

# AusCann

## AGM Presentation

November 15, 2021

*Layton Mills - CEO*



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# AusCann Snapshot

## Cannabinoid-based healthcare Company

- ✓ An Australian pioneer developing evidence-based healthcare solutions derived from the Cannabis plant for under-served medical needs in humans and companion animals;

## 1<sup>st</sup> Australian veterinary registration commenced

- ✓ Commenced 1<sup>st</sup> registration with the APVMA for a patented first-in-class cannabinoid veterinary medicine for skin and immune health in dogs; Market size of over \$1B<sub>1</sub>

## Path to FDA approval for Phase 2 veterinary drug

- ✓ Pathway to FDA-CVM registration in U.S with INAD file opened for THC/CBD veterinary medicine for pain, Inflammation and Quality of Life in dogs; Market size of over \$1B<sub>2</sub>

## Fast-tracking human drug development

- ✓ Leveraging animal/human synergies to fast-track human programs with first exploratory study in Spinal Cord Injury in planning for early 2022; Market size of over \$6B<sub>3</sub>

## Well Funded for Growth Milestones

- ✓ \$14m cash at bank to execute on future growth milestones, and a net asset backing of \$0.10c; Strong upside for investors<sub>4</sub>

APVMA (Australian, Pesticides and Veterinary Medicines Authority), FDA-CVM (Food and Drug Administration, Centre for Veterinary Medicine), INAD (Investigational New Animal Drug application), THC (tetrahydrocannabinol), CBD (Cannabidiol)

1 and 2. AusCann analysis based on Vetnosis, AnimalPharm, and other public and proprietary data sources

3. Coherent Market Insights, Spinal Cord Injury Therapeutics Market Analysis

4. As at June 30, 2021

AusCann

# Strategic Overview

## Mission

- ✓ To be the Australian leader in taking **approved** cannabinoid-based medicines **to the world**

## Purpose

- ✓ To deliver on the **promise** of pharmaceutically made cannabinoid-based medicine

## Business Model

- ✓ **Immediate revenues** through regulatory approved veterinary medicines and special access medical cannabis frameworks in global markets; and
- ✓ **Reinvest** in high-value human drug development, with significant upside for shareholders through regulatory approved human drug candidates

## Strategic Focus

### Yesterday

- ✓ Restructuring AusCann to improve cost base and refocus on high-value R&D
- ✓ Exit non-strategic loss-making operations
- ✓ Enhance R&D and pipeline through acquisition of CannPal
- ✓ Develop defensible IP through R&D and novel technologies

### Today

- ✓ Progressing 1<sup>ST</sup> Australian approved veterinary medicine for immediate Revenues;
- ✓ Progressing 1<sup>ST</sup> FDA-CVM approved veterinary medicine for near term upside;
- ✓ Fast tracking high-value human drug development via internal R&D and know-how

### Tomorrow

- ✓ Commencing first-in-human study in patients with Spinal Cord Injury (**in design phase**)
- ✓ Assessing other novel conditions for potential drug development opportunities
- ✓ Long term growth through internal product development and/or M&A opportunities



# Key Milestones in 2021



Successfully completed the acquisition of CannPal Animal Therapeutics Ltd by way of Scheme of Arrangement

**45%**  
reduction

The net cash used in operating activities was reduced by 45%<sup>1</sup> in the FY21 due to reductions in statutory expenses and operational efficiencies

**1st**

submission

Submitted the Company's first cannabinoid-based registration dossier for regulatory approval

**\$2.94m**

R&D

Direct research and development expenses were \$2,947,926, which accounted for 51% of the Company's net cash operating cash outflows for FY21<sup>2</sup>

**\$44.4m**

net assets

Well-funded with net assets of \$44.4m and a net cash position of \$13,679,923 as of June 30, 2021

## March 2021

Successfully completed the acquisition of CannPal Animal Therapeutics Ltd by way of Scheme of Arrangement

## April 2021

Received clinical results for the Company's 8-week Phase 2A pilot study for FDA veterinary drug candidate, CPAT-01, confirming improvements in pain, lameness and quality of life in dogs with osteoarthritis

## June 2021

Advanced the Australian product registration strategy for first-in-class veterinary medicine for skin and immune health in dogs, with receipt of an agreed registration timeline and strategy from the APVMA

## September 2021

Engaged knoell Animal Health to advise on the CPAT-01 clinical Phase 2 program and U.S regulatory strategy for FDA-CVM registration

## September 2021

Commenced a strategic review to support the development of new cannabinoid-based drug candidates for human registration

## October 2021

Completed 90-day Target Animal Safety Study for DermaCann® in the U.S, confirming the product to be safe and well tolerated in dogs

## October 2021

Submitted a pre-submission meeting conference request with the FDA-CVM for CPAT-01; meeting expected to be held in December 2021

1. Excluding non-cash and once off acquisition related costs

2. Excluding non-cash and once off acquisition related costs

# Experienced Board and Management



**Max Johnston**

Chairman

Johnson & Johnson, Medical  
Developments Int'l, Polynovo,  
Bard1



**Geoff Starr**

Non-executive Director

MARS Global Pet Care, Unilever,  
George Western Foods



**Bruce McHarrie**

Non-executive Director

Adherium, Phylogica, Telethon Kids  
Institute, BioScience Managers, Rothschild



**Dr Kate Adams**

Non-executive Director

BSc, BVMS, Bcomm, Owner of  
Bondi Veterinary Hospital



**Robert Clifford**

Non-executive Director

Brand implementation, business strategy  
and planning, large multinationals



**Krista Bates**

Interim Chair

Lavan law firm, AAMEG, Clifford  
Chance, Credit Intelligence



**Chris Mews**

Non-executive Director

Merchant Group, Polynovo, VPCL,  
Chartered Accountant



**Layton Mills**

Chief Executive Officer

FMCG and Lifesciences entrepreneur  
with over 12 years of development  
experience



**Dr Margaret Curtis**

Chief Scientific Officer

17 years' of experience with Animal  
Health Company Elanco, helped gain  
approval for 20+ drugs in 100+ countries














**Charles Altshuler**

Chief Financial Officer

16 year career with leading ASX listed  
Companies, including Blackmores and  
BOD Australia

# World Leading R&D Collaborators

Regulatory and Research Support		
■ Non-clinical & clinical Support	Intervivo	
■ Regulatory Support	Intuit Consultants	
■ Regulatory & Clinical Support	Penny Cain	
■ Regulatory & Clinical Support	Paul Dick & Associates	
■ Regulatory & Clinical Support	knoell Animal Health LLC	
■ Research Support	Sherelle Casey	
■ Research & Clinical Support	Klifovet A.G	
■ Clinical Support	Genesis Research Services	
■ Regulatory & Clinical Support	Clindata	
■ Regulatory Support	AP Pharma	
■ Clinical Support	Summit Ridge	

Safety, CMC Development & Commercial		
■ CMC Development	Mark Smith	
■ Supply Chain	Nick Tuminello	
■ Toxicology and Safety	Dr Jeff Sherman	
■ Commercialisation	Eric Graves	

Scientific Advisory Board		
■ Chief Medical Advisor	Dr Marc Russo	
■ Scientific Advisory Board	Dr Peter Georgius	
■ Scientific Advisory Board	Dr Sachin Shetty	
■ Scientific Advisory Board	Professor Peter Gonski	
■ Scientific Advisory Board	Dr Ted Whittem	



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# AusCann

Lead Veterinary  
Programs





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DermaCann®



# DermaCann® CBD Oral Solution

## Product summary

- ✓ A standardised oral CBD-based veterinary medicine developed for skin and immune health in dogs
- ✓ Patented formulation shown to reduce inflammation in dogs with atopic dermatitis in a randomised, double-blind, placebo-controlled trial
- ✓ cGMP manufacturing and 24 months stability at room temp confirmed
- ✓ Seeking “first-in-class” product registrations for legal sale through veterinarians in global markets
  - Australian submission as a veterinary medicine **(Commenced)**
  - New Zealand submission as a veterinary medicine **(Commenced)**
  - South African submission as a complementary medicine **(Commenced)**
  - Other registration markets **(Under Review)**
- ✓ Advanced discussions with commercial partners for South Africa, Australia and New Zealand
- ✓ Commercialisation plans underway for U.S launch in early 2022



# Opportunity in Dermatology

## Significant unmet need and large market size

- ✓ The top four reasons for a vet consultation is dermatology (excluding preventive care)
- ✓ No cure for atopic dermatitis; can only be managed through therapeutic intervention, diet and/or lifestyle
- ✓ Market dominated by two products offered by a single Company, accounting for 70% market share
- ✓ Cannabinoids provide a new and novel therapeutic option for dogs with dermatological conditions
- ✓ Safety profile of DermaCann® allows for it to be used stand-alone, or concurrently with common therapies for multi-modal treatment
- ✓ The global canine dermatology market is estimated at over US\$1.2B (Fig.1), with a CAGR of 9% through 2027
- ✓ In a product concept survey for DermaCann with 150 pet owners in the U.S with dogs diagnosed with atopic dermatitis, superior ratings were confirmed for “Believability”, “Likelihood to Use” and “Need for Product” (Fig.2)\*

## Canine Dermatology Market Size and Opportunity

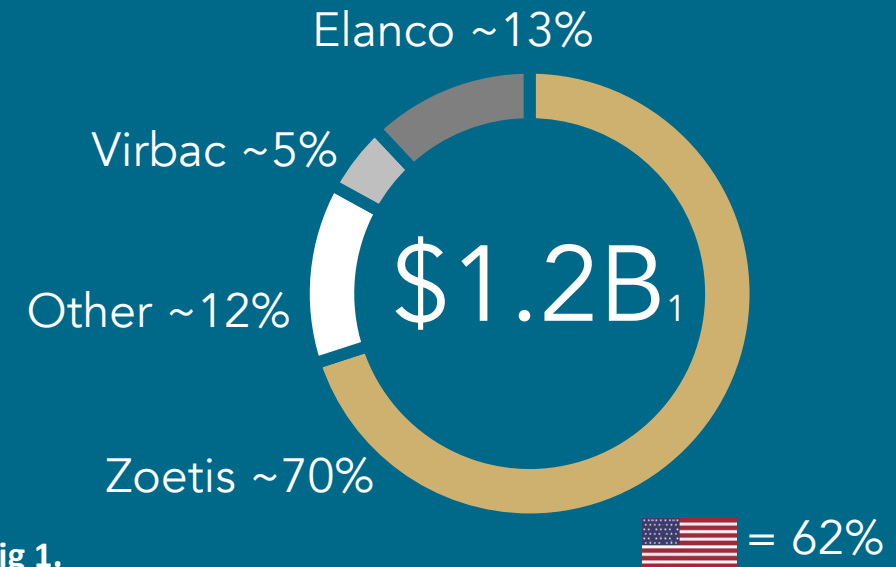


Fig 1.

Fig 2. Dog Owners (n=151) Top 2 Box Score



# First-in-class Product Supported by Research

Strong execution in research and development for over 3 years

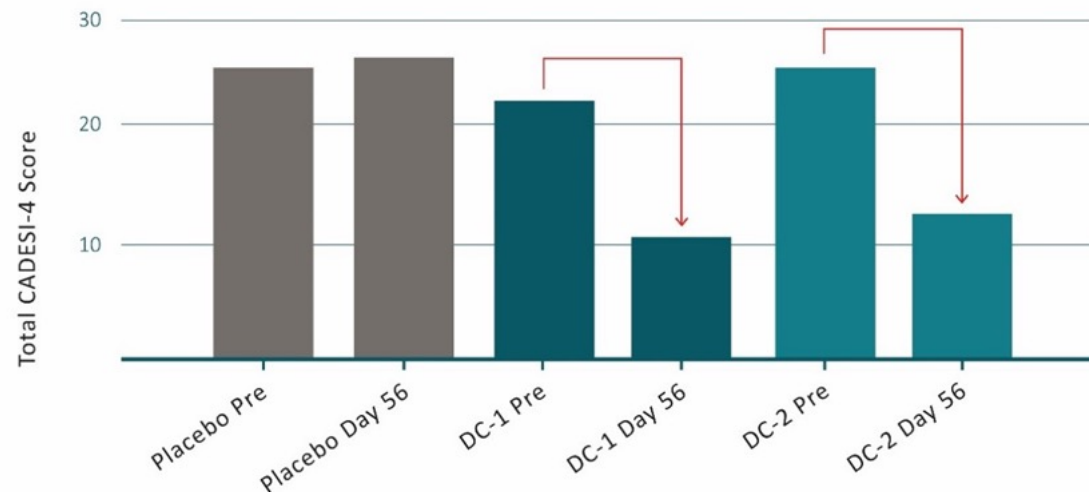
- Commenced cGMP manufacture ✓ Complete
- Lab batch stability program - **24 months** ✓ Complete
- 8 x GLP *In-vitro/In-vivo* cannabinoid safety studies ✓ Complete
- GLP user safety studies ✓ Complete
- Randomised, placebo-controlled efficacy study - **13 dogs** ✓ Complete
- Pilot batch stability program - **18 months** ✓ Ongoing
- U.S target animal safety study (TAS) - **20 dogs** ✓ Complete
- Manufacturing scale up/process validation (U.S/NZ) ✓ Commenced • Q4 2021
- Commercialisation in first markets (U.S and South Africa) ✓ Commenced • Early 2022
- Product submissions in Australia and New Zealand ✓ Commenced • Late 2022



# Shown to be Safe and Effective for Reducing Inflammatory Lesions

- A world first placebo-controlled trial using oral hemp derived CBD to assess the support of healthy skin function in dogs with atopic dermatitis
- Dogs diagnosed with canine atopic dermatitis by veterinary dermatologists were eligible for the trial
- 13 dogs completed the trial over 8 weeks, in 3 treatment groups; 8 received DermaCann® treatment and 5 received placebo
- DermaCann® was found to be well absorbed and well tolerated in treated dogs
- Mean CADESI-4 Score to assess inflammatory lesions was significantly ( $P < 0.1$ ) reduced (51%)<sup>1</sup> due to treatment compared with placebo<sup>1</sup>
- Placebo dogs had higher use of breakthrough medications (60%) compared with DermaCann (25%) treated dogs
- Biomarker results provided support for the anti-inflammatory mechanism of action for DermaCann®

✓ *DermaCann® was found to be safe and effective in lesion reduction associated with canine atopic dermatitis (CAD), supporting its use as a beneficial therapy in a CAD management regimen*



Mean CADESI-4 scores in dogs treated with placebo or DermaCann® (DermaCann® formulation 1 (DC-1) or DermaCann® formulation 2 (DC-2)); Results from pre-treatment (day 0) to day 56

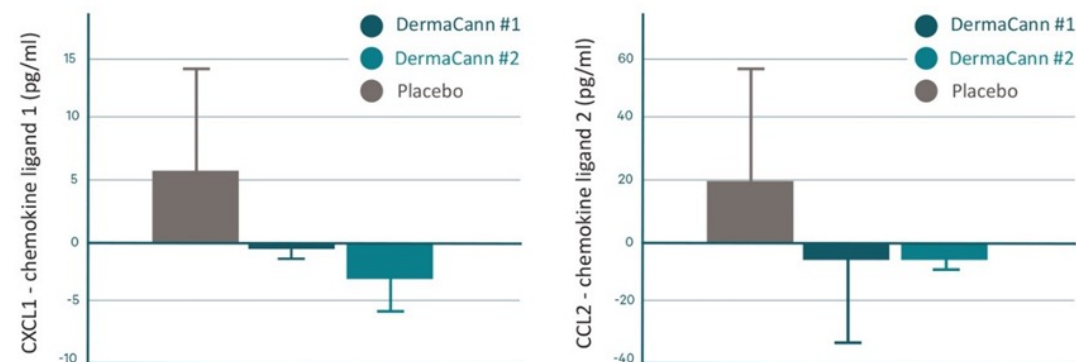


Fig 2. Biomarker results provided support for the anti-inflammatory and immune enhancing mechanism of action for DermaCann®

1. 51% the mean of CADESI-4 scores in dogs treated with placebo or DermaCann® groups combined (DermaCann formulation 1 (DC-1) or DermaCann formulation 2 (DC-2)). Results from pre-treatment (day 0) to day 56.

Fig 2. Changes in CXCL1 and CCL2 expression in dogs with Atopic Dermatitis after treatment with 2 different DermaCann® formulations, or placebo, as assessed by ex-vivo biomarker analyses in canine blood plasma samples.

CPAT-01



# CPAT-01 – Oral THC:CBD Oil

## Targeting world 1<sup>st</sup> FDA-registered veterinary medicine

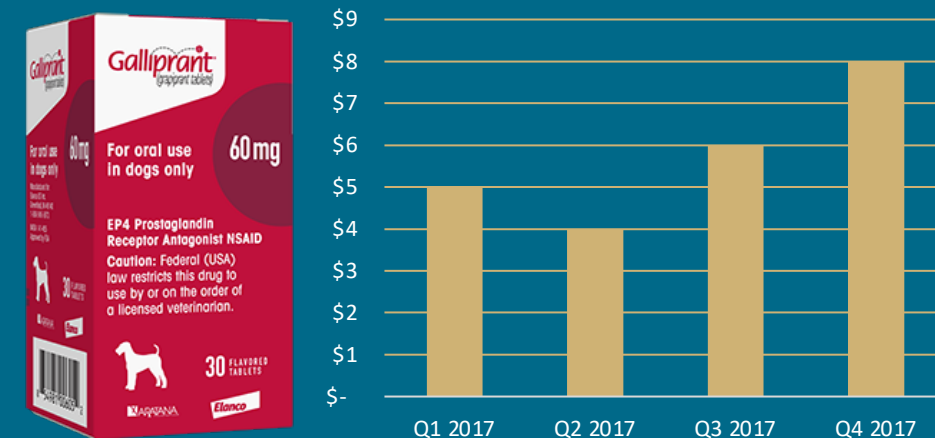
- A standardized pharmaceutical product derived from THC and CBD extracts for pain, inflammation and quality of life in dogs with osteoarthritis
- Progressing FDA-CVM registration pathway with INAD file opened and barrier-to-innovation fee waiver (reducing sponsor costs)
- Significant market size, with very little differentiation
- Galliprant, a recently approved NSAID for osteoarthritis in dogs had 1<sup>st</sup> year U.S revenues of USD\$23M, and is forecasted to reach peak sales of USD\$100m+<sup>1</sup>
- Upcoming Key Catalysts include:
  - ✓ Ongoing CMC work and GMP material for clinical trial
  - ✓ The commencement of the Phase 2C clinical trial with the advisory board, study design, FDA protocol concurrence and site recruitment to be finalised
  - ✓ Ongoing toxicological work - 28 day repeat dose study
- *A successful Phase 2C study would enable a predictable path towards the first U.S FDA registered cannabinoid medicine for dogs*

## Canine Pain Management Market Size and Opportunity

“The global veterinary pain management market is projected to grow at a Compound Annual Growth Rate of 8.0%, to reach US\$1.6B BY 2023”<sup>2</sup>



### Galliprant First Year U.S Sales by Quarter (\$millions)



# Leading FDA-CVM Veterinary Program

A globally leading development program for FDA registration with consistent execution

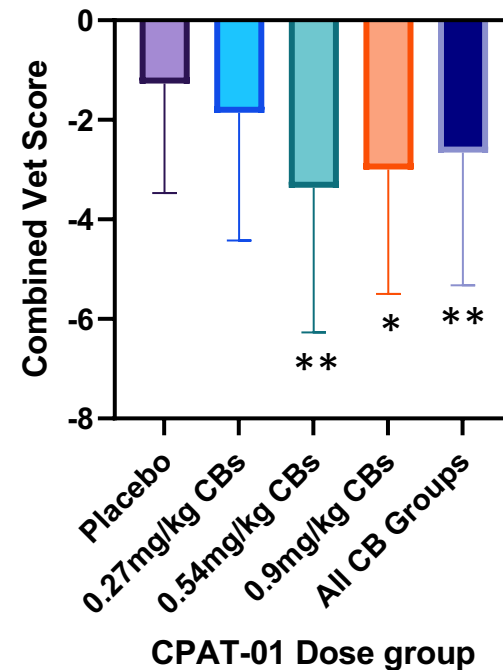
- Manufacture of product for pilot clinical and pilot TAS ✓ Complete
- Phase 1A - single dose - 2:1 and 1:2 (THC:CBD) ratios tested - **11 dogs** ✓ Complete
- Phase 1B - single dose - 1:2 ratio tested at 3 doses and THC/CBD separately – **48 dogs** ✓ Complete
- Gene expression/Chemokine/Cytokine profiling – ***In Phase 1A and 1B dogs*** ✓ Complete
- Phase 2A – 8 week dose characterisation study in dogs with osteoarthritis- **55 dogs** ✓ Complete
- Phase 2B Pilot Target Animals Safety (TAS) – **16 dogs** ✓ Complete
- Population Pharmacokinetic Study - ***Including all CannPal studies*** ✓ Complete
- Open INAD with the FDA-CVM ✓ Complete
- GLP In-vitro/in-vivo cannabinoid genotoxicity program ✓ Ongoing
- Commencement of QBD product manufacturing program ✓ Commenced
- FDA-CVM Pre Submission Conference Meeting - ***Requested*** ✓ Commenced
- Phase 2C Effectiveness Program – ***In design Phase*** ✓ Commenced



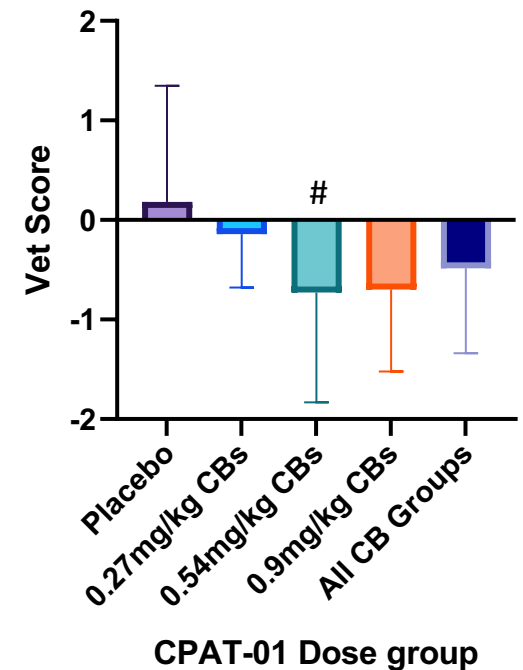
# Shown to Positively Influence Pain and Inflammation Pathways in Dogs

- The first double-blind randomized controlled trial to assess the benefits of THC and CBD in client-owned dogs with veterinary diagnosed osteoarthritis
- Dogs were randomized to 4 treatment groups and dosed orally, twice daily for 56 days; 46 dogs completed treatment
- Vet lameness scoring (VLS) was assessed by clinical lameness, joint mobility, pain on palpation, weight bearing and overall vet impression at day 0, 28 and 56
- The within group analyses for Total VLS showed an improvement for all groups; This was significant for the highest CPAT-01 dose groups and all groups combined, when compared with baseline
- Owner scoring included the Canine Brief Pain Inventory (CBPI), Canine Orthopaedic Index (COI) and Hudson Activity Scale (HAS) every 2 weeks
- A significant improvement ( $P < 0.05$ ) in Total COI for all CPAT-01 treatments combined compared with baseline was observed
- The quality of life (QOL) section of the scoring appeared to have the most marked effect in the COI, particularly at 14 days

**Mean Total Lameness Vet Score Reduction over 56 days**



**Joint Stiffness Reduction over 56 days**

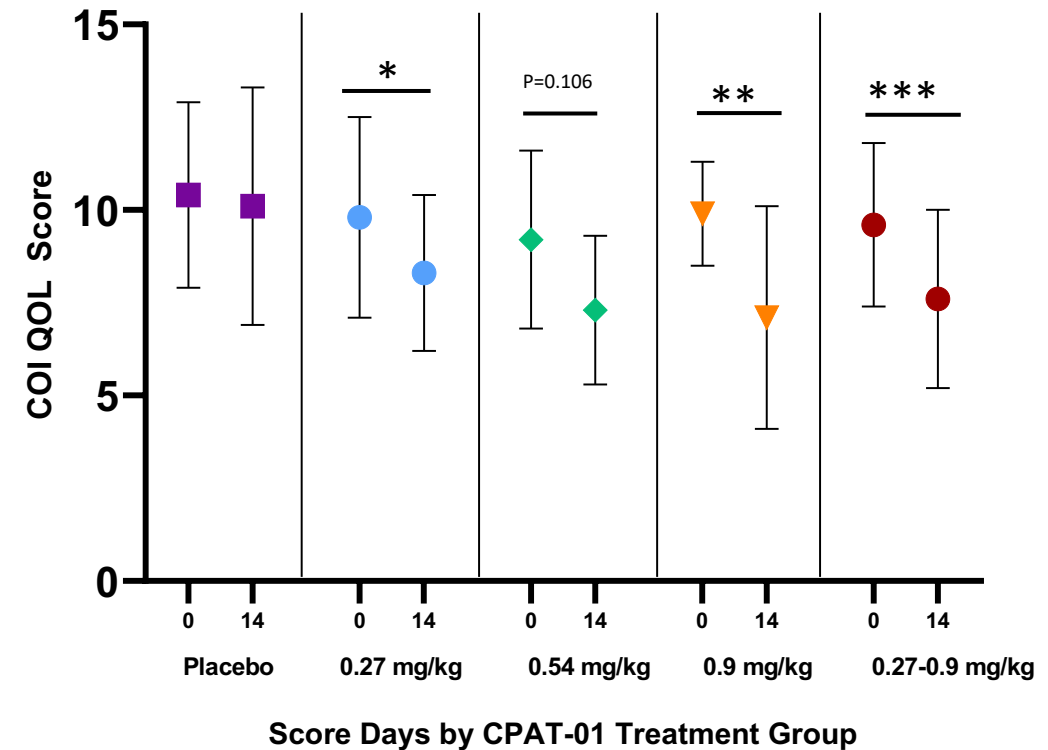


1. \* $P < 0.1$ , \*\* $P < 0.05$  - Compared with baseline, within groups comparison  
2. # $P < 0.1$ , Compared with baseline, between groups comparison

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**Quality of Life in Canine Orthopedic Index (COI)  
Scores by CPAT-01 Treatment group over first 14 days**



1. Owner scoring included the Canine Brief Pain Inventory (CBPI), Canine Orthopaedic Index (COI) and Hudson Activity Scale (HAS) every 2 weeks
2. Mean QOL with SD error bars \* $P < 0.1$ , \*\* $P < 0.05$ , \*\*\* $P < 0.01$  compared with day 0, within group comparison

# Next Steps - Phase 2C

Progressing U.S FDA-CVM pathway to registration with Phase 2C effectiveness program

Phase 2C Milestone	Q4 2021	Q1 2022	Q2 2022	Q3 2022
PSC Meeting	December 9th			
FDA-CVM - Memorandum of Conference (MOC)		Received 45 days after PSC with agreed U.S Regulatory path		
Protocol Design and Ethics Approval		Phase 2C protocol design and ethics submission		
Clinical Trial Sites and Manufacture of CTM		Confirm clinical trial sites and prepare GMP clinical trial material		
Recruitment and study commencement				Commence study recruitment and treatment

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Cannabinoids for  
Spinal Cord Injury





# Spinal Cord Injury Overview

## What is Spinal Cord Injury?

- Damage to the spinal cord that results in a loss of functional mobility or feeling and results in symptoms such as spasticity, pain, depression and a significant impairment in quality of life. Causes include;
  - Motor Vehicle Accidents = 38.4%
  - Falls = 30.5%
  - Violence 13.5%
  - Sports related Accidents = 8.9%
  - Other causes = 8.7%
- **250,000 – 500,000** new SCI cases estimated per year worldwide
- **80%** experience spasticity
- **60%** experience pain
- Current symptomatic treatments neither optimal nor adequate



# Cannabinoids for SCI

## Cannabinoid based therapies for Spinal Cord Injury

- Current evidence suggests that **cannabinoids may reduce pain and spasticity** in people with SCI, although its effect magnitude and clinical significance are unclear<sup>1</sup>
- **60%** reported it offered “great relief” from other symptoms, including spasticity, pain, sleeplessness and anxiety<sup>1</sup>
- **More effective** and **fewer side effects** than prescription medications<sup>1</sup>
- **70%** of current and previous cannabis users with SCI reported using medical cannabis to address spasms<sup>2</sup>
- Those who had never tried cannabis reported that they would mainly use cannabis to alleviate pain and spasticity if it were legalized<sup>3</sup>
- But information is lacking on optimal dosage, method of use, composition, and concentration of compounds



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# Fast-tracking Human R&D

## Exploratory trial in design phase for Spinal Cord Injury

AusCann engaged the Clinical Research division of Cannvalate to conduct a technical review of the Company's existing research assets for the development of cannabinoid-based drug candidates for potential marketing approval via the U.S Food and Drug Administration

### Overview and Next Steps

- The scope of the assessment included a technical review of the Company's existing animal data and research, including safety and toxicological data which may be used to fast track human drug development
- Spinal Cord Injury was identified as an underdeveloped area with an addressable market size of US\$6B
- The aim of the discovery trial is to generate initial clinical data on the benefits of the Company's proprietary cannabinoid-based formulations for people suffering from symptoms associated with Spinal Cord Injury
- This data may be used to support a human drug development program for marketing approval via the U.S FDA
- The initial study will commence upon approval by a human research ethics committee ("HREC"), with an initial HREC submission expected to be submitted in early 2022

# Upcoming Catalysts

## Timeline



First FDA-CVM Meeting for CPAT-01;  
Planned for Early December

Q4 2021



Commence Clinical Trial in Spinal Cord Injury;  
Ethics Submission in Early 2022

H1 2022



1<sup>st</sup> Sales of DermaCann in South Africa and U.S;  
In Advanced Discussions with Key Partners

H1 2022



Commence Phase 2C Trial for CPAT-01; On  
Pathway to Potential FDA Registration

H1 2022



Product Registrations for DermaCann in  
Australia and New Zealand

Q2 2022



Continue to explore growth opportunities  
through internal development and/or M&A

ONGOING

AusCann



# Why Invest in AusCann?

## Better value for Investors

### **Leveraging synergies between human and animal drug development provides better value to shareholders**

- Veterinary blockbusters have peak sales of over US\$100m and are quicker to market; Provides revenue stream for reinvestment into human programs with a higher return on investment
- Animal research can accelerate human drug development with shared datasets and learnings; De-risks human pathway

## First-in-class Veterinary registrations

### **AusCann has taken the global leadership position for approved, cannabinoid-based veterinary medicines**

- Commenced Australian and New Zealand registration for first-in-class cannabinoid-based veterinary medicine for skin and immune health in dogs; Commencing commercialisation in U.S and South Africa in early 2022
- First Company to file an INAD for a cannabinoid-based veterinary drug with the FDA-CVM; Phase 2 drug candidate targeting pain, inflammation and quality of life in dogs with osteoarthritis; Combined Global markets of over US\$1B

## Significant human upside

### **Accelerating cannabinoid drug-development programs in high value need states for human registration**

- Commencing clinical study for THC and CBD in patients with Spinal Cord Injury; Market size of over US 6\$B
- Completing feasibility assessments in other populations with neurological conditions

## Restructured for growth

### **A restructured Company, with an experienced team and funded to reach key catalysts and inflection points**

- Well capitalized with \$13m net cash at bank and total net assets as of June 30 of \$44m
- World leading expertise in designing robust cannabinoid research, with evidence of consistent cost-effective execution
- A pipeline that provides immediate, medium, and long-term value for consistent growth

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# AusCann

*Delivering on the **promise** of pharmaceutically  
made **cannabinoid-based medicine***

*Thank you*