

April 1, 2024



# CNS Pharmaceuticals Reports Full Year 2023 Financial Results and Highlights Recent Corporate and Clinical Achievements

***Lead program, Berubicin, successfully passed pre-planned interim futility analysis milestone with recommendation from DSMB to proceed without modification in potentially pivotal GBM study***

***Berubicin study enrollment completed; Topline data expected in first half of 2025***

***Clinical progress represents important steps towards Berubicin potentially addressing the most aggressive type of brain cancer with an average survival of only 14 to 16 months after diagnosis and no cure***

**HOUSTON, TX / ACCESSWIRE / April 1, 2024 [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 full year ended December 31, 2023 and outlined recent corporate and clinical development highlights.**

John Climaco, CEO of CNS Pharmaceuticals, stated, "There remains a tremendous unmet medical need for an effective treatment for GBM, and we are dedicated to advancing this important program forward to bring much needed hope for patients. Over the course of 2023 we made significant progress with our lead development program, Berubicin, having recently achieved four primary objectives toward which we were actively working: maintain a rapid pace of enrollment to reach our pre-planned interim analysis; complete planned enrollment; bolster buy-in from investigators; and expand our board indicating a strong support system from industry leaders."

"In addition to reaching complete enrollment we have also successfully completed the interim futility analysis and received a recommendation from the independent Data Safety Monitoring Board (DSMB) to continue the study without modification, which we believe is a monumental step towards our objective of seeing Berubicin approved. Additionally, we have added noteworthy members to our Board who have the knowledge and expertise to help drive our efforts forward. With these achievements behind us, we are closer to fulfilling our mission and promise to patients and shareholders to bring Berubicin across the finish line towards approval," concluded Mr. Climaco.

## **Recent Achievements**

- Closed a public offering for gross proceeds of \$4.0 million;
- Appointed biotech commercialization leader Amy Mahery to the Company's Board of Directors;
- Announced successful outcome to the pre-planned interim futility analysis of efficacy and safety in the Company's ongoing global, potentially pivotal trial of Berubicin for the treatment of GBM; and
- Reached full enrollment in study of Berubicin for the treatment of GBM.

### **Berubicin Clinical Development Progress**

The trial design of our potentially pivotal trial of Berubicin included a pre-planned, non-binding interim futility analysis. The Company reached the criteria required by the study protocol to conduct this interim futility analysis, which an independent DSMB is responsible for conducting. The DSMB's charter mandated that they review the primary endpoint, Overall Survival, as well as secondary endpoints and safety data to determine whether the efficacy data for the risk-benefit profile warrants modification or discontinuation of the study. On December 18, 2023, the Company released the DSMB's recommendation which was to continue the study without modification. Management remains blinded to the data underlying the recommendation of the DSMB.

The Company expects to report topline data from its study of Berubicin in the first half of 2025, although it is impossible to accurately predict how long patients on the study may survive, which could impact the timing of the release of topline data.

For more information about Berubicin clinical trial, visit [clinicaltrials.gov](https://clinicaltrials.gov) and reference identifier NCT04762069.

### **Summary of Financial Results for the Full Year 2023**

The net loss for the year ended December 31, 2023 was approximately \$18.9 million compared to approximately \$15.3 million for the comparable period in 2022. The change in net loss is primarily attributable to increased research and development costs.

The Company reported research and development expenses of \$14.1 million for the year ended December 31, 2023 compared to approximately \$9.3 million for the comparable period in 2022. The increase in research and development expenses during the period were mainly attributed to the timing of research organization (CRO) expenses and patient treatment costs related to continued progress with our clinical trial for Berubicin.

General and administrative expenses were approximately \$4.8 million for the year ended December 31, 2023 compared to approximately \$6.0 million for the comparable period in 2022. This change is primarily attributable to a decrease of approximately \$792,000 in professional expenses, \$488,000 in employee compensation, \$141,000 in stock-based compensation and \$92,000 in insurance expenses. These changes were offset by increases of approximately \$145,000 in travel expenses, board of director compensation of \$96,000, advertising and marketing of \$68,000 and other general and administrative expenses of \$7,000.

As of December 31, 2023, the Company had cash of approximately \$0.5 million. Subsequent to the end of 2023, the Company closed a \$4.0 million public offering with participation from healthcare-focused institutional investors, retail investors, and certain officers and directors of the Company. Management anticipates that its cash on hand as of

December 31, 2023, combined with capital raised subsequent to December 31, 2023, is sufficient to fund its planned operations into but not beyond the latter half of the second quarter of 2024.

### **About Berubicin**

Berubicin is the Company's novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier, for the treatment of GBM, an aggressive and incurable form of brain cancer.

Berubicin is currently being evaluated in a potentially pivotal, multicenter, open-label, randomized controlled study in adult patients with recurrent GBM (WHO Grade IV) after failure of standard first-line therapy and compared to Lomustine. The study has enrolled 252 patients across 46 clinical trial sites in the U.S., Italy, France, Spain, and Switzerland. The primary endpoint of the study is Overall Survival (OS), a rigorous endpoint the FDA has recognized as the basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm.

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.

### **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](http://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 include, without limitation, the Company's timing of release of final data from the Berubicin trial expected to occur in the first half of 2025, the ability to continue to fund the trial to completion and release of final data, and the ability to obtain FDA marketing approval for Berubicin. 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 market and other conditions and 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, except as required by law.

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**SOURCE:** CNS Pharmaceuticals, Inc.

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