

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): August 13, 2021

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

Nevada
(State or other jurisdiction of
incorporation or organization)

001-39126
(Commission File Number)

82-2318545
(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 August 13, 2021, CNS Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021 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 August 13, 2021](#)
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: August 13, 2021



CNS Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Business Outlook

Recently granted FDA Fast Track Designation for Berubicin for treatment of recurrent Glioblastoma Multiforme (GBM) provides an accelerated pathway to potential approval and commercialization

Potentially pivotal study for lead program evaluating Berubicin in the treatment of adult GBM is on track

Platform opportunities for expansion into additional oncology indications with significant unmet needs

HOUSTON, TX (August 13, 2021) – **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 (CNS), today reported its financial results for the quarter ended June 30, 2021. Additionally, the Company provided a clinical update of its anti-cancer drug candidates currently in development for the treatment of primary and metastatic brain and CNS cancer.

Recent Highlights

- Commenced patient enrollment in potentially pivotal US-based trial evaluating the efficacy and safety of Berubicin in the treatment of recurrent GBM;
- Granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for lead investigational drug candidate, Berubicin, for the treatment of patients with recurrent GBM; and

"Over the course of the second quarter, our team continued to execute on corporate, clinical and regulatory strategies to drive our Berubicin program toward regulatory approval as fast as possible. We are guided by our passion to answer one of the most devastating unmet clinical needs in medicine: unbelievably, patients suffering today from recurrent GBM still cannot turn to a single approved treatment anywhere in the world for hope. Simply put, this must change and we are the company to change it. With the FDA's recent award of Fast Track Designation for our lead program, we believe we are poised to finally bring a desperately-needed treatment to GBM patients potentially through this accelerated pathway. Building on a foundation of sixty years of successful anthracycline use against numerous deadly cancers as well as powerful data from our Phase I study of Berubicin, the only anthracycline which appears to cross the blood brain barrier in adults, we whole heartedly believe in its potential to transform the current treatment landscape and the lives of patients," commented John Climaco, CEO of CNS Pharmaceuticals. "After a quarter of amazing progress we are well positioned for even more significant advancements of our development programs which we expect will continue to drive shareholder value in the near and long term."

Clinical Programs Update

Berubicin – Novel anthracycline

CNS' lead product candidate, Berubicin, is a novel anthracycline and the first drug of its kind which appears to cross the blood-brain barrier. Berubicin is currently in development for the treatment of a number of serious brain and CNS oncology indications. The Company recently announced the commencement of its potentially pivotal US-based study evaluating the efficacy of Berubicin in the treatment of adult GBM, one of the most aggressive types of brain cancer. Patient dosing is expected to commence in the third quarter of 2021.

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. Taken together we believe these important designations can be seen as a recognition of the significance of not only the unmet clinical need in GBM, but of our Berubicin program.

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

Berubicin Upcoming Milestones

Berubicin Development in the U.S.

- Commence patient dosing in potentially pivotal study to evaluate efficacy of Berubicin in the treatment of adult GBM in Q3 2021.

Berubicin Development in the EU with Sublicensee Partner

- Initiate Phase 2 multicenter clinical trial of Berubicin in adults with GBM in the second half of 2021;
- Initiate Phase 1 pediatric study in the second half of 2021; and
- Interim analysis of the first 18 patients in adult Phase 2 study expected in 2022.

WP1244 Portfolio - Novel class of DNA-binding agents

The Company continues to advance the development of its WP1244 drug technology, 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 WP1244 in the treatment of brain cancers, pancreatic, ovarian, and lymphomas.

WP1244 Upcoming Milestones

- File IND in 2022.

Summary of Financial Results for Second Quarter 2021

The net loss for the six months ended June 30, 2021 was approximately \$3.8 million compared to approximately \$2.4 million for the comparable period in 2020. The change in net loss is attributable to increased personnel and activity associated with preparing for the Company's clinical trials in 2021. The Company reported research and development expenses of \$4.8 million for the six months ended June 30, 2021 compared to approximately \$2.1 million for the comparable period in 2020. The expenses incurred during the period were related to drug manufacturing and labor related to the preparation of the Company's Phase 2 study. General and administrative expense was approximately \$2.5

million for the six months ended June 30, 2021 compared to approximately \$2.3 million for the comparable period in 2020.

As of June 30, 2021, the Company had cash and subscription receivable (fully collected on July 1, 2021) of approximately \$10.5 million and working capital of approximately \$12.1 million. Our current expectation is that our cash on hand (including the subscription receivable collected in full on July 1, 2021) is sufficient to fund our operations into the second quarter of 2022. 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, 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 WP1244 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. Forward-looking statements in this press release include, without limitation, the ability of the Company's cash runway to extend until Q2 2022 and the timing of patient dosing to commence. 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.

CONTACTS:

Investor Relations Contact

JTC Team, LLC
Jenene Thomas
833-475-8247
CNSP@jtcir.com