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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 21, 2020

CNS Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**001-39126**	**82-2318545**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

2100 West Loop South, Suite 900
Houston, Texas 77027
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (800) 946-9185

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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

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

Title of each class	Trading Symbols(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	CNSP	The NASDAQ Stock Market LLC

Item 8.01 Other Events.

On December 21, 2020, CNS Pharmaceuticals, Inc. (the "Company"), filed with the Securities and Exchange Commission a Form S-1 registration statement. The prospectus which forms a part of such registration statement contains certain supplemental and revised disclosure regarding the Company's business in the sections entitled "Prospectus Summary" and "Risk Factors". Portions of such sections are attached hereto as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Portions of "Prospectus Summary" and "Risk Factors" section of CNS Pharmaceuticals, Inc.'s Registration Statement on Form S-1 filed December 21, 2020

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 21, 2020

CNS PHARMACEUTICALS, INC.

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

Exhibit 99.1

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus carefully, including the "Risk Factors" section, our historical consolidated financial statements and the notes thereto, each included elsewhere in this prospectus.

Overview

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

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

Berubicin was discovered at MD Anderson by Dr. Waldemar Priebe, the founder of the Company. Through a series of transactions, Berubicin was initially licensed to Reata. Reata conducted a Phase I clinical trial on Berubicin but subsequently allowed their IND with the FDA to lapse for strategic reasons. This required us to obtain a new IND for Berubicin before beginning further clinical trials. On December 17, 2020, we announced that our IND application with the FDA for Berubicin for the treatment of Glioblastoma Multiforme was in effect. We intend to initiate our trial during the first quarter of 2021 to investigate the efficacy of Berubicin in adults with Glioblastoma Multiforme who have failed first-line therapy. Recent correspondence between us and the FDA resulted in modifications to our previously disclosed trial design, including designating overall survival (OS) as the primary endpoint of the study. OS is a rigorous endpoint that the FDA has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.

The planned Phase 2 trial will evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their disease, and results will be compared to the current standard of care, with 2 to 1 randomization of the 243 patients to Berubicin or Lomustine. Subjects receiving Berubicin will be administered a 2-hour IV infusion of 7.5 mg/m2 berubicin hydrochloride daily for three consecutive days followed by 18 days off (21-day cycle). Lomustine is administered orally. The trial will include an interim analysis that will evaluate the comparative effectiveness of these treatments. The trial's adaptive design is intended to allow this interim analysis of the data to demonstrate meaningful differences in efficacy between treatments and then to allow an adjustment to the size of the patient population in the trial for maximum efficiency in terms of time in development. Even if Berubicin is approved, there is no assurance that patients will choose an infusion treatment, as compared to the current standard of care, which requires oral administration.

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

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

On December 28, 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from HPI in an agreement we refer to as the HPI License. HPI is affiliated with Dr. Priebe, who controls a majority of our shares. Under the HPI License we obtained the exclusive right to develop certain chemical compounds for use in the treatment of cancer anywhere in the world. In the HPI License we agreed to pay HPI: (i) development fees of $750,000 over a three-year period beginning November 2019; (ii) a 2% royalty on net sales; (iii) a $50,000 per year license fee; (iv) milestone payments of $100,000 upon the commencement of a Phase II trial and $1.0 million upon the approval of an New Drug Application ("NDA") for Berubicin; and (v) 200,000 shares of our common stock. The patents we licensed from HPI expired in March 2020.

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

With the Reata Agreement and the HPI License, we believe we have obtained all rights and intellectual property necessary to develop Berubicin. As stated earlier, it is our plan to obtain additional intellectual property covering other compounds which, subject to the receipt of additional financing, may be developed into drugs for brain and other cancers.

On January 10, 2020, we entered into a Patent and Technology License Agreement (the "1244 Agreement") with The Board of Regents of The University of Texas System, an agency of the State of Texas, on behalf of the UTMDACC. Pursuant to the 1244 Agreement, we obtained a royalty-bearing, worldwide, exclusive license to certain intellectual property rights, including patent rights, related to our WP1244 drug technology. In consideration, we must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) for sales of licensed products developed under the 1244 Agreement. The term of the 1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the 1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate the 1244 Agreement in the event that we fail to meet certain commercial diligence milestones.

On March 20, 2020, we entered into a Development Agreement with WPD Pharmaceuticals ("WPD") (the "Development Agreement"), a company founded by Dr. Priebe. Pursuant to the Development Agreement, WPD agreed to use its commercially reasonable efforts in good faith to develop and commercialize certain products that WPD had previously sublicensed, solely in the field of pharmaceutical drug products for the treatment of any viral infection in humans, with a goal of eventual approval of in certain territories consisting of: Poland, Estonia, Latvia, Lithuania, Belarus, Ukraine, Romania, Armenia, Azerbaijan, Georgia, Slovakia, Czech Republic, Hungary, Uzbekistan, Kazakhstan, Greece, Austria, Russia, Netherlands, Turkey, Belgium, Switzerland, Sweden, Portugal, Norway, Denmark, Ireland, Finland, Luxembourg, Iceland. Pursuant to the Development Agreement, we agreed to pay WPD the following payments: (i) an upfront payment of $225,000 to WPD (paid in April 2020); and (ii) within thirty days of the verified achievement of the Phase II Milestone, (such verification shall be conducted by an independent third party mutually acceptable to the parties hereto), we will make a payment of $775,000 to WPD. WPD agreed to pay us a development fee of 50% of the net sales for any products in the above territories; provided that Poland shall not be included as a territory after WPD receives marketing approval for a product in one-half of the countries included in the agreed upon territories or upon the payment by WPD to

us of development fees of $1.0 million. The term of the Development Agreement will expire on the expiration of the sublicense pursuant to which WPD has originally sublicensed the products, which will occur upon the expiration of the patents subject to the sublicense agreement, the earliest of which expires in 2024.

On May 7, 2020, pursuant to the WP1244 Portfolio license agreement described above, the Company entered into a Sponsored Research Agreement with UTMDACC to perform research relating to novel anticancer agents targeting CNS malignancies. The Company agreed to fund approximately $1,134,000 over a two-year period. The Company will pay and record $734,000 in 2020 related to this agreement in research and development expenses in the Company's Statements of Operations. The remainder will be paid and recorded in 2021. The principal investigator for this agreement is Dr. Priebe. As of September 30, 2020, the Company has paid $334,000 in research and development expenses to UTMDACC.

On May 1, 2020, the Securities and Exchange Commission ("SEC") announced a temporary suspension of trading in our securities due to statements made by us and others in press releases issued between March 23, 2020 and April 13, 2020 concerning our business, including the status of development of a drug candidate labeled WP1122, the status of testing WP1122's impact on COVID-19, and the ability to expedite regulatory approval of any such treatment. Pursuant to the suspension order, the trading halt was initiated at 9:30 a.m. EDT on May 4, 2020 and terminated at 11:59 p.m. EDT on May 15, 2020. Commencing May 18, 2020, the Nasdaq Stock Market placed a halt on the trading of our common stock pending the receipt of additional information. This halt was lifted on May 28, 2020. We believe in the accuracy and adequacy of our public disclosures, but can provide no assurances that we will not encounter future similar actions, which may adversely affect the holders of our common stock. Since the trading halt was lifted, we have not received any further communication from the SEC or Nasdaq on the foregoing.

On September 15, 2020, we entered into a purchase agreement, and a registration rights agreement, with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase up to $15.0 million worth of our common stock. Under the terms and subject to the conditions of the purchase agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $15.0 million worth of shares of our common stock. Such sales of common stock, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period. As consideration for Lincoln Park's irrevocable commitment to purchase our common stock upon the terms of and subject to satisfaction of the conditions set forth in the purchase agreement, upon execution of the purchase agreement, we issued 201,991 shares of common stock to Lincoln Park as commitment shares.

Risks Relating to Our Business

As a preclinical stage pharmaceutical company, our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our securities. In particular, you should consider the following risks, which are discussed more fully in the section entitled "Risk Factors":

- we will require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations;
- we currently do not have regulatory approval for any drug candidates, in the United States or elsewhere, and although we plan to conduct clinical trials in the United States for Berubicin in the future, there is no assurance that we will be successful in our clinical trials or receive regulatory approval in a timely manner, or at all;
- we intend to commence our Phase 2 clinical trial for Berubicin in the first quarter of 2021, and may encounter unforeseen delays due to the effects of the COVID-19 outbreak, including, without limitation, delays in recruitment for our clinical trials and delays in the production of our drug product;
- we currently do not carry product liability insurance covering any of our drug candidates and, although we intend to obtain product liability insurance for future clinical trial liability that we may incur, there can be no assurance that we will secure adequate coverage or that, even if we do so, any such coverage will be sufficient to prevent the exposure of our operations to significant potential liability in the future;
- the three patents we have licensed from HPI expired in March 2020. Additionally, our products and technologies are complex and any patents we obtain in the future may not be sufficient to protect our products where a series of patents may be needed. Further, we may not have the necessary financial resources to enforce or defend our future patents or patent applications. In addition, any patent applications we may have made or may make relating to inventions for our actual or potential products and technologies may not result in patents being issued or may result in patents that provide insufficient or incomplete coverage for our inventions;
- third parties may claim that the manufacture, use or sale of our technologies infringes their intellectual property rights. As with any litigation where such claims may be asserted, we may have to seek licenses, defend infringement actions or challenge the validity of those patents in the patent office or the courts. If these are not resolved favorably, we may not be able to continue to develop and commercialize our drug candidates. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property. If we are found liable for infringement or are not able to have these patents declared invalid or unenforceable, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or technologies by patents of others. We may not have identified, or be able to identify in the future, U.S. or foreign patents that pose a risk of potential infringement claims;

- Prior to our IPO, we completed related party transactions that were not conducted on an arm's length basis. We acquired our license rights from HPI, and Dr. Waldemar Priebe, our founder and largest shareholder, controls HPI. Since this transaction was not conducted on an arm's length basis, it is possible that the terms were less favorable to us than in an arm's length transaction;
- our chief medical officer and chief science officer are currently working for us on a part time basis. Our chief executive officer, chief medical officer and chief science officer, also provide services for other companies in our industry and such other positions may create conflicts of interest for such officers in the future;
- we have never been profitable, have not generated significant revenue to date and we expect to incur significant additional losses to fund our clinical trials;
- the pharmaceutical industry is subject to significant regulation and oversight in the U.S., in addition to approval of products for sale and marketing;
- our short-to-medium term prospects depend largely on our ability to develop and commercialize one drug candidate, Berubicin, and our ability to generate revenues in the future will depend heavily on the successful development and commercialization of Berubicin;

- we may be subject to delays in our clinical trials, which could result in increased costs and delays or limit our ability to obtain regulatory approval for any drug candidates;

- we have never commercialized any of our drug candidates, including Berubicin, and, even if approved, our drug candidates may not be accepted by healthcare providers or healthcare payors; and

- we may be unable to maintain and protect our intellectual property assets, which could impair the advancement of our pipeline and commercial opportunities.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as the term is used in The Jumpstart Our Business Startups Act of 2012 (JOBS Act), and therefore, we may take advantage of certain exemptions from various public company reporting requirements, including:

- a requirement to only have two years of audited financial statements and only two years of related selected financial data and management's discussion and analysis;

- exemption from the auditor attestation requirement on the effectiveness of our internal controls over financial reporting;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenues, have more than $700.0 million in market value of our capital stock held by non-affiliates or issue more than $1.07 billion of non-convertible debt over a three-year period. We may choose to take advantage of some, but not all, of the available benefits of the JOBS Act. We have taken advantage of some of the reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. In addition, the JOBS Act provides that an emerging growth company can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Company Information

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

RISK FACTORS

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

Risks Related to our Business

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 are using the proceeds from this offering 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;
- any delays in our clinical trials caused by the COVID-19 outbreak;
- whether we are successful in obtaining an accelerated approval pathway with the FDA related to Berubicin;
- the progress, costs, results of and timing of our clinical trials for Berubicin;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;

- our ability to maintain, expand and enforce the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- our need and ability to hire additional management and scientific and medical personnel;

- the effect of competing drug candidates and new product approvals;

- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

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

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

We have completed related party transactions with entities affiliated with our largest shareholder.

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

On March 20, 2020, we entered into a Development Agreement with WPD, a company founded by Dr. Priebe. Pursuant to the Development Agreement, WPD agreed to use its commercially reasonable efforts in good faith to develop and commercialize certain products that WPD had previously sublicensed, solely in the field of pharmaceutical drug products for the treatment of any viral infection in humans, with a goal of eventual approval of in certain territories in Eastern Europe and parts of Asia. Pursuant to the Development Agreement, we agreed to pay WPD the following payments: (i) an upfront payment of $225,000 to WPD (paid in April 2020); and (ii) within thirty days of the verified achievement of the Phase II Milestone, (such verification shall be conducted by an independent third party mutually acceptable to the parties hereto), we will make a payment of $775,000 to WPD. WPD agreed to pay us a development fee of 50% of the net sales for any products in the above territories; provided that Poland shall not be included as a territory after WPD receives marketing approval for a product in one-half of the countries included in the agreed upon territories or upon the payment by WPD to us of development fees of $1.0 million.

Due to the relationship between our company and Dr. Priebe, it is possible that the terms of our agreements with HPI and WPD were less favorable to us than in a transaction negotiated with an unaffiliated third party.

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

We expect to commence our clinical trial for Berubicin in the first quarter of 2021. The COVID-19 outbreak may delay recruitment in our clinical trial and may continue or worsen. In addition, it may delay our ability to have our drug product manufactured. It may also delay the approvals of our product candidate due to its effect on the activities of the FDA, EMA or other health authorities, which could result in delays in meetings related to our planned clinical trials. The spread of COVID-19 may also slow potential enrollment of clinical trials and reduce the number of eligible patients for our clinical trials. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. In addition, certain of our collaborative relationships with facilities and institutions in the United States and Europe may be materially and adversely impacted by protective measures taken by those institutions or federal and state agencies and governing bodies to restrict access to, or suspend operations at, such facilities. Such protective measures, including quarantines, travel restrictions and business shutdowns, may also have a material negative affect on our core operations.

Our licensed U.S. patents expired in March 2020, the expiration of our patents may subject us to increased competition, and the Orphan Drug Designation we received for Berubicin will not bar approval of other similar products under certain circumstances.

The U.S. patents for Berubicin that we licensed from HPI expired in March 2020, and such expiration may subject us to increased competition. On June 10, 2020, the FDA granted Orphan Drug Designation ("ODD") for Berubicin for the treatment of malignant gliomas. ODD from the FDA is available for drugs targeting diseases with less than 200,000 cases per year. ODD may enable market exclusivity of 7 years from the date of approval of a NDA in the United States. During that period the FDA generally could not approve another product containing the same drug for the same designated indication. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. The ODD now constitutes our primary intellectual property protections although we are exploring if there are other patents that could be filed related to Berubicin to extend additional protections. However, we can provide no assurance that we will be able to file or receive additional patent protection. The failure to obtain additional patent protection will reduce the barrier to entry for competition for Berubicin, which may adversely affect our operations.

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

Certain of our key employees are currently part-time and/or provide services for other biotechnology development efforts, including companies, with respect to our

chief executive officer and chief medical officer, which are developing anti-cancer drug candidates. Specifically, John M. Climaco, our chairman and chief executive officer, is also serving as a director for Moleculin Biotech, Inc., a company also actively developing anticancer drugs. Sandra Silberman, our chief medical officer, is the chief medical officer for New Products at Moleculin, and Donald Picker, our chief science officer, is the chief scientific officer at Moleculin. In addition to our officers' part-time status, since Mr. Climaco, Dr. Silberman and Dr. Picker are associated with another company that is developing anti-cancer drug candidates, they may encounter conflicts of interest in the future.

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

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