

**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): May 15, 2023

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:

<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 15, 2023, 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 ended March 31, 2023. 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 May 15, 2023
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: May 15, 2023

By: /s/ Gail Farfel

Name: Gail Farfel

Title: Chief Executive Officer



ProMIS Neurosciences Announces First Quarter 2023 Financial Results and Recent Highlights

- Received FDA clearance for investigational new drug (IND) application for lead therapeutic candidate, PMN310, in Alzheimer's disease
- Presented preclinical data supporting target identification and candidate differentiation across pipeline of antibody therapeutics at international neurology conferences

TORONTO, Ontario and CAMBRIDGE, Massachusetts – May 15, 2023 – ProMIS Neurosciences Inc. (TSX: PMN) (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 its first quarter 2023 financial results and recent highlights.

"In the first quarter, we completed the required steps that enabled us to file our PMN310 IND in April in order to advance PMN310 toward the clinic. Last week, we announced that the FDA cleared our IND for PMN310 in Alzheimer's disease, which is an exciting milestone for ProMIS" said Gail Farfel, Ph.D., Chief Executive Officer of ProMIS Neurosciences. "Additionally, we presented key data on PMN310, as well as data supporting an amyloid-beta vaccine candidate and a new target for ALS treatment at neurology conferences in March. We look forward to progressing our programs through the rest of 2023."

Recent Highlights

Alzheimer's Disease Program (PMN310)

PMN310, ProMIS' lead compound, is a novel monoclonal antibody which is highly selective for toxic oligomers of amyloid-beta that are believed to be a major driver of AD. The Company has the following updates:

- Received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for PMN310 for the treatment of AD.
- Presented *in vitro* preclinical data in which PMN310 demonstrated greater selectivity for target toxic oligomers compared to other amyloid-beta (A β)-directed antibodies, at the International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders (AD/PD 2023).
- Presented PMN310 preclinical dataset including data showing PMN310 protected memory function in two rodent models of AD at the 75th American Academy of Neurology (AAN) Annual Meeting.

Discovery Programs

- ProMIS continues to advance its amyloid-beta vaccine program based on its oligomer target epitope(s) and gave a platform presentation on results from mouse vaccination studies at the AAN Annual Meeting.
 - The Company presented preclinical data supporting the receptor of activated C-kinase 1 (RACK1) as a potential target in ALS and frontotemporal lobar degeneration with TDP-43-immunoreactive pathology (FTLD-TDP) at the AAN Annual Meeting.
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- Johanne Kaplan, Ph.D., ProMIS' Chief Development Officer will chair the upcoming ALS Drug Development Summit taking place on May 16-18 in Boston.

First Quarter 2023 Financial Highlights

- Cash and cash equivalents were \$3.3 million as of March 31, 2023, compared to \$5.9 million as of December 31, 2022.
- Research and development expenses were \$3.5 million for the quarter ended March 31, 2023, compared to \$1.9 million for the same period in 2022. The increase was primarily attributable to increased spending on PMN310 to finalize drug product manufacturing and costs to complete the IND filing.
- General and administrative expenses were \$1.4 million as of March 31, 2023, compared to \$2.0 million for the same period in 2022.
- Net loss was \$5.0 million for the quarter ended March 31, 2023, compared to \$2.1 million for the same period in 2022.

About ProMIS Neurosciences Inc.

ProMIS Neurosciences Inc. is a development 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), an alpha-synucleinopathy. 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 Toronto, Ontario and Cambridge, Massachusetts. ProMIS is listed on Nasdaq and the Toronto Stock Exchange under the symbol PMN.

Forward-looking Statements

Neither the TSX nor Nasdaq has reviewed and neither accepts 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", "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 targeting of toxic misfolded proteins that the Company believes may directly address fundamental AD pathology (including the belief and understanding that toxic oligomers of amyloid-beta are a major driver of AD) and have greater therapeutic potential due to reduction of off-target activity, the initiation of the Company's first-in-human study in 2023 and its ability to enroll the requisite number of patients, dose each patient in the intended manner and progress the study, ProMIS' pipeline, management's belief that its patented platform technology has created an antibody candidate specific to toxic misfolded oligomers known to be present in Alzheimer's disease, which may have greater therapeutic potential due to off-target activity, the progression of earlier stage antibody candidates for ALS (PMN267) and MSA (PMN442), the timing and significance of presentations related to 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, the ability to optimize the impact of its collaborations on its development programs, statements regarding the timing of regulatory filings regarding its development programs, 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 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 information form available on www.SEDAR.com, in Item 1A of its Annual Report on Form 10-K for the year ended December 31, 2022 and the section entitled "Risk Factors" in its Post-Effective Amendment No. 1 to Form S-1, filed March 17, 2023, each as filed with the 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.

PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

(expressed in US dollars, except share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash	\$ 3,331,801	\$ 5,875,796
Short-term investments	31,134	31,009
Prepaid expenses and other current assets	1,045,671	996,682
Total current assets	4,408,606	6,903,487
Property and equipment, net	—	321
Intangible assets, net	19,668	20,838
Total assets	<u>\$ 4,428,274</u>	<u>\$ 6,924,646</u>
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 6,987,026	\$ 2,975,398
Accrued liabilities	1,718,573	3,437,646
Total current liabilities	8,705,599	6,413,044
Warrant liability	1,901,722	1,859,374
Total liabilities	<u>10,607,321</u>	<u>8,272,418</u>
Commitments and contingencies (Note 10)		
Shareholders' deficit:		
Series 1 Convertible Preferred Shares, no par value, 70,000,000 shares authorized, 70,000,000 shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Common shares, no par value, unlimited shares authorized, 8,579,284 shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	79,233,571	79,101,061
Accumulated other comprehensive loss	(199,723)	(195,369)
Accumulated deficit	(85,212,895)	(80,253,464)
Total shareholders' deficit	<u>(6,179,047)</u>	<u>(1,347,772)</u>
Total liabilities and shareholders' deficit	<u>\$ 4,428,274</u>	<u>\$ 6,924,646</u>

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations and Comprehensive Loss

(expressed in US dollars, except share amounts)

	March 31, 2023	March 31, 2022
Operating expenses:		
Research and development	\$ 3,510,252	\$ 1,902,832
General and administrative	1,460,419	2,035,686
Total operating expenses	<u>4,970,671</u>	<u>3,938,518</u>
Loss from operations	<u>(4,970,671)</u>	<u>(3,938,518)</u>
Other income (expense):		
Change in fair value of financial instruments	(41,665)	1,980,672
Interest expense on convertible debt	—	(147,773)
Other income	52,905	10,774
Total other income (expense), net	<u>11,240</u>	<u>1,843,673</u>
Net loss	(4,959,431)	(2,094,845)
Other comprehensive loss		
Foreign currency translation adjustment	(4,354)	47,841
Comprehensive loss	<u>\$ (4,963,785)</u>	<u>\$ (2,047,004)</u>
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.29)
Weighted-average shares outstanding of common shares, basic and diluted	<u>8,579,284</u>	<u>7,195,529</u>

For further information:

Visit us at www.promisneurosciences.com

For Investor Relations, please contact:

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