2,215,667 Shares of Common Stock

11,117,667 Pre-Funded Warrants to Purchase up to 11,117,667 Shares of Common Stock

13,333,334 Series A Common Warrants to Purchase up to 13,333,334 Shares of Common Stock

13,333,334 Series B Common Warrants to Purchase up to 13,333,334 Shares of Common Stock

11,117,667 Shares of Common Stock Underlying such Pre-Funded Warrants

13,333,334 Shares of Common Stock Underlying such Series A Common Warrants

13,333,334 Shares of Common Stock Underlying such Series B Common Warrants

CNS Pharmaceuticals, Inc.

We are offering on a reasonable best efforts basis 2,215,667 shares of our common stock together with series A warrants (each, a "Series A warrant") to purchase up to 13,333,334 shares of our common stock and series B warrants (each, a "Series B warrant" and together with the Series A warrant, the "common warrants") to purchase up to 13,333,334 shares of our common stock, at a combined public offering price of $0.30 per share and accompanying common warrants. Each common warrant will be exercisable for one share of our common stock and have an exercise price of $0.30 per share. The Series A warrants will be exercisable immediately and will expire five years from the date of issuance and the Series B warrants will be exercisable immediately and will expire 18 months from the date of issuance. The shares of common stock and common warrants will be issued separately and will be immediately separable upon issuance but will be purchased together in this offering. This prospectus also relates to the shares of common stock issuable upon exercise of the common warrants sold in this offering.

We are also offering pre-funded warrants (the "pre-funded warrants" and together with the common warrants, the "warrants") to purchase up to 11,117,667 shares of common stock to those investors whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, in lieu of shares of common stock that would result in beneficial ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant is exercisable for one share of common stock and has an exercise price of $0.001 per share. The combined purchase price per pre-funded warrant and accompanying common warrants is equal to $0.299, which is equal to the combined purchase price per share of common stock and accompanying common warrants less $0.001. Each pre-funded warrant will be exercisable immediately upon issuance and may be exercised at any time until exercised in full. The pre-funded warrants and common warrants will be issued separately and will be immediately separable upon issuance but will be purchased together in this offering. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. This prospectus also relates to the shares of common stock issuable upon exercise of the pre-funded warrants sold in this offering.

We refer to the common stock and warrants to be sold in this offering collectively as the "securities."

These securities are being sold in this offering to certain purchasers under a securities purchase agreement dated January 29, 2024 between us and such purchasers. The securities are expected to be issued in a single closing and the combined public offering price per share of common stock or pre-funded warrant and accompanying common warrants will be fixed for the duration of this offering. We will deliver all securities to be issued in connection with this offering delivery versus payment or receipt versus payment, as the case may be, upon receipt of investor funds received by us.

Our common stock is listed on the Nasdaq Capital Market under the symbol "CNSP." On January 29, 2024 the last reported sale price of our common stock on Nasdaq was $0.3318 per share. There is no established public trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the warrants on any national securities exchange or other trading system.

We have engaged A.G.P./Alliance Global Partners to act as our lead placement agent and Maxim Group LLC as co-placement agent (together, the "placement agents") in connection with this offering. The placement agents have agreed to use their reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agents are not purchasing or selling any of the securities we are offering and the placement agents are not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to compensate the placement agents as set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. Because there is no minimum number of securities or minimum aggregate amount of proceeds for this offering to close, we may sell fewer than all of the securities offered hereby, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. Because there is no escrow account and there is no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. This offering will end no later than February 1, 2024, except that the shares of common stock underlying the warrants will be offered on a continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act").

You should read this prospectus, together with additional information described under the heading "Where You Can Find More Information," carefully before you invest in any of our securities.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act and we have elected to comply with certain reduced public company reporting requirements.

Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 6 of this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and accompanying Common Warrants	Per Pre-Funded Warrant and accompanying Common Warrants	Total
Public offering price	$ 0.30	$ 0.299	$ 3,988,882.53
Placement agent fees [1]	$ 0.021	$ 0.0209	$ 279,221.78
Proceeds to us, before expenses[2]	$ 618,171.09	$ 3,091,489.66	$ 3,709,660.76

(1) We have agreed to pay the placement agents a cash fee equal to 7.0% of the aggregate proceeds of this offering and to reimburse the placement agents for certain of its offering-related expenses. See "Plan of Distribution" beginning on page 66 of this prospectus for a description of the compensation to be received by the placement agents.

(2) The amount of the proceeds to us presented in this table does not give effect to any exercise of the warrants.

Delivery of the shares and warrants is expected to be made on or about February 1, 2024, subject to satisfaction of customary closing conditions.

Joint Placement Agents

A.G.P. **Maxim Group LLC**

The date of this prospectus is January 29, 2024

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC to register the securities offered hereby under the Securities Act. We may also file a prospectus supplement or post-effective amendment to the registration statement of which this prospectus forms a part that may contain material information relating to these offerings. You should carefully read this prospectus before deciding to invest in our securities.

We have not, and the placement agents have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the placement agents have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

This prospectus may contain references to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM symbols. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus carefully, including the "Risk Factors" section in this prospectus. References in this prospectus to "we", "us", "its", "our" or the "Company" are to CNS Pharmaceuticals, Inc., as appropriate to the context.

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 Houston Pharmaceuticals, Inc. ("HPI") and The University of Texas M.D. Anderson Cancer Center ("UTMDACC") and own pursuant to a collaboration and asset purchase agreement with Reata Pharmaceuticals, Inc. ("Reata").

We believe our lead drug candidate, Berubicin, may be a significant development 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 an important new therapeutic alternative 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. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to cross the blood brain barrier in significant concentrations targeting brain cancer cells. While our focus is currently on the development of 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.

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 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.

The current trial being conducted will evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their

disease, and results will be compared to the efficacy of Lomustine, a current standard of care in this setting, with a 2 to 1 randomization of the estimated 243 patients to Berubicin or Lomustine. Patients receiving Berubicin will be 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 included a pre-planned, non-binding interim futility analysis which was conducted by an independent Data Safety Monitoring Board (DSMB) to recommend whether this study should continue as planned based on Berubicin showing statistically significant value as a second-line treatment for patients with glioblastoma compared with Lomustine. The analysis was to be conducted after at least 50% of the patients in the interim analysis population (30-50% of total expected patients for the trial) were able to be evaluated as having failed the primary efficacy endpoint (death). This recommendation reviewed the number of deaths on each arm to ensure that the overall survival of patients receiving Berubicin showed a statistically significant comparability to or was even higher than those receiving Lomustine. The median survival of patients receiving second-line treatment for glioblastoma has historically been shown to be approximately 6 months. We have historically used 6 months as an estimate for the median time to a 50% mortality rate. On December 18, 2023, we released the conclusion of the DSMB in its entirety as provided to us, which was that we continue our CNS-201 trial without modification. Management remains blinded to the data underlying the recommendation of the DSMB. 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 Dr. Priebe, our founder. 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) 6,667 shares of our common stock. The patents we licensed from HPI expired in March 2020.

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 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 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.

With the Reata Agreement and the HPI License, we believe we have obtained 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 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. In consideration, we must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) for 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 the WP1244 Agreement in the event that we fail to meet certain commercial diligence milestones. We have not met the commercial diligence milestones required as of the date hereof. As such, UTMDACC has the right to terminate the WP1244 Agreement upon notice to us. As of November 14, 2023, UTMDACC has not notified us of its intention to terminate the WP1244 Agreement.

On May 7, 2020, pursuant to the WP1244 portfolio license agreement described above, we entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. We agreed to fund approximately $1,134,000 over a two-year period. We paid and recorded $334,000 in 2020 related to this agreement in research and development expenses in our statements of operations. The remaining $800,000 was paid in 2021. The principal investigator for this agreement is Dr. Priebe. The work conducted under this Sponsored Research Agreement has produced a new mesylate salt of WP1244 termed WP1874. We believe the enhanced solubility of this salt may increase its ability to be formulated for use in an IV infusion, while maintaining similar potency and toxicity characteristics. As such, WP1874 will be the primary focus in our development efforts of the WP1244 portfolio. This agreement was extended and expired on March 31, 2023.

Recent Developments

Warrant Exercise Inducement Transaction

On October 16, 2023, we entered into a warrant exercise inducement offer letter (the "Inducement Letter") with a holder of certain existing warrants ("Existing Warrants") to receive new warrants (the "Inducement Warrants") to purchase up to a number of shares of common stock equal to 200% of the number of warrant shares issued pursuant to the exercise of such Existing Warrants to purchase shares of common stock, pursuant to which the warrant holder agreed to exercise for cash its Existing Warrants to purchase up to 1,878,000 shares of the Company's common stock, at $1.28 per share, in exchange for the Company's agreement to issue Inducement Warrants to purchase up to 3,756,000 shares of the Company's common stock (the "Inducement Warrant Shares").

Each Inducement Warrant has an exercise price equal to $1.28. The Inducement Warrants will be exercisable on the six-month anniversary of the date of issuance and may be exercised for a period of five years therefrom. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate proportional adjustment in the event of share dividends, share splits, reorganizations or similar events affecting the Company's common stock and the exercise price.

A holder may not exercise any portion of the Inducement Warrant to the extent that the holder, together with its affiliates and any other persons acting as a group together with any such persons, would own more than 4.99% (or, at the election of the purchaser, 9.99%) of the number of shares of common stock outstanding immediately after exercise (the "Beneficial Ownership Limitation"); provided that a holder with a Beneficial Ownership Limitation of 4.99%, upon notice to the Company and effectivesixty-one (61) days after the date such notice is delivered to us, may increase the Beneficial Ownership Limitation so long as it in no event exceeds 9.99% of the number of shares of common stock outstanding immediately after exercise.

If, at the time a holder exercises its Inducement Warrants, a registration statement registering the issuance of the shares of common stock underlying the Inducement Warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may only exercise its Inducement Warrants (either in whole or in part), at such time by means of a cashless exercise in which the holder shall be entitled to receive upon such exercise the net number of shares of common stock determined according to a formula set forth in the Inducement Warrants, which generally provides for a number of shares of common stock equal to (A) (1) the volume weighted average price on (x) the trading day preceding the notice of exercise, if the notice of exercise is executed and delivered on a day that is not a trading day or prior to the opening of "regular trading hours" on a trading day or (y) the trading day of the notice of exercise, if the notice of exercise is executed and delivered after the close of "regular trading hours" on such trading day, or (2) the bid price on the day of the notice of exercise, if the notice of exercise is executed during "regular trading hours" on a trading day and is delivered within two hours thereafter, less (B) the exercise price, multiplied by (C) the number of shares of common stock the Inducement Warrant was exercisable into, with such product then divided by the number determined under clause (A) in this sentence.

In the event of a fundamental transaction, as described in the Inducement Warrants and generally including any reorganization, recapitalization or reclassification of the Company's common stock, the sale, transfer or other disposition of all or substantially all of the Company's properties or assets, the Company's consolidation or merger with or into another person, the acquisition of more than 50% of the Company's outstanding shares of common stock, the holders of the Inducement Warrants will be entitled to receive upon exercise of the Inducement Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Inducement Warrants immediately prior to such fundamental transaction. Additionally, in the event of a fundamental transaction, the Company or any successor entity will, at the option of the holder of a Inducement Warrant exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction (or, if later, the date of the public announcement thereof), purchase the Inducement Warrant from the holder by paying to the holder an amount of consideration equal to the value of the remaining unexercised portion of such Inducement Warrant on the date of consummation of the fundamental transaction based on the Black-Scholes option pricing model, determined pursuant to a formula set forth in the Inducement Warrants. The consideration paid to the holder will be the same type or form of consideration that was offered and paid to the holders of shares of common stock in connection with the fundamental transaction; provided that if no such consideration was offered or paid, the holders of common stock will be deemed to have received common stock of the successor entity in such fundamental transaction for purposes of this provision of the Inducement Warrants.

In connection with the offering pursuant to this prospectus, we amended the terms of the Inducement Warrants to purchase the Inducement Warrant Shares to reduce the exercise price of such Inducement Warrants to: (i) equal the exercise price of the common warrants sold in this offering; and (ii) extend the term during which the Inducement Warrants could remain exercisable to the term of the Series A common warrants sold in this offering. The amendment of the Inducement Warrants is subject to shareholder approval. See "Description of Common Warrants-Amendment to Outstanding Inducement" Warrants for further information.

Company Information

Our principal executive offices are located at 2100 West Loop South, Suite 900, Houston, TX 77027 and our telephone number is (800) 946-9185. Our website address is www.cnspharma.com. The information on or accessible through our website is not part of this prospectus.

The Offering

Common stock we are offering	2,215,667 shares of common stock.
Pre-funded warrants we are offering	We are also offering 11,117,667 pre-funded warrants to purchase up to 11,117,667 shares of common stock in lieu of shares of common stock to any purchaser whose purchase of shares of common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the purchaser's election, 9.99%) of our outstanding common stock immediately following the consummation of this offering. Each pre-funded warrant will be exercisable for one share of common stock, will have an exercise price of $0.001 per share, will be immediately exercisable, and may be exercised at anytime until exercised in full. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the pre-funded warrants.
Common warrants we are offering	We are also offering 13,333,334 Series A warrants to purchase up to 13,333,334 shares of common stock and 13,333,334 Series B warrants to purchase up to 13,333,334 shares of common stock. Each common warrant will be exercisable for one share of common stock, and will have an exercise price of $0.30 per share. Each Series A warrant will be exercisable immediately, and will expire five years from the date of issuance. Each Series B warrant will be exercisable immediately, and will expire 18 months from the date of issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Common stock outstanding immediately before this offering	6,214,598 shares (as adjusted for the exercise and full delivery of the Existing Warrants in the Warrant Exercise Inducement Transaction described above and sales under the Company's Capital on Demand™ Sales Agreement subsequent to September 30, 2023)
Common stock outstanding immediately after this offering	19,547,932 shares, assuming the full exercise of all pre-funded warrants and assuming none of the common warrants issued in this offering are exercised.

Use of proceeds	We estimate that the net proceeds from this offering will be approximately $3.4 million, after deducting the placement agent fees and estimated offering expenses payable by us. We intend to use the proceeds from this offering primarily to fund our CNS-201 trial, which is a global potentially pivotal trial of Berubicin for Glioblastoma, for other research and development, and for working capital. See "Use of Proceeds."

Reasonable best efforts offering	We have agreed to offer and sell the securities offered hereby to the purchasers through the placement agents. The placement agents are not required to buy or sell any specific number or dollar amount of the securities offered hereby, but will use their reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. See "Plan of Distribution" on page 66 of this prospectus.
Amendment to certain outstanding warrants	In connection with the offering pursuant to this prospectus, we amended the terms of the Inducement Warrants to purchase the Inducement Warrant Shares to reduce the exercise price of such Inducement Warrants to: (i) equal the exercise price of the common warrants sold in this offering; and (ii) extend the term during which the Inducement Warrants could remain exercisable to the term of the Series A common warrants sold in this offering. The amendment of the Inducement Warrants is subject to shareholder approval. If such shareholder approval is not obtained by the date that is six months following the closing of this offering, then we agreed to (i) automatically amend the exercise price of the Inducement Warrants to be the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of our common stock on the date that is six months following the closing date of this offering (if and only if such new exercise price on the repricing date is lower than the exercise price of the Inducement Warrants then in effect), and (ii) extend the expiration date of the Inducement Warrants to the date that is five (5) years from the issuance date of the Series A common warrants.
Risk Factors	An investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page 6 of this prospectus and the other information included in this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities.
Nasdaq listing symbol	Our common stock is listed on The Nasdaq Capital Market under the symbol "CNSP." There is no established trading market for the common warrants or pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the common warrants or pre-funded warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the common warrants and pre-funded warrants will be limited.

The number of shares of common stock to be outstanding after this is based on 6,214,598 shares outstanding as of January 18, 2024, which includes 129,530 shares issued under the Company's Capital on Demand™ Sales Agreement subsequent to September 30, 2023, 1,878,000 shares of common stock issued and yet to be issued to the holder of the Existing Warrants that were exercised pursuant to the Inducement Letter discussed in the above section "Recent Developments - Warrant Exercise Inducement Transaction" and excludes:

- 4,240,727 shares of common stock underlying outstanding warrants at a weighted average exercise price of $3.02 per share (assuming the reduction of the exercise price of the Inducement Warrants is completed as discussed in the section "Prospectus Summary – Recent Developments - Warrant Exercise Inducement Transaction");
- 328,770 shares of common stock underlying outstanding options with a weighted average exercise price of $20.35 per share, which options vest over a three to four-year period;
- 35,707 shares of common stock underlying Restricted Stock Units which vest over a four-year period and Performance Units which vest based on our performance against predefined share price targets and the achievement of Positive Interim, Clinical Data as defined by the Board;
- 545,610 shares available for future issuance under the CNS Pharmaceuticals, Inc. 2020 Stock Plan; and
- 26,666,668 shares of common stock issuable upon the exercise of the common warrants issued in this offering.

Except as otherwise indicated, the information in this prospectus assumes no exercise of options or exercise of warrants or sale of pre-funded warrants in this offering.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before investing in our securities, you should consider carefully the risks and uncertainties discussed under "Risk Factors" in our latest annual report on Form 10-K and subsequent quarterly reports on Form 10-Q and current reports on Form 8-K. You should carefully consider each of the following risks, together with all other information set forth in this prospectus, including the financial statements and the related notes, before making a decision to buy our securities. If any of the following risks actually occurs, our business could be harmed. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to this Offering

The results of the interim analysis of our CNS-201 trial may not be indicative of the final results from this trial.

We reached the criteria required by the study protocol for our CNS-201 trial to conduct a pre-planned, non-binding futility analysis, which an independent Data Safety Monitoring Board ("DSMB") reviewed on an unblinded basis to determine whether or not to recommend continuing the study. The DSMB reviewed the number of deaths in each arm to ensure that the overall survival of patients receiving Berubicin shows at least a statistically significant comparability to those receiving Lomustine as defined in the protocol. In December 2023, we released the conclusion of the DSMB in its entirety as provided to the Company, which was that we continue our CNS-201 trial without modification. Management remains blinded to the data underlying the recommendation of the DSMB. The conclusions of the DSMB may not be indicative of the final results of our CNS-201 trial, which we will not have until year end 2024 at the earliest.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our common stock to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering primarily to fund our CNS-201 trial, which is a global potentially pivotal trial of Berubicin for glioblastoma, for other research and development, and for working capital. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We will require substantial funding, 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 are using the proceeds from this offering to, among other uses, advance Berubicin through clinical development, including our current CNS-201 trial, which is a global potentially pivotal trial of Berubicin for glioblastoma. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and commercialize 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 Berubicin would likely be delayed. Further, there can be no assurance that the costs we will need to incur to obtain regulatory approval of 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 will require additional financing of approximately $12 million (before taking into account the expected proceeds from this offering) to complete the CNS-201 trial, which is a global potentially pivotal trial of Berubicin for glioblastoma, plus such additional working capital to fund our operations and other pre-clinical programs during the pendency of the trial. We believe that our existing cash and cash equivalents plus the proceeds from this offering (assuming we complete the maximum offering of which there is no assurance) will be sufficient to meet our projected operating requirements into the second quarter of 2024. Such projections are subject to changes in our internally funded preclinical and clinical activities, including unplanned preclinical and clinical activity. 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 planned interim futility analysis of our CNS-201 global clinical trials of Berubicin in glioblastoma demonstrates clinical benefit of at least equivalence versus the Lomustine control arm results;
- 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 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.

Purchasers in this offering will experience immediate and substantial dilution in net tangible book value.

The public offering price per share of common stock and related common warrants and the public offering price of each pre-funded warrant and related common warrants will be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock after giving effect to this offering. Assuming the sale of 13,333,334 shares of our common stock and accompanying warrants to purchase up to 13,333,334 shares of common stock at a combined public offering price of $0.30 per share, assuming no sale of any pre-funded warrants in this offering, no exercise of the warrants being offered in this offering and after deducting the placement agent fees and commissions and estimated offering expenses payable by us, you will incur immediate dilution in pro forma as adjusted net tangible book value of approximately $0.088 per share. As a result of the dilution to investors purchasing securities in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of the liquidation of our company. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you participate in this offering. To the extent shares are issued under outstanding options and warrants at exercise prices lower than the public offering price of our common stock in this offering, you will incur further dilution.

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

We will require additional, substantial financing in order to complete our clinical trials. We intend to seek to raise additional funds for our operations, to finance acquisitions or to develop strategic relationships by issuing equity or convertible debt securities in addition to the securities issued in this offering, 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 75,000,000 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.

There is no public market for the common warrants or pre-funded warrants being offered in this offering.

There is no established public trading market for the common warrants or pre-funded warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or pre-funded warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Stock Market. Without an active market, the liquidity of the common warrants and pre-funded warrants will be limited.

Holders of our common warrants and pre-funded warrants will have no rights as a common stockholder until they acquire our common stock.

Until holders of our common warrants and pre-funded warrants acquire shares of our common stock upon exercise of such common warrants or pre-funded warrants, the holders will have no rights with respect to shares of our common stock issuable upon exercise of such common warrants or pre-funded warrants. Upon exercise of the common warrants or pre-funded warrants, holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

If we do not maintain a current and effective prospectus relating to the common stock issuable upon exercise of the common warrants and pre-funded warrants, public holders will only be able to exercise such common warrants and pre-funded warrants on a "cashless basis."

If we do not maintain a current and effective prospectus relating to the shares of common stock issuable upon exercise of the common warrants and pre-funded warrants at the time that holders wish to exercise such warrants, they will only be able to exercise them on a "cashless basis," and under no circumstances would we be required to make any cash payments or net cash settle such warrants to the holders. As a result, the number of shares of common stock that holders will receive upon exercise of the common warrants and pre-funded warrants will be fewer than it would have been had such holders exercised their common warrants or pre-funded warrants for cash. We will do our best efforts to maintain a current and effective prospectus relating to the shares of common stock issuable upon exercise of such warrants until the expiration of such warrants. However, we cannot assure you that we will be able to do so. If we are unable to do so, the potential "upside" of the holder's investment in our company may be reduced.

The common warrants and pre-funded warrants are speculative in nature.

The common warrants and pre-funded warrants offered hereby do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the pre-funded warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of $0.001 per share and holders of the common warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price per share equal to the public offering price of shares of common stock in this offering. Moreover, following this offering, the market value of the pre-funded warrants and common warrants will be uncertain and there can be no assurance that the market value of such warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the common warrants, and consequently, whether it will ever be profitable for holders of the common warrants to exercise the common warrants.

This is a "best efforts" offering. No minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agents have agreed to use their reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agents have no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations and may need to raise additional funds to complete such short-term operations. Such additional fundraises may not be available or available on terms acceptable to us.

We may be required to repurchase the common warrants, which may prevent or deter a third party from acquiring us.

The common warrants 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 common warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the common 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.

If our stock price fluctuates after the offering, you could lose a significant part of your investment.

The market price of our common stock could be subject to wide fluctuations in response to, among other things, the risk factors described in this prospectus, and other

factors beyond our control, such as fluctuations in the valuation of companies perceived by investors to be comparable to us. Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political, and market conditions, such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock. In the past, many companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

This offering may cause the trading price of our common stock to decrease.

The price per share, together with the number of shares of common stock we issue if this offering is completed, may result in an immediate decrease in the market price of our common stock. This decrease may continue after the completion of this offering.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. We may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of the securities will be the sole source of gain, if any, for the foreseeable future.

Risks Related to the Company's Business and Industry

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, 2022 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 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 Berubicin, we do not have any other clinical-stage drug candidates in our portfolio. As such, we are dependent on the success of Berubicin in the near term. We cannot provide you any assurance that we will be able to successfully advance Berubicin through the development process.

We have in the past completed related party transactions, some of which that were not conducted on an arm's length basis.

We have entered into transactions with entities affiliated with our founder, Dr. Waldemar Priebe, including:

- We acquired the patent rights to Berubicin pursuant to a license agreement with Houston Pharmaceuticals, Inc.
- We entered into a sublicense agreement with WPD Pharmaceuticals, Inc., an entity with which Dr. Priebe is affiliated, which granted a WPD a license to Berubicin in a specified territory (primarily in eastern Europe and western Asia).
- We entered into a sublicense agreement with Animal Life Sciences, LLC ("ALI"), which granted an exclusive sublicense to Berubicin for the treatment of cancer in non-human animals.

We entered into the above agreements related to Berubicin with HPI, WPD and ALI prior to our IPO, at a time during which we did not have an independent board of directors. As such, due to the related party relationship between our Company and these entities, the negotiation of these agreements was not conducted on an arm's length basis. As such, it is possible that the terms were less favorable to us than in a transaction negotiated in an arm's length transaction.

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.

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 WP1244/WP1874, 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 pre-clinical work related to other drug candidate, WP1244/WP1874. 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 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 Berubicin will receive regulatory approval, and without regulatory approval we will not be able to market Berubicin.

Our business currently depends largely on the successful development and commercialization of Berubicin. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of 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 prospectus indicating that 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 Berubicin and do not indicate that Berubicin will achieve favorable efficacy results in any later stage trials or that the FDA or any comparable agency will ultimately determine that 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 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 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 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 Berubicin (or our other product candidates) are significant. If 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 Berubicin that we will need to conduct prior to seeking regulatory approval. However, we do not have agreements for supplies of 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 Berubicin if it is 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 cGMP, 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 expired in March 2020, the expiration of our patents may subject us to increased competition, and the Orphan Drug Designation we received for Berubicin will not bar approval of other similar products under certain circumstances.

The U.S. patents for Berubicin that we licensed from HPI expired in March 2020, and such expiration may subject us to increased competition. 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 we are exploring if there are other patents that could be filed related to Berubicin to extend additional protections. However, 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 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 December 31, 2023, we have 3 full-time employees. We also have 2 officers serving as part-time employees. 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 medical officer and chief science officer are currently working for us on a part-time basis. Our chief executive officer, chief medical 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 medical officer, which are developing anti-cancer drug candidates. Specifically, John M. Climaco, our chairman and chief executive officer, is also serving as a director for Moleculin Biotech, Inc., a company also actively developing anticancer drugs. Sandra Silberman, our chief medical officer, is also the chief medical officer for New Products at Moleculin. Donald Picker, our chief science officer, is the chief scientific officer at Moleculin.

In addition to our officers' part-time status, since Mr. Climaco, Dr. Silberman 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, Dr. Silberman 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, 2022, 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. As a result of the material weakness with the third-party CRO, the Company corrected previously issued financial statements for the periods ended December 31, 2021, March 31, 2022, June 30, 2022, and September 30, 2022 to properly reflect research and development expenses and the related liability in these periods that were previously not recorded. 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, 2022 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, 2022, 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.

In May 2020, the SEC issued an order suspending the trading of our common stock and Nasdaq issued a trading halt in our common stock.

On May 1, 2020, the SEC, pursuant to Section 12(k) of the Exchange Act, ordered the temporary suspension of trading in our securities because of questions regarding the accuracy and adequacy of information in the marketplace about us and our securities. Pursuant to the suspension order, the suspension commenced at 9:30 a.m. EDT on May 4, 2020 and terminated at 11:59 p.m. EDT on May 15, 2020. On May 15, 2020, Nasdaq issued a trading halt in our common stock pending the receipt of requested information, which halt was released on May 28, 2020. We believe in the accuracy and adequacy of our public disclosures, but can provide no assurances that we will not encounter future similar actions, which may adversely affect the holders of our common stock.

If we are unable to maintain compliance with the listing requirements of The Nasdaq Capital Market, our common stock may 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.

We have in the past, and we may again in the future, fail to comply with the continued listing requirements of the Nasdaq Capital Market, which would subject our common stock to being delisted. In particular, on August 17, 2023, we received a letter (the "Letter") from the staff of the Listing Qualifications Department (the "Staff") of Nasdaq which notified us that we were not in compliance with Nasdaq's Listing Rule 5550(b)(1) (the "Listing Rule"), which requires that we maintain a minimum of $2.5 million in stockholders' equity, and that we also did not, at such time, meet the alternatives of market value of listed securities or net income from continuing operations set forth in the Listing Rule.

The Letter did not have any immediate effect on the listing of our common stock on Nasdaq and we had 45 calendar days to submit a plan to regain compliance. We timely submitted our plan to regain compliance with the Listing Rule, our plan was accepted and the Staff granted an extension until February 13, 2024 (the "Extension Period") to evidence compliance. We are seeking to regain compliance with the Listing Rule prior to the end of the Extension Period. However, there can be no assurance that we will be able to regain compliance with the Listing Rule prior to the end of the Extension Period, or at all, or that our common stock will remain listed on Nasdaq.

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.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains certain forward-looking statements that involve substantial risks and uncertainties. All statements contained in this prospectus, other than statements of historical facts, are forward-looking statements including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate", "believe", "estimate", "expect", "intend", "may", "plan", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, 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.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and

expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this prospectus that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

USE OF PROCEEDS

We estimate that the net proceeds from the offering will be approximately $3.4 million, based on a public offering price of $0.30 per share and accompanying common warrants and $0.299 per pre-funded warrant and accompanying common warrants, after deducting the placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants. The combined public offering price per share (or pre-funded warrant) and common warrants will be fixed for the duration of this offering.

We intend to use the net proceeds for (i) our CNS-201 trial, which is a global potentially pivotal trial of Berubicin for glioblastoma; (ii) other research and development; and (iii) working capital.

We estimate that our CNS-201 trial will cost approximately $12 million (excluding such additional working capital to fund our operations and other pre-clinical programs during the pendency of the trial) and, as such, we will require significant additional financing even if we complete the maximum offering hereunder. 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 securities, which may occur at prices lower than the offering price of our common stock in this offering.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the application of these proceeds. Net offering proceeds not immediately applied to the uses summarized above will be invested in short-term investments such as money market funds, commercial paper, U.S. treasury bills and similar securities investments pending their use.

DILUTION

If you invest in our securities in this offering, your interest will be diluted immediately to the extent of the difference between the public offering price paid by the purchasers of the shares of common stock (and pre-funded warrants) and related common warrants sold in this offering and the as adjusted net tangible book value per shares of common stock after this offering.

As of September 30, 2023, our as reported net tangible book value was $(1.7) million, or $(0.414) per share of common stock. Net tangible book value per share represents our total tangible assets, less our total liabilities, divided by the number of outstanding shares of our common stock. After giving effect to: (i) 1,878,000 shares of common stock issued and to be issued to the holder of the Existing Warrants that were exercised pursuant to the Inducement Letter discussed in the section "Prospectus Summary – Recent Developments - Warrant Exercise Inducement Transaction"; and (ii) 129,530 shares issued under the Company's Capital on Demand™ Sales Agreement subsequent to September 30, 2023 for gross proceeds of $222,312, our as adjusted net tangible book value was $0.7 million, or $0.118 per share of common stock.

Dilution represents the difference between the amount per share paid by purchasers in this offering and the as adjusted net tangible book value per share of common stock after the offering. After giving effect to the sale of 13,333,334 shares of common stock and accompanying common warrants in this offering at an offering price of $0.30 per share, and after deducting placement agent fees and estimated offering expenses payable by us, but without adjusting for any other change in our net tangible book value subsequent to September 30, 2023, our pro forma as adjusted net tangible book value would have been $0.212 per share. This represents an immediate increase in net tangible book value on a reported basis of $0.626, and on a proforma basis of $0.094 per share to our existing stockholders and immediate dilution of $0.088 per share to new investors

purchasing securities at the public offering price. The dilution figures assume no sale of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis, and excludes the proceeds, if any, from the exercise of any common warrants issued in this offering. The following table illustrates the dilution in net tangible book value per share to new investors as of September 30, 2023:

Public offering price per share and accompanying common warrants			$	0.30
Historical net tangible book value per share at September 30, 2023 (as adjusted)	$	0.118		
Increase in net tangible book value per share to the existing stockholders on a proforma basis attributable to —this offering.	$	0.094		
Proforma as adjusted net tangible book value per share after this offering			$	0.212
Dilution in net tangible book value per share to new investors on a proforma as adjusted basis			$	0.088

The number of shares of common stock to be outstanding after this offering is based on 4,207,068 shares outstanding as of September 30, 2023 plus 129,530 shares issued under the Company's Capital on Demand™ Sales Agreement subsequent to September 30, 2023, 1,878,000 shares of common stock issued and yet to be issued to the holder of the Existing Warrants that were exercised pursuant to the Inducement Letter discussed in the above section "Recent Developments - Warrant Exercise Inducement Transaction", and excludes:

- 4,240,727 shares of common stock underlying outstanding warrants at a weighted average exercise price of $3.89 per share (assuming the reduction of the exercise price of the Inducement Warrants is completed as discussed in the section "Prospectus Summary – Recent Developments - Warrant Exercise Inducement Transaction" the weighted average exercise price will be reduced to $3.02 per share);

- 328,770 shares of common stock underlying outstanding options with a weighted average exercise price of $20.35 per share, which options vest over a three to four-year period;

- 35,707 shares of common stock underlying Restricted Stock Units which vest over a four-year period and Performance Units which vest based on our performance against predefined share price targets and the achievement of Positive Interim, Clinical Data as defined by the Board;

- 545,610 shares available for future issuance under the CNS Pharmaceuticals, Inc. 2020 Stock Plan; and

- the shares of common stock issuable upon exercise of the common warrants in this offering.

The discussion and table above assume no exercise of the common warrants. To the extent that the warrants are exercised, you may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

CAPITALIZATION

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

- on an actual basis;

- on an as adjusted basis to give effect to 129,530 shares issued under the Company's Capital on Demand™ Sales Agreement subsequent to September 30, 2023, 1,878,000 shares of common stock issued and to be issued to the holder of the Existing Warrants that were exercised pursuant to the Inducement Letter discussed in the section "Prospectus Summary – Recent Developments - Warrant Exercise Inducement Transaction";

- on a pro forma as adjusted basis to give further effect to the issuance and sale of 13,333,334 shares of our common stock and accompanying common warrants in this offering at an offering price of $0.30 per share, after deducting the placement agent fees and estimated offering expenses payable by us, and assuming no issuance of pre-funded warrants and no exercise of the common warrants.

You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements

and related notes included in this prospectus.

	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	$ 909,547	$ 3,384,798	$ 6,802,536
Notes Payable	41,904	41,904	41,904
Stockholders' equity (deficit):			
Common stock, par value $0.001 per share: 75,000,000 shares authorized as of September 30, 2023; 4,207,068 shares issued and outstanding as of September 30, 2023; 6,214,598 shares issued and outstanding pro forma; 19,547,932 shares issued and outstanding pro forma as adjusted;	4,207	6,215	19,548
Additional paid-in capital	62,446,694	64,919,937	68,324,342
Accumulated deficit	(64,191,653)	(64,191,653)	(64,191,653)
Total stockholders' equity (deficit)	(1,740,752)	734,499	4,152,237
Total capitalization	$ (1,698,848)	$ 776,403	$ 4,194,141

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 prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. 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 prospectus.

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 HPI and UTMDACC and own pursuant to a collaboration and asset purchase agreement with Reata.

We believe our lead drug candidate, Berubicin, may be a significant development 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. 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. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to cross the blood brain barrier in significant concentrations targeting brain cancer cells. While our focus is currently on the development of 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.

Results of Operations for the Three Months Ended September 30, 2023 Compared to the Three Months Ended September 30, 2022

General and Administrative Expense

General and administrative expense was approximately $1,123,000 for the three months ended September 30, 2023 compared to approximately $1,211,000 for the comparable period in 2022. The decrease in general and administrative expense was mainly attributable to decreases of approximately $73,000 in legal and professional expenses, $29,000 in insurance expenses and $68,000 in stock compensation and $6,000 in other general and administrative expenses, which were offset by increases of approximately $15,000 in marketing and advertising, $28,000 in board compensation and $45,000 in travel expenses.

Research and Development Expense

Research and development expense was approximately $3,411,000 for the three months ended September 30, 2023 compared to approximately $2,208,000 for the comparable period in 2022. The increase 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 remain relatively consistent with the current quarter throughout the remainder of the trial as site activation efforts and the associated costs thereof transition into reimbursing clinical trial sites for patient treatment costs as site and patient enrollment increases. We expect to incur increased research and development costs in the future as we continue our clinical trial for Berubicin primarily due to higher patient enrollment and the associated cost of treating these patients.

Net Loss

The net loss for the three months ended September 30, 2023 was approximately $4,523,000 compared to approximately $3,420,000 for the comparable period in 2022. The change in net loss is attributable to an increase in CRO expenses and patient treatment costs related to continued progress with our clinical trial for Berubicin, a credit to research and development expense in the prior year period for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, as well as increases in legal and professional fees and other expenses.

Results of Operations for the Nine Months Ended September 30, 2023 Compared to the Nine Months Ended September 30, 2022

General and Administrative Expense

General and administrative expense was approximately $3,662,000 for the nine months ended September 30, 2023 compared to approximately $3,815,000 for the comparable period in 2022. The decrease in general and administrative expense was mainly attributable to decreases of approximately $175,000 for employee compensation and taxes, $111,000 in stock-based compensation, $117,000 in legal and professional expenses, and $69,000 in insurance expenses, which were offset by increases of approximately $112,000 in marketing and advertising, $70,000 in board compensation and $118,000 in travel expenses, and $19,000 in other expenses.

Research and Development Expense

Research and development expense was approximately $9,824,000 for the nine months ended September 30, 2023 compared to approximately $6,318,000 for the comparable period in 2022. The increase 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 remain relatively consistent with the current quarter throughout the remainder of the trial as site activation efforts and the associated costs thereof transition into reimbursing clinical trial sites for patient treatment costs as site and patient enrollment increases. We expect to incur increased research and development costs in the future as we continue our clinical trial for Berubicin primarily due to higher patient enrollment and the associated cost of treating these patients.

Net Loss

The net loss for the nine months ended September 30, 2023 was approximately $13,476,000 compared to approximately $10,137,000 for the comparable period in 2022. The change in net loss is attributable to an increase in CRO expenses related to continued progress with our clinical trial for Berubicin, a credit to research and development expense in the prior year period for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials.

Results of Operations for the Year Ended December 31, 2022 Compared to the Year Ended December 31, 2021

General and Administrative Expense

General and administrative expense was $5,967,052 for the year ended December 31, 2022 compared to $4,680,840 for 2021. The change is attributable to an increase of approximately $1,096,000 in professional expenses, $315,000 in employee compensation, $334,000 related to the write off of deferred offering costs and $84,000 in other general and administrative expenses. These changes were offset by decreases of $502,000 in stock-based compensation and advertising and marketing of $41,000.

Research and Development Expense

Research and development expense was $9,300,055 for the year ended December 31, 2022 compared to $9,805,075 for 2021. The decrease in research and development expenses during the period was mainly attributed to the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year, and this lower level of manufacturing activity is expected to continue throughout this year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in contract research organization (CRO) expenses related to continued progress with our Berubicin clinical trial. 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 remain relatively consistent with the year-to-date run-rate throughout the remainder of the trial as site activation efforts and the associated costs thereof transition into reimbursing clinical trial sites for patient treatment costs as site and patient enrollment increases. We expect to incur increased research and development costs in the future as we continue our clinical trial.

Interest Expense

Interest expense was $7,027 and $9,285 for the years ended December 31, 2022 and 2021, respectively.

Net Loss

The net loss for the year ended December 31, 2022 was $15,274,134 compared to $14,495,200 for 2021. The change in net loss is primarily attributable to decreased research and development costs.

Liquidity and Capital Resources

On September 30, 2023, we had cash of approximately $910,000 and we had a working capital deficit of approximately $2,007,000. We fund our operations from proceeds from equity sales.

We believe that our cash on hand is sufficient to fund our planned operations into, but not beyond, the fourth quarter of 2023, and with the cash received subsequent to September 30, 2023 for the Inducement Warrant Shares, is sufficient to fund our planned operations into the first quarter of 2024.

Our plan of operations is primarily focused on completing a clinical trial for Berubicin. We estimate that we will require additional financing of approximately $9.4 to $13.4 million to complete the clinical trial for Berubicin (taking into account our cash on hand as of September 30, 2023 of approximately $0.9 million), approximately $5.0 million to support near-term WP1244/WP1874 preclinical work, plus such additional working capital to fund our operations during the pendency of the trial. The timing and costs of clinical trials are difficult to predict and trial plans may change in response to evolving circumstances and as such the foregoing estimates may prove to be inaccurate.

We will need to raise additional capital in order to meet our 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.

Summary of Cash Flows

Cash used in operating activities

Net cash used in operating activities was approximately $11,604,000 and $8,252,000 for the nine months ended September 30, 2023 and 2022, respectively, and mainly included payments made for clinical trial preparation, officer compensation, insurance, marketing and professional fees to our consultants, attorneys and accountants.

Cash provided by financing activities

Net cash provided by financing activities was approximately $2,460,000 for the nine months ended September 30, 2023, related to the sale of common stock and exercise of warrants, which were offset by the repayment of notes payable. Net cash provided by financing activities was approximately $10,280,000 for the nine months ended September 30, 2022, related to the sale of common stock and exercise of warrants, which were offset by the repayment of notes payable.

Off-balance Sheet Arrangements

As of September 30, 2023, 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 milestones fees to HPI 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. As a result, management is required to routinely make judgments and estimates about the effects of matters that are inherently uncertain. Actual results may differ from these estimates under different conditions or assumptions. Management determined there were no critical accounting estimates.

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 Houston Pharmaceuticals, Inc. ("HPI") and The University of Texas M.D. Anderson Cancer Center ("UTMDACC") and own pursuant to a collaboration and asset purchase agreement with Reata Pharmaceuticals, Inc. ("Reata").

We believe our lead drug candidate, Berubicin, may be a significant development 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 an important new therapeutic alternative 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. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to cross the blood brain barrier in significant concentrations targeting brain cancer cells. While our focus is currently on the development of 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.

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 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.

The current trial being conducted will evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their disease, and results will be compared to the efficacy of Lomustine, a current standard of care in this setting, with a 2 to 1 randomization of the estimated 243 patients to Berubicin or Lomustine. Patients receiving Berubicin will be 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 included a pre-planned, non-binding interim futility analysis which was conducted by an independent Data Safety Monitoring Board (DSMB) to recommend whether this study should continue as planned based on Berubicin showing statistically significant value as a second-line treatment for patients with glioblastoma compared with Lomustine. The analysis was to be conducted after at least 50% of the patients in the interim analysis population (30-50% of total expected patients for the trial) were able to be evaluated as having failed the primary efficacy endpoint (death). This recommendation reviewed the number of deaths on each arm to ensure that the overall survival of patients receiving Berubicin showed a statistically significant comparability to or was even higher than those receiving Lomustine. The median survival of patients receiving second-line treatment for glioblastoma has historically been shown to be approximately 6 months. We have historically used 6 months as an estimate for the median time to a 50% mortality rate. On December 18, 2023, we released the conclusion of the DSMB in its entirety as

provided to us, which was that we continue our CNS-201 trial without modification. Management remains blinded to the data underlying the recommendation of the DSMB. 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 Dr. Priebe, our founder. 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) 6,667 shares of our common stock. The patents we licensed from HPI expired in March 2020.

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 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 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.

With the Reata Agreement and the HPI License, we believe we have obtained 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 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. In consideration, we must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) for 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 the WP1244 Agreement in the event that we fail to meet certain commercial diligence milestones. We have not met the commercial diligence milestones required as of the date hereof. As such, UTMDACC has the right to terminate the WP1244 Agreement upon notice to us. As of November 14, 2023, UTMDACC has not notified us of its intention to terminate the WP1244 Agreement.

On May 7, 2020, pursuant to the WP1244 portfolio license agreement described above, we entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. We agreed to fund approximately $1,134,000 over a two-year period. We paid and recorded $334,000 in 2020 related to this agreement in research and development expenses in our statements of operations. The remaining $800,000 was paid in 2021. The principal investigator for this agreement is Dr. Priebe. The work conducted under this Sponsored Research Agreement has produced a new mesylate salt of WP1244 termed WP1874. We believe the enhanced solubility of this salt may increase its ability to be formulated for use in an IV infusion, while maintaining similar potency and toxicity characteristics. As such, WP1874 will be the primary focus in our development efforts of the WP1244 portfolio. This agreement was extended and expired on March 31, 2023.

Market for Cancer Drugs and Berubicin

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 lead 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 currently limited pre-clinical and clinical data, Berubicin appears to show that it can cross the BBB. However, there is no assurance that Berubicin will be able to demonstrate such traits in more fulsome clinical trials.

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 Berubicin 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 Berubicin. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears in animal models and limited clinical data derived from a Phase 1 human clinical trial to cross the BBB and target cancer cells. 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.

Currently, there are no curative therapies for glioblastoma. In the clinical trial completed by Reata in February 2009, Berubicin demonstrated one durable complete response lasting over 14 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 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 these results are reproducible and if regulatory approval is secured to market Berubicin, based on its apparent ability to cross the BBB combined with its mechanism of action, more thoroughly discussed below, we believe this drug has the potential to become an effective treatment 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 respond very poorly), primarily due to the O6-methylguanine methyltransferase ("MGMT") enzyme, which is a DNA repair pathway in glioblastoma cells. When methylated, the enzyme has reduced DNA repair activity, and increases the activity of TMZ; thus unmethylated patients have greater DNA repair activity, and this confers a poorer prognosis. Given the different mechanism of action of Berubicin, patients with unmethylated MGMT may show a better outcome and this will be explored by stratification to the MGMT methylation status of patients on the current trial. This could potentially be used to support an application for approval of Berubicin as a frontline therapy, however, we believe that the most prudent initial investigational objective is the current stratified trial that can either serve as a registration trial or provide sufficient data to power an additional registration trial.

Berubicin

Our first product under development is Berubicin, a development stage anthracycline intended to treat glioblastoma. 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 evidence developed from animal models and limited clinical data derived from a Phase 1 human clinical trial, 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, Dr. Priebe created a library of high-affinity and sequence-selective deoxyribonucleic acid ("DNA")-binding agents 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 reresection, 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. If Berubicin shows efficacy in clinical trials, of which there is no assurance, it could become the primary drug treatment because TMZ is ineffective in this patient population.

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, with Dr. Priebe as the Scientific Founder. 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.

On May 24, 2019, our sublicensee, WPD, signed the Granting Agreement with the Polish National Center for Research and Development for co-funding of research and development work in the amount of 22,033,066 PLN (approximately US $5,798,875) for new drug development as a part of the project “New approach to glioblastoma treatment addressing the critical unmet medical need”, undertaken pursuant to the WPD Sublicense. The grant will be co-funded by the European Union, under the Smart Growth Operational Program 2014-2020, Sectoral Programme InnoNeuroPharm, Priority Axis I: Support R&D carried out by enterprises, Measure 1.2 Sectorial programs R&D. This grant funding is dependent upon WPD funding a portion of the trial estimated at 35-40% of the total cost, and we can provide no assurance that they can or will be able to do so. The main goal of the WPD Project is to implement the first in the world multicenter pediatric phase I clinical trial and phase II clinical trials in adults, in order to continue to explore the safety and efficacy of Berubicin. The WPD Project will also include preclinical tests to determine the prospective use of Berubicin with temozolomide and with other compounds being developed by WPD as candidates for anticancer drugs.

Berubicin 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.

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 are conducting a randomized, controlled multicenter study that will evaluate the efficacy of Berubicin versus Lomustine (CCNU, CeeNU®, or Gleostine®) in patients with recurrent glioblastoma. Randomization to the two therapies (Berubicin or Lomustine) will be 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 will 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 will 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 will be 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 to be 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.

The current trial being conducted will evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their disease, and results will be compared to the efficacy of Lomustine, a current standard of care in this setting, with a 2 to 1 randomization of the estimated 243 patients to Berubicin or Lomustine. Patients receiving Berubicin will be 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 included a pre-planned, non-binding interim futility analysis which was conducted by an independent Data Safety Monitoring Board (DSMB) to recommend whether this study should continue as planned based on Berubicin showing statistically significant value as a second-line treatment for patients with glioblastoma compared with Lomustine. The analysis was to be conducted after at least 50% of the patients in the interim analysis population (30-50% of total expected patients for the trial) were able to be evaluated as having failed the primary efficacy endpoint (death). This recommendation reviewed the number of deaths on each arm to ensure that the overall survival of patients receiving Berubicin showed a statistically significant comparability to or was even higher than those receiving Lomustine. The median survival of patients receiving second-line treatment for glioblastoma has historically been shown to be approximately 6 months. We have

historically used 6 months as an estimate for the median time to a 50% mortality rate. On December 18, 2023, we released the conclusion of the DSMB in its entirety as provided to us, which was that we continue our CNS-201 trial without modification. Management remains blinded to the data underlying the recommendation of the DSMB. 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.

Assuming final data from the above-described CNS-201 study is positive (and depending on the strength and quality of such data) at its completion we may seek an expedited pathway to approval to market Berubicin from relevant regulatory authorities, we may look for a partner with which to conduct a Phase 3 study, or we may attempt to raise sufficient capital to conduct such a study on our own. The goal of these potential Phase 3 studies, should they be necessary, is 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

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. We have licensed the right to certain intellectual property covering products comprised of anthracycline antibiotic compound, methods for manufacture and use for the treatment of cancer. The licensed intellectual property originally included certain material patents in the United States and their foreign counterparts throughout the world. The U.S. patents have expired, and as such, we may be subject to increased competition.

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 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 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 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 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:

- 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 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. We believe that our potentially pivotal CNS-201 study of Berubicin for the treatment of recurrent GBM is such a study. 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 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, 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 6,667 shares of the Company's common stock valued at $1.35 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, 2022 and 2021, the Company recognized $275,000 and $450,000 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 in related party transactions which are reviewed and approved by the Company's audit committee based upon the standards of providing superior pricing and time to delivery than that available from unrelated third parties.

With the Reata Agreement and the HPI License, we believe we have obtained 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 August 30, 2018, we entered into a sublicense agreement with WPD Pharmaceuticals, Inc., or WPD, pursuant to which we 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. As of December 31, 2021, WPD has demonstrated that it has exercised commercially reasonable development efforts under this agreement. 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 that is majority-owned by an entity controlled by Dr. Priebe, our founder.

On August 31, 2018, we entered into a sublicense agreement with Animal Life Sciences, LLC, or 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. Priebe, our founder, holds 38% of the membership interests of ALI.

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 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 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 Agreement. The term of the Agreement expires on the last to occur of: (a) the expiration of all patents subject to the Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate this 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.

On May 7, 2020, pursuant to the WP1244 Agreement described above, the Company entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. The Company agreed to fund approximately $1,134,000 over a two-year period. During the year ended December 31, 2020, the Company paid $334,000 and accrued $400,000 related to this agreement in research and development expenses in the Company's Consolidated Statements of Operations. During the year ended December 31, 2021, the Company paid $800,000 to UTMDACC related to this agreement. The principal investigator for this agreement is Dr. Priebe. The work conducted under this Sponsored Research Agreement has produced a new mesylate salt of WP1244 termed WP1874. We believe the enhanced solubility of this salt may increase its ability to be formulated for use in an IV infusion, while maintaining similar potency and toxicity characteristics. As such, WP1874 will be the primary focus in our development efforts of the WP1244 portfolio. This agreement was extended and expired on March 31, 2023.

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 5,870.27 upon delivery of 2 vials each of berubicin and berubicinol reference standards, (ii) PLN 873,201.00 upon delivery of a first batch of 150 berubicin drug product vials, and (iii) PLN 873,201.00 upon delivery of a second batch of 150 berubicin drug product vials. As of December 31, 2022, the reference standards had been delivered and were recognized in Accounts Receivable and as a reduction to research & development expense. As of March 31, 2023, the first batch of berubicin drug product vials had been ordered and was delivered in April 2023.

Employees

As of December 31, 2023, we had three full time employees. We also have two part-time employees serving as our chief medical and scientific officers, and accordingly, a high percentage of the work performed for our development projects is conducted by qualified part-time staff and independent contractors.

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 prospectus unless expressly noted.

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.

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.

MANAGEMENT

The following table sets forth the names and ages of all of our directors and executive officers as of January 1, 2024. Our officers are appointed by, and serve at the

pleasure of, the Board of Directors.

Name	Age	Position
John M. Climaco	54	Chief Executive Officer
Christopher S. Downs	45	Chief Financial Officer
Sandra L. Silberman	68	Chief Medical Officer
Donald Picker	78	Chief Science Officer
Faith L. Charles	62	Director and Chair of the Board of Directors
Jerzy (George) Gumulka	74	Director
Jeffry R. Keyes	50	Director
Andrzej Andraczke	80	Director
Carl Evans	76	Director
Bettina Cockroft	56	Director

Set forth below is biographical information about each of the individuals named in the tables above:

John M. Climaco, Esq. – Chief Executive Officer and Director. Mr. Climaco joined CNS in September 2017 as its Chief Executive Officer. Mr. Climaco has served in leadership roles in a variety of healthcare companies. From April 2015 to June 2017 Mr. Climaco served as the Executive Vice-President of Perma-Fix Medical S.A where he managed the development of a novel method to produce Technitium-99. Mr. Climaco also served as President and CEO of Axial Biotech, Inc., a DNA diagnostics company, from January 2003 to January 2013. In the process of taking Axial from inception to product development to commercialization, Mr. Climaco created strategic partnerships with Medtronic, Johnson & Johnson and Smith & Nephew. Mr. Climaco currently serves as a director of several public companies including Moleculin Biotech, Inc., a pharmaceutical company focused on anticancer drug candidates, where he has served since May 2017. Mr. Climaco served on the boards of Digirad, Inc., a leading national provider of imaging services, from May 2012 until April 2020, and Birner Dental Management Services, Inc., a provider of practice management services in the dental industry, since June 2017. Mr. Climaco also served as a director of PDI, Inc., a provider of outsourced commercial services to pharma companies, in 2015, and InfuSystem Holdings, Inc., the largest supplier of infusion services to oncologists in the U.S., from April 2012 to April 2014. Mr. Climaco obtained his Juris Doctorate Degree from the University of California Hastings College of Law in San Francisco, CA in January 2000 and a Bachelor of Philosophy from Middlebury College in Middlebury, VT, in May 1991. Mr. Climaco is active with the State Bar of Utah. We believe Mr. Climaco's history with our company, coupled with his vast experience with development stage companies and his legal background provides him with the qualifications to serve as a director.

Christopher S. Downs, CPA – Chief Financial Officer. Mr. Downs has served as our chief financial officer since the closing of our IPO in November 2019. From March 2018 until September 2019, Mr. Downs served as vice president of finance and treasurer of Innovative Aftermarket Systems, L.P., a privately held provider of finance and insurance solutions. Mr. Downs served as director of finance (from June 2011 to September 2013), vice president and treasurer (October 2013 to August 2016), executive vice president and interim chief financial officer (August 2016 to May 2017), and executive vice president, interim chief financial officer and member of the office of the president (May 2017 to March 2018) for InfuSystem Holdings, Inc., a supplier of infusion services to oncologists in the United States. Mr. Downs spent 10 years in investment banking with various firms including Citigroup. Mr. Downs has also served as a director of EBET, Inc., a technology company developing and operating platforms focused on esports and competitive gaming, from March 2021. Mr. Downs is a graduate of the United States Military Academy at West Point where he earned his Bachelor of Science. Mr. Downs earned his MBA at Columbia Business School and his Master of Science in Accounting at the University of Houston-Clear Lake. Mr. Downs is a Certified Public Accountant in Utah and Texas.

Sandra L. Silberman, MD PhD – Chief Medical Officer. Dr. Silberman joined CNS in December 2017 and currently serves on a part-time basis. Dr. Silberman has served as chief medical officer for new products of Moleculin Biotech, Inc. since November 2017 on a part-time basis. Dr. Silberman advanced several original, proprietary compounds into Phases I through III during her work with leading biopharmaceutical companies, including BristolMyers Squibb, AstraZeneca, Imclone and Roche. Dr. Silberman is a Hematologist/Oncologist who earned her B.A., Sc.M. and Ph.D. from the Johns Hopkins University School of Arts and Sciences, School of Public Health and School of Medicine, respectively, and her M.D. from Cornell University Medical College, and then completed both a clinical fellowship in Hematology/Oncology as well as a research fellowship in tumor immunology at the Brigham & Women' s Hospital and the Dana Farber Cancer Institute in Boston, MA. Dr. Silberman is currently devoting only 45% of her work time to us and provides services as needed to us.

Donald Picker, PhD - Chief Science Officer. Dr. Picker has served as our part-time chief science officer since June 2019. Dr. Picker has served as the chief scientific officer of Moleculin Biotech, Inc. since August 2017 after serving as its chief operating officer from July 2015 until August 2017 and as its president from January 2016 to August 2017. In 2007, Dr. Picker became the chief executive officer of IntertechBio Corp. From 2006 through 2007, Dr. Picker was the President of Tapestry Pharmaceuticals. From 1998 to 2003, Dr. Picker was CEO of Synergy Pharmaceuticals. Synergy was merged into Callisto Pharmaceuticals where he was vice present of research and development until 2006. From 2017 to 2018, Dr. Picker served on our board of directors. Dr. Picker received his B.S. degree from Brooklyn Polytechnic University and his PhD from SUNY Albany in 1975. Dr. Picker is currently devoting only 25% of his work time to us and provides services as needed to us.

Faith L. Charles, JD – Director and Chair of the Board of Directors. Ms. Charles joined our board of directors on December 30, 2022 and currently serves as chair of the board of directors. Ms. Charles has been a corporate transactions and securities partner at the law firm of Thompson Hine, LLP, since 2010. She leads Thompson Hine's Life Sciences practice and co-heads the securities practice, advising public and emerging biotech and pharmaceutical companies in the U.S. and internationally. Ms. Charles negotiates complex private and public financing transactions, mergers and acquisitions, licensing transactions and strategic collaborations. She serves as outside counsel to a myriad of life sciences companies and is known in the industry as an astute business advisor, providing valuable insights into capital markets, corporate governance and strategic development. From 2018 until October 2021, Ms. Charles served on the board of directors and as a member of the audit committee and chair of the compensation committee of Entera Bio, a publicly traded biotechnology company. She also serves on the Board of Directors of several private life science companies. Ms. Charles founded the Women in Bio Metro New York chapter and chaired the chapter for five years. She currently serves on the national board of Women in Bio. Ms. Charles is also a member of the board of Red Door Community (formerly Gilda's Club New York City.) She has been recognized as a Life Sciences Star by Euromoney's LMG Life Sciences, has been named a BTI Client Service All-Star, and was named by Crain's New York Business to the list of 2020 Notable Women in the Law. Ms. Charles holds a JD degree from The George Washington University Law School and a B.A. in Psychology from Barnard College, Columbia University. Ms. Charles is a graduate of Women in Bio's Boardroom Ready Program, an Executive Education Program taught by The George Washington University School of Business. Ms. Charles' qualifications to serve on our Board include her leadership skills and her vast legal experience representing companies in the biotech and pharmaceutical field.

Jerzy (George) Gumulka, PhD – Director. Dr. Gumulka joined our board of directors on November 8, 2017. Dr. Gumulka has been retired since 2016. From 2001 until his retirement, he served as a Global Technology Manager ASC, a Technology Manager, Special Projects/New Technology Platforms, Kraton Polymers US LLC, and a Technical Director of Kraton Polymers do Brasil. Prior to his employment at Shell Chemical Company and Kraton Polymers US LLC, Dr. Gumulka worked at BioSpectrum, Inc. (aka IML) and was involved in the development and application of Human Immune Interferon (INF-γ) and Interleukin-2 in the HIV-focused clinical studies and animal models. Dr. Gumulka co-authored patents on the production and purification of INF-□ and Interleukin-2, and in the field of analytical chemistry, environmental and polymer science. Dr. Gumulka is the recipient of the 2011 Presidential Green Chemistry Challenge Award. Dr. Gumulka served on the Board of Directors of Moleculin LLC from 2010 through 2016. Dr. Gumulka received a Ph.D. from the University of Warsaw, Warsaw, Poland. We believe Dr. Gumulka's technical knowledge and experience in the field of biochemistry coupled with his vast experience in corporate leadership provide him with the qualifications to serve as a director.

Jeffry R. Keyes – Director. Mr. Keyes joined our board on June 25, 2018. Mr. Keyes is currently the Chief Financial Officer of Spinal Elements, Inc., a private equity backed medical device company, a role that he has held since April 2022. From April 2018 to August 2022, Mr. Keyes was the Chief Financial Officer of Custopharm, Inc., a

private equity backed developer of generic sterile injectable pharmaceuticals. From September 2012 to April 2018, Mr. Keyes was the Chief Financial Officer and Corporate Secretary of Digirad Corporation, a publicly traded healthcare services and medical device company. From August 2011 until September 2012, Mr. Keyes was Corporate Controller of Sapphire Energy, Inc., a venture capital backed start-up renewable energy company. From April 2011 to August 2011, Mr. Keyes was the Corporate Controller of Advanced BioHealing, Inc., a venture backed provider of regenerative medicine solutions, until its sale to Shire, PLC in August 2011. Prior to April 2011 Mr. Keyes held a variety of leadership roles in healthcare and medical device companies in finance, accounting, and M&A support, and he started his career in public accounting. Mr. Keyes earned a B.A. degree in accounting from Western Washington University and is a certified public accountant licensed by the Washington State Board of Accountancy. Mr. Keyes is considered a financial expert under relevant rules of the SEC, the NYSE and NASDAQ. We believe Mr. Keyes' financial knowledge and experience, which qualify him as an Audit Committee Financial Expert, coupled with his vast experience in corporate leadership provides him with the qualifications to serve as a director.

Andrzej Andraczke – Director. Mr. Andraczke joined our board on July 9, 2018. Mr. Andraczke is currently Chief Executive Officer of Pol-Tex Holdings, LLC, a role he has held since November 2012. He is also currently Chief Technology Officer of Syntech LLC (Ireland), a role he has held since November 2017. From March 2000 through November 2012, Mr. Andraczke was Vice-President of Pol-Tex Methane. Mr. Andraczke earned a M.Sc. in Engineering from Warsaw Technical University. We believe Mr. Andraczke's vast experience in corporate leadership provides him with the qualifications to serve as a director.

Carl Evans – Director. Mr. Evans joined our board on July 9, 2018. Mr. Evans has been retired since 2015. From 2011 until his retirement Mr. Evans was Executive Vice President – Exploration for KMD Operating Company, LLC. Prior to 2011, he managed international and domestic oil exploration and production projects for several oil companies, including British Petroleum, Texaco, and Pennzoil. Mr. Evans earned Bachelor of Science degree in Geology from the University of California, Los Angeles. We believe Mr. Evan's vast experience in corporate leadership provides him with the qualifications to serve as a director.

Bettina M. Cockroft, MD – Director. Dr. Cockroft joined our board on May 3, 2023. From September 2019 to May 2023, Dr. Cockroft was Senior Vice President and Chief Medical Officer of Sangamo Therapeutics, Inc., a publicly-held biotechnology company, where she oversaw clinical development activities and operations. She has over 20 years of experience in the biopharmaceutical industry and has worked across multiple therapeutic areas and led programs in several countries. Prior to joining Sangamo, Dr. Cockroft served on the senior leadership team at Cytokinetics, Inc., a publicly-held biopharmaceutical company, where she was responsible for clinical development of fast skeletal muscle troponin activators in diseases such as Amyotrophic Lateral Sclerosis and Spinal Muscular Atrophy. She served as Vice President, Clinical Research, Neurology, at Cytokinetics from August 2017 to September 2019. From October 2016 to July 2017, Dr. Cockroft served as a pharmaceutical executive consultant, and before that, from September 2013 to September 2016, she served as Chief Medical Officer of Auris Medical AG, a biopharmaceutical company, where she led and grew the clinical development team responsible for two Phase 3 programs. Dr. Cockroft also held roles of increasing responsibility at Merck Serono S.A., Novartis Consumer Health and Menarini Ricerche earlier in her career. Dr. Cockroft has served as a member of the board of directors of Annexon, Inc. since January 2022. Dr. Cockroft received a M.B.A. from MIT Sloan School of Management and a M.D. from the University of Genova. We believe Dr. Cockroft's extensive experience in the biotechnology field provides her with the qualifications to serve as a director.

No director is related to any other director or executive officer of our company or our subsidiaries, and there are no arrangements or understandings between a director and any other person pursuant to which such person was elected as director.

Director Independence

The rules of the Nasdaq Stock Market, or the Nasdaq Rules, require a majority of a listed company's board of directors to be composed of independent directors. In addition, the Nasdaq Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the Nasdaq Rules, a director will only qualify as an independent director if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Nasdaq Rules also require that audit committee members satisfy independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In considering the independence of compensation committee members, the Nasdaq Rules require that our board of directors must consider additional factors relevant to the duties of a compensation committee member, including the source of any compensation we pay to the director and any affiliations with our company.

Our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Mr. Climaco, are independent as defined under the Nasdaq Rules.

The independent directors meet as often as necessary to fulfill their responsibilities, including meeting at least twice annually in executive session without the presence of non-independent directors and management.

EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the years ended December 31, 2023 and 2022, which consist of our principal executive officer and our two other most highly compensated executive officers, are: (i) John Climaco, our chairman and chief executive officer; (ii) Chris Downs, our chief financial officer; and (ii) Sandra Silberman, our chief medical officer.

Summary Compensation Table – 2023

Name and Principal Position	Year	Salary ($)	Stock Awards ($)(1)	Option awards ($) (1)	Nonequity incentive plan compensation ($) (2)	Total ($)
John Climaco, Chief Executive Officer	2023	525,000	-	-	-	525,000
	2022	525,000	-	14,178	288,750	827,928
Christopher Downs, Chief Financial Officer	2023	340,000	-	-	-	340,000
	2022	340,000	-	5,224	136,000	481,224

Sandra Silberman, Chief Medical Officer	2023	200,000	-	-	-	200,000
	2022	200,000	-	1,306	80,000	281,306

(1) Represents the full grant date fair value of the awards calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the named executive officer. For a summary of the assumptions made in the valuation of the awards, please see Note 5 to our financial statements as of and for the period ended December 31, 2022 included in our Form 10-K. Option awards for the 2022 calendar year were granted in March 2023.

(2) The Compensation Committee of the Board of Directors has not determined the achievement of the corporate goals set forth in the non-equity incentive plan for bonus compensation for 2023. Such determination will be made during the first quarter of 2024.

Narrative Disclosure to Summary Compensation Table

We review compensation annually for all employees, including our executives. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the individual executive's performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short and long-term results that are in the best interests of our stockholders and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives. Our Compensation Committee typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the Compensation Committee then determines the compensation for each executive officer. Our Compensation Committee, without members of management present, discusses and ultimately approves the compensation of our executive officers.

Annual Base Salary

For 2023, the base salaries for Mr. Climaco, Mr. Downs, and Dr. Silberman did not change from the prior year and were $525,000, $340,000, and $200,000, respectively.

Annual Bonus and Non-Equity Incentive Plan Compensation

We seek to motivate and reward our executives for achievements relative to our corporate goals and objectives for each fiscal year. For the 2022 compensation year, the target bonus for Mr. Climaco, Mr. Downs and Dr. Silberman were 55%, 40%, and 40%, respectively, of their base salary.

The actual performance-based annual bonus paid is calculated by multiplying the executive's annual base salary, target bonus percentage, the percentage attainment of the corporate goals established by the Board for such year. However, the Compensation Committee is not required to calculate bonuses in this manner and retains discretion in the amounts it awards and the factors it takes into consideration in determining bonus amounts. At the end of the year, the Compensation Committee reviews our performance against our goals and objectives and approves the extent to which we achieved each of our corporate goals and objectives, and, for each named executive officer, the amount of the bonus awarded.

For 2022, bonuses were awarded based on our achievement of specified corporate goals, including the clinical trial progress of Berubicin, our ability to maintain sufficient funding, and certain Chemistry, Manufacturing and Controls ("CMC") development goals. Based on the level of achievement, our Compensation Committee awarded Mr. Climaco, Mr. Downs and Dr. Silberman 100% of their potential bonuses for 2022. These actual bonus amounts are reflected in the "Non-Equity Incentive Plans" column of the Summary Compensation Table above.

For 2023, bonuses will be awarded at the discretion of the board of directors based on our achievement of specified corporate goals. The Compensation Committee of the Board of Directors has not determined the achievement of the corporate goals set forth in the non-equity incentive plan for bonus compensation for 2023. Such determination will be made during the first quarter of 2024.

Long-Term Incentives

Each year our Compensation Committee provides for equity grants to each of our named executive officers to provide for long-term performance incentive. Awarded in 2023 for services provided in 2022, Mr. Climaco, Mr. Downs and Dr. Silberman received stock option grants of 16,476 options, 6,067 options and 3,337 options, respectively. Each stock option is convertible into one share of our common stock, and vests as follows: (i) 50% of the grant will vest in four equal annual installments over 2 years; (ii) 25% of the grant will vest if within 24 months from issuance the average the closing price of our common stock over a ten trading day period exceeds $6.00 (subject to pro rata adjustment for stock splits or similar events); and (iii) 25% of the grant will vest if within 36 months from issuance the average the closing price of our common stock over a ten trading day period exceeds $24.00 (subject to pro rata adjustment for stock splits or similar events).

Employment Agreements

John Climaco

On September 1, 2017, we entered into an employment agreement with John Climaco pursuant to which Mr. Climaco agreed to serve as our Chief Executive Officer commencing on such date for an initial term of three years. On September 1, 2020, we entered into an amendment to the employment agreement. The amendment extends the term of employment under the employment agreement 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.

Other Executive Arrangements

On June 28, 2019, we entered into employment letters with Drs. Silberman and Picker. 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.

Outstanding Equity Awards

The following table sets forth certain information concerning our outstanding options for our named executive officers on December 31, 2023.

Outstanding Equity Awards At Fiscal Year-End —2023

	Option Awards					Stock Awards (2)	
Name	Grant Date of Equity Award	Number of Securities Underlying Unexercised Options (#) Exercisable (1)	Number of Securities Underlying Unexercised Options (#) Unexercisable (1)	Option Exercise Price ($)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($) (3)
John Climaco	3/29/2023		16,467	0.996	3/27/2033		
	4/28/2022					18,750	23,813
	2/5/2021	5,167	5,167	100.80	2/5/2031		
	6/28/2019	14,650	-	60.00	6/28/2029		
Christopher	3/29/2023		6,067	0.996	3/27/2033		
Downs	4/28/2022					7,815	9,925
	2/5/2021	2,184	2,183	100.80	2/5/2031		
	11/13/2019	9,992	-	120.00	11/13/2029		
Sandra	3/29/2023		3,337	0.996	3/27/2033		
Silberman	4/28/2022					3,907	4,962
	2/5/2021	700	700	100.80	2/5/2031		
	6/28/2019	4,167	-	60.00	6/28/2029		
	12/22/2017	2,500	-	1.35	12/22/2027		

(1) The shares underlying the options vest in equal annual installments over a four-year period (i.e., one-quarter of each grant vests on the first, second, third and fourth anniversary of the grant date).

(2) Consists of restricted stock unit awards that vest as follows:

- 25% of the RSU grant will vest in four (4) equal annual installments over 4 years, provided officer is serving in such position on each vesting date;
- 25% of the RSU grant will vest if within 24 months from grant the average the closing price of the Company's common stock over a ten trading day period exceeds $60.00 (subject to pro rata adjustment for stock splits or similar events);
- 25% of the RSU grant will vest if within 36 months from grant the average the closing price of the Company's common stock over a ten trading day period exceeds $120.00 (subject to pro rata adjustment for stock splits or similar events);
- 25% of the RSU grant will vest if within 24 months from issuance the Company achieves "Positive Interim, Clinical Data" as defined by the Board of Directors.

(3) Based on the closing price of our common stock on December 29, 2023 of $1.27.

Director Compensation

The following table sets forth the total compensation earned by our non-employee directors in 2023 (Mr. Climaco did not earn additional compensation during 2023 for his services on the Board, and his compensation is fully reflected in the "—Summary Compensation Table" above):

Name	Fees earned or paid in cash ($)	Option Awards ($) (1)	Total ($)
Faith L. Charles	70,000	42,640	112,640
Jerzy (George) Gumulka	51,200	63,963	115,163
Jeffry R. Keyes	71,500	63,963	135,463
Andrzej Andraczke	49,500	63,963	113,463
Carl Evans	51,000	63,963	114,963
Bettina Cockroft	26,667	31,639	58,305

(1) Represents the full grant date fair value of the awards calculated in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by the director. The assumptions made in the valuation of the awards were: (i) fair value of common stock on measurement date between $1.90 and $2.27; (ii) risk free interest rate between 3.38% and 4.37%; (iii) volatility between 114.30% and 118.09%; (iv) dividend yield of zero; and (iv) expected term (in years) between 5.5 and 6.3. As of December 31, 2023, the aggregate number of shares outstanding under all options to purchase our common stock held by our non-employee directors were: Dr. Gumulka – 45,428 shares; Mr. Keyes – 45,428 shares; Mr. Andraczke – 45,428 shares; Mr. Evans – 45,428 shares; Ms. Charles – 29,815 shares; Ms. Cockroft – 18,074 shares. None of our non-employee directors held stock awards other than options as of December 31, 2023.

In July 2021, our compensation committee recommended to our Board and our Board approved the following policy for compensating non-employee members of the Board. Each independent director shall receive annual cash compensation of $40,000. In addition, the chairperson of the Audit Committee, Compensation Committee and Nominating and Governance Committee shall receive an annual compensation of $12,000, $7,700 and $5,500, respectively; the other members of such committees shall receive an annual compensation of $5,500, $4,000 and $3,500, respectively; and the lead independent director shall receive annual compensation of $12,000. On December 30, 2022, concurrent with the appointment of Ms. Charles to the Board as a director and election as Chair of the Board, our compensation committee recommended to our Board and our Board approved the following policy for compensating a non-executive Chair of the Board of Directors: an additional $30,000 annual cash compensation.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Transactions with Related Persons

On December 28, 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from Houston Pharmaceuticals, Inc. ("HPI") in an agreement we refer to as the HPI License. Dr. Waldemar Priebe, our founder, controls HPI. 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 after our IPO; (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) 200,000 shares of our common stock. Unrelated to this agreement we purchased $441,075 of pharmaceutical products from HPI for use in our clinical trials during 2021.

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 that is majority-owned by an entity controlled by our founder Dr. Priebe.

On February 19, 2021, CNS entered into an Investigational Medicinal Product Supply Agreement with WPD. CNS agreed to sell the Berubicin drug product to WPD at historical cost of manufacturing without markup so that WPD may conduct the clinical trials contemplated by the sublicense agreement. WPD agreed to pay CNS the following payments: (i) an upfront payment of $131,073 upon execution of the agreement, (ii) a payment of $262,145 upon final batch release and certification performed by WPD's subcontractor, and (iii) a final payment of $262,145 upon Clinical Trial Application acceptance by the relevant regulatory authority. All three milestones have been met as of December 31, 2021. In addition, as of December 31, 2021, the drug product with a cost of approximately $655,000 has been delivered to WPD and is being held at a third party depot. As such, the full amount of approximately $655,000 was due from WPD. As of December 31, 2021, CNS had invoiced the three amounts plus pass through cost for a total of $656,938. As of December 31, 2022, the Company had received payments for the first and second amounts due for a total of $393,182 and entered into a settlement agreement whereby WPD agreed to return 168 vials (approximately 40% of the total) to us in settlement of the final amount owed. On October 24, 2022, the Company received confirmation from our third party depot service provider that the vials had been transferred into our inventory. As such, this matter is now fully resolved.

On August 31, 2018, we entered into a sublicense agreement with Animal Life Sciences, LLC, or 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. Priebe holds 38% of the membership interests of ALI.

Our scientific advisory board included Dr. Priebe until August 25, 2022, after which time he was no longer a member of the scientific advisory board. On July 15, 2021, our compensation committee recommended to our board and our board approved cash compensation to each scientific advisory board member of $68,600 annually.

Policies and Procedures for Related Party Transactions

Our audit committee charter provides that our audit committee is responsible for reviewing and approving in advance any related party transaction. This will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In determining whether to approve a proposed transaction, our Audit Committee will consider all relevant facts and circumstances including: (i) the materiality and character of the related party's direct or indirect interest; (ii) the commercial reasonableness of the terms; (iii) the benefit or perceived benefit, or lack thereof, to us; (iv) the opportunity cost of alternate transactions; and (v) the actual or apparent conflict of interest of the related party.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information, as of December 31, 2023, regarding beneficial ownership of our common stock by:

- each of our directors;
- each of our named executive officers;
- all directors and officers as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than five percent of our shares of common stock.

Beneficial ownership is determined according to the rules of the SEC, and generally means that person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security and includes options that are currently exercisable or exercisable within 60 days. Each director or officer, as the case may be, has furnished us with information with respect to beneficial ownership. Except as otherwise indicated, we believe that the beneficial owners of common stock listed below, based on the information each of them has given to us, have sole investment and voting power with respect to their shares, except where community property laws may apply. Except as otherwise noted below, the address for each person or entity listed in the table is c/o CNS Pharmaceuticals, Inc., 2100 West Loop South, Suite 900, Houston, TX 77027.

Name and address of beneficial owner	Shares Beneficially Owned	Percentage of Class [1]
John Climaco	76,778 [2][3]	1.2%
Christopher S. Downs	52,086 [2][4]	*
Sandra Silberman	8,813 [2][5]	*
Faith Charles	1,361 [2][6]	*
Jerzy (George) Gumulka	15,626	*
Jeffry R. Keyes	6,323	*
Andrzej Andraczke	5,953	*
Carl Evans	6,078	*
Bettina Cockroft	1,847 [7]	*
Directors and Officers as a group (11 persons)	**185,216**	**3.88%**

* Less than 1%.

(1) Based on 6,214,598 shares of common stock outstanding as of December 31, 2023. (as adjusted for the exercise and full delivery of the Existing Warrants in the Warrant Exercise Inducement Transaction described above).

(2) The restricted stock units granted to Mr. Climaco, Mr. Downs and Dr. Silberman vest, in part, on the achievement of certain stock price and clinical trial milestones. For purposes of the above table, we have assume that the foregoing milestones have not been achieved until such time as the board of directors makes a determination that they have been achieved. See “Item 11. Executive Compensation – Executive Officer Compensation – Narrative Disclosure to Summary Compensation Table – Long-Term Incentives” for details on the foregoing restricted stock unit grants.

(3) Includes options to purchase 6,700 shares of common stock which are exercisable within 60 days of December 31, 2023 and 1,250 restricted stock units which have vested by December 31, 2023.

(4) Includes options to purchase 2,609 shares of common stock which are exercisable within 60 days of December 31, 2023 and 521 restricted stock units which have vested by December 31, 2023.

(5) Includes options to purchase 1,184 shares of common stock which are exercisable within 60 days of December 31, 2023 and 260 restricted stock units which have vested by December 31, 2023.

(6) Includes options to purchase 194 shares of common stock which are exercisable within 60 days of December 31, 2023.

(7) Includes options to purchase 1,153 shares of common stock which are exercisable within 60 days of December 31, 2023.

DESCRIPTION OF CAPITAL STOCK

The following summary of the rights of our capital stock is not complete and is subject to and qualified in its entirety by reference to our articles of incorporation and bylaws, copies of which are filed as exhibits to the registration statement of which this prospectus forms a part, which are incorporated by reference herein, and the applicable provisions of the Nevada Revised Statutes.

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. 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. We have no shares of preferred stock outstanding. 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.

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.

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.

DESCRIPTION OF PRE-FUNDED WARRANTS

The following summary of certain terms and provisions of pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Form. The pre-funded warrants will be issued as individual warrant agreements to the investors. You should review the form of pre-funded warrant, filed as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions applicable to the pre-funded warrants.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the pre-funded warrants is $0.001 per share of common stock. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price of the pre-funded warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise. If, at any time after the holder's purchase of pre-funded warrants, such holder exercises its pre-funded warrants and a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the pre-funded warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the pre-funded warrants to the holders.

Transferability. Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing. We do not plan on applying to list the pre-funded warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the pre-funded 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 pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the pre-funded warrant.

DESCRIPTION OF COMMON WARRANTS

The following summary of certain terms and provisions of common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Series A Warrant

Form. The Series A warrants will be issued as individual warrant agreements to the investors. You should review the form of Series A warrant, filed as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions applicable to the Series A warrants.

Exercisability. The Series A warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the Series A warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Series A warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series A warrants. Purchasers of Series A warrants in this offering may also elect prior to the issuance of the Series A warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a Series A warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the Series A warrants is $0.30 per share of common stock. The Series A warrants will be immediately exercisable and may be exercised for a period of five years after issuance. The exercise price of the Series A warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise. If, at any time after the holder's purchase of Series A warrants, such holder exercises its Series A warrants and a registration statement registering the issuance of the shares of common stock underlying the Series A warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the Series A warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the Series A warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the Series A warrants to the holders.

Transferability. Subject to applicable laws, the Series A warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Series A warrant to us together with the appropriate instruments of transfer.

Exchange Listing. We do not plan on applying to list the Series A warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Series A warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series A warrants will be entitled to receive upon exercise of the Series A warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series A warrants immediately prior to such fundamental transaction. In the case of certain fundamental transactions affecting us, a holder of Series A warrants, upon exercise of such warrants after such fundamental transaction, will have the right to receive, in lieu of shares of our common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the Series A warrants been exercised immediately prior to such fundamental transaction. In lieu of such consideration, a holder of Series A warrants may instead elect to receive a cash payment based upon the Black-Scholes value of their Series A warrants.

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

Series B Warrant

Form. The Series B warrants will be issued as individual warrant agreements to the investors. You should review the form of Series B warrant, filed as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions applicable to the Series B warrants.

Exercisability. The Series B warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the Series B warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Series B warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series B warrants. Purchasers of Series B warrants in this offering may also elect prior to the issuance of the Series B warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a Series B warrant. In lieu of fractional shares, we will pay the holder an amount

in cash equal to the fractional amount multiplied by the exercise price.

Duration and Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the Series B warrants is $0.30 per share of common stock. The Series B warrants will be immediately exercisable and may be exercised for a period of 18 months years after issuance. The exercise price of the Series B warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise. If, at any time after the holder's purchase of Series B warrants, such holder exercises its Series B warrants and a registration statement registering the issuance of the shares of common stock underlying the Series B warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of common stock underlying the Series B warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of common stock determined according to a formula set forth in the Series B warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the Series B warrants to the holders.

Transferability. Subject to applicable laws, the Series B warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Series B warrant to us together with the appropriate instruments of transfer.

Exchange Listing. We do not plan on applying to list the Series B warrants on the Nasdaq Capital Market, any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Series B 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 Series B warrants will be entitled to receive upon exercise of the Series B warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series B warrants immediately prior to such fundamental transaction. In the case of certain fundamental transactions affecting us, a holder of Series B warrants, upon exercise of such warrants after such fundamental transaction, will have the right to receive, in lieu of shares of our common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the Series B warrants been exercised immediately prior to such fundamental transaction. In lieu of such consideration, a holder of Series B warrants may instead elect to receive a cash payment based upon the Black-Scholes value of their Series B warrants.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a Series B warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Series B warrant.

Amendment to Outstanding Inducement Warrants

In connection with the offering pursuant to this prospectus, we amended the terms of the Inducement Warrants to purchase the Inducement Warrant Shares to reduce the exercise price of such Inducement Warrants to: (i) equal the exercise price of the common warrants sold in this offering; and (ii) extend the term during which the Inducement Warrants could remain exercisable to the term of the Series A common warrants sold in this offering. The amendment of the Inducement Warrants is subject to shareholder approval. If such shareholder approval is not obtained by the date that is six months following the closing date of this offering, then we agreed to (i) automatically amend the exercise price of the Inducement Warrants to be the Minimum Price (as defined in Nasdaq Listing Rule 5635(d)) of our common stock on the date that is six months following the closing date of this offering (if and only if such new exercise price on the repricing date is lower than the exercise price of the Inducement Warrants then in effect), and (ii) extend the expiration date of the Inducement Warrants to the date that is five (5) years from the issuance date of the Series A common warrants. For further information about the Inducement Warrants, see "Prospectus Summary—Recent Developments—Warrant Exercise Inducement Transaction".

PLAN OF DISTRIBUTION

A.G.P./Alliance Global Partners has agreed to act as our lead placement agent and Maxim Group LLC has agreed to act as our co-placement agent in connection with this offering subject to the terms and conditions of the placement agent agreement dated January 29, 2024. The placement agents are not purchasing or selling any of the securities offered by this prospectus, nor are they required to arrange the purchase or sale of any specific number or dollar amount of securities, but have agreed to use their reasonable best efforts to arrange for the sale of all of the securities offered hereby. We will enter into a securities purchase agreement (the "purchase agreement") directly with the investors who purchase our securities in this offering, at the investors' option. Investors who do not enter into the purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

We expect this offering to be completed not later than two business days following the commencement of the offering and we will deliver the securities being issued to each investor upon receipt of such investor's funds for the purchase of the securities offered pursuant to this prospectus and we will deliver all securities to be issued in connection with this offering delivery versus payment (DVP)/receipt versus payment (RVP) upon receipt of investor funds received by us. We expect to deliver the securities being offered pursuant to this prospectus on or about February 1, 2024.

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

Placement Agent Fees, Commissions and Expenses

This offering is being conducted on a reasonable best efforts basis and the placement agents have no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of securities. Upon the closing of this offering, we will pay the placement agents a cash transaction fee equal to 7.0% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the placement agents for up to $75,000 for the placement agents' legal fees and up to $25,000 of the aggregate gross proceeds of the offering for certain reasonable non-accountable fees and expenses.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us, assuming the sale of all the shares of common stock we are offering and no exercise of any warrants.

	Per Share and Accompanying Common Warrants	Per Pre-Funded Warrant and Accompanying Common Warrants	Total
Public offering price	$ 0.30	$ 0.299	$ 3,988,882.53
Placement agent fees	$ 0.021	$ 0.0209	$ 279,221.78
Proceeds, before expenses, to us	$ 618,171.09	$ 3,091,489.66	$ 3,709,660.76

We estimate that the total expenses of the offering payable by us, excluding the total placement agent fees, will be approximately $200,000.

Lock-Up Agreements

Our directors and executive officers have entered into lock-up agreements. Under these agreements, these individuals have agreed, subject to specified exceptions, not to sell or transfer any shares of common stock or securities convertible into, or exchangeable or exercisable for, our shares of common stock during a period ending 90 days after the closing of this offering, without first obtaining the written consent of the lead placement agent. Specifically, these individuals have agreed, in part, not to:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended;

- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our securities, whether any such transaction is to be settled by delivery of our shares of common stock, in cash or otherwise;

- make any demand for or exercise any right with respect to the registration of any of our securities;

- publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge;

- or other arrangement relating to any of our securities.

Notwithstanding these limitations, these shares of common stock may be transferred under limited circumstances, including, without limitation, by gift, will or intestate succession.

In addition, we have agreed that, subject to certain exceptions, we will not (i) conduct any issuances of our common stock for a period of 90 days following closing of this offering or (ii) enter into a variable rate transaction (as defined in the purchase agreement) for a period of 180 days following closing of this offering; provided that for the period commencing on the 91st day following the closing date of this offering, we will be permitted to make sales under our Capital on Demand™ Sales Agreement.

Regulation M

Each placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the shares sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, each placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares by the placement agent acting as principal. Under these rules and regulations, the placement agents:

- may not engage in any stabilization activity in connection with our securities; and

- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "CNSP." There is no established public market for the common warrants or pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants or pre-funded warrants on any national securities exchange.

Discretionary Accounts

The placement agents do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Other Relationships

In October 2023, we completed the warrant inducement transaction discussed in the section "Prospectus Summary – Recent Developments - Warrant Exercise Inducement Transaction". We engaged A.G.P./Alliance Global Partners to act as our financial advisor in connection with the transaction and paid A.G.P./Alliance Global Partners a fee of $145,000.

The placement agents and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The placement agents and certain of their respective affiliates may in the future perform various commercial and investment banking and financial advisory services for us and our affiliates, for which they will receive customary fees and expenses.

In the ordinary course of their various business activities, the placement agents and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the placement agents or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The placement agents and their respective affiliates may hedge such exposure by entering into transactions that consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The placement agents and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by ArentFox Schiff LLP, Washington, DC. The placement agents are being represented by Sullivan & Worcester LLP, New York, New York, in connection with this offering.

EXPERTS

The financial statements of the Company as of December 31, 2022 and 2021, and for the years then ended, have been included in this registration statement in reliance upon the report of MaloneBailey, LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act for the securities being offered by this prospectus. This prospectus, which is part of the registration statement, does not contain all of the information included in the registration statement and the exhibits. For further information about us and the securities offered by this prospectus, you should refer to the registration statement and its exhibits. References in this prospectus to any of our contracts or other documents are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. SEC filings are also available to the public at the SEC's website at *www.sec.gov*.

We are subject to the reporting and information requirements of the Exchange Act and, as a result, we file periodic and current reports, proxy statements and other information with the SEC. We make our periodic reports and other information filed with or furnished to the SEC, available, free of charge, through our website as soon as reasonably practicable after those reports and other information are filed with or furnished to the SEC. Additionally, these periodic reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above.

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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, 2022 and 2021, and the related statements of operations, stockholders' equity, 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, 2022 and 2021, 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 3 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operations that raise 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the 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, 2023

CNS Pharmaceuticals, Inc.
Balance Sheets

	December 31, 2022	December 31, 2021 As Revised
Assets		
Current Assets:		
Cash and cash equivalents	$ 10,055,407	$ 5,004,517
Prepaid expenses and other current assets	2,509,238	2,472,933
Total current assets	12,564,645	7,477,450
Noncurrent Assets:		

Prepaid expenses, net of current portion	482,806	929,688
Property and equipment, net	5,664	16,109
Deferred offering costs	–	334,138
Total noncurrent assets	488,470	1,279,935
Total Assets	$ 13,053,115	$ 8,757,385
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 3,681,900	$ 1,981,445
Accrued expenses	828,391	224,949
Notes payable	409,968	387,794
Total current liabilities	4,920,259	2,594,188
Total Liabilities	4,920,259	2,594,188
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and 0 shares issued and outstanding	–	–
Common stock, $0.001 par value, 75,000,000 shares authorized and 1,617,325 and 949,052 shares issued and outstanding, respectively	1,617	949
Additional paid-in capital	58,846,916	41,603,791
Accumulated deficit	(50,715,677)	(35,441,543)
Total Stockholders' Equity	8,132,856	6,163,197
Total Liabilities and Stockholders' Equity	$ 13,053,115	$ 8,757,385

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Operations

	Year Ended December 31, 2022	Year Ended December 31, 2021 As Revised
Operating expenses:		
General and administrative	$ 5,967,052	$ 4,680,840
Research and development	9,300,055	9,805,075
Total operating expenses	15,267,107	14,485,915
Loss from operations	(15,267,107)	(14,485,915)
Other expenses:		
Interest expense	(7,027)	(9,285)
Total other expenses	(7,027)	(9,285)
Net loss	$ (15,274,134)	$ (14,495,200)
Loss per share - basic	$ (11.22)	$ (16.50)
Loss per share - diluted	$ (11.22)	$ (16.50)
Weighted average shares outstanding - basic	1,361,737	878,443
Weighted average shares outstanding - diluted	1,361,737	878,443

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Stockholders' Equity
For the years ended December 31, 2022 and 2021

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance December 31, 2020	813,350	$ 813	$ 34,893,514	$ (20,946,343)	$ 13,947,984
Common stock issued for cash, net	68,784	69	4,653,752	–	4,653,821
Exercise of warrants	63,585	64	332,686	–	332,750
Stock-based compensation	3,333	3	1,723,839	–	1,723,842
Net loss	–	–	–	(14,495,200)	(14,495,200)
Balance December 31, 2021 - As revised	949,052	949	41,603,791	(35,441,543)	6,163,197
Common stock issued for cash, net	463,316	463	16,037,630	–	16,038,093
Exercise of warrants	204,957	205	2,529	–	2,734
Stock-based compensation	–	–	1,202,966	–	1,202,966
Net loss	–	–	–	(15,274,134)	(15,274,134)
Balance December 31, 2022	1,617,325	$ 1,617	$ 58,846,916	$ (50,715,677)	$ 8,132,856

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Cash Flows

	Year Ended December 31, 2022	Year Ended December 31, 2021 As Revised
Cash Flows from Operating Activities:		
Net loss	$ (15,274,134)	$ (14,495,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,202,966	1,723,842
Depreciation	11,756	13,070
Write off of deferred offering cost	334,138	–
Loss on disposal of fixed assets	3,111	–
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	860,451	(1,520,281)
Accounts payable	1,700,455	1,035,115
Accrued expenses	603,442	(294,855)
Net cash used in operating activities	(10,557,815)	(13,538,309)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(4,422)	(5,748)
Net cash used in investing activities	(4,422)	(5,748)
Cash Flows from Financing Activities:		
Payments on notes payable	(427,700)	(477,490)
Proceeds from exercise of warrants	2,734	332,750
Proceeds from sale of common stock	16,038,093	4,653,821
Net cash provided by financing activities	15,613,127	4,509,081
Net change in cash and cash equivalents	5,050,890	(9,034,976)
Cash and cash equivalents, at beginning of period	5,004,517	14,039,493
Cash and cash equivalents, at end of period	$ 10,055,407	$ 5,004,517
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 8,094	$ 9,774
Cash paid for income taxes	$ –	$ –
Supplemental disclosure of non-cash investing and financing activities:		
Cashless exercise of warrants	$ –	$ 1,756
Prepaid expense financed with note payable	$ 449,874	$ 425,990

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
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 August 25, 2022, 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-30. The reverse stock split became effective on November 28, 2022 on a 1-for-30 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 – Correction of Previously Issued Financial Statements

In the course of preparing its fiscal year 2022 financial statements, the Company identified errors in the financial statements for the year ended December 31, 2021 and its unaudited financial statements for the periods ended March 31, 2022, June 30, 2022, and September 30, 2022. The errors pertain to understatements in research and development expenses and accrued expenses amounting to $458,622 for the year ended December 31, 2021 and $367,439 for the three months ended March 31, 2022, the six months ended June 30, 2022 and the nine months ended September 30, 2022 resulting from additional trial sites costs which were not reported to the Company by our CRO.

The Company assessed the materiality of these misstatements on prior periods' financial statements in accordance with SEC Staff Accounting Bulletin ("SAB") No. 99, Materiality, codified in ASC 250 ("ASC 250"), Presentation of Financial Statements, and concluded that these misstatements were not material to any prior annual or interim periods. Accordingly, in accordance with ASC 250 (SAB No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements), the Financial Statements as of December 31, 2021, and the year then ended, which are presented herein, have been revised. The following are selected line items from the Company's balance sheets, statements of operations and statements of cash flows for the affected periods illustrating the effect of these corrections:

Balance Sheet	As of December 31, 2021		
	As Reported	Adjustment	As Revised
Accounts payable	$ 1,522,823	$ 458,622	$ 1,981,445
Total current liabilities	2,135,566	458,622	2,594,188
Total liabilities	2,135,566	458,622	2,594,188
Accumulated deficit	(34,982,921)	(458,622)	(35,441,543)
Total stockholders' equity	6,621,819	(458,622)	6,163,197

Balance Sheet (Unaudited)	As of March 31, 2022		
	As Reported	Adjustment	As Revised
Accounts payable	$ 489,716	$ 826,061	$ 1,315,777
Total current liabilities	1,069,300	826,061	1,895,361
Total liabilities	1,069,300	826,061	1,895,361
Accumulated deficit	(37,767,260)	(826,061)	(38,593,321)
Total stockholders' equity	14,802,567	(826,061)	13,976,506

Balance Sheet (Unaudited)	As of June 30, 2022		
	As Reported	Adjustment	As Revised
Accounts payable	$ 490,886	$ 826,061	$ 1,316,947
Total current liabilities	923,856	826,061	1,749,917
Total liabilities	923,856	826,061	1,749,917
Accumulated deficit	(41,333,212)	(826,061)	(42,159,273)
Total stockholders' equity	11,523,456	(826,061)	10,697,395

Balance Sheet (Unaudited)	As of September 30, 2022		
	As Reported	Adjustment	As Revised
Accounts payable	$ 1,005,043	$ 826,061	$ 1,831,104

Total current liabilities	1,244,303	826,061	2,070,364
Total liabilities	1,244,303	826,061	2,070,364
Accumulated deficit	(44,752,765)	(826,061)	(45,578,826)
Total stockholders' equity	8,393,624	(826,061)	7,567,563

Statement of Operations	For the year ended December 31, 2021		
	As Reported	Adjustment	As Revised
Research and development	$ 9,346,453	$ 458,622	$ 9,805,075
Total operating expenses	14,027,293	458,622	14,485,915
Loss from operations	(14,027,293)	(458,622)	(14,485,915)
Net loss	(14,036,578)	(458,622)	(14,495,200)
Loss per share - basic and diluted	(15.98)	(0.52)	(16.50)

Statement of Operations (Unaudited)	For the three months ended March 31, 2022		
	As Reported	Adjustment	As Revised
Research and development	$ 1,521,364	$ 367,439	$ 1,888,803
Total operating expenses	2,781,773	367,439	3,149,212
Loss from operations	(2,781,773)	(367,439)	(3,149,212)
Net loss	(2,784,339)	(367,439)	(3,151,778)
Loss per share - basic and diluted	(2.15)	(0.28)	(2.44)

Statement of Operations (Unaudited)	For the six months ended June 30, 2022		
	As Reported	Adjustment	As Revised
Research and development	$ 3,742,703	$ 367,439	$ 4,110,142
Total operating expenses	6,346,114	367,439	6,713,553
Loss from operations	(6,346,114)	(367,439)	(6,713,553)
Net loss	(6,350,291)	(367,439)	(6,717,730)
Loss per share - basic and diluted	(4.83)	(0.28)	(5.11)

Statement of Operations (Unaudited)	For the nine months ended September 30, 2022		
	As Reported	Adjustment	As Revised
Research and development	$ 5,950,616	$ 367,439	$ 6,318,055
Total operating expenses	9,765,129	367,439	10,132,568
Loss from operations	(9,765,129)	(367,439)	(10,132,568)
Net loss	(9,769,844)	(367,439)	(10,137,283)
Loss per share - basic and diluted	(7.40)	(0.27)	(7.67)

Statement of Cash Flows	For the year ended December 31, 2021		
	As Reported	Adjustment	As Revised
Cash Flows from Operating Activities:			
Net loss	$ (14,036,578)	$ (458,622)	$ (14,495,200)
Accounts payable	576,493	458,622	1,035,115
Net cash used in operating activities	(13,538,309)	–	(13,538,309)

Statement of Cash Flows (Unaudited)	For the three months ended March 31, 2022		
	As Reported	Adjustment	As Revised
Cash Flows from Operating Activities:			
Net loss	$ (2,784,339)	$ (367,439)	$ (3,151,778)
Accounts payable	(1,033,107)	367,439	(665,668)
Net cash used in operating activities	(3,077,199)	–	(3,077,199)

Statement of Cash Flows (Unaudited)	For the six months ended June 30, 2022		
	As Reported	Adjustment	As Revised
Cash Flows from Operating Activities:			

Net loss	$ (6,350,291)	$ (367,439)	$ (6,717,730)
Accounts payable	(1,031,937)	367,439	(664,498)
Net cash used in operating activities	(6,439,733)	–	(6,439,733)

Statement of Cash Flows (Unaudited)	For the nine months ended September 30, 2022		
	As Reported	Adjustment	As Revised
Cash Flows from Operating Activities:			
Net loss	$ (9,769,844)	$ (367,439)	$ (10,137,283)
Accounts payable	(517,780)	367,439	(150,341)
Net cash used in operating activities	(8,252,492)	–	(8,252,492)

Note 3 – 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 or debt 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 at period end combined with the funds raised subsequent to year end is sufficient to fund its planned operations into but not beyond the near term. 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, 2022 was $9,805,407. 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. 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 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, 2022, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 4,133,252 common shares, and options for 93,001 common shares. As of December 31, 2021, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 140,512 common shares, and options for 95,501 common shares.

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.

Recent Accounting Pronouncements

The Company does not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Note 4 – Note Payable

On November 14, 2022, the Company entered into a short-term note payable for an aggregate of $449,874, bearing interest at 5.88% per year to finance certain insurance policies. Principal and interest payments related to the note will be repaid over a 11-month period with the final payment due on October 31, 2023. As of December 31, 2022, the Company's note payable balance was $409,968.

On November 8, 2021, the Company entered into a short-term note payable for an aggregate of $425,990, bearing interest at 3.3% per year to finance certain insurance policies. Principal and interest payments related to the note will be repaid over a 11-month period with the final payment due on September 30, 2022. During the year ended December 31, 2022, the Company repaid the full balance of the note. As of December 31, 2022 and 2021, the Company's note payable balance was $0 and $387,794, respectively.

Note 5 – 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 August 25, 2022, 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-30, 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-thirty (1:30) 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 November 28, 2022 on a 1-for-30 basis without any change in the par value per share, which remained at $0.001.

Common Stock

2022

The Company engaged H.C. Wainwright & Co., LLC ("Wainwright"), to act as placement agent related to the Securities Purchase Agreement described below. The Company agreed to pay Wainwright an aggregate fee equal to 7.0% of the gross proceeds received by the Company from the sale of the securities in the transaction. The Company also issued to Wainwright or its designees warrants to purchase up to 5.0% of the aggregate number of shares of Common Stock sold in the transactions (the "Placement Agent Warrants"), or 20,176 Placement Agent Warrants. The Placement Agent Warrants have substantially the same terms as the Common Warrants, except that the Placement Agent Warrants have an exercise price equal to 125% of the offering price, or $35.625 per share. The Company also paid Wainwright $50,000 for non-accountable expenses and $10,000 for legal fees and expenses.

On January 5, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors for the sale by the Company of (i) 316,316 shares (the "Shares") of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 87,193 shares of

common stock and (iii) warrants to purchase up to an aggregate of 403,509 shares of common stock (the "Common Warrants" and, collectively with the Pre-Funded Warrants, the "Warrants"), in a private placement offering. The combined purchase price of one share of common stock (or one Pre-Funded Warrant) and the accompanying Common Warrant is $28.50.

Subject to certain ownership limitations, the Warrants are exercisable upon issuance. Each Pre-Funded Warrant is exercisable into one share of common stock at a price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof). Each Common Warrant is exercisable into one share of common stock at a price per share of $24.60 (as adjusted from time to time in accordance with the terms thereof) and will expire on the fifth anniversary of the date of issuance. The gross proceeds from the Purchase Agreement were $11,497,385 resulting in net proceeds, after payment of commissions and expenses, received by the Company of $10,625,786.

On November 30, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an institutional investor for the sale by the Company of (i) 147,000 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 1,742,764 shares of Common Stock and (iii) warrants to purchase up to an aggregate of 1,889,764 shares of Common Stock (the "Common Warrants" and, collectively with the Pre-Funded Warrants, the "Warrants"), in a public offering. The combined purchase price of one share of Common Stock and accompanying Common Warrant is $3.175 and the combined purchase price of one Pre-Funded Warrant and accompanying Common Warrant is $3.174.

Subject to certain ownership limitations, the Warrants are exercisable upon issuance. Each Pre-Funded Warrant is exercisable into one share of Common Stock at a price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof). Each Common Warrant is exercisable into one share of Common Stock at a price per share of $3.03 (as adjusted from time to time in accordance with the terms thereof) and will expire on the fifth anniversary of the date of issuance. Each Pre-Funded Warrant is exercisable into one share of Common Stock at a price per share of $0.001 (as adjusted from time to time in accordance with the terms thereof). The gross proceeds to the Company from the offering were $5.998 million, resulting in net proceeds, after payment of commissions and expenses, received by the Company of $5,412,308.

On November 30, 2022, in connection with the offering, the Company also entered into a warrant amendment agreement (the "Warrant Amendment Agreement") with the investor in the offering. Under the Warrant Amendment Agreement, the Company agreed to amend certain existing warrants (the "Existing Warrants") to purchase up to an aggregate of (i) 16,667 shares of common stock at an exercise price of $66.00 per share and an expiration date of December 28, 2025 and (ii) 210,527 shares of common stock at an exercise price of $24.60 per share and an expiration date of January 10, 2027, as follows: (i) to lower the exercise price of the Existing Warrants to $3.03 per share, and (ii) to extend the expiration date of the Existing Warrants to five years following the closing of the offering.

On November 30, 2022, the Company entered into a placement agency agreement with H.C. Wainwright & Co., LLC ("Wainwright") and Brookline Capital Markets, a division of Arcadia Securities, LLC ("Brookline" and collectively with Wainright, the "Placement Agents") (the "Placement Agreement"), pursuant to which the Company has agreed to pay the Placement Agents an aggregate fee equal to 7.0% of the gross proceeds received by the Company from the sale of the securities in the transaction. Pursuant to the Placement Agreement, the Company will also issue to the Placement Agents or their designees warrants to purchase up to 5.0% of the aggregate number of shares of Common Stock issued in the offering and issuable upon the exercise of the pre-funded warrants issued in the offering (the "Placement Agent Warrants"), or 94,488 Placement Agent Warrants. The Placement Agent Warrants have substantially the same terms as the Common Warrants, except that the Placement Agent Warrants have an exercise price equal to 125% of the offering price, or $3.7875 per share, subject to adjustments. The Company also agreed to reimburse certain expenses of Wainwright, including a non-accountable expense allowance of $50,000, legal fees and expenses in an amount up to $100,000 and clearing fees of $15,950. The Company also agreed to pay Wainwright a tail fee equal to the cash compensation in this offering, if any investor, who was contacted or introduced to the Company by Wainwright during the term of its engagement, provides the Company with capital in any public or private offering or other financing or capital raising transaction during the nine-month period following expiration or termination of our engagement of Wainwright. In addition, with certain exceptions, for a period of seven month following the closing of the offering, the Company has granted Wainwright the right to act as sole book-runner, sole manager, sole placement agent or sole agent with respect to any financing or refinancing of indebtedness; and if the Company decides to raise funds by means of a public offering (including at-the-market facility) or a private placement or any other capital-raising financing of equity, equity-linked or debt securities, the Company has granted Wainwright the right to act as sole book-running manager, sole underwriter or sole placement agent for such financing.

As consideration for entering into a purchase agreement with Lincoln Park Capital Fund, LLC in fiscal year 2020, the Company recorded as deferred offering costs of $440,902, on the balance sheet. As of December 31, 2021, unamortized deferred offering costs totaled $334,138. During the year ended December 31, 2022, the Company wrote off the remaining $334,138 deferred offering costs to the statement of operations.

2021

In January 2021, the Company entered into a twelve-month agreement with an investor relations firm that includes the issuance of 834 restricted shares of common stock. Upon signing the agreement, 209 shares vested immediately, and the remaining 625 shares will vest quarterly over the remainder of the agreement. The Company may terminate the agreement at any time during the twelve-month period with a fifteen-day notice. During the year ended December 31, 2021, the Company issued 834 common shares and recognized $50,500 of stock-based compensation related to the agreement and will issue the remaining shares over the service period.

During the year ended December 31, 2021, the Company issued 2,500 shares of common stock and recognized $140,250 of expense for investor relations services for a four month period ending September 2021.

On February 12, 2021, the Company entered into a Capital on Demand™ Sales Agreement (the "Agreement") with JonesTrading Institutional Services LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC (collectively, the "Agent"). Pursuant to the terms of the Agreement, 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, 2021, the Company sold 68,784 shares of common stock to the Agent for net proceeds of $4,653,821.

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 66,667 shares of common stock. No key employee may receive more than 16,667 shares of common stock (or options to purchase more than 16,667 shares of common stock) in a single year.

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 100,000 shares of common stock. No key employee may receive more than 25,000 shares of common stock (or options to purchase more than 25,000 shares of common stock) in a single year.

During the year ended December 31, 2021, the Board of Directors approved grants of 24,633 options to officers, employees, board of directors and a consultant. The exercise price of the options ranges from $54.00 to $100.80 and the options expire ten-years following issuance. The total fair value of these option grants at issuance was $1,969,712. Of the 24,633 options issued, 4,267 options vest on the first anniversary date of issuance, 2,500 options have a vesting term of 25% vest upon issuance, 50% vest upon Board approving a business development acquisition and 25% vest over a three year period in equal installments on each of the succeeding three anniversary dates. The remaining options issued vest in four equal annual installments beginning on the first anniversary following issuance.

During the years ended December 31, 2022 and 2021, the Company recognized $1,149,364 and $1,533,092 of stock-based compensation, respectively, related to outstanding stock options. At December 31, 2022, the Company had $1,318,183 of unrecognized expenses related to options.

The following table summarizes the stock option activity for the year ended December 31, 2022 and 2021:

	Options	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2020	73,368	$ 60.00
Granted	24,633	89.70
Exercised	–	–
Forfeited	(2,500)	61.80
Expired	–	–
Outstanding, December 31, 2021	95,501	67.50
Granted	–	–
Exercised	–	–
Forfeited	(2,500)	70.50
Expired	–	–
Outstanding, December 31, 2022	93,001	$ 67.42

The aggregate fair value of the options measured during the year ended December 31, 2021 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31, 2021
Fair value of common stock on measurement date	$54.00 to $100.80 per share
Risk free interest rate (1)	0.28% to 1.28%
Volatility (2)	128.17% to 130.72%
Dividend yield (3)	0%
Expected term (in years)	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, 2022, the outstanding stock options have a weighted average remaining term of 6.73 years and the aggregate intrinsic value of options vested and outstanding were $9,626. As of December 31, 2022, there were no awards remaining to be issued under the 2017 Plan and 35,580 awards remaining to be issued under the 2020 Plan.

Stock Warrants

The following table summarizes the stock warrant activity for the years ended December 31, 2022 and 2021:

	Warrants	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2020	228,740	$ 97.20
Granted	–	–
Exercised	(88,228)	24.60
Forfeited	–	–
Expired	–	–
Outstanding, December 31, 2021	140,512	142.83
Granted	4,237,900	2.88
Exercised	(204,957)	0.01
Forfeited	–	–
Expired	(40,203)	330.00
Outstanding, December 31, 2022	4,133,252	$ 4.35

During the year ended December 31, 2022, the Company received $2,734 in cash proceeds from the exercise of 204,957 warrants previously issued at an exercise price range of $0.01 to $0.03.

During the year ended December 31, 2021, the Company received $332,750 in cash proceeds from the exercise of 5,041 warrants previously issued at an exercise price of $66.00. In addition, the Company received notices to exercise 83,187 warrants on a cashless basis resulting in the issuance of 58,544 shares of common stock.

As of December 31, 2022 the outstanding and exercisable warrants have a weighted average remaining term of 4.84 years and with an intrinsic value of $3,898,375.

Restricted Stock Units

On April 28, 2022, the Compensation Committee approved cash bonuses totaling $213,000 to the officers of the Company. In addition, the officers and employees were awarded a total of 9,523 Restricted Stock Units that partially vest over 4 years. The Company valued the RSUs based on the stock price at grant which total $95,399.

During the year ended December 31, 2022, the Company recognized $17,887 of stock-based compensation, related to outstanding stock RSUs. At December 31, 2022, the Company had $77,512 of unrecognized expenses related to outstanding RSUs.

The following table summarizes the RSUs activity for the year ended December 31, 2022:

	RSUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2021	–	$ –
Granted	9,523	10.02
Vested	–	–
Forfeited	–	–
Non-vested, December 31, 2022	9,523	$ 10.02

Performance Units

On April 28, 2022, the Compensation Committee approved, the officers and employees were awarded a total of 28,563 PUs. For awards granted in 2022, they vest as follows: (i) 9,521 of the PU grant will vest if within 24 months from issuance the average the closing price of the Company's common stock over a ten trading day period exceeds $60.00 (subject to pro rata adjustment for stock splits or similar events), (ii) 9,521 of the PU grant will vest if within 36 months from issuance the average the closing price of the Company's common stock over a ten trading day period exceeds $120.00 (subject to pro rata adjustment for stock splits or similar events) and (iii) 9,521 of the PU grant will vest if within 24 months from issuance the Company achieves "Positive Interim, Clinical Data" as defined by the Board of Directors. To the extent that the market and/or "Positive Interim Clinical Data" conditions are not met, the applicable portions of the PUs will not vest and will be cancelled. The fair value at grant date of these performance units was $169,663. Compensation expense is recognized over the derived service period for the PUs with market conditions and over the requisite service period for PUs with performance conditions on the date when achievement of such conditions are deemed probable.

The fair value of each performance unit with market conditions (vesting terms (i) and (ii)) is estimated at the date of grant using a Monte Carlo simulation with the following assumptions: underlying stock price $10.02, hurdle prices ranging from $60.00 -$120.00, expected terms ranging from 2-3 years, cost of equity 18.7% and risk-free rate of 2.8%.

During the year ended December 31, 2022, the Company recognized $21,928 for vesting term (i), $13,787 for vesting term (ii) and $0 for vesting term (iii), related to outstanding stock PUs. At December 31, 2022, the Company had $133,948 of unrecognized expenses related to PUs.

The following table summarizes the PUs activity for the year ended December 31, 2022:

	PUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2021	–	$ –
Granted	28,563	5.94
Vested	–	–
Forfeited	–	–
Non-vested, December 31, 2022	28,563	$ 5.94

Note 6 – 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 February 6, 2021, the compensation committee of the board of directors set Mr. Climaco's 2021 annual base salary to $525,000.

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 February 6, 2021, the compensation committee of the board of directors set Drs. Silberman and Picker 2021 annual base salaries to $200,000 and $115,000, respectively.

On September 14, 2019, the Company, entered into an employment agreement with Christopher Downs to serve as its Chief Financial Officer commencing on the closing date of the Company's IPO, which occurred on November 13, 2019. The initial term of the Employment Agreement will continue for a period of three years. Pursuant to the employment agreement, the compensation committee of the board of directors reviews the base salary payable to Mr. Downs annually during the term of the agreement. On February 6, 2021, the compensation committee of the board of directors set Mr. Downs' 2021 annual base salary to $340,000.

Scientific Advisory Board

On July 15, 2021, our Board approved the following compensation policy for the Scientific Advisory Board members. The Scientific Advisory board consisted of Dr. Waldemar Priebe, our founder and related party, and Dr. Sigmond Hsu. Each scientific advisory board member shall receive annual cash compensation of $68,600. During the year ended December 31, 2022, the Company paid $76,087 related to the Scientific Advisory Board compensation. As of August 25, 2022, Dr. Waldemar Priebe is no longer a member of the Scientific Advisory Board. As of December 31, 2022, the Company has accrued $100,134 related to 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 6,667 shares of the Company's common stock valued at $1.35 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, 2022 and 2021, the Company recognized $275,000 and $450,000 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 in related party transactions which are reviewed and approved by the Company's audit committee based upon the standards of providing superior pricing and time to delivery than that available from unrelated third parties. During the years ended December 31, 2022 and 2021, the Company expensed $41,075 and $441,075 respectively related to the purchase of pharmaceutical products from HPI.

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 that is majority-owned by an entity controlled by Dr. Priebe, our founder.

On February 19, 2021, CNS entered into an Investigational Medicinal Product Supply Agreement with WPD, a related party. CNS agreed to sell the Berubicin drug product to WPD at historical cost of manufacturing without markup so that WPD may conduct the clinical trials contemplated by the sublicense agreement. WPD agreed to pay CNS the following payments: (i) an upfront payment of $131,073 upon execution of the agreement, (ii) a payment of $262,145 upon final batch release and certification performed by WPD's subcontractor, and (iii) a final payment of $262,145 upon Clinical Trial Application acceptance by the relevant regulatory authority. All three milestones have been met as of December 31, 2021. In addition, as of December 31, 2021, the drug product with a cost of approximately $655,000 has been delivered to WPD and is being held at a third party depot. As such, the full amount of approximately $655,000 is due from WPD. As of December 31, 2021, CNS has invoiced the three amounts plus pass through cost for a total of $656,938. As of December 31, 2022, the Company has received payments for the first and second amounts due for a total of $393,182 and has entered into a settlement agreement whereby WPD agreed to return 168 vials (approximately 40% of the total) to us in settlement of the final amount owed. On October 24, 2022, the Company received confirmation from our third party depot service provider that the vials had been transferred into our inventory. As such, this matter is now fully resolved.

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 5,870.27 upon delivery of 2 vials each of berubicin and berubicinol reference standards, (ii) PLN 873,201.00 upon delivery of a first batch of 150 berubicin drug product vials, and (iii) PLN 873,201.00 upon delivery of a second batch of 150 berubicin drug product vials. As of December 31, 2022, the reference standards had been delivered and were recognized in Accounts Receivable and as a reduction to research & development expense. As of March 29, 2023, the first batch of berubicin drug product vials have been ordered but not yet delivered.

On August 31, 2018, the Company entered into a sublicense agreement with Animal Life Sciences, LLC ("ALI"), a related party, 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, our founder, is also the founder and a shareholder of ALI, holds 38% of the membership interests of ALI.

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 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 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 ("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 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 Agreement. The term of the Agreement expires on the last to occur of: (a) the expiration of all patents subject to the Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate this 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. During the years ended December 31, 2022 and 2021, the Company paid $58,222 and $48,668, respectively.

On May 7, 2020, pursuant to the WP1244 Portfolio license agreement described above, the Company entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. The Company agreed to fund approximately $1,134,000 over a two-year period. During the year ended December 31, 2020, the Company paid $334,000 and accrued $400,000 related to this agreement in research and development expenses in the Company's Consolidated Statements of Operations. During the year ended December 31, 2021, the Company paid $800,000 to UTMDACC related to this agreement. The Company has no further payment obligations as of December 31, 2021. This agreement was extended and now expires on March 31, 2023. The principal investigator for this agreement is Dr. Waldemar Priebe, our founder.

Anti-Viral Portfolio

On March 20, 2020, the Company entered into a Development Agreement ("Agreement") with WPD Pharmaceuticals ("WPD"), a company founded by Dr. Waldemar Priebe, the founder of the Company. Pursuant to the Agreement, WPD agreed to use its commercially reasonable efforts in good faith to develop and commercialize certain products that WPD had previously sublicensed, solely in the field of pharmaceutical drug products for the treatment of any viral infection in humans, with a goal of eventual approval of in certain territories consisting of: Germany, Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland.

Pursuant to the Agreement, the Company agreed to pay WPD the following payments: (i) an upfront payment of $225,000 to WPD (paid in April 2020); and (ii) within thirty days of the verified achievement of the Phase II Milestone, (such verification shall be conducted by an independent third party mutually acceptable to the parties hereto), the Company will make a payment of $775,000 to WPD. WPD agreed to pay the Company a development fee of 50% of the net sales for any products in the above territories; provided that Poland shall not be included as a territory after WPD receives marketing approval for a product in one-half of the countries included in the agreed upon territories or upon the payment by WPD to the Company of development fees of $1.0 million. The term of the Agreement will expire on the expiration of the sublicense pursuant to which WPD has originally sublicensed the products.

Nasdaq Capital Markets Listing Qualifications

On February 18, 2022, the Company received a deficiency letter from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") notifying the Company that for the last 30 consecutive business days the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued inclusion in Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). The deficiency letter does not result in the immediate delisting of the Company's common stock from Nasdaq.

The Company was initially provided an initial period of 180 calendar days, or until August 17, 2022, to regain compliance with the Bid Price Rule. The Company was granted a second 180 calendar day period, or until February 13, 2023, to regain compliance since it met the continued listing requirement for market value of publicly held shares and all other initial listing standards required by Nasdaq, except for the minimum bid price requirement.

On November 28, 2022, the Company's Board of Directors effected a one-for-thirty (1:30) reverse stock split of the Company's common stock pursuant to such authority granted by the Company's stockholders at the Company's annual meeting of stockholders completed on August 25, 2022. On December 13, 2022, the Company received a letter from Nasdaq notifying the Company that it had regained compliance with Bid Price Rule 5550(a)(2) as a result of the closing bid price of the Company's common stock being at $1.00 per share or greater for the 10 consecutive business days from November 29, 2022 through December 12, 2022. Accordingly, the Company is in compliance with the Bid Price Rule and Nasdaq considers the matter closed.

Note 7 – 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, 2022	Year Ended December 31, 2021
Income tax benefit computed at the statutory rate	$ 3,206,000	$ 3,042,000
Tax effect of:		

True-ups and non-deductible expenses	(194,000)	(100,000)
Change in valuation allowance	(3,012,000)	(2,942,000)
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, 2022	As of December 31, 2021
Deferred income tax assets		
Net operating losses	$ 8,603,000	$ 5,860,000
Stock-based compensation	715,000	533,000
Deferred income tax liability		
Prepaid expenses	(628,000)	(715,000)
Valuation allowance	(8,690,000)	(5,678,000)
Net deferred income tax assets	$ –	$ –

As of December 31, 2022, the Company has an operating loss carry forward of approximately $40,966,000, which expires commencing in 2037.

Note 8 – Subsequent Events

Subsequent to December 31, 2022, a total of 609,000 Pre-Funded Warrants (exercisable into one share of common stock at a price per share of $0.001) were exercised by investors in the financing completed on November 30, 2022.

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 were awarded a total of 29,988 Options that partially vest over 4 years, partially vest upon the Company's common stock price exceeding various closing prices ranging from $6.00 - $24.00 per share.

CNS Pharmaceuticals, Inc.
Balance Sheets
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 909,547	$ 10,055,407
Prepaid expenses and other current assets	1,152,298	2,509,238
Total current assets	2,061,845	12,564,645
Noncurrent Assets:		
Prepaid expenses, net of current portion	262,731	482,806
Property and equipment, net	3,470	5,664
Total noncurrent assets	266,201	488,470
Total Assets	$ 2,328,046	$ 13,053,115
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 4,026,894	$ 4,510,291
Notes payable	41,904	409,968
Total current liabilities	4,068,798	4,920,259
Total Liabilities	4,068,798	4,920,259
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, 75,000,000 shares authorized and 4,207,068 and 1,617,325 shares issued and outstanding, respectively	4,207	1,617
Additional paid-in capital	62,446,694	58,846,916
Accumulated deficit	(64,191,653)	(50,715,677)
Total Stockholders' Equity (Deficit)	(1,740,752)	8,132,856
Total Liabilities and Stockholders' Equity (Deficit)	$ 2,328,046	$ 13,053,115

See accompanying notes to the unaudited financial statements.

CNS Pharmaceuticals, Inc.
Statements of Operations
(Unaudited)

	Three months ended September 30, 2023	Three months ended September 30, 2022	Nine months ended September 30, 2023	Nine months ended September 30, 2022
Operating expenses:				
General and administrative	$ 1,123,268	$ 1,211,102	$ 3,661,853	$ 3,814,513
Research and development	3,410,572	2,207,913	9,823,884	6,318,055
Total operating expenses	4,533,840	3,419,015	13,485,737	10,132,568
Loss from operations	(4,533,840)	(3,419,015)	(13,485,737)	(10,132,568)
Other income (expenses):				
Interest income	12,883	–	20,685	–
Interest expense	(1,838)	(538)	(10,924)	(4,715)
Total other income (expense)	11,045	(538)	9,761	(4,715)
Net loss	$ (4,522,795)	$ (3,419,553)	$ (13,475,976)	$ (10,137,283)
Loss per share - basic	$ (1.08)	$ (2.56)	$ (4.05)	$ (7.67)
Loss per share - diluted	$ (1.08)	$ (2.56)	$ (4.05)	$ (7.67)
Weighted average shares outstanding - basic	4,177,069	1,334,417	3,327,636	1,321,065
Weighted average shares outstanding - diluted	4,177,069	1,334,417	3,327,636	1,321,065

See accompanying notes to the unaudited financial statements.

CNS Pharmaceuticals, Inc.
Statements of Stockholders' Equity (Deficit)
For the nine months ended September 30, 2023 and 2022
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance December 31, 2022	1,617,325	$ 1,617	$ 58,846,916	$ (50,715,677)	$ 8,132,856
Exercise of warrants	609,000	609	–	–	609
Stock-based compensation	–	–	290,313	–	290,313
Net loss	–	–	–	(4,931,947)	(4,931,947)
Balance March 31, 2023	2,226,325	2,226	59,137,229	(55,647,624)	3,491,831
Common stock issued for cash, net	659,677	660	1,968,447	–	1,969,107
Exercise of warrants	1,254,958	1,255	723,804	–	725,059
Stock-based compensation	–	–	289,670	–	289,670
Net loss	–	–	–	(4,021,234)	(4,021,234)
Balance June 30, 2023	4,140,960	4,141	62,119,150	(59,668,858)	2,454,433
Common stock issued for cash, net	63,729	64	132,787	–	132,851
Stock-based compensation	2,379	2	194,757	–	194,759
Net loss	–	–	–	(4,522,795)	(4,522,795)
Balance September 30, 2023	4,207,068	$ 4,207	$ 62,446,694	$ (64,191,653)	$ (1,740,752)

Balance December 31, 2021	949,052	$ 949	$ 41,603,791	$ (35,441,543)	$ 6,163,197
Common stock issued for cash, net	316,316	316	10,625,470	–	10,625,786
Exercise of warrants	87,193	87	2,529	–	2,616
Stock-based compensation	–	–	336,685	–	336,685
Net loss	–	–	–	(3,151,778)	(3,151,778)
Balance March 31, 2022	1,352,561	1,352	52,568,475	(38,593,321)	13,976,506
Stock-based compensation	–	–	286,841	–	286,841
Net loss	–	–	–	(3,565,952)	(3,565,952)
Balance June 30, 2022	1,352,561	1,352	52,855,316	(42,159,273)	10,697,395
Stock-based compensation	–	–	289,721	–	289,721
Net loss	–	–	–	(3,419,553)	(3,419,553)
Balance September 30, 2022	1,352,561	$ 1,352	$ 53,145,037	$ (45,578,826)	$ 7,567,563

See accompanying notes to the unaudited financial statements.

CNS Pharmaceuticals, Inc.
Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Cash Flows from Operating Activities:		
Net loss	$ (13,475,976)	$ (10,137,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	774,742	913,247
Depreciation	3,181	9,375
Loss of disposal of fixed assets	757	2,635
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,577,015	1,134,824
Accounts payable and accrued expenses	(483,397)	(175,290)
Net cash used in operating activities	(11,603,678)	(8,252,492)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,744)	(4,423)
Net cash used in investing activities	(1,744)	(4,423)
Cash Flows from Financing Activities:		
Payments on notes payable	(368,064)	(348,534)
Proceeds from exercise of warrants	725,668	2,616
Proceeds from sale of common stock	2,101,958	10,625,786
Net cash provided by financing activities	2,459,562	10,279,868
Net change in cash and cash equivalents	(9,145,860)	2,022,953
Cash and cash equivalents, at beginning of period	10,055,407	5,004,517
Cash and cash equivalents, at end of period	$ 909,547	$ 7,027,470
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 10,924	$ 5,782
Cash paid for income taxes	$ –	$ –

See accompanying notes to the unaudited 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.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation - The accompanying unaudited financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United Stated of America ("U.S. GAAP") for interim unaudited financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. The unaudited financial statements include all adjustments (consisting of normal recurring adjustments) which are, in the opinion of management, necessary in order to make the condensed financial statements not misleading. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the final results that may be expected for the year ending December 31, 2023. For more complete financial information, these unaudited financial statements should be read in conjunction with the audited financial statements for the period ended December 31, 2022 included in our Form 10-K filed with the SEC on March 31, 2023 ("Form 10-K"). Notes to the financial statements which would substantially duplicate the disclosures contained in the audited financial statements for the most recent fiscal period, as reported in the Form 10-K, have been omitted.

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 is sufficient to fund its planned operations into but not beyond the near term. 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 as of September 30, 2023 was $659,547. 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.

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 for stock options and restricted stock units.

Restricted Stock Units ("RSUs") - Our RSUs vest over 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 September 30, 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 2,268,827 common shares unvested restricted stock units of 7,144 common shares, unvested performance units of 28,563 and options for 328,770 common shares, respectively. For the nine months ended September 30, 2022, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 524,000 common shares, unvested restricted stock units of 9,523 common shares, unvested performance units of 28,563 and options for 93,001 common shares, respectively.

Reclassification - Certain reclassifications may have been made to our prior year's financial statements to conform to our current year presentation. These reclassifications had no effect on our previously reported results of operations or accumulated deficit.

Recent Accounting Pronouncements - In June 2016, the FASB issued Accounting Standards Update No. 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The Company adopted this standard on January 1, 2023, which had no material impact on the Company's financial statements.

Note 3 – Note Payable

On November 14, 2022, the Company entered into a short-term note payable for an aggregate of $449,874, bearing interest at 5.88% 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 31, 2023. As of September 30, 2023 and December 31, 2022, the Company's note payable balance was $41,904 and $409,968, 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.

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 nine months ended September 30, 2023, the Company sold 723,406 shares of common stock to the Agent for net proceeds of $2,101,958.

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 66,667 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 100,000 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 745,800 shares of common stock.

On December 30, 2022, the Board of Directors of the Company appointed Faith Charles as an independent member of the Company's Board of Directors and as Chairperson of the Board of Directors. Ms. Charles will receive an annual retainer for her service as Chairperson of $30,000 and, on the date of her appointment, was granted a ten-year option to purchase 3,500 shares of Company common stock at an exercise price of $2.40 vesting in 36 equal monthly installments succeeding the issuance date. The total fair value of these option grants at issuance was $7,091.

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 29,988 options at an exercise price of $0.996. 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 2,099 shares of Company common stock at an exercise price of $1.67 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 6,500 options to Dr. Cockroft. The options have a ten-year term at an exercise price of $2.27 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 193,690 options to the board of directors. The options have a ten-year term at an exercise price of $1.90 and vest on the first anniversary date of issuance. The total fair value of these option grants at issuance was $313,846.

During the nine months ended September 30, 2023 and 2022, the Company recognized $727,864 and $877,510 of stock-based compensation, respectively, related to outstanding stock options. At September 30, 2023, the Company had $940,197 of unrecognized expenses related to outstanding options.

The following table summarizes the stock option activity for the nine months ended September 30, 2023:

	Options	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2022	93,001	$ 67.42
Granted	235,777	1.78
Exercised	–	–
Forfeited	(8)	120.00
Expired	–	–
Outstanding, September 30, 2023	328,770	$ 20.35
Exercisable, September 30, 2023	82,261	$ 60.99

As of September 30, 2023, the outstanding stock options have a weighted average remaining term of 8.79 years and aggregate intrinsic value of options vested and outstanding of $0 and $4,318, respectively. As of September 30, 2023, there were no awards remaining to be issued under the 2017 Plan and 545,610 awards remaining to be issued under the 2020 Plan.

Stock Warrants

During the nine months ended September 30, 2023, the Company received $725,668 in cash proceeds from the exercise of 238,958 warrants previously issued at an exercise price of $3.03 and 1,625,000 warrants previously issued at an exercise price of $0.001.

The following table summarizes the stock warrant activity for the nine months ended September 30, 2023:

	Warrants	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2022	4,133,252	$ 4.35
Granted	–	–
Exercised	(1,863,958)	0.39
Forfeited	–	–
Expired	(467)	45.00
Outstanding, September 30, 2023	2,268,827	$ 7.59
Exercisable, September 30, 2023	2,268,827	$ 7.59

As of September 30, 2023, the outstanding and exercisable warrants have a weighted average remaining term of 4.02 years and had no aggregate intrinsic value.

Restricted Stock Units

During the nine months ended September 30, 2023, the Company recognized $17,888 of stock-based compensation, related to outstanding RSUs. At September 30, 2023, the Company had $59,624 of unrecognized expenses related to outstanding RSUs.

The following table summarizes the RSUs activity for the nine months ended September 30, 2023:

	RSUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2022	9,523	$ 10.02
Granted	–	–
Vested	(2,379)	10.02
Forfeited	–	–
Non-vested, September 30, 2023	7,144	$ 10.02

Performance Units

During the nine months ended September 30, 2023, the Company recognized $28,990 related to outstanding stock PUs. At September 30, 2023, the Company had $104,958 of unrecognized expenses related to PUs.

The following table summarizes the PUs activity for the nine months ended September 30, 2023:

	PUs	Weighted-Average Grant Date Fair Value
Non-vested, December 31, 2022	28,563	$ 5.94
Granted	–	–
Vested	–	–
Forfeited	–	–
Non-vested, September 30, 2023	28,563	$ 5.94

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 February 6, 2021, the compensation committee of the board of directors set Mr. Climaco's 2021 annual base salary to $525,000.

On June 28, 2019, we entered into employment letters with Drs. Silberman and Picker. 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 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.

Scientific Advisory Board

On July 15, 2021, our Board approved the following compensation policy for members of the Scientific Advisory Board. The Scientific Advisory board consists of Dr. Sigmond Hsu. The scientific advisory board member shall receive annual cash compensation of $68,600. During the nine months ended September 30, 2023 and 2022, the Company paid $0 and $76,087 related to the Scientific Advisory Board compensation. As of September 30, 2023, the Company has accrued $151,584 related to Dr. 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 6,667 shares of the Company's common stock valued at $1.35 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 nine months ended September 30, 2023 and 2022, the Company recognized $37,500 and $262,500, 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 in related party transactions which are reviewed and approved by the Company's audit committee based upon the standards of providing superior pricing and time to delivery than that available from unrelated third parties. During the nine months ended September 30, 2023 and 2022, the Company expensed $0 and $41,075 respectively related to the purchase of pharmaceutical products from HPI.

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 that is majority-owned by an entity controlled by Dr. Priebe, our founder.

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 September 30, 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, our founder, is also the founder and a shareholder of ALI, holds 38% of the membership interests of ALI.

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 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 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 ("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 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 Agreement. The term of the Agreement expires on the last to occur of: (a) the expiration of all patents subject to the Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate this 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 required as of the date hereof. As such, UTMDACC has the right to terminate the Agreement upon notice to the Company. As of the date of this report, UTMDACC has not notified the Company of its intention to terminate the Agreement. During the nine months ended September 30, 2023 and 2022, the Company paid $45,092 and $49,607, respectively.

On May 7, 2020, pursuant to the WP1244 Portfolio license agreement described above, the Company entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. The Company agreed to fund approximately $1,134,000 over a two-year period, which has been fully paid by the Company in 2021. This agreement was extended and expired on March 31, 2023. The principal investigator for this agreement is Dr. Waldemar Priebe, our founder.

Note 6 – Subsequent Events

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 1,878,000 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 3,756,000 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 $1.28 per share (the "Reduced Exercise Price"). The Company received aggregate gross proceeds of $2,403,840 from the exercise of the Existing Warrants before deducting financial advisory fees and other expenses payable by it. Pursuant to the Inducement Letter, although the exercise of the warrants has occurred and full payment of the exercise price has been made, the Holder has directed that a number of shares be held in abeyance and not yet issued until they direct us to do so. As such, the shares have not been issued and do not appear in our count of common shares outstanding.

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. Subsequent to the quarter ended on September 30, 2023, the Company sold 129,530 shares of common stock to the Agent for net proceeds of $215,641.

2,215,667 Shares of Common Stock

11,117,667 Pre-Funded Warrants to Purchase up to 11,117,667 Shares of Common Stock

13,333,334 Series A Common Warrants to Purchase up to 13,333,334 Shares of Common Stock

13,333,334 Series B Common Warrants to Purchase up to 13,333,334 Shares of Common Stock

11,117,667 Shares of Common Stock Underlying such Pre-Funded Warrants

13,333,334 Shares of Common Stock Underlying such Series A Common Warrants

13,333,334 Shares of Common Stock Underlying such Series B Common Warrants

CNS Pharmaceuticals, Inc.

Joint Placement Agents

A.G.P. **Maxim Group LLC**

PROSPECTUS

January 29, 2024