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 18, 2023

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 7.01. Regulation FD Disclosure.

On December 18, 2023, CNS Pharmaceuticals, Inc. (the "Company") issued a press release announcing the recommendation of the independent Data Safety Monitoring Board that the Company's ongoing global, potentially pivotal trial of the investigational agent, Berubicin for the treatment of glioblastoma multiforme continue without any modification. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 8.01. Other Events.

On December 18, 2023, the Company announced the recommendation of the independent Data Safety Monitoring Board that the Company's ongoing global, potentially pivotal trial of the investigational agent, Berubicin for the treatment of glioblastoma multiforme continue without any modification.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press release dated December 18, 2023
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.

CNS Pharmaceuticals, Inc.

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

Dated: December 18, 2023

Exhibit 99.1

CNS Pharmaceuticals Announces Successful Interim Analysis of Efficacy and Safety Data in Potentially Pivotal Study of Berubicin

Independent DSMB recommends continuing clinical trial of Berubicin without modification

Enrollment expected to be complete in early Q1 2024

HOUSTON, TX (December 18, 2023) – CNS Pharmaceuticals, Inc. (NASDAQ: CNSP) (CNS or the Company), a biopharmaceutical company specializing in the development of novel treatments for primary and metastatic cancers in the brain and central nervous system, today announced the recommendation of the independent Data Safety Monitoring Board (DSMB) that the Company's ongoing global, potentially pivotal trial of the investigational agent, Berubicin for the treatment of glioblastoma multiforme (GBM) continue without any modification. The recommendation follows the DSMB's pre-specified futility analysis of unblinded (to the DSMB only) efficacy and safety data in the Company's trial of Berubicin versus Lomustine, a standard of care in patients with recurrent GBM. More specifically, the DSMB reviewed the primary endpoint of overall survival (OS) and secondary efficacy measures progression-free survival (PFF) and overall response rate (ORR), as well as safety data in evaluable patients. In order to support continuing the trial, Berubicin's efficacy had to be at least comparable to Lomustine's on the primary endpoint (OS).

"Having successfully reached this milestone, we believe that this recommendation reflects Berubicin's acceptable efficacy and safety profile, as defined in the trial protocol, as of the interim analysis. Building on the foundation of strong enrollment laid by our team, our investigators and their patients, the independent findings of the DSMB add to the Phase 1 trial data, where 44% of treated patients received a clinical benefit of stable disease or better," said John Climaco, CEO of CNS Pharma. "Finding an effective treatment for GBM remains one of the great challenges in oncology, and more meaningful options for the many patients who fail first-line therapy are still desperately needed after decades of research. With this recommendation to continue the study, our long-held belief that Berubicin will ultimately address the unmet clinical need of GBM patients now moves closer to becoming reality."

The potentially pivotal study of Berubicin is a multicenter, open-label, randomized controlled study in adult patients with recurrent GBM (WHO Grade IV) after failure of standard first-line therapy and compared to Lomustine. Overall Survival is a rigorous endpoint that the FDA has recognized as the basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.

For more information about this trial, visit clinicaltrials.gov and reference identifier NCT04762069.

The FDA has granted CNS Pharmaceuticals Fast Track Designation for Berubicin, which enables more frequent interactions with the agency for guidance on expediting the development and review process. Additionally, the Company has received Orphan Drug Designation from the FDA for using Berubicin to treat malignant glioma, which may provide seven years of marketing exclusivity upon approval of a New Drug Application (NDA).

About Berubicin

Berubicin is an anthracycline, a class of anticancer agents that are among the most powerful chemotherapy drugs and effective against more types of cancer than any other class of chemotherapeutic agents. Anthracyclines are designed to utilize natural processes to induce deoxyribonucleic acid (DNA) damage in targeted cancer cells by interfering with the action of topoisomerase II, a critical enzyme enabling cell proliferation. Berubicin treatment of brain cancer patients appeared to demonstrate positive responses that include one durable complete response in a Phase 1 human clinical trial conducted by Reata Pharmaceuticals, Inc. Berubicin was developed by Dr. Waldemar Priebe, Professor of Medicinal Chemistry at The University of Texas MD Anderson Cancer Center.

About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals is a clinical-stage pharmaceutical company developing a pipeline of anti-cancer drug candidates for the treatment of primary and metastatic cancers of the brain and central nervous system. The Company's lead drug candidate, Berubicin, is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier. Berubicin is currently in development for the treatment of a number of serious brain and CNS oncology indications including glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer.

For more information, please visit www.CNSPharma.com, and connect with the Company on Twitter, Facebook, and LinkedIn.

Forward-Looking Statements

Some of the statements in this press release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the Company's timing of the final analysis, the ability to complete enrollment and the timing thereof, and the ability to commercialize the product even if the trial is successful. These statements relate to future events, future expectations, plans and prospects. Although CNS believes the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. CNS has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including those discussed under Item 1A. "Risk Factors" in CNS's most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in its Form 10-Q filings and in its other public filings with the SEC. Any forward-looking statements contained in this press release speak only as of its date. CNS undertakes no obligation to update any forward-looking statements contained in this press release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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