

**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 10, 2025

PROMIS NEUROSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada
(State or other jurisdiction
of incorporation)

001-41429
(Commission
File Number)

98-0647155
(IRS Employer
Identification No.)

Suite 200, 1920 Yonge Street,
Toronto, Ontario
(Address of principal executive
offices)

M4S 3E2
(Zip Code)

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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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 January 10, 2025, ProMIS Neurosciences Inc. (the “Company”) issued a press release (the “Press Release”) announcing the initiation of its Phase 1b clinical trial (PRECISE-AD) evaluating its lead therapeutic candidate, PMN310, in Alzheimer’s disease (“AD”). 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 8.01 Other Events.

On January 10, 2025, the Company issued the Press Release announcing the initiation of its Phase 1b clinical trial (PRECISE-AD) evaluating its lead therapeutic candidate, PMN310, in AD. The ongoing Phase 1b PRECISE-AD trial will assess the safety, tolerability, and pharmacokinetics of PMN310 over 12 months of treatment in 100 patients with mild cognitive impairment due to AD (Stage 3 AD) or early AD (Stage 4 AD). The study will also evaluate key biomarkers and clinical measures of efficacy to gather data on PMN310’s therapeutic potential. Results from the recently completed Phase 1a study in healthy volunteers demonstrated a generally favorable safety and tolerability profile, with drug concentrations in cerebrospinal fluid supporting its potential for robust target engagement in patients with AD. The Company anticipates reporting certain interim data in the first half of 2026.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Certain information in this Current Report on Form 8-K constitutes forward-looking statements and forward-looking information (collectively, “forward-looking information”) within the meaning of applicable securities laws. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as “plans”, “excited to”, “targets”, “expects” or “does not expect”, “is expected”, “an opportunity exists”, “is positioned”, “estimates”, “intends”, “assumes”, “anticipates” or “does not anticipate” or “believes”, or variations of such words and phrases or state that certain actions, events or results “may”, “could”, “would”, “might”, “will” or “will be taken”, “occur” or “be achieved”. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Specifically, this Current Report on Form 8-K contains forward-looking information relating to the Company’s plans and expectations for the Phase 1b study of PMN310. Statements containing forward-looking information are not historical facts but instead represent management’s current expectations, estimates and projections regarding the future of our business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by the Company as of the date of this Current Report on Form 8-K, are subject to known and unknown risks, uncertainties and assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including, but not limited to, the risk that clinical data from healthy volunteers may not be indicative of future results in patients, the Company’s ability to fund its operations and continue as a going concern, its accumulated deficit and the expectation for continued losses and future financial results. Important factors that could cause actual results to differ materially from those indicated in the forward-looking information include, among others, the factors discussed throughout the “Risk Factors” section of the Company’s most recently filed Annual Report on Form 10-K for the year ended December 31, 2023 and in its subsequent filings filed with the United States Securities and Exchange Commission. Except as required by applicable securities laws, the Company undertakes no obligation to publicly update any forward-looking information, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated January 10, 2025</u>
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: January 10, 2025

By: /s/ Neil Warma

Name: Neil Warma

Title: Chief Executive Officer



ProMIS Neurosciences Initiates Phase 1b Clinical Trial (PRECISE-AD) in Alzheimer's Disease

Targeting toxic oligomers without binding to plaque, designed to reduce the risk of ARIA and potentially deliver enhanced outcomes for patients

CAMBRIDGE, Massachusetts – January 10, 2025 – ProMIS Neurosciences Inc. (Nasdaq: PMN), a clinical-stage biotechnology company focused on developing precision therapies for neurodegenerative diseases, today announced the initiation of its Phase 1b clinical trial (PRECISE-AD) evaluating its lead therapeutic candidate, **PMN310**, in Alzheimer's disease (AD).

PMN310, a humanized IgG1 antibody, is engineered to selectively target toxic oligomers of amyloid-beta (A β O)—which are believed to be a key driver of Alzheimer's pathology—while avoiding interaction with plaque deposits. This mechanism is designed to help reduce the risk of amyloid-related imaging abnormalities (ARIA), a common side effect associated with existing therapies, potentially offering a differentiated product profile.

The ongoing Phase 1b PRECISE-AD trial will assess the safety, tolerability, and pharmacokinetics of PMN310 over 12 months of treatment in 100 patients with mild cognitive impairment (MCI) due to AD (Stage 3 AD) or early AD (Stage 4 AD). The study will also evaluate key biomarkers and clinical measures of efficacy to gather data on PMN310's therapeutic potential. Results from the recently completed Phase 1a study in healthy volunteers demonstrated a generally favorable safety and tolerability profile, with drug concentrations in cerebrospinal fluid supporting its potential for robust target engagement in patients with AD.

"The initiation of the PRECISE-AD trial is a major milestone in our journey to develop PMN310 as a potential treatment for AD," said Neil Warma, CEO of ProMIS Neurosciences. "Current AD treatments offer only modest efficacy, often accompanied by significant side effect challenges such as ARIA, leaving a substantial unmet need for new options. We believe PMN310 has the potential to deliver on this need through its selective targeting mechanism."

"We have partnered with some of the best AD treatment centers in the U.S. for this trial and they are actively screening and enrolling patients. The PRECISE-AD trial has been carefully designed to generate robust clinical data, including biomarker insights and efficacy signals that will guide the next phase of development. We are excited about the opportunity to deliver real innovation to patients and look forward to sharing updates as we progress, with certain interim data anticipated in the first half of 2026."

"Flourish Research is excited to partner with ProMIS Neurosciences on the research and development of their novel medication PMN310," said Cameron S. Olezene, M.D., Principal Investigator at Flourish Research in Philadelphia, one of the first sites to become activated in the PRECISE-AD trial. "Monoclonal antibodies targeting toxic amyloid-beta species are the first treatments that have shown disease modifying capacity for Alzheimer's disease. It is often preferable to have multiple therapeutics available as treatment options. Thus, PMN310 is exciting because of its novel targeting of amyloid oligomers, potentially offering another solution for physicians and their patients."

Mr. Warma added "the trial name, **PRECISE-AD**, was chosen to reflect our focus on **P**ersonalized, **R**obust, and **E**ffective Clinical **I**ntervention with **S**pecificity and **E**xcellence in addressing Alzheimer's Disease. This name underscores our commitment to precision therapies, leveraging advanced science to selectively target the root causes of AD and deliver meaningful outcomes for patients. It also reflects the goal of the study design, which is to demonstrate PRECISE targeting of toxic oligomers by PMN310 in Alzheimer's disease."

The 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 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 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 (A β O), which are believed to be the most toxic and pathogenic form of A β , relative to A β monomers and amyloid plaques. Soluble A β O have been observed to be potent neurotoxins that bind to neurons, impair synaptic function and induce neurodegeneration. By selectively targeting toxic soluble A β O, 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 A β oligomers and to not bind plaque or monomers. Oligomers are known to drive disease progression in AD and, to date, PMN310 appears to selectively bind oligomers. ProMIS successfully completed a Phase 1a clinical study with PMN310 in healthy volunteers and has initiated a Phase 1b clinical trial in AD patients. ProMIS has offices in Cambridge, Massachusetts and Toronto, Ontario.

Forward-Looking Statements

Nasdaq has not reviewed and does not accept responsibility for the adequacy or accuracy of this release. Certain information in this news release constitutes forward-looking statements and forward-looking information (collectively, "forward-looking information") within the meaning of applicable securities laws. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "targets", "expects" or "does not expect", "is expected", "excited about", "an opportunity exists", "is positioned", "estimates", "intends", "assumes", "anticipates" or "does not anticipate" or "believes", or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might", "will" or "will be taken", "occur" or "be achieved". In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Specifically, this news release contains forward-looking information relating to the Company's plans and expectations for the Phase 1b study of PMN310, the potential for PMN310 to positively benefit patients with AD, the targeting of toxic misfolded proteins in neurodegenerative diseases that the Company believes may directly address fundamental AD pathology (including the belief and understanding that toxic oligomers of A β are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity, the potential for PMN310's mechanism of action to reduce the risk of amyloid-related imaging abnormalities (ARIA), management's belief that its patented platform technology has created an antibody candidate specific to toxic misfolded oligomers known to be present in AD, therapeutic activity and preferential targeting of toxic soluble aggregates by A β -directed antibodies and the potential implications thereof, the Company's pipeline, including application of its platform to other diseases, . Statements containing forward-looking information are not historical facts but instead represent management's current expectations, estimates and projections regarding the future of our business, future plans, strategies, projections, anticipated events and trends, the economy and other future conditions. Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by the Company as of the date of this news release, are subject to known and unknown risks, uncertainties and assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including, but not limited to, the risk that clinical data from healthy volunteers may not be indicative of future



results in patients, risks related to progressing the Company's Phase 1b trial and the Company's ability to fund its operations and continue as a going concern, its accumulated deficit and the expectation for continued losses and future financial results. Important factors that could cause actual results to differ materially from those indicated in the forward-looking information include, among others, the factors discussed throughout the "Risk Factors" section of the Company's most recently filed Annual Report on Form 10-K for the year ended December 31, 2023 and in its subsequent filings filed with the United States Securities and Exchange Commission. Except as required by applicable securities laws, the Company undertakes no obligation to publicly update any forward-looking information, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

For further information:

Visit us at www.promisneurosciences.com.

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