

# PharmAust LIMITED

## ASX: PAA

ACN 094 006 023

**Investor Presentation**
**AGM 2016**

**November 2016**

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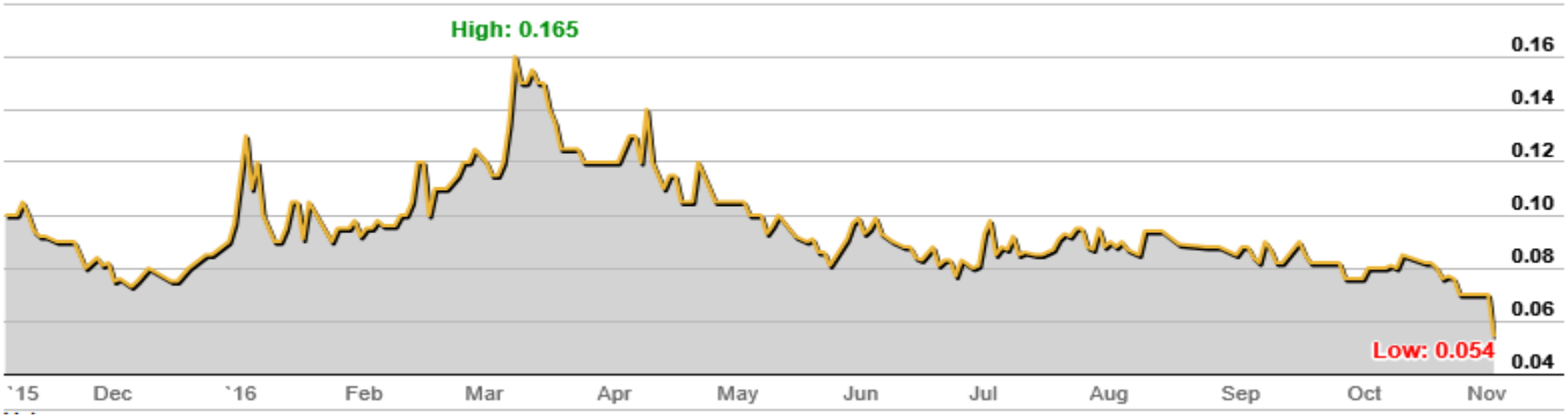
# Financial Snapshot

| PharmAust Limited | |
|---|---|
| ASX Code | PAA |
| Shares on Issue | 92.5 million |
| Market Cap. (at 7c per share) | $6.5 million |
| Cash (30 Sep 2016) | $423k |
| R&D Tax Incentive Application | $406k |
| Debt | $562k |
| Epichem Annual Sales (est) | **$2.4 million** |

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

| Board & Management | |
|---|---|
| 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




PharmAust LIMITED

**ASX: PAA**

# Business Overview

| | |
|---|---|
| Proprietary Technology | • MPL Approved for Vet (Novartis Animal Health)<br>• Patents for use in cancer PharmAust |
| Option with Novartis Animal Health | • Efficacy in Canine Cancer -> Option Exercise |
| Epichem Contract Sales | • 2016 - $2.4M<br>• 2017 - $3.0M |
| Phase II Canine | • Cambridge, Sydney & Brisbane |
| NASDAQ | • Underwriting Agreement Joseph Gunnar & Co LLC<br>• Funding for Phase II MAN |

# Key Drivers for 2017

**Phase II Outcome (Canine)**

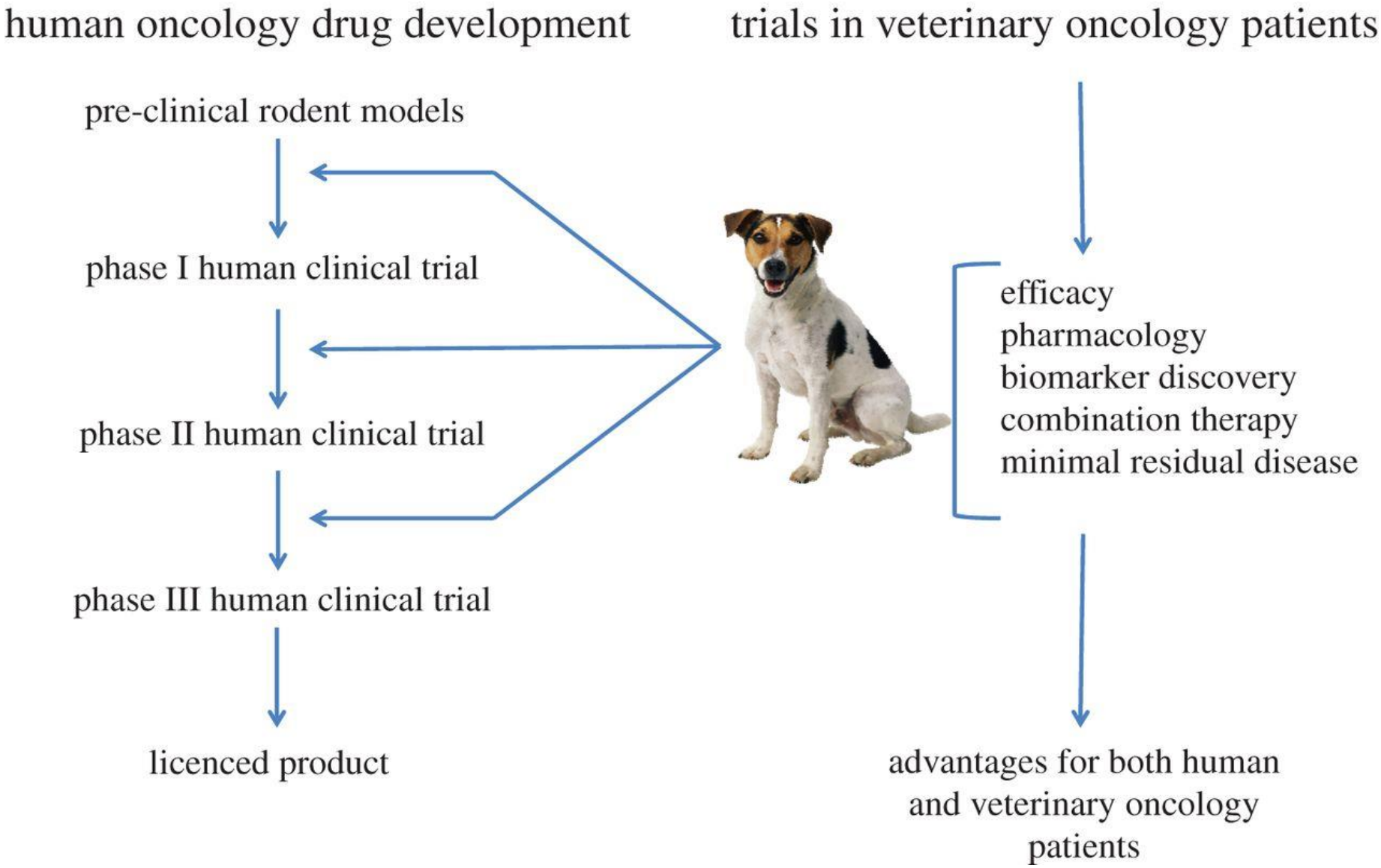
**Option Exercise by Novartis-Elanco**

**NASDAQ Listing and Capital Raise**

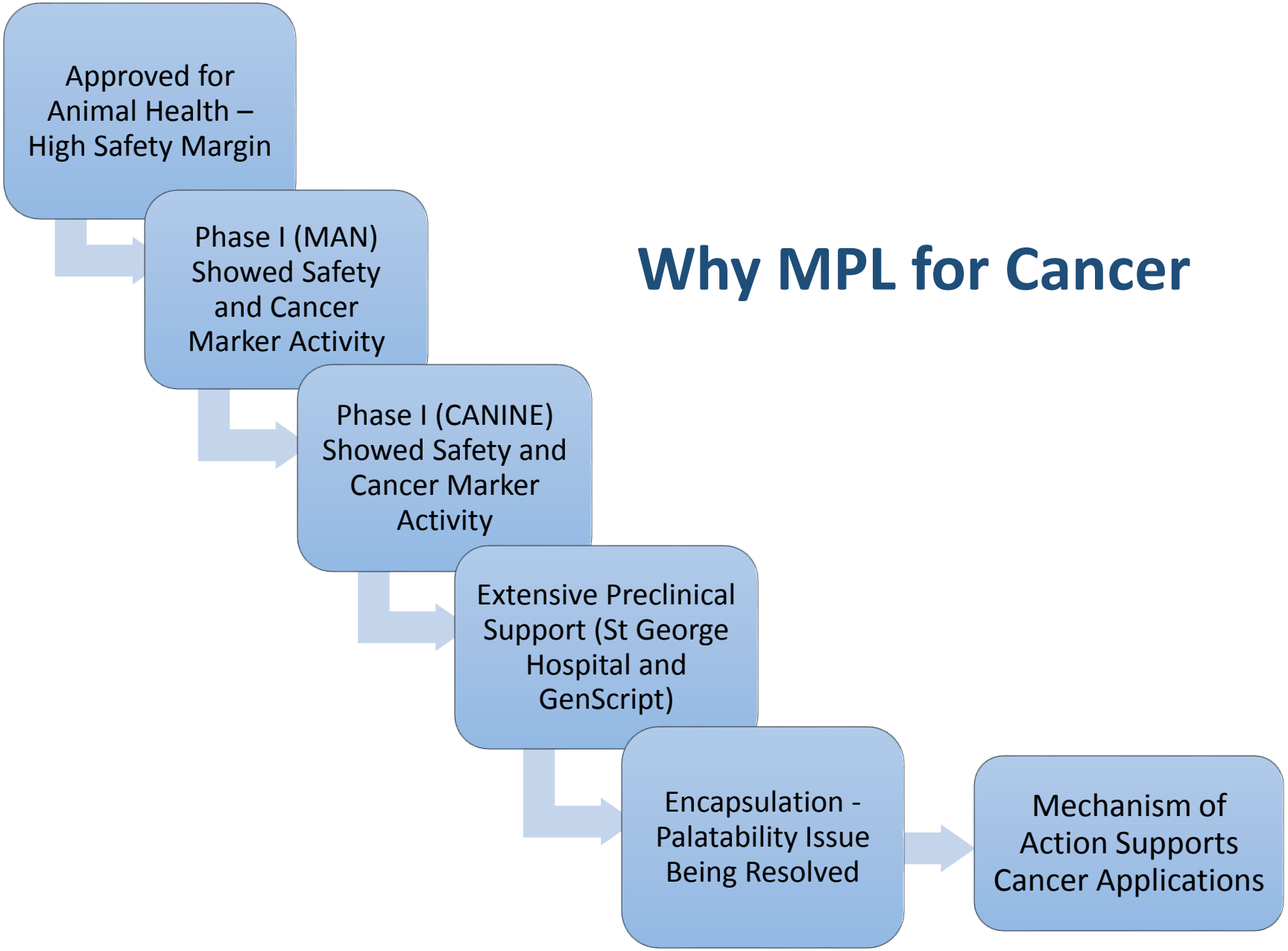
**Initiation Phase II (MAN)**

**Growth of Epichem Business**

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



# Why MPL for Cancer

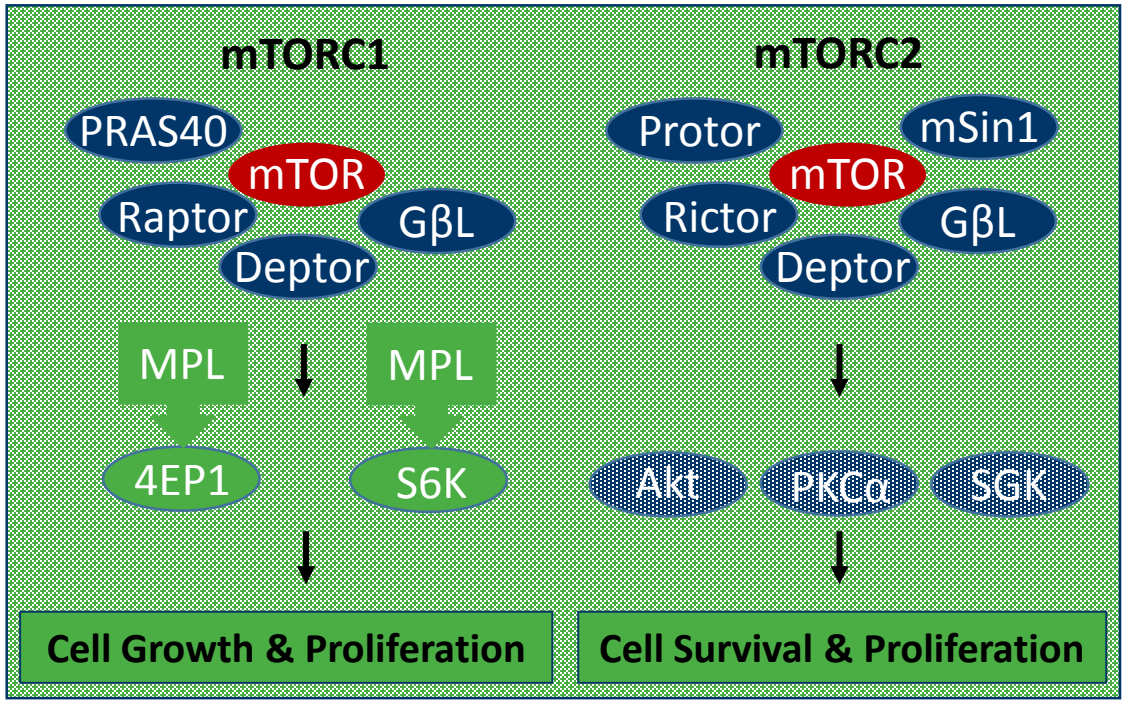


# High s6k Correlates with Multiple Negative Outcomes

High s6k (p70s6k) in patients correlates with:

- ❖ Resistance to therapy
- ❖ Aggressive disease
- ❖ Poor prognosis
- ❖ High 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*, 2478-2500; doi:10.3390/cancers3022478

# 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:

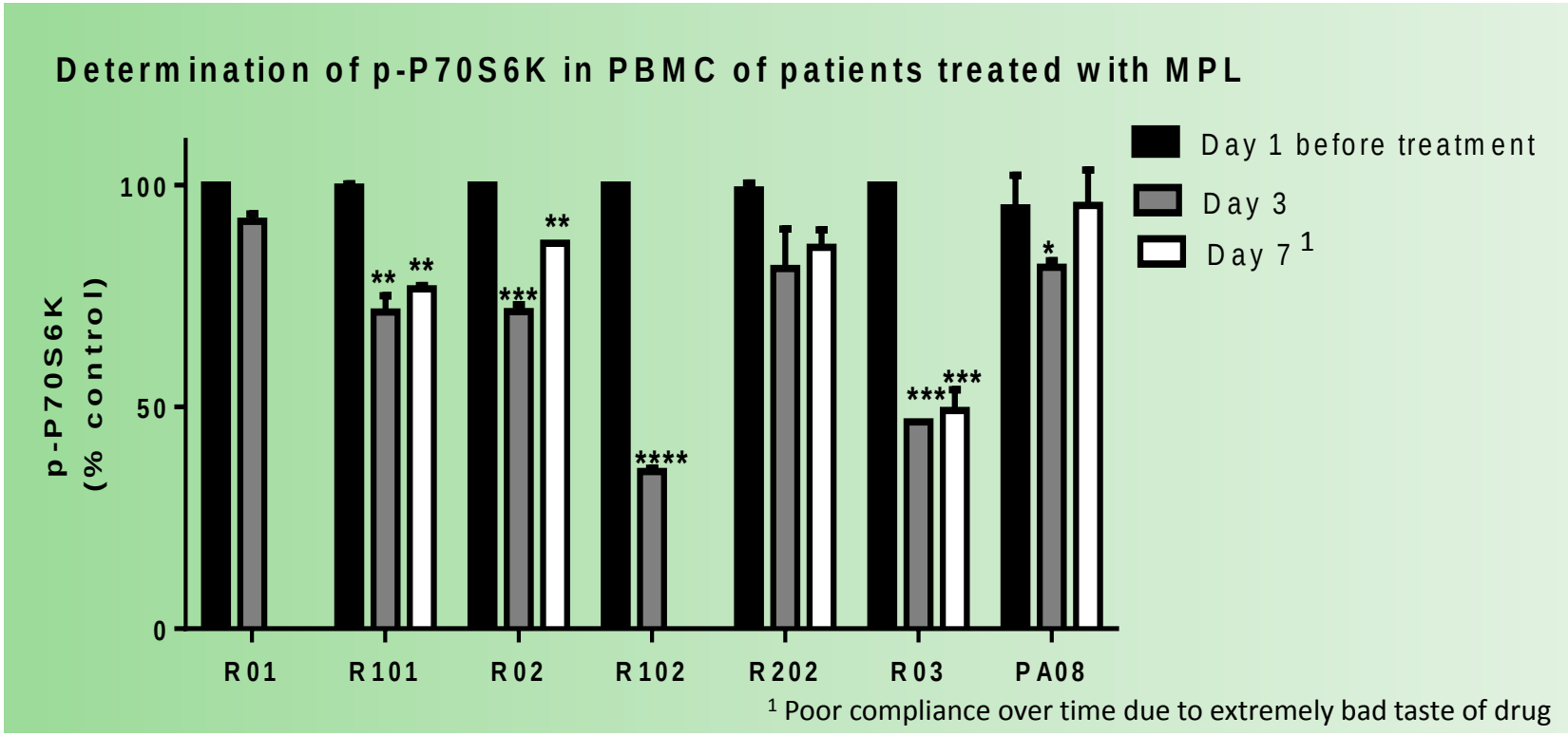
- Resistance to therapy
- Aggressive disease
- Poor prognosis
- High metastasis

1) Rapamune (Rapamycin) – sirolimus (Pfizer): kidney rejection – tested in cancers:
2015 sales = US $200 million

2) Afinitor - everolimus (Novartis): European Medicines Agency for renal cell carcinoma: 2015 annual sales = US $300 million

3) Torisel - temsirolimus (Pfizer): EMA approval for renal cell carcinoma
2015 annual sales = US $300 million

# Suppression of p70s6k by MPL in Humans

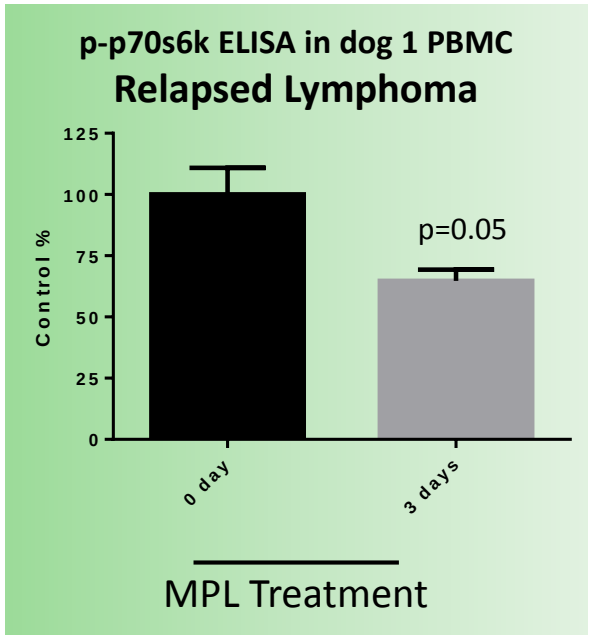


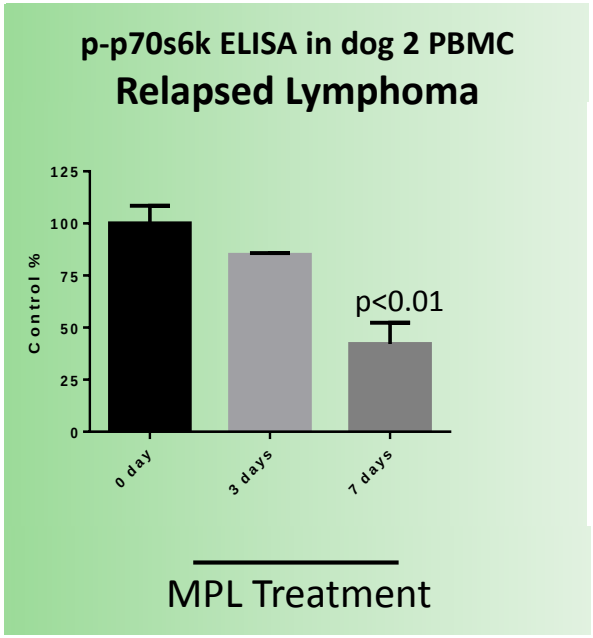

| COMPARISON | SIGNIFICANT | | p-VALUE |
|---|---|---|---|
| Day 1 vs. Day 3 | Yes | *** | 0.0004 |
| Day 1 vs. Day 7 | Yes | ** | 0.0020 |



PBMC: Immune cells in blood

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







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

| COMPASSIONATE USE CHEMOTHERAPY COMBINATION | | | | | | | |
|---|---|---|---|---|---|---|---|
| **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 | Carboplatin, 250 mg/m2 | 28 | PD | None |
| Dog 2 | Appendicular OSA pumonary metastases | Yes | 4.8 | Carboplatin, 250 mg/m2 | 23 | PD - anecdotal improved QOL | None |

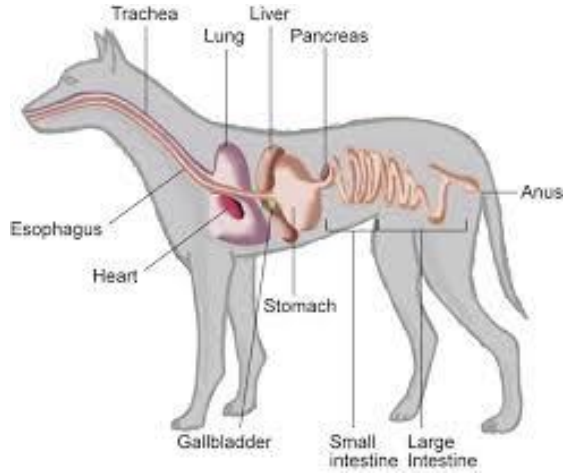
# Canine Cancer Trial

## Department of Veterinary Medicine, University of Cambridge, UK



**Aims:**

- Extend on Phase I canine cancer trial undertaken in Sydney which showed suppression of cancer marker p-Rps6kb1
- Demonstrate tumour regression or progression free survival
- Outcome trigger for Co-development with partner




UNIVERSITY OF CAMBRIDGE

# 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.

# In Summary

## MPL Achieved Key Preclinical and Clinical Endpoints

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

# 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 on:**
  - **Types of Cancer ideally suited to MPL Therapy**
  - **Whether to use with Chemotherapy**
  - **Stage of Progression for Treatment**

# 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
- Over 50 MPL analogues are available for development and jointly owned with Nihon Nohyaku
- PharmAust holds patents on the use of MPL and other amino-acetonitriles (AADs) in cancer
- Epichem has synthesized further novel compound of MPL for PharmAust
- Underwritten US Listing and Fund-Raise in 2017 to support Phase II (MAN)

# Experienced Management

**Dr. Roger Aston, Executive Chairman**

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

**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**

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

**Sam Wright, Director & Company Secretary**

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



# PharmAust LIMITED


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

DR ROGER ASTON
**Executive Chairman**
rogeraston@pharmaust.com
Phone: 61 (0) 402 762 204


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