Appendix 4C & Quarterly Update

Highlights from the December 2023 Quarter:

- **Phase 1 MEND study of monepantel (MPL) for MND/ALS successfully concluded, with all patients in the final Cohort 4 completing their last dose**
- **MPL Orphan Drug Designation application filed with the US FDA**
- **Invitation received from FightMND to submit a grant application to support the upcoming adaptive Phase 2/3 Study**
- **Encouraging results from Phase 2 study of MPL for treating B-cell lymphoma in dogs**
- **$3.5 million raised at a premium through oversubscribed placement; further ~$396,000 through options offer & ~$553,000 through R&D tax rebate**
- **Management team strengthened with key appointments**
- **Attendance at key local and international symposiums for MND/ALS**
- **PharmAust ends the quarter in a strong cash position of $5.5 million**

Planned activities for H1 CY2024

- **Phase 1 MEND Study Top-Line Results**
- **Pre-IND meeting with the FDA for the development of a Phase 2 clinical trial for MND**
- **Outcome of the Orphan Drug Application for monepantel use in MND**
- **Updates from the Open-Label Study due to start Q1 CY2024**
- **Canine Cancer Marketing Study due to be released**
- **Investigational New Animal Drug (INAD) application submission**
- **Attendance at ALS Drug Development Summit in Boston MA, USA**

31 January 2024 – Perth, 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 ending 31 December 2023.

MOTOR NEURONE DISEASE PROGRAM

PharmAust completes Phase 1 MEND Study and files for Orphan Drug Designation

On 1 December 2023, PharmAust Limited announced the successful completion of its Phase 1 MEND Study of monepantel (MPL) for treating motor neurone disease (MND/ALS). This milestone was marked by all patients completing the study, with the release of top-line results anticipated in Q1 CY24.

Importantly, all patients could swallow and breathe unassisted and expressed interest in participating in a 12-month Open-Label Extension (OLE) Study. The Phase 1 MEND Study involved 12 patients with MND/ALS and aimed to determine the recommended Phase 2 dose of MPL based on safety and preliminary efficacy.

A Safety Monitoring Committee oversaw the new dose levels during the progression of the study. There were no deaths or treatment-related serious adverse events reported. Supported by the grant from FightMND, PharmAust also applied for Orphan Drug Designation (ODD) with the United States (US) Food and Drug Administration, aligning with its plan to commence an adaptive Phase 2/3 study in H1 CY24. This designation could offer significant incentives, including tax credits and 7-year market exclusivity post-approval.

Compassionate-Use Program

All 12 patients involved in the Phase 1 MEND Study were pleased and available to continue treatment with MPL under a compassionate-use program administered by their treating physician, either Associate Professor Susan Mathers or Professor Dominic Rowe, to be eligible for the OLE study that is due to commence early in 2024.

FightMND Invites PharmAust to Apply for Phase 2/3 Grant Funding

In December, the Company announced that FightMND, Australia's leading not-for-profit foundation for Motor Neurone Disease (MND) research, had invited the company to submit a complete grant application to support its upcoming Phase 2/3 clinical study. This study, expected to commence in the first half of 2024, is a multicentre, randomised, placebo-controlled, adaptive Phase 2/3 clinical study aimed at evaluating the safety and efficacy of MPL in patients with MND/ALS over 48 weeks.

The primary goal of this study is to assess the efficacy of MPL compared to a placebo on the progression of MND/ALS. This assessment will be based on changes from the baseline in disease severity, measured by the ALS Functional Rating Scale-Revised (ALSFRS-R) total score and patient survival. The adaptive design of the study allows for an interim analysis at Week 24, offering the potential for early termination for either success or futility (lack of benefit/ineffective outcome).

FightMND's invitation follows PharmAust's successful Letter of Intent submission and could result in support of up to $1.8 million per grant. This funding would significantly aid PharmAust in offsetting the costs of this crucial drug development phase.

CANINE ONCOLOGY PROGRAM

Data from Canine Oncology Study Supports Progression to Registration Studies

On October 9 2023, the Company announced positive top-line data from its Phase 2 veterinary clinical study of MPL for treating Canine B-Cell Lymphoma. The study, designed as a Phase 2 open-label, single-arm dose-finding study, involved various MPL dosing regimens to determine the most effective and safe treatment option. A clinically safe and efficacious dosing regimen was established, with a loading dose of 100 mg/kg body weight followed by a maintenance dose of 25 mg/kg, based on efficacy and safety data.

The study yielded encouraging results, showing that MPL treatment was safe, well-tolerated, and resulted in no treatment-related deaths or severe adverse reactions. The Overall Clinical Benefit was 35% (14 out of 40 dogs), with a median Time to Progression (TTP) of 28 days, favourably compared to the most recent FDA-approved product for B-cell and T-cell lymphoma, LAVERDIA™. MPL also demonstrated a significant competitive advantage over LAVERDIA™ in terms of Quality of Life (QoL) and Level of Function (LoF) as assessed by dog owners.

Given these positive outcomes, PharmAust plans to use this data to open an Investigational New Animal Drug (INAD) application with the United States Food and Drug Administration’s Center for Veterinary Medicine (CVM) and proceed with pivotal studies in 2024 to support product registration. The study's success marks a significant step towards commercialising MPL as a new treatment option for canine B-cell lymphoma.

CORPORATE

New Management Hires

PharmAust further strengthened its management team with two key appointments during the quarter.

Dr. Carol Worth joined the Company as the Chemistry, Manufacturing and Controls (CMC) Operations Manager, bringing over 30 years of experience in the pharmaceutical industry. Her expertise is expected to significantly contribute to the GMP manufacture of MPL and provide clinical supplies for upcoming studies.

John Clark has over 20 years of experience managing global phase I – IV clinical trials and has been appointed Clinical Operations Manager. His role will focus on leading global clinical operations as PharmAust positions itself as a leading developer in neurodegenerative medicines.

PharmAust Raises $3.5 Million at a Premium

PharmAust raised approximately $3.46 million in December through an oversubscribed placement led by Blue Ocean Equities. This strategic financial move involved issuing about 34.6 million new shares at an issue price of $0.10 per share and a 2:3 free attaching option exercisable at $0.15, expiring on 31 December 2025. The offer price represented a 10.8% premium to the 30-day volume-weighted average price (VWAP), reflecting growing confidence from new institutional shareholders in the company's recent achievements and prospects.

Merchant Biotech Fund and associated parties applied for $2.1m, while the remaining $1.4 million was placed with other institutional and sophisticated investors, including PharmAust's Finance Director and Company Secretary, Sam Wright. The funds raised will be used to prepare for upcoming human studies, further manufacturing MPL tablets for human and canine studies, and strengthen working capital.

Options Offer

In November 2023, PharmAust initiated an Options Offer to holders of lapsed PAAO Listed Options, aiming to raise to $396,124.56 by offering new options at 0.5 cents each. This strategic financial move was designed to bolster the company's funding for its ongoing and future projects.

The Offer concluded with an impressive 93% uptake, resulting in a total subscription of 367,747.68. This high level of participation by the optionholders demonstrated strong confidence in PharmAust's direction and potential. The shortfall was placed by Blue Ocean Equities.

R&D Tax Incentive Refund

PharmAust also announced the receipt of a refund from the Australian Taxation Office (ATO) under the Research and Development Tax Incentive (RDTI) scheme. The company received a sum of $553,435.28 as a refundable amount on its 2023 Tax Return. The RDTI scheme, jointly administered by the ATO and AusIndustry, provides up to a 43.5% refundable tax offset on eligible expenses for research and development activities.

Australia and New Zealand MND Research Symposium

PharmAust was a proud Silver Sponsor of the 2nd Australian and New Zealand MND Research Symposium held in Wollongong, NSW in November 2023. Dr. Michael Thurn, John Clark and Associate Professor Susan Mathers represented PharmAust at the Symposium.

Attendance at International ALS/MND Symposium

PharmAust CEO Dr. Michael Thurn attended the 34th International Symposium on ALS/MND in Basel, Switzerland, from 6-8 December 2023. This significant event, dedicated to ALS and MND research, provided an excellent opportunity for PharmAust to engage with global stakeholders and update them on the clinical progress of MPL for ALS/MND treatment.

UPCOMING CATALYSTS FOR H1 CY2024

PharmAust has a number of important upcoming catalysts across both the MND and canine oncology programs due this quarter.

Pre-IND Meeting

Early in January 2024, PharmAust announced that the US FDA had granted PharmAust a Pre-Investigational New Drug (Pre-IND) meeting for MPL for the treatment of MND/ALS. The request was submitted on 15 December 2023, and the FDA has committed to provide written responses by 13 February 2024. The pre-IND meeting aims to confirm the details and acceptability of PharmAust's proposed ongoing development program, including the requirements for non-clinical and clinical pharmacology, clinical chemistry, and manufacturing controls. Importantly, the pre-IND meeting PharmAust with an opportunity to seek feedback from the FDA on the design of its planned Phase 2/3 adaptive clinical study and gain insights into the FDA's requirements for monepantel to be potentially granted accelerated approval. With these considerations in hand, PharmAust will be able to proceed confidently with filing its full IND application in Q2 CY 2024.

Orphan Drug Designation

PharmAust submitted the request for ODD in November 2023 to the FDA's Office of Orphan Products Development. The request was based on preclinical mechanistic data that demonstrates monepantel can induce autophagy in diseased cells. In late January 2024, the FDA sent a response letter requesting PharmAust to submit additional clinical data in support of granting the ODD application for the treatment of MND/ALS. PharmAust is due to release its Phase 1 MEND Study clinical data this quarter and will submit an amendment to the FDA following data release.

Open-Label Extension Study

In late January PharmAust announced it has received approval from Monash Health Human Research Ethics Committee (HREC) to commence an OLE study of MPL in patients with Motor Neurone Disease (MND)/Amyotrophic Lateral Sclerosis (ALS) at Calvary Health Care Bethlehem, Melbourne.

The OLE Study is a multicentre, 12-month study designed to allow the 12 patients who participated in the Phase 1 MEND Study to continue to receive further treatment with MPL. Patients will receive a daily dose of 10 mg/kg body weight of MPL for 12 months. The study is expected to commence at Calvary Health Care Bethlehem led by Associate Professor Susan Mathers, in February 2024, with patients at Macquarie University, led by Professor Dominic Rowe, to follow soon after. The OLE study will further test the hypotheses that MPL administration to individuals living with MND/ALS will safely reduce disease-associated protein accumulation in motor neurons and provide therapeutic benefits.

Phase 1 MEND Study Top-Line Results

Top-line results from the Phase 1 MEND Study are on-track to be released this coming quarter. The database has now been locked and statistical analysis of the data is current underway. In January 2024, PharmAust announced that it had partnered with leading clinical study design specialist Berry Consultants to design and analyse the planned adaptive Phase 2/3 clinical study for MPL in patients with MND/ALS. The lead statistician will be Berry Consultants Director & Senior Statistical Scientist Dr Melanie Quintana, an expert in innovative clinical trial design of rare neurodegenerative diseases. Berry Consultants will be involved in the statistical analysis of the Phase 1 MEND Study data.

Canine Minor Use Minor Species Waiver Application

PharmAust has requested a Minor Use Minor Species waiver of the Sponsor's Fee (US$150,000) for the fiscal year 2024 under the US Animal Drug User Fee Act (ADUFA). The application to the FDA's Center for Veterinary Medicine (CVM) was based on the determination that the proposed indication for MPL, the treatment of canine B-Cell Lymphoma, meets the eligibility for a minor use classification of affecting fewer than 70,000 dogs annually in the US.

Investigation Canine Oncology Commercial Market Assessment

PharmAust has commissioned US-based Pharmaceutical Consulting Firm SmartPharma to performed a commercial assessment of MPL. The commercial assessment of the potential of MPL for the treatment of canine B-Cell Lymphoma will focus on the US market, and will include market sizing, market dynamics, qualitative and quantitative market research with veterinarians and dog owners to validate forecast assumptions, and a 10-year forecast of revenue potential.

New Animal Drug Application

PharmAust plans to open an Investigational New Animal Drug (INAD) file with the US FDA CVM Office of New Animal Drug Evaluation (ONADE) for monepanetal has for the treatment of canine B-Cell Lymphoma. A summary of the scientific rationale for the development of monepantel including data generated from the pre-clinical and Phase 2 clinical study, will be submitted to the FDA. Sponsors of new animal drugs typically submit a request to open an INAD file when they have enough pilot data to start discussing the development process with the FDA and/or they want to begin shipping drug for use in investigational studies in the US.

Scientific Advisory Board Appointments

PharmAust will look to bolster its scientific advisory capacity for both programs by making key appointments to its Scientific Advisory Board (SAB) this coming quarter. The SAB members will each have extensive experience in the development, regulation and commercialisation of animal health and neurodegenerative products.

APPENDIX 4C QUARTERLY CASH FLOW REPORT

PharmAust's cash position at 31 December 2023 was $5.5 million. The company is adequately funded to continue its current activities and will continue to demonstrate appropriate fiscal management.

During the quarter, payments for Research and Development of $0.578 million represented costs involved with the development of the Company's primary drug candidate, Monepantel (MPL).

Payments for Staff Costs represent salaries for directors, executive and general management.

Payments for Administration and Corporate Costs represent general costs associated with running the Company, including ASX fees, share registry, legal fees, rent, etc.

The aggregate amount of payments to related parties and their associates included in the current quarter Cash flows from operating activities were $0.148 million comprising Directors' fees, salaries and superannuation.

Cash outflows for the quarter were in line with management expectations. Please refer to the attached Appendix 4C for further details on cash flows for the quarter.

The Board authorises this announcement.

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

MPL is a potent and safe inhibitor of the mTOR pathway. This pathway plays a central role in cell 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 neurone disease (MND/ALS).

PAA’s lead MPL program is for the treatment of MND/ALS, a rare, incurable disease. The company is currently completing a Phase 1 study in patients with MND/ALS. Top-line results are expected to be announced in Q1 CY2024. PAA anticipates starting a Phase 2 study in H1 CY 2024 that could lead to accelerated approval with the US Food and Drug Administration in 2026.PAA is preparing to start a pivotal field trial in dogs with B-Cell Lymphoma to enable product registration in the US in 2025. PAA has previously successfully completed a Phase 1 oncology clinical study of monepantel in humans and pilot studies in canine cancer.

PharmAust Investor Hub:

For any enquiries regarding the Quarterly or other aspects concerning PharmAust, we encourage you to utilise our Investor Hub. 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 visit: 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	December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	150	461
1.2	Payments for		
	(a) research and development	(578)	(998)
	(b) product manufacturing and operating costs		(58)
	(c) advertising and marketing	(28)	(53)
	(d) leased assets		
	(e) staff costs	(132)	(390)
	(f) administration and corporate costs	(167)	(622)
1.3	Dividends received (see note 3)		
1.4	Interest received	2	3
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	553	553
1.8	Other (GST)	9	(18)
1.9	**Net cash from / (used in) operating activities**	**(192)**	**(1,122)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
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)	3,929	4.032
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
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**	**3,929**	**3,867**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,725	2,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(192)	(1,122)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,929	3,867
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**5,463**	**5,463**

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	5,451	1,194
5.2	Call deposits	12	531
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)**	**5,463**	**1,725**

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	148
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.

Director's Salaries & Superannuation

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 (please specify)		
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.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(**192**)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,463
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	5,463
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	28.5

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:

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?

Answer: 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?

Answer: 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?

Answer: 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.

31 January 2024

Date: .....

By the board

Authorised by: .....
(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.