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

FORM 10-K

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

For the fiscal year ended December 31, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39126

CNS Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CNSP	The NASDAQ Stock Market LLC

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

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

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

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

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

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

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

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

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of the registrant's common stock outstanding as of February 12, 2021 was 25,300,868.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders to be filed with the SEC no later than 120 days after the end of the registrant's fiscal year are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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

Cautionary Statement About Forward-Looking Statements

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

While we believe we have identified material risks, these risks and uncertainties are not exhaustive. Other sections of this report may describe additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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

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

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

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

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

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

PART I

Item 1. Business.

Overview

We are a clinical pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anti-cancer drug candidates for the treatment of brain and central nervous system tumors, based on intellectual property that we license under license agreements with 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, if approved by the FDA, may be a significant discovery in the treatment of glioblastoma. Glioblastoma are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful chemotherapy drugs known. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to have crossed the blood brain barrier and target brain cancer cells. While our current focus is solely on the development of Berubicin, we are also in the process of attempting to secure intellectual property rights in additional compounds that may be developed into drugs to treat cancers.

Berubicin was discovered at MD Anderson by Dr. Waldemar Priebe, the founder of the Company. Through a series of transactions, Berubicin was initially licensed to Reata. Reata conducted a Phase I clinical trial on Berubicin 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 intend to initiate our trial during the first quarter of 2021 to investigate the efficacy of Berubicin in adults with Glioblastoma Multiforme who have failed first-line therapy. Recent correspondence between us and the FDA resulted in modifications to our previously disclosed 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 planned Phase 2 trial 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 current standard of care, with 2 to 1 randomization of the 243 patients to Berubicin or Lomustine. Subjects 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 (21-day cycle). Lomustine is administered orally. The trial will include an interim analysis that will evaluate the comparative effectiveness of these treatments. The trial's adaptive design is intended to allow this interim analysis of the data to demonstrate meaningful differences in efficacy between treatments and then to allow an adjustment to the size of the patient population in the trial for maximum efficiency in terms of time in development. 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, which we refer to as the Reata Data.

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, who controls a majority of our shares. Under the HPI License we obtained the exclusive right to develop certain chemical compounds for use in the treatment of cancer anywhere in the world. In the HPI License we agreed to pay HPI: (i) development fees of $750,000 over a three-year period beginning November 2019; (ii) a 2% royalty on net sales; (iii) a $50,000 per year license fee; (iv) milestone payments of $100,000 upon the commencement of a Phase II trial and $1.0 million upon the approval of an New Drug Application ("NDA") for Berubicin; and (v) 200,000 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 the Company is 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 "1244 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 1244 Agreement, we obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to our 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 1244 Agreement. The term of the 1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the 1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate the 1244 Agreement in the event that we fail to meet certain commercial diligence milestones.

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. The Company paid and recorded $334,000 in 2020 related to this agreement in research and development expenses in the Company's Statements of Operations. The remaining $720,000 will be paid in 2021, of which $400,000 was accrued at December 31, 2020. The principal investigator for this agreement is Dr. Priebe.

Market for Cancer Drugs and Berubicin

Cancer is the second leading cause of death in the United States behind heart disease. In 2016, there were an estimated 15.5 million cancer survivors in the United States. In 2018, the American Cancer Society estimated that nearly 1.7 million new cases would be diagnosed and over 600,000 Americans would die from cancer.

Digestive, reproductive, breast and respiratory cancers comprise 65% of expected cancer diagnoses in 2018, 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 penetrate the BBB. We believe that based on 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. Temozolomide may extend progression free survival ("PFS") but has never been shown to be curative of any brain cancers.

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 effective therapies for glioblastoma. In the clinical trial completed in February 2009, Berubicin demonstrated one durable complete response (considered clinically to be a cure) lasting over 11 years in a glioblastoma patient. This patient remains disease free and clinically stable as of November 6, 2020.

In the trial, 25 of the 35 patients enrolled were evaluable for response. In a prior clinical trial, Berubicin has also shown promising data in a patient population that currently has a dismal median survival rate of only 14.6 months from glioblastoma diagnosis and few effective therapeutic options. If the early results are proven to be reproducible and if we secure regulatory approval to market Berubicin, its apparent ability to cross the BBB combined with its mechanism of action, more thoroughly discussed below, has the potential to become an effective treatment for this deadly cancer.

In the United States, 22,850 new glioblastoma patients are diagnosed, and 15,300 patients die of this deadly disease annually (National Cancer Institute 2015). 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 for treatment is surgery, radiation, and chemotherapy with TMZ. TMZ, the current chemotherapeutic component of the 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 only improved by 2.5 months versus radiation alone. At least 50% of TMZ treated patients do not respond to TMZ, primarily due to the over-expression of O6-methylguanine methyltransferase ("MGMT") and/or lack of a DNA repair pathway in glioblastoma cells. Given the different mechanism of action of Berubicin, these patients may show a better outcome and our planned phased 2 clinical trial could 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 a phase 2 stratified trial that can either serve as a registration trial or provide sufficient data to power a phase 3 registration trial.

Based on data relating to the mechanism of action of Berubicin, as well as clinical results from the Phase 1 study in brain tumors performed by Reata, the prior developer of Berubicin, we 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 the preferred standard as an endpoint for clinical trials in Neuro-Oncology. 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 trial will include an interim analysis to estimate the likelihood of achieving statistical significance for the primary endpoint, OS, after approximately 50% of enrolled patients have reached 6 months on study.

Assuming data from the above described Phase 2 study is positive (and depending on the strength and quality of such data) at its completion we may seek 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.

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 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, unlike 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 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 future 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.

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 CNS 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) and/or 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 and 10 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 ongoing berubicin clinical trials was halted. Reata submitted a request to inactive 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. Furthermore, should our human trials demonstrate a significant improvement in glioblastoma patient outcomes, the FDA may grant us an accelerated review schedule under its Breakthrough Therapy Designation.

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 a 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. The main goal of the WPD Project is to implement the first in the world multicenter pediatric phase I clinical trial to determine maximum tolerated dose (MTD) and phase IB and II clinical trials in adults, in order to attempt to determine 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.

The WPD Project includes the implementation of the following stages of R&D:

1. Scientific Advice Procedure implementation; Regulatory documentation for "First in Children" and phase Ib and II clinical trial in adults preparation;

2. IP Manufacturing according to GMP;

3. Possible In vitro studies on anticancer activity of Berubicin in combination with TMZ and other WPD molecules;

4. "First in children" and Phase Ib in adults clinical trials conducting;

5. Phase II in adults clinical trial conducting.

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 6, 2020.

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 6, 2020.

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 the preferred standard as an endpoint for clinical trials in Neuro-Oncology. 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 trial will include an interim analysis to estimate the likelihood of achieving statistical significance for the primary endpoint, OS, after approximately 50% of enrolled patients have reached 6 months on study.

Assuming data from the above described Phase 2 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. While the percentage of patients who survive two years from the diagnosis of glioblastoma has more than tripled from 8% to 25% in the last five years, largely because of the use of TMZ, the overall survival 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 patented 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.

We plan 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

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

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

Post-Approval Requirements

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

Orphan Drug exclusivity prevents for seven years the approval of another product with the same active moiety for the same rare disease. 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. 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. In exchange for these rights, we agreed to pay Reata an amount equal to 2.25% of the net sales of Berubicin for a period of 10 years from our first commercial sale of Berubicin plus $10,000. Reata also agreed to use commercially reasonable efforts, at the Company's expense, to provide development assistance related to the product and/or product intellectual property. The Reata Agreement will terminate ten years after the date of the first commercial sale of product, provided the agreement may be earlier terminated due to a material breach of the agreement by either party, or if either party undergoes a bankruptcy event.

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. Under the HPI License we obtained the exclusive right to develop certain patented 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 NDA for Berubicin; and (v) 200,000 shares of our common stock. We had the right, although we chose not to exercise such right, exercisable before December 28, 2020, to terminate the HPI License in full upon payment to HPI in the amount of $2,000,000 (the "Buy-Out Fee"). Upon payment of the Buy-Out Fee, (i) our obligation to pay any additional development payments, license fee and the milestone payments would have ceased; (ii) HPI would have transferred ownership of all development data in its possession to us promptly; and (iii) HPI would have transferred to us any regulatory submissions including any IND, NDA or ANDA related to the patent rights. The payment of the Buy-Out Fee would not have relieved us of our obligation to use commercially reasonable development efforts to develop a licensed product by the development deadline as provided in the HPI License.

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. In the event that WPD fails to use commercially reasonable development efforts to by the foregoing three-year deadline, we have the right to terminate this sublicense 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 and largest shareholder.

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.

On January 10, 2020, we entered into a Patent and Technology License Agreement (the "1244 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 1244 Agreement, we obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to our 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 1244 Agreement. The term of the 1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the 1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate the 1244 Agreement in the event that we fail to meet certain commercial diligence milestones.

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. The Company paid and recorded $334,000 in 2020 related to this agreement in research and development expenses in the Company's Statements of Operations. The remaining $720,000 will be paid in 2021, of which $400,000 was accrued at December 31, 2020. The principal investigator for this agreement is Dr. Priebe.

On March 20, 2020, we entered into a Development Agreement with WPD Pharmaceuticals ("WPD") (the "Development Agreement"), a company founded by Dr. Priebe. Pursuant to the Development 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: 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 Development Agreement, we 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), we will make a payment of $775,000 to WPD. WPD agreed to pay us 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 us of development fees of $1.0 million. The term of the Development Agreement will expire on the expiration of the sublicense pursuant to which WPD has originally sublicensed the products, which will occur upon the expiration of the patents subject to the sublicense agreement, the earliest of which expires in 2024.

Employees

As of February 11, 2021, 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.

Legal Proceedings

We are not subject to any litigation.

Properties

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

Available Information

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

Item 1A. Risk Factors.

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

Risks Related to the Company's Business and Industry

We will require substantial funding, 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 our IPO and subsequent funding to, among other uses, advance Berubicin through clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in 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 $16.0 to $20.0 million to complete the Phase 2 trial for Berubicin, approximately $2.0 million to support near-term WP1244 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 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.

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

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

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

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

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

Our auditors have indicated in their report on our financial statements for the fiscal year ended December 31, 2020 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.

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 largest shareholder, 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, which granted an exclusive sublicense to Berubicin for the treatment of cancer in non-human animals.

- We entered into a development agreement with WPD Pharmaceuticals, Inc., which granted us an economic interest in WPD's development of an anti-viral portfolio.

We entered into the above agreements related to Berubicin with HPI and WPD 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 private placements and the issuance of convertible notes. The continuation of the Company as a going concern is dependent upon our ability to obtain continued financial support from its stockholders, necessary equity financing to continue operations and the attainment of profitable operations. As of December 31, 2020 the Company has incurred an accumulated deficit of $20,946,343 since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, 2020 is sufficient to fund its planned operations through but not beyond calendar year 2021.

To date, we have devoted most of our financial resources to corporate overhead, clinical trial preparation 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, 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 no 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 preclinical pharmaceutical company with no operating history. Our operations to date have been limited to acquiring our technology portfolio. We have not yet commenced any clinical trials or 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 filing 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 conducted 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. A number of 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 analyses 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.

The COVID-19 outbreak may delay recruitment in our clinical trials and may continue or worsen, may affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to our planned clinical trials and ultimately of reviews and approvals of our product candidates.

The COVID-19 outbreak has delayed recruitment in clinical trials and may continue or worsen. Additionally, it may delay the approvals of our product candidates due to its effect on the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned clinical trials. The spread of COVID-19 may also slow potential enrollment of clinical trials and reduce the number of eligible patients for our clinical trials. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

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 is approved, after the approved product has been marketed. The range and potential severity of possible side effects from therapies such as Berubicin are significant. If Berubicin 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.

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 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.

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 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 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. 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 February 11, 2021, 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 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. 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 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 bel able to contract for such supplies on acceptable terms, if at all. Any such failure to supply or delay caused by such contract manufacturers 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.

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 could cause 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, and as of the year ended December 31, 2020, identified a material weakness in our internal controls due to the lack of sufficient personnel to allow for segregation of duties. While management is working to remediate the material weakness, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to maintain effective internal control over financial reporting, our financial statements, including related disclosures, may be inaccurate, which could have a material adverse effect on our business.

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, 2020 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 and as of the year ended December 31, 2020, due to a material weakness in our internal controls due to the lack of segregation of duties. 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 remediate this material weakness, 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 remediation efforts, there is no assurance we will not encounter accounting errors in the future. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information.

Our executive officers, directors, major stockholder and their respective affiliates exercise significant control over us, which will limit our stockholders ability to influence corporate matters and could delay or prevent a change in corporate control.

The holdings of our executive officers, directors, founder and their affiliates, are, in the aggregate, approximately 42.2% of our outstanding common stock. As a result, these stockholders will be able to influence our management and affairs and control the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets.

These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock at the time of this report, and these stockholders may have interests, with respect to their common stock, that are different from those of our other stockholders and the concentration of voting power among one or more of these stockholders may have an adverse effect on the price of our common stock.

In addition, this concentration of ownership might adversely affect the market price of our common stock by: (1) delaying, deferring or preventing a change of control of our Company; (2) impeding a merger, consolidation, takeover or other business combination involving our Company; or (3) discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our Company.

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

We intend to seek to raise additional funds, finance acquisitions or develop strategic relationships by issuing equity or convertible debt securities, which would reduce the percentage ownership of our existing stockholders. Our board of directors has the authority, without action or vote of the stockholders, to issue all or any part of our authorized but unissued shares of common or preferred stock. Our articles of incorporation authorize us to issue up to 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.

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.

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

Item 3. Legal Proceedings.

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

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

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

Holders of Common Equity

As of January 29, 2021, we had approximately 6,635 stockholders of record of our common stock. This does not include beneficial owners of our common stock.

Dividends

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

Recent Sales of Unregistered Securities

There have been no sales of unregistered securities during the quarter ended December 31, 2020.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the year ended December 31, 2020.

Equity Compensation Plan Information

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

Item 6. Selected Financial Data.

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

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

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

Overview

We are a preclinical stage pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anti-cancer drug candidates for the treatment of brain and central nervous system tumors, based on intellectual property that we license under a license agreements with HPI and The University of Texas M.D. Anderson Cancer Center and own pursuant to a collaboration and asset purchase agreement with Reata.

We believe our lead drug candidate, Berubicin, if approved by the FDA, may be a significant discovery in the treatment of glioblastoma. Glioblastoma are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful chemotherapy drugs known. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to have crossed the Blood Brain Barrier and target brain cancer cells. While our current focus is solely on the development of Berubicin, we are also in the process of attempting to secure intellectual property rights in additional compounds that may be developed into drugs to treat cancers.

Berubicin was discovered at MD Anderson by Dr. Waldemar Priebe, the founder of the Company. Through a series of transactions, Berubicin was initially licensed to Reata. Reata conducted a Phase I clinical trial on Berubicin but subsequently allowed their IND with the FDA to lapse for strategic reasons. This will require us to obtain a new IND for Berubicin before beginning further clinical trials.

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, which we refer to as the Reata Data.

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. Under the HPI License we obtained the exclusive right to develop certain patented chemical compounds for use in the treatment of cancer anywhere in the world. In the HPI License we agreed to pay HPI: (i) development fees of $750,000 over a three-year period beginning November 2019; (ii) a 2% royalty on net sales; (iii) a $50,000 per year license fee; (iv) milestone payments of $100,000 upon the commencement of a Phase II trial and $1.0 million upon the approval of an NDA for Berubicin; and (v) 200,000 shares of our common stock.

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 "1244 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 1244 Agreement, we obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to our 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 1244 Agreement. The term of the 1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the 1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate the 1244 Agreement in the event that we fail to meet certain commercial diligence milestones.

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. The Company paid and recorded $334,000 in 2020 related to this agreement in research and development expenses in the Company's Statements of Operations. The remaining $720,000 will be paid in 2021, of which $400,000 was accrued at December 31, 2020. The principal investigator for this agreement is Dr. Priebe.

Results of Operations for the Year Ended December 31, 2020 Compared to the Year Ended December 31, 2019

General and Administrative Expense

General and administrative expense was $4,392,873 for the year ended December 31, 2020 compared to $1,978,643 for 2019. The increase in general and administrative expense, was mainly the result of closing our IPO in November 2019 which allowed us to substantially increase our operations. The details of the change is attributable to an increase of approximately $480,000 for stock-based compensation, an increase of $667,000 in employee compensation and taxes, compensation to the Board of Directors of $180,000, an increase of $302,000 in professional fees, an increase of $495,000 in insurance expenses, and an increase of $431,000 in other corporate expenses. These changes were offset by a decrease of $154,000 in recruiting fees in 2020.

Research and Development Expense

Research and development expense was $5,061,734 for the year ended December 31, 2020 compared to $1,854,334 for 2019. The expenses incurred during the year were related to patent maintenance cost and contract labor related to the preparation of our Phase II study. We expect to incur increased research and development costs in the future as our product development activities expand.

Interest Expense

Interest expense was $3,264 and $26,152 for the years ended December 31, 2020 and 2019, respectively. The decrease in interest expense was mainly the result of the payoff of our convertible notes payable issued in 2017 bearing interest at the rate of 10% per annum.

Net Loss

The net loss for the year ended December 31, 2020 was $9,457,871 compared to $3,877,211 for 2019. The change in net loss is attributable to increased personnel and activity associated with preparing for our clinical trials in 2020.

Liquidity and Capital Resources

On December 31, 2020, we had cash of $14,039,493 and we had working capital of $13,590,415. We have historically funded our operations from proceeds from debt and equity sales.

On November 13, 2019, we closed our IPO of 2,125,000 shares of common stock at a price to the public of $4.00 per share, followed shortly by the exercise of the over-allotment option issued to the underwriter which resulted in an additional 318,750 shares of common stock being issued at the IPO price of $4.00 per share.

On December 28, 2020, we closed a follow-on offering of 5,750,000 shares of common stock at a price to the public of $2.00 per share (including a full over-allotment option). Each share issued included 0.5 warrants to purchase a common share at a price of $2.20. We believe that the proceeds from this issuance and our cash on hand are sufficient to fund our planned operations through, but not beyond, 2021.

Our plan of operations is primarily focused on using the proceeds from the follow-on offering to complete a Phase II clinical trial for Berubicin. We estimate that we will require additional financing, beyond the proceeds of the offering, of approximately $18 million to complete the trial, approximately $2.0 million to support near-term WP1244 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 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 $7,318,018 and $3,553,472 for the years ended December 31, 2020 and 2019, respectively, and mainly included payments made for clinical trial preparation, officer compensation, marketing and professional fees to our consultants, attorneys and accountants.

Cash used in investing activities

Net cash used in operating activities was $17,945 and $20,120 for the years ended December 31, 2020 and 2019 and included payments furniture and equipment.

Cash provided by financing activities

Net cash provided by financing activities was $14,134,168 and $10,259,747 for the years ended December 31, 2020 and 2019. We received net proceeds of $14,222,249 from the issuance of common stock during the year ended December 31, 2020.

On November 13, 2019, we closed our IPO of 2,125,000 shares of common stock at a price to the public of $4.00 per share, followed shortly by the exercise of the over-allotment option issued to the underwriter which resulted in an additional 318,750 shares of common stock being issued at the IPO price of $4.00 per share.

On December 28, 2020, we closed a follow-on offering of 5,750,000 shares of common stock at a price to the public of $2.00 per share (including a full over-allotment option). Each share issued included 0.5 warrants to purchase a common share at a price of $2.20.

Off-balance Sheet Arrangements

As of December 31, 2020, 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 development 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. We consider critical accounting policies to be those that require more significant judgments and estimates in the preparation of our financial statements, including the following: long lived assets; intangible assets valuations; and income tax valuations. Management relies on historical experience and other assumptions believed to be reasonable in making its judgment and estimates. Actual results could differ materially from those estimates.

Management believes its application of accounting policies, and the estimates inherently required therein, are reasonable. These accounting policies and estimates are periodically reevaluated, and adjustments are made when facts and circumstances dictate a change.

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.

Research and Development Costs - Research and development costs are expensed as incurred.

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

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

Item 8. Financial Statements and Supplementary Data.

CNS Pharmaceuticals, Inc.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CNS Pharmaceuticals, Inc. (the "Company") as of December 31, 2020 and 2019, 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, 2020 and 2019, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

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

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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
February 12, 2021

CNS Pharmaceuticals, Inc.
Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 14,039,493	$ 7,241,288
Prepaid expenses	1,456,350	652,622
Total current assets	15,495,843	7,893,910
Noncurrent Assets:		
Property and equipment, net	23,431	18,165
Deferred offering costs	334,138	–
Total noncurrent assets	357,569	18,165
Total Assets	$ 15,853,412	$ 7,912,075
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 946,330	$ 243,666
Accounts payable and accrued expenses - related party	–	45,833
Accrued expenses	519,804	21,500
Notes payable	439,294	–
Total current liabilities	1,905,428	310,999
Total Liabilities	1,905,428	310,999
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 23,856,151 and 16,450,234 shares issued and outstanding, respectively	23,856	16,450
Additional paid-in capital	34,870,471	19,073,098
Accumulated deficit	(20,946,343)	(11,488,472)
Total Stockholders' Equity	13,947,984	7,601,076
Total Liabilities and Stockholders' Equity	$ 15,853,412	$ 7,912,075

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Operations

	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating expenses:		
General and administrative	$ 4,392,873	$ 1,978,643
Research and development	5,061,734	1,854,334
Total operating expenses	9,454,607	3,832,977
Loss from operations	(9,454,607)	(3,832,977)
Other expenses:		
Interest expense	(3,264)	(26,152)
Amortization of debt discount	–	(18,082)
Total other expenses	(3,264)	(44,234)
Net loss	$ (9,457,871)	$ (3,877,211)
Loss per share - basic and diluted	$ (0.57)	$ (0.28)
Weighted average shares outstanding - basic and diluted	16,618,441	13,647,908

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Stockholders' Equity
For the years ended December 31, 2020 and 2019

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance December 31, 2018	12,694,504	$ 12,695	$ 7,049,268	$ (7,611,261)	$ (549,298)
Common stock issued for cash	3,261,250	3,261	10,291,486	–	10,294,747
Common stock issued for services	75,000	75	149,925	–	150,000
Stock-based compensation	–	–	477,096	–	477,096
Common stock issued for extinguishment of convertible notes payable and accrued interest	228,329	228	342,265	–	342,493
Conversion of SAFE agreements	191,151	191	763,058	–	763,249
Net loss	–	–	–	(3,877,211)	(3,877,211)
Balance December 31, 2019	16,450,234	16,450	19,073,098	(11,488,472)	7,601,076
Common stock and warrants issued for cash, net	7,203,926	7,204	14,108,281	–	14,115,485
Common stock issued for deferred offering costs	201,991	202	395,700	–	395,902
Stock-based compensation	–	–	1,293,392	–	1,293,392
Net loss	–	–	–	(9,457,871)	(9,457,871)
Balance December 31, 2020	23,856,151	$ 23,856	$ 34,870,471	$ (20,946,343)	$ 13,947,984

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Cash Flows

	Year Ended December 31, 2020	Year Ended December 31, 2019
Cash Flows from Operating Activities:		
Net loss	$ (9,457,871)	$ (3,877,211)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,293,392	477,096
Common stock issued for services	–	150,000
Amortization of debt discount	–	18,082
Deferred financing cost	–	102,225
Depreciation	11,096	1,955
Loss on disposal of fixed assets	1,583	–
Changes in operating assets and liabilities:		
Prepaid expenses	(321,353)	(619,622)
Accounts payable	702,664	108,570
Accounts payable and accrued expenses - related party	(45,833)	45,039
Accrued expenses	498,304	40,394
Net cash used in operating activities	(7,318,018)	(3,553,472)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(17,945)	(20,120)
Net cash used in investing activities	(17,945)	(20,120)
Cash Flows from Financing Activities:		
Payment of deferred offering costs	(45,000)	–
Payments on notes payable	(43,081)	(35,000)
Proceeds from sale of common stock and warrants	14,222,249	10,294,747
Net cash provided by financing activities	14,134,168	10,259,747
Net change in cash and cash equivalents	6,798,205	6,686,155
Cash and cash equivalents, at beginning of period	7,241,288	555,133
Cash and cash equivalents, at end of period	$ 14,039,493	$ 7,241,288
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 1,708	$ 3,993
Cash paid for income taxes	$ –	$ –
Supplemental disclosure of non-cash investing and financing activities:		
Common stock issued for deferred offering costs	$ 395,902	$ –
Prepaid expenses financed with note payable	$ 482,375	$ –
Deferred offering costs of fset against additional paid in capital	$ 106,764	$ –
Conversion of SAFE agreements	$ –	$ 763,249
Common stock and warrants issued for extinguishment of convertible notes payable and accrued interest	$ –	$ 342,493

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.

Note 2 – Summary of Significant Accounting Policies

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

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

Liquidity and Going Concern - These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain equity financings to continue operations. The Company has a history of and expects to continue to report negative cash flows from operations and a net loss. Management believes that the cash on hand 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, 2020 was $13,789,493. 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	2-3 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.

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, 2020, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 6,861,630 common shares, and options for 2,200,736 common shares. As of December 31, 2019, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included warrants to purchase 3,986,630 common shares, and options for 1,764,500 common shares.

Research and Development Costs - Research and development costs are expensed as incurred.

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 December 2019, the FASB issued ASU No. 2019-12 - Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 is part of the FASB's overall simplification initiative and seeks to simplify the accounting for income taxes by updating certain guidance and removing certain exceptions. The updated guidance is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact of adopting this new accounting standard on its financial statements and related disclosures.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company will adopt ASU 2020-10 as of the reporting period beginning January 1, 2021. The adoption of this update is not expected to have a material effect on the Company's financial statements.

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 3 – Note Payable

During the year ended December 31, 2020, the Company entered into a short-term note payable for an aggregate of $482,375, bearing interest at 4.25% 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, 2021. As of December 31, 2020, the Company's note payable balance was $439,294.

Note 4 – Equity

The Company has authorized shares of common stock to 75,000,000 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.

Common Stock

On April 11, 2019, the Company's board of directors approved a Bridge Offering private placement up to a maximum of 817,500 shares of common stock at $2.00 per share. As of December 31, 2019, 817,500 shares have been sold for proceeds net of fundraising expenses of $1,507,170.

On April 11, 2019, the Company entered into a consulting agreement with a consultant to provide services and advice related to social media, investor relations, marketing and public markets. The initial term of the agreement is twelve months. As consideration for entering into this agreement the Company issued a total of 75,000 shares of common stock. The shares vest over an eight-month period in equal monthly installments provided that the consultant is providing services on each vesting date. If the agreement is terminated prior to full vesting the Company shall have the right to repurchase unvested shares from the consultant for $0.001 per share. During the year ended December 31, 2019, $150,000 of expense has been recognized related to this agreement.

On November 13, 2019, the Company closed its IPO of 2,125,000 shares of its common stock at a price to the public of $4.00 per share. The net proceeds from the offering were $7,601,827 after deducting $898,173 of underwriting fees and other offering expenses.

On November 20, 2019, the Company closed the issuance of an additional 318,750 shares of its common stock pursuant to the exercise in full of the underwriters' over-allotment option in connection with its IPO. The additional shares were sold at the IPO price of $4.00 per share less underwriting discounts and commissions of $89,250 for total net proceeds of $1,185,750.

During the year ended December 31, 2018, the Company entered into SAFE agreements (Simple Agreement for Future Equity) with investors through a Regulation Crowdfunding campaign in exchange for cash investments totaling $628,558. Upon an initial public offering of the Company's common shares or a change of control, the amount invested under the SAFE agreements automatically converted into the Company's common shares. The number of shares the SAFE agreement investors received was based on a 16% discount to the pricing in the triggering equity financing. The SAFE agreements had no interest rate or maturity date and the SAFE investors had no voting right prior to conversion. The SAFE agreements were recorded as a liability of $763,249 as of December 31, 2018. On November 13, 2019, upon the closing of the IPO, the amount invested under the SAFE agreements automatically converted into 191,151 common shares, and the $269,399 of funds held in escrow were released to the Company.

On September 15, 2020, Company entered into a purchase agreement (the "Purchase Agreement"), and a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $15.0 million worth of the Company's common stock, $0.001 par value per share(the "Common Stock").

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million worth of shares of the Company's Common Stock. Such sales of Common Stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the date on which all of conditions precedent are satisfied, the "Commencement Date"), including that a registration statement covering the resale of shares of Common Stock that have been and may be issued under the Purchase Agreement has been declared effective by the SEC, a final prospectus in connection therewith is filed and the other conditions set forth in the purchase agreement are satisfied.

Thereafter, under the Purchase Agreement, on any business day selected by the Company that the closing sale price of the Common Stock equals or exceeds the threshold price set forth in the Purchase Agreement, the Company may direct LPC to purchase up to 30,000 shares of Company Common Stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 50,000 shares, provided that the closing sale price of the Common Stock is not below $2.00 on the purchase date; (ii) the Regular Purchase may be increased to up to 75,000 shares, provided that the closing sale price of the Common Stock is not below $2.50 on the purchase date; (iii) the Regular Purchase may be increased to up to 100,000 shares, provided that the closing sale price of the Common Stock is not below $3.00 on the purchase date; and (iv) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the Common Stock is not below $4.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. In addition, after the Commencement Date, the Company may direct Lincoln Park to purchase, on two separate occasions that must be at least 30 business days apart, $1,000,000 worth of Common Stock per such purchase (each, a "Tranche Purchase"). The purchase price per share for each Regular Purchase and each Tranche Purchase will be based on prevailing market prices of the Common Stock immediately preceding the time of sale. There are no upper limits on the price per share that Lincoln Park must pay for shares of Common Stock under the Purchase Agreement. In addition to Regular Purchases and Tranche Purchases, the Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the Common Stock equals or exceeds the threshold price at the times set forth in the Purchase Agreement. The above-referenced share amount limitations and closing sale price thresholds are subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement.

As consideration for entering into the purchase agreement, the Company issued 201,991 shares of common stock to Lincoln Park as a commitment fee. The shares were valued at approximately $395,902 and were recorded as deferred offering costs on the balance sheet. In addition to the commitment shares, the Company recorded $45,000 of due diligence expenses and legal fees as deferred offering costs. The deferred charges will be charged against paid-in capital upon future proceeds from the sale of common stock under this agreement. During the year ended December 31, 2020, $106,764 of deferred offering cost were charged against paid-in capital. As of December 31, 2020, unamortized deferred offering costs totaled $334,138.

During the year ended December 31, 2020, the Company sold 1,453,926 shares of common stock to Lincoln Park under the Purchase Agreement for net proceeds of $3,632,249.

On December 22, 2020, the Company entered into an underwriting agreement with A.G.P./Alliance Global Partners (the "Underwriters"), in connection with a public offering (the "Offering") of an aggregate of (i) 5,000,000 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), and (ii) warrants to purchase 2,500,000 shares of Common Stock (the "Warrants"). In addition, the Company granted the Underwriter a 45-day option to purchase up to an additional 750,000 Shares and/or 375,000 Warrants to cover over-allotments, if any. Each Share sold in the Offering was sold together with a Warrant to purchase 0.5 shares of Common Stock as a fixed combination. The Shares and accompanying Warrants were sold at a price to the public of $2.00, less underwriting discounts and commissions. The Warrants are exercisable immediately, will expire on December 28, 2025 and have an exercise price of $2.20 per share, subject to anti-dilution and other adjustments for certain stock splits, stock dividends, or recapitalizations. The Company used the Black-Scholes option valuation model to estimate the fair value of the warrants with the following assumptions: fair value of common stock on December 28, 2020, the measurement date, $1.85, exercise price of $2.20, expected term of 5 years, volatility of 130.30% and risk free interest rate of 0.38%. As of December 31, 2020, the fair value of the 2,875,000 warrants issued was $4,485,441 and recorded to additional paid in capital as a cost of capital. The Offering, including the full over-allotment securities, closed on December 28, 2020 and the Company received net proceeds of $10,590,000 after deducting underwriting discounts, commissions and underwriter expenses associated with the Offering.

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 2,000,000 shares of common stock. No key employee may receive more than 500,000 shares of common stock (or options to purchase more than 500,000 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 3,000,000 shares of common stock. No key employee may receive more than 750,000 shares of common stock (or options to purchase more than 750,000 shares of common stock) in a single year.

During the year ended December 31, 2019, the Board of Directors approved grants of 1,189,500 options to officers and employees of the Company. The exercise price of the options ranges from $2.00 to $4.00 and expire ten-years following issuance. The total fair value of these option grants at issuance was $2,717,445. All of the issued options in 2019 vest in four equal annual installments beginning on the first anniversary following issuance.

During the year ended December 31, 2020, the Board of Directors approved grants of 561,236 options to employees, Scientific Advisory Board members and members of the Board of Directors. The exercise price of the options ranges from $2.06 to $2.47 and expire ten-years following issuance. The total fair value of these option grants at issuance was $1,115,508. 300,000 of the issued options vest in four equal annual installments beginning on the first anniversary following issuance. 261,236 of the issued options vest in one annual installment on the first anniversary of the grant date.

During the years ended December 31, 2020 and 2019, the Company recognized $1,208,154 and $400,834 of stock-based compensation, respectively, related to outstanding stock options. At December 31, 2020, the Company had $2,258,502 of unrecognized expenses related to options.

The following table summarizes the stock option activity for the years ended December 31, 2020 and 2019:

	Options	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2018	675,000	$ 0.91
Granted	1,189,500	2.50
Exercised	–	–
Forfeited	(100,000)	2.00
Expired	–	–
Outstanding, December 31, 2019	1,764,500	$ 1.92
Granted	561,236	2.27
Exercised	–	–
Forfeited	(125,000)	2.20
Expired	–	–
Outstanding, December 31, 2020	2,200,736	$ 2.00

The following table discloses information regarding outstanding and exercisable options at December 31, 2020:

	Outstanding			Exercisable	
Exercise Price	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Option Shares	Weighted Average Exercise Price
$4.00	300,000		8.85	75,000	
$2.47	186,236		9.45	–	
$2.21	175,000		9.20	–	
$2.06	75,000		9.70	–	
$2.00	789,500		8.49	197,375	
$1.50	400,000		7.42	300,020	
$0.045	275,000		6.89	256,250	
Total	2,200,736	$ 2.00	8.32	828,645	$ 1.40

As of December 31, 2020, the aggregate intrinsic value of options vested and outstanding was $528,599. The aggregate fair value of the options measured during the years ended December 31, 2020 and 2019 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31, 2020	Year Ended December 31,2019
Fair value of common stock on measurement date	$2.06 to $2.47 per share	$2.00 to $4.00 per share
Risk free interest rate (1)	0.33% to 0.82%	1.74% to 2.00%
Volatility (2)	122.79% to 128.57%	102.55% to 106.71%
Dividend yield (3)	0%	0%
Expected term (in years)	5.5 - 6.3	10

(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, 2020, there are no awards remaining to be issued under the 2017 Plan and 2,799,264 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, 2020 and 2019:

	Warrants	Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2018	3,674,130	$ 4.08
Granted	312,500	$ 2.87
Exercised	–	–
Forfeited	–	–
Expired	–	–
Outstanding, December 31, 2019	3,986,630	$ 3.99
Granted	2,875,000	$ 2.20
Exercised	–	–
Forfeited	–	–
Expired	–	–
Outstanding, December 31, 2020	6,861,630	$ 3.24

During the years ended December 31, 2020 and 2019, the Company recognized $85,238 and $76,262 of stock-based compensation, respectively, related to outstanding stock warrants. At December 31, 2020, the Company had $0 of unrecognized expenses related to warrants.

The following table discloses information regarding outstanding and exercisable warrants at December 31, 2020:

	Outstanding			Exercisable	
Exercise Price	Number of Warrant Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Warrant Shares	Weighted Average Exercise Price
$11.00	1,206,059		1.64	1,206,059	
$4.00	148,750		3.85	148,750	
$2.20	2,875,000		4.99	2,875,000	
$2.00	63,750		3.43	63,750	
$1.75	100,000		3.29	100,000	
$1.50	14,000		2.45	14,000	
$0.70	2,454,071		3.00	2,454,071	
Total	6,861,630	$ 3.24	3.62	6,861,630	$ 3.24

As of December 31, 2020 the aggregate intrinsic value of warrants vested and outstanding was $2,657,317.

Other

On April 17, 2019, the Company entered into an agreement with a foreign registered broker dealer to assist in fundraising on the Company's behalf. Fees for these services consisted of a cash fee of 10% of amounts raised and an equity fee of 10% of the amounts raised. The equity fee was payable in five-year common stock warrants with an exercise price of $2.00 per share. The Company used the Black-Scholes option valuation model to estimate the fair value of the warrants. As of December 31, 2019, 63,750 warrants with a fair value of $101,206 were issued under this agreement and recorded to additional paid in capital as a cost of capital.

On June 3, 2019, the Company engaged The Benchmark Company, LLC ("Benchmark") to act as exclusive financial advisor related to the Company's NASDAQ Initial Public Offering. Benchmark was compensated a success fee of 7% of the gross offering proceeds, expense allowance of 1% of the gross offering proceeds and warrants equal to 7% of the shares sold with a five-year term and an exercise price equal to the price of the initial public offering. In addition, the Company agreed to reimburse Benchmark for expenses. On November 13, 2019, the Company closed its initial public offering of 2,125,000 shares of its common stock at a price to the public of $4.00 per share. In conjunction with the closing Benchmark was issued 148,750 common stock warrants with a term of five years and an exercise price of $4.00. The warrants become exercisable on May 5, 2020. The Company used the Black-Scholes option valuation model to estimate the fair value of the warrants. As of December 31, 2019, the fair value of the 148,750 warrants issued was $451,722 and recorded to additional paid in capital as a cost of capital.

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. The agreement provides for an initial annual salary of $150,000. The annual salary shall increase at the completion of the Company's initial public offering to an annual salary of $300,000. Pursuant to the employment agreement, the Company and Mr. Climaco agreed to issue Mr. Climaco 900,000 shares of common stock in exchange for $900, which purchase was finalized on September 30, 2017. The common shares may be reacquired by the Company if employment is terminated prior to the initial public offering. After the completion of the initial public offering a portion of the shares may be reacquired by the Company if employment is terminated prior to the expiration of the agreement. Effective March 1, 2019, the employment agreement was amended to increase the annual salary to $186,000 and establish Mr. Climaco as a full-time employee. On June 28, 2019, the compensation committee of the board of directors agreed to modify Mr. Climaco's compensation to increase the annual base salary to $440,000 and Mr. Climaco will be entitled to a cash bonus with a target of 55% of his base salary following the initial public offering. On September 1, 2020, the Company entered into an amendment to the employment agreement with John 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. On February 5, 2021, the compensation committee of the board of directors agreed to modify Mr. Climaco's compensation to increase the annual base salary to $525,000 and granted a ten-year option to purchase 310,000 shares of common stock with an exercise price of $3.36 per share vesting annually in four equal installments.

On June 28, 2019, we entered into employment letters with Drs. Silberman and Picker pursuant to which we agreed to the following compensation terms: (i) Dr. Silberman agreed to commit 50% of her time to our matters in exchange for a base salary, commencing upon the successful closing of the IPO, of $175,000; commencing at the end of 2019, an annual cash bonus target of 28% of her base salary (prorated for any partial years); and a ten-year option to purchase 125,000 shares of common stock with an exercise price of $2.00 per share vesting annually in four equal installments; and (ii) Dr. Picker agreed to commit 25% of his time to our matters in exchange for a base salary, commencing upon the successful closing of the IPO, of $91,000; commencing at the end of 2019, an annual cash bonus target of 36% of his base salary (prorated for any partial years); and a ten-year option to purchase 100,000 shares of common stock with an exercise price of $2.00 per share vesting annually in four equal installments. On February 5, 2021, the compensation committee of the board of directors agreed to modify Drs. Silberman and Picker compensation to increase their annual base salary to $200,000 and $115,000 and granted a ten-year option to purchase 42,000 and 24,000 shares of common stock with an exercise price of $3.36 per share vesting annually in four equal installments, 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. The employment agreement provides for an initial annual base salary of $300,000. Mr. Downs may receive an annual bonus (pro rated for 2019), targeted at 35% of base salary. Under the agreement, upon the closing of the IPO, Mr. Downs was granted a ten-year option to purchase 300,000 shares at an exercise price per share equal to the public offering price per share of the shares sold in the IPO. The option vests in four equal installments on each of the succeeding four anniversary dates of the option grant, provided Mr. Downs is employed by the Company on each such vesting date. On February 5, 2021, the compensation committee of the board of directors agreed to modify Mr. Downs' compensation to increase the annual base salary to $340,000 and granted a ten-year option to purchase 131,000 shares of common stock with an exercise price of $3.36 per share vesting annually in four equal installments.

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 owned by the person who controls a majority of our shares. 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; 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 200,000 shares of the Company's common stock valued at $0.045 per share to HPI upon execution of the agreement. Our rights pursuant to the HPI License are contingent on us raising at least $7.0 million within 12 months from the effective date of the HPI License, a date which was extended by an additional 12 months by the payment of $40,000. On November 13, 2019, the Company closed its IPO and as a result completed the acquisition of the intellectual property discussed in the HPI agreement. As of December 31, 2020 and December 31, 2019, $0 and $45,833 is payable to HPI related to the above agreements, respectively. During the years ended December 31, 2020 and 2019, the Company recognized $237,500 and $0, respectively related to this agreement. Separate from this agreement, the Company entered into a series of transactions with Davos Pharmaceuticals to supply raw starting materials for the production of Berubicin. Davos negotiated to obtain these materials from HPI. Due to the related party relationship with HPI, this agreement was considered and approved by the Audit Committee. Approval was granted based on lowest cost and fastest time to delivery offered by HPI versus other suppliers from whom Davos had obtained quotes. During the years ended December 31, 2020 and 2019, the Company recognized $0 and $385,000, respectively related to these agreements with Davos.

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. 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 and largest shareholder.

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

On January 29, 2019, the Company entered into a consulting agreement with WPD, a related party. The agreement is for a period of one year, with compensation of $5,000 per month. The consulting services include the full-time services of a technical researcher currently employed by WPD. During the year ended December 31, 2019, the Company paid $30,000 to WPD related to the consulting agreement.

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 year ended December 31, 2020, the Company paid $138,018 to UTMDACC related to this agreement.

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. The Company paid and recorded $334,000 in 2020 related to this agreement in research and development expenses in the Company’s Statements of Operations. The remaining $720,000 will be paid in 2021, of which $400,000 was accrued at December 31, 2020. The principal investigator for this agreement is Dr. Waldemar Priebe, who controls a majority of the Company’s share.

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.

Note 6 – Income Taxes

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

	Year Ended December 31, 2020	Year Ended December 31, 2019
Income tax benefit computed at the statutory rate	$ 1,986,000	814,000
Non-deductible expenses	(227,000)	(83,000)
Change in valuation allowance	(1,759,000)	(731,000)
Provision for income taxes	$ –	–

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

	As of December 31, 2020	As of December 31, 2019
Deferred income tax assets		
Net operating losses	$ 2,707,000	$ 948,000
Valuation allowance	(2,707,000)	(948,000)
Net deferred income tax assets	$ –	$ –

The Company has an operating loss carry forward of approximately $12,892,000.

Note 7 – Subsequent Events

Subsequent to December 31, 2020, the Company received $332,750 in cash proceeds from the exercise of 151,250 warrants previously issued at an exercise price of $2.20. In addition, the Company received notices to exercise 1,580,140 warrants on a cashless basis resulting in issuance of 1,293,467 shares of common stock.

Subsequent to December 31, 2020, the Company entered into a transaction with HPI, a related party, to supply starting materials for the manufacturing of Berubicin API valued at $385,000.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Attestation Report of the Registered Public Accounting Firm

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

Management’s Report on Internal Control Over Financial Reporting

Our chief executive officer and our chief financial officer are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Our management concluded that our internal control over financial reporting were, and continue to be ineffective, as of December 31, 2020 due to a lack of segregation of duties and the lack of formal documentation of our control environment.

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

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

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

Changes in Internal Control over Financial Reporting

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

Item 9B. Other Information.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020.

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

Item 11. Executive Compensation

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information regarding our equity compensation plans at December 31, 2020:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities (by class) remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	2,200,736	$ 2.00	2,799,264
Equity compensation plans not approved by security holders (2)	326,500	$ 2.81	–

(1) Represents shares of common stock issuable upon exercise of outstanding stock options and rights under our 2017 and 2020 Stock Plans.
(2) Consists of warrants issued to the underwriter in our IPO and follow-on offering and to consultants.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference to our Proxy Statement for the 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2020.

PART IV

Item 15. Exhibits, Financial Statement Schedules

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

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

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

3. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Amended and Restated Articles of Incorporation of CNS Pharmaceuticals, Inc. (filed as exhibit 2.1 to the Company's Form 1-A file no. 024-10855)
3.2	Amended and Restated Bylaws of CNS Pharmaceuticals, Inc. (filed as exhibit 2.2 to the Company's Form 1-A file no. 024-10855)
4.1	Form of warrant issued to convertible debt holders (filed as exhibit 3.2 to the Company's Form 1-A file no. 024-10855)
4.2	Form of Underwriter Warrant (filed as exhibit 4.4 to the Company's Form 1-A Amendment file no. 024-10855)
10.1	Amended And Restated Patent License Agreement effective as of December 28, 2017 between CNS Pharmaceuticals, Inc. and Houston Pharmaceuticals, Inc. (filed as exhibit 6.1 to the Company's Form 1-A file no. 024-10855)
10.2	Collaboration and Asset Purchase Agreement between CNS Pharmaceuticals, Inc. and Reata Pharmaceuticals, Inc. dated November 21, 2017 (filed as exhibit 6.2 to the Company's Form 1-A file no. 024-10855)
10.3 **	2017 Stock Plan of CNS Pharmaceuticals, Inc. (filed as exhibit 6.3 to the Company's Form 1-A file no. 024-10855)
10.4 **	Employment Agreement between CNS Pharmaceuticals, Inc. and John M. Climaco dated September 1, 2017 (filed as exhibit 6.4 to the Company's Form 1-A file no. 024-10855)
10.5 **	Consulting Agreement between CNS Pharmaceuticals, Inc. and Fresh Notion Financial Services dated July 27, 2017 (filed as exhibit 6.5 to the Company's Form 1-A file no. 024-10855)
10.6	Sublicense Agreement between CNS Pharmaceuticals, Inc. and WPD Pharmaceuticals, Inc. dated August 30, 2018 (filed as exhibit 6.6 to the Company's Form 1-A Amendment file no. 024-10855)
10.7	Sublicense Agreement between CNS Pharmaceuticals, Inc. and Animal Life Sciences, LLC. dated August 31, 2018 (filed as exhibit 6.7 to the Company's Form 1-A Amendment file no. 024-10855)
10.8 **	Employment Letter between CNS Pharmaceuticals, Inc. and Donald Picker (filed as exhibit 10.8 to the Company's Form 1-A Amendment file no. 024-10855)

10.9 **	Employment Letter between CNS Pharmaceuticals, Inc. and Sandra Silberman (filed as exhibit 10.9 to the Company's Form 1-A Amendment file no. 024-10855)
10.10 **	Employment Agreement between CNS Pharmaceuticals, Inc. and Christopher Downs (filed as exhibit 10.10 to the Company's Form 1-A Amendment file no. 024-10855)
10.11 * +	Patent and Technology License 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, dated January 10, 2020
10.12 **	Non-Employee Director Compensation Plan (filed as exhibit 10.12 to the Company's Form 10-K filed March 12, 2020)
10.13	Development Agreement between CNS Pharmaceuticals, Inc. and WPD Pharmaceuticals dated March 20, 2020 (filed as exhibit 10.1 to the Company's Form 8-K filed March 26, 2020)
10.14 **	2020 Stock Plan of CNS Pharmaceuticals, Inc. (filed as exhibit 99.2 to the Company's Form S-8, file no. 333-239998, filed on July 22, 2020
10.15**	Amendment to Employment Agreement between CNS Pharmaceuticals, Inc. and John Climaco dated September 1, 2020 (filed as exhibit 99.1 to the Company's Form 8-K filed September 4, 2020)
10.16	Purchase Agreement, dated as of September 15, 2020, by and between the Company and Lincoln Park Capital Fund, LLC (filed as exhibit 10.1 to the Company's Form 8-K filed September 21, 2020)
10.17	Registration Rights Agreement, dated as of September 15, 2020, by and between the Company and Lincoln Park Capital Fund, LLC (filed as exhibit 10.2 to the Company's Form 8-K filed September 21, 2020)
23.1	Consent of MaloneBailey LLP
31.1 *	Certification of Principal Executive Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
31.2 *	Certification of Principal Financial Officer pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended
32.1 *	Certification of Principal Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2 *	Certification of Principal Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS *	XBRL Instance Document
101.SCH *	XBRL Taxonomy Extension Schema Document
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB *	XBRL Taxonomy Extension Label Linkbase Document
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document

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

Item 16. 10-K Summary

None.

SIGNATURES

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

CNS PHARMACEUTICALS, INC.

Date: February 12, 2021 By: /s/ John Climaco

John Climaco
Chief Executive Officer and Director

(Principal Executive Officer)

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

Date: February 12, 2021 By: /s/ John Climaco

John Climaco
Chief Executive Officer, President and Director

(Principal Executive Officer)

Date: February 12, 2021 /s/ Christopher Downs

Christopher Downs
Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: February 12, 2021 /s/ Jerzy (George) Gumulka

Jerzy (George) Gumulka
Director

Date: February 12, 2021 /s/ Carl Evans

Carl Evans
Director

Date: February 12, 2021 /s/ Jeffry Keyes

Jeffry Keyes
Director

Date: February 12, 2021 /s/ Andrzej Andraczke

Andrzej Andraczke
Director

EXHIBIT 31.1

CERTIFICATION BY OFFICER

I, John Climaco, certify that:

1. I have reviewed this Form 10-K for the year ended December 31, 2020 of CNS Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 12, 2021

By: /s/ John Climaco

John Climaco
Chief Executive Officer and President

EXHIBIT 31.2

CERTIFICATION BY OFFICER

I, Christopher Downs, certify that:

1. I have reviewed this Form 10-K for the year ended December 31, 2020 of CNS Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 12, 2021

By: /s/ Christopher Downs

Christopher Downs
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

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

The Form 10-K for the year ended December 31, 2020 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 12, 2021

By: /s/ John Climaco

John Climaco
Chief Executive Officer and President

EXHIBIT 32.2

CERTIFICATION OF OFFICER

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

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

The Form 10-K for the year ended December 31, 2020 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 12, 2021

By: /s/ Christopher Downs

Christopher Downs
Chief Financial Officer