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): August 13, 2025

PROMIS NEUROSCIENCES INC.

(Exact name of registrant as specified in its charter)

Ontario, Canada	**001-41429**	**98-0647155**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
Suite 200, 1920 Yonge Street, Toronto, Ontario		**M4S 3E2**
(Address of principal executive offices)		**(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:

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 2.02 Results of Operations and Financial Condition

On August 13, 2025, ProMIS Neurosciences Inc. (the "Company") issued a press release, which is available on its website (www.promisneurosciences.com under “Investors/Financial Results”), reporting its financial condition and financial results as of and for the three and six months ended June 30, 2025. A copy of the press release is being furnished as Exhibit 99.1 to this report and is incorporated by reference into this Item 2.02.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 13, 2025
104	Cover Page Interactive Data File (embedded within 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: August 13, 2025

By: /s/ Neil Warma
Name: Neil Warma
Title: Chief Executive Officer

Exhibit 99.1

ProMIS Neurosciences Announces Second Quarter 2025 Financial Results & Corporate Highlights

U.S. FDA Grants Fast Track Designation for PMN310 in Alzheimer's Disease, enhancing program's potential for priority review

PRECISE-AD Phase 1b Trial in Alzheimer's Disease Progressing on Schedule: Over 50% enrolled, no cases of ARIA and no patient dropouts to date

Strengthened Financial Position with $21.6 Million in Gross Proceeds Raised in July 2025

Cambridge, Massachusetts – August 13, 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 Parkinson's disease (PD), today announced financial results for the second quarter ended June 30, 2025.

"The team's exceptional focus and execution in the first half of 2025 culminated in what has been an extraordinary past month for ProMIS and its key stakeholders," said Neil Warma, Chief Executive Officer of ProMIS Neurosciences. "As of August 12, enrollment in the PRECISE-AD Phase 1b Alzheimer's disease trial has surpassed 50% of the planned 128 patients, marking strong recruitment progress. Importantly, no cases of amyloid-related imaging abnormalities (ARIA), including brain swelling or microhemorrhage, have been observed to date, and no patient dropouts have been reported, reinforcing PMN310's potential favorable safety profile. At this stage, we remain on track to deliver 6-month blinded interim results in 2Q 2026 and final topline results in 4Q 2026."

"In addition, our recent FDA Fast Track designation for PMN310 underscores the urgent need for safer, more effective Alzheimer's treatments. Building on this regulatory milestone and the positive clinical progress of PRECISE-AD, we secured approximately $21.6 million in gross proceeds to accelerate PMN310's advancement toward its next phase of development," added Mr. Warma.

Corporate Highlights

EpiSelect™ Drug Discovery Engine

In July 2025, ProMIS presented on its proprietary protein-misfolding platform, EpiSelect™ at AAIC 2025 in a presentation titled Protein misfolding-specific epitope identification for passive and active immunotherapy of neurodegenerative diseases (**Abstract Number:** 98670)

The presentation highlighted the following:

- Toxic misfolded proteins underlie the pathogenesis of neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease (PD), amyotrophic lateral sclerosis (ALS) and frontotemporal dementia (FTD). Generation of therapeutic antibodies selectively targeting only disease-misfolded protein isoforms, while sparing normal or irrelevant isoforms of the same protein, has not yet been successfully achieved by conventional immunization strategies
- ProMIS Neurosciences has developed a computational platform (EpiSelect™) to identify conformational epitopes that are uniquely exposed on toxic misfolded proteins, which can then be used to generate misfolding-specific antibodies or vaccine formulations
- Application of the ProMIS platform produced PMN310, a clinical stage, humanized monoclonal antibody candidate that has been shown to be highly selective for toxic amyloid-beta oligomers (AβO) without significant reactivity with amyloid-beta monomers or fibrils, thereby avoiding target distraction by these more abundant species, and reducing the risk of brain edema and microhemorrhages associated with the targeting of vascular/ parenchymal amyloid. Similarly, specific epitopes for alpha-synuclein toxic oligomers/soluble fibrils that drive

synucleinopathies, and for pathogenic TDP-43 in ALS/FTD have been identified and lead candidate antibodies generated
- The precise conformation of these epitopes has been translated into vaccines inducing an antibody response selective for pathogenic molecular species in preclinical mouse vaccination studies

Alzheimer's Disease Program (PMN310)

ProMIS' lead candidate, PMN310, is a humanized IgG1 antibody directed toward toxic AβO that are believed to be a major driver of AD.

- As of August 12, 2025, ProMIS has enrolled over 50% of the planned 128 patients in the PRECISE-AD Phase 1b Alzheimer's disease trial. No cases of ARIA, including brain swelling or microhemorrhage, have been observed to date and no patient dropouts have been reported.
    - In May 2025, the DSMB recommended continuation of the trial as planned without any modification and clearance to proceed to the next dosing level, from the 5mg/kg dose of PMN310 in the first cohort to the 10mg/kg dose for the second cohort
- In July 2025:
    - Announced PMN310 was granted Fast Track Designation by the FDA
    - Showcased the following posters at AAIC 2025:
        - **Title:** PRECISE-AD, A Phase 1b, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of PMN310 in Patients with Early Alzheimer's Disease (**Poster Number:** 103159)
            - Based on the encouraging results from the Phase 1a trial (NCT06105528) of PMN310, ProMIS initiated PRECISE-AD, a Phase 1b clinical trial in AD patients. PRECISE-AD (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 Mild Cognitive Impairment due to Alzheimer's disease and mild Alzheimer's disease (Stage 3 and Stage 4 AD)
            - PRECISE-AD will be the first study to examine the effects of a monoclonal antibody directed solely against AβO on biomarkers associated with AD pathology and clinical outcomes. Safety will be a primary outcome of the study with particular emphasis on assessing the expectation that, as a non-plaque binder, PMN310 will have a reduced risk of ARIA. The study is powered to provide 95% confidence for detection of ARIA
            - The study has been designed with a sample size intended to provide sufficient power to provide meaningful insight into effects of PMN310 on biomarkers and clinical outcomes. Plasma biomarkers ptau217, GFAP, Aβ42/Aβ40, NfL will be measured at Baseline and 3-month intervals and CSF biomarkers, which also include total tau, pT243, SNAP25, and neurogranin, will be measured at Baseline, Month 6 and Month 12. Cognitive outcomes (CDR-SB, ADAS-cog, ADAS-ADL, IADRS, CGI) will be assessed at Baseline, Month 6 and Month 12
        - **Title:** Leveraging recent advances in biomarkers to optimize early phase drug development in Alzheimer's Disease (**Poster Number:** 103841)
            - Biomarkers are now used in both AD diagnosis and prediction of disease progression. Several clinical trials have utilized biomarker outcomes (amyloid-PET scans and cerebrospinal fluid (CSF) measures of Aβ and tau). Blood-based biomarkers offer advantages of lower costs and easier sample collection. Given their potential to predict both disease trajectory and clinical benefit, we investigated the relationship between biomarkers and clinical outcomes in recent trials of anti-amyloid antibodies for AD.
            - Compared to amyloid-PET, downstream biomarkers like plasma pTau have the potential to provide a more broadly applicable read-out for treatment efficacy, especially for treatments whose mechanism of action is not directly aimed at plaque removal.
                - *Key Highlights*
                    - The group-level correlation between a biomarker treatment effect and clinical endpoint treatment effect is a measurement of the biomarker's ability to predict clinical outcome in a clinical trial.
                    - Cohen's d effect size of plasma pT217 or pT181 as a biomarker outcome was three times greater than the Cohen's d values of clinical outcome CDR-SB, leading to higher power or lower sample sizes (about one ninth since it is a squared relationship).

        - The correlation of group-level plasma pT217 or pT181 with clinical outcome CDR-SB was approximately 0.786 with p values of 0.036.
- ProMIS expects to report blinded six-month interim results from PRECISE-AD in 2Q 2026, with topline results anticipated in 4Q 2026. The six-month interim analysis will include biomarker and safety data (including incidence of ARIA), with final analysis to include clinical outcome measures

ProMIS continues to advance its PMN311 Aβ vaccine program in AD based on its oligomer target epitope.

Key Pipeline Programs

- **Amyotrophic Lateral Sclerosis Disease Program (PMN267)**
    - PMN267 is a humanized IgG1 antibody directed against toxic misfolded TDP-43 as a potential therapeutic target for ALS and is ready to progress to IND-enabling studies

- **Parkinson's Disease (PD) and Multiple System Atrophy (MSA) Disease Program (PMN442)**
    - PMN442 is a humanized IgG1 antibody and is ProMIS's lead candidate for PD, MSA and other synucleinopathies based on its selective binding and protective activity against pathogenic forms of alpha-synuclein and is ready to progress to IND-enabling studies

Second Quarter 2025 Financial Highlights

- Cash and cash equivalents were $4.5 million as of June 30, 2025, compared to $1.0 million as of June 30, 2024. Subsequently, in July 2025, ProMIS received aggregate gross proceeds of $21.6 million across multiple transactions, including a Registered Direct Offering, Private Placements and Warrant Exercises.

- Research and development expenses were $8.7 million for the second quarter ended June 30, 2025, compared to $1.6 million for the same period in 2024. The increase was primarily attributable to expenditures on the PRECISE-AD Phase 1b trial for PMN310.

- General and administrative expenses were $1.4 million for the second quarter ended June 30, 2025, compared to $1.1 million for the same period in 2024.

- Net loss was $10.1 million for the second quarter ended June 30, 2025, compared to a net loss of $2.6 million for the same period in 2024. The net loss was primarily attributable to the increase in clinical trial expenditures.

About ProMIS Neurosciences Inc.

ProMIS Neurosciences is a clinical-stage biotechnology company committed to the discovery and development of therapeutic antibodies and vaccines selective for toxic oligomers associated with the development and progression of neurodegenerative and other misfolded protein diseases. The Company's proprietary target discovery engine, EpiSelect™, has been shown to predict novel targets known as Disease Specific Epitopes (DSEs) on the molecular surface of misfolded proteins that cause neurodegenerative and other misfolded protein diseases, including Alzheimer's disease (AD), amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD), multiple system atrophy (MSA), and Parkinson's Disease (PD). ProMIS has offices in Cambridge, Massachusetts (USA) and Toronto, Ontario (CAN).

About PMN310

PMN310, the Company's lead product candidate for the treatment of AD, is a potentially best-in-class, humanized monoclonal antibody that has been designed to selectively target only the toxic oligomers, avoiding plaque, thereby potentially reducing or eliminating ARIA liability and improving safety. In addition, because PMN310 may not to be limited by off-target binding or side effects, PMN310 could potentially offer an improved efficacy profile over other amyloid-directed antibody therapeutics. PMN310 was granted Fast Track designation by the U.S. Food and Drug Administration in July 2025.

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 Phase 1b study in AD patients and expectations of such study results, including interim results in the first half of 2026 and topline results by the end of 2026, statements relating to the Company's progress, including enrollment and dosing for its Phase 1b clinical trial, the potential for such studies to provide the first proof-of-concept data for PMN310, the potential that PMN310 has the potential 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 Aβ are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity, a computationally-derived Aβ vaccine for AD and the Company’s PMN310 antibody and vaccine candidate, 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 Aß-directed antibodies and the potential implications thereof, the Company’s pipeline, including its platform, including the capabilities thereof and the application of its platform to other diseases, statements regarding discovery candidates, timing of IND-enabling studies, preclinical data, recent presentations of such preclinical data and the takeaways therefrom, the ability to continue its growth and realize the anticipated contribution of the members of its board of directors and executives to its operation and progress, use of capital expenses, future accumulated deficit and other financial results in the future, ability to fund operations, the ability to maintain enough liquidity to execute its business plan and its ability to continue as a going concern. 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 preclinical results or early clinical results may not be indicative of future results, 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, 2024 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:

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PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

(expressed in U.S. dollars, except share amounts)

(unaudited)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash	$ 4,510,119	$ 13,291,167
Short-term investments	33,051	33,051
Prepaid expenses and other current assets	4,966,326	5,587,238
Total current assets	9,509,496	18,911,456
Total assets	$ 9,509,496	$ 18,911,456
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 2,780,179	$ 1,737,463
Accrued liabilities	7,043,908	480,962
Total current liabilities	9,824,087	2,218,425
Share-based compensation liability	62,395	199,263
Warrant liability	5,592	5,592
Total liabilities	9,892,074	2,423,280
Commitments and contingencies		
Shareholders' (deficit) equity:		
Common Shares, no par value, unlimited shares authorized, 32,689,190 shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Additional paid-in capital	108,140,611	107,546,433
Accumulated other comprehensive loss	(371,184)	(371,184)
Accumulated deficit	(108,152,005)	(90,687,073)
Total shareholders' (deficit) equity	(382,578)	16,488,176
Total liabilities and shareholders' (deficit) equity	$ 9,509,496	$ 18,911,456

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations

(expressed in U.S. dollars, except share amounts)

(unaudited)

	For the Three Months Ended June 30, 2025	For the Three Months Ended June 30, 2024	For the Six Months Ended June 30, 2025	For the Six Months Ended June 30, 2024
Operating expenses:				
Research and development	$ 8,749,784	$ 1,625,821	$ 14,214,034	$ 3,749,599
General and administrative	1,434,877	1,087,885	3,430,723	2,640,758
Total operating expenses	10,184,661	2,713,706	17,644,757	6,390,357
Loss from operations	(10,184,661)	(2,713,706)	(17,644,757)	(6,390,357)
Other income (expense):				
Change in fair value of financial instruments	—	59,087	—	44,954
Interest expense	—	—	—	(76,774)
Other income	67,632	30,962	179,825	163,432
Total other income (expense), net	67,632	90,049	179,825	131,612
Net loss	$ (10,117,029)	$ (2,623,657)	$ (17,464,932)	$ (6,258,745)
Net loss per share, basic and diluted	$ (0.29)	$ (0.13)	$ (0.50)	$ (0.32)
Weighted-average of outstanding Common Shares, basic and diluted	34,851,203	19,770,739	34,851,203	19,544,908