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): February 25, 2025

PROMIS NEUROSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada	**001-41429**	**98-0647155**
(State or other jurisdiction	**(Commission**	**(IRS Employer**
of incorporation)	**File Number)**	**Identification No.)**

Suite 200, 1920 Yonge Street,	
Toronto, Ontario	**M4S 3E2**
(Address of principal executive	**(Zip Code)**
offices)	

Registrant's telephone number, including area code: (416) 847-6898

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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Shares, no par value per share	PMN	The Nasdaq Capital Market

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. ☐

Item 7.01 Regulation FD Disclosure.

On February 25, 2025, ProMIS Neurosciences Inc. (the "Company") issued a press release (the "Press Release") announcing important progress in the PRECISE-AD Phase 1b clinical trial with the dosing of multiple patients with its lead drug candidate, PMN310, designed for the treatment of Alzheimer's disease. A copy of the press release is attached hereto as Exhibit 99.1.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated February 25, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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.

PROMIS NEUROSCIENCES INC.

Date: February 25, 2025

By: /s/ Neil Warma

Name: Neil Warma
Title: Chief Executive Officer

Exhibit 99.1

ProMIS Neurosciences Doses First Patients in Phase 1b PRECISE-AD Trial of PMN310 for Alzheimer's Disease

Rapid Enrollment and Dosing of First Patients Encouraging and Underscores Unmet Need for Better Treatment Options for Alzheimer's Disease

Six-month Interim Results Expected in 1H 2026 with Topline Results Anticipated in 2H 2026

CAMBRIDGE, Massachusetts – February 25, 2025 – ProMIS Neurosciences Inc. (Nasdaq: PMN), a clinical-stage biotechnology company focused on the generation and development of antibody therapeutics targeting toxic misfolded proteins in neurodegenerative diseases such as Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS) and multiple system atrophy (MSA), today announced important progress in the PRECISE-AD Phase 1b clinical trial with the dosing of multiple patients with its lead drug candidate, PMN310, designed for the treatment of Alzheimer's disease (AD). The dosing of several patients marks an important milestone in assessing the safety, tolerability, and pharmacokinetics of PMN310 and underscores ProMIS's commitment to addressing the urgent need for targeted therapies in AD by selectively targeting toxic oligomers, which we believe to be a key driver of disease progression.

PMN310 is a humanized monoclonal antibody (mAb) designed and developed to selectively target only soluble amyloid-beta oligomers (AβOs), which are believed to be the most toxic and pathogenic form of Aβ, while avoiding any binding to Aβ monomers and amyloid plaques.

"The initiation of dosing in multiple patients in our Phase 1b PRECISE-AD trial marks a significant milestone for ProMIS Neurosciences," said Neil Warma, Chief Executive Officer of ProMIS Neurosciences. "With a growing need for more effective and safer treatments for Alzheimer's disease, we are excited to take this critical step toward demonstrating PMN310's potential to make a real difference for patients and their families. We look forward to generating clinical data and furthering our commitment to transforming Alzheimer's treatment."

"The PRECISE-AD trial has been carefully designed to generate potentially robust clinical data, including biomarker insights and efficacy signals that will guide the next phase of development. We believe PMN310's selective binding to toxic Aβ oligomers and not to plaque or monomers differentiates it from other drugs currently on the market or in development and we believe we have the potential to deliver a more effective and well-tolerated treatment for patients suffering from Alzheimer's disease," added Mr. Warma.

"As physicians dedicated to advancing Alzheimer's research, we are excited to be part of the PRECISE-AD trial evaluating PMN310," said Yaneicy Gonzalez-Rojas, M.D. and Ahmad Aswad, M.D., Investigators of the PRECISE-AD clinical trial. "Alzheimer's disease remains one of the greatest unmet medical needs, and patients urgently need new treatment options that are both effective and well-tolerated. Current AD treatments offer only modest efficacy and are often accompanied by significant side effects, such as ARIA. PMN310's novel and selective targeting of amyloid oligomers has shown disease modifying capacity for AD in preclinical models, which we believe is promising and offers hope to Alzheimer's patients and their loved ones."

About PRECISE-AD Phase 1b Clinical Trial

The ongoing PRECISE-AD Phase 1b clinical trial (NCT06750432) is a randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics (PK) of multiple ascending doses (5, 10, 20 mg/kg) of intravenous PMN310 in patients with Stage 3 and Stage 4 AD. The study will also evaluate key biomarkers and clinical measures of efficacy to gather data on PMN310's therapeutic potential. The PRECISE-AD study plans to enroll approximately 100 subjects across 22 active sites in the United States. Eligible patients will be dosed monthly at one of the three dose levels or placebo over 12 months with assessment of safety, tolerability, PK, and pharmacodynamic blood- and brain-based markers of treatment effect at baseline and at every three months. Frequent MRI scans throughout the study will be conducted to monitor for emergence of ARIA.

About PMN310

PMN310 is a humanized monoclonal antibody (mAb) designed and developed based on its selectivity for soluble amyloid-beta oligomers (AβOs), which are believed to be the most toxic and pathogenic form of Aβ, relative to Aβ monomers and amyloid plaques. Soluble AβOs have been observed to be potent neurotoxins that bind to neurons, impair synaptic function and induce neurodegeneration. By selectively targeting toxic soluble AβOs, PMN310 aims to directly address the growing body of evidence indicating they may be the

primary underlying cause of the neurodegenerative process in Alzheimer's disease. PMN310 has successfully completed a Phase 1a clinical study (NCT06105528), a double-blind, placebo-controlled, single ascending dose study of the safety, tolerability and pharmacokinetics of PMN310 infusions in healthy volunteers.

About ProMIS Neurosciences Inc.

ProMIS Neurosciences Inc. is a clinical stage biotechnology company focused on generating and developing antibody therapeutics selectively targeting toxic misfolded proteins in neurodegenerative diseases such as Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS) and multiple system atrophy (MSA). The Company's proprietary target discovery engine applies a thermodynamic, computational discovery platform - ProMIS™ and Collective Coordinates - to predict novel targets known as Disease Specific Epitopes on the molecular surface of misfolded proteins. PMN310, the Company's lead product candidate for the treatment of AD, is a differentiated, humanized monoclonal antibody that has been designed to specifically bind toxic Aβ oligomers and to not bind plaque or monomers. Oligomers are known to drive disease progression in AD and PMN310 appears to selectively bind oligomers. PMN 310 has successfully completed a Phase 1a clinical study and is dosing Alzheimer's disease patients in a Phase 1b clinical trial in AD patients. ProMIS has offices in Cambridge, Massachusetts and Toronto, Ontario.

Forward-Looking Statements

For further information:

Visit us at www.promisneurosciences.com

Please submit media inquiries to info@promisneurosciences.com

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