



**October 13th 2020 | CannPal Animal Therapeutics Limited | ASX: CP1
ASX ANNOUNCEMENT**

CannPal Animal Health Investment USA Presentation

Key Highlights

- CannPal is participating in the Kisaco Animal Health Investment USA conference and the presentation is attached for release;
- Animal Health Investment USA is the premier investment forum showcasing new opportunities in animal health and connecting businesses together with financial investors and strategic corporate partners;
- This year's conference is held virtually due to the challenges associated with COVID-19.

October 13th 2020: Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is participating in the Kisaco Animal Health Investment USA conference and the presentation is enclosed with this release.

The Kisaco Animal Health Investment USA Conference is the premier investment forum showcasing the industry's most exciting emerging companies in animal health and connecting businesses together with financial investors and strategic corporate partners.

This year, in light of Covid-19, the conference will be held virtually.

About CannPal Animal Therapeutics

CannPal Animal Therapeutics Limited (ASX: CP1) is an animal health Company with a mission to provide pet owners and veterinarians with access to high quality, evidence based, plant derived therapeutic products to promote better health and well-being for animals.

Presently, the Company is focused on the development of pharmaceutical and nutraceutical products for dogs, for commercialisation in various markets around the world, using compounds derived from the hemp and cannabis plant.

To learn more please visit: www.cannpal.com

ENDS

This announcement has been approved and authorised to be given to ASX by Mr Geoff Starr, the Chairman of CannPal Animal Therapeutics Limited.

For further information, please contact:

CannPal Animal Therapeutics

Layton Mills

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Animal Health Investment USA

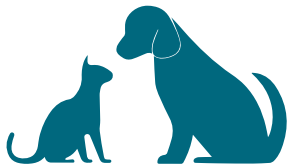
Company Overview

October 2020



Company Highlights

An ASX listed Animal Health Company with a pipeline that provides long term upside potential, supported by near term revenue catalysts



Clear focus

An animal health Company developing therapeutic products for the companion animal market



Upside Potential

A lead phase 2 FDA pharmaceutical program for pain and inflammation in dogs



Path to Revenue

A nutraceutical pipeline in the commercialisation phase for complementary revenue



Senior Leadership

Entrepreneurial team supported by an experienced Board and highly skilled advisers and consultants – all invested in CannPal's success



Layton Mills

Founder/Managing Director

- FMCG entrepreneur with over 11 years in product development
- Launched retail and consumer goods in the Australian market;
- Experienced in brand development and CPG.



Dr Margaret Curtis

Head of R&D

- Qualified veterinarian with 17 years' of director experience with market leading animal health company, Elanco;
- Has gained approval for over 20 drugs in over 100 countries.

- ✓ **Board and management** made up of leaders from the animal health industry, major pharma and large MNCs



- ✓ **Broader R&D team** involved in regulatory approval for over 50 veterinary medicines



Strategic Focus

3 complementary revenue streams, linked by our mission to develop evidence-based therapeutics for pets, derived from hemp and cannabis compounds



Pharmaceuticals

- Drugs used to treat a disease;
- Requires regulatory approval;
- Standardized cGMP drug product;
- Longer time to market and higher development costs;
- Not always suitable for long term use;
- ✓ A lead Phase 2 candidate for long term upside and high ROI



Nutraceuticals

- Products that may assist in managing a disease;
- Can be sold prescription or non-prescription (OTC);
- Safer for longer term use and as an adjunctive therapy;
- Shorter time to market, with less cost in the development;
- ✓ A lead nutraceutical for sale through veterinary channels



Dietary Supplements

- Products that support natural defence systems and normal health function;
- Low level of regulatory scrutiny;
- Ideal for longer term use as part of a balanced diet;
- Cost effective development and ideal speed to market;
- ✓ Complementary revenue with first product in beta launch

Lead Pharmaceutical: CPAT-01

A lead pharmaceutical candidate developed using active ingredients from the cannabis plant to target pain and inflammation in dogs

- ✓ A standardized pharmaceutical product derived from natural THC and CBD extracts;
- ✓ Synergistic effects combining CBD with THC to reduce the psychotropic effects of THC;
- ✓ Favourable industry tailwinds given the growing prevalence of obesity and arthritis in dogs;
- ✓ Formulated as an oral liquid solution to allow for compliance and more standardised dosing;
- ✓ The veterinary pain and inflammation market is worth over US\$1b globally.

Regulatory Focus

- ✓ FDA approval as a prescription veterinary medicine (INAD filed)

Current Status

- ✓ Completed Phase 2A efficacy and Phase 2B safety pilot studies

Market Strategy

- ✓ Seeking licencing or co-development partner post Phase 2

CPAT-01: Stage of Development

Consistent execution with significant key milestones reached since 2018

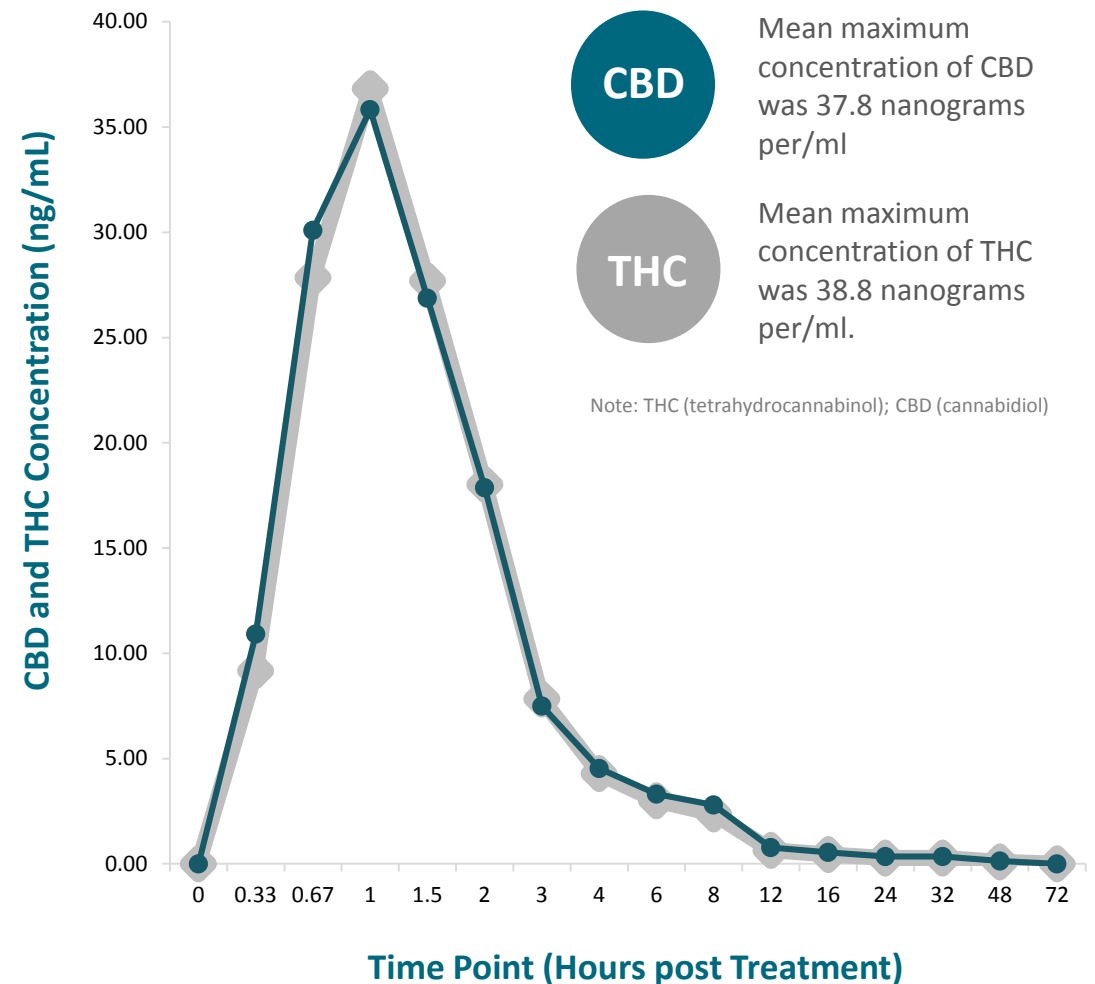
Key Milestone	Status	Target timeframe
Phase 1A Pharmacokinetics (PK) - 11 dogs	✓ Complete	
Phase 1B Dose ranging, safety and PK - 48 dogs	✓ Complete	
Gene expression/Chemokine/Cytokine POC	✓ Complete	
<i>In-vitro/in-vivo</i> cannabinoid gentotoxicology program	✓ Complete	
Phase 2A Pilot Dose Determination Study - 46 dogs	✓ Complete	• Report Q4 2020
Phase 2B Pilot Target Animals Safety (TAS) - 16 dogs	✓ Complete	
File INAD with the FDA-CVM	✓ Complete	
Chemistry, Manufacturing and Controls (CMC)	✓ Commenced	• Ongoing

CPAT-01: Phase 1 PK

The initial target dose was found to be bioavailable with a wide safety margin, minimal psychotropic effects and no adverse events

✓ Phase 1: Safe, Bioavailable and Palatable

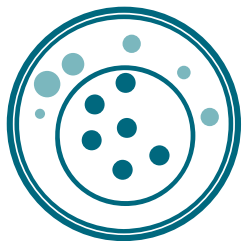
- Excellent safety profile seen across various cannabinoid formulations;
- CPAT-01 was well absorbed in its current proprietary formulation;
- No evidence of adverse effects were observed at the target dosage given;
- No palatability issues noted to date;
- Early indications of a stable formulation;
- Early indications of physiological function in immune and inflammatory pathways.



CPAT-01: Phase 1 MOA

Significant changes in gene pathways and biomarkers known to modulate anti-inflammatory processes were seen in treatment groups compared to placebo

- Potential for different mechanisms of action;
- Targeting endo-cannabinoid system through cannabinoid receptor modulation;
- Potential to influence the inflammatory cascade through chemokines and cytokines;
- Potential for modulation of the immune response, through various processes;
- Potential for adjunctive benefits through modulation of mood and sedation.



Inflammatory/Immune genes and biomarkers were significantly influenced in Phase 1 research*

Upregulated Chemokine ligand 5 (CCL5)

- ✓ codes for a chemokine important in recruiting white blood cells to inflammatory sites - *Schall et al 1988. PACHER, et al 2006*

Downregulated interleukin 8 (IL-8)

- ✓ codes for a chemokine important in recruiting white blood cells to inflammatory sites - *Schall et al 1988. PACHER, et al 2006*

Reduction of GM-CSF

- ✓ consistent with effects seen in humans treated with CBD and THC - *Pellati et al 2018*

Increased Interleukin 15

- ✓ consistent with an upregulation of IL-15 reported to modulate the immune response in humans – *Patidar et al. 2016*

CPAT-01: Phase 2A Study Design

First double-blind randomized controlled study in dogs with osteoarthritis using a combination of cannabidiol (CBD) and tetrahydrocannabinol (THC)

✓ **55 dogs, randomized to 4 treatment groups, dosed orally, bid for 56 days. 46 dogs completed treatment.**

- A (placebo) – MCT at 0.02 or 0.03ml/kg;
- B (0.75x dose) – 0.27 mg/kg CBD and THC in 2:1 ratio; 0.015 or 0.03ml/kg;
- C (2.5x dose) – 0.9 mg/kg CBD and THC in 2:1 ratio; 0.033 or 0.05ml/kg;
- D (1.5x dose) – 0.54 mg/kg CBD and THC in 2:1 ratio; 0.02, 0.03 or 0.06ml/kg.

✓ **Confirmation of Drug Absorption**

✓ **Effectiveness Assessment**

- Daily owner observations;
- Owner Canine Brief Pain Inventory (CBPI), Hudson Activity Scale (HAS) and Canine Orthopaedic Index (COI) every 2 weeks, clinical observations, twice daily; daily food intake; weekly body weights;
- Veterinarian lameness score, at start and 2 timepoints across the study.

✓ **Safety Assessment**

- Physical exams, clinical pathology and urinalysis;
- Daily owner observations;
- Adverse events.



✓ **Report available Q4 2020**

CPAT-01: Phase 2B TAS

No safety concerns with the use of CPAT-01 in healthy adult Beagles when administered 5 times the target dose (5x) twice daily for 90 days

✓ **16 dogs, randomized to four treatment groups, dosed orally, bid for 90 days.**

- Target dose (**T1**) - 0.6 mg/kg cannabidiol (CBD) and 0.3 mg/kg tetrahydrocannabinol (THC);
- **T3** and **T5** - respectively 3 x and 5 x the amount of **T1**;
- **T0** – water, volume equivalent to the T5 dose.

✓ **Safety variables assessed in this study were:**

- Clinical observations, twice daily; daily food intake; weekly body weights;
- Physical exams, clinical pathology and urinalysis at start and 3 timepoints across the study;
- Other variable including histopathology at study end for T5 only.

Results of possible clinical and/or toxicological relevance to the use of CPAT-01:

Gastro intestinal signs	✓ Hypersalivation, vomiting, loose faeces with mucus but only groups T3 and T5
Neurological signs	✓ Ataxia, tremors, spastic movement, and increased sensitivity to sound and fast movements but only in groups T3 and T5 ✓ Observations were self-limiting and only appeared within the first 3 days
Body weight and food intake	✓ Reduced in association with test article dose ✓ Mostly in groups T3 and T5 after week 1
Other variables including histopathology	✓ No other findings associated with test article administration were identified

CPAT-01: Summary

- ✓ CPAT-01 has demonstrated positive influence on pain and inflammation pathways in dogs;
- ✓ An easily dosed and bioavailable formulation with a promising CMC profile;
- ✓ No safety concerns with use of CPAT-01 in healthy adult Beagles when administered up to 3.0 mg/kg CBD and 1.5 mg/kg THC, twice daily for 90 day;
- ✓ The Company is progressing with regulatory milestones with its INAD in advance of planning for a Phase 3 program.

Next Steps	Status	Timeframe
Finalise Phase 2A Dose Determination Study	✓ Commenced	• Q4 2020
Commence Phase 1 cGMP product formulation	✓ Commenced	• Q4 2020
Pre-submission Meeting conference with FDA	✓ Commenced	• Q1 2021
Seek commercialisation partner	• In progress	• 2021
Phase 2C Dose Confirmation Study	• Not complete	• TBA
Phase 3 Pivotal program FDA concurrence	• Not complete	• TBA

Lead Nutraceutical: DermaCann

Lead nutraceutical product developed using active ingredients from the hemp plant to target dermatological skin conditions in dogs

- ✓ A lead nutraceutical in development for healthy skin and immune function in dogs;
- ✓ A Complementary product to be used as part of a Canine Atopic Dermatitis therapy regime;
- ✓ A patent pending hemp-derived cannabidiol (CBD) formulation with no THC;
- ✓ Superior product quality with cGMP manufacturing and good stability profile;
- ✓ Developing a robust dossier with safety, efficacy and manufacturing data.



DermaCann: Development

A strategic development plan to commercialise a best-in-class CBD nutraceutical, supported by safety, manufacturing and efficacy data

Milestones to date	Status	Target timeframe
Confirm cGMP manufacturer	✓ Complete	
Lab batch stability program - 18 months	✓ Complete	
<i>In-vitro/In-vivo</i> cannabinoid safety studies	✓ Complete	
User safety studies	✓ Complete	
Field efficacy study - 13 dogs	✓ Complete	
Pilot batch stability program - 12 months	✓ In progress	• Ongoing
Manufacturing scale up/Process validation	✓ In progress	• Ongoing
Target Animal Safety (TAS) study - 20 dogs	✓ In progress	• Q1 2021
Dossier preparations for initial markets	✓ Commenced	• Ongoing
Commercial evaluation in other markets (US)	✓ Commenced	• Ongoing

DermaCann: Study Design

First double-blind randomized controlled trial using oral hemp derived CBD to assess the support of healthy skin function in dogs with Atopic Dermatitis (CAD)

✓ **3 treatment groups** (*Dogs with Canine Atopic Dermatitis diagnosed by veterinary dermatologists were eligible. 13 participated in total.*)

- DermaCann #1 – 1ml/10kg bid
- DermaCann #2 – 1ml/10kg bid
- Placebo (MCT oil) – 1ml/10kg BID

✓ **Outcome measures:**

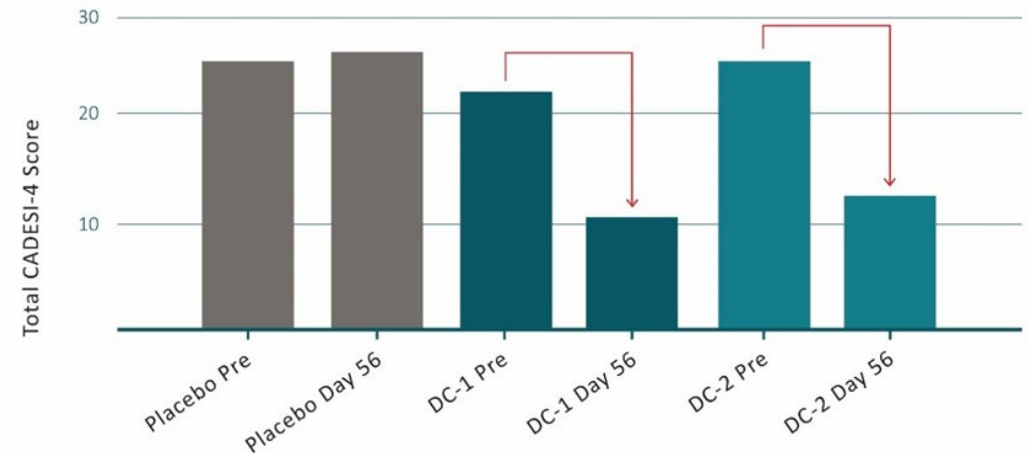
- CBD Absorption
- Safety Assessment
 - Daily owner observations
 - physical exams, clinical pathology and urinalysis at start and 2 timepoints across the study
 - Adverse events
- Effectiveness Assessment
 - CADESI-4 Score
 - Visual Assessment Scores for pruritis and odour
 - QOL and Skin/Hair Likert Scales
- Mode of Action Assessment
 - Inflammatory biomarkers
 - Gene expression was reported for subset of dogs to explore relationships with clinical outcomes.



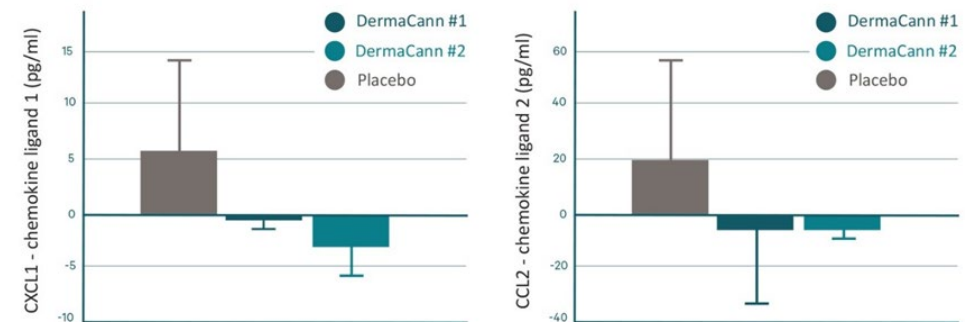
DermaCann: Results

A safe and clinically supported skin and immune nutraceutical for dogs

- ✓ DermaCann was well absorbed and well tolerated in treated dogs;
- ✓ Mean CADESI-4 Score was significantly ($P < 0.1$) reduced (51%) due to treatment compared with placebo;
- ✓ Mean pruritis and odour scores reduced for all groups. There was no significant difference between placebo and treatment;
- ✓ Placebo dogs had higher use of breakthrough medications (60%) compared with DermaCann (25%) treated dogs;
- ✓ Biomarker results provided support for DermaCann's anti-inflammatory and immune enhancing MOA;
- ✓ *DermaCann is considered to be safe and effective in lesion reduction associated with CAD, supporting its use as a beneficial therapy in a CAD management regimen.*



Mean of 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.



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.

DermaCann: Market Positioning

A complementary animal health product which can be used by veterinarians as an adjunct therapy as part of a multi-modal treatment regime



- ✓ A hemp-derived nutraceutical to promote healthy skin and immune function in dogs
- ✓ Estimated total nutraceutical market size of over US\$690m (28% sold through vet clinics)
- ✓ Adjunct therapies can complement pharmaceutical products as part of a safer multi-modal long term treatment plan
- ✓ The only clinically supported CBD nutraceutical for skin health in dogs



- ✓ Market leading skin disease pharmaceutical for the control of pruritus associated with allergic dermatitis in dogs
- ✓ For moderate to severe disease
- ✓ Effective but with safety concerns
- ✓ Expensive product for long term use
- ✓ **Est 2018 annual sales of US\$500m**

Nutraceuticals

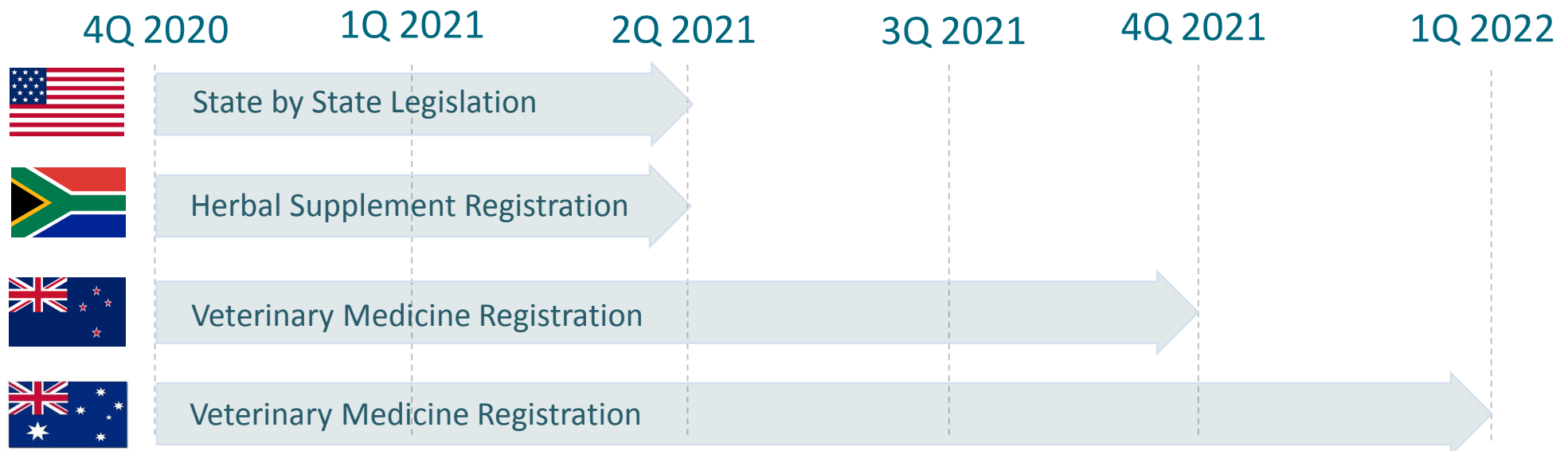
Pharmaceuticals

Disease progression

DermaCann: Summary

- ✓ DermaCann is a patented CBD-derived animal health product, supported by an efficacy, safety and manufacturing data pack for commercialisation in global markets;
- ✓ Seeking regulatory approval in Australia, New Zealand and South Africa for veterinary prescription;
- ✓ Commenced commercialisation activities in legal markets such as the United States;
- ✓ Exploring other markets, including Asia and South America.

Expected timeline for commercialisation



Dietary Supplements

Developing evidence-based pet supplements using patented and proprietary microencapsulation technology licenced by the CSIRO

- ✓ Secured the global, exclusive licencing rights to MicroMAX encapsulation technology for use in animal health;
- ✓ MicroMAX was developed by Australia's leading Science and Industrial Research Organisation, CSIRO;
- ✓ Microencapsulation technology enables the protection and enhanced delivery of key active ingredients, with a focus on oils;
- ✓ Commenced pilot market trial in the U.S via the Amazon platform for Hip & Joint Supplement under new "max by CannPal" brand;
- ✓ Oil formulation central to the product significantly reduced inflammatory biomarkers through in-vitro research model.



Thank You

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