

ASX: PAA

**AGM 2016** 

**Investor Presentation** 

November 2016

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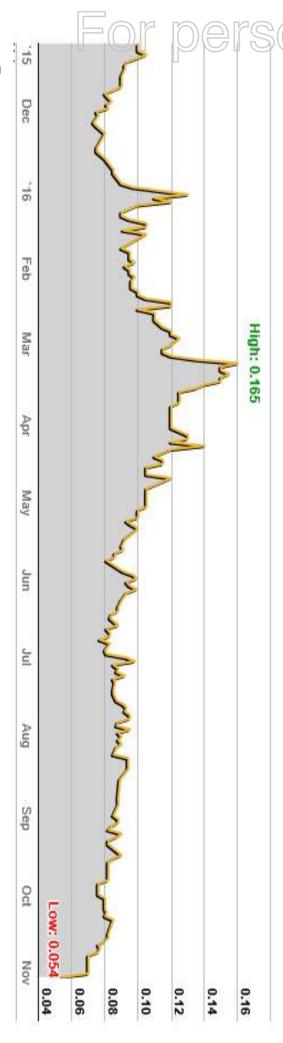
## **Financial Snapshot**

92.5 million	Market Cap. (at 7c per share) \$6.5 million	<b>Cash (30 Sep 2016)</b> \$423k		•	\$562k	Debt \$562k Epichem Annual Sales (est) \$2.4 million
	92.5 million					

Professor David Morris         7.2%           Dr Roger Aston         5.7%           Top 20         48.9%	Shareholders	
	Professor David Morris	7.2%
	Dr Roger Aston	5.7%
	Top 20	48.9%

Board & Management	ement
Dr Roger Aston	Executive Chairman
Mr Robert C Bishop	Executive Director
Dr Wayne Best	Non Executive Director
Mr Sam Wright	Non Executive Director

1. Ex Price \$0.16, Expiry Date 3 September 2018





# **Business Overview**

### Technology

Option with Novartis

**Animal Health** 

## Proprietary

- MPL Approved for Vet (Novartis Animal Health)
- Patents for use in cancer PharmAust

## **Epichem Contract**

Efficacy in Canine Cancer -> Option Exercise

## Sales

- 2016 \$2.4M
- 2017 \$3.0M

## Phase II Canine

Cambridge, Sydney & Brisbane

### NASDAQ

- Underwriting Agreement Joseph Gunnar & Co LLC
- Funding for Phase II MAN



# Key Drivers for 2017

Phase II Outcome (Canine)

Option Exercise by Novartis-Elanco

**NASDAQ Listing and Capital Raise** 

Initiation Phase II (MAN)

**Growth of Epichem Business** 



# Performance of MPL in Canines (Phase II (CANINES) **Underpins Outcomes in PHASE II (MAN)**

human oncology drug development phase III human clinical trial phase II human clinical trial phase I human clinical trial pre-clinical rodent models licenced product trials in veterinary oncology patients advantages for both human and veterinary oncology efficacy combination therapy biomarker discovery pharmacology minimal residual disease

patients

ersonal

High Safety Margin Animal Health –

Approved for

Marker Activity **Showed Safety** and Cancer

Phase I (MAN)

Showed Safety and Phase I (CANINE) Cancer Marker Activity

**Extensive Preclinical** Support (St George Hospital and GenScript)

Palatability Issue **Encapsulation** -**Being Resolved** 

Cancer Applications **Action Supports** Mechanism of

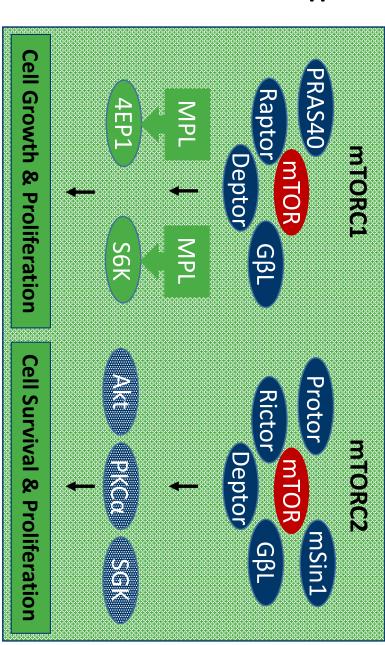
# Why MPL for Cancer

# High s6k Correlates with Multiple Negative Outcomes

## High s6k (p70s6k) in patients correlates with:

- Resistance to therapy
- Aggressive disease
- Poor prognosisHigh metastasis

## Two complexes of mTOR (mammalian target of rapamycin)



mTOR pathway depiction by:

Marc Dufour, Anne Dormond-Meuwly, Nicolas Demartines and Olivier Dormond *Cancers 2011, 3, 2*478-2500; doi:10.3390/cancers3022478



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## High metastasis

# Elevated p-RPS6KB1(p70s6k) is Associated with Poor Outcomes in Cancer

High p-RPS6KB1 in patients with colorectal, lung, ovarian, pancreatic and hepatic cancers correlates with:

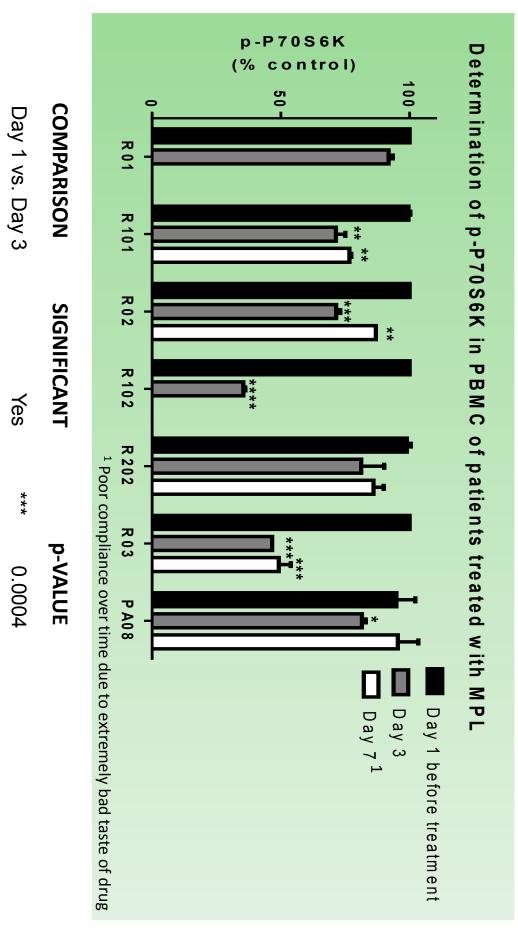
- Resistance to therapy
- Aggressive disease
- Poor prognosis
- 1) Rapamune (Rapamycin) sirolimus (Pfizer): kidney rejection tested in

2015 sales = US \$200 million

cancers:

- carcinoma: 2015 annual sales = US \$300 million Afinitor - everolimus (Novartis): European Medicines Agency for renal cell
- 3) Torisel temsirolimus (Pfizer): EMA approval for renal cell carcinoma 2015 annual sales = US \$300 million

# Suppression of p70s6k by MPL in Humans





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Day 1 vs. Day 7

Yes

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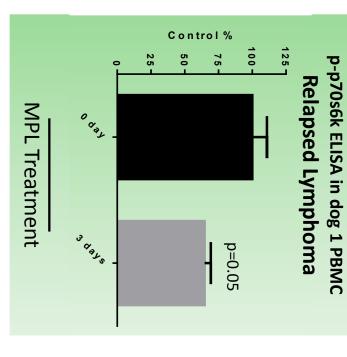
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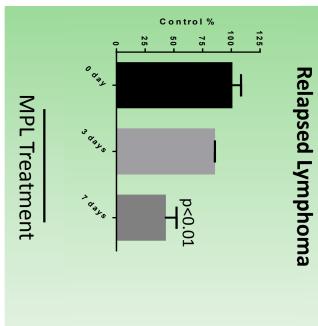
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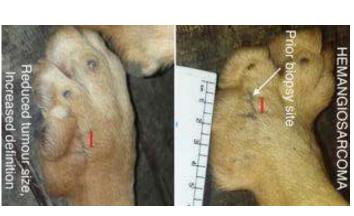
PBMC: Immune cells in blood

# Suppression of p70s6k and tumour size and increased Quality of Life by MPL in Canines

p-p70s6k ELISA in dog 2 PBMC







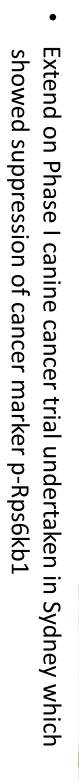
8 dogs (Lymphoma, Melanoma, Adenocarcinoma, Osteosarcoma) – increased QOL but poor taste

		COMPASSI	ONATE USE C	COMPASSIONATE USE CHEMOTHERAPY COMBINAT	INATION		
Dog	Tumour Type	Capsule	Dose (mg/kg bw)	Combination Therapy	Duration (days)	Outcome	Safety Events
Dog 1	Oral malignant melanoma nodal metastasis	Yes	3.5	n2	28	PD	None
Dog 2	Appendicular OSA pumonary Yes 4.8 Carboplatin, 250 mg/r metastases	Yes	4.8	n2	23	23 PD - anecdotal None	None

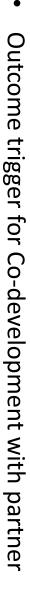


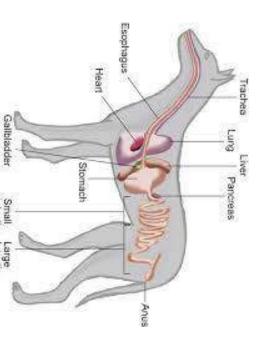
# Canine Cancer Trial Department of Veterinary Medicine, University of Cambridge, UK

### Aims:













# Effects of MPL in Canine Mammary Cancer

Pretreatment 1.9.16



4 Weeks 29.9.16



8 Weeks 27.10.16



**Progressive Disease** 

**Progressive Disease** 

Stable disease

## Major palatability drawback of MPL in human and Canine Trials being Resolved by Encapsulation



Compliance for more than 3 days of treatment in both man and canines was challenging in Phase I due to the remarkably foul taste of the MPL (Zolvix) liquid formulation manufactured by Novartis.

## MPL Achieved Key Preclinical and Clinical In Summary **Endpoints**

- Safety Excellent safety profile as predicted from preclinical models
- cancer markers in man Active dose – Identified dosage of MPL from effects on
- tumours (p70s6K and p4E-BP-1) Efficacy – Determined efficacy by markers and effects on
- Synergy Demonstrated synergy in mouse model systems with many cytotoxic drugs currently in use



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## Potential for MPL Performance in Phase II (MAN)

- Success in Phase II Canine Trials will Underpin **Expectations in Phase II (MAN)**
- Reformulation of MPL into Dry Powder in Capsule for Trial in MAN
- **Exploratory Phase II Canine Trial will provide guidance**
- Types of Cancer ideally suited to MPL Therapy
- Whether to use with Chemotherapy
- Stage of Progression for Treatment



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## In Summary

- Novartis Animal Health registered Zolvix (MPL) for the treatment of parasitic diseases in animals
- Extensive manufacturing and toxicology already established by global major pharma company
- owned with Nihon Nohyaku Over 50 MPL analogues are available for development and jointly
- acetonitriles (AADs) in cancer PharmAust holds patents on the use of MPL and other amino-
- Epichem has synthesized further novel compound of MPL for **PharmAust**
- (MAN) Underwritten US Listing and Fund-Raise in 2017 to support Phase II



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# **Experienced Management**

# Dr. Roger Aston, Executive Chairman

recently CEO of Mayne Pharma Group. Antibody Technology, QinetiQ, pSivida, Clinuvel, HalcyGen and Ascent Pharma Health. More record in both fields. Previously at Wellcome Research Laboratories, Peptech, Cambridge Dr Aston is both a scientist and seasoned biotechnology entrepreneur, with a successful track

## Robert Bishop, Executive Director

30 years experience in corporate finance and equity capital markets both as a lawyer and an investment banker

## Dr. Wayne Best, Director

industry. He is also the Managing Director of PharmAust's subsidary Epichem Pty Ltd. 30 years experience in synthetic and medicinal chemistry both in academia, government and

# Sam Wright, Director & Company Secretary

finance. experience in the administration of ASX listed companies, corporate governance and corporate 20 years experience in the pharmaceutical, biotech and healthcare industry. Extensive



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SAM WRIGHT

**Director & Company Secretary** sam@pharmaust.com Phone: 61 (0) 408 900 277

DR ROGER ASTON

rogeraston@pharmaust.com **Executive Chairman** 

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