

Investor update

14 May 2024 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAOA) (“PharmAust” or “the Company”), a clinical-stage biotechnology company, announced several updates following recent changes to the Board of Directors and management team.

The first meeting of the new PharmAust Board was convened on Monday 13 May 2024. This update is provided to outline work that is now underway to strengthen the foundation of PharmAust whilst providing an overview of the forward direction for the Company.

Changes to the Board of Directors

As previously announced, transitional arrangements have been implemented by the Company that include the appointment of Mr Sam Wright as Interim Chairman of PharmAust, Mr John Clark as Interim CEO and Managing Director and Mr Marcus Hughes as Non-Executive Director.

PharmAust advises that Mr Neville Bassett AM has resigned as a Non-Executive Director of the Company.

Work has commenced to recruit additional experienced Directors who will strengthen the PharmAust Board and bring a renewed focus on good corporate governance, effective strategy, shareholder engagement and commercial acumen as the company enters a transformational stage.

The Company is prioritising this task and will update shareholders on the appointment of Directors as work progresses. All appointments will be presented to shareholders for ratification at the next Annual General Meeting. Similarly, the establishment of permanent management arrangements will be progressed once the new Board has been finalised.

Interim Chairman Sam Wright added: “Our thanks go to Neville for his service as a Director of PharmAust for the past five and a half years, during which time he provided calm, well considered counsel to the Company. We wish him the best in all future endeavours.”

Strategic focus

PharmAust’s Board is focused on delivering shareholder value as it pursues the commercialisation of monepantel (MPL) for the treatment of human neurodegenerative diseases.

The recently completed Phase 1 MEND study of MPL in MND/ALS has shown that the drug crosses the blood-brain barrier and is safe to use at therapeutically meaningful doses in this vulnerable patient cohort. Additionally, preliminary efficacy data shows that the administration of MPL at a dose of 10mg/kg may slow the progression of MND/ALS by up to 58% and increase life expectancy by as much as 56.5 months, depending on the severity of the disease at baseline. These outcomes are especially notable compared to currently approved treatments, which only extend life expectancy by 2 to 6 months.

PharmAust has lodged an application for Orphan Drug Designation (ODD) with the US Food and Drug Administration (FDA) for the treatment of MND/ALS with MPL, which is expected to be determined by mid-June. ODD status carries a suite of concessions and benefits, including tax credits for clinical trials, exemptions from user fees and the potential for 7-years of market exclusivity upon approval.

Work on the design and implementation of a pivotal adaptive Phase 2/3 clinical trial of MPL in MND/ALS is well progressed. Trial commencement is anticipated in H2 CY24, subject to necessary approvals.

Given their similar pathogenesis, pre-clinical work is set to commence exploring the utility of MPL as a treatment in other human neurodegenerative diseases, such as Alzheimer's Disease and Parkinson's Disease. This work is being undertaken to help build the Company's understanding of the potential for MPL to be useful in more common neurodegenerative diseases, which will inform the addressable market for MPL.

Further updates

PharmAust has experienced significant change over recent weeks. The Board would like to extend its thanks to shareholders for their understanding, loyalty, commitment and patience as the Company undergoes this important transformation.

The Board is more determined than ever to pursue the commercialisation of MPL in human neurodegenerative diseases and looks forward to providing further updates to shareholders as we enter this exciting new phase.

In line with this, an investor webinar will be held with Managing Director John Clark, as detailed below.

Investor webinar

PharmAust will be holding an investor webinar this **Friday 17 May at 11:00am AEST** to provide an update on recent announcements and the strategy of the Company looking forward.

Shareholders, investors and interested parties are invited to register for the webinar at: https://us02web.zoom.us/webinar/register/WN_C5HBbU1hRgmFVraT1cve8g

A recording will be available at the above link shortly after the conclusion of the live session, and the replay will also be available via the Company's website and social media channels. Questions can be submitted in advance to matt@nwrcommunications.com.au

The Board authorises this announcement.

Enquiries:

John Clark
Managing Director
investorenquiries@pharmaust.com

P +61 (8) 9202 6814
F +61 (8) 9467 6111
W www.pharmaust.com

Media:

Matthew Wright
NWR Communications
matt@nwrcommunications.com.au
0451 896 420

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 human and animal health applications. The company is focused on repurposing monepantel (MPL) for human neurodegenerative diseases.

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 protein is broken down into macromolecules to be reused. This autophagic process is disrupted in most neurodegenerative diseases, including motor neuron disease (MND/ALS).

PAA’s lead MPL program is for the treatment of MND/ALS, a rare, incurable disease. The company recently announced positive top-line results for its Phase 1 study in patients with MND/ALS. PAA anticipates commencing enrolment in its pivotal registration adaptive Phase 2/3 clinical study in H2 CY 2024 that could lead to accelerated approval with the US Food and Drug Administration in 2026.

The Neurodegenerative Disease Market size is estimated at USD 55.12 billion in 2024, and is expected to reach USD 77.82 billion by 2029, growing at a CAGR of 7.14% during the forecast period (2024-2029).¹

¹ <https://www.mordorintelligence.com/industry-reports/neurodegenerative-disease-market>

PharmAust Investor Hub:

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning PharmAust. This platform offers an opportunity to submit questions, share comments, and view video summaries of key announcements.

Access the investor hub by scanning the QR code or visiting:
<https://investorhub.pharmaust.com/>

