Chairman's AGM Address

9 October 2024 – Melbourne, Australia: PharmAust Limited (ASX:PAA) (**PharmAust** or the **Company**) provides a copy of the Chairman's address, which will be delivered at the Company's Annual General Meeting today.

ADDRESS BY THE CHAIRMAN, SERGIO DUCHINI

Ladies and Gentlemen, Shareholders,

Welcome to the Annual General Meeting of PharmAust Limited.

Thank you for joining us, whether you are attending in person or virtually. It is my pleasure to address you today as the newly appointed Chair, as we reflect on a transformative year for our Company and an exciting path ahead.

Our year has been defined by strong clinical results, a new strategy and focus, and a refreshed Board and management team. We have realigned our strategy to focus on accelerating the development of monepantel (MPL) for patients with Amyotrophic Lateral Sclerosis (ALS), the most common form of motor neurone disease. This has meant we have deprioritised our other programs in veterinary and cancer treatments so that we can devote our resources to this promising product candidate.

This past year, we made significant strides towards providing a much-needed treatment for ALS patients. We were delighted to report positive Phase 1 MEND study results which showed that compared to matched controls, MPL slowed the progression of disease by 39%. These results were well received by the patient community who unfortunately do not have many treatment options.

Equally, we are very excited that MPL has been accepted for inclusion in the prestigious HEALEY ALS Platform Trial. The HEALEY trial provides independent validation by global ALS experts of MPL's potential. It is an innovative platform trial that involves a large-scale collaboration across 70+ clinical sites in the US to evaluate several drug candidates simultaneously. The inclusion of MPL in the trial not only enhances patient access but also reduces study costs and accelerates timelines.

Equally, we have made strong progress via our regulatory authority engagement program. A pivotal moment this year was when the US Food and Drug Administration (FDA) granted PharmAust Orphan Drug Designation for MPL, providing significant financial incentives and enhancing MPL's commercial potential.

In September 2024, we submitted a request for Orphan Medicinal Product Designation (OMPD) with the European Medicines Agency (EMA) for MPL, following constructive discussions with the EMA and the Committee for Orphan Medicinal Products. If granted, this designation would also offer significant commercial benefits, including ten years of market exclusivity across the European Union. A decision is expected from the EMA by December 2024.

Our clinical results, along with these regulatory milestones support our confidence in the potential of MPL as a treatment for ALS. They also position your Company as a leader in the neurodegenerative disease market, which is projected to reach USD 77.82 billion by 2029*.
I am very proud of our team for achieving these operational milestones which we will be elaborated on in greater detail by our CEO, Michael Thurn in his presentation today.

During the year, we were delighted to welcome Mr. Marcus Hughes, an experienced ASX-listed tax and finance director, and Dr. Katie MacFarlane, a US pharmaceutical executive, as Non-executive Directors. I was delighted to join the Board as Non-executive Chairman, and we were pleased to appoint Dr. Michael Thurn, our Chief Executive Officer, to the Board as Managing Director.

These additions have greatly strengthened our Board and management team, bringing extensive experience in governance, finance, pharmaceutical drug development, and commercialisation. We are well positioned to execute our refreshed strategy.

Importantly, we are also in a strong financial position, with A$22 million raised this year through an institutional placement and share purchase plan. These funds are being directed towards advancing our clinical and commercial strategy for MPL. On behalf of the Board, I'd like to thank our shareholders for their ongoing support.

With an advancing clinical stage product, a refreshed strategy and a strong team at the helm, we are very excited about our future ahead and feel now is the right time to step forward with a new company identity. As such, we are proposing to rebrand to become Neurizon Therapeutics.

Neurizon Therapeutics name and brand reflect our commitment to advancing neural research and our mission to lead the development of neurodegenerative diseases. It combines our focus on neurodegenerative diseases with the promising horizon for patients.

Importantly, this new identity reinforces our key strategic priorities: (1) advancing patient access to innovative ALS treatments, (2) accelerating hope by partnering with the world's leading neurologists and Mass General's Healey ALS Platform Trial, and (3) unlocking the potential of MPL to treat a range of neurodegenerative diseases.

Neurizon Therapeutics aligns with the performance-led culture established by the Company's new Board and management team, accurately reflecting our core business purpose and strategy, now and into the future. We encourage you to support the resolution to change our name.

The year ahead promises to be exciting as we look forward to commencing enrolment in the HEALEY ALS Platform Trial in Q1 2025. This pivotal study could potentially lead to accelerated approval from the FDA, positioning MPL as a treatment option for ALS as early as 2026.

I would like to take this opportunity to thank my fellow board members, our management team, and all of our employees for their dedication and commitment. Together, we are building a company that is not only advancing innovative treatments for neurodegenerative diseases but also creating real hope for patients and their families.

Thank you for your continued confidence in PharmAust. We have a bright future ahead, and your support and involvement are integral to our journey ahead.

Sergio Duchini
Chairman, PharmAust Limited

Mordor Intelligence, Neurodegenerative Disease - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts 2019 – 2029

This announcement is authorised for release by the Board of Directors of PharmAust Limited.

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About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (ASX Code: PAA). PAA is a clinical-stage biotechnology company developing therapeutics for neurodegenerative diseases. The company is focused on repurposing monepantel (MPL) for amyotrophic lateral sclerosis (ALS). ALS is the most common form of motor neurone disease (MND) and affects both upper and lower motor neurons.

MPL is a potent and safe inhibitor of the mTOR pathway. This pathway plays a central role in the growth and proliferation of cancer cells and degenerating neurons. The mTOR pathway regulates the cellular “cleaning process”, where toxic proteins are broken down into macromolecules to be reused. This autophagic process is disrupted in most neurodegenerative diseases, including ALS.

The company announced positive top-line results for its Phase 1 MEND study in patients with ALS in February this year. MPL was recently selected for inclusion in the HEALEY ALS Platform Trial and anticipates commencing enrolment in Q4 CY 2024. This single pivotal study could potentially lead to accelerated approval with the US Food and Drug Administration for monepantel for the treatment of ALS in 2026.

In 2024, the Neurodegenerative Disease Market size is estimated to be worth USD 55.12 billion, with a forecast growth (CAGR) of 7.14% the market size is expected to reach USD 77.82 billion by 2029.[1]

[1] https://www.mordorintelligence.com/industry-reports/neurodegenerative-disease-market

PharmAust Investor Hub:

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