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): June 11, 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 June 11, 2020, CNS Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for its lead product Berubicin for the treatment of malignant gliomas. 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 June 11, 2020

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: June 11, 2020

Exhibit 99.1

CNS Announces the FDA has Granted Orphan Drug Designation for Brain Cancer Drug Berubicin

HOUSTON, June 11, 2020 /PRNewswire/ -- CNS Pharmaceuticals, Inc., (Nasdaq: CNSP) ("CNS" or the "Company"), a biopharmaceutical company specializing in the development of novel treatments for primary and metastatic cancers of the brain and central nervous system, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for its lead product Berubicin for the treatment of malignant gliomas.

"We are pleased to receive Orphan Drug Designation for Berubicin, our lead candidate. The designation provides Berubicin with a special status that can accelerate its development to treat malignant gliomas, and provides CNS with the potential for market exclusivity upon the drug's approval," stated John Climaco, CEO of CNS Pharmaceuticals. "In the Phase 1 trial of Berubicin to treat glioblastoma, one of the world's most aggressive cancers, under a prior developer, 44% of the patients demonstrated a significant improvement in progression free survival, and one patient experienced a complete response. We look forward to continuing to execute on our strategic plan and initiating a Phase II trial evaluating the effect of Berubicin on patients with glioblastoma later this year."

Chief Medical Officer of CNS, Dr. Sandra Silberman, stated, "We are excited to continue to drive the development of Berubicin and work towards addressing a critical unmet medical need. Glioblastoma currently has a dismal survival rate of only 14.6 months from its diagnosis. We believe Berubicin, which based on limited clinical data appears to be the first anthracycline to cross over the blood brain barrier in adults, provides a potentially novel therapy for the treatment of malignant gliomas."

The FDA grants Orphan Drug Designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. Due to small patient numbers, treatment for these rare diseases would not be considered economically feasible without government programs to support their economic viability. Orphan drug status is intended to facilitate drug development for rare diseases and may provide several benefits to drug developers, including tax credits for qualified clinical trials costs, exemptions from certain FDA application fees, and seven years of market exclusivity upon regulatory product approval.

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.

About CNS Pharmaceuticals, Inc.

CNS Pharmaceuticals is developing novel treatments for primary and metastatic cancers of the brain and central nervous system. Its lead drug candidate, Berubicin, is proposed for the treatment of GBM, an aggressive and incurable form of brain cancer. CNS holds a worldwide exclusive license to the Berubicin chemical compound and has acquired all data and know-how from Reata Pharmaceuticals related to a completed Phase 1 trial with Berubicin in GBM which Reata conducted in 2006. In this trial, 44% of patients experienced a statistically significant improvement in progression-free survival. This 44% disease control rate was based on 11 patients (out of 25 evaluable patients) with stable disease, plus responders. One patient experienced a durable complete response and remains cancer-free as of February 20, 2020. In the second half of 2020, CNS expects to commence a Phase 2 clinical trial of Berubicin for the treatment of GBM in the U.S., while a sub-licensee partner undertakes a Phase 2 trial in adults and a first-ever Phase 1 trial in pediatric GBM patients in Poland. Its second drug candidate, WP1244, is a novel DNA binding agent that has been shown in preclinical studies to be 500-times more potent than the chemotherapeutic agent daunorubicin in inhibiting tumor cell proliferation. For more information, please visit www.cnspharma.com.

Forward-Looking Statements

Some of the statements in this 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 include, without limitation, the Company's ability to initiate a Phase II trial evaluating the effect of Berubicin on patients with glioblastoma later this year. These statements relate to future events, future expectations, plans and prospects. Although CNS believes that 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 in our SEC filings, including under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. CNS undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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