



## PharmAust Appendix 4C and Shareholders' Update (Q2, 2019 FY)

**31 January 2019 – 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 December 2018.

The business has progressed very successfully on several fronts in the quarter under review.

### 1. PharmAust progressed monepantel tablet programme

On 15 October 2018, the Company announced that it has completed the testing of different monepantel tablet prototypes in healthy Beagle dogs in collaboration with BRI Biopharmaceutical Research Inc.

The levels tested represented those that PharmAust had nominated for the first stage of the dose escalation programs for both human and dog anti-cancer clinical trials.

The levels of monepantel in the blood using just one tablet exceeded the levels predicted to achieve anti-cancer activity. These anti-cancer activity levels had been calculated from PharmAust's: (i) *in vitro* work on cancer cell lines, (ii) *in vivo* work on cancer cell lines engrafted into mice and (iii) the earlier clinical trial in human patients with cancer. This type of blood work was not previously performed during PharmAust's earlier reported clinical pilot study in dogs with B-cell lymphoma due to ethical considerations surrounding the withdrawal of sufficient blood to perform these tests in such pilot studies.

Importantly, by extrapolation it appeared that monepantel levels in the blood of these healthy Beagle dogs, and using just one new tablet, more than reached those shown to give anti-cancer activity in the previous pilot study in dogs with B-cell lymphoma.

This meant that PharmAust now had sufficient data to take the best biologically performing and most financially economical tablet to manufacture through a scale up process to provide cGMP grade tablets using its cGMP grade monepantel.

It also meant that the tablets could be used in formal dose escalation studies in healthy Beagle dogs to determine the maximum dose that can be given and with what safety margin. This is a necessary part of the normal drug development process. From previous studies in dogs and sheep, it appeared that blood levels for anti-cancer activity already fall within a very acceptable safety margin, yet this must be formally proven to regulatory authorities before continuing to market, particularly since the tablet represents a completely new formulation to the liquid formulation which is on the market.

## **2. PharmAust Developed GMP Method for Monepantel Analogues**

On 29 October 2018 PharmAust announced that it had, in collaboration with Syngene International Ltd, completed the development of a prototype Good Manufacturing Practice (GMP) method suitable for the scale up manufacture of aminoacetonitriles, such as monepantel and its analogues, for use in clinical trials.

GMP is a globally recognised standard that requires rigorous, controlled and continually documented processes to provide fully characterised drugs with very high levels of purity for safe and effective use when administered to patients.

## **3. PharmAust Commenced GMP Tablet Manufacture for Canine Clinical Anti-Cancer Trials**

Following the earlier announcement of the development of a prototype Good Manufacturing Practice (GMP) method suitable for the scale up manufacture of monepantel, on 13 November 2018, PharmAust announced that it had reached an agreement with Catalent Pharma Solutions for the scaled-up manufacture of GMP-grade monepantel tablets suitable for use in the upcoming trials in dogs with cancer.

Catalent, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, was engaged to provide scaled GMP tablet formulation and manufacture for clinical trials from its facility in San Diego, USA.

This was important because the availability of GMP-tablets will not only provide a more palatable and easier-to-use product, it will also provide dogs, owners, veterinarians and PharmAust with the highest standards of product development.

The agreement provided for sufficient tablets to be made to undertake the required dose escalation Phase I study in healthy Beagle dogs. The Phase I clinical study is intended to determine the numbers of tablets and the optimal frequency of administration to ensure maximum safety and provide information on the optimum dosing levels for the upcoming efficacy studies.

The Company's intention is that Phase II studies will follow, with the aim of confirming the anti-cancer activity of monepantel tablets in dogs with B-cell lymphoma, as previously announced by PharmAust on 13 December 2017. That study had demonstrated that monepantel in capsules has significant anti-cancer activity and no demonstrable adverse side-effects.

## **4. Monepantel synthesised in accordance with scalable GMP process is active *in vitro***

On 3 December 2018, PharmAust announced that, in collaboration with the Olivia Newton-John Cancer Research Institute in Melbourne (ONJCRI), it had demonstrated anti-cancer activity for monepantel manufactured according to its recently developed aminoacetonitrile GMP production method with Syngene, as announced on 29 October 2018.

Researchers at the ONJCRI tested monepantel manufactured to this method *in vitro* upon human cancer cell lines and non-cancer cell lines. Cancer cell lines showed the expected sensitivity to treatment with the PharmAust monepantel, while non-cancer cells were relatively unaffected.

Cancer cell lines tested included those for cancers that PharmAust will be targeting in Phase II trials in humans.

This outcome will allow further preclinical work understanding exactly how monepantel kills cancer cells.

## **5. Annual General Meeting**

The AGM was held in Perth on 9 November 2018 and all resolutions were comfortably passed. The AGM was a useful forum for shareholders to meet the Directors and ask any questions.

## **6. New Director appointed, Mr Neville Bassett, AM.**

In the quarter the Company announced that Neville Bassett had been appointed to the PharmAust Board effective 1 October 2018.

Mr Bassett is a Chartered Accountant specialising in corporate, financial and management advisory services. He has been involved with numerous public company listings and capital raisings. His involvement in the corporate arena has also taken in mergers and acquisitions and includes significant knowledge and exposure to the Australian financial markets. He has a wealth of experience in matters pertaining to the Corporations Act, ASX listing requirements, corporate taxation and finance.

He is chairman of Westar Capital Limited (the holder of an Australian Financial Services Licence) and was awarded a Member of the Order of Australia (AM) in the 2015 Australia Day Honours.

## **7. Epichem laboratory expansion**

On 8 November 2018, Epichem hosted the official opening of its laboratory expansion, following the earlier move to its new facility in September 2015. It is an honour to have the Hon. Ben Wyatt MLA, the Treasurer of Western Australia, and Professors Robert Stick and Dieter Wege, whose names the laboratories carry, at the event.

## **8. Subsequent events**

Since the end of the period under review, the Company has continued to make progress and has made various significant ASX announcements relating to:

- Monepantel's principal metabolite shows anti-cancer activity,
- Optimisation of monepantel uptake – beneficial impact of monepantel absorption in canines in specific dietary conditions, and
- PharmAust and Elanco execute Data Sharing Agreement.

PharmAust has made its annual R&D grant application and anticipates receiving around \$680,000 by the end of March 2019.

Epichem has received notification that a major discovery contract will be renewed for 2019 and also expects to receive a customer payment of over \$600,000 imminently.

**Enquiries:  
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Executive Chairman  
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**Mr Robert Bishop  
Executive Director  
Tel: 0417 445 180**

**About PharmAust (PAA):**

PAA is a clinical-stage company developing targeted cancer 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 synthetic drug manufacturer which generated \$3.05m in revenues in the 2018 FY

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway - a key driver of cancer. MPL has been evaluated in Phase 1 clinical trials in humans and dogs. MPL treatment was well-tolerated and produced a significant reduction in key prognostic biomarkers. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as it advances the drug into Phase 2 clinical trials.

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## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

PharmAust Limited

**ABN**

35 094 006 023

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

December 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	801	1,912
1.2 Payments for		
(a) research and development	(114)	(534)
(b) product manufacturing and operating costs		
(c) advertising and marketing	(22)	(42)
(d) leased assets		
(e) staff costs	(670)	(1,413)
(f) administration and corporate costs	(463)	(897)
1.3 Dividends received (see note 3)		
1.4 Interest received	3	7
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other (GST)	18	(19)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(446)</b>	<b>(986)</b>

**2. Cash flows from investing activities**

2.1 Payments to acquire:

(a) property, plant and equipment	(2)	(20)
(b) businesses (see item 10)		
(c) investments		

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Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
(d) intellectual property		
(e) other non-current assets		
2.2 Proceeds from disposal of:		
(a) property, plant and equipment		
(b) businesses (see item 10)		
(c) investments		
(d) intellectual property		
(e) 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 Net cash from / (used in) investing activities</b>	<b>(2)</b>	<b>(20)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares		
3.2 Proceeds from issue of convertible notes		
3.3 Proceeds from exercise of share options		
3.4 Transaction costs related to issues of shares, convertible notes or options		
3.5 Proceeds from borrowings		135
3.6 Repayment of borrowings	(36)	(36)
3.7 Transaction costs related to loans and borrowings		
3.8 Dividends paid		
3.9 Other (provide details if material)		
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(36)</b>	<b>99</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	1,452	1,875
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(446)	(986)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(2)	(20)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	(36)	99

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<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.5	Effect of movement in exchange rates on cash held		
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>968</b>	<b>968</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	958	1,442
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)	10	10
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>968</b>	<b>1,452</b>

<b>6.</b>	<b>Payments to directors of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to these parties included in item 1.2	170
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

Director's Salaries & Superannuation

<b>7.</b>	<b>Payments to related entities of the entity and their associates</b>	<b>Current quarter \$A'000</b>
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3	Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

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8. <b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	932	311
8.2 Credit standby arrangements		
8.3 Other (please specify)		
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

The lender is EFIC (Export Finance and Insurance Corporation), the term is four years, it is not secured, we are not expecting any additional loans in the foreseeable future, the interest rate is variable at 6.05% plus the Bank Bill Swap Rate.

9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	350
9.2 Product manufacturing and operating costs	
9.3 Advertising and marketing	25
9.4 Leased assets	
9.5 Staff costs	600
9.6 Administration and corporate costs	275
9.7 Other (provide details if material)	
<b>9.8 Total estimated cash outflows</b>	<b>1,250</b>

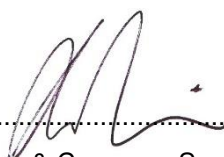
10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

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**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.

Sign here: .....  ..... Date: 31 January 2019  
(Director & Company Secretary)

Print name: Sam Wright  
.....

**Notes**

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.

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