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Pitt Street Research Life Sciences Conference
28 November 2019

ASX: PAA

ACN 094 006 023

Corporate Structure



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

Pitney Pharmaceuticals: “repurposing” a registered drug (Monepantel) in oncology

Corporate Snapshot

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ASX Code:	PAA
Market Cap at \$0.11	\$35M
Cash (at 25 November 2019)	\$3.2M
Debt (EFIC)	\$325K
Epichem Revenue Forecast 2019-2020	\$4.2M

Total Shares on Issue	301,814,647
Options (Unlisted)	56,801,956
Top 20 Own	35%
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

- Director or chairman on a number of boards carrying out late stage drug development.
- Extensive national and international experience

Colin La Galia, Epichem Chief Executive Officer

- > 30 years experience in the pharmaceutical and healthcare industries.
- Director or chairman on a number of boards carrying out late stage drug development.

PharmAust Background

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- Lead product is **Monepantel** (MPL) – a repurposed drug already approved for Veterinary use by Elanco Animal Health (US \$10.7b)
- PharmAust **patented MPL** as an **anti-cancer drug** (mTOR pathway)
- **Clinical strategy** targeting **MPL** for **vet and human** applications
- **Epichem**: profitable business, forecast revenues of \$4.2m in FY2019/20
- **Option Agreement** with **Elanco US Inc** for veterinary cancer applications



Elanco Animal Health – Option Agreement



- Elanco Animal Health (NYSE:ELAN) – **MC=\$10.7B US**
- **Monepantel** compound is owned by **Elanco**, approved for the treatment of parasitic infections in sheep (patent protection to 2024)
- **Option Agreement** with Elanco to exclusive, worldwide **royalty bearing** license to commercialise MPL for treatment of **Cancer in Animals**
- **Commercial Outcome** would allow PharmAust to focus on **Human Cancer** market

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**



Monepantel (MPL) In Oncology

A UNIQUE ANTI-CANCER PARADIGM

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

MANUFACTURE
IN PLACE
THROUGH
PARTNER

ALLOWS HIGH
DOSE THERAPY

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

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

ACCESS TO
REGISTRATION
DOSSIER FOR
SAFETY,
TOXICOLOGY

VALIDATION IN
VARIOUS
CANCER
MODELS

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

Comparatives: MPL And Chemotherapy (USD 52 billion)

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

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

>\$2 Billion market for approved mTOR Drugs

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

Drug	Company	Approved Indications	2018 Sales (USD million)	Side effects
Sirolimus (rapamycin)	Pfizer	Transplantation	> 1000 (?)	Infections Nausea Weakness Diarrhea Fever, Rash Swelling Cough Vomiting Itching Chest Pain Headache
Torisel (temsirolimus)		Transplantation Renal cell carcinoma Mantle Cell Lymphoma		
Afinitor (everolimus)	Novartis	Transplantation Renal cell carcinoma Breast Cancer NET (Gut, lung pancreas) TSC	> 1600	

<https://www.novartis.com/investors/financial-data/product-sales>; Rocco Monto, 2018

Initial Market - Pets and Cancer

- 6 million dogs diagnosed with cancer annually in the US
- Significant **unmet need** for **new** oncology drugs (US\$500m - USD\$1b market = 25% of market)
- **Side effects** associated with products and treatments are **limiting market growth** (Monepantel comparatively has **minor side effects and no toxicity**)
- Vet **therapeutic market** dominated by **repurposed drugs** already approved for use in humans and/or animals (= **monepantel**)
- Pet Insurance now commonplace: wtp = \$2 - \$5k/ treatment¹
- Canines are a close reflection of human outcomes with MPL

US Dog Population¹



> 90m

1. http://www.americanpetproducts.org/press_industrytrends.asp

Phase II Trial in Canines

TARGETTING B CELL LYMPHOMA IN PET OWNERS' DOGS



- **Despite poor taste** and **low dose**, past trial in B cell lymphoma demonstrated **successful outcome** (14 days, 6/7 stable disease and reductions in tumour sizes)
- **Untreated**, dogs get sicker and 50% mortality at **30 days** (range: 1 – 124 days). Current rescue protocol response rates are between 30 and 72% with a range of 1 to 5 months.
- Developed a **new tablet**: micronized, **no palatability issue**, **high dose**, **no toxicity**
- **Matched dosing and safety** with Elanco safety dossier: high short term and low long-term doses identified
- **Revisit** pet dogs with B cell lymphoma, but **with new tablet** in a **28-day trial**: continue **long term** for 3, 6 and 12+ months: **four referral sites** around Australia

PharmAust – Current Status and Next Steps

- Successful **\$2.0m** Rights Issue to **existing shareholders** completed in **April 2019**
- **Oversubscribed** placement primarily to Australian and Singaporean **fund management institutions** raises **\$2.4m** in **October 2019**
- **Sufficient funds** to complete **Phase II in dogs** as well as **progression of the human trial**, including further development of formulation & manufacture of additional tablets
- **Phase II trial** on dogs with lymphoma – **commenced Sep 2019** at the University of Melbourne's U-Vet Werribee Animal Hospital
- **Elanco Option Agreement** covers veterinary uses only
- Canine success would open the door to **human use - > USD 52 billion market**
- **Epichem** – new CEO and 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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