

November 15, 2023



CNS Pharmaceuticals Reports Third Quarter 2023 Financial Results and Reiterates Company is on Track to Achieve Milestones for Berubicin Potentially Pivotal Study Before Year End

- *Enrollment numbers rise to 239 in ongoing potentially pivotal study of Berubicin for treatment of GBM; Expected full enrollment in December 2023*
- *Topline data from preplanned interim analysis from ongoing Berubicin potentially pivotal study expected in December 2023*
- *Raised \$2.6 million subsequent to quarter-end*

HOUSTON, TX / ACCESSWIRE / November 15, 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 September 30, 2023 and reiterated upcoming milestones.

"Over the course of 2023, we have demonstrated solid execution and rapid progression of enrollment in our ongoing potentially pivotal study of Berubicin. We are preparing for the most significant milestones for patients, the Company and our stockholders in just a few short weeks, with interim data expected in December 2023," commented John Climaco, CEO of CNS Pharmaceuticals. "With topline data from our interim analysis expected in the coming weeks, we are poised to determine whether or not the independent Data Safety Monitoring Board recommends continuing the study. We are hopeful that by the end of this study Berubicin will ultimately demonstrate life-saving value as a second-line treatment for patients with recurrent glioblastoma. We look forward to an exciting remainder of the year and building value for all stakeholders in the near and long-term."

Recent Clinical Achievements

- Achieved enrollment of 239 patients; The Company has opened 45 clinical trial sites of the 60 sites selected across the U.S., Italy, France, Spain, and Switzerland.
- [Presented updated results](#) from ongoing potentially pivotal study of Berubicin in adult patients with recurrent GBM after failure of standard first line therapy at the 2023 SNO/ASCO CNS Cancer Conference.

Upcoming Expected Milestones

- Report topline results of interim analysis expected in December 2023. Enrollment will continue during the interim analysis.
- Complete enrollment in December 2023.

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, which may provide seven years of marketing exclusivity upon approval of an NDA.

Summary of Financial Results for the Third Quarter 2023

The net loss for the three months ended September 30, 2023 was approximately \$4.5 million compared to approximately \$3.4 million for the comparable period in 2022. The change in net loss is attributable to an increase in research organization (CRO) expenses and patient treatment costs related to continued progress with the Company's clinical trial for Berubicin, 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 \$3.4 million for the three months ended September 30, 2023 compared to approximately \$2.2 million for the comparable period in 2022. The increase in research and development expenses during the period was mainly attributed to increasing enrollment and the timing of CRO expenses related to continued progress with the Company's clinical trial for Berubicin.

General and administrative expense was approximately \$1.1 million for the three months ended September 30, 2023 compared to approximately \$1.2 million for the comparable period in 2022.

As of September 30, 2023, the Company had cash of approximately \$0.9 million. In addition, in October 2023, the Company raised an additional \$2.6 million in a warrant inducement transaction and placements on the ATM facility. The Company's current expectation is that the cash on hand and cash raised in October is sufficient to fund our operations through the end of the fourth 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 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 December 2023, the ability to continue to open additional clinical trial sites on a timely basis, and the Company's expected cash runway into, but not beyond, the first quarter of 2024. 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

SOURCE: CNS Pharmaceuticals, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/803418/cns-pharmaceuticals-reports-third-quarter-2023-financial-results-and-reiterates-company-is-on-track-to-achieve-milestones-for-berubicin-potentially-pivotal-study-before-year-end>