

## 30 May 2017 – Perth, Australia: PharmAust Shareholders Update and Roadmap

Dear Shareholders,

It's been a busy start to the year for PharmAust.

In this update, we would like to recap on several exciting developments that have informed our commercialisation and development strategies for monepantel (MPL), PharmAust's lead drug candidate currently undergoing Phase II clinical trials in dogs. We also wish to share with you our Roadmap of planned activities for the remainder of 2017.

The year began with a successful financing where the company raised \$3.24m (thanks to shareholders and the team at Argonaut for your ongoing support) and also the appointment of a new executive team (Dr Richard Hopkins as CEO and Dr Richard Mollard as CSO) to accelerate the company's development plans.

Most recently, PharmAust was delighted to announce preliminary results from our Phase II pilot trial being undertaken in dogs diagnosed with lymphoma, where MPL is being used as a front-line therapy. Preliminary analysis showed 3 of 4 (75%) dogs achieved stable disease and tumour reduction when dosed daily with MPL over a limited period of 2 weeks. Given that dogs would typically show progressive disease over this time, we believe these data provide strong evidence for MPL clinical efficacy.

When considered alongside results from previous Phase I/II MPL clinical trials undertaken in dogs, the company believes it has now achieved all key clinical endpoints relating to safety and efficacy. To our knowledge, this is also the first report of an mTOR inhibitor, such as MPL, showing clinical activity against lymphoma in dogs. As lymphoma is one of the most common types of cancer diagnosed in dogs, this outcome has positive implications for our ability to impact the veterinary oncology market.

A successful outcome to the Phase II pilot trial will also meet one of the key requirements to progress discussions with Novartis Animal Health/Elanco regarding the Option Agreement.

In terms of Epichem, the company remains on-track to deliver a record \$3m in revenues for the 2016/17 financial year. Epichem expects to continue growing revenues at >20%/yr as it expands to meet demand for its Drug Discovery services and high-margin Catalogue businesses.

The 2017 Roadmap below set-outs a timetable for the next phase of the company's preclinical and clinical development plans for MPL and its wholly owned subsidiary Epichem. Successful delivery on these goals will generate multiple value accretion catalysts that will reposition your company for commercial success in both the veterinary and human pharmaceutical markets.

**Table 1: Roadmap of major PharmAust activities for calendar 2017**

Activity	Details	Quarter
Complete Phase II Trial Subsection in Lymphoma Dogs	<ul style="list-style-type: none"> <li>• Confirm Safety</li> <li>• Show Tumour regression and/or Stable Disease</li> </ul>	Q3-Q4
Complete MPL Reformulation	<ul style="list-style-type: none"> <li>• Higher dose</li> <li>• Better taste</li> <li>• Ready for Phase I-II clinical trials</li> </ul>	Q4
Initiate Phase II Clinical Trial Subsection in dogs using reformulated MPL	<ul style="list-style-type: none"> <li>• Dose escalation, max dose,</li> <li>• Efficacy,</li> <li>• Combination therapy</li> </ul>	Q4
Initiate preparations for Human Clinical Trial	<ul style="list-style-type: none"> <li>• Identify clinical centres</li> <li>• Engage clinical advisory team (one identified)</li> </ul>	Q4
Novartis/Elanco Option Agreement	<ul style="list-style-type: none"> <li>• Progress discussions towards strategic partnership</li> </ul>	Q4
Growth of Epichem Business	<ul style="list-style-type: none"> <li>• Phase 2 lab expansion,</li> <li>• ISO 17025 accreditation,</li> <li>• Expansion of high-margin catalogue business</li> </ul>	Q2-4

## **Description of Major Activities:**

### **1. Complete Phase II Pilot Trial in Lymphoma Dogs (Q3-Q4, 2017):**

Anticipate completion of recruitment and treatment of up to 10 dogs by late Q3, early Q4, 2017. This Pilot study has been designed to ensure outcomes can achieve significance that will inform an expanded Phase II clinical development programme.

**2. Complete Reformulation Strategy (Q4, 2017):** Reformulate MPL to address poor palatability of the current Zolvix formulation.

The bad taste of the current Zolvix/MPL formulation has made patient compliance an ongoing challenge. While reformulation into gelatin capsules has partially addressed this problem, it does not represent a long-term solution

Aims of the reformulation strategy are as follows:

1. Overcome the foul taste of Zolvix by combining MPL with different excipients.
2. Deliver up to 10 times more drug/dose to reduce patient pill burden and further improve compliance.
3. Standardise formulation/manufacturing process for all phases of clinical development – a key requirement for commercialisation.

### **3. Initiate Phase II Clinical Trial in Dogs Using Reformulated MPL (Q4, 2017):**

Reformulated MPL will facilitate delivery of much higher doses of drug and ensure much better compliance. Key clinical endpoints will include efficacy, dose escalation, maximal therapeutic dose, and safety. All outcomes will inform the design of Phase II clinical trials in humans.

By Q4, 2017 the company will report on the design of the clinical trial, efforts to expand the number of trial sites and appoint a world class advisory team.

### **4. Initiate Preparations for Human Clinical Trial (Q4, 2017):**

By Q4, 2017 will report on efforts to identify clinical trial sites in the US and Australia and also appoint a world class clinical advisory team.

### **5. Novartis/Elanco Option Agreement (Q4, 2017):**

Continue to progress discussions aimed at establishing a strategic partnership with Elanco and to exercise the Option to License agreement for veterinary applications of MPL.

Importantly, recent preliminary data suggesting clinical efficacy of MPL in the dog lymphoma trial meets a key requirement for the Option Agreement.

## **6. Continued Growth of Epichem Business**

Epichem remains on track to report record revenues of \$3m for the 2016/17 financial year. Forecasting >20% growth for next FY.

Key drivers for further growth include:

- Expected approval of loan to facilitate second phase expansion of laboratory capacity (Q2, 2017)
- Approval for ISO 17025 Accreditation (Q3-4, 2017). Considered the top-tier of “Testing and Quality Assurance” classifications for laboratories. Application will be submitted in Q2 with approval expected late Q3 – early Q4.
- Accreditation will facilitate access to new international customers who can only engage with suppliers with this level of accreditation. Approval is expected to drive increased revenues from high-margin catalogue business.

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### **About PharmAust (PAA):**

PAA is a clinical-stage company developing targeted cancer 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 synthetic drug manufacturer which is forecast to generate Aus\$3m in revenues in 2017 at a CAGR of 28%.

PAA's lead drug candidate is Monopantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway - a key driver of cancer. MPL has been evaluated in Phase 1 clinical trials in humans and dogs. MPL treatment was well-tolerated and produced a significant reduction in key prognostic biomarkers. Further, 50% of end-stage Individuals achieved stable disease at low therapeutic doses providing support for MPL efficacy observed in preclinical studies.

PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as it advances the drug into Phase 2 clinical trial.