

## PharmAust Shareholders Update

22 August 2017

Dear Shareholder

I'm pleased to present this latest investor update .

From a personal perspective, settling into the role of CEO over the past six months has certainly been a steep learning curve. The experience, however, has reaffirmed my excitement about the commercial potential of this company.

PharmAust is developing a repurposed market-approved drug to lower the risks and costs of clinical development. This is a proven model for generating strong returns for shareholders.

Our lead compound Monepantel (MPL), has recently been granted multiple patents in major global markets, delivering us a strong intellectual property (IP) position. Unlike many repurposed drugs, Monepantel has a novel mechanism of action with broad application across many cancer types. This further strengthens the commercial value of our IP.

Why is PharmAust developing MPL for cancer? MPL has proven to be a very safe cancer drug in clinical trial. By avoiding side-effects, MPL can address unmet medical needs and improve patient quality of life during and following treatment in a manner not possible with conventional chemotherapies.

PharmAust's unique strategy is to develop MPL to treat cancers in both dogs and humans. This provides early access to the companion animal cancer drug market, which is valued at close to US\$1 billion/yr. Additionally, treatments that work effectively in dogs, are recognised as being highly predictive of the way drugs behave in human clinical trials. Such outcomes are highly valued by potential pharma partners and regulators alike. Hence, trials undertaken using MPL in dogs will inform and accelerate parallel efforts to develop MPL as a human cancer therapy

This approach differentiates PharmAust from its peers and provides access to multiple early and later-stage value inflexion catalysts.

Finally, the recent news that PharmAust is reformulating MPL to improve taste and dose, clears the way to expand our ongoing clinical trial programs in 2018. We look forward to updating the market on these plans over the coming months.

On the Roadmap we announced in May (table below), I'm pleased to report we remain on-track for all major milestones.

### **Phase II Cancer Trial in Dogs Diagnosed with Lymphoma (Q3/Q4)**

We continue to make steady progress to complete the Phase II trial in dogs diagnosed with lymphoma. The primary goal is to show that using MPL as a front-line therapy is associated with stable disease and/or tumour regression.

A successful outcome to the studies is expected to catalyse commercial opportunities with companies such as Elanco and also to inform the design of our follow-on clinical trials using reformulated MPL.

We recently received the latest shipment of capsules and have also expanded the number of registered sites participating in the veterinary study. We remain on-track to report on the outcome of the clinical trials in Q3/early Q4 this year.

#### **MPL Reformulation (Q4)**

In June 2017 PharmAust appointed BRI Pharmaceutical Research to reformulate MPL. The key objectives are to i) overcome the unpleasant taste of the current formulation and ii) increase the dose of monepantel in each tablet or capsule to reduce overall pill burden.

BRI recently confirmed it is making good progress towards the first major milestone scheduled for late August. PharmAust expects to update the market on the outcome from this work in September.

#### **Prepare for Clinical Trials using Reformulated MPL (Q4)**

PharmAust is engaging with regulatory and clinical consultants to develop our clinical trial plans using the reformulated MPL. The company is also in discussion with key global opinion leaders to join our clinical advisory team. PharmAust expects to announce the first of these appointments and to reveal details of its clinical development plans in Q4 this year.

#### **Elanco Option Agreement (Q4)**

PharmAust is progressing several options with regards the option agreement with Elanco. The company expects to report on the outcome of these efforts in Q4, 2017.

#### **Epichem (Q4)**

In July PharmAust was delighted to announce that Epichem generated record revenues of \$3.05m for the 2017 financial year (FY). Epichem has forecast revenues of \$4m for 2018 FY.

Epichem was also pleased to announce a 50% expansion to its existing laboratory space and hood capacity to meet increasing demand. This expansion will be part-funded by a \$466K loan from the Export Finance Insurance Commission (Efic), to be repaid over four years.

Finally, in Q2, 2017 Epichem submitted its applications for both ISO17025 and ISO17034 Quality Accreditation, which represent the highest international standards for the production of reference standards. An on-site audit by the regulatory body was completed early this month and an outcome to the application process is expected by Q4, 2017.

#### **Conferences**

Dr Richard Hopkins recently attended the Bioshares Investor event in Queenstown, New Zealand. This is Australia's prime biotech CEO and investor event. In May, Dr Richard Mollard attended the Australian and New Zealand College of Veterinary Scientists (ANZCVS) conference in Queensland. Feedback was very encouraging with a number of veterinarians expressing interest in MPL and its

potential to address an unmet need for new oncology treatments. PharmAust is continuing discussions aimed at expanding the number of centres willing to participate in clinical trials using reformulated MPL

**Website Upgrade (Q3):**

PharmAust is rebuilding its website using a modern platform and also upgrading the content. The company expects to launch the new website in Q3, 2017.

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

Activity	Details	Quarter
Complete Phase II compassionate use trial 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>Appoint reformulation CRO ✓</li> <li>Higher dose</li> <li>Better taste</li> <li>Ready for Phase I-II clinical trials</li> </ul>	Q4
Prepare for human and dog clinical trials 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</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>	Q4

I trust this gives you a snapshot of the company and a sense of its momentum as it moves rapidly towards a number of key strategic milestones.

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We will continue to keep shareholders informed via our announcements, this quarterly update and forums we hold from time to time in Australia's capital cities.

Thank you for your support.

Yours faithfully

Richard Hopkins

Chief Executive Officer

**Enquiries:**

**Dr Richard Hopkins**

CEO

Tel: 0405 656 868

[rhopkins@pharmaust.com](mailto:rhopkins@pharmaust.com)

**Dr Roger Aston**

Executive Chairman

Tel: 0402 762 204

[raston@pharmaust.com](mailto:raston@pharmaust.com)

**About Epichem:**

Epichem is a wholly owned subsidiary of the ASX listed company PharmAust Limited. Located in Technology Park, Western Australia, Epichem has been delivering products and services in synthetic and medicinal chemistry to the global drug discovery and pharmaceutical industries in 35 countries worldwide for over 12 years. Epichem has a newly constructed state-of-the-art laboratory and has world class equipment and expertise in synthetic and medicinal chemistry for the cost effective synthesis of drug analogue libraries and intermediates. It also has a rapidly growing catalogue of pharmaceutical reference standards. More information at [www.epichem.com.au](http://www.epichem.com.au)

**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.

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