

**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 8, 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 March 8, 2023, ProMIS Neurosciences Inc. (the "Company") issued a press release, which is available on its website ([www.promisneurosciences.com](http://www.promisneurosciences.com) under "Investors/Financial Results"), reporting its financial condition and financial results as of and for the year ended December 31, 2022. 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**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated March 8, 2023</a>
104	Cover Page Interactive Data File (embedded within 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: March 8, 2023

By: /s/ Gail Farfel

Name: Gail Farfel

Title: Chief Executive Officer

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## ProMIS Neurosciences Announces Full Year 2022 Financial Results and Recent Highlights

- Completed all preclinical studies and manufacturing to support PMN310 IND submission to U.S. Food and Drug Administration
- Preclinical data that further characterize ongoing programs, including PMN310, to be presented in 2023

**TORONTO, Ontario and CAMBRIDGE, Massachusetts – March 8, 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 full year 2022 financial results and recent highlights.

“This year looks to be a pivotal one for ProMIS as we continue our plans to advance PMN310, our novel Alzheimer’s disease product candidate, and expect to file our IND within the next 60 days,” said Gail Farfel, Ph.D., Chief Executive Officer of ProMIS Neurosciences. “Progressing to the clinical stage of development will be a significant step toward our goal of delivering a next-generation therapy to patients with Alzheimer’s disease who have limited options to slow cognitive decline. In addition, we are working to advance two discovery programs, PMN267 and PMN442, towards IND readiness and advancing our amyloid vaccine for AD. We look forward to sharing data from our ongoing efforts over the coming months.”

### Recent Highlights and Anticipated Milestones

#### Alzheimer’s Disease Program (PMN310)

PMN310, ProMIS’s 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:

- Progressed preparation of the PMN310 investigational new drug application (IND), which is expected to be submitted to the U.S. Food and Drug Administration (FDA) within the next 60 days.
- Completed successful manufacture and packaging of PMN310 drug product under good manufacturing process (cGMP) for planned clinical trials.
- Completed non-human primate toxicology and pharmacokinetics studies, as well as tissue cross-reactivity studies under good laboratory practice (GLP) conditions to support first-in-human studies. PMN310 administered as a 30-minute weekly IV infusion to cynomolgus monkeys at dose levels of up to 1200 mg/kg/day was not associated with any adverse effects. As a human equivalent dose, 1200 mg/kg/day in the cynomolgus monkey equates to 5 times higher than the planned highest dose for the Phase 1 trials.
- Plans to initiate a Phase 1a clinical trial of PMN310 subject to the filing and clearance of an IND application with the FDA. The planned Phase 1a single ascending dose trial in healthy volunteers will test single doses in the range of approximately 2.5 to 60 mg/kg in adults.
- Plans to share new preclinical data that further characterize PMN310 at upcoming medical meetings in March and April 2023.

#### Discovery programs

- ProMIS continues to advance its amyloid-beta vaccine program with the aim of developing an AD vaccine based on its oligomer target epitope(s) conjugated to a carrier protein in formulation with an adjuvant. The Company plans to provide preclinical data on vaccine optimization studies at a medical meeting in April 2023.
  - In April 2022, ProMIS announced the selection of monoclonal antibody PMN267 directed against misfolded TDP-43 as the lead candidate for an ALS indication based on its selective binding profile and activity in cell systems and a mouse model of disease. PMN267 has been humanized in a human IgG1 framework for future testing.
  - ProMIS has selected monoclonal antibody PMN442 as its alpha-synuclein antibody lead candidate for MSA based on its selective binding and protective activity against pathogenic forms of alpha-synuclein. PMN442 has been humanized in a human IgG1 framework for future testing.
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## Full Year 2022 Financial Highlights

- Cash and cash equivalents were \$5.9 million as of December 31, 2022, compared to \$16.9 million as of December 31, 2021.
- Research and development expenses were \$16.1 million for the year ended December 31, 2022, compared to \$4.6 million for the same period in 2021. The increase is primarily attributable to increased spending on the PMN310 program as the Company prepares to file an IND.
- General and Administrative expenses were \$7.3 million for the year ended December 31, 2022, compared to \$3.7 million for the same period in 2021.
- Net loss was \$18.1 million for the year ended December 31, 2022, compared to \$9.8 million for the same period in 2021.

## 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). The Company's proprietary target discovery engine is based on the use of two complementary techniques. The Company applies its 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 may directly address fundamental AD pathology (including 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 Company's intention to file an IND for PMN310, the initiation of the Company's first-in-human study subject to FDA clearance of its IND, 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, management's anticipated timing of enrollment of the first subject in our Phase 1a trial in the first half of 2022, the progression of earlier stage antibody candidates for ALS (PMN267) and MSA (PMN442), 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. 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](http://www.SEDAR.com), and in Item 1A of each of its Form 10 Registration Statement and its Quarterly Reports on Form 10-Q for the quarters ended June 30, 2022 and September 30, 2022, 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.

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PROMIS NEUROSCIENCES INC.

Consolidated Balance Sheets

(expressed in US dollars, except share amounts)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash	\$ 5,875,796	\$ 16,943,905
Short-term investments	31,009	33,248
Prepaid expenses and other current assets	996,682	737,316
Total current assets	6,903,487	17,714,469
Property and equipment, net	321	4,671
Intangible assets, net	20,838	27,614
Total assets	<u>\$ 6,924,646</u>	<u>\$ 17,746,754</u>
<b>Liabilities and Shareholders' (Deficit) Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,975,398	\$ 408,981
Accrued liabilities	3,437,646	520,093
Total current liabilities	6,413,044	929,074
Convertible debt, net of issuance costs and debt discount	—	3,906,057
Derivative liability	—	5,379,878
Warrant liability	1,859,374	1,871,687
Total liabilities	<u>8,272,418</u>	<u>12,086,696</u>
Commitments and contingencies		
Shareholders' (deficit) equity:		
Series 1 Convertible Preferred Shares, no par value, 70,000,000 shares authorized, 70,000,000 and 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	—	—
Common shares, no par value, unlimited shares authorized, 8,579,284 and 7,195,529 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	79,101,061	68,039,178
Accumulated other comprehensive loss	(195,369)	(187,919)
Accumulated deficit	(80,253,464)	(62,191,201)
Total shareholders' (deficit) equity	<u>(1,347,772)</u>	<u>5,660,058</u>
Total liabilities and shareholders' (deficit) equity	<u>\$ 6,924,646</u>	<u>\$ 17,746,754</u>

PROMIS NEUROSCIENCES INC.

Consolidated Statements of Operations and Comprehensive Loss

(expressed in US dollars, except share amounts)

	Years Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 16,087,168	\$ 4,627,386
General and administrative	7,292,744	3,663,707
Total operating expenses	23,379,912	8,291,093
Loss from operations	(23,379,912)	(8,291,093)
Other income (expense):		
Change in fair value of financial instruments	4,176,767	(1,095,636)
Interest expense on convertible debt	(282,064)	(416,286)
Gain on extinguishment of convertible debt and derivative liability	1,307,421	—
Other income	115,525	12,909
Total other income (expense), net	5,317,649	(1,499,013)
Net loss	(18,062,263)	(9,790,106)
Other comprehensive loss		
Foreign currency translation adjustment	(7,450)	(137,188)
Comprehensive loss	\$ (18,069,713)	\$ (9,927,294)
Net loss per share, basic and diluted	\$ (2.41)	\$ (1.69)
Weighted-average shares outstanding of common shares, basic and diluted	7,502,609	5,785,617

For further information:  
Visit us at [www.promisneurosciences.com](http://www.promisneurosciences.com)

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

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