November 14, 2024

ProMIS Neurosciences Announces Third Quarter 2024 Financial Results and Recent Highlights

Presented full dataset from first-in-human Phase 1a clinical trial demonstrating PMN310was generally well-tolerated with monthly dosing and that PMN310 demonstrated CSF levels indicative of potential target engagement in patients with Alzheimer's disease

On track to initiate Phase 1b clinical trial in patients with Alzheimer's disease by end of 2024

CAMBRIDGE, Massachusetts and TORONTO, Ontario, Nov. 14, 2024 (GLOBE NEWSWIRE) -- 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, 2024, and provided a corporate update.

"We made significant progress in the third quarter, highlighted by the positive results from our first-in-human Phase 1a clinical trial of PMN310 and the closing of a strong equity financing that could provide up to $122.7 million to advance our pipeline of neurodegenerative product candidates," said Neil Warma, CEO of ProMIS Neurosciences. "Results from our Phase 1a study showed that PMN310 was generally safe and well-tolerated and achieved concentrations in the cerebrospinal fluid (CSF) indicating its potential for target engagement in AD patients. Additionally, these results have confirmed the dosing levels for the planned multiple ascending dose Phase 1b clinical trial in 100 patients with mild cognitive impairment due to AD and early AD, which is on track to start by the end of 2024."

"These early clinical outcomes reinforce our confidence in PMN310's unique therapeutic profile and the impact it may have on AD patients, their families, and healthcare providers," added Mr. Warma. "As toxic oligomers are recognized as key drivers of AD progression, we believe PMN310's selective binding to these oligomers differentiates it from other drugs currently on the market or in development and strengthens the case for its continued advancement and positioning as a promising option in the AD treatment landscape."

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 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 two 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 October 2024, ProMIS presented positive data from all five cohorts in its first-in-human Phase 1a clinical trial of PMN310 in healthy volunteers at the 17th Clinical Trials on Alzheimer's Disease (CTAD) Conference, which took place from October 29 – November 1, 2024, in Madrid, Spain. The results showed PMN310 was generally well-tolerated in all five SAD cohorts (2.5, 5, 10, 20 and 40 mg/kg) of the Phase 1a clinical trial and, importantly, crossed the blood brain barrier in healthy volunteers in a dose dependent manner with PK suggesting that monthly dosing may provide levels of PMN310 adequate for target engagement in AD patients. The complete dataset from all five cohorts reinforces previously reported data from the first four cohorts of the Phase 1a trial announced in July 2024.

- ProMIS is on-track to initiate its PMN310 Phase 1b clinical trial by year-end 2024.

ProMIS continues to advance its Ab 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.

Amyotrophic Lateral Sclerosis Disease Program (PMN267)

PMN267 is a humanized IgG1 antibody directed against toxic misfolded TDP-43 as a potential therapeutic target for amyotrophic lateral sclerosis (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 paper published 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 accessed here, and the *Open Biology* publication can be accessed here.

Corporate

- In July 2024, ProMIS completed a private investment in public equity (PIPE) financing that may 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. 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.

Third Quarter 2024 Financial Highlights

- Cash and cash equivalents were $21.5 million as of September 30, 2024, compared to $12.6 million as of December 31, 2023. During the quarter, the Company completed a PIPE financing that provided initial upfront funding of $30.3 million, and which has the potential to provide an additional $92.4 million tied to the potential exercise of warrants.

- Research and development expenses were $2.6 million for the three months ended September 30, 2024, compared to $1.1 million for the same period in 2023. The increase was primarily attributable to costs related to the execution of the PMN310 Phase 1a clinical trial and preparation for the PMN310 Phase 1b clinical trial.

- General and administrative expenses increased to $1.9 million for the quarter ended September 30, 2024, compared to $1.4 million for the same period in 2023.

- Net income was $9.3 million for the quarter ended September 30, 2024, compared to a net loss of $2.4 million for the same period in 2023. The increase in net income was primarily attributable to a gain on the change in fair value of our warrant liabilities of $17.0 million.

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. PMN310, the Company’s lead product candidate for the treatment of AD, is a differentiated, humanized monoclonal antibody that has been designed to specifically bind toxic Aβ oligomers and to not bind plaque or monomers. 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 study in AD patients by year-end 2024 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, 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:

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PROMIS NEUROSCIENCES INC.

Condensed Consolidated Balance Sheets

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 21,536,898	$ 12,598,146
Short-term investments	32,358	32,358
Prepaid expenses and other current assets	2,941,279	988,641
Total current assets	24,510,535	13,619,145
Total assets	$ 24,510,535	$ 13,619,145
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,575,235	$ 7,843,136
Accrued liabilities	1,059,852	1,506,526
Total current liabilities	2,635,087	9,349,662
Share-based compensation liability	340,090	422,002
Warrant liability	14,262,138	94,185
Total liabilities	17,237,315	9,865,849
Commitments and contingencies		
Shareholders' equity:		
Series 2 Convertible Preferred Shares, no par value, unlimited shares authorized, 0 and 1,166,667 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—

Common shares, no par value, unlimited shares authorized, 32,689,190 and 18,885,254 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	98,093,270	97,590,426
Accumulated other comprehensive loss	(371,184)	(371,184)
Accumulated deficit	(90,448,866)	(93,465,946)
Total shareholders' equity	7,273,220	3,753,296
Total liabilities and shareholders' equity	$ 24,510,535	$ 13,619,145

PROMIS NEUROSCIENCES INC.

Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)

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

	For the Three Months Ended September 30, 2024	For the Three Months Ended September 30, 2023	For the Nine Months Ended September 30, 2024	For the Nine Months Ended September 30, 2023
Operating expenses:				
Research and development	$ 2,563,774	$ 1,142,160	$ 6,313,373	$ 5,658,127
General and administrative	1,870,903	1,375,380	4,511,660	4,729,969
Total operating expenses	4,434,677	2,517,540	10,825,033	10,388,096
Loss from operations	(4,434,677)	(2,517,540)	(10,825,033)	(10,388,096)
Other income (expense):				
Change in fair value of financial instruments	16,969,126	119,019	17,014,080	683,568
Interest expense	—	(75,413)	(76,775)	(124,595)
Other income	235,912	113,286	399,344	197,070

Loss on issuance of common shares, warrants, and pre-funded warrants in July 2024 PIPE	(3,494,536)	—	(3,494,536)	—
Total other income (expense), net	13,710,502	156,892	13,842,113	756,043
Net income (loss)	9,275,825	(2,360,648)	3,017,080	(9,632,053)
Other comprehensive income (loss)				
Foreign currency translation adjustment	—	—	—	(175,815)
Comprehensive income (loss)	$ 9,275,825	$ (2,360,648)	$ 3,017,080	$ (9,807,868)
Net income (loss) per share, basic	$ 0.31	$ (0.19)	$ 0.13	$ (0.98)
Net income (loss) per share, diluted	$ 0.31	$ (0.19)	$ 0.13	$ (0.98)
Weighted-average shares outstanding of common shares, basic	30,023,675	12,370,830	22,953,751	9,861,719
Weighted-average shares outstanding of common shares, diluted	30,067,095	12,370,830	23,676,104	9,861,719

Source: ProMIS Neurosciences Inc.