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): January 3, 2025

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 January 3, 2025, CNS Pharmaceuticals, Inc. (the "Company") posted the investor presentation set forth in Exhibit 99.1 on its website.

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 8.01 Other Events

Subsequent to the filing of the Company's Form 10-Q for the quarter ended September 30, 2024, the Company has sold 17,475,827 shares of common stock pursuant to its at-the-market sales agreement. As of January 3, 2025, the Company has 74,962,533 shares of common stock outstanding.

Item 9.01 Financial Statements and Exhibits

No.	Description
99.1	Presentation dated January 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: January 3, 2025

Exhibit 99.1

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

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

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

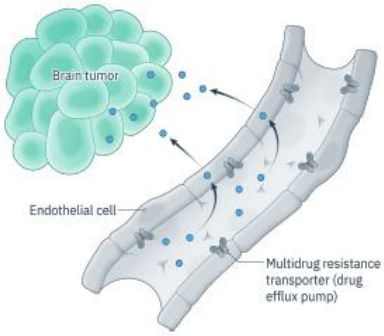
Glioblastoma Multiforme (GBM)

Most Aggressive, Deadly and Currently Incurable Brain Cancer

12 – 18 MONTHS
Average life expectancy[1]

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

$1B+
Global annual sales TMZ
Only approved first line drug (off patent 12 years)



The Blood Brain Barrier Limits the Ability of Cancer Therapeutics to Gain Access to Brain Tumors

- Passive: Tight junctions protect the brain from harmful substances while allowing essential nutrients to pass through
- Active: Efflux transporters actively pump many drugs back into the bloodstream, limiting concentration in the brain

CNS Pharmaceuticals

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

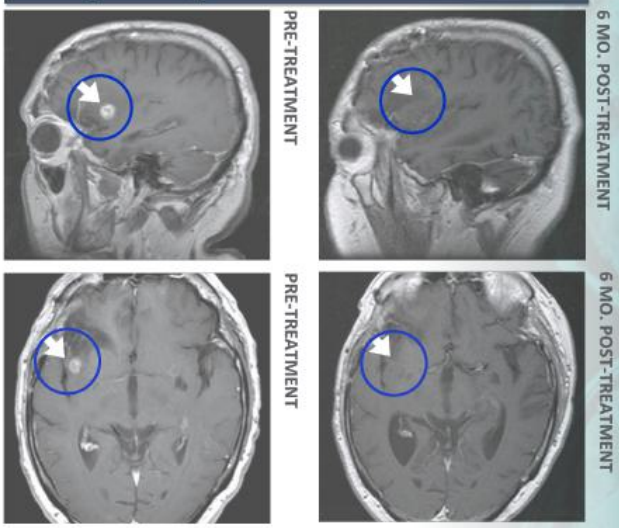
44% of subjects demonstrated "stable disease or better"

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

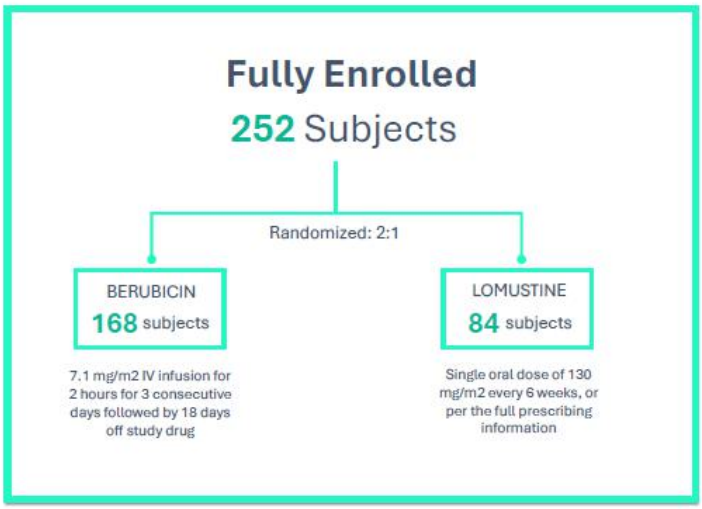
CNS Pharmaceuticals

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

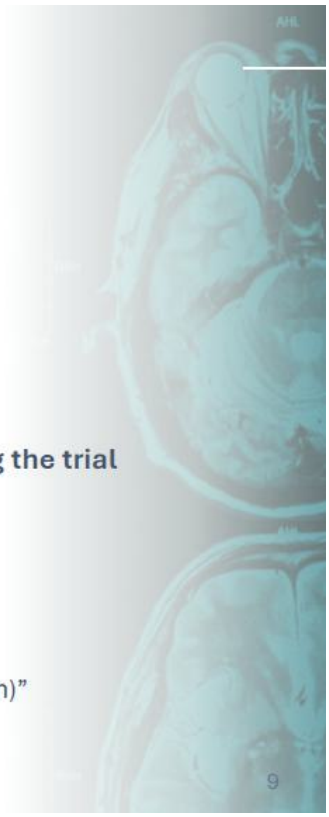


Interim Analysis and Rationale

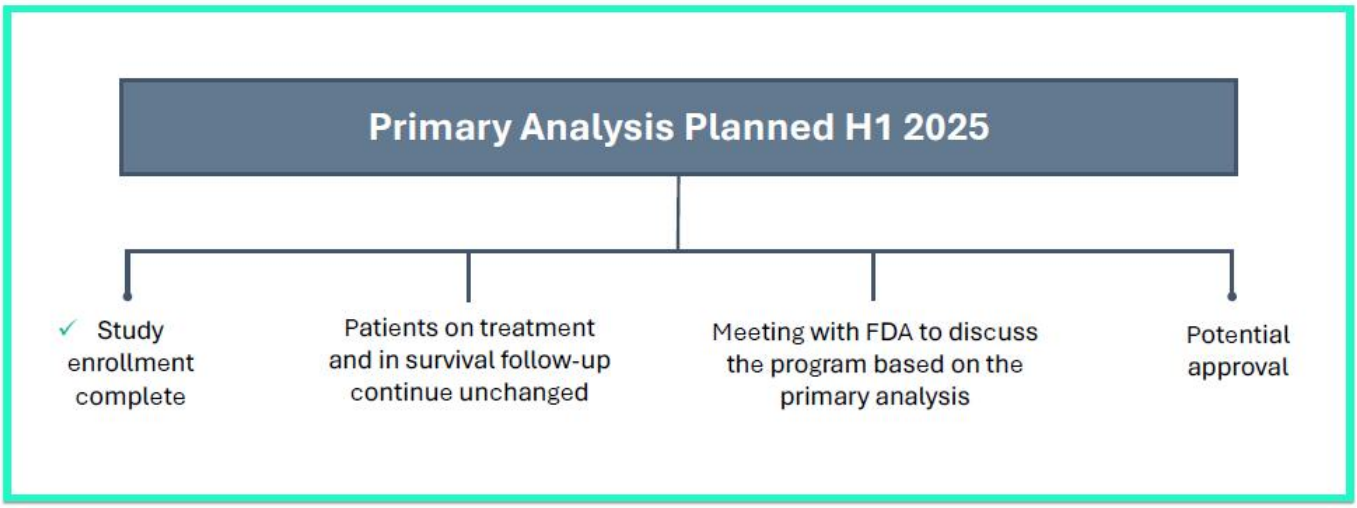
- **Independent Data Safety Monitoring Board (DSMB)**
  - Subject matter experts (oncologists, statistician)
  - Independently oversaw and monitored the clinical trial
  - Ensured the safety of the patients and the integrity of the data collected

- **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



A Much Bigger Story beyond GBM

INDICATION	PATIENT POPULATION	EST. U.S. NEW PATIENTS ANNUALLY	COMMENTS
Primary Brain Tumors	**Relapsed High Grade Gliomas**	**15,000 $2.3B Market in 2022**	**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

BrainCNS Pharmaceuticals

Intellectual Property

Orphan Drug

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

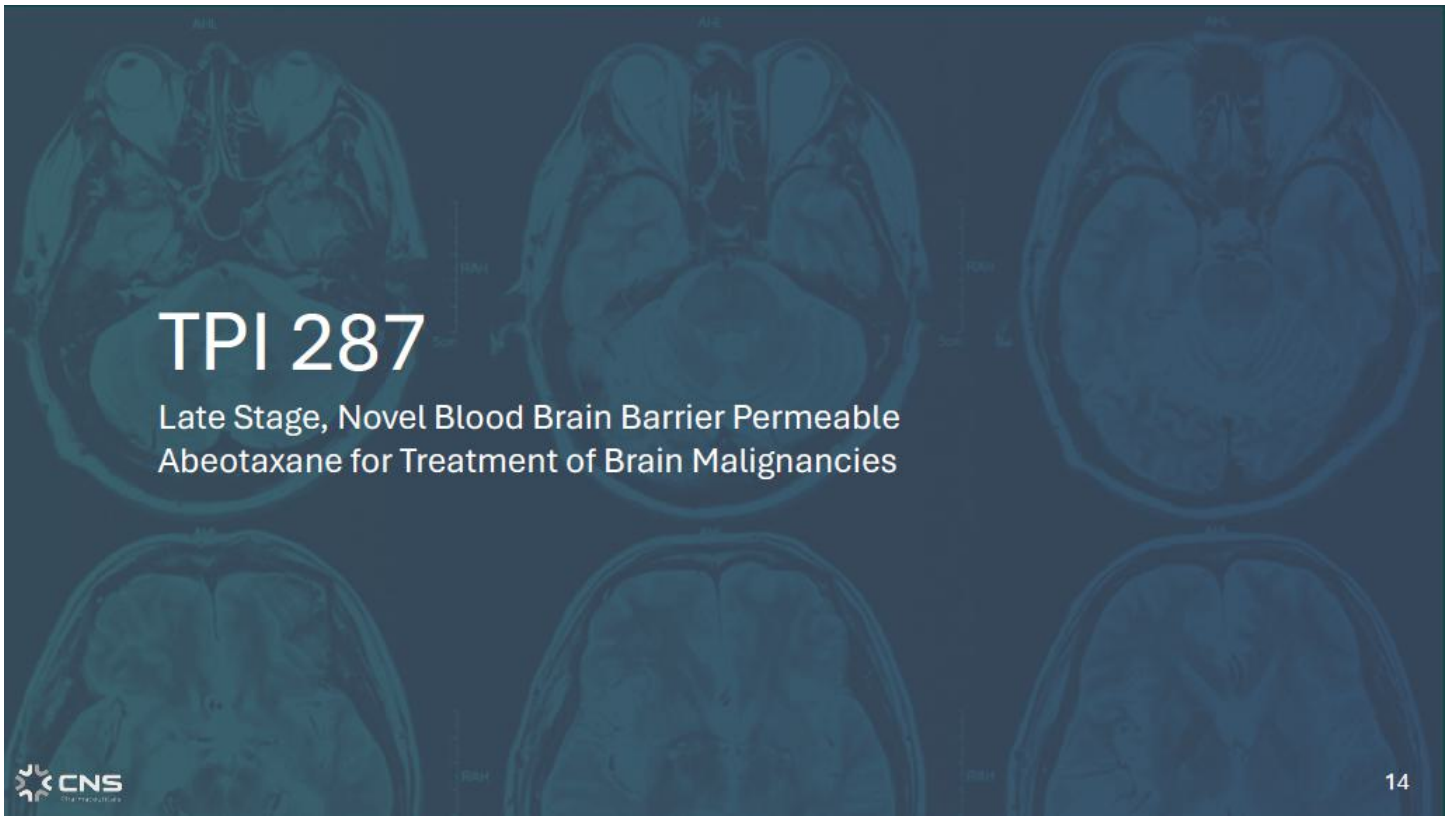
New Chemical Entity

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

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

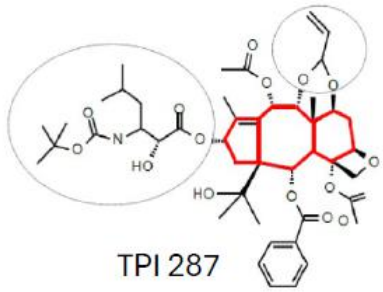
Commercial Planning

- 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


TPI 287
Late Stage, Novel Blood Brain Barrier Permeable
Abeotaxane for Treatment of Brain Malignancies
CNS
14

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

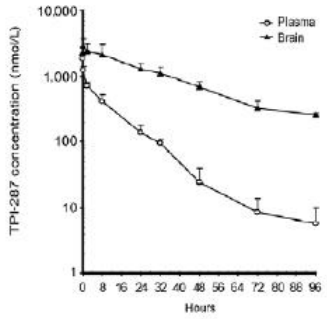
Paclitaxel

Readily Penetrates the Blood Brain Barrier in Animal Models

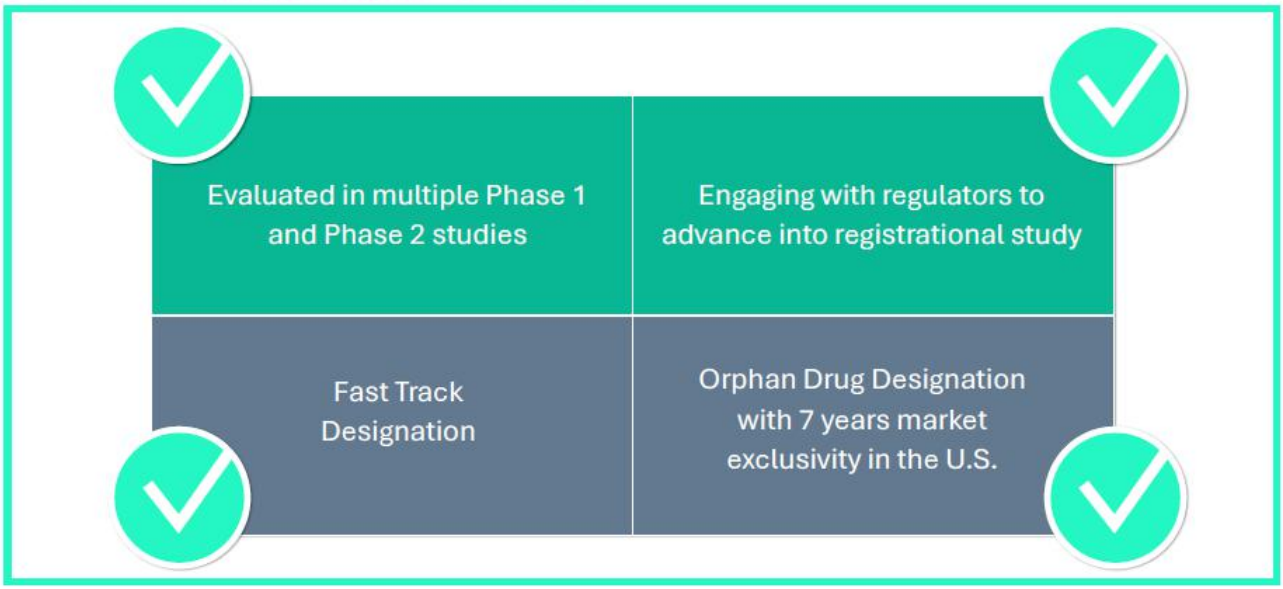
	COMPOUND	Blood ug*hr/ml	Brain ug*hr/g	Brain:Blood
Wild-type	paclitaxel	3.2	1.6	0.5
	docetaxel	8.7	2.5	0.3
	TPI 287	16.8	65.9	3.9
Pgp knock-out	paclitaxel	4.7	18.6	4.0
	docetaxel	9.0	15.4	1.7
	TPI 287	N/A	N/A	

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.

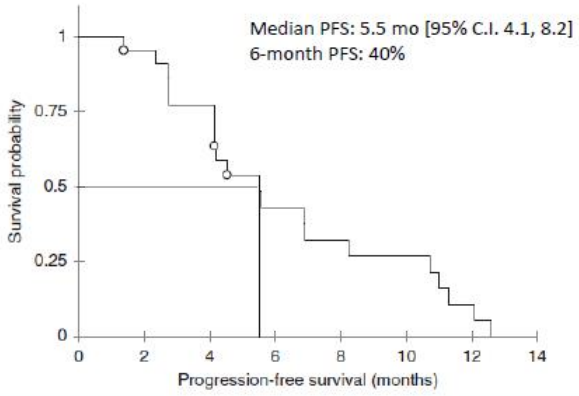


Clinical Trials with TPI 287

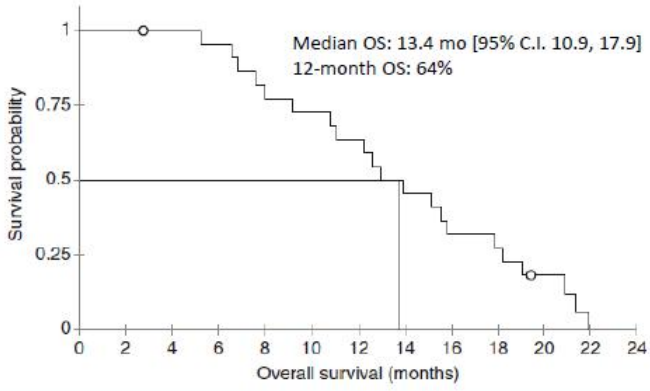


TPI 287 in Combination with Bevacizumab for the Treatment of Recurrent Glioblastoma

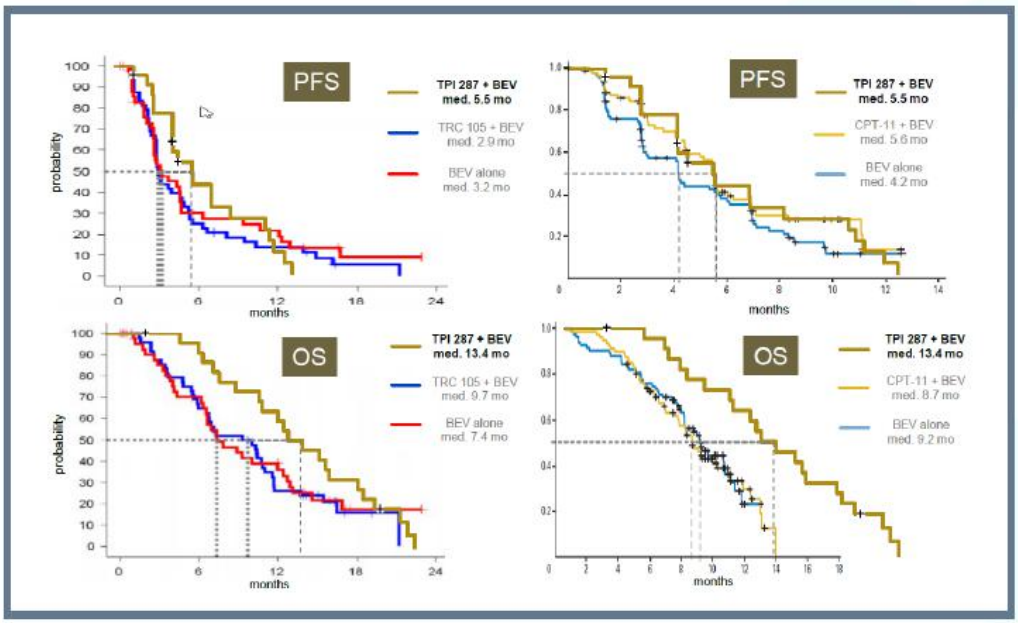
Progression-Free Survival



Overall Survival



Improved GBM Survival in Combination with Bevacizumab



* Graphs represent aggregate data from multiple studies

Management Team

John M. Climaco, Esq PRESIDENT & CHIEF EXECUTIVE OFFICER

Twenty-one years experience managing the operations, strategies and finances of public and private lifescience companies.

Christopher S. Downs, CPA CHIEF FINANCIAL OFFICER

Nearly 20 years of finance and investment banking experience primarily in the healthcare industry

Sandra L. Silberman, MD, PhD CHIEF MEDICAL OFFICER

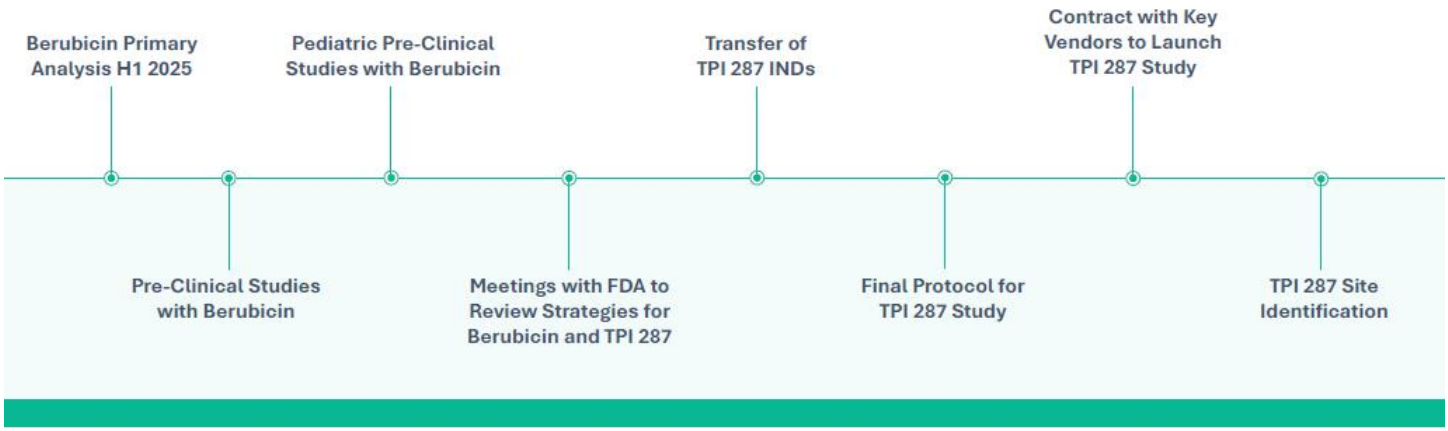
Board certified hematologist/medical oncologist with extensive experience in clinical development of novel therapies for the treatment of cancer. Frm Head Global Clinical Development at Novartis.

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.

CNS Pharmaceuticals

2025 Milestones



Investment Highlights

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