

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 2019

Previous period – For the year ended 30 June 2018

Results for Announcement to the Market

	30 June 2019	30 June 2018	Change	Change
	\$'000	\$'000	\$'000	%
Revenue	4,365	3,295	1,070	33%
Loss for the year after tax from continuing operations	(1,617)	(2,521)	(904)	(36%)
Loss attributable to members of the parent entity	(1,617)	(2,521)	(904)	(36%)

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.

Operating Results

The results of the consolidated entity for the year ended 30 June 2019 was a loss, after income tax expense of \$1,617,041 (2018: loss of \$2,521,679).

Financial Position

The net assets of the consolidated entity were \$7,390,061 as at 30 June 2019 (2018: \$7,138,218).

Dividends

Since the end of the financial year, no dividend has been paid, declared or recommended.

Review of Operations

PITNEY PHARMACEUTICALS PTY LIMITED – 100% OWNED SUBSIDIARY

PharmAust Limited is primarily focused on cancer therapy in humans and canines. Pitney Pharmaceuticals Pty Ltd owns a number of patent families offering protection for the use of Monepantel (MPL) in cancer therapy and potentially for other diseases governed by the mTOR pathway (mechanistic Target Of Rapamycin). The discovery of this possible mechanism of action for the lead product MPL diversifies the potential applications of this molecule, for diseases of the central nervous system. MPL is an approved anthelmintic drug distributed by global major Elanco Animal Health Inc, for the treatment of parasitic diseases in sheep. PharmAust is repurposing MPL for veterinary clinical markets and introducing monepantel into the human market. The fact that MPL is already approved for use in animals in a number of major jurisdictions (EU/UK, Australia) means that the development process for PharmAust is simpler and cheaper than it would be if MPL were a new API (Active Pharmaceutical Ingredient).

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PharmAust has signed an agreement with UNSW-NSI, the commercial arm of the University of NSW to acquire all the rights to MPL in exchange for all of the rights to the “mucin” project. PharmAust believes that divesting the mucin IP to consolidate the MPL IP, places PharmAust in a strong position for licensing and co-development of MPL with partners.

In order to further the development of its products and add value for shareholders, PharmAust executed an Option to License Agreement with Elanco during 2018. The Agreement between PharmAust and Elanco supersedes the Research and Option Agreement signed with Novartis Animal Health, which prevailed since 2012. In the period 2018-2019 financial year, PharmAust has worked closely with Elanco to prepare the ground for the undertaking of a key Phase II trial in canines with cancer. Successful completion of this trial is a key aspect of the Option Agreement with Elanco.

Achievements during the financial year include:

1. The receipt of 25 kg of GMP grade monepantel from Elanco Animal Health Inc in accordance with the Option Agreement, announced on the 18th of April 2018 to support the clinical trial program and to support a series of Phase I studies on pharmacokinetics, safety and palatability of MPL,
2. The execution of a Data and Regulatory Rights Agreement with Elanco US Inc to facilitate the development of monepantel as an anticancer therapeutic in dogs. Under this agreement, Elanco has permitted PharmAust to reference certain Elanco controlled safety and blood chemistry data that were generated for the regulatory approval of monepantel in Australia, New Zealand and 27 countries within the European Union, as an anti-parasitic drug in livestock animals. Given that livestock animals are destined for human consumption, data and documentation generated for this purpose are required to be extremely comprehensive, adhering to a very high level of precision and detail.
3. The completion of preclinical studies to reformulate monepantel (MPL) into a tablet. This work was conducted in collaboration with BRI Biopharmaceutical Research Inc., Vancouver, Canada. The new tablet will be taken into trials in canines with cancer and PharmAust expects this new tablet to also be taken into trials in humans with cancer as well as neurological diseases,
4. The completion of several optimisation steps resulting in the successful scale up manufacture of PharmAust’s new monepantel tablets from Good Laboratory Practice (GLP) to Good Manufacturing Practice (GMP) standards.
 - a. In collaboration with BRI Pharmaceutical Research, PharmAust showed that micronisation of monepantel successfully meets the company’s minimal requirements for dosing and oral bioavailability,
 - b. In collaboration with BRI Pharmaceutical Research and Catalent Pharma Solutions in San Diego, USA., PharmAust also successfully completed its monepantel taste masking program in healthy beagle dogs, eradicating the poor taste associated with the previous liquid formula,
 - c. In collaboration with BRI Pharmaceutical Research and Catalent Pharma Solutions in San Diego, USA., PharmAust demonstrated specific dietary requirements for uptake of monepantel into the blood,
 - d. In collaboration with Catalent San Diego Inc, USA, both GLP and GMP-grade monepantel tablets suitable for use in the upcoming trials in pet owner’s dogs with cancer were successfully manufactured to scale in sufficient numbers for both its Phase I and Phase II trials in dogs. Catalent is a #1 pharma/biotech contract provider in the US for scaled GMP tablet formulation in preparation for clinical trials.
5. The signing of an Agreement with a major US CRO to conduct Phase I Trials in healthy beagle dogs using the tablets manufactured by Catalent. These trials enabled determination of tablet dosing requirements to reach anticipated anticancer levels of monepantel in the blood, as well as confirming the very high safety profile of monepantel at these levels.
6. The completion of development of an independent prototype GMP method applicable for the scale up of the drug monepantel itself as well as PharmAust’s library of monepantel analogues

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and for use in clinical trials as next generation products. This work was conducted in collaboration with Syngene International Ltd

7. The demonstration of anticancer activity of monepantel's major metabolite monepantel sulfone against cancer types treated in PharmAust's earlier Phase I/II clinical trial in humans. This work was conducted in collaboration with the Olivia Newton-John Cancer Research Institute where work on the mechanism of action of monepantel at the molecular level has continued.
8. The successful accreditation of PharmAust as an Animal Research Authority for conducting clinical trials in dogs with cancer.

Research and Development Targets 2019-2020:

1. To execute an agreement with Elanco Inc. which provides PharmAust with the freedom to evaluate and develop an anticancer product based on MPL for the treatment of human cancers. PharmAust has commenced discussions with Elanco as regards permission to commercially develop a human cancer product based on MPL. It should be noted that Novartis/Elanco patents on MPL begin to expire in 2023, following such expiration the PharmAust patents would have Freedom to Operate.
2. To identify Clinical Centers prepared to evaluate the new MPL tablet in humans in Phase I/II trials, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015. Furthermore, to determine the pharmacokinetic parameters, dietary enhancements and safety of the newly formulated tablet in humans in Phase I/II trials,
3. To undertake a "First Line Therapy" clinical trial, mutually agreed upon with Elanco, in canines with naturally occurring cancer to determine the safety and value of MPL as a cancer therapy. The outcome of this trial will be an important milestone in developing the future collaboration and Licence with Elanco.

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.

During the year, 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

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internationally and elevates Epichem's status, global market access and competitiveness in a growing world market.

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 FY20.

On 8 November 2018, Epichem hosted the official opening of its laboratory expansion, following the earlier move to its new facility in September 2015. It is an honour to have the Hon. Ben Wyatt MLA, the Treasurer of Western Australia, and Professors Robert Stick and Dieter Wege, whose names the laboratories carry, at the event.

During the year, Epichem was awarded an extension to its contract with a leading Californian biotechnology company, Unity Biotechnology, Inc. Epichem was also awarded another one year extension to its current contract with Drugs for Neglected Diseases initiative (DNDi), extending that relationship to 11 years. The contract, which will see Epichem continue to provide synthetic & medicinal chemistry support to DNDi's drug discovery projects and will generate \$1.24M in revenues in the 2019 calendar year.

During the year, PharmAust announced that Epichem had paid off its debt liability on time for a major state-of-the-art laboratory purpose built in 2015 and expanded in 2018. Epichem's revenues have made a significant upturn over the period 2015 to 2019, increasing 74% to \$3.8 million in FY19. Budgeted revenues for FY20 are \$4.2 million (subject to continuation of existing contracts). With the loan facility repaid the money saved on interest and principal will go straight to improving the bottom line.

PHARMAUST LTD – PARENT ENTITY

Annual General Meeting

The Annual General Meeting of the Shareholders of PharmAust Limited was held on 9 November 2018 at RSM on Level 32, 2 The Esplanade, Perth, Western Australia. All resolutions that were put were unanimously passed on a show of hands.

Pro-Rata Non-Renounceable Rights Offer

As announced on 18 February 2019, PharmAust sought to raise up to approximately \$2 million by a pro-rata non-renounceable rights offer of up to approximately 80 million shares on the basis of 2 new shares for every 5 shares held at an issue price of 2.5 cents per New Share. The Company lodged an offer document for the Offer with the ASX on 26 February 2019.

The Company received subscriptions for approximately 52 million shares raising \$1.3 million. All Directors took up their Rights Issue entitlements in full, investing \$192,584.83 into the Company.

Shortfall Placement Oversubscribed

On 11 April 2019, the Company advised that the shortfall from the entitlement offer had been successfully placed through the lead manager to the issue, Alto Capital Pty Ltd, raising additional gross proceeds of approximately \$700,000. The shortfall placement was heavily oversubscribed. The shortfall placement comprised approximately 28 million shares at 2.5 cents per share. The proceeds from the placement and entitlement offer totalled \$2 million, before costs.

PharmAust receives \$672k Research and Development Tax Incentive Refund

During the year, PharmAust was pleased to confirm the receipt of a Research and Development (R&D) Tax Incentive refund of \$672,250 for the 2017/2018 financial year.

The refund relates to the eligible expenditure on the company's lead molecule, monepantel, which has been undergoing further evaluation in clinical trial in dogs and which is currently being reformulated for expanded clinical development in humans and companion animals.

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The R&D Tax Incentive scheme is a programme jointly administered by the Australian Taxation Office and AusIndustry, under which companies can receive up to a 43.5% refundable tax offset of eligible expenses on research and development activities.

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 2019.

Attachments forming part of the Appendix 4E:

Preliminary Financial Report of PharmAust Limited for the year ended 30 June 2019 is attached.

Signed By



Sam Wright
Director & Company Secretary
30 August 2019

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PharmAust Limited
Preliminary Statement of Comprehensive Income
For the year ended 30 June 2019

	CONSOLIDATED	
	2019	2018
	\$	\$
Revenue	3,670,457	2,871,345
Other income	694,097	424,559
	4,364,554	3,295,904
Raw materials and consumables used	(333,632)	(289,318)
Employee benefits expense	(2,979,374)	(3,561,963)
Depreciation expense	(172,430)	(118,605)
Finance costs	(47,822)	(28,352)
Research and development expenses	(1,039,136)	(463,875)
Administration expenses	(1,409,201)	(1,355,470)
	(1,617,041)	(2,521,679)
(Loss) before income tax expense		
Income tax expense	-	-
	(1,617,041)	(2,521,679)
(Loss) after income tax expense		
Other comprehensive income	-	-
	(1,617,041)	(2,521,679)
Total comprehensive (loss) for the year		
	(1,617,041)	(2,521,679)
Basic and diluted loss per share (cents per share)	(0.74)	(1.72)

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

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PharmAust Limited
Preliminary Statement of Financial Position
as at 30 June 2019

	CONSOLIDATED	
	2019	2018
	\$	\$
CURRENT ASSETS		
Cash and cash equivalents	2,090,625	1,875,431
Trade and other receivables	258,842	248,353
Other current assets	58,509	58,568
Inventory	611,816	574,015
TOTAL CURRENT ASSETS	<u>3,019,792</u>	<u>2,756,367</u>
NON-CURRENT ASSETS		
Intangible assets	3,107,476	3,107,476
Plant and equipment	2,468,449	2,494,154
TOTAL NON-CURRENT ASSETS	<u>5,575,925</u>	<u>5,601,630</u>
TOTAL ASSETS	<u>8,595,717</u>	<u>8,357,997</u>
CURRENT LIABILITIES		
Trade and other payables	738,839	616,825
Borrowings	143,384	424,634
Provisions	105,601	151,708
TOTAL CURRENT LIABILITIES	<u>987,824</u>	<u>1,193,167</u>
NON-CURRENT LIABILITIES		
Borrowings	181,230	1,007
Provisions	36,601	25,605
TOTAL NON-CURRENT LIABILITIES	<u>217,831</u>	<u>26,612</u>
TOTAL LIABILITIES	<u>1,205,656</u>	<u>1,219,779</u>
NET ASSETS	<u>7,390,061</u>	<u>7,138,218</u>
EQUITY		
Issued capital	51,388,306	49,371,354
Reserves	1,907,392	2,055,460
Accumulated losses	(45,905,637)	(44,288,596)
TOTAL EQUITY	<u>7,390,061</u>	<u>7,138,218</u>

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

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PharmAust Limited
Preliminary Statement of Changes in Equity
for the year ended 30 June 2019

	Issued Capital \$	Accumulated Losses \$	Options Reserve \$	Total Equity \$
As at 1 July 2017	47,604,668	(41,766,917)	1,077,296	6,915,047
Loss for the year	-	(2,521,679)	-	(2,521,679)
Total comprehensive (loss) for the year	-	(2,521,679)	-	(2,521,679)
Shares issued (net)	1,766,686	-	-	1,766,686
Share based payment	-	-	978,164	978,164
As at 30 June 2018	49,371,354	(44,288,596)	2,055,460	7,138,218
As at 1 July 2018	49,371,354	(44,288,596)	2,055,460	7,138,218
Loss for the year	-	(1,617,041)	-	(1,617,041)
Total comprehensive (loss) for the year	-	(1,617,041)	-	(1,617,041)
Shares issued (net)	2,016,952	-	-	2,016,952
Conversion of performance rights	-	-	(148,068)	(148,068)
As at 30 June 2019	51,388,306	(45,905,637)	1,907,392	7,390,061

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

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PharmAust Limited
Preliminary Statement of Cash Flows
for the year ended 30 June 2019

	NOTE	CONSOLIDATED	
		2019	2018
		\$	\$
Cash Flows From Operating Activities			
Receipts from customers		3,659,968	2,845,179
Payments to suppliers and employees		(5,860,249)	(4,792,183)
Other income		676,299	387,656
Interest received		17,798	36,903
Interest and other costs of finance		(47,822)	(28,352)
Net cash used in operating activities	19b	<u>(1,554,006)</u>	<u>(1,550,797)</u>
Cash Flows From Investing Activities			
Payments for plant and equipment		(146,725)	(868,929)
Net cash used in investing activities		<u>(146,725)</u>	<u>(868,929)</u>
Cash Flows From Financing Activities			
Proceeds from share issues (net)		2,016,952	1,766,686
Proceeds/(Repayment) of borrowing (net)		(101,027)	(61,859)
Net cash provided by financing activities		<u>1,915,925</u>	<u>1,704,827</u>
Net increase/(decrease) in cash held		215,194	(714,899)
Cash at the beginning of the financial year		<u>1,875,431</u>	<u>2,590,330</u>
Cash at the end of the financial year	19a	<u><u>2,090,625</u></u>	<u><u>1,875,431</u></u>

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

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Notes to the preliminary financial statements
for the financial year ended 30 June 2019

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.

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

i) Segment Performance

Consolidated

2019	Corporate \$	Pharmaceutical \$	Total \$
Revenue			
External sales	-	3,671,633	3,671,633
Other external revenue	653,257	39,664	692,921
Inter-segment revenue	-	-	-
Total segment revenue	653,257	3,711,297	4,364,554
Inter-segment elimination			-
Total revenue per statement of comprehensive income			4,364,554
Results			
Segment result from continuing operations before tax	(1,936,221)	319,180	(1,617,041)

Consolidated

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

Note 3. Contingent Assets

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

Note 4. Contingent Liabilities

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

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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: Epicchem Pty Ltd	Australia	Ordinary	100	100
Pitney Pharmaceuticals Pty Ltd	Australia	Ordinary	100	100

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