

**ASX Release** 



PL Pitney Pharmaceuticals Limited

29th January 2016

## Appendix 4C - Quarterly Report & Company Update For the period ended 31 December 2015

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

During the quarter, the Company continued to make progress with the development of its key anti-cancer product, Monepantel ("MPL" or "PPL-1"). On 21 October, PharmAust reported that it had received the Phase I Clinical Trial Synopsis from CPR Pharma Services, who have worked with CMAX-IDT to successfully complete PharmAust's firstin-man clinical trial of PPL-1 at the Royal Adelaide Hospital.

### **Outcomes of Clinical Trial**

### SAFETY

PPL-1 demonstrated a very good safety profile as compared with many other established anticancer drugs. Whilst PPL-1 was well tolerated in humans, adverse events (AEs) deemed to be related to study medication included nausea, vomiting, diarrhoea, and decreased appetite. The poor palatability of PPL-1 is believed to be the major contributor to these AEs and responsible for poor patient compliance in taking the drug during the trial. Although a number of Serious Adverse Events (SAEs) were noted during the study, they were not related to the study medication. To address the palatability issues of PPL-1, PharmAust has appointed Juniper Pharma Services, a subsidiary of Juniper Pharmaceuticals, Inc. (Nasdaq: JNP), to reformulate monepantel (MPL) for its Phase II studies currently in planning and preparation.

### ORAL ABSORPTION

The pharmacokinetics of PPL-1 indicate rapid absorption and peak blood levels (4-6 hours) following oral administration of the drug. The blood levels of PPL-1 are in line with the levels observed for other anticancer drugs.

### ANTI-CANCER ACTIVITY

PPL-1 showed activity against cancer through the suppression of tumour marker p70S6K which is highly significant when the data from 7 patients is combined and analysed (at day 3 of treatment p<0.0004 and at day 7 of treatment p<0.002). Furthermore, evaluation of white blood cells of patients who have received PPL-1 for three consecutive days has shown that the levels of p-4E-BP1 cancer marker are significantly reduced as compared to its levels at Day 1 before treatment started. Of the 4 subjects with post-dose RECIST assessment (tumour measurements) at a dose level of 5 mg/kg, 2 were classified as stable disease and 2 were classified as progressive disease.

Dr Aston said "This is a very strong result for our Phase I trial which will now allow us to proceed as soon as possible to a Phase II evaluation of PPL-1. Preliminary discussions with physicians at both the Royal Adelaide Hospital and at Clinical Research Centres in the UK signal strong interest to evaluate PPL-1 where first line therapy has failed. Following some additional contractual studies, which we will report upon, we expect to be able to select what chemotherapy is preferred to be used in conjunction with PPL-1 in the next trial. Furthermore, the Phase I study has confirmed that PPL-1 is absorbed orally in quantities that result in suppression of the cancer marker p70s6k in peripheral immune cells; this gives us much confidence that the drug is active on markers that have been correlated with aggressive features of cancer, such as growth, invasion and metastasis."

### Annual General Meeting

On 27 October, PharmAust held its Annual General Meeting of Shareholders at Epichem Pty Ltd, Suite 5, 3 Brodie-Hall Drive, Bentley, Western Australia. All resolutions that were put were unanimously passed on a show of hands, including the resolution authorising a consolidation of the Company's Issued Capital on the following basis:

(a) every 20 Shares to be consolidated into 1 Share; and

(b) every 20 Options be consolidated into 1 Option and the exercise price of each Option to be amended in inverse proportion to this ratio in accordance with ASX Listing Rule 7.22.1

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### PharmAust Appoints RedChip to undertake Global Investor Relations Program

On 24 November, PharmAust announced that it appointed RedChip Companies ("RedChip") to provide a comprehensive global investor relations program to expand the Company's retail and institutional shareholder base in the U.S, Europe, Asia and Latin America.

RedChip is a world leader in investor relations, financial media, and research for microcap, small-cap, and mid-cap stocks. Founded in 1992 and headquartered in Orlando, Florida, with affiliates in New York, Pittsburgh, Paris and Seoul, RedChip has helped hundreds of companies achieve their capital markets goals and has been ranked by Inc. Magazine as one of the fastest growing privately held investor relations firms in the U.S. RedChip's platform includes a weekly television show, "The RedChip Money Report," which reaches more than 160 million households in Australia, Europe, Asia, and Latin America (<u>http://www.redchip.com/tv</u>).

RedChip has now commenced execution of an investor relations program to showcase PharmAust's product pipeline to retail and institutional investors globally.

### GenScript to Complete Further Pre-Clinical Validation for Phase II Trial

During the quarter PharmAust appointed GenScript to investigate the use of PPL-1/monepantel in conjunction with current "Standard of Care" in preparation for PharmAust's investigation of monepantel in Phase II.

Following PharmAust's demonstration that combinations of chemotherapy and monepantel result in synergy with respect to anticancer activity, the company will be investigating and validating the various combinations in different cancers in GenScript's model systems. This work programme will be as a prelude to PharmAust initiating its Phase II trial.

GenScript is the leading gene, peptide, protein and antibody research partner for fundamental life science research, translational biomedical research, and pre-clinical pharmaceutical development. Since their establishment in 2002, GenScript has exponentially grown to become a global leading biotech company that provides life sciences services and products to scientists over 100 countries worldwide. PharmAust will be accessing their in vitro and in vivo pharmacology capability to optimise its treatment regiments for the Phase II trial.

### Epichem Awarded Two Year Contract Extension from DNDi

Wholly owned subsidiary, Epichem Pty Ltd, has been awarded a two year extension to its current contract with Drugs for Neglected Diseases initiative (DNDi).

The contract, which was due to finish on 31 December 2015, will now see Epichem continue to provide synthetic & medicinal chemistry support to DNDi's drug discovery projects until 31 December 2017. The extension will generate a further \$2.3M in revenues for Epichem during that period.

Epichem's Managing Director, Dr Wayne Best, said "Everyone in the company is delighted to have been given the opportunity to continue contributing to the important work undertaken by DNDi."

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.

On 19th January 2015, Epichem received \$559,925 from DNDi for work continuing on its flagship project on Chagas disease. This payment is not included in this Appendix 4C – Quarterly Report as it was received after 31 December 2015.

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Rule 4.7B

# **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")

December 2015

### **Consolidated statement of cash flows**

Cash flows related to operating activities		Current quarter \$A'000	Year to date (6 months) \$A'000
1.1	Receipts from customers	355	1,052
1.2	Payments for (a) staff costs (b)advertising and marketing	(491)	(1,016)
	(c)research and development	(181)	(340)
	(d) leased assets	(8)	(16)
	(e) other working capital	(673)	(1,074)
1.3	Dividends received		
1.4	Interest and other items of a similar nature received	4	18
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Other (GST)	(169)	(30)
	Net operating cash flows	(826)	(1,346)

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

		Current quarter \$A'000	Year to date (6 months) \$A'000
1.8	Net operating cash flows (carried forward)	(826)	(1,346)
	Cash flows related to investing activities		
1.9	Payment for acquisition of:		
	(a) businesses (item 5)		
	<ul><li>(b) equity investments</li><li>(c) intellectual property</li></ul>		
	(d) physical non-current assets	(3)	(1,439
	(e) other non-current assets		(-,
1.10	Proceeds from disposal of:		
	(a) businesses (item 5)		
	(b) equity investments		
	(c) intellectual property		
	<ul><li>(d) physical non-current assets</li><li>(e) other non-current assets</li></ul>		
	(c) 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		(1.10)
	Net investing cash flows	(3)	(1,439
1.14	Total operating and investing cash flows		
		(829)	(2,785
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.		
1.16	Proceeds from sale of forfeited shares	05	74
1.17 1.18	Proceeds from borrowings Repayment of borrowings	95 (15)	74
1.19	Dividends paid	(13)	(1.
1.20	Other		
	Net financing cash flows	80	72
	Net increase (decrease) in cash held	(749)	(2,059
1.21	Cash at beginning of quarter/year to date	2,101	3,41
1.22	Exchange rate adjustments to item 1.20	-	
1.23	Cash at end of quarter		

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

Current quarter

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

		\$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	133
1.25	Aggregate amount of loans to the parties included in item 1.11	
1.26	Explanation necessary for an understanding of the transactions	

### Non-cash financing and investing activities

Director's Salaries & Superannuation

- 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		

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

### **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.		n in the consolidated statement of cash flows) to	Current quarter \$A'000	Previous quarter \$A'000
)	4.1	Cash on hand and at bank	342	2,091
	4.2	Deposits at call		
	4.3	Bank overdraft		
_	4.4	Other (Term Deposit)	1,010	10
_		Total: cash at end of quarter (item 1.23)	1,352	2,101

#### 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**

- This statement has been prepared under accounting policies which comply with accounting 1 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 /does not\* (delete one) give a true and fair view of the matters disclosed.

Sign here:	(Director & Company Secretary)	29 January 2016 Date:
	Sam Wright	
Print name:		

NA

**Notes** 

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

- 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.

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