



**PharmAust**  
L I M I T E D

# APPENDIX 4C AND QUARTERLY UPDATE

30 JANUARY 2023

**ASX: PAA**

ACN 094 006 023





# HIGHLIGHTS

- PharmAust has successfully completed dosing of the first cohort of six MND patients
- Monepantel (MPL) tablets have been well tolerated at the first dosing level
- All of the patients in cohort 1 have elected to continue on MPL
- \$173k received from FightMND
- \$654k was deemed refundable by the ATO under the R&D tax incentive
- Additional MPL being manufactured for future human and canine clinical trials
- Phase 2 trial continues in canines with B-cell lymphoma in Australia, New Zealand and USA
- Two dogs have had a partial response (>30% decrease in cancer tumour) and eight others have enjoyed a stable disease response
- PharmAust in confidential discussions with potential licensing partners for canine cancer
- Epichem growth on Net Profit was realised at 71% higher than for the same quarter 2021
- 31 December 2022 bank balance of approximately \$2.07 million, enabling pursuit of various preclinical and clinical commitments

# PHASE I/II MND TRIAL

PharmAust previously announced it has received a funding commitment of A\$881,085 for a Phase I/II trial examining the effects of Monepantel (MPL) in Motor Neurone Disease (MND), otherwise known as Lou Gehrig's disease or Amyotrophic Lateral Sclerosis (ALS).

These funds have been granted by FightMND, the largest independent funder of MND research in Australia. The trial is being overseen by Principal Investigator, Dr Susan Mathers of Calvary Health Care, Bethlehem, Melbourne and includes a second trial site headed by Professor Dominic Rowe of the Centre for Motor Neurone Disease Research Faculty of Medicine and Health Research at Macquarie University in Sydney.

The trial has successfully completed treatment the first cohort of six patients. Importantly, all of the patients in treatment level 1 have elected to continue on MPL treatment.

The MPL tablets have been well tolerated by patients in the first cohort of the trial and the Safety Monitoring Committee will review data from each Dosage Level for continued safety and pharmacokinetic data up to cycle.

Patient recruitment at the next dosing level of MPL is underway and progressive cohorts will receive escalating oral treatment doses of MPL tablets.

The ALS/MND addressable market is US\$3.6Bn globally with Riluzole already reaching ~US\$1Bn in annual sales. According to the International Alliance of ALS/MND Associations, MND affects over 350,000 of the world's population and kills more than 100,000 people every year.

Pre-clinical studies in MND models support the evaluation of MPL in slowing disease progression by clearing harmful materials in a motor neurone that adhere and impair functioning.

With success in the clinic, PharmAust expects that in due course MPL could receive orphan drug designation by the FDA for the indication of motor neurone disease. Such designations come with a number of financial and supportive benefits. The US Orphan Drug Act provides for granting special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor.





# PHASE II CANINE CANCER TRIALS

Veterinary trial centres have been set up in Australia, New Zealand and the United States to evaluate the anti- cancer benefit of MPL in dogs diagnosed with B-cell lymphoma and which have not received any treatment for the lymphoma.

PharmAust is recruiting pet dogs with untreated B cell lymphoma to finalise the Phase 2 evaluation of the drug MPL, which has successfully demonstrated statistically effective anti-cancer activity in the Phase 2 trial.

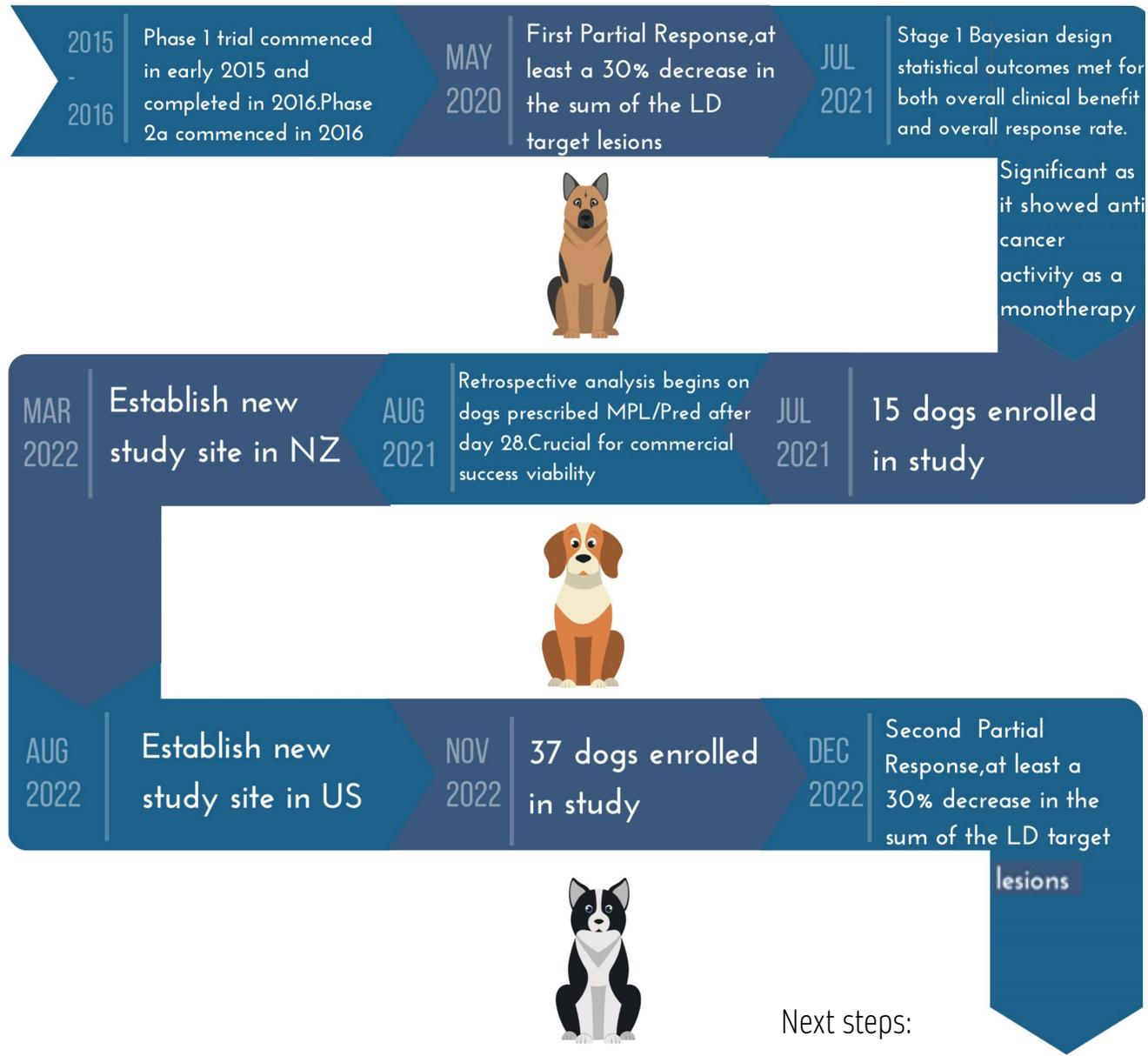
Thirty three dogs have been treated using MPL monotherapy so far (excluding the 5 dogs removed from the study) . With continued positive outcomes, PharmAust is preparing for a successful Phase 2 completion and the commencement of a subsequent Phase 3 registration trial.

**Two dogs have had a partial response** as assessed by the administering veterinarians. **Partial response is a decrease in tumour size (sum of longest diameter as defined by RECIST criteria) of >30%, no new lesions.**

Side effects were minimal or not detected. In comparison, the most common side effects of a dog being treated with chemotherapy include gastrointestinal effects (vomiting, diarrhea or loss of appetite) and decreases in blood cell counts. Also, during chemotherapy, owners need to take precautions when handling their pets and their waste. Drugs may be excreted in the urine and faeces, so pregnant women and children should not be assigned the duty to clean up urine and faeces for the duration of therapy.

PharmAust requires greater than or equal to 18 dogs with an overall clinical benefit out of 46 dogs to meet its statistical endpoint.

PharmAust is pleased to provide a video recording of the fireside chat with Anusha Aubert and Dr Kim Agnew providing a further update on the canine trials - <https://www.pharmaust.com/fireside-chat-with-dr-kim/>



# PET DOG PHASE 2 TRIAL: TREATMENT NAÏVE B CELL LYMPHOMA

CURRENT STATUS OF ENTIRE STUDY ENROLLED DOGS (DAY 28 EVALUATION)

REQUIRE 8 OF A FURTHER 22 DOGS WITH SD AT D28 TO MEET BAYESIAN OUTCOMES FOR SUCCESSFUL PHASE 2 TRIAL

Study metric	# Dogs	#Dogs SD (Stable Disease)		#Dogs PD (Progressive Disease)	#Dogs (Plasma analysis)	#Dogs (On study)
		#Dogs PR (Partial Response)	#Dogs SD (Stable Disease)			
Fully completed	24	2	8	14		
Partially completed*	4				4	
On study**	2					2
<b>Total # dogs</b>	<b>30</b>	<b>10</b>		<b>14</b>	<b>4</b>	<b>2</b>

\*4 dogs partially completed and awaiting plasma analysis to confirm RECIST outcome.  
 \* 4 partially completed dogs are counted as recruits  
 \*\*2 dog on trial

**RECIST DEFINITIONS**

PR = > 30% tumour reduction  
 SD = <30 % tumour reduction and not >20% tumour increase

**Dogs not included**

4 dogs removed from the study due to lack of compliance with tablet administration instructions  
 5 dogs with plasma MPLS < target level (5 uM)  
 1 dog removed from study due to death on Day 4

# CANINE TREATMENT NAÏVE B CELL LYMPHOMA SUMMARY POINTS

- In dogs treated with Monepantel/Prednisolone as ongoing therapy after Monepantel alone, PD outcomes at D28 do NOT appear to be associated with poorer clinical outcomes and/or shorter (OST - Overall Survival Times) over the life of the dog
- No matter the treatment protocol, most dogs with Lymphoma will die from Lymphoma
- Stabilisation (as opposed to regression) of lymphoma with good Quality of Life (QoL) is an excellent and recognised outcome accommodating treatments with MPL alone or in conjunction with prednisolone

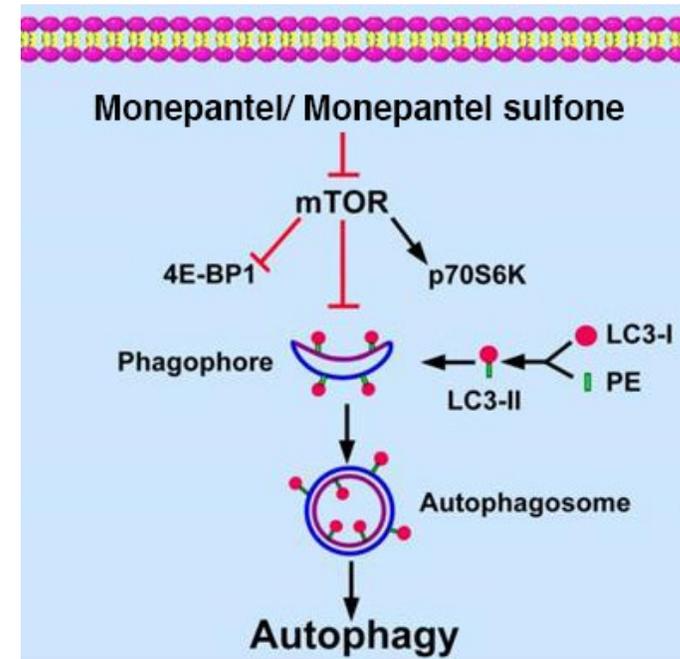
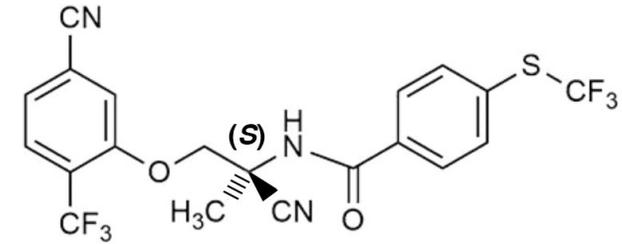


MPL trial participant

## PHASE II HUMAN CANCER TRIAL

Further to the responses and outcomes in canines, PharmAust continues to take key steps towards progressing the evaluation of MPL in human trials. Clinical interest has focused on leukaemia, glioblastoma, oesophageal, gastrointestinal, ovarian and pancreatic cancers.

PharmAust has identified a Principal Investigator in the United States to evaluate the new MPL tablet in human Phase 2 cancer trials, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015 and pharmacokinetic data for tablets in humans currently being produced in the MND trial.



## COVID-19 TESTING

PharmAust previously demonstrated MPL's antiviral activity in two independent laboratories in Australia and another in Europe.

PharmAust has identified Ergomed Clinical Research, a subsidiary of the London Stock Exchange listed Ergomed plc (LON: ERGO) to be the contract research organisation (CRO) for the COVID-19 clinical trials.

Importantly, PharmAust is relying on the MND trial to provide the important Phase 1 pharmacokinetic (PK) data for future human trials in MND, cancer and COVID-19.

This will allow PharmAust to undertake a Phase 2 trial in COVID-19, rather than a Phase 1 study, which will facilitate faster recruitment as the company has been advised by the CRO that COVID-19 infected patients generally prefer participating in a Phase 2 study.



# ELANCO'S PATENTS



The composition of matter patent for MPL held by Elanco is set to expire in November 2024 in all territories excluding the US where Elanco's rights can continue until October 2025.

PharmAust plans to undertake human trials for MND, Cancer and COVID during 2023 and, if successful in one or all of these indications, the Company will seek a licence from Elanco to commercialise MPL in humans. However, in view of the key Elanco patents expiry dates, the Board believes that a licence may not be required for Cancer and COVID 19 and MND but phase 2 and phase 3 trials will still need to be undertaken in likelihood with a partner.

Assuming the Phase 3 registration trial in canine cancer is successful, PharmAust will need to lodge a registration dossier with relevant territories.

PharmAust considers that its current and future activities would not represent an infringement of any patent's in force covering MPL (and that a licence would therefore not be required) on the basis that they would be covered by experimental use exemptions and/or exemptions to infringement provided for uses of an invention which are solely for purposes connected with obtaining regulatory approval.

# EPICHEM PTY LTD - 100% OWNED SUBSIDIARY

Building on the already very strong Qtr 1 FY23 performance, all Epichem service departments have shown additional growth to finish Qtr 2 FY23 very well. All teams have been committed to revenue raising projects throughout and once again have met all required timelines and positive customer responses. This would normally mean little to no growth because everyone is at capacity, however the business has been able to demonstrate growth. In addition, growth on Net Profit was realised at 71% higher than for the same quarter in CY 2021.

Noteworthy are increases in Custom Standards (>400%); Analytical Chemistry (300%) (note both of these are off a small base) Consultancy and Investigations (83%). This growth in these areas demonstrates the value of diversification in the business offerings and places less reliance by the business on the big Medicinal Chemistry contracts. As has been mentioned contracts will come and go. That said, preliminary feedback at the closure of the Chevron project holds promise. As well, strong client engagement discussions, especially in the Medicinal Chemistry arm show promise to mitigate the change felt in the DNDi contract changes.

Completion of the Shell/NERA project with OHD has left the report with Shell for consideration of next steps. Once Epichem is in a position to share more, an announcement will follow.

Operational reviews have taken place in this Qtr as well, which includes assessment of fee structures, operational costs etc to be more commensurate with supplier and stakeholder pricing changes etc and ensure continued viability for the business.



# COMMUNICATION

In October 2022, the Company appointed Anusha Aubert, an experienced pharmaceutical sales and marketing professional, as Epichem BDM & PharmAust investor relations.

Ms Aubert will develop and action a tailored and dynamic Business Development/Sales/Marketing strategy and plan to achieve Business Development, revenue and profit growth in line with both the Epichem Pty Ltd and the PharmAust Ltd strategic objectives. She will also be responsible for investor relations, digital communications, social media marketing, producing and distributing investor focused videos and preparing online targeted investor advertising as well as other initiatives as they emerge.

In the last five years, Anusha has held sales and marketing roles in global pharmaceutical companies, Novartis and Mundipharma. Anusha is a qualified Analytical Chemist, having worked in both WA and SA in predominantly oil and gas executing both analytical and business development roles.

Since Anusha's appointment, PharmAust has substantially increased its engagement with existing shareholders and potential investors. The Company attended Australia's largest Life Sciences Conference, AusBiotech 2022 and has held live webinars on the MND trial and Epichem as well as a number of recorded podcasts and video Q&A interviews which are available on the PharmAust website. Dr Aston will attend Animal Health, Nutrition and Technology Innovation Europe to be held in March 2023 in London.

The first in a series of "Fireside Chats" was recorded during the Quarter between Anusha and the Principal Investigator of the MPL Canine Trial, Dr Kim Agnew. PharmAust looks forward to providing further Fireside Chats.

To further improve dialogue between shareholders and the Company, we will be using a new email address for your communication. Emails can be sent to: [investorenquiries@pharmaust.com](mailto:investorenquiries@pharmaust.com)





# APPENDIX 4C QUARTERLY CASH FLOW REPORT

PharmAust's cash position at 31 December 2022 was \$2.07 million with total available funding for future operating activities of \$2.3m. The company is adequately funded to continue its current activities and will continue to demonstrate appropriate fiscal management.

During the quarter, payments for Research and Development of \$0.220 million represented costs involved with the development of the Company's primary drug candidate, Monepantel (MPL).

Payments for Product Manufacturing and Operating Costs represent wholly owned subsidiary Epichem Pty Ltd's expenditure allocated to manufacturing and operating.

Payments for Staff Costs represent salaries for laboratory, administration, sales and general management.

Payments for Administration and Corporate Costs represent general costs associated with running the Company, including ASX fees, share registry, legal fees, rent, etc.

The aggregate amount of payments to related parties and their associates included in the current quarter Cash flows from operating activities were \$0.148 million comprising Directors' fees, salaries and superannuation.

Cash outflows for the quarter were in line with management expectations. The cash balance at 31 December 2022 was \$2.07 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter.



THIS ANNOUNCEMENT IS AUTHORISED BY THE BOARD

ENQUIRIES:

ANUSHA AUBERT, INVESTOR RELATIONS

[INVESTORENQUIRIES@PHARMAUST.COM](mailto:INVESTORENQUIRIES@PHARMAUST.COM)

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

PharmAust Limited

**ABN**

35 094 006 023

**Quarter ended ("current quarter")**

December 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	798	1,878
1.2 Payments for		
(a) research and development	(220)	(475)
(b) product manufacturing and operating costs	(242)	(614)
(c) advertising and marketing	(29)	(72)
(d) leased assets	(34)	(67)
(e) staff costs	(519)	(1,248)
(f) administration and corporate costs	(96)	(311)
1.3 Dividends received (see note 3)		
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives	681	681
1.8 Other (GST)	62	96
<b>1.9 Net cash from / (used in) operating activities</b>	<b>402</b>	<b>(131)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		
(d) investments		
(e) intellectual property		
(f) other non-current assets		

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
2.2 Proceeds from disposal of:		
(a) entities		
(b) businesses		
(c) property, plant and equipment		
(d) investments		
(e) intellectual property		
(f) 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)		
<b>2.6 Net cash from / (used in) investing activities</b>		

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2 Proceeds from issue of convertible debt securities		
3.3 Proceeds from exercise of options		
3.4 Transaction costs related to issues of equity securities or convertible debt securities		
3.5 Proceeds from borrowings		
3.6 Repayment of borrowings	(220)	(223)
3.7 Transaction costs related to loans and borrowings		
3.8 Dividends paid		
3.9 Other (provide details if material)		
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(220)</b>	<b>(223)</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	1,891	2,427
4.2 Net cash from / (used in) operating activities (item 1.9 above)	402	(131)
4.3 Net cash from / (used in) investing activities (item 2.6 above)		

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(220)	(223)
4.5	Effect of movement in exchange rates on cash held		
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>2,073</b>	<b>2,073</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	1,064	1,979
5.2	Call deposits	1,009	12
5.3	Bank overdrafts		
5.4	Other (provide details)		
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,073</b>	<b>1,891</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	148
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

Director's Salaries & Superannuation

## Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities		
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 <b>Total financing facilities</b>		
7.5 <b>Unused financing facilities available at quarter end</b>		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	402
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,073
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	2,073
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	N/A
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

## 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.

30 January 2023

Date: .....

By the board

Authorised by: .....  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.