Table of Contents

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, 2019

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 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 March 11, 2020 was 16,450,234.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of this registrant's definitive proxy statement for its 2020 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.

TABLE OF CONTENTS

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 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 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 ("BBB") 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.

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 obtaining Orphan Drug exclusivity and accelerated approval to be an important part of our development strategy for our drug candidates. Notwithstanding these potential opportunities, and the fact that Reata applied for and was subsequently granted ODD for Berubicin (then known as Reata RTA 744), we can provide no assurance that our drugs will receive Orphan Drug designation or, if approved, exclusivity or any other special designation that could, among other things, provide for accelerated approval.

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 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 February 13, 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 transform the 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 the data relating to the mechanism of action of Berubicin, as well as initial clinical results in the Phase 1 study completed by the prior developer of Berubicin, we are planning a multicenter Phase 2 study that will evaluate the efficacy of Berubicin in subjects who have glioblastoma that has recurred or progressed following prior radiation therapy and TMZ, which are the standards of care for newly diagnosed glioblastoma. Based on data available from the Reata phase I clinical trial (RTA 744-C-0401), we currently plan to propose to FDA that the first trial conducted under the CNS IND will be a phase 2 study at the maximum tolerated dose ("MTD") determined in the Reata phase 1 trial. Thus, subjects 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).

Efficacy will be measured in terms of progression free survival, which is a major endpoint in studies of glioblastoma, using accepted methodology (magnetic resonance imaging ("MRI"), including both pre- and post-gadolinium T1-weighted scans and T2/fluid attenuated inversion recovery ("FLAIR") images), corticosteroid usage, and neurologic status (as measured by neurologic exam and the patient's performance on standardized exams). All of these are considered important in terms of a disease that after failure of primary therapy is almost uniformly fatal.

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 January 31, 2019, our sublicensee, WPD, announced that it will receive funding in the amount 22,033,066 PLN (approximately US $5,798,875) for new drug development as a part of the project "New approach to glioblastoma treatment addressing the critical unmet medical need". This announcement follows the recommendation by the Polish National Center for Research and Development of a list of projects for co-financing 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, which list included WPD's project "New Approach to Glioblastoma Treatment Addressing the Critical Unmet Medical Need," (the "WPD Project") undertaken pursuant to the WPD Sublicense. 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 the 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. 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, one patient achieved a complete response. In such trial, 25 of the 35 patients enrolled were evaluable for response. The patient remained on study through seven cycles of therapy before being withdrawn for elevated liver function tests unrelated to drug study. The patient was under observation from November 2006 through December 2008 and remained disease free as of December 31, 2008. Further, the patient remains disease free and clinically stable as of February 13, 2020.

Study design

Study RTA 744-C-0401 was a Phase I dose-finding and pharmacokinetic study of intravenous Berubicin injection in patients with recurrent or refractory anaplastic astrocytoma, anaplastic oligodendroglioma, anaplastic mixed oligo-astrocytoma, glioblastoma multiforme or gliosarcoma, with or without concurrent treatment with enzyme-inducing anticonvulsant drug therapy.

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 anticonvulsant drugs. 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 in a planned dose escalation Group B (patients on enzyme-inducing anticonvulsant drugs) was not initiated after it was determined that the standard of care had changed and an insufficient number of patients being treated with enzyme-inducing anticonvulsant drugs would make it difficult to accrue the requisite number of patients to this group. The MTD was determined in a stepwise fashion for the remaining two groups of patients: initially, patients who were not taking concurrent enzyme-inducing anticonvulsant drugs were enrolled in “Group A”. Once the MTD was determined in Group A, a new group of patients (Group C) was enrolled into the study to evaluate the tolerability and MTD of Berubicin when administered once a week.

Study Objectives

Primary objectives:

- To determine the MTD and dose limiting toxicity of Berubicin injection in patients with recurrent or refractory primary brain tumors;
- To determine the qualitative and quantitative toxic effects of Berubicin injections;
- To characterize these two primary objectives in: a) patients who were not receiving enzyme-inducing anticonvulsant drugs and received Berubicin administered three times daily every 21 days (Group A); b) patients who were receiving concurrent enzyme-inducing anticonvulsant drugs and received Berubicin administered three times daily every 21 days (Group B); and c) patients who were not receiving enzyme-inducing anticonvulsant drugs and received Berubicin administered once weekly for four weeks repeated every five weeks (Group C).

Secondary objectives:

- To characterize the multiple-dose pharmacokinetics of Berubicin in patients enrolled in the 3 groups described above;
- To document any potential antitumor activity of Berubicin in those patients with measurable disease.
- To correlate pharmacokinetic information with clinical (efficacy and safety) responses.

Study Results

The first patient was enrolled in 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. Of the 54 total patients treated, six new patients (four males and two females) were enrolled onto the study and treated during this report period. One additional male patient remained on treatment during this report period. 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. Time since initial brain tumor diagnosis ranged from four months to 301 months (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 administered 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 drug study. The patient was under observation from November 2006 through December 2008 and remained disease free as of December 31, 2008. Further, the patient remains disease free and clinically stable as of February 13, 2020.

One additional patient (7.5 mg/m2/day) achieved an unconfirmed partial response as best recorded response. An “unconfirmed” partial response means that the patient did not have a second imaging study that again demonstrated the response. The patient had an 80% reduction in tumor volume after two cycles of therapy. At the end of four cycles of therapy, although the initial lesion remained reduced, the patient developed a new lesion on MRI and was assessed as having disease progression. Ten additional patients in Group A had stable disease of 2-to-8 cycles in duration; median 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:

1. complete response
2. partial response
3. stable disease
4. progression

The measurements 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 for the purpose of comparison.

Complete response

- Imaging features
  - Disappearance of all enhancing disease (measurable and non-measurable)
  - Sustained for at least four weeks
  - No new lesions
- Clinical features
  - No corticosteroids

o Clinically stable or improved

Partial response

- Imaging features
  - 50% or more decrease of all measurable enhancing lesions
  - Sustained for at least 4 weeks
  - No new lesions
- Clinical features
  - Stable or reduced corticosteroids
  - Clinically stable or improved

Stable disease

- Imaging features
  - Does not qualify for complete response, partial response or progression
- Clinical features
  - Clinically stable

Progression

- Imaging features
    - 25% of more increase in enhancing lesions
    - Any new lesions
- Clinical features
    - Clinical deterioration

Summary of Adverse Events: The adverse events experienced 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 large number of central nervous system events is consistent with the underlying central nervous system malignant disease in these patients. Myelosupression and Myelotoxicity are expected here and are consistent with the known toxicities of the anthracycline class of medications. Myelosupressive and Myelotoxic events are generally manageable by a competent clinical team.

Based on the data relating to the mechanism of action of Berubicin, as well as initial clinical results in the Phase 1 study completed by the prior developer of Berubicin, we are planning a multicenter Phase 2 study that will evaluate the efficacy of Berubicin in subjects who have glioblastoma that has recurred or progressed following prior radiation therapy and TMZ, which are the standards of care for newly diagnosed glioblastoma. Based on data available from the Reata phase I clinical trial (RTA 744-C-0401), we currently plan to propose to FDA that the first trial conducted under the CNS IND will be a phase 2 study at the maximum tolerated dose determined in the Reata phase 1 trial. Thus, subjects 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). Our choice of clinical trial plan, while not in its final form nor approved by FDA at this date, is largely informed by the prior Reata trial.

Efficacy will be measured in terms of PFS, which is a major endpoint in studies of glioblastoma, using accepted methodology (magnetic resonance imaging, MRI, including both pre- and post-gadolinium T1-weighted scans and T2/fluid attenuated inversion recovery (FLAIR) images), corticosteroid usage, and neurologic status (as measured by neurologic exam and the patient's performance on standardized exams). All of these are considered important in terms of a disease that after failure of primary therapy is almost uniformly fatal.

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.

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 treatment from glioblastoma is surgery, radiation, and chemotherapy with TMZ. While the percentage of patients who survive two years from diagnosis of glioblastoma has more than tripled in the last five years, from 8% to 25%, largely because of the use of temozolomide, five-year, progression free survival remains dismal. There are currently at least 87 different experimental therapies under development in the United States. Thus, 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.

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 includes at least three material patents in the United States and their foreign counterparts throughout the world. The U.S. patents have varying expiration dates and, when these patents expire, we may be subject to increased competition. We have three U.S. patents which expire in March 2020. We intend to apply for orphan drug status with the FDA for the use of Berubicin for the treatment of malignant gliomas, and if we are successful, of which there is no assurance, we may obtain market exclusivity of up to 7 years from the date of approval of a NDA in the United States. During that period FDA generally could not approve another product with the same active pharmaceutical ingredient for the same indication. At the same time, 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 receive orphan drug status or that we will be able to file or receive additional patent protection. The failure to receive such orphan drug status or to obtain additional patent protection will reduce the barrier to entry for competition for Berubicin, which may adversely affect our operations. As of the date of this report, we had not applied for orphan drug status for Berubicin.

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 have the 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 will cease; (ii) HPI will transfer ownership of all development data in its possession to us promptly; and (iii) HPI shall transfer to us any regulatory submissions including any IND, NDA or ANDA related to the patent rights. The payment of the Buy-Out Fee does not relieve 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.

Employees

As of March 11, 2020, 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 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 $7.0 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.

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

We acquired the patent rights to Berubicin pursuant to a license agreement with Houston Pharmaceuticals, Inc., a company affiliated with our largest shareholder. Due to the relationship between our Company and Houston Pharmaceuticals, Inc., the negotiation of the license agreement 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, 2019 the Company has incurred an accumulated deficit of $11,488,472 since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, 2019 is sufficient to fund its planned operations into but not beyond calendar year 2021.

To date, we have devoted most of our financial resources to corporate overhead 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 IND or 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.

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 intend to 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 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 expire in 2020 and the expiration of our patents may subject us to increased competition.

The U.S. patents for Berubicin that we have licensed from HPI have varying expiration dates and, when these patents expire, we may be subject to increased competition. We have three U.S. patents related to Berubicin which expire in March 2020. We intend to apply for orphan drug status with the FDA for the use of Berubicin for the treatment of malignant gliomas, and if we are successful, of which there is no assurance, we may obtain market exclusivity of up to 7 years from the date of approval of a NDA in the United States. During that period FDA generally could not approve another product with the same active pharmaceutical ingredient for the same indication. At the same time, 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 receive orphan drug status or that we will be able to file or receive additional patent protection. The failure to receive such orphan drug status or 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 March 11, 2020, 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, as well as a consultant for Trovagene, Inc. 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. In particular, we do not carry product liability insurance covering any clinical trials liability that we may incur. Although we intend to obtain such insurance before we commence any clinical trials, 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.

We are not subject to Sarbanes-Oxley regulations and lack the financial controls and safeguards required of public companies.

We do not have the internal infrastructure necessary, and are not required, to complete an attestation about our financial controls that would be required under Section 404 of the Sarbanes Oxley Act of 2002. There can be no assurance that there are no significant deficiencies or material weaknesses in the quality of our financial controls. We expect to incur additional expenses and diversion of management's time if and when it becomes necessary to perform the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements.

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

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, major stockholders and their affiliates, are, in the aggregate, approximately 61.2% 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.

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.

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.

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 February 20, 2020, we had approximately 670 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, 2019.

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, 2019.

Use of Proceeds from Registered Offering

On November 13, 2019, we completed the initial public offering, or IPO, of our common stock pursuant to which we issued and sold 2,125,000 shares of our 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. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-232443), which was declared effective by the SEC on November 7, 2019. We received net proceeds of approximately $8.7 million, after deducting underwriting discounts and commissions and offering expenses borne by us. None of the expenses incurred by us were direct or indirect payments to any of (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock, or (iii) our affiliates. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on November 8, 2019 pursuant to Rule 424(b)(4). The Benchmark Company, LLC acted as sole book-running manager for the offering. The offering commenced on November 7, 2019 and did not terminate before all securities registered in the registration statement were sold.

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.

Results of Operations for the Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

General and Administrative Expense

General and administrative expense was $1,978,643 for the year ended December 31, 2019 compared to $860,520 for 2018. The increase in general and administrative expense, was mainly attributable to an increase of approximately $444,000 for stock-based compensation, $104,000 in employee compensation and taxes, $102,000 for investor relations services, $154,000 in recruiting fees, $75,000 in public listing fees and $102,000 related to the write off of previously capitalized deferred issuance cost.

Research and Development Expense

Research and development expense was $1,854,334 for the year ended December 31, 2019 compared to $21,267 for 2018. 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 of $26,152 and $28,615 for the year ended December 31, 2019 and 2018, respectively, included expense accrued on our notes payable and 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, 2019 was $3,877,211 compared to $7,391,899 for 2018. The change in net loss is attributable to a loss on settlement of our convertible debt in the amount of $6,286,841 during the year ended December 31, 2018, representing the fair value of the common stock and warrants issued extinguish convertible notes payable and accrued interest. These changes were offset by increased personnel and activity associated with preparing for our IPO and clinical trials in 2019.

Liquidity and Capital Resources

On December 31, 2019, we had cash of $7,241,288 and we had working capital of $7,582,911. 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. We believe that the proceeds from the IPO and our cash on hand are sufficient to fund our planned operations beyond the near term.

Our plan of operations is primarily focused on using the proceeds from the IPO to complete a Phase II clinical trial for Berubicin. We estimate that we will require additional financing, beyond the proceeds of the IPO, of approximately $7.0 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 $3,553,472 and $716,385 for the years ended December 31, 2019 and 2018 and mainly included payments made for clinical trial preparation, officer compensation, marketing and professional fees to our consultants, attorneys and accountants for services related to completion of our audit and preparation of our public offering filings.

Cash provided by financing activities

Net cash provided by financing activities was $10,259,747 and $1,160,975 for the years ended December 31, 2019 and 2018. We received net proceeds of $10,294,747 from the issuance of common stock during the year ended December 31, 2019.

Since our inception and through December 31, 2019, we have funded our operations through the sale and issuance of common stock and convertible and non-convertible notes payable. During the year ended December 31, 2018, we issued a convertible note to our lender. The note proceeds were $300,000. The note bore interest at 10% per annum and was scheduled to mature on the earlier of 12 to 18 months after issuance or the completion of an initial public offering of our securities. During the year ended December 31, 2018, $86,825 of these convertible notes converted into shares of common stock and common stock warrants.

In March 2018, we commenced an offering pursuant to Regulation CF of the Securities Act pursuant to which we offered units of SAFE securities. The offering ended on June 11, 2018 and we issued $628,558 of SAFE securities. Pursuant to the terms of the SAFE securities, upon completion of our IPO, the purchaser of the SAFE security automatically received a number of shares of our common stock equal to the purchase amount divided by the product of (a) 84% multiplied by (b) the public offering price per share in our IPO.

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.

Off-balance Sheet Arrangements

As of December 31, 2019, 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 Pharmaceutical, Inc. (the "Company") as of December 31, 2019 and 2018 and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018 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.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ MaloneBailey, LLP
www.malonebailey.com
We have served as the Company's auditor since 2019
Houston, Texas
March 12, 2020

CNS Pharmaceuticals, Inc.
Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 7,241,288	$ 282,736
Restricted cash	–	272,397
Prepaid expenses	652,622	33,000
Total current assets	7,893,910	588,133
Fixed Assets		
Furniture and equipment, net	18,165	–
Long-Term Assets:		
Deferred issuance costs	–	95,200
Total Assets	$ 7,912,075	$ 683,333
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 243,666	$ 128,071
Accounts payable and accrued expenses - related party	45,833	794
Accrued expenses	21,500	23,599
Convertible notes payable, net of discount	–	281,918
Notes payable	–	35,000
SAFE agreements	–	763,249
Total current liabilities	310,999	1,232,631
Total Liabilities	310,999	1,232,631
Commitments and contingencies		
Stockholders' Equity (Deficit):		
Preferred stock, $0.001 par value, 5,000,000 shares authorized and 0 shares issued and outstanding	–	–
Common stock, $0.001 par value, 75,000,000 shares authorized and 16,450,234 and 12,694,504 shares issued and outstanding, respectively	16,450	12,695
Additional paid-in capital	19,073,098	7,049,268
Accumulated deficit	(11,488,472)	(7,611,261)
Total Stockholders' Equity (Deficit)	7,601,076	(549,298)
Total Liabilities and Stockholders' Equity (Deficit)	$ 7,912,075	$ 683,333

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Operations

	Year Ended December 31, 2019	Year Ended December 31, 2018
Operating expenses:		
General and administrative	$ 1,978,643	$ 860,520
Research and development	1,854,334	21,267
Total operating expenses	3,832,977	881,787
Loss from operations	(3,832,977)	(881,787)
Other expense:		
Loss on settlement of liabilities	–	(6,286,841)
Loss on change in fair value of SAFE agreements	–	(122,120)
SAFE agreement expenses	–	(54,454)
Interest expense	(26,152)	(28,615)
Amortization of debt discount	(18,082)	(18,082)
Total other expense	(44,234)	(6,510,112)
Net loss	$ (3,877,211)	$ (7,391,899)
Loss per share - basic and diluted	$ (0.28)	$ (0.70)
Weighted average shares outstanding - basic and diluted	13,647,908	10,510,551

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Stockholders' Equity (Deficit)
For the years ended December 31, 2019 and 2018

	Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Paid-in Capital	Deficit	Equity (Deficit)
Balance, December 31, 2017	10,270,667	$ 10,271	$ 150,559	$ (219,362)	$ (58,532)
Common stock issued for cash	260,337	260	390,240	–	390,500
Common stock issued for services	5,000	5	7,495	–	7,500
Stock-based compensation	–	–	102,740	–	102,740
Placement agent warrants issued with convertible notes	–	–	15,163	–	15,163
Common stock and warrants issued for extinguishment of convertible notes payable and accrued interest	2,158,500	2,159	6,383,071	–	6,385,230
Net loss	–	–	–	(7,391,899)	(7,391,899)
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

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Cash Flows

	December 31, 2019	December 31, 2018
Cash Flows from Operating Activities:		
Net loss	$ (3,877,211)	$ (7,391,899)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	477,096	110,240
Common stock issued for services	150,000	–
Amortization of debt discount	18,082	18,082
Deferred financing cost	102,225	–
Depreciation	1,955	–
Loss on change in fair value of SAFE agreements	–	122,120
SAFE agreement expenses	–	54,454
Loss on settlement of convertible notes payable	–	6,286,841
Changes in operating assets and liabilities:		
Prepaid expenses	(619,622)	18,651
Accounts payable	108,570	85,574
Accounts payable-related party	45,039	(14,206)
Accrued expenses	40,394	(6,242)
Net cash used in operating activities	(3,553,472)	(716,385)
Cash Flows from Investing Activities:		
Purchase of furniture and equipment	(20,120)	–
Net cash used in investing activities	(20,120)	–
Cash Flows from Financing Activities:		
Proceeds from convertible notes payable	–	300,000
Payment of placement agent fee	–	(21,000)
Payments of deferred issuance costs	–	(95,200)
Payments on notes payable	(35,000)	–
Proceeds from SAFE agreements	–	586,675
Proceeds from sale of common stock	10,294,747	390,500
Net cash provided by financing activities	10,259,747	1,160,975
Net change in cash, cash equivalents and restricted cash	6,686,155	444,590
Cash, cash equivalents and restricted cash, at beginning of period	555,133	110,543
Cash, cash equivalents and restricted cash, at end of period	$ 7,241,288	$ 555,133
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 3,993	$ –
Cash paid for income taxes	$ –	$ –
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of SAFE agreements	$ 763,249	$ –
Common stock and warrants issued for extinguishment of convertible notes payable and accrued interest	$ 342,493	$ 98,389
Placement agent warrants issued with convertible notes payable	$ –	$ 15,163

See accompanying notes to the financial statements.

Note 1 – Nature of Business

CNS Pharmaceuticals, Inc. 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 - 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. On November 13, 2019, the Company closed its initial public offering ("IPO") of 2,125,000 shares of its 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. The completion of the IPO resolved the previously disclosed substantial doubt regarding the Company's ability to continue as a going concern. The Company has a history of and expects to continue to report negative cash flows from operations and a net loss. However, management believes that the cash on hand is sufficient to fund its planned operations beyond the near term.

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, 2019 was $6,991,288.

Restricted Cash - The following table provides a reconciliation of cash, cash and cash equivalents and restricted cash reported within the balance sheet that sum to the total of the same such amounts shown in the statements of cash flows. The Company's restricted cash is discussed below in Note 4.

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 7,241,288	$ 282,736
Restricted cash	–	272,397
Total	$ 7,241,288	$ 555,133

Property and Equipment - Property and equipment will be 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 years
Machinery and equipment	5 years
Furniture and office equipment	7 years

Repairs and maintenance costs are expensed as incurred.

Long-lived Asset - 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.

Beneficial Conversion Feature - From time to time, the Company has issued convertible notes that have conversion prices that create an embedded beneficial conversion feature on the issuance date. A beneficial conversion feature exists on the date a convertible note is issued when the fair value of the underlying common stock to which the note is convertible into is in excess of the remaining unallocated proceeds of the note after first considering the allocation of a portion of the note proceeds to the fair value of any attached equity instruments, if any related equity instruments were granted with the debt. The Company estimated the fair value of its common stock on the dates issued. The intrinsic value of the beneficial conversion feature is recorded as a debt discount with a corresponding amount to additional paid-in capital, if any. The debt discount is amortized to interest expense over the life of the note using the effective interest method.

Fair Value of Financial Instruments - The carrying value of short-term instruments, including cash and cash equivalents, restricted cash, 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, 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. As of December 31, 2018, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included notes convertible to 200,000 common shares, warrants to purchase 3,674,130 common shares, and options for 675,000 common shares.

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), which will replace numerous requirements in U.S. GAAP, including industry-specific requirements, and provide companies with a single revenue recognition model for recognizing revenue from contracts with customers. The core principle of the new standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB approved a proposal to defer the effective date of the guidance until annual and interim reporting periods beginning after December 15, 2017. The Company adopted this standard as of January 1, 2018. The adoption of this standard did not have an impact on the Company's financial statements as the Company has generated no revenue to date.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities. ASU 2016-01 affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. ASU 2016-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted this standard as of January 1, 2018. The adoption of this standard did not have a significant impact on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under ASU 2016-02, an entity will be required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. For public companies, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company adopted this standard as of January 1, 2019. The adoption of this standard did not have an impact on the Company's financial statements due to the lack of lease agreements for the Company at this time. The Company elected the short-term lease recognition exemption for its leases. For those leases with a lease term of 12 months or less, the Company will not recognize ROU assets or lease liabilities.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230). This ASU applies to all entities that are required to present a statement of cash flows under Topic 230. The amendments provide guidance on eight specific cash flow issues and includes clarification on how these items should be classified in the statement of cash flows and is designed to help eliminate diversity in practice as to where items are classified in the cash flow statement. Furthermore, in November 2016, the FASB issued additional guidance on this Topic that requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with earlier application permitted for all entities. The Company adopted this standard as of January 1, 2018. The adoption of this standard did not have a significant impact on the Company's financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718) - Improvements to Nonemployee Share-Based Payment Accounting, which aligns the accounting for share-based payment awards issued to employees and nonemployees. Under ASU No. 2018-07, the existing employee guidance will apply to nonemployee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attribution of compensation cost. The cost of nonemployee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for nonemployee awards. The Company adopted this guidance on January 1, 2019 with no impact to its consolidated 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 –Notes Payable

Convertible Notes Payable

On June 14, 2018, the Company entered into an agreement to issue a 10% convertible note in an aggregate of $300,000 in principal amount of convertible notes, which principal and accrued interest automatically converted into shares of common stock upon the closing of the Company's IPO at a conversion rate of $1.50 per share. In conjunction with this convertible note payable a placement fee of 14,000 warrants were issued. The warrants have a 5-year life and an exercise price of $1.50. These warrants were recorded for $15,163 as a debt discount. In addition, $21,000 of placement agent fees were paid related to this note which was also recorded as a debt discount. As of December 31, 2019, the debt discount was fully amortized. On November 13, 2019, upon the closing of the IPO, the 10% convertible note of $300,000 in principal plus accrued interest of $42,493 automatically converted into 228,329 shares of common stock at a conversion rate of $1.50 per share.

On December 31, 2018, the Company amended the convertible notes it issued in 2017 to allow the notes to be converted prior to the Company's IPO at the holders' option. Certain debtholders then exercised their right to convert the outstanding principal and accrued interest of their outstanding notes on December 31, 2018. A total of $38,670 of outstanding principal and $3,128 of accrued interest was converted into 2,158,500 shares of common stock. Additionally, certain note holders entered into settlement agreements to extinguish their remaining principal balance of $48,155 and remaining accrued interest of $8,434 in exchange for 2,454,071 warrants to purchase common stock at an exercise price of $0.70 per share for a term of five years. The December 31, 2018 amendment, conversion and settlement was accounted for as an extinguishment of debt and a loss on extinguishment of $6,286,841 was recognized.

Notes Payable

During 2017, the Company issued two notes payable for total cash proceeds of $35,000. The notes bear interest at the rate of 10% per year and originally matured on January 31, 2018. Prior to maturity, the notes were extended through September 30, 2018, and again extended through December 31, 2018. The notes and accrued interest were paid in full in January 2019.

Note 4 – SAFE Agreements

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.

In accordance with the SAFE agreements, 50% of the funds raised, net of all fees associated with the use of a campaign platform were held in an escrow account to be released to the Company upon successfully acquiring the patent rights from HPI and upon the Company's spending on Phase 2 clinical trials of an amount equal to at least half of the escrow funds prior to December 28, 2019.

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.

Note 5 – Equity

In October 2018 the Company amended the articles of incorporation to increase the 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 January 12, 2018, the Company issued 5,000 shares of common stock valued at $7,500 to a consultant for services.

On April 10, 2018, the Company engaged Boustead Securities, LLC ("Boustead") to act as exclusive financial advisor related to the Company's IPO. The agreement expired in April 2019 prior to the Company completing its IPO. Upon expiration of the agreement, $102,225 of underwriting fees previously capitalized as deferred issuance costs were expensed. In addition, an entity related to Boustead was a holder of the Company's outstanding convertible debt. On November 13, 2019, upon the closing of the IPO, the 10% convertible note of $300,000 in principal plus accrued interest of $42,493 automatically converted into 228,329 shares of common stock at a conversion rate of $1.50 per share.

During the year ended December 31, 2018, the Company issued 260,337 shares of common stock for cash proceeds of $390,500.

On December 31, 2018, the Company issued 2,158,500 shares of common stock upon conversion of debt and accrued interest. See Note 3.

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.

Stock Options

In 2017, the Board of Directors of the Company approved the CNS Pharmaceuticals, Inc. 2017 Stock Plan (the "Plan"). The Plan allows for the Board of Directors to grants 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.

On February 19, 2018, the Company issued non-qualified stock options to a new member of our Scientific Advisory Committee. The options cover 100,000 shares, have an original life of ten years and vest in four equal installments on each of the succeeding four anniversary dates. The exercise price is $1.50 for these options. The fair value of the options was $138,017 on the grant date.

On June 25, 2018, the Company issued non-qualified stock options to a new member of the board of directors. The options cover 100,000 shares, have an original life of ten years and vest over 36 months. The options had a fair value of $138,016 at grant date. The exercise price per share is $1.50 for these shares.

On July 9, 2018, the Company issued non-qualified stock options to two new members of the board of directors. The options cover 200,000 shares, have an original life of ten years and vest over 36 months. The options had a fair value of $276,024 at grant date. The exercise price per share is $1.50 for these shares.

On June 28, 2019, the Board of Directors approved a grant 889,500 to officers and employees of the Company. The options vest in four equal annual instalments beginning on the first anniversary following issuance. The options have a ten-year term and have an exercise price of $2.00 per share. The fair value of the options at issuance was $1,631,737.

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. 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. The fair value of the options at issuance was $1,085,708.

During the years ended December 31, 2019 and 2018, the Company recognized $400,834 and $102,740 of stock-based compensation, respectively, related to outstanding stock options. At December 31, 2019, the Company had $2,753,499 of unrecognized expenses related to options.

The following table summarizes the stock option activity for the years ended December 31, 2019 and 2018:

	Options		Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2017	275,000	$	0.045
Granted	400,000		1.5
Exercised	–		–
Forfeited	–		–
Expired	–		–
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

The following table discloses information regarding outstanding and exercisable options at December 31, 2019:

	Outstanding			Exercisable	
Exercise Price	Number of Option/Warrant Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Option Shares	Weighted Average Exercise Price
$4.00	300,000		9.86	–	
$2.00	789,500		9.50	–	
$1.50	400,000		8.42	175,012	
$0.045	275,000		7.89	181,956	
Total	1,764,500	$1.92	9.06	356,968	$0.76

As of December 31, 2019, the aggregate intrinsic value of options vested and outstanding was $1,139,318. The aggregate fair value of the options measured during the years ended December 31, 2019 and 2018 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	Year Ended December 31, 2019	Year Ended December 31,2018
Fair value of common stock on measurement date	$2.00 to $4.00 per share	$1.50 per share
Risk free interest rate (1)	1.74% to 2.00%	2.5% to 2.88%
Volatility (2)	102.55% to 106.71%	106.4% to 106.9%
Dividend yield (3)	0%	0%
Expected term (in years)	10	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, 2019, there are 235,500 awards remaining to be issued under the Plan.

Stock Warrants

The following table summarizes the stock warrant activity for the year ended December 31, 2019:

	Warrants		Weighted-Average Exercise Price Per Share
Outstanding, December 31, 2017	1,206,059	$	11.00
Granted	2,468,071		0.70
Exercised	–		–
Forfeited	–		–
Expired	–		–
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

In April 2019, the Company entered into two consulting agreements with consultants to provide services and advice related to company operations, investor relations, marketing, corporate structure, financing and public markets. The initial term of the agreement is eighteen months. As consideration for entering into this agreement the Company issued to each consultant 50,000 common stock warrants with a term of five years and an exercise price of $1.75. The warrants vest over an eighteen-month period in equal monthly installments provided that the consultant is providing services on each vesting date. In addition, each consultant will earn $5,000 per month for these services. Payment of the cash portion of the fee were accrued until the Company completed its IPO on November 13, 2019. During the year ended 2019, the Company paid $80,000 related to the two consulting agreements.

The common stock warrants were valued at $161,500 and were recognized over the 18-month vesting term. During the year ended December 31, 2019, $76,262 has been recognized as an expense. At December 31, 2019, the Company had $85,238 of unrecognized expenses related to options.

The following table discloses information regarding outstanding and exercisable warrants at December 31, 2019:

	Outstanding			Exercisable	
Exercise Price	Number of Option/Warrant Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Option Shares	Weighted Average Exercise Price
$11.00	1,206,059		2.64	1,206,059	
$2.00	63,750		4.43	63,750	
$4.00	148,750		4.86	–	
$1.75	100,000		4.29	44,448	
$1.50	14,000		3.45	14,000	
$0.70	2,454,071		4.00	2,454,071	
Total	3,986,630	$3.99	3.63	3,782,328	$4.02

As of December 31, 2019, the aggregate intrinsic value of warrants vested and outstanding was $8,232,129.

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 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, 2019	Year Ended December 31, 2018
Income tax benefit computed at the statutory rate	$ 814,200	1,552,300
Non-deductible expenses	(83,400)	(1,369,000)
Change in valuation allowance	(730,800)	(183,300)
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, 2019	As of December 31, 2018
Deferred income tax assets		
Net operating losses	$ 947,600	$ 216,800
Valuation allowance	(947,600)	(216,800)
Net deferred income tax assets	$ –	$ –

The Company has an operating loss carry forward of approximately $4,512,000, which expires commencing in 2037.

Note 7 – Commitments and Contingencies

Employment and Consulting 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 July 27, 2017, the Company entered into a consulting agreement with a company owned by Mr. Matthew Lourie pursuant to which Mr. Lourie agreed to serve as Chief Financial Officer of the Company on a part time basis commencing on such date for an initial term of one year, which will be automatically renewed for additional one-year terms unless either party chooses to cancel the agreement with 30 days-notice. The agreement provides for a monthly compensation of $5,000 and a one-time right to purchase 15,000 shares of common stock at $0.001 per share. The common shares may be reacquired by the Company if the agreement is terminated by Mr. Lourie 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 the agreement is terminated by Mr. Lourie prior to two years after the initial public offering. The board agreed to waive the reacquisition right on these shares. On November 13, 2019, upon the closing of the IPO, Mr. Lourie resigned as Chief Financial Officer but continued to provide consulting services based on an hourly rate.

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.

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. Unrelated to this agreement the Company purchased $385,000 of pharmaceutical products from HPI for use in their clinical trials. As of December 31, 2019, $45,833 is payable to HPI related to the above agreements.

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.

Note 8 – Subsequent Events

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.

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, 2019. 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, 2019 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.

On March 12, 2020, our board of directors approved the following policy for compensating our independent members of the board:

- Each independent director shall receive annual cash compensation of $35,000. In addition, the chair person of the Audit Committee, Compensation Committee and Nominating and Governance Committee shall receive an annual compensation of $10,000, $7,000 and $5,000, respectively; the other members of such committees shall receive an annual compensation of $5,000, $3,500 and $3,000, respectively; and the lead independent director shall receive annual compensation of $10,000. In addition, we agreed to pay a one-time make-whole payment to the independent directors as follows: (i) Jeff Keyes - $6,554.79; (ii) Jerzy (George) Gumulka - $3,972.60; (iii) Carl Evans - $3,972.60; and (iv) Andrzej Andraczke - $3,376.71.

On March 12, 2020, our board of directors appointed Mr. Keyes to serve as its lead independent director, a newly created position.

On March 12, 2020, our compensation committee approved the following cash bonus payments to its executive officers: John Climaco, Chief Executive Officer - $193,600; Christopher Downs, Chief Financial Officer - $25,000; Donald Picker, Chief Scientific Officer - $20,100; and Sandra Silberman, Chief Medical Officer - $20,083.

In addition, the compensation committee determined that the compensation arrangements with its executive officers for the 2020 compensation year related to base salary and bonus targets as a percentage of base salary shall remain the same as 2019.

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 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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
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: March 12, 2020 By: /s/ John Climaco

John Climaco
Chief Executive Officer and Director

(Principal Executive Officer)

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

Date: March 12, 2020 By: /s/ John Climaco

John Climaco
Chief Executive Officer, President and Director

(Principal Executive Officer)

Date: March 12, 2020 /s/ Christopher Downs

Christopher Downs
Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: March 12, 2020 /s/ Jerzy (George) Gumulka

Jerzy (George) Gumulka
Director

Date: March 12, 2020 /s/ Carl Evans

Carl Evans
Director

Date: March 12, 2020 /s/ Jeffry Keyes

Jeffry Keyes
Director

Date: March 12, 2020 /s/ Andrzej Andraczke

Andrzej Andraczke
Director

Exhibit 10.11

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. THE REDACTED TERMS HAVE BEEN MARKED WITH THREE ASTERISKS [***]

Patent and Technology License Agreement

This Patent and Technology License Agreement ("Agreement") is made on this 10th day of January, 2020, by and between The Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, on behalf of The University of Texas M. D. Anderson Cancer Center ("UTMDACC"), a member institution of System, and CNS Pharmaceuticals, Inc., a Nevada corporation having a principal place of business located at 2100 West Loop South, Suite 900, Houston, Texas 77027 ("Licensee").

Recitals

A. Board owns Licensed Subject Matter (defined below).

B. Board, through UTMDACC, has determined that development and commercialization of the Licensed Subject Matter is in the public's best interest and is consistent with Board's educational and research missions and goals.

C. Board desires to have the Licensed Subject Matter developed and commercialized for the benefit of Licensee, the inventors, Board, System, UTMDACC, and the public.

D. Licensee desires to secure a license to practice the Licensed Subject Matter.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the parties agree as follows:

I. Effective Date

1.1 This Agreement is effective as of the date written above ("Effective Date").

II. Definitions

As used in this Agreement, the following terms have the meanings indicated:

2.1 **Affiliate** means, as to any person or other entity, any other person or entity that, directly or through one or more intermediaries, is in control of, is controlled by, or is under common control with, such person or entity. For purposes of this definition, "control" of a person or entity means the power, directly or indirectly, to (i) vote twenty five percent (25%) or more of the equity interests having ordinary voting power for the election of directors (or persons performing similar functions) of such person or entity, or (ii) direct or cause the direction of the management and policies of such person or entity, whether by contract or otherwise. As to any natural person, members of such person's family, including such person's spouse, parent, siblings, descendants (including adoptive relationships and stepchildren), and the spouses of each such natural person shall be deemed an Affiliate.

2.2 **Corporate Expenses** means, without prejudice to Section 4.6, all reasonable out-of-pocket costs and expenses, including, without limitation, fees of outside legal counsel, incurred by MD Anderson in connection with (i) evaluating documents or information provided pursuant to Section 4.5 or (ii) seeking counsel with regard to elections under Section 4.6.

2.3 **FDA** means the United States Food and Drug Administration.

2.4 **Investigational New Drug Application (IND)** means (a) the submission made to the FDA to receive approval to conduct a clinical investigation with an investigational new drug that is subject to 21 C.F.R. § 312 or any future revisions or substitutes thereof; or (b) a similar submission to the applicable regulatory agency in any national jurisdiction other than the United States.

2.5 **Licensed Field** means all field of use.

2.6 **Licensed Product(s)** means any material, composition, product or service comprising, using, or made using any portion of Licensed Subject Matter.

2.7 **Licensed Subject Matter** means (a) Patent Rights, (b) Technology Rights, and/or (c) inventions and/or discoveries covered by Patent Rights and/or Technology Rights.

2.8 **Licensed Territory** means worldwide.

2.9 **NDA** means: (a) the submission made to the FDA to receive Regulatory Approval, as more fully defined by 21 C.F.R. § or any future revisions or substitutes thereof; or (b) a similar submission to the equivalent applicable regulatory agency in any national jurisdiction other than the United States.

2.10 **Net Sales** means the gross revenues received by Licensee or, where applicable, its Sublicensees from a Sale less sales discounts actually granted (including, without limitation, where such discounts are granted on Licensed Products sold to managed care entities or pharmaceutical benefit management service entities), sales and/or use taxes actually paid, import and/or export duties actually paid, outbound transportation actually prepaid or allowed, and amounts actually allowed or credited due to returns (not exceeding the original billing or invoice amount), all as recorded by Licensee or its Sublicensees in their official books and records in accordance with accounting principles generally accepted in the United States.

2.11 **Patent Expenses** means reasonable and documented out-of-pocket expenses incurred by UTMDACC in preparing (including conducting prior art searches, if any), filing, prosecuting (including post-grant proceedings), defending, enforcing and maintaining patent applications and patents under Patent Rights in the Licensed Territory.

2.12 **Patent Rights** means Board's rights in:

(a) the patents and patent applications listed in Exhibit I to this Agreement;

(b) all non-provisional patent applications that claim priority to any of the provisional applications listed in Exhibit I, provided that the claims of such non-provisional applications are entitled to claim priority to such provisional applications;

(c) all divisionals, continuations and continuations-in-part of the non-provisional patent applications identified in (a) and (b), above, provided that the claims of such continuations-in-part are entitled to claim priority to at least one of the patent applications identified in (a) or (b), above;

(d) all reissues, reexaminations, extensions, and foreign counterparts of any of the patents or patent applications identified in (a), (b) or (c), above; and

(e) any patents that issue with respect to any of the patent applications listed in (a), (b), (c) or (d), above.

2.13 **Phase I Study** means: (a) that portion of the FDA submission and approval process which provides for the first introduction into humans of a product with the purpose of determining human toxicity, metabolism, absorption, elimination and other pharmacological action as more specifically defined in 21 C.F.R. § 312.21(a) or any future revisions or substitutes thereof; or (b) a similar clinical study in any national jurisdiction other than the United States.

2.14 **Phase II Study** means: (a) that portion of the FDA submission and approval process which provides for early controlled clinical studies conducted to obtain preliminary data on the effectiveness of a product for a particular indication, as more specifically defined by the rules and regulations of the FDA, including 21 C.F.R. § 312.21(b) or any future revisions or substitutes thereof; or (b) a similar clinical study in any national jurisdiction other than the United States.

2.15 **Phase III Study** means: (a) that portion of the FDA submission and approval process in which expanded clinical studies are conducted to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of a product, as more specifically defined by the rules and regulations of the FDA, including 21 C.F.R. § 312.21(c) or any future revisions or substitutes thereof; or (b) a similar clinical study in any national jurisdiction other than the United States.

2.16 **Regulatory Approval** means the approval by a Regulatory Authority that is needed in a particular jurisdiction to market or Sell a Licensed Product in that jurisdiction.

2.17 **Regulatory Authority** means the governmental authority responsible for granting any necessary licenses or approvals for the marketing, Sale or use of a Licensed Product in a particular jurisdiction, including without limitation, the FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare).

2.18 **Royalty-Free Practitioner** means UTMDACC and the following individuals: Wei Guo, M.D. and Charles Conrad, M.D. ("Physician Inventor(s)") and any partner or associate who practices medicine with the Physician Inventors, but with respect to such partner or associate, only for such time as he/she is engaged in a bone fide medical practice with the Physician Inventors.

2.19 **Sale(s), Sell(s), or Sold** means the transfer or disposition of a Licensed Product, for value, to a person or entity other than Licensee, a Sublicensee, or a Royalty-Free Practitioner; provided, however, a transfer or disposition of a Licensed Product for value between or among Licensee and/or any Sublicensees where Licensee or any such Sublicensee acquires such Licensed Product for end use shall be included in the definition of Sale(s), Sell(s), or Sold. For clarity, transfer of a Licensed Product to a third party shall not be included within the definition of Sale(s), Sell(s), or Sold under this Agreement if (i) the Licensed Product was transferred at no charge to the third party, including such transfers for promotional purposes, or (ii) the Licensed Product was obtained by the third party for the limited purpose of evaluating the product for further development and not for resale or redistribution.

2.20 **Sponsored Research Agreement** means the sponsored research agreement by and between UTMDACC and CNS Pharmaceuticals, Inc., whereby Waldemar Priebe, Ph.D. as the principal investigator will be conducting research on the design and development of small molecule drugs with high CNS uptake.

2.21 **Sublicense Agreement** means any written agreement pursuant to which Licensee (or a Sublicensee) grants to any third party any of the license rights granted to Licensee under this Agreement, including, but not limited to, the right to manufacture, have manufactured, use, import, offer to sell and/or sell Licensed Products within the Licensed Territory for use within the Licensed Field.

2.22 **Sublicensee** means any person or entity, other than Licensee, that is a named party to a Sublicense Agreement as a grantee of any license rights.

2.23 **Sublicensing Consideration** means any and all consideration (e.g., cash and non-cash consideration, such as securities) received by Licensee from any Sublicensee pursuant to Section 3.2 hereof, including, without limitation, (i) up-front payments, (ii) marketing, distribution, franchise, option, license, or documentation fees, (iii) bonus and milestone payments, (iv) equity securities of such Sublicensee, and (v) amounts received by Licensee for Licensee's equity or other securities in excess of fair market value of such equity or other securities; provided, however, Sublicensing Consideration shall not include: (A) amounts received as running royalties for which UTMDACC receives a running royalty under Section 4.1; (B) reimbursement amounts for patent expenses directly related to Patent Rights, provided that the applicable Sublicense Agreement expressly states such reimbursement amounts shall be for such patent expenses; or (C) funds paid by a Sublicensee for future research that is directly related to the Licensed Subject Matter and to be performed by Licensee or its contractors, including reasonable overhead or indirect expenses (provided, however, such overhead or indirect fees shall not be in excess of the overhead or indirect fees charged by UTMDACC for any federally funded research), if (x) the respective Sublicense Agreement expressly states that such funds are for research to be performed by Licensee after the actual date of signatory execution of the Sublicense Agreement and (y) Licensee does in fact perform such research after execution of, and in accordance with, the Sublicense Agreement. For the avoidance of doubt, Licensee shall not deduct from Sublicensing Consideration any of the following:

(1) any amounts received from a Sublicensee as reimbursement or recoupment of research expenses incurred by Licensee before the actual date of signatory execution of the Sublicense Agreement; or

(2) any payments by a Sublicensee for Licensee's achievement of research or similar milestone events.

2.24 **Technology Rights** means Board's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, designs, drawings or data created at UTMDACC before the Effective Date by the inventor(s) listed in Exhibit A while employed at UTMDACC and within the Licensed Field which:

(a) are not covered by Patent Rights;

(b) facilitate and relate solely to the practice, development, manufacture, use, and/or selling of invention(s) claimed in the patents and/or patent applications listed in the definition of Patent Rights; and

(c) have no obligations or encumbrances in favor of or benefitting any third party and are not otherwise subject to contractual or legal restrictions that would preclude an exclusive license to Licensee under this Agreement.

2.25 **Valid Claim** means a claim of (a) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other governmental body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or finally determined by the relevant governmental authority to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (b) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

III. License

3.1 Subject to Sections 6.1, 13.2 and 13.3 below and the timely payment by Licensee to UTMDACC of all consideration as provided herein, Board, through UTMDACC, hereby grants to Licensee:

(a) a royalty-bearing, sublicensable to the extent set forth in Section 3.2 below, exclusive license under Patent Rights to (i) manufacture, have manufactured, use, import, offer to sell and/or sell Licensed Products within Licensed Territory for use within Licensed Field;

(b) a royalty-bearing, sublicensable to the extent set forth in Section 3.2 below, non-exclusive license under Technology Rights to (i) manufacture, have manufactured, use, import, offer to sell and/or sell Licensed Products within Licensed Territory for use within Licensed Field. UTMDACC agrees that its Office of Technology Commercialization (OTC) will not knowingly grant a license under Technology Rights to any third party and will promptly notify Licensee of any license grant under Technology Rights to any third party by UTMDACC of which it becomes aware;

(c) The license grant under (a) above is further subject to the following rights retained by Board and UTMDACC to:

(1) Publish the general scientific findings from research related to Licensed Subject Matter, subject to the terms of Article X–Confidential Information and Publication; and
(2) Use Licensed Subject Matter for patient care, research, teaching, and other academically-related purposes; and
(3) Transfer Licensed Subject Matter to academic or research institutions solely for non-commercial research use.

The parties hereby acknowledge and agree that any exercise by Licensee (or a Sublicensee) of the license grant set forth in this Section 3.1 beyond the scope agreed to under this Agreement shall be deemed a material breach of this Agreement.

3.2 Licensee may enter into a Sublicense Agreement, subject to the following:

(a) The Sublicense Agreement cannot exceed the scope and rights granted to Licensee hereunder. Sublicensee must agree in writing to be bound by terms and conditions consistent with this Agreement and shall agree that Board and UTMDACC are third party beneficiaries of the Sublicense Agreement. In the event of termination of this Agreement, continued sublicense rights shall be governed by Section 3.3 below. Licensee may grant a Sublicensee the right to grant further sub-Sublicense Agreements consistent with this Agreement, in which case such sub-Sublicense Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of this Agreement;

(b) Licensee must deliver to UTMDACC a complete and accurate copy of each Sublicense Agreement granted by Licensee or a Sublicensee, and any modification or termination thereof, within thirty (30) days following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide UTMDACC an accurate English translation in addition to a copy of the original agreement. If UTMDACC has any concerns with such Sublicense Agreement, Licensee will use commercially reasonable efforts to work with UTMDACC and any such Sublicensee to address such concerns; and

(c) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Board and UTMDACC for all of Licensee's duties and obligations contained in this Agreement, including without limitation the payment of running royalties due under Section 4.1 whether or not paid to Licensee by a Sublicensee. Each Sublicense Agreement will contain a right of termination by Licensee in the event that the Sublicensee breaches and fails to timely cure (i) the payment or reporting obligations affecting Board and/or UTMDACC or (ii) any other terms and conditions of the Sublicense Agreement that would constitute a breach of this Agreement if such acts were performed by Licensee; provided that, in the event that a Sublicensee is an Affiliate, such Sublicense Agreement will contain a termination right by UTMDACC if such Affiliate Sublicensee breaches and fails to timely cure the payment or reporting obligations affecting Board and/or UTMDACC.

3.3 If this Agreement is terminated, all existing Sublicense Agreements between Licensee and a Sublicensee shall be assigned to UTMDACC upon termination; provided, however, if UTMDACC cannot reasonably meet all of Licensee's obligations, or extend all rights extended to a Sublicensee, under any such Sublicense Agreement, UTMDACC shall have the right to terminate such Sublicense Agreement, but UTMDACC agrees to negotiate in good faith with each then-existing Sublicensee that: (i) is then in good standing under the respective Sublicense Agreement as of the date of termination of this Agreement, and (ii) provides UTMDACC with written notice within thirty (30) calendar days after termination of this Agreement, where such notice states that such Sublicensee desires to enter into negotiations for an agreement with UTMDACC granting rights under Patent Rights and Technology Rights. UTMDACC shall negotiate in good faith in accordance with this Section 3.3.

IV. Consideration, Payments and Reports

4.1 In consideration of rights granted by Board to Licensee under this Agreement, Licensee agrees to pay UTMDACC each of the following:

(a) Patent Expenses. All Patent Expenses incurred by or for UTMDACC before or after the Effective Date for so long as this Agreement remains in effect; provided, however, that, in the event of termination by Licensee in accordance with Section XII, Licensee shall only be obligated to pay or reimburse such Patent Expenses incurred prior to the date notification of such termination is received by UTMDACC. UTMDACC will invoice Licensee after the Agreement has been fully executed by all parties for Patent Expenses incurred as of the Effective Date, unless agreed otherwise by Licensee, and on a quarterly basis thereafter. All undisputed portions of the invoiced amounts will be due and payable by Licensee within sixty (60) calendar days of the date of the invoice. At the election of UTMDACC, Licensee will either pay prosecution counsel directly for Patent Expenses or will reimburse UTMDACC for such Patent Expenses. Patent Expense payment delinquencies (whether owed directly to prosecution counsel or to UTMDACC) will be considered a payment default under Section 12.3(b).

(b) Upfront Licensee Fee. A nonrefundable upfront license fee in the amount of $[***], as follows:

(i) $[***] shall be due and payable (without invoice) within forty-five (45) days after the Effective Date; and

(ii) $[***] shall be due and payable (without invoice) prior to the date that is eight (8) months after the Effective Date.

The above upfront licensee fees will not reduce the amount of any other payment provided for in this Article IV, and the payment under Section 4.1(b)(i) is due and payable within forty-five (45) calendar days after the Agreement has been fully executed by all parties.

(c) Annual Maintenance Fee. A nonrefundable annual maintenance fee ("Annual Maintenance Fee") shall be due and payable (without invoice) within thirty (30) calendar days of each anniversary of the Effective Date. The first Annual Maintenance Fee shall be $[***]. Thereafter, the Annual Maintenance Fee shall increase by $[***] per year up to a maximum of $[***] per year. Each respective Annual Maintenance Fee payment shall be due and payable (without invoice) within thirty (30) calendar days of each anniversary of the Effective Date (e.g., an Annual Maintenance Fee of $[***] will be due and payable following the second anniversary of the Effective Date, an Annual Maintenance Fee of $[***] will be due and payable following the third anniversary of the Effective Date, and so on). Upon first Sale, the Annual Maintenance Fees shall cease and Licensee will no longer be obligated to pay any Annual Maintenance Fees, in connection with this Agreement, that would otherwise accrue after first Sale, subject to Section 4.1(e). The Annual Maintenance Fee will not reduce the amount of any other payment provided for in this Article IV.

(d) Running Royalty. A running royalty on the Sales of Licensed Products as follows:

If annual global Net Sales are less than or equal to $[***],

(i) [***] percent ([***]%) of the Net Sales of Licensed Products covered by a Valid Claim;

(ii) [***] percent ([***]%) of the Net Sales of Licensed Products not covered by a Valid Claim;

If annual global Net Sales are greater than $[***],

(iii) [***] percent ([***]%) of the Net Sales of Licensed Products covered by a Valid Claim; and

(iv) [***] percent ([***]%) of the Net Sales of Licensed Products not covered by a Valid Claim.

Licensee acknowledges and agrees that the subject matter covered by Technology Rights not included in a patent application or patent under Patent Rights is valuable and provides Licensee with a competitive advantage and head start in the further research, development, and commercialization of Licensed Products, and the royalty payments for Licensed Products not covered by a Valid Claim are appropriate in light of the foregoing

(e) Minimum Annual Royalty. After first Sale of a Licensed Product, minimum annual royalties ("Minimum Annual Royalties") as follows:

(i) $[***] upon the first anniversary of the Effective Date occurring after the first Sale; and

(ii) $[***] upon the second and subsequent anniversaries of the Effective Date occurring after the first Sale,

The respective Minimum Annual Royalties are due and payable (without invoice) within thirty (30) calendar days following each such anniversary of the Effective Date occurring after the first Sale; provided, however, in the event that there is less than a twelve (12) month period between the first Sale, and the first anniversary of the Effective Date occurring after the first Sale, then Licensee shall pay UTMDACC the following:

(1) the Annual Maintenance Fee due for that year multiplied by the fraction, A/C, where A is the number of months between the anniversary of the Effective Date preceding the first Sale, and the first Sale, and C is twelve (12); and

(2) the Minimum Annual Royalties multiplied by the fraction, B/C, where B is the number of months between the first Sale, and the first anniversary of the Effective Date which follows the first Sale, C is twelve (12), and A + B = twelve (12).

Running royalties accrued under Section 4.1(d) and paid to UTMDACC for the one year period preceding an anniversary of the Effective Date shall be credited against the Minimum Annual Royalties due on that anniversary date.

(f) Milestones. The following milestone payments (each, a "Milestone Payment"), upon the first time such milestone event is achieved with respect to a Licensed Product, regardless of whether the milestone event is achieved by Licensee or a Sublicensee:

Milestone Event	Milestone Payment
Commencement of a Phase I Study of a Licensed Product	$[***]
Commencement of a Phase II Study of a Licensed Product	$[***]
Commencement of a Phase III Study of a Licensed Product	$[***]
Filing of a NDA for a Licensed Product	$[***]
Receipt of Regulatory Approval for a Licensed Product in the United States	$[***]
Receipt of Regulatory Approval for a Licensed Product in the first of any of the following jurisdictions: France, Germany, Italy, Spain or the United Kingdom	$[***]
Receipt of Regulatory Approval for a Licensed Product in the first of any of the following jurisdictions: China, Japan or South Korea	$[***]

With respect to the Milestone Payments due upon the commencement of Phase I Study for a Licensed Product, Phase II Study for a Licensed Product, and Phase III Study for a Licensed Product, the Milestone Payments shall be payable on each Licensed Product, on a Licensed Product-by-Licensed Product basis, and UTMDACC shall receive the Milestone Payments whenever a milestone is achieved with respect to any such Licensed Product. With respect to the Milestone Payments due upon the filing of a NDA for a Licensed Product and receipt of Regulatory Approval for a Licensed Product, the Milestone Payments shall be payable on each Licensed Product, on a Licensed Product-by-Licensed Product, and UTMDACC shall receive the Milestone Payments whenever a milestone is achieved with respect to any such Licensed Product.

Solely with regard to the "Receipt of Regulatory Approval for a Licensed Product" Milestone Event, Milestone Payments due under this listed Milestone Event in Section 4.1(f) and paid to UTMDACC during the one year period preceding an anniversary of the Effective Date may be credited against the running royalty due in that preceding year, following payment of the Milestone Payment, for Sales of the Licensed Product and in the country upon which the Milestone Payment became due and payable.

(g) Sublicensing Consideration. The following percentages of Sublicensing Consideration:

(i) [***] percent ([***]%) of all Sublicensing Consideration received prior to or on the date of commencement of a Phase II Study of the Licensed Product;

(ii) [***] percent ([***]%) of all Sublicensing Consideration received after the date of commencement of a Phase II Study of the Licensed Product.

(h) Assignment Fee. A fee ("Assignment Fee") of $[***] (in consideration for UTMDACC consenting to the assignment), due and payable prior to any assignment pursuant to Section 11.1 below, except where such assignment is in conjunction with an acquisition giving rise to a Success Payment Event.

(i) Corporate Expenses. All Corporates Expenses incurred by UTMDACC for so long as this Agreement remains in effect; provided, however, that, in the event of termination by Licensee in accordance with Section XII, Licensee shall only be obligated to pay or reimburse such Corporate Expenses incurred prior to the date notification of such termination is received by UTMDACC. UTMDACC will invoice Licensee after the Agreement has been fully executed by all parties for Corporate Expenses incurred after the Effective Date, unless agreed otherwise by licensee, and on a quarterly basis thereafter. At the election of UTMDACC, Licensee will either pay outside legal counsel directly for Corporate Expenses or will reimburse UTMDACC for such Corporate Expenses. Corporate Expense payment delinquencies (whether owed directly to outside legal counsel or to UTMDACC) will be considered a payment default under Section 12.3(b)

4.2 Unless otherwise provided in Section 4.1, all payments owed thereunder are due and payable within thirty (30) calendar days after March 31, June 30, September 30, and December 31 of each year during the Term, at which time Licensee will also deliver to UTMDACC a true and accurate report, giving such particulars of the business conducted by Licensee and its Sublicensees, during the preceding three (3) calendar months under this Agreement as necessary for UTMDACC to account for Licensee's payments hereunder. This report will include pertinent data, including, but not limited to each of the following:

(a) The accounting methodologies used to account for and calculate the items included in the report and any differences in such accounting methodologies used by Licensee since the previous report;
(b) A list of Licensed Products produced for the three (3) preceding calendar months;
(c) The total quantities of Licensed Products produced;
(d) The total Sales for each Licensed Product;
(e) The calculation of Net Sales (e.g., itemize the permitted deductions from the gross consideration received from a Sale), segregated on a Licensed Product-by-Licensed Product, and a jurisdiction-by-jurisdiction basis, or an affirmative statement that no Sales were made;
(f) The royalties so computed and due to UTMDACC and/or Minimum Annual Royalties;
(g) All Sublicensing Consideration received by Licensee and payments due to UTMDACC therefrom;
(h) All other amounts due to UTMDACC herein.

Simultaneously with the delivery of each such report, Licensee agrees to pay UTMDACC the amount due, if any, for the period of such report. These reports are required even if no payments are due. Licensee shall provide UTMDACC with reasonable access, as requested in writing, to all documents and other records reasonably necessary for UTMDACC to evaluate the reports provided hereunder.

In addition to the reports described in the foregoing paragraph of this Section 4.2, Licensee shall deliver to UTMDACC all financial statements and other periodic reports that are delivered to Licensee’s stockholders. Such financial statements and period reports shall be delivered to UTMDACC simultaneously with Licensee’s delivery of such financial statements and period reports to Licensee’s stockholders or publication of such financial statements and period reports with the U.S. Securities and Exchange Commission, whichever is earlier. Licensee acknowledges and agrees that it shall observe this covenant regardless of whether it is required by applicable law or regulation to file financial statements and period reports with the U.S. Securities and Exchange Commission.

4.3 (a) For purposes of this Section 4.3, “Success Payment Event” means any of the following events:

(i) an acquisition of a majority of Licensee's stock or equity, whether by merger, consolidation, tender offer, or otherwise;

(ii) a direct or indirect acquisition (including an exclusive license or sublicense) of a majority of Licensee's assets;

(iii) the market capitalization of the Licensee exceeding $[***] for thirty consecutive trading days, if the Licensee’s stock is publicly traded on a nationally recognized stock exchange (this Success Payment Event shall only be deemed to occur on one occasion); or

(iv) the Licensee executing a transaction that ascribes a value to the Licensee’s stock in excess of $[***].

(b) Licensee shall make a one-time payment to UTMDACC upon the first to occur of any of the Success Payment Events (such payment hereinafter "Success Payment"), as follows:

(i) if, at the time of the first occurrence of a Success Payment Event, Licensee has not yet commenced a Phase I Study of a Licensed Product, a payment equal to the greater of [***] percent ([***]%) of the total value of the Licensee's stock or $[***];

(ii) if, at the time of the first occurrence of a Success Payment Event, Licensee has commenced a Phase I Study of a Licensed Product, a payment equal to the greater of [***] percent ([***]%) of the total value of the Licensee's stock or $[***]; or

(iii) if, at the time of the first occurrence of a Success Payment Event, Licensee has commenced a Phase II Study of a Licensed Product, a payment equal to the greater of [***] percent ([***]%) of the total value of the Licensee's stock or $[***].

For purposes of this Section 4.3, "commenced" shall mean the enrollment of at least one human subject in said trial, and all calculations based on the value of the "stock" or "equity" or "market capitalization" of the Licensee shall be based on the total value of all issued and outstanding shares of preferred and common stock of the Licensee at the time of such calculation.

Any acquirer of such stock, equity, or assets or exclusive licensee or sublicensee of such assets and any successor entity to Licensee shall be obligated to assume Licensee's obligations pursuant to this paragraph, and Licensee shall require such acquirer to agree in writing to do so. In the event of a dividend or other distribution by Licensee to stockholders occurring simultaneously, or in connection with, an event that gives rise to an obligation to pay a Success Payment, Licensee shall pay UTMDACC the greater of (i) the Success Payment amount or (ii) [***] percent ([***]%) of the total proceeds distributed to stockholders. In the event that Licensee makes a dividend or other distribution to stockholders independently from an event giving rise to an obligation to pay a Success Payment, Licensee shall pay UTMDACC [***] percent ([***]%) of the total proceeds distributed to stockholders.

4.4 For purposes of Section 4.3 above, the total value of Licensee's stock or equity shall be:

(i) In the case of Sections 4.3(a)(i) or 4.3(a)(ii) above where the acquisition is a cash acquisition, the total consideration received by Licensee and its subsidiaries or Licensee's stockholders in connection with the acquisition;

(ii) In the case of Sections 4.3(a)(i) or 4.3(a)(ii) above where the acquisition is made with stock, then in accordance with the following formula: P*Q, where P equals the total number of shares of the acquiring company provided to Licensee, and Q is the price per share of the acquiring entity stock as specified in or implied by the relevant acquisition agreement; and

(iii) In the case of Sections 4.3(a)(i) or 4.3(a)(ii) above where the acquisition is made with securities or property other than stock of the acquirer, value of the total consideration received by Licensee and its subsidiaries or Licensee's stockholders in connection with the acquisition as promptly determined by agreement of the parties or by an independent appraiser mutually agreeable to the parties.

4.5 Simultaneously with the closing of a transaction giving rise to an obligation to make a Success Payment under Section 4.3 above, the Chief Financial Officer of Licensee shall certify in writing to UTMDACC the total value of Licensee's stock or equity and shall provide UTMDACC with all documents and information reasonably requested by UTMDACC related to the calculation of such total value and the Success Payment owed to UTMDACC. Licensee shall not take any action for the purpose of circumventing its obligation to make the Success Payment under Section 4.3 above. If Licensee takes or proposes to take any action for the purpose of circumventing its obligation to make the Success Payment, UTMDACC will be entitled to the following remedies: (i) such money damages from Licensee as may be established by competent proof; (ii) attorney's fees incurred by UTMDACC in enforcing its rights under this Agreement; and (iii) injunctive or other equitable relief to restrain any action taken or proposed to be taken for the purpose of circumventing the Success Payment.

4.6 The Success Payment due under Section 4.3 above must be paid at the closing of the transaction giving rise to the Success Payment Event or, in the case of a Success Payment Event triggered under Section 4.3(a)(iii), within two (2) business days after the event described in Section 4.3(a)(iii) occurs. If all or a portion of the consideration paid to Licensee or its stockholders as part of the Qualified Transaction or other transaction giving rise to the obligation to make the Success Payment is received by Licensee or its stockholders over time, then Licensee shall be obligated to make the Success Payment to UTMDACC in stages as and when consideration is received by Licensee or its stockholders. By way of example and for illustrative purposes only, in the case of a transaction described in Section 4.3(a) of this Agreement, if Licensee receives a portion of the consideration on the closing date of such transaction and the remaining consideration after the expiration of an escrow period, UTMDAC shall be entitled to receive a Success Payment from Licensee within two (2) business days of the closing date of such transaction and within two (2) business days of Licensee's receipt of the consideration held in escrow.

4.7 Licensee shall notify UTMDACC in writing immediately upon achievement of any of the milestones set forth in Section 4.1(f). Each of the milestone payments set forth in Section 4.1(f) shall be paid by Licensee to UTMDACC (without invoice) within thirty (30) calendar days of achieving the milestone event and shall not reduce the amount of any other payment provided for in this Article IV.

4.8 During the Term and for one (1) year thereafter, Licensee agrees to keep complete and accurate records of Sales and Net Sales, whether made by Licensee or its Sublicensee, ("Records") in sufficient detail to enable the royalties and other payments due hereunder to be determined. The Records, which provide support for Licensee's payment of consideration due pursuant to this Agreement, shall at all times be available to UTMDACC, or its designee, for audit during regular business hours; provided, however, such audit shall not occur more than once per calendar year and such audit shall be conducted, at UTMDACC's sole expense, by an independent third party to be mutually agreed upon by Licensee and UTMDACC. If any amounts due to UTMDACC are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period so examined, then notwithstanding the foregoing Licensee will pay the cost of the audit. Licensee shall pay accrued interest at the highest rate allowed by applicable law on any and all late payments under this Agreement (regardless of whether the deficiency is identified by audit or otherwise), with such interest commencing on the date after the due date.

4.9 In the event that this Agreement is terminated, pursuant to Section 12.3(h), prior to its expiration date, Licensee shall pay UTMDACC a termination fee in the amount of $[***] ("Termination Fee"). In the event of such termination, Licensee shall pay UTMDACC the Termination Fee at least three (3) business days prior to the date of termination. Upon such payment of the Termination Fee, UTMDACC shall not be entitled to any further damages arising from such termination pursuant to Section 12.3(h); provided however, Licensee shall not be permitted to terminate this Agreement unless and until all amounts due and payable pursuant to Article IV have been paid to UTMDACC.

4.10 Licensee, by itself or through its Sublicensees, if any, will use commercially reasonable efforts to make Licensed Products commercially available in the Licensed Field within the Licensed Territory. Within thirty (30) calendar days following each anniversary of the Effective Date, Licensee will deliver to UTMDACC a written progress report as to Licensee's (and any Sublicensee's) efforts and accomplishments during the preceding year, and plans for the upcoming year, to establish and maintain a bona fide, funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program for the purposes of commercializing Licensed Subject Matter in the Licensed Territory.

4.11 All amounts payable hereunder by Licensee will be paid in United States funds without deductions for taxes, assessments, fees, or charges of any kind. Payments shall be by checks made payable to The University of Texas M. D. Anderson Cancer Center, and sent by United States mail to [***], or by wire transfer to:

[***].

4.12 No payments due or royalty rates owed under this Agreement will be reduced as the result of co-ownership of Licensed Subject Matter by Board and another party, including, but not limited to, Licensee.

4.13 If payment requires delivery of an invoice, then (a) UTMDACC's delay in providing an invoice shall not excuse or waive any payment obligation of Licensee, but the deadline for Licensee's payment shall be extended by the period of such delay; (b) an invoice shall be deemed to be delivered to Licensee if transmitted to Licensee's address in Section 14.2; and (c) any failure by Licensee to update its billing address shall not excuse timely payment.

V. Patents, Inventions and Sponsored Research

5.1 If after consultation with Licensee both parties agree that a new patent application should be filed for Licensed Subject Matter, UTMDACC will prepare and file appropriate patent applications, and Licensee will pay the related Patent Expenses for such new patent. If Licensee notifies UTMDACC that it does not intend to pay any portion of the Patent Expenses for such new patent application or new patent, or if Licensee fails to promptly confirm its intent to pay any portion of the Patent Expenses for such new patent application or new patent upon inquiry from UTMDACC, or if Licensee is in arrears or otherwise in default or late on any payments due under Section 4.1, then UTMDACC may, in its sole discretion, elect to file, not file, continue prosecution or maintenance, or abandon such new patent application or new patent at its own expense without further notice to Licensee. In the event Licensee fails to pay (subject to Section 12.3) or provides written notice of its intent not to pay any portion of new patent expenses, then Licensee's rights within the scope of such new patent or new patent application under the Patent Rights shall terminate in their entirety. For purposes of clarity, any termination of any rights in a new patent application or new patent under this Section 5.1 shall have no effect whatsoever on Licensee's rights hereunder in any other portion of the Patent Rights.

5.2 Both parties acknowledge that deadlines for responding to patent office communications may be set forth in various governmental or agency laws, rules, or regulations. Both parties shall cooperate with one another in satisfying such deadlines.

5.3 UTMDACC will or will instruct prosecution counsel to: (i) provide Licensee with a copy of any applications for which Licensee is obligated to pay the cost of filing, as well as copies of any documents received or filed during prosecution thereof, and give Licensee at least seven (7) calendar days to review the text of each patent application before any such filing is due; (ii) consult with Licensee with respect thereto; (iii) supply Licensee with a copy of the application as filed, together with notice of its filing date and serial number; and (iv) keep Licensee advised of the status of actual and prospective patent filings. UTMDACC shall give Licensee the opportunity to provide comments on and make requests of UTMDACC concerning the preparation, filing, prosecution, protection, defense and maintenance of the Patent Rights, and shall seriously consider such comments and requests; however, final decision-making authority shall vest in UTMDACC. The parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will keep all privileged information received pursuant to this Section confidential.

5.4 If Licensee is more than thirty (30) days in arrears on any payment or obligation due under this Agreement, Board, UTMDACC, and the counsel prosecuting licensed patents and patent applications shall have no obligation to confer or otherwise communicate with, or provide any information to, Licensee under this Article V unless and until Licensee is no longer in arrears on all payments and obligations under this Agreement.

5.5 Notwithstanding anything stated to the contrary in Section 12.3, if Licensee does not execute and deliver to UTMDACC the Sponsored Research Agreement within sixty (60) days after the Effective Date, this Agreement shall terminate upon written notice from UTMDACC.

5.6 If, in addition to the sponsored research agreement referenced in Section 5.5 above Licensee desires to sponsor research for or related to the Licensed Subject Matter, and particularly where Licensee receives payments for sponsored research pursuant to a sublicense under this Agreement, Licensee (a) will notify UTMDACC in writing of all opportunities to conduct this sponsored research (including clinical trials, if applicable), (b) will solicit research and/or clinical proposals from UTMDACC for this purpose, and (c) will give good faith consideration to funding any such proposals at UTMDACC.

VI. Infringement by Third Parties

6.1 Licensee, at its expense, must enforce any patent exclusively licensed hereunder against infringement by third parties in the Licensed Field within the Licensed Territory. Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by UTMDACC in providing cooperation in such enforcement. Any recovery for actual damages or punitive or enhanced damages in excess of Licensee's documented, third-party expenses in enforcing the Patent Rights and amounts actually reimbursed by Licensee to UTMDACC under this Section 6.1 shall be shared by Licensee with UTMDACC as follows: either (a) the applicable royalty set forth in Section 4.1(d) for any monetary recovery that is for sales of Licensed Products lost due to the infringement and fifty percent (50%) of related punitive damages; or (b) fifty percent (50%) of both reasonable royalties awarded and related punitive damages in any monetary recovery in which the award is for reasonable royalties. Licensee must notify UTMDACC in writing of any potential infringement in the Licensed Field within the Licensed Territory within thirty (30) calendar days of actual knowledge thereof. If Licensee does not file suit against a substantial infringer in the Licensed Field within the Licensed Territory within six (6) months of actual knowledge thereof, then Board or UTMDACC may, at its sole discretion, enforce any patent licensed hereunder on behalf of itself and Licensee, with UTMDACC retaining all recoveries from such enforcement, and/or reduce the license granted in Section 3.1(a) to a non-exclusive license.

VII. Patent Marking

7.1 Licensee agrees that all packaging containing individual Licensed Product(s), documentation therefor, and, when possible, actual Licensed Product(s) sold by Licensee and/or Sublicensees will be appropriately marked with the number of any applicable patent(s) licensed hereunder in accordance with each country's patent laws, including Title 35, United States Code, to the extent such marking is necessary or required to fully preserve Patent Rights in each such country and the right to recover damages for infringement thereof.

VIII. Indemnification and Insurance

8.1 LICENSEE AGREES TO HOLD HARMLESS AND INDEMNIFY BOARD, SYSTEM, UTMDACC, THEIR REGENTS, OFFICERS, EMPLOYEES, STUDENTS AND AGENTS (THE "UT INDEMNITEES") FROM AND AGAINST ANY THIRD PARTY CLAIMS, DEMANDS, OR CAUSES OF ACTION WHATSOEVER, COSTS OF SUIT AND REASONABLE AND DOCUMENTED ATTORNEY'S FEES (INCLUDING, WITHOUT LIMITATION, THOSE COSTS ARISING ON ACCOUNT OF ANY INJURY OR DEATH OF PERSONS OR DAMAGE TO PROPERTY) (COLLECTIVELY, "CLAIMS") CAUSED BY, OR ARISING OUT OF, OR RESULTING FROM, THE EXERCISE OR PRACTICE BY: (I) LICENSEE, ITS OFFICERS, ITS AFFILIATES OR THEIR OFFICERS, EMPLOYEES, AGENTS OR REPRESENTATIVES OF THE RIGHTS GRANTED HEREUNDER; OR (II) A SUBLICENSEE OR ITS OFFICERS, EMPLOYEES, AGENTS, AFFILIATES, OR REPRESENTATIVES OF RIGHTS GRANTED UNDER A SUBLICENSE AGREEMENT, EXCEPT, IN EITHER CASE, TO THE EXTENT SUCH CLAIM ARISES FROM OR IS CAUSED BY THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF A UT INDEMNITEE. LICENSEE'S OBLIGATIONS TO INDEMNIFY AND HOLD HARMLESS HEREUNDER ARE SUBJECT TO: (A) TO THE EXTENT AUTHORIZED BY THE TEXAS CONSTITUTION AND THE LAWS OF THE STATE OF TEXAS AND SUBJECT TO THE STATUTORY DUTIES OF THE TEXAS ATTORNEY GENERAL, THE UT INDEMNITEE GIVING LICENSEE CONTROL OF THE DEFENSE AND SETTLEMENT OF THE CLAIM AND DEMAND; AND (B) TO THE EXTENT AUTHORIZED BY THE TEXAS CONSTITUTION AND THE LAWS OF THE STATE OF TEXAS AND SUBJECT TO STATUTORY DUTIES OF THE TEXAS ATTORNEY GENERAL, THE UT INDEMNITEE PROVIDING THE ASSISTANCE REASONABLY REQUESTED BY LICENSEE, AT LICENSEE'S EXPENSE.

8.2 IN NO EVENT SHALL EITHER OF LICENSEE OR A UT INDEMNITEE BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF, OR IN CONNECTION WITH, THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER BOARD, SYSTEM OR UTMDACC KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING LIMITATION OF LICENSEE'S LIABILITY IN THIS SECTION 8.2 SHALL NOT APPLY TO CLAIMS AGAINST LICENSEE FOR INDEMNIFICATION (SECTION 8.1) OR FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF BOARD'S OR UTMDACC'S INTELLECTUAL PROPERTY RIGHTS.

8.3 **SCOPE OF INDEMNIFICATION OF UT INDEMNITEES.**

LICENSEE'S OBLIGATIONS TO HOLD HARMLESS AND INDEMNIFY THE UT INDEMNITEES IN SECTION 8.1, AND THE LIMITATION OF LIABILITY IN SECTION 8.2 SHALL INCLUDE, BUT ARE NOT LIMITED TO, ANY CLAIM ALLEGING STRICT STATUTORY LIABILITY, PRODUCT DEFECT LIABILITY, OR ANY UT INDEMNITEE'S OWN NEGLIGENCE (WHETHER SOLE OR CONCURRENT) THAT ARISES OUT OF, RELATES TO, IS CAUSED IN WHOLE OR IN PART BY, OR RESULTS FROM THE USE OR SALE OF ANY LICENSED PRODUCTS.

8.4 Beginning at the time when any Licensed Subject Matter or Licensed Product is being distributed or Sold (including for the purpose of obtaining regulatory approvals) by Licensee, an Affiliate, or by a Sublicensee, Licensee, at its sole cost and expense, shall (or, at a Sublicensee's sole cost and expense, Licensee shall require such Sublicensee to) procure and maintain commercial general liability insurance in amounts not less than $[***] per incident and $[***] annual aggregate, and Licensee shall use reasonable efforts to have the UT Indemnitees named as additional insureds. In connection therewith:

(a) Such commercial general liability insurance shall provide: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement; and (iii) coverage for litigation costs;

(b) The minimum amounts of insurance coverage required herein shall not be construed to create a limit of Licensee's liability with respect to its indemnification under this Agreement;

(c) Licensee shall provide UTMDACC with written evidence of such insurance within thirty (30) calendar days of its procurement. Additionally, Licensee shall provide UTMDACC with written notice of at least fifteen (15) calendar days prior to the cancellation, non-renewal or material change in such insurance; and

(d) Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any Licensed Subject Matter developed pursuant to this Agreement is being commercially distributed or sold by Licensee, an Affiliate or by a Sublicensee or agent of Licensee; and (ii) the five (5) year period immediately after such period.

IX. Use of Name

9.1 Licensee will not use the name of (or the name of any employee of) UTMDACC, System or Board in any advertising, promotional or sales literature, on its Web site, or for the purpose of raising capital without the advance express written consent of Board secured through:

The University of Texas
M. D. Anderson Cancer Center
Legal Services, Unit 1674
P.O. Box 301407
Houston, TX 77230-1407

Notwithstanding the above, Licensee may use the name of (or name of an employee of) UTMDACC, System or Board in routine business correspondence, as needed in appropriate regulatory submissions, or to make factually accurate statements about the existence of this Agreement, without UTMDACC, System or Board's express written consent.

X. Confidential Information and Publication

10.1 UTMDACC and Licensee each agree that all information contained in documents marked "confidential" and forwarded to one by the other (i) are to be received in strict confidence, (ii) are to be used only for the purposes of this Agreement, and (iii) will not be disclosed by the recipient party, its agents or employees without the prior written consent of the disclosing party, except to the extent that the recipient party can establish by competent written proof that such information:

(a) was in the public domain at the time of disclosure;
(b) later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns;
(c) was lawfully disclosed to the recipient party by a third party having the right to disclose it;
(d) was already known by the recipient party at the time of disclosure; or
(e) was independently developed by the recipient party without use of the disclosing party's confidential information.

10.2 Each party's obligation of confidence hereunder will be fulfilled by using at least the same degree of care with the disclosing party's confidential information as it uses to protect its own confidential information, but always at least a reasonable degree of care. This obligation will exist while this Agreement is in force and for a period of three (3) years thereafter. For the avoidance of doubt, nothing stated herein is intended to prohibit Licensee from exercising any of the rights granted to Licensee in Section 3.1.

10.3 UTMDACC reserves the right to publish the general scientific findings from research related to Licensed Subject Matter, with due regard to the protection of Licensee's confidential information. UTMDACC will submit the manuscript of any proposed publication to Licensee at least thirty (30) calendar days before publication, and Licensee shall have the right to review and comment upon the publication in order to protect Licensee's confidential information. Upon Licensee's request, publication may be delayed up to sixty (60) additional calendar days to enable Licensee to secure adequate intellectual property protection of Licensee's confidential information that would otherwise be affected by the publication.

10.4 In the event that the recipient party is required to disclose the disclosing party's confidential information under operation of applicable law, regulation, or order of a court or governmental administrative body having competent jurisdiction, the recipient party shall, to the extent practicable, provide the disclosing party reasonable notice of such potential disclosure so that that the disclosing party may seek a protective order or other appropriate protection or legal relief to prevent or limit such disclosure. If, in the absence of, or pursuant to the terms of, such protection or legal relief, the recipient party is nonetheless required by applicable law, regulation, or order of a court or governmental administrative body having competent jurisdiction to disclose any portion of the disclosing party's confidential information, the required disclosure shall be permitted under this Agreement but shall be limited to only that portion of the disclosing party's confidential information that is required to be disclosed.

XI. Assignment

11.1 Except in connection with a transaction giving rise to a Success Payment Event under Section 4.3(a)(ii), Licensee may not assign any rights under this Agreement without the prior written consent of UTMDACC, which shall not be unreasonably withheld, and any attempt by Licensee to assign rights under this Agreement without UTMDACC's prior written consent shall render the assignment null and void. For any assignment to be effective, the assignee must assume in writing (a copy of which writing will be provided to UTMDACC) all of Licensee's interests, rights, duties, and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if the assignee were the original party (i.e., Licensee) to the Agreement.

XII. Term and Termination

12.1 Subject to Sections 12.2, 12.3 and 12.4 below, the term of this Agreement is from the Effective Date until the last to occur of: (a) the expiration of all patents issued under Patent Rights (if any) and the cancellation, withdrawal, or express abandonment of all patent applications under Patents Rights (if any), or (b) the date that is the fifteenth (15th) anniversary of the Effective Date ("Term").

12.2 In addition to any other rights or remedies under this Agreement, UTMDACC shall have the right to terminate this Agreement in the event that Licensee fails to meet each of the following commercial diligence milestones by the corresponding dates (each, a "Diligence Milestone"):

Diligence Milestone Event	Deadline
Initiated PC toxicology to support filing of an IND or NDA for the Licensed Product	Within the eighteen (18) month period following the Effective Date
File an IND for the Licensed Product	Within the three (3) year period following the Effective Date
Commencement of Phase I Study	Within the five (5) year period following the Effective Date

12.3 Subject to any rights herein which survive termination, this Agreement will earlier terminate in its entirety:

(a) automatically, if Licensee becomes bankrupt or insolvent and/or if the business of Licensee shall be placed in the hands of a receiver, assignee, or trustee, whether by voluntary act of Licensee or otherwise;

(b) upon thirty (30) calendar days written notice from UTMDACC, if Licensee breaches or defaults on the payment or report obligations of Article IV (excluding the license documentation fee specified in Section 4.1(b), for which no cure period applies), or use of name obligations of Article IX, unless, before the end of such thirty (30)-calendar day notice period, Licensee has cured the default or breach to UTMDACC's satisfaction, and so notifies UTMDACC, stating the manner of the cure;

(c) immediately, upon written notice from UTMDACC, if Licensee fails to timely pay the upfront license fee specified in Section 4.1(b);

(d) upon ninety (90) calendar days written notice from UTMDACC if Licensee breaches or defaults on any other obligation under this Agreement, unless, before the end of such ninety (90) calendar-day notice period, Licensee has cured the default or breach to UTMDACC's reasonable satisfaction and so notifies UTMDACC, stating the manner of the cure;

(e) at any time by mutual written agreement between Licensee and UTMDACC upon one hundred eighty (180) calendar days written notice to all parties and subject to any terms herein which survive termination; or

(f) immediately if Section 12.2 or Section 14.9 is invoked;

(g) upon ten (10) days written notice from UTMDACC if Licensee has defaulted or been late on its payment obligations pursuant to the terms of this Agreement on any two (2) occasions in a twelve month period;

(h) by Licensee's written notice to UTMDACC, effective as of the thirtieth (30th) day following delivery of such notice if the Termination Fee has been paid pursuant to Section 4.9.

12.4 Upon termination of this Agreement:

(a) nothing herein will be construed to release either party of any obligation maturing prior to the effective date of the termination;

(b) Licensee covenants and agrees to remain bound by the provisions of Articles IV (Consideration, Payments and Reports), VIII (Indemnification and Insurance), IX (Use of Board and UTMDACC's Name) and X (Confidential Information and Publication) of this Agreement;

(c) Licensee may, for a period of one year after the effective date of the termination, Sell all Licensed Products and parts therefor that it has on hand at the date of termination, if Licensee pays the earned royalty thereon and any other amounts that become due during such one (1) year period pursuant to Article IV of this Agreement;

(d) Subject to Section 12.4(c), Licensee agrees to cease and desist any use and all Sales of the Licensed Subject Matter and Licensed Products; and

XIII. Representations, Warranties and Covenants

13.1 Except for the rights, if any, of the Government of the United States of America ("Government") as set forth below, Board and UTMDACC represent and warrant their belief that (a) Board is the sole owner of the right, title, and interest in and to Licensed Subject Matter, (b) Board has the right to grant licenses thereunder, (c) Board has not granted licenses thereunder to any other entity that would restrict rights granted hereunder except as stated herein.

13.2 Licensee understands that the Licensed Subject Matter may have been developed under a funding agreement with the Government and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any such agreement and any applicable law or regulation. To the extent that there is a conflict between any such agreement, applicable law or regulation and this Agreement, the terms of such Government agreement, applicable law or regulation shall prevail. Licensee agrees that Licensed Products used or Sold in the United States will be manufactured substantially in the United States, unless a written waiver is obtained in advance from the Government. Licensee will promptly advise UTMDACC if such a written waiver is requested and/or obtained.

13.3 LICENSEE UNDERSTANDS AND AGREES THAT BOARD AND UTMDACC, BY THIS AGREEMENT, MAKE NO REPRESENTATION AS TO THE OPERABILITY OR FITNESS FOR ANY USE, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF THE LICENSED SUBJECT MATTER. BOARD AND UTMDACC, BY THIS AGREEMENT, ALSO MAKE NO REPRESENTATION AS TO WHETHER ANY PATENT COVERED BY PATENT RIGHTS IS VALID OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY BOARD IN THE LICENSED FIELD, NOR DO BOARD AND UTMDACC MAKE ANY REPRESENTATION THAT THE INVENTIONS CONTAINED IN PATENT RIGHTS DO NOT INFRINGE ANY OTHER PATENTS NOW HELD OR THAT WILL BE HELD BY OTHERS OR BY BOARD.

13.4 Licensee, by execution hereof, acknowledges, covenants and agrees that Licensee has not been induced in any way by Board, System, UTMDACC or employees thereof to enter into this Agreement, and further warrants and represents that (a) Licensee is entering into this Agreement voluntarily; (b) Licensee has conducted sufficient due diligence with respect to all items and issues pertaining to this Agreement; and (c) Licensee has adequate knowledge and expertise, or has used knowledgeable and expert consultants, to adequately conduct such due diligence, and agrees to accept all risks inherent herein.

XIV. General

14.1 This Agreement, together with any exhibits and/or fully executed amendments hereto, constitutes the entire and only agreement between the parties for Licensed Subject Matter and all other prior negotiations, representations, agreements and understandings related to the subject matter of this Agreement are superseded hereby. Neither party has relied on any such prior communication in entering into this Agreement. No agreements altering or supplementing the terms hereof will be made except by a written document signed by both parties.

14.2 Any notice required by this Agreement shall be in writing and shall be deemed to have been sufficiently given for all purposes thereof when sent by first class mail, reputable international courier (e.g., Federal Express or UPS), or electronic mail return receipt requested, but solely with respect to patent prosecution-related matters, and shall be evidenced by the postmark at the point of mailing or by the dated delivery receipt of the courier or by return receipt. All notices and any correspondence respecting this Agreement shall be transmitted as follows:

To UTMDACC, if by mail:
The University of Texas M. D. Anderson Cancer Center
Strategic Industry Ventures/Office of Technology Commercialization
Unit 1669
P.O. Box 301407
Houston, Texas 77230-1407

To UTMDACC, if by courier:
The University of Texas M. D. Anderson Cancer Center
Strategic Industry Ventures/Office of Technology Commercialization
1MC9.2216
7007 Bertner Avenue
Houston, Texas 77030-3907

To UTMDACC, for patent prosecution-related matters:
For prosecution related matters: [***].

To Licensee by mail or courier:

CNS Pharmaceuticals, Inc.
2100 West Loop South, Suite 900
Houston, Texas 77027
Attention: John Climaco

or other physical addresses or email addresses as may be given from time to time under the terms of this notice provision.

14.3 Licensee must comply with all applicable federal, state and local laws and regulations in connection with its activities pursuant to this Agreement. Licensee acknowledges that the Licensed Subject Matter is subject to U. S. export control jurisdiction. Licensee agrees to comply with all applicable international and national laws that apply to the Licensed Subject Matter, including U.S. Export Administration Regulations, as well as end-user, end-use, and destination restrictions applied by the United States.

14.4 This Agreement will be construed and enforced in accordance with the laws of the United States of America and of the State of Texas, without regard to its conflict of law provisions. The Texas State Courts of Harris County, Texas (or, if there is exclusive federal jurisdiction, the United States District Court for the Southern District of Texas) shall have exclusive jurisdiction and venue over any dispute arising out of this Agreement, and Licensee consents to the jurisdiction and venue of such courts and hereby explicitly waives the rights to any other venue to which it might be entitled by cause of action, domicile or otherwise. Nothing in this Agreement shall be deemed as a waiver by Board, System or UTMDACC of its sovereign immunity.

14.5 Notwithstanding the foregoing, to the extent that Chapter 2260, Texas Government Code, as it may be amended from time to time ("Chapter 2260"), is applicable to this Agreement, Licensee acknowledges and agrees that the dispute resolution process provided for in Chapter 2260 shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Board and/or UTMDACC or the State of Texas.

14.6 Failure of either party to enforce a right under this Agreement will not act as a waiver of right or the ability to later assert that right relative to the particular situation involved.

14.7 Headings included herein are for convenience only and will not be used to construe this Agreement.

14.8 If any part of this Agreement is for any reason found to be unenforceable, all other parts nevertheless will remain enforceable.

14.9 In the event that Licensee brings an action before any court, agency or tribunal seeking to invalidate or otherwise challenge the enforceability of or Board's ownership of any patent included in the Patent Rights, then UTMDACC may immediately terminate this Agreement upon written notice to Licensee. Any dispute regarding the validity, enforceability or ownership of any patent included in the Patent Rights shall be litigated in the courts located in Houston, Texas, and Licensee agrees not to challenge personal jurisdiction in that forum. To the extent that Licensee unsuccessfully challenges the validity or enforceability of any patent included in the Patent Rights, Licensee agrees to reimburse UTMDACC and Board for all costs and fees (including attorney's fees) paid by UTMDACC and Board in defending against such challenge. Licensee understands and agrees that, in the event Licensee successfully challenges the validity or enforceability of any patent included in the Patent Rights, all payments or other consideration made or otherwise provided by Licensee to UTMDACC prior to a final, non-appealable adjudication of invalidity and/or unenforceability shall be non-refundable. The obligations of this Section shall survive the expiration or termination of this Agreement.

14.10 If Licensee desires to sponsor research for or related to the Licensed Subject Matter, and particularly where Licensee receives payments for sponsored research pursuant to a sublicense under this Agreement, Licensee (a) will notify UTMDACC in writing of all opportunities to conduct this sponsored research (including clinical trials, if applicable), (b) will solicit research and/or clinical proposals from UTMDACC for this purpose, and (c) will give good faith consideration to funding the proposals at UTMDACC.

14.11 This Agreement may be executed in one (1) or more counterparts, by original, facsimile or PDF signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature. In the event signatures are exchanged by facsimile and/or in ".pdf" format, each party shall thereafter promptly provide an original signature page to the other party.

14.12 UTMDACC, as an agency of the State of Texas and a member institution of The University of Texas System, is subject to the constitution and laws of the State of Texas and, under the constitution and laws of the State of Texas, possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted under the constitution and laws of the State of Texas. Moreover, notwithstanding the generality or specificity of any provision of this Agreement, the provisions of this Agreement as they pertain to UTMDACC are enforceable only to the extent authorized by the constitution and laws of the State of Texas. No party to this Agreement will be required to perform any act or to refrain from any act that would violate any applicable law, including the constitution and laws of the State of Texas. Licensee verifies that it does not "boycott Israel" (as defined in Texas Government Code Section 808.001), and subject to or as otherwise required by applicable law, will not boycott Israel for so long as this Agreement remains in effect.

[Signatures Appear on Following Page]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS System, on behalf of
THE UNIVERSITY OF TEXAS M. D. ANDERSON
CANCER CENTER

By /s/ Ben Melson
Printed Name: Ben Melson
Title: Senior Vice President and Chief Financial Officer

Date: January 10, 2020

CNS Pharmaceuticals, Inc.

By /s/ John Climaco
Printed Name: John Climaco
Title: CEO

Date: January 10, 2020

Approved as to Content:

By /s/ Ferran Prat
Ferran Prat, J.D., Ph.D.
Senior Vice President
Research Administration & Industry Relations
Strategic Industry Ventures
The University of Texas
M. D. Anderson Cancer Center

Date: January 10, 2020

EXHIBIT I

MDA No.	Inventors (Include M.D.).	IDR Title	All U.S. and foreign patent application/patent numbers (country code and serial number – only include pending or issued applications).
MDA11-124	Waldemar Priebe, Timothy Madden, Arkadiusz Kazimierski, Wei Guo (MD), Izabela Fokt, Charles Conrad (MD)	Unique DNA Binding Agents with Anticancer Activity (WP1244)	PCT Ser: PCT/US2016/052144 US Ser: 10,358,439 EP Ser: 168473890 CHK Ser: 19119283.0 CN Ser: 201680066385.9 JP Ser: 2018513780 CA Ser: 2,998,867 AU Ser: 2016323777 IN Ser: 201817010926

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. THE REDACTED TERMS HAVE BEEN MARKED WITH THREE ASTERISKS [***]

Exhibit 10.12

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Board of Directors of CNS Pharmaceuticals, Inc. (the "**Company**") has approved the following Non-Employee Director Compensation Policy (this "**Policy**"), which establishes compensation to be paid to non-employee directors of the Company, effective as of March 12, 2020, to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

Applicable Persons

This Policy shall apply to each director of the Company who is not an employee of, or compensated consultant to, the Company or any Affiliate (each, an "**Outside Director**"). "Affiliate" shall mean a corporation which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

Cash Fees

Commencing April 1, 2020, the following annual cash fees shall be paid to the Outside Directors and to each Outside Director serving as Chairperson of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, as applicable:

Cash						
Base	Committee Chair			Committee Member		
	Audit	Compensation	Nominating & Governance	Audit	Compensation	Nominating & Governance
$35,000	$10,000	$7,000	$5,000	$5,000	$3,500	$3,000

Note: Chair and Committee member compensation are not additive.

* In addition, the Lead Independent Director position shall receive an additional annual fee of $10,000.

Per meeting payment. In addition, each Outside Director shall receive $2,500 attendance at face-to-face board meetings (no compensation for telephonic meetings).

Cash payments payable to Outside Directors shall be paid quarterly in arrears. For any portion of a fiscal year in which the Outside Director begins providing service, quarterly payments shall be pro-rated based on a 365-day year calculation. If an Outside Director dies, resigns or is removed during any quarter, he or she shall be entitled to a cash payment on a pro rated basis through his or her last day of service based on a 365-day year calculation.

The Company shall pay a one-time make-whole payment to the directors as follows: (i) Jeff Keyes - $6,554.79; (ii) Jerzy (George) Gumulka - $3,972.60; (iii) Carl Evans - $3,972.60; and (iv) Andrzej Andraczke - $3,376.71.

Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Outside Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and Committees thereof or in connection with other business related to the Board of Directors.

Amendments

The Compensation Committee or the Board of Directors shall review this Policy from time to time to assess whether any amendments in the type and amount of compensation provided herein should be adjusted in order to fulfill the objectives of this Policy.

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, 2019 of CNS Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 12, 2020

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, 2019 of CNS Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 12, 2020

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, 2019 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

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, 2019 (the "Report") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

By: /s/ Christopher Downs

Christopher Downs
Chief Financial Officer