

ASX Announcement

28 October 2022

Avecho Quarterly Activities Report and Appendix 4C

Key Highlights

- Preparation being finalised for the commencement of the **Phase III CBD soft-gel program** for an insomnia indication;
- **Further studies planned with the Lambert Initiative**, focusing on targeted applications of topical cannabinoid gels enhanced with TPM®;
- Canine study demonstrates **enhanced bioavailability of Avecho's oral cannabidiol ("CBD") compared to Epidiolex®**;
- Promising **business development and partnership discussions** underway for recreational cannabis market in the US and broader portfolio of Avecho products; and
- Cash balance of \$2.25m on 30 September 2022.

Melbourne, Australia, 28 October 2022 - Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), focused on developing and commercialising innovative products using its proprietary Tocopheryl Phosphate Mixture ("TPM®") drug delivery system, has today released its Quarterly Activities Report and Appendix 4C for the quarter ended 30 September 2022.

CBD soft-gel capsule: Phase III Trial gaining momentum

The Company remains focused on the development of its CBD soft-gel capsule for over-the-counter registration with the TGA for an insomnia-related indication.

Avecho has now completed the Phase III study design and assembled the complete suite of service providers that will be responsible for all aspects of the study. This has been undertaken in close collaboration with a team of sleep and regulatory experts. Ethics approval for the study is anticipated in Q4 to allow the enrolment and dosing of patients early 2023.

The Phase III protocol is rigorous, having been designed with subsequent US Food and Drug Administration ("FDA") and EMEA submissions front of mind. This trial design will increase the likelihood of licensing the product in overseas markets – a significant commercial opportunity.

Topical CBG gel for Osteoarthritis: clinical trial planning underway

Earlier this calendar year, Avecho announced positive results from a Phase II Trial, undertaken in partnership with the Lambert Initiative for Cannabinoid Therapeutics, testing a proprietary topical CBD gel for the management of painful symptoms associated with osteoarthritis ("OA") of the hand.

Emerging evidence suggests that further cannabinoids, including CBG, may have even better pharmacological activity for specific indications, including osteoarthritis. Avecho has begun including a wide range of minor cannabinoids into both its oral and topical formulations containing TPM®. The products are being assessed for their performance and stability over time. Laboratory experiments have already shown the topical CBG TPM® gel has significantly increased transdermal absorption when combined with TPM®.

Avecho and The Lambert Initiative will now proceed to a small Phase II clinical trial examining the application of the topical CBG gel to patients suffering painful osteoarthritis of the fingers and hands.



Canine study: examines bioavailability of Avecho's oral cannabidiol ("CBD") compared to Epidiolex®

The Company announced compelling interim results from comparative pharmacokinetic studies conducted in the UK this quarter, showing that Avecho's oral CBD product has increased bioavailability compared to Epidiolex®, the only FDA approved CBD product.

The study was conducted to generate comparative absorption results in a second animal model, confirming the increased performance of Avecho's proprietary TPM® formulations versus simple CBD oil formulations routinely prescribed to patients. Epidiolex® was included for further comparison in response to queries from potential licensees. While Avecho CBD formulations demonstrated increased absorption, they did not produce an accompanying increase in gastrointestinal upset that can accompany high doses of CBD.

Importantly, the study also investigated the effect of TPM® on other commercial formulations. Dissolving TPM® into Epidiolex® also increased CBD bioavailability, with Epidiolex® + TPM® increasing the CBD absorption by approximately 4-times when compared to CBD alone. This study highlights the promising opportunities that exist for TPM® in establishing a point of differentiation in the growing medicinal, consumer and recreation cannabis markets.

Recreational Cannabis: Focused business development in the US

Avecho is now commencing strategic outreach in North American markets to educate key recreational cannabis companies about how TPM® can enhance their products.

In addition to its effect on the absorption of cannabinoids in oils, initial findings have demonstrated that the inclusion of TPM® in edible gummies containing cannabis may increase the onset, duration or magnitude of effect. Avecho has engaged with specialist consulting firms to progress this opportunity in North America, with the intent of broadening the number of recreational cannabis companies differentiating their products through the inclusion of TPM®.

Recreational cannabis represents a large and lucrative additional market for Avecho, with sales of cannabis-related products totalling US\$17.5B in 2020.

Broader portfolio: License, partnership, and revenue opportunities

Avecho is continuing its engagement with potential partners and licensees, across its portfolio of CBD and broader human health products.

The Company's proprietary TPM® drug delivery system is now being leveraged to develop differentiated and highly competitive cannabinoid products for a variety of markets.

Avecho's original CBD soft-gel partner, Perland Pharmaceuticals, has now completed the protocol for their Phase 1b osteoarthritis study, and will file an IND with the FDA to support the study in the coming months. Catalent has manufactured the clinical supply and is now completing the product release and supporting documentation. Dosing is scheduled to commence Q1 next year. This partnership will place the CBD capsule before the FDA and provide a potential pathway for another indication too.

Corporate: significant R&D tax incentive return

During the quarter ended 30 September 2022, Avecho had net operating outflow of \$853K, including \$211K invested in R&D activities. Administration and corporate costs were \$324K during the quarter.

Avecho continues to manufacture and sell Vital ET® to Ashland for use in the global personal care industry, receiving \$667K from sales made during the current year to date.



At the end of the quarter, the Company held \$2.25m in cash.

Payments to related parties and their associates during the quarter, as outlined in Section 6 of the accompanying Appendix 4C to this quarterly activities report, were \$53K.

For enquiries, please contact

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This announcement has been authorised by the Board of Directors of Avecho Biotechnology Limited.

About Avecho

Avecho Biotechnology Limited (ASX: AVE) develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called TPM® (Tocopherol Phosphate Mixture). TPM® is derived from Vitamin E using unique, proprietary and patented processes and is proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Avecho's major projects include delivering TPM® enhanced injectable, oral and topical products for the human health market, including the recently announced application of TPM® to cannabinoids. The Company is also developing TPM® to enhance feed efficiency and health of livestock.

See more here - avecho.com.au

Forward-Looking Statements

Certain statements in this announcement are forward looking statements. Forward looking statements can generally be identified by the use of words such as "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", "may", "assume" and words of similar import. These forward-looking statements speak only as at the date of this announcement. These statements are based on current expectations and beliefs and, by their nature, are subject to a number of known and unknown risks and uncertainties that could cause the actual results, performances and achievements to differ materially from any expected future results, performance or achievements expressed or implied by such forward looking statements.

No representation, warranty or assurance (express or implied) is given or made by AVE that the forward-looking statements contained in this announcement are accurate, complete, reliable or adequate or that they will be achieved or prove to be correct. Except for any statutory liability which cannot be excluded, AVE and its respective officers, employees and advisers expressly disclaim any responsibility for the accuracy or completeness of the forward looking statements and exclude all liability whatsoever (including negligence) for any direct or indirect loss or damage which may be suffered by any person as a consequence of any information in this announcement or any error or omission therefrom.

Subject to any continuing obligation under applicable law or relevant listing rules of the ASX, AVE disclaims any obligation or undertaking to disseminate any updates or revisions to any forward looking statements in these materials to reflect any change in expectations in relation to any forward looking statements or any change in events, conditions or circumstances on which any statement is based. Nothing in these materials shall under any circumstances create an implication that there has been no change in the affairs of AVE since the date of the announcement.

Appendix 4C

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

Name of entity

AVECHO BIOTECHNOLOGY LIMITED

ABN

32 056 482 403

Quarter ended ("current quarter")

30 SEP 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	4	768
1.2 Payments for		
(a) research and development	(211)	(780)
(b) product manufacturing and operating costs	(20)	(508)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	(262)	(674)
(f) administration and corporate costs	(324)	(571)
(g) patent portfolio costs	(43)	(166)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	4
1.5 Interest and other costs of finance paid	(1)	(2)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,008
1.8 Other (EMDG)	-	20
1.9 Net cash from / (used in) operating activities	(853)	(901)

*A percentage of staff costs are reallocated in payments for research and development.

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(h) entities	-	-
(i) businesses	-	-
(j) property, plant and equipment	(5)	(53)
(k) investments	-	-
(l) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
	(m) other non-current assets	-	-
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	(5)	(53)

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 – Payment of principal element of lease liabilities	(20)	(60)
3.10	Net cash from / (used in) financing activities	(20)	(60)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,129	3,265
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(853)	(901)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5)	(53)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(20)	(60)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	2,251	2,251

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	2,165	2,043
5.2	Call deposits	86	1,086
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)	2,251	3,129

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	(53)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7.	Financing facilities <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>	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.		
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(853)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,251
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,251
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.64
	<i>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.</i>	
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	
	<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

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 2022

Authorised by: By the Board of Avecho Biotechnology Limited
(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.