29th January 2021 | CannPal Animal Therapeutics Limited | ASX: CP1
ASX ANNOUNCEMENT

CannPal 4C Quarterly Cash Flow Report for December 2020 Quarter

Key Highlights

- Received Interim safety, pharmacologic and biomarker results from the Company's Phase 2A Pilot Dose Ranging study supporting the safe use of CPAT-01 in client owned dogs with osteoarthritis;
    - Laboratory indicators of health including liver and kidney function confirmed that CPAT-01 can be safely used across a wide range of breed and ages of dogs;
    - Neopterin, a broad indicator of inflammation, was significantly (P<0.05) decreased in dogs treated with greater than or equal to 0.54 mg/kg cannabinoids compared with untreated dogs at day 56 after treatment;
    - Mood biomarkers analysed revealed significant decrease (P<0.05) in the plasma tryptophan to serotonin ratio when dogs treated with cannabinoids were compared to placebo treated dogs;
    - Decreases (P>0.1) in MIP-A and IL1-B, along with corresponding increases (P>0.1) in IL1RA seen at 56 days in the highest dose group, support the anti-inflammatory mode of action of CPAT-01 for dogs with osteoarthritis.
- Entered into a Collaborative Research Agreement with the University of Melbourne to commence an *ex-vivo* study on the mechanism of action for DermaCann®;
- Progressed dossier preparation for the registration of DermaCann® in South Africa as an approved herbal supplement for inflammation associated with Atopic Dermatitis in dogs;
- Commenced preparations to transfer the manufacturing of novel microencapsulated formulations from pilot scale to a commercial manufacturing partner using CSIRO's patented MicroMAX® technology;
- Closing cash balance of $1.41m as at December 31, 2020.

29th January 2021: Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is pleased to update the market on its progress in the December 2020 quarter and attaches its Appendix 4C Quarterly Cash Flow report for the period.

The Company had a cash balance of $1.41m with operating outflows totalling $553k for the quarter, with $312k related to the costs associated with the research and development of the Company's lead pharmaceutical and nutraceutical products.

During the quarter, the Company lodged an application for a rebate under the Export Market Development Grant, for activities related to the pilot trial of its joint health nutraceutical in the U.S via the Amazon platform. The estimated grant entitlement is a value of $83,085.

There were no related party payments for the period other than director fees in the ordinary course of business of $33,000.

CPAT-01

During the quarter the Company completed its quality assurance and quality control (QA/QC) appraisals of the critical clinical and safety databases for the Company's Phase 2A Pilot Dose Ranging study for CPAT-01 in client owned animals with osteoarthritis. This data has now been provided to Clindata, a globally recognised provider of statistical analyses, to evaluate the data for indicators of the clinical safety, effects and mode of action of CPAT-01 when used for treating pain and inflammation in dogs with osteoarthritis.

CPAT-01 is a standardised pharmaceutical product derived from natural THC and CBD extracts formulated into a liquid oral solution to provide veterinarians with a safe and effective veterinary medicine for pain and inflammation in dogs.

The veterinary pain and inflammation market is worth over US$1b globally and there is a need for viable treatment alternatives for dogs, particularly the elderly where current treatments for pain and inflammation may be undesirable due to their potential negative side effect profiles.

The Company is pleased to report that post the quarter, CannPal received Interim safety, pharmacologic and mood biomarker results that support the safe use of CPAT-01 in client owned dogs with osteoarthritis.

Study Design

The Phase 2A pilot study was a world first clinical trial in which CPAT-01 was given to client owned animals diagnosed with osteoarthritis, to support the safe use of THC and CBD as a viable treatment for pain and inflammation in dogs.

The study was a randomised, double blind, placebo-controlled dose ranging study, in which client owned dogs diagnosed with osteoarthritis were assigned to 1 of 4 treatment groups (Placebo, 0.27mg/kg, 0.54mg/kg and 0.9mg/kg cannabinoids) and dosed twice daily over a period of 8 weeks. The study protocol included several subjective pain, mobility and quality of life (QOL) assessments as well as objective measures of a range of biomarkers and clinical safety outcomes.

The recruitment target for the trial was 60 dogs, however, substantial slowing in enrolment due to the impact of COVID-19, and the social distancing measures implemented in Australia, led CannPal to the decision to finish the study with 46 dogs having completed treatment.

The purpose of the study was to generate initial data into the effects of CPAT-01 for pain and inflammation in a population of client owned animals diagnosed with osteoarthritis. This data will provide key insights which will be used to help inform the design of the Company's ongoing pilot and pivotal research programs for CPAT-01.

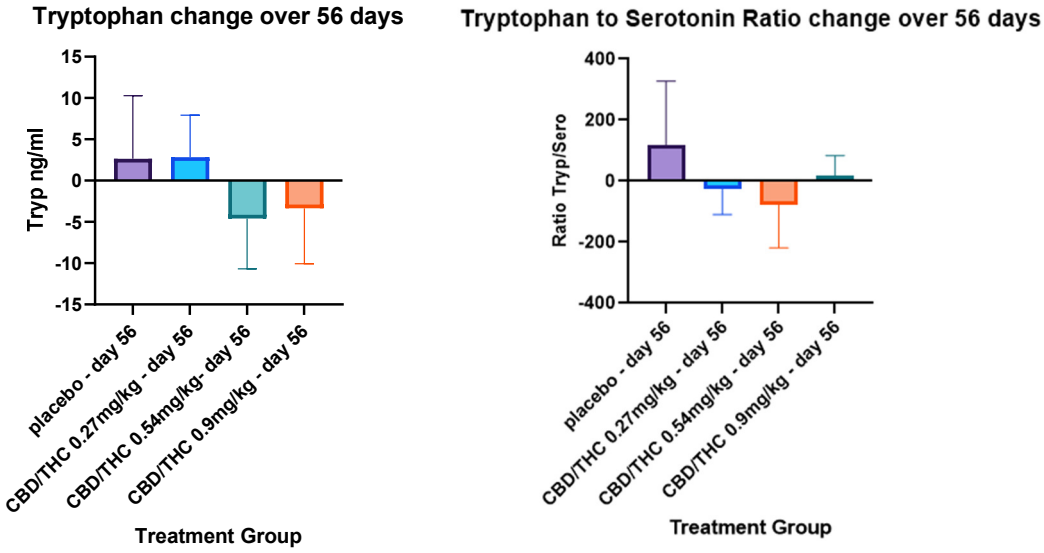
Key *In-Vivo* Biomarker Results:

ELISA biomarker testing was conducted on a subset of the plasma samples for 28 dogs that were moderately to severely affected with osteoarthritis prior to treatment.

Univariate analyses have shown Neopterin, a broad indicator of inflammation, was significantly ($P<0.05$) decreased in dogs treated with greater than or equal to 0.54 mg/kg cannabinoids compared with untreated dogs at day 56 after treatment.

Decreases ($P>0.1$) in MIP-A and IL1-B were also seen along with corresponding increases ($P>0.1$) in IL1RA seen at 56 days in the highest dose group. This is consistent with in-vitro work that suggests a role of IL1RA in the protection of the joint cartilage and synovium associated with canine arthritis, supporting the anti-inflammatory mode of action of CPAT-01.

Mood biomarkers analysed in the same subset of moderately to severely affected dogs revealed a significant (P<0.05) decrease in the tryptophan to serotonin ratio in dogs treated with cannabinoids compared with placebo, and in dogs treated with greater than or equal to 0.54 mg/kg cannabinoids compared with untreated dogs at day 56 after treatment. This is an exciting result that suggests a modulating role of CPAT-01 in the tryptophan to serotonin pathways in dogs.



Under stressful conditions tryptophan is deviated away from serotonin production and in this study, increasing serotonin in the presence of decreasing tryptophan reflects the modulation of important pathways that have been shown to be associated with positive mood and a feeling of wellbeing.

Stress makers such as Aldosterone, epinephrine, norepinephrine, dopamine and cortisol were also modulated by treatment.

These results (also considering the role of neopterin in biological pathways associated with wellbeing) are believed to be the first-time that mood modification has been chemically documented in dogs with painful osteoarthritis treated with THC and CBD.

Clinical Owner and Veterinary Scoring

The Subjective clinical Veterinary and Owner Scoring Assessments are in the process of being finalised by the Company's contracted veterinary research organisation, Clindata, and these results are expected to be reported to market in Q1 2021.

The data generated from this study will help inform the design of the Company's ongoing Phase 2 program for presentation to the Food and Drug Administration, Centre for Veterinary Medicine (FDA/CVM) at the Company's PSC (Pre-submission meeting conference).

CannPal has now re-commenced preparations to submit a request for its PSC with the FDA/CVM, which will be used as an opportunity to share its Phase 1 and Pilot Phase 2 data, and receive formal guidance on its U.S development and regulatory plan for CPAT-01.

DermaCann®

During the quarter, CannPal advanced its manufacturing scale up of DermaCann®, the Company's lead nutraceutical product in development for healthy skin and immune function in dogs.

This has included preparations to manufacture cGMP (current Good Manufacturing Practices) clinical trial material to be used for a 16 dog Target Animal Safety study (TAS) which remains on track for commencement in the United States in Q1 2021.

The Target Animal Safety study will be used to complement the Company's successful clinical efficacy study for market registration dossiers in several key registration markets, including Australia and New Zealand. CannPal released results from its efficacy study in Q3 2020 and was delighted to announce that DermaCann® treatment substantially reduced the symptoms of Atopic Dermatitis in client owned dogs when treated twice daily over a period of 8 weeks **[ASX Announcement: July 21, 2020]**.

During the quarter, the Company also progressed its dossier preparation for the registration of DermaCann® in South Africa, as an approved herbal supplement for inflammation associated with Atopic Dermatitis in dogs. The dossier is expected to be submitted for registration with the South African Department of Agriculture, Forestry and Fisheries (DAFF) in Q1 2021.

The Company was also pleased to enter into a Collaborative Research Agreement with the University of Melbourne during the quarter, to further assess the core active ingredients of its DermaCann® formulation in dogs through an *ex vivo* assessment of activation in canine blood samples.

This research is expected to provide supportive data on the anti-inflammatory mechanism of action for DermaCann®, to add to the Company's growing body of evidence for the product to support the commercialisation of DermaCann® in 2021.

The global canine skin and dermatitis market is worth over US$1b globally, and the launch of DermaCann® will provide the veterinary market with a novel CBD-derived and clinically validated product to be used as a beneficial therapy in a canine atopic dermatitis management regimen.

Pilot Launch of Joint Health Supplement

During the Quarter, the Company commenced preparations to transfer the manufacturing of novel microencapsulated animal health formulations from CSIRO's pilot plant facility to a commercial manufacturing partner. CannPal commenced a small-scale commercial trial for a new Joint Health Supplement for dogs produced using CSIRO's MicroMAX® technology. The product became available for trial under a new direct to consumer brand on the Amazon platform in the U.S in July 2020.

Transferring from pilot scale to a commercial partner will allow CannPal the capacity to manufacturer novel microencapsulated ingredients using CSIRO's patented MicroMAX® technology, for the development of animal health products at scale.

MicroMAX® is a patented encapsulation technology platform designed to encapsulate microscopic droplets of oil in a special food grade material, to protect bioactive ingredients from oxidation, and help deliver them to the gastrointestinal (GI) tract.

In December 2020, CannPal was granted an exclusive, global licence to the patented technology for use in the field of Animal Therapeutics **[ASX Announcement: Jan 6, 2020]**.

CannPal will continue with its commercial trial for the product during the technical transfer phase and does not intend for revenues to be material during the pilot evaluation, while the Company continues to place focus and resources on its lead pharmaceutical and nutraceutical products.

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

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

ENDS

For further information, please contact:

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
CannPal Animal Therapeutics Limited	
ABN	**Quarter ended ("current quarter")**
88 612 791 518	31 December 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	11	17
1.2	Payments for		
	(a) research and development	(312)	(843)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(25)	(55)
	(f) administration and corporate costs	(241)	(362)
1.3	Dividends received (see note 3)		
1.4	Interest received	1	3
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		686
1.8	Other – ATO cash boost	13	50
1.9	**Net cash from / (used in) operating activities**	**(553)**	**(504)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
2.6	**Net cash from / (used in) investing activities**		

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other (provide details if material)		
3.10	**Net cash from / (used in) financing activities**		

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,964	1,915
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(553)	(504)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)		
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**1,411**	**1,411**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	1,411	1,964
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**1,411**	**1,964**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	33
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

The payment in 6.1 above was for normal directors' fees in the ordinary course of business.

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(553)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	1,411
8.3	Unused finance facilities available at quarter end (Item 7.5)	
8.4	Total available funding (Item 8.2 + Item 8.3)	1,411
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	2.55

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 29 January 2021

Authorised by: By the Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.