

#### **ASX Announcement**

29 October 2024

# **Avecho Quarterly Activities Report and Appendix 4C**

**Melbourne, Australia, 29 October 2024:** Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 30 September 2024.

During the quarter, the Company continued its pivotal Phase III Clinical Trial (the "Trial") for its proprietary TPM®-enhanced CBD soft-gel capsule targeting insomnia. In addition, the Company commenced a major manufacturing campaign for its US partner, Ashland. Further updates on the study are outlined below.

#### PHASE III STUDY BEGINS DOSING PATIENTS

In March 2024, Avecho commenced patient recruitment for its Phase III Clinical Trial evaluating the efficacy of its oral cannabidiol TPM®-enhanced soft-gel capsule for the treatment of insomnia.

The Trial is enrolling patients at multiple sites across Melbourne, Sydney, Central Coast NSW, Brisbane, and Perth. Participants are assigned to treatment groups receiving nightly doses of either 75mg or 150mg of cannabidiol, compared to a placebo, over an 8-week period to assess their effectiveness in improving insomnia symptoms.

As of now, 58 patients are actively receiving study medication, with over ~200 additional individuals being referred to trial sites to confirm eligibility. The Trial employs specific inclusion and exclusion criteria, which, while preventing enrolment of a number of willing participants, are essential for ensuring the selection of appropriate candidates. To further enhance recruitment efforts, the Company has engaged with potential new trial sites throughout the quarter, aiming to expand to additional catchment areas.

Avecho's Trial is targeting eligible participants aged 18 and older who have experienced difficulties with falling asleep, staying asleep, or waking up earlier than desired for at least three months, or who have been diagnosed with insomnia. Participants should also have a regular pattern of time spent in bed, whether sleeping or attempting to sleep.

Individuals experiencing sleep challenges and wishing to participate are encouraged to visit our clinical trial recruitment portal at <a href="mailto:cbdinsomniastudy.com">cbdinsomniastudy.com</a>.

Dr. Paul Gavin, CEO of Avecho, stated: "We have gained valuable insights into the eligibility criteria that affect patient recruitment and retention. Our experiences have highlighted how patient compliance and the placebo effect could threaten the success of an insomnia trial. The design strategies we implemented to address these variables are already demonstrating their effectiveness, and we are confident we have minimized their potential negative impact on our trial outcome."



#### **INCREASED MANUFACTURING FOR VITAL-ET**

Toward the end of the quarter, the Company commenced a large manufacturing campaign for its US partner, Ashland LLC, to supply 6.4 T of Vital-ET. This manufacturing campaign continued throughout October 2024, bringing the total amount of Vital-ET manufactured for Ashland in 2024 to 11 T. An additional order for has already been placed for January 2025.

Ashland purchased the manufacturing rights to Vital-ET from Avecho in 2019. Avecho has continued to manufacture Vital-ET on Ashland's behalf, producing 38.7 T that has generated ~A\$3.5M in revenue since selling the rights.

# **CORPORATE**

During the quarter ended 30 September 2024, the Company invested ~A\$1,203K in Research and Development ("R&D") activities and incurred employment, administration and corporate costs of ~A\$483K. In addition, the Company received R&D Loan from Endpoints Capital of ~A\$630K during the quarter ended on 30 September 2024. At 30 September 2024, the Company held ~A\$3.6M 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 - 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	Quarter ended ("current quarter")
32 056 482 403	30 September 2024

Con	solidated 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	90	489
1.2	Payments for		
	(a) research and development	(1,203)	(2,414)
	(b) product manufacturing and operating costs	(218)	(325)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(162)	(468)
	(f) administration and corporate costs	(241)	(657)
	(g) patent portfolio costs	(80)	(173)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	12	56
1.5	Interest and other costs of finance paid	(2)	(6)
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	(1,804)	(2,432)

<sup>\*</sup>A percentage of staff costs are reallocated to 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 -
	(k) investments -
	(I) intellectual property -

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

Cons	solidated 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	-	-

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	(19)	(57)
3.9(b)	Others	631	631
3.10	Net cash from / (used in) financing activities	612	574

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,838	5,504
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,804)	(2,432)

Cons	solidated 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)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	612	574
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,646	3,646

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	3,630	4,822
5.2	Call deposits	16	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)	3,646	4,838

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	-
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 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, interate, 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		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,804)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,646
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,646
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.02
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item	8.5 as "N/A". Otherwise, a

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 questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

# **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.

Date: 29 October 2024

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.
- 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.