

Appendix 4C and Quarterly Update

29 October 2020 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical stage oncology company, is pleased to present its Appendix 4C Quarterly Report and Shareholders' Update for the period ended 30 September 2020.

HIGHLIGHTS:

- PharmAust receives funding of \$881,085 from FightMND for Phase I clinical trial in humans with Motor Neurone Disease
- Following *in vitro* work demonstrating inhibition of SARS-CoV-2 replication, PharmAust and Leiden University (Netherlands) to evaluate Monepantel suitability for *Ex-Vivo* Human COVID-19 Testing
- The Company 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
- Olivia Newton-John Cancer Research Institute (ONJCRI) screening for gene expression supports monepantel's (MPL's) safety profile on non-cancer cells
- ONJCRI further reveals pathways regulating how MPL selectively causes cancer cells to stop growing and to self-destruct
- Engaging with leading global veterinary pharmaceutical companies to commercially license MPL for anti-cancer treatments in pet animals
- Canine compassionate use treatment with MPL tablets ongoing and follow-up canine trial to optimize dosing of monepantel in canine patients with B cell lymphoma
- Discussions with prospective oncologists in Europe will continue with the aim of undertaking a Phase I/II human cancer trial
- Epichem embarks on biofuels and fine chemicals proprietary project, converting carbon-based feedstock into ethanol and valuable organic compounds
- Bank balance of approximately \$4 million, enabling pursuit of various preclinical and clinical commitments

ACTIVITY TIMELINE:

Activity	Details	Timing (CY)
Compassionate use in pet dogs	On-going with current MPL tablets	Q4 2020 and ongoing
Commence manufacture of 10 kg of MPL	For evaluation in Human Clinical Trials: FightMND, COVID-19 and Human Cancer.	Q4 2020
COVID-19 pre organoid work	To enable transition to organoids, requirement for COVID-19 Human Clinical Trial	Q4 2020
Phase II pet dog cancer trial continuation	Current tablets, optimizing dosing	Q1 2021
Continuation mechanism of action work with ONJCRI	Looking at MPL effects in genetic pathways and targets	Q1/Q2 2021
Organoid work	Prerequisite for COVID-19 Human Clinical Trials	Q1/Q2/Q3 2021
Complete manufacture of 10 kg of MPL	For use in Human Clinical Trials: FightMND, COVID-19 and Human Cancer.	Q3 2021
Phase III pet dog cancer trial	Current tablets, after Phase II trial continuation	Q3/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 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 neurodegenerative Phase II trial	After initial PK data from FightMND trial	Q1 2022

Olivia Newton-John Cancer Research Institute (ONJCRI) Evaluates Monepantel Anti-Cancer Mechanism

During the quarter, researchers in the Cell Death and Survival Laboratory at the ONJCRI conducted an RNA sequencing screen comprehensively investigating how the entire genome of cancer cells respond when treated with MPL. In particular, this approach identifies which genes are switched-on and which genes are switched-off by MPL. One non-cancer cell line was used as control and the three cancer cell lines were melanoma, lung cancer and ovarian cancer.

The ONJCRI researchers found that changes in gene expression in the non-cancer cell genome were relatively modest when compared to the changes in the three cancer cell lines. This observation supports previous studies indicating that MPL does not affect non-cancer cells and has selectivity towards cancer cells. Particularly, the ONJCRI demonstrated that cancer cell genes involved in promoting cell division were suppressed, while those involved in inducing cell death (apoptosis and autophagy) were induced.

These observations are consistent with other data showing that MPL acts to stop cancer cells from dividing and to self-destruct. A number of genes identified from this screen will now be investigated further to establish the mechanism of action of MPL and to enable differentiation of MPL's effects on cancer cells compared to other anti-cancer drugs.

The work by the ONJCRI is supported in part by a \$50,000 Innovation Connections grant from the Commonwealth Department of Industry, Innovation and Science.

PharmAust's Chief Scientific Officer Dr Richard Mollard said, "It is terrific to have independent confirmation of MPL's specificity to cancer cells as well as a comprehensive dissection of the genetic pathways associated with MPL's anti-cancer action. This systematic work will facilitate PharmAust's applications for human clinical trials with regulatory agencies such as the TGA in Australia, the FDA in the US and the EMA in Europe, particularly as it demonstrates the selective nature of how MPL may operate physiologically."

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 this data as a sound platform to springboard into undertaking dose optimisation and eventually phase III.

The necessity for dose optimisation became apparent from the fact that the high dose of MPL adopted for the study was associated with a degree of inappetence (loss of appetite) in some dogs. However, the pet dog with the lowest blood levels of MPL had no inappetence and the best tumour outcome: a greater than 60% regression of all tumours, with some tumours showing complete regression. As announced on 21 January 2019, diet plays a strong role in MPL uptake into the blood. Data demonstrate that inappetence will be resolved by targeting lower dosing at mealtimes in the next trial, with these lower dosing levels correlating with maximum anti-cancer activity. The Company remains convinced of the value of dose optimisation.

Although the formal phase II trial was concluded when the principal investigator determined that the hypothesis and end points had been met, some veterinarians from the trial continue to evaluate MPL in pet dogs with cancer under compassionate use, outside of the trial. These veterinarians are keen to continue working with PharmAust in future formalised studies. PharmAust has sufficient MPL and tablets for all canine trials.

If our strategy is correct and we can demonstrate that MPL is consistently effective in tumour regression in most canine patients, this will likely strengthen our negotiating position with both third party veterinary and human pharmaceutical companies.

We now 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. We can engage with different groups on different cancer treatments using MPL or in combination. This greatly broadens our areas of activity and potential for mutually beneficial multiple collaborations and partnerships. Animal healthcare companies in the US and Germany have already approached PharmAust for discussions.

Furthermore, as the "composition of matter" patents held by third parties on MPL begin to expire fairly soon, we will have more flexibility in seeking partners given the much longer life of our patents covering cancer, neurodegenerative diseases and COVID-19.

Phase II Human Cancer Trial

PharmAust continues to make key steps towards progressing the evaluation of MPL in human trials. The Company received confirmation that the MPL human trial paper was successfully published in a peer review journal describing the historic trial undertaken in Adelaide and the performance of MPL.

PharmAust has conducted further tablet formulation and pharmacokinetic studies aiming to increase uptake of monepantel into the blood and reduce tablet numbers for future human trials.

PharmAust currently has two separate batches of GMP-grade monepantel under stability studies testing the shelf-life of the formulation. These stability studies show a robust tablet and will support relevant submission filings to human trial ethics committees.

The Company is engaging with leading global pharmaceutical companies to discuss human collaborations and engage in discussions with them on identifying the optimal cancers to target. PharmAust is seeking to identify a suitable Clinical Oncology Unit 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 has engaged a third GMP manufacture program for monepantel tablets in Q3/4 2021 to cater for a human cancer Phase II trial which is expected to commence in Q1 2022.

COVID-19 Testing

Having undertaken our studies at the Walter and Elisa Hall Institute for Medical Research in Melbourne and then confirmatory work at 360biolabs Pty Ltd, which provides quality assured services in virology and immunology, we are confident that we are seeing meaningful anti-viral activity.

PharmAust has entered into a Service Agreement with researchers in the Netherlands to test the effects of monepantel and monepantel sulfone on the replication of SARS-CoV-2 in cell lines. The purpose is to determine their applicability for testing these compounds in ex-vivo human SARS-CoV-2 infection models (cultured human airway epithelial tissue). The studies have now commenced and the final data report is expected to be received in December 2020.

A vaccine for COVID-19 is yet to be developed. The only anti-viral drug on the market currently approved for the treatment of COVID-19 infection is remdesivir (Gilead Science, Inc). Remdesivir is not a cure and in a clinically controlled trial it reduced time to recovery of hospitalised patients in intensive care from 15 to 11 days. With this success, early predictions were for annual sales of US\$2-7.7 billion by 2022.

MPL may have a distinct advantage over many other drugs in development given that it has already been used in human clinical trials and is a very well-known drug with a high safety profile. Remdesivir is an intravenous therapy whereas MPL can be administered orally in tablet form. This means patients could be treated earlier when they first test positive rather than intensive care patients hospitalised with COVID-19.

PharmAust Awarded Grant for Monepantel Phase I trial in Motor Neurone Disease

During the Quarter, PharmAust 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 while remaining subject to approval from the Institutional Human Research Ethics Committees, Phase I trial recruitment will commence as soon as possible in 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.

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.

Epichem recently entered into a HoA to develop and commercialise the biomass/feedstock oxidative process that can turn waste into fuels. The technology is a world-first because of its potential to turn a wide range of waste and biomass feedstock into valuable fuels, fine chemicals, agricultural growth stimulants and ethanol. The Company sees this as a low cost but high potential initiative in a very scalable and disruptive business that may have multiple uses and customers. The Subscription and Shareholders Agreement is being finalised for the Joint Venture Company between Obsidian and Epichem.

Revenues for the quarter were \$811k (c.f. \$901k). OPEX was \$790k (c.f. \$952k). Epichem made a profit this quarter of \$20,830 c.f. the previous comparative quarter's loss of -\$51,141.

Appendix 4C – Quarterly Cash Flow Report

PharmAust's cash position at 30 September 2020 was \$3.9 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 \$0.125 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.

\$1.5 million was raised during the quarter from the exercise of options.

Cash outflows for the quarter were in line with management expectations. The cash balance at 30 September 2020 amounted to \$3.9 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter and subsequent events outlined below.

This announcement is authorised by the Board.

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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 2020

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	772	772
1.2 Payments for		
(a) research and development	(125)	(125)
(b) product manufacturing and operating costs	(348)	(348)
(c) advertising and marketing	(66)	(66)
(d) leased assets		
(e) staff costs	(672)	(672)
(f) administration and corporate costs	(118)	(118)
1.3 Dividends received (see note 3)		
1.4 Interest received	5	5
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	282	282
1.8 Other (provide details if material)	(19)	(19)
1.9 Net cash from / (used in) operating activities	(290)	(290)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(22)	(22)
(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	(22)	(22)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,501	1,501
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	(92)	(92)
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	1,408	1,408

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,879	2,879
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(290)	(290)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(22)	(22)

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)	1,408	1,408
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	3,976	3,976

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	964	865
5.2	Call deposits	3,012	2,012
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)	3,976	2,877

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	
<i>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.</i>		

Director's Salaries & Superannuation

7. Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	1,204	146
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 Total financing facilities	1,204	146
7.5 Unused financing facilities available at quarter end		
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(290)
8.2 Cash and cash equivalents at quarter end (item 4.6)	3,976
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	3,686
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	12.7
<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 September 2020

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.