

## Appendix 4C and Quarterly Update

**29 April 2021 – Perth, Australia:** PharmAust Limited (ASX:PAA), a clinical stage oncology company, is pleased to present its Appendix 4C Quarterly Report and Shareholders' Update for the period ended 31 March 2021.

### HIGHLIGHTS:

- Six dogs have completed assessment under the Phase IIb trial
- Monepantel in this stage of the study indicated no material adverse events
- Inappetence side-effects appear marginalised by current dose reduction
- Current trial provides an indicative optimal plasma level and target therapeutic dose
- PharmAust will continue recruitment to obtain further supportive evidence for efficacy to support a Phase III registration trial
- Engaging with leading global veterinary pharmaceutical companies to commercially license MPL for anti-cancer treatments in pet animals
- Syngene commences manufacture of GMP-Grade Monepantel for Human Clinical Trials
- Leiden University Medical Center (LUMC) has generated indicative data that MPL and MPLS again demonstrate antiviral activity in non-human primate systems
- LUMC is now moving forward and transitioning to human cultured cells
- PharmAust is increasing its focus on COVID-19 with EU and US collaborators expressing interest in preparing the ground for clinical evaluation of MPL in humans
- PharmAust & Olivia Newton-John Cancer Research Institute to continue MPL preclinical investigations
- Discussions with prospective oncologists in Italy and the United Kingdom continue with the aim of undertaking a Phase II human cancer trial
- Epichem awarded \$200K WasteSorted e-Waste Grant for its Oxidative Hydrothermal Dissolution (OHD) technology
- Epichem embarks on biofuels and fine chemicals proprietary project, converting carbon-based feedstock into ethanol and valuable organic compounds
- Bank balance of approximately \$3.94 million, enabling pursuit of various preclinical and clinical commitments

### ACTIVITY TIMELINE:

Activity	Details	Timing (CY) (est)
Compassionate use in pet dogs	Completed to reserve tablets for Phase III trial	N/A
COVID-19 pre organoid work	To enable transition to organoids, requirement for COVID-19 Human Clinical Trial	Q2 2021
Phase IIb pet dog cancer trial continuation	Dose optimization trial with current tablets	Q2 2021
Continuation mechanism of action work with ONJCRI	Looking at MPL effects in gene expression and targets	Q2 – Q4 2021
Organoid work	Important precursor for COVID-19 Human Clinical Trials	Q2/Q3 2021
Complete manufacture of 10 kg of MPL	For use in Human Clinical Trials: FightMND, COVID-19 and Human Cancer	Q3/Q4 2021
Phase III pet dog cancer trial	Current tablets, after Phase IIb trial completion	Q4 2021
Tablet manufacture	Smaller dose tablets for human trials	Q3/Q4 2021
Commence FightMND Phase I/II trial	After 3 month tablet stability data	Q4 2021
Commence COVID-19 Phase I/II trial	After initial PK data from FightMND trial	Q1 2022
Commence human cancer Phase II trial	After initial PK data from FightMND trial	Q1 2022
Commence alternative Phase II trial in further neurodegenerative diseases	After initial PK data from FightMND trial	Q1/Q2 2022

## **Phase II Canine Cancer Trial**

As previously announced, in our recent phase II trial in canines with B-Cell Lymphoma, the most prevalent canine cancer, we observed both tumour regression as well as stable disease. The Company considered these data a sound platform to springboard into undertaking dose optimisation and eventually Phase III registration studies.

During the quarter, PharmAust was pleased to report that six dogs with stage 4 to 5 B-cell lymphoma completed assessment across the five participating trial sites. Treatment of one dog was not in compliance with the dosing instructions (MPL after meal) and that dog was withdrawn from the trial.

Some mild and occasional inappetence was reported in some dogs but this appeared insignificant and difficult to attribute solely to MPL. Pleasingly, side-effect levels were below those of other conventional anticancer drugs and trial veterinarians report that, at day 28, all participating dogs were in good spirits and well within themselves. As such the owners had elected to continue treating their dogs with MPL on compassionate use, post-trial.

A further six pet dogs that did not meet the trial inclusion criteria were being treated under compassionate use with MPL in varying combinations with other anticancer drugs.

Interim analysis of its Phase IIb trial has provided further supportive evidence of the monepantel blood plasma levels required to suppress B cell lymphoma growth in pet owners' dogs. PharmAust is now in a good position to further optimise treatment levels of MPL to facilitate design and execution of a Phase III study. Monepantel in this stage of the study indicated no material adverse events.

As data emerges, we plan to contact a wider group of leading global pharmaceutical companies to discuss veterinary collaborations and engage in discussions with them on identifying the optimal cancers to target commercially. Animal healthcare companies in the US and Germany have shown initial interest and approached PharmAust for discussions. PharmAust has engaged the services of Dr Kim Agnew (Hon BSc, BVSc, MACVSc) to assist with this process. Dr Agnew has 25 years of experience in the animal health industry with business development, product development, regulatory affairs, clinical research, technical support and pharmacovigilance.

Dr. Agnew worked for 20 years at Elanco Animal Health in a variety of management roles including Research and Regulatory Manager, Innovation Manager and Associate Director of Research and Development. Following this, he worked for 5 years at Merial, now Boehringer Ingelheim, as the Research and Development Leader.

Dr. Agnew has been involved in the ground-up development and commercialization of 15 new products, numerous line extensions to existing products, and is named in 6 product development patents.

Furthermore, Dr. Agnew has developed a broad network across various Universities in Australia and has been instrumental in gaining industry support for multiple Australian Research Council (ARC) Linkage Grant collaborations and research projects leveraging the very high quality of science research available in Australia and New Zealand.

## **Phase II Human Cancer Trial**

PharmAust continues to take key steps towards progressing the evaluation of MPL in human trials. The Company is beginning to engage with leading global pharmaceutical companies to discuss human collaborations and engage in discussions with them on identifying the optimal cancers to target.

PharmAust has identified suitable Clinical Oncology Units in Italy and the United Kingdom to evaluate the new MPL tablet in humans in a Phase II trial, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015. PharmAust will continue to look for further sites to broaden recruitment possibilities.

Previously, PharmAust demonstrated prevention of tumour progression and suppression of tumour cancer markers associated with the mTOR mechanism of action. The trial was stopped early, however, due to the highly unpalatable nature of the liquid formulation employed at the time. Since then, PharmAust has successfully reformulated MPL into a tablet that resolves the palatability issues. Following successful preclinical work in rats and dogs comparing the liquid and tablet formulations, PharmAust can now tailor tablet dosage to achieve more effective target blood levels known to elicit anticancer activity.

Commencement of a human cancer Phase II trial is expected in Q1 CY 2022.

## **COVID-19 Testing**

PharmAust previously demonstrated MPL's antiviral activity in two independent laboratories in Australia in both primate and non-primate cell cultures (announced on 4 June, 18 June, 25 August and 9 September 2020). Data from extensive testing at LUMC, examining the effects of MPL and MPLS in specialised COVID-19 non-human primate systems, once again indicate their antiviral activity.

Solubility issues of MPL in these in vitro systems remain challenging yet do not impact PharmAust's clinical programs. PharmAust has resolved the issues of solubility for administration to patients by developing the MPL tablet dosage form. MPL is quickly and efficiently converted into MPLS in the body, with MPLS representing the dominant form in the plasma. PharmAust and LUMC are currently progressing the antiviral development program to testing in human cells.

Associate Professor Martijn van Hemert, principal investigator at LUMC stated, "There are indications for an antiviral effect in these assays, but solubility issues under the conditions required for cell-based screening complicate analysis. Additional experiments will now be performed on SARS-CoV-2 infected human lung cell lines."

PharmAust's Chief Scientific Officer, Dr Richard Mollard stated, "Testing highly insoluble drugs such as MPL in established complex culture conditions is notoriously difficult. PharmAust is very grateful to Associate Professor van Hemert and his team for their extensive and exhaustive efforts with MPL. We look forward to updating the market as these programs continue."

PharmAust has prepared an Executive Summary, is preparing an Investigator's Brochure and has been engaging with clinicians in the United States as well as Eastern and Caucasus countries and The Balkans about a Phase I trial in human patients to treat COVID-19.

GMP-quality MPL production for human clinical trials has commenced at Syngene International Ltd (India). In light of the recent outbreak of COVID in India, PharmAust contacted Syngene this week and they confirmed that their timeline to manufacture GMP grade MPL currently remains unchanged.

## **Phase I/II Human Trial in Motor Neurone Disease**

PharmAust previously announced it has received funding of A\$881,085 for a Phase I 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 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.

Preparations for the trial have already commenced and a submission was made to the Institutional Human Research Ethics Committees on 25 March. Phase I trial recruitment will commence as soon as possible in CY 2021, likely to be Q4 after PharmAust has 3 months of tablet stability data. The funding agreement provides that PharmAust shall own all intellectual property generated from the study.

PharmAust has not received any funding from FightMND as yet. The first instalment of \$201,615.00 is due to be received after GMP manufacture of MPL has been completed.

## **Virtual Investor Briefing**

PharmAust held a Virtual Investor Briefing on Thursday 11th February which provided investors the opportunity for Q&A with Executive Chairman, Dr Roger Aston, Chief Scientific Officer, Dr Richard Mollard and Epicchem CEO, Colin La Galia. A recording is available on the company's website - <https://pharmaust.com/pharmaust-videos/>

### **PharmAust Receives \$750k R&D Tax Incentive Refund**

During the quarter, the Company announced that the Australian Taxation Office (“ATO”) has recognised the innovation of the Research and Development being developed by wholly owned subsidiaries, Epichem Pty Ltd and Pitney Pharmaceuticals Pty Limited. The Company had previously lodged an application with AusIndustry following advice from PharmAust’s consultants that the R&D may qualify for a research and Development Tax Rebate on its 2020 tax return

Following approval from the ATO of the Company’s application for a Research and Development rebate, an amount of \$755,594.57 was deemed refundable on PharmAust’s 2020 Tax Return and paid to PharmAust.

### **Epichem Pty Ltd (100% wholly owned subsidiary)**

Epichem continues to support the PharmAust drug development pipeline with lead drug development and validation, drug candidate pipeline manufacture and analysis, drug reformulation, GMP synthesis and stability support as well as drug inventory dispensing to clinical trial centres.

Epichem continues to pursue opportunities to create its own IP portfolio with the assignment of specific projects to individual chemists. This will also allow Epichem to maximise the R&D Tax Incentive as well as act as an R&D project incubator for PAA.

### **Waste To Fuels Technology**

During the quarter, Epichem, through its subsidiary Epichem OHD Pty Ltd, entered into a licensing agreement with Illinois-based Thermaquatica Inc to research, develop and promote a novel, innovative and disruptive waste to fuels technology.

Epichem OHD will advance the novel, disruptive and innovative OHD technology using biomass/feedstock flow reactor material science. The flow reactor is a world-first with its potential to turn a wide range of waste and biomass feedstock into valuable fuels, fine chemicals, agricultural growth stimulants and ethanol.

Epichem OHD is capitalising on recent Australian policies at national, state and local government levels towards zero organic waste to landfill.

Colin La Galia, Epichem CEO, presented at an Investor Luncheon and a recording is available on the company’s website - <https://pharmaust.com/pharmaust-videos/>

### **Appendix 4C – Quarterly Cash Flow Report**

PharmAust’s cash position at 31 March 2021 was \$3.94 million. The company is adequately funded to continue its current activities during these uncertain times and will continue to demonstrate appropriate fiscal restraint.

During the quarter, payments for Research and Development of \$0.367 million represented costs involved with the development of the Company’s primary drug candidate, Monepantel (MPL) and salary allocations of Dr Richard Mollard who is 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 \$0.161 million comprising Directors’ fees, salaries and superannuation.

Cash outflows for the quarter were in line with management expectations. The cash balance at 31 March 2021 was \$3.94 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter and subsequent events outlined below.

### **Subsequent Events**

Epichem received \$180,000 from the WasteSorted e-Waste Grant in April 2021 being the first instalment of \$200,000 payable from the Western Australian Government New Industries Fund.

These funds are not included in this Appendix 4C as they were received after 31 March 2021.

**This announcement is authorised by the Board.**

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#### **About PharmAust (PAA):**

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 \$3.5 million in revenue in FY 2020.

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**

35 094 006 023

**Quarter ended ("current quarter")**

March 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	738	2,059
1.2 Payments for		
(a) research and development	(367)	(662)
(b) product manufacturing and operating costs	(273)	(779)
(c) advertising and marketing	(41)	(126)
(d) leased assets	(25)	(53)
(e) staff costs	(493)	(1,769)
(f) administration and corporate costs	(196)	(400)
1.3 Dividends received (see note 3)		
1.4 Interest received	1	15
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	1,032	1,458
1.8 Other (provide details if material)	(8)	(22)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>368</b>	<b>(281)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		(34)
(d) investments		
(e) intellectual property		
(f) other non-current assets		

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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)		
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>		<b>(34)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		1,542
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	(36)	(164)
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(36)</b>	<b>1,377</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	3,610	2,879
4.2	Net cash from / (used in) operating activities (item 1.9 above)	368	(281)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		(34)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(36)	1,377
4.5	Effect of movement in exchange rates on cash held		
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>3,942</b>	<b>3,942</b>

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	2,430	598
5.2	Call deposits	1,512	3,012
5.3	Bank overdrafts		
5.4	Other (provide details)		
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>3,942</b>	<b>3,610</b>

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	161
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. <b>Financing facilities</b> <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>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	454	74
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 <b>Total financing facilities</b>	454	74
7.5 <b>Unused financing facilities available at quarter end</b>		
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. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	368
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,942
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	3,942
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	10.7
<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.

29 April 2021

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.