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): December 11, 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

On December 11, 2024, CNS Pharmaceuticals, Inc. (the "Company"), will hold a virtual analyst and investor day meeting at which the presentation set forth in Exhibit 99.1 will be reviewed.

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

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Presentation dated December 11, 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: December 11, 2024

Exhibit 99.1


NASDAQ: CNSP
December 11, 2024
CNS
Pharmaceuticals
Virtual Analyst &
Investor Day

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.

CNS Pharmaceuticals

John M. Climaco, Esq
President &
Chief Executive Officer

Sandra L. Silberman, MD, PhD
Chief Medical Officer

Zena Muzyczenko
Vice President,
Clinical Operations

Agenda

- Opening and Introductions
- CNS Pharma Overview
- Glioblastoma Multiforme: The Patient Journey and Unmet Need
- The Blood Brain Barrier and Overcoming This Significant Challenge
- Berubicin: A Novel Anthracycline Designed to Cross the Blood Brain Barrier
- Berubicin: Clinical Data and Path to Potential Approval
- TPI 287: A Novel, Blood Brain Barrier Permeable Abeotaxane
- CNS Pharma: Positioned for a Transformational 2025

Prof. Michael Weller, MD

- Director of Department of Neurology, Universitatsspital, Zurich, Switzerland since 2008
- Member of Swiss Neurological Society, German Society for Neurology, German Cancer Society, European Association for Neuro-Oncology, Society for Neuro-Oncology, European Society of Medical Oncology, and American Society of Clinical Oncology
- Member of the Board, European Organisation for Research and Treatment of Cancer
- President, Swiss Neuro-Oncology Society
- Chairman of the Department of General Neurology at the University Hospital Tübingen, Germany, where he had previously received his education in clinical neurology
- Postdoctoral fellowship at the Department of Clinical Immunology, University Hospital Zurich, Switzerland, followed where he identified death receptor targeting as a potential treatment strategy for malignant gliomas
- Received several awards in recognition of his contributions to cancer research, including the German Cancer Award in 2007
- Dr. Weller was involved in major practice-changing clinical trials including the registration trial for temozolomide in glioblastoma
- Has co-authored more than 600 original publications in peer-reviewed journals, including *The New England Journal of Medicine*, *Science*, *Nature*, *Nature Medicine*, *Lancet Oncology*, *PNAS*, *The Journal of Clinical Investigation*, and *The Journal of Clinical Oncology*
- Dr. Weller has been a member of the *ESMO Open* Editorial Board since 2016 and was a member of the ESMO Educational Committee, 2012-2016. He has also been a member of ESMO CNS Tumors Faculty Group since 2012

Samuel Goldlust, MD

- Board-certified and fellowship-trained neuro oncologist with Saint Luke's Cancer Specialists
- Specialized training in neuro-oncology and extensive experience treating patients with primary and metastatic brain tumors as well as the neurological complications of cancer
- Passionate about research and focused on the development of novel and more effective treatments for glioblastoma and other brain tumors, including options when standard chemotherapy, radiation and surgery have proven ineffective
- Completed his residency training in neurology at New York University Hospitals and was selected to serve as Chief Resident
- Received fellowship training in neuro-oncology at Memorial Sloan Kettering Cancer Center and was promoted to Chief Fellow in his final year
- Dr. Goldlust frequently treats conditions like Brain Cancer, Hypothalamus Cancer and Cancer of Cerebral Meninges along with other conditions at varying frequencies

Erin Dunbar, MD

- Founding physician of the Brain Tumor Center and Director of Neuro-Oncology at Piedmont Atlanta Hospital, Piedmont Atlanta, GA
- She specializes in the comprehensive care of brain and spine tumor patients who are battling both primary and metastatic tumors
- Completed fellowships in Neuro-oncology at Johns Hopkins University, in Hospice and Palliative Medicine at the Malcom Randall VA Medical Center and in Medical-oncology at the University of Florida
- Avid clinical researcher and a collaborator with organizations, including the National Cancer Institute and other national brain tumor centers

CNS Pharma Overview

John M. Climaco, Esq
President &
Chief Executive Officer

Overview

Lead Program: Berubicin, a Novel Anthracycline

- First drug of its class to appear to cross the blood-brain barrier
- **A clinical trial designed to be pivotal now** fully enrolled
- The primary analysis of data in the 1st half of 2025
- No evidence of cardiotoxicity in hundreds of patients
- Developed at **MD Anderson Cancer Center – Ranked #1 in Cancer Care in the US**

Pipeline Expansion with In-License of TPI 287

- Late-stage, novel, blood brain-barrier permeable taxane-derivative (abeotaxane) for treatment of brain malignancies
- Studies in over 350 patients to date, include clinical trials as monotherapy and combination with bevacizumab
- Orphan Designation for 7 years granting US marketing exclusivity
- Fast Track Designation expediting review of data

CNS Pharmaceuticals

A Focused and Targeted CNS Oncology Pipeline

Program	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Highlights
Berubicin	Glioblastoma Multiforme (GBM)	Potentially Pivotal				• Study fully enrolled • Primary analysis data expected H1 2025
TPI 287	Glioblastoma Multiforme (GBM)					• Recently in-licensed • Plan to engage with regulators to design potential registration study

Proven Execution and Milestones

Berubicin Development Program

Next Steps	Primary Analysis from Potentially Pivotal Study	H1 2025

Glioblastoma Multiforme: The Patient Journey

Prof. Michael Weller, MD

Samuel Goldlust, MD

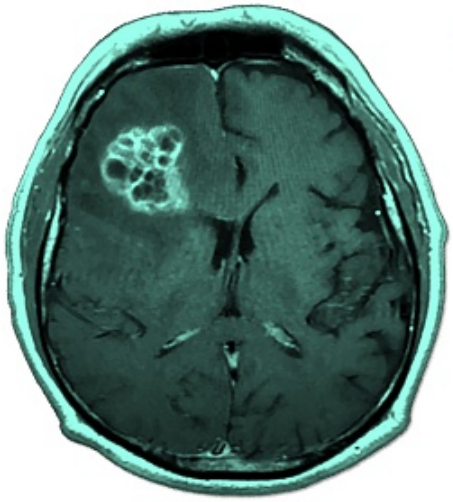
Erin Dunbar, MD

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 Expectancy[1]

>50,000
New Cases in the 8 Major Markets[2] Each Year[3]

>151,000
Forecast of Annual New Cases in the 8 Major Markets[2] by 2027[3]

~48%
Of All Primary Malignant Brain Tumors[1]

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)

GBM: Treatment

Treatment depends upon the stage of disease, which may include:

Surgery	Chemotherapy Common Drugs	Radiation	Tumor Treating Fields
			
Craniotomy - a surgical procedure that involves removing a section of the skull to access the brain. The bone is replaced after surgery Resection of brain tumor or retrieve a sample of the brain tumor	Temozolomide PCV - Procarbazine hydrochloride, Lomustine (CCNU) and Vincristine sulfate Bevacizumab	Treatment that uses x-rays and other high-energy rays to kill abnormal cells	Magnetic fields applied to the skull

GBM Current Standard of Care

Standard of Care	US	Europe	Comments
Resection and Radiotherapy	X	X	First Line
Temozolomide	X	X	First Line*
Tumor Treating Fields	X		First Line
Lomustine (CCNU)	X		Second Line
PCV (Procarbazine, CCNU, Vincristine)	X		Second Line
Bevacizumab	X		Third Line
Clinical Trials	X	X	First, Second and Third Line

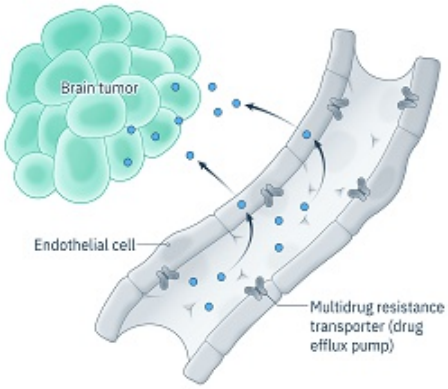
**Europe does not usually administer any drugs after the primary diagnosis in patients with an unmethylated MGMT promotor; the US usually provides Temozolomide to all patients*

The Blood Brain Barrier and Overcoming This Significant Challenge

Sandra L. Silberman, MD, PhD
Chief Medical Officer

The Blood Brain Barrier (BBB)

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



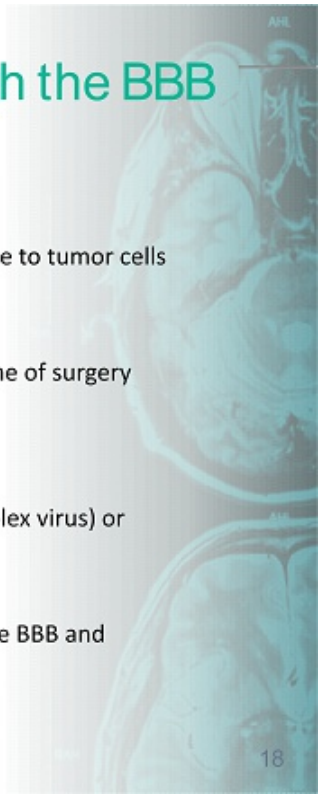
Key Functions

- 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

CNS Pharmaceuticals

Strategies for Therapies to Gain Access through the BBB



Liposomal Formulations

- Resemble the lipid bilayer of the endothelial cell membrane
- Can circumvent mechanisms that transport drugs out of the brain and that confer resistance to tumor cells

Intratumoral/Intracerebral or Intrathecal Administration:

- Clinically established, useful to treat CNS disorders including brain tumors and seizures
  - Intratumoral: Injections or infusions of drugs directly into the tumor –available at the time of surgery
  - Intrathecal: Injections into the CSF - inadequate for delivery to tissue or cellular targets

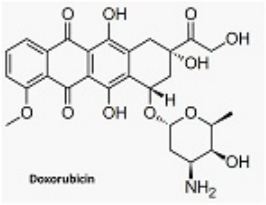
Viral Vectors:

- Neurotropic viruses, i.e., viruses that can infect neural cells
  - Invade either by the neural network and axonal transport (eg rabies virus or herpes simplex virus) or invade the CNS from the bloodstream (retroviruses)

Ultrasound

- Ultrasound-mediated drug delivery – non-invasive using ultrasound to temporarily open the BBB and deliver drugs into the brain

Berubicin: A Novel Anthracycline Designed to Cross the Blood Brain Barrier



Doxorubicin

Berubicin

Molecule derived from the structure of other anthracyclines

Structure

- Discovered due to molecular modeling and structure-based rational design through computational chemistry
- Chosen based on its ability to circumvent P-glycoprotein and MRP1 (Multi-Drug Resistance Protein), which are part of the mechanisms that transport drugs out of resistant cells, as well as the normal brain due to the BBB

Activity:

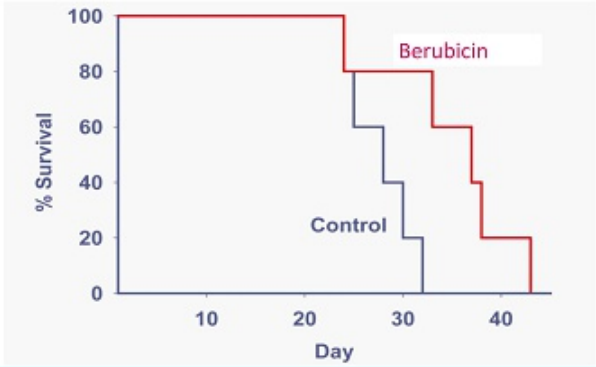
- The mechanism of action is comparable to other anthracyclines; poisoning Topoisomerase II and disrupting DNA repair
- Berubicin is more potent than Doxorubicin in cellular assays
- Levels of Berubicin are higher in multidrug-resistant cells
- Berubicin increases the survival of mice with orthotopic gliomas

CNS Pharmaceuticals

Berubicin Increases Survival in Mouse Glioma Model

Tumors in the natural setting require compounds to cross the BBB to be effective

- Nude mice (*nu/nu*) were seeded with U-87 MG cells by direct intracerebral injection
- Implanted mice were treated with two doses of Berubicin by intraperitoneal (i.p.) injection at 10 mg/kg on Day 1 and 5 mg/kg on Day 10
- U-87 MG tumor-bearing mice treated with Berubicin showed a 33% increase in survival relative to placebo-treated control animals



Berubicin: First-In-Human Trial

Sandra L. Silberman, MD, PhD
Chief Medical Officer

Berubicin: First-In-Human Trial Design

35 Subjects with recurrent or refractory glioblastoma multiforme (GBM) or other primary brain cancers

29 were GBM, 4 AO and 2 AA

DOSE

Intravenous berubicin 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**

PRIOR THERAPIES

The median number of prior therapies was **(5) five**

71% of the patients had received at least four prior therapies, including any combination of chemotherapy, radiation and resection

Berubicin: Results of Phase 1 Dose-Finding and PK Study

CNS Pharmaceuticals

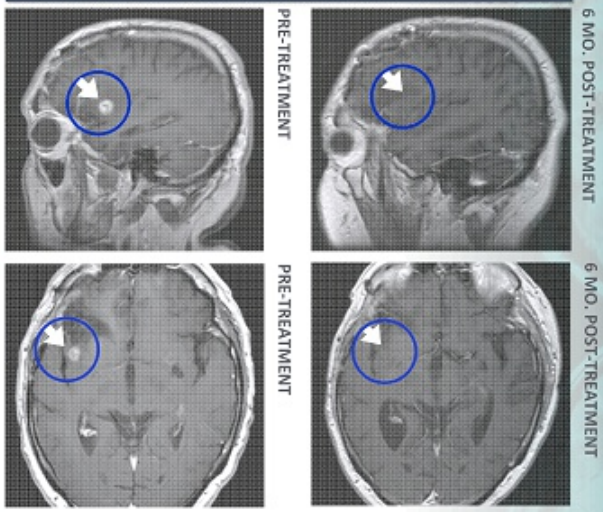
44% of subjects demonstrated "stable disease or better"

Two 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*



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

Berubicin:
Clinical Data Generated to Date

Prof. Michael Weller, MD

Samuel Goldlust, MD

Erin Dunbar, MD

Established Clinical Global Infrastructure and Network

Zena Muzyczenko
Vice President,
Clinical Operations

Clinical Development Infrastructure Optimized for Brain Cancer Drug Development

Relationships	Program Development Infrastructure & Efficiencies
• Deliberate establishment of a global, CNS focused network • Commitment to work in this disease • Deep understanding of the landscape of clinical trials in GBM	• Seamless transition to our next asset • Built to last • Set up for success

Berubicin:
Designed-to-Be-Pivotal Clinical Trial and Path to Potential Approval

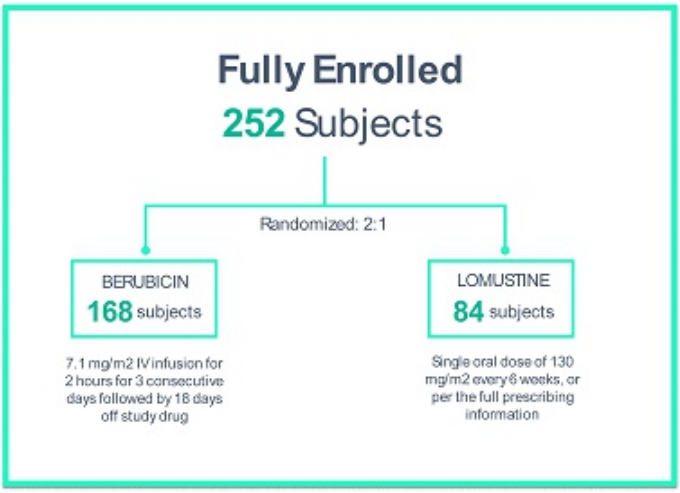
Sandra L. Silberman, MD, PhD
Chief Medical Officer

Berubicin

✓45 centers in 5 countries
✓252 patients randomized
✓Pivotal endpoint 6-12 months

Announced Independent Data Safety Monitoring Board (DSMB) Recommendation on 12/18/23 Continuation of Clinical Trial of Berubicin Without Modification

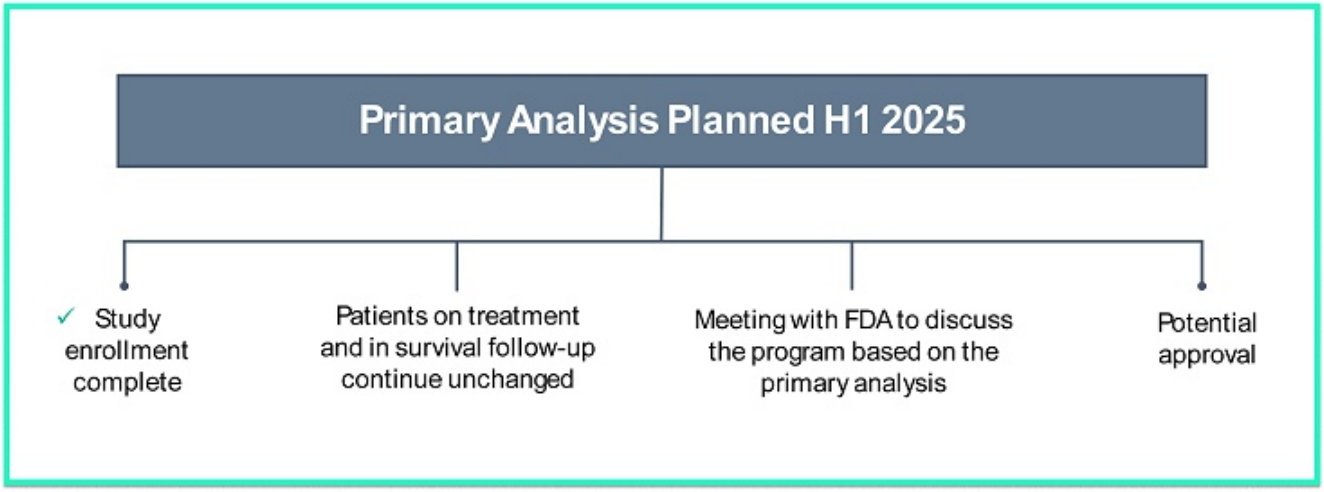
Primary Analysis from Trial Expected 1st Half 2025



Interim Analysis and Rationale

- **Independent Data Safety Monitoring Board (DSMB)**
  - Subject matter experts (oncologists, statistician)
  - Independently oversaw and monitored the clinical trial
  - Ensured the safety of the patients and the integrity of the data collected
- **DSMB made informed decisions about continuing, modifying or stopping the trial based on the accumulating safety and efficacy data**
- **Planned interim analysis to reject futility of investigational drug**
  - 07Dec2023 DSMB review of the interim safety and efficacy data
  - Concluded that CNS201 should be "Continued as planned (without modification)"

Berubicin: Next Major Milestone



Berubicin:
Potentially Pivotal Clinical Trial

Prof. Michael Weller, MD

Samuel Goldlust, MD

Erin Dunbar, MD

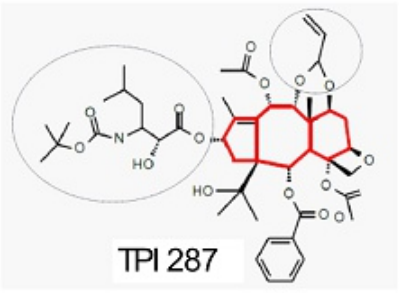
TPI 287

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

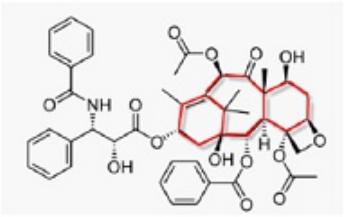
Sandra L. Silberman, MD, PhD
Chief Medical Officer

TPI 287: A Novel Taxane Derivative

- **Taxanes**
  - A class of chemotherapy that binds to microtubules and prevents them from breaking down 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



TPI 287



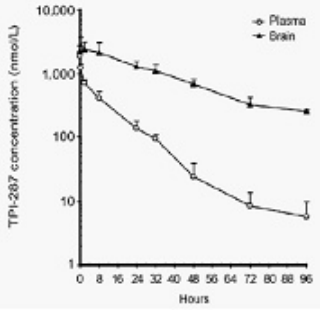
Paclitaxel

Readily Penetrates the Blood Brain Barrier in Animal Models

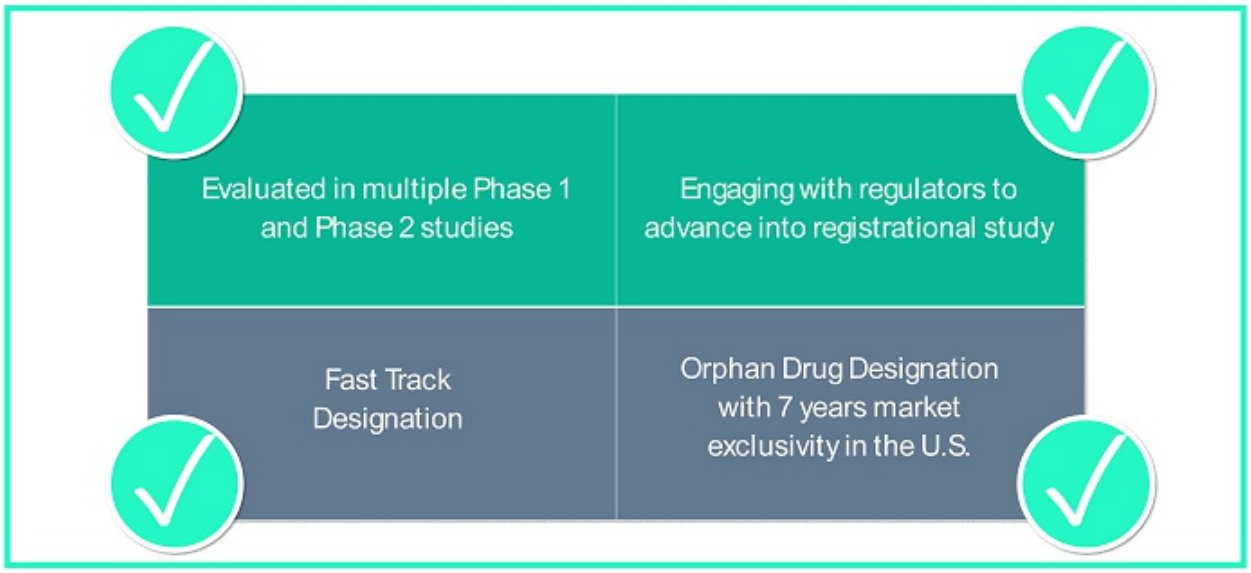
	COMPOUND	Blood ug*hr/ml	Brain ug*hr/g	Brain:Blood
Wild-type	paclitaxel	3.2	1.6	0.5
	docetaxel	8.7	2.5	0.3
	TPI 287	16.8	65.9	3.9
Pgp knock-out	paclitaxel	4.7	18.6	4.0
	docetaxel	9.0	15.4	1.7
	TPI 287	N/A	N/A	

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

Phase 1 trial of TPI 287, a microtubule stabilizing agent, in combination with bevacizumab in adults with recurrent glioblastoma

Samuel Goldlust, MD

Neuro-Oncology Advances

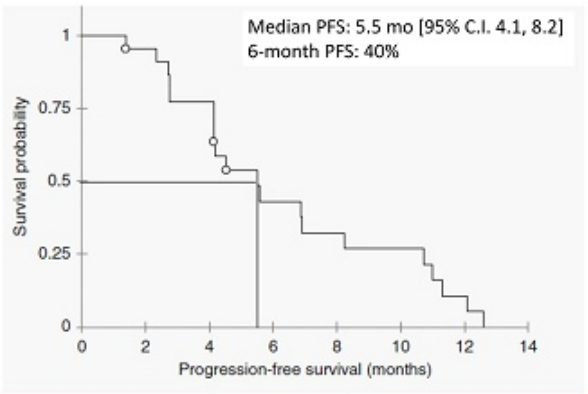
Phase 1 trial of TPI 287, a microtubule stabilizing agent, in combination with bevacizumab in adults with recurrent glioblastoma

Key Points

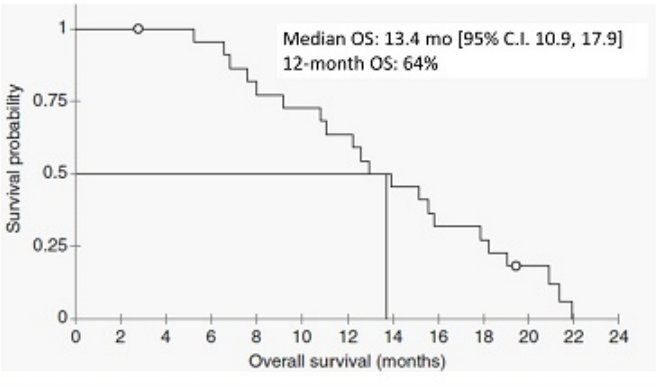
- TPI 287 and bevacizumab were well tolerated in recurrent glioblastoma.
- Preliminary efficacy was encouraging.

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

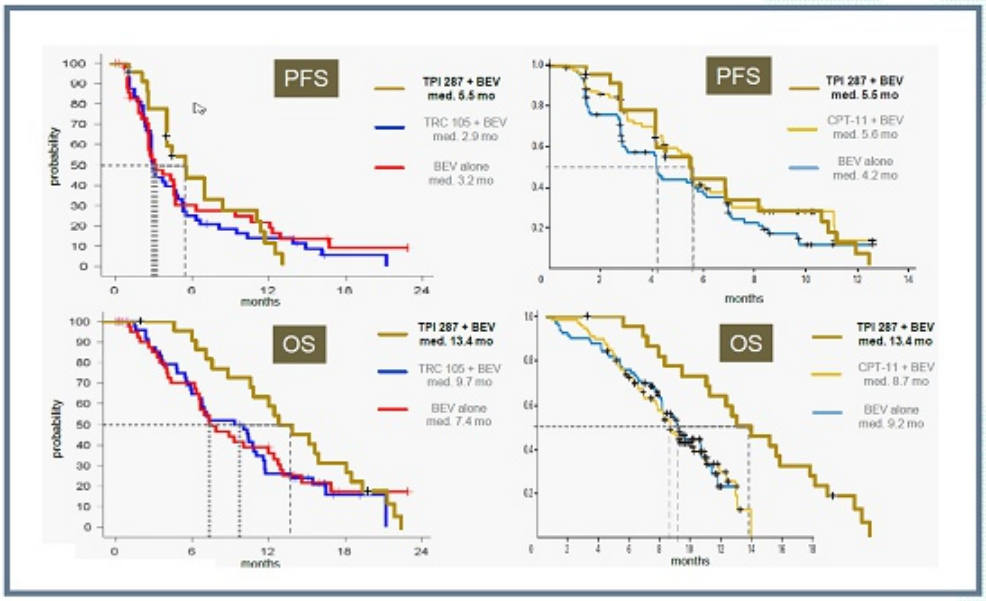
Progression-Free Survival



Overall Survival



Improved GBM Survival in Combination with Bevacizumab



* Graphs represent aggregate data from multiple studies

TPI 287:

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

Prof. Michael Weller, MD

Samuel Goldlust, MD

Erin Dunbar, MD

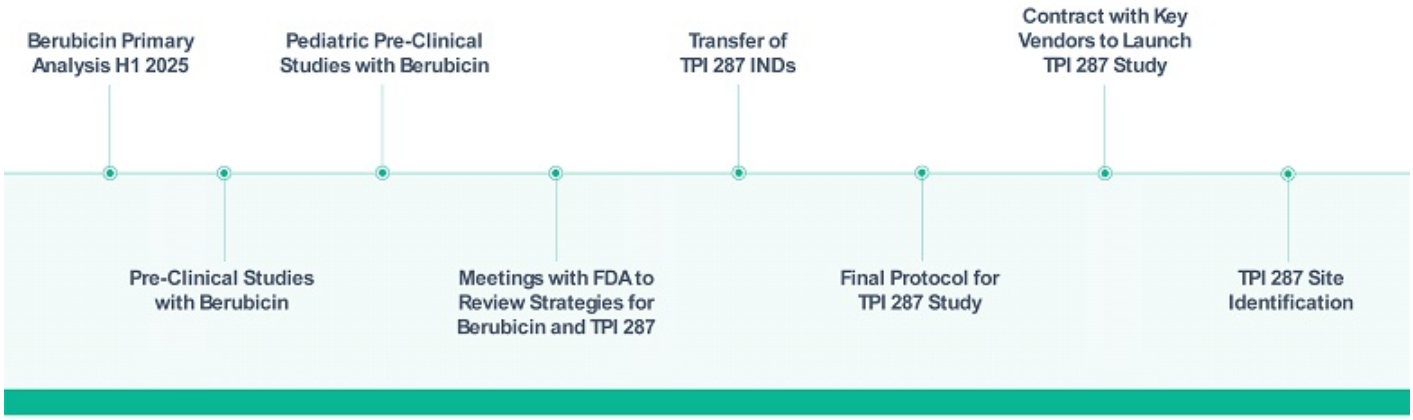
CNS Pharma Positioned for a Transformational 2025

John M. Climaco, Esq
President &
Chief Executive Officer

Commercial Planning

- Key Appointment of Amy Mahery to Board of Directors
- Commercial Strategy Under Development
- Focus on Hiring the Right People
  - Medical Affairs/Medical Liaisons
  - Product Launch & Commercialization Specialist

2025 Milestones




Q&A


CNS
Pharmaceuticals
Investor & Media Relations:
JTC Team, LLC
Jenene Thomas
908.824.0775
CNSP@JTCIR.com
NASDAQ: CNSP