

# APPENDIX 4C AND QUARTERLY UPDATE

28 APRIL 2023

**ASX: PAA** 

ACN 094 006 023







# **HIGHLIGHTS**

- PharmAust has successfully completed dosing of all 12 patients in Cohorts 1 & 2 of the MND trial
- Monepantel (MPL) tablets have been well tolerated and all patients who have completed the 29 day trial have elected to continue on MPL
- Arrival of 10,000 additional MPL tablets for MND trial and other human 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
- Louie the beagle surpasses 300 days with stable disease and continued excellent Quality of Life
- PharmAust in advanced confidential discussions with potential licensing partners for canine cancer
- PharmAust granted European Patent relating to the use of MPL Combinations in Cancer
- 31 March 2023 available funding of approximately \$1.6 million, enabling pursuit of various preclinical and clinical commitments





# PHASE I/II MND TRIAL

- PharmAust has successfully completed all 12 patients in Cohorts 1 and 2 for the MND trial
- The interim analysis evaluating changes in biomarkers, pharmacokinetics and pharmacodynamics is expected to be available in late May 2023
- Five patients have now surpassed the 6-month-mark on MPL without any safety issues, and one patient has shown no disease progression
- MPL well tolerated by all MND patients with no signs of material adverse events all patients have elected to remain on MPL treatment post Day 29
- PharmAust will continue with MPL dose escalation for Cohorts 3 and 4 to determine the optimum dose for a Phase 2 trial
- Indicatory evidence for MND severity and progression during the trial will also be examined
- PharmAust expects to proceed to Phase 2 with favourable efficacy biomarker results under the interim analysis
- Executive Chairman Dr Roger Aston said, "Patients electing to continue using Monepantel after participating in the current trial for Motor Neurone Disease, provides increased comfort on our safety data particularly when viewed against the Riluzole (current standard of care) safety data reporting a 14% rejection rate by patients for ongoing use".





# PHASE II CANINE CANCER TRIALS

- Phase 2 trial continues in canines with B-cell lymphoma in Australia, New Zealand and USA
- Additional study sites in Austin and Dallas, TX
- Dog recruitment at new US sites expected to commence in May and close out the 8 US dogs required to complete the 10 dogs in the US
- New Australian sites actively being pursued
- Two dogs have had a partial response (>30% decrease in cancer tumour) and eight others have enjoyed a stable disease response
- One patient (Louie the beagle) surpasses 300 days with stable disease and continued excellent Quality of Life (QoL), as attested by dog owner testimonials
- MPL/Prednisone extends survival three-fold, to a median of 150 days, while maintaining QoL
- Assay results from 10 x plasma samples expected by late May 2023
- MPL Phase 2 Trial expected to be completed by mid-2023
- PharmAust's commercial strategy aimed at bridging the options of standard-of-care with chemotherapy is on target
- PharmAust in advanced confidential discussions with potential licensing partners for canine cancer
- Bella's Story: Living with B Cell Lymphoma and Anti-Cancer Drug Trial



# 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 19 DOGS WITH SD AT D28 TO MEET BAYESIAN OUTCOMES FOR SUCCESSFUL PHASE 2 TRIAL

| Study outcome   | Dogs with<br>Monepantel blood<br>results | Dogs without<br>Monepantel blood<br>results | Total # Dogs |
|---|--|---|--------------|
| Partial Response  | 1  | 1+~   | 10           |
| Stable Disease  | 8  | 0   | 10           |
| Progressive Disease                                       | 14                                       | 3+~   | 17           |
| Completed but waiting for blood results before assignment |  | 6~  | 6            |
| On study  |  | 1   | 1            |
|   |  |   | 34           |

**NOTE: \*** Maximum dogs to enrol is 46 (A further 12 dogs can be enrolled)

**NOTE**: + Dogs without blood results complete assigned to PR (x1) and PD (x3) where the results will not change the stated outcome

NOTE: ~ 10 dogs will receive blood results by end May 2023. (The one dog on study will be later)

#### Dogs not included

4 dogs removed from the study due to lack of compliance with tablet administration instruction

1 dog removed due to death on Day 4

5 dogs with plasma MPLS < target level (5 uM)

#### RECIST DEFINITIONS

PR = > 30% tumour reduction

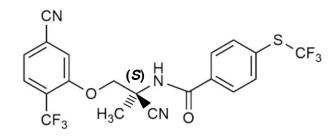
SD = <30 % tumour reduction and not >20% tumour increase

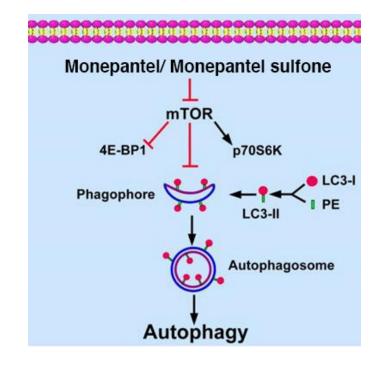


#### PHASE II HUMAN CANCER TRIAL

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.







### ARRIVAL OF ADDITIONAL MPL TABLETS

The receipt of approximately 10,000 tablets will ensure continued availability of MPL tablets for the Phase 1/2 MND trial and ongoing maintenance dosage.

PharmAust notes that, thus far, all patients have elected to remain on MPL post Day 29 and wish to continue receiving PharmAust's MPL tablets. Continuation of access and treatment with Investigational Product is a permitted option in the protocol.

The additional tablets are also sufficient to commence one or more other human clinical trials.

GMP tablet manufacture is a key component for undertaking GCP (Good Clinical Practice) trials and will enable the data emerging from forthcoming trials to be admissible to the U.S. FDA to support new drug registration programs. Furthermore, adoption of GMP standards ensures products meet the highest standards of safety and efficacy.

The MPL tablets were manufactured in collaboration with Syngene International Ltd., an integrated research, development and manufacturing services company and Catalent Pharma Solutions (NYSE: CTLT) who performed the production of the cGMP-grade MPL tablets suitable for use in the upcoming human trials.

The tablets will be stored in the stability chamber at wholly owned subsidiary, Epichem Pty Ltd in Perth.



## EPICHEM PTY LTD - 100% OWNED SUBSIDIARY

Active client engagement discussions continue as Epichem strives to build a robust pipeline. We are observing a higher uptake from the mining and oil and gas sector for Epichem's Production and Analytical expertise upon which we continue to capitalise. To increase the service offerings to clients, the business now offers stability chamber services presenting a valuable resource offering for which there is increasing appetite across all sectors.

Whilst the DNDi relationship drew to a close at the end of the quarter, we maintain good contact with the key stakeholders with the aim of building future engagement when they are in a position to do so.

Business Development prospects are constantly being undertaken and engagement with NERA, Austrade and the Department of Jobs, Tourism, Science and Innovation (JTSI) has resulted in financial support to attend relevant trade shows and conferences to source new business.

As previously communicated, completion of the funded Shell/NERA project with OHD late last year left the report with Shell for consideration of next steps. Once Epichem is in a position to share where this might progress, an announcement will follow.

This quarter saw David Richardson join Epichem as Corporate Services Manager. David has previously held senior finance roles in much larger organisations including, not limited to, PrimeWest Ltd and Doric Group Pty Ltd. David joining provides further financial expertise to facilitate ongoing operational reviews to ensure continued viability for the business.





# APPENDIX 4C QUARTERLY CASH FLOW REPORT

PharmAust's cash position at 31 March 2023 was \$1.3 million with total available funding for future operating activities of \$1.6 million. 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 \$0.383 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. 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



### **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    | March 2023                        |  |

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$A'000 |
|-----|--|----------------------------|---------------------------------------|
| 1.  | Cash flows from operating activities           |                            |                                       |
| 1.1 | Receipts from customers                        | 636                        | 2,514                                 |
| 1.2 | Payments for                                   |                            |                                       |
|     | (a) research and development                   | (383)                      | (857)                                 |
|     | (b) product manufacturing and operating costs  | (291)                      | (906)                                 |
|     | (c) advertising and marketing                  | (33)                       | (105)                                 |
|     | (d) leased assets                              |                            | (67)                                  |
|     | (e) staff costs                                | (541)                      | (1,789)                               |
|     | (f) administration and corporate costs         | (200)                      | (511)                                 |
| 1.3 | Dividends received (see note 3)                |                            |                                       |
| 1.4 | Interest received                              | 3                          | 4                                     |
| 1.5 | Interest and other costs of finance paid       |                            |                                       |
| 1.6 | Income taxes paid                              |                            |                                       |
| 1.7 | Government grants and tax incentives           |                            | 681                                   |
| 1.8 | Other (GST)                                    | (7)                        | 89                                    |
| 1.9 | Net cash from / (used in) operating activities | (816)                      | (947)                                 |

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

ASX Listing Rules Appendix 4C (17/07/20)

| Con | solidated statement of cash flows              | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$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   | (223) |
| 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  | (223) |

| 4.  | Net increase / (decrease) in cash and cash equivalents for the period |       |       |
|-----|---|-------|-------|
| 4.1 | Cash and cash equivalents at beginning of period                      | 2,074 | 2,427 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above)       | (816) | (947) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above)       |       |       |

| Con | solidated statement of cash flows                                | Current quarter<br>\$A'000 | Year to date (9<br>months)<br>\$A'000 |
|-----|--|----------------------------|---------------------------------------|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) |                            | (223)                                 |
| 4.5 | Effect of movement in exchange rates on cash held                |                            |                                       |
| 4.6 | Cash and cash equivalents at end of period                       | 1,258                      | 1,258                                 |

| 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<br>\$A'000 | Previous quarter<br>\$A'000 |
|-----|---|----------------------------|-----------------------------|
| 5.1 | Bank balances   | 335                        | 1,064                       |
| 5.2 | Call deposits   | 923                        | 1,009                       |
| 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)   | 1,258                      | 2,073                       |

| 6.  | Payments to related parties of the entity and their associates   | Current quarter<br>\$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 ation for, such payments. | e a 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<br>amount at quarter<br>end<br>\$A'000 | Amount drawn at<br>quarter end<br>\$A'000 |
|-----|---|---|---|
| 7.1 | Loan facilities   | 302   |   |
| 7.2 | Credit standby arrangements   |   |   |
| 7.3 | Other (please specify)  |   |   |
| 7.4 | Total financing facilities  | 302   |   |
| 7.5 | Unused financing facilities available at qu   | arter end   | 302                                       |

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 – 31 January 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)  | (816)                      |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6)  | 1,258                      |
| 8.3 | Unused finance facilities available at quarter end (item 7.5)  | 302                        |
| 8.4 | Total available funding (item 8.2 + item 8.3)  | 1,560                      |
| 8.5 | Estimated quarters of funding available (item 8.4 divided by item 8.1)   | 1.9                        |
|     | Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5. | 8.5 as "N/A". Otherwise, a |

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: No – net cash from operating activities in the March quarter was \$816k versus \$947k YTD. The increase this quarter predominantly relates to the manufacture of an additional 10,000 MPL tablets for the MND trial and other human trials.

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: PharmAust has requested a trading halt of its securities pending an announcement of a capital raising.

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: Yes – as per above

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**

- 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.

|                | 28 April 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.
- 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.