

## **ASX Announcement**

30 January 2025

## Avecho Quarterly Activities Report and Appendix 4C

**Melbourne, Australia, 30 January 2025:** Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 31 December 2024 ("Q4").

During the quarter, the Company advanced its Phase III Clinical Trial (the "Trial") for its proprietary TPM<sup>®</sup>-enhanced CBD capsule designed to treat insomnia. The product remains on track to reach its interim analysis in 2025, a pivotal milestone for the Company. Avecho continues to advance licensing opportunities for the CBD capsule. Additionally, the Company successfully completed a major manufacturing campaign for its U.S. partner, Ashland, with further details provided below.

## PHASE III STUDY BEGINS DOSING PATIENTS

As of December 2024, approximately 70 participants had received study medication on the Phase III trial. Patient enrolment in 2024 was steady but slower than anticipated, due to the stringent inclusion and exclusion criteria used to define patient eligibility, as well as the careful design aimed at optimizing the trial's chances of success.

Insights from the 2024 recruitment phase revealed several opportunities to refine our approach for accelerating enrolment in 2025. Key improvements include adjustments to the inclusion/exclusion criteria and the addition of new of recruitment sites.

In December 2024, Avecho submitted an amendment to the human research ethics committee to revise the inclusion/exclusion criteria. The revisions were approved and will be implemented starting January 2025, broadening eligibility to include a number of previously ineligible participants who had expressed interest in the study. These individuals will be contacted to confirm their continued interest in participating.

The amendment also approved two additional trial sites, one on the Gold Coast and one in Sydney, which are expected to begin operations in early 2025. Additional sites may be added later in the year to further support recruitment efforts.

Dr. Paul Gavin, CEO of Avecho, commented, "As we move into 2025, Avecho is strategically positioned to potentially achieve a significant industry milestone—becoming the first company to report positive results in a Phase III clinical trial with a CBD product for insomnia indications. The upcoming interim analysis represents a key inflection point in our development program, which has already opened up substantial opportunities for partnership discussions and licensing agreements both locally and globally."

### **BUSINESS DEVELOPMENT**

Avecho CEO, Dr Paul Gavin, was an invited speaker at the 7<sup>th</sup> Annual CB1, CB2 & Cannabinoid Drug Development Summit in Boston during November 2024, where he presented the Company's research on mechanisms used to increase cannabinoid absorption from a range of dosage forms.

The Summit was a unique opportunity to present to key stakeholders interested in the potential of pharmaceutical cannabinoids, and was especially timely given Avecho's CBD product is in a pivotal Phase III trial heading toward an interim read-out in 2025.



Avecho has spent considerable time over the last three years engaging with potential partners for its CBD product in Australia. The Company is advancing qualified opportunities and anticipates providing market updates on this front.

## INCREASED MANUFACTURING FOR VITAL-ET

Avecho continues to support its U.S, partner, Ashland LLC, in the production and supply of Vital-ET<sup>®</sup> for the global personal care market.

In Q4 2024, the Company successfully completed a significant manufacturing campaign, delivering 6.4 tonnes of Vital-ET to Ashland. This campaign brought the total amount of Vital-ET produced for Ashland in 2024 to 11 tonnes. A subsequent manufacturing campaign of 5.4 tonnes was completed in January 2025, with additional orders planned throughout the year.

#### CORPORATE

During the quarter ended 31 December 2024, the Company invested  $\sim$ A\$1,196K in Research and Development ("R&D") activities and incurred employment, administration and corporate costs of  $\sim$ A\$248K. In addition, the Company received R&D Loan from Endpoints Capital of  $\sim$ A\$301K during the quarter ended on 31 December 2024. At 31 December 2024, the Company held  $\sim$ A\$2.374M in cash.

Payments to related parties and their associates during the quarter, as outlined in Section 6 of the accompanying Appendix 4C to these quarterly activities report, were ~A\$66K.

#### For enquiries, please contact

Dr Paul Gavin Chief Executive Officer Avecho Biotechnology Limited +61 3 9002 5000

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

#### About Avecho

Avecho Biotechnology Limited develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (TPM®). 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 and is also developing TPM® to enhance the feed efficiency and health of livestock.

See more here - <u>avecho.com.au</u>

#### 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	Quarter ended ("current quarter")
32 056 482 403	31 December 2024

Cor	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	77	566
1.2	Payments for		
	(a) research and development	(1,196)	(3,610)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	(176)	(501)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(77)	(545)
	(f) administration and corporate costs	(124)	(781)
	(g) patent portfolio costs	(47)	(220)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	8	64
1.5	Interest and other costs of finance paid	(1)	(7)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,066
1.8	Other (EMDG)	-	-
1.9	Net cash from / (used in) operating activities	(1,536)	(3,968)

\*A percentage of staff costs are reallocated to payments for research and development, and product manufacturing and operating costs.

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(h) entities	-	-
	(i) businesses	-	-
	(j) property, plant and equipment	-	-
	(k) investments	(16)	(16)

Appendix 4C Quarterly cash flow report for entities subject to Listing Rule 4.7B

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	(I) intellectual property	-	-
	(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	(16)	(16)

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(a)	Other – Payment of principal element of lease liabilities	(20)	(77)
3.9(b)	Others	301	932
3.10	Net cash from / (used in) financing activities	281	855

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,646	5,504
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,536)	(3,968)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(16)	(16)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	281	855
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	2,375	2,375

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	2,375	3,630
5.2	Call deposits	-	16
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)	2,375	3,646

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	(66)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ nation for, such payments.	le a description of, and an

7.	<b>Financing facilities</b> 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 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.		
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,536)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,375
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,375
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.55

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: The Company elected to pay a number of large R&D invoices prior to the conclusion of 2024 in order for them to be eligible for last year's R&D tax reimbursement. Consequently, the spend was higher than normal. The Company does not expected to have the same magnitude of spend in Q1 2025.

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: The Company has been engaged in licensing negotiations that would provide the capital necessary to continue the current Phase III clinical trial. These conversations are anticipated to conclude in early 2025. If a licensing agreement is unable to be executed, the Company will consider other steps to raise further capital to continue its research. The Company is also eligible to receive further funds from its R&D tax reimbursement early via its R&D loan arrangement with Endpoint Capital.

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: Yes, the Company is comfortable that it will secure a partner for its R&D program. In addition, the R&D spend made at the conclusion of 2024 is eligible for a further loan from Endpoint Capital to provide the Company's tax reimbursement early.

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.

## **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: 30 January 2025

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

#### Notes

- 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.