

**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): November 14, 2023

PROMIS NEUROSCIENCES INC.

(Exact name of registrant as specified in its charter)

Ontario, 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 November 14, 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 and nine months ended September 30, 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 November 14, 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: November 14, 2023

By: /s/ Gail Farfel

Name: Gail Farfel

Title: Chief Executive Officer



ProMIS Neurosciences Announces Third Quarter 2023 Financial Results and Recent Highlights

Raised \$20.4 million in PIPE gross proceeds to support continued development of Company's PMN310 and novel antibody therapeutics targeting toxic misfolded proteins in neurodegenerative diseases

Dosing of first subjects in first-in-human Phase 1a clinical trial of PMN310 as a treatment for Alzheimer's disease expected in November

CAMBRIDGE, Massachusetts, November 14, 2023 – 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 third quarter ended September 30, 2023 and provided a corporate update.

"The third quarter was marked by significant progress across both our clinical and corporate initiatives," said Gail Farfel, Ph.D., Chief Executive Officer of ProMIS Neurosciences. "We are excited to begin dosing subjects in our first-in-human trial of PMN310 as a treatment for Alzheimer's disease (AD). Our confidence in PMN310 is bolstered by compelling nonclinical data that demonstrate PMN310's greater selectivity for toxic amyloid beta oligomers, which indicate its potential for greater therapeutic benefit and an improved safety profile compared with currently available treatments. We look forward to dosing the first subjects in our Phase 1a clinical study of PMN310 this month and expect to have early cohort results in the first half of 2024."

"We were encouraged by the recent clinical results presented by Acumen Pharmaceuticals which showed in a small, 3-month study that targeting soluble amyloid beta oligomers in AD patients can improve biomarkers of pTau181 and neurogranin. These results replicated biomarker findings from the CLARITY-AD trial of lecanemab, which also predominantly targets soluble amyloid beta oligomers. We are encouraged by these new clinical findings, as we believe PMN310 is the most specific antibody targeting soluble amyloid beta oligomers, and we look forward to demonstrating its effect in the clinic.

"Importantly, we strengthened our balance sheet with an equity financing that raised in excess of \$20 million in gross proceeds to support continued development of PMN310 and the ongoing development of our novel antibody therapies for neurodegenerative diseases through a number of potentially value-creating milestones."

Recent Highlights

Alzheimer's Disease Program (PMN310)

PMN310, ProMIS' lead compound, is a humanized IgG1 antibody directed against toxic amyloid-beta oligomers (A β O) that are believed to be a major driver of AD.

- ProMIS obtained Investigation Review Board approval at its clinical site, is currently screening subjects and expects to dose the first participants in a first-in-human Phase 1a clinical trial of PMN310 as a potential treatment for AD in November 2023. The Phase 1a clinical trial is a double-blind, placebo-controlled, single ascending dose study of the safety, tolerability and pharmacokinetics of PMN310 infusions in up to five cohorts of eight healthy volunteers. PMN310 exposure levels in blood and cerebrospinal fluid (CSF) will be evaluated as well as safety. In October 2023, the PMN310 Phase 1a trial was added to the clinicaltrials.gov database (Study NCT06105528).
-

- In July 2023, ProMIS presented preclinical data at AAIC 2023 indicating greater selectivity, compared with approved therapies, of PMN310 for toxic A β O translating into potentially greater clinical benefit, improved safety profile, reduced incidence of A β -related imaging abnormalities (ARIA) and preserved memory function.

Discovery Programs

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

- In July 2023, the Company presented preclinical data from mouse vaccination studies at AAIC 2023. Immunization with an A β O epitope-based vaccine was shown to induce robust, long-term antibody responses focused on toxic oligomers without potentially detrimental cross-reactivities. These promising data support further evaluation of this vaccine approach for AD prevention with the potential for sustained anti-disease activity and ease of use with fewer doses compared to chronic antibody treatment.

Corporate

- In November 2023, Dr. Farfel was a speaker at the CNS Summit in Boston, MA and Johanne Kaplan, Ph.D., Chief Development Officer at ProMIS, participated in a Canadian ITN (Initiative for Translational Neuroscience) event in Montreal in a Round Table discussion on “Improving public-private partnerships to advance drug discovery.”
- In August 2023, ProMIS completed a private placement of 9,945,969 common shares and 954,725 pre-funded warrants, for gross proceeds of \$20.4 million. 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.
- In July 2023, ProMIS consolidated trading of its shares on the Nasdaq Capital Market and completed a voluntary delisting of its common shares from the Toronto Stock Exchange (TSX).

Third Quarter 2023 Financial Highlights

- Cash and cash equivalents were \$16.9 million as of September 30, 2023, compared to \$5.9 million as of December 31, 2022. During the quarter, the Company raised \$20.4 million in gross proceeds from a private investment in public equity financing, less \$2.7 million of issuance costs.
- Research and development expenses were \$1.1 million for the three-months ended September 30, 2023, compared to \$4.6 million for the same period in 2022. The decrease was primarily attributable to a decrease in direct research and development expenses following the submission of the PMN310 Investigational New Drug application with the U.S. Food and Drug Administration in April 2023.
- General and administrative expenses modestly decreased to \$1.4 million for the quarter ended September 30, 2023, compared to \$1.5 million for the same period in 2022, largely the result of a decrease in share-based compensation costs and professional consulting fees.
- Net loss was \$2.4 million for the quarter ended September 30, 2023, compared to a net loss of \$6.0 million for the same period in 2022.

About ProMIS Neurosciences Inc.

ProMIS Neurosciences Inc. is a clinical 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 - 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 Toronto, Ontario and Cambridge, Massachusetts. To learn more, visit the Company’s website at www.promisneurosciences.com.

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 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 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 Phase 1a study and its ability to enroll the requisite number of patients, dose each patient in the intended manner and progress the study, statements related to the presentation of data and the significance of such data, information on the Company’s beliefs regarding the significance of preclinical data, the Company’s pipeline, statements regarding a computationally-derived amyloid-beta (A β) 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 Alzheimer’s disease, management’s belief that this specificity may indicate greater therapeutic potential due to lower off-target activity and reduce the risk of brain edema and microhemorrhages (ARIA) associated with plaque-binding antibodies and management’s belief that PMN310 can selectively bind to toxic A β O in AD brain extract in a way that was minimally impacted by monomer competition better than competing A β -directed antibodies, and the anticipated use of proceeds from the private placement. 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, and in the Company’s subsequent Quarterly Reports on Form 10-Q, 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.

For Investor Relations, please contact:

Stern Investor Relations
Anne Marie Fields, Managing Director
annemarie.fields@sternir.com

PROMIS NEUROSCIENCES INC.

Condensed Consolidated Balance Sheets
(expressed in US dollars, except share amounts)
(Unaudited)

| | September 30, 2023 | December 31, 2022 |
|--|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash | \$ 16,868,347 | \$ 5,875,796 |
| Short-term investments | 31,824 | 31,009 |
| Prepaid expenses and other current assets | 957,785 | 996,682 |
| Total current assets | 17,857,956 | 6,903,487 |
| Property and equipment, net | — | 321 |
| Intangible assets, net | 18,022 | 20,838 |
| Total assets | <u>\$ 17,875,978</u> | <u>\$ 6,924,646</u> |
| Liabilities and Shareholders' Deficit | | |
| Current liabilities: | | |
| Accounts payable | \$ 8,414,596 | \$ 2,975,398 |
| Accrued liabilities | 1,436,740 | 3,437,646 |
| Share-based compensation liability - short-term | 49 | — |
| Total current liabilities | 9,851,385 | 6,413,044 |
| Share-based compensation liability | 992,348 | — |
| Warrant liability | 277,356 | 1,859,374 |
| Total liabilities | 11,121,089 | 8,272,418 |
| Commitments and contingencies | | |
| Shareholders' deficit: | | |
| Series 1 Convertible Preferred Shares, no par value, 70,000,000 shares authorized, 70,000,000 shares issued and outstanding as of September 30, 2023 and December 31, 2022 | — | — |
| Common shares, no par value, unlimited shares authorized, 18,525,254 and 8,579,284 shares issued and outstanding as of September 30, 2023 and December 31, 2022 | — | — |
| Additional paid-in capital | 97,011,590 | 79,101,061 |
| Accumulated other comprehensive loss | (371,184) | (195,369) |
| Accumulated deficit | (89,885,517) | (80,253,464) |
| Total shareholders' equity (deficit) | 6,754,889 | (1,347,772) |
| Total liabilities and shareholders' equity (deficit) | <u>\$ 17,875,978</u> | <u>\$ 6,924,646</u> |

PROMIS NEUROSCIENCES INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(expressed in US dollars, except share amounts)
(Unaudited)

| | For the Three Months Ended September 30, 2023 | For the Three Months Ended September 30, 2022 | For the Nine Months Ended September 30, 2023 | For the Nine Months Ended September 30, 2022 |
|---|--|--|---|---|
| Operating expenses: | | | | |
| Research and development | \$ 1,142,160 | \$ 4,570,562 | \$ 5,658,127 | \$ 9,702,978 |
| General and administrative | 1,375,380 | 1,483,573 | 4,729,969 | 5,154,324 |
| Total operating expenses | 2,517,540 | 6,054,135 | 10,388,096 | 14,857,302 |
| Loss from operations | (2,517,540) | (6,054,135) | (10,388,096) | (14,857,302) |
| Other income (expense): | | | | |
| Change in fair value of financial instruments | 119,019 | 61,407 | 683,568 | 2,972,272 |
| Other interest expense | (75,413) | — | (124,595) | — |
| Interest expense on convertible debt | — | — | — | (282,064) |
| Gain on extinguishment of convertible debt and derivative liability | — | — | — | 1,307,421 |
| Other income | 113,286 | 35,853 | 197,070 | 62,915 |
| Total other income (expense), net | 156,892 | 97,260 | 756,043 | 4,060,544 |
| Net loss | (2,360,648) | (5,956,875) | (9,632,053) | (10,796,758) |
| Other comprehensive loss | | | | |
| Foreign currency translation adjustment | — | (131,874) | (175,816) | (82,397) |
| Comprehensive loss | \$ (2,360,648) | \$ (6,088,749) | \$ (9,807,869) | \$ (10,879,155) |
| Net loss per share, basic and diluted | \$ (0.19) | \$ (0.83) | \$ (0.98) | \$ (1.50) |
| Weighted-average shares outstanding of common shares, basic and diluted | 12,370,830 | 7,195,529 | 9,861,719 | 7,195,529 |