

# **ASX Release**

19th June 2018 | CannPal Animal Therapeutics Limited ACN: 612 791 518 | ASX:CP1

#### Non-Deal Roadshow Presentation

19th June 2018: Animal health company CannPal Animal Therapeutics Limited (ASX:CP1) ("CannPal" or "the Company") is pleased to release a new corporate overview, to be presented to investors as part of a non-deal roadshow across Australia in the coming weeks.

The presentation is being used to update investors on the Company's key operational and research activities since the IPO, particularly the recently completed Phase 1A Pharmacokinetic and Safety study, as well as key milestones over the coming months which outline CannPal's investment case and strategy.

#### Key investment highlights

#### Pharmaceutical-focused animal health company

- Targeting unmet needs in the animal health market
- Addressing a significant and rapidly growing animal health market

#### Lead product in clinical stage

- Pre-validated lead drug candidate developed to target pain in companion animals
- Successfully completed Phase 1A study and fully funded for Phase 2

#### Accelerated development pathway

- Relatively faster regulatory approval timelines for animal health products
- Resulting in significantly lower development costs

#### Exciting development product portfolio

- Lead nutraceutical product provides near term revenue potential
- Active R&D pipeline including drug discovery and additional indications identified

### Experienced leadership team

- Extensive commercialisation experience in the animal health industry
- Knowledgeable R&D team in place with proven track record of gaining regulatory approval for more than 50 veterinary medicines

### CannPal's Founder and Managing Director, Layton Mills:

"I'm looking forward to updating investors on the progress we've made since our IPO. Expansion to CannPal's R&D team, strategic partnerships established and the recent completion of the successful Phase 1A study provide CannPal with a strong platform to grow shareholder value.

We are focused on progressing our lead pharmaceutical product through the pilot phase and leveraging our existing research capabilities to develop additional pharmaceutical and nutraceutical products to capitalise on early value creation opportunities."











# **ASX** Release

#### **About CannPal Animal Therapeutics**

CannPal Animal Therapeutics Limited (ASX: CP1) is a pharmaceutical-focused animal health Company researching the benefits of medical cannabis for companion animals. CannPal is researching and developing medicines derived from cannabinoids to provide veterinarians with clinically validated and standardised therapeutics to treat animals in a safe and ethical way.

CannPal has identified a significant opportunity to benefit from the rapidly growing medical cannabis and health markets by developing innovate therapeutics derived from the cannabis plant. The Company is working closely with regulatory authorities and veterinary research organisations conducting clinical trials to commercialise therapeutic products that will meet regulatory approval and support the health and well-being of companion animals. To learn more please visit: <a href="https://www.cannpal.com">www.cannpal.com</a>

#### **ENDS**

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Investor Presentation

# Key investment highlights





Pharmaceuticalfocused animal health company



✓ Addressing a significant and rapidly growing animal health market



Lead product in clinical stage

- ✓ Pre-validated lead drug candidate developed to target pain in companion animals (with a growing market size of >US\$1bn p.a.)
- ✓ Successfully completed Phase 1A study and fully funded for Phase 2



Accelerated development pathway

- ✓ Relatively **faster regulatory approval timelines** for animal health products (compared to human trials)
- ✓ Resulting in significantly lower development costs



Exciting development product portfolio

- ✓ Lead nutraceutical product provides **near term revenue potential**
- ✓ Active R&D pipeline including drug discovery and additional indications identified



Experienced leadership team

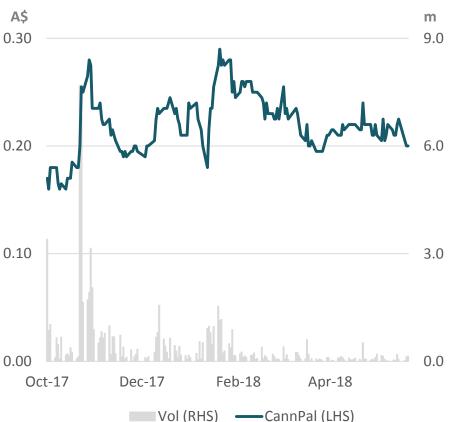
- ✓ Extensive commercialisation experience in the animal health industry
- ✓ Knowledgeable R&D team in place with proven track record of gaining regulatory approval for more than 50 veterinary medicines

# Corporate overview



# CannPal is an animal therapeutics company with a highly aligned senior leadership team

# **Share price performance (since listing)**



# **Trading information**

Share price (as at 15-Jun-18)	A\$0.200
52 week low / high	A\$0.155 / A\$0.310
Shares <sup>1</sup>	93.1m
Market capitalisation	A\$18.6m
Cash (as at 31-Mar-18)	A\$5.5m
Debt (as at 31-Mar-18)	-
Enterprise value	A\$13.1m

Key snareholders (June 2018)	
Merchant Opportunities Fund – investment fund	18.5%
Gemelli – HNW investor	9.6%
Pepanne – HNW investor	8.2%
Layton Mills – managing director	8.1%
Tania Vidovic – HNW investor	7.4%

Includes escrowed shares (50.0m) and excludes options (12.5m; exercise price: A\$0.20 to A\$0.25; expiry: June-20 to Nov-22) and performance rights (1.9m)

# Recent achievements



CannPal has established a strong platform to progress its clinical development programs

Pre-IPO	Dec 2017	Mar 2018	Jun 2018
Pre-Oct 2017	4Q CY2017	1Q CY2018	2Q CY2018
<ul> <li>✓ Identified a clear unmet need</li> <li>✓ Engaged with strategic partners</li> <li>✓ Achieved validation with the FDA</li> <li>✓ Established an experienced team</li> <li>✓ Raised seed and Series A capital</li> </ul>	✓ ASX listing  ✓ Ethics approval Prohibited substance permits (NSW; APVMA)  ✓ Import license (ODC)  ✓ Dr Margaret Curtis appointed  ✓ UQ research agreement ✓ SME status (EMA)	<ul> <li>✓ All domestic / international import permits secured</li> <li>✓ Commenced Phase 1A study of CPAT-01D</li> <li>✓ Dr Jeffrey Sherman and Kevin Willard appointed</li> <li>✓ Commenced development of DermaCann formulation</li> </ul>	<ul> <li>✓ Entered into JayChem manufacturing agreement</li> <li>✓ Successful Phase 1A study for CPAT-01D</li> <li>✓ Expanded CPAT-01 development into cats</li> <li>✓ Ongoing discussion with additional research partners</li> </ul>

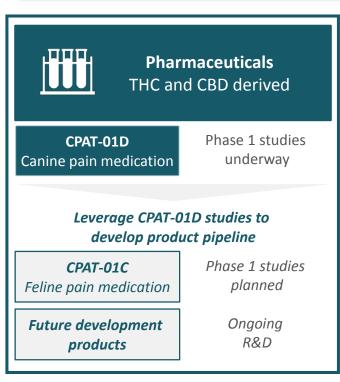
Since listing in October 2017, CannPal has expanded its R&D team, entered into strategic partnerships, received required approvals to commence Phase 1 studies, and achieved successful pharmacokinetic and safety results for its leading product, CPAT-01

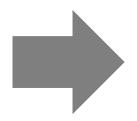
# Strategic focus



CannPal is primarily focused on the development of CPAT-01D, while developing a strong pipeline of other animal pharmaceutical and nutraceutical products

# Pre-validated medical cannabis compounds





Leverage CPAT-01 studies to advance nutraceuticals and develop early revenue generation opportunities



Nutraceuticals

CBD derived

**DermaCann**Canine skin health

Future development products

Manufacturer appointed

Ongoing R&D

Seek regulatory approval as "dietary supplement" or "feed additive"

- ✓ GMP / GLP approved manufacturers
- ✓ Quality control
- ✓ Broad distribution channels

Core focus

Note: THC (tetrahydrocannabinol); CBD (cannabidiol)

# Senior leadership



Entrepreneurial founder supported by an experienced Board and highly skilled management and R&D team – all invested in CannPal's success



Geoff Starr
Non-Executive Chairman

- Over 32 years of executive experience, including 9 years leading MARS Global pet care
- Significant global experience having worked 13 years in Asia and 10 years in the US and Europe
- Previously held executive positions in Unilever and George Western Foods



**Layton Mills**Founder / Managing Director

- Experienced FMCG entrepreneur with over 9 years in brand and product development
- Launched numerous retail and consumer goods brands in the Australian market
- International business experience across Europe, Asia and North America

Cannpal's board and management made up of renowned leaders from the animal health industry, major pharma and large MNCs













Cannpal's broader R&D team have been involved in gaining regulatory approval for over 50 veterinary medicines















CannPal's senior leadership saw a significant unmet market opportunity within the animal health sector, with pain management being the primary initial focus

# Global animal health industry



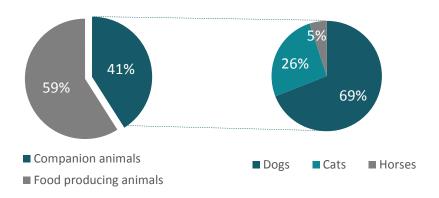
The companion animal market for dogs and cats is a significant and growing market, with the US and Europe accounting for ~77% of the global market

## Global animal health industry



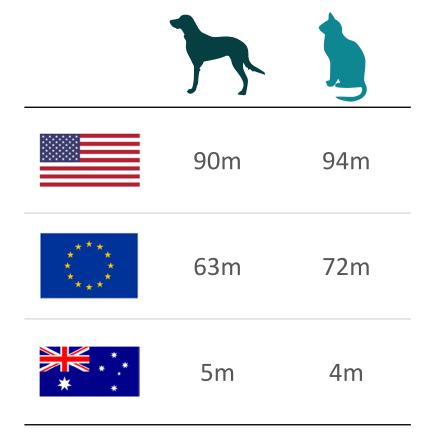
US\$31bn

## **Market composition**



The companion animals market for dogs and cats is estimated to be approximately US\$12bn

# **Population by species**



Source: Company filings; Statista; American Pet Products Association; IFAH Europe; Australian Veterinary Association

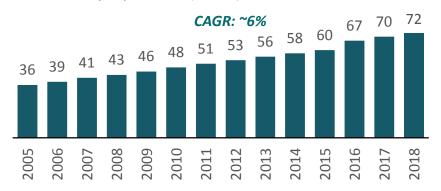
# Key animal health trends



The animal health market is underpinned by favourable industry trends and key growth drivers – reflected in the US pet drug market growing >20% from 2015 to 2017

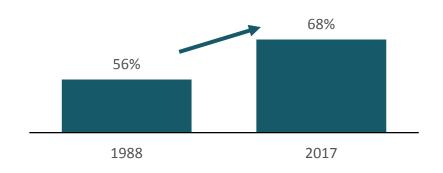
## Increase in US pet spending

US Pet Industry Expenditure (US\$bn)



# Increase in pet ownership levels

US household pet ownership (%)



## **Increased pet lifespan**

Lifespan increase (2002-2012 data)



# High prevalence of arthritis and obesity

1 in 5 dogs has arthritis<sup>1</sup>



**56%** obesity rate in the US

Majority of cats show evidence of arthritis



**60%** obesity rate in the US

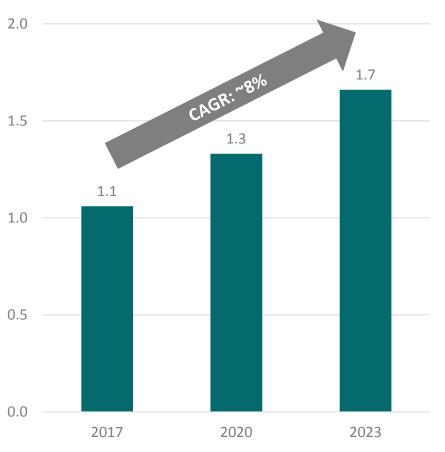
Notes: 1. Over the age of 7

Source: Statista; Pet Obesity Prevention; Vetnosis; American Pet Products Association; Packaged Facts

# Targeting a significant opportunity CannPal®

CannPal's lead product is at the forefront of a fast growing and significant market opportunity worth >US\$1bn p.a.

# Global veterinary pain medications revenue (US\$bn)



# **Favourable market dynamics**

### **Existing products have inferior characteristics**

 Non-steroidal anti-inflammatory drugs (NSAIDs), which dominate the market, have onerous label warnings, significant side effects and high levels of toxicities

# Limited product innovation to date

- Average age of animal health product portfolios is ~15 years
   no more lifecycle strategies for current treatments
- Slowing investment in animal health R&D M&A is the key strategy for majors seeking competitive advantage

# Strong market demand for novel treatment

- **Strong demand from veterinarians** for improved products for treating chronic pain in dogs and cats
- Currently no pain medication approved for chronic use in pet cats in the US (over 3 consecutive days)

## Significant and valuable opportunity

• **Ideally positioned to gain market traction** in a target indication with favourable market dynamics

Source: The Veterinary Cancer Society; various internal company research reports

# Development process



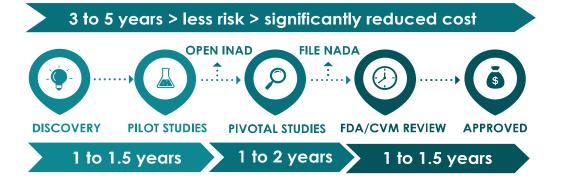
Accelerated development pathway for animal drugs results in relatively lower risk and significantly reduced costs

# **Animal drug development**



**Human drug development** 









CannPal is fully funded for pilot studies and remains on track to release data in 2019

Source: Tufts Center for the Study of Drug Development

# Benefits of using medical cannabis CannPal®



Cannabis is rich in phytocannabinoids which stimulate receptors throughout the body to trigger therapeutic functions to treat a range of diseases, including pain and inflammation

#### Source of cannabinoids



**Endocannabinoids** (naturally produced)



**Synthetic** cannabinoids



**Phytocannabinoids** (cannabis plant)

### Benefits of phytocannabinoids

- Great side effect profiles
- Safety and efficacy already tested and validate in humans
- Cost effective

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- Fast growing market
- New regulatory pathways

## **Endocannabinoid receptors**

CB1

- Concentrated in the brain and CNS
- Sparsely populates other parts of the human body
- Affected primarily by THC

CB2

- Mostly in peripheral organs, especially cells associated with the immune disease
- Affected by both THC and CBD

### **Endocannabinoid system**

Regulates a variety of psychological processes

Pain

**Appetite** 

Sleep patterns

**Immune** system

Inflammation





Research to date indicates that it is possible to target receptors using specific phytocannabinoids found in the cannabis plant (i.e. THC and CBD), to influence physiological functions and restore the body's homeostasis

# CPAT-01D: product overview



CannPal's Lead Drug Candidate, CPAT-01D, has been developed using active ingredients from the cannabis plant, which is rich in phytocannabinoids, to target symptoms of pain

#### **Overview**

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CPAT-01D	Other pharmaceutical products
	CannPal will leverage its CPAT-01 R&D to seek out additional opportunities to optimise shareholder value
	-

Product overview	Developed using active ingredients (both THC and CBD) from the cannabis plant to target symptoms of pain in dogs
Current status	Phase 1A pharmacokinetic and safety study completed Phase 1B dose ranging + pharmacokinetic + safety study, to commence in 3Q CY2018
Commercialisation strategy	Multiple options including seeking strategic partners for partnership and licencing opportunities

# **Key benefits**

- ✓ Cost-effective, safe alternative to existing pain medication for dogs with less side effects
- Favourable industry tailwinds given the growing prevalence of obesity and arthritis in dogs
- ✓ Synergistic effects of combining CBD with THC (i.e. entourage effect): CBD promotes longer half life of THC, reduces the psychoactivity of THC and influences different THC receptors
- ✓ Formulated as a solution and packed into single dose syringes for oral administration

Global canine anti-inflammatory products market





There are little to no pain medications approved for companion animals that are suitable for safe long term use and NSAID's are widely known for negative side effect profiles

Source: Statista, Vetnosis, American Pet Products Association, Packaged Facts, Future Market Insights

# CPAT-01D: study design and results CannPal®

# CannPal is pleased to announce the successful completion of its pharmacokinetic and safety study for CPAT-01D

### Phase 1A: overview

- "First in Dog" use of proprietary oral cannabinoid formulations containing both THC and CBD
- Pharmacokinetic and safety study
- 11 dogs (8 treated / 3 control)
- Male beagles: varied age/weight
- Endpoints: No adverse effects; determination of dose proportionality; indications of expected Tmax, Cmax, AUC and half life; visual observations

#### Phase 1A: results

- Excellent safety profile at the initial target dose
- ✓ No adverse events were observed at the dosage administered
- ✓ All observational endpoints were met
- ✓ CPAT-01D was well absorbed in its current formulation
- ✓ Identified a range of blood plasma concentrations that indicate a potential safe therapeutic window

# Excellent pharmacokinetic and safety results provide support for proceeding to Phase 1B

Phase 1B: study design		Phase 1B: endpoints		
•	Dose ranging + pharmacokinetic + safety study	•	Early indication of dose range	
•	48 dogs (40 treated / 8 control)	•	Cannabinoid impact on identified gene expression targets	
•	1 NSW purpose built research site	•	Tolerability at 5x estimated dose	
•	Mixed beagles and foxhounds	•	Ongoing visual observations	
•	Variable weight, age, sex parameters	•	Additional pharmacokinetic parameters	

# CPAT-01D: market positioning



# CPAT-01D addresses a clear unmet need of providing approved pain medication for companion animals with significant competitive advantages

### **Overview**

- CPAT-01 has synergistic benefits due to its unique mode of action that is desirable for pain treatment
- Oral liquid solutions are ideal to allow for dose titration and owner compliance
- There are limited pain medications approved for companion animals, that are suitable for safe long term
- NSAIDs which dominate the pet pain market are widely known for negative side effect profiles

	CannPal <sup>®</sup> Animal Therapeutics	zoetis	A PATANA THERAPEUTICS	Boehringer Ingelheim
Key comparisons	CPAT-01	Rymadil	Galliprant	Metacam
Anti Inflammatory	<b>Y</b>	lacksquare	<b>Y</b>	<b>Y</b>
Additional modes of action	<b>~</b>			
Oral liquid solution	$\mathbf{V}$			<b>S</b>
Suited to longer term use	$\overline{\mathbf{Y}}$			
Minimal side effects	$\mathbf{V}$			
First-to-market advantage <sup>1</sup>	<b>S</b>			

<sup>1.</sup> No approved generics

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# CPAT-01D: near term milestones



# CannPal is fully funded to progress the clinical development of CPAT-01D into pilot studies

✓ CannPal has received all necessary permits to conduct ongoing studies of CPAT-01D in dogs

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✓ Successfully completed Phase 1A Pharmacokinetic and safety study (conducted between March and May 2018)

Clinical development timeline	Q3 CY2018	Q4 CY2018	Q1 CY2019	Q2 CY2019
Phase 1A: Pharmacokinetic and safety study	Results			
Phase 1B: Dose ranging + pharmacokinetic + safety study		Results		
Phase 2A: Pilot dose determination and population pharmacokinetic studies				Results
Phase 2B: Pilot target animal safety studies				
Ongoing toxicology studies				
Open INAD with FDA				

# CPAT-01C: overview



CannPal is extending its CPAT-01 product range to target pain in cats – a pharmacokinetic and safety study is planned for 2H CY2018 and will leverage knowledge gained from the CPAT-01D studies

# CPAT-01D Pain medication for dogs CPAT-01C Pain medication for cats

# Developed using active ingredients (both **Product** THC and CBD) from the cannabis plant to overview target symptoms of pain in cats Phase 1A pharmacokinetic and safety study commencing in 2H CY2018 Current Phase 1B dose ranging + pharmacokinetic status + safety study (subject to Phase 1A results) Multiple options including seeking Commercialisation strategic partners for partnership and strategy licencing opportunities

Source: Statista, Vetnosis, American Pet Products Association, Packaged Facts, Future Market Insights 1. Non-steroidal anti-inflammatory drugs

# **Key benefits**

- Significant market opportunity, given there is a clear unmet need for long term pain medication for cats
- ✓ There are only two NSAIDs¹ approved to treat pain in cats in the US, and none for long term use
- ✓ Favourable industry tailwinds given the growing prevalence
  of obesity and arthritis in cats
- Development of CPAT-01C is de-risked by successful pharmacokinetic and safety studies for CPAT-01D with an accelerated development timeline anticipated

# Global feline anti-inflammatory products market



Estimated market size

US\$380m+

Significant upside to market size given the current lack of approved products for treating pain in cats

# Nutraceuticals: overview



# CannPal is also developing nutraceuticals using compounds from the less regulated hemp plant, as part of an early revenue generation strategy

#### **Overview**

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Product overview	Cannabidiol (CBD) derived, regulatory approved medicine that may assist in promoting healthy skin in dogs
Current status	Commissioned GMP contract manufacturer, Jaychem Industries. Stability testing of lab samples to occur in H2 2018
Market ready	Mid 2019 (DermaCann)
Commercialisation strategy	CannPal is likely to seek master distribution agreements with strategic partners

# **Key benefits**

- ✓ Early revenue generation strategy to de-risk commercialisation of pharmaceutical products
- ✓ Nutraceuticals aren't required to follow the same clinical trial pathway as a pharmaceuticals
- ✓ Consistent product quality: GMP/GLP approved
- ✓ First to market benefits: only regulatory approved CBD-based nutraceutical products for companion animals

# **Global dietary supplements market**



US\$1.5bn+

CannPal is actively seeking additional CBDbased opportunities in major global markets to optimise shareholder value

Source: Statista, Vetnosis, American Pet Products Association, Packaged Facts

# Commercialisaton strategy

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# CannPal has a comprehensive strategy in place to optimise shareholder value

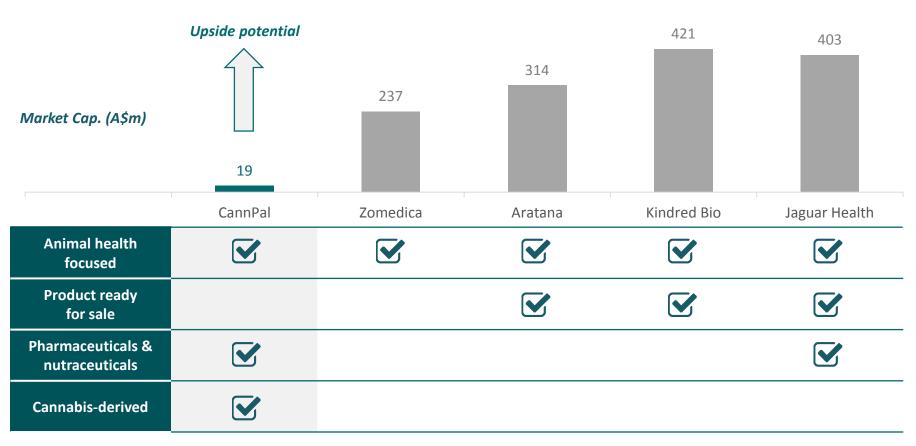
202	Establishment	Establish unmet needs in animal health, where current treatments are inferior (due to cost or side effects)	✓
	Identification	Identify drug candidate(s) – specifically where cannabinoids have shown efficacy and safety tolerances in human models	✓
	Validation	Clinically validate drug candidate(s) in target animal species through well-controlled clinical studies with GMP/GLP-approved clinical research organisations	In progress
	Development	Develop validated drug candidate(s) into novel medicines with innovative and bio-available delivery systems with proprietary intellectual property	In progress
\$	Commercialisation	Active management of product portfolio and aligning with strategic partners (i.e. out-licence model for marketing and regulatory approval after the completion of clinical trials)	In progress

# International animal health peers 🔀 CannPal®



Unique investment proposition with significant value upside potential exists when compared to other global animal health peers with comparable product portfolio

CannPal vs. other key international animal health peers



Source: Company filings, Bloomberg (as at 15-Jun-2018)

# Value considerations



Recent animal health transactions demonstrate significant value that can be realised by progressing the development of CannPal's product portfolio

Acquiror (Licensee)
/ Target (Licensor)

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Date	Date April 2016	
Value	US\$85m Includes upfront payment of US\$45m, ongoing royalties, milestone	US\$85m  Represents an aggregate equity value - based on US\$6.72 per share
Deal type	and KPI payments  License	Corporate
Commentary	<ul> <li>Elanco exclusively licensed the global rights to Galliprant from Aratana</li> <li>Galliprant is an FDA-approved therapeutic for control of pain and inflammation associated with canine osteoarthritis</li> </ul>	<ul> <li>Nexvet is a biologic therapeutics company developing monoclonal antibody therapies for companion animals to treat chronic pain</li> <li>Nexvet's lead drug candidates were at Phase 3 at the time of takeover</li> </ul>

# Key catalysts



Core focus

# Significant clinical and operational catalysts are expected over the next 12 months

# **Pharmaceuticals**

- Commencement of CPAT-01D Phase 1B study 3Q CY2018
- CPAT-01D Phase 1B results announced 40 CY2018
- CPAT-01C phase 1A study 2H CY2018
- Commencement of CPAT-01D Phase 2A study 4Q CY2018
- Commencement of CPAT-01D Phase 2B study 1Q CY2019
- CPAT-01D Phase 2A results announced 2Q CY2019
- Strategic partnership / licencing discussions ongoing

**Nutraceuticals** 

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- DermaCann 6 month stability test results 1Q CY2019
- DermaCann market ready 2Q CY2019
- Strategic partnership / licencing discussions ongoing

Early revenue generation opportunities



# **Board of directors**







- Experienced FMCG entrepreneur with over 9 years spent in brand and product development, particularly in mainstream grocery channels;
- International Business Experience with the ACT Government;
- Launched a number of consumer goods brands in the Australian Market.



#### Geoff Starr Non-Executive Chairman

- 32 years' experience building and transforming businesses in household, food, chemical, agribusiness and pet care: 9 years in senior executive roles at MARS Global Pet care; 13 years in Asia, 10 years global experience, including USA and Europe;
- Executive positions including, Unilever, George Western Foods.



#### Max Johnstone Non-Executive Director

- 11 years as President, Chief Executive Officer and Executive Director of Johnson & Johnson Pacific;
- Extensive overseas experience in leading businesses in both Western and Central-Eastern Europe, Africa as well as Asia- Pacific;
- Board positions on a number of highly regarded ASX listed Companies.



#### Dr Kate Adams Non-Executive Director

- Co-owner of Bondi Veterinary Hospital and Founder of tech startup, Thankly;
- Held senior leadership roles for the Federal Attorney-General's Portfolio including as Analyst, Principal Adviser and Chief of Staff for a number of Royal Commissions;
- Bachelor of Science, Masters of Data Analytics, Bachelor of Veterinary Medicine and Surgery.



### Robert Clifford Non-Executive Director

- Over 20 years of experience in Brand implementation and Business Strategy and Planning
- Senior leadership roles in large multinational private and public corporations in Australia, China and Ireland
- Former President of the Irish Australian Chamber of Commerce

# Management and R&D team





# Dr Margaret Curtis: Head of Clinical Development

- Qualified veterinarian with 17 years' of director experience with market leading animal health company, Elanco;
- Contributed to the development of animal health products for Elanco globally;
- Has gained approval for over 20 drugs in over 100 countries;
- Lead global teams across Australia, USA, Europe, Asia and Latin America.



# Dr Jeffrey Sherman: Lead Toxicology

- Board certified senior Toxicologist with in depth knowledge of VICH GLP and GCP
- Diplomat of the American Board of Toxicology with extensive experience in risk assessment, FDA regulations and veterinary medicines
- Local, state, federal and international jurisdiction legislative experience



### **Kevin Willard: Senior Formulations Chemist**

- Expertise in formulation development, processing (clinical trial manufacture and technical transfer) and GMP Quality;
- Specialised in CMC (Chemistry, Manufacturing and Controls) technical writing;
- 34 years of experience working with market leading Elanco Animal Health and Eli Lilly



# Baden Bowen: Chief Financial Officer and Company Secretary

- 30 years experience as a chartered accountant specialising in ASX listed Companies
- Highly skilled in Company secretarial duties and Corporate Governance
- Bachelor of Commerce, Accounting and Finance

# Advisory board





#### Mara Gordon: Medical Cannabis Adviser

- Founder of Zelda Therapeutics, Aunt Zelda's and Calla Spring Wellness
- Specialises in the development of treatment protocols utilising Bio Pharmaceutical grade cannabis extracts for seriously ill patients



# Dr Ted Whittem: Commercial Veterinary Adviser

- Former Head of School at the Melbourne Veterinary School;
- Former Chairman of the Examination Committee of the American College of Veterinary Clinical Pharmacology;
- 7 years as the head of R&D with Jurox Animal Health, brining over 30 products to market.



# Dr Rayson Tan: Chief Scientific Officer

- Experienced veterinary consultant with a PhD in veterinary oncology, BVSc in veterinary medicine and surgery and BSc in veterinary research;
- Currently serves as the regulatory and ethics executive for the Garvan Institute of Medical Research and is exceptionally proficient in biomedical and veterinary science.



# Amanda Reiman: Cannabis Regulatory Adviser

- Former Manager of Marijuana Law and Policy at the Drug Policy Alliance, California
- Worked to develop the DPA's marijuana reform work relating to litigation, legislative drafting, campaign strategy and policy advocacy in state, federal and international jurisdictions

# Disclaimer

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# Thank You www.cannpal.com

# Inquiries

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