

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, 2025

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))

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.

On April 9, 2025, 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 is being furnished and shall not be “filed” for the purpose of the Securities Exchange Act of 1934, as amended (“Exchange Act”), nor shall it be incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended (“Securities Act”), unless specifically identified therein as being incorporated by reference.

Item 9.01. Financial Statements and Exhibits.

| No. | Description |
|------------|-----------------------------------------------------------------------------|
| 99.1 | Presentation dated April 2025 |
| 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 9, 2025



Forward Looking Statements

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.



Overview

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

Strong Financial Position

Proven Clinical Development "Engine" with Global Trial Site Network in Place to Accelerate Complex CNS Focused Trials

Advancing Lead Product Candidate, TPI 287 for treatment of Glioblastoma Multiforme (GBM)

- Late-stage, novel, blood brain-barrier permeable taxane-derivative (abeotaxane)
- Studies in over 350 patients to date, include clinical trials as monotherapy and combination with bevacizumab

Reported Primary Analysis of Berubicin Monotherapy in 2nd line GBM

- Ongoing analysis of outcomes ongoing to determine next steps



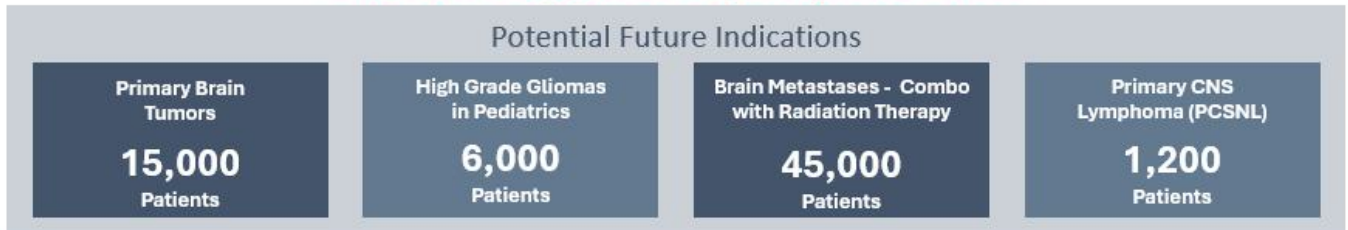
1. Did not a statistically significant difference in overall survival, the primary endpoint



A Focused and Targeted CNS Oncology Pipeline

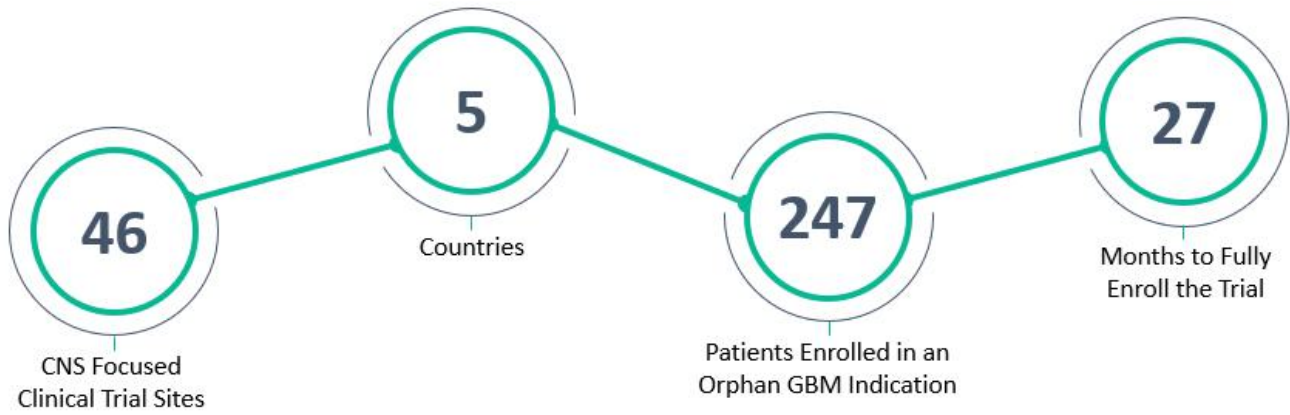
| Program | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 | Highlights |
|---------|-------------------------------|-------------|---------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| TPI 287 | Glioblastoma Multiforme (GBM) | [Redacted] | | | | <ul style="list-style-type: none"> Studied in over 350 patients to date Plan to engage with regulators to design potential registration study in 2025 |

A Much Bigger Story Beyond GBM



Established "Engine" to Execute Global CNS Clinical Trials

Key Learnings and Established Network From Berubicin Monotherapy Potentially Pivotal Trial



Successfully Built CNS Trial Network and Enrolled Patients in Record Time, All During a Global Pandemic



Proven Clinical Development Infrastructure Optimized for Brain Cancer Drug Development

Relationships

- Deliberate establishment of a global, CNS focused network
- Commitment to work in this disease
- Deep understanding of the landscape of clinical trials in GBM

Program Development Infrastructure & Efficiencies

- Seamless transition to our next asset
- Built to last
- Set up for success

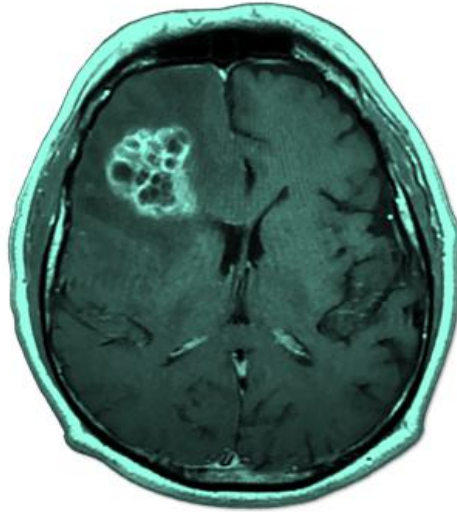


Glioblastoma Multiforme (GBM)

One of the most aggressive, deadly and treatment-resistant cancers that forms in the brain

Current standard of care ineffective in ~60% of patients

Can affect cognition, mood, behavior and organ function



12 – 18 MONTHS

Average Life Expectancy¹

>50,000

New Cases in the 8 Major Markets² Each Year³

>151,000

Forecast of Annual New Cases in the 8 Major Markets² by 2027³

~48%

Of All Primary Malignant Brain Tumors¹



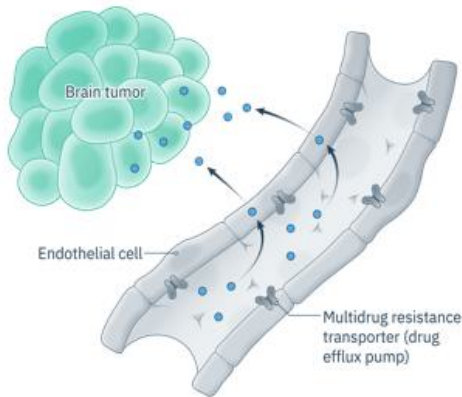
1: <https://braintumor.org/take-action/about-gbm/>

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)

Highly Selective, Semi-Permeable Barrier that Separates the Circulating Blood from the Brain



Key Functions

- **Protection:**
 - Blocks toxins, pathogens and potentially harmful molecules from entering the brain by transporters that bind to these substances and deliver them back to the bloodstream
- **Selective Permeability:**
 - Allows essential nutrients like glucose and amino acids to pass through while restricting larger or harmful molecules
- **Maintaining Homeostasis:**
 - Ensures a controlled environment for proper neuronal function

Drug Delivery to the Brain is Challenging Due to the BBB's Selective Nature, Limiting the Access and Effectiveness of Cancer Therapies in the Brain



TPI 287

Late Stage, Novel Blood Brain Barrier Permeable
Abeotaxane for Treatment of Brain Malignancies

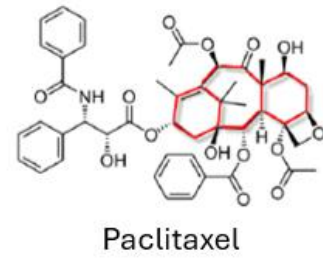
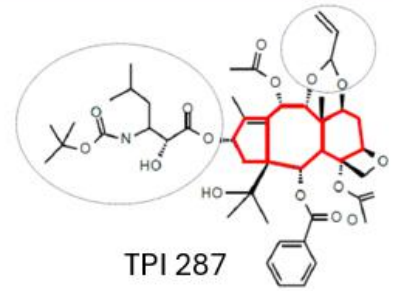
TPI 287: A Novel Taxane Derivative

- **Taxanes**

- A class of chemotherapy that binds to microtubules and prevents them from functioning normally, which stops cancer cells from dividing
- A substrate for P-glycoprotein (Pgp), which is upregulated in cells that become taxane-resistant, and is part of the BBB

- **TPI 287**

- A derivative of taxane (abeotaxane) that is not a substrate for Pgp
- Effective in taxane-resistance and able to cross the BBB

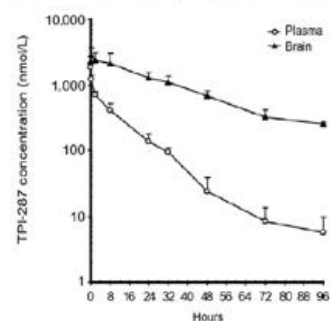


Readily Penetrates the Blood Brain Barrier in Animal Models

| | COMPOUND | Blood ug*hr/ml | Brain ug*hr/g | Brain:Blood |
|---------------|------------|----------------|---------------|-------------|
| Wild-type | paclitaxel | 3.2 | 1.6 | 0.5 |
| | docetaxel | 8.7 | 2.5 | 0.3 |
| | TPI 287 | 16.8 | 65.9 | 3.9 |
| Pgp knock-out | paclitaxel | 4.7 | 18.6 | 4.0 |
| | docetaxel | 9.0 | 15.4 | 1.7 |
| | TPI 287 | N/A | N/A | |

Single-dose IV bolus:
 paclitaxel dosed 10 mg/kg AUC cal. 0-8 hr blood, 0-12 hr. brain (*Clin Can Research*. 9:2849. 2003).
 docetaxel dosed 33 mg/kg AUC cal. 0-8 hr blood, 0-12 hr. brain (*Eur J Can*. 40:1269. 2004).
 TPI 287 dosed 20 mg/kg AUC cal. 0-96 hr blood and brain (*Mol Can Ther*. 11:1959. 2012).

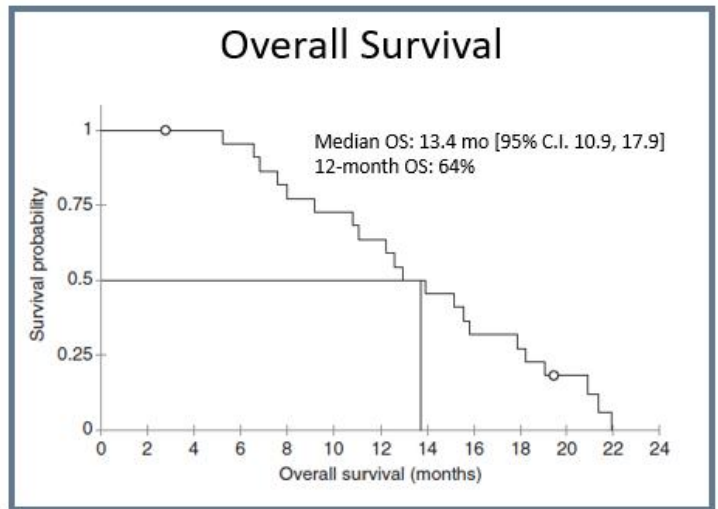
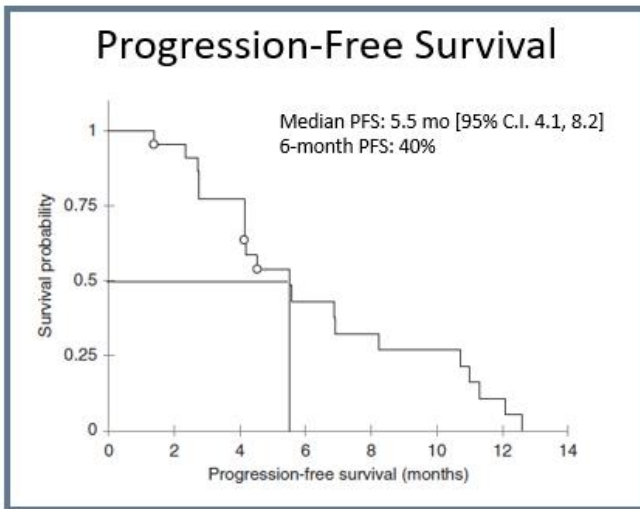
~ 64x greater concentration in brain vs plasma 4 days after single dose in mouse.



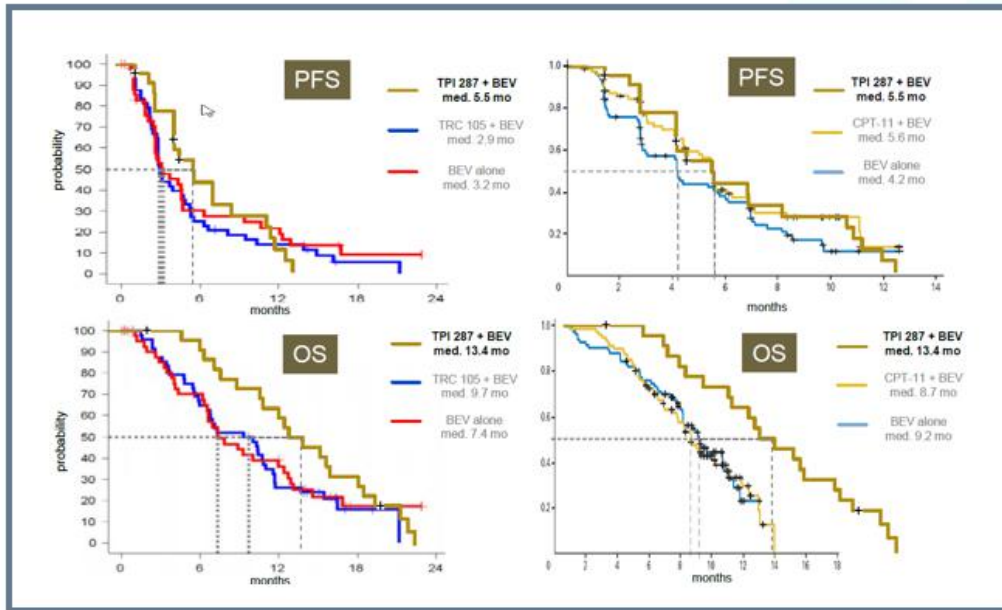
Clinical Trials with TPI 287



TPI 287 in Combination with Bevacizumab for the Treatment of Recurrent Glioblastoma



Improved GBM Survival in Combination with Bevacizumab



* Graphs represent aggregate data from multiple studies



Berubicin

Evaluation of Strategic Options
May Provide Potential for Upside

Berubicin

Reported Primary Analysis of Berubicin in 2nd line GBM

Ongoing analysis of outcomes ongoing to determine next steps



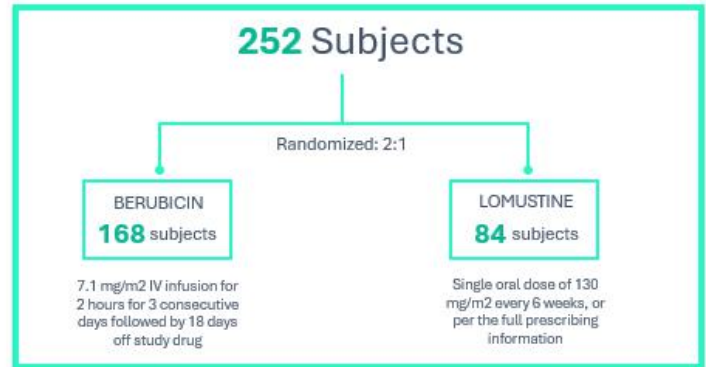
1. Did not show a statistically significant difference in overall survival, the primary endpoint

Summary of Primary Analysis

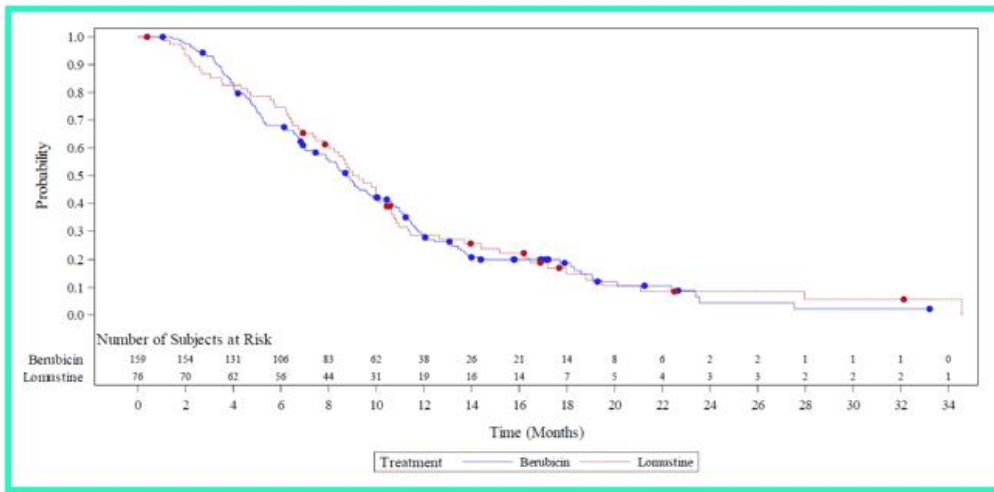
Showed clinically relevant outcomes comparable to Lomustine across multiple endpoints¹

Safety profile continues to be favorable, including the absence of anthracycline related cardiotoxicity

Analysis of outcomes are ongoing, including advanced imaging review, PK, and clinical endpoints



Berubicin Demonstrated Comparable Overall Survival Compared to Standard of Care, Lomustine



Intellectual Property

Orphan Drug

Orphan Drug Designation gives marketing exclusivity in US market for 7-years from approval

CNS is exploring potential new patent filings covering manufacturing and other areas and additional Orphan indications

New Chemical Entity

Upcoming filing after final data in the E.U. for Orphan Drug Designation may provide 10-years of protection in Europe

Financial Snapshot

NASDAQ: CNSP

Strong Financial Position with Sufficient Capital to Fund Operations Into the First Quarter of 2025

\$6.5 Million

Cash

As of December 31, 2024

~50K

Volume

Average 3 months

~\$4 Million

Market Cap

As of April 1, 2025





~\$9.9 Million

Cash Position Does Not Include Subsequent Sale of Shares After Dec. 31, 2024 with Net Proceeds of \$9.9 Million



The number of shares of the registrant's common stock outstanding as of March 31, 2025 was 2,944,381

Management Team

| | |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>John M. Climaco, Esq PRESIDENT & CHIEF EXECUTIVE OFFICER</p> <p>Twenty-one years experience managing the operations, strategies and finances of public and private lifescience companies.</p> |
|  | <p>Christopher S. Downs, CPA CHIEF FINANCIAL OFFICER</p> <p>Nearly 20 years of finance and investment banking experience primarily in the healthcare industry</p> |
|  | <p>Sandra L. Silberman, MD, PhD CHIEF MEDICAL OFFICER</p> <p>Board certified hematologist/medical oncologist with extensive experience in clinical development of novel therapies for the treatment of cancer. Former Head Global Clinical Development at Novartis.</p> |
|  | <p>Donald Picker, PhD CHIEF SCIENTIFIC OFFICER</p> <p>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.</p> |





CNS
Pharmaceuticals

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