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PHARMAUST LIMITED (ASX.PAA)

JP Equity Partners Desk Note - July '22

PHARMAUST APPROACHES CORPORATE OUTCOME ON MONEPANTEL

PharmAust Limited (ASX.PAA) "PharmAust" or "the Company", a clinical stage biotechnology company, approaches an inflection point in its development with several clinical trials set to commence in FY23 of which 3 are Phase 2/3 trials. This represents multiple avenues to a billion dollar drug success opportunities. PharmAust's sole focus is the repurposing of the drug Monepantel (MPL) for multiple targeted therapeutics in both humans and animals. MPL is a novel, potent and non-toxic inhibitor of the mTOR (mammalian Target Of Rapamycin) pathway, a pathway that is key in influencing cancer growth, neurodegenerative diseases and even viral activity. The global mTOR inhibitor market now exceeds US$2.5Bn annually and PharmAust is well-positioned for a corporate outcome to commercialise MPL's use in veterinary cancers in the short-term and then in human cancers thereafter.

As a repurposed drug, MPL is already registered in 38 countries as well as being TGA approved. Additional to the substantial time and costs savings of repurposing marketed drugs, MPL's comparatively low, almost non-toxic nature, provides a significant advantage over existing oncological, and neurodegenerative therapies. This non-toxic nature preserves the recipients immune system from obliteration (common in chemotherapy and rapamycin alternatives) during therapy, allowing for optionality on high MPL dosages, & resulting in better quality of life (QOL) outcomes.

MPL's anticancer therapeutic properties provide a significant value proposition as a cheaper and ethical alternative to chemotherapy in Canines. Additionally, human-canine cancers are very similar with high overlap in treatments/outcomes, this bodes well for MPL's to disrupt as a human anticancer therapy, a ~US$125Bn/year market.

KEY TAKEAWAYS

PIVOTAL 12 MONTH PERIOD FOR PHARMAUST, A POTENTIAL COMPANY MAKER | Corporate outcome on MPL vet anticancer licensing or Phase 2 Human cancer trial.

MPL - A PROVEN, CHEAPER, MORE ETHICAL CANINE ANTICANCER ALTERNATIVE | Phase 2b Canine trials on aggressive B-Cell Lymphomas successful and continue to improve, demonstrating increased progression-free survival, even tumor regression.

POTENTIAL CORPORATE OUTCOME ON MPL VET ANTICANCER APPLICATION | The highly marketable, progression free survival outcome and recurring revenues from commercialisation of MPL for Canines an attractive partnership for Big Pharma.

MULTIPLE PHASE 2/3 TRIALS = MULTIPLE AVENUES TO A US$1BILLION+ SUCCESS | MPL's targeted Cancer, Motor Neurone Disease (MND) and COVID-19 therapies all represent multiple US$1Bn+ addressable markets serviced by more toxic alternatives.

MND PHASE 1 CLINICAL TRIAL DATA TO FAST-TRACK COVID-19 PHASE 2 TRIALS | The FightMND funded, Phase 1 MND human trial should present pharmacokinetic (PK) data that will allow MPL COVID-19 trials to skip to Phase 2 saving $1.5m.

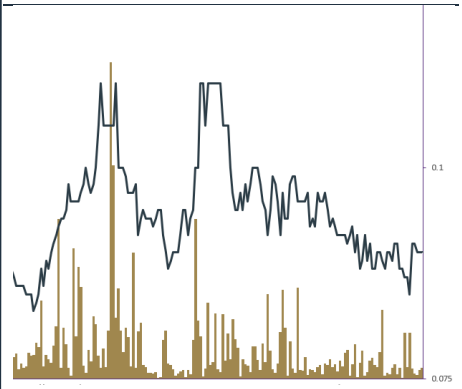
PAA IN DISCUSSIONS WITH BIG PHARMA AHEAD OF PHASE 3 CANINE TRIAL | Big Pharma funding agreement prior to Phase 3 trials an optimal outcome for PAA.

'REMARKABLE RESULTS' IN COVID-19 ENTICES MPL AS AN ANTIVIRAL THERAPY | Preliminary data from the Walter & Eliza Hall Institute demonstrates MPL suppression of COVID-19 virus infectivity by up to ~95%. Phase 2 human trials planned.

CORPORATE SNAPSHOT

GICS Sector	Biotech
Share Price (c)	9.1
52 Week High/Low (c)	7.1 - 12.0
Market Capitalisation ($M)	28.8
Cash ($M)	~2.8
Shares On Issue (M)	316.9
Options (M)	81.2

SHARE PRICE PERFORMANCE



BOARD OF DIRECTORS

Dr Roger Aston	Executive Chairman
Robert Bishop	Executive Director
Sam Wright	Finance Director
Neville Bassett AM	Non-Exec Director
Fiona Milner	Epichem GM

MAJOR SHAREHOLDERS

Board and Management	9.3%
Darcy Family SF	7.02%
Van Blommestein SF	5.37%
Top 20%	36.74%

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REPURPOSING MONEPANTEL - ANTICANCER THERAPEUTIC

THE PROBLEM - Solid Tumor Treatment and Immune System Preservation

Chemotherapy kills cancer cells, however unfortunately it carries a rather nasty side-effect in that it also targets regular healthy cells. It is a highly toxic treatment that harms the body's immune system which whilst producing the desired outcome of attacking cancers. Chemotherapy can often leave the bodies systems permanently damaged.

mTOR inhibitors are commonly used today as targeted cancer therapies including the likes of; Rapamycin, Everolimus and Sirolimus, all of which boast +$1Bn in annual sales. Despite mTOR inhibitors effectiveness in preventing cancer cell growth and proliferation, these drugs are all immunosuppressants, meaning they attack healthy tissues simultaneously with cancers. As such the human body can only remain on these cancer treatments for short periods of time without immune system obliteration, unlike the potential of MPL treatment.

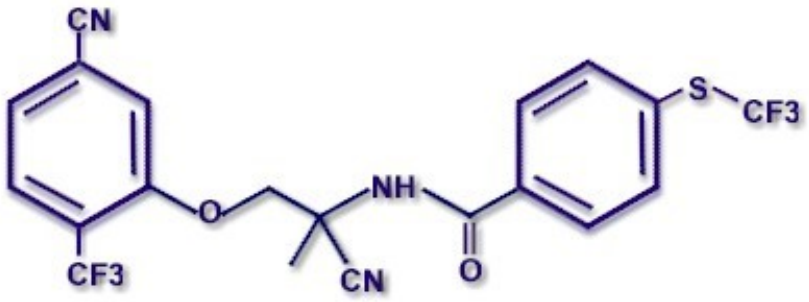

Figure 1: Monepantel —Developed by Novartis Animal Health (Elanco)

Why Monepantel?

Monepantel was developed by Novartis Animal Health under the name Zolvix as an anti-parasitic in the livestock industry in 1994. Novartis demonstrated extensive clinical data showing MPL to be highly safe and non-toxic to the immune system. Hence, today MPL is an TGA approved drug that is currently registered in 38 countries worldwide.

MPL's mechanism of action is inhibiting the mTOR pathway, a pathway key in governing both cell growth and proliferation in solid state tumors. MPL effectively acts to suffocate cancers of its key proteins that allow cell growth, whilst simultaneously promoting autophagy which works towards preserving the body's healthy cells, including the mopping up of dying cancer cells.

MPL Anticancer Therapy—Progression Free Cancer Survival

PharmAust believe MPL can act as a frontline anticancer therapy, which could act to suffocate targeted cancers over extended periods of time, safely and with good quality of life outcomes. MPL presents a highly attractive drug success outcome as a take-home, safe, continuous usage, recurring revenue model, that can provide progression free cancer survival, which clinical trials have shown to be a viable standalone end-point .

MPL patients could live with the stable disease in solid tumors, cancer progression free, as an alternative to harmful and expensive chemotherapy. This potential long-term end-point outcome and its recurring drug sales revenue, would present an extremely attractive partnership opportunity for Big Pharma players and is no doubt why PharmAust are currently in discussions with major pharmaceutical producers.

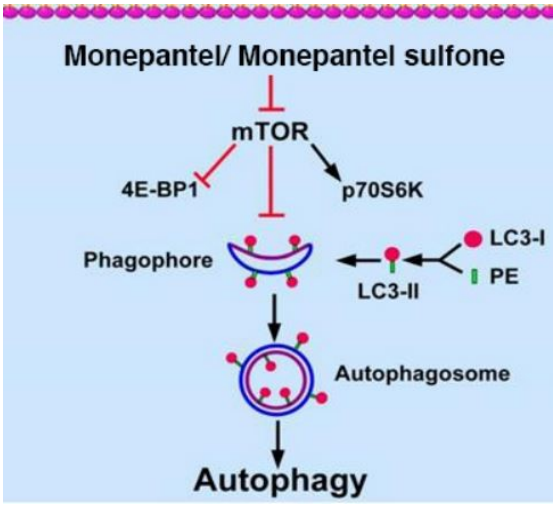

Figure 2: Monepantel / Monepantel Sulfone MoA

COMMERCIAL SUCCESS OF REPURPOSED DRUGS

Competitive Advantages of Repurposing

Repurposed drugs dominate the veterinary market and are increasing in popularity for human products due in large to the considerable savings in both time to development and overall cost compared with traditional drug development. Historic safety data and existing regulatory approvals present a far superior commercial model to traditional drug discovery. From 2007-2020, 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.

Leveraging MPL's Historic Data

As a repurposed drug, MPL has a significant history of safe and effective use in both humans (clinical trials) and animals (Zolvix). Currently sold for the treatment of parasitic infections in sheep, Novartis conducted extensive clinical trial data during development that led to MPL being TGA approved and considered exceedingly non-toxic compared to other mTOR inhibitors.

During development, Novartis' clinical trials were also conducted in Canine Beagles. PharmAust has leveraged this quality PK data in their own Canine Cancer trials as well as in design for human cancer trials.

The overlap of human-canine cancers and the targeted therapeutics is highly correlated affording PharmAust the ability to translate existing successful Phase 2 Canine trial data when proposing Phase 2 Human Cancer trials.

Repurposed Drug Commercial Successes

The extensive success of repurposed drugs is highlighted in the chart below (figure 3) with multiple repurposed brands achieving billions in annual sales yoy. Of particular note is Spravato, an S-enantiomer 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 highlighted a need for new novel depression drugs.

BRAND NAME	ORIGINAL INDICATION	NEW INDICATION	PHARMACEUTICAL COMPANY	MAX ANNUAL SALES
SPRAVATO	Anaesthetic (Ketamine)	Depression	Janssen/J&J	Estimate $500 Million 2021
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/Multi Myeloma	Celgene	$535 Million 2008
REVATIO	Angina/ED	PA Hypertension	Pfizer	$525 Million 2008
PROPECIA	Hypertension	Male Pattern Baldness	Merck	$429 Million 2008
ELMIRON	DVT	Interstitial Cystitis	Janssen/J&J	$400 Million 2015

Figure 3: Repurposed Drugs or Biologics and Peak Sales—post 2007

CANINE CANCER THERAPY—RESULTS ATTRACTING GLOBAL ATTENTION

CANCER IN CANINES - LOW RISK CLINICAL TRIALS

As previously mentioned canines typically suffer from majority of the same cancers as humans due to highly similar gene systems. MPL, which is registered in 38 countries for use in animals also has extensive data from Novartis' clinical trial usage of MPL in Canine Beagles. PharmAust decided to develop a new cancer treatment for pets that they could later translate to humans (normally done in reverse) as the logical course of development.

The 4 strategic benefits of pursuing cancer treatment in pet dogs prior to humans include:

- Canine clinical trials are highly predictive for humans
- Lower risk of failure thanks to extensive existing data in beagles
- Provides high-quality preclinical data for humans, and
- MPL's value proposition for cancer in canines and potential substantial market share

PHASE 2 MPL CANINE B-CELL LYMPHOMA - Positive Results Garnering Human Trial Attention

Data to date from PharmAust's Phase 2 trial in canines with B-Cell Lymphoma has demonstrated anticancer activity and increased progression-free survival by MPL. These outcomes continue to improve with fine tuning and the average trial participants are doubling their mean survival time over prednisolone alone (the current standard-of-care method) and quadrupling survival over no treatment, particularly impressive given B-Cell Lymphoma is a notoriously aggressive cancer.

Dogs in the trials remain active with a high quality of life (QOL) throughout when compared to palliative steroid therapy, with many participants choosing to remain on MPL post-trial allowing PharmAust to iron out an optimum drug blood plasma level to Phase 3 trials.

These successful Phase 2 results and continued improving outcomes bode well for further human cancer trials in CY 2022 and have additionally spurred discussions with Big Pharma on a MPL licensing/sale going forward.

VALUE PROPOSITION OF MPL - POSITIONING FOR 60% - 80% CANCER MARKET SHARE

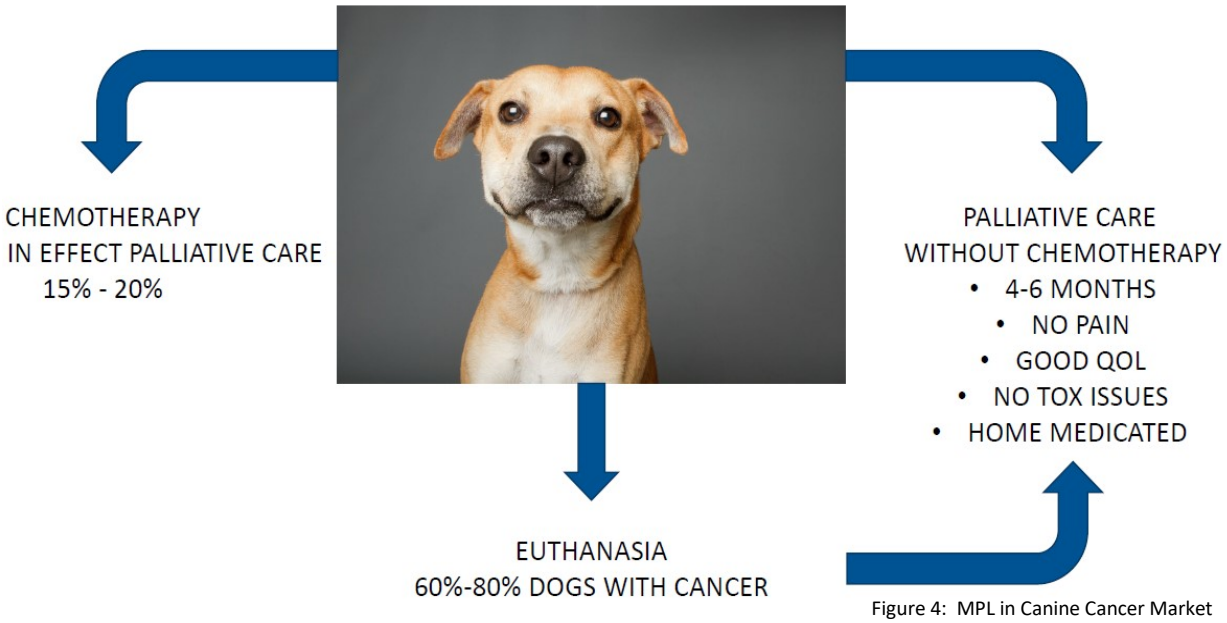

Figure 4: MPL in Canine Cancer Market

- Good safety profile with no chemotherapy side-effects or ethical issues
- Considerably cost effective alternative to expensive Chemotherapy ($5,000—$10,000)
- Substantially extended survival (4-6 months and growing) by inducing a stable disease
- Administration of the drug at home by the owner
- Good quality of life QOL compared with steroid palliative care & chemotherapy
- High quality data from aggressive B-Cell Lymphoma cancer bodes well for human trials

MULTI-TIER DEVELOPMENT STRATEGY - MULTIPLE AVENUES TO A $1Bn DRUG

With 3 human clinical trials for MPL set to commence in the next 12 months including 2 of those being Phase 2 trials in human cancer and COVID-19, not only does PharmAust have multiple 'shots on goal' at a +$1bn drug success but they have indicated that they may already be dealing on one of these avenues, with an interested Big Pharma in the coming year.

MULTIPLE AVENUES TO A BILLION DOLLAR DRUG SUCCESS:

- A possible 'Corporate Outcome' in the short-term is realistic, whether it be licensing or sale of MPL's veterinary applications in canine cancers, following the commercially relevant Phase 2 outcomes. It would make sense for PharmAust to partner with Big Pharma ahead of an expensive Phase 3 trial and have them take on the funding of a Phase 3 ahead of commercialising the product
- The addressable COVID-19 market, should Phase 2 COVID-19 trial results demonstrate prevention against SARS-COV2 induced cell death, would be a ~US$10Bn+ range market
- ALS/MND addressable market is US$3.6Bn with Riluzole already reaching ~US$1Bn in annual sales
- Finally, the biggest market of them all, and the one that is very much in play with clinical outcomes in canines facilitating rapid translation to humans, is the 'Blue Sky' US$125Bn Human Cancer industry

BLUE SKY—MPL's APPLICATION IN HUMAN CANCERS

High quality data from the aggressive B-Cell Lymphoma cancer trial in canines suggests positive correlation/translation for targeting multiple different cancers in humans. With good data in dogs over significant periods of stable disease and progression-free survival, PharmAust is set to commence Phase 2 Human Cancer trials. If MPL human trials return similar efficacy as in canines, this would be an absolute game changer and major entry into the US$125Bn human cancer industry.

PharmAust's canine results are now being recognised internationally as well, with clinical interest in offers to PharmAust for focussed Phase 1/2 trials in Glioblastoma, Esophageal and even Pancreatic cancers coming out of the UK, Italy and US. These offers highlight the inflection point that PharmAust now finds itself.

Seen below (figure 5) are the multiple Phase 1/2 trials that are ongoing and commencing for PharmAust over the incumbent 12 months. Listed below the trial types and therapeutic targets, are the tablets being used, what stage/Phase trial the drug development is in and the existing treatments /market size applicable to a successful drug outcome for MPL and PharmAust.

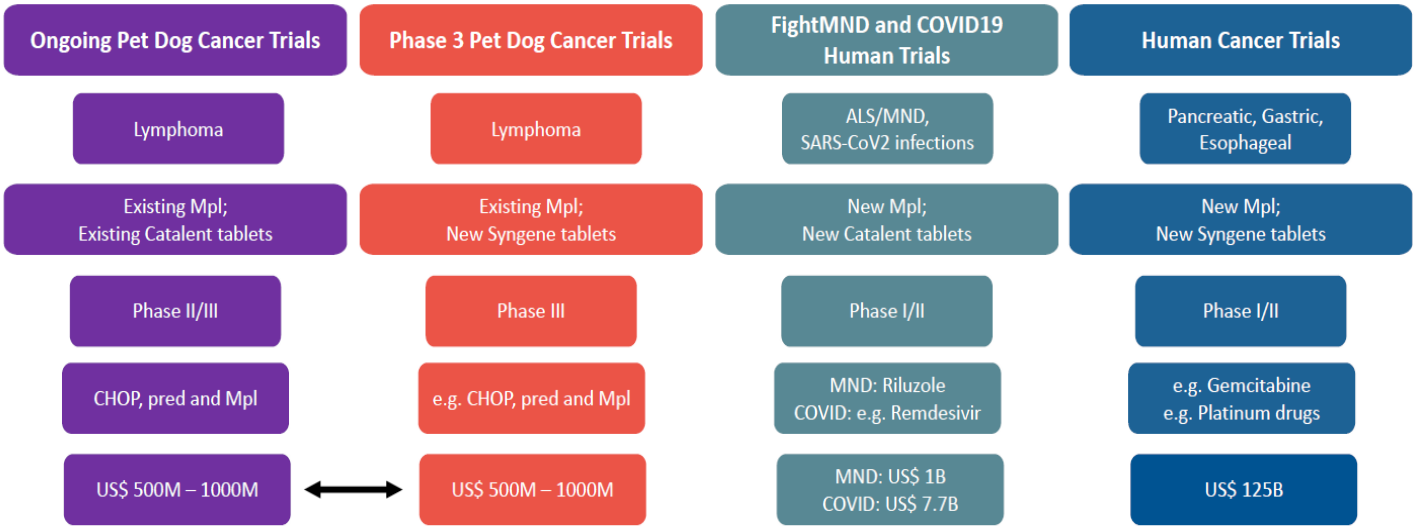

Figure 5: PharmAust multiple Phase 1/2 trials over the next 12 months

FULLY FUNDED PHASE 1 MND TRIAL - Fight MND

$880k Funded Phase 1 Motor Neurone Disease/Amyotrophic Lateral Sclerosis Trial - MND/ALS

In late 2020, the head researchers for FightMND (the largest MND research funder in Australia), identified MPL as a potential therapy for MND/ALS. MND/ALS is a rare and fatal neurodegenerative disease that slowly attacks the brain and nerves over time.

FightMND wish to measure markers in spinal fluid of sufferers to observe if MPL can reduce protein markers and perhaps in combination therapy extend life and even decrease symptoms.

mTOR Inhibitors Application to MND

As an mTOR inhibitor, MPL induces autophagy, a mechanism that clears misprocessed and excessive intracellular protein in neural cells associated with the cause of ALS/MND. It is hypothesised that MPL will benefit the health of patients neural cells by regulating these proteins and potentially reducing the symptoms of ALS/MND.

The current standard-of-care for ALS/MND is Riluzole, which is a $1bn per year drug within the broader $3.6bn ALS/MND market. If MPL can help to reduce symptoms and even extend life in ALS/MND sufferers it too has this commercial potential.

Phase 1 MND Trial Provides Important PK Data to-skip-to Phase 2 COVID-19 Trials

MND trial to provide important PK data for both the MND and COVID-19 trials, allowing PharmAust to undertake skip to a Phase 2 study in COVID-19. The Phase 2 will now take place 6-9 months earlier than previously, additionally PharmAust will save around $1.5 million.

PHASE 2 COVID-19 TRIALS IN UNVACCINATED PATIENTS

In April 2020 PharmAust and the Walter and Eliza Hall Institute of Medical Research in Melbourne, Victoria highlighted MPL's mechanism of action as inhibitor against cancer growth could be highly beneficial in the treatment of COVID-19. Repeated cell culture experiments confirmed the promising data of MPL against COVID-19, showing both MPL and monepantel sulfone (MPLS) treatment suppressed COVID-19 cell-to-cell infectivity by ~95%. Joint head of Infectious Diseases and Immune Defence division Marc Pellegrini stated that "demonstrating twice, that infectivity of COVID-19 virus particles can be suppressed by up to ~95% in cell cultures is a remarkable outcome."

MPL and MPLS both protect against SARS-COV2 induced cell death

Further collaborations by testing laboratories prior to clinical trials concluded MPL and MPLS also reduced viral RNA in culture virus media as well as reduced viral secondary infections. Trials have now been designed to test if MPL competes to prevent hijacking of host autophagy machinery and permits COVID-19 destruction.

The Phase 2 COVID-19 trial is expected to commence following the Phase 1 MND trial PK data.

Trial In Unvaccinated Patients—Eastern Block Countries EU

3-6 clinical centres in Eastern Europe have expressed interest in participating in the study.

Following successful Phase 1 PK data from the MND trial, a Phase 2 COVID-19 trial will commence skipping Phase 1 and saving $1.5m.

Additionally PharmAust signed an agreement to evaluate MPL in "humanised" mice, which will express the receptors that the COVID-19 virus binds to in humans. Efficacy in the anti-viral model will provide further evidence of the anti-viral effects of MPL.

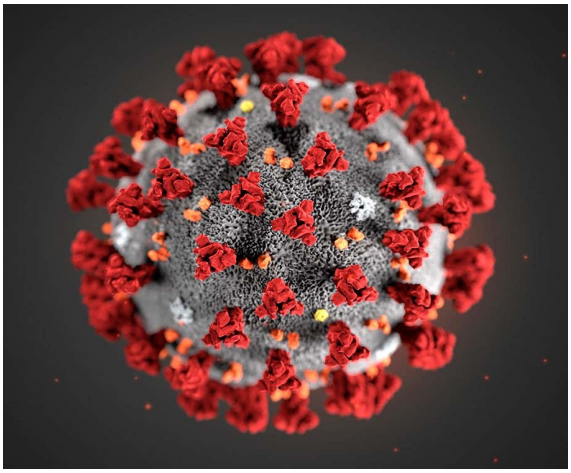

Figure 6: COVID-19 Graphic

CORPORATE OUTCOME ON VETERINARY CANCER APPLICATION

Potential Licensing Deal

Phase II results in B-Cell Lymphoma have shown MPL to be a very safe drug that promotes a high quality of life as well as being able to sustain an end-point outcome in progression free survival. The fact that MPL can acts as a cancer suppressor with the potential to be taken for long periods of time at high doses, presents a previously unmatched recurring revenue outcome for a licensing partner that should command a higher premium.

A licensing deal would be most amenable to PharmAust, allowing them the ability to deal on MPL's veterinary cancer application and leave them fully funded for any future human cancer clinical trials, whilst additionally receiving a handsome future royalty fee for MPL sales in canines.

Typically a licensing deal involves an upfront cash payment, plus remuneration of costs spent on developing drug which would now be ~$20m—$25m, as well as a 10-12% royalty on all sales of the drug and additional milestone payments. Such a deal would mark a significant commercial outcome for PharmAust and see them more than fully funded for all foreseeable future clinical trials.

Extensive Suite of MPL/mTOR Patents

PharmAust has maintained an active program of patenting MPL for cancer, as well as now COVID-19 and MND therapeutics, as well as even more diseases and disorders reliant on mTOR pathway/MPL analogues. Protection of the companies intellectual property IP is vital, with MPL coming off patent from Elanco in 2024. A broad range of patent protection surrounding MPL, provides a growth opportunity for PharmAust into the future.

The MPL compound is currently owned by Elanco, with composition-of matter patent protection out to 2024. PharmAust requesting the unused license from Elanco to commercialise the drug should another partner arise, would not be unheard of. This is common in the pharmaceutical industry and should pose minimal risks to PharmAust's commercialisation of MPL going forward.

Figure 7: Phase 2 Canine Cancer trial participants

EPICHEM — WORLD CLASS CHEMISTRY PROVIDER

Epichem is a wholly owned subsidiary of PharmAust Limited and Australia's premier provider of 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 in medical grade synthetic and organic chemistry services. Epichem has a global client base and provides services to 35 countries.

OHD Technology - Shell Australia Pilot Deal

Oxidatidtive Hydrothermal Dissolution (OHD) is a innovative non-toxic input technology that is being investigated by Epichem to develop the OHD system to allow for the removal of harmful e-waste and its conversion into valuable end user products. Using $200k WasteSorted e-waste government grant, Epichem successfully developed and processed e-waste with their innovative OHD technology in Q1 2022 which secured a recycling pilot program with Shell Australia to convert plastic waste into biodegradable/repurposed products. Success of the e-waste project confirmed:

- OHD technology successfully processes e-waste samples
- OHD technology removes plastics via oxidative dissolution, thereby concentrating major metals such as gold, tin, copper
- Conversion of plastics in the e-waste into small organic molecules that can potentially be repurposed and/or made biodegradable
- Continuous flow and semi-batch processing capability

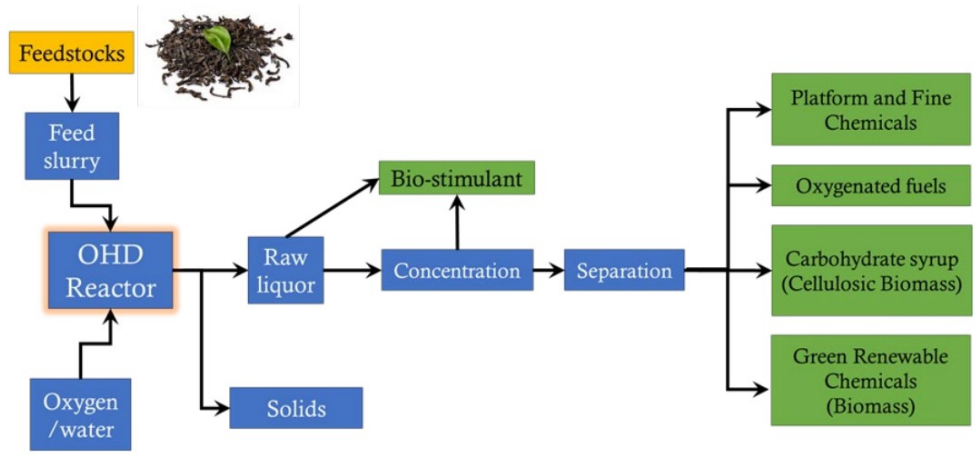

Figure 8: Oxidative Hydrothermal Dissolution reactor flow sheet

UPCOMING CATALYSTS

- **Imminent Commencement of Fully Funded Phase 1 - Human MND trial**
- **Initial Safety & PK data from Phase 1 MND trials to fast-track Phase 2 Human Anticancer and COVID-19 trials**
- **Syngene major delivery of GMP grade MPL for clinical trials**
- **Phase 2 Human Cancer Trials to commence post MND PK data**
- **MPL Phase 3 Vet Cancer trial commencement in combo with prednisolone**
- **Corporate Outcome expected FY23 on the licensing or sale of MPL's Vet Cancer applications following commercially valuable Phase 2 outcomes**

KEY MANAGEMENT

Dr Roger Aston

Executive Chairman

- Dr Aston has extensive experience on boards and as CEO & Chairman of many private and publically listed biotechnology companies
- +30 years experience in the pharmaceutical and healthcare industries

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

Finance Director

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

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.
- Chairman of Westar Capital Ltd

Fiona Milner

Epichem General Manager

- Ms Milner has 25 years experience working in multinational companies in the pharmaceutical industry
- She recently worked as Regional Manager for Novartis Pharmaceuticals prior to joining Epichem

KEY RISKS

Market Risks: PharmAust Ltd is an ASX listed company. Potential unseen/uncontrollable market conditions, global market tensions could have large impacts on the share price and valuation.

Supply Risk: PharmAust relies heavily upon multiple suppliers of there GMT grade MPL tablets one in India (Syngene) and one in the USA, should delays occur or a supplier pull out on a delivery, it would take considerable time and money to find a replacement.

Corporate Outcome Risk: We have assumed that PAA has been able to grow its customers at a non-linear growth rate over the short and medium term. This may not be the case for forecasting out to 3 years financially can be unpredictable.

Funding Risk: As a publicly listed company there is the potential the next Phase of funding requirements, may be subject to uncontrollable external factors or dilution.

Operational Risk: Any future operations of the Company may not successfully demonstrate Monepantel to its full operational and technical capabilities.

Management Risk: Adverse events or unforeseen situations may occur in which management may not be retained by or underperform due to personal/uncontrollable factors.

Intellectual Property: The company currently has multiple patents protecting their IP in the uses of MPL in numerous therapeutics. In the event that intellectual property protection is obtained, there is still a risk of intellectual property infringement and litigation concerning intellectual property held by others.

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.

Regulatory Compliance Issues: Anything from accounting issues, manufacturing practices and product recalls could materially impact our current licensing/deal forecasts.

SOURCES

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