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ProMIS Neurosciences Announces Third Quarter 2021 Results

TORONTO and CAMBRIDGE, Mass., Nov. 12, 2021 (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 toxic oligomers implicated in the development of neurodegenerative diseases, today announced its operational and financial results for the three and nine months ended September 30, 2021.

"We are pleased to be ramping up our efforts to advance our lead asset, PMN 310, closer toward the clinic," said Gene Williams, ProMIS' Chairman and CEO. "The financing we secured earlier this year is enabling us to unlock the potential of our platform, which we believe could have significant impact on the treatment of several neurological diseases, including Alzheimer's Disease (AD), Parkinson's Disease and ALS. The strengthening of our management team and Board this quarter has also enabled us to leverage worldwide development and patent expertise and strengthen our overall competitive position."

Corporate Highlights

- 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, we announced the closing of a public offering for gross proceeds of US\$20,125,000 (CDN\$25,522,525).
- On October 7, 2021, we announced that we would hold a special general meeting of shareholders (the "Special Meeting") on December 1, 2021. We set October 18, 2021, as the record date for the Special Meeting. The purpose of the Special Meeting is to ask shareholders to grant the Board of Directors 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.

People

- 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, PhD, to the board of directors. Dr Shafmaster has approximately 30 years of experience providing intellectual property advice to biotechnology and pharmaceutical industries.

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 joins 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. He will be working with Mr. Williams and the leadership of the PMN310 project team, whose key members include:
 - Michael Grundman, MD, Senior Medical Adviser. Prior to joining the pharmaceutical industry, Dr. Grundman was Associate Director of the Alzheimer’s Disease Cooperative Study at the University of California, San Diego (“UCSD”) and is currently an Adjunct Professor of Neurosciences at UCSD. Dr. Grundman previously served on the FDA Peripheral and Central Nervous System Advisory Committee.
 - Ernest Bush, PhD, Head of Pharmacology/Toxicology. Dr. Bush has 35 years of experience working in the field of biomedical research and development, driving development of innovative therapies for treatment of human diseases. He has served as a consultant in non-clinical development providing advice and insight into Investigational New Drug (“IND”) enabling programs, pre-clinical data-set analysis for due diligence and evaluation and audits of Good Laboratory Practices (“GLP”) bioanalytical and toxicology facilities and studies.
 - Dennis Chen, PhD, Head of Manufacturing. Dennis has more than 25 years of prior pharmaceutical experience in working with companies from virtual to global and all phases of development. Dennis provides Regulatory Affairs, Chemistry, Chemistry, Manufacturing and Controls (“CMC”) and Biopharmaceutical Development support to ProMIS with expertise in peptides, proteins and oligonucleotides.

Financial Results

Results of Operations – Three months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended

September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
Revenues	\$ 5,101	\$ -	\$ 5,101
Operating expenses			
Research and development	\$ 1,192,865	\$ 1,053,769	\$ 139,096
General and administrative	852,695	510,264	342,431
Total operating expenses	<u>2,045,560</u>	<u>1,564,033</u>	<u>481,527</u>
Loss from operations	2,040,459	1,564,033	476,426
Other income	(1,078,483)	-	(1,078,483)
Net loss	<u>\$ 961,976</u>	<u>\$ 1,564,033</u>	<u>\$ (602,057)</u>

Research and Development

Research and development expenses consist of the following:

	Three Months Ended September 30,		
	2021	2020	Change
Direct research and development expenses by program:	\$ 590,940	\$ 390,917	\$ 200,023
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	218,210	488,888	(270,678)
Consulting expense	180,604	73,885	106,719
Patent expense	187,734	98,411	89,323
Amortization expense	<u>15,377</u>	<u>1,668</u>	<u>13,709</u>
Total research and development expenses	<u>\$ 1,192,865</u>	<u>\$ 1,053,769</u>	<u>\$ 139,096</u>

The increase in research and development expense for the three months ended September 30, 2021, compared to the three months ended September 30, 2020, is primarily attributed to increased costs associated with external contract research organizations for internal programs of \$200,023 as the company ramps up key internal programs, increased patent expense of \$89,323 due to increased maintenance fees, increased outside consultants of \$106,719 and increase in amortization of property and equipment and intangible asset of \$13,709 offset by decreased contracted research salaries and associated costs of \$247,792 due to reduction in compensation to management and attrition of contract staff and decreased share-based compensation of \$22,886 due to the forfeiture of share options.

General and Administrative

General and administrative expenses consist of the following:

	Three Months Ended September 30,		
	2021	2020	Change
Personnel related (including stock-based compensation)	\$ 374,055	\$ 242,571	\$ 131,484
Professional and consulting fees	470,493	337,446	133,047
Facility-related and other	8,147	(69,753)	77,900
Total general and administrative expenses	\$ 852,695	\$ 510,264	\$ 342,431

The increase for the three months ended September 30, 2021, compared to the three same period in 2020, is primarily attributable to by an increase in share-based compensation of \$212,237 due to the grant of share options, increased legal expense of \$52,959, increased to other professional fees of \$150,162 and foreign exchange losses of \$88,451 due to the foreign exchange on U.S. denominated assets and liabilities offset by a reduction in contracted corporate salaries and associated facility costs of \$91,304 due to reduction in compensation to management and attrition of contracted staff and decreased investor relations of \$70,074 due to scale down of investor relations activities and consultants

Other Income

The increase in other income is primarily the change in the fair value of the derivative liability associated with the convertible debenture financing warrant liability arising from the August 2021 financing.

Results of Operations – Nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
Revenues	\$ 5,101	\$ 1,578	\$ 3,523
Operating expenses			
Research and development	2,451,985	2,926,242	(474,257)
General and administrative	1,554,509	2,051,506	(496,997)
Total operating expenses	4,006,494	4,977,748	(971,254)
Loss from operations	4,001,393	4,976,170	(974,777)
Other expense	4,857,346	-	4,857,346
Net loss	\$8,858,739	\$4,976,170	\$3,882,569

Research and Development

Research and development expenses consist of the following:

	Nine Months Ended September 30,		
	2021	2020	Change
Direct research and development expenses by program:	\$ 1,173,873	\$ 885,179	\$ 288,694
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	476,161	1,566,083	(1,089,922)
Consulting expense	370,052	176,898	193,154
Patent expense	386,018	293,078	92,940
Other operating costs	45,881	5,004	40,877
Total research and development expenses	\$ 2,451,985	\$ 2,926,242	\$ (474,257)

The decrease in research and development expense for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020, reflects the conservation of cash resources and decreased contract salaries and associated costs of \$921,576 due to reduction in compensation to management and attrition of contracted staff and decreased share-based compensation of \$168,346 due to forfeiture of unvested/vested share options due to termination of consulting arrangement offset by increased costs associated with external contract research organizations for internal programs of \$288,694 as the company ramps up key internal programs, increased patent expense of \$92,940 due to increased maintenance fees, increased consulting expense of \$193,154 and increase in amortization of property and equipment and intangible asset of \$40,877.

General and Administrative

General and administrative expenses consist of the following:

	Nine Months Ended September 30,		
	2021	2020	Change
Personnel related (including stock-based compensation)	\$ 802,356	\$ 910,769	\$ (108,413)
Professional and consulting fees	950,285	1,083,745	(133,460)
Facility-related and other	(198,132)	56,992	(255,124)
Total general and administrative expenses	\$ 1,554,509	\$ 2,051,506	\$ (496,997)

The decrease for the nine months ended September 30, 2021, compared to the same period in 2020, is primarily attributable to a reduction in contracted corporate salaries and associated facility costs of \$342,084 due to reduction in compensation to management and attrition of contracted staff, decreased investor relations of \$451,033 due to a reduction of investor relation activities and consultants and foreign exchange gains of \$204,561 on U.S. denominated assets and liabilities offset by increased legal expense of \$152,531, increased other professional fees of 165,042 and increased share-based compensation of \$183,108, related to the grant of share options.

Other Expense

The increase in other expense is primarily the valuation of the derivative liability associated with the convertible debenture financing.

Outlook

Going forward we will focus on therapeutic programs in our core business area of differentiated antibodies for neurodegenerative and other mis-folded protein diseases.

PMN310, ProMIS antibody therapy selective for toxic oligomers in Alzheimer's disease, is our highest priority. In Q3, we made significant progress, in line with plans, on all the program elements discussed in the prospectus supplement in August 2021, including cell line development, GLP toxicology work, and CMC manufacturing. We are on track to complete all IND enabling work in H2 2022.

The top priority for our scientific validation efforts, largely centered in Dr. Neil Cashman's lab at UBC, is currently our ALS portfolio. This portfolio includes antibodies targeting mis-folded forms of TDP-43, RACK1, SOD1, and ataxin2. The most advanced of these is the program targeting TDP-43. We have initiated both in vitro assays (assessing the impact of drug on motor neuron cell lines) and in vivo (mouse model) assays and expect readouts over the next several months.

In addition, we are continuing to expand the application of our unique discovery platform, with which we can "rationally design" antibodies to be selective for only mis-folded, pathogenic proteins involved in disease. Our Chief Physics Officer, David Wishart, and his team are pursuing multiple novel targets. We have acquired access to the AlphaFold database of over 300,000 normal protein conformations, which is the starting point for our predictions of conformational epitopes on mis-folded molecular species using our proprietary computational algorithm Collective Coordinates.

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](#)

For Investor Relations please contact:
Alpine Equity Advisors

Nicholas Rigopoulos, President
nick@alpineequityadv.com
Tel. 617 901-0785

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Source: ProMIS Neurosciences Inc.