





# PharmAust Appendix 4C and Shareholders' Update (Q4, 2018 FY)

**31 July 2018 – 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 ending 30 June 2018.

The business has been progressing successfully on several fronts.

## 1. Re-formulation of monepantel (MPL) into tablet form:

- a. The MPL active has now been reformulated during the past two months into therapeutic doses that are both palatable and bioavailable. Following a number of pilot manufacturing runs for the optimisation of MPL tablets, PharmAust has settled on a formulation that will palatably achieve therapeutic levels without the necessity for excessive tablet consumption (previously a challenge with the liquid Zolvix formulation).
- b. With the help of our manufacturing contractors BRI Pharmaceutical Research, Avista Pharma Solutions and Catalent, a ready-to-use prototype is expected to be available in calendar Q3 2018 to enable the canine trials. Catalent is a global provider of tailored formulation and manufacturing solutions.

#### 2. Canine clinical trial protocol:

During the past three months PharmAust has developed a canine Phase II clinical trial protocol with the assistance of its Clinical Advisory Board.

Dr Claire Cannon (BVSc (Hons), DACVIM (Oncology) at U-Vet and the University of Melbourne will lead the trial as our Principal Investigator. The trial is designed to determine the therapeutic potential of MPL in canine clinical oncology as well as provide a better understanding of the ultimate commercial use of the drug. The trial is based on our successful study in canines with lymphoma as announced on 13 December 2017 where it was shown that:

- i. MPL achieved primary endpoints for safety and efficacy
- ii. 6 out of 7 dogs achieved stable disease and reduction in tumour size
- iii. Monepantel: first mTOR inhibitor to show clinical benefit in dogs with cancer
- iv. Outcome supports progression to clinical trial using reformulated monepantel

Preparations for the trials in canines with cancer are now underway. Data collection is expected to commence during Q4 2018 and continue in 2019 as PharmAust moves through the Phase I and Phase II clinical stages.

#### 3. Effects of MPL in a variety of human cancer cell lines

In conjunction with our recent canine program to optimise the reformulation of monepantel and prepare for the canine clinical trial protocol, PharmAust has also been working with Dr Doug Fairlie PhD at the Olivia Newton John Cancer Centre in Melbourne to further analyse tumours for which MPL should be preferentially used. This work has independently confirmed that MPL is effective at killing selected tumour cells.

This data, together with the data generated from the trial for canines with cancer, will form a basis to commence clinical trials in humans.

#### 4. Intellectual property

As there is growing evidence that neuro-degenerative diseases can be slowed down by blocking the mTOR pathway, PharmAust has registered intellectual property on the effects of monepantel on neurodegenerative diseases such as Alzheimer's and Parkinson's diseases. PharmAust plans to more closely assess potential commercial outcomes in these areas in FY19.

#### 5. Current clinical program and development timelines (calendar years):

ACTIVITY	Q3 (2018)	Q4 (2018)	Q1 (2019)	Q2 (2019)	Q3 (2019)
Finalise formulation					
Scale up tablet manufacture for Phase I and II trials					
Canine recruitment, reference dosing and PK Phase I trial					
Phase II stage					

### 6. CEO

Dr Roger Aston has taken up the position of CEO and continued his role of Executive Chairman at the request of the PharmAust Board.

#### 7. Epichem strong commercial progress in calendar Q1 and Q2 2018:

- **a.** On 18 January 2018 PAA announced that Epichem Pty Ltd was awarded a one year extension to its current contract with Drugs for Neglected Diseases initiative (DND*i*).
- b. On 7 June 2018 PAA announced that Epichem had received an extension to its contract with California-based Unity Inc.
- c. On 2 July 2018 PAA announced that Epichem gained accreditation from NATA (The National Association of Testing Authorities, Australia) to ISO17034:2016. Epichem is one of the first companies in Australia to achieve this internationally regarded standard of quality assurance for reference material production to support pharmaceutical drug manufacturing. Accreditation by NATA is highly regarded both locally and internationally and elevates Epichem's status, global market access and competitiveness in a growing world market.
- d. Epichem's laboratory expansion works are completed and deliver an additional six fumehoods. In conjunction with the expanded facilities and the additional accreditation, we expect to see accelerating Epichem revenues in FY19.
- e. Epichem received \$490,000 in July 2018 from DNDi for work continuing on its flagship project on Chagas disease. This payment is not included in this Appendix 4C as it was received after 30 June 2018.

### 8. Director share purchases on market

During the quarter Messrs Bishop and Wright purchased an additional 500,000 shares each on-market at a combined cost of \$40,000.

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 Aus\$3.05m in revenues in the 2017 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 trial

+Rule 4.7B

# **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	Quarter ended ("current quarter")		
35 094 006 023	June 2018		

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	509	3,001
1.2	Payments for		
	(a) research and development	(133)	(922)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(762)	(2,817)
	(f) administration and corporate costs	(299)	(1,304)
1.3	Dividends received (see note 3)		
1.4	Interest received	9	37
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		354
1.8	Other (GST)	8	(30)
1.9	Net cash from / (used in) operating activities	(669)	(1,682)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(469)	(814)
	(b) businesses (see item 10)		
	(c) investments		

<sup>+</sup> See chapter 19 for defined terms

1 September 2016

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 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)		
2.6	Net cash from / (used in) investing activities	(469)	(814)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	1	1,861
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		(107)
3.5	Proceeds from borrowings	140	140
3.6	Repayment of borrowings		(207)
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	141	1,687

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	2,872	2,684
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(669)	(1,682)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(469)	(814)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	141	1,687

<sup>+</sup> See chapter 19 for defined terms 1 September 2016

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	1,876	1,876

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	1,866	1,865
5.2	Call deposits		1,000
5.3	Bank overdrafts		
5.4	Other (provide details)	10	10
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,876	2,875

6.	Payments to directors of the entity and their associates	Current quarter \$A'000	
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		ns included in	
Director's Salaries & Superannuation			

7.	Payments to related entities of the entity and their associates	Current quarter \$A'000
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 transactio items 7.1 and 7.2	ns included in

+ See chapter 19 for defined terms 1 September 2016

8.	Financing facilities available Add notes as necessary for an understanding of the position	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1	Loan facilities	932	325
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.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	350
9.2	Product manufacturing and operating costs	
9.3	Advertising and marketing	
9.4	Leased assets	
9.5	Staff costs	600
9.6	Administration and corporate costs	300
9.7	Other (provide details if material)	
9.8	Total estimated cash outflows	1,250

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	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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<sup>+</sup> See chapter 19 for defined terms

#### **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:	(Director & Company Secretary)	31 July 2018  Date:
	Sam Wright	
Print name:		

#### **Notes**

- 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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<sup>+</sup> See chapter 19 for defined terms