

## AusCann Quarterly Cash Flow Report and Market Update for September 2021 Quarter

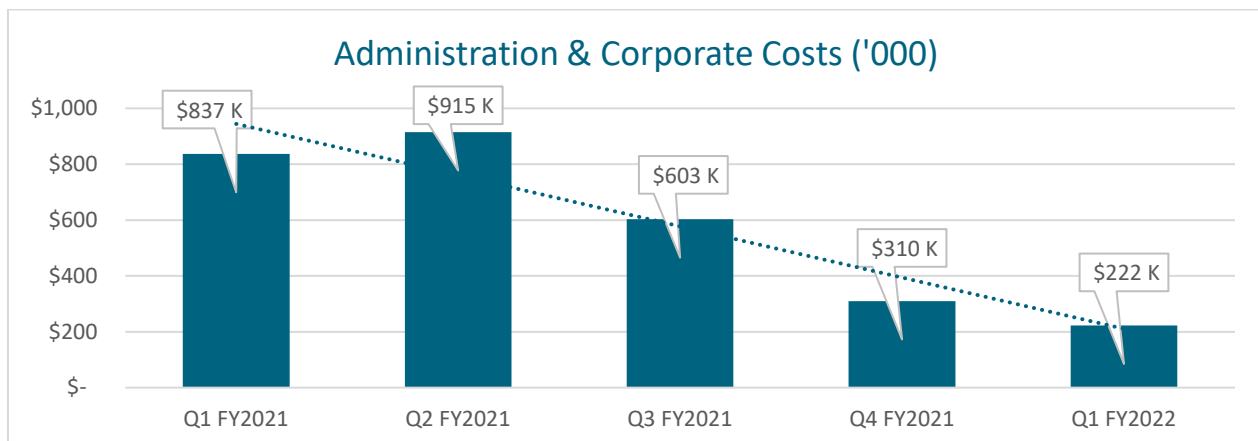
### Key Highlights

- Commenced first Australian cannabinoid product registration with regulatory filing for DermaCann®, in development for anti-inflammatory and immune support in dogs with dermatological conditions;
- Engaged Knoell Animal Health LLC to advance the CPAT-01 Phase 2 clinical program and U.S regulatory strategy with the Food and Drug Administration, Centre for Veterinary Medicine;
- Commenced a strategic review of AusCann’s internal research assets for the development of new cannabinoid-based drug candidates for human registration pathways;
- Continued reductions in administration and corporate costs of 28% versus the prior quarter due to operational efficiencies; a 73% reduction versus the same period in the prior year;
- The Company remains well-funded with \$12.5m net cash as at September 30.

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

AusCann remains well funded with net cash of \$12.5m as at September 30, 2021. Operating outflows totalled \$1.16m for the quarter, with \$788k (67%) related to research and development costs in respect of the Company’s core human and animal programs.

The Company reduced administration and corporate costs by an additional 28% versus the prior quarter, complementing a quarter on quarter reduction for the previous 3 periods due to operational efficiencies post the merger of AusCann and CannPal, and a more fit-for-purpose Company, unburdened by non-strategic loss making operations.



The revised Company structure and cost base will support continued progress for the Business, allowing for more resources to be allocated to core revenue generating activities for the Company’s lead human and animal health programs, including the commercialisation of DermaCann® in early 2022 and new human drug development opportunities.

There were no related party payments for the period except for Directors’ fees of \$71k paid from the pool of fees approved by shareholders.

## **Key Operational Updates**

### *Commenced First Australian Product Registration with Regulatory Filing for DermaCann®*

During the quarter the Company was pleased to announce that it had submitted its first module to the Australian Pesticides and Veterinary Medicines Authority ('APVMA') to commence the submission of its dossier for the registration of DermaCann®, a world 'first in class' cannabinoid-based medicine in development for anti-inflammatory and immune support in dogs with dermatological conditions.

The Toxicology module was submitted following a positive response to a Pre-Application Assistance request with the APVMA, outlining a project plan with agreed milestones for a time-shift application which allows for the staged submission of supporting data packages for longer module assessments (such as Toxicology) while other supporting data packages are being prepared for submission.

The Safety and Toxicological evaluation of DermaCann® was led by Dr Margaret Curtis, Head of Research and Development for AusCann, and Dr Jeffery Sherman, a Board-certified toxicologist who commenced consulting on the dossier in 2018. It included almost 2,000 pages of supporting data and literature and was the result of over 3 years of research and dossier preparation including 8 independent in-vitro and in-vivo toxicology GLP studies (Good Laboratory Practises) completed across Hungary, Germany and the United States.

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.

### *Engaged Knoell Animal Health to Advance CPAT-01 U.S Program with the FDA-CVM*

During the quarter AusCann entered into an agreement with Knoell Animal Health LLC (Knoell) to be part of its clinical expert advisory group for the CPAT-01 Phase 2 development program and U.S regulatory strategy ahead of its Pre-Submission Conference meeting with the Food and Drug Administration, Centre for Veterinary Medicine ('FDA-CVM').

CPAT-01 is a cannabinoid-based veterinary drug candidate in development for FDA-CVM approval for the management of pain, inflammation and decreased quality of life in dogs with osteoarthritis. The veterinary pain and inflammation market is worth over US\$1b globally and there's an unmet need for safe and viable long term treatment options for dogs suffering from painful conditions.

Dr Laura Trembl is AusCann's technical manager for the project, bringing over 20 years of experience in companion animal practice and veterinary drug development with Companies such as Bayer and Aratana Therapeutics, including early stage development and late stage pivotal field studies for both the FDA-CVM and the United States Department of Agriculture, Center for Veterinary Biologics.

Dr Trembl has managed a number of canine pain and anti-inflammatory development programs which has included the U.S FDA approval for Nocita (a long lasting analgesic for post-surgical pain in dogs), and the EU marketing authorisation for Galliprant (a market leading Nonsteroidal Anti-Inflammatory Drug for dogs with osteoarthritis).

### *Progressed Cannabinoid Drug Development Review for Human Registration Opportunities*

During the quarter AusCann was pleased to announce that it had appointed the Clinical Research division of Cannvalate Pty Ltd, to complete a strategic review of AusCann's existing animal data and research assets to support the development of new cannabinoid-based drug candidates for human registration pathways.

Cannvalate is an Australian cannabis Company with three main divisions, including a full-service Clinical Research Organisation with in-house access to an established network of clinical trial research professionals including protocol designers, medical affairs, quality assurance, scientific affairs, biostatistics, data management, pharmacokinetics, project management, monitoring, safety and pharmacovigilance.

The scope of the assessment is to address U.S FDA regulatory pathways, commercial feasibility, clinical trial mapping and the pathology and symptoms for target indications with a high likelihood of response to cannabinoid therapy in pre-identified therapeutic indications, with initial addressable markets of over US\$2B globally.

The technical assessment also includes a review of AusCann's existing animal safety, toxicology, pharmacokinetic and biomarker data which may be used to accelerate the development of human cannabinoid-based drug candidates for FDA registration pathways. This can shorten the path to market for AusCann by leveraging existing data to meet certain technical requirements for future product registration dossiers.

#### *Update on Neuvis® Commercialisation*

The Company has been pleased with the continued endorsement by healthcare practitioners for AusCann's proprietary SEDDS technology (self-emulsifying drug delivery system) during the launch of the Neuvis® 1:1 THC:CBD hard-shell capsules, under the Special Access Pathway (SAS-B).

The number of prescribers has grown quarter on quarter, with repeat prescriptions accounting for 75% in the previous quarter, further endorsing the Company's commitment to providing reliable, standardised and differentiated cannabinoid-based medicines to patients in Australia.

However, while SAS-B is an important path to facilitate the compassionate use of much needed medicine, the Company does not expect it to be a scalable commercial pathway in the current business environment without necessary regulatory change, which we expect over time.

As such, the Company will continue to leverage SAS-B as a low-cost pathway to generate key learnings and real world insights on the Company's Neuvis® platform and cannabis-based medicines, while continuing to focus resources on product registration opportunities to maximise return on investment across the Company's portfolio, including the Neuvis® technology.

### **ENDS**

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

#### **For more information, please contact:**

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#### **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**

72 008 095 207

**Quarter ended**

30 September 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	6	6
1.2 Payments for		
(a) research and development	(788)	(788)
(b) product manufacturing and operating costs	(17)	(17)
(c) advertising and marketing	(11)	(11)
(d) leased assets	(4)	(4)
(e) staff costs	(107)	(107)
(f) administration and corporate costs	(222)	(222)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	11	11
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,132)</b>	<b>(1,132)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities (net of cash acquired)	-	-
(b) businesses	-	-
(c) property, plant and equipment	(25)	(25)
(d) investments	-	-
(e) intellectual property	(9)	(9)
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(34)</b>	<b>(34)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
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	724
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings & acquisition cost	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>724</b>	<b>724</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	13,680	13,680
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,132)	(1,132)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(34)	(34)

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	724	724
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>13,238</b>	<b>13,238</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	15	15
5.2	Call deposits	12,499	12,499
5.3	Bank overdrafts	724	724
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>13,238</b>	<b>13,238</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	71
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<b>Explanation of payments to related parties.</b>		
- 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		

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Overdraft (refer below)	1,000	1,000
<b>7.4 Total financing facilities</b>	<b>1,000</b>	<b>1,000</b>
<b>7.5 Unused financing facilities available at quarter end</b>		276
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.		
Overdraft facility granted by Westpac to coincide with the timing of the maturity of the term deposit of \$1,000,000. On 6 October 2021 (the maturity date) the overdraft was set off against the maturing term deposit and the overdraft was cleared to zero. Interest rate 6.09% pa, establishment fee \$2,250. Security: \$1,000,000 of notice saver account. \$723,916 was drawn down on 30 September 2021.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9) (excluded Government grants and tax incentives)	(1,132)
8.2 Cash and cash equivalents at quarter end (item 4.6)	13,238
8.3 Unused finance facilities available at quarter end (item 7.5)	276
8.4 Total available funding (item 8.2 + item 8.3)	13,514
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>12</b>
Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as N/A. Otherwise a figure for the estimated quarters of funding available must be included in item 8.5	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 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: N/A	
8.6.2 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: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	

Note where item 8.5 is less than 2 quarters, all of the questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

## 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: 28 October 2021

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.
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.