

Appendix 4C and Quarterly Update

Highlights:

- Phase 1 MND Study successfully completed the 3rd dose level cohort
 - Encouraging safety and interim biomarker analysis points to a positive treatment effect
 - Safety Monitoring Committee recommended escalating to the next and final dose level
 - Final patient to complete all their study visits due this quarter
 - Top-line results expected Q1CY2024
 - PharmAust intends to apply for FDA Orphan Drug Designation
- Phase 2 canine cancer study continues to demonstrate promising results
- Dr Michael Thurn, PhD appointed as Chief Executive Officer
- Cash position of approximately \$1.7 million at quarter end, with \$1.1 million expected to be received before 31 December 2023

30 October – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, is pleased to present its Appendix 4C and Quarterly Activities Report for the period ending 30 September 2023. During the quarter PharmAust continued to successfully execute its monepantel (MPL) clinical programs for motor neurone disease and canine oncology.

Motor Neurone Disease (MND/ALS) Study

The Phase 1 MEND study is an open label, multicentre study involving 12 patients with MND/ALS with the goal of determining the recommended Phase 2 MPL dose based on safety and preliminary efficacy. Three of the 4 dose level Cohorts have now been completed without any safety concerns and despite some patients receiving treatment continuously for over 12 months. The Safety Monitoring Committee (SMC) recommended proceeding to the next and final dose level Cohort of 10 mg/kg (bodyweight).

MND/ALS is a serious and debilitating disease characterised by progressive degeneration of nerve cells in the spinal cord and brain. MND/ALS affects voluntary control of the arms and legs, eventually leading to difficulty in breathing and is always fatal. While there is no cure, the standard-of-care treatment for MND/ALS is Riluzole that prolongs life on average by 2-3 months.

During the quarter, further pharmacokinetic (MPL and its major metabolite, MPL sulfone [MPLS]), pharmacodynamic (mTOR pathway markers p-RPS6KB1 and p-EIF4EBP1) and biomarker (urinary p75ECD and plasma neurofilament light chain [NfI]) data was released. These data were required and assessed by the SMC before patients could escalate to the higher dose level.

The pharmacokinetic data was as expected showing plasma levels MPLS increased with dose. Target engagement of the mTOR pathway by monepantel was also apparent in patient's peripheral blood mononuclear cells (PMBCs).

Of particularly interest to the SMC was the biomarker data. Urinary p75ECD levels decreased in 3 out of the 6 patients where data was available. Plasma Nfl levels remained stable or did not significantly change in 11 out of 12 patients. Nfl is a validated biomarker for axonal damage used to monitor the progression of a variety of neurological disorders. Clinical research has shown that increasing Nfl levels in the cerebrospinal fluid and plasma correlate with disease progression.

Subsequent to the quarter, patients in the 4th and final dose level Cohort have successfully completed dosing with no safety concerns. Patients have one last follow-up visit before data collation and analysis begins. Top-line data is expected to be released in Q1CY2024. PharmAust is currently finalising a 12-

month Open Label Extension (OLE) Study for Ethics approval. All 12 patients are expected to take part in the OLE Study.

On the back of these encouraging safety and preliminary efficacy results, PharmAust intends to submit an Orphan Drug Designation (ODD) application with the United States (US) Food and Drug Administration (FDA). An ODD comes with a generous set of financial and regulatory incentives such as tax credits, 7-year marketing exclusivity, fee waivers, and the opportunity to apply for grants to support clinical studies. It also gives sponsors access to specialised regulatory assistance from the FDA's Office of Orphan Products Development (OOPD). This support can expedite the development process by providing guidance on how best to design clinical trials that meet regulatory approval requirements.

PharmAust's Phase 1 MND study is supported by a \$881,085 grant from FightMND, Australia's largest independent funder of MND/ALS research with the final instalment of \$150,142 expected to be received this week.

Veterinary Oncology Study

PharmAust is conducting a Phase 2 study trialling monepantel (MPL) as a daily treatment for dogs with B-Cell Lymphoma. The open-label, single-arm dose-finding study aims to determine a clinically safe and efficacious dose of MPL to take forward in a pivotal study to support registration.

B-Cell Lymphoma is an aggressive form of cancer – without treatment it is often fatal within weeks of diagnosis. PharmAust's studies have shown MPL extends survival three-fold to a median of 150 days while maintaining excellent quality of life. Significantly, MPL is a cost-effective way for patients to safely manage their pet's cancer at home, an important factor in the viability of a commercial companion animal drug.

During the quarter, updates on the progress of the study were made. Most notable was that one dog (Louie the beagle) cancer remained stable after 1 year of treatment with MPL. Other data was also released showing that treatment with MPL extends survival three-fold, to a median of 150 days. A distinguishing feature of the dogs treated with MPL is the excellent quality of life experienced by the dog. This is in stark contrast to what dogs experience when subjected to expensive chemotherapy regimens.

Subsequent to the quarter, PharmAust announced the Phase 2 Study had been completed and presented encouraging top-line results showing daily treatment with monepantel compared favourably to the most recent FDA approved B-Cell and T-Cell Lymphoma treatment, LAVERDIA[™]. MPL data will be used to open an Investigational New Animal Drug (INAD) application with the US FDA's Centre for Veterinary Medicine (CVM) and to begin product registration studies in 2024.

An estimated six million dogs are diagnosed with cancer annually in the US, with B-Cell Lymphoma being one of the most common subtypes. Many common canine cancers are recognised as being very similar to human cancers with dogs increasingly recognised as excellent models for human disease. PharmAust intends to develop and commercialise MPL as a treatment for canine cancers to capitalise on the large market while using the data to de-risk future trials in human cancers.

New CEO Appointment

In August PharmAust appointed Dr Michael Thurn, PhD as Chief Executive Officer (CEO). Dr Thurn has substantial experience in drug discovery, development, regulation and commercialisation through leadership roles ranging from research organisations to publicly listed biotechnology companies. He brings invaluable experience executing Phase 1 and 2 clinical trials and business development strategies for animal and health products.

Dr Roger Aston remains Chairman of the Board and has transitioned into a non-executive role and continues to advise PharmAust with his 40 years' experience in the pharmaceutical and healthcare industry.

Epichem Liquidation

PharmAust announced the voluntary liquidation of its wholly owned subsidiary Epichem. The decision was largely due to the loss of the longstanding DNDi research contract that funded Epichem to research new treatments for neglected diseases. Epichem then operated at a loss that was funded by PharmAust.

Contract research organisations are costly and heavily dependent on a pharmaceutical sector still recovering after COVID-19. Despite best efforts Epichem was unable to secure key long-term contracts to replace DNDi. With shareholder funds in the forefront, after taking advice, the Company reluctantly decided to put Epichem into voluntary liquidation in order to focus on the clinical development of MPL.

PR & Marketing

PharmAust is committed to increasing market awareness and creating significant value for our shareholders and to that end has commenced an non-deal investor roadshow this week in Sydney, Melbourne, Adelaide, Perth, Singapore and Hong Kong. PharmAust will also attend a number of conferences including Australian and New Zealand MND Research Symposium, Emerging ASX Gems virtual conference and International Symposium on ALS/MND. The latest company presentation accompanies this announcement.

Appendix 4C Quarterly Cash Flow Report

PharmAust's cash position at 30 September 2023 was \$1.725 million with total available funding for future operating activities of \$2.2 million. The company is adequately funded to continue its current activities and will continue to demonstrate appropriate fiscal management.

FightMND grant instalment of \$0.150 million from the completion of the Cohort 4 is expected this week. A Research and Development Tax Incentive (RDTI payment of \$0.553 million is expected in November and subject to shareholder approval at the AGM, PharmAust expects to raise \$0.396 million under the Options Offer to existing Listed Option Holders.

During the quarter, payments for Research and Development of \$0.420 million represented costs involved with the development of the Company's primary drug candidate, MPL.

Payments for Product Manufacturing and Operating Costs represent wholly owned subsidiary Epichem Pty Ltd's expenditure allocated to manufacturing and operating for the month of July 2023 prior to liquidation.

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. Please refer to the attached Appendix 4C for further details on cash flows for the quarter.

The Board authorises this announcement.

Investor update

November 2023





Dr Michael Thurn



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Repurposing monepantel for the treatment of canine cancers and human neurodegenerative diseases



Board & Management

Dr Roger Aston	Non-Exec Chairman	Hybrid Holdings Pty Ltd <darcy a="" c="" family="" fund="" super=""></darcy>	7.02%
Dr Michael Thurn	Chief Executive Officer	Mr Gerald James Van Blommestien & Mrs Gillian Van	
Mr Robert Bishop	Executive Director	Blommestein <van a="" blommestein="" c="" f="" s=""></van>	5.56%
Mr Neville Bassett AM	Non-Exec Director	Dr Roger Aston	4.75%
Mr Sam Wright	Non-Exec Director & Company Secretary	Board & Management	8.50%



Capital Structure (AUD\$)			
Current Share Price (27-Oct-23)	\$0.073		
52 Week Low / High	\$0.115/ \$0.06		
No. of Shares Outstanding	348,774,940		
Market Capitalisation	\$24.1 m		
Cash (as at 30-Sep-23)	\$1.725 m		
Debt (as at 30-Sep-23)	Nil		
Net Cash*	\$1.725 m		
Enterprise Value	\$22.4 m		
Unlisted Options (10c/15c)	18.9 m		
Enterprise Value (fully diluted)	\$26.9 m		

* Excludes R&D Tax Incentive payment of \$0.553 million and subject to shareholder approval at the AGM \$0.396 million under the Options Offer to existing Listed Option Holders, FightMND grant instalment of \$0.150 m due Q4 CY2023

Top Shareholders*



Product candidates for both human and animal health applications



Human and Animal Health

Clinical stage biotechnology company focused on large and growing markets in human and animal health



Strong IP Position Strong intellectual property with patent protection beyond 2030



Repurposing Monepantel

Repurposing an approved veterinary product – monepantel – anthelmintic for sheep



Pipeline Synergies Pipeline synergies to leverage commercial infrastructure across human and animal health applications

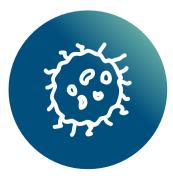


Motor Neurone Disease

Lead clinical program for the treatment of motor neurone disease (MND/ALS)



Experienced Management Experienced management team with demonstrated execution capabilities



Canine B-Cell Lymphoma

Phase 2 Veterinary program for the treatment of dogs with B-Cell Lymphoma



Broad Investor Base Healthy mix of loyal institutional and retail investors







Advancing multiple synergistic product opportunities in human and animal health by repurposing monepantel

	Human Health					
Indication	Preclinical	Phase 1	Phase 2	Phase 3	Approved / Marketed	Next Catalysts
Motor Neurone Disease				Accelerated approval possible based on Phase 2 data		 Orphan Drug Designation Phase 1 Top-line Results Q1 2024 Open IND
Cancers						 Under review Seek partnership opportunities

	Animal Health					
Indication	Preclinical	Phase 1	Phase 2	Field Study / TASS	Approved / Marketed	Next Catalysts
Canine B-Cell Lymphoma					itional l possible	Open INADBegin Field Study
Cancers		~				 Under review Seek partnership opportunities

IND – Investigational New Drug

INAD – Investigational New Animal Drug

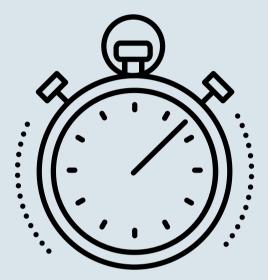
TASS – Target Animal Safety Trial



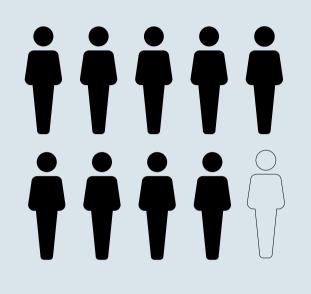


MND /ALS Statistics & Treatments

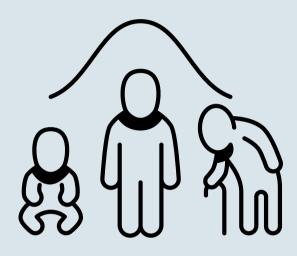
There is no cure and MND/ALS is always fatal



Every **90 minutes** someone is **diagnosed and dies** with MND/ALS



90% of cases occur without a family history



Onset is usually between the ages of 40 & 70 years







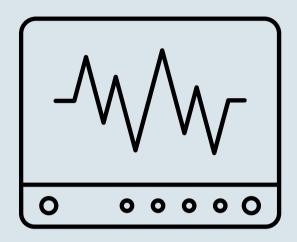
Qalsody (tofersen) Developed to treat ALS associated with a mutation in the superoxide dismutase 1 (*SOD1*) gene. The FDA approved Qalsody to treat *SOD1*-ALS in 2023.



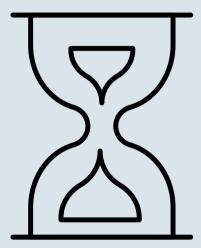
Rilutek (riluzole) This was the first FDA-approved drug available to treat ALS — in 1995. It inhibits glutamate release and prolongs life ~3 months.

These drugs provide limited relief and slow disease progression by only months





Life expectancy on average is just over 2 years



By **2040 the incidence** of MND/ALS is expected to **increase by 70%**



Radicava™ (edaravone)

The FDA approved Radicava™ in 2017, making it the first new treatment specifically for ALS in 22 years. Prolongs life ~6 months.



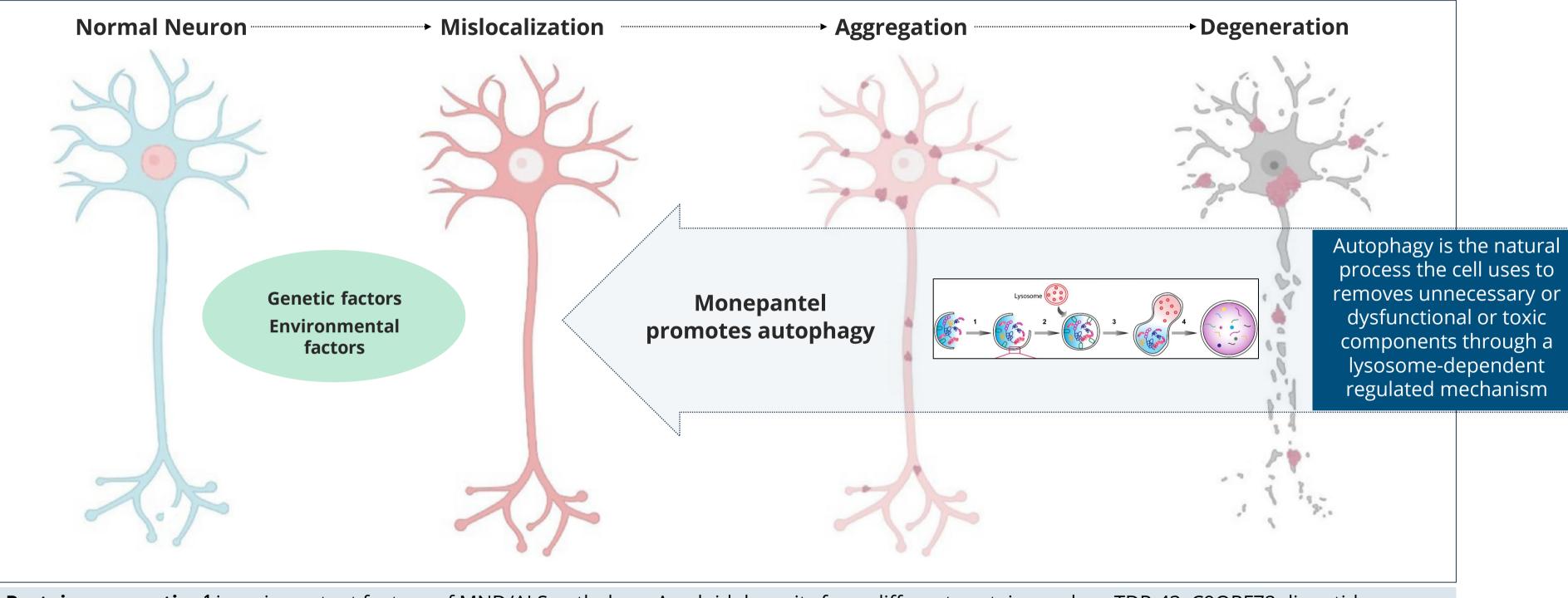
Relyvrio (AMX0035)

RELYVRIO is a combination of two drugs, sodium phenylbutyrate and taurursodiol. The FDA approved RELYVRIO for use to treat ALS in 2022. Prolongs life ~ 9 months.



MND /ALS pathology & disease progression

Characterised by progressive degeneration of nerve cells in the spinal cord and brain, MND/ALS affects the voluntary control of the arms and legs, eventually leading to trouble with breathing and death



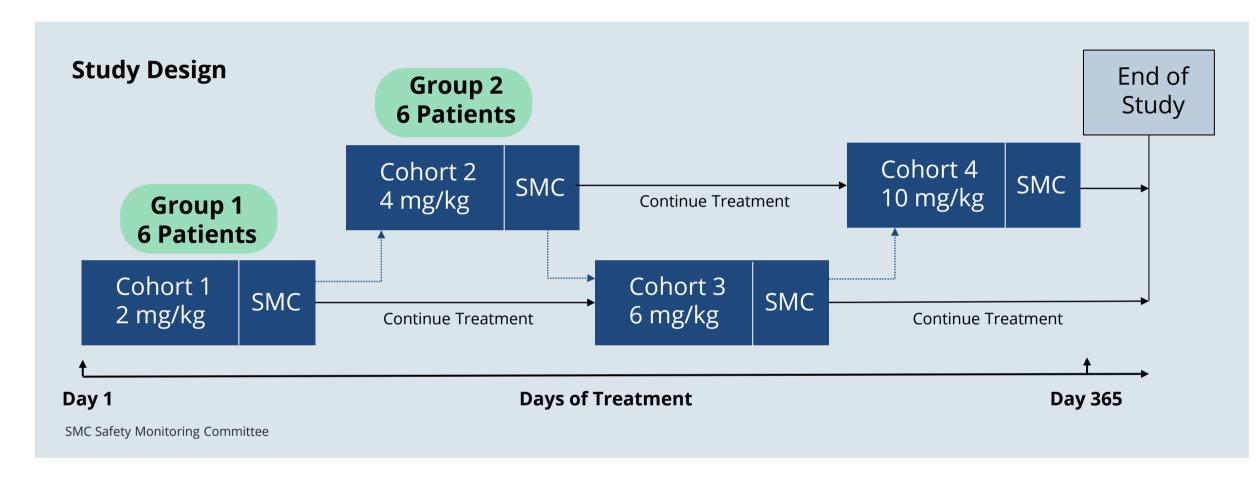
Protein aggregation¹ is an important feature of MND/ALS pathology. Amyloid deposits from different proteins such as TDP-43, C9ORF72 dipeptide repeats, phosphorylated high molecular weight neurofilament protein, rho guanine nucleotide exchange factor, and FUS have been detected in MND/ALS motor neurons. These aberrant protein deposits become toxic to the cells, leading to neurodegeneration and are targets for therapeutic interventions.

¹Suk, T.R., Rousseaux, M.W.C. The role of TDP-43 mislocalization in amyotrophic lateral sclerosis. *Mol Neurodegeneration* **15**, 45 (2020). https://doi.org/10.1186/s13024-020-00397-1





The Phase 1 MEND Study is an open label, multicentre study involving 12 patients with MND/ALS with the goal of determining the recommended Phase 2 dose based on safety and preliminary efficacy





- All patients in Cohort 4 have successfully completed dosing
- Treatment well tolerated even after escalation to Cohort 4 and over 12 months of continuous treatment
- Study completion activities underway to support release of top-line data in Q1CY24
- Patients have elected to continue treatment with monepantel under a compassionate use program
- Patients will be eligible to enrol in a 12-month open label extension study expected to commence Q1CY24
- Data will be used to support an Orphan Drug Designation application and to open an IND with the US FDA to commence a Phase 2 \bullet Study in H1CY24

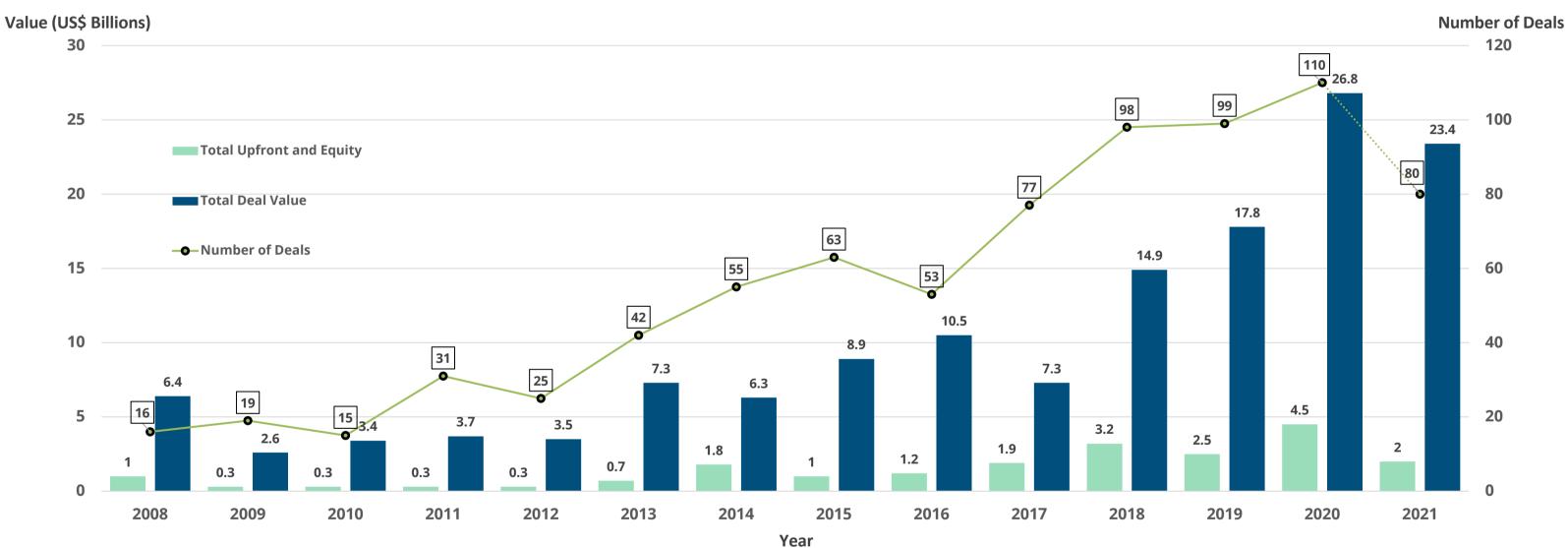


Principal Investigator Assoc. Prof Susan Mathers commented: "All of the participants have tolerated the study drug very well with no safety issues, despite a year of treatment. As investigators, we are very grateful for the enthusiastic support and commitment from our patients and their families. Like them, we eagerly await the study results."



Rare disease market

The global rare disease treatment market reached >US\$195 billion in 2022 and is expected to reach US\$435 billion by 2032 (CAGR > 8.5%)¹



High Value R&D Deals²

Rapidly Growing Segment

Supported by the clinical and commercial success of therapies for rare diseases, as well as the increasing opportunities to directly target the root cause of rare genetic diseases with novel platforms

Increase in FDA Approvals

Rare disease drug approvals are now keeping pace with other novel drugs and comprised half of all FDA approvals between 2015 and 2022

Amgen purchased Horizon Therapeutics for US\$27.8 billion, Biogen acquired Reata Pharmaceuticals for US\$7.3 billion, AstraZeneca's Alexion bought Pfizer's early-stage gene therapy portfolio for up to US\$1 billion and Novartis purchased Chinook Therapeutics for US\$3.2 billion



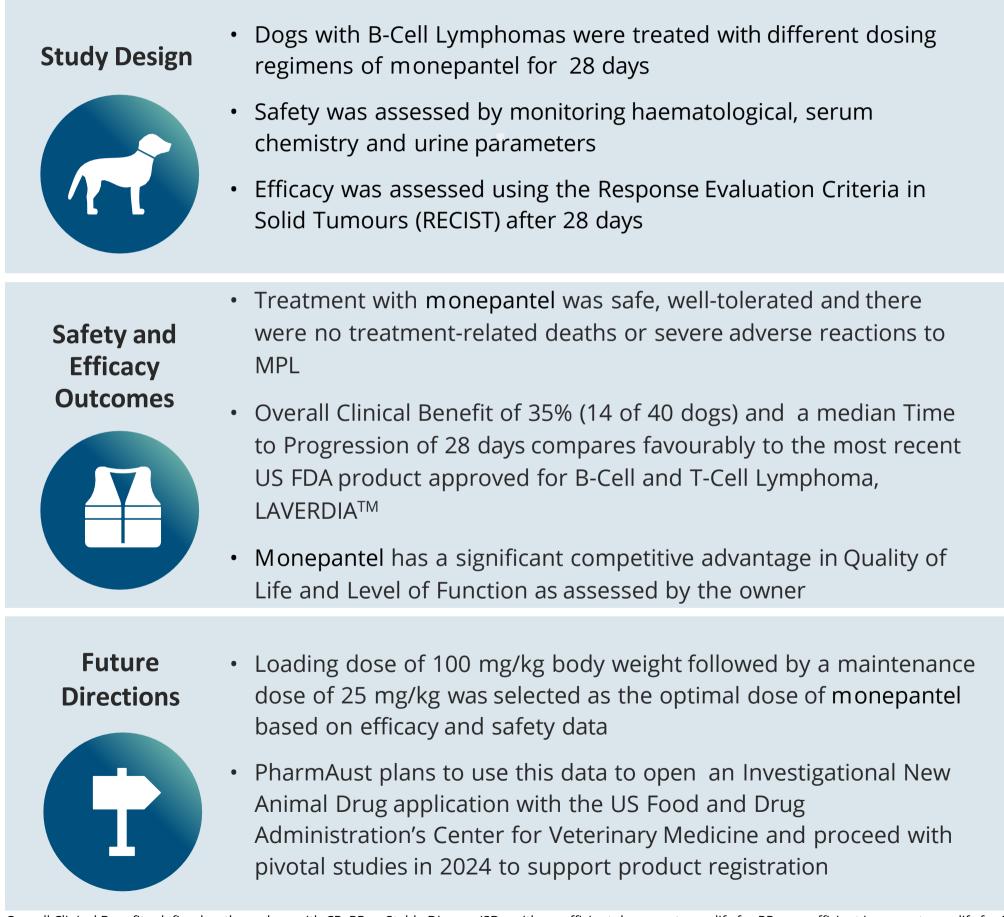
High Deal Values

High List Price

39% of orphan drugs have list prices above US\$100,000 per year

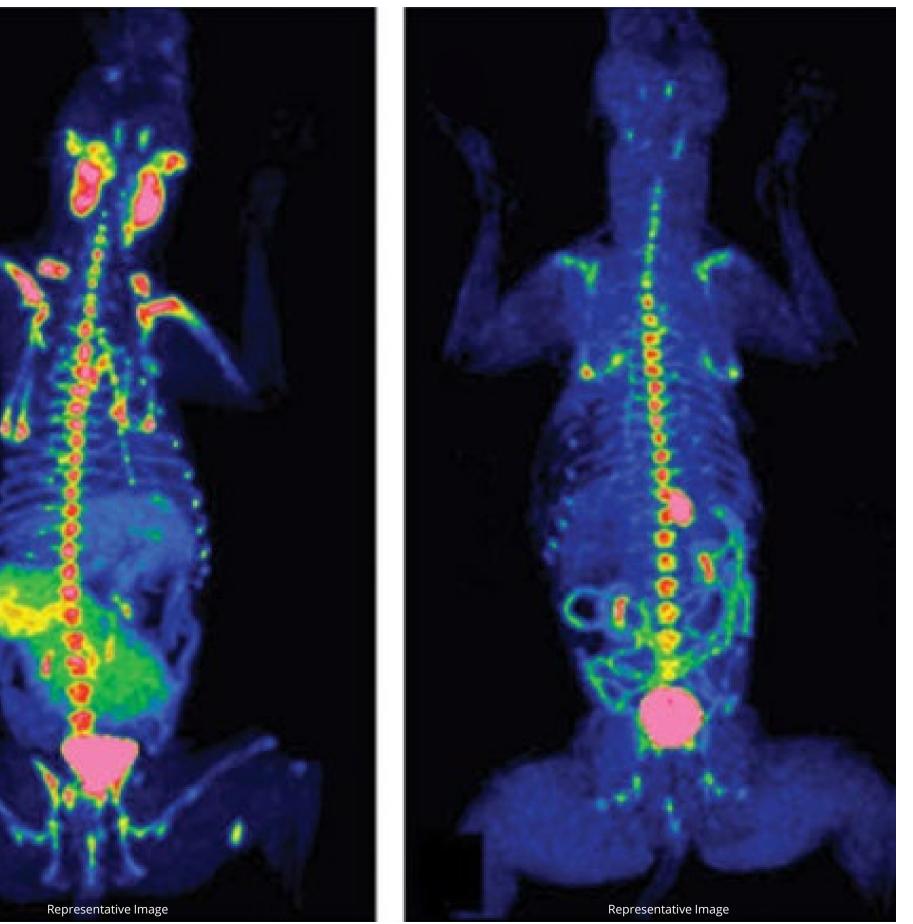


Phase 2 Canine Study Overview



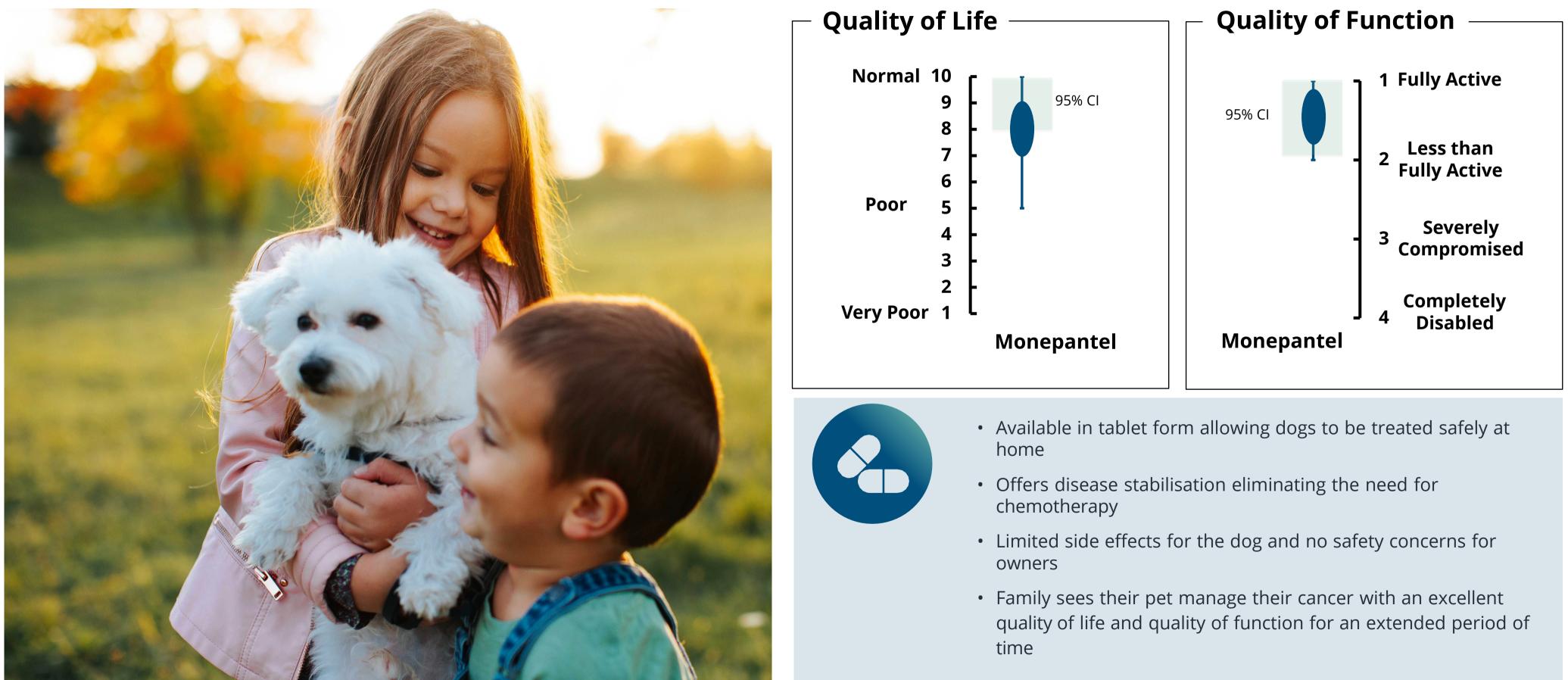
Overall Clinical Benefit - defined as those dogs with CR, PR or Stable Disease (SD; neither sufficient decrease to qualify for PR nor sufficient increase in the mean sum of the longest diameter of all target lesions with reference to the smallest mean sum longest diameter recorded] of all target lesions).; Time to progression - TTP - defined as the time from the first date of treatment to the date that the dog developed clinical or radiographic signs of PD or died from any cause, including euthanasia.





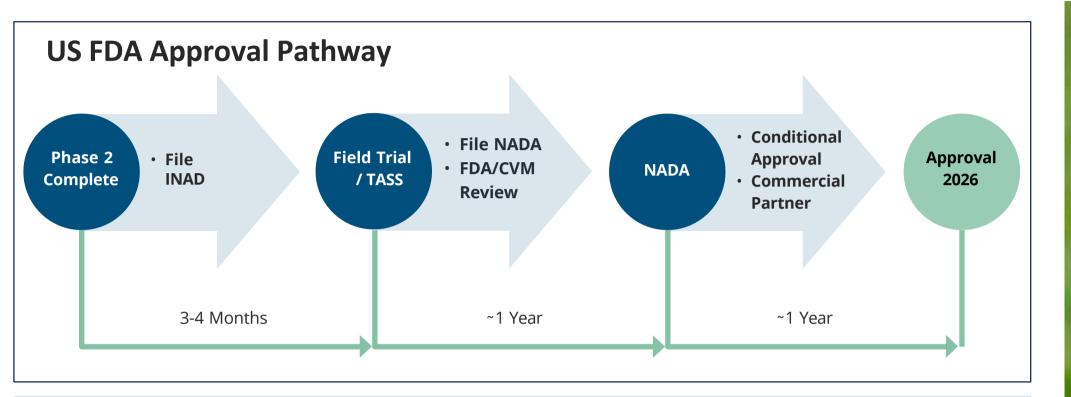


New treatment paradigm









Commercial Strategy



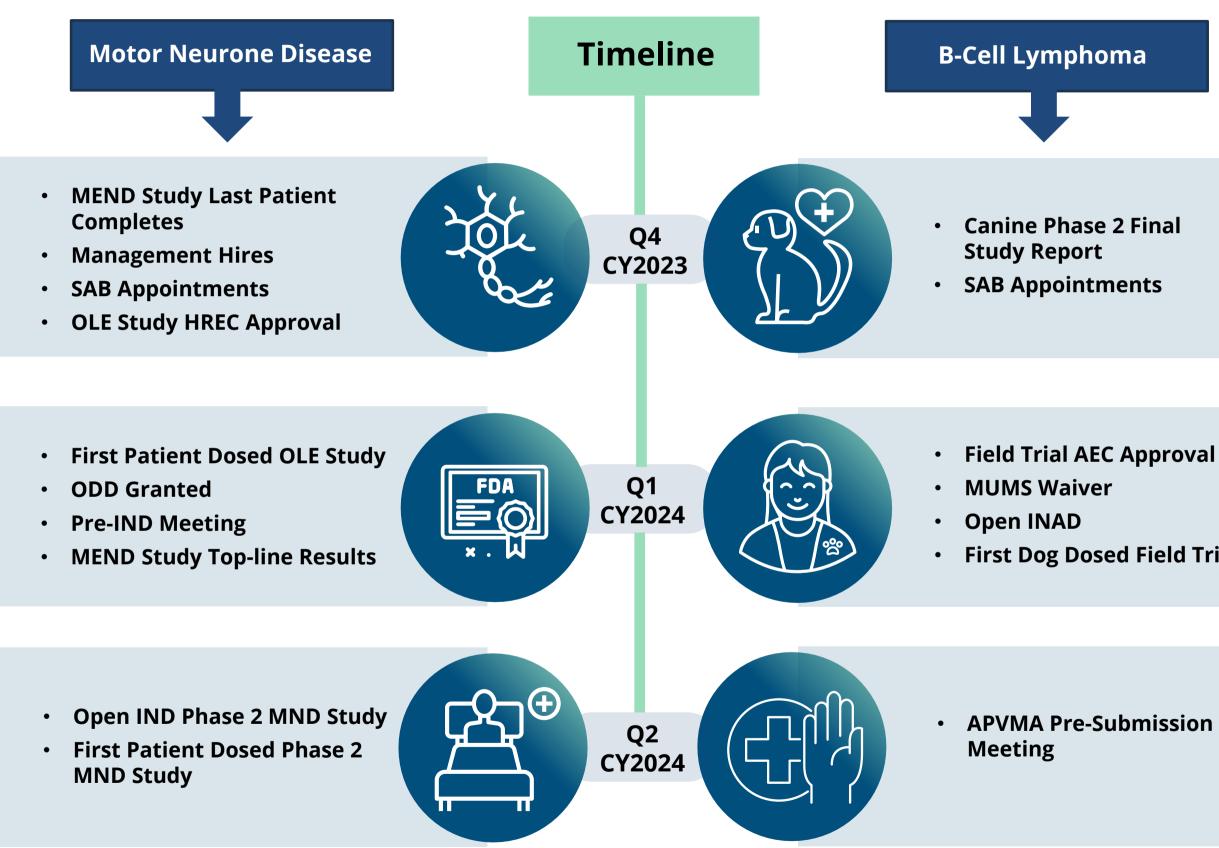
- The potential for PharmAust to achieve a major value inflexion point by advancing MPL through to product registration with the Center of Veterinary Medicine
- The minor investment required over a short period of time to conduct the pivotal registration studies
- LAVERDIA[™], the most recently approved treatment for B-Cell and T-Cell Lymphoma, was acquired¹ by Dechra Pharmaceuticals PLC (LSE:DPH) for US\$64.5 million in 2022.
- Business development to be conducted in parallel







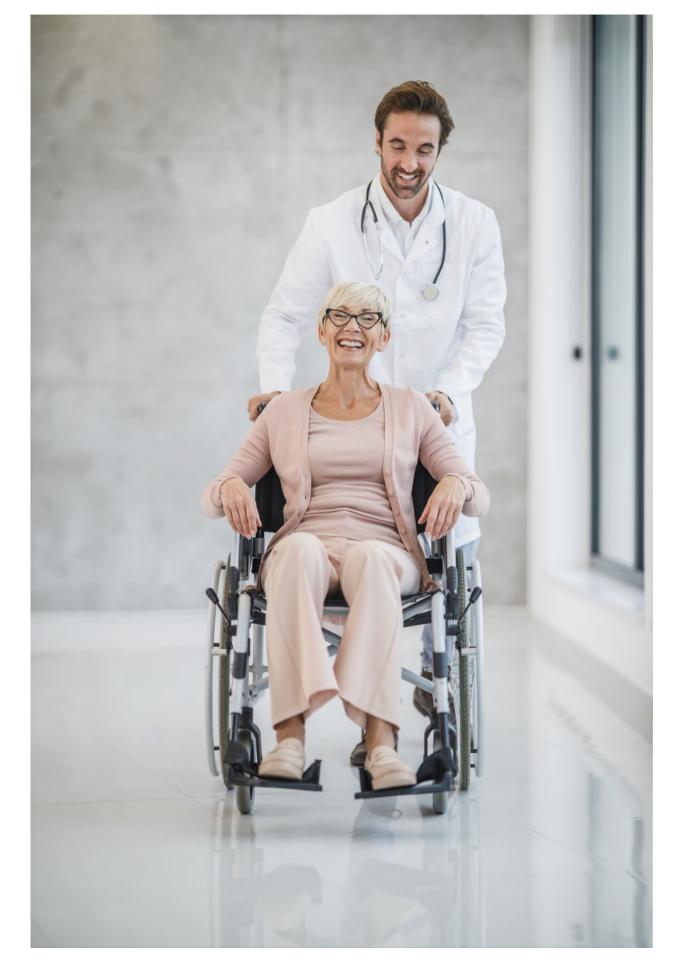




SAB – Scientific Advisory Board; OLE – Open Label Extension; ODD – Orphan Drug Designation; IND – Investigational New Drug; AEC – Animal Ethics Committee; MUMS – Minor Use Minor Species; INAD – Investigational New Animal Drug; APVMA - Australian Pesticides and Veterinary Medicines Authority



• First Dog Dosed Field Trial





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Appendix 4C

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

Name of entity PharmAust Limited ABN Quarter ended ("current quarter") 35 094 006 023 September 2023

Con	isolidated 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	311	311
1.2	Payments for		
	(a) research and development	(420)	(420)
	 (b) product manufacturing and operating costs 	(58)	(58)
	(c) advertising and marketing	(25)	(25)
	(d) leased assets		
	(e) staff costs	(258)	(258)
	(f) administration and corporate costs	(455)	(455)
1.3	Dividends received (see note 3)		
1.4	Interest received	2	2
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		
1.8	Other (GST)	(27)	(27)
1.9	Net cash from / (used in) operating activities	(930)	(930)

2. Ca	ash flows from investing activities	
2.1 Pa	Payments to acquire or for:	
(a)) entities	
(b)) businesses	
(c)) property, plant and equipment	
(d)) investments	
(e)) intellectual property	
(f)	other non-current assets	

Con	solidated 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)	103	103
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		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (Epichem closing cash at bank)	(165)	(165)
3.10	Net cash from / (used in) financing activities	(62)	(62)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,717	2,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(930)	(930)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Con	solidated 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)	(62)	(62)
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of period	1,725	1,725

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	1,194	728
5.2	Call deposits	531	1,989
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)	1,725	2,717

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	
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a ation for, such payments.	description of, and an

Director's Salaries & Superannuation

7.	Financing facilities 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.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000	
7.1	Loan facilities	443		
7.2	Credit standby arrangements			
7.3	Other (please specify)			
7.4	Total financing facilities	443		
7.5	Unused financing facilities available at quarter end 44		443	
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.			
	The available loan facility is with Innovation Structured Finance Co., LLC serviced via Radium Capital and is an advance on 80% of the Company's R&D Tax Incentive (RDTI) for the for the period 1 July 2022 – 30 June 2023. The interest rate for the loan facility is 15% per annum. Repayment is timed to coincide with receipt of PharmAust's 2023FY RDTI refund. No funds have been drawndown.			

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(930)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,725
8.3	Unused finance facilities available at quarter end (item 7.5)	443
8.4	Total available funding (item 8.2 + item 8.3)	2,168
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.3

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.

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

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.

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 October 2023

Date:

By the board

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.