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ProMIS Neurosciences Announces Fiscal Year 2021 Results

TORONTO, Ontario and CAMBRIDGE, Massachusetts , March 17, 2022 (GLOBE NEWSWIRE) -- ProMIS Neurosciences, Inc. (TSX: PMN) (OTCQB: ARFXF) (“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 fiscal year ended December 31, 2021.

“2021 was an excellent year for ProMIS including strong capital formation which enabled us to advance and expand our portfolio of differentiated therapeutic product candidates such as Alzheimer’s disease (AD), ALS, and Schizophrenia,” said Gene Williams, ProMIS’ Chairman and CEO. “We feel privileged that leading global experts continue to join our Scientific Advisory Board (SAB), accomplished executives are joining our Board of Directors, and that we have been able to supplement our strong management team, and we expect to continue those trends. We were grateful for the strong shareholder support for the resolution necessary to qualify for a potential listing on a major North American stock exchange presuming we meet the required listing standards. While biotechnology markets and specific disease sectors within biotechnology have cyclical ups and downs, we are well positioned to continue making substantive progress in our programs that could allow us to capitalize when markets rebound, as we believe they will.”

PMN310, an antibody selective for toxic oligomers in AD, is ProMIS’ lead product candidate. In the fourth quarter of 2021, the Company made significant progress on the program elements.

Producer cell line development is advancing. The genetic sequence of PMN310 has been transfected into Chinese hamster ovary (CHO) cells, the standard production cells for antibody manufacturing. We have contractually secured manufacturing slots for material to be used in Good Laboratory Practice (GLP) toxicology studies and for current Good Manufacturing Practice (cGMP) material for use in the initial clinical trials of PMN310, if allowed to proceed. In addition, we have contractually secured slots for GLP toxicology studies of various durations in nonhuman primates to support our single ascending dose/multiple ascending dose (SAD/MAD) trials. We have initiated pilot toxicology and pharmacokinetics (PK) studies to provide important information to support our GLP toxicology studies. We expect those PK studies to be completed in the second quarter of 2022. We also have secured slots for pilot and GLP tissue cross reactivity (TCR) studies, which are required for an investigational new drug (IND) application, in addition to GLP toxicology. The pilot TCR study was initiated fourth quarter of 2021 with an expected completion in second quarter 2022. Development of assays to measure drug levels in both nonhuman primate and human studies have been initiated and are expected to complete

development in second quarter of 2022. Vendors have been contracted to perform these assays for our GLP studies.

In addition, in March 2022, we announced the results from a study assessing chronic systemic administration of PMN310 in a transgenic mouse model of Alzheimer's disease, where the cognitive deficit is driven by toxic amyloid-beta oligomers. The results were positive, showing that PMN310 prevented a cognitive deficit as measured by performance in the water maze task.

Cash expenditures for PMN310 in the six months ended December 31, 2021 were approximately \$3.8 million. The largest component of this was a \$2.7 million up-front and additional payments to our manufacturing vendor to secure manufacturing slots necessary for the filing of an IND and dosing of patients in our initial clinical trials. In addition, \$834,000 of other external expenses and \$326,000 was incurred for consulting fees of the program team, 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 the University of British Columbia (UBC), is the Company's ALS portfolio. This portfolio includes antibodies targeting misfolded forms of TDP-43, RACK1, and superoxide dismutase 1 (SOD1). TDP-43 is the focus of the PMN267 program. We are conducting both *in vitro* assays (assessing the impact of the drug on patient-derived motor neuron cell lines) and *in vivo* assays (mouse model) and expect initial data in the first half of 2022. In addition, we are exploring different therapeutic modalities in our ALS portfolio. We have disclosed data from our proof of concept work exploring "intrabody" versions of TDP-43 antibodies, a research proxy for a vectorized antibody in a gene therapy vector. We believe this therapeutic approach could enhance therapeutic benefit inside the motor neurons where misfolded TDP-43 aggregates are a root cause of disease pathology, leading to toxic misfolding of other proteins including RACK1 and SOD1. ProMIS' capability to create highly selective antibodies is most critical in this application, since physiologically important TDP-43 is active inside the neuron and should be avoided by the intrabodies in order to reduce the possibility of harmful side effects. Based on the characterization of selected antibodies/intrabodies to date, we have declared PMN267 as our lead product candidate for the treatment of ALS. 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 individual misfolded proteins is expected to provide a benefit, 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, PROTAC). 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 six months ended December 31, 2021, our total expenditures for the ALS portfolio were \$299,000, not including allocations of senior management time.

Other key projects

In the six months ended December 31, 2021 we made significant progress on other key projects, in addition to our top priorities PMN310 for AD and PMN267 for ALS. We have engaged with a leading global expert in alpha synuclein to collaborate on further *in vitro* and *in vivo* validation of our potential therapies targeting alpha synuclein, both as extracellular antibodies and as intrabodies. Based on the characterization of selected antibodies to date, we have declared PMN442 as our lead alpha synuclein product candidate. Data from *in vivo* testing in mouse disease models are expected in the second half of 2022.

In our amyloid vaccine program, based on successful pilot work, University of Saskatchewan vaccine and infectious disease organization (VIDO) is conducting mouse studies in collaboration with ProMIS for the development of an optimized vaccine against Alzheimer's disease, conjugating our peptide antigens to a carrier protein in formulation with an adjuvant. David Wishart, our Chief Physics Officer, and his team, are pursuing multiple novel targets including DISC1 involved in the pathogenesis of schizophrenia.

Recent Corporate Highlights

On May 12, 2021, Rudolph Tanzi, Ph.D., was appointed as the Chair of the Company's Scientific Advisory Board (SAB). Dr. Tanzi is the Joseph P. and Rose F. Kennedy Professor of Neurology at Harvard University and Vice-Chair of Neurology, Director of the Genetics and Aging Research Unit, and Co-Director of the Henry and Allison McCance Center for Brain Health at Massachusetts General Hospital.

On May 21, 2021, the Company re-initiated the path to an IND application for PMN310 in Alzheimer's with the start of producer cell line development. This key first step in the manufacturing of antibody therapeutics is being conducted by Selexis, SA, using its proprietary SUREtechnology Platform™.

On May 27, 2021, Dr. David Wishart, Distinguished University Professor in the Departments of Biological Sciences and Computing Science at the University of Alberta, was appointed as Chief Physics Officer.

On June 3, 2021, the Company announced that it had filed a preliminary Prospectus with the securities regulators in each of the provinces and territories of Canada, except Quebec. The Prospectus, when made final, will allow the Company to make offerings of common shares, warrants, units, debt securities, subscription receipts, convertible securities or any combination thereof for up to an aggregate total of US\$50 million during the 25-month period that the Prospectus is effective.

On July 2, 2021, the Company announced the voting results of its annual meeting of shareholders held on June 30, 2021, in Vancouver, British Columbia, Canada. All resolutions described in the Management Proxy Circular and placed before the meeting were approved by the shareholders.

On July 8, 2021, the Company announced that it had filed and obtained a receipt for the Prospectus with the securities regulators in each of the provinces and territories of Canada, except Quebec.

On August 25, 2021, the Company announced the closing of a public offering for gross proceeds of US\$20,125,000 (CDN\$25,522,525).

On October 7, 2021, ProMIS announced that it would hold a special general meeting of shareholders (the “Special Meeting”) on December 1, 2021. The Company set October 18, 2021, as the record date for the Special Meeting. The purpose of the Special Meeting was to ask shareholders to grant the Board the authority, exercisable in the Board’s discretion, to consolidate (or reverse split) the Company’s issued and outstanding common shares in furtherance of a potential listing of the Company’s shares on a stock exchange in the United States, subject to meeting applicable quantitative and qualitative listing standards of such stock exchange. There can be no assurance that the Company will complete a listing on a stock exchange in the United States.

On December 2, 2021, the shareholders of the Company passed the share consolidation resolution at its special general meeting of shareholders.

On January 18, 2022, ProMIS appointed Dr. Carsten Korth to its SAB.

On January 27, 2022, ProMIS appointed Dr. Cheryl Wellington to its SAB.

On February 3, 2022, ProMIS appointed Dr. Guy Rouleau and Dr. Alain Dagher to its Scientific Advisory Board.

Financial highlights as of and for the year ended December 31, 2021, include:

- In March 2021, the Company completed a US\$7.0 million (CDN\$8.7 million) private placement of unsecured convertible debentures (Debentures).
- In August 2021, the Company raised gross proceeds of \$25,522,525 (\$23,426,746 net of share issuance costs).
- On December 31, 2021, the Company had funds available for operating activities (cash, cash equivalents and short-term investments) of \$21,486,042, as compared to \$1,071,004 at December 31, 2020. Our cash is sufficient to finance the Company’s operations through the end of 2023.

Additions to Board of Directors

- On May 19, 2021, the Company appointed Neil Warma, to the Company’s Board of Directors. Mr. Warma has been a healthcare entrepreneur for more than 25 years having managed and advised numerous biotechnology and pharmaceutical companies.
- On September 1, 2021, the Company appointed Josh Mandel-Brehm to the Board of Directors. Mr. Mandel-Brehm has held various key business development and operations leadership roles at leading biotechnology companies.
- On September 23, 2021, the Company appointed Maggie Shafmaster, JD, Ph.D., to the Board of Directors. Dr. Shafmaster has approximately 30 years of experience providing intellectual property advice to biotechnology and pharmaceutical industries.

Senior Management Team

On October 22, 2021, the Company announced the expansion of its senior management team. The following changes were announced:

- Eugene Williams, formerly Executive Chairman, takes on the role of Chairman and Chief Executive Officer (“CEO”), with immediate effect.
- Dr. Elliot Goldstein resigned from his current role as CEO with immediate effect and continues to support us as President and special consultant to the CEO.
- Gavin Malenfant joined our senior management team as Chief Operating Officer. Mr. Malenfant brings more than 30 years of biopharmaceutical experience to our team, with special focus on providing expert management and oversight of drug development programs. The top priority in the near term will be to support the timely development of the PMN310 program to completion of IND enabling activities, anticipated in the second half of 2022.

Financial Results

Results of Operations – For the years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Years Ended December 31,		Change
	2021	2020	
Revenues	\$ 16,410	\$ 1,787	\$ 14,623
Operating expenses			
Research and development	6,310,299	3,183,149	3,127,150
General and administrative	4,224,609	2,481,030	1,743,579
Total operating expenses	10,534,908	5,664,179	4,870,729
Loss from operations	10,518,498	5,662,392	4,856,106
Other expense	1,265,917	-	1,265,917
Net loss	\$ 11,784,415	\$ 5,662,392	\$ 6,122,023

Revenues

The increase in revenues in the year ended December 31, 2021 represent royalties received on the Company’s assays.

Research and Development

Research and development expenses consist of the following:

	Years Ended December 31,		Change
	2021	2020	

Direct research and development expenses by program:	\$4,293,649	\$ 976,700	\$3,316,949
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	812,278	1,672,145	(859,867)
Consulting expense	588,164	173,712	414,452
Patent expense	557,957	344,864	213,093
Other operating costs	58,251	15,728	42,523
Total research and development expenses	\$6,310,299	\$3,183,149	\$3,127,150

The increase in research and development expense for the year ended December 31, 2021, compared to the year ended December 31, 2020, reflects increased costs associated with external contract research organizations for internal programs of \$3,316,949 as the Company ramps up key internal programs and contract research organization costs, increased patent expense of \$213,093 due to increased maintenance and filing fees, increased consulting expense of \$414,452 and increase in amortization of property and equipment and intangible asset of \$42,523 offset by decreased contract salaries and associated costs of \$859,867 due to reduction in compensation to management and attrition of contracted staff and decreased share-based compensation of \$154,015 due to forfeiture of unvested/vested share options due to termination of consulting arrangement.

General and Administrative

General and administrative expenses consist of the following:

	Years Ended December 31,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 1,279,197	\$ 1,191,967	\$ 87,230
Professional and consulting fees	2,801,237	1,311,427	1,489,810
Facility-related and other	144,175	(22,364)	166,539
Total general and administrative expenses	\$ 4,224,609	\$ 2,481,030	\$ 1,743,579

The increase for the year ended December 31, 2021, compared to the same period in 2020, is primarily attributable to an increase in legal expenses of \$159,113, increased other professional, legal and consulting fees of 423,378, additional one-time fees of \$459,051 related to a potential listing on a stock exchange in the United States, (subject to meeting applicable quantitative and qualitative listing standards of such stock exchange), increased share-based compensation of \$306,695 related to the grant of share options, expensing of share issuance costs associated with the issuance of warrants in the August 2021 financing and base shelf costs of \$717,806 and foreign exchange of expense of \$166,539 on U.S. denominated assets and liabilities offset by a reduction in contracted corporate salaries and associated facility costs of \$219,465 due to reduction in compensation to management and attrition of contracted staff and a decreased investor relations of \$332,558 due to a reduction of investor relation activities and consultants. Note that there can be no assurance that the

Company will complete a listing on a stock exchange in the United States.

Other Expense

The increase in other expense is primarily the valuation of the derivative liability associated with the convertible debenture financing and associated interest expense of \$2,990,375 offset by the decrease in fair value of the warrant liability of \$1,411,467 and the gain on the sale of lab equipment of \$75,198.

About ProMIS Neurosciences, Inc.

ProMIS Neurosciences, Inc. is a development stage biotechnology company 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 Parkinson's disease (PD). 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 PD. ProMIS is headquartered in Toronto, Ontario, with offices in Cambridge, Massachusetts. ProMIS is listed on the Toronto Stock Exchange under the symbol PMN, and on the OTCQB Venture Market under the symbol ARFXF.

Visit us at www.promisneurosciences.com, follow us on [Twitter](#) and [LinkedIn](#)

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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, 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 and financial condition 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. 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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