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): October 21, 2022

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))

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

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. ☐

Item 8.01 Other Events.

On October 21, 2022, 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 section entitled "Prospectus Summary". 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" section of CNS Pharmaceuticals, Inc.'s Registration Statement on Form S-1 filed October 21, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Dated: October 24, 2022

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 securities. You should read this entire prospectus carefully, including the "Risk Factors" section in this prospectus and under similar captions in the documents incorporated by reference into this prospectus. References in this prospectus to "we", "us", "its", "our" or the "Company" are to CNS Pharmaceuticals, Inc., as appropriate to the context.

Overview

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

We believe our lead drug candidate, Berubicin, may be a significant development in the treatment of Glioblastoma Multiforme ("Glioblastoma") and other CNS malignancies, and if approved by the U.S. Food and Drug Administration ("FDA"), could potentially give Glioblastoma patients an important new therapeutic alternative to the current standard of care. Glioblastomas are tumors that arise from astrocytes, which are star-shaped cells making up the supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly, and they are supported by a large network of blood vessels. Berubicin is an anthracycline, which is a class of drugs that are among the most powerful and extensively used chemotherapy drugs known. Based on limited clinical data, we believe Berubicin is the first anthracycline that appears to cross the blood brain barrier in therapeutic concentrations targeting brain cancer cells. While our focus is currently on the development of Berubicin, we are also in the process of attempting to secure intellectual property rights to additional compounds that we plan to develop into drugs to treat CNS and other cancers.

Berubicin was discovered at UTMDACC by Dr. Waldemar Priebe, our founder. Dr. Priebe served as a member of our scientific advisory board until August 2022. Through a series of transactions, Berubicin was initially licensed to Reata. Reata initiated several Phase I clinical trials with Berubicin for CNS malignancies, one of which was for malignant gliomas, but subsequently allowed their IND with the FDA to lapse for strategic reasons. This required us to obtain a new IND for Berubicin before beginning further clinical trials. On December 17, 2020, we announced that our IND application with the FDA for Berubicin for the treatment of Glioblastoma Multiforme was in effect. We initiated this trial for patient enrollment during the second quarter of 2021 with the first patient dosed during the third quarter of 2021 to investigate the efficacy of Berubicin in adults with Glioblastoma Multiforme who have failed first-line therapy. Correspondence between us and the FDA resulted in modifications to our initial trial design, including designating overall survival (OS) as the primary endpoint of our current CNS-201 trial, which is a global potentially pivotal trial of Berubicin for Glioblastoma. OS is a rigorous endpoint that the FDA has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.

The current CNS-201 trial being conducted will evaluate the efficacy of Berubicin in patients with Glioblastoma Multiforme who have failed primary treatment for their disease, and results will be compared to the efficacy of Lomustine, a current standard of care in this setting, with a 2 to 1 randomization of the estimated 243 patients to Berubicin or Lomustine. Patients receiving Berubicin will be administered a 2-hour IV infusion of 7.5 mg/m2 berubicin hydrochloride daily for three consecutive days followed by 18 days off (a 21-day cycle). Lomustine is administered orally once every six weeks. The trial will include an interim analysis that will evaluate the comparative effectiveness of these treatments, which is an adaptive design intended to demonstrate that there are no differences in efficacy between treatments (futility analysis). 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 estimate that the remaining cost of our CNS-201 trial will be approximately $20-$24 million.

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

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

On December 28, 2017, we obtained the rights to a worldwide, exclusive royalty-bearing, license to the chemical compound commonly known as Berubicin from HPI in an agreement we refer to as the HPI License. HPI is affiliated with Dr. Priebe. 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 we are exploring if there are other patents that could be filed related to Berubicin to extend additional protections.

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 portfolio of WP1244 drug technology. In consideration, we must make payments to UTMDACC including an up-front license fee, annual maintenance fee, milestone payments and royalty payments (including minimum annual royalties) for sales of licensed products developed under the 1244 Agreement. The term of the 1244 Agreement expires on the last to occur of: (a) the expiration of all patents subject to the 1244 Agreement, or (b) fifteen years after execution; provided that UTMDACC has the right to terminate the 1244 Agreement in the event that we fail to meet certain commercial diligence milestones.

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

Recent Developments

Nasdaq

On February 18, 2022, we received a deficiency letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") notifying us that for the last 30 consecutive business days the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), we were provided an initial period of 180 calendar days to regain compliance with the Bid Price Rule. We requested an additional 180 days in which to regain compliance, including by effecting a reverse stock split, if necessary, and, on August 18, 2022, we received notice from Nasdaq informing us that we had been granted an additional 180-day period, or until February 13, 2023, to regain compliance with the minimum bid price requirement. If we do not regain compliance with the Bid Price Rule by February 13, 2023, the Staff will provide written notification to us that our common stock will be delisted. We would then be entitled to appeal the Staff's determination to a NASDAQ Hearings Panel and request a hearing.

On August 26, 2022, we announced the results of our 2022 Annual Meeting of Stockholders. At the annual meeting, our stockholders approved an amendment to our amended and restated articles of incorporation to effect a reverse stock split of the outstanding shares of our common stock, at a split ratio of between 1-for-2 and 1-for-30 as determined by our Board of Directors in their sole discretion, prior to the one-year anniversary of the annual meeting.

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.