

ASX Release

30<sup>th</sup> October 2015

## **Appendix 4C - Quarterly Report & Company Update For the period ended 30 September 2015**

**PharmAust Limited** (“PharmAust”) (ASX: PAA) is pleased to provide an update and review of its activities.

### **PITNEY PHARMACEUTICALS PTY LTD – 100% OWNED SUBSIDIARY**

During the quarter, the Company continued to make progress with the development of its key anti-cancer product, Monepantel (“MPL” or “PPL-1”).

#### **MPL CLINICAL TRIAL IN HUMANS**

On 23rd July, the Company reported the successful closure of its Phase I (Phase IIa) “first in man” trial where seven patients were assessed for tumour markers at the Royal Adelaide Hospital. PharmAust received confirmation that the last patient, who was treated at the higher dose of MPL (25mg/kg), showed meaningful suppression of key cancer marker p70S6K. Importantly, during the trial, both principal end points were successfully met, namely:

1. MPL demonstrated a very good safety profile as compared with many other established anticancer drugs, and
2. MPL showed activity against cancer through the suppression of a key cancer marker.

In the trial, seven patients were treated with MPL for various time periods and measurements were successfully taken for anticancer activity through marker suppression (p70S6K). Three patients completed the full 28-day treatment period. One patient was not included in the cancer marker results as they only received a single dose of the drug. One patient received the higher dose of MPL (25mg/kg).

#### **MPL CLINICAL TRIAL IN CANINES**

Following the announcement that MPL significantly suppressed a key cancer marker in two dogs evaluated, and has been safe and well tolerated by all the dogs treated with the drug so far, the Company decided to move to the next stage of clinical evaluations which make use of the “synergy” discovery (announced to the market 17th February 2014).

During the quarter, PharmAust advised that it had completed the treatment of two canine patients with MPL in combination with Carboplatin, one of the “standard of care” chemotherapy drugs used in both human and veterinary anticancer medicine. Neither dog suffered any adverse events despite the fact they both had progressive, advanced cancers and few treatment options. Executive Chairman, Dr Aston stated, “Combining chemotherapy with MPL in a target species with a natural cancer, is an important step for PharmAust. There is a highly significant synergy between chemotherapy and MPL without enhancement of the associated side-effects commonly seen with anticancer drugs. As such, the lack of any adverse events in canines is an exciting outcome. Furthermore, this gives us much confidence in moving forward with Phase II combination therapies in man.”

#### **NEXT STEPS**

The first stage (Phase I) of both human and vet trials have been completed successful by demonstrating safety and activity against cancer in both species.

Both the human and the canine trials are awaiting the identification of a suitable GMP manufacturer which can reformulate the drug into capsules to a standard acceptable for regulators such as the TGA and the FDA. Both the human and canine trials to date have used “hospital or hospital pharmacy prepared formulations” - either liquid in a bottle or capsules for the dogs.



Once PharmAust has properly formulated material, the vet surgeries will reinstate trials in canines, and our proposed Phase II trials in humans will commence. Preliminary discussions with physicians at both the Royal Adelaide Hospital and at Clinical Research Centres in the UK, USA and Australia signal strong interest to evaluate MPL where first line therapy has failed.

PharmAust's other pipeline products Albendazole and Mucin will be developed with partners.

In the coming months, PharmAust expects to meet with the global animal health company with which it has a collaborative research and option agreement, to evaluate the commercial opportunities of MPL.

## **EPICHEM PTY LTD – 100% OWNED SUBSIDIARY**

During the quarter, Epichem reported the completion of their new laboratory in WA's Technology Park which became fully operational at the site on 11 September. The new laboratory is over twice the size of its previous laboratory at Murdoch University and has provision for additional expansion in the future. The extra capacity of the new facilities will allow Epichem to rapidly grow its business to our 5-year target of \$10 million pa.

Managing Director of Epichem, Dr Wayne Best, stated, "Not only does the new laboratory provide significant extra capacity but its improved design offers significant improvements in efficiency". Dr Best added that "The timing couldn't be better for the expansion. With most of Epichem's business being for the export market, the current low Australian Dollar adds significantly to our competitiveness and profitability."

Epichem's expert team of medicinal chemists is also supporting PharmAust's oncology programmes and has made a number of novel analogues of MPL. While still at the early pre-clinical research stage, if successful, this research could ultimately lead to a new drug with improved properties which is wholly owned by PharmAust.

Epichem continued to promote its products and services both within Australia and overseas with staff attending a number of conferences and tradeshows including AusBiotech in Melbourne and ChemOutsourcing in New Jersey, USA. Most notably, Epichem was an exhibitor at CPhI WorldWide in Madrid, Spain, which is the world's premier trade show for the pharmaceutical industry attended by 36,000 delegates. Feedback from CPhI was excellent with a number of new customers and prospects resulting.

Epichem has a new tag line to better reflect our business offerings: "Our Formula. Your Success". The Epichem website ([www.epichem.com.au](http://www.epichem.com.au)) and other promotional media are currently being refreshed.

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# Appendix 4C

## Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005.

Name of entity

PharmAust Limited

ABN

35 094 006 023

Quarter ended ("current quarter")

September 2015

### Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (3 months) \$A'000
1.1 Receipts from customers	698	698
1.2 Payments for		
(a) staff costs	(524)	(524)
(b) advertising and marketing		
(c) research and development	(160)	(160)
(d) leased assets	(8)	(8)
(e) other working capital	(401)	(401)
1.3 Dividends received		
1.4 Interest and other items of a similar nature received	14	14
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Other (GST)	(139)	(139)
<b>Net operating cash flows</b>	<b>(520)</b>	<b>(520)</b>

+ See chapter 19 for defined terms.

**Appendix 4C**  
**Quarterly report for entities**  
**admitted on the basis of commitments**

	Current quarter \$A'000	Year to date (3 months) \$A'000
1.8 Net operating cash flows (carried forward)	(520)	(520)
<b>Cash flows related to investing activities</b>		
1.9 Payment for acquisition of:		
(a) businesses (item 5)		
(b) equity investments		
(c) intellectual property		
(d) physical non-current assets	(1,436)	(1,436)
(e) other non-current assets		
1.10 Proceeds from disposal of:		
(a) businesses (item 5)		
(b) equity investments		
(c) intellectual property		
(d) physical non-current assets		
(e) other non-current assets		
1.11 Loans to other entities		
1.12 Loans repaid by other entities		
1.13 Proceeds from acquisitions of controlled entity		
	(1,436)	(1,436)
<b>Net investing cash flows</b>		
1.14 <b>Total operating and investing cash flows</b>	(1,956)	(1,956)
<b>Cash flows related to financing activities</b>		
1.15 Proceeds from issues of shares, options, etc.	1	1
1.16 Proceeds from sale of forfeited shares		
1.17 Proceeds from borrowings	645	645
1.18 Repayment of borrowings		
1.19 Dividends paid		
1.20 Other		
<b>Net financing cash flows</b>	646	646
<b>Net increase (decrease) in cash held</b>	(1,310)	(1,310)
1.21 Cash at beginning of quarter/year to date	3,411	3,411
1.22 Exchange rate adjustments to item 1.20	-	-
1.23 <b>Cash at end of quarter</b>	2,101	2,101

+ See chapter 19 for defined terms.

### Payments to directors of the entity and associates of the directors

### Payments to related entities of the entity and associates of the related entities

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	138
1.25	Aggregate amount of loans to the parties included in item 1.11	
1.26	Explanation necessary for an understanding of the transactions	
	Director's Salaries & Superannuation	

### Non-cash financing and investing activities

- 2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

- 2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

### Financing facilities available

Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities		
3.2	Credit standby arrangements		

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**Reconciliation of cash**

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1 Cash on hand and at bank	2,091	729
4.2 Deposits at call		222
4.3 Bank overdraft		
4.4 Other (Term Deposit)	10	2,460
<b>Total: cash at end of quarter (item 1.23)</b>	<b>2,101</b>	<b>3,411</b>

**Acquisitions and disposals of business entities**

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity		
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		

**Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does ~~not~~ <sup>does not</sup> (delete one) give a true and fair view of the matters disclosed.

Sign here:  ..... Date: 30 October 2015 .....

(Director & Company Secretary)

Print name: Sam Wright .....

+ See chapter 19 for defined terms.

## 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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 1026: Statement of Cash Flows* apply to this report except for the paragraphs of the Standard set out below.
  - 6.2 - reconciliation of cash flows arising from operating activities to operating profit or loss
  - 9.2 - itemised disclosure relating to acquisitions
  - 9.4 - itemised disclosure relating to disposals
  - 12.1(a) - policy for classification of cash items
  - 12.3 - disclosure of restrictions on use of cash
  - 13.1 - comparative information
3. **Accounting Standards.** ASX will accept, for example, the use of International Accounting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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