

**"PharmAust is harnessing drugs targeting novel mechanisms to control cancer"**



**Pitney Pharmaceuticals Pty Ltd:**  
**"repurposing" Monepantel in**  
**oncology and in mTOR Disease**

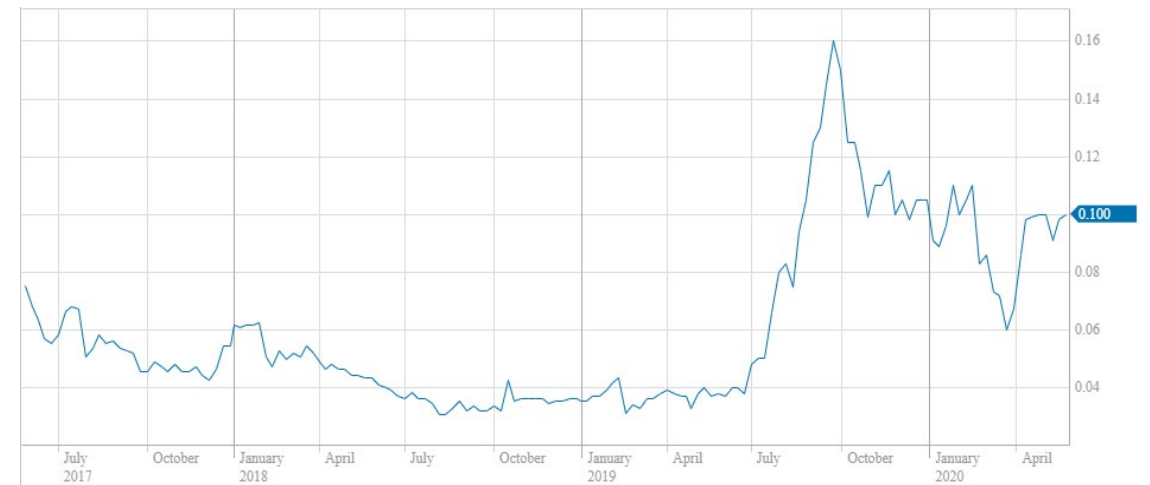


**Epichem Pty Ltd:**  
**Medicinal & Synthetic Chemistry**  
**Expected 2019-2020 sales A\$ 3.46m+**

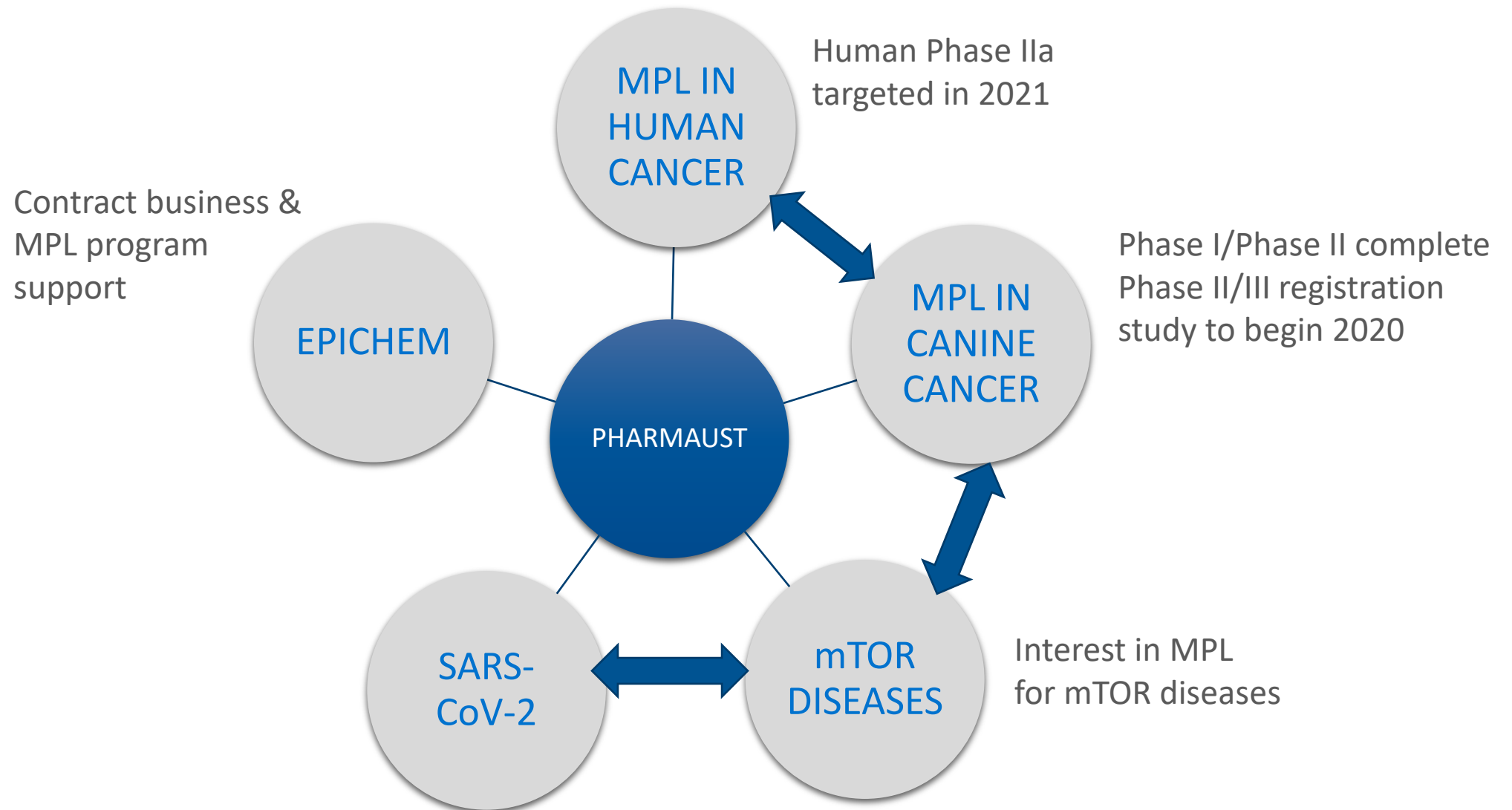
# About PharmAust Limited (ASX:PAA)

- PharmAust is an Australian clinical stage oncology company repurposing the drug Monepantel (MPL) for targeted cancer therapeutics in humans & animals
- Successful canine phase II clinical trials recently completed & results to be presented to the MPL compound owner and partner referred to here as Vet Major, providing opportunity to activate its 6-month exclusive option over the licensing of MPL
- Wholly owned and profitable subsidiary, Epichem: Sales ~\$3.46m in FY2019/20 & support for MPL program
- Extensive Board experience in pharmaceutical, healthcare & corporate finance industries

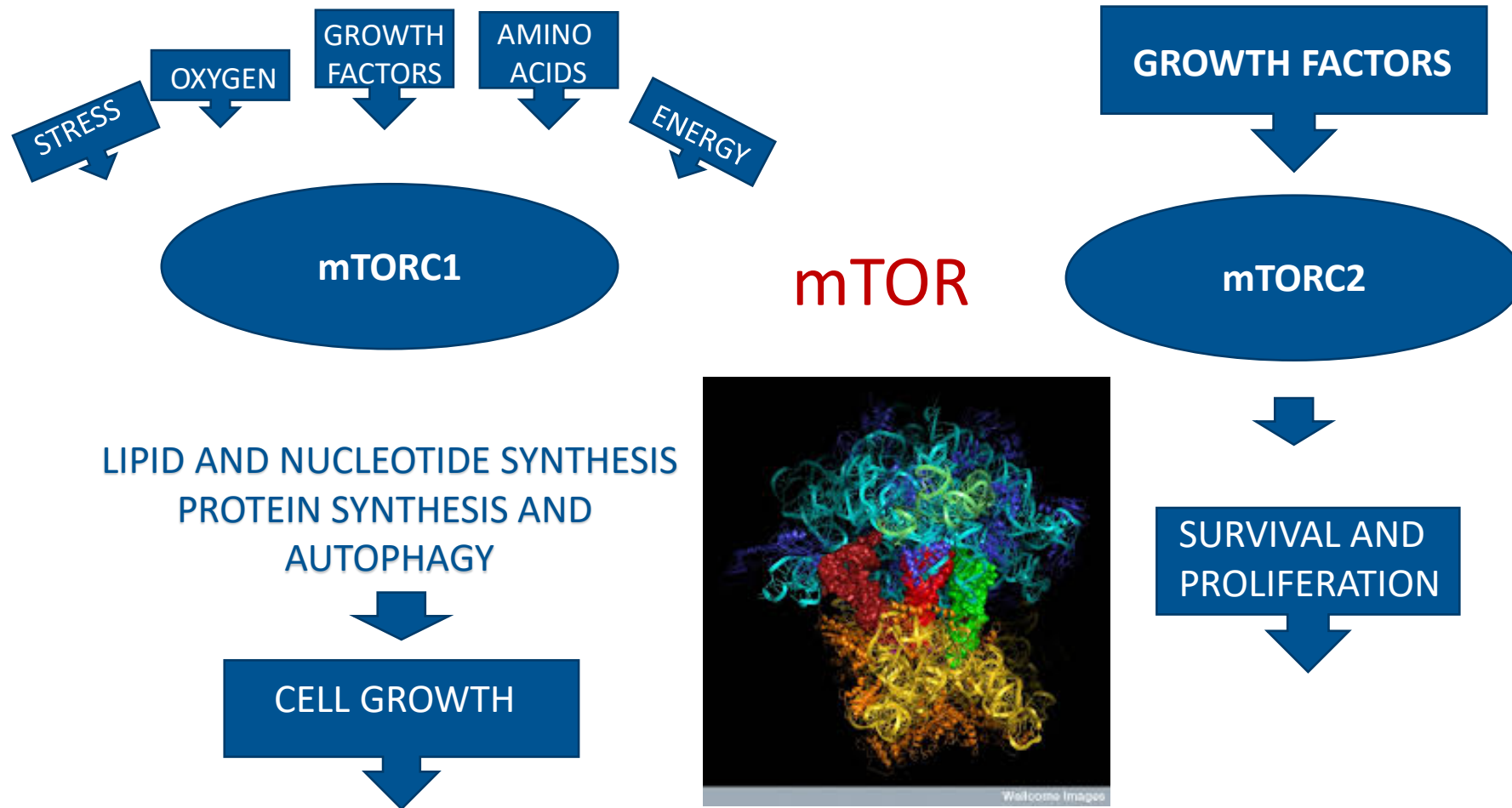
ASX Code:	PAA
Market Cap at \$0.11	\$35M
Cash (approx at May 2020)	~\$2.9M
Debt (EFIC: Epichem lab expansion)	\$217K
Epichem Revenue Forecast FY2020	\$3.46M
Total Shares on Issue	302,021,053
Options (Unlisted)	15,500,000
Top 20 Own	37%
Board/Exec Own	9.3%



# PharmAust Strategy



# mTOR – What Does it Do



<https://www.abc.net.au/radionational/programs/healthreport/battling-mutating-cancer-cells/12326932>



# PharmAust – Current Status

## PHASE II CANINE TRIAL

- **Outcome of Phase II B Cell lymphoma veterinary clinical trial**
- 100% Survival during the trial (Typically 50% of untreated dogs would not survive for 28 days)
- 1 canine showed highly significant 60% regression of all of its tumours with one tumour completely disappearing within 14 days
- A further 5 canines on trial showed stable target tumours

## VET MAJOR

- **Vet Major has supported the Phase II trial by providing 25kg of MPL**
- PharmAust has developed & formulated MPL from Vet Major into palatable high release tablets suitable for canine & human use
- Vet Major will review data in relation to next step with option agreement

## EXPANDING APPLICATIONS OF MPL

- **Outcome in canine trial opens door for use of MPL in human cancer trials**

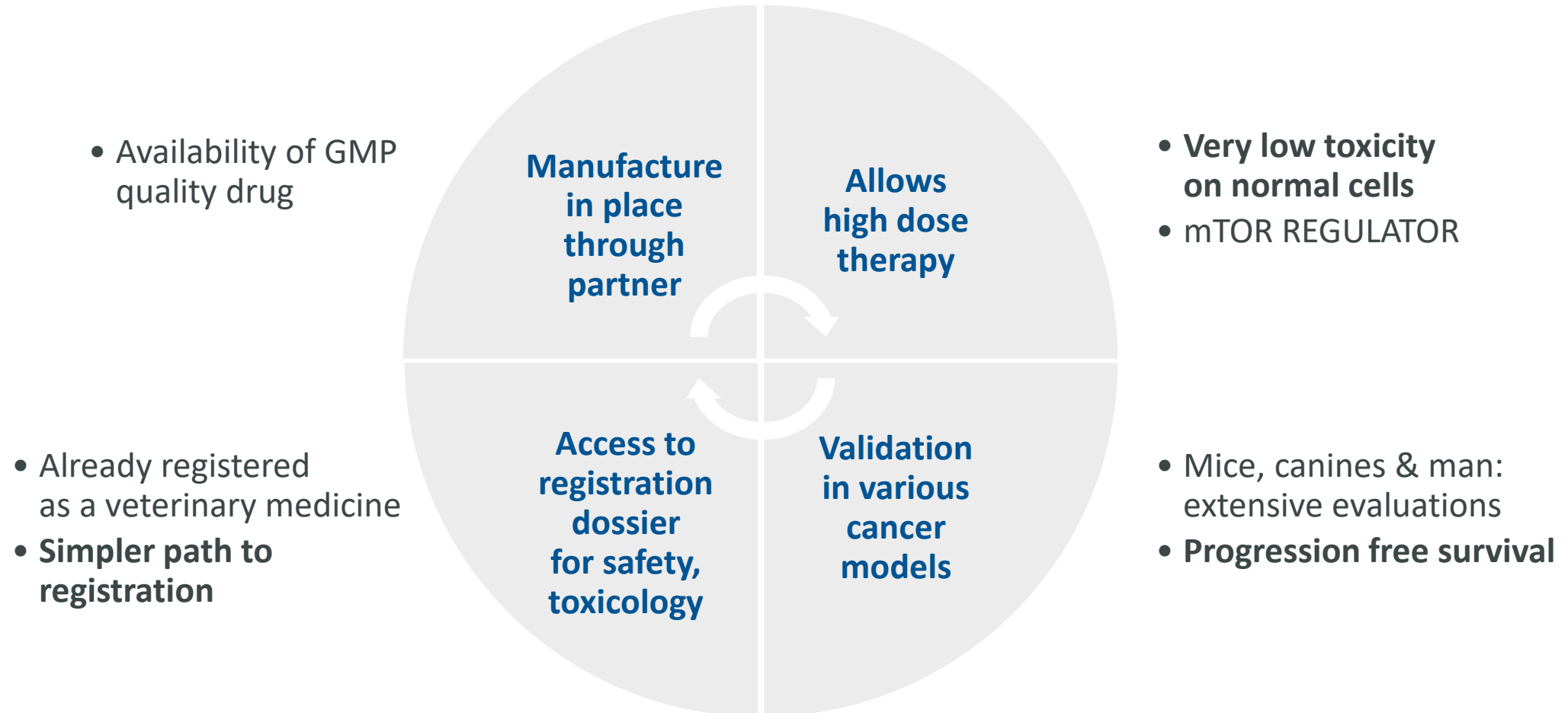
## SARS-CoV-2 COVID-19

- **Preliminary preclinical trials of MPL in SAR-CoV-2 (COVID-19) infection shows significant reduction of infectivity in culture**



# Monepantel (MPL) In Oncology

## A UNIQUE ANTI-CANCER PARADIGM



# PharmAust Commercial Catalysts

## MPL

Repurposing drug approved for veterinary use

## PATENTS

PharmAust has granted patents for the use MPL in cancer & other diseases

## CLINICAL STRATEGY

MPL ready for dose optimisation & evaluation for use in standard of care in vet (Phase III) & Phase IIa in man

## COVID-19

New commercial opportunity in antiviral therapy based on mTOR activity of MPL

## EPICHEM

Sales ~\$3.46m in FY2019/20 & support for MPL program



# INTELLECTUAL PROPERTY

Numerous Cancers included in Patents for MPL

mTOR Pathway for Aminoacetonitriles

Synergy & Benefit of Combinations with other Cancer Treatments

Cover for numerous analogues of MPL

Use of MPL and aminoacetonitrile in COVID-19

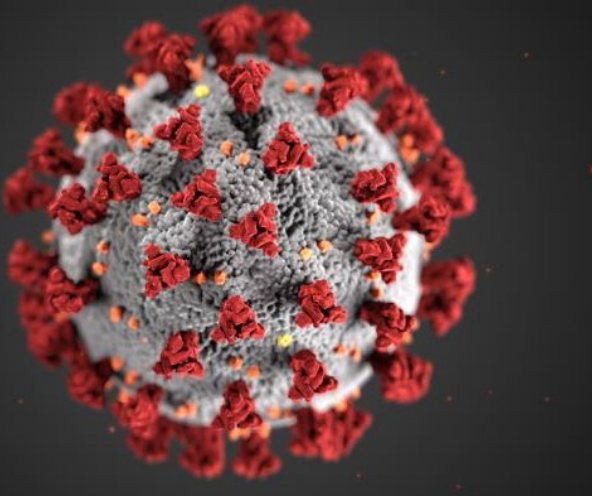


# Vet Major Animal Health – Option Agreement

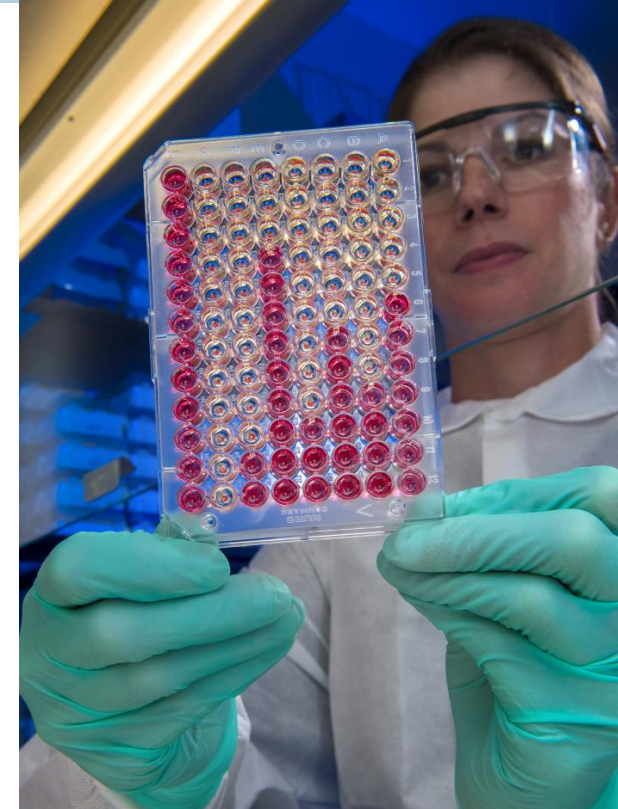
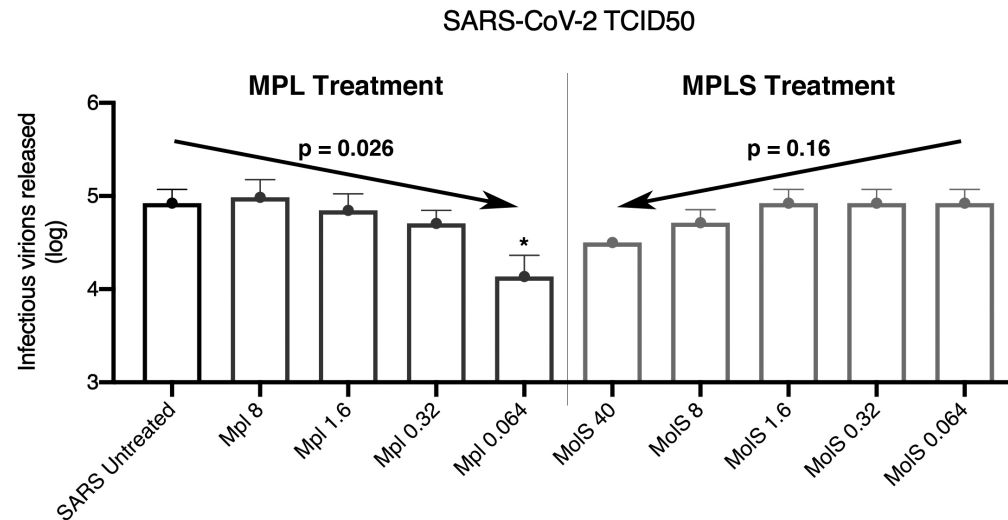
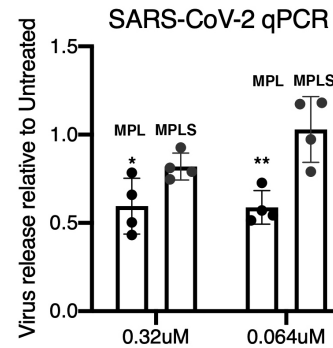


- **Monepantel** compound is owned by **Vet Major**, approved for treatment of parasitic infections in sheep (patent protection to 2024)
- **Option agreement** with Vet Major to exclusive, worldwide **royalty bearing** license to commercialise MPL for treatment of **cancer in animals**
- Vet Major Option period ending six months after receipt of the final report on the recent canine trial
- Upon Option exercise, parties enter into a negotiation period not lasting more than six months to agree terms of the **license agreement** including **commercial payments to PharmAust**
- Should Vet Major not proceed to exercise the option PharmAust will be free to seek alternative commercialisation partners
- A **licensing deal** typically involves an **upfront cash payment** in recognition of the investment in **developing the drug, as well as a royalty on sales of the drug plus additional milestone payments** for successful achievement of registration milestones
- Such a deal would mark a significant **commercial outcome** for PharmAust & see it fully funded to focus on **human cancer** market

# SARS-CoV-2 – COVID-19



- Vaccines will take time to test & introduce
- Changes in the viral structure may require changes to the vaccine
- Other than remdesivir little available to treat pre or post intensive care stage



- Reduced virus RNA
- Reduced infectivity

# >\$2 Billion market for approved mTOR Drugs

## THE MORE IMPORTANT LIMITATIONS OF mTOR DRUGS ARE SIDE EFFECTS AND RESISTANCE

Compound	Company	Approved Indications	2013 – 2019 Annual Sales Cancer (USD million)	Side effects
<b>Sirolimus (rapamycin)</b> Temsirolimus	Pfizer	<b>Transplantation</b> Transplantation renal canal cell carcinoma Mantle cell Tympoma	Sirolimus Temsirolimus 1,000*	infections nausea weakness diarrhea fever rash swelling cough vomiting itching chest pain headache
Afinintor (Everolimus)	Novartis	Transplantation renal canal cell carcinoma breast cancer NET (gut, lung, pancreas) TSC	>1500**	

\*Flewell and Goldman 2007, R. Monto, The Fountain, 2018, Random House USA Inc p 195

\*\* <https://www.novartis.com/investors/financial-data/product-sales>;



# Initial Market - Pets & Cancer

- 6 million dogs diagnosed with cancer annually in the US
- Significant **unmet need** for **new oncology drugs**  
(Estimated unpublished reports of US\$500m-US\$1b market, representing 25% of total available market. <sup>1</sup>US market alone = ~USD 100 million)
- **Side effects** associated with products & treatments are **limiting market growth** (**Monepantel** comparatively has **minor side effects & no toxicity**)
- Vet **therapeutic market** dominated by **repurposed drugs** already approved for use in humans &/or animals (= **monepantel**)
- Pet insurance now commonplace: wtp = \$2 - \$5k/ treatment<sup>2</sup>
- Canines are a close reflection of human outcomes with MPL

## US Dog Population<sup>1</sup>



1. Global Industry Report, 2020 - 2027

2. [http://www.americanpetproducts.org/press\\_industrytrends.asp](http://www.americanpetproducts.org/press_industrytrends.asp)

# PharmAust – Next Steps

- Canine trial – Present to Vet Major as per Option Agreement
- Re-Open human use programme - >USD52b market
- Progression of the human trial including further development of formulation & manufacture of additional tablets
- COVID-19 discussions with Walter and Eliza Hall Institute for any further required preclinical work
- Open discussions with key centres for use of MPL in COVID-19 patients



# EPICHEM PTY LTD: Medicinal & Synthetic Chemistry Expertise

Worldwide customer base in pharmaceutical, mining, agriculture and animal health sectors  
State of the art facilities

## Medicinal Chemistry & Drug Discovery

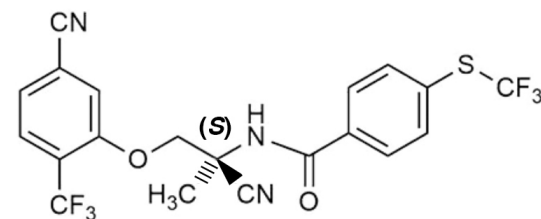
- Hit-to-Lead projects
- Lead optimisation towards candidate selection
- Synthesis of analogue libraries and scale up
- IP Generation
- Drug conjugates, fluorescent tags & metabolites
- Cost effective, flexible FTE contract options

## Supporting PharmAust Drug Development Pipeline

- Lead drug development & validation
- Drug candidate pipeline manufacture & analysis
- Drug reformulation, GMP synthesis & stability support
- Drug inventory dispensing to clinical trial centres

## Proven Track Record of Success

- SFC chromatography, computational chemistry, X-ray, ADMET, HPLC, LC-MS, GC-MS, NMR, Karl Fischer, melting point apparatuses
- ISO 9001 Certified; NAT 17025 & 17034 Accredited
- 2019 WA Exporter of the Year Award for International Health
- GHP Biotechnology 2020 Awards Most Innovative Chemistry Service Provider - Australia
- GHP Biotechnology 2020 Awards Best in Organic Chemistry Solutions



# Experienced Board & Management Team

## Dr Roger Aston, Executive Chairman & CEO

- > 30 years experience in the pharmaceutical & healthcare industries
- Director or chairman on a number of boards carrying out late stage drug development
- Former CEO of Mayne Pharma Ltd

## Robert Bishop, Executive Director

- > 30 years experience in corporate finance and equity capital markets
- Lawyer and an investment banker

## Sam Wright, Finance Director & Co Sec

- > 20 years experience in biotech and healthcare
- Extensive experience in relation to public company responsibilities, including ASX & ASIC compliance, corporate governance & statutory financial reporting

## Neville Bassett, Non-Executive Director

- Member of the Order of Australia (AM)
- > 35 years working in accounting, finance & stockbroking
- Chairman of Westar Capital Ltd

## Dr Richard Mollard, Chief Scientific Officer

- CEO of subsidiary Pitney Pharmaceuticals Pty Limited
- Ex University Louis Pasteur/ IGBMC/ Bristol Myers Squibb, University of Michigan/ Eli Lilly & Co & Monash University
- Honorary Fellow at the University of Melbourne

## Colin La Galia, Epichem CEO

- > 25 years of pharmaceutical, diagnostics & healthcare senior executive experience
- Ex Abbott Rapid Diagnostics in Toxicology, Alere Inc, Origin Healthcare, Hollywood Fertility Centre, GlaxoSmithKline & Merck Sharpe & Dohme

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