
**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): November 12, 2025

PROMIS NEUROSCIENCES INC.

(Exact name of registrant as specified in its charter)

Canada
(State or other jurisdiction
of incorporation)

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

001-41429
(Commission
File Number)

98-0647155
(IRS Employer
Identification No.)

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 2.02 Results of Operations and Financial Condition

On May 12, 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 months and nine months ended September 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 November 12, 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: November 12, 2025

By: /s/ Neil Warma

Name: Neil Warma

Title: Chief Executive Officer



ProMIS Neurosciences Announces Third Quarter 2025 Financial Results & Corporate Highlights

Phase 1b trial in Alzheimer's disease is over 85% enrolled: Cohorts 1 and 2 are fully enrolled

PMN310 continues to demonstrate a favorable safety profile

On track to report 6-month interim data in Q2 2026 and final 12-month top-line results in Q4 2026

Cambridge, Massachusetts – November 12, 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 third quarter ended September 30, 2025.

"2025 has been a year of intense focus and successful execution for the team at ProMIS," said Neil Warma, Chief Executive Officer of ProMIS Neurosciences. "We have reinforced the Company's strong foundation both strategically and clinically by bringing in additional capital to support our stated goals and adding Slanix Paul Alex, Pharm.D., President and Portfolio Manager for Ally Bridge Group's Public Equity strategy to our Board. Collectively, this amplifies awareness amongst the investment community as we approach the nearing completed enrollment of our PRECISE-AD trial evaluating our first clinical candidate, PMN310, which was designed using our proprietary EpiSelect™ computational drug discovery engine. All of this is ultimately preparing the Company for its multiple key anticipated inflection points in 2026 and endeavoring to deliver on its promise of developing next-generation therapies for AD and for other neurodegenerative disorders."

Corporate Highlights

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. PMN310 was granted Fast Track Designation by the U.S. Food and Drug Administration .

- As of November 12, 2025, ProMIS has fully enrolled Cohorts 1 and 2 and is well into Cohort 3, with complete enrollment expected before the end of the year. PMN310 continues to demonstrate a favorable safety profile, with respect to incidence of amyloid-related imaging abnormalities (ARIA) and serious adverse events (SAEs).
- On September 3, 2025, ProMIS announced that the independent Data and Safety Monitoring Board (DSMB) for its ongoing PRECISE-AD Phase 1b clinical trial unanimously recommended that the Company proceed to the third and final dose escalation cohort evaluating PMN310 for the treatment of AD.

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.
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Third Quarter 2025 Financial Highlights

- Cash and cash equivalents were \$15.4 million as of September 30, 2025, compared to \$13.3 million as of December 31, 2024. The increase in cash was attributable to multiple transactions in July 2025, including a registered direct offering, private placements and discounted warrant exercises, where we received aggregate gross proceeds of approximately \$21.6 million.
- Research and development expenses were \$9.8 million for the third quarter ended September 30, 2025, compared to \$2.6 million for the same period in 2024. The increase was primarily attributable to expenditures on the PRECISE-AD Phase 1b clinical trial for PMN310.
- General and administrative expenses were \$2.0 million for the third quarter ended September 30, 2025, compared to \$1.9 million for the same period in 2024.
- Loss from operations was \$11.8 million for the third quarter ended September 30, 2025, compared to an operating loss of \$4.4 million for the same period in 2024. The increased operating loss was primarily attributable to expenditures on the PRECISE-AD Phase 1b clinical trial for PMN310.

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 and the PRECISE-AD Trial for Alzheimer's Disease (AD)

PMN310, the Company's lead product candidate for the treatment of AD, is a humanized monoclonal antibody that has been designed to selectively target only the toxic oligomers, avoiding plaque, thereby potentially reducing or eliminating amyloid-related imaging abnormalities (ARIA) liability. In addition, because PMN310 may not 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.

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 AD and mild AD (Stage 3 and Stage 4 AD). PRECISE-AD will be the first study to examine the effects of a monoclonal antibody directed solely against Aβ on biomarkers associated with AD pathology and clinical outcomes. Safety will be a primary outcome of the study with particular emphasis on assessing whether, as a non-plaque binder, PMN310 may 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.

EpiSelect™ Drug Discovery Engine

Toxic misfolded proteins underlie the pathogenesis of neurodegenerative diseases such as Alzheimer's disease (AD), 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 potentially 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 and 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.

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, including DSMB approval to advance to third and final dose escalation cohort and planned timing for completion and anticipated data read out of interim results in the second 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 A β are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity, a computationally-derived A β 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 A β -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, 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:

Visit us at www.promisneurosciences.com

Please submit media inquiries to info@promisneurosciences.com

For Investor Relations, please contact:

Kaytee Bock Zafereo

katherine.rock@promisneurosciences.com

PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

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

(unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash	\$ 15,399,165	\$ 13,291,167
Short-term investments	33,051	33,051
Prepaid expenses and other current assets	6,025,931	5,587,238
Total current assets	<u>21,458,147</u>	<u>18,911,456</u>
Total assets	<u>\$ 21,458,147</u>	<u>\$ 18,911,456</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,211,485	\$ 1,737,463
Accrued liabilities	7,999,562	480,962
Total current liabilities	<u>12,211,047</u>	<u>2,218,425</u>
Share-based compensation liability	54,153	199,263
Warrant liability	5,592	5,592
Total liabilities	<u>12,270,792</u>	<u>2,423,280</u>
Commitments and contingencies		
Shareholders' equity:		
Common Shares, no par value, unlimited shares authorized, 53,811,110 and 32,689,190 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	129,290,671	107,546,433
Accumulated other comprehensive loss	(371,184)	(371,184)
Accumulated deficit	(119,732,132)	(90,687,073)
Total shareholders' equity	<u>9,187,355</u>	<u>16,488,176</u>
Total liabilities and shareholders' equity	<u>\$ 21,458,147</u>	<u>\$ 18,911,456</u>

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations

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

(unaudited)

	For the Three Months Ended September 30, 2025	For the Three Months Ended September 30, 2024	For the Nine Months Ended September 30, 2025	For the Nine Months Ended September 30, 2024
Operating expenses:				
Research and development	\$ 9,797,418	\$ 2,563,774	\$ 24,011,452	\$ 6,313,373
General and administrative	1,953,014	1,870,903	5,383,737	4,511,660
Total operating expenses	11,750,432	4,434,677	29,395,189	10,825,033
Loss from operations	(11,750,432)	(4,434,677)	(29,395,189)	(10,825,033)
Other income (expense):				
Change in fair value of financial instruments	—	16,969,126	—	17,014,080
Interest expense	—	—	—	(76,775)
Other income	170,306	235,912	350,130	399,344
Loss on issuance of Common Shares, warrants, and pre-funded warrants in July 2024 PIPE	—	(3,494,536)	—	(3,494,536)
Total other income, net	170,306	13,710,502	350,130	13,842,113
Net (loss) income	\$ (11,580,126)	\$ 9,275,825	\$ (29,045,059)	\$ 3,017,080
Net (loss) income per share, basic	\$ (0.24)	\$ 0.31	\$ (0.78)	\$ 0.13
Net (loss) income per share, diluted	\$ (0.24)	\$ 0.31	\$ (0.78)	\$ 0.13
Weighted-average outstanding Common Shares, basic	48,833,799	30,023,675	37,078,745	22,953,751
Weighted-average outstanding Common Shares, diluted	48,833,799	30,067,095	37,078,745	23,676,104