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): April 9, 2024

CNS Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**001-39126**	**82-2318545**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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 7.01. Regulation FD Disclosure.

Representatives of CNS Pharmaceuticals, Inc. (the "Company") will use the presentation set forth as Exhibit 99.1 herein in connection with various meetings from time to time with the investment community.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Exhibit Description**
99.1	CNS Pharmaceuticals, Inc. Investor Presentation – April 2024
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: April 12, 2024

Exhibit 99.1

FORWARD LOOKING STATEMENTS

CNS PHARMACEUTICALS

This presentation incorporates information from materials filed with the SEC and contains forward-looking statements. All statements contained herein other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section of most recent Form 10-K as updated by any subsequent Form 10-Q filings. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward looking statements.

INVESTMENT HIGHLIGHTS

Developing Anti-Cancer Drug Candidates for the Treatment of Primary and Metastatic Brain and CNS Cancer

Lead Program Initially Developed at The University of Texas MD Anderson Cancer Center

Lead Program: Berubicin

- Optimized anthracycline analog that appears to cross the blood brain barrier in clinical trials
- Fully enrolled **potentially pivotal** clinical trial ongoing
- No evidence of cardiotoxicity seen in clinical trials
- Interim Analysis - DSMB recommended to ***continue the trial*** without modification
- Final top-line data anticipated in first half of 2025

Seasoned management team with significant drug development experience

CNS PHARMACEUTICALS NASDAQ: CNSP	
Stock Price (as of 3/28/24)	$0.362
Shares Outstanding (as of 3/28/24)	10.6M
Market Capitalization (as of 3/28/24)	$3.8M
Cash (as of 12/31/23) *Adjusted for financing on 2/1/24*	$4.2M

GLIOBLASTOMA MULTIFORME (GBM)

One of the Most Aggressive, Deadly and Treatment-Resistant Cancers That Forms in the Brain

12 – 18 MONTHS
Average life expectancy[1]

>50,000
New cases in the 8 Major Markets[2] each year[3]

>62,000
Forecast of annual new cases in the 8 Major Markets[2] by 2027[3]

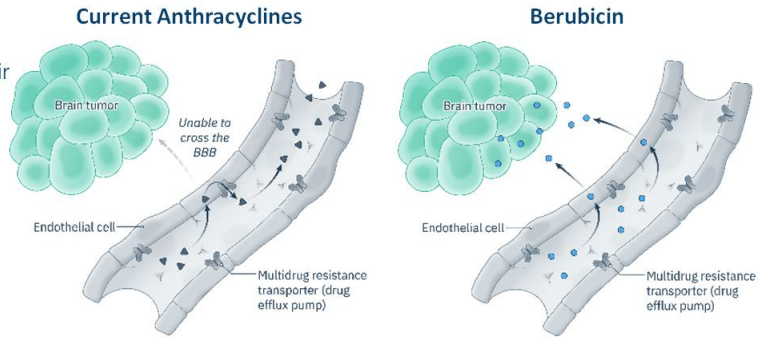
~48%
Of all primary malignant brain tumors[1]

NOTES:
1. https://braintumor.org/take-action/about-gbm/
2. 8 Major Markets includes USA, France, Germany, Italy, Spain, UK, Japan and urban China
3. Global Data, "Glioblastoma Multiforme (GBM): Opportunity Analysis and Forecasts to 2027" (2017)

THE BLOOD BRAIN BARRIER (BBB)

A Tight Layer of Highly Specialized Cells Surrounding the Brain that Prevent Harmful Substances from Penetrating into the Brain

- Previously studied anthracyclines have shown no efficacy in brain tumors due to their inability to cross the blood-brain barrier
- Berubicin is a next generation anthracycline that appears to cross the blood brain barrier and kill tumor cells in the brain
- This represents a potentially new treatment for patients with glioblastoma multiforme (GBM), an aggressive and currently incurable form of brain cancer



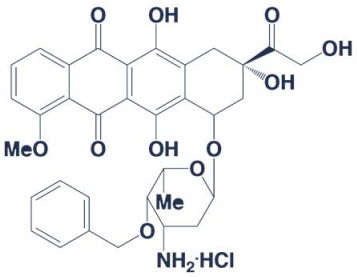
BERUBICIN FOR THE TREATMENT OF GBM

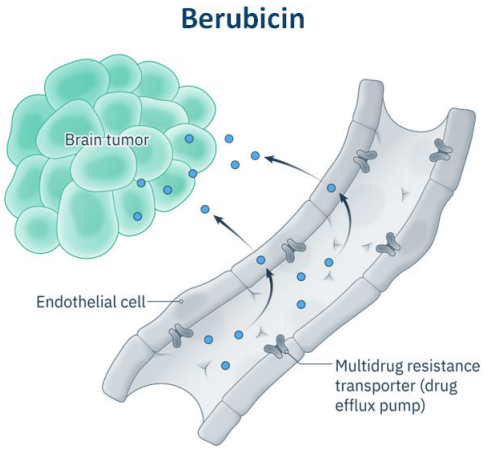
First Novel Anthracycline Appears to Cross the Blood-Brain Barrier (BBB) and Concentrates in Tumor Tissue Within the Brain

- Anthracyclines have been proven to be among the most effective anti-cancer treatments
- Berubicin achieves high brain concentrations and selective uptake in tumor tissue, which provides the potential for limited off-site toxicity
- Berubicin is designed to abrogate transport by MDR-associated ATP Binding Cassette (ABC) Transporter Proteins

BERUBICIN: DESIGNED TO CROSS THE BBB AND CONCENTRATE IN THE TUMOR

- Synthetic 4'-O-Benzylated doxorubicin analog
- Topoisomerase II Inhibitor
- Highly cytotoxic
- Highly lipophilic





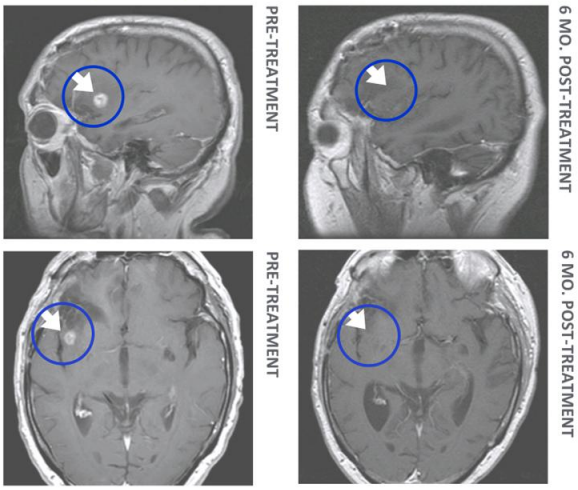
PHASE 1 STUDY DESIGN

- Thirty-five patients with recurrent or refractory glioblastoma multiforme (GBM) or other primary brain cancers
- Berubicin administered intravenously over 2 hours for 3 consecutive days (one course) every 21 days. Doses were escalated using an accelerated titration design and ranged from 1.2 to 9.6 mg/m2/day.
- Plasma levels of Berubicin and its primary metabolite, the 13-hydroxy derivative berubicinol, were measured by high-performance liquid chromatography-tandem mass spectrometry assays, pharmacokinetic parameters were evaluated, and statistical tests applied

PHASE 1 STUDY RESULTS

- 44% of subjects demonstrated "stable disease or better[1]"
- Two partial responses with up to 80% tumor shrinkage
- Extremely well tolerated with a good safety profile (no off-target toxicities)
- **DURABLE COMPLETE RESPONSE (CR)**
  - One subject remains cancer-free ~17 years following treatment

Complete Response at 6-month Post Treatment*

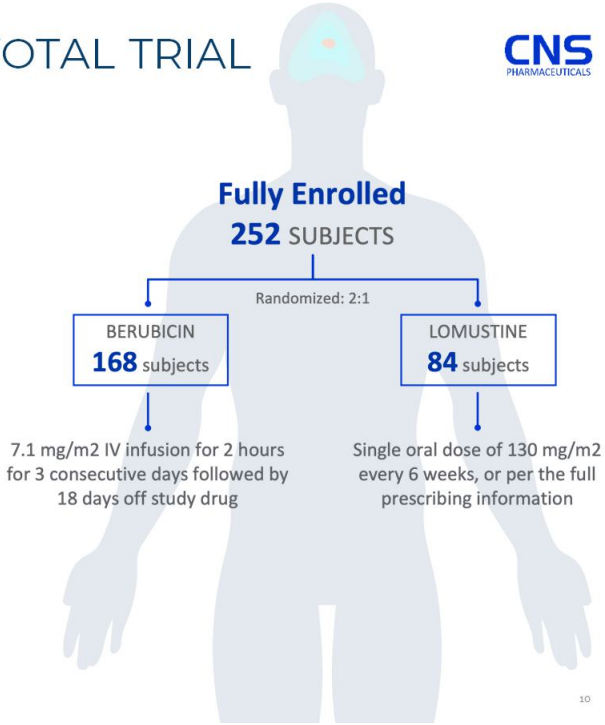


1. SD is defined as 0-25% by dimensional product as performed by MacDonald Criteria.

* This does not always mean the cancer is cured. Also called a complete remission: www.cancer.gov/publications/dictionaries/cancer-terms/def/complete-response

ONGOING POTENTIALLY PIVOTAL TRIAL

- **Dose**
  Berubicin 7.1 mg/m2 IV infusion vs.
  Lomustine 130 mg/m2 oral
- **Clinical Sites**
  47 centers across North America and Europe
- **Primary Endpoint**
  Overall Survival (OS)
- **Secondary Endpoints**
  Progression Free Survival (PFS); Objective Response Rate (ORR); Individual Components of the ORR (CR/PR); Disease Control Rate (DCR); Safety of the Current Dose and Schedule Pharmacokinetics (PK)
- **Topline Data**
  Expected first half of 2025



PATH TOWARDS POTENTIAL FDA APPROVAL

- ***Independent Data Safety Monitoring Board (DSMB) Recommended Continuing Clinical Trial of Berubicin Without Modification***

- The trial design included a pre-planned, non-binding interim futility analysis. We 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, we 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.

MULTIPLE PIPELINE EXPANSION OPPORTUNITIES

INDICATION	PATIENT POPULATION	EST. U.S. NEW PATIENTS ANNUALLY	COMMENTS
Primary Brain Tumors	Relapsed High Grade Gliomas	15,000	Existing data in this population
High Grade Gliomas in Pediatrics	High Grade Gliomas	6,000	High Grade Gliomas are the most common malignant brain tumors in children, and represent the greatest cause of cancer-related deaths under the age of 19
Brain Metastases - Combination with Radiation Therapy	Metastatic Breast Cancer	45,000	Anthracyclines are highly effective against breast cancer and historically used first line Growing trend to treat Her-2+ women with Herceptin without anthracycline to minimize cardiotoxicity Success could drive off-label use in breast cancer patients at risk of developing brain metastases
Primary CNS Lymphoma (PCSNL)	2nd Line After Methotrexate Failure	1,200	Accelerated approval opportunity (no 2nd line therapy) Anthracycline sensitive Small population would make trial a challenge

INTELLECTUAL PROPERTY

- Berubicin's primary protection is currently the Orphan Drug Designation which may enable marketing exclusivity in US market for 7-years post NDA approval
- Additional protection is offered as a New Chemical Entity
- CNS is exploring potential additional patent filings covering manufacturing and other areas and additional Orphan indications (see previous slide)
- Upcoming filing after final data in the E.U. for Orphan Drug Designation may provide 10-years of protection in Europe following marketing approval

NASDAQ: CNSP

MANAGEMENT TEAM

CNS PHARMACEUTICALS

John M. Climaco, Esq PRESIDENT & CHIEF EXECUTIVE OFFICER
Distinctive record of business successes and more than 15 years of experience managing the operations, strategies and finances of public and private companies.

Christopher S. Downs, CPA CHIEF FINANCIAL OFFICER
Nearly 20 years of finance and investment banking experience primarily in the healthcare industry including significant M&A transaction experience, experience in raising both public and private capital across the capital structure, and bank debt financing.

Sandra L. Silberman, MD, PhD CHIEF MEDICAL OFFICER
Board certified hematologist/medical oncologist with extensive experience in clinical development of novel therapies for the treatment of cancer. Played key roles in the development of many drugs including Gleevec™, for which she led global clinical development at Novartis.

Donald Picker, PhD CHIEF SCIENTIFIC OFFICER
Over 35 years of drug development experience and responsible for the development of Carboplatin, one of the world's leading cancer drugs, acquired by Bristol-Myers Squibb and with annual sales of over $500 million.

NASDAQ: CNSP

BOARD OF DIRECTORS

Faith Charles
CHAIR OF THE BOARD OF DIRECTORS

Ms. Charles has been a corporate transactions and securities partner at the law firm of Thompson Hine, LLP, since 2010. She currently leads Thompson Hine's Life Sciences practice and co-heads the securities practice, advising public and emerging biotech and pharmaceutical companies in the U.S. and internationally. Ms. Charles negotiates complex private and public financing transactions, mergers and acquisitions, licensing transactions and strategic collaborations.

John M. Climaco, Esq
PRESIDENT, CEO AND DIRECTOR

John M. Climaco, Esq. is the Chairman and CEO of CNS Pharmaceuticals, Inc. For 15 years Mr. Climaco has served in leadership roles in a variety of healthcare companies. Recently Mr. Climaco served as the Executive Vice-President of Perma-Fix Medical S.A where he managed the development of a novel method to produce Technitium-99. Previously Mr. Climaco served as President and CEO of Axial Biotech, Inc., a DNA diagnostics company.

Amy Mahery
INDEPENDENT DIRECTOR

Ms. Mahery has more than twenty years of experience in the biopharmaceutical industry. Currently, she serves as Chief Commercial Officer of Roivant Sciences, a company developing and commercializing transformative medicines and technologies by building agile, focused companies called Vants.

Jeffry R. Keyes
INDEPENDENT DIRECTOR

Mr. Keyes is currently the Chief Financial Officer of Custopharm, Inc., a private equity backed developer of generic sterile injectable pharmaceuticals, a role he has held since April 2018. From September 2012 to April 2018, Mr. Keyes was the Chief Financial Officer and Corporate Secretary of Digirad Corporation, a publicly traded healthcare services and medical device company. From August 2011 until September 2012, Mr. Keyes was Corporate Controller of Sapphire Energy, Inc., a venture capital backed start-up renewable energy company.

Dr. Bettina Cockroft, M.D., M.B.A
INDEPENDENT DIRECTOR

Dr. Cockroft is a well-established industry executive with over 30 years of experience in the biopharmaceutical industry with clinical development expertise across multiple therapeutic areas. Over the course of her notable career, she has successfully led multiple clinical development programs and has a proven track record executing programs through drug development, commercial launch and beyond, having played a key role in the approval of several drugs for neurological, cardiovascular and infectious diseases.

Dr. George Gumulka, PhD
INDEPENDENT DIRECTOR

Dr. Gumulka has been retired since 2016. From 2001 until his retirement he served as a Global Technology Manager ASC, a Technology Manager, Special Projects/New Technology Platforms, Kraton Polymers US LLC and a Technical Director of Kraton Polymers do Brasil. Dr. Gumulka served on the Board of Directors of Moleculin LLC from 2010 through 2016. Dr. Gumulka received a PhD from the University of Warsaw, Warsaw, Poland.

Carl Evans
INDEPENDENT DIRECTOR

Mr. Evans has been retired since 2015. From 2011 until his retirement Mr. Evans was Executive Vice President – Exploration for KMD Operating Company, LLC. Prior to 2011, he managed international and domestic oil exploration and production projects for several oil companies, including British Petroleum, Texaco, and Pennzoil.

UPCOMING VALUE DRIVING MILESTONES

Berubicin

- ✓ Orphan Drug Designation → June 2020
- ✓ IND Accepted for Berubicin → Dec 2020
- ✓ Initiated Potentially Pivotal Global Berubicin trial for GBM → May 2021
- ✓ Fast Track Designation → June 2021
- ✓ Patient Dosing in Potentially Pivotal Study Expected to Commence → Sept 2021
- ✓ Approval from Switzerland EC and CA to Open Sites → April 2022
- ✓ Approval from France EC and CA to Open Sites → April 2022
- ✓ Approval from Spain EC and CA to Open Sites → April 2022
- ✓ Pivotal Trial Expansion into France and Spain → Sept 2022
- ✓ Enrollment of 200th Patient → Sept 2023
- ✓ Enrollment of 229th Patient → Oct 2023
- ✓ Successful Interim Analysis/Data → Dec 2023
- ✓ Completion of Planned Enrollment → Jan 2024

Next Steps

- **Target Topline Results from Potentially Pivotal Study → H1 2025**

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