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): March 31, 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 March 31, 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 year ended December 31, 2024. 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 March 31, 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: March 31, 2025

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

Exhibit 99.1

ProMIS Neurosciences Announces Full Year 2024 Financial Results and Recent Highlights

Rapid Enrollment and Dosing of First Patients in PRECISE-AD Trial Underscores the Unmet Need for Better Treatment Options for Alzheimer's Disease

PRECISE-AD Six Month Interim Results Expected in 1H 2026 with Topline Results Anticipated by end of 2026

CAMBRIDGE, Massachusetts – March 31, 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 financial results for the fiscal year ended December 31, 2024 and provided a corporate update.

"2024 was a transformational year for ProMIS Neurosciences as we reached a major milestone with the initiation of our 100-patient Phase 1b clinical trial for PMN310, our lead antibody candidate for AD," said Neil Warma, Chief Executive Officer of ProMIS Neurosciences. "Our strong momentum from 2024 has carried into the first quarter of 2025 as we have successfully dosed multiple patients in the Phase 1b study, which was carefully designed to generate a robust body of clinical data, including biomarker insights and evaluation of potential efficacy and safety signals. PMN310 is uniquely designed to selectively target toxic oligomers of amyloid-beta, which we believe is a key differentiator from both approved treatments and those currently in development. With strong enthusiasm from investigators and patients, we are pleased with the study's momentum and remain on track to deliver interim data in 2026, which we believe could validate PMN310 as a potential best-in-class treatment for AD. This progress was made possible by the successful completion of our Phase 1a trial and securing up to $122.3 million in funding in 2024, providing the financial foundation to advance PMN310 and our broader pipeline."
"In addition to our progress in AD, we continue to advance our programs in ALS and Parkinson's disease (PD) while also identifying a lead vaccine candidate, PMN440, targeting multiple synucleopathies," Warma continued. "Our commitment to innovation is further reflected in the expansion of our intellectual property (IP) portfolio, with 23 newly granted or allowed patents since January 2024, seventeen of which relate to PMN310. We also received our first patent allowance relating to PMN442 and PMN440, strengthening our position in the alpha-synuclein space. With a well-funded clinical program, a robust pipeline, and a growing IP estate, ProMIS is well-positioned to drive the next wave of innovation in neurodegenerative diseases."

Recent Highlights

Alzheimer's Disease Program (PMN310)

ProMIS' lead candidate, PMN310, is a humanized IgG1 antibody directed toward toxic amyloid-beta (Ab) oligomers (AβO) that are believed to be a major driver of AD.

- Based on the encouraging results from the Phase 1a study of PMN310, ProMIS initiated a Phase 1b clinical trial (PRECISE-AD) and has since successfully dosed multiple patients with PMN310. 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 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.

- ProMIS expects to report six-month interim results from PRECISE-AD in the first half of 2026, with topline results anticipated by the end of 2026. We anticipate the six-month interim analysis will include impact of biomarkers and safety (incidence of ARIA), with final analysis to include clinical outcome measures.

- PMN310 successfully completed a Phase 1a clinical study (NCT06105528), a double-blind, placebo-controlled, single ascending dose (SAD) study of the safety, tolerability and pharmacokinetics of PMN310 infusions in healthy volunteers. The trial consisted of five SAD cohorts that included 40 subjects across two active sites in the United States.

    - In October 2024, ProMIS presented positive data from all five cohorts in its first-in-human Phase 1a clinical trial of PMN310 in healthy volunteers at the 17th Clinical Trials on Alzheimer's Disease (CTAD) Conference. The results showed PMN310 was generally well-tolerated in all five SAD cohorts (2.5, 5, 10, 20 and 40 mg/kg) and, importantly, crossed the blood brain barrier in healthy volunteers in a dose dependent manner with PK suggesting that monthly dosing may provide levels of PMN310 adequate for target engagement in AD patients. The complete dataset from all five cohorts reinforces previously reported data from the first four cohorts announced in July 2024.

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

- ProMIS will present preclinical data at the American Alzheimer's and Parkinson's Disease (AD/PD) International Conference in Vienna, Austria from April 1-4, 2025 and at the Academy of Neurology (AAN) Annual Meeting in San Diego, CA from April 5-9, 2025. The presentations titled, "Novel approach to optimization of Alzheimer's vaccine configuration for maximal targeting of toxic amyloid-beta oligomers" and "Rational design of Alzheimer's vaccine to maximize selective targeting of toxic amyloid-beta oligomers," will highlight data demonstrating that maximal reactivity was observed with immune IgG against the monovalent vaccine containing epitope 301, the target of PMN310.

Amyotrophic Lateral Sclerosis Disease Program (PMN267)

PMN267 is a humanized IgG1 antibody directed against toxic misfolded TDP-43 as a potential therapeutic target for amyotrophic lateral sclerosis (ALS).

- ProMIS will present a virtual oral presentation of preclinical data at the 2025 AD/PD Conference titled, "Selective targeting of pathogenic TDP-43 with misfolding-specific monoclonal antibodies and intrabodies against a pathogenic loss-of-structure epitope in the N-terminal domain," providing proof-of-concept evidence that supports selective targeting of misfolded toxic aggregates of TDP-43 as a potentially safe and effective avenue to treat neurodegenerative diseases, which is the target of PMN267.

Multiple Synucleinopathies Disease Vaccine Program (PMN440)

- ProMIS will present preclinical data at the 2025 AD/PD International Conference and at the AAN Annual Meeting titled, "Novel approach to optimization of alpha-synuclein vaccine composition for maximal targeting of toxic alpha-synuclein species" and "Rational design of a vaccine for synucleinopathies using computationally-derived conformational B cell epitopes to selectively target pathogenic alpha-synuclein species." These data sets will showcase the potential of vaccinations with conformational *B* cell epitopes to produce high affinity antibodies with the desired selectivity for pathogenic Asyn and supports the development of PMN440 as a treatment for synucleinopathies, such as PD, dementia with Lewey bodies and MSA.

Full Year 2024 Financial Highlights

- Cash and cash equivalents were $13.3 million as of December 31, 2024, compared to $12.6 million as of December 31, 2023. During the third quarter of 2024, the Company completed a public investment in private equity (PIPE) financing that provided initial upfront funding of $30.3 million and the potential to provide an additional $92.4 million tied to the exercise of warrants.

- Research and development expenses were $10.6 million for the fiscal year ended December 31, 2024, compared to $7.9 million for the same period in 2023. The increase was primarily attributable to costs related to the execution of the Phase 1a clinical trial and cost related to the initiation of the Phase 1b clinical trial.

- General and administrative expenses decreased to $6.2 million for the year ended December 31, 2024, compared to $6.4 million for the same period in 2023.

- Net income was $2.8 million for the full year ended December 31, 2024, compared to a net loss of $13.2 million for the same period in 2023. The net income was primarily attributable to a gain on the change in fair value of our warrant liabilities of $22.6 million.

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

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 initiation of 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 application of its platform to other diseases, statements regarding 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, including the use of proceeds from the PIPE financing, 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

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PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

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

(unaudited)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash	$ 13,291,167	$ 12,598,146
Short-term investments	33,051	32,358
Prepaid expenses and other current assets	5,587,238	988,641
Total current assets	18,911,456	13,619,145
Total assets	$ 18,911,456	$ 13,619,145
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,737,463	$ 7,843,136
Accrued liabilities	480,962	1,506,526
Total current liabilities	2,218,425	9,349,662
Share-based compensation liability	199,263	422,002
Warrant liability	5,592	94,185
Total liabilities	2,423,280	9,865,849
Commitments and contingencies		
Shareholders' equity:		
Series 2 Convertible Preferred Shares, no par value, unlimited shares authorized, 0 and 1,166,667 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Common shares, no par value, unlimited shares authorized, 32,689,190 and 18,885,254 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	107,546,433	97,590,426
Accumulated other comprehensive loss	(371,184)	(371,184)
Accumulated deficit	(90,687,073)	(93,465,946)
Total shareholders' equity	16,488,176	3,753,296
Total liabilities and shareholders' equity	$ 18,911,456	$ 13,619,145

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations and Comprehensive Income (Loss)

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

(unaudited)

	Years Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 10,637,976	$ 7,883,165
General and administrative	6,189,502	6,379,568
Total operating expenses	16,827,478	14,262,733
Loss from operations	(16,827,478)	(14,262,733)
Other income (expense):		
Change in fair value of financial instruments	22,581,477	866,738
Interest expense	(76,775)	(201,390)
Other income	626,184	384,903
Loss on issuance of common shares, warrants, and pre-funded warrants in July 2024 PIPE	(3,524,535)	—
Total other income (expense), net	19,606,351	1,050,251
Net income (loss)	2,778,873	(13,212,482)
Net income (loss) per share, basic	$ 0.11	$ (1.07)
Net income (loss) per share, diluted	$ 0.11	$ (1.07)
Weighted-average shares outstanding of common shares, basic	25,919,965	12,292,707
Weighted-average shares outstanding of common shares, diluted	26,461,731	12,292,707