





# **Appendix 4C and Quarterly Update**

**20 July 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 June 2022.

#### **HIGHLIGHTS:**

- Completed tablet manufacture and accelerated stability data
- Protocols and ethics/regulatory approvals in place for MND human trial
- Alithia Life Sciences appointed trial manager of MND human trial
- MND trial has commenced and is open for patient recruitment
- \$300k received from FightMND
- \$700k received from R&D Tax Incentive Refund
- \$200k received from prepayment of forecast R&D rebate
- PharmAust's European CRO partner, Ergomed, has identified seven hospitals in five countries showing interest in testing the effects of MPL upon COVID-19 patients
- PharmAust to undertake a Phase 2 study in COVID-19 rather than a Phase 1 study
- Canine cancer trial indicates the combination of MPL + prednisolone more than doubles life expectancy of dogs compared with standard-of-care Prednisone only therapy
- 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
- Multiple dogs recruited for canine trials in New Zealand
- Fiona Milner appointed Epichem General Manager
- Epichem awarded grant for recycling pilot
- 30 June 2022 bank balance of approximately \$2.4 million, enabling pursuit of various preclinical and clinical commitments (an additional \$383k received from DNDi in July 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 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 will be overseen by Dr Susan Mathers of Calvary Health Care, Bethlehem, Melbourne and will include 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 funding agreement provides that PharmAust shall own all intellectual property generated from the trial.

During the Quarter, PharmAust received the first and second instalment payments from FightMND in the total amount of \$300,845. The first instalment was dependent on PharmAust commencing manufacture of cGMP (current Good Manufacturing Practice) grade MPL tablets. The second instalment of \$99,230 was paid after the completion of the 1-month GMP accelerated stability of the newly prepared MPL tablets.

The third instalment of \$173,034.80 is payable 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.

During the Quarter, PharmAust also announced the appointment of Alithia Life Sciences Pty Ltd to manage the Phase 1/2 trial. Alithia will provide project and site management and support of for the study. The appointment is fully funded through the Drug Development grant awarded by FightMND.

Protocols and ethics/regulatory approvals are in place for the evaluation of MPL in Motor Neurone Disease. The trial will test 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.

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.

PharmAust will report on the recruitment and treatment of the first patient that fulfills the inclusion criteria and provide updates thereafter.

## **Phase II Canine Trials**

PharmAust has made significant progress in the clinical trials of its primary drug candidate, Monepantel (MPL). The commercial target is to develop and partner a product that supersedes the use of prednisolone alone and can reduce or replace the use of chemotherapy in dogs.

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.

Of the 16 pet dogs with assayed plasma levels > optimum dose, 13 have achieved stable lesions. This includes one dog with a partial response (60% regression). 9 of the 16 dogs with plasma levels > optimum dose 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 a therapy specific duration.

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 in CY 2022.

Discussions have commenced for FDA registration and GCP implementation.

PharmAust is 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 are continuing.

Plans are to continue and expand the current trial in Australia, New Zealand and the USA for registration of MPL as an anticancer drug in canines with B-cell lymphoma. A number of canine patients have already been recruited for canine trials in New Zealand.

During the quarter, PharmAust announced an agreement with Pathway Vet Alliance T/A Thrive Pet Healthcare and Heart of Texas (HoT) Veterinary Specialty Centre in the USA to join the MPL pet dog B cell lymphoma trial. PharmAust sent sufficient tablets for HoT to treat up to 10 dogs in the first canine monepantel pilot study conducted in the US

Trial recruitment continues in Australia with PharmAust successfully fulfilling interim Phase 2 trial endpoints. 27 pet dogs have now been treated using MPL monotherapy. With continued positive outcomes, PharmAust is preparing for a successful Phase 2 completion and the commencement of a subsequent registration trial.



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.

#### **COVID-19 Testing**

PharmAust has been identifying clinical centres capable of sourcing patients with the required COVID-19 progression and vaccination status. PharmAust requires unvaccinated patients with progressive infection in order to satisfy the inclusion criteria for determining anti-viral activity. Ukraine was one of the countries initially proposed, however, this is of course no longer tenable, and the Company re-focused the search in other smaller Eastern EU and some non-EU states that have large populations of unvaccinated patients.

Encouragingly, three clinical centres in Romania and Bosnia [not in EU] have expressed interest in participating and recruiting sufficient numbers of qualifying patients for the study.

Next steps include providing protocols for the study and qualification of the identified clinical centres. We continue to search for contingency sites including in Poland. This critical step of site selection, both in terms of clinical suitability and patient recruitment numbers, has resulted in an unavoidable delay in the commencement of the Phase 1 COVID-19 trial.

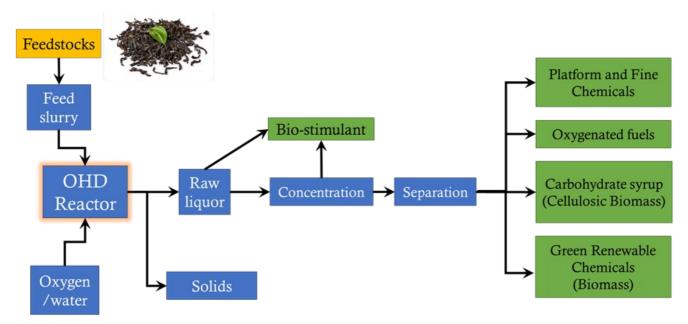
However, this has enabled us to further review the trial rationale and, given the timing of the commencement of the MND trial, the Board has decided to rely on the MND trial to provide the important Phase 1 pharmacokinetic (PK) data for both the MND and COVID-19 trials. We believe this will allow PharmAust to undertake a Phase 2 study in COVID-19 rather than a Phase 1 study.

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. Ergomed has previously advised that COVID-19 infected patients generally prefer participating in a Phase 2 study (instead of Phase 1) – so conducting a Phase 2 study will facilitate faster recruitment.

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

## **EPICHEM PTY LTD - 100% OWNED SUBSIDIARY**

PharmAust's wholly owned subsidiary, Epichem Pty Ltd, continues to advance it's innovative, novel and disruptive waste conversion and re-purposing technology, Oxidative Hydrothermal Dissolution (OHD). A benchtop flow reactor has been built and commissioned for operation. Proof of concept work has been carried out and determined on Coal and Ligno-cellulosic Biomass.



Epichem has partnered with the Curtin University WA School of Mines to research and develop OHD for use in mineral extraction. This project will investigate the potential of OHD liquors for hydrometallurgy and mineral processing applications.

Epichem is also in confidential discussions with organisations to validate the conversion and re-purposing potential of their respective feedstock and biomass.

# **Epichem Awarded Grant for Recycling Pilot**

Epichem was awarded a \$45,200 Challenge Grant from NERA (National Energy Resources Australia) as part of NERA's challenge fund.

The GeneratER open innovation challenge program will fund a pilot for Epichem's OHD technology to assist a multinational oil and gas energy company in providing a carbon neutral solution for recycling plastic waste. The OHD process liquefies plastic, changing its chemical structure to the extent that the reformed plastic is biodegradable or can be repurposed into another end-product. This solution has application across other industries and sectors where plastic waste is prevalent.

This partnership, made possible through NERA's GeneratER program, involves Epichem assisting a multinational oil and gas energy company in improving plastic recycling across operations in WA, Qld and the NT, using its novel circular economy waste recycling solution that converts plastics into reusable products.

Epichem will use a process that liquefies plastic, changing its chemical structure to make it biodegradable or able to be repurposed into another end-product. This solution has applications across other industries and sectors where plastic waste is prevalent.

Epichem are excited to progress to the pilot phase of the program and demonstrate our technology's application in the energy resources sector.

# Fiona Milner appointed Epichem General Manager

During the Quarter, the Company was pleased to announce that experienced pharmaceutical executive Fiona Milner has joined Epichem as its new General Manager commencing 29 June 2022.

Ms Milner has 25 years' experience working in multinational companies in the pharmaceutical industry.

Most recently she was the Regional Sales Manager for Novartis Pharmaceuticals and has held a number of roles in this organisation over the last 14 years. She received the International First Line Manager Award in 2011 and 2019 from Novartis' Global CEO in Basel, Switzerland (one of only 35 recognised across the globe). She was also nominated for the 'Telstra Business Woman of the Year' Award in 2010 and 2011.

Prior to this, Ms Milner was the State Manager at pharmaceutical company Sanofi Aventis, a role she held for 11 years. Notably during her tenure, she grew and led the WA State branch in 2007 to contribute a Business Unit Total of \$56.4M to national sales. She received the Sanofi State of the Nation award six times and was also awarded Manager of the Year.

Ms Milner is based in Perth and holds a Bachelor of Science (BSc) in Zoology and Physiology as well as Diploma of Education majoring in Science and Mathematics.

# Resignation of Dr Mollard and integration of Epichem services

On 27 May 2022, PharmAust announced that Dr Richard Mollard, tendered his resignation and gave the Company six months' notice as required under his contract.

The Board have improved efficiency regarding personnel and staffing by leveraging Epichem's existing infrastructure.

PharmAust intends to capitalise on Epichem's expertise and networks across the pharmaceutical industry and to integrate the Chief Scientific Officer role as much as possible to reduce duplication of costs.

#### Appendix 4C - Quarterly Cash Flow Report

PharmAust's cash position at 30 June 2022 was \$2.43 million. The company is adequately funded to continue its current activities during these uncertain times and will continue to demonstrate appropriate fiscal management.

During the quarter, payments for Research and Development of \$0.400 million represented costs involved with the development of the Company's primary drug candidate, Monepantel (MPL) and salary allocations of Dr Richard Mollard who was 100% focused on R&D activities.

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.

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 June 2022 was \$2.43 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter

#### **Subsequent Events**

Epichem received \$382,856 in July 2022 from DNDi for work continuing on its flagship project on Chagas disease. These funds are not included in this Appendix 4C as they were received after 30 June 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 that generated \$2.2 million in revenue in FY 2021.

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.



# **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	June 2022

Con	solidated 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	1,195	4,040
1.2	Payments for		
	(a) research and development	(400)	(1,034)
	(b) product manufacturing and operating costs	(292)	(1,598)
	(c) advertising and marketing	(45)	(260)
	(d) leased assets	(33)	(66)
	(e) staff costs	(620)	(2,568)
	(f) administration and corporate costs	(233)	(772)
1.3	Dividends received (see note 3)		
1.4	Interest received		1
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	614	664
1.8	Other (provide details if material)	(13)	23
1.9	Net cash from / (used in) operating activities	84	(1,571)

2.	Cash flows from investing activity	
2.1	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	

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 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)		738
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	210	210
3.6	Repayment of borrowings		(38)
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	210	910

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,134	3,089
4.2	Net cash from / (used in) operating activities (item 1.9 above)	84	(1,571)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Con	solidated 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)	210	910
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	2,428	2,428

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	2,416	2,122
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)	2,428	2,134

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	
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include ation for, such payments.	e a description of, and an

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	210	210
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities	210	210
7.5	Unused financing facilities available at qu	arter 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 – 31 January 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)	84
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,428
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	2,428
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

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**

- 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.

	20 July 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".
- 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.