancers, including glioblastoma, the most aggressive form of brain cancer. In the clinical trial completed by Reata in February 2009, Berubicin demonstrated one durable complete response lasting over 17 years in a patient treated on the original Phase 1 clinical trial. This patient remains disease free and clinically stable as of November 2022 (the date of the patient's most recent confirmed MRI).

The Phase 1 trial was in a patient population that had a median survival rate of only 14.6 months from glioblastoma diagnosis and few effective therapeutic options. In this trial, 25 of the 35 patients enrolled were evaluable for response, and there was 1 complete response, 1 partial response, and 1 minor response, all indicative of tumor shrinkage. In addition, 8 other patients had stable disease, for a disease control rate ("DCR") of 44%. If in consultation with the FDA we determine a path forward exists for Berubicin, despite not showing statistically significant superiority to Lomustine, and regulatory approval is secured to market it, we believe this drug has the potential to become an important therapeutic option for this deadly cancer.

In the eight major markets for pharmaceuticals (the US, France, Germany, Italy, Spain, the UK, Japan and China), approximately 55,000 new glioblastoma patients were diagnosed in 2021 with a median survival rate for these patients of only 15 months (GlobalData, 2018). Due to the lack of effective therapies, the five-year survival rate of glioblastoma ranges from 13% for younger aged patients (20 to 44 years) to 1% for older populations (over 44 years). The current standard of care for first-line treatment is surgery, radiation, and chemotherapy with TMZ. TMZ, the current chemotherapeutic component of the first-line standard of care for glioblastoma, has limited efficacy. In the TMZ final clinical trial performed before submitting for FDA approval (573 patients), overall survival was improved by 2.5 months versus radiation alone, a clearly significant improvement in survival. However, at least 50% of TMZ treated patients do not respond to TMZ (or have responded very poorly), primarily due to the O6-methylguanine methyltransferase ("MGMT") enzyme, which is a DNA repair pathway in glioblastoma cells.

Berubicin

Our first product under development is Berubicin, a development stage anthracycline intended to treat glioblastoma and with potential to treat other neuro-oncology indications. Berubicin is an anthracycline, a class of drugs that are among the most powerful chemotherapy drugs known. Berubicin intercalates into DNA and interrupts topoisomerase II activity, resulting in the inhibition of DNA replication and repair, and ultimately RNA and protein synthesis. Based on clinical and preclinical data, Berubicin appears to cross the blood brain barrier and target cancer cells, specifically glioblastoma, more effectively and efficiently than any other known anthracyclines.

Berubicin hydrochloride (HCl) is a novel synthetic anthracycline with a chemical structure similar to doxorubicin HCl, a cytotoxic anthracycline topoisomerase II inhibitor isolated from cultures of Streptomyces peucetius var. caesius. Doxorubicin HCl Injection and Doxorubicin HCl for Injection, drugs related in chemical structure and mechanism of action to Berubicin, are approved by the FDA for the treatment of various cancers, including acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin lymphoma, Non-Hodgkin lymphoma, metastatic breast cancer, metastatic Wilms' tumor, metastatic neuroblastoma, metastatic soft tissue sarcoma, metastatic bone sarcomas, metastatic ovarian carcinoma, metastatic transitional cell bladder carcinoma, metastatic thyroid carcinoma, metastatic gastric carcinoma, and metastatic bronchogenic carcinoma, as well as part of a multiagent adjuvant chemotherapy for the treatment of women with axillary lymph node involvement after resection of primary breast cancer. A liposomal formulation of doxorubicin HCl is also approved for the treatment of ovarian cancer, AIDS-related Kaposi's sarcoma, and multiple myeloma.

Doxorubicin HCl is not indicated for cancers of the brain, where it has limited efficacy due to its poor penetration through the blood-brain barrier. Further, even for those cancers that doxorubicin HCl is indicated, development of drug resistance remains a problem. In an effort to develop a second-generation anthracycline topoisomerase II inhibitor that can circumvent the BBB and the development of drug resistance, a library of high-affinity and sequence-selective deoxyribonucleic acid ("DNA")-binding agents was created and screened against a panel of P-glycoprotein 1 (Pgp) and multidrug resistance-associated protein 1 (MRP1)-overexpressing cells. This led to the identification of berubicin HCl, which preclinical studies appear to show to be less affected by multidrug transporters than doxorubicin, to be potentially more potent as an inhibitor of cell growth and inducer of apoptosis than doxorubicin, to sequester preferentially in tumor tissue versus brain tissue, and to improve overall survival in an intracranial orthotopic glioma model. There is no assurance that Berubicin will be able to demonstrate such traits in clinical trials.

Glioblastoma has an unfavorable prognosis mainly due to its high propensity for tumor recurrence, which is inevitable after a median survival time of 32–36 weeks. A plethora of monotherapy and combination chemotherapy strategies have been evaluated in patients with recurrent glioblastoma. Although these can result in some minor improvements in progression-free survival, with an estimation of approximately 30% after six months, no obvious increase in survival has been associated with any particular regimen since the Stupp regimen of TMZ and radiation (2005).

Despite aggressive initial treatment, most patients develop recurrent diseases which can be treated with re-resection, systemic treatment with targeted agents or cytotoxic chemotherapy, reirradiation, or radiosurgery. Research into novel therapies is investigating alternative temozolomide regimens, convection-enhanced delivery, immunotherapy, gene therapy, antiangiogenic agents, poly ADP ribose polymerase inhibitors, or cancer stem cell signaling pathways. Overall, the 5-year survival rate is <10%, with a final mortality rate of close to 100%. Therefore, the development of novel therapeutic options for patients with recurrent glioblastoma remains a priority. Given the short-term efficacy and low survival rate of glioblastoma and other central nervous system patient groups, we believe there is a significant unmet need, and financial opportunity.

Less than 40% of glioblastoma patients have a genetic variation which makes their tumors initially more responsive to TMZ. However, because nearly all these patients will quickly become resistant, Berubicin could be prescribed after failure with TMZ. The remaining 60% of patients initially fail to respond to TMZ, primarily due to the over-expression of O6-methylguanine methyltransferase (MGMT) conferring a lack of a DNA repair pathway in glioblastoma cells.

Reata licensed in berubicin HCl with the intent of developing it for commercialization. On December 28, 2004, Reata filed an initial IND (IND 68,279; Serial No. 000) for an injection formulation of berubicin HCl (RTA 744 Injection) for the treatment of anaplastic astrocytoma, anaplastic oligodendroglioma, anaplastic mixed oligo-astrocytoma, glioblastoma, and gliosarcoma. Three clinical trials were initiated under IND 68,279, two phase 1 trials and one phase 2 trial. The initial phase 1 trial (Study RTA 744-C-0401) was completed and the maximum tolerated dose determined. A 44% disease control response rate was observed. The disease control rate was based on patients with stable disease plus responses. In the trial, out of 25 patients, one patient achieved a complete response, 1 patient had a partial response, 1 patient had a minor response, and 8 patients achieved a stable response. The 44% disease control response rate is based on these 11 patients (out of 25 patients). Regardless, in 2008, Reata decided to curtail development of RTA 744 Injection for strategic reasons. Further enrollment in the two other ongoing berubicin clinical trials was halted. Reata submitted a request to inactivate the IND on March 17, 2011 (Serial No. 054) and requested that the IND be withdrawn on June 10, 2016 (Serial No. 0055). IND 68,279 was not withdrawn due to safety or efficacy concerns, but rather due to the above noted corporate reprioritization.

CNS was formed in 2017. Reata sold CNS all rights to the berubicin investigational drug data, including the data submitted under IND 68,279, and CNS has assumed sole authority, discretion, and responsibility with respect to the development of the drug. As a result of the Reata Agreement, we are the direct beneficiaries of the 4 years of active clinical development work performed by Reata, including the execution of multiple Phase 1 human clinical trials.

Berubicin Phase 1 Clinical Trial

In the first clinical trial for Berubicin, which was referred to as Study RTA 744-C-0401, 25 of the 35 patients enrolled were evaluable for response. One patient achieved a complete response, remained on study through seven cycles of therapy and was withdrawn for adverse events unrelated to Berubicin. The patient was disease free as of November 2022.

Study design

Study RTA 744-C-0401 was a Phase 1 dose-finding, safety and pharmacokinetic (PK) study of intravenous Berubicin injection in patients with recurrent or refractory anaplastic astrocytoma, anaplastic oligodendroglioma, anaplastic mixed oligo-astrocytoma, glioblastoma multiforme or gliosarcoma.

The study was an open-label, accelerated dose-escalation study to determine the maximum tolerated dose starting with patients who were not taking concurrent enzyme-inducing anti-epileptic drugs (EIAEDs) that could interfere with Berubicin drug metabolism. Intra-patient dose-escalation was allowed after a patient had received a minimum of 4 cycles. Berubicin injection was administered either daily for three consecutive days repeated every three weeks (Group A), or once-weekly for four-consecutive weeks repeated every five weeks (Group C). Enrollment for a planned dose escalation in Group B (patients on EIAEDs) was not initiated after it was determined that the standard of care had changed and an insufficient number of patients being treated with these anti-epileptic drugs would make it difficult to accrue the requisite number of patients. The MTD for the remaining groups was determined in a stepwise fashion such that once the MTD for Group A (three days in a row every 3 weeks) was determined, Group C was initiated at the MTD from Group A, given on a weekly basis for 4 of every 5 weeks to evaluate the tolerability and MTD of Berubicin on this alternative schedule.

Study Results

The first patient was enrolled into the study in November 2005 and as of February 2009, the study was closed to accrual with no active patients remaining on study. Berubicin was administered to a total of 54 patients (35 male and 19 female) with ages ranging from 25 to 70 years. Thirty-seven of the patients (69%) entered the study with a diagnosis of glioblastoma multiforme, seven of which were secondary to transformation from anaplastic astrocytoma. The time from the initial brain tumor diagnosis to enrollment on the study ranged from four months to 301 months (this last timing for a patient diagnosed with childhood anaplastic astrocytoma).

Efficacy: Twenty-five of the 35 patients enrolled in Group A were evaluable for response (under the Macdonald criteria described below). One patient receiving Berubicin at 2.4 mg/m2/day achieved a complete response. The patient remained on study through 7 cycles of therapy before being withdrawn for elevated liver function tests unrelated to study drug, and in follow-up remains disease free and clinically stable as of November 2022.

One additional patient receiving Berubicin at 7.5 mg/m2/day achieved an unconfirmed partial response as their best recorded response, unconfirmed since the scan showing the partial response required a second scan corroborating the response. Although the patient had an 80% reduction in tumor volume after two cycles of therapy, at the end of four cycles of therapy when an additional scan was obtained, despite the fact that the initial lesion remained reduced, the patient developed a new lesion and was assessed as having disease progression, thus the PR could not be confirmed. Ten additional patients in Group A had stable disease of 2-to-8 cycles in duration, with a median progression free survival of four cycles (12 weeks). In Group C, seven patients were evaluable for response and all had progressive disease. Twelve patients were discontinued from the study prior to the end of cycle 2 due to clinical deterioration and/or disease progression.

Macdonald criteria: The Macdonald criteria, similarly to other systems, divides response into four types of response based on imaging (MRI) and clinical features:

Assessment	**Imaging Features**	**Clinical Features**
Complete Response (CR)	▪ Disappearance of all enhancing disease (measurable and non-measurable) ▪ Sustained for at least four weeks ▪ No new lesions	▪ No corticosteroids ▪ Clinically stable or improved
Partial Response (PR)	▪ 50% or more decrease of measurable enhancing lesions ▪ Sustained for at least four weeks ▪ No new lesions	▪ Stable or reduced corticosteroids ▪ Clinically stable or improved
Stable Disease (SD)	▪ Does not qualify for CR, PR or progression	▪ Clinically stable
Progression	▪ 25% or more increase in enhancing lesions ▪ Any new lesions	▪ Clinical deterioration

Measurements of lesions are obtained from axial post contrast T1 images. The maximal diameter is obtained, and then the second diameter is obtained at right angles to the first. The product of these measurements is then used as the size of the lesion for the purpose of comparison.

Summary of Adverse Events: The adverse events documented during Study RTA 744-C-0401 for all CTC grades of severity and regardless of relationship to study medication are identified below.

Serious Adverse Event	Number of Patients Experiencing Adverse Event
Pulmonary embolism	5
Convulsion	5
Urinary tract infection	1
Peripheral motor neuropathy	1
Peripheral sensory neuropathy	1
Urinary retention	1
Nausea	4
Vomiting	5
Constipation	1
Leukopenia	1
Neutropenia	1
Headache	3
Speech disorder	1
Pyramidal tract syndrome	3
Somnolence	1
Dehydration	3
Brain oedema	1
Papilloedema	1
Eyelid ptosis	1
Macular oedema	1
Syncope	2
Deep vein thrombosis	1
Loss of consciousness	1
Embolism	1
Hemiparesis	1
Hydrocephalus	1
Muscle atrophy	1
Thrombocytopenia	1
Disease progression	3
Mental status changes	4
Thrombosis	1
Sepsis	1
Depressed level of consciousness	1
Dyspnoea	2

The larger number of events related to the central nervous system is consistent with the impact of the underlying malignant disease in the brain of these patients. Myelosupression, i.e., a decrease in the number of bone-marrow derived cells, is expected and consistent with the known toxicities of anthracyclines, which can be managed by the use of effective supportive care.

Berubicin Phase 2 Clinical Trial

Based on data relating to the mechanism of action of Berubicin, as well as clinical results from the Phase 1 study in brain tumors performed by Reata, the prior developer of Berubicin, we initiated a randomized, controlled multicenter study intended to evaluate the efficacy of Berubicin versus Lomustine (CCNU, CeeNU®, or Gleostine®) in patients with recurrent glioblastoma. Randomization to the two therapies (Berubicin or Lomustine) was on a 2:1 basis with 2 patients receiving Berubicin for every patient randomized to Lomustine. Lomustine is a drug considered effective in patients with glioblastoma that has recurred or progressed following first line therapy. From the data available from the Reata Phase 1 clinical trial (RTA 744-C-0401), the FDA has agreed that the dosage for Berubicin will be at the maximum tolerated dose ("MTD") determined in that trial. Thus, patients randomized to the Berubicin arm receive a 2-hour IV infusion of 7.5 mg/m2 berubicin hydrochloride daily for three consecutive days followed by 18 days off (21-day cycle). Patients randomized to Lomustine receive a single oral dose of 130 mg/m2 (rounded to the nearest 5 mg) every 6 weeks, or per the full prescribing information for Lomustine incorporating institutional standards at each study site.

Efficacy was measured by the benefit of Berubicin vs. Lomustine in terms of overall survival (OS), considered by the FDA as the only endpoint acceptable for clinical trials in Neuro-Oncology which form the basis for a request for approval of a New Drug Application. Secondary endpoints using accepted radiologic methodology (magnetic resonance imaging "MRI"), including both pre- and post-gadolinium T1-weighted scans and T2/fluid attenuated inversion recovery ("FLAIR") images will evaluate objective response rates (ORR), which include complete responses (CR) and partial responses (PR) as per RANO (Response Assessment for Neuro-Oncology), and progression free survival at 6 months (PFS6). Additional information collected include event free survival (EFS), corticosteroid usage, neurologic status, quality of life, and safety, and for Berubicin, the pharmacokinetics (PK) at the dose and schedule employed. On March 25, 2025, we released the results of the primary analysis of the Berubicin trial. While Berubicin showed clinically relevant outcomes comparable (although the trial was not powered to determine non-inferiority) to Lomustine across multiple endpoints, it did not demonstrate a statistically significant difference in overall survival, the primary endpoint.

The trial included a pre-planned, non-binding interim futility analysis which was conducted by an independent DSMB to recommend whether this study should continue as planned, be discontinued, or be modified to address safety concerns. The trial design called for this interim analysis to be conducted after at least 50% of the patients in the interim analysis population (30-50% of total expected patients for the trial) can be evaluated as having failed the primary efficacy endpoint of Overall Survival. The median survival of patients receiving second-line treatment for glioblastoma has historically been shown to be approximately 6 months. The DSMB's charter mandated that they review the primary endpoint, Overall Survival, as well as secondary endpoints and safety data to determine whether the efficacy data for the risk-benefit profile warrants modification or discontinuation of the study. On December 18, 2023, we released the DSMB's recommendation which was to continue the study without modification.

We are currently exploring what path forward, if any, may be available for Berubicin. Our planning process will involve consultation with and input from the FDA. If a path forward is identified, we may look for a partner with which to conduct any additional studies which may be required, or we may attempt to raise sufficient capital to conduct such studies on our own. The goal of these additional studies, should they be necessary, would be to develop a body of evidence to support a successful application with the FDA and/or other similar regulatory agencies around the world. Should we obtain approval from the FDA or other international regulatory agencies to market Berubicin, we will either partner with third parties to sell and distribute it to physicians and patients, or we will develop our own sales force to do so.

Competition

We operate in a highly competitive segment of the pharmaceutical market, which market is highly competitive as a whole. We face competition from numerous sources including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors may have significantly greater financial, product development, manufacturing and marketing resources. Additionally, many universities and private and public research institutes are active in cancer research, and some may be in direct competition with us. We may also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The unmet medical need for more effective cancer therapies is such that oncology drugs are one of the leading class of drugs in development. These include a wide array of products against cancer targeting many of the same indications as our drug candidates. While the introduction of newer targeted agents may result in extended overall survival, induction therapy regimens are likely to remain a cornerstone of cancer treatment in the foreseeable future.

The current standard for the initial treatment of glioblastoma is surgery, followed by radiation in combination with TMZ, followed by maintenance TMZ. Treatment with Lomustine is considered to be the standard of care for recurrent glioblastoma even though it is not formally approved by the FDA for this purpose, a fact which highlights the lack of available options for treatment. While the percentage of patients who survive two years from the diagnosis of glioblastoma has increased because of the use of TMZ, overall survival for GBM patients remains dismal. There are currently at least 77 different experimental therapies under clinical development in the United States for recurrent GBM based on the clinicaltrials.gov website. Thus, we are operating in a highly competitive clinical trial environment, moving towards the pharmaceutical market, which is also extremely competitive for patients with GBM. We also face competition from numerous sources including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors may have significantly greater cancer research capabilities, as well as financial, product development, manufacturing, and marketing resources. Additionally, many universities and private and public research institutes are active in cancer research, and some may be in direct competition with us. In addition, we also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Intellectual Property

When we licensed TPI 287 from Cortice on July 29, 2024, it had previously been granted Orphan Drug Designation ("ODD")by the FDA. On June 10, 2020, the FDA granted Orphan Drug Designation for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. We do not hold or license any patents related to Berubicin and the ODD now constitutes our primary intellectual property protections although the Company is exploring if there are other patents that could be filed related to Berubicin to extend additional protections.

On July 24, 2021, the Company received Fast Track Designation from the FDA for Berubicin. Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

We are exploring the possibility to file additional patent applications that potentially might allow for further increase of the exclusive market protection for use of TPI 287 and Berubicin. However, we can provide no assurance that we will be able to file or receive additional patent protection. The failure to receive such additional patent protection will reduce the barrier to entry for competition for TPI 287 and Berubicin, which may adversely affect our operations.

Governmental Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical drug product candidates that we develop must be approved by the FDA before they may be marketed and distributed.

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act, and implementing regulations. Pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA and related enforcement activity could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a pharmaceutical product may be marketed in the United States generally involves the following:

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- Submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical studies may begin;
- Performance of adequate and well-controlled human clinical studies according to the FDA's current good clinical practices ("GCP"), to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of an NDA for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced, to assess compliance with current good manufacturing practices ("cGMP"), to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product's identity, strength, quality and purity;
- Potential FDA audit of the preclinical and clinical study sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals, and continued compliance is inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the pharmaceutical product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the pharmaceutical product candidate. These early proof-of-principle studies are done using sound scientific procedures and thorough documentation. The conduct of the single and repeat dose toxicology and toxicokinetic studies in animals must comply with federal regulations and requirements including good laboratory practices. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA has concerns and notifies the sponsor. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. If resolution cannot be reached within the 30-day review period, either the FDA places the IND on clinical hold or the sponsor withdraws the application. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical studies for various reasons. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such clinical study.

Clinical studies involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, how the results will be analyzed and presented and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical studies must be conducted in accordance with GCP. Further, each clinical study must be reviewed and approved by an independent institutional review board ("IRB") at, or servicing, each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined. While such designations are not officially defined by the regulatory agencies (including the FDA), the generally accepted meanings are:

- Phase 1: The pharmaceutical product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients, with a goal of characterizing the safety profile of the drug and establishing a maximum tolerable dose.

- Phase 2: With the maximum tolerable dose established in a Phase 1 trial, the pharmaceutical product is evaluated in a limited patient population at the MTD to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, to determine dosage tolerance, optimal dosage and dosing schedule and to identify patient populations with specific characteristics where the pharmaceutical product may be more effective.

- Phase 3: Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. The studies must be well controlled and usually include a control arm for comparison. One or two Phase 3 studies are usually required by the FDA for an NDA approval, depending on the disease severity and other available treatment options. In some instances, an NDA approval may be obtained based on Phase 2 clinical data with the understanding that the approved drug can be sold subject to a confirmatory trial to be conducted post-approval.

Post-approval studies, or Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are often used to gain additional experience from the treatment of patients in the intended therapeutic indication. The FDA also may require Phase 4 studies, Risk Evaluation and Mitigation Strategies ("REMS") and post-marketing surveillance, among other things, to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies may complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees. A waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has 10 months after the 60-day filing date in which to complete its initial review of a standard review NDA and respond to the applicant, and six months after the 60-day filing date for a priority review NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs.

After the NDA submission is accepted for filing, the FDA reviews the NDA application to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the pharmaceutical product approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the pharmaceutical product. If the FDA concludes that a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites as well as the site where the pharmaceutical product is manufactured to assure compliance with GCP and cGMP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. In addition, the FDA will require the review and approval of product labeling.

The NDA review and approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical studies designed to further assess pharmaceutical product safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

On July 24, 2021, the Company received Fast Track Designation from the FDA for Berubicin. The Company intends to seek Fast Track Designation for TPI 287 as well.

The FDA's Fast Track program is intended to expedite or facilitate the process for reviewing new pharmaceutical products that meet certain criteria. Specifically, new pharmaceutical products are eligible for Fast Track designation if they are intended to treat a serious condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, if the FDA determines that the schedule is acceptable and if the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for market, including a Fast Track program, may also be eligible for other FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it is intended to treat a serious condition and it offers a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new pharmaceutical product designated for priority review in an effort to facilitate the review. Additionally, accelerated approval may be available for a product intended to treat a serious condition that provides meaningful therapeutic benefit over existing treatments, which means the product may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint. As a condition of accelerated approval, the FDA may require the sponsor to perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires pre-approval of promotional materials for products receiving accelerated approval, which could impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-Approval Requirements

Any pharmaceutical products for which the Company receives FDA approvals are subject to continuing regulation by the FDA, including, among other things, cGMP compliance, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, actions by the U.S. Department of Justice and/or U.S. Department of Health and Human Services' Office of Inspector General, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available pharmaceutical products for off-label uses, manufacturers may not directly or indirectly market or promote such off-label uses.

We expect to rely on third parties for the production of clinical and commercial quantities of our products. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Pharmaceutical product manufacturers and other entities involved in the manufacture and distribution of approved pharmaceutical products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical product candidates for which we may obtain regulatory approval. In the United States and in markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part upon the availability of reimbursement from third-party payers. Third-party payers include government payers such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. The process for determining whether a payer will provide coverage for a pharmaceutical product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the pharmaceutical product. Third-party payers may limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not, and frequently does not, include all of the FDA-approved pharmaceutical products for a particular indication. Third-party payers 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. A payer's decision to provide coverage for a pharmaceutical product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, in the United States there is a growing emphasis on comparative effectiveness research, both by private payers and by government agencies. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our pharmaceutical product candidates may not be considered medically necessary or cost-effective. To the extent other drugs or therapies are found to be more effective than our products, payers may elect to cover such therapies in lieu of our products and/or reimburse our products at a lower rate.

Orphan Drug exclusivity prevents for seven years the approval of another product with the same active moiety for the same rare disease. On June 10, 2020, the FDA granted Orphan Drug Designation for Berubicin for the treatment of malignant gliomas. If a product is a new chemical entity (i.e., generally that the moiety has not previously been approved), it may receive five years of exclusivity, during which period FDA may not accept for review certain NDAs for another product with the same moiety. If approval of a product required new clinical data, it may convey three years of exclusivity against approval of certain NDAs for similar products.

The marketability of any pharmaceutical product candidates for which we may receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect this will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we may receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

International Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our future drugs. Whether or not we obtain FDA approval for a drug, we must obtain approval of a drug by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the drug in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of our future drugs.

License Agreements

On November 21, 2017, we entered into the Reata Agreement. Pursuant to the Reata Agreement we purchased all of Reata's intellectual property and development data regarding Berubicin, including all trade secrets, knowhow, confidential information and other intellectual property rights.

On December 28, 2017, the Company entered into a Technology Rights and Development Agreement with HPI. Pursuant to this agreement, the Company obtained a worldwide exclusive license to the chemical compound commonly known as WP744. In exchange for these rights, the Company agreed to pay consideration to HPI as follows: (i) a royalty of 2% of net sales of any product utilizing WP744 for a period of ten years after the first commercial sale of such; and (ii) $100,000 upon beginning Phase II clinical trials (paid in 2021); and (iii) $200,000 upon the approval by the FDA of a New Drug Application for any product utilizing WP744; and (iv) a series of quarterly development payments totaling $750,000 beginning immediately after the Company's raise of $7,000,000 of investment capital. In addition, the Company issued 3 shares of the Company's common stock valued at $3,000 per share to HPI upon execution of the agreement. On November 13, 2019, the Company closed its IPO, thereby fulfilling all conditions precedent and completing the acquisition of the intellectual property discussed in the HPI agreement. During the years ended December 31, 2024 and 2023, the Company recognized $50,000 and $50,000 related to this agreement, respectively. Unrelated to this agreement, from time to time, the Company purchases pharmaceutical products from HPI which are necessary for the manufacturing of Berubicin API and drug product. On March 23, 2025, the Company terminated the HPI License.

On July 29, 2024, the Company entered into the Cortice Agreements, pursuant to which Cortice granted the Company an exclusive license to the intellectual property rights related to certain patents around the compound TPI 287 in the United States, Canada, Mexico and Japan. The term of the license will expire, other than due to a breach of the Cortice Agreements, at the end of the royalty term with respect to any licensed product in any of the included territories, which begins upon the first commercial sale in such territory and ends on the latest of (i) ten years after such sale, (ii) the expiration of regulatory or marketing exclusivity for such licensed product in such country, or (c) the expiration of the last to expire valid patent claim in such country covering such licensed product.

Employees

As of March 31, 2025, we had four full time employees. We also have one part-time employee serving as our chief scientific officer, and accordingly, a high percentage of the work performed for our development projects is conducted by qualified part-time staff and independent contractors.

Legal Proceedings

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. We have insurance policies covering any potential losses where such coverage is cost effective.

We are not at this time involved in any additional legal proceedings that we believe could have a material effect on our business, financial condition, results of operations or cash flows.

Properties

Our corporate headquarter is located in a leased facility in Houston, Texas. We believe our facilities are sufficient to meet our current needs and that suitable space will be available as and when needed. We do not own any real property.

Available Information

Our Internet address is www.cnspharma.com. On this Web site, we post the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission ("SEC"): our Annual Reports on Form 10-K; our Quarterly Reports on Form 10-Q; our Current Reports on Form 8-K; our proxy statements related to our annual stockholders' meetings; and any amendments to those reports or statements. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. All such filings are also available on our Web site free of charge. The charters of our audit, nominating and governance and compensation committees and our Code of Business Conduct and Ethics Policy are also available on our Web site and in print to any stockholder who requests them. The content on our Web site is not incorporated by reference into this Form 10-K unless expressly noted.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully all of the material risks described below, together with the other information contained in this Form 10-K. If any of the following events occur, our business, financial condition, results of operations and cash flows may be materially adversely affected.

Risks Related to the Company's Business and Industry

We will require substantial funding to complete our clinical trials, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We have used the proceeds from our previous financings to, among other uses, advance Berubicin through clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in the near term in order to complete clinical development and commercialize TPI 287 and Berubicin. If the FDA requires that we perform additional nonclinical studies or clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential approval of TPI 287 and Berubicin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of TPI 287 and Berubicin will not increase.

We will continue to require substantial additional capital to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our products under development.

We estimate that we have sufficient capital to take us into the first quarter of 2026, a period during which we would likely expect to initiate a trial of TPI 287, as well as complete the Phase 2 Berubicin trial including its further analysis. In addition, we have working capital to fund our operations during this period (with such operations estimated at $4.5 to $5.0 million per annum). We do not currently have a firm trial design for TPI 287 so estimates of development cost are not available, however, regardless of trial design, the cost of bringing TPI 287 to regulatory approval for marketing will require significant additional financing. The timing and costs of clinical trials are difficult to predict and as such the foregoing estimates may prove to be inaccurate. We have no commitments for such additional needed financing and will likely be required to raise such financing through the sale of additional equity or debt securities.

The amount and timing of our future funding requirements will depend on many factors, including but not limited to:

- whether our plan for clinical trials will be completed on a timely basis;
- whether we are successful in obtaining an accelerated approval pathway with the FDA related to Berubicin;
- the progress, costs, results of and timing of our clinical trials for TPI 287 and Berubicin;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing drug candidates and new product approvals;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern. Such "going concern" opinion could impair our ability to obtain financing.

Our auditors have indicated in their report on our financial statements for the fiscal year ended December 31, 2024 that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations. A "going concern" opinion could impair our ability to finance our operations through the sale of equity, incurring debt, or other financing alternatives. Our ability to continue as a going concern will depend upon the availability and terms of future funding. If we are unable to achieve this goal, our business would be jeopardized and we may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment.

Our success depends greatly on the success of TPI 287 and Berubicin's development for the treatment of glioblastoma, and our pipeline of product candidates beyond this lead indication is extremely early stage and limited.

Other than TPI 287 and Berubicin, we do not have any other clinical-stage drug candidates in our portfolio. As such, we are dependent on the success of TPI 287 and Berubicin in the near term. We cannot provide you any assurance that we will be able to successfully advance TPI 287 and Berubicin through the development process or that we will be able to secure other additional assets for development.

We have never been profitable, we have no products approved for commercial sale, and we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability. Therefore, we may not be able to continue as a going concern.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. Our ability to continue as a going concern is dependent upon our generating cash flow from sales that are sufficient to fund operations or finding adequate financing to support our operations. To date, we have had no revenues and have relied on equity-based financing from the sale of securities in public and private placements and the issuance of convertible notes. The continuation of the Company as a going concern is dependent upon our ability to obtain necessary equity or debt financing to continue operations and the attainment of profitable operations. As of December 31, 2024 the Company has incurred an accumulated deficit of $84,424,704 since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, 2024, combined with capital raised subsequent to December 31, 2024, is sufficient to fund its planned operations within one year after the date that the financial statements are issued.

To date, we have devoted most of our financial resources to corporate overhead, preparing for and conducting the clinical trial and marketing of our securities. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of and seek regulatory approvals for Berubicin and TPI 287, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If Berubicin or any of our other drug candidates fail in clinical trials or do not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.

We are a clinical pharmaceutical company with limited operating history. Our operations to date have been limited to acquiring our technology portfolio, preparing for and conducting our Berubicin clinical trial, and preparing for and conducting our TPI 287 clinical trial. We have not yet obtained any regulatory approvals for any of our drug candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our operating results are expected to significantly fluctuate from quarter to quarter or year to year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our product candidates in clinical development, including our ability to receive approval from the FDA for TPI 287 and Berubicin;
- delays in the commencement, enrollment and timing of clinical trials;
- difficulties in identifying patients suffering from our target indications;
- the success of our clinical trials through all phases of clinical development;
- potential side effects of our product candidate that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop drug candidates;
- our ability to identify and develop additional drug candidates beyond Berubicin;
- competition from existing products or new products that continue to emerge;
- our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations (CROs);
- our ability to establish or maintain collaborations, licensing, or other arrangements;
- our ability to defend against any challenges to our intellectual property including, claims of patent infringement;
- our ability to enforce our intellectual property rights against potential competitors;

- our ability to secure additional intellectual property protection for our developing drug candidates and associated technologies;
- our ability to attract and retain key personnel to manage our business effectively; and
- potential product liability claims.

These factors are our best estimates of possible factors but cannot be considered a complete recitation of possible factors that could affect the Company. Accordingly, the results of any historical quarterly or annual periods should not be relied upon as indications of future operating performance.

We cannot be certain that TPI 287 and Berubicin will receive regulatory approval, and without regulatory approval we will not be able to market TPI 287 and Berubicin.

Our business currently depends largely on the successful development and commercialization of TPI 287 and Berubicin. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of TPI 287 and Berubicin for the treatment of glioblastoma.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA. We have not submitted any marketing applications for any of our product candidates.

NDAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive, and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete, and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators in other jurisdictions have their own procedures for approval of product candidates. Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply with prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product candidates or other products. Also, regulatory approval for any of our product candidates may be withdrawn.

If we are unable to obtain approval from the FDA, or other regulatory agencies, for Berubicin and our other product candidates, or if, subsequent to approval, we are unable to successfully commercialize Berubicin or our other product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations, likely resulting in the total loss of principal for our investors.

Any statements in this filing indicating that TPI 287 and Berubicin has demonstrated preliminary evidence of efficacy are our own and are not based on the FDA's or any other comparable governmental agency's assessment of TPI 287 and Berubicin and do not indicate that TPI 287 and Berubicin will achieve favorable efficacy results in any later stage trials or that the FDA or any comparable agency will ultimately determine that TPI 287 and Berubicin is effective for purposes of granting marketing approval.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for TPI 287 and Berubicin and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We do not know whether any future trials or studies of our other product candidates will begin on time or will be completed on schedule, if at all. The start or end of a clinical study is often delayed or halted due to changing regulatory requirements, manufacturing challenges, including delays or shortages in available drug product, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. The rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, that include the age and condition of the patients and the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and/or availability of investigational treatment options for the relevant disease.

A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including, but not limited to:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected drug-related side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our product candidates;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- difficulty in enrolling research subjects in clinical trials including the inability to enroll any subjects at all;
- high dropout rates and high fail rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;

- greater than anticipated clinical trial costs;
- poor effectiveness of our product candidates during clinical trials; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

We have never completed a clinical trial or submitted an NDA before, and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and our collaborators or we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit, or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Many companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

If TPI 287 and Berubicin is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially and possibly irreparably harmed.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we or any of our potential future collaborators may conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If we are unable to bring Berubicin to market, or to acquire other products that are on the market or can be developed, our ability to create long-term stockholder value will be limited.

Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We may publicly disclose preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of preliminary or interim data by us could result in volatility in the price of shares of our common stock.

In addition, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the approvability of the particular drug candidate and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug candidate or our business. If the interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our current or any our future drug candidate, our business, operating results, prospects or financial condition may be materially harmed.

Our product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if TPI 287 and Berubicin (or our other product candidates) are approved, after the approved product has been marketed. The range and potential severity of possible side effects from therapies such as TPI 287 and Berubicin (or our other product candidates) are significant. If TPI 287 and Berubicin (or our other product candidates) causes undesirable or unacceptable side effects in the future, this could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;

- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

If the FDA does not find the manufacturing facilities of our future contract manufacturers acceptable for commercial production, we may not be able to commercialize any of our product candidates, or such commercialization efforts may be delayed until we can contract with manufacturers with facilities acceptable to the FDA or other regulatory authorities.

We do not have any manufacturing capabilities and we do not intend to manufacture the pharmaceutical products that we plan to sell. We utilize contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of drug product for our pre-clinical development and clinical trials of TPI 287 and Berubicin that we will need to conduct prior to seeking regulatory approval. However, we do not have agreements for supplies of TPI 287 and Berubicin or any of our other product candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize TPI 287 or Berubicin if they are approved. Additionally, the facilities used by any contract manufacturer to manufacture Berubicin or any of our other product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We will be completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and the FDA's current good manufacturing practice standards, or GMP, and other requirements of any governmental agency whose jurisdiction to which we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into third-party sales and marketing arrangements, the problems with which could materially harm our business at any time.

We have no sales, marketing, or distribution experience. To develop sales, distribution, and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that Berubicin or any of our other product candidates will be approved by the FDA. For product candidates where we decide to perform sales, marketing, and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third-party sales collaborators may not be able to build and maintain an effective marketing or sales force. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend.

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek to enter into collaborations with companies that have more experience. Additionally, if any of our product candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to enter into arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our product candidates.

One or more of our collaboration partners may not devote sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us, or the favorability of which is dependent on conditions that are out of our control or unknowable at the time of execution. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our product candidates, we would face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them. As a result, we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition could be materially and adversely affected.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe, and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the diseases that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any of our product candidates that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive.

If our competitors market products that are more effective, safer or less expensive or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Our licensed U.S. patents for Berubicn expired in March 2020 and the patents for TPI 287 will expire before commercialization is reasonably possible, and the expiration of our patents may subject us to increased competition, and the Orphan Drug Designations for TPI 287 and Berubicin will not bar approval of other similar products under certain circumstances.

The U.S. and foreign patents for TPI 287 will all expire in 2028 well before commercialization is reasonably possible. The U.S. patents for Berubicin that we previously licensed from Houston Pharmaceuticals, Inc. expired in March 2020. Such patent expirations may subject us to increased competition. TPI 287 held Orphan Drug Designation when we licensed it from Cortice and on June 10, 2020, the FDA granted Orphan Drug Designation for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of an NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD now constitutes our primary intellectual property protections although we are exploring if there are other patents that could be filed related to Berubicin to extend additional protections. The ODD similarly strengthens our TPI 287 patent protections and would become our primary protection upon expiration of those patents, however, we are also exploring new patent opportunities related to TPI 287. Nevertheless, we can provide no assurance that we will be able to file or receive additional patent protection. The failure to obtain additional patent protection will reduce the barrier to entry for competition for TPI 287 or Berubicin, which may adversely affect our operations.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may from time to time seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, then that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced. Additionally, the validity of our patents and the patents we have licensed may be challenged if a petition for post grant proceedings such as interpartes review and post grant review is filed within the statutorily applicable time with the U.S. Patent and Trademark Office (USPTO). These lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our intellectual property rights. In addition, in recent years the U.S. Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license.

We may be subject to claims that our employees and contractors have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products 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, 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. 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 will need to expand our operations and increase the size of our Company, and we may experience difficulties in managing growth.

As of March 31, 2025, we have four full-time employees. We also have 1 officer serving as part-time employee. As we advance our product candidates through preclinical studies and clinical trials, we will need to increase our product development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. Our management, personnel, and systems currently in place may not be adequate to support this future growth. If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel, and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital.

We are highly dependent on the development, regulatory, commercialization and business development expertise of our management team, key employees, and consultants. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development, and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into noncompete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Our chief science officer is currently working for us on a part-time basis. Our chief executive officer and chief science officer, also provide services for other companies in our industry and such other positions may create conflicts of interest for such officers in the future.

Certain of our key employees are currently part-time and/or provide services for other biotechnology development efforts, including companies, with respect to our chief executive officer and chief science officer, which are developing anti-cancer drug candidates. Specifically, John M. Climaco, our chief executive officer, is also serving as a director for Moleculin Biotech, Inc., a company also actively developing anticancer drugs. Donald Picker, our chief science officer, is the chief scientific officer at Moleculin.

In addition to our officers' part-time status, since Mr. Climaco and Dr. Picker are associated with other companies that are developing anti-cancer drug candidates, they may encounter conflicts of interest in the future. Although we do not believe that the drug candidates we are currently pursuing compete with the types of drug candidates being pursued by the other companies Mr. Climaco and Dr. Picker are associated with, there is no assurance that such conflicts will not arise in the future.

We do not expect that our insurance policies will cover all of our business exposures thus leaving us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. There can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect our operations to significant potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Although dependent on certain key personnel, we do not have any key man life insurance policies on any such people.

We are dependent on John M. Climaco, Christopher Downs, Sandra Silberman, and Donald Picker in order to conduct our operations and execute our business plan, however, we have not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if any of John M. Climaco, Christopher Downs, Sandra Silberman, or Donald Picker die or become disabled, we will not receive any compensation to assist with such person's absence. The loss of such person could negatively affect us and our operations.

There are limited suppliers for active pharmaceutical ingredients ("API") used in our drug candidates. Problems with the third parties that manufacture the API used in our drug candidates, or in the supply chain between the manufacturer and CNS, may delay our clinical trials or subject us to liability.

We do not currently own or operate manufacturing facilities for clinical or commercial production of the API used in any of our drug candidates. We have no experience in API manufacturing, and we lack the resources and the capability to manufacture any of the APIs used in our drug candidates, on either a clinical or commercial scale. As a result, we rely on third parties to supply the API used in each of our drug candidates and commercial couriers to deliver the manufactured API to us. We expect to continue to depend on third parties to supply the API for our current and future product candidates and to supply the API in commercial quantities. We are ultimately responsible for confirming that the APIs used in our product candidates are manufactured in accordance with applicable regulations.

Our third-party suppliers and couriers may not carry out their contractual obligations or meet our deadlines. In addition, the API they supply to us may not meet our specifications and quality policies and procedures or they may not be able to supply the API in commercial quantities. If we need to find alternative suppliers for the API used in any of our product candidates, we may not be able to contract for such supplies on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers or couriers would have an adverse effect on our ability to continue clinical development of our product candidates or commercialization of our product candidates.

If our third-party drug suppliers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we could be subject to certain product liability claims in the event such failure to comply resulted in defective product that caused injury or harm.

We may not be able to recover from any catastrophic event affecting our suppliers.

Our suppliers may not have adequate measures in place to minimize and recover from catastrophic events that may substantially destroy their capability to meet customer needs and any measures they may have in place may not be adequate to recover production processes quickly enough to support critical timelines or market demands. These catastrophic events may include weather and geologic events such as tornadoes, earthquakes, floods, tidal waves, volcanic eruptions, and fires as well as infectious disease epidemics, acts of war, acts of terrorism and nationalization of private industry. In addition, these catastrophic events may render some or all of the products at the affect facilities unusable.

We may be materially adversely affected in the event of cyber-based attacks, network security breaches, service interruptions, or data corruption.

We rely on information technology to process and transmit sensitive electronic information and to manage or support variety of business processes and activities. We use technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements. Our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shut down student computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, technology for communication failures, user errors or catastrophic events. Although we have developed systems and processes that are designed to protect proprietary or confidential information and prevent data loss and other security breaches, such measures cannot provide absolute security. If our systems are breached or suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may significantly suffer and we may be subject to litigation, government enforcement actions or potential liability. Security breaches could also cause us to incur significant remediation costs, result in product development delays, disrupt key business operations, including development of our product candidates, and divert attention of management and key information technology resources.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance limit. Events involving limitations to liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, the FDIC, took control and was appointed receiver of Silicon Valley Bank (to which the Company had no exposure). If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

Risks Related to Our Common Stock

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

We are required pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, 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. Our management concluded that our internal controls over financial reporting were, and continue to be, ineffective as of December 31, 2024, identified a material weakness in our internal controls due to the lack of sufficient personnel to allow for segregation of duties (resulting from the limited number of personnel available), limited access to timely and complete information regarding the status of costs incurred in the activation of investigational sites and costs from treating patients in our study which is a result of the use of a third-party Contract Research Organization (“CRO”) to manage the study, and the lack of formal documentation of our control environment. While management is working to remediate the material weaknesses, 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.

Failure to continue improving our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, and the related rules and regulations of the SEC. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

Management performed an annual assessment as of December 31, 2024 of the effectiveness of our internal control over financial reporting for its annual report. Our management concluded that our internal control over financial reporting was, and continues to be, ineffective as of December 31, 2024, due to material weaknesses in our internal controls due to the lack of segregation of duties (resulting from the limited number of personnel available), limited access to timely and complete information regarding the status of costs incurred in the activation of investigational sites and costs from treating patients in our study which is a result of the use of a third-party Contract Research Organization ("CRO") to manage the study, and the lack of formal documentation of our control environment. For as long as we remain an "emerging growth company" as defined in the JOBS Act, we have and intend to consider to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We may continue to take advantage of these reporting exemptions until we are no longer an "emerging growth company." To mitigate the lack of segregation of duties material weaknesses, we engaged an outside firm to assist management with such accounting and will continue to use outside firms as a resource to deal with other non-recurring or unusual transactions. However, notwithstanding our mitigation efforts, there is no assurance we will not encounter accounting errors in the future. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

Our current stockholders' ownership may be diluted if additional capital stock is issued to raise capital, to finance acquisitions or in connection with strategic transactions.

We intend to seek to raise additional funds, finance acquisitions or develop strategic relationships by issuing equity or convertible debt securities, which would reduce the percentage ownership of our existing stockholders. Our board of directors has the authority, without action or vote of the stockholders, to issue all or any part of our authorized but unissued shares of common or preferred stock. Our articles of incorporation authorize us to issue up to 300,000,000 shares of common stock and 5,000,000 shares of preferred stock. Future issuances of common or preferred stock would reduce your influence over matters on which stockholders vote and would be dilutive to earnings per share. In addition, any newly issued preferred stock could have rights, preferences, and privileges senior to those of the common stock. Those rights, preferences, and privileges could include, among other things, the establishment of dividends that must be paid prior to declaring or paying dividends or other distributions to holders of our common stock or providing for preferential liquidation rights. These rights, preferences and privileges could negatively affect the rights of holders of our common stock, and the right to convert such preferred stock into shares of our common stock at a rate or price that would have a dilutive effect on the outstanding shares of our common stock.

We have in the past been unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, and any future failure to maintain compliance could subject our common stock to be delisted from The Nasdaq Capital Market, which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on The Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly-held shares, market value of listed shares, minimum bid price per share, and minimum stockholder's equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from The Nasdaq Capital Market.

During 2024, we were not in compliance with the requirement to maintain a closing bid price of $1.00 per share (the "Minimum Bid Price Requirement") pursuant to Nasdaq Listing Rule 5550(a)(2), and we were not in compliance with the minimum $2,500,000 stockholders' equity requirement for continued listing set forth in Listing Rule 5550(b) (the "Equity Requirement"). As of the date of this filing, we are in compliance with both requirements. However, with respect to the Equity Requirement, pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we are subject to a Mandatory Panel Monitor until September 10, 2025. If, within that monitoring period, the Staff finds us again out of compliance with the Equity Requirement, notwithstanding Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and Staff will not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Listing Rule 5810(c)(3). With respect to the Minimum Bid Price Requirement, since we completed a reverse split on February 21, 2025, if we fall out of compliance with the Minimum Bid Price Requirement prior to February 21, 2026, we will not be eligible for any compliance period specified in Listing Rule 5810(c)(3)(A). In either case described in the preceding two sentences, the Staff will issue a Delist Determination Letter and we will have an opportunity to request a hearing. Our common stock may be at that time be delisted from Nasdaq.

There can be no assurance that we will continue to meet the continued listing requirements of The Nasdaq Capital Market and could be subject to delisting at a future time. Delisting from The Nasdaq Capital Market would adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

We may be required to repurchase certain of our warrants upon a fundamental transaction, which may prevent or deter a third party from acquiring us.

Certain of our warrants to purchase common stock provide that in the event of a "Fundamental Transaction" (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our common stock), each warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the warrant for a purchase price in cash equal to the Black-Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such common warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.

General Risk Factors

As a biotechnology company, we may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. As a small-cap company, we are more likely than our larger competitors to lack coverage from securities analysts. In addition, even if we receive analyst coverage, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline.

As an "emerging growth company" under the Jumpstart Our Business Startups Act, or JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements.

As an "emerging growth company" under the JOBS Act, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. We are an emerging growth company until the earliest of:

- the last day of the fiscal year during which we have total annual gross revenues of $1.235 billion or more;
- the last day of the fiscal year following the fifth anniversary of our IPO, which occurred in November 2019;
- the date on which we have, during the previous 3-year period, issued more than $1 billion in non-convertible debt; or
- the date on which we are deemed a "large accelerated issuer" as defined under the federal securities laws.

For so long as we remain an emerging growth company, we will not be required to:

- have an auditor report on our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis);
- submit certain executive compensation matters to shareholders advisory votes pursuant to the "say on frequency" and "say on pay" provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010;
- include detailed compensation discussion and analysis in our filings under the Securities Exchange Act of 1934, as amended, and instead may provide a reduced level of disclosure concerning executive compensation;
- may present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A; and
- are eligible to claim longer phase-in periods for the adoption of new or revised financial accounting standards under §107 of the JOBS Act.

We intend to take advantage of all of these reduced reporting requirements and exemptions, other than the longer phase-in periods for the adoption of new or revised financial accounting standards under §107 of the JOBS Act.

Certain of these reduced reporting requirements and exemptions were already available to us due to the fact that we also qualify as a "smaller reporting company" under SEC rules. For instance, smaller reporting companies are not required to obtain an auditor attestation and report regarding management's assessment of internal control over financial reporting; are not required to provide a compensation discussion and analysis; are not required to provide a pay-for-performance graph or CEO pay ratio disclosure; and may present only two years of audited financial statements and related MD&A disclosure.

We cannot predict if investors will find our securities less attractive due to our reliance on these exemptions. If investors were to find our common stock less attractive as a result of our election, we may have difficulty raising financing in the future.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

There have been an increasing number of cyberattacks on companies around the world, which have caused operational failures, compromised sensitive corporate or customer data, and/or resulted in significant financial damages. These attacks have occurred over the internet, through malware, viruses or attachments to e-mails, or through inside actors with access to systems within the organization.

Risk Management and Strategy

We have recently implemented additional security measures as part of an evolving cybersecurity posture and will continue to devote resources to address security vulnerabilities in an effort to prevent cyberattacks and mitigate the damage that could result from such an attack. All employees have recently begun receiving cybersecurity training and other education regarding their use of computers, information technology, and sensitive data including specifically how to recognize common attack strategies. As the Company does not have a physical office location, it does not have a local network or in-house servers and proprietary applications. We therefore utilize third parties applications and resources to support our information technology ("IT") needs. All applications utilized by the Company are Software as a Service ("SaaS") offerings. As our applications are developed and managed by third parties, we are dependent on these providers for many functions including disaster recovery during a disaster or cyber incident. Our goal is to only utilize the most secure and trusted providers for our IT needs. Our business continuity plans are evaluated against evolving security and service level standards, which includes evaluating those cybersecurity threats associated with our use of key third party service providers.

Our cybersecurity management strategy consists of utilizing a combination of employee education, preventative controls, detective controls, and periodic third-party cybersecurity testing. During fiscal year 2023 we began to deploy and utilize enterprise scale technology to support an appropriate cybersecurity posture including: endpoint detection and response, firewalls, security information and event management, email security, multifactor authentication, and vulnerability management. As part of the service offering from our outsourced IT security services provider, cybersecurity related alerts will be issued to us as relevant situations develop. These alerts will be evaluated in concert with our IT provider and in the event an alert requires action within our environment, such actions will be taken promptly. Our process and cybersecurity posture will continue to be refined based on the results of periodic cybersecurity assessments conducted jointly with our IT provider. We have recently begun reporting on cybersecurity in reports to the Board of Directors and will continue to do so.

To operate our business, we rely upon certain third-party service providers to perform a variety of functions, such as outsourced business critical functions, clinical research, professional services, SaaS platforms, managed services, cloud-based infrastructure, content delivery, encryption and authentication technology, corporate productivity services, and other functions. We are developing certain vendor management processes designed to help to manage cybersecurity risks associated with our use of certain of these providers. Depending on the nature of the services provided, the sensitivity and quantity of information processed, and the identity of the service provider, our vendor management process may include reviewing the cybersecurity practices of such provider, contractually imposing obligations on the provider related to the services they provide and/or the information they process, conducting security assessments, conducting on-site inspections, requiring their completion of written questionnaires regarding their services and data handling practices, and conducting periodic re-assessments during their engagement. For our largest third-party provider, our Contract Research Organization ("CRO") which is helping us manage our global trial of Berubicin, we are currently conducting a security assessment and review including their cybersecurity practices, protocols and protections, handling of information protected by HIPAA, and physical security.

Governance

The Board of Directors is responsible for oversight of cybersecurity risk. Our Chief Financial Officer and Chief Executive Officer are the members of management responsible for managing and assessing our cybersecurity practices and have recently commenced reporting on such practices and risks. The plan for the future is that they will continue to report to the Board on cybersecurity at least quarterly. Should any cybersecurity threat or incident be detected, our senior management team would timely report such threat or incident to the Board of Directors and provide regular communications and updates throughout the incident and any subsequent investigation, in order that the impact, materiality, and reporting requirements of such incident are appropriately identified and assessed for further necessary or appropriate action to be taken.

We believe we are appropriately staffed (as supported by our outsourced IT provider) to support a healthy cybersecurity posture given our size and scope. Our Chief Financial Officer, who reports to the Chief Executive Officer, is directly responsible for IT functions and has earned a Master of Business Administration and also a Master of Science degree in Accounting with a Management Information Systems concentration.

To date, there have been no risks identified from cybersecurity threats or previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect the company. However, despite all of the above aforementioned efforts, a cyberattack, if it occurred, could cause system operational problems, disrupt service to clinical trial sites, compromise important data or systems or result in an unintended release of confidential information. See “Item 1A. Risk Factors” for additional discussion of cybersecurity risks impacting our Company.

Item 2. Properties.

Our corporate and executive offices are located in a leased facility in Houston, Texas. We believe our facilities are sufficient to meet our current needs and that suitable space will be available as and when needed. We do not own any real property.

Item 3. Legal Proceedings.

From time to time in the ordinary course of our business, we may be involved in legal proceedings, the outcomes of which may not be determinable. The results of litigation are inherently unpredictable. Any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, require significant amounts of management time and result in diversion of significant resources. However, we are currently not a party to any pending legal actions. We have insurance policies covering any potential losses where such coverage is cost effective.

We are not at this time involved in any additional legal proceedings that we believe could have a material effect on our business, financial condition, results of operations or cash flows.

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.

Our common stock has been listed on the NASDAQ Capital Market under the symbol "CNSP" since November 8, 2019.

Holders of Common Equity

As of March 28, 2025, we had approximately 5 stockholders of record of our common stock holding shares directly with the transfer agent. This does not include beneficial owners of our common stock.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in any financing instruments, provisions of applicable law and other factors the board deems relevant.

Recent Sales of Unregistered Securities

Except as previously disclosed on Form 8-K, there were no sales of unregistered securities during the year ended December 31, 2024.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the year ended December 31, 2024.

Equity Compensation Plan Information

See Part III, Item 12 to this Form 10-K for information relating to securities authorized for issuance under our equity compensation plans.

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 results of operations in conjunction with the financial statements and the related notes appearing elsewhere in this Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties, including those set forth under "Cautionary Statement About Forward-Looking Statements." Actual results and experience could differ materially from the anticipated results and other expectations expressed in our forward-looking statements as a result of a number of factors, including but not limited to those discussed in this Item and in Item 1A - "Risk Factors." Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this Form 10-K.

Overview

We are a clinical stage pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anti-cancer drug candidates for the treatment of brain and central nervous system tumors, based on intellectual property that we license under license agreement Cortice and own pursuant to a collaboration and asset purchase agreement with Reata.

We believe our drug candidates, TPI 287 and Berubicin, may be significant developments in the treatment of Glioblastoma and other CNS malignancies, and if approved by the FDA could give Glioblastoma patients an important new therapeutic alternative to the current standard of care. Glioblastoma are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. TPI 287 is an abeotaxane (derived from the taxane family of drugs) and Berubicin is an anthracycline. Both of these are classes of drugs that are among the most powerful and extensively used chemotherapy drugs known. Based on clinical and preclinical data, we believe TPI 287 is the first taxane to appear to cross the BBB and Berubicin is the first anthracycline to appear to cross the BBB, both in significant concentrations targeting brain cancer cells. While our focus is currently on the development of TPI 287 and Berubicin, we are also in the process of attempting to secure intellectual property rights to additional compounds that we plan to develop into drugs to treat CNS cancers.

TPI 287 represents a promising candidate for treating cancers involving the CNS, as well as those that have become resistant to traditional taxane therapies. While it has shown promise in limited clinical trials, further clinical development is necessary to determine its future in neuro-oncology. TPI 287 is an abeotaxane and is an investigational chemotherapy agent classified as a third-generation taxane derivative. It was developed to address some of the limitations of earlier taxanes like paclitaxel (Taxol) and docetaxel (Taxotere), particularly issues related to drug resistance and poor penetration of the BBB. As a synthetic, lipophilic compound, TPI 287 is designed to be brain-penetrant, allowing it to reach CNS tumors more effectively than its predecessors. Like other taxanes, TPI 287's mechanism of action is to stabilize microtubules, which disrupts cell division and induces apoptosis. However, one of its notable advantages is its reduced susceptibility to drug efflux pumps such as P-glycoprotein (P-gp), a common mechanism by which cancer cells develop resistance to chemotherapy. This feature gives TPI 287 potential utility in treating drug-resistant cancers in the CNS.

TPI 287 had previously been granted Orphan Drug Designation by the FDA. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD strengthens our intellectual property protections although the Company is exploring if there are other patents that could be filed related to TPI 287 to extend additional protections.

Berubicin was discovered at UTMDACC by Dr. Waldemar Priebe, the founder of the Company. Through a series of transactions, Berubicin was initially licensed to Reata. Reata initiated several Phase I clinical trials with Berubicin for CNS malignancies, one of which was for malignant gliomas, but subsequently allowed their IND with the FDA to lapse for strategic reasons. This required us to obtain a new IND for Berubicin before beginning further clinical trials. On December 17, 2020, we announced that our IND application with the FDA for Berubicin for the treatment of Glioblastoma Multiforme was in effect. We dosed the first patient in this trial during the third quarter of 2021. Correspondence between the Company and the FDA resulted in modifications to our initial trial design, including designating overall survival (OS) as the primary endpoint of the study. OS is a rigorous endpoint that the FDA has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.

We do not have manufacturing facilities and all manufacturing activities are contracted out to third parties. Additionally, we do not have a sales organization.

On November 21, 2017, we entered into a Collaboration and Asset Purchase Agreement with Reata (the "Reata Agreement"). Pursuant to the Reata Agreement we purchased all of Reata's intellectual property and development data regarding Berubicin, including all trade secrets, knowhow, confidential information and other intellectual property rights.

On December 28, 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from HPI in an agreement we refer to as the HPI License. HPI is affiliated with our founder, Dr. Priebe. Under the HPI License we obtained the exclusive right to develop certain chemical compounds for use in the treatment of cancer anywhere in the world. In the HPI License we agreed to pay HPI: (i) development fees of $750,000 over a three-year period beginning November 2019; (ii) a 2% royalty on net sales; (iii) a $50,000 per year license fee; (iv) milestone payments of $100,000 upon the commencement of a Phase II trial and $1.0 million upon the approval of an NDA for Berubicin; and (v) 3 shares of our common stock. The patents we licensed from HPI expired in March 2020. On March 23, 2025, the Company terminated the HPI License.

On June 10, 2020, the FDA granted Orphan Drug Designation ("ODD") for Berubicin for the treatment of malignant gliomas. The ODD now constitutes our primary intellectual property protection for Berubicin although the Company is exploring if there are other patents that could be filed related to Berubicin to extend additional protections.

On January 10, 2020, we entered into a Patent and Technology License Agreement (the "WP1244 Agreement") with The Board of Regents of The University of Texas System, an agency of the State of Texas, on behalf of the UTMDACC. Pursuant to the WP1244 Agreement, we obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to our portfolio of WP1244 drug technology. On April 25, 2024, UTMDACC provided notice to us if its intent to terminate the WP1244 Agreement if we fail to pay the annual maintenance fee of $50,000, as well as $1,300 in expenses. On May 25, 2024 the WP1244 Agreement was terminated. There are no termination penalty provisions in the Agreement.

On July 24, 2021, the Company received Fast Track Designation from the FDA for Berubicin. Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need

On July 29, 2024, the Company entered into an Exclusive License Agreement and Stock Purchase Agreement (collectively, the "Cortice Agreements") with Cortice Biosciences, Inc. ("Cortice") pursuant to which Cortice granted the Company an exclusive license to the intellectual property rights related to certain patents around the compound TPI 287 in the United States, Canada, Mexico and Japan. The term of the license will expire, other than due to a breach of the Cortice Agreements, at the end of the royalty term with respect to any licensed product in any of the included territories, which begins upon the first commercial sale in such territory and ends on the latest of (i) ten years after such sale, (ii) the expiration of regulatory or marketing exclusivity for such licensed product in such country, or (c) the expiration of the last to expire valid patent claim in such country covering such licensed product.

Our plan of operations is primarily focused on completing a clinical trial for TPI 287 and finishing the on-going trial of Berubicin. We estimate that we have sufficient capital to take us into the first quarter of 2026, a period during which we would likely expect to initiate a trial of TPI 287, as well as complete the Berubicin trial including its final analysis. In addition, we have working capital to fund our operations during this period (with such operations estimated at $4.5 to $5.0 million per annum). We do not currently have a firm trial design for TPI 287 so estimates of development cost are not available, however, regardless of trial design, the cost of bringing TPI 287 to regulatory approval for marketing will require significant additional financing. The timing and costs of clinical trials are difficult to predict and as such the foregoing estimates may prove to be inaccurate. We have no commitments for such additional needed financing and will likely be required to raise such financing through the sale of additional equity or debt securities.

Results of Operations for the Year Ended December 31, 2024 Compared to the Year Ended December 31, 2023

General and Administrative Expense

General and administrative expense was approximately $5,612,000 for the year ended December 31, 2024 compared to approximately $4,770,000 for 2023. The increase in general and administrative expense was mainly attributable to increase of approximately $756,000 in professional expenses, $440,000 in employee compensation. These changes were offset by decrease of approximately $104,000 in stock-based compensation, $49,000 in insurance expenses, $21,000 in travel expenses, board of director compensation of $9,000, advertising and marketing of $119,000 and other general and administrative expenses of $52,000.

Research and Development Expense

Research and development expense was approximately $9,290,000 for the year ended December 31, 2024 compared to approximately $14,096,000 for 2023. The decrease in research and development expenses during the period was mainly attributed to the timing of research organization (CRO) expenses and patient treatment costs related to continued progress with our clinical trial for Berubicin. Our CRO expenditures are primarily for labor related to activating selected trial sites, managing patient enrollment processes, collecting and managing data from patient treatments throughout the trial, processing reimbursement to the sites for patient treatment, and assisting with necessary submissions to amend the IND. CRO expenditures are expected to begin to taper off throughout the remainder of the trial as we are no longer activating sites and no longer enrolling patients after January 2024. We expect our research and development costs to taper off in the near future as we move toward completion of our clinical trial for Berubicin primarily due to patients moving from active treatment to follow-up leading to decreasing costs of treating and following these patients as more patients eventually succumb to their disease, then toward year end 2025 we expect costs related to the future trial of TPI 287 to begin increasing to levels similar to those seen during our trial of Berubicin.

Other Income (Expense)

Interest income was approximately $60,000 and $28,000 for the years ended December 31, 2024 and 2023, respectively. Interest expense was approximately $16,000 and $14,000 for the years ended December 31, 2024 and 2023, respectively.

Net Loss

The net loss for the year ended December 31, 2024 was approximately $14,858,000 compared to approximately $18,851,000 for 2023. The change in net loss is primarily attributable to increased research and development costs.

Liquidity and Capital Resources

On December 31, 2024, we had cash of approximately $6,461,000 and we had a working capital of approximately $6,134,000. We have historically funded our operations from proceeds from debt and equity sales.

On February 1, 2024, the Company completed a public offering of (i) 889 shares of common stock; (ii) pre-funded warrants to purchase 4,448 shares of common stock; (iii) Series A Warrants to purchase up to an aggregate of 5,342 shares of common stock ; and (iv) Series B Warrants to purchase up to an aggregate of 5,342 shares of common stock The net proceeds to the Company from the offering were $3,331,000, after deducting the placement agents' fees and other offering expenses.

On June 14, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 6,720 shares of common stock and pre-funded warrants to purchase 601 shares of common stock in lieu thereof in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 7,321 shares of common stock. The gross proceeds to the Company from the offering was approximately $1.37 million, resulting in net proceeds, after payment of commissions and expenses, received by the Company of $1,203,267.

On June 26, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 11,360 shares of common stock in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 11,360 shares of common stock. The gross proceeds to the Company from the offering were approximately $1.39 million resulting in net proceeds, after payment of commissions and expenses, received by the Company of $1,221,146.

On July 3, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 28,500 shares of common stock in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 28,500 shares of common stock. The gross proceeds to the Company from the offering were approximately $1.98 million, before deducting the financial advisor fees and other estimated offering expenses payable by the Company. After payment of commissions and expenses, the proceeds received by the Company was $1,787,000.

On July 26, 2024, the Company entered into a Sales Agreement (the "AGP ATM Sales Agreement") with A.G.P./Alliance Global Partners ("AGP"). Pursuant to the terms of the AGP ATM Sales Agreement, the Company originally was permitted to sell from time to time through AGP, as sales agent or principal, shares of the Company's common stock, par value $0.001 per share with initial aggregate sales price of up to $5.2 million. On July 30, 2024, the Company increased the aggregate sales price of common shares that may be sold under the AGP ATM Sales Agreement to $25.0 million (not including the original $5.2 million). On March 20, 2025, the Company increased the aggregate sales price of common shares that may be sold under the AGP ATM Sales Agreement to $43.5 million (including $6.4 million remaining from the previous increase). As of December 31, 2024, the Company has sold 991,773 shares pursuant to the AGP ATM Sales Agreement for net proceeds of approximately $13.7 million. $882,539 of the net proceeds was deposited on January 10, 2025. As of December 31, 2024, the Company recorded a subscription receivable for $882,539.

On October 23, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 74,000 shares of common stock in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 278,943 shares of common stock. The gross proceeds to the Company from the offering were approximately $3 million, before deducting the financial advisor fees and other estimated offering expenses payable by the Company. After payment of commissions and expenses, the proceeds received by the Company was $2,725,907.

We estimate that we have sufficient capital to take us into the first quarter of 2026, a period during which we would likely expect to initiate a trial of TPI 287, as well as complete the Berubicin trial including its final analysis. In addition, we have working capital to fund our operations during this period (with such operations estimated at $4.5 to $5.0 million per annum). We do not currently have a firm trial design for TPI 287 so estimates of development cost are not available, however, regardless of trial design, the cost of bringing TPI 287 to regulatory approval for marketing will require significant additional financing. The timing and costs of clinical trials are difficult to predict and as such the foregoing estimates may prove to be inaccurate. We have no commitments for such additional needed financing and will likely be required to raise such financing through the sale of additional equity or debt securities.

We will need to raise significant additional capital in the future in order to meet our future obligations and execute our business plan. If we are unable to raise sufficient funds, we will be required to develop and implement an alternative plan to further extend payables, reduce overhead or scale back our business plan until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful and if it is not successful we may need to cease operations entirely.

Summary of Cash Flows

Cash used in operating activities

Net cash used in operating activities was approximately $17,113,000 and $14,140,000 for the years ended December 31, 2024 and 2023, respectively, and mainly included payments made for drug development (including the cost of our trial of Berubicin), contract labor, officer compensation, stock-based compensation, marketing and professional fees to our consultants, attorneys and accountants.

Cash used in investing activities

Net cash used in investing activities was approximately $4,000 and $4,000 for the years ended December 31, 2024 and 2023 and included payments for furniture and equipment.

Cash provided by financing activities

Net cash provided by financing activities was approximately $23,030,000 and $4,637,000 for the years ended December 31, 2024 and 2023, respectively. We received net proceeds of approximately $23,376,000 from the issuance of common stock during the year ended December 31, 2024.

Off-balance Sheet Arrangements

As of December 31, 2024, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Purchase Commitments

We do not have any material commitments for capital expenditures, although we are required to pay certain milestone fees and royalties to Reata and Cortice as described in the section "Overview" above.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, exempts an "emerging growth company" such as us from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates, assumptions and judgments that affect the amounts reported in the financial statements, including the notes thereto. We consider critical accounting policies to be those that require more significant judgments and estimates in the preparation of our financial statements. Management relies on historical experience and other assumptions believed to be reasonable in making its judgment and estimates. Actual results could differ materially from those estimates.

Management believes its application of accounting policies, and the estimates inherently required therein, are reasonable. These accounting policies and estimates are periodically reevaluated, and adjustments are made when facts and circumstances dictate a change. As of December 31, 2024, there was no critical audit estimates.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

CNS Pharmaceuticals, Inc.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
CNS Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CNS Pharmaceuticals, Inc (the "Company") as of December 31, 2024 and 2023, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

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

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2019.
Houston, Texas
March 31, 2025

CNS Pharmaceuticals, Inc.
Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 6,461,378	$ 548,721
Deferred offering costs	20,637	202,859
Subscription receivable	882,539	–
Prepaid expenses and other current assets	1,293,954	839,590
Total current assets	8,658,508	1,591,170
Noncurrent Assets:		
Prepaid expenses, net of current portion	36,430	104,750
Property and equipment, net	6,005	4,933
Total noncurrent assets	42,435	109,683
Total Assets	$ 8,700,943	$ 1,700,853
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 2,198,260	$ 5,832,162
Notes payable	326,072	300,806
Total current liabilities	2,524,332	6,132,968
Total Liabilities	2,524,332	6,132,968
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and 0 shares issued and outstanding	–	–
Common stock, $0.001 par value, 300,000,000 shares authorized and 1,413,556 and 2,486 shares issued and outstanding, respectively	1,414	2
Additional paid-in capital	90,599,901	65,134,786
Accumulated deficit	(84,424,704)	(69,566,903)
Total Stockholders' Equity (Deficit)	6,176,611	(4,432,115)
Total Liabilities and Stockholders' Equity (Deficit)	$ 8,700,943	$ 1,700,853

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Operations

	Year ended December 31, 2024	Year ended December 31, 2023
Operating expenses:		
General and administrative	$ 5,611,800	$ 4,769,502
Research and development	9,290,143	14,095,606
Total operating expenses	14,901,943	18,865,108
Loss from operations	(14,901,943)	(18,865,108)
Other income (expenses):		
Interest income	60,262	27,687
Interest expense	(16,120)	(13,805)
Total other income (expense)	44,142	13,882
Net loss	$ (14,857,801)	$ (18,851,226)
Loss per share - basic	$ (38.87)	$ (12,509.11)
Loss per share - diluted	$ (38.87)	$ (12,509.11)
Weighted average shares outstanding - basic	382,241	1,507
Weighted average shares outstanding - diluted	382,241	1,507

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Stockholders' Equity (Deficit)
For the years ended December 31, 2024 and 2023

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance December 31, 2022	636	$ 1	$ 58,848,532	$ (50,715,677)	$ 8,132,856
Common stock issued for cash, net	342	–	2,317,599	–	2,317,599
Exercise of warrants	1,507	1	2,961,238	–	2,961,239
Stock-based compensation	1	–	1,007,417	–	1,007,417
Net loss	–	–	–	(18,851,226)	(18,851,226)
Balance December 31, 2023	2,486	2	65,134,786	(69,566,903)	(4,432,115)
Common stock issued for cash and warrants, net	1,113,242	1,114	24,008,828	–	24,009,942
Exercise of warrants, net	284,006	284	21,041	–	21,325
Stock-based compensation	–	–	838,957	–	838,957
Shares issued for license agreement	11,468	12	596,291	–	596,303
Stock issued for stock split rounding	2,354	2	(2)	–	–
Net loss	–	–	–	(14,857,801)	(14,857,801)
Balance December 31, 2024	1,413,556	$ 1,414	$ 90,599,901	$ (84,424,704)	$ 6,176,611

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Cash Flows

	Years Ended December 31, 2024	Years Ended December 31, 2023
Cash Flows from Operating Activities:		
Net loss	$ (14,857,801)	$ (18,851,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	838,957	1,007,417
Depreciation	3,306	4,134
Common stock issued for license agreement	596,303	–
Loss on disposal of fixed assets	(190)	498
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(59,972)	2,377,275
Accounts payable and accrued expenses	(3,633,902)	1,321,871
Net cash used in operating activities	(17,113,299)	(14,140,031)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(4,188)	(3,901)
Net cash used in investing activities	(4,188)	(3,901)
Cash Flows from Financing Activities:		
Payments of deferred offering costs	(66,750)	(202,859)
Payments on notes payable	(300,806)	(438,733)
Proceeds from exercise of warrants	21,325	2,961,239
Proceeds from sale of common stock	23,376,375	2,317,599
Net cash provided by financing activities	23,030,144	4,637,246
Net change in cash and cash equivalents	5,912,657	(9,506,686)
Cash and cash equivalents, at beginning of period	548,721	10,055,407
Cash and cash equivalents, at end of period	$ 6,461,378	$ 548,721
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 13,599	$ 13,805
Cash paid for income taxes	$ –	$ –
Supplemental disclosure of non-cash investing and financing activities:		
Prepaid expense financed with note payable	$ 326,072	$ 329,571
Reclassification of deferred offering costs to equity	248,972	–
Common stock issued for subscription receivable	882,539	–
Stock issued for stock split rounding	2	–

See accompanying notes to the financial statements.

Note 1 – Nature of Business

CNS Pharmaceuticals, Inc. ("we", "our", the "Company") is a clinical pharmaceutical company organized as a Nevada corporation on July 27, 2017 to focus on the development of anti-cancer drug candidates.

On April 30, 2024, the stockholders of the Company approved an amendment to the Company's amended and restated articles of incorporation (the "Amendment") to effect the reverse stock split at a ratio in the range of 1-for-2 to 1-for-50. The reverse stock split became effective on June 4, 2024 on a 1-for-50 basis without any change in the par value per share, which remained at $0.001. The reverse stock split has been retroactively adjusted throughout these financial statements and footnotes.

On November 26, 2024, the stockholders of the Company approved an amendment to the Company's amended and restated articles of incorporation (the "Amendment") to effect the reverse stock split at a ratio in the range of 1-for-2 to 1-for-50. The reverse stock split became effective on February 21, 2025 on a 1-for-50 basis without any change in the par value per share, which remained at $0.001. The reverse stock split has been retroactively adjusted throughout these financial statements and footnotes.

Note 2 – Summary of Significant Accounting Policies

The accompanying financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and in accordance with the rules and regulations of the United States Securities and Exchange Commission (the "SEC"). The Company's fiscal year end is December 31.

Use of Estimates in Financial Statement Presentation - The preparation of these financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Liquidity and Going Concern - These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain equity financings to continue operations. The Company has a history of and expects to continue to report negative cash flows from operations and a net loss. Management believes that the cash on hand, combined with aggressive working capital management, will allow us to continue operating Within one year after the date that the financial statements are issued. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements, other collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

Cash and Cash Equivalents - The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically, the Company may carry cash balances at financial institutions in excess of the federally insured limit of $250,000. The amount in excess of the FDIC insurance at December 31, 2023 was $6,211,378. The Company has not experienced losses on these accounts and management believes, based upon the quality of the financial institutions, that the credit risk with regard to these deposits is not significant.

Property and Equipment - Property and equipment is recorded at cost and depreciated over their estimated useful lives using the straight-line depreciation method as follows:

Leasehold improvement	**Shorter of estimated useful lives or the term of the lease**
Computer equipment	3 years
Machinery and equipment	5 years
Furniture and office equipment	7 years

Repairs and maintenance costs are expensed as incurred.

Impairment of Long-lived Assets - The Company evaluates its long-lived tangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of a long-lived asset is measured by comparison of the carrying amount to the expected future undiscounted cash flows that the asset is expected to generate. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value.

Fair Value of Financial Instruments - The carrying value of short-term instruments, including cash and cash equivalents, accounts payable and accrued expenses, and short-term notes approximate fair value due to the relatively short period to maturity for these instruments.

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value maximize the use of observable inputs and minimize the use of unobservable inputs. The Company utilizes a three-level valuation hierarchy for disclosures of fair value measurements, defined as follows:

Level 1 - inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.

Level 3 - inputs to the valuation methodology are unobservable and significant to the fair value.

The Company does not have any assets or liabilities that are required to be measured and recorded at fair value on a recurring basis.

Related Parties - The Company follows ASC 850, Related Party Disclosures, for the identification of related parties and disclosure of related party transactions.

Income Taxes - The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of reported assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company must then assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of Accounting Standards Codification (ASC) 740-10 which prescribes a recognition threshold and measurement attribute for financial statement disclosure of tax positions taken, or expected to be taken, on its tax return. The Company evaluates and records any uncertain tax positions based on the amount that management deems is more likely than not to be sustained upon examination and ultimate settlement with the tax authorities in the tax jurisdictions in which it operates.

Stock-based Compensation - Employee and non-employee share-based compensation is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the requisite service period.

Restricted Stock Units ("RSUs") - Our RSUs vest over two or four years from the date of grant. The fair value of RSUs is the market price of our common stock at the date of grant.

Performance Units ("PUs") - The PUs vest based on our performance against predefined share price targets and the achievement of Positive Interim, Clinical Data as defined by the Board.

Loss Per Common Share - Basic loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, the weighted-average number of common shares outstanding excludes common stock equivalents, because their inclusion would be anti-dilutive. As of December 31, 2024, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 59,579 common shares, unvested restricted stock units of 114 common shares, unvested performance units of 5 and options for 270 common shares, respectively. As of December 31, 2023, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 1,732 common shares, unvested restricted stock units of 6 common shares, unvested performance units of 19 and options for 157 common shares, respectively.

Research and Development Costs - Research and development costs are expensed as incurred. The Company recognized the benefit of refundable research and development tax credits as a reduction of research and development expenses when there is reasonable assurance that the amount claimed will be recovered.

Segments Reporting

The Company manages its operations as a single segment for the purpose of assessing performance and making operating decisions. The Company's Chief Operating Decision Maker ("CODM") is its Chief Executive Officer. The CODM allocates resources and evaluates the performance of the Company using information about combined net income from operations. All significant operating decisions are based upon an analysis of the Company as one operating segment, which is the same as its reporting segment. See statement of operations for information about combined net income from operations.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure." The ASU updates reportable segment disclosure requirements, primarily through requiring enhanced disclosures about significant segment expenses and information used to assess segment performance. The amendments do not change how segments are determined, aggregated, or how thresholds are applied to determine reportable segments. We adopted ASU No. 2023-07 during the year ended December 31, 2024.

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses" to improve disclosures about the nature of expenses in commonly presented financial statement captions. ASU 2024-03 is effective for all public business entities for annual reporting periods beginning after December 15, 2026, on either a prospective or retrospective basis. Early adoption permitted. Management is currently evaluating the impact of this accounting standard update on its consolidated financial statements and related disclosures.

Note 3 – Note Payable

On November 28, 2024, the Company entered into a short-term note payable for an aggregate of $326,072, bearing interest at 9.24% per year to finance certain insurance policies. Principal and interest payments related to the note will be repaid over an 11-month period with the final payment due on October 8, 2025. As of December 31, 2024, the Company's note payable balance was $326,072.

On November 28, 2023, the Company entered into a short-term note payable for an aggregate of $329,571, bearing interest at 9.74% per year to finance certain insurance policies. Principal and interest payments related to the note will be repaid over an 11-month period with the final payment due on October 8, 2024. As of December 31, 2024 and 2023, the Company's note payable balance was $0 and $300,806, respectively.

Note 4 – Equity

The Company has authorized 75,000,000 shares of common stock having a par value of $0.001 per share. In addition, the Company authorized 5,000,000 shares of preferred stock to be issued having a par value of $0.001. The specific rights of the preferred stock shall be determined by the board of directors. On May 2, 2024, the Company filed a Certificate of Amendment to its Amended and Restated Articles of Incorporation with the Secretary of State of the State of Nevada to increase the number of the Company's authorized shares of common stock from 75,000,000 shares to 300,000,000 shares.

On April 30, 2024, the stockholders of the Company approved an amendment to the Company's amended and restated articles of incorporation (the "Amendment") to effect the reverse stock split at a ratio in the range of 1-for-2 to 1-for-50, with such ratio to be determined in the discretion of the Company's board of directors and with such reverse stock split to be effected at such time and date, if at all, as determined by the Company's board of directors in its sole discretion prior to the one-year anniversary of the annual meeting.

Pursuant to such authority granted by the Company's stockholders, the Company's board of directors approved a one-for-fifty (1:50) reverse stock split of the Company's common stock and the filing of the Amendment to effectuate the reverse split. The reverse stock split became effective on June 4, 2024 on a 1-for-50 basis without any change in the par value per share, which remained at $0.001. The reverse stock split has been retroactively adjusted throughout these financial statements and footnotes.

On April 30, 2024, the Company held its scheduled 2024 Annual Meeting of Stockholders at which the Company's stockholders approved amendments to the Company's 2020 Equity Plan (the "2020 Plan") including an increase in the number of shares of common stock, par value $0.001 per share, authorized for issuance under the 2020 Plan by 1,400 shares. As amended, the number of shares of the common stock that may be issued under the 2020 Plan is 1,739 shares (this includes the 1,400 share increase).

On November 26, 2024, the stockholders of the Company approved an amendment to the Company's amended and restated articles of incorporation (the "Amendment") to effect the reverse stock split at a ratio in the range of 1-for-2 to 1-for-50, with such ratio to be determined in the discretion of the Company's board of directors and with such reverse stock split to be effected at such time and date, if at all, as determined by the Company's board of directors in its sole discretion prior to the one-year anniversary of the annual meeting.

Pursuant to such authority granted by the Company's stockholders, the Company's board of directors approved a one-for-fifty (1:50) reverse stock split of the Company's common stock and the filing of the Amendment to effectuate the reverse split. The reverse stock split became effective on February 21, 2025 on a 1-for-50 basis without any change in the par value per share, which remained at $0.001. The reverse stock split has been retroactively adjusted throughout these financial statements and footnotes.

Common Stock

2024

On January 29, 2024, the Company entered into a placement agency agreement with A.G.P./Alliance Global Partners ("AGP") and Maxim Group LLC ("Maxim" and collectively with AGP, the "Placement Agents") (the "Placement Agreement") for the public offering by the Company of (i) 889 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock") (ii) pre-funded warrants to purchase 4,448 shares of Common Stock (the "Pre-Funded Warrants"); (iii) Series A Warrants to purchase up to an aggregate of 5,342 shares of Common Stock (the "Series A Warrants"); and (iv) Series B Warrants to purchase up to an aggregate of 5,342 shares of Common Stock (the "Series B Warrants", and together with the Series A Warrants, the "Common Warrants)). The Common Warrants and Pre-Funded Warrants are collectively referred to herein as the ("Warrants"). The combined purchase price of one share of Common Stock and accompanying Common Warrants was $750.00 and the combined purchase price of one Pre-Funded Warrant and accompanying Common Warrants was $747.50. In connection with the offering, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional investors that participated in the offering. As of December 31, 2024, 4,448 of the Pre-Funded Warrants have been exercised. The closing of the sales of these securities occurred on February 1, 2024. The net proceeds to the Company from the offering were $3,331,000, after deducting the placement agents' fees and other offering expenses.

On June 14, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 6,720 shares of the Company's common stock and pre-funded warrants to purchase 601 shares of common stock in lieu thereof (the "June 14 Pre-Funded Warrants") in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 7,321 shares of common stock (the "June 14 Common Warrants"). The combined purchase price of one share of common stock (or pre-funded warrant in lieu thereof) and accompanying June 14 Common Warrant was $187.50. The closing of this offering and private placement occurred on June 17, 2024.

Subject to certain ownership limitations, each of the June 14 Common Warrants is immediately exercisable, has an exercise price of $181.00 per share, and expire five years from the date of issuance. Each June 14 Pre-Funded Warrant is exercisable into one share of common stock at a price per share of $0.05 (as adjusted from time to time in accordance with the terms thereof). The gross proceeds to the Company from the offering was approximately $1.37 million, resulting in net proceeds, after payment of commissions and expenses, received by the Company of $1,203,267.

On June 26, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 11,360 shares of the Company's common stock in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 11,360 shares of common stock (the "June 26 Common Warrants"). The combined purchase price of one share of common stock and accompanying June 26 Common Warrant was $122.50. The closing of the offering and private placement occurred on June 27, 2024 (the "Closing Date").

Subject to certain ownership limitations, each of the June 26 Common Warrants is immediately exercisable, has an exercise price of $116.00 per share, and expire five years from the date of issuance. The June 26 Common Warrants may only be exercised on a cashless basis if there is no registration statement registering, or a prospectus contained therein in not available for, the resale of the shares of common stock underlying the June 26 Common Warrants. The gross proceeds to the Company from the offering were approximately $1.39 million resulting in net proceeds, after payment of commissions and expenses, received by the Company of $1,221,146.

On July 3, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 28,500 shares of the Company's common stock in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 28,500 shares of common stock (the "July 3 Common Warrants"). The combined purchase price of one share of common stock and accompanying July 3 Common Warrant is $69.50. The closing of this offering and private placement occurred on July 5, 2024.

Subject to certain ownership limitations, each of the July 3 Common Warrants is immediately exercisable, has an exercise price of $63.00 per share, and expire five years from the date of issuance. The gross proceeds to the Company from the offering were approximately $1.98 million, before deducting the financial advisor fees and other estimated offering expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the Common Warrants. After payment of commissions and expenses, the proceeds received by the Company was $1,787,000.

On July 26, 2024, the Company entered into a Sales Agreement (the "AGP ATM Sales Agreement") with A.G.P./Alliance Global Partners ("AGP"). Pursuant to the terms of the AGP ATM Sales Agreement, the Company originally was permitted to sell from time to time through AGP, as sales agent or principal, shares of the Company's common stock, par value $0.001 per share with initial aggregate sales price of up to $5.2 million. On July 30, 2024, the Company increased the aggregate sales price of common shares that may be sold under the AGP ATM Sales Agreement to $25.0 million (not including the original $5.2 million). On March 20, 2025, the Company increased the aggregate sales price of common shares that may be sold under the AGP ATM Sales Agreement to $43.5 million (including $6.4 million remaining from the previous increase). As of December 31, 2024, the Company has sold 991,773 Shares pursuant to the AGP ATM Sales Agreement for net proceeds of approximately $13.7 million. $882,539 of the net proceeds was deposited on January 10, 2025. As of December 31, 2024, the Company recorded a subscription receivable for $882,539.

On October 23, 2024, the Company entered into securities purchase agreements with institutional investors for the sale by the Company of 74,000 shares of the Company's common stock in a registered direct offering. In a concurrent private placement, the Company also sold to the investors unregistered warrants to purchase up to an aggregate of 278,943 shares of common stock (the "July 3 Common Warrants"). The per share purchase price of each share of common stock was $8.50 per share and the purchase price for each Pre-Funded Warrant was $8.45 per Pre-Funded Warrant. The closing of this offering and private placement occurred on October 23, 2024.

Subject to certain ownership limitations, each of the October 23 Common Warrants is immediately exercisable, has an exercise price of $0.05 per share, and expire five years from the date of issuance. The gross proceeds to the Company from the offering were approximately $3 million, before deducting the financial advisor fees and other estimated offering expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the Common Warrants. After payment of commissions and expenses, the proceeds received by the Company was $2,725,907.

Common share issued for license agreement

On July 29, 2024, the Company entered into an Exclusive License Agreement and Stock Purchase Agreement (collectively, the "Cortice Agreements") with Cortice Biosciences, Inc. ("Cortice") pursuant to which Cortice granted the Company an exclusive license to the intellectual property rights related to certain patents around the compound TPI 287 in the United States, Canada, Mexico and Japan. The term of the license will expire, other than due to a breach of the Cortice Agreements, at the end of the royalty term with respect to any licensed product in any of the included territories, which begins upon the first commercial sale in such territory and ends on the latest of (i) ten years after such sale, (ii) the expiration of regulatory or marketing exclusivity for such licensed product in such country, or (c) the expiration of the last to expire valid patent claim in such country covering such licensed product.

Pursuant to the Cortice Agreements, the Company agreed to issue Cortice 11,468 shares of the Company's common stock upon the closing of the transaction, which occurred on July 29, 2024, and 867 shares of Company common stock upon the receipt of shareholder approval of such issuance as required by the rules of the Nasdaq Stock Market. The Company also agreed to make milestone payments to Cortice in either cash or shares of Company common stock (at Cortice's option) upon: (i) meeting the primary endpoint a pivotal trial for a licensed product – either $15.0 million or 8,223 shares of Company common stock; (ii) FDA acceptance of an New Drug Application for a licensed product – either $30.0 million or 16,446 shares of Company common stock; (iii) the first commercial sale in the United States of a licensed product – either $45.0 million or 24,668 shares of Company common stock; and (iv) the first commercial sale in Japan of a licensed product – either $10.0 million or 4,112 shares of Company common stock. The Company's obligation to pay the above milestones in Company common stock is subject to the receipt of shareholder approval as required by the rules of the Nasdaq Stock Market. The Company also agreed to pay Cortice royalties on sales of licensed products of between 3.0%-7.5%. Finally, to the extent Cortice is required to pay any milestone payments to the original holder of the intellectual property rights licensed, the Company has agreed to make such payments to Cortice. As of December 31, 2024, there were no accruals related to the milestone payments and the Company issued 11,468 Shares with a fair value of $596,303 pursuant to the Cortice Agreement.

2023

Pursuant to the terms of the Capital on Demand™ Sales Agreement with JonesTrading Institutional Services LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC (collectively, the "Agent"), the Company may sell from time to time, through the Agent, shares of the Company's common stock with an aggregate sales price of up to $20.0 million. During the year ended December 31, 2023, the Company sold 342 shares of common stock to the Agent for net proceeds of $2,317,599.

During the year ended December 31, 2023, the Company issued 1,497 shares of common stock from the exercise of warrants.

Stock Options

In 2017, the Board of Directors of the Company approved the CNS Pharmaceuticals, Inc. 2017 Stock Plan (the "2017 Plan"). The 2017 Plan allows for the Board of Directors to grant various forms of incentive awards for up to 27 shares of common stock.

In 2020, the Board of Directors of the Company approved the CNS Pharmaceuticals, Inc. 2020 Stock Plan (the "2020 Plan"). The 2020 Plan allows for the Board of Directors to grant various forms of incentive awards for up to 40 shares of common stock. The 2020 Plan was amended effective as of August 9, 2023, which was approved by the Company's stockholders at the Company's annual meeting on September 14, 2023. The amendment increased the 2020 Plan by 298 shares of common stock.

2024

On January 19, 2024, the Board of Directors of the Company approved the issuance of 5 options to Ms. Mahery as compensation for her appointment to our Board of Directors. The options have a ten-year term at an exercise price of $632.50 and vest in 36 equal monthly installments succeeding the issuance date. The total fair value of these option grants at issuance was $2,728.

On April 7, 2024, the Board of Directors approved grants of 108 options to officers, employees, and board of directors. The options have a ten-year term at an exercise price of $646.5. Of the 108 options issued, 35 options vest on the first anniversary or at the time of the 2025 shareholder meeting, whichever occurs first and 73 options vest in 36 equal monthly installments over 3 years. The total fair value of these option grants at issuance was $58,335.

2023

On March 29, 2023, the Board of Directors approved, based upon the recommendation of the Compensation Committee, cash bonuses totaling $550,750 to the officers of the Company. In addition, the officers and an employee were awarded a total of 12 options with a ten-year term at an exercise price of $2,490. Of the options issued, 50% vest over 2 years and 50% vest upon the Company's common stock price exceeding various closing prices ranging from $6.00 - $24.00 per share. The total fair value of these option grants at issuance was $25,820.

On May 3, 2023, the Board of Directors of the Company appointed Bettina M. Cockroft, M.D., M.B.A as an independent member of the Company's Board of Directors. Dr. Cockroft was granted a ten-year option to purchase 1 share of Company common stock at an exercise price of $4,175 vesting in 36 equal monthly installments succeeding the issuance date. The total fair value of these option grants at issuance was $3,514.

On August 4, 2023, the Board of Directors approved the issuance of 3 options to Dr. Cockroft. The options have a ten-year term at an exercise price of $5,675 and vest in 36 equal monthly installments succeeding the issuance date. The total fair value of these option grants at issuance was $12,771.

On August 27, 2023, the Board of Directors approved the issuance of 79 options to the board of directors. The options have a ten-year term at an exercise price of $4,750 and vest on the first anniversary date of issuance. The total fair value of these option grants at issuance was $313,846.

During the years ended December 31, 2024 and 2023, the Company recognized $684,181 and $949,982 of stock-based compensation, respectively, related to outstanding stock options. At December 31, 2024, the Company had $94,968 of unrecognized expenses related to options.

The following table summarizes the stock option activity for the years ended December 31, 2024 and 2023:

	Options	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2022	51	$ 168,547.02
Granted	106	4,460.14
Exercised	–	–
Forfeited	–	–
Expired	–	–
Outstanding, December 31, 2023	157	56,287.36
Granted	113	645.88
Exercised	–	–
Forfeited	–	–
Expired	–	–
Outstanding, December 31, 2024	270	$ 33,000.37
Exercisable, December 31, 2024	175	$ 48,148.42

The aggregate fair value of the options measured during the years ended December 31, 2024 and 2023 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Fair value of common stock on measurement date	$632.50 to $646.50 per share	$1.00 to $2.40 per share
Risk free interest rate (1)	3.80% to 4.39%	3.38% to 4.37%
Volatility (2)	102.25% to 118.36%	114.13% to 118.09%
Dividend yield (3)	0%	0%
Expected term (in years)	5.5 – 6.3	5.5 – 6.3

(1) The risk-free interest rate was determined by management using the market yield on U.S. Treasury securities with comparable terms as of the measurement date.
(2) The trading volatility was determined by calculating the volatility of the Company's peer group.
(3) The Company does not expect to pay a dividend in the foreseeable future.

As of December 31, 2024, the outstanding stock options have a weighted average remaining term of 8.16 years and the aggregate intrinsic value of options vested and outstanding was $0. As of December 31, 2024, there were no awards remaining to be issued under the 2017 Plan and 28 awards remaining to be issued under the 2020 Plan.

As of December 31, 2023, the outstanding stock options have a weighted average remaining term of 8.54 years and the aggregate intrinsic value of options vested and outstanding was $8,217.

Stock Warrants

The following table summarizes the stock warrant activity for the years ended December 31, 2024 and 2023:

	Warrants	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2022	1,597	$ 8,875.44
Granted	1,544	3,220.82
Exercised	(1,407)	2,090.82
Forfeited	–	–
Expired	(2)	77,274.54
Outstanding, December 31, 2023	1,732	9,709.31
Granted	341,858	36.50
Exercised	(284,006)	0.13
Forfeited	–	–
Expired	(5)	202,500
Outstanding, December 31, 2024	59,579	$ 465.88

On October 16, 2023, the Company entered into a warrant exercise inducement offer letter (the “Inducement Letter”) with a holder of certain existing warrants (“Holder”) to receive new warrants to purchase up to a number of shares of common stock equal to 200% (the “Inducement Warrants”) of the number of warrant shares issued pursuant to the exercise of such certain existing warrants to purchase shares of common stock (the “Existing Warrants”) pursuant to which the Holder agreed to exercise for cash their Existing Warrants to purchase up to 751 shares of the Company’s common stock, at a Reduced Exercise Price (as defined below), in exchange for the Company’s agreement to issue the Inducement Warrants to purchase up to 1,502 shares of the Company’s common stock (the “Inducement Warrant Shares”). The Existing Warrants consist of: (i) warrants, originally issued on December 22, 2020 and amended on December 5, 2022; (ii) warrants, originally issued on January 10, 2022 and amended on December 5, 2022; and (iii) warrants issued on December 5, 2022. Pursuant to the Inducement Letter, the exercise price for such Existing Warrants was reduced to $3,200 per share (the “Reduced Exercise Price”). In connection with the warrant inducement, the Company estimated the fair value of the warrants based on the Black-Scholes option pricing model and recorded a deemed dividend to additional paid in capital of $5,571,694.

The aggregate fair value of the warrants measured during the year ended December 31, 2023 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31, 2023
Fair value of common stock on measurement date	$4,000 per share
Risk free interest rate (1)	4.72%
Volatility (2)	124.66%
Dividend yield (3)	0%
Expected term (in years)	4.2 – 5.0

(1) The risk-free interest rate was determined by management using the market yield on U.S. Treasury securities with comparable terms as of the measurement date.
(2) The trading volatility was determined by calculating the volatility of the Company.
(3) The Company does not expect to pay a dividend in the foreseeable future.

During the year ended December 31, 2024, the Company received $21,325 in net cash proceeds from the exercise of 4,448 warrants issued at an exercise price of $2.5, 14 warrants issued at an exercise price of $750 and 279,944 warrants issued at an exercise price of $0.05. As of December 31, 2024, the remaining weighted average term for the outstanding stock warrant is 4.09 years.

During the year ended December 31, 2023, the Company received $2,961,239 in net cash proceeds from the exercise of 753 warrants issued at an exercise price of $3,200, 96 warrants issued at an exercise price of $7,575 and 650 warrants previously issued at an exercise price of $2.5.

As of December 31, 2023 the outstanding and exercisable warrants have a weighted average remaining term of 4.64 years and an intrinsic value of $15,245.

Restricted Stock Units

On April 7, 2024, the Board of Directors approved grants of 108 RSUs to officers, employees, and board of directors. Of the 108 RSUs issued, 35 RSUs vest on the first anniversary or at the time of the 2025 shareholder meeting, whichever occurs first and 73 RSUs vest in 8 equal quarterly installments over 2 years. The Company valued the RSUs based on the stock price at grant which total $58,335.

During the years ended December 31, 2024 and 2023, the Company recognized $54,414 and $23,850 of stock-based compensation, related to outstanding RSUs, respectively. At December 31, 2024, the Company had $68,275 of unrecognized expenses related to outstanding RSUs.

The following table summarizes the RSUs activity for the years ended December 31, 2024 and 2023:

	RSUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2022	–	$ –
Granted	6	25,050.00
Vested	–	–
Forfeited	–	–
Non-vested, December 31, 2023	6	25,050.00
Granted	108	648.25
Vested	–	–
Forfeited	–	–
Non-vested, December 31, 2024	114	$ 1,932.55

Performance Units

During the years ended December 31, 2024 and 2023, the Company recognized $100,362 and $33,585 related to outstanding stock PUs, respectively. At December 31, 2024, the Company had $0 of unrecognized expenses related to PUs.

The following table summarizes the PUs activity for the years ended December 31, 2024 and 2023:

	PUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2022	19	$ 14,581.58
Granted	–	–
Vested	–	–
Forfeited	–	–
Non-vested, December 31, 2023	19	14,581.58
Granted	–	–
Vested	(6)	25,050.00
Forfeited	(8)	9,750.00
Non-vested, December 31, 2024	5	$ 9,750.00

Note 5 – Commitments and Contingencies

Executive Employment Agreements

On September 1, 2017, the Company entered into an employment agreement with Mr. John Climaco pursuant to which Mr. Climaco agreed to serve as Chief Executive Officer and Director of the Company commencing on such date for an initial term of three years. On September 1, 2020, the Company entered into an amendment to the employment agreement with Mr. Climaco. The amendment extends the term of employment under the Employment Agreement, which was originally for a three-year period, for additional twelve-month periods, unless and until either the Company or Mr. Climaco provides written notice to the other party not less than sixty days before such anniversary date that such party is electing not to extend the term. If the Company provides notice of its election not to extend the term, Mr. Climaco may terminate his employment at any time prior to the expiration of the term by giving written notice to the Company at least thirty days prior to the effective date of termination, and upon the earlier of such effective date of termination or the expiration of the term, Mr. Climaco shall be entitled to receive the same severance benefits as are provided upon a termination of employment by the Company without cause. Pursuant to the Amendment, the severance benefits shall be twelve months of Mr. Climaco's base salary. Such severance payment shall be made in a single lump sum sixty days following the termination, provided that Mr. Climaco has executed and delivered to the Company and has not revoked a general release of the Company. Pursuant to the employment agreement, the compensation committee of the board of directors reviews the base salary payable to Mr. Climaco annually during the term of the agreement. On March 6, 2025, the compensation committee of the board of directors set Mr. Climaco's annual base salary to $580,000.

On June 28, 2019, we entered into employment letters with Drs. Silberman and Picker pursuant to which Dr. Silberman agreed to commit 50% of her time to our matters; and Dr. Picker agreed to commit 25% of his time to our matters. On March 6, 2025, the compensation committee of the board of directors set Drs. Silberman and Picker annual base salaries to $247,000 and $120,000, respectively.

In March 2024, the Board of Directors approved, based upon the recommendation of the Compensation Committee, cash bonuses totaling $240,608 to the officers of the Company payable upon completion of a subsequent round of financing and a determination by the Board that such financing is sufficient for the Company's needs after payment of such bonus.

On March 6, 2025, the Board of Directors approved, based upon the recommendation of the Compensation Committee, cash bonuses totaling $631,243 to the officers of the Company.

Scientific Advisory Board

The Scientific Advisory board is consisted of one member, Dr. Sigmond Hsu. Dr. Hsu receives annual cash compensation of $68,600. As of December 31, 2024 and 2023, the Company has accrued $177,309 and $168,734, respectively, for Mr. Hsu's Scientific Advisory Board compensation.

WP744 Portfolio (Berubicin)

On November 21, 2017, the Company entered into a Collaboration and Asset Purchase Agreement with Reata Pharmaceuticals, Inc. ("Reata"). Through this agreement, the Company purchased all of Reata's rights, title, interest and previously conducted research and development results in the chemical compound commonly known as Berubicin. In exchange for these rights, the Company agreed to pay Reata an amount equal to 2.25% of the net sales of Berubicin for a period of 10 years from the Company's first commercial sale of Berubicin plus $10,000. Reata also agreed to collaborate with the Company on the development of Berubicin, from time to time.

On December 28, 2017, the Company entered into a Technology Rights and Development Agreement with Houston Pharmaceuticals, Inc. ("HPI"). HPI is affiliated with Dr. Waldemar Priebe, our founder. Pursuant to this agreement, the Company obtained a worldwide exclusive license to the chemical compound commonly known as WP744. In exchange for these rights, the Company agreed to pay consideration to HPI as follows: (i) a royalty of 2% of net sales of any product utilizing WP744 for a period of ten years after the first commercial sale of such; and (ii) $100,000 upon beginning Phase II clinical trials (paid in 2021); and (iii) $200,000 upon the approval by the FDA of a New Drug Application for any product utilizing WP744; and (iv) a series of quarterly development payments totaling $750,000 beginning immediately after the Company's raise of $7,000,000 of investment capital. In addition, the Company issued 3 shares of the Company's common stock valued at $3,375 per share to HPI upon execution of the agreement. On November 13, 2019, the Company closed its IPO, thereby fulfilling all conditions precedent and completing the acquisition of the intellectual property discussed in the HPI agreement. During the years ended December 31, 2024 and 2023, the Company recognized $50,000 and $50,000, respectively, related to this agreement. Unrelated to this agreement, from time to time, the Company purchases pharmaceutical products from HPI which are necessary for the manufacturing of Berubicin API and drug product. During the years ended December 31, 2024 and 2023, the Company expensed $0 related to the purchase of pharmaceutical products from HPI. This agreement was terminated March 23, 2025.

On August 30, 2018, we entered into a sublicense agreement with WPD Pharmaceuticals, Inc. ("WPD"). Pursuant to the agreement, the Company granted WPD an exclusive sublicense, even as to us, for the patent rights we licensed pursuant to the HPI License within the following countries: Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Moldova, Romania, Bulgaria, Serbia, Macedonia, Albania, Armenia, Azerbaijan, Georgia, Montenegro, Bosnia, Croatia, Slovenia, Slovakia, Czech Republic, Hungary, Chechnya, Uzbekistan, Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan, Greece, Austria, and Russia. The sublicense agreement provides that WPD must use commercially reasonable development efforts to attempt to develop and commercialize licensed products in the above mentioned territories, which means the expenditure of at least $2.0 million on the development, testing, regulatory approval or commercialization of the licensed products during the three year period immediately following the date of the sublicense agreement. In the event that WPD fails to use commercially reasonable development efforts by the foregoing three-year deadline, we have the right to terminate this sublicense agreement. As of December 31, 2021, the Company has received reports of the WPD expenditures related to this agreement, has conducted due inquiry into validating those expenditures, and has determined that WPD has exercised commercially reasonable development efforts and has therefore fulfilled the terms of the agreement necessary to secure their rights under the sublicense in perpetuity subject to the ongoing obligations of the sublicense. In consideration for the rights granted under the sublicense agreement, to the extent we are required to make any payments to HPI pursuant to the HPI License as a result of this sublicense agreement, WPD agreed to advance us such payments, and to pay us a royalty equal to 1% of such payments. WPD is a Polish corporation and was affiliated with Dr. Priebe. This agreement was terminated March 23, 2025.

On November 21, 2022, CNS entered into an Investigational Medicinal Product Supply Agreement with Pomeranian Medical University ("PUM") in Szczecin, Poland. CNS agreed to sell berubicin hydrochloride drug product (and related reference standards) to PUM at a discount to the historical cost of manufacturing so that PUM may conduct an investigator-initiated clinical trial of Berubicin in CNS lymphomas. PUM agreed to pay CNS the following payments: (i) PLN 5,870 upon delivery of 2 vials each of berubicin and berubicinol reference standards, (ii) PLN 873,201 upon delivery of a first batch of 150 berubicin drug product vials, and (iii) PLN 873,201 upon delivery of a second batch of 150 berubicin drug product vials. As of December 31, 2022, the reference standards were delivered, and the Company recognized $1,302 in accounts receivable and as a reduction to research and development expense. In April 2023, the first batch of berubicin drug product vials were delivered, and the Company recognized $196,303 in accounts receivable and as a reduction to research and development expense. As of December 31, 2023, the outstanding accounts receivable balance of $197,605 was collected in full.

On August 31, 2018, the Company entered into a sublicense agreement with Animal Life Sciences, LLC ("ALI"), pursuant to which we granted ALI an exclusive sublicense, even as to us, for the patent rights we licensed pursuant to the HPI License solely for the treatment of cancer in non-human animals through any type of administration. In consideration for the rights granted under the sublicense agreement, ALI agreed to issue us membership interests in ALI equal to 1.52% of the outstanding ALI membership interests. As additional consideration for the rights granted, to the extent we are required to make any payments to HPI pursuant to the HPI License as a result of this sublicense agreement, ALI agreed to advance us such payments, and to pay us a royalty equal to 1% of such payments. Dr. Waldemar Priebe was an affiliate of ALI. This agreement was terminated March 23, 2025.

On June 10, 2020, the FDA granted Orphan Drug Designation ("ODD") for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of an NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD now constitutes our primary intellectual property protections although the Company is exploring if there are other patents that could be filed related to Berubicin to extend additional protections.

On July 24, 2021, the Company received Fast Track Designation from the FDA for Berubicin. Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

WP1244 Portfolio

On January 10, 2020, Company entered into a Patent and Technology License Agreement (the "WP1244 Agreement") with The Board of Regents of The University of Texas System, an agency of the State of Texas, on behalf of The University of Texas M. D. Anderson Cancer Center ("UTMDACC"). Pursuant to the WP1244 Agreement, the Company obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to the Company's recently announced WP1244 drug technology. In consideration, the Company must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) on sales of licensed products developed under the WP1244 Agreement. The term of the WP1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the WP1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate this WP1244 Agreement in the event that the Company fails to meet certain commercial diligence milestones. The commercial diligence milestones are as follows (i) initiated PC toxicology to support filing of Investigational New Drug Application ("IND") or New Drug Application ("NDA") for the Licensed Product within the eighteen (18) month period following the Effective Date (ii) file and IND for the Licensed Product within three (3) year period following the Effective Date and (iii) Commencement of Phase I Study within the five (5) year period following the Effective Date. The Company has not met the commercial diligence milestones and has not paid the annual maintenance fee required as of the date hereof. On May 25, 2024 the WP1244 Agreement was terminated. There are no termination penalty provisions in the Agreement. During the year ended December 31, 2024 and 2023, the Company paid $52,537 and $55,092, respectively.

Cortice Biosciences, Inc. Exclusive License Agreement

On July 29, 2024, the Company entered into an Exclusive License Agreement with Cortice Biosciences, Inc. ("Cortice") pursuant to which Cortice granted the Company an exclusive license to the intellectual property rights related to certain patents around the compound TPI 287 in the United States, Canada, Mexico and Japan. The term of the license will expire, other than due to a breach of the Cortice Agreements, at the end of the royalty term with respect to any licensed product in any of the included territories, which begins upon the first commercial sale in such territory and ends on the latest of (i) ten years after such sale, (ii) the expiration of regulatory or marketing exclusivity for such licensed product in such country, or (c) the expiration of the last to expire valid patent claim in such country covering such licensed product. Pursuant to the Cortice Agreements, the Company agreed to issue Cortice 11,468 shares of the Company's common stock upon the closing of the transaction, which occurred on July 29, 2024, and 867 shares of Company common stock upon the receipt of shareholder approval of such issuance as required by the rules of the Nasdaq Stock Market. The Company also agreed to make milestone payments to Cortice in either cash or shares of Company common stock (at Cortice's option) upon: (i) meeting the primary endpoint a pivotal trial for a licensed product – either $15.0 million or 8,223 shares of Company common stock; (ii) FDA acceptance of an New Drug Application for a licensed product – either $30.0 million or 16,446 shares of Company common stock; (iii) the first commercial sale in the United States of a licensed product – either $45.0 million or 24,668 shares of Company common stock; and (iv) the first commercial sale in Japan of a licensed product – either $10.0 million or 4,112 shares of Company common stock. The Company's obligation to pay the above milestones in Company common stock is subject to the receipt of shareholder approval as required by the rules of the Nasdaq Stock Market. The Company also agreed to pay Cortice royalties on sales of licensed products of between 3.0%-7.5%. Finally, to the extent Cortice is required to pay any milestone payments to the original holder of the intellectual property rights licensed, the Company has agreed to make such payments to Cortice. As of December 31, 2024, there were no accruals related to the milestone payments and the Company issued 11,468 Shares with a fair value of $596,303 pursuant to the Cortice Agreement.

Note 6 – Income Taxes

The Company is subject to United States federal income taxes at an approximate rate of 21%. The reconciliation of the provision for income taxes at the United States federal statutory rate compared to the Company's income tax expense as reported is as follows:

	Year Ended December 31, 2024	Year Ended December 31, 2023
Income tax benefit computed at the statutory rate	$ 3,120,000	$ 3,959,000
Tax effect of:		
True-ups and non-deductible expenses	(585,000)	118,000
Change in valuation allowance	(2,535,000)	(4,077,000)
Provision for income taxes	$ –	$ –

Significant components of the Company's deferred tax assets and liabilities after applying enacted corporate income tax rates are as follows:

	As of December 31, 2024	As of December 31, 2023
Deferred income tax assets		
Net operating losses	$ 7,923,000	$ 6,672,000
Stock-based compensation	999,000	873,000
Capitalized 174 expenses	6,659,000	5,420,000
Deferred income tax liability		
Prepaid expenses	(279,000)	(198,000)
Valuation allowance	(15,302,000)	(12,767,000)
Net deferred income tax assets	$ –	$ –

As of December 31, 2024, the Company currently has net operating loss carryforwards of approximately $37,727,000. Approximately $200,000 of the net operating loss carryforward will begin to expire in 2037. The remaining net operating loss carryforward post-2017 may be carried forward indefinitely.

The Tax Reform Act of 1986 limits the use of net operating loss carryforwards in certain situations where changes occur in the stock ownership of a company. In the event that the Company has a change in ownership, utilization of carryforwards could be limited.

Note 7 – Subsequent Events

On November 26, 2024, the stockholders of the Company approved the granting to the Company's board of directors of the discretion to effect the reverse stock split at a ratio in the range of 1-for-2 to 1-for-50. Upon the approval of the Company's board of directors, The reverse stock split became effective on February 21, 2025 on a 1-for-50 basis without any change in the par value per share, which remained at $0.001. The reverse stock split has been retroactively adjusted throughout these financial statements and footnotes.

On March 11, 2025, the Company approved the issuance of options to purchase 263,537 shares of common stock to the management group, subject to approval of an increase in the Company's equity plan by the Company's shareholders. Each of the options will vest as follows: (i) 50% on the six month anniversary of the issuance date; (ii) 25% on the 12 month anniversary of the issuance date; and (iii) 25% on the 18 month anniversary of the issuance date. The exercise price of the option is $2.50, the closing price on the date of the Board's approval of the compensation plan.

On March 20, 2025, the Company increased the aggregate sales price of common shares that may be sold under the AGP ATM Sales Agreement to $43.5 million. Subsequent to December 31, 2024, the Company has sold 1,530,985 Shares pursuant to the AGP ATM Sales Agreement for net proceeds of approximately $9.9 million.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, including our chief executive officer, who serves as our principal executive officer, and our chief financial officer, who serves as our principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Form 10-K. Based on this evaluation, our chief executive officer and our chief financial officer, concluded that as a result of the material weaknesses in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective at ensuring that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding disclosure.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting for as long as we are an "emerging growth company" pursuant to the provisions of the Jumpstart Our Business Startups Act.

Management's Report on Internal Control Over Financial Reporting

Our chief executive officer and our chief financial officer are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Our management concluded that our internal control over financial reporting were, and continue to be ineffective, as of December 31, 2024 due to a lack of segregation of duties (resulting from the limited number of personnel available), limited access to timely and complete information regarding the status of costs incurred in the activation of investigational sites and costs from treating patients in our study which is a result of the use of a third-party Contract Research Organization ("CRO") to manage the study, and the lack of formal documentation of our control environment. Management is commencing actions to address the lack of formal documentation of our control environment, although this will not address the lack of segregation of duties. Management is also working with the CRO to improve the timeliness and completeness of the data reported to the Company to address this material weakness, as well as conducting increased analytical analysis of such data to be performed by the Company.

A material weakness is a control deficiency (within the meaning of the Public Company Accounting Oversight Board ("PCAOB") Auditing Standard 1305) or combination of control deficiencies that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of certain events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In light of the material weakness described above, we performed additional analysis and other post-closing procedures to ensure our financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent calendar year that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the year ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2024.

Our Board of Directors has adopted a written Code of Business Conduct and Ethics applicable to all officers, directors and employees, which is available on our website (www.cnspharma.com) under "Governance Documents" within the "Corporate Governance" section. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of this Code and by posting such information on the website address and location specified above.

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2024.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2024.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2024:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities (by class) remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	59,698	$ 18.55	545,610

(1) Represents shares of common stock issuable upon exercise of outstanding stock options and rights under our 2017 and 2020 Stock Plans.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2024.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed or furnished as part of this Form 10-K:

1. Financial Statements. Reference is made to the Index to Financial Statements under Item 8, Part II hereof.

2. Financial Statement Schedules. The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Annual Report on Form 10-K.

3. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Amended and Restated Articles of Incorporation of CNS Pharmaceuticals, Inc. (filed as exhibit 2.1 to the Company's Form 1-A file no. 024-10855)
3.2	Certificate of Amendment to the Amended and Restated Articles of Incorporation of CNS Pharmaceuticals, Inc., filed with the Secretary of State of the State of Nevada (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Commission on November 28, 2022)
3.3	Certificate of Amendment to the Amended and Restated Articles of Incorporation of CNS Pharmaceuticals, Inc., filed with the Secretary of State of the State of Nevada (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Commission on May 3, 2024)
3.4	Certificate of Amendment to the Amended and Restated Articles of Incorporation of CNS Pharmaceuticals, Inc., filed with the Secretary of State of the State of Nevada (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Commission on June 5, 2024)
3.5	Amended and Restated Bylaws of CNS Pharmaceuticals, Inc. (filed as exhibit 3.1 to the Company's Form 8-K filed August 15, 2023)
4.1 *	Description of Securities of CNS Pharmaceuticals, Inc.
4.2	Form of Warrant issued in January 2022 offering (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on January 6, 2022)
4.3	Form of Common Warrant issued in November 2023 offering (filed as exhibit 4.8 to the Company's Form S-1 file no. 333-267975)
4.4	Form of Placement Agent Warrant issued in November 2023 offering (filed as exhibit 4.9 to the Company's Form S-1 file no. 333-267975)
4.5	Form of Inducement Warrant issued in October 2023 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on October 17, 2023)

Exhibit Number	Description of Document
4.6	Form of Series A Common Warrant issued January 2024 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on February 2, 2024)
4.7	Form of Series B Common Warrant issued January 2024 (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Commission on February 2, 2024)
4.8	Form of Pre-Funded Warrant issued January 2024 (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the Commission on February 2, 2024)
4.9	Form of Warrant issued June 14 2024 (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Commission on June 14, 2024)
4.9	Form of Pre-Funded Warrant issued June 14 2024 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on June 14, 2024)
4.10	Form of Warrant issued June 26 2024 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on June 26, 2024)
4.11	Form of Warrant issued July 3 2024 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on July 3, 2024)
4.12	Form of Pre-Funded Warrant issued October 23 2024 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Commission on October 24, 2024)
10.1	Amended And Restated Patent License Agreement effective as of December 28, 2017 between CNS Pharmaceuticals, Inc. and Houston Pharmaceuticals, Inc. (filed as exhibit 6.1 to the Company's Form 1-A file no. 024-10855)
10.2	Collaboration and Asset Purchase Agreement between CNS Pharmaceuticals, Inc. and Reata Pharmaceuticals, Inc. dated November 21, 2017 (filed as exhibit 6.2 to the Company's Form 1-A file no. 024-10855)
10.3 **	2017 Stock Plan of CNS Pharmaceuticals, Inc. (filed as exhibit 6.3 to the Company's Form 1-A file no. 024-10855)
10.4 **	Employment Agreement between CNS Pharmaceuticals, Inc. and John M. Climaco dated September 1, 2017 (filed as exhibit 6.4 to the Company's Form 1-A file no. 024-10855)
10.5	Sublicense Agreement between CNS Pharmaceuticals, Inc. and WPD Pharmaceuticals, Inc. dated August 30, 2018 (filed as exhibit 6.6 to the Company's Form 1-A Amendment file no. 024-10855)
10.6	Sublicense Agreement between CNS Pharmaceuticals, Inc. and Animal Life Sciences, LLC. dated August 31, 2018 (filed as exhibit 6.7 to the Company's Form 1-A Amendment file no. 024-10855)
10.7 **	Employment Letter between CNS Pharmaceuticals, Inc. and Donald Picker (filed as exhibit 10.8 to the Company's Form S-1 Amendment file no. 333-232443)

Exhibit Number	Description of Document
10.8 **	Employment Letter between CNS Pharmaceuticals, Inc. and Sandra Silberman (filed as exhibit 10.9 to the Company's Form S-1 Amendment file no. 333-232443)
10.9 **	Employment Agreement between CNS Pharmaceuticals, Inc. and Christopher Downs (filed as exhibit 10.10 to the Company's Form S-1 Amendment file no. 333-232443)
10.10 **	2020 Stock Plan of CNS Pharmaceuticals, Inc. (as amended) (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on May 3, 2024)
10.11**	Amendment to Employment Agreement between CNS Pharmaceuticals, Inc. and John Climaco dated September 1, 2020 (filed as exhibit 99.1 to the Company's Form 8-K filed September 4, 2020)
10.12	Non-Employee Director Compensation Policy effective July 15, 2021 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the Commission on August 12, 2022)
10.13	Form of Placement Agent Agreement in November 2023 offering (filed as exhibit 10.21 to the Company's Form S-1 file no. 333-267975)
10.14	Form of Securities Purchase Agreement in January 2024 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on February 2, 2024)
10.15	Form of Amendment to Common Stock Warrants (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Commission on February 2, 2024)
10.15	Form of Securities Purchase Agreement in June 14 2024 offering (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on June 14, 2024)
10.16	Financial Advisory Agreement between CNS Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Commission on June 14, 2024)
10.17	Form of Securities Purchase Agreement in June 26 2024 offering (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on June 26, 2024)
10.18	Financial Advisory Agreement between CNS Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Commission on June 26, 2024)
10.19	Form of Securities Purchase Agreement in July 3 2024 offering (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on July 3, 2024)
10.20	Financial Advisory Agreement between CNS Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Commission on July 3, 2024)
10.21	Sales Agreement, dated July 26, 2024, by and between CNS Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed with the Commission on July 26, 2024)

Exhibit Number	Description of Document
10.22	Form of Waiver and Consent (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on July 26, 2024)
10.23	Exclusive License Agreement between CNS Pharmaceuticals, Inc. and Cortice Biosciences, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on July 30, 2024)
10.24	Stock Purchase Agreement between CNS Pharmaceuticals, Inc. and Cortice Biosciences, Inc. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Commission on July 30, 2024)
10.25	Form of Securities Purchase Agreement in October 23 2024 offering (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Commission on October 24, 2024)
10.26	Placement Agency Agreement between CNS Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed with the Commission on October 24, 2024)
19.1 *	Insider Trading Policy
23.1 *	Consent of MaloneBailey LLP
31.1 *	Certification of Principal Executive Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
31.2 *	Certification of Principal Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
32.1 *	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2 *	Certification of Principal Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97	CNS Pharmaceuticals, Inc. Restatement Recoupment Policy (incorporated by reference to Exhibit 97 to the Annual Report on Form 10-K filed with the Commission on April 1, 2024)
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)**
101.SCH	Inline XBRL Taxonomy Extension Schema Document**
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document**
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document**
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document**
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document**
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Management contract or compensatory plan, contract or arrangement.

\+ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

Item 16. 10-K Summary

None.

SIGNATURES

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

CNS PHARMACEUTICALS, INC.

Date: March 31, 2025 By: /s/ John Climaco

John Climaco
Chief Executive Officer and Director
(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 capacity and on the dates indicated.

Date: March 31, 2025 By: /s/ John Climaco

John Climaco
Chief Executive Officer, President and Director
(Principal Executive Officer)

Date: March 31, 2025 /s/ Christopher Downs

Christopher Downs
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 31, 2025 /s/ Faith Charles

Faith Charles
Director

Date: March 31, 2025 /s/ Jerzy (George) Gumulka

Jerzy (George) Gumulka
Director

Date: March 31, 2025 /s/ Jeffry Keyes

Jeffry Keyes
Director

Date: March 31, 2025 /s/ Bettina Cockroft

Bettina Cockroft
Director

Date: March 31, 2025 /s/ Amy Mahery

Amy Mahery
Director

EXHIBIT 4.1

DESCRIPTION OF THE COMPANY'S SECURITIES

The following summary is a description of the material terms of our capital stock. This summary is not complete, and is qualified by reference to our amended and restated articles of incorporation, and our amended and restated bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated articles of incorporation, our amended and restated bylaws and the applicable provisions of the Nevada Revised Statutes for additional information.

Our amended and restated articles of incorporation authorize us to issue up to 75,000,000 shares of common stock and 5,000,000 shares of preferred stock.

Common Stock

Shares of our common stock have the following rights, preferences and privileges:

Voting

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Any action at a meeting at which a quorum is present will be decided by a majority of the voting power present in person or represented by proxy, except in the case of any election of directors, which will be decided by a plurality of votes cast. There is no cumulative voting.

Dividends

Holders of our common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available for payment, subject to the rights of holders, if any, of any class of stock having preference over the common stock. Any decision to pay dividends on our common stock will be at the discretion of our board of directors. Our board of directors may or may not determine to declare dividends in the future. See "Dividend Policy." The board's determination to issue dividends will depend upon our profitability and financial condition any contractual restrictions, restrictions imposed by applicable law and the SEC, and other factors that our board of directors deems relevant.

Liquidation Rights

In the event of a voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of our common stock will be entitled to share ratably on the basis of the number of shares held in any of the assets available for distribution after we have paid in full, or provided for payment of, all of our debts and after the holders of all outstanding series of any class of stock have preference over the common stock, if any, have received their liquidation preferences in full.

Other

Our issued and outstanding shares of common stock are fully paid and nonassessable. Holders of shares of our common stock are not entitled to preemptive rights. Shares of our common stock are not convertible into shares of any other class of capital stock, nor are they subject to any redemption or sinking fund provisions.

Preferred Stock

We are authorized to issue up to 5,000,000 shares of preferred stock. Our articles of incorporation authorizes the board to issue these shares in one or more series, to determine the designations and the powers, preferences and relative, participating, optional or other special rights and the qualifications, limitations and restrictions thereof, including the dividend rights, conversion or exchange rights, voting rights (including the number of votes per share), redemption rights and terms, liquidation preferences, sinking fund provisions and the number of shares constituting the series. Our board of directors could, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of common stock and which could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, a majority of our outstanding voting stock.

Warrants

As of December 31, 2024, we had outstanding warrants to purchase an aggregate of 59,579 shares of common stock at a weighted average exercise price of $465.88, expiring between December 28, 2025 and October 24, 2029.

With respect to the foregoing warrants, in the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will have the right at any time prior to the consummation of the fundamental transaction to require us to repurchase the warrants for a purchase price in cash equal to the Black-Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such common warrant on the date of such fundamental transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.
Except by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Articles of Incorporation and Bylaw Provisions

Our articles of incorporation and bylaws include a number of anti-takeover provisions that may have the effect of encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include:

Advance Notice Requirements. Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of stockholders. These procedures provide that notice of stockholder proposals must be timely and given in writing to our corporate Secretary. Generally, to be timely, notice must be received at our principal executive offices not fewer than 120 calendar days prior to the first anniversary date on which our notice of meeting and related proxy statement were mailed to stockholders in connection with the previous year's annual meeting of stockholders. The notice must contain the information required by the bylaws, including information regarding the proposal and the proponent.

Special Meetings of Stockholders. Our bylaws provide that special meetings of stockholders may be called at any time by only the Chairman of the Board, the Chief Executive Officer, the President or the board of directors, or in their absence or disability, by any vice president.

No Written Consent of Stockholders. Our articles of incorporation and bylaws provide that any action required or permitted to be taken by stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing by such stockholders.

Amendment of Bylaws. Our stockholders may amend any provisions of our bylaws by obtaining the affirmative vote of the holders of a majority of each class of issued and outstanding shares of our voting securities, at a meeting called for the purpose of amending and/or restating our bylaws.

Preferred Stock. Our articles of incorporation authorizes our board of directors to create and issue rights entitling our stockholders to purchase shares of our stock or other securities. The ability of our board to establish the rights and issue substantial amounts of preferred stock without the need for stockholder approval may delay or deter a change in control of us. See "Preferred Stock" above.

Nevada Takeover Statute

The Nevada Revised Statutes contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. Nevada's "acquisition of controlling interest" statutes (NRS 78.378 through 78.3793, inclusive) contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights. These laws will apply to us if we were to have 200 or more stockholders of record (at least 100 of whom have addresses in Nevada appearing on our stock ledger) and do business in the State of Nevada directly or through an affiliated corporation, unless our articles of incorporation or bylaws in effect on the tenth day after the acquisition of a controlling interest provide otherwise. These laws provide that a person acquires a "controlling interest" whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one-fifth or more, but less than one-third, (2) one-third or more, but less than a majority or (3) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares which it acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become "control shares" to which the voting restrictions described above apply. These laws may have a chilling effect on certain transactions if our amended and restated articles of incorporation or amended and restated bylaws are not amended to provide that these provisions do not apply to us or to an acquisition of a controlling interest, or if our disinterested stockholders do not confer voting rights in the control shares.

Nevada's "combinations with interested stockholders" statutes (NRS 78.411 through 78.444, inclusive) provide that specified types of business "combinations" between certain Nevada corporations and any person deemed to be an "interested stockholder" of the corporation are prohibited for two years after such person first becomes an "interested stockholder" unless the corporation's board of directors approves the combination (or the transaction by which such person becomes an "interested stockholder") in advance, or unless the combination is approved by the board of directors and 60% of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates. Furthermore, in the absence of prior approval certain restrictions may apply even after such two-year period. For purposes of these statutes, an "interested stockholder" is any person who is (1) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (2) an affiliate or associate of the corporation and at any time within the two previous years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then-outstanding shares of the corporation. The definition of the term "combination" is sufficiently broad to cover most significant transactions between a corporation and an "interested stockholder". These laws generally apply to Nevada corporations with 200 or more stockholders of record. However, a Nevada corporation may elect in its articles of incorporation not to be governed by these particular laws, but if such election is not made in the corporation's original articles of incorporation, the amendment (1) must be approved by the affirmative vote of the holders of stock representing a majority of the outstanding voting power of the corporation not beneficially owned by interested stockholders or their affiliates and associates, and (2) is not effective until 18 months after the vote approving the amendment and does not apply to any combination with a person who first became an interested stockholder on or before the effective date of the amendment. We have not made such an election in our original articles of incorporation or in our amended and restated articles of incorporation

Limitations on Liability and Indemnification of Officers and Directors

Our articles of incorporation and bylaws limit the liability of our officers and directors and provide that we will indemnify our officers and directors, in each case, to the fullest extent permitted by the Nevada Revised Statutes.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "CNSP".

Transfer Agent

The transfer agent for our common stock is Continental Stock Transfer and Trust.

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EXHIBIT 19.1

Insider Trading Policy
CNS Pharmaceuticals, Inc.
Effective March 1, 2022

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Introduction

The Board of Directors of CNS has adopted this policy to provide guidelines to all directors, officers, associates and consultants of CNS with respect to trading in CNS securities, as well as the securities of publicly traded companies with whom CNS has a business relationship.

This policy has been designed to prevent insider trading or even allegations of insider trading. Your strict adherence to this policy will help safeguard CNS' reputation and will further ensure that CNS conducts its business with the highest level of integrity and in accordance with the highest ethical standards. Each CNS associate is responsible for the consequences of his or her actions. You are responsible for understanding and complying with this policy.

Federal and state securities laws prohibit the purchase or sale of a company's securities by anyone who is aware of material information about that company that is not generally known or available to the public. These laws also prohibit anyone who is aware of material nonpublic information from disclosing this information to others who may trade. Companies and their controlling persons may also be subject to liability if they fail to take reasonable steps to prevent insider trading by company personnel.

It is important that you understand the breadth of activities that constitute illegal insider trading and the consequences, which can be severe. Cases have been successfully prosecuted against trading by associates through foreign accounts, trading by family members and friends, and trading involving only a small number of shares. Both the U.S. Securities and Exchange Commission (the "SEC") and the Financial Industry Regulatory Authority ("FINRA") investigate and are very effective at detecting insider trading. Both the SEC and the U.S. Department of Justice pursue insider trading violations vigorously.

Sanctions and Penalties

Violations of the insider trading laws can result in severe civil and criminal sanctions. For example, under U.S. securities laws, individuals may be subject to imprisonment for up to 20 years, criminal fines of up to $5 million and civil fines of up to three times the profit gained or loss avoided. Failure to comply with this policy may also subject you to sanctions imposed by CNS, up to and including immediate dismissal for cause, whether or not your failure to comply with this policy results in a violation of law.

Persons Covered

As a director, officer, associate or consultant of CNS or its subsidiaries, this policy applies to you. The same restrictions that apply to you apply to your family members who reside with you, anyone else who lives in your household, and any family members who do not live in your household but whose transactions in CNS securities are directed by you or are subject to your influence or control (such as parents or children who consult with you before they trade in CNS securities). You are responsible for making sure that any transaction in securities covered by this policy by any of these people complies with this policy.

Definition of Material Non-Public Information

"Material non-public information" is any material information about CNS that has not yet become publicly available.

Information is "material" if a reasonable investor would likely consider it important in making a decision to buy, hold or sell securities. Any information that could reasonably be expected to affect the price of the security is material. The information may be positive or negative. Financial information is frequently material, even if it covers only part of a fiscal period or less than all of CNS's operations, since either of these might convey enough information about CNS's consolidated results to be considered material information. Other common examples of information that may be material include:

- information regarding sales, revenues or earnings (including projections);
- financial forecasts of any kind, including earnings estimates or changes in previously announced earnings estimates;
- significant business trends and metrics;
- significant proposed mergers, acquisitions, investments or divestitures;
- significant developments in products or services;
- gain or loss of substantial customers;
- execution or termination of significant contracts;
- financings or restructurings;
- significant unusual gains or losses;
- changes in business strategies;
- developments in significant litigation or government investigations;
- public or private debt or equity offerings;
- significant changes in senior management;
- CNS share repurchases; or
- stock splits or dividend information.

It is not possible to define all categories of material information, and you should recognize that the public, the media and the courts may use hindsight in judging what is material. Therefore, it is important to err on the safe side and assume information is material if there is any doubt.

Information is "non-public" if it is not generally known or available to the public. Information may still be non-public even though it is widely known within CNS.

Release of information to the media does not immediately mean the information has become publicly available. Information is considered to be available to the public only when it has been released broadly to the marketplace (such as by a press release or an SEC filing) and the investing public has had time to absorb and evaluate it. Ordinarily, information about CNS should not be considered public until at least one full trading day has passed following its formal release to the market. For example, if CNS announces earnings before trading begins on a Tuesday, the first time you can buy or sell CNS securities is the opening of the market on Wednesday (assuming you are not aware of other material non-public information at that time). If, however, CNS announces earnings after trading begins that Tuesday, the first time you can buy or sell CNS securities is the opening of the market on the Thursday.

Requirements Applicable to Everyone

No trading in CNS securities while aware of material non-public information

You are prohibited from engaging in any transaction in CNS securities while aware of material non-public information about CNS. It makes no difference whether or not you relied upon or used material non-public information in deciding to trade – if you are aware of material non-public information about CNS, the prohibition applies. You should avoid even the appearance of an improper transaction to preserve CNS's reputation for adhering to the highest ethical standards of conduct.

This prohibition covers virtually all transactions in CNS securities. “Securities” includes common stock, options to purchase common stock, debt securities, preferred stock and derivative securities such as put and call options, warrants, swaps, caps and collars. Transactions in CNS securities include purchases, sales, pledges, hedges, loans and gifts of CNS securities, as well as other direct or indirect transfers of CNS securities. Certain of these transactions are addressed in more detail below and may not be permitted under this policy. This prohibition extends to trades of CNS securities in which you have any “beneficial” or other interest, or over which you exercise investment control, including:

- transactions in CNS securities held in joint accounts or accounts of persons or entities controlled directly or indirectly by you;
- transactions in CNS securities for which you act as trustee, executor or custodian; and
- transactions in any other account or investment involving in any way any CNS securities over which you exercise any direct or indirect control.

***Stock Option Exercises*.**

- **Exercise and Hold.** This prohibition does not apply to the exercise of stock options issued under CNS plans if the exercise price is paid in cash or through CNS withholding a portion of the shares underlying the options and the underlying shares acquired (net of any withholding) are held (not sold into the market). Similarly, CNS may withhold underlying shares to satisfy tax withholding requirements.
- **Exercise and Sell / Cashless Exercise.** This prohibition does apply, however, to sales of the underlying stock and broker-assisted cashless exercises of options, as well as to any other market sales for the purpose of generating the cash needed to cover the costs of exercise.

***Vesting of Restricted Stock or Settlement of Performance Stock Units*.** This prohibition does not apply to the automatic deduction of shares by CNS from your restricted stock or performance stock unit account to satisfy the minimum statutory tax withholding liability upon the vesting of restricted stock or settlement of performance stock units. The prohibition does apply, however, to any open market sale of vested shares, including to satisfy tax liabilities.

***10b5-1 Plans*.** This prohibition does not apply to trades made pursuant to a valid “10b5-1 plan” approved by CNS as described below.

***Dividend Reinvestment Plan*.** This prohibition does not apply to purchases of CNS stock under the CNS dividend reinvestment plan (if such a plan has been established, which as of the date of this policy, one has not been established) that result from your reinvestment of dividends paid on CNS stock held in such plan. This prohibition does apply, however, to other purchases of CNS stock under the plan that result from additional contributions you choose to make to the dividend reinvestment plan, or to increases or decreases in your level of participation in the plan. This prohibition also applies to your sale of any CNS securities purchased pursuant to the plan.

Event-specific blackout periods may apply

Although you are always responsible for monitoring for yourself whether you possess material non-public information, from time to time CNS may decide to impose a special trading blackout on those who are aware of particular information that CNS determines may be considered material non-public information. This kind of trading blackout may be imposed in connection with a potential acquisition, a financial analyst conference, an anticipated positive or negative earnings surprise or other material development. If you are subject to the blackout, you may not trade in any CNS securities, except pursuant to a 10b5-1 plan previously approved by CNS, until notified that the blackout has ended.

The Compliance Officer (which shall initially be the Chief Financial Officer) , in consultation with the Chief Executive Officer and the Chief Financial Officer, will determine whether an event-specific blackout should be imposed. The existence of an event-specific blackout will not be generally announced. If you are covered by the event-specific blackout, you will be notified by the Compliance Officer. Any person made aware of an event-specific blackout should not disclose the existence of the blackout to anyone else.

No trading in securities of other companies while aware of material non-public information.

CNS may engage in business transactions with companies whose securities are publicly traded. These transactions may include, among other things, mergers, acquisitions, divestitures or renewal or termination of significant contracts or other arrangements. Information learned in connection with these transactions or relationships may constitute material non-public information about the other company. You are prohibited from trading in the securities of these companies while aware of material non-public information about the companies and from communicating that information to any other person for such use.

No "tipping" of material non-public information

You may not pass material non-public information about CNS or any other company on to others or otherwise make unauthorized disclosure or use of this information, regardless of whether you profit or intend to profit by the tipping, disclosure, or use. This practice, known as "tipping", also violates the securities laws and can result in the same civil and criminal penalties that apply to insider trading, even though you did not trade and did not gain any benefit from another's trading.

Frequent trading of CNS securities is strongly discouraged

Frequent trading of CNS securities can create an appearance of wrongdoing even if the decision to trade was based solely on public information such as stock price ranges and other market events. You are strongly discouraged from trading in CNS securities for short-term trading profits. Daily or frequent trading, which can be time-consuming and distracting, is strongly discouraged. CNS reserves the right to request brokerage account statements to assure compliance with this and other provisions of the policy.

No short sales of CNS securities

You may not engage in short sales of CNS securities (sales of securities that are not then owned), including "sales against the box" (short sales not exceeding the number of shares already owned). Generally, short sales are transactions whereby a person will benefit from a decline in the price of the securities, and CNS believes it is inappropriate for associates to engage in these transactions with respect to CNS securities.

No trading in derivatives of CNS

You may not trade in derivatives of an CNS security, such as exchange-traded put or call options and forward transactions.

No hedging transactions

Certain forms of hedging or monetization transactions may offset a decrease, or limit your ability to profit from an increase, in the value of CNS securities you hold, enabling you to continue to own CNS securities without the full risks and rewards of ownership. CNS believes that such transactions separate the holder's interests from those of other stockholders. Therefore, you and any person acting on your behalf are prohibited from purchasing any financial instruments (such as prepaid variable forward contracts, equity swaps, collars or exchange funds) or otherwise engaging in any transactions that hedge or offset any decrease in the market value of CNS securities or limit your ability to profit from an increase in the market value of CNS securities.

No margin accounts or pledges

Securities held in a margin account or pledged as collateral for a loan may be sold without your consent by the broker if you fail to meet a margin call or by the lender in foreclosure if you default on the loan. Because a margin or foreclosure sale may occur at a time when you are aware of material nonpublic information or otherwise are not permitted to trade in CNS securities, you are prohibited from holding CNS securities in a margin account or pledging CNS securities as collateral for a loan.

Limited use of standing orders

Standing orders should be used only for three business days. A standing order placed with a broker to sell or purchase stock at a specified price leaves you with no control over the timing of the transaction. A standing order transaction executed by the broker when you are aware of material nonpublic information may result in unlawful insider trading. A standing order incorporated into a 10b5-1 plan approved by CNS is permitted.

No trading on rumors

Rumors within CNS concerning matters which, if true, would be material non-public information are deemed to constitute material non-public information for purposes of this policy. Accordingly, you should not trade on the basis of these rumors.

Material non-public information must be kept confidential

Material non-public information about CNS or its business partners is the property of CNS, and unauthorized disclosure or use of that information is prohibited. That information should be maintained in strict confidence and should be discussed, even within CNS, only with persons who have a "need to know." You should exercise the utmost care and circumspection in dealing with information that may be material non-public information. Conversations in public places, such as hallways, elevators, restaurants and airplanes, involving information of a sensitive or confidential nature should be avoided. Written information should be appropriately safeguarded and should not be left where it may be seen by persons not entitled to the information. The unauthorized disclosure of information could result in serious consequences to CNS, whether or not the disclosure is made for the purpose of facilitating improper trading in securities.

Participation in electronic bulletin boards, chat rooms, blogs or websites must be consistent with this Policy

Any written or verbal statement that would be prohibited under the law or under this policy is equally prohibited if made on electronic bulletin boards, chat rooms, blogs, websites or any other form of social media, including the disclosure of material non-public information about CNS or material non-public information with respect to other companies that you come into possession of as an associate of CNS.

Public disclosures should be made only by designated persons

No individuals other than specifically authorized personnel should release material information to the public or respond to inquiries from the media, analysts, investors or others outside of CNS. You should not respond to these inquiries unless expressly authorized to do so and should refer any inquiries to the Chief Executive Officer or Chief Financial Officer.

Post-employment transactions may be prohibited

The portions of this policy relating to trading while in possession of material non-public information and the use or disclosure of that information continue to apply to transactions in CNS securities even after termination of employment or association with CNS. If you are aware of material non-public information about CNS when your employment or other business relationship with CNS ends, you may not trade in CNS securities or disclose the material non-public information to anyone else until that information is made public or becomes no longer material.

Exceptions

In certain limited circumstances, a transaction otherwise prohibited by this policy may be permitted if, prior to the transaction, the Compliance Officer determines that the transaction is not inconsistent with the purposes of this policy. The existence of a personal financial emergency does not excuse you from compliance with this policy and will not be the basis for an exception to the policy for a transaction that is inconsistent with the purposes of the policy.

Additional Requirements Applicable to Restricted Persons

"Restricted Persons" are those who are at an enhanced risk of possessing inside information and who therefore must exercise greater diligence to comply with insider trading prohibitions. This group includes all members of the Board of Directors, officers and certain senior finance, clinical, legal, HR, business development, investor relations, corporate communication and management associates, as well as any other associates in a role that makes it likely they will have involvement with material non-public information. This list is updated on a quarterly basis by the Chief Financial Officer in consultation with the Compliance Officer. You will be notified by the Chief Financial Officer if you are considered a Restricted Person under this policy, and you will remain so until notified of a change in such status.

If you are a Restricted Person that is not a director or executive officer, the procedures set forth in this section of the policy will cease to apply to your transactions in CNS securities upon the expiration of any blackout period that is applicable to your transactions at the time your employment or other relationship with CNS ends. Directors will remain Restricted Persons for a period of six months following the last day of service as a director of CNS, and executive officers will remain Restricted Persons for a period of six months following the last day of employment with CNS.

Quarterly blackout periods

No Restricted Person may trade in CNS securities during a quarterly blackout period, regardless of whether they are then actually aware of material non-public information.
A quarterly blackout period is in effect with respect to each quarterly earnings announcement, starting on the 15th day of the third month of the applicable CNS fiscal quarter and ending when two full trading days have passed following the filing of Form 10-Q or Form 10-K with the SEC (as appropriate for the period). CNS has selected this period because it is the time when there is likely to be material non-public information about CNS that may be available to Restricted Persons. Note, that if you are in possession of material non-public information following the announcement of earnings and/or the filing of the 10-Q/10-K, the other provisions of this policy would remain in effect to prohibit you from trading.
For certain Restricted Persons designated by the Compliance Officer, in consultation with the Chief Executive Officer and the Chief Financial Officer from time to time, the quarterly blackout period may start prior to the 15th day of the third month of the quarter.

Notwithstanding the above, a quarterly blackout period does not prohibit trading in CNS securities pursuant to a valid pre-existing 10b5-1 plan approved by CNS as described below.

Trading pre-clearance requirement for certain Restricted Persons

Certain Restricted Persons designated by the Chief Financial Officer, in consultation with the Chief Executive Officer and the Compliance Officer from time to time, must obtain pre-clearance by CNS's Compliance Officer or, in his or her absence, CNS's Chief Executive Officer (each an "Approving Person") before engaging in any transaction involving CNS securities, including, but not limited to, purchases, sales, and gifts. Those Restricted Persons who are required to obtain pre-clearance will be notified from time to time by the Compliance Officer of the applicable pre-clearance or other procedures applicable to them. Each Approving Person should consult with the other Approving Person, or his or her designee, prior to granting pre-clearance for trades. Neither Approving Person may engage in a transaction in CNS securities unless the other Approving Person has pre-cleared the transaction.

The Approving Persons are under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit a transaction, even if it would not violate the federal securities laws or a specific provision of this policy. In certain circumstances, other associates may be asked to clear with an Approving Person all proposed transactions before initiating them. The fact that a particular intended trade has been denied pre-clearance should be treated as confidential information and should not be disclosed to any person unless authorized by the Approving Person.

If a request for pre-clearance is approved, you have three business days to effect the transaction (or, if sooner, before commencement of a quarterly or event-specific blackout period). Under no circumstance may a person trade while aware of material non-public information about CNS, even if pre-cleared. Thus, if you become aware of material non-public information after receiving pre-clearance, but before the trade has been executed, you must not effect the pre-cleared transaction.

CNS's approval of any particular transaction under this pre-clearance procedure does not insulate any Restricted Person from liability under the securities laws. Under the law, the ultimate responsibility for determining whether an individual is aware of material non-public information about CNS rests with that individual in all cases.

10b5-1 Plans

SEC Rule 10b5-1(c) of the Securities Exchange Act of 1934 permits corporate insiders to establish written trading plans (commonly referred to as "10b5-1 plans") that can be useful in enabling insiders to plan ahead without fear that they might become exposed to material non-public information that will prevent them from trading. Where a valid 10b5-1 plan has been established at a time when the insider was not in possession of material non-public information, trades executed as specified by the plan do not violate the securities laws or this policy even if the insider is in possession of material non-public information at the time the trade is executed. Trades executed as specified by the plan are not subject to the pre-clearance requirement.

To qualify as a 10b5-1 plan for purposes of this policy, the plan must be approved in advance by the Compliance Officer, and you should allow at least five business days for that approval. These pre-planned trading programs are available only to officers and such other CNS associates as may be designated from time to time by the Chief Executive Officer, the Chief Financial Officer and the Compliance Officer. For more information about how to establish a 10b5-1 plan, please contact the Compliance Officer. CNS reserves the right to disapprove any submitted plan, and to suspend or instruct you to terminate any plan that it has previously approved.

Inquiries

Any questions about this policy, its application to a proposed transaction, or the requirements of applicable laws should be directed to the Chief Financial Officer or Compliance Officer.

Adopted by the Board of Directors on March 1, 2022:

/s/ *John Climaco*
John Climaco
Chairman and Chief Executive Officer

/s/ *Christopher S. Downs*
Christopher S. Downs
Secretary to the Board and Chief Financial Officer

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-3 (File Nos. 333-262262, 333-275671 and 333-279285), Forms S-8 (File Nos. 333-239998 and 333-275699), and Forms S-1 (File Nos. 333-249068, 333-267975, 333-251530, 333-275973, and 333-280790) of our report dated March 31, 2025 with respect to the audited financial statements of CNS Pharmaceuticals, Inc. (the "Company") appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2024.

/s/ MaloneBailey, LLP
www.malonebailey.com

Houston, Texas
March 31, 2025

EXHIBIT 31.1

CERTIFICATION BY OFFICER

I, John Climaco, certify that:

1. I have reviewed this Form 10-K for the year ended December 31, 2024 of CNS Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and we have:

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

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

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

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

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

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

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

Date: March 31, 2025

By: /s/ John Climaco

John Climaco
Chief Executive Officer and President

EXHIBIT 31.2

CERTIFICATION BY OFFICER

I, Christopher Downs, certify that:

1. I have reviewed this Form 10-K for the year ended December 31, 2024 of CNS Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and we have:

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

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

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

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

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

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

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

Date: March 31, 2025

By: /s/ Christopher Downs

Christopher Downs
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of CNS Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Form 10-K for the year ended December 31, 2024 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2025

By: /s/ John Climaco

John Climaco
Chief Executive Officer and President

EXHIBIT 32.2

CERTIFICATION OF OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of CNS Pharmaceuticals, Inc., a Nevada corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Form 10-K for the year ended December 31, 2024 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2025

By: /s/ Christopher Downs
Christopher Downs
Chief Financial Officer