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 8, 2024

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 8, 2024, 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, 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 August 8, 2024
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 8, 2024

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

Exhibit 99.1

ProMIS Neurosciences Announces Second Quarter 2024 Financial Results and Recent Highlights

Reported positive topline data from first-in-human Phase 1a clinical trial of PMN310 as a treatment for Alzheimer's disease that met objectives for tolerability, safety and pharmacokinetics

Secured up to $122.7 million in private placement financing from leading healthcare specialty funds to advance Phase 1b study of PMN310 in Alzheimer's disease patients in second half 2024

CAMBRIDGE, Massachusetts and TORONTO, Ontario – August 8, 2024 – 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 second quarter ended June 30, 2024 and provided a corporate update.

"We are coming off a very important and successful few months for ProMIS as we reported positive top-line Phase 1a data and closed on a strong financing, which could bring in up to $122.7 million to support our Alzheimer's candidate and pipeline compounds," said Neil Warma, CEO of ProMIS Neurosciences.

"We believe these events have transformed ProMIS and now place us at the forefront of companies developing therapies for dementia, as we advance one of the most promising candidates in the clinic for Alzheimer's disease. Top-line data from the first four of five cohorts in the Phase 1a clinical trial showed PMN310 to be generally safe and well-tolerated and, importantly, showed that PMN310 crossed into the central nervous system in quantities suggesting we may see potential target engagement in the upcoming Phase 1b clinical study."

"Given that PMN310 is designed to bind only to toxic oligomeric forms of amyloid beta and to avoid any binding to amyloid beta plaque, we do not expect to see elevated levels of swelling or bleeding of the brain known as ARIA, a serious side effect that has been associated with almost all of the plaque-binding drugs on the market and in development. The apparent selectivity of PMN310 could potentially differentiate it significantly in its efficacy and safety profile as it continues through clinical development in an upcoming Phase 1b trial. This randomized, placebo controlled, double blind clinical trial is expected to enroll 100 patients and will not only evaluate critical biomarkers and incidence of ARIA but will also extend for 12 months to enable us to measure important clinical endpoints. The trial design is particularly robust and comprehensive for a Phase 1b study, in order to validate PMN310's significant differentiation on efficacy and safety. We are excited to be moving quickly to initiate this clinical study in the coming months," added Mr. Warma.

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 Alzheimer's disease (AD).

- The Phase 1a clinical trial was a randomized, double-blind, placebo-controlled trial evaluating the safety and tolerability of PMN310 in healthy normal volunteers (NCT06105528). The trial consisted of five single-ascending dose (SAD) cohorts and was designed to evaluate the safety, tolerability, and pharmacokinetics (PK), of intravenous doses of PMN310. The trial completed enrollment of all 40 subjects across 2 active sites in the United States. The trial was initiated based on encouraging nonclinical studies of PMN310 that support the selective targeting of AβOs.

- In July 2024, ProMIS reported positive data from the first four cohorts in its first-in-human Phase 1a clinical trial of PMN310 in healthy volunteers. PMN310 was well-tolerated through the first four SAD dose cohorts (2.5, 5, 10, 20 mg/kg), with no treatment-emergent serious adverse events (SAEs) observed after administration of PMN310. Cerebrospinal fluid (CSF) was collected on days 3 and 29 after PMN310 administration. Tests showed that the levels of PMN310 in the CSF increased proportionally with the dosage on both days 3 and 29. Even at the lowest dose, PMN310 appeared present at over 100 times the concentration of the oligomers in the CNS. The half-life of PMN310 in CSF was approximately 25 days, which is supportive of once per month dosing.

- The Company expects to report topline results from all five cohorts in the second half of 2024 and to present the full dataset at an upcoming medical meeting.

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

- In July 2024, the Company presented preclinical data in a poster at the Alzheimer's Association International Conference (AAIC), which took place from July 29-August 1, 2024 in Philadelphia. The poster titled, "Novel approach to optimization of Alzheimer's vaccine configuration for maximal targeting of toxic amyloid-beta oligomers," highlighted data demonstrating that maximal reactivity was observed with immune IgG against the monovalent vaccine containing epitope 301, the target of PMN310, the Company's clinical-stage monoclonal antibody.

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.

- In August 2024, ProMIS announced the publication of two papers highlighting the role of toxic misfolded superoxide dismutase-1 (SOD1) aggregates in the pathogenesis of ALS. One paper published in *Acta Neuropathologica* is titled, "Seeding activity of human superoxide dismutase 1 aggregates in familial and sporadic amyotrophic lateral sclerosis postmortem neural tissues by real-time quaking-induced conversion," and the other publication in the online journal, *Open Biology,* is titled, "Amyloidogenic regions in beta-strands II and III modulate the aggregation and toxicity of SOD1 in living cells." The *Acta Neuropathologica* publication can be accessedhere, and the *Open Biology* publication can be accessedhere.

- In April 2024, the Company announced the publication of supportive preclinical data for PMN267 as a potential therapeutic agent for ALS in the *Journal of Biological Chemistry* in an article titled, "Tryptophan residues in TDP-43 and SOD1 modulate the cross-seeding and toxicity of SOD1." The publication can be accessed here.

Corporate

- In July 2024, ProMIS completed a private investment in public equity (PIPE) financing that will provide up to $122.7 million in gross proceeds, which includes an initial upfront funding of $30.3 million and up to $92.4 million tied to exercise of warrants based on the Company achieving certain milestones, with certain of the warrants being subject to shareholder approval. The PIPE financing included participation from new and existing healthcare specialist investors such as Great Point Partners, LLC, Armistice Capital, Ally Bridge Group, Sphera Healthcare, and other institutional and individual accredited investors. Proceeds from the private placement are expected to be used to advance the clinical development of PMN310, as well as for working capital and other general corporate expenses.

Second Quarter 2024 Financial Highlights

- Cash and cash equivalents were $1.0 million as of June 30, 2024, compared to $12.6 million as of December 31, 2023. Following the close of the quarter, in July 2024, the Company completed a PIPE financing that provided initial upfront funding of $30.3 million and which has the potential to provide an addition $92.4 million tied to exercise of warrants based on the Company achieving certain milestones, with certain of the warrants being subject to shareholder approval.

- Research and development expenses were $1.6 million for the three-months ended June 30, 2024, compared to $1.0 million for the same period in 2023, primarily attributable to a $0.9 million increase in direct research and development expenses related to PMN310 Phase 1a clinical trial costs, offset by a decrease of $0.2 million in consulting expenses.

- General and administrative expenses decreased to $1.1 million for the quarter ended June 30, 2024, compared to $1.9 million for the same period in 2023, which included one-time costs of $0.8 million related to expensing previously deferred financing costs.

- Net loss was $2.6 million for the quarter ended June 30, 2024, compared to a net loss of $2.3 million for the same period in 2023.

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. Using this unique approach, the Company is developing novel antibody therapeutics for AD, ALS and MSA. 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 announcement of results of all five cohorts of the Company’s Phase 1a study, plans to advance PMN310 into a Phase 1b MAD study in AD patients and expectations of such study results, 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, including data announced regarding ALS, 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 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, 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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PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

(expressed in US dollars, except share amounts)

(unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 992,463	$ 12,598,146
Short-term investments	32,358	32,358
Prepaid expenses and other current assets	384,776	988,641
Total current assets	1,409,597	13,619,145
Total assets	$ 1,409,597	$ 13,619,145
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 2,015,167	$ 7,843,136
Accrued liabilities	1,156,789	1,506,526
Total current liabilities	3,171,956	9,349,662
Share-based compensation liability	465,488	422,002
Warrant liability	49,231	94,185
Total liabilities	3,686,675	9,865,849
Commitments and contingencies		
Shareholders' (deficit) equity:		
Series 2 Convertible Preferred Shares, no par value, unlimited shares authorized, 1,166,667 shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common shares, no par value, unlimited shares authorized, 18,961,116 and 18,885,254 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	97,818,797	97,590,426
Accumulated other comprehensive loss	(371,184)	(371,184)
Accumulated deficit	(99,724,691)	(93,465,946)
Total shareholders' (deficit) equity	(2,277,078)	3,753,296
Total liabilities and shareholders' (deficit) equity	$ 1,409,597	$ 13,619,145

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations and Comprehensive Loss
(expressed in US dollars, except share amounts)
(unaudited)

	For the Three Months Ended June 30, 2024	For the Three Months Ended June 30, 2023	For the Six Months Ended June 30, 2024	For the Six Months Ended June 30, 2023
Operating expenses:				
Research and development	$ 1,625,821	$ 1,005,715	$ 3,749,599	$ 4,515,967
General and administrative	1,087,885	1,894,169	2,640,758	3,354,588
Total operating expenses	2,713,706	2,899,884	6,390,357	7,870,555
Loss from operations	(2,713,706)	(2,899,884)	(6,390,357)	(7,870,555)
Other income (expense):				
Change in fair value of financial instruments	59,087	606,214	44,954	564,549
Interest expense	—	(49,182)	(76,774)	(49,182)
Other income	30,962	30,878	163,432	83,783
Total other income (expense), net	90,049	587,910	131,612	599,150
Net loss	(2,623,657)	(2,311,974)	(6,258,745)	(7,271,405)
Other comprehensive loss				
Foreign currency translation adjustment	—	(171,462)	—	(175,816)
Comprehensive loss	$ (2,623,657)	$ (2,483,436)	$ (6,258,745)	$ (7,447,221)
Net loss per share, basic and diluted	$ (0.13)	$ (0.27)	$ (0.32)	$ (0.85)
Weighted-average shares outstanding of common shares, basic and diluted	19,770,739	8,579,284	19,544,908	8,579,284