Quarterly Report & Appendix 4C
Q4 FY24

Highlights:

- **Transformative quarter pivoting PharmAust's focus to neurodegenerative diseases**
- **Board of Directors skills refreshed and enhanced with the appointments of a new, experienced Chair, NEDs and CEO**
- **Executive leadership team enhanced with the key appointments in manufacturing, science, and business development**
- **Monepantel granted Orphan Drug Designation for the treatment of ALS by the US FDA**
- **PharmAust granted Small and Medium-Sized Enterprise status by the EMA**
- **Open-Label Extension Study receives final Ethics Committee approval and completes enrolment**
- **Additional impressive survival data for patients who continue to receive treatment with monepantel from the Phase 1 MEND Study**
- **Berry Consultants independently presents positive Phase 1 MEND Study data at major international conference**
- **Acceptance of monepantel into the prestigious HEALEY ALS Platform Trial provides independent validation of monepantel's potential, post quarter**
- **Successful $10 million capital raise via placement to new and existing institutional and sophisticated investors**
- **Share Purchase Plan exceeds expectations and raising a further $7.8 million**
- **Strong cash balance of $10.66 million as at 30 June, plus $7.8 million from completed SPP**

Planned activity for Q1 FY25:

- **Design of monepantel regimen-specific protocol for HEALEY ALS Platform Trial**
- **Submission of Orphan Medicinal Product Designation application to the EMA**
- **Continuation of GMP manufacture campaign, engineering batch in progress**
- **Preparations for US FDA IND filing for monepantel**

29 July 2024 – Melbourne, Australia: PharmAust Limited (ASX: PAA & PAAOA) ("PharmAust" or "the Company"), a clinical-stage biotechnology company, is pleased to present its Appendix 4C and Quarterly Activities Report for the period ended 30 June 2024.

During the quarter, PharmAust achieved significant milestones in the development of monepantel (MPL) for Amyotrophic Lateral Sclerosis (ALS). These include securing final ethics committee approval for the Open-Label Extension (OLE) study, obtaining United States (US) Food and Drug Administration (FDA) Orphan Drug Designation (ODD) and European Medicines Agency (EMA) Small and Medium-Sized Enterprise (SME) status, poster presentation of the positive Phase 1 MEND study results at the annual meeting of the European Network to Cure ALS (ENCALS) in Stockholm, and reporting impressive survival data from the Phase 1 MEND Study patients that continue to receive treatment with MPL.

Chief Executive Officer, Dr Michael Thurn commented: "This quarter has been transformational for PharmAust. The refreshed Board of Directors coupled with further strategic appointments to the management team will allow PharmAust to fully capitalise on the significant advancements achieved this quarter in our mission to develop a viable treatment for patients with ALS. From being able to continue treating patients from our Phase 1 MEND Study that started back in October 2022 in our open-label extension study, being awarded Orphan Drug status for monepantel by the US FDA, releasing additional impressive survival data for patients with ALS and capping this off by being accepted into the prestigious HEALEY ALS Platform Trial, we have made substantial strides. These achievements have not gone unnoticed with new institutional and sophisticated investors together with our existing shareholders participating in our recent very successful financing. The $17.8 million raised leaves us in a financially strong position as we continue to execute our strategy towards fast-tracking our efforts to bring much-needed new therapy to patients with ALS."

Orphan Drug Designation

In May, the US FDA granted PharmAust an ODD for MPL for the treatment of ALS. The ODD entitles companies to receive greater support and engagement from the US FDA and provides important financial incentives such as tax credits, grants, and seven years of market exclusivity, significantly enhancing MPL's commercial potential.

Open-Label Extension Study

In May, approval was received from Macquarie University Human Research Ethics Committee (HREC) to commence the Open-Label Extension (OLE) study of MPL in patients with ALS at Macquarie University, Sydney, allowing the final patients from the completed Phase 1 MEND study to be screened for participation. The OLE study was subsequently fully enrolled during the quarter, enabling the collection of long-term safety and efficacy data.

Impressive Survival Benefit

PharmAust reported a statistically significant survival benefit for MPL compared to untreated matched-controls from the historical control PRO-ACT database. The analysis conducted by Berry Consultants results included a statistically significant 91% reduction in the risk of death compared to matched-controls, reinforcing MPL's potential in treating this debilitating condition.

Positive Data from the Phase 1 MEND study presented at ENCALS Annual Meeting

In June, Berry Consultants independently presented data from the successful Phase 1 MEND study at the Annual Meeting of the European Network to Cure ALS (ENCALS) in Stockholm. The meeting is the largest and most significant ALS conference held annually in Europe.

The poster presentation highlighted the significant survival benefit and reduced disease progression observed in patients treated with MPL. This compelling data, drawing positive attention from the scientific community, underscores the promising potential of MPL in treating ALS and reinforces the collaborative efforts between PharmAust and Berry Consultants in advancing the research.

PharmAust's Non-Executive Chairman, Sergio Duchini and the Company's Chief Operating Officer, John Clark attended the ENCALS annual meeting in person and took the opportunity to meet with industry representatives, global clinical trial service providers and key opinion leaders.

Small and Medium-Sized Enterprise Status Awarded
In June, PharmAust was granted SME status by the EMA, entitling the company to receive regulatory fee incentives and additional support from the EMA, streamlining regulatory engagement and the Company's ability to advance MPL for the treatment of Amyotrophic Lateral Sclerosis (ALS).

Acceptance into the HEALEY ALS Platform Trial
Following the close of the period in July, MPL was accepted into the prestigious and well-recognised HEALEY ALS Platform Trial in the US. Inclusion in the HEALEY trial provides independent validation by global ALS experts of MPL's potential as an ALS treatment. The innovative platform trial is a large-scale collaboration across 70+ clinical sites in the US to evaluate several drug candidates simultaneously, increasing patient access, reducing study costs, and shortens study completion timelines. MPL's inclusion in this trial is a significant step towards FDA approval, enhances PharmAust's visibility within the ALS research community and is a critical advancement in our mission to offer a viable treatment for ALS.

Corporate Summary
On a corporate front, the Company pivoted its commercialisation strategy to deliver shareholder value to solely focusing on the development of MPL for the treatment of neurodegenerative diseases. Based on MPL's mechanism of action, turning on a natural cellular "cleaning process" known as autophagy by inhibiting the intracellular mTOR pathway, MPL may have considerable utility in other neurodegenerative diseases, including Alzheimer's, Parkinson's and Huntington's disease, where the autophagic process is disrupted. In 2024, the size of the neurodegenerative disease market is estimated to be worth USD $55.12 billion and is expected to reach USD $77.82 billion (CAGR of 7.14%) by 2029.[1]

To implement this refreshed strategy, PharmAust appointed experienced Chair, Mr Sergio Duchini as Non-executive Chairman, and experienced ASX-listed tax and finance director, Mr Marcus Hughes and US Pharmaceutical executive, Dr Katie MacFarlane as Non-executive Directors to the Board. The Board refresh has brought best practice professionals to the steward the company with considerable knowledge, networks and multinational corporate skill sets in governance, finance and pharmaceutical drug development and commercialisation.

After returning to the Company as Chief Executive Officer, Dr Michael Thurn was promoted to the position of Managing Director. Additional appointments were also made to the PharmAust's management team, Dr Herbert Brinkman as Head of Manufacturing, Dr Nicky Wallis as Chief Scientific Officer and Mr Paul Field as Business Development Advisor. The quality and extensive experience of these appointments further reinforces the company's vision of becoming a world-leader in the development of treatments for neurodegenerative diseases.

The company also relocated its headquarters to Melbourne to foster closer working relationships between the Board of Directors and management team. Experienced ASX-listed Company Secretary, Mr Stefan Ross also joined the PharmAust team.

During the quarter, PharmAust successfully raised a total of $17.8 million, via a placement ($10 million) in June 2024 and following the close of the period additional funds were raised via a Share Purchase Plan (SPP; $7.8 million) that was completed in July 2024. Directors and Management participated to the value of approximately $1 million, with participation subject to shareholder approval (where applicable) at the AGM.

Cash Flow Summary
During the quarter, PharmAust continued to fund the advancement of its clinical development program for MPL.

PharmAust had net cash outflows from operating activities of $2.09 million during the quarter and held $10.66 million in cash and cash equivalents as at 30 June 2024.

During the quarter, PharmAust invested $1.48 million in R&D activities, and had $8.80 million in net cash inflows from financing activities, mainly in relation to completion of the Tranche 1 Placement to institution and sophisticated investors (including fees associated with the capital raising), and the exercise of options during the quarter.

Payments to related parties and their associates during the quarter, which are outlined in Section 6 of the accompanying Appendix 4C to this quarterly activity report, were $192k. These payments included non-executive director fees and consulting fees as well as salary (including superannuation) for the CEO and Managing Director.

PharmAust successfully raised $10 million via an institutional and sophisticated investor placement during the quarter. A further $7.8 million was raised subsequent to the end of the quarter via a Share Purchase Plan (SPP). The funds raised will be used to finalise preparations for the HEALEY ALS Platform Trial in patients with ALS, GMP manufacturing, preclinical models for other neurodegenerative diseases, regulatory filings, working capital and offer costs.

A copy of the Appendix 4C - Quarterly Cash Flow Report for the quarter is attached.

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 recently announced positive top-line results for its Phase 1 MEND study in participants with ALS. MPL has been 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 FDA for MPL 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:

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/

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
PharmAust Limited	
ABN	**Quarter ended ("current quarter")**
35 094 006 023	30 June 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	461
1.2	Payments for		
	(a) research and development	(1,481)	(4,398)
	(b) product manufacturing and operating costs	-	(58)
	(c) advertising and marketing	(21)	(120)
	(d) leased assets	-	-
	(e) staff costs	(279)	(809)
	(f) administration and corporate costs	(313)	(1,227)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	5
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	553
1.8	Other (provide details if material)	1	(14)
1.9	**Net cash from / (used in) operating activities**	**(2,093)**	**(5,607)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments in term deposits with maturities longer than 3 months	-	-
	(k) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(l) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	9,148	14,051
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	279	279
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(624)	(624)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (Epichem closing cash at bank)	-	(165)
3.10	**Net cash from / (used in) financing activities**	**8,803**	**13,541**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,941	2,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,093)	(5,607)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

	Consolidated statement of cash flows	Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	8,803	13,541
4.5	Effect of movement in exchange rates on cash held	9	9
4.6	**Cash and cash equivalents at end of period**	**10,660**	**10,660**

5.	**Reconciliation of cash and cash equivalents** at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	9,648	1,929
5.2	Call deposits*	1,012	2,012
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**10,660**	**3,941**

6.	**Payments to related parties of the entity and their associates**	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	192
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (Premium financing)	-	-
7.4	**Total financing facilities**	**-**	**-**

7.5	**Unused financing facilities available at quarter end**	-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	
	N/A	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,093)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,660
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,660
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**5.09**
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.	
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions: N/A	
	8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	N/A	
	8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	N/A	
	8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	N/A	
	Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.	

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 29 July 2024

Authorised by: By the Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.