ProMIS Neurosciences Announces Second Quarter 2022 Financial and Operating Results

TORONTO, Ontario and CAMBRIDGE, Massachusetts, Aug. 15, 2022 (GLOBE NEWSWIRE) -- ProMIS Neurosciences, Inc. (TSX: PMN) (Nasdaq: PMN) ("ProMIS" or the "Company"), a biotechnology company focused on the discovery and development of antibody therapeutics targeting misfolded proteins such as toxic oligomers, implicated in the development of neurodegenerative diseases, today announced its operational and financial results for the three months ended June 30, 2022.

"Q2 was another quarter of strong progress for ProMIS Neurosciences," according to Gene Williams, Chairman and CEO. "We completed the work necessary to list on Nasdaq, effective July 7. We want to thank our shareholders for their strong support during this process. Our lead program for Alzheimer's disease, PMN310, remains on track for an investigational new drug application, or IND, filing by the end of this year, following valuable written feedback from the FDA on our pre-IND submission. In addition, two other candidate antibodies are undergoing "humanization", a process required for use in humans and the first step to support future IND filings, subject to discussions with the FDA. Those are PMN267, targeting misfolded TDP-43 in ALS, and PMN442, targeting misfolded alpha-synuclein in MSA (multiple system atrophy). We believe our unique discovery platform will also allow us to make "vaccine versions" of our antibody targets. We previously reported that a vaccine version of PMN310's target showed positive initial results, eliciting strong antibody responses with selectivity for toxic amyloid-beta oligomers in preclinical testing. A second proprietary ProMIS therapeutic vaccine program has been initiated. Dr. Neil Cashman's lab at UBC received a Weston Family Foundation Grant to conduct early work on an alpha synuclein therapeutic vaccine. Our discovery lab continues to address new disease-causing misfolded proteins with our unique discovery engine, as we seek to rapidly expand our IP and product candidate portfolio. To support our progress, we will continue to add to our strong and experienced management team. Later this year, we and many others are looking forward to the readout of the Eisai lecanemab pivotal trial which, if positive, could be a strong catalyst for the Alzheimer's field. We believe that that fact, combined with our planned PMN310 IND filing, the progress of our other programs, and early signs of a biotech market strengthening, could lead to a positive second half of the year."

ProMIS lead program PMN310: Potential Next Generation Therapy for AD

PMN310, an antibody therapy selective for toxic amyloid-beta oligomers in AD, is our lead product candidate. In the second quarter of 2022, the Company made significant progress on the program elements.

Producer cell line development has been completed. We have manufactured material to be

used in Good Laboratory Practice ("GLP") toxicology studies and are on track for producing current Good Manufacturing Practice ("cGMP") material for use in the initial clinical trials of PMN310, if allowed to proceed. We have completed pilot toxicology, pharmacokinetics and tissue cross reactivity ("TCR") studies and secured slots for the formal GLP studies that are required for an IND. Development of assays to measure drug levels in nonhuman primates and in human studies was completed in the second quarter of 2022. Vendors have been contracted to perform these assays in support of our GLP studies.

In addition, we have initiated formulation development with two vendors, with the goal of developing a high concentration formulation that can support subcutaneous dosing as a future step to improve overall convenience and patient compliance. We expect completion of formulation work in the third quarter of 2022.

Dr. Neil Cashman gave a presentation on the ProMIS discovery platform and PMN310 antibody program entitled "Selective antibody targeting of pathogenic proteins: Maximizing target engagement, minimizing target distraction" at the Neuro4D conference in Mainz, Germany.

Expenditures for PMN310 in the three months ended June 30, 2022 were approximately $1.8 million, not including allocations of senior management time.

ALS Portfolio, including TAR-DNA binding protein 43 (TDP-43)

The top priority for our scientific validation efforts, largely centered in Dr. Neil Cashman's laboratory at UBC, is currently the Company's amyotrophic lateral sclerosis ("ALS") portfolio. This portfolio includes antibodies targeting misfolded forms of TDP-43, receptor of activated protein C kinase 1 ("RACK1"), and superoxide dismutase 1 ("SOD1"). Based on the binding profile and activity of selected antibodies/intrabodies against misfolded TDP-43, we have declared PMN267 as our lead candidate for the treatment of ALS. The evidence to date supports potential use of PMN267 both as an intrabody or as a conventional antibody acting inside neurons as well as outside neurons to stop the cell-to-cell propagation of toxic TDP-43 aggregates. PMN267 is currently being humanized in a human IgG1 framework for future clinical testing.

ProMIS' capability to create highly selective antibodies is most critical for intracellular activity since physiologically important TDP 43 is active inside the neuron and should be avoided by the intrabodies to reduce the possibility of harmful side effects. In addition, with world expert RNA scientist, Dr. Michelle Hastings, ProMIS is exploring antisense oligonucleotide ("ASO") therapeutic approaches, and with Dr. Justin Yerbury, is exploring protein degradation ("PROTACS") approaches in ALS.

While targeting TDP-43 has promising therapeutic potential, we believe an optimal disease modifying therapeutic approach to ALS may require addressing multiple misfolded protein targets (TDP-43, RACK1, and SOD1), with different modalities (antibody, gene therapy vectorized antibody, ASO, PROTACS). ProMIS' preclinical data in the ALS space were shared in May 2022 at the ALS Drug Development Summit in Boston, in platform presentations entitled "Antibody vectorization for selective targeting of intracellular aggregates of misfolded TDP-43" and "Gene therapies for sporadic ALS: An emerging concept". In addition to pursuing development of PMN267, we are exploring the scientific interaction between therapies addressing these various targets, and our goal is to identify

and develop a portfolio of complementary therapies that alone and/or together may play a significant role in effectively treating disease.

In the three months ending June 30, 2022, our total expenditure for the ALS portfolio was $0.3 million, not including allocations of senior management time.

Other key projects

We continue to make considerable progress on other key projects, in addition to our top priorities PMN310 and PMN267. Based on the characterization of selected antibodies to date, we have declared PMN442 as our lead alpha-synuclein product candidate. In vivo testing in mouse disease models is ongoing and results are expected in the second half of 2022. PMN442 is currently being humanized in a human IgG1 framework for future clinical testing

In the amyloid vaccine program, the results of our initial studies with the University of Saskatchewan Vaccine and Infectious Disease Organization ("VIDO") were presented at the T21 Research Society Conference in Long Beach, CA in June 2022 in a talk entitled: "Vaccination approach for prevention and early intervention in Alzheimer's disease: Selective targeting of computationally-derived conformational B cell epitopes of soluble amyloid-beta toxic oligomers". Building on the data obtained with VIDO, additional mouse studies are ongoing with VIDO with the goal of developing an optimized AD vaccine, conjugating our peptide antigens to a carrier protein in formulation with an adjuvant. A vaccination study in a mouse model of AD is ongoing.

David Wishart, our Chief Physics Officer, and his team are pursuing multiple novel targets including DISC1 involved in the pathogenesis of schizophrenia. ASO approaches to target pathogenic DISC1 are also being explored with Dr. Michelle Hastings.

Recent Corporate Highlights

In April 2022, the Company announced the appointment of Dr. Larry Altstiel M.D., Ph.D. to the role of Chief Medical Officer. Dr. Altstiel brings decades of medical expertise in neurodegenerative diseases and experience in the pharmaceutical industry, formerly serving as vice president and head of neuroscience and clinical research at Pfizer, Inc. (NYSE: PFE), where he led the selection of drug candidates, development and oversight of multiple preclinical studies and clinical studies from Phase 1 through Phase 3. He is currently part time Chief Medical Officer at Pinteon Therapeutics.

In April 2022, the Company announced that it nominated monoclonal antibody PMN267 as the lead candidate for its ALS program based on its binding profile and activity in cell systems. Using ProMIS's discovery platform, ProMIS generated high-affinity monoclonal antibodies that are selective for the misfolded toxic form of TDP-43 and recent data generated by two independent sources have now provided additional support for the therapeutic potential of PMN267.

In May 2022, the Company announced its participation at the Neuro4D International Conference, held at the Atrium Hotel in Mainz, Germany on May 16-17, 2022. In the conference session "From Disease Insights to Therapeutic Options," Dr. Neil Cashman, ProMIS's Chief Scientific Officer and a member of the Conference Advisory Committee,

delivered an oral presentation, entitled: "Abeta oligomers in Alzheimer's disease: target engagement and target distraction." A large body of scientific data has implicated misfolded oligomers as the toxic molecular species of amyloid-beta ("Abeta") relevant to Alzheimer's disease. In his presentation, Dr. Cashman discussed the importance of selectivity for toxic Abeta oligomers in order to avoid "target distraction", namely the absorption of antibodies by monomers which can reduce effective targeting of oligomers, and binding to plaque and vascular deposits which has been associated with adverse events such as brain edema.

The Company filed a registration statement on Form 10 filed with the U.S. Securities and Exchange Commission on June 22, 2022, as amended June 30, 2022 and July 1, 2022 (the "Form 10 Registration Statement") to register the Company's common shares (the "Common Shares") under Section 12(b) of the Securities Exchange Act of 1934, as amended, in connection with its application to list its Common Shares on the Nasdaq Capital Market (the "Nasdaq").

In June 2022, the Company announced that it entered into debenture amendments to settle indebtedness via the issuance of shares of Series 1 Preferred Shares ("Series 1 Shares") of the Company. The debenture amendments allowed for the settlement of indebtedness under the amended debentures in Series 1 Shares in lieu of Common Shares at the option of the holder. The Series 1 Shares are convertible into Common Shares at a ratio of 1:1 in accordance with their terms.

In June 2022, to meet the criteria to list its Common Shares on Nasdaq, the Board of Directors of the Company also approved a 1-for-60 reverse share split of the Company's issued and outstanding Common Shares.

In July 2022, the Company announced that it received final approval from Nasdaq to list its Common Shares on Nasdaq. The Company's Common Shares began trading on Friday, July 8, 2022, under the symbol "PMN". The Company's Common Shares continue to trade on the TSX under the same symbol "PMN". Concurrent with the listing of ProMIS' Common Shares on Nasdaq, the Common Shares ceased to be quoted on the OTCQB.

Financial highlights as of and for thesix months ended June 30, 2022, include:
On June 30, 2022, the Company had funds available for operating activities (cash, cash equivalents and short-term investments) of $8.9 million, as compared to $17.0 million on December 31, 2021. We expect our cash is sufficient to finance the Company's operations for the next twelve months.

Financial Results

Results of Operations – For the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

| | Three Months Ended June 30, | | |
	2022	**2021**	**Change**
Operating expenses			

Research and development	$	3,229,584	$	754,302	$ 2,475,282
General and administrative		1,635,065		351,114	1,283,951
Total operating expenses		4,864,649		1,105,416	3,759,233
Loss from operations		(4,864,649)		(1,105,416)	(3,759,233)
Other income/(expense), net		2,119,611		879,873	1,239,738
Net loss	$	(2,745,038)	$	(225,543)	$ (2,519,495)

Research and Development

The following table summarizes the period-over-period changes in research and development expenses for the periods presented:

	Three Months Ended June 30,		
	2022	**2021**	**Change**
Direct research and development expenses by program			
PMN310	$ 1,837,309	$ 235,497	$ 1,601,812
ALS	293,654	87,910	205,744
Platform and other programs	193,677	10,796	182,881
Indirect research and development expenses:			
Personnel related expense, including share-based compensation	546,160	261,196	284,964
Consulting expense	297,350	143,354	153,996
Other operating costs	61,434	15,549	45,885
Total research and development expenses	$ 3,229,584	$ 754,302	$ 2,475,282

Research and development expenses increased by $2.5 million, or 382%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. This increase is attributable to a $2.0 million increase in direct research and development expenses related to a $1.6 million increase in spending on our lead program, PMN310, largely attributable to $1.1 million of expenses on pre-clinical preparation costs and $0.5 million on external research costs, $0.2 million in external research costs on ALS portfolio projects and a $0.2 million increase on our platform technology and other projects. The $0.2 million increase in consulting expense relates to various consultants advising on the preparation of the IND and design of preclinical and clinical trials. The increase of $0.3 million in personnel related expenses relates to the engagement of full-time and additional management personnel.

General and Administrative Expenses

The following table summarizes the period-over-period changes in general and administrative expenses for the periods presented:

Three Months Ended
June 30,

	2022	2021	Change
Personnel related, including share-based compensation	$ 324,500	$ 166,357	$ 158,143
Professional and consulting fees	1,117,957	201,481	916,476
Patent expense	139,210	117,728	21,482
Facility-related and other	53,399	(134,452)	187,851
Total general and administrative expenses	$ 1,635,066	$ 351,114	$1,283,952

General and administrative expenses increased by $1.3 million, or 369%, for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The increase in professional and consulting fees included $0.3 million of one-time fees incurred in relation our Nasdaq listing, increased consulting fees of $0.2 million and legal fees of $0.1 million, and an increase in investor relations expenses of $0.2 million. Additional drivers included an increase in salaries, recruiting and other personnel related expenses of $0.2 million and foreign exchange costs increased by $0.2 million.

Other Expense (Income)

Other income increased by $1.2 million for the three months ended June 30, 2022 compared to the three months ended June 30, 2021. The increase was primarily due to a $1.3 million gain on extinguishment of convertible debt and derivative liability, offset by a $0.1 million decrease from the change in fair value of the derivative liability and warrant liabilities.

Results of Operations – For the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 5,132,416	$ 973,893	$ 4,158,523
General and administrative	3,670,751	699,492	2,971,259
Total operating expenses	8,803,167	1,673,385	7,129,782
Loss from operations	(8,803,167)	(1,673,385)	(7,129,782)
Other (expense)/income, net	3,963,284	(4,661,469)	8,624,753
Net loss	$ (4,839,883)	$ (6,334,854)	$ 1,494,971

Research and Development Expenses

The following table summarizes the period-over-period changes in research and development expenses for the periods presented:

	Six Months Ended June 30,		
	2022	**2021**	**Change**
Direct research and development expenses by program			
PMN310	$2,835,605	$263,659	$2,571,946
ALS	404,058	116,834	287,224
Platform and other programs	308,030	89,868	218,162
Indirect research and development expenses:			
Personnel related expense, including share-based compensation	998,928	317,805	681,123
Consulting expense	506,180	153,905	352,275
Other operating costs	79,615	31,822	47,793
Total research and development expenses	$5,132,416	$973,893	$4,158,523

Research and development expenses increased by $4.2 million, or 427%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. This increase is attributable to a $3.1 million increase in direct research and development expenses related to a $2.6 million increase in spending on our lead program, PMN310, largely attributable to $1.7 million of expenses on pre-clinical preparation costs and $1.1 million on external research costs, $0.3 million increase in expenses on external research costs on ALS portfolio projects and a $0.2 million increase in spending on our platform technology and other projects. Personnel related expenses increased by $0.7 million due to the engagement of additional personnel, including a part-time chief medical officer and chief operating officer, as well as the engagement of certain management personnel on a full-time basis in 2022. The $0.4 million increase in consulting expense relates to various consultants advising on the preparation of the IND and design of preclinical and clinical trials.

General and Administrative Expenses

The following table summarizes the period-over-period changes in general and administrative expenses for the periods presented:

	Six Months Ended June 30,		
	2022	**2021**	**Change**
Personnel related, including share-based compensation	$ 802,525	$ 345,857	$ 456,668
Professional and consulting fees	2,524,643	360,451	2,164,192
Patent expense	254,802	160,114	94,688
Facility-related and other	88,781	(166,930)	255,711
Total general and administrative expenses	$ 3,670,751	$ 699,492	$ 2,971,259

General and administrative expenses increased by $3.0 million, or 425%, for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. Personnel costs increased by $0.6 million due to the addition of full-time management and employees offset

by a $0.1 million decrease in stock compensation. The $2.2 million increase in professional and consulting fees was due to $1.1 million of one-time costs related to our listing on Nasdaq, increased consulting fees of $0.3 million, an increase of $0.4 million in investor relations expenses, an increase of $0.1 million in recruiting costs, an increase in legal fees of $0.2 million and Board payments of $0.1 million. Patent fees increased by $0.1 million and foreign exchange costs increased by $0.2 million.

Other Expense (Income)

Other income increased by $8.6 million for the six months ended June 30, 2022 compared to the six months ended June 30, 2021. The increase was primarily due to a $7.4 million change in fair value of the derivative liability and warrant liabilities and a $1.3 million gain on extinguishment of convertible debt and derivative liability, offset by $0.1 million additional interest expense incurred on the Debentures.

About ProMIS Neurosciences, Inc.

ProMIS Neurosciences Inc. is a development stage biotechnology Corporation focused on discovering and developing antibody therapeutics selectively targeting toxic oligomers implicated in the development and progression of neurodegenerative diseases, in particular Alzheimer's disease ("AD"), amyotrophic lateral sclerosis ("ALS") and multiple system atrophy ("MSA"). The Corporation's proprietary target discovery engine is based on the use of two complementary techniques. The Corporation 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, ProMIS is developing novel antibody therapeutics for AD, ALS and MSA. ProMIS is headquartered in Toronto, Ontario, Canada with offices in Cambridge, Massachusetts, U.S.A. ProMIS is listed on the Toronto Stock Exchange and under symbol PMN, and on the Nasdaq Capital Market Nasdaq under symbol PMN.

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Source: ProMIS Neurosciences Inc.