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PHARMAUST LIMITED
Desk Note - Sept 2019

COMPANY OVERVIEW

PharmAust Limited (ASX:PAA) "PharmAust" or "the Company" is an Australian clinical stage oncology company repurposing the drug Monepantel (MPL) for targeted cancer therapeutics in both humans and animals. The company is at a pivotal stage in their development with canine phase 2 clinical trials commencing imminently. Canine trial results are expected by Q4'19, activating large pharma partner Elanco Animal Health's (Elanco) option to license MPL as an anti-cancer vet therapeutic, marking a potential major corporate outcome for PharmAust. The company's wholly owned subsidiary Epichem, is a profitable world class medical chemistry company with ~$4.2million in annual revenues expected for FY 2020.

Repurposed drugs dominate the veterinary market and are increasing in popularity in human products due to the considerable saving on cost and time of drug development. Historic safety data and regulatory approvals present a far superior commercial model to traditional drug discovery. As a repurposed drug, MPL has a significant history of safe and effective use in both humans (clinical trials) and animals (on market), it is currently sold for the treatment of parasitic infections in sheep (by Elanco). MPL's non-toxic, anti-cancer therapeutic properties provide a significant value proposition in becoming a potential chemotherapy alternative, not only for the animal applications but the future potential disruption of a ~$47billion human chemotherapy market.

Figure 1: PharmAust Logo

INVESTMENT HIGHLIGHTS

SOLID TUMOR TREATMENT MARKET IN THE 100'S OF $BILLIONS | Solid tumor treatment market US$121billion in 2018, expected to reach US$424billion by 2027.

NON-TOXIC ALTERNATIVE TO CHEMOTHERAPY | Unlike Chemotherapy which attacks both the cancer and also normal cells, MPL is exceptionally non-toxic to normal cells and a potential replacement therapy to chemotherapy a ~$47billion pa market.

PIVOTAL PHASE 2 TRIALS TO ACTIVATE BIG PHARMA LICENCING OPTION | Successful canine trials would activate the exclusive option agreement with big pharma partner Elanco ($10B) over the global licensing of MPL for animals.

DRUG REPURPOSING ENSURES HIGH PROBABILITY OF SUCCESS | Substantive historic safety and toxicity data for MPL from previous big pharma developer (Elanco).

FUNDED BY PROFITABLE SUBSIDIARY EPICHEM | Epichem is profitable and has projected ~$4.2million in revenues, contributing to PharmAust in accelerating MPL.

CONTINUED COMMERCIAL SUCCESS OF REPURPOSED DRUGS | Drug repurposing is a faster and less capital intensive commercial alternative to new drug development.

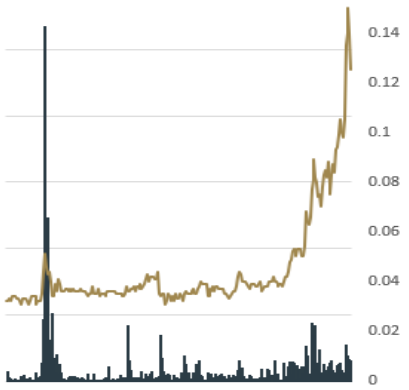
EXTENSIVE SUITE OF INTERNATIONAL PATENTS | PharmAust have an impressive suite of patents over the use of MPL and its analogues as an anti-cancer product.

SUCCESSFUL PHASE 1 CLINICAL TRIALS IN HUMANS & DOGS | All trials have achieved primary clinical endpoints in both safety and reduction of tumor markers.

CORPORATE SNAPSHOT

GICS Sector	Pharmaceuticals
Shares on Issue (M)	280.22
Share Price ($)	0.125
52 Week High/Low ($)	0.03 - 0.15
Market Cap ($M)	35.03
Cash ($M)	~2.0
Debt ($M)	0.325
Unlisted Options (M)	56.9

12-MONTH SHARE PRICE



BOARD OF DIRECTORS

Dr Roger Aston	Executive Chairman
Robert Bishop	Executive Director
Sam Wright	Director & Co-Sec
Neville Bassett AM	Non-Exec Director
Dr Richard Mollard	CSO

MAJOR SHAREHOLDERS

Board and Management	9.3%
Hybrid Holdings Pty Ltd	7.55%
Van Blommestein SF AC	4.37%
Top 20%	37.54%

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PHARMAUST LTD — DRUG REPURPOSING SPECIALISTS

PharmAust's key objective is to develop, synthesise and commercialise ethical, safe and effective pharmaceuticals through the company's two wholly owned subsidiaries—Epichem and Pitney Pharmaceuticals. PharmAust's core focus is evaluating MPL's potential repurposing, for the treatment of cancers through it's drug development arm Pitney Pharmaceuticals. Traditionally the Company hasn't profit shared but with significant corporate milestones approaching, profits may be spread to ensure accelerated conversion of contracts and commercialisation of MPL.

Provide services in synthetic and medicinal chemistry to the drug discovery and pharmaceutical industries across the globe. Epichem have a projected ~$4.2million in revenue this FY and have historically not profit shared across subsidiaries, instead opting to expand Epichem to take on more contracts.

Are evaluating PharmAust's lead drug candidate MPL for the treatment of various forms of cancers in both animals and humans. This integrated approach of simultaneous evaluation is expected to save considerable time and costs in development, additional to the drug repurposing benefits.

COMMERCIAL SUCCESS OF REPURPOSED DRUGS

Current regulatory stringency, time and costs involved in new drug development has resulted in existing registered drug repurposing as a far more efficient and popular alternative. From 2007-19, 30-40% of the approved drugs or biologics launched for the first time in the US were either drugs repurposed for new indications or reformulations of existing drugs.

The extensive success of repurposed drugs is highlighted in the chart below (figure 2) with multiple repurposed brands achieving billions in annual sales. Of particular note is Spravato, an S-antinomer for the well-known anaesthetic Ketamine which the FDA approved on just a single positive placebo-controlled trial after numerous unsuccessful trials, after the FDA

BRAND NAME	ORIGINAL INDICATION	NEW INDICATION	PHARMACEUTICAL COMPANY	MAX ANNUAL SALES
SPRAVATO	Anaesthetic (Ketamine)	Treatment Resistant Depression	Janssen/J&J	Approved March 2019
REVLIMID	Anti-Nausea	Multiple Myeloma	Celgene	$9.7 Billion 2018
TECFIDERA	Psoriasis	Multiple Sclerosis	Biogen/IDEC	$4.0 Billion 2017
VIAGRA	Angina	Erectile Dysfunction	Pfizer	$2.05 Billion 2008
GEMZAR	Anti-Viral	Various Cancers	Eli Lilly	$1.72 Billion 2008
RITUXAN	Various Cancers	Rheumatoid Arthritis	Biogen & Roche	$7.1 Billion 2015
EVISTA	Osteoporosis	Invasive Breast Cancer	Eli Lilly	$1.07 Billion 2011
PROSCAR	Hypertension	BPH	Merck	$741 Million 2008
THALOMID	Anti-Nausea	Leprosy/Multiple Myeloma	Celgene	$535 Million 2008
REVATIO	Angina/ED	PA Hypertension	Pfizer	$525 Billion 2008
PROPECIA	Hypertension	Male Pattern Baldness	Merck	$429 Million 2008
ELMIRON	DVT	Interstitial Cystitis	Janssen/J&J	$400 Million 2015

Figure 2: Repurposed Drugs or Biologics and Peak Sales post 2007

MONEPANTEL — A SIGNIFICANT VALUE PROPOSITION

Current Solid Tumor Treatments—Preserving The Immune System

Chemotherapy kills cancer cells as well as unfortunately normal cells by stopping any growth, and it is considered a highly toxic treatment that harms the body's immune system which has significant side-effects. The mTOR inhibitors Afinitor and Rapamune (Rapalogues) are considered immunosuppressants as well, meaning the body cannot remain on these therapies for extended periods of time without the immune system substantially suffering.

Monepantel MPL was developed by Novartis Animal Health (Now owned by Elanco), under the name Zolvix as an anti-parasitic in the livestock industry. It inhibits the mTOR pathway, a known driver of cancer growth, effectively acting to suffocating cancer whilst preserving the body's healthy cells. Extensive clinical data from Elanco show MPL to be safe and extremely non-toxic, allowing the ability to increase dosage significantly to target cancer, without major side-effects.

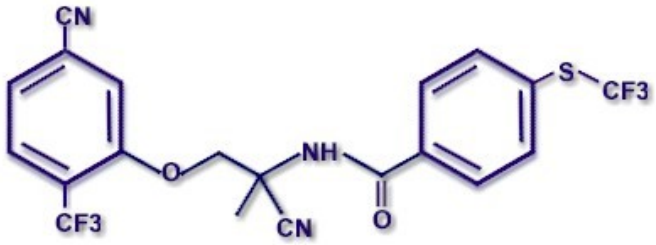

Figure 3: Monepantel —Developed by Novartis Animal Health (Elanco)

PharmAust initially identified MPL as a frontline therapy for cancer, then proceeded to explore it in conjunction with chemotherapy. Encouraging results and low toxicity has opened up the potential for higher doses and MPL therapy to be a viable stand-alone end-point therapy, where patients can live with the stable disease, progression free as an alternative to Chemotherapy (~$47billion pa industry) and its harmful side effects.

Figure 4: Healthy Beagle Puppy

Cancer In Dogs

Dogs typically suffer from majority of the same cancers as humans with very similar gene systems. The Company's dual development strategy for MPL's use in animals and humans is quite strategic in that the company wish to translate cancer treatment from pet dogs to humans (normally done in reverse). This results in significantly lower requirements for preclinical or pilot human safety trials, in addition to the already reduced costs and time of taking a repurposed drug through the development process as opposed to developing a new drug.

Reformulation

The only major setback through PharmAust's repurposing has been the unpalatability of the liquid MPL, Zolvix as both humans, and dogs rejected/regurgitated the drug used in clinical trials. This resulted in the Company having to reformulate the drug into a new palatable tablet form for further canine trials. This reformulation occupied a majority of 2018 but was extremely successful reporting micronization of MPL by BRI Pharmaceuticals and increased dosing and taste masking was achieved.

MPL + Metabolite Increased Effectiveness

In January this year researchers at the Olivia Newton-John Cancer Research Institute demonstrated monepantel's major metabolite retains anti-cancer activity similar to monepantel. The MPL metabolite showed relatively little effect upon healthy non-cancer cells and essentially acts as a "double kick" in killing cancer cells along side MPL.

Figure 5: Laboratory Drug Development

MONEPANTEL — ADDRESSABLE CANCER MARKET

Monepantel Therapy Recurring Revenue

MPL acts as a cancer suppressor with the potential to be taken for long periods of time at high doses to stop cancer progression. This is owing to its high safety and non-toxicity, essentially creating a therapeutic drug unlike any currently available, which can potentially be taken continuously, resulting in recurring sales to the licencee. If commercialised it is likely this drug would be priced at a premium, in line with other cancer therapies.

Companion Pet Health Market

1-in-4 dogs die of cancer, with an ageing Australian population and an increasing middle class, our companion pets are likely to be the driving veterinary expenditure increases. A 2018 report by Market Research Future predicted the companion animal segment of the animal health market is growing continuously and is expected to grow at a 9.6% CAGR during 2017–2023, reaching US$20 billion in 2023.

Improved surgical, therapeutic, and medical capabilities for companion animals will likely lead to increased life-expectancy in pets accordingly. Dogs are among the most popular pets, followed by cats. In 2017 there were a total of 60.2 million pets in households.

Pet Drug Market

The pet drug market was estimated at ~$10.2billion in 2018, with the willingness of owners to pay for treatment increasing to a threshold of $5,500 per companion pet. The US market is experiencing these effects and the animal health industry has witnessed considerably high-value mergers and acquisitions between major industry players. Not excluding PharmAust partner Elanco's $7.6billion merger with Bayer.

Human Oncology Market

If PharmAust's MPL repurposing is to capture even a small market share of the existing cancer therapy market, it is in for a significant re-rating in valuation.

MPL is currently aiming to be a superior alternative to chemotherapy treatment in cancer which stand alone is a ~$47billion per annum industry.

Solid Tumor Market

The broader solid tumour applications of MPL as a cancer therapy drug could see PharmAust carve out a slice of the global treatment market, valued at US$121.3billion in 2018. Expected to reach US$ 424.6billion by 2027, expanding at a CAGR of 15.0% from 2019 to 2027.

ELANCO PARTNERSHIP — GLOBAL LICENCING OPTION OVER ANIMAL MPL

Option Agreement

In April 2018, PharmAust signed an option agreement with Elanco to develop MPL in dog cancers. Under the terms of the agreement, Elanco have supplied the Good Manufacturing Process GMP grade MPL, for use in the recent dog cancer trials.

PharmAust has granted Elanco an option ("the Elanco Option") to negotiate for an exclusive, worldwide royalty bearing commercial licence to use PharmAust's intellectual property in the field of treatment of cancer in animals. PharmAust will manage clinical trials that will assess the efficacy and safety of monepantel in dogs diagnosed with various cancers.

PharmAust will fund trial costs with the Elanco Option activating upon submission of the final report from the imminent Phase 2 Clinical Trials for Canine Cancer.

Upon Elanco's exercise of the Elanco Option, the parties shall enter into a negotiation period not lasting more than six months to agree the terms of the license agreement, including commercial payments to PharmAust.

The "Blue Sky" Human Market

A commercial outcome for veterinary applications would allow PharmAust to refocus on development for the much larger human market.

Should Elanco not proceed to exercise the option PharmAust will be free to seek alternative commercialisation partners.

Resulting Supply Scale-up

The agreement provides a twofold benefit to PharmAust in securing a stable supply of GMP-grade MPL that provides a scale-up opportunity ahead of dog cancer trials as well as build the relationship with a potential commercial partner.

The extensive 2019 clinical trials through the option agreement terms saw 2,000 tablets delivered in February for Phase 1 trials and 7,750 MPL tablets recently arriving ahead of pivotal September phase 2 clinical trial, progressing to the commercialisation of the drug.

Figure 6: Elanco Logo

PATENTS, PROTECTION AND CORNERING MPL THERAPY MARKET

Extensive Suite of MPL/mTOR Patents

PharmAust has maintained an active program of patenting MPL for cancer, as well as for other diseases and disorders reliant on mTOR pathway and also for MPL analogues for which the potency may be greater or more selective. Protection of the companies intellectual property IP is vital, with MPL coming off patent in 2024. A broad range of patent protection surrounding MPL, provides a growth opportunity for PharmAust into future non-cancer indications.

Supply Chain

The MPL compound is owned by Elanco, with composition-of matter patent protection out to 2024. Elanco has a first right of refusal to option use of the compound for the treatment of canine cancers. If Elanco does not take up the option, then PharmAust would require a license from Elanco to commercialise the drug independently or through another partner. However a strong relationship through the option agreement and regular collaboration should abate the potential risk.

Market Competitors

PharmAust has taken all the necessary precautions and registered patent protections available. Therefore, should a larger competitor want to enter this market using MPL or its analogues, they would need to enter into a deal with PharmAust.

Figure 7: IP Folder graphic

DUAL CLINICAL TRIAL DEVELOPMENT

PharmAust has a dual clinical development strategy for veterinary and human cancers as developing new cancer treatments from pet dogs to humans offers 3 strategic benefits. It is highly predictive, lowers risk of failure, and provides high-quality preclinical data. Many studies validate the use of dog models in studying cancer biology. Studies have shown that cancers in dogs show the same interplay of genetics, age, and environmental exposures as in humans, and that these similarities are stronger than they are between humans and mice.

Brain cancer cells in mice that are resistant to temozolamide were killed by MPL in preclinical trials, indicating its potential to be used in patients resistant to chemotherapy. Invitro studies also show that the treatment of ovarian cancer cells with MPL resulted in reduced cell viability, inhibition of cell proliferation, and suppression of colony formation.

Early Phase Clinical Trials

Early phase trials indicated a MPL's superiority in toxicity compared with most competitors. Pfizer and Novartis already have marketed mTOR drugs.

'FIRST IN MAN' Trial

MPL showed preclinical activity in pancreatic and colorectal cancers as a monotherapy (stand-alone therapy) in mice xenografts. Based on these preclinical results, the company evaluated the anti-cancer activity of MPL in a Phase I 'first in man' trial. This was a Phase I dose evaluation study, carried out at Royal Adelaide Hospital (RAH) in patients with solid tumours.

"6 from 6 of the human participants displayed reduction in p70S6k marker (mTOR pathway) and 4 of 5 patients showing a reduction in p-4E-BP1, whilst reporting better safety profiles than other anti-cancer drugs."

Early Phase 1 Human Clinical Trial—Royal Adelaide Hospital

PHASE 1 CANINE TABLET CLINICAL TRIAL 2019

PharmAust's phase 1 of Monepantel trials showed positive outcomes for patients with solid cancerous tumours that had failed to respond to conventional chemotherapy.

Figure 8: Drug Sythesising Graphic—PharmAust website

EPICHEM — WORLD CLASS CHEMSTRY PROVIDER

Epichem is a wholly owned subsidiary of PharmAust Limited, they provide services in synthetic and medicinal chemistry to the drug discovery and pharmaceutical industries. The Company is ISO accredited from NATA (The National Association of Testing Authorities, Australia), an internationally recognised standard of expertise which is matched by their new state-of-the-art equipped Bentley laboratory which has provided services to 35 countries worldwide for over 16 years.

Epichem Highlights Include:

- A profitable business with ~$4.2million in revenues projected for FY '19/20.
- Collaboration with not-for-profit Drugs for Neglected Disease initiative (DNDi) as part of a consortium to find a cure for Chagas Disease.
- Could not meet demand for services contracts at previous facility.
- Recent expansion of its laboratory space by ~50% in May 2018 in order to accommodate new business.
- Epichem export to 33 countries worldwide with potential to become one of a select group of providers globally.
- Significant R&D tax incentive refunds.

An increasing inclination of major pharma companies toward outsourcing activities related to clinical trials and increasing R&D expenditure is expected to boost demand for Epichem's services, presenting a unique opportunity for Epichem to become a controlling supplier of chemistry services in Australasia.

Figure 9: Epichem Logo

Figure 10: Epichem Laboratory

UPCOMING CATALYSTS

- **PHASE 2 CLINICAL TRIALS FOR CANINE CANCER TREATMENT**
- **PHASE 2 INITIAL RESULTS AND PRIMARY OUTCOME DATA**
- **PHASE 2 SECONDARY END-POINT DATA AND STATISTICAL SIGNIFICANCE**
- **ELANCO 6-MONTH OPTION AGREEMENT ON GLOBAL LICENSING**
- **FURTHER ADVANCED CLINICAL TRIALS FOR MPL IN HUMANS**
- **PIPELINE OF FUTURE DRUG DEVELOPMENT FOR NON ONCOLOGY APPLICATIONS WITH MPL-LIKE MOLECULES**

KEY MANAGEMENT

Dr Roger Aston

Executive Chairman

- Dr Aston has extensive experience on boards and as Chief Executive Officer of many private and publically listed biotechnology companies
- He has +30 years experience in the pharmaceutical and healthcare industries
- Director or chairman on a number of boards carrying out late stage drug development

Robert Bishop

Executive Director

- Mr Bishop has +30 years experience in corporate finance and equity capital markets.
- Experience as a Lawyer and an investment banker.

Sam Wright

Director and Co-Sec

- Mr Wright has +20 years experience in biotech and healthcare.
- Extensive experience in relation to public company responsibilities, including ASX and ASIC compliance, corporate governance, statutory financial reporting, and shareholder relations.

Neville Bassett

Non-Executive Director

- Mr Bassett is a CA with a Member of the Order of Australia (AM).
- 35 years working in accounting, finance and stockbroking.

Dr Richard Mollard

Chief Scientific Officer

- Dr Mollard has +20 years experience in biotech and pharmaceuticals.
- Extensive national and international experience.

KEY RISKS

Competing products: There are several solid state tumor drugs currently in use and in development, providing a potentially crowded market. That considered through successful phase II/III trials MPL should be the top available treatment.

Clinical Trial Risk: There is a possibility that late-stage trials (Phase II/III) are unable to show the required efficacy profile or report an intolerable safety concern with MPL. Phase II trials are considered the highst risk phase of drug development.

Manufacturing Risk: Given Elance are the rightful owners of the compound Monepantel, there is a licencing risk should Elanco not take up the global licencing rights for MPL.

IP Risk: Failure to obtain new patents or protect issued patents may negatively impact the PharmAust share price.

Funding Risks: A delay in achieving a partnership and subsequent upfront/milestone payments may have an impact on PharmAust's clinical program development.

Timing risks: Delays in timelines may inhibit optimal partnerships, milestone payments and long-term revenues. Delays can be caused by but not limited to; trial requirements & recruitment rates; the FDA approval process; Other products reaching market.

Regulatory compliance issues: Anything from accounting issues, manufacturing practices and product recalls could materially impact our current earnings forecasts.

Poor Design of Clinical Studies: It is imperative that the correct personnel are in place to optimally design all clinical trials. As many biotech companies have experienced, an incorrectly designed study will inevitably lead to detrimental results.

SOURCES

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7. *PharmAust Limited ASX Announcement—PharmAust Appendix 4C and Shareholders', 31st of January 2019*
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