# ASX: PAA

ACN 094 006 023

PharmAust LIMITED

Investor Roadshow Presentation September 2019

# Corporate Structure

PharmAust LIMITED

100%

epichem

**Epichem Synthetic Medicinal Chemistry**
**Expected 2019-2020 sales A$4.2m**

100%

PPL

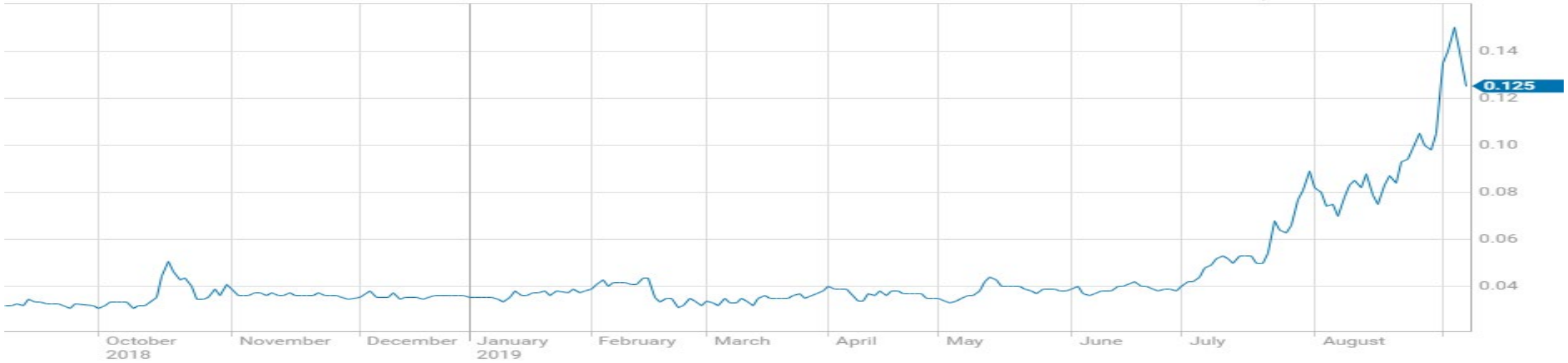
Pitney Pharmaceuticals Limited

**Pitney Pharmaceuticals Focus on Developing and repurposing a registered drug (Monepantel) in oncology**

# Corporate Snapshot

| ASX Code: | PAA |
|---|---|
| Market Cap at $0.12 | $33.6M |
| Cash (as at 30 June 2019) | $2.1M |
| Debt (EFIC) | $325K |
| Epichem Revenue Forecast 2019-2020 | $4.2M |

| Total Shares on Issue | 280,221,192 |
|---|---|
| Options (Unlisted) | 56,895,412 |
| Top 20 Own | 37% |
| Board/Exec Own | 9.3% |



# Experienced Board & Management Team

## Dr. Roger Aston, Executive Chairman

- > 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

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

## Neville Bassett, Non-Executive Director

- Member of the Order of Australia (AM)
- > 35 years working in accounting, finance and stockbroking

## Sam Wright, Director & Company Secretary

- > 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.

## Dr Richard Mollard, Chief Scientific Officer

- > 20 years experience in biotech and pharma
- Extensive national and international experience.

## Dr Wayne Best, Epichem Chairman

- > 30 years experience in synthetic and medicinal chemistry in academia and industry
- Chairman of PharmAust's subsidiary Epichem

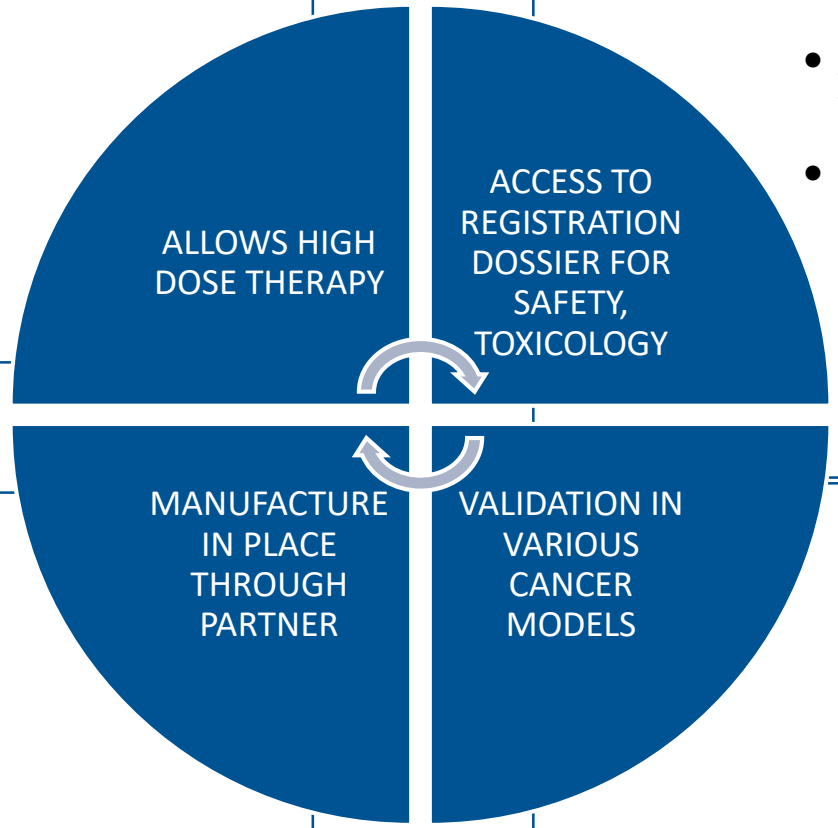
# CHEMOTHERAPY (Global Sales $52bln) MAINSTAY OF CANCER TREATMENT

- Chemotherapy kills rapidly dividing cells
- Typically tumour cells replicate more quickly than normal cells and this difference is harnessed in chemotherapy to selectively kill cancer
- Side Effects during chemotherapy arise because normal cells also need to divide and they become casualties (immune system, digestive system and hair follicle)
- Monepantel, being an mTOR inhibitor acts differently and demonstrates minimal toxicology

# MONEPANTEL (MPL) IN ONCOLOGY
# A UNIQUE ANTICANCER PARADIGM

- **VERY LOW TOXICITY ON NORMAL CELLS**
- mTOR REGULATOR

- ALREADY REGISTERED AS A VETERINARY MEDICINE
- **SIMPLER PATH TO REGISTRATION**




- AVAILABILITY OF GMP QUALITY DRUG
- **PARTNER PROVIDES DRUG**

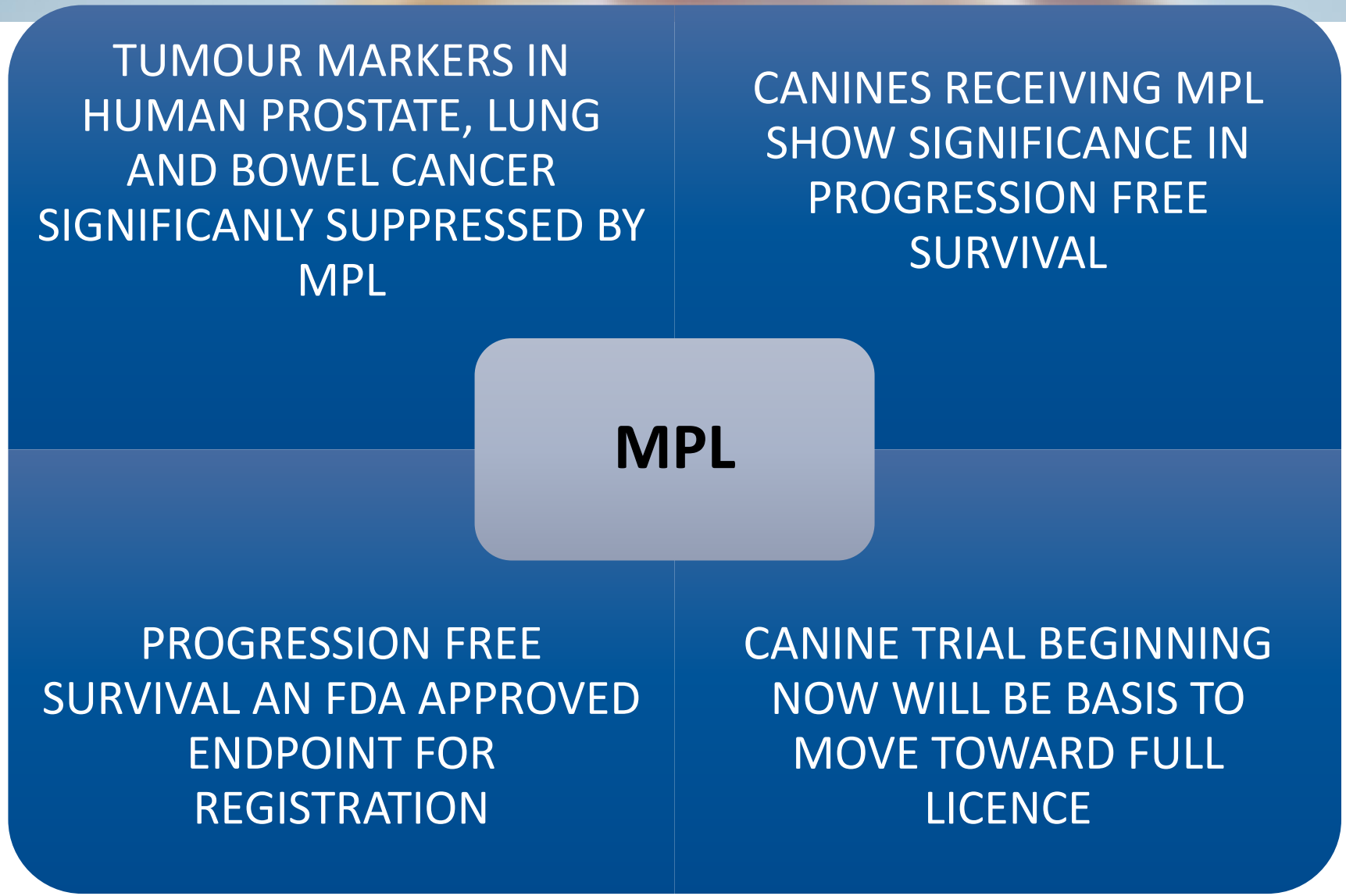
- EXTENSIVE EVALUATIONS IN MICE, CANINES AND MAN
- **PROGRESSION FREE SURVIVAL**

# COMPARATIVES
# MPL AND CHEMOTHERAPY

**THE SINGLE MOST IMPORTANT LIMITATION OF CHEMOTHERAPY IS DOSE LIMITING TOXICITY**

| ACTIVITY | MPL | CHEMOTHERAPY |
|---|---|---|
| PROGRESSION FREE SURVIVAL | ++++ | ++ |
| IMMUNOSUPPRESSION | + | ++++ |
| HIGH DOSE TOXICITY | + | +++++ |
| RESISTANCE | ? | ++++ |
| REGRESSION | ++ | +++++ |

# RISK MITIGATION IN NEXT STAGE DEVELOPMENT



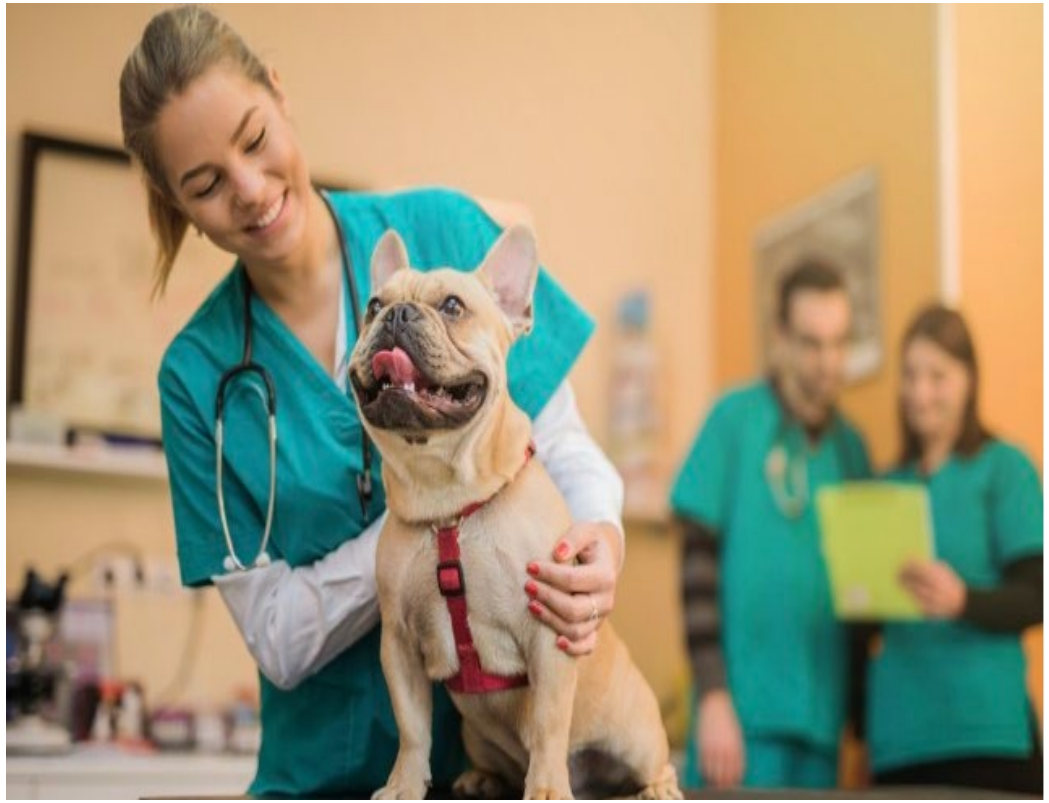
# Background Summary

- Lead product is **Monepantel** (MPL) – a repurposed drug already approved for Veterinary use by Elanco US Inc
- PharmAust **patented MPL** as an **anti-cancer drug**
- **Clinical strategy** targeting **MPL** for **vet and human** applications
- **Option Agreement** with **Elanco US Inc** for veterinary cancer applications
- **Epichem**: profitable business, forecast revenues of $4.2m in FY2019/20

# Preparing for Pivotal Phase II Trial in Canine Cancer During 2019

## KEY CLINICAL ENDPOINTS

1. Safety
2. Lack of Toxicity
3. Progression Free Survival
4. Regression
5. Administration by Owner at Home
6. Suppression of Tumour Markers



# Clinical Outcomes To Commercial Opportunities

Human Phase I Trial (efficacy / poor taste)

Pilot phase II (2017) in lymphoma trial in dogs
Shows MPL effective at Progression-Free Survival
Using poor formulation

mTOR pathway (p-p70S6K)

Extensive Reformulation Program: 2018 - 2019
Establishes New, High Dose, Palatable Tablet

Extensive Phase I Program During 2019 Establishes Optimum Dosing for Canine Trials

PIVOTAL PHASE II TRIAL 2019

COMMERCIAL AND CLINICAL OUTCOMES

Elanco

ACCELERATED HUMAN DEVELOPMENT PROGRAM

# Fast Track Strategy

ON MARKET DRUG

ZOLVIX MONEPANTEL

OPTION AGREEMENT

Elanco

PharmAust LIMITED

NOW OWNED BY ELANCO

NOVARTIS ANIMAL HEALTH

Elanco

BAYER

RESEARCHED BY VOC & OTHERS

VETERINARY ONCOLOGY CONSULTANTS

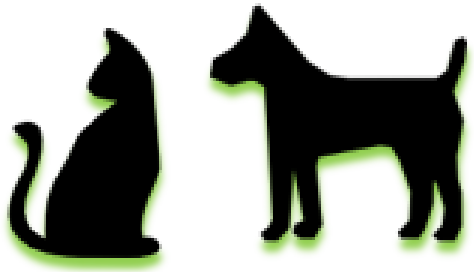
# >$2 Billion market for approved mTOR Drugs

| Drug | Approved Indications | Company | 2016 Sales (US$m)[1] |
|---|---|---|---|
| Sirolimus | Transplantation | Pfizer | 170 |
| Rapalogues (Afinitor/Torisel) | Transplantation<br>Renal Cell Carcinoma<br>Breast Cancer<br>Pancreatic Neuroendocrine Tumours<br>Mantle Cell Lymphoma | Novartis/Pfizer | >2,000 |

1. Global Data

# Trends in Companion Animal Health Market (US:2016)

**US Dog/Cat Populations (2016)[1]**



94m 90m

- Total Pet Expenditure: $70b[1]
- Vet Care Expenditure $17b[1]
- Pet drug market $10.2b in 2018[2] (8% CAGR)
- Willingness to pay more for treatment[3] ($2K-$5K/treatment)

1. http://www.americanpetproducts.org/press_industrytrends.asp 2. Competition in the Pet Medications Industry (2015) *3. AP-Petside.com Poll, conducted by GfK Roper Public Affairs and Media: April 7-12, 2010*

# Initial Market -Pets and Cancer

- 1 in 4 dogs die of cancer - 6 million diagnosed annually in US
- Pets are living longer (50% dogs > 10 yrs often die of cancer)
- Significant **unmet need** for **new** **oncology drugs (US$500m - USD$1b market)**
- **Side effects** associated with products and treatments are **limiting market growth** (**Monepantel** comparatively has **little or no side effects**)
- Vet **therapeutic market** dominated by **repurposed drugs** already approved for use in humans and/or animals (**= monepantel**)
- Pet Insurance now commonplace
- Canines are a close reflection of human outcomes with MPL

Elanco strategically enters therapeutic oncology arena by the purchase of Aratana
Elanco Global No. 3 Animal Health Company

# Product Areas of Focus

**Elanco is an established leader with flagship brands and a global presence.** They're focused on investing and innovating in the animal health priorities that mean the most to their customers and the animals in their care.

## COMPANION ANIMAL

**Companion Animal Disease Prevention**

**Companion Animal Therapeutics**

## FOOD ANIMAL

**Food Animal Future Protein & Health**

**Ruminants & Swine**

# PharmAust – current status and next steps

- Successful rights issue completed earlier in year
- Sufficient funds to complete Phase II in dogs as well as initiate clinical trials in humans
- Successful micronisation and tablet manufacture
- Phase II canine trial on dogs with lymphoma – commenced Sep 2019
- Open label trial – interim dossier to be presented to Elanco Nov/Dec 2019
- Elanco Option Agreement covers veterinary uses only
- Canine success would open door to Human use - a much larger market
- Epichem – state of the art laboratories a key to further growth and profitability


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

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