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): May 16, 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))

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 2.02 Results of Operations and Financial Condition.

On May 16, 2022, CNS Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the period ended March 31, 2022 and recent operational highlights. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	**Exhibit Description**
99.1	Press release dated May 16, 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.

CNS Pharmaceuticals, Inc.

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

Dated: May 16, 2022

Exhibit 99.1

CNS Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update

Recent approvals of Potentially Pivotal Berubicin Study into Switzerland, France, and Spain expected to significantly drive patient enrollment

Opportunities for Berubicin to be used in additional oncology indications with significant unmet needs

HOUSTON, TX (May 16, 2022) – 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 reported its financial results for the quarter ended March 31, 2022 and provided a clinical update of its anti-cancer drug candidates currently in development for the treatment of primary and metastatic brain and CNS cancer.

"Since the start of 2022, we have significantly expanded our international presence with clinical approvals in Spain, France and Switzerland received for our potentially pivotal study of Berubicin for the treatment of GBM. Once again our team demonstrated its operational, clinical and regulatory expertise this quarter. These efforts enable us to continue building momentum with patient enrollment – the cornerstone of any successful drug development program. The unmet need in GBM is enormous and knows no geographic borders and this critically important and state of the art trial will, most importantly, advance a much needed potential treatment option to patients. We have been and remain laser focused on executing on all of our operational efforts and look forward to an exciting year ahead," commented John Climaco, CEO of CNS Pharmaceuticals.

Clinical Programs Update

Berubicin – Novel anthracycline

CNS' lead product candidate, Berubicin, is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier. Berubicin is currently being evaluated in a potentially pivotal global study evaluating its efficacy and safety in the treatment of GBM. The potentially pivotal global trial is an adaptive, multicenter, open-label, randomized and controlled study in adult patients with recurrent glioblastoma multiforme (WHO Grade IV) after failure of standard first-line therapy. Approximately 243 patients with GBM after failure of standard first line therapy will be randomized in a 2:1 ratio to receive Berubicin or lomustine for the evaluation of Overall Survival, the primary endpoint of the study. Overall Survival is a rigorous endpoint that the U.S. Food and Drug Administration (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.

A pre-planned, non-binding futility analysis will be performed after approximately 30 to 50% of all planned patients have completed the primary endpoint at 6 months. This review will include additional evaluation of safety as well as secondary efficacy endpoints. Enrollment will not be paused during this interim analysis.

The FDA recently granted CNS Pharmaceuticals Fast Track Designation for Berubicin which enables more frequent interactions with the FDA to expedite the development and review process. As previously announced, the Company also received Orphan Drug Designation from the FDA which may provide seven years of marketing exclusivity upon approval of an NDA.

For more information about the potentially pivotal Berubicin trial, visit clinicaltrials.gov and reference identifier NCT04762069.

Upcoming Milestones

- Continue to expand potentially pivotal study to evaluate efficacy of Berubicin in the treatment of adult GBM into additional countries;
- Interim analysis of the trial when 30-50% of the total expected patients have been on study for 6 months (expected during first half of 2023); and
- Complete enrollment in potentially pivotal clinical trial for GBM.

WP1244 Portfolio - Novel class of DNA-binding agents

The Company continues to advance the development of its WP1244 drug technology portfolio, which utilizes anthracycline and distamycin-based scaffolds to create small molecule agents and is believed to be 500x more potent than daunorubicin in inhibiting tumor cell proliferation. Preclinical studies of WP1244 demonstrated high uptake in the brain with antitumor activity. The Company's development work has produced a new mesylate salt of WP1244, now identified as WP1874. 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. Going forward, WP1874 will be the primary focus in our development efforts of the WP1244 portfolio. CNS Pharmaceuticals is also evaluating the use of WP1244/WP1874 in the treatment of other primary brain and central nervous system cancers, as well as cancers metastatic to the brain including pancreatic, ovarian, and lymphomas.

Upcoming Milestones

- File IND in 2023.

Summary of Financial Results for the First Quarter 2022

The net loss for the three months ended March 31, 2022 was approximately $2.8 million compared to approximately $3.6 million for the comparable period in 2021. The change in net loss is primarily attributable to increased drug manufacturing activities in 2021 in preparation for the commencement of the Company's clinical trials as well as the timing of annual employee incentive compensation, partially offset by an increase in contract research organization expenses as we are now actively conducting the trial of Berubicin.

The Company reported Research and development expenses of $1.5 million for the three months ended March 31, 2022 compared to approximately $2.2 million for the comparable period in 2021. The change in net loss is primarily attributable to increased drug manufacturing activities in 2021 in preparation for the commencement of the Company's clinical trials, as well as by the payment of annual employee incentive compensation during the three months ended March 31, 2021 and not having been paid by March 31, 2022, offset by an increase in expenses during the three months ended March 31, 2022 related to contract research organization (CRO) activites in conducting our trial of Berubicin.

General and administrative expense was approximately $1.3 million for the three months ended March 31, 2022 compared to approximately $1.4 million for the comparable period in 2021. This change is primarily due to the payment of annual employee incentive compensation during the three months ended March 31, 2021 and not having been paid by March 31, 2022.

As of March 31, 2022, the Company had cash of approximately $12.4 million and working capital of approximately $13.7 million. In early January 2022, the Company completed an offering of common stock and warrants for gross proceeds of $11.5 million. The Company’s current expectation is that the cash on hand and the proceeds from the offering during January is sufficient to fund our operations into the first quarter of 2023. The timing and costs of clinical trials are difficult to predict and trial plans may change in response to evolving circumstances and as such the foregoing estimates may prove to be inaccurate.

About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals 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.

Additionally, the Company is advancing the development of its WP1244 drug technology portfolio, which utilizes anthracycline and distamycin-based scaffolds to create small molecule agents and is believed to be 500x more potent than daunorubicin in inhibiting tumor cell proliferation. Preclinical studies of WP1244 demonstrated high uptake in the brain with antitumor activity. CNS Pharmaceuticals is evaluating the use of the WP1244 portfolio in the treatment of brain cancers, pancreatic, ovarian, and lymphomas.

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. 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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