

Appendix 4C and Quarterly Update

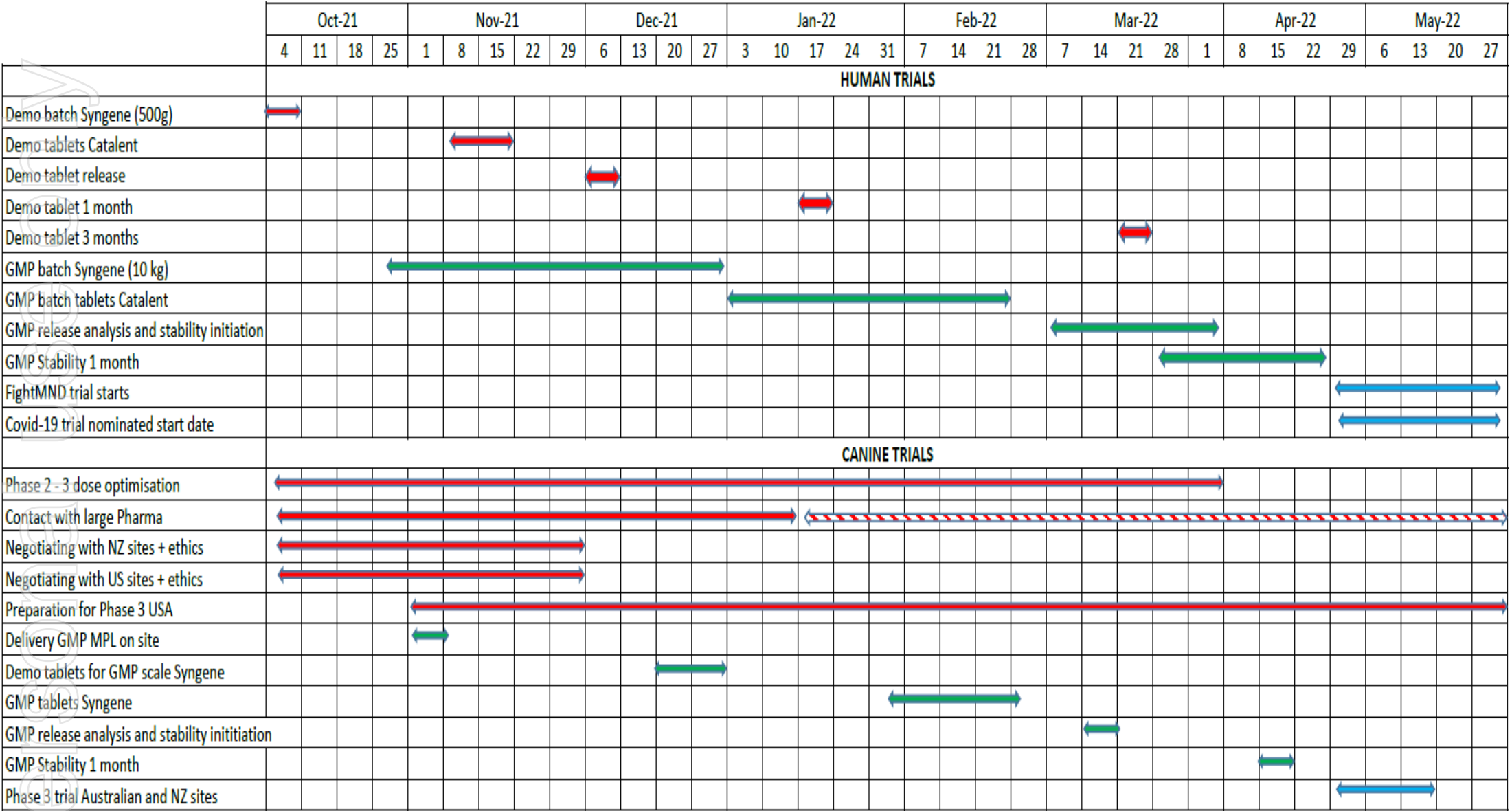
29 October 2021 – Perth, Australia: PharmAust Limited (ASX: PAA), a clinical stage biotechnology company, is pleased to present its Appendix 4C and Quarterly Update for the period ended 30 September 2021.

HIGHLIGHTS:

- Success in Phase 2 Trial in pet dogs with B cell lymphoma
- PharmAust identifies optimum MPL drug plasma range for treatment of dogs
- Phase 2 trial indicates the combination of MPL + prednisolone more than doubling life expectancy of dogs compared with standard-of-care
- PharmAust will seek input for the phase 3 trial from potential licensing partners
- Syngene has commenced manufacture of GMP-Grade Monepantel for Human Clinical Trials
- Three individual laboratories demonstrate MPL and MPLS protect against cell death in vitro following infection with SARS-CoV2
- PharmAust is in mature negotiations with a European CRO to identify trial sites for a Phase 1 trial in human patients to treat COVID-19
- PharmAust and WEHI investigating MPL in HTLV-1 viral infections
- PharmAust files patent for monepantel in viral diseases
- Epichem completes final loan repayment of laboratory
- Epichem completes build of a benchtop flow reactor to showcase its OHD Technology
- PharmAust rewards Shareholders with an attractively priced options offer
- Bank balance of approximately \$2.5 million, enabling pursuit of various preclinical and clinical commitments



CURRENT ESTIMATED ACTIVITY TIMELINE:



Phase II Canine Cancer Trial

During Phase 2a and Phase 2b studies, MPL demonstrated effective anti-cancer activity which supports continued development into Phase 3.

PharmAust has determined an optimum drug plasma range for anticancer activity and minimal side effects.

Of the seven pet dogs treated with drug plasma levels of MPL in the optimum range, six achieved stable disease and one had a partial response (60% regression), with some tumours completely disappearing, as assessed by the administering veterinarians. Side effects were minimal or not detected.

Of the six pet dogs that achieved stable disease, five continued to take MPL in combination with prednisolone after the trial ended. To date, these five dogs have achieved much higher than expected mean and median survival times, of 125 and 138 days respectively. This 138 day median survival compares favourably with a recently reported 60 day median survival for similar pet dogs treated only with standard-of-care prednisolone.

All pet dog owners reported very high quality of life for their pet dogs while taking MPL. A testimonial page has been added to the PAA website.

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 pet's waste. Drugs may be excreted in the urine and faeces, so it is not advisable for children to play with their pets.

Discussions have commenced for FDA registration and GCP implementation.

PharmAust is in confidential exploratory discussions with leading global pharmaceutical companies to co-develop and commercialise MPL for the treatment of veterinary cancers.

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 glioblastoma, esophageal, gastrointestinal and pancreatic cancer.

PharmAust has identified Principal Investigators in Italy and the United Kingdom to evaluate the new MPL tablet in humans in Phase 2 trials, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015. PharmAust will continue to look for further sites to broaden recruitment possibilities.

Commencement of a human cancer Phase II trial is expected in Q3/4 CY 2022.

COVID-19 Testing

In collaboration with three independent laboratories, PharmAust has investigated the capacity of MPL and MPLS *in vitro* to inhibit:

- i) SARS-CoV2-induced cell death,
- ii) SARS-CoV2 RNA release from the cell, and
- iii) SARS-CoV2 RNA infection of neighbouring cells.

All three laboratories demonstrated that both MPL and MPLS protect against cell death *in vitro* following infection with SARS-CoV2. Furthermore, two laboratories investigated the effects of MPL and MPLS upon the early stages of the SARS-CoV2 virus lifecycle by examining RNA release into the culture media.

PharmAust has been actively engaging with Contract Research Organisations ("CRO") in Australia, Thailand, the United Kingdom, United States as well as Eastern and Caucasus countries and The Balkans for the evaluation of MPL in a Phase I trial in human patients to treat COVID-19.

PharmAust is in mature negotiations with a European CRO to identify trial sites for testing MPL in people infected with the virus causing COVID-19.

HTLV-1 Testing

During the Quarter, PharmAust executed a Research Services Agreement with the Walter and Eliza Hall Institute (WEHI), Melbourne to investigate the effects of monepantel (MPL) upon human T-lymphotrophic virus-1 (HTLV-1) infections *in vitro*.

This work follows upon PharmAust's COVID-19 program, aiming to further understand the anti-viral activity of MPL and to broaden the scope of targets for MPL's use. The study of HTLV-1 is of particular significance due to the readily available nature of highly and particularly relevant *in vitro* and *in vivo* preclinical virus infection models, potentially providing PharmAust with further data to support future human trials.

Like the COVID-19 work, the HTLV-1 work will be conducted at WEHI by a group led by Professor Marc Pellegrini. Work will commence upon cell lines in culture. Dependent upon outcomes and subsequent agreement, the group aims to then move to *in vivo* preclinical models. The fee payable under the agreement is not material to the company. Preliminary data are anticipated in December 2021.

Phase I/II Human Trial in Motor Neurone Disease

PharmAust previously announced it has received a funding commitment of A\$881,085 for a Phase I 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 will be overseen by Dr Susan Mathers of Calvary Health Care, Bethlehem, Melbourne and will include 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.

With success in the clinic, PharmAust expects that in due course MPL will 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 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.

PharmAust is in final negotiations with organisations that will provide the necessary MND trial services: clinical oversight, regulatory oversight, monitoring, pharmacokinetic analysis and pharmacodynamic analysis.

PharmAust has not received any funding from FightMND as yet. The first instalment of \$201,615 is due to be received after GMP manufacture of MPL for this trial has been completed.

Manufacturing of GMP-grade MPL Active Pharmaceutical Ingredient and GMP-grade MPL tablets

PharmAust previously announced the commencement of production of two batches of 10kg each of GMP-grade MPL for research and development (R&D) purposes and clinical trials in humans. The GMP-grade MPL compound is being manufactured in collaboration with Syngene International Ltd., an integrated research, development and manufacturing services company and Catalent Pharma Solutions (NYSE: CTLT) will perform scaled-up manufacture of GMP-grade monepantel tablets suitable for use in the upcoming human trials.

PharmAust can report that the 500g demonstration batch of MPL generated demonstrates a greater purity profile than the previous GMP batches used in the Phase 1 trial in humans and the Phase 2a and 2b trials in pet dogs with B cell lymphoma. The demonstration batch has now arrived in the US for the preparation of the new smaller tablet design for use in the MND and COVID-19 trials in humans.

Success in the manufacture of this demonstration batch means that PharmAust is now in the process of scaling up a GMP batch ready for the FightMND and COVID-19 trials to commence around April 2022.

Syngene has requested an extra three to four weeks for delivery of GMP monepantel due to technical challenges related to the more than 150 chemical reactions that must be carried out in sequential order, and with the GMP reporting overlays required sequentially for each step. Getting this correct is important because for any reported deviation, investigations must occur meaning the program may then be set back several months for just one deviation. PharmAust is still negotiating a tablet manufacturing booking adjustment. PharmAust will report how this might impact the start date for the FightMND clinical trial when rescheduled tablet manufacturing dates have been confirmed. Tentatively rescheduling may be completed by November 5.

Epichem Completes Final Loan Repayment

During the Quarter, Epichem paid off its debt liability on time for a major laboratory expansion in Technology Park, Western Australia.

This is the final milestone in repaying two EFA loans for construction of the two purpose-built, state of the art laboratories at Technology Park in 2015 and 2018. With the loan facility repaid the money saved on interest and principal will go straight to improving the bottom line. The new laboratories have provided jobs for an additional 20 employees making Epichem one of Australia's top employers of PhD educated individuals in the medical science and technology SME sector.

Epichem's CEO, Colin La Galia stated; "Epichem's ability to repay the loan without deferral over six years demonstrates the strength of this specialist business. We thank EFA for its support which has enabled us to grow and export services to over 40 countries."

Waste To Fuels Technology

During the Quarter, Epichem completed building its benchtop Oxidative Hydrothermal Dissolution (OHD) Flow Reactor to research, develop and promote a novel, innovative and disruptive waste to fuels technology.

The flow reactor is located at Epichem's purpose-built state of the art laboratory at Technology Park in Bentley, Western Australia.

Epichem is in discussions with several mining and fertiliser stakeholders regarding the use of its OHD Technology.

Epichem will continue to seek government support and project grant funding to accelerate the initiative

PR & Marketing

During July, Chief Scientific Officer, Dr Richard Mollard presented at the Australian and New Zealand College of Veterinary Scientists (ANZCVS) Annual Scientific Conference, "Science Week".

PharmAust held a Virtual Investor Briefing on Thursday 12 August 2021. Executive Chairman, Dr Roger Aston provided a brief update on the status of the development of MPL including discussion on the various initiatives including Phase III Canine Cancer Trial, Phase II Human Cancer Trial, Phase I Human COVID-19 Trial, Phase I/II Human Trial in Motor Neurone Disease, manufacture of GMP grade MPL and other activities. Epichem CEO, Colin La Galia provided an update on wholly owned subsidiary Epichem Pty Ltd including the status on the exciting biofuels and fine chemicals proprietary project. Chief Scientific Officer, Dr Richard Mollard and all PharmAust directors were on the call taking questions.

Epichem's OHD technology was featured on Chanel 7 news on Monday 16 August and Epichem's Chemistry capability showcased on GWN 7 News on July 6.

Dr Richard Mollard presented as part of the Broker Briefing Tech & Biotech Investor Webinar on Thursday 9 September 2021.

Colin La Galia was interviewed to a captive audience on the primetime morning show on CNBC Asia/Pacific. CNBC is the recognized world leader in business news and provides real-time financial market coverage and business content consumed by more than 355 million people per month across all platforms.

Loyalty Options

In recognition of the support of shareholders, the directors of PharmAust are conducting a rights offer on the basis of 1 option for every 4 shares held at an issue price of 1 cent per option. The options have an exercise price of 20 cents and an expiry date of 31 October 2023. Application will be made for quotation of the options.

The primary purpose of the offer is to reward eligible Shareholders with an attractively priced options offer. The Directors are entitled to participate in the offer and have each advised that they intend to subscribe for their full entitlement.

PharmAust Executive Chairman, Dr Roger Aston, commented "We are pleased to provide this offer to our shareholders as recognition of their invaluable support to the Company. We are making good progress in our projects and look forward to achieving further milestones as we commence a number of clinical trials in 2022."

Appendix 4C – Quarterly Cash Flow Report

PharmAust's cash position at 30 September 2021 was \$2.5 million. The company is adequately funded to continue its current activities during these uncertain times and will continue to demonstrate appropriate fiscal restraint.

During the quarter, payments for Research and Development of \$0.137 million represented costs involved with the development of the Company's primary drug candidate, Monepantel (MPL) and salary allocations of Dr Richard Mollard who is 100% focused on R&D activities.

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 activities.

Payments for Administration and Corporate Costs represent general costs associated with running the Company, including ASX fees, 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 \$0.161 million comprising Directors' fees, salaries and superannuation.

Cash outflows for the quarter were in line with management expectations. The cash balance at 30 September 2021 was \$2.5 million. Please refer to the attached Appendix 4C for further details on cash flows for the quarter

This announcement is authorised by the Board.

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About PharmAust (PAA):

PharmAust Limited is listed on the Australian Securities Exchange (code: PAA) and the Frankfurt Stock Exchange (code: ECQ). PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company that generated \$2.2 million in revenue in FY 2021.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL demonstrated objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as well as neurodegenerative disease as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

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")

September 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	802	802
1.2 Payments for		
(a) research and development	(137)	(137)
(b) product manufacturing and operating costs	(247)	(247)
(c) advertising and marketing	(95)	(95)
(d) leased assets	(26)	(26)
(e) staff costs	(666)	(666)
(f) administration and corporate costs	(117)	(117)
1.3 Dividends received (see note 3)		
1.4 Interest received		
1.5 Interest and other costs of finance paid		
1.6 Income taxes paid		
1.7 Government grants and tax incentives		
1.8 Other (provide details if material)	(2)	(2)
1.9 Net cash from / (used in) operating activities	(489)	(489)
2. Cash flows from investing activities		
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 (3 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)		
2.6	Net cash from / (used in) investing activities		

3.	Cash flows from financing activities		
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	(38)	(38)
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
3.10	Net cash from / (used in) financing activities	(38)	(38)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,032	3,032
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(489)	(489)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(38)	(38)
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	2,504	2,504

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	2,492	3,020
5.2	Call deposits	12	12
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	2,504	3,032

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
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

7. Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities		
7.2 Credit standby arrangements		
7.3 Other (please specify)		
7.4 Total financing facilities		
7.5 Unused financing facilities available at quarter end		
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.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(489)
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,504
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	2,015
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.12
<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.

29 October 2021

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.