

Quarterly Cash Flow Report and Market Update for December 2021 Quarter

Key Highlights

- Completed a 90-day Target Animal Safety Study for DermaCann® in the U.S, confirming the product to be safe and well tolerated in dogs
- Submitted final regulatory data modules for DermaCann® product registration in Australia
- Held successful Pre-Submission Conference meeting ('PSC') with the U.S FDA-CVM for CPAT-01
- Appointment of Tod McGrouther as new Chairperson and director resignations
- Continued reductions in administration and corporate costs by 21% versus prior quarter; 81% reduction versus the same period in the prior year
- The Company remains well-funded with \$11.4m net cash as at December 31

28 January 2022 - **AusCann Group Holdings Limited** (ASX: AC8) ('AusCann' or 'the Company') is pleased to update the market on its progress in the December 2021 quarter and attaches its Appendix 4C Quarterly Cash Flow report for the period.

AusCann remains well funded with net cash of \$11.4 as at December 31, 2021. Operating outflows totalled \$1.05m for the quarter, with \$717k (68%) related to research and development costs in respect of the Company's core human and animal programs.

The Company further reduced administration and corporate costs by 21% versus the prior quarter, complementing a quarter-on-quarter reduction for the previous 4 periods as the Company continues to optimise towards a more fit-for-purpose medicinal cannabis Company.



The revised Company structure and cost base allows for more resources to be allocated to core revenue generating activities for the Company's lead human and animal health programs and better positions the Company to capitalise on other business development opportunities, including M&A, as the industry continues to evolve in 2022.

There were no related party payments for the period except for Directors' fees of \$99k paid from the pool of fees approved by shareholders.



Key Operational Updates

Completed DermaCann® High Dose Tolerance Target Animal Safety Study in the U.S

During the quarter, the Company was pleased to announce that it had completed a 90-day Target Animal Safety study (TAS) for DermaCann®, confirming the product to be safe and well tolerated for use in dogs at up to 5 times the current planned dose.

The TAS study is a requirement for the DermaCann® regulatory submissions in Australia and New Zealand.

The safety study was completed at a veterinary research site in the United States and 15 healthy beagles were randomised into three groups for the trial (5 dogs per group);

- 1. Group 1 control dogs received no treatment
- Group 2 3 X dogs received 3X the recommended daily dose (3 mg/kg) of DermaCann®; and
 Group 3 5 X dogs received 5X the recommended daily dose (5 mg/kg) of DermaCann®

Dogs treated with DermaCann for 92 days at 3X and 5X the planned upper dose rate were clinically well tolerated with no clinically relevant nor statistical differences between treated and control dogs identified for all physical examinations, clinical observations, haematology and food/water consumption parameters.

Haematological parameters for all dogs remained within normal ranges with no difference compared to untreated dogs. Serum chemistry was also largely unimpacted by treatment. A mild increase in alkaline phosphatase (ALP) was observed with the 3X and 5X DermaCann® treatments compared to placebo which is a well-documented response to CBD in humans and animals. All other clinical chemistry results were normal, supporting DermaCann® to be safe and effective product for use in dogs at up to 5X the planned dose.

Submitted Final Regulatory Data Modules for DermaCann® Product Registration in Australia

Following the completion of the TAS study, the Company was pleased to announce that it had submitted its final regulatory data modules to the Australian Pesticides and Veterinary Medicines Authority ('APVMA') to complete the submission of its dossier for the registration of DermaCann® as an approved veterinary medicine for anti-inflammatory and immune support in dogs with dermatological conditions.

The Environment, Safety and Efficacy regulatory modules were submitted with supporting documentation that has been generated by the Company in the last 3 years of development. This complements the submission of the Toxicology and Chemistry regulatory modules previously announced to market.

The data in the final regulatory filings included;

- A randomised placebo-controlled double-blind study in client owned dogs with atopic dermatitis, which demonstrated a significant reduction in CADESI-4 scores (veterinarian scored, multi point skin damage and redness assessments) and inflammatory biomarkers, in dogs treated with DermaCann compared with placebo [ASX:CP1 Announcement July 21, 2020];
- A randomised controlled Target Animal Safety Study in healthy colony-housed beagles conducted by Summit Ridge Farms, Pennsylvania, confirming DermaCann® to be safe for use at 1x, 3x an 5x the planned therapeutic dose [ASX:AC8 Announcement October 13, 2021];
- Safety and efficacy data on the use of all proprietary ingredients used in DermaCann to provide strong literature-based support for the use of DermaCann® as a complementary therapy in the management of dermatological condition in dogs.

The overall dossier in which these modules form the final components is in the process of being reviewed under an APVMA agreed time shift application plan [ASX:AC8 Announcement July 20, 2021].

Completion of the review of all modules is anticipated at the end of September 2022. Subject to approval, DermaCann® will become a world 'first in class' regulatory approved oral cannabinoid based veterinary

Registered address: Level 5, 35 Havelock Street, West Perth WA 6005 Mailing address: PO Box 1746, Wangara WA 6947 T: +61 6305 0705 E: info@auscann.com.au www.auscann.com.au



product for skin health in dogs, and the first regulatory-approved veterinary medicine containing cannabinoids in Australia.

The global canine skin and dermatitis market is worth an estimated US\$1.5B globally and, subject to registration, DermaCann® is expected to become the first APVMA-approved medicine containing cannabinoids to be supplied via prescription through Australian veterinarians.

Held Successful Pre-Submission Meeting with the FDA-CVM to Advance CPAT-01 U.S Program

During the quarter the Company was pleased to announce that it had held its Pre-Submission Conference meeting ('PSC') with the U.S Food and Drug Administration, Centre for Veterinary Centre ('FDA-CVM') to discuss the development program and regulatory pathway for CPAT-01 in the United States.

The PSC meeting package included an overview of the CPAT-01 program, with specific questions relating to technical sections required for a New Animal Drug Application ('NADA') to seek approval for CPAT-01.

The meeting was attended by representatives in various divisions from the FDA-CVM, including the Division of Companion Animal Drugs, Manufacturing Technologies, Toxicology, Environment, Clinical Pharmacology and Target Animal Safety. The representatives were highly engaged in the meeting and confirmed that the development program and manufacturing strategy for PAT-01 is consistent with the agency's expectations.

A Memorandum of Conference ('MOC') with formal guidance from the meeting will be provided within 45 days and AusCann will use the formal feedback from the MOC to finalise its study plan for its Phase 2C clinical effectiveness trial. The purpose of the Phase 2C is to generate final pilot data to inform the design of the Company's Phase 3 pivotal program to support a NADA for the approval of CPAT-01, as a world "first-in-class" U.S FDA registered veterinary medicine.

Appointment of New Chairperson and Director Resignations

During the quarter, the Board announced the appointment of Mr Tod McGrouther as the Company's new Chairperson of the Board, following the resignation of Max Johnstone in November 2021. Mr Tod McGrouther has over 35 years' experience in the Australian capital markets primarily in the areas of equity capital markets and corporate advisory.

Since 2018 Mr McGrouther has been a Director of European Cannabis Corporation Limited ("ECC"), an Australian company which has built and operates a German EU GMP certified medicinal cannabis growth facility located in Spanchevo, Macedonia. ECC has also built and operates a German EU GMP certified medicinal cannabis extraction facility located in Skopje, Macedonia.

ECC also holds all relevant licenses and approvals to operate a pharmaceutical distribution business in Dortmund, Germany.

Mr McGrouther is currently a Non-Executive Director of three ASX listed companies - NSX Limited, Urbanise Limited and Love Group Limited. Mr McGrouther is also Chairman of The National Stock Exchange of Australia Limited a subsidiary of NSX Limited.

During the Quarter Dr Kate Adams, Bruce McHarrie and Mr Geoff Starr resigned from their positions as Non-Executive Directors of the Company.

ENDS

This ASX announcement was authorised for release by the Board of AusCann.

For more information, please contact:

Layton Mills Chief Executive Officer info@auscann.com.au +61 8 6305 0705



ABOUT AUSCANN

AusCann Group Holdings Limited (ASX:AC8) is an Australian-based company focused on the development and commercialisation of cannabinoid-derived therapeutic products to address unmet needs for humans and animals within Australia and internationally. Our key difference is the commitment to rigorous product development, focused on providing reliable, stable and standardised cannabinoid-derived therapeutics products, whilst generating robust safety, quality assurance and efficacy data to support market access in various regulatory environments around the world.

Appendix 4C

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

Name of entity

AusCann Group Holdings Limited

ABN Quarter ended

72 008 095 207 31 December 2021

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	3	9
1.2	Payments for		
	(a) research and development	(717)	(1,505)
	(b) product manufacturing and operating costs	(98)	(115)
	(c) advertising and marketing	(75)	(86)
	(d) leased assets	(3)	(7)
	(e) staff costs	(115)	(222)
	(f) administration and corporate costs	(175)	(397)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	19
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Property Rental and outgoings income	123	123
1.9	Net cash from / (used in) operating activities	(1,049)	(2,181)

2.	Cas	sh flows from investing activities	
2.1	Payments to acquire or for:		
	(a)	entities (net of cash acquired)	-
	(b)	businesses	-
	(c)	property, plant and equipment	-
	(d)	investments	-
	(e)	intellectual property	(36)
	(f)	other non-current assets	-

ASX Listing Rules Appendix 4C (17/07/20)

Page 1

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	(36)	(70)

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	-	724
3.6	Repayment of borrowings	(724)	(724)
3.7	Transaction costs related to loans and borrowings & acquisition cost	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	(724)	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	13,238	13,680
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,049)	(2,181)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(36)	(70)

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)	(724)	-
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	11,429	11,429

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	605	15
5.2	Call deposits	10,824	12,499
5.3	Bank overdrafts	-	724
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	11,429	13,238

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	99
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Explanation of payments to related parties.

- Payment of remuneration to directors for director services.

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	Total facility amount at quarter end	Amount drawn at quarter end \$A'000
	sources of finance available to the entity.	\$A'000	
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Overdraft (refer below)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	arter 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.	Estim	ated cash available for future operating activities	\$A'000
8.1		sh from / (used in) operating activities (item 1.9) ded Government grants and tax incentives)	(1,049)
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	11,429
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	-
8.4	Total a	vailable funding (item 8.2 + item 8.3)	11,429
8.5	Estima	ated quarters of funding available (item 8.4 divided by .1)	11
	item 8.5	he entity has reported positive net operating cash flows in item 1.9, answer as N/A. Otherwise a figure for the estimated quarters of funding available included in item 8.5	
8.6	If item	8.5 is less than 2 quarters, please provide answers to the followin	ng questions:
	8.6.1.	Does the entity expect that it will continue to have the current le cash flows for the time being and, if not, why not?	vel of net operating
	Answe N/A	r:	
	8.6.2.	Has the entity taken any steps, or does it propose to take any steash to fund its operations and, if so, what are those steps and believe that they will be successful?	
	Answe N/A	r:	
	8.6.3.	Does the entity expect to be able to continue its operations and objectives and, if so, on what basis?	to meet its business
	Answe N/A	r:	
	Note wh		

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.

28 January 2022

Date:			

Authorised by: .The Board of Directors. of AusCann Group Holdings Ltd.... (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.
- 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".
- 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.