## Appendix 4E

### Preliminary Final Statements to the Australian Securities Exchange

#### PharmAust Limited and its controlled entities ABN 35 094 006 023

Reporting period – For the year ended 30 June 2018 Previous period – For the year ended 30 June 2017

### **Results for Announcement to the Market**

	30 June	30 June	Change	Change
	2018	2017		
	\$'000	\$'000	\$'000	%
Revenue	3,295	3,333	(38)	(1%)
Loss for the year after tax from continuing operations	(2,521)	(1,343)	(1,178)	(88%)
Loss attributable to members of the parent entity	(2,535)	(1,608)	(927)	58%

### Dividends

No Dividends have been declared or paid during the financial year ended 30 June 2018.

#### Other significant information

The principal continuing activities constituted by PharmAust Limited and the entities it controlled during the year were to develop its own drug discovery intellectual property for the treatment of different types of cancers in humans and animals, as well as providing highly specialised medicinal and synthetic chemistry services on a contract basis to clients.

The results of the consolidated entity for the year ended 30 June 2018 was a loss, after income tax expense, of \$2,521,679 (2017: loss of \$1,343,614). The net assets of the consolidated entity were \$7,138,218 as at 30 June 2018 (2017: \$6,915,047).

#### **Review of operations**

### PITNEY PHARMACEUTICALS PTY LIMITED – 100% OWNED SUBSIDIARY

During the past 12 months the Company's focus has been primarily directed towards three Research and Development Targets with its lead product MPL in cancer therapy. These three targets are:

- 1. to undertake a "First Line Therapy" clinical trial in canines with naturally occurring cancer to determine the safety and value of MPL as a cancer therapy, and
- 2. to identify a formula that can provide both palatable and high dose MPL tablet for clinical development
- 3. Using the new formula, finalise Phase I and II Clinical Trial Protocols suitable for testing the anticancer activity of MPL in canines with cancer

All three of the above goals have been successfully achieved.

### Results from the First Line Clinical Trial in Canines with Naturally Occurring Cancer

The first line therapy clinical trial in canines with B-cell lymphoma was successfully completed during the 2017-2018 calendar year. This trial was undertaken using gelatin encapsulated MPL liquid. The use of MPL liquid meant that only sub-optimal doses could be tested. However, the trial confirmed

#### PharmAust Limited Supplementary Appendix 4E information For the year ended 30 June 2018

MPL's presumed anticancer activity and has provided PharmAust with full confidence to explore this potential in more formal clinical studies. The trial showed that:

- for the first time, inhibition of the mTOR signaling pathway is associated with anticancer efficacy in dogs with naturally occurring cancers,
- six out of seven dogs administered gelatin encapsulated MPL liquid achieved stable disease,
- six out of seven dogs administered gelatin encapsulated MPL liquid achieved reductions in tumour size,
- stable disease and reductions in tumour size were accompanied by a high MPL safety profile,
- administration of MPL was associated with reductions in PharmAust's identified tumour marker,
- due to poor palatability and a relatively low permissible dose, it was confirmed that MPL liquid is not an ideal formula for effectively administering MPL to canines with cancer,
- reformulation is required to realise MPL's full anticancer potential, and
- progression to formal Phase I and Phase II clinical trials using reformulated MPL is warranted.

### Successful Tablet Reformulation

In May 2018 PharmAust announced that it had successfully reformulated monepantel into a tablet. This tablet will replace MPL liquid for use in the upcoming formal Phase I and Phase II clinical trials. In collaboration with BRI Pharmaceutical Research and AVISTA Pharma Solutions, PharmAust showed that a micronised tablet-based formulation was superior to MPL liquid in delivering monepantel at high doses suitable for taking into dose escalation clinical studies in canines. Since this time, and in further collaboration with BRI Pharmaceutical Research and Catalent Inc., PharmAust has optimised the presentation of the tablet so that it is now suitable for taking into Phase II clinical trials and coating with taste enhancers.

# Finalisation of the Formal Canine Clinical Phase I and II Protocols

PharmAust has completed development of its Phase I and Phase II clinical trial study protocol for the use of MPL as an anticancer agent in canines with naturally occurring cancers. PharmAust has included the use of the new tablet in the study designs as well as identified cancer targets of interest, received ethics approvals from relevant authorities and recruited veterinarians willing to participate in these trials.

#### **Research and Development Targets 2018-2019**

During the next 12 months, the Company's focus will be aimed at:

- further examining the mechanism of action of MPL upon cancer cells with the newly commenced collaboration with Dr Doug Fairlie at the Olivier Newton John Cancer Centre,
- validating preliminary studies demonstrating activity of MPL upon neurodegenerative diseases such as Parkinson's Disease,
- conducting scale up manufacture of the tablets formulated for use in canines with cancer to cGMP quality
- performing optimization studies specifically for palatability and dosing for humans with cancer,
- determining the pharmacokinetic parameters, dietary enhancements and safety of the newly formulated tablet in both canines and humans in Phase I trials,
- undertaking Phase II trials for efficacy in canines with the new tablet and in accordance with the newly signed option agreement with Elanco, and
- identifying Clinical Centers prepared to evaluate the new MPL tablet in humans in Phase I and II trials, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015.

Preparations for the trials in canines with cancer are now underway with tablet prototype finalisation, preliminary pharmacokinetics testing in canines, scale-up tablet manufacture and Phase I trial initiation sequentially commencing in Q3/Q4, 2018.

#### PharmAust Limited Supplementary Appendix 4E information For the year ended 30 June 2018

## Factors Supporting PharmAust's Focus on MPL as an Anti-Cancer Drug:

- 1. Demonstration of activity against naturally occurring B-cell lymphoma in dogs,
- 2. Demonstration of a very good safety profile in animals tested to date, as well as the human participants in the clinical trial conducted at the Royal Adelaide Hospital,
- 3. Demonstration of activity against a key cancer marker in humans and canines,
- 4. Extensive preclinical R&D package evaluating MPL in many cancers,
- 5. Independent validation of monepantel's specificity towards malignant cell lines and relatively benign effects upon non malignant cell lines by the newly commenced collaboration with Dr Doug Fairlie at the Olivia Newton John Cancer Centre,
- 6. Publications in peer-review journals describing anti-cancer activity of MPL in preclinical models,
- 7. The fact that MPL is already approved for the treatment of parasitic infections in farm animals, which implies that the drug has received extensive regulatory consideration as it is used in food-chain animals,
- 8. The successful reformulation of MPL by BRI/Avista into a prototype tablet formulation,
- 9. New Option to Licence Agreement entered into with Elanco Inc, a global provider of veterinary products,
- 10. The provision by Elanco of 5kg of GMP-quality MPL.

### 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.

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

Epichem, PharmAust's wholly owned subsidiary, has continued to make strong progress towards key operational milestones as well as build the contract sales and income activities.

Epichem has been delivering synthetic and medicinal chemistry services to the drug discovery and pharmaceutical industries worldwide since 2003. Epichem offers a range of rare and hard to find pharmaceutical impurities, degradants and metabolites of active ingredients and excipients, particularly for OTC and generic drugs.

Epichem has been at the forefront of synthesizing new and difficult to obtain standards and many of these are exclusive to Epichem and not available elsewhere. This range is continually expanding in response to customer requests and developments in the industry. Epichem is globally competitive with clients in 39 countries and is rapidly expanding its reach.

Epichem also excels in custom synthesis and contract drug discovery, boasting a highly skilled team of scientists, most with a PhD and industry experience. This valuable investment in people allows Epichem to lead drug discovery programs, perform custom synthesis, conduct optimisation and method development for scale-up and engage in high-level problem solving.

Epichem has a long history of helping pharmaceutical companies identify trace impurities and has produced a range of pharmaceutical reference standards to aid the industry in detecting and measuring these impurities, ultimately assisting in the quality assurance and control of its clients' medicines.

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.

#### PharmAust Limited Supplementary Appendix 4E information For the year ended 30 June 2018

## Epichem wins prestigious WA Exporter of the Year Award

Epichem won its fifth WA Export Award and was awarded the prestigious 'WA Exporter of the Year' award at the 29th WA Industry and Export Awards in October 2017. 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.

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Dr Wayne Best, Chairman of Epichem, said "We're proud to be named 'WA Exporter of the Year', which recognises the hard work and dedication from our outstanding team. Epichem has now won a WA Export Award in each of the five years it has entered and is in the WA Export Hall of Fame. Epichem has also won a prestigious Australian Export Award in the Small Business category.

We're particularly pleased with this year's award as it recognises the strong growth in revenues we've achieved following the decision to expand our laboratory space. Epichem is also finalising a new standards accreditation to offer its services to a wider range of global customers. Delivery on these outcomes is expected to drive continued revenue growth."

## Epichem gains prestigious international ISO accreditation

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.

### Extensions to major customer contracts

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*). On 7 June 2018 PAA announced that Epichem had received an extension to its contract with California-based Unity Inc.

### **Epichem Expands Laboratory to Accelerate Growth**

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.

### CORPORATE

#### **Annual General Meeting**

The Annual General Meeting of the Shareholders of PharmAust Limited was held on 29 November 2017 at Epichem Pty Ltd Suite 5, 3 Brodie Hall Drive, Technology Park, Bentley, Western Australia. All resolutions that were put were unanimously passed on a show of hands.

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

PharmAust was pleased to announce it raised \$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 at \$0.045 per share to sophisticated investors.

In addition, officers of PAA subscribed for an additional 2.611m shares to raise up to \$118,000, which received Shareholder approval at an extraordinary general meeting held on 26 February 2018.

## **Net Tangible Assets**

	30 June 2018	30 June 2017
Net tangible (liabilities)/ assets per share (cents/share)	2.03	2.42

## Control gained over entities and loss of control over entities

During the financial year the Company did not gain or lose control over any entity.

### Details of associates and joint venture entities

The company has no associates or joint venture entities

# **Audit Status**

This report is based on accounts which are in the process of being audited. The Audited Annual Report is expected to be released by 30 September 2018.

### Attachments forming part of the Appendix 4E:

Preliminary Financial Report of PharmAust Limited for the year ended 30 June 2018 is attached.

Signed By

31 August 2018

Sam Wright **Finance Director** 

#### PharmAust Limited Preliminary Statement of Comprehensive Income For the year ended 30 June 2018

		CONSOLIDATED	
		2018	2017
		\$	\$
	Revenue	2,871,345	2,854,176
J	Other income	424,559	479,329
		3,295,904	3,333,505
	Raw materials and consumables used	(289,318)	(340,617)
	Employee benefits expense	(3,561,963)	(2,522,959)
	Depreciation expense	(118,605)	(123,085)
	Finance costs	(28,352)	(59,377)
	Research and development expenses	(463,875)	(329,302)
	Administration expenses	(1,355,470)	(1,301,779)
	(Loss) before income tax expense	(2,521,679)	(1,343,614)
		(2,021,070)	(1,010,011)
	Income tax expense		
	(Loss) after income tax expense	(2,521,679)	(1,343,614)
	Other comprehensive income		
	Total comprehensive (loss) for the year	(2,521,679)	(1,343,614)
	Design and diluted loss per chara (cente per chara)	(1.70)	(1.09)
	Basic and diluted loss per share (cents per share)	(1.72)	(1.08)

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying notes.

#### PharmAust Limited Preliminary Statement of Financial Position as at 30 June 2018

	Conso	LIDATED
	2018	2017
	\$	\$
CURRENT ASSETS		
Cash and cash equivalents	1,875,431	2,590,330
Trade and other receivables	248,353	222,187
Other current assets	58,568	44,668
Inventory	574,015	486,773
TOTAL CURRENT ASSETS	2,756,367	3,343,958
NON-CURRENT ASSETS		
Intangible assets	3,107,476	3,107,476
Plant and equipment	2,494,154	1,743,829
TOTAL NON-CURRENT ASSETS	5,601,630	4,851,305
TOTAL ASSETS	8,357,997	8,195,263
		-,
CURRENT LIABILITIES	0/0.005	00/070
Trade and other payables	616,825	361,873
Borrowings	424,634	206,250
Provisions	177,313	388,104
TOTAL CURRENT LIABILITIES	1,218,772	956,227
NON-CURRENT LIABILITIES		
Borrowings	1,007	281,250
Provisions	-	42,739
TOTAL NON-CURRENT LIABILITIES	1,007	323,989
TOTAL LIABILITIES	1,219,779	1,280,216
NET ASSETS	7,138,218	6,915,047
EQUITY		
Issued capital	49,371,354	47,604,668
Reserves	2,055,460	1,077,296
Accumulated losses	(44,288,596)	(41,766,917)
TOTAL EQUITY	7,138,218	6,915,047

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

### PharmAust Limited Preliminary Statement of Changes in Equity for the year ended 30 June 2018

	Issued Capital \$	Accumulated Losses \$	Options Reserve \$	Total Equity \$
As at 1 July 2016 Loss for the year Total comprehensive (loss) for the year	44,463,072	(40,423,303) (1,343,614) (1,343,614)	983,492 - -	5,023,261 (1,343,614) (1,343,614)
Shares issued (net)	3,141,596	- (1,040,014)	-	3,141,596
Share based payment As at 30 June 2017	47,604,668	(41,766,917)	93,804 1,077,296	<u>93,804</u> <u>6,915,047</u>
As at 1 July 2017 Loss for the year	47,604,668	(41,766,917) (2,521,679)	1,077,296	<u>6,915,047</u> (2,521,679)
Total comprehensive (loss) for the year		(2,521,679)	-	(2,521,679)
Shares issued (net) Share based payment	1,766,686	-	- 978,164	1,766,686 978,164
As at 30 June 2018	49,371,354	(44,288,596)	2,055,460	7,138,218

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes

### PharmAust Limited Preliminary Statement of Cash Flows for the year ended 30 June 2018

			CONSOLIDATED	
		Νοτε	2018 \$	2017 \$
D	Cash Flows from Operating Activities Receipts from customers Payments to suppliers and employees Other income Interest received Interest and other costs of finance		2,845,179 (4,792,182) 387,656 36,903 (28,352) (1,550,796)	2,726,008 (4,401,626) 453,401 25,928 (59,377) (1,255,666)
	Net cash used in operating activities Cash Flows from Investing Activities Payments for plant and equipment		(1,550,798)	(1,255,666) (57,023)
	Net cash used in investing activities		(868,930)	(57,023)
	Cash Flows from Financing Activities Proceeds from share issues (net) Proceeds/(Repayment) of borrowing (net) Net cash provided by financing activities		1,766,686 (61,859) 1,704,827	3,141,595 (120,399) 3,021,196
	Net (decrease)/increase in cash held		(714,899)	1,708,507
	Cash at the beginning of the financial year		2,590,330	881,823
	Cash at the end of the financial year		1,875,431	2,590,330

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

#### PharmAust Limited Notes to the preliminary financial statements for the financial year ended 30 June 2018

## Note 1. Basis of Preparation

This preliminary final report has been prepared in accordance with ASX Listing Rule 4.3A and the disclosure requirements of ASX Appendix 4E. This report is to be read in conjunction with any public announcements made by PharmAust Limited during the reporting period in accordance with the continuous disclosure obligations arising under the Corporations Act 2001 and Australian Securities Exchange Listing Rules.

The Preliminary Financial Statements of PharmAust Limited and its controlled entities, comply with International Financial Reporting Standards as issued by the International Accounting Standards Board

### New and Revised Accounting Standards and Interpretations

In the current year, the Consolidated Entity has adopted all of the new and revised Standards and Interpretations issued by the Australian Accounting Standards Board that are relevant to its operations and effective for the current annual reporting period. The adoption of these new and revised Standards and Interpretations has not resulted in a significant or material change to the Consolidated Entity's accounting policies.

## Note 2. Segment reporting

### Segment Information

### Identification of reportable segments

The Group has identified its operating segments based on the internal reports that are reviewed and used by the Directors (chief operating decision makers) in assessing performance and determining the allocation of resources.

### **Descriptions of segments**

i. Corporate

The corporate segment covers all the corporate overhead expenses.

ii. Pharmaceutical

The pharmaceutical segment provides products and services in synthetic and medicinal chemistry to the drug discovery and pharmaceutical industries.

### Basis of accounting for purposes of reporting by operating segments

### a. Accounting policies adopted

All amounts reported to the Directors, being the chief decision makers with respect to operating segments, are determined in accordance with accounting policies that are consistent to those adopted in these financial statements.

#### b. Intersegment transactions

There are intersegment sales and purchase within the consolidated entity.

Intersegment loans payable and receivable are initially recognised at the consideration received/to be received net of transaction costs.

#### c. Segment assets

Where an asset is used across multiple segments, the asset is allocated to the segment that receives majority economic value from the asset. In the majority of instances, segment assets are clearly identifiable on the basis of their nature and physical location.

#### d. Segment liabilities

Liabilities are allocated to segments where there is a direct nexus between the incurrence of the liability and the operations of the segment.

#### PharmAust Limited Notes to the preliminary financial statements for the financial year ended 30 June 2018

The consolidated entity operates in three business segments as disclosed below:

#### i) Segment Performance

#### Consolidated

2018	Corporate \$	Pharmaceutical \$	Total \$
Revenue External sales Other external revenue Inter-segment sales Total segment revenue Inter-segment elimination Total revenue per statement of comprehensive income	388,720 	2,890,057 17,127 <u>93,199</u> 3,000,383	2,890,057 405,847 93,199 3,389,103 (93,199) 3,295,904
<b>Results</b> Segment result from continuing operations before tax	(2,535,506)	13,827	(2,521,679)
Consolidated			
2017	Corporate \$	Pharmaceutical \$	Total \$
2017 Revenue External sales Other external revenue Inter-segment sales Total segment revenue Inter-segment elimination Total revenue per statement of comprehensive income	•		

#### Note 3. Contingent Assets

There are no contingent assets at the date of this report.

#### Note 4. Contingent Liabilities

The consolidated entity has the following contingent liabilities at reporting date:

### Issue of additional shares

As part of Share Sale Agreement to acquire Pitney Pharmaceuticals Pty Ltd, the consolidated entity will issue additional shares of 2.5 million (post consolidation of 20 to 1) each to the seller upon meeting the three milestones.

The three milestones are:

• Milestone 1 - One of the consolidated entity's products being granted investigational new drug (IND) status from the US Food and Drug Administration and the Company receiving an IND number issued by the US Food

### PharmAust Limited Notes to the preliminary financial statements for the financial year ended 30 June 2018

and Drug Administration within 5 years of the Settlement Date and provided this is no later than 31 October 2018;

- Milestone 2 Commencement of treatment of the first patient under a Phase II Trial with the product Albendazole within 5 years of the Settlement Date and provided this is no later than 31 October 2018; and
- Milestone 3 Commencement of treatment of the first patient under a Phase II Trial using the product Monepantel within 5 years of the Settlement Date and provided this is no later than 31 October 2018.

### Note 5. Controlled entities

	COUNTRY OF CORPORATION	CLASS OF SHARES	EQUITY HOLDING 2018 %	Equity Holding 2017 %
Parent Entity: PharmAust Limited	Australia	-	-	-
Name of Controlled Entity: Epichem Pty Ltd Pitney Pharmaceuticals Pty Ltd	Australia Australia	Ordinary Ordinary	100 100	100 100