





## Appendix 4C and Quarterly Update

**31 January 2022 – Perth, Australia:** PharmAust Limited (ASX: PAA), a clinical stage biotechnology company, is pleased to present its Appendix 4C and Quarterly Update for the period ended 31 December 2021.

#### HIGHLIGHTS:

- Syngene has commenced manufacture of GMP-Grade Monepantel for Human Clinical Trials
- Three individual laboratories have demonstrated that MPL and MPLS protect against cell death in vitro following infection with SARS-CoV2
- PharmAust is in advanced negotiations with a European CRO to identify trial sites for a Phase 1 trial in human patients to treat COVID-19 expected to commence around May 2022
- PharmAust and WEHI investigating MPL in HTLV-1 viral infections
- Protocols and ethics/regulatory approvals are now in place for MND human trial
- Commencement of the MND trial is expected in May 2022
- Success in Phase 2 trial in pet dogs with B cell lymphoma
- PharmAust identifies optimum MPL drug plasma range for treatment of dogs
- Phase 2 trial indicates the combination of MPL + prednisolone more than doubles life expectancy of dogs compared with standard-of-care
- PharmAust will seek input for the canine cancer registration trial from potential licensing partners
- Plans are to conduct the registration trial in canines with B-cell lymphoma in Australia, New Zealand and the USA
- All permissions granted for canine trials in New Zealand, tablets on site.
- Epichem was awarded an extension to its current contract with DNDi
- Epichem appoints a new Head of Chemistry
- Epichem completes WasteSorted e-Waste Grant from the Western Australian Government New
  Industries Fund using OHD technology, final results pending
- Proof of concept work has been determined on Coal and Ligno-cellulosic Biomass
- PharmAust rewards Shareholders with an attractively priced options offer
- Bank balance of approximately \$2.64 million, enabling pursuit of various preclinical and clinical commitments

#### ACTIVITY TIMELINE:

			Jan-22				Feb	-22			I	Mar-22	2			Apr	-22			Ma	y-22			Jun	-22	
	3	10	17	24	31	7	14	21	28	7	14	21	28	1	8	15	22	29	6	13	20	27	3	10	17	24
													Humai	n Trials	;											
Demo tablet 1 month			$\leftarrow$																							
Demo tablet 3 months												$\longleftrightarrow$														
GMP batch Syngene (10 kg)			-		1		-																			
GMP batch tablets Catalent										<	$ \rightarrow $															
GMP release analysis and stability initiation													$\leftarrow$	$\rightarrow$												
GMP Stability 1 month																			-	$\rightarrow$						
FightMND trial starts																						←				
Covid-19 trial nominated start date																						<		$ \longrightarrow $		
PK data Level 1 FightMND																										
PK data Level 2 FightMND																										
Cancer trial in humans																										
													Canine	e Trials												
MPL tablet export permissions APVMA																										
Phase 2 - 3 dose optimisation (AUS/NZ)					}		8	1	3					1		1	}			8	3	$\rightarrow$				
Contact with large Pharma					}				2							1	1			8	}					$\rightarrow$
Negotiating with US sites + ethics																										
Delivery GMP MPL on site US						$\longleftrightarrow$																				
Start US sites						←			{					1		1	{		$\rightarrow$							
Clinical trials to support registration	-	I			]		2	r I	2				2	1		1	1			1	1	1				$ \longrightarrow $

			Jul-22				Aug	g-22				Sep-22				Oct	-22			Νον	-22			Dec	-22	
	1	8	15	22	29	5	12	19	26	2	9	16	23	30	7	14	21	28	4	11	18	25	2	9	16	23
													Humar	n Trials	1											
PK data Level 1 FightMND								-																		
PK data Level 2 FightMND					[										$\leftarrow$		$ \longrightarrow $									
Cancer trial in humans																							ŧ			
													Canine	e Trials	5											
Contact with large Pharma	$\leftarrow$		2		2		2							ļ												
Clinical trials to support registration	<b>—</b>		5	8	1			1	1			1														

#### Phase II Canine Trials

PharmAust has made significant progress in the clinical trials of its primary drug candidate, Monepantel (MPL).

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

PharmAust has determined an optimum drug plasma range for anticancer activity and minimal side effects.

Of the seven pet dogs treated with drug plasma levels of MPL in the optimum range, six achieved stable disease of target lesions and one had a partial response (60% regression), with some tumours completely disappearing, as assessed by the administering veterinarians. 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 pet's waste. Drugs may be excreted in the urine and faeces, so it is not advisable for children to play with their pets.

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, comparing favourably to 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 exploratory discussions with several leading global pharmaceutical companies to codevelop and commercialise MPL for the treatment of veterinary cancers.

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.



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 glioblastoma, esophageal, gastrointestinal and pancreatic cancers.

PharmAust has identified Principal Investigators in Italy and the United Kingdom to evaluate the new MPL tablet in humans in Phase 2 trials, 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.

Commencement of a human cancer Phase II trial is expected in Q4 CY 2022.

#### COVID-19 Testing

In collaboration with three independent laboratories, PharmAust has investigated the capacity of MPL and MPLS *in vitro* to inhibit:

- i) SARS-CoV2-induced cell death,
- ii) SARS-CoV2 RNA release from the cell, and
- iii) SARS-CoV2 RNA infection of neighbouring cells.

All three laboratories demonstrated that both MPL and MPLS protect against cell death *in vitro* following infection with SARS-CoV2. Furthermore, two laboratories investigated the effects of MPL and MPLS upon the early stages of the SARS-CoV2 virus lifecycle by examining RNA release into the culture growth media *in vitro*.

Trial sites to participate in the evaluation of tablet formulated MPL in COVID-19 are currently being identified by the Company's CRO partner in Europe. PharmAust has filed a PCT application which, amongst other aspects, is directed towards the use of MPL and aminoacetonitrile derivatives as antiviral agents and claims an earliest priority date of 11 May 2020. The application is open for public inspection.

#### 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.

PharmAust has not received any funding from FightMND as yet. The first instalment of \$201,615 is due to be received after GMP manufacture of MPL for this trial has been completed.

Protocols and ethics/regulatory approvals are now 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.

Commencement of the MND trial is expected around May 2022.

#### HTLV-1 Testing

PharmAust executed a Research Services Agreement with the Walter and Eliza Hall Institute (WEHI), Melbourne to investigate the effects of monepantel (MPL) upon human T-lymphotrophic virus-1 (HTLV-1) infections *in vitro*.

This work follows upon PharmAust's COVID-19 program and aims to further understand the anti-viral activity of MPL and to broaden the scope of targets for MPL's use. The study of HTLV-1 is of particular significance due to the readily available nature of highly and particularly relevant *in vitro* and *in vivo* preclinical virus infection models, potentially providing PharmAust with further data to support future human trials.

PharmAust will update shareholders with results as they are received.

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

#### **Drugs for Neglected Diseases Initiative (DNDi)**

On 13 December 2021, Epichem was awarded an extension to its current contract with Drugs for Neglected Diseases *initiative* (DND*i*) (<u>www.dndi.org</u>).

The contract renewal will see Epichem continue to provide its synthetic and medicinal chemistry expertise to support DND*i*'s drug discovery projects, aimed at developing new treatments for neglected diseases, until 31<sup>st</sup> December 2022. The extension is expected to generate up to AUD\$1.02M in revenues for Epichem during CY 2022. This will mark our 14<sup>th</sup> consecutive year with DND*i* supporting their important work and we look forward to continuing our long-standing partnership and collaboration and important relationship with them.

#### New Appointment: Head of Chemistry- Dr Gary Pitt

Epichem welcomes Dr Gary Pitt as it's new Head of Chemistry

Gary brings more than 20 years' experience in drug discovery and development within the pharmaceutical industry and academia, in both the UK and Australia

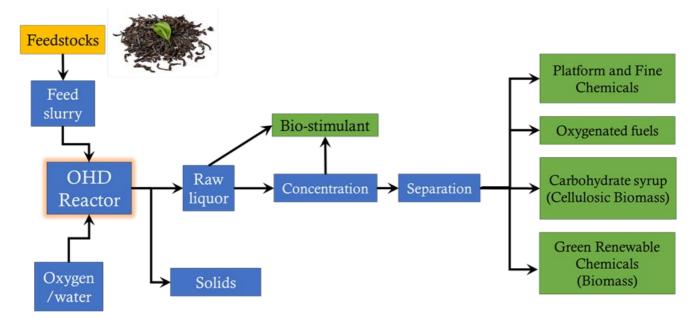
He has created and lead chemistry teams for major research groups through many stages of the Drug Discovery Pipeline in areas including immunology, oncology, urology and infectious diseases.

He is a key inventor on more than twenty patents and has contributed to numerous medicinal chemistry projects that have progressed through to pre-clinical and Phase I and II clinical trials.

Gary joins Epichem from 360biolabs and, prior to that, the Walter and Eliza Hall Institute of Medical Research, where he was responsible for developing and implementing structures and processes to establish Australia's first National Drug Discovery Centre (NDDC).

#### **Oxidative Hydrothermal Dissolution (OHD)**

Epichem 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 completed a WA Government New Industries Fund WasteSorted e-waste Grant project to convert e-waste using OHD. The grant funding supported Epichem's use Oxidative Hydrothermal Dissolution technology to convert e-waste into useful end products, recover valuable metals and produce useful high value chemicals. The research and development program supported a new and innovative solution to process collected e-waste and reduce the amount of e-waste ending up in landfill. The WasteSorted e-Waste grants support the WA Waste Avoidance and Resource Recovery Strategy 2030 objectives - to avoid waste, recover more value and resources from waste and protect the environment from the impacts of waste.

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The final outcomes and findings of the OHD Grant Project will be presented to the WA Department of Jobs, Tourism, Science and Innovation on 16 February 2022.

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

Epichem was recently recognised and awarded as the 2021 WA Exporter of the Year for International Health. Epichem has been widely recognised having won the coveted WA Exporter Award on five occasions and is in the WA Export Hall of Fame.

#### Annual General Meeting

On 21 October 2021, PharmAust held its Annual General Meeting of Shareholders as a virtual meeting. All resolutions that were put were passed by a poll.

#### **Loyalty Options**

In recognition of the support of shareholders, the directors of PharmAust conducted a rights offer on the basis of 1 option for every 4 shares held at an issue price of 1 cent per option. The options have an exercise price of 20 cents and an expiry date of 31 October 2023.

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

PharmAust's cash position at 31 December 2021 was \$2.64 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 \$0.313 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 \$0.148 million comprising Directors' fees, salaries and superannuation.

Cash outflows for the quarter were in line with management expectations. The cash balance at 31 December 2021 was \$2.64 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter

This announcement is authorised by the Board.

Enquiries: Dr Roger Aston Executive Chairman rogeraston@pharmaust.com

Mr Sam Wright Finance Director sam@pharmaust.com

P +61 (8) 9202 6814 F +61 (8) 9467 6111 W <u>www.pharmaust.com</u> T @<u>PharmAust</u>

#### 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 \$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.



PharmAust

### 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 2021

Con	isolidated 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	922	1,724
1.2	Payments for		
	(a) research and development	(313)	(450)
	(b) product manufacturing and operating costs	(514)	(761)
	(c) advertising and marketing	(48)	(144)
	(d) leased assets		(26)
	(e) staff costs	(589)	(1,256)
	(f) administration and corporate costs	(92)	(209)
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		
1.8	Other (provide details if material)	(21)	(23)
1.9	Net cash from / (used in) operating activities	(656)	(1,145)

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

Con	solidated 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)	738	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		
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	738	700

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,562	3,089
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(656)	(1,145)
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 (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	738	700
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	2,644	2,644

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	2,632	2,550
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)	2,644	2,562

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 a ation for, such payments.	a description of, and an

Director's Salaries & Superannuation

7.	<b>Financing facilities</b> 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 qu	arter end	
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are propo include a note providing details of those facil	or unsecured. If any add osed to be entered into af	itional financing

8.	Estim	nated cash available for future operating activities	\$A'000
8.1	Net ca	sh from / (used in) operating activities (item 1.9)	(656)
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	2,644
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	
8.4	Total a	available funding (item 8.2 + item 8.3)	1,988
8.5	Estim item 8	ated quarters of funding available (item 8.4 divided by .1)	3.03
		the entity has reported positive net operating cash flows in item 1.9, answer iter or the estimated quarters of funding available must be included in item 8.5.	m 8.5 as "N/A". Otherwise, a
8.6	If item	8.5 is less than 2 quarters, please provide answers to the follow	ving questions:
	8.6.1	Does the entity expect that it will continue to have the current cash flows for the time being and, if not, why not?	level of net operating
	Answe	er: N/A	
	8.6.2	Has the entity taken any steps, or does it propose to take any cash to fund its operations and, if so, what are those steps an believe that they will be successful?	
	Answe	er: N/A	
	8.6.3	Does the entity expect to be able to continue its operations ar objectives and, if so, on what basis?	nd to meet its business
	Answe	er: N/A	
	Note: w	here item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 abo	ve 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 2022

Date:

By the board

#### 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.