

31st July 2019 | CannPal Animal Therapeutics Limited ACN: 612 791 518 | ASX:CP1

# CannPal 4C Quarterly Cash Flow Report for June 2019 Quarter

## Highlights for the quarter ending 30 June 2019

- Successfully completed Phase 1B gene expression analysis for CPAT-01, identifying additional gene pathways for potential pain and inflammation modulation in dogs;
- Commenced Phase 2A pilot dose determination study for CPAT-01, with clinic enrollment complete and dog recruitment underway;
- Completed clinic enrollment for DermaCann field safety and efficacy study; and
- Expanded evaluation of CSIRO-patented microencapsulation technology, with successful pilot dietary supplement production through Next Generation Pet Foods.

**31st July 2019:** Animal health company **CannPal Animal Therapeutics Limited (ASX:CP1)** ("CannPal" or "the Company") is pleased to update the market on its progress in the June 2019 quarter and attaches its Appendix 4C Quarterly Cash Flow report and market update for the period ending 30 June 2019.

#### Corporate

The Company had a cash balance of \$3.3 million with operating cash outflows totalling \$836,000 for the quarter, with \$722,000 related to the costs associated with the research and development of the Company's lead pharmaceutical and nutraceutical drug candidates.

CannPal remains well capitalized for FY20, providing the runway required to reach key milestone's previously communicated to the market, including the CPAT-01 Phase 2A and B pilot studies, and the development of DermaCann.

#### CPAT-01

During the quarter, the Company successfully completed the analysis of additional blood samples taken from the Phase 1B dose ranging and pharmacokinetic study for CPAT-01.

The results Identified new genes that were significantly influenced by treatment (p<0.05), and provided the Company with early insights into the dose response of cannabinoids in dogs ahead of the Company's Phase 2 program for CPAT-01, in development for pain and inflammation control in dogs.

The Phase 1B results compliment the results of Phase 1A which were presented in detail at the AVA (Australian Veterinary Association) Innovation, Research and Development Symposium during the quarter [ASX Announcement: April 18, 2019].

Phase 1B included the analysis of blood samples taken from an additional 48 dogs, to support the results from the 11 dog Phase 1A study, and included the evaluation of different concentrations of the target CPAT-01 formulation for early indications of dose response.

The results of Phase 1A and B have provided the Company with a significant pre-clinical











data pack including research in 59 dogs spanning across pharmacokinetics (fasted and fed), safety, inflammatory biomarkers, gene expression and early dose response data.

This data pack will be used to file the Company's INAD (Investigational New Animal Drug) application with the FDA/CVM (Food and Drug Administration/Centre for Veterinary Medicine).

Subsequent to the end of the quarter, the Company completed preparations for its INAD request, which is expected to be filed with the FDA in August 2019.

#### Commencement of Phase 2A

The Company is also delighted to announce that it has commenced the Phase 2A pilot dose determination study for CPAT-01, in client owned animals with osteoarthritis.

The clinical trial is an 8 week randomised, double-blind, placebo-controlled study in dogs diagnosed with osteoarthritis, with an estimated 60 dogs expected to participate in the trial.

12 veterinary clinics have been enrolled for the study with 6 across NSW and 6 across Queensland participating. Dog recruitment has commenced, with canine assessments for first patients already underway in NSW. Clinical trial material has now been imported, and first patient dosing is expected to commence in August 2019.

If your dog displays signs of osteoarthritis such as limping, slowness getting up and reluctance to walk up or down stairs, then you might also be eligible to participate in the study.

If your dog is older than 6 months, weighs more than 10kg and displays some of the behaviours above, you can visit the study landing page via the link below, to learn more about the trial.



https://osteoarthritis2019.invetus.com/

# **Nutraceuticals**

The Company is also pleased to announce it is in the final stages of preparation to commence the field safety and efficacy study for DermaCann, an oral liquid nutraceutical in development for skin health in dogs.

The study is a randomised, double-blind, placebo-controlled trial in client owned animals with symptoms associated with atopic dermatitis and/or allergic dermatitis. 30 dogs are expected to be recruited for the trial.









Veterinary clinic enrollment has been completed and import permits for clinical trial material have been finalised. Patient recruitment is expected to commence in August 2019.

The Company intends to submit an application for Complimentary Animal Health Product approval (CAHP) with the Australian Pesticides and Veterinary Medicines Authority (APVMA) at the completion of the study. A CAHP approval would allow veterinarians the ability to prescribe DermaCann as an orally consumed animal remedy to pet owners in Australia.

There are no prescription animal medicines legally available for sale in the Asia-Pacific market containing cannabidiol (CBD), and the Company believes there's a significant market opportunity for an evidence based, compliant and regulatory approved therapeutic product for dogs containing CBD.

#### CSIRO Research Collaboration

The company has also progressed its evaluation of CSIRO's microencapsulation technology. CannPal and CSIRO are undertaking research into the use of CSIRO-patented technologies to enhance the delivery of hemp and cannabis derived compounds in animal health [ASX Announcement Jun 28, 2018].

During the quarter the Company successfully completed a pilot nutraceutical production run using one of CannPal's proprietary oil formulations, with Australian pet food manufacturer, Next Generation Pet Foods.

The Company is exploring the applicability of CSIRO's technology using hemp and plant-derived compounds in various delivery formats for animals, and will continue to assess commercial opportunities utilizing the technology as it progresses through the evaluation.

## CannPal's Chairman, Mr Geoff Starr:

"It's been a great year for CannPal and I continue to be pleased by Management's focused progress across the Company's core research programs. We're entering into the new financial year in a strong financial position, with some exciting milestones ahead."

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

"I'm extremely pleased with the key milestones achieved during the quarter, including the commencement of our Phase 2A study for CPAT-01, and our readiness to commence the field safety and efficacy study for DermaCann. Both of these trials are globally significant milestones, as they represent regulatory progress that is yet to be matched by an animal health Company developing cannabinoid-derived products for pets."

#### **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 innovative 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: <u>www.cannpal.com</u>

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## For further information, please contact:

#### CannPal

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+Rule 4.7B

# **Appendix 4C**

# Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

## Name of entity

CannPal Animal Therapeutics Limited			
ABN	Quarter ended ("current quarter")		
88 612 791 518	30 June 2019		

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(715)	(1,544)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(29)	(108)
	(f) administration and corporate costs	(92)	(558)
1.3	Dividends received (see note 3)		
1.4	Interest received	48	104
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives		297
1.8	Other (provide details if material)		
1.9	Net cash from / (used in) operating activities	(788)	(1,809)

2.	Cash flows from investing activities	
2.1	Payments to acquire:	
	(a) property, plant and equipment	
	(b) businesses (see item 10)	
	(c) investments	

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<sup>+</sup> See chapter 19 for defined terms

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	(d) intellectual property		
	(e) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment		
	(b) businesses (see item 10)		
	(c) investments		
	(d) intellectual property		
	(e) 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 shares
3.2	Proceeds from issue of convertible notes
3.3	Proceeds from exercise of share options
3.4	Transaction costs related to issues of shares, convertible notes or options
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 quarter/year to date	4,093	5,114
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(788)	(1,809)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		
4.4	Net cash from / (used in) financing activities (item 3.10 above)		

<sup>+</sup> See chapter 19 for defined terms 1 September 2016

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	3,305	3,305

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	555	343
5.2	Call deposits	2,750	3,750
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)	3,305	4,093

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	42
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
6.3	Include below any explanation necessary to understand the transaction items 6.1 and 6.2	ns included in
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7.	Payments to related entities of the entity and their	Current quarter
	associates	\$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	
7.3	Include below any explanation necessary to understand the transaction items 7.1 and 7.2	ns included in

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<sup>+</sup> See chapter 19 for defined terms 1 September 2016

8.	Financing facilities available Add notes as necessary for an understanding of the position	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1	Loan facilities		
8.2	Credit standby arrangements		
8.3	Other (please specify)		
8.4	Include below a description of each facility ab whether it is secured or unsecured. If any add proposed to be entered into after quarter end	ditional facilities have bee	n entered into or are

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	391
9.2	Product manufacturing and operating costs	
9.3	Advertising and marketing	
9.4	Leased assets	
9.5	Staff costs	26
9.6	Administration and corporate costs	162
9.7	Other (provide details if material)	
9.8	Total estimated cash outflows	579

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity		
10.2	Place of incorporation or registration		
10.3	Consideration for acquisition or disposal		
10.4	Total net assets		
10.5	Nature of business		

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<sup>+</sup> See chapter 19 for defined terms 1 September 2016

### **Compliance statement**

- 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.

Sign here: Date: 31 July 2019

Company Secretary

Print name: Baden Maxwell Bowen

#### **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- 2. If this quarterly 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 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.

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<sup>+</sup> See chapter 19 for defined terms