

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): April 30, 2024

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:

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 7.01 Regulation FD Disclosure.

On April 30, 2024, ProMIS Neurosciences Inc. (the “Company”) issued a press release announcing the publication of a paper titled, “Relationship between therapeutic activity and preferential targeting of toxic soluble aggregates by amyloid-beta-directed antibodies,” in the online journal, bioRxiv (the “Press Release”). 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 April 30, 2024, the Company issued the Press Release referenced above. The study characterized and compared the binding profile of various amyloid-beta (A $\beta$ )-directed antibodies to monomers, soluble oligomers and insoluble A $\beta$  fibrils. The results indicate that selectivity for soluble toxic A $\beta$  oligomers may be a driver of clinical efficacy and indicated that PMN310 displayed the greatest degree of oligomer selectivity. PMN310, the Company’s novel monoclonal antibody being evaluated as a treatment for Alzheimer’s disease (“AD”), is currently undergoing Phase 1a clinical studies in healthy volunteers, with initial safety and pharmacokinetic data expected in mid-2024.

A $\beta$ -directed antibodies tested clinically for therapeutic activity against AD have shown varying degrees of efficacy. A side-by-side comparison of antibody binding to different molecular species of A $\beta$  conducted by ProMIS provided insight into the observed variability in clinical outcomes. A correlation was observed between reported clinical efficacy and the ability of an antibody to retain binding to soluble oligomers from AD brains when faced with monomer competition. PMN310 showed a high degree of resistance to monomer competition. Importantly, unlike all other antibodies tested, PMN310 also avoided binding to plaque and vascular deposits of Ab. Consequently, PMN310, may reduce the risk of brain edema (ARIA-E) and microhemorrhages (ARIA-H) often associated with plaque-binding antibodies. This premise is supported by the results showing that weekly dosing of a murine version of PMN310 at very high doses (800 mg/kg) for 26 weeks in a mouse model of AD did not cause any detectable brain hemorrhages upon microscopic examination.

## 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 study and reported therapeutic activity and preferential targeting of toxic soluble aggregates by A $\beta$ -directed antibodies and the potential implications thereof, the Company’s expectations regarding its clinical development of its lead product, PMN310, for AD, and the Company’s anticipated top-line data readout for our Phase 1a study in the first half of 2024 and plans to advance into a Phase 1b multiple ascending dose study in AD patients. 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 the results of nonclinical studies and early clinical trials are not necessarily predictive of future results with PMN310, 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.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release, dated April 30, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: April 30, 2024

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

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## ProMIS Neurosciences Publishes Study Highlighting Oligomer Selectivity and Benefit of Amyloid-Beta-Directed Antibodies

*Study results support differentiation of PMN310 from other amyloid-beta-directed antibodies*

**CAMBRIDGE, Massachusetts and TORONTO, Ontario – April 30, 2024** – ProMIS Neurosciences Inc. (Nasdaq: PMN), a 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 the publication of a paper titled, “Relationship between therapeutic activity and preferential targeting of toxic soluble aggregates by amyloid-beta-directed antibodies,” in the online journal, *bioRxiv*.

The study characterized and compared the binding profile of various amyloid-beta (A $\beta$ )-directed antibodies to monomers, soluble oligomers and insoluble Ab fibrils. The results indicate that selectivity for soluble toxic A $\beta$  oligomers may be a driver of clinical efficacy and indicated that PMN310 displayed the greatest degree of oligomer selectivity. PMN310, the Company’s novel monoclonal antibody being evaluated as a treatment for Alzheimer’s disease (AD), is currently undergoing Phase 1a clinical studies in healthy volunteers, with initial safety and pharmacokinetic data expected in mid-2024.

“The data in this publication highlight PMN310’s high degree of selectivity for toxic A $\beta$  oligomers and its differentiation from other Ab-directed antibodies,” stated Neil Warma, Chief Executive Officer of ProMIS Neurosciences. “We believe that PMN310’s ability to avoid both monomer and plaque binding has the potential to improve efficacy and reduce the risk of amyloid-related imaging abnormalities (ARIA), a key indicator of edema and microhemorrhage risk associated with plaque binding antibody therapies currently on the market and in development. We look forward to the top-line data readout for our Phase 1a study in the coming months and to advancing PMN310 into a Phase 1b multiple ascending dose study in AD patients.”

A $\beta$ -directed antibodies tested clinically for therapeutic activity against AD have shown varying degrees of efficacy. A side-by-side comparison of antibody binding to different molecular species of A $\beta$  conducted by ProMIS provided insight into the observed variability in clinical outcomes. A correlation was observed between reported clinical efficacy and the ability of an antibody to retain binding to soluble oligomers from AD brains when faced with monomer competition. PMN310 showed a high degree of resistance to monomer competition. Importantly, unlike all other antibodies tested, PMN310 also avoided binding to plaque and vascular deposits of Ab. Consequently, PMN310, may reduce the risk of brain edema (ARIA-E) and microhemorrhages (ARIA-H) often associated with plaque-binding antibodies. This premise is supported by the results showing that weekly dosing of a murine version of PMN310 at very high doses (800 mg/kg) for 26 weeks in a mouse model of AD did not cause any detectable brain hemorrhages upon microscopic examination.

The complete article can be accessed online here.

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## **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 - ProMIST™ 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**

This press release 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 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", "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 news release contains forward-looking information relating to the study and reported therapeutic activity and preferential targeting of toxic soluble aggregates by Aβ-directed antibodies and the potential implications thereof, the Company's expectations regarding its clinical development of its lead product, PMN310, for AD, and the Company's anticipated top-line data readout for our Phase 1a study in the first half of 2024 and plans to advance into a Phase 1b multiple ascending dose study in AD patients. 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 the results of nonclinical studies and early clinical trials are not necessarily predictive of future results with PMN310, 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](http://www.promisneurosciences.com)

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Please submit media inquiries to [info@promisneurosciences.com](mailto:info@promisneurosciences.com).

**For Investor Relations, please contact:**

Stern Investor Relations

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