

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 14, 2023

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))

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 2.02 Results of Operations and Financial Condition.

On August 14, 2023, CNS Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the period ended June 30, 2023 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.	Description
99.1	Press Release dated August 14, 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: August 14, 2023



CNS Pharmaceuticals Reports Second Quarter 2023 Financial Results and Reiterates Upcoming Milestones

Continued rapid pace of enrollment with ~75% of expected patients now enrolled in ongoing potentially pivotal study evaluating Berubicin for the treatment of GBM

Topline data from interim analysis from ongoing Berubicin potentially pivotal study on track before year end

HOUSTON, TX (August 14, 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 reported its financial results for the quarter ended June 30, 2023, provided a corporate update and reiterates upcoming milestones.

“We are approaching the most important milestone to date since we launched CNS Pharma. We are just a few months away from reporting topline results from our Berubicin potentially pivotal study interim analysis and, although we do not know what the data looks like at this time, we remain hopeful as we also approach full enrollment of the trial,” commented John Climaco, CEO of CNS Pharmaceuticals. “Looking ahead, we remain focused on executing on all of our operational efforts and importantly, taking our Berubicin trial for GBM across the finish line. We are poised for an exciting remainder of the year with significant milestones anticipated in the near term and look forward to optimizing our opportunities to build value for all shareholders in the near and long-term.”

Recent Clinical Achievements

- Presented updated results from the on-going potentially pivotal study evaluating Berubicin in a poster presentation at the 2023 SNO/ASCO CNS Cancer Conference.
- Announced enrollment of 180 patients; The Company has opened 46 clinical trial sites of the 60 sites selected across the U.S., Italy, France, Spain, and Switzerland.
- Announced that the Company has reached the criteria required by the study protocol to conduct a pre-planned, non-binding futility analysis, which an independent Data Safety Monitoring Board will review to determine whether to recommend continuing the study as planned based on Berubicin showing potential value as a second-line treatment for patients with glioblastoma (GBM).
- Pace of enrollment is rapidly accelerating with the first 75 patients taking 18 months to enroll while the second 75 patients took less than 6 months to enroll.

Recent Corporate Achievements

- Completed the initial phase of investigation with Shareholder Intelligence Services, LLC into potential naked short selling. As part of the investigation, the Company believes it was able to identify and eliminate the majority of the reported naked short selling activity, although there is no assurance the Company’s common stock will not experience such pressure in the future. The investigation is moving into its second phase of monitoring and taking further actions to continue to reduce the level of naked short selling.

Upcoming Expected Milestones for Potentially Pivotal Trial of Berubicin for GBM, in the order expected:

- Achieve enrollment of 200th patient in Q3 2023.
- Report topline results of interim analysis expected in Q4 2023.
- Complete enrollment in Q4 2023.

Summary of Financial Results for the Second Quarter 2023

The net loss for the three months ended June 30, 2023 was approximately \$4.0 million compared to approximately \$3.6 million for the comparable period in 2022. The change in net loss is attributable to an increase in research organization (CRO) expenses related to continued progress with the Company's clinical trial, a credit to research and development expense in the prior year period for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, as well as increases in legal and professional fees and other expenses.

The Company reported research and development expenses of \$2.8 million for the three months ended June 30, 2023 compared to approximately \$2.2 million for the comparable period in 2022. The increase in research and development expenses during the period were mainly attributed to the timing of CRO expenses related to continued progress with the Company's clinical trial.

General and administrative expense was approximately \$1.2 million for the three months ended June 30, 2023 compared to approximately \$1.3 million for the comparable period in 2022. The decrease in general and administrative expense was mainly attributable to decreases of approximately \$176,000 for employee compensation and taxes, \$100,000 in legal and professional expenses, \$22,000 in insurance expenses and \$12,000 in other expenses, which were offset by increases of approximately \$60,000 in marketing and advertising, \$24,000 in board compensation and \$39,000 in travel expenses.

As of June 30, 2023, the Company had cash of approximately \$4.3 million and working capital of approximately \$2.1 million. The Company's current expectation is that the cash on hand is sufficient to fund operations into the fourth quarter of 2023, through the topline data readout for the Berubicin potentially pivotal study. The timing and costs of clinical trials are difficult to predict and trial plans and timing of milestones may change in response to evolving circumstances and as such the foregoing estimates may prove to be inaccurate.

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 interim analysis to occur in the fourth quarter of 2023, the ability to continue to open additional clinical trial sites on a timely basis, and the Company's projected cash runway. 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