



Pitney Pharmaceuticals Limited

# PharmAust Appendix 4C and Shareholders Update (Q2, 2018 FY)

## Key Highlights

- Phase II Dog Lymphoma Trial confirmed Monepantel clinical benefit with 6 out of 7 treated dogs achieving stable disease and a reduction in tumour size
- Monepantel reformulation project successfully increases dose and improves taste. On track for clinical trial in humans and dogs in 2018.
- Key global opinion leaders appointed to PharmAust's Veterinary Clinical Advisory team
- Successfully completed an oversubscribed placement to sophisticated investors to raise \$1.873m. Proceeds will be used to accelerate clinical development of monepantel and to support further strategic investment in Epichem

**31 January 2018 – Perth, Australia:** PharmAust Limited (ASX:PAA), a clinical stage oncology company, is pleased to announce its Appendix 4C Quarterly Report and Shareholders Update for the period ending 31 December 2017.

During the quarter the company successfully achieved several major milestones that have opened the path to clinical trial in 2018. The company announced a successful outcome to its clinical trial in dogs diagnosed with Lymphoma, confirmed it has made significant progress towards identifying a formulation that improves dose and palatability and appointed three global leaders to its Veterinary Clinical Advisory Board.

Following the completion of a successful capital raise, the company is now well positioned to deliver on its goal of re-initiating clinical development of monepantel in humans and dogs in 2018. Details on these programme will be provided later in Q3, FY2018.

Cash Position:

PharmAust ended the quarter with \$2.946 million in cash.

Looking forward to Q3, FY2018 PharmAust is expecting to receive funds from the R&D rebate, which should be in-keeping with the amount received during the previous financial year. As part of the recent capital raise, the company has also received commitments from PharmAust Board members and executives to raise an additional \$118,000 subject to shareholder

approval. The company is also expecting a cash-flow positive quarter from Epichem following the recent extension to its DNDi contract.

## **Major Activities**

## Phase II Cancer Trial in Dogs Diagnosed with Lymphoma

A Phase II pilot trial in dogs diagnosed with lymphoma was completed with the key primary endpoints of safety and efficacy successfully achieved. Six of seven dogs diagnosed with B-cell lymphoma and treated with monepantel (MPL) developed stable disease (86%), with a median reduction in tumour size of 4%.

The objective of the trial was to assess the efficacy of PharmAust's lead molecule, MPL, as a first line therapy in dogs diagnosed with B-cell lymphoma that had not received any previous chemotherapy. The dogs were treated for two weeks with daily doses of MPL as first-line therapy before commencing conventional chemotherapy.

#### **Reformulation of Monepantel**

In collaboration with BRI Pharmaceutical Research, PharmAust has successfully identified a dry powder formulation that successfully meets the company's minimal requirements for dosing as either a capsule or tablet, taste masking and oral bioavailability.

BRI is currently optimising the method. Once finalised, the formulation will be scaled to produce sufficient quantities of drug for clinical trial which will commence in 2018.

#### Appointment of prestigious Veterinary Clinical Advisory Board

PharmAust was delighted to announce the appointment of three global opinion leaders to its Veterinary Advisory Board. The Board is chaired by Dr Angela Frimberger, who is leading PharmAust's dog clinical trials, along with Dr Barbara Kitchell, a world leading Veterinary Oncologist based in the US and Dr Christian Schirvel, who was previously the Global Head of Business Development and Licensing at Elanco. Together this team is advising PharmAust on its clinical and commercial development plans for monepantel.

#### **Preparations for Clinical Trial**

Preparation for clinical trial in humans and dogs is well advanced. In addition to the appointment of the advisory team, we have identified sites for the canine clinical trials and also shortlisted a panel of regulatory consultants who will help co-ordinate the human clinical trial programme. Further details on the clinical development plans will be released by the end of Q3, FY2018.

#### Epichem

Epichem is on-track to complete the expansion of its laboratory space by Q3, FY2018.

Epichem also submitted its applications for both the ISO17025 and ISO17034 Quality Accreditations, which represent the highest international standards for the production of reference standards. Discussions are continuing with the accreditation authorities to finalise the approval process.

Epichem was awarded the prestigious 'WA Exporter of the Year' award at the 29<sup>th</sup> WA Industry and Export Awards for the fifth time. Epichem also received the coveted Health and Biotechnology Award. Coordinated by the Department of Jobs, Tourism, Science and Innovation and managed by the Export Council of Australia, the awards recognise and honour the "best of the best" in Western Australian business.

Finally, Epichem Pty Ltd, was awarded a one year extension to its current contract with Drugs for Neglected Diseases *initiative* (DND*i*) (www.dndi.org). The contract, which will see Epichem continue to provide synthetic & medicinal chemistry support to DND*i*'s drug discovery projects and will generate \$1.3M in revenues during 2018.

#### Website Upgrade (Q3):

PharmAust was delighted to launch its new website which uses a modern platform to highlight the unique clinical and commercial direction of the company.

#### Successful Placement to Raise \$1.87m

PharmAust was pleased to announce it has received commitments to raise \$ 1.873 million through an oversubscribed Placement to sophisticated investors.

Funds were raised via an oversubscribed placement of 39,000,000 fully paid ordinary shares (the maximum allowed under the company's 25% capacity) at \$0.045 per share to sophisticated investors. This represents a discount of 10.9% discount to the 5-Day VWAP of \$0.0505 and a 8.2% discount to the last close (1 December 2017) of \$0.049.

In addition, officers of PAA have subscribed for an additional 2.611m shares to raise up to \$118,000, subject to Shareholder approval at an extraordinary general meeting to be held in February 2018.

Proceeds will be used to accelerate clinical development of monepantel, the company's lead drug candidate, and to support further strategic investment in Epichem.

We will continue to keep shareholders informed via our announcements, quarterly updates and investor forums we hold from time to time in Australia's capital cities.

Thank you for your support.

Yours faithfully

RM Hop

**Richard Hopkins** 

**Chief Executive Officer** 

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#### 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	December 2017

Consolidated 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	405	1,183
1.2	Payments for		
	(a) research and development	(305)	(412)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(757)	(1,365)
	(f) administration and corporate costs	(370)	(739)
1.3	Dividends received (see note 3)		
1.4	Interest received	10	16
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)	(1)	6
1.9	Net cash from / (used in) operating activities	(1,018)	(1,312)

2.	Cash flows from investing activities	
2.1	Payments to acquire:	
	(a) property, plant and equipment	(20)
	(b) businesses (see item 10)	
	(c) investments	

Appendix 4C Quarterly report for entities subject to Listing Rule 4.7B

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)		
2.6	Net cash from / (used in) investing activities	0	20

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	1,755	1,755
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)	(107)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		(94)
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	1,648	1,555

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	2,316	2,684
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,018)	(289)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,648	(94)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	2,946	2,946

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	1,936	1,306
5.2	Call deposits	1,000	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)	2,946	2,316

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 explanatio in items 6.1 and 6.2

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 transaction items 7.1 and 7.2	ns included in

n necessary	to understar	nd the trans	actions inclu	uded i

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	466	0
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	450
9.6	Administration and corporate costs	450
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		

#### **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 2018 Date: ..... ..... (Director & Company Secretary)

Sign here:

Sam Wright

Print name: .....

#### 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.