



Appendix 4C and Quarterly Update

31 October 2022 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical stage biotechnology company, is pleased to present its Appendix 4C and Quarterly Update for the period ended 30 September 2022.

HIGHLIGHTS:

- MND trial has commenced and has recruited first four patients
- \$173k received from FightMND
- Additional MPL being manufactured for future human and canine clinical trials
- PharmAust in confidential discussions with potential licensing partners for canine cancer
- Phase 2 trial continues in canines with B-cell lymphoma in Australia, New Zealand and USA
- Experienced pharmaceutical sales and marketing professional appointed as Epichem BDM & PharmAust Investor Relations
- 30 September 2022 available funding of approximately \$2.2 million, enabling pursuit of various preclinical and clinical commitments (an additional \$173k received from FightMND in October is not included)

Phase I/II Human Trial in Motor Neurone Disease

PharmAust previously announced it has received a funding commitment of A\$881,085 for a Phase I/II trial examining the effects of Monepantel (MPL) in Motor Neurone Disease (MND), otherwise known as Lou Gehrig's disease or Amyotrophic Lateral Sclerosis (ALS).

These funds have been granted by FightMND, the largest independent funder of MND research in Australia. The trial is being overseen by Principal Investigator, Dr Susan Mathers of Calvary Health Care, Bethlehem, Melbourne and includes a second trial site headed by Professor Dominic Rowe of the Centre for Motor Neurone Disease Research Faculty of Medicine and Health Research at Macquarie University in Sydney.

The first four patients have been recruited and dosing with MPL has commenced, with a number of additional patients currently undergoing screening. The trial is testing the safety and tolerability of MPL in patients living with MND. The trial is also set up to look for signs that MPL can slow the progression of MND. This data, in conjunction with concurrent animal studies, will determine whether MPL should go on to be tested in larger Phase 2 studies.

PharmAust was also pleased to announce that ethics approval has been granted to make a few minor amendments to the Clinical Study Protocol to refine the study design and accelerate recruitment.

The ALS/MND addressable market is US\$3.6Bn with Riluzole already reaching ~US\$1Bn in annual sales. According to the International Alliance of ALS/MND Associations, MND affects over 350,000 of the world's population and kills more than 100,000 people every year.

Pre-clinical studies have shown that MPL can slow disease progression in MND models by clearing harmful materials in a motor neurone that stick together and impair functioning.

With success in the clinic, PharmAust expects that in due course MPL could receive orphan drug designation by the FDA for the indication of motor neurone disease. Such designations come with a number of financial and supportive benefits. The Orphan Drug Act provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor.

Subsequent to balance date, PharmAust received the third instalment of \$173,034.80 from FightMND upon recruitment of the first patient. Further instalments for a total commitment of \$881,085 will be paid by FightMND to PharmAust as additional milestones relating to the clinical trial are met. The funding agreement provides that PharmAust shall own all intellectual property generated from the trial.

Phase II Canine Cancer Trials

PharmAust has made significant progress with its lead drug candidate, (MPL) in its canine cancer trials. PharmAust's commercial target is to develop and partner a product that supersedes the current use of prednisolone alone and/or can reduce or replace the use of chemotherapy in dogs. The use of MPL in canine cancer potentially offers canine cancer patients a much better safety profile with much reduced adverse events typically associated with chemotherapy.

During Phase 2a and Phase 2b studies in canines, MPL demonstrated effective anti-cancer activity, which supports continued development into Phase 3 registration trials.

PharmAust has determined an optimum drug plasma range for anti-cancer activity and minimal side effects.

During the Quarter, PharmAust announced that it had recruited the first pet dog with B cell lymphoma in its US canine trial. Dr Meighan Daly DeHart and the medical oncology team at Pathway Vet Alliance dba as Thrive Pet Healthcare and Heart of Texas (HoT) Veterinary Specialty Center in the US will treat up to 10 dogs that will support the INAD submission required to start regulatory approval process for Phase 3 and MUMS status in the US.

During the Quarter, one of the canine patients completed his 100th day on MPL monotherapy and the owner reported he is still doing very well. Two canine patients are currently tied on 191 days on MPL + prednisolone.

Status of current trial

Veterinary trial centres have been set up in Australia, New Zealand and the United States to evaluate the anti-cancer benefit of MPL in dogs newly diagnosed with B-cell lymphoma and have not received any previous cancer treatment.

PharmAust is recruiting pet dogs with untreated B cell lymphoma to finalise the Phase 2 evaluation of the drug MPL, which has demonstrated effective anti-cancer activity and minimal side effects.

The table below outlines the status of all dogs in the study. Please note the explanation of the definitions used in the table. PharmAust is expecting the remaining plasma assays to be presented in the next quarterly report.

Total # dogs enrolled to date	#Dogs fully completed study*	# Dogs partially completed study**	# Dogs fully completed study - suboptimal blood levels***	#Dogs withdrawn from study****
33	16	8	5	4

*Fully completed - All study assessments complete, final grading confirmed PLUS blood testing for Monepantel completed.

Monepantel levels are in optimum range

Partially completed – All study assessments complete, final grading confirmed. Blood testing for Monepantel **NOT completed

*** All study assessments are complete, Final grading confirmed PLUS blood testing for Monepantel completed. Monepantel levels in sub-optimum range

**** Dogs withdrawn from the study due to lack of compliance with study protocol (usually due to dosing dogs incorrectly or given therapy not allowed in protocol)

Twenty-nine pet dogs have been treated using MPL monotherapy (excluding the 4 dogs removed from the study) . With continued positive outcomes, PharmAust is preparing for a successful Phase 2 completion and the commencement of a subsequent Phase 3 registration trial.

Of the 16 pet dogs with optimum blood levels, 13 have achieved stable target lesions. This includes one dog with a partial response (60% regression).

Nine of the 16 dogs with optimum blood levels have achieved stable disease by RECIST (Response Evaluation Criteria in Solid Tumours). Side effects were minimal or not detected. In comparison, the most common side effects of a dog being treated with chemotherapy include gastrointestinal effects (vomiting, diarrhea or loss of appetite) and decreases in blood cell counts. Also, during chemotherapy, owners need to take precautions when handling their pets and their waste. Drugs may be excreted in the urine and faeces, so it is not advisable for children to play with their pets for the duration of therapy.

PharmAust requires greater than or equal to 18 dogs with a clinical benefit out of 46 dogs to meet its statistical endpoint.

Post-trial, some veterinarians and the respective pet owners have elected to continue MPL treatment and, sometimes, in combination with prednisolone. The combination of MPL with prednisolone has provided average extension of survival to these pet dogs of 16-24 weeks, more than double the life expectancy than standard of care (palliative steroid therapy) that typically provides for 6-8 week survival in association with a range of adverse events. Canines treated with MPL during the trial and after the trial at this optimum level experienced a high quality of life and minimum adverse events were reported. These canine outcomes bode well for further human cancer trials to be pursued.

Discussions have commenced for FDA registration and GCP implementation.

PharmAust is now in confidential discussions with a leading global pharmaceutical company to co-develop and commercialise MPL for the treatment of veterinary cancers. Dialogue with other potential partners is continuing.

MPL is already approved for veterinary use for a different indication in food-chain animals. PharmAust is endeavouring to repurpose MPL as a safe and effective cancer treatment without the associated side effects of chemotherapy.

For further information on the study and to read the experiences of other enrolled pets and their parents visit <https://www.pharmaust.com/veterinary-trial-testimonials/>



Pet dogs in the MPL tablet Phase 2 trial enjoying time with their owners

Phase II Human Cancer Trial

Further to the responses and outcomes in canines, PharmAust continues to take key steps towards progressing the evaluation of MPL in human trials. Clinical interest has focused on leukaemia, glioblastoma, oesophageal, gastrointestinal, ovarian and pancreatic cancers.

PharmAust has identified a Principal Investigator in the United States to evaluate the new MPL tablet in human Phase 2 cancer trials, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015.

COVID-19 Testing

PharmAust has engaged *Ergomed Clinical Research*, a subsidiary of the London Stock Exchange listed Ergomed plc (LON: ERGO) to be the contract research organisation (CRO) for the COVID-19 clinical trials.

PharmAust is relying on the MND trial to provide the important Phase 1 pharmacokinetic (PK) data for both the MND and COVID-19 trials.

This will allow PharmAust to undertake a Phase 2 trial in COVID-19, rather than a Phase 1 study, which will facilitate faster recruitment as the company has been advised by the CRO that COVID-19 infected patients generally prefer participating in a Phase 2 study.

From a timing viewpoint, the Phase 2 will now take place 6-9 months earlier than it would have had PharmAust conducted a Phase 1 prior. From a financial viewpoint, an expedited study into Phase 2 will also benefit PharmAust, saving around \$1.5 million.

EPICHEM PTY LTD - 100% OWNED SUBSIDIARY

Epichem Pty Ltd has started the new financial year strongly with the start of the new General Manager Fi (Fiona) Milner, and more recently Anusha Aubert (details below) as the new Business Development Manager.

All of the service departments in Epichem have been highly focused on revenue raising projects and contracts and are delivering well on all of these within timelines set, and with very positive customer feedback. Discovery Services in qtr 4, 2022 particular delivered in excess of 121% change of performance vs qtr 4 2021 which is the result of the full department committed to 4 major client projects in Medicinal chemistry.

Equally Analytical services has been performing strongly, 83% improvement for qtr 4, 2022 vs Qtr 4 2021. For example, Qtr 1 FY2023 saw the engagement of Chevron for a significant project already well underway and delivering excellent customer feedback on both progress and results.

Work with OHD (Oxidative Hydrothermal Dissolution) technology continues to build momentum and high engagement with an array of clients across various industries. Near completion of a significant project for Shell/NERA, aided by a NERA grant, sees not only promising results (yet to be finalised), it also promises to raise the tide for future engagements at both Government and major private company levels.

Similarly, early stage collaborations between academia and Epichem around OHD are creating opportunities for grant support for not only further development in evaluating its potential with various feedstocks, also increasing the likely advocacy across a variety of industry applications.

Appointment of Anusha Aubert

In October 2022, the Company appointed Anusha Aubert, an experienced pharmaceutical sales and marketing professional, as Epichem BDM & PharmAust investor relations.

Ms Aubert will develop and action a tailored and dynamic Business Development/Sales/Marketing strategy and plan to achieve Business Development, revenue and profit growth in line with both the Epichem Pty Ltd and the PharmAust Ltd strategic objectives. She will also be responsible for investor relations, digital communications,

social media marketing, producing and distributing investor focused videos and preparing online targeted investor advertising as well as other initiatives as they emerge.

In the last five years, Anusha has held sales and marketing roles in global pharmaceutical companies, Novartis and Mundipharma. Anusha is a qualified Analytical Chemist, having worked in both WA and SA in predominantly oil and gas executing both analytical and business development roles.

Appendix 4C – Quarterly Cash Flow Report

PharmAust's cash position at 30 September 2022 was \$1.9 million with total available funding for future operating activities of \$2.2m. 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 \$0.255 million represented costs involved with the development of the Company's primary drug candidate, Monepantel (MPL).

Payments for Product Manufacturing and Operating Costs represent wholly owned subsidiary Epichem Pty Ltd's expenditure allocated to manufacturing and operating.

Payments for Staff Costs represent salaries for laboratory, administration, sales and general management activities as well as a one off severance payment.

Payments for Administration and Corporate Costs represent general costs associated with running the Company, including ASX fees, 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. The cash balance at 30 September 2022 was \$1.9 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter

Subsequent Events

Subsequent to balance date, PharmAust received the third instalment of \$173,034.80 from FightMND upon recruitment of the first patient. These funds are not included in this Appendix 4C as they were received after 30 September 2022.

This announcement is authorised by the Board.

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About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (code: PAA) and the Frankfurt Stock Exchange (code: ECQ). PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company which generated \$3.4 million in sales of goods & services in FY 2022.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL demonstrated objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as well as neurodegenerative disease as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

About Epichem Pty Ltd:

Epichem is a wholly owned subsidiary of the ASX listed company PharmAust Limited. Located in Technology Park, Western Australia, Epichem has been delivering products and services in synthetic and medicinal chemistry to the global drug discovery and pharmaceutical industries in over 40 countries worldwide for over 18 years.

Epichem has newly constructed purpose-built, state-of-the-art laboratories and has world class equipment and expertise in synthetic and medicinal chemistry to support drug discovery projects, and for the cost-effective synthesis of drug analogue libraries and intermediates. It also has a rapidly growing catalogue of pharmaceutical reference standards.

Epichem also specialises in Custom Synthesis, Analytical Chemistry and Materials Science. Epichem is the winner of the WA Industry Export Award 2021 for International Health, an award also won in 2019, 2018 and 2017, the 2020 Inspiring Story of Celebrating Remarkable Resilience Nomination for WA for the Australian Export and Investment Awards and the 2021 and 2020 GHP Biotechnology Award winner for Most Innovative Chemistry Service Provider – Australia and Best in Organic Chemistry Solutions. Epichem has been inducted into the WA Export Hall of Fame.



Appendix 4C

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

Name of entity

PharmAust Limited

ABN

35 094 006 023

Quarter ended ("current quarter")

September 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,080	1,080
1.2 Payments for		
(a) research and development	(255)	(255)
(b) product manufacturing and operating costs	(372)	(372)
(c) advertising and marketing	(43)	(43)
(d) leased assets	(33)	(33)
(e) staff costs	(729)	(729)
(f) administration and corporate costs	(215)	(215)
1.3 Dividends received (see note 3)		
1.4 Interest received		
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other (provide details if material)	34	34
1.9 Net cash from / (used in) operating activities	(533)	(533)
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 (3 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)		
3.2 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)	(3)
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 (provide details if material)		
3.10 Net cash from / (used in) financing activities	(3)	(3)

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	2,427	2,427
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(533)	(533)
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 (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(3)	(3)
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	1,891	1,891

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	1,979	2,415
5.2	Call deposits	12	12
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)	1,891	2,427

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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
7.1 Loan facilities	471	210
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 Total financing facilities	471	210
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.	
	The loan facility is with Innovation Structured Finance Co., LLC serviced via Radium Capital and is an advance on 80% of the Company's R&D Tax Incentive (RDTI) for the for the period 1 July 2021 – 30 June 2022. The interest rate for the loan facility is 15% per annum. Repayment is timed to coincide with receipt of PharmAust's 2022FY RDTI refund. An advance of \$210,116 was received in May 2022.	

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(533)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,891
8.3 Unused finance facilities available at quarter end (item 7.5)	261
8.4 Total available funding (item 8.2 + item 8.3)	2,152
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.04
<i>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.</i>	
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
<i>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.</i>	

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 October 2022

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.