

FORM C-AR

CNS Pharmaceuticals, Inc.



This Form C-AR (including the cover page and all exhibits attached hereto, the "Form C- AR") is being furnished by CNS Pharmaceuticals, Inc., a Nevada Corporation (the "Company", as well as references to "we", "us", or "our") for the sole purpose of providing certain information about the Company as required by the Securities and Exchange Commission ("SEC").

THIS FORM C-AR DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR SELL SECURITIES.

No federal or state securities commission or regulatory authority has passed upon the accuracy or adequacy of this document. The U.S. Securities and Exchange Commission does not pass upon the accuracy or completeness of any disclosure document or literature. The Company is filing this Form C-AR pursuant to Regulation CF (§ 227.100 et seq.) which requires that it must file a report with the Commission annually and post the report on its website at www.cnspharma.com no later than 120 days after the end of each fiscal year covered by the report. The Company may terminate its reporting obligations in the future in accordance with Rule 202(b) of Regulation CF (§ 227.202(b)) by 1) being required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended, 2) filing at least one annual report pursuant to Regulation CF and having fewer than 300 holders of record, 3) filing annual reports for three years pursuant to Regulation CF and having assets equal to or less than \$10,000,000, 4) the repurchase of all the Securities sold pursuant to Regulation CF by the Company or another party, or 5) the liquidation or dissolution of the Company.

The date of this Form C-AR is April 30, 2019.

Forward Looking Statement Disclosure

This Form C-AR contains forward-looking statements that are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C-AR are forward-looking statements. Forward-looking statements give the Company's current reasonable expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "estimate," "expect," "project," "plan," "intend," "believe," "may," "should," "can have," "likely" and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events.

As you read and consider this Form C-AR, you should understand that these statements are not guarantees of performance or results. They involve risks, uncertainties (many of which are beyond the Company's control) and assumptions. Although the Company believes that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect its actual operating and financial performance and cause its performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of these assumptions prove incorrect or change, the Company's actual operating and financial performance may vary in material respects from the performance projected in these forward- looking statements.

Any forward-looking statement made by the Company in this Form C-AR speaks only as of the date of this Form C- AR. Factors or events that could cause our actual operating and financial performance to differ may emerge from time to time, and it is not possible for the Company to predict all of them. The Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

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About this Form C-AR

You should rely only on the information contained in this Form C-AR. We have not authorized anyone to provide you with information different from that contained in this Form C-AR. You should assume that the information contained in this Form C-AR is accurate only as of the date of this Form C-AR, regardless of the time of delivery of this Form C-AR. Our business, financial condition, results of operations, and prospects may have changed since that date.

Statements contained herein as to the content of any agreements or other document are summaries and, therefore, are necessarily selective and incomplete and are qualified in their entirety by the actual agreements or other documents.

SUMMARY

The following summary is qualified in its entirety by more detailed information that may appear elsewhere in this Form C-AR and the Exhibits hereto.

CNS Pharmaceuticals, Inc. (the “Company”) is a pre-clinical pharmaceutical Nevada corporation, formed on July 27, 2017 to focus on the development of anti-cancer drug candidates.

The Company is located at 2100 West Loop South, Suite 900, Houston, TX 77027.

The Company’s website is www.cnspharma.com

The information available on or through our website is not a part of this Form C-AR.

The Business

CNS Pharmaceuticals, Inc. is a preclinical stage pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anticancer drug candidates for the treatment of brain and central nervous system tumors. Our work is based on a license agreement with Houston Pharmaceuticals, Inc. (“HPI”) and a collaboration and asset purchase agreement with Reata Pharmaceuticals, Inc. (“Reata”).

We believe our lead drug candidate, Berubicin, if approved by the FDA, may be a significant discovery in the treatment of glioblastoma. Glioblastoma are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful chemotherapy drugs known. 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 successful 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.

RISK FACTORS

We will require substantial additional 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 intend to use the proceeds from our past and future offerings 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.

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.

If we do not raise substantial financing, we will not have sufficient funds to complete the Phase 2 trial for Berubicin and we will require additional financing, for which we have no commitments, to complete the trial.

We will require substantial additional financing to complete the Phase 2 clinical trial for Berubicin. We do not have any commitments for additional financing and there is no assurance that we will be able to raise the additional financing required to complete the Phase 2 trial for Berubicin. Even if we are able to raise such financing, it may be highly dilutive to current investors.

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, 2018, the Company has incurred an accumulated deficit of \$7,611,261 since inception and had not yet generated any revenue from operations. These factors raise substantial doubt regarding our ability to continue as a going concern.

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.

NDA's must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. NDA's 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.

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 inter partes 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.

We currently have no full-time and 2 part-time employees. We also have 2 officers serving as part-time contractors. 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 our chief financial officer are currently working for us on a part-time basis. Our chief executive officer and chief medical 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.

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. Matthew Lourie, our chief financial officer, is currently also providing consulting services related to financial reporting to other public and private entities. Sandra Silberman, our chief medical officer, is also the chief medical officer for New Products at Moleculin, as well as a consultant for Trovogene, Inc.

As we progress, if the full-time services of a CFO are required and the current officers cannot provide that level of commitment, we will need to identify a suitable CFO who can dedicate such time to our Company. We can provide no assurance that we will be able to successfully identify and retain a qualified candidate for this position.

In addition to our officers' part-time status, since Mr. Climaco and Dr. Silberman are associated with other companies that are developing anti-cancer drug candidates, they may encounter conflicts of interest in the future. Although we do not believe that the drug candidates we are currently pursuing compete with the types of drug candidates being pursued by the other companies Mr. Climaco and Dr. Silberman 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, Sandra Silberman, MD PhD, and Matthew Lourie 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, Sandra Silberman, MD PhD, or Matthew Lourie 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.

BUSINESS

Description of the Business

CNS Pharmaceuticals, Inc. is a preclinical stage pharmaceutical company organized as a Nevada corporation in July 2017 to focus on the development of anticancer drug candidates for the treatment of brain and central nervous system tumors. Our work is based on a license agreement with Houston Pharmaceuticals, Inc. ("HPI") and a collaboration and asset purchase agreement with Reata Pharmaceuticals, Inc. ("Reata").

We believe our lead drug candidate, Berubicin, if approved by the FDA, may be a significant discovery in the treatment of glioblastoma. Glioblastoma are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful chemotherapy drugs known. 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 successful 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. Our review of the Reata Data leads us to believe that Berubicin may have greater potential for efficacy and safety in glioblastoma patients than currently available therapies.

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. Our rights pursuant to the HPI License are contingent on us raising at least \$7,000,000 within 12 months from the effective date of the HPI License, a date which can be extended by an additional 12 months by the payment of a nominal fee (On December 28, 2018, the agreement with HPI was amended to defer the payment of the extension fee until June 30, 2019). In the HPI License we agreed to pay HPI: (i) development fees of \$750,000 over a three-year period beginning after the \$7.0 million raise is complete; (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, if we are able to raise \$7.0 million, we believe we will have obtained all rights and intellectual property necessary to develop Berubicin. As stated earlier, it is the Company’s 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.

Market for Cancer Drugs and Berubicin

Cancer is the second leading cause of death in the United States behind heart disease. In 2016, an estimated 15.5 million people in the United States were living with a past or current diagnosis of cancer and, the American Cancer Society estimates that in 2019, nearly 1.7 million new cases will be diagnosed and over 600,000 Americans will 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 approximately \$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 blood brain barrier (“BBB”). We believe that pre-clinical and clinical data on Berubicin demonstrates that it can cross the BBB, making it a potentially effective therapy for glioblastoma and other brain cancers.

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. Temolozomide 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. 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. Berubicin is the first anthracycline shown in animal models to cross the blood brain barrier and target cancer cells. In 2009, 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. 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 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. The current standard for treatment is surgery, radiation, and chemotherapy with TMZ. TMZ, the current standard of treatment 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 GBM cells. Given the different mechanism of action of Berubicin, these patients may show a better outcome and our planned phase 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 compelling 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 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, at its completion we intend to either look for a partner with which to conduct a Phase 3 study, or to raise sufficient capital to conduct such a study on our own. The goal of these studies is to develop a body of evidence to support a successful application with the U.S. Food and Drug Administration (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. Unlike other anthracycline derivatives, Berubicin has been

shown in animal models and in a Phase 1 human clinical trial to cross the blood brain barrier and targets cancer cells, specifically glioblastoma.

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 (BBB). 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 have shown to be less affected by multidrug transporters than doxorubicin, to be 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.

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 resection, systemic treatment with targeted agents or cytotoxic chemotherapy, reirradiation, or radiosurgery. Research into novel therapies is investigating alternative temozolomide regimens, convection-enhanced delivery, immunotherapy, gene therapy, antiangiogenic agents, poly ADP ribose polymerase inhibitors, or cancer stem cell signaling pathways. Overall, the 5-year survival rate is <10%, with a final mortality rate of close to 100%. Therefore, the development of novel therapeutic options for patients with recurrent glioblastoma remains a priority. Given the short-term efficacy and low survival rate of glioblastoma and other 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 GBM cells. Berubicin 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, GBM, 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 (MTD) determined. A 44% disease control response rate was observed. 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 successful execution of multiple Phase I human clinical trials. Berubicin received an Orphan Drug designation by the FDA in 2013, providing seven years of marketing exclusivity after FDA approval. 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 confirm 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 developing by the WPD as a 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. 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 and remained disease free as of December 31, 2008.

The above mentioned patient remains disease free and clinically stable as of March 28, 2018, at his last clinical visit.

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 (“MTD”) 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 27, 2006 and remained disease free as of March 28, 2008. The patient remains disease free and clinically stable as of March 28, 2018, at his last clinical visit.

One additional patient (7.5 mg/m²/day) achieved an unconfirmed partial response as best recorded 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

- o Disappearance of all enhancing disease (measurable and non-measurable)
- o Sustained for at least four weeks
- o No new lesions
- Clinical features
 - o No corticosteroids
 - o Clinically stable or improved

Partial response

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

Stable disease

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

Progression

- Imaging features
 - o 25% or more increase in enhancing lesions
 - o Any new lesions
- Clinical features
 - o 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.

<u>Serious Adverse Event</u>	<u>Number of Patients Experiencing Adverse Event</u>
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. Myelosuppression and Myelotoxicity are expected here and are consistent with the known toxicities of the anthracycline class of medications. Myelosuppressive and Myelotoxic events are generally manageable by a competent clinical team.

Based on the compelling 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). 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 success of Reata. It is the collective opinion of Drs. Silberman, Hsu, Picker, Walling and Priebe that with a successful path already demonstrated by Reata, we should attempt to follow that path to the greatest extent practical.

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, at its completion we intend to either look for a partner with which to conduct a Phase 3 study, or to raise sufficient capital to conduct such a study on our own. The goal of these studies is to develop a body of evidence to support a successful application with the U.S. Food and Drug Administration (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. Our rights pursuant to the HPI License are contingent on us raising at least \$7,000,000 within 12 months from the effective date of the HPI License, a date which can be extended by an additional 12 months by the payment of a nominal fee.

Governmental/Regulatory Approval and Compliance

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 ("MTD").
- 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 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.

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.

Litigation

There are no existing legal suits pending, or to the Company's knowledge, threatened, against the Company.

DIRECTORS, OFFICERS AND EMPLOYEES

Directors & Executive Officers

The following table sets forth the names and ages of all of our directors and executive officers as of January 1, 2019. Our officers are appointed by, and serve at the pleasure of, the Board of Directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
John M. Climaco	50	Chairman of the Board and Chief Executive Officer
Matthew Lourie	38	Chief Financial Officer
Sandra L. Silberman	63	Chief Medical Officer
Jerzy (George) Gumulka	68	Director
Jeffry R. Keyes	46	Director
Andrzej Andraczke	75	Director
Carl Evans	71	Director

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

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

Matthew Lourie, CPA – Chief Financial Officer. Mr. Lourie joined CNS in July 2017 and currently serves on a part-time basis. Mr. Lourie has extensive management, accounting and financial experience. Mr. Lourie currently owns and operates (founded May 2017) Fresh Notion Financial Services and provides consulting and reporting services to other public and private companies. Mr. Lourie served as an audit partner of the PCAOB registered firm MaloneBailey from November 2014 through April 2017, where he oversaw audits and financial reporting of SEC registrants. In addition, he served as the Corporate Controller of a public company with over 300 locations across the country from April 2013 through October 2014. Mr. Lourie is a graduate of the University of Houston where he earned both his Bachelor of Business Administration Accounting and his Masters of Science in Accounting. Mr. Lourie is a Certified Public Accountant in Texas.

Sandra L. Silberman, MD PhD – Chief Medical Officer. Dr. Silberman joined CNS in December 2017 and currently serves on a part-time basis. Dr. Silberman has played key roles in the development of many drugs including Gleevec™, for which she led the global clinical development at Novartis. Dr. Silberman advanced several original, proprietary compounds into Phases I through III during her work with leading international biopharmaceutical companies, including BristolMyers Squibb, AstraZeneca, Imclone, Eisai and Roche. Since 2006, Dr. Silberman has served as an Independent Consultant to the Biopharmaceutical Industry. Dr. Silberman is a Hematologist/Oncologist who earned her B.A., Sc.M. and Ph.D. from the Johns Hopkins University School of Arts and Sciences, School of Public Health and School of Medicine, respectively, and her M.D. from Cornell University Medical College, and then completed both a clinical fellowship in Hematology/Oncology as well as a research fellowship in tumor immunology at the Brigham & Women’s Hospital and the Dana Farber Cancer Institute in Boston, MA. Dr. Silberman also currently also serves as an attending physician in the Duke Hematology/Oncology Fellowship program at the Durham VA Medical Center.

Jerzy (George) Gumulka, PhD – Director. Dr. Gumulka joined our board of directors on November 8, 2017. Dr. Gumulka has been retired since 2016. From 2001 until his retirement he served as a Global Technology Manager ASC, a Technology Manager, Special Projects/New Technology Platforms, Kraton Polymers US LLC and a Technical

Director of Kraton Polymers do Brasil. Dr. Gumulka served on the Board of Directors of Moleculin LLC from 2010 through 2016. Dr. Gumulka received a PhD from the University of Warsaw, Warsaw, Poland.

Jeffry R. Keyes – Director. Mr. Keyes joined our board on June 25, 2018. Mr. Keyes is currently the Chief Financial Officer of Custopharm, Inc., a private equity backed developer of generic sterile injectable pharmaceuticals, a role he has held since April 2018. From September 2012 to April 2018, Mr. Keyes was the Chief Financial Officer and Corporate Secretary of Digirad Corporation, a publicly traded healthcare services and medical device company. From August 2011 until September 2012, Mr. Keyes was Corporate Controller of Sapphire Energy, Inc., a venture capital backed start-up renewable energy company. From April 2011 to August 2011, Mr. Keyes was the Corporate Controller of Advanced BioHealing, Inc., a venture backed provider of regenerative medicine solutions, until its sale to Shire, PLC in August 2011. Prior to April 2011 Mr. Keyes held a variety of leadership roles in healthcare and medical device companies in finance, accounting, and M&A support, and he started his career in public accounting. Mr. Keyes earned a B.A. degree in accounting from Western Washington University and is a certified public accountant licensed by the Washington State Board of Accountancy. Mr. Keyes is considered a financial expert under relevant rules of the SEC, the NYSE and NASDAQ.

Andrzej Andraczke – Director. Mr. Andraczke joined our board on July 9, 2018. Mr. Andraczke is currently Chief Executive Officer of Pol-Tex Holdings, LLC, a role he has held since November 2012. He is also currently Chief Technology Officer of Syntech LLC (Ireland), a role he has held since November 2017. From March 2016 to April 2016 Mr. Andraczke served as an expert witness for the International Chamber of Commerce for downhole air hammer drilling of the well in volcanic rocks for a geothermal project in Slovakia. From March 2000 through November 2012 Mr. Andraczke was Vice-President of Pol-Tex Methane. Mr. Andraczke earned a M.Sc. in Engineering from Warsaw Technical University.

Carl Evans – Director. Mr. Evans joined our board on July 9, 2018. Mr. Evans has been retired since 2015. From 2011 until his retirement Mr. Evans was Executive Vice President – Exploration for KMD Operating Company, LLC. Prior to 2011, he managed international and domestic oil exploration and production projects for several oil companies, including British Petroleum, Texaco, and Pennzoil. Mr. Evans earned Bachelor of Science degree in Geology from the University of California, Los Angeles.

Employees

As of March 1, 2019, we had one full time employee and one part-time employee. We also have two officers serving as part-time contractors, and accordingly, a high percentage of the work performed for our development projects is outsourced to qualified independent contractors.

CAPITALIZATION AND OWNERSHIP

Capitalization

The following table sets forth information, as of March 15, 2019, regarding beneficial ownership of our common stock by:

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

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

Name and address of beneficial owner	Shares beneficially owned	Percentage owned (1)
John Climaco	900,000 (2)	7.1%
Matthew Lourie	30,000 (3)	*
Sandra Silberman	18,750 (4)	*
Jerzy (George) Gumulka	55,560 (5)	*
Jeffrey R. Keyes	27,780 (6)	*
Andrzej Andraczke	27,780 (6)	*
Carl Evans	27,780 (6)	*
Directors and Officers as a group	1,087,650	8.5%
5% or greater shareholders		
Waldemar Priebe	9,029,000 (7)	71.1%
* Less than 1%.		

- (1) Based on 12,694,504 shares of common stock outstanding as of March 15, 2019.
- (2) Consists of 900,000 shares of our common stock that we have the right to repurchase if Mr. Climaco's employment with us is terminated, at a purchase price of \$0.01 per share, as follows: (i) if the termination occurs prior to our raising \$4.0 million we can repurchase 100% of the shares; (ii) if the termination occurs after we raise \$4.0 million, but prior to us completing an initial public offering or raising \$8.0 million in funding, we can repurchase 75% of the shares; and (iii) if the termination occurs after we complete an initial public offering or raise \$8.0 million in funding, we can purchase a pro rata portion of 50% of the shares based on the portion of the three-year term remaining in Mr. Climaco's employment term.
- (3) Consists of 30,000 shares of our common stock that we have the right to repurchase if Mr. Lourie terminates his services with us, at a purchase price of \$0.01 per share, as follows: (i) if the termination occurs prior to our IPO we can repurchase 100% of the shares; (ii) if the termination occurs within one year of our IPO, we can repurchase two-thirds of the shares; and (iii) if the termination occurs within two years of our IPO, we can repurchase one-third of the shares.
- (4) Consists of shares underlying options to purchase 75,000 shares with exercise prices of \$0.045 per share, and which vests in four equal annual installments succeeding date of grant, provided the individual is providing service to CNS on such vesting dates.
- (5) Consists of shares underlying options to purchase 100,000 shares with exercise prices of \$0.045 per share, and which vests in 36 equal monthly installments succeeding date of grant, provided the individual is providing service to CNS on such vesting dates.
- (6) Consists of shares underlying options to purchase 100,000 shares with exercise prices of \$1.50 per share, and which vests in 36 equal monthly installments succeeding date of grant, provided the individual is providing service to CNS on such vesting dates.
- (7) Of the amount in the table, 200,000 shares are held by Houston Pharmaceuticals, Inc. Dr. Priebe has voting and dispositive power over the shares held by Houston Pharmaceuticals, Inc.

The Company has conducted the following prior Securities offerings in the past three years:

Description of Capital Stock

Common Stock

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

Voting

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

Dividends

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

Liquidation Rights

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

Other

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

Preferred Stock

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

Convertible Notes and Warrants

On June 15, 2018, we entered into an agreement to issue 10% convertible notes in an aggregate of \$300,000 in principal amount of convertible notes, which principal and accrued interest will automatically convert into shares of common stock upon the closing of our IPO offering at a conversion rate of \$1.50 per share.

In August and September 2017, we issued an aggregate of \$86,825 in principal amount of convertible notes (the “2017 Notes”), at conversion prices ranging from \$0.001 to \$0.045 per share. The note holders also collectively received in the aggregate warrants to purchase 1,206,059 shares of our common stock at an exercise price of \$11.00 per share. On December 31, 2018, the Company amended the 2017 convertible notes to allow the notes to be converted

prior to the Company's IPO at the holder's 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 and a loss on extinguishment of \$6,286,841 was recognized. As of December 31, 2018, none of the 2017 Notes remained outstanding.

Regulation CF Offering

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 was terminated on June 11, 2018 and we issued \$628,558 of SAFE securities to investors and \$12,571 of SAFE securities as commission fee to a vendor. Pursuant to the terms of the SAFE securities, if we complete our IPO offering and become listed on the Nasdaq Stock Market, the purchaser of the SAFE security will automatically receive 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 offering.

Articles of Incorporation and Bylaw Provisions

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

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

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

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

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

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

Nevada Takeover Statute

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

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

Limitations on Liability and Indemnification of Officers and Directors

Our articles of incorporation and bylaws limit the liability of our officers and directors and provide that we will indemnify our officers and directors, in each case, to the fullest extent permitted by the Nevada Revised Statutes. We expect to obtain additional directors' and officers' liability insurance coverage prior to the completion of our IPO offering.

Description of Exempt Offerings

Except as set forth below, in the three years preceding this filing, we have not issued any securities that were not registered under the Securities Act:

Upon the formation of CNS Pharmaceuticals, Inc., for services rendered we issued 8,829,000 shares of common stock to entities controlled by our founder, Dr. Waldemar Priebe.

In July 2017, we entered into a consulting agreement with an entity controlled by Matthew Lourie pursuant to which Mr. Lourie agreed to serve as our Chief Financial Officer. In connection with the consulting agreement, we agreed that Mr. Lourie would purchase 15,000 shares of common stock at a purchase price of \$0.001 per share; provided that if Mr. Lourie terminates his services with us, we have certain repurchase rights. In November 2017, we

issued an additional 15,000 shares of common stock to Mr. Lourie for services. These shares are subject to same buyback provision as discussed above.

In September 2017, in connection with John Climaco's employment agreement, we agreed that Mr. Climaco would purchase 900,000 shares of common stock at a purchase price of \$0.001 per share; provided that if Mr. Climaco's employment with us is terminated we have certain repurchase rights.

In August 2017, we issued 10% convertible notes in an aggregate of \$975 in principal amount of convertible notes. The note holders also received in the aggregate warrants to purchase 289,575 shares of common stock at an exercise price of \$11.00 per share. In August 2017, we also issued 10% convertible notes in an aggregate of \$23,450 in principal amount of convertible notes. The note holders also received in the aggregate warrants to purchase 504,644 shares of common stock at an exercise price of \$11.00 per share. In September 2017, we issued 10% convertible notes in an aggregate of \$62,400 in principal amount of convertible notes. The note holders also received in the aggregate warrants to purchase 411,840 shares of our common stock at an exercise price of \$11.00 per share. On December 31, 2018, we amended the 2017 convertible notes to allow the notes to be converted prior to our IPO at the holder's 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.

In December 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from Houston Pharmaceuticals, Inc. In the license agreement, we agreed to issued Houston Pharmaceuticals, Inc. 200,000 shares of common stock.

Between December 2017 and March 2018, we sold 327,004 shares of common stock at \$1.50 per share in a private placement.

In March 2018, we commenced an offering pursuant to Regulation CF of the Securities Act pursuant to which it offered units of SAFE securities. The offering was terminated on June 11, 2018 and we issued \$628,558 of SAFE securities to investors and \$12,571 of SAFE securities as commission fee to a vendor. Pursuant to the terms of the SAFE securities, if we completes our IPO and become listed on the Nasdaq Stock Market, the purchaser of the SAFE security will automatically receive a number of shares of common stock equal to the purchase amount divided by the product of (a) 84% multiplied by (b) the public offering price per share in the IPO offering.

On June 15, 2018, we entered into an agreement to issue 10% convertible notes in an aggregate of \$300,000 in principal amount of convertible notes, which principal and accrued interest will automatically convert into shares of common stock upon the closing of the IPO offering at a conversion rate of \$1.50 per share.

All of the securities above were issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, other than the SAFE securities which were issued pursuant to Regulation CF of the Securities Act.

FINANCIAL INFORMATION

Please see the financial information listed on the cover page of this Form C-AR and attached hereto in addition to the following information. Financial statements are attached hereto as Exhibit A.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the notes thereto included in this report. The following discussion contains forward-looking statements. Actual results could differ materially from the results discussed in the forward-looking statements. See "Risk Factors" above.

Plan of Operations

Our plan of operations is primarily focused on using the proceeds from a planned IPO to complete a Phase 2 clinical trial for Berubicin. Even if we complete this planned offering, we estimate that we will require substantial additional financing to complete the trial 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.

Results of Operations

Year Ended December 31, 2018 compared to the Period from July 27, 2017 (inception) through December 31, 2017

We were formed on July 27, 2017; therefore, the financial information for 2017 is from the inception through December 31, 2017.

General and Administrative Expense

General and administrative expense was \$860,520 for the year ended December 31, 2018 compared to \$182,467 for the period from July 27, 2017 (inception) to December 31, 2017.

The expense was mainly attributable to compensation of approximately \$375,000 related to our various officers and new employees, of which approximately \$103,000 was paid in common stock. We also incurred approximately \$237,000 of advertising expenses related to our Regulation CF fundraising campaign hosted at www.Republic.co, \$124,000 of legal expenses and \$50,000 of audit and accounting fees.

Research and Development Expense

Research and development expense was \$21,267 for the year ended December 31, 2018 compared to \$32,638 for the period from July 27, 2017 (inception) to December 31, 2017. The expenses incurred in both periods were related to patent maintenance cost. We expect to incur increased research and development costs in the future as our product development activities expand.

Interest and Other Expenses

The Company recognized a loss on settlement of its 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.

Interest expense was \$28,615 for the year ended December 31, 2018, compared to \$4,257 for the period from July 27, 2017 (inception) to December 31, 2017, related to interest accrued on our notes payable and convertible notes payable issued in 2018 and 2017 bearing interest at the rate of 10% per annum.

The Company amortized debt discount of \$18,082 during the year ended December 31, 2018. The debt discount was comprised of \$7,582 for the warrants on a convertible note issued in June 2018, and \$10,500 of placement agent fees.

During the year ended December 31, 2018, the Company incurred a total of \$41,883 of commission and other fees on the SAFE agreement which were settled out of the proceeds. The Company recorded a loss on change in fair value of SAFE agreements of \$122,120 during the year ended December 31, 2018. In addition, the Company recorded a commission of \$12,571 as an increase to the SAFE agreement liability.

Net Loss

Net loss for the year ended December 31, 2018 was \$7,391,899 compared to \$219,362 for the period from July 27, 2017 (inception) to December 31, 2017.

Liquidity and Capital Resources

On December 31, 2018, we had cash of \$282,736 and we had a working capital deficit of \$644,498. On December 31, 2017, we had cash of \$110,543 and a working capital deficit of \$58,532. We have historically funded our operations from proceeds from debt and equity sales.

Cash used in operating activities

Net cash used in operating activities was \$716,385 for the year ended December 31, 2018 and \$112,197 for the period from July 27, 2017 (inception) to December 31, 2017 and mainly included payments made for 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 \$1,160,975 for the year ended December 31, 2018 and \$222,740 for the period from July 27, 2017 (inception) to December 31, 2017. We received \$100,915 net proceeds from sale of our common stock and \$121,825 from the issuance of notes payable and convertible notes payable during the period from July 27, 2017 (inception) to December 31, 2017 and \$390,500 from the issuance of common stock during the year ended December 31, 2018. In addition, during the year ended December 31, 2018 we received net proceeds of \$279,000 from the issuance of a convertible note payable and \$586,675 from the closing of our SAFE agreements.

Since our inception and through December 31, 2018, we have funded our operations through the sale and issuance of common stock and convertible and non-convertible notes payable. From August 2017 to June 2018, we issued various convertible notes to our lenders. The note proceeds were \$386,825. Each note bears interest at 10% per annum and are 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, if we complete our IPO offering and become listed on the Nasdaq Stock Market, the purchaser of the SAFE security will automatically receive 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 offering.

We do not have any material commitments for capital expenditures, although we are required to pay certain development fees to HPI as described above.

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, 2018, the Company has incurred an accumulated deficit of \$7,611,261 since inception and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, 2018 is sufficient to fund its planned operations into but not beyond one year from the date of the issuance of these financial statements. These factors raise substantial doubt regarding our ability to continue as a going concern.

We will have additional capital requirements for 2019. We may need to seek additional financing, which may or may not be available to us, while we attempt to raise additional capital through the sale of our common stock.

Critical Accounting Policies

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.

Stock-based Compensation - Employee share-based payment 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.

Share-based awards to non-employees are expensed over the period in which the related services are rendered at their fair value.

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

RESTRICTIONS ON TRANSFER

The securities we sold pursuant to Regulation CF may not be transferred by any Investor of such Securities during the one-year holding period beginning when the Securities were issued, unless such Securities are transferred: 1) to the Company, 2) to an accredited investor, as defined by Rule 501(d) of Regulation D promulgated under the Securities Act, 3) as part of an IPO or 4) to a member of the family of the Investor or the equivalent, to a trust controlled by the Investor, to a trust created for the benefit of a member of the family of the Investor or the equivalent, or in connection with the death or divorce of the Investor or other similar circumstances. "Member of the family" as used herein means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother/father/daughter/son/sister/brother-in-law, and includes adoptive relationships. Remember that although you may legally be able to transfer the Securities, you may not be able to find another party willing to purchase them.

TRANSACTIONS WITH RELATED PERSONS AND CONFLICTS OF INTEREST

Related Person Transactions

Upon the formation of CNS, for services rendered we issued 8,829,000 shares of our common stock to entities controlled by our founder Dr. Waldemar Priebe.

In connection with Mr. Climaco employment agreement, we agreed that Mr. Climaco would purchase 900,000 shares of our common stock at a purchase price of \$0.001 per share; provided that if Mr. Climaco's employment with us is terminated we have the right to repurchase from Mr. Climaco, at a purchase price of \$0.01 per share, the purchase shares as follows: (i) if the termination occurs prior to our raising \$4.0 million we can repurchase 100% of the shares; (ii) if the termination occurs after we raise \$4.0 million, but prior to us completing an initial public offering or raising \$8.0 million in funding, we can repurchase 75% of the shares; and (iii) if the termination occurs after we complete an initial public offering or raise \$8.0 million in funding, we can purchase a pro rata portion of 50% of the shares based on the portion of the three-year term remaining in Mr. Climaco's employment term.

On July 27, 2017, we entered into a consulting agreement with an entity controlled by Matthew Lourie pursuant to which Mr. Lourie agreed to serve as our Chief Financial Officer. The consulting agreement is terminable by either party on 30 days' notice. In connection with the consulting agreement, we agreed that Mr. Lourie would purchase 15,000 shares of our common stock at a purchase price of \$0.001 per share; provided that if Mr. Lourie terminates his services with us we have the right to repurchase from Mr. Lourie, at a purchase price of \$0.01 per share, the purchase shares as follows: (i) if the termination occurs prior to our IPO we can repurchase 100% of the shares; (ii) if the termination occurs within one year of our IPO, we can repurchase two-thirds of the shares; and (iii) if the termination occurs within two years of our IPO, we can repurchase one-third of the shares. On November 8, 2017, the Company issued an additional 15,000 shares of common stock to Mr. Lourie for services. These shares are subject to same buyback provision as discussed above.

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. Dr. Priebe controls HPI.

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. Our rights pursuant to the HPI License are contingent on us raising at least \$7,000,000 within 12 months from the effective date of the HPI License, a date which can be extended by an additional 12 months by the payment of a nominal fee. In the HPI License we agreed to pay HPI: (i) development fees of \$750,000 over a three-year period beginning after the \$7.0 million raise is complete; (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.

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 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. The Company paid \$30,000 for the first six months upon execution of the agreement.

Policies and Procedures for Related Party Transactions

Our audit committee charter provides that our audit committee will be responsible for reviewing and approving in advance any related party transaction. This will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. All of the transactions described in this section occurred prior to the creation of our audit committee and the adoption of this policy.

OTHER INFORMATION

The Company has not failed to comply with the ongoing reporting requirements of Regulation CF § 227.202 in the past.

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C-AR and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

CNS PHARMACEUTICALS, INC.
(Issuer)

By: /s/ John Climaco
John Climaco
Chief Executive Officer

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C-AR has been signed by the following persons in the capacities and on the dates indicated.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ John Climaco</u> John Climaco	President, Chief Executive Officer and Director (Principal Executive Officer)	April 30, 2019
<u>/s/ Matthew Lourie</u> Matthew Lourie	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 30, 2019
<u>/s/ Jerzy (George) Gumulka</u> Jerzy (George) Gumulka	Director	April 30, 2019
<u>/s/ Carl Evans</u> Carl Evans	Director	April 30, 2019
<u>/s/ Jeffry Keyes</u> Jeffry Keyes	Director	April 30, 2019
<u>/s/ Andrzej Andraczke</u> Andrzej Andraczke	Director	April 30, 2019

Exhibit A - Financial Statements

**CNS Pharmaceuticals, Inc.
Index to Financial Statements**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CNS Pharmaceuticals, Inc. (the "Company") as of December 31, 2018 and 2017, and the related statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2018 and the period from July 27, 2017 (inception) through December 31, 2017, 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, 2018 and 2017, and the results of its operations and its cash flows for the year ended December 31, 2018 and the period from July 27, 2017 (inception) through December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

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

Basis for Opinion

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

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

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

/s/ *MaloneBailey, LLP*
www.malonebailey.com

We have served as the Company's auditor since 2019.

Houston, Texas
March 26, 2019

CNS Pharmaceuticals, Inc.
Balance Sheets

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 282,736	\$ 110,543
Restricted cash	272,397	–
Prepaid expenses	33,000	51,651
Total current assets	<u>588,133</u>	<u>162,194</u>
Long-Term Assets:		
Deferred issuance costs	95,200	–
Total Assets	<u>\$ 683,333</u>	<u>\$ 162,194</u>
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 128,071	\$ 42,497
Accounts payable - related party	794	15,000
Accrued expenses	23,599	41,404
Convertible notes payable, net of discount	281,918	86,825
Notes payable	35,000	35,000
SAFE agreements	763,249	–
Total current liabilities	<u>1,232,631</u>	<u>220,726</u>
Total Liabilities	<u>1,232,631</u>	<u>220,726</u>
Commitments and contingencies		
Stockholders' 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 12,694,504 and 10,270,667 shares issued and outstanding, respectively	12,695	10,271
Additional paid-in capital	7,049,268	150,559
Accumulated deficit	(7,611,261)	(219,362)
Total Stockholders' Deficit	<u>(549,298)</u>	<u>(58,532)</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 683,333</u>	<u>\$ 162,194</u>

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Operations

	Year Ended December 31, 2018	Period from July 27, 2017 (Inception) through December 31, 2017
Operating expenses:		
General and administrative	\$ 860,520	\$ 182,467
Research and development	<u>21,267</u>	<u>32,638</u>
Total operating expenses	<u>881,787</u>	<u>215,105</u>
Loss from operations	<u>(881,787)</u>	<u>(215,105)</u>
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	(28,615)	(4,257)
Amortization of debt discount	(18,082)	-
Total other expense	<u>(6,510,112)</u>	<u>(4,257)</u>
Net loss	<u>\$ (7,391,899)</u>	<u>\$ (219,362)</u>
Loss per share - basic and diluted	<u>(0.70)</u>	<u>(0.02)</u>
Weighted average shares outstanding - basic and diluted	<u>\$ 10,510,551</u>	<u>\$ 9,568,752</u>

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Stockholders' Deficit

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Deficit</u>	<u>Stockholders'</u>
			<u>Capital</u>		<u>Deficit</u>
Balance (at inception) July 27, 2017	–	\$ –	\$ –	\$ –	\$ –
Issuance of founder shares	9,074,000	9,074	–	–	9,074
Common stock issued to officers	930,000	930	40,260	–	41,190
Common stock issued for research and development expense	200,000	200	8,800	–	9,000
Common stock issued for cash	66,667	67	99,933	–	100,000
Stock-based compensation	–	–	590	–	590
Warrants and beneficial conversion feature on convertible notes payable	–	–	976	–	976
Net loss	–	–	–	(219,362)	(219,362)
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	<u>12,694,504</u>	<u>\$ 12,695</u>	<u>\$ 7,049,268</u>	<u>\$ (7,611,261)</u>	<u>\$ (549,298)</u>

See accompanying notes to the financial statements.

CNS Pharmaceuticals, Inc.
Statements of Cash Flows

	December 31, 2018	Period from July 27, 2017 (Inception) through December 31, 2017
Cash Flows from Operating Activities:		
Net loss	\$ (7,391,899)	\$ (219,362)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	110,240	49,939
Amortization of note payable discount	18,082	976
Loss on change in fair value of SAFE agreements	122,120	–
SAFE agreement accrued expenses	54,454	–
Loss on settlement of convertible debt	6,286,841	–
Common stock issued for research and development expense	–	9,000
Changes in operating assets and liabilities:		
Prepaid expenses	18,651	(51,651)
Accounts payable	85,574	42,497
Accounts payable-related party	(14,206)	15,000
Accrued expenses	(6,242)	41,404
Net Cash Used in Operating Activities	<u>(716,385)</u>	<u>(112,197)</u>
Cash Flows from Financing Activities:		
Proceeds from convertible debt	300,000	86,825
Payment of placement agent fee	(21,000)	–
Payments of deferring issuance cost	(95,200)	–
Proceeds from notes payable	–	35,000
Proceeds from related party advances	–	85
Payments on related party advances	–	(85)
Proceeds from SAFE agreements	586,675	–
Proceeds from sale of common stock	390,500	100,000
Proceeds from common stock issued to officers	–	915
Net Cash Provided by Financing Activities	<u>1,160,975</u>	<u>222,740</u>
Change in cash and cash equivalents and restricted cash	444,590	110,543
Cash and cash equivalents and restricted cash, at beginning of period	<u>110,543</u>	<u>–</u>
Cash and cash equivalents and restricted cash, at end of period	<u>\$ 555,133</u>	<u>\$ 110,543</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	<u>\$ –</u>	<u>\$ –</u>
Cash paid for income taxes	<u>\$ –</u>	<u>\$ –</u>
Supplemental disclosure of non-cash investing and financing activities:		
Convertible notes payable and accrued interest settled with common stock and warrants	<u>\$ 98,389</u>	<u>\$ –</u>
Placement agent warrants issued with convertible notes payable	<u>\$ 15,163</u>	<u>\$ 976</u>

See accompanying notes to the financial statements

CNS Pharmaceuticals, Inc.
Notes to the Financial Statements

Note 1 – Nature of Business

CNS Pharmaceuticals, Inc. is a pre-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 audited financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for financial information, 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.

Going Concern - These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The continuation of the Company as a going concern is dependent upon the ability of the Company to obtain continued financial support from its stockholders, necessary equity financing to continue operations and the attainment of profitable operations. As of December 31, 2018, the Company has incurred an accumulated deficit of \$7,611,261 since inception, and had not yet generated any revenue from operations. Additionally, management anticipates that its cash on hand as of December 31, 2018 is sufficient to fund its planned operations into but not beyond the near term. These factors raise substantial doubt regarding the Company’s ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances and licensing arrangements and delay planned cash outlays or a combination thereof. Management cannot be certain that such events or a combination thereof can be achieved.

Cash and Cash Equivalents - The Company considers all highly liquid accounts with original maturities of three months or less at the date of acquisition to be cash equivalents. Periodically, the Company may carry cash balances at financial institutions in excess of the federally insured limit of \$250,000. The amount in excess of the FDIC insurance at December 31, 2018 was \$32,736.

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

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash and cash equivalents	\$ 282,736	\$ 110,543
Restricted cash	272,397	–
Total	<u>\$ 555,133</u>	<u>\$ 110,543</u>

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

Intangible Assets - Intangible assets with finite lives will be amortized using the straight-line method over their estimated period of benefit. If an intangible asset is identified as an in-process research & development (“IPR&D”) asset, then no amortization will occur until the development is complete. If the associated research and development effort is abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its statements of operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

We evaluate the recoverability of intangible assets periodically and take into account events or circumstances that warrant revised estimates of useful lives or that indicate that impairment exists. Intangible assets are tested for impairment on an annual basis, and between annual tests if indicators of potential impairment exist, using a fair-value-based approach.

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, accounts payable and accrued expenses, and short-term notes approximate fair value due to the relatively short period to maturity for these instruments. The long-term debt approximate fair value since the related rates of interest approximate current market rates.

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.

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 share-based payment 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.

Share-based awards to non-employees are expensed over the period in which the related services are rendered at their fair value.

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, 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. As of December 31, 2017, the Company's potentially dilutive shares and options, which were not included in the calculation of net loss per share, included notes convertible to 4,060,942 common shares, warrants to purchase 1,206,059 common shares, and options for 275,000 common shares.

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

Subsequent Events - The Company's management reviewed all material events through March 26, 2019 the date these financial statements were available to be issued for subsequent event disclosure consideration.

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 is currently evaluating the impact that this standard will have on its financial statements, but does not believe it will have a material impact on the Company's financial statements due to the lack of lease agreements for the Company at this time.

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.

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 various dates during 2017, the Company entered into seven unsecured convertible promissory notes and warrants for aggregate proceeds of \$86,825. Each note bears interest at 10% per annum and are scheduled to mature on the earlier of one year after issuance or the completion of an initial public offering ("IPO") of the Company's securities. Each debt holder was issued common stock warrants as further discussed in the Equity footnote.

These notes will to be automatically converted according to their terms into shares of the Company's common stock at the applicable conversion price upon the Company's IPO to the extent and provided that no holder of these notes was or will be permitted to convert such notes to the extent that the holder or any of its affiliates would beneficially own in excess of 4.99% of our common stock after such conversion. After the completion of the Company's IPO and until such time as the notes are converted into shares of common stock, the maturity date of the notes will automatically be extended until fully converted, we will not be permitted to repay the notes, and accrued interest relating to the notes will continue to accrue. In August 2018, the maturity date of these notes was extended an additional six months.

The convertible notes were analyzed for a beneficial conversion feature on various issuance dates. A total discount of \$488 was recorded as a beneficial conversion feature which was fully amortized at December 31, 2017. The Company also recorded a debt discount related to the relative fair value of the warrants in the amount of \$488 which was fully amortized at December 31, 2017.

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 will automatically convert into shares of common stock upon the closing of a public offering 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. During the year ended December 31, 2018, \$18,082 of the discount was amortized leaving an unamortized balance of \$18,082 at December 31, 2018.

On December 31, 2018, the Company amended the 2017 convertible notes 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 and a loss on extinguishment of \$6,286,841 was recognized.

The table below represents the shares that are convertible at December 31, 2018 relating to the principal amounts of the remaining convertible notes payable and excludes any shares that are convertible relating to the associated accrued interest:

Issuance Date	Principal Balance, December 31, 2018	Conversion Rate	Shares convertible into at December 31, 2018	Warrants issued with convertible notes
June 14, 2018	\$ 300,000	\$ 1.50	200,000	–
Less: Discount	(22,543)			
Total	\$ 277,457		200,000	–

Issuance Date	Principal Balance, December 31, 2017	Conversion Rate	Shares convertible into at December 31, 2017	Warrants issued with convertible notes
August 7, 2017	\$ 150	\$ 0.001	150,000	44,500
August 7, 2017	75	0.001	75,000	22,275
August 8, 2017	750	0.001	750,000	222,750
August 16, 2017	20,000	0.0138	1,449,275	430,400
August 29, 2017	3,450	0.0138	250,000	74,244
September 6, 2017	26,000	0.045	577,778	171,600
September 7, 2017	36,400	0.045	808,889	240,240
Total	\$ 86,825		4,060,942	1,206,059

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 will automatically convert into the Company's common shares. The number of shares the SAFE agreement investors will receive is based on a 16% discount to the pricing in the triggering equity financing. The SAFE agreements do not limit the number of shares that the issuer could be required to issue upon conversion. If there is a voluntary termination of operations, a general assignment for the benefit of the Company's creditors or any other liquidation, dissolution or winding up of the Company voluntary or involuntary before the SAFE agreements terminate upon conversion, subject to the preferences applicable to any series of preferred stock, the Company will distribute its entire assets legally available for distribution with equal priority between the investors of SAFE agreements (on an as converted basis based on a valuation of common stock as determined in good faith by the Company's board of directors) and common stock holders. The SAFE agreements have no interest rate or maturity date and the SAFE investors have 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 will be held in an escrow account. The escrow funds will 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. If the escrow funds are not released to the Company before December 28, 2019, the funds will be distributed to the SAFE agreement investors. Such distribution will not reduce the number of common shares that the investors will receive upon conversion.

As of December 31, 2018, the SAFE agreements have not yet converted as a qualifying financing had not yet occurred. The SAFE agreements are recorded as a liability until conversion occurs. As of December 31, 2018, the Company received \$314,278 of proceeds related to this agreement. The Company incurred a total of \$41,883 of commission and other fees which were settled out of the proceeds. The remaining \$272,397 is reflected as a Restricted Cash until released according to the SAFE agreement. In addition, the Company recorded a commission of \$12,571 as an increase to the SAFE agreement liability. During the year ended December 31, 2018 a loss of \$122,120 was recorded to adjust the SAFE agreement liability to fair value.

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

In July 2017, the Company issued a total of 9,074,000 shares of common stock to a founding group of seven companies and individuals for services valued at \$9,074 or par value. In addition, in July 2017 the Company issued 15,000 shares of common stock to its Chief Financial Officer, Matthew Lourie, in exchange for \$15. The shares issued to Mr. Lourie are subject to a buyback provision as discussed in Note 7.

On September 30, 2017, the Company issued 900,000 shares of common stock to John Climaco related to his role as Chief Executive Officer. Mr. Climaco paid \$900 for his shares on October 19, 2017. The Company determined that the fair value of the shares issued for services was \$39,600 in excess of the amount paid and has recorded this value as stock-based compensation. The shares issued to Mr. Climaco are subject to a buyback provision as discussed in Note 7.

On November 8, 2017 the Company issued an additional 15,000 shares of common stock to Matthew Lourie for services. These shares are subject to a buyback provision as discussed in Note 7. An expense of \$675 was recorded as compensation.

On December 28, 2017, the Company issued 200,000 shares of common stock to Houston Pharmaceuticals, Inc., an entity controlled by a member of our founding group and majority shareholder. The fair value of the shares, or \$9,000, was recorded as an expense related to the acquisition of the license discussed in Note 7.

On December 28, 2017 after the acquisition of the license discussed in Note 7, the Company issued 66,667 shares of common stock for cash proceeds of \$100,000.

On January 12, 2018, the Company issued 5,000 shares of common stock valued at \$7,500 to a consultant for services.

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.

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 grant various forms of incentive awards for up to 2,000,000 shares of common stock. No key employee may receive more than 500,000 shares of common stock (or options to purchase more than 500,000 shares of common stock) in a single year.

On November 8, 2017, the Company issued non-qualified stock options to 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 \$8,294 at grant date. The exercise price per share is \$0.045 for these shares.

On December 22, 2017, the Company issued non-qualified stock options to our Chief Medical Officer. The options cover 75,000 shares, have an original life of ten years and vest in four equal installments on each of the succeeding four anniversary dates. The options had fair value of \$3,110 at grant date. The exercise price is \$0.045 for these shares.

During 2017, the Company recorded \$590 stock compensation expense in relation to the common stock options issued to the directors and officer.

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.

During the years ended December 30, 2018 and 2017, the Company recognized \$102,740 and \$590 of stock-based compensation, respectively, related to outstanding stock options. At December 31, 2018, the Company had \$460,132 of unrecognized expenses related to options.

The following table summarizes the stock option activity for the years ended December 31, 2018 and the period from July 27, 2017 (inception) through December 31, 2017:

	<u>Options</u>	<u>Weighted-Average Exercise Price Per Share</u>
Outstanding, July 27, 2017 (inception)	—	
Granted	275,000	\$ 0.045
Exercised	—	—
Forfeited	—	—
Expired	—	—
Outstanding, December 31, 2017	<u>275,000</u>	0.045
Granted	400,000	1.50
Exercised	—	—
Forfeited	—	—
Expired	—	—
Outstanding, December 31, 2018	<u><u>675,000</u></u>	0.91

The following table discloses information regarding outstanding and exercisable options at December 31, 2018:

	<u>Outstanding</u>			<u>Exercisable</u>	
	<u>Number of Option/Warrant Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Life (Years)</u>	<u>Number of Option Shares</u>	<u>Weighted Average Exercise Price</u>
\$1.50	400,000		9.42	50,004	
\$0.045	275,000		8.89	77,784	
Total	<u><u>675,000</u></u>	\$0.91	9.21	<u><u>127,788</u></u>	\$0.63

As of December 31, 2018, the aggregate intrinsic value of options vested and outstanding was \$97,008. The aggregate fair value of the options measured during the year ended December 31, 2018 and the period from July 27, 2017 through December 31, 2017 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	<u>Year Ended December 31, 2018</u>	<u>Period from July 27, 2017 (inception) through December 31, 2017</u>
Fair value of common stock on measurement date	\$1.50 per share	\$0.045 per share
Risk free interest rate ⁽¹⁾	2.5% to 2.88%	2.33% to 2.48%
Volatility ⁽²⁾	106.4% to 106.9%	107.6% to 107.8%

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, 2018, there are 1,325,000 awards remaining to be issued under the Plan.

Stock Warrants

During 2017, the Company issued 1,206,059 common stock warrants all of which were granted in conjunction with the issuance of the convertible notes payable (see Note 3) and had a fair value at the grant date of \$491. All warrants have an exercise price of \$11.00, an original life of five years and are currently exercisable.

On June 14, 2018, in conjunction with the issuance of a 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.

On December 31, 2018, the Company 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 following table summarizes the stock warrant activity for the year ended December 31, 2018 and the period from July 27, 2017 (inception) through December 31, 2017:

	<u>Warrants</u>	<u>Weighted-Average Exercise Price Per Share</u>
Outstanding, July 27, 2017 (inception)	–	\$ –
Granted	1,206,059	11.00
Exercised	–	
Forfeited	–	
Expired	–	
Outstanding, December 31, 2017	<u>1,206,059</u>	11.00
Granted	2,468,071	0.70
Exercised	–	
Forfeited	–	
Expired	–	
Outstanding, December 31, 2018	<u><u>3,674,130</u></u>	\$ 4.08

The following table discloses information regarding outstanding and exercisable warrants at December 31, 2018:

<u>Exercise Price</u>	<u>Outstanding</u>			<u>Exercisable</u>	
	<u>Number of Option/Warrant Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Life (Years)</u>	<u>Number of Option Shares</u>	<u>Weighted Average Exercise Price</u>
\$11.00	1,206,059		3.64	1,206,059	
\$1.50	14,000		4.45	14,000	
\$0.70	2,454,071		5.00	2,454,071	
Total	<u><u>3,674,130</u></u>	\$4.08	<u><u>4.55</u></u>	<u><u>3,674,130</u></u>	\$4.08

As of December 31, 2018, the aggregate intrinsic value of warrants vested and outstanding was \$1,963,257. The aggregate fair value of the warrants issued measured during the year ended December 31, 2018 and the period from July 27, 2017 through December 31, 2017 were calculated using the Black-Scholes option pricing model based on the following assumptions:

	<u>Year Ended December 31, 2018</u>	<u>Period from July 27, 2017 (inception) through December 31, 2017</u>
Fair value of common stock on measurement date	\$1.50 per share	\$0.001 to 0.045 per share
Risk free interest rate ⁽¹⁾	2.50% - 2.81%	1.13% - 1.22%
Volatility ⁽²⁾	93.0% - 106.2%	91.5% - 91.8%
Dividend yield ⁽³⁾	0%	0%
Expected term (in years)	5	5

- (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.

Other

On April 10, 2018, the Company engaged Boustead Securities, LLC ("Boustead") to act as exclusive financial advisor related to the Company's NASDAQ Initial Public Offering. Boustead will be compensated a success fee of 7% 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 Boustead for expenses. The initial term of the agreement will expire upon the earlier of one year or six months from the final closing of the initial public offering. In addition, an entity related to Boustead is a holder of the Company's outstanding convertible debt as of December 31, 2018.

Note 6 – Income Taxes

The Company is subject to United States federal income taxes at an approximate rate of 35%. 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 (rounded to nearest \$00):

	<u>Year Ended December 31, 2018</u>	<u>From July 27, 2017 (Inception) to December 31, 2017</u>
Income tax benefit computed at the statutory rate	\$ 1,552,300	76,800
Non-deductible expenses	(1,369,000)	(21,000)
Effect of U.S. tax law change ⁽¹⁾	–	(22,300)
Change in valuation allowance	(183,300)	(33,500)
Provision for income taxes	<u>\$ –</u>	<u>–</u>

On December 22, 2017, the Tax Cuts and Jobs Act was signed into law, which among other changes reduces the federal corporate tax rate to 21%. Our U.S. deferred tax assets as of December 31, 2017 were re-measured from 35% to 21%.

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

	As of December 31, 2018	As of December 31, 2017
Deferred income tax assets		
Net operating losses	\$ 216,800	\$ 33,500
Valuation allowance	(216,800)	(33,500)
Net deferred income tax assets	<u>\$ –</u>	<u>\$ –</u>

The Company has an operating loss carry forward of approximately \$1,032,000, 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 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.

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 can be extended by an additional 12 months by the payment of a nominal fee. On December 28, 2018, the agreement with HPI was amended to defer the payment of the extension fee until June 30, 2019.

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”), 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.

Note 8 – Subsequent Events

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. The Company paid \$30,000 for the first six months upon execution of the agreement.