August 15, 2022

CNS Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Corporate Update

Continued execution on clinical operations for potentially pivotal global trial evaluating Berubicin for the treatment of Glioblastoma Multiforme ("GBM")

Enrollment progressing with 23 clinical trial sites open to-date of the 54 sites selected across the U.S., Italy, France, Spain, and Switzerland, and European enrollment expected imminently

HOUSTON, Aug. 15, 2022 /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 in the brain and central nervous system, today reported its financial results for the quarter ended June 30, 2022 and provided a clinical update of its anti-cancer drug candidates currently in development for the treatment of primary and metastatic brain and CNS cancer.

"Within the past 6 months alone, we have executed on a number of clinical and operational advancements including expanding our global presence with clinical approvals in Spain, France and Switzerland to drive patient enrollment forward, as well as expanding eligibility for patients to participate in our potentially pivotal study of Berubicin for the treatment of GBM with our recently amended protocol, which was approved by the FDA, Swissmedic, National Agency for the Safety of Medicine and Health Products (ANSM) Competent Authority and corresponding European ethics committees. Our focus and priorities remain on advancing our clinical development program for Berubicin to ultimately bring a meaningful treatment to GBM patients, families and clinicians, who currently have extremely limited and often ineffective treatment options," commented John Climaco, CEO of CNS Pharmaceuticals.

Clinical Programs Update

Berubicin – Novel anthracycline

CNS' lead product candidate, Berubicin, is a novel anthracycline and the first anthracycline to appear to cross the blood-brain barrier. Berubicin is currently being evaluated in a potentially pivotal global study evaluating its efficacy and safety in the treatment of GBM. The potentially pivotal trial is an adaptive, multicenter, open-label, randomized and controlled study in adult patients with recurrent glioblastoma multiforme (WHO Grade IV[1]) after failure of standard first-line therapy. The primary endpoint of the study is Overall Survival (OS), which is a rigorous endpoint that the FDA has recognized as a basis for approval of oncology drugs when a statistically significant improvement can be shown relative to a randomized control arm. Results from the trial will compare Berubicin to a current standard of care (Lomustine), with a 2 to 1 randomization of patients to receive either Berubicin or Lomustine. The recently amended protocol expands eligibility for the study to patients who have received additional treatments as part of the first line therapy for their disease considering advancements in this area. This change was made due to the complexity of new agents introduced as a component of first line therapy, which allows an additional group of patients that can enroll on the study after what may constitute multiple procedures as their initial treatment.

A pre-planned, non-binding futility analysis will be performed after approximately 30 to 50% of all planned patients have completed the primary endpoint at 6 months. This review will include additional evaluation of safety as well as secondary efficacy endpoints. Enrollment will not be paused during this interim analysis.

The FDA previously 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.

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

Upcoming Milestones

- Continued site initiations across the U.S., Italy, France, Spain, and Switzerland for potentially pivotal study to evaluate efficacy of Berubicin in the treatment of adult GBM;
- Regulatory and ethics approval in Italy;
- Commencement of patient enrollment across European clinical sites;
- Interim analysis of the trial when 30-50% of the total expected patients have been on study for 6 months (expected mid-year 2023); and
- Complete enrollment in potentially pivotal clinical trial for GBM.

WP1244 Portfolio - Novel class of DNA-binding agents

The Company continues to advance the development of its WP1244 drug technology portfolio, 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. The Company's development work has produced a new mesylate salt of WP1244, now identified as WP1874. The enhanced solubility of this salt may increase its ability to be formulated for use in an IV infusion, while maintaining similar potency and toxicity characteristics. Going forward, WP1874 will be the primary focus in our development efforts of the WP1244 portfolio. CNS Pharmaceuticals is also evaluating the use of WP1244/WP1874 in the treatment of other primary brain and central nervous system cancers, as well as cancers metastatic to the brain including pancreatic, ovarian, and lymphomas.

Upcoming Milestones

- File IND in 2023.

Summary of Financial Results for the Second Quarter 2022

The net loss for the three months ended June 30, 2022 was approximately $3.6 million compared to approximately $3.8 million for the comparable period in 2021. The change in net loss is attributable to decreases in the timing of drug development expenses (significant manufacturing activity occurred in the prior year period with much less occurring in the current year), as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in contract research organization (CRO) expenses related to continued progress with our Phase 2 clinical trial as well as increases in legal and professional fees and other expenses.

The Company reported research and development expenses of $2.2 million for the three months ended June 30, 2022 compared to approximately $2.7 million for the comparable period in 2021. The decrease in research and development expenses during the period were mainly attributed to the timing of drug development expenses, as well as a credit to research and development expense for the funds collected from WPD Pharmaceuticals related to their purchase of Berubicin drug product for their clinical trials, partially offset by an increase in CRO expenses related to continued progress with our Phase 2 clinical trial.

General and administrative expense was approximately $1.3 million for the three months ended June 30, 2022 compared to approximately $1.1 million for the comparable period in 2021. This increase in general and administrative expense was mainly attributable to an increase in employee compensation (due to the timing of annual employee incentive compensation) and taxes and legal and professional fees, which were offset with decreases in stock-based compensation and other expenses.

As of June 30, 2022, the Company had cash of approximately $9.0 million and working capital of approximately $10.5 million. The Company's current expectation is that the cash on hand and the proceeds from the offering during January is sufficient to fund our operations into 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 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 portfolio, 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 the WP1244 portfolio 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 Company's ability to meet the milestones described in this release under the sections labeled "Upcoming Milestones" above, the Company's forecasted cash burn rate, and the timing of opening new sites in Europe. 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.

View original content to download multimedia:https://www.prnewswire.com/news-releases/cns-pharmaceuticals-reports-second-quarter-2022-financial-results-and-provides-corporate-update-301605578.html

SOURCE CNS Pharmaceuticals, Inc.