

## ASX Announcement

31 October 2025

### Avecho Quarterly Activities Report and Appendix 4C

#### Key Highlights

- Recruitment continues in Avecho's pivotal Phase III CBD TPM<sup>®</sup> insomnia trial, with 160 patients dosed with study medication.
- Results from the interim analysis remain anticipated in H1 2026.
- \$2.5 million capital raise completed post-quarter, providing funding to accelerate manufacturing and regulatory preparations for TGA submission

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

#### Phase III CBD Clinical Trial Recruitment Update

Recruitment in Avecho's pivotal Phase III clinical trial evaluating the CBD TPM<sup>®</sup> soft-gel capsule for the treatment of insomnia has continued throughout the quarter, with 160 participants now dosed with study medication.

Recruitment during the third quarter was moderately slower than previous months, primarily due to an increase in seasonal winter illness across clinical trial sites, which temporarily affected participant screening and randomisation rates. However, activity levels have since normalised, and the Company remains focused on completing recruitment of the remaining participants required for the interim analysis cohort later this year. A firm timeline to the interim analysis will be established after the recruitment of the final patient, but is anticipated to be H1 2026.

In collaboration with Sandoz AG, Avecho has also revised its planned statistical analysis to enhance the sensitivity and robustness of the trial's primary outcome measures. This revision, developed with input from Sandoz's global biostatistics team, further strengthens the scientific and regulatory foundation of the study.

The multicentre, double-blind, placebo-controlled trial is the largest of its kind, assessing the efficacy and safety of nightly doses of 75 mg and 150 mg of CBD TPM<sup>®</sup> against placebo over eight weeks. Participants record both the duration and quality of their sleep using validated questionnaires and daily sleep diaries.

Following the March 2025 licensing agreement with Sandoz AG, three new clinical sites were activated in Sydney and the Gold Coast, significantly accelerating recruitment across Melbourne, Perth, Sydney, and the Gold Coast.

A successful outcome from this trial would support a Therapeutic Goods Administration (TGA) submission for over-the-counter registration of the CBD TPM<sup>®</sup> soft-gel capsule as a treatment for insomnia — a first in the Australian market.

#### Operational Outlook

Avecho's primary operational focus remains the successful execution and completion of the pivotal Phase III insomnia trial. The Company continues to collaborate closely with Sandoz AG to ensure strong alignment across regulatory, manufacturing, and commercial planning.

With the statistical analysis plan finalised and recruitment approaching completion for the interim analysis cohort, Avecho has begun preparations for the next stage of manufacturing and regulatory



work that will support a TGA submission. This includes validation of scaled manufacturing processes and production of registration batches through Avecho's contract manufacturer.

Internationally, the licensing agreement with Sandoz AG has continued to attract interest from additional pharmaceutical partners seeking opportunities to license the CBD TPM<sup>®</sup> capsule in other territories. Avecho is leveraging the Australian agreement as a benchmark to pursue new licensing discussions across additional geographies, where regulatory interest in cannabinoid-based sleep therapies is expanding rapidly.

### **Corporate and Financial Update**

During the quarter, operational cash flows were directed primarily toward advancing the Phase III insomnia trial and supporting the related manufacturing and regulatory activities.

At 30 September 2025, Avecho held a cash balance of \$4.6 million. Payments to related parties and their associates during the quarter, as outlined in Section 6 of the accompanying Appendix 4C, totalled approximately \$67K.

Following the conclusion of the quarter, Avecho announced the successful completion of a \$2.5 million capital raise. The placement was strongly supported by institutional and sophisticated investors and provides funding to accelerate manufacturing scale-up, technology transfer activities with Procap, and regulatory preparations ahead of the planned TGA submission and to diversify Avecho's investor base.

### **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 develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (TPM<sup>®</sup>). TPM<sup>®</sup> 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 lead asset is a proprietary cannabidiol ("CBD") TPM soft-gel capsule demonstrated to increase CBD absorption. The CBD soft-gel capsule is currently undergoing Phase III clinical development for the treatment of insomnia.

See more here - [avecho.com.au](https://avecho.com.au)

### **About Insomnia**

Insomnia is a sleep disorder defined as dissatisfaction with sleep quantity or quality associated with difficulty initiating sleep, difficulty maintaining sleep and the inability to return to sleep on awakening. It can manifest as a primary indication or be symptom of other disorders, including anxiety and depression. Chronic insomnia is the most prevalent manifestation, characterised by insomnia symptoms occurring at least three nights per week and for at least three months. Consequences of insomnia include daytime sleepiness, poor memory function, decline in concentration with negative impacts on social and work activities. Approximately 10-30% of the global population have symptoms of insomnia, with 10-15% classified as chronic<sup>3</sup>. Based on the current global population, up to 237M people are

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affected with the sleep economy and sleep aids market estimated to reach US\$950Bn by 2032<sup>1</sup>. In Australia, as many as ~60% of the population have at least some symptoms of insomnia with a total cost to the Australian economy estimated to be A\$19.1 billion<sup>2</sup>. In August 2023, the Australian Government issued a statement indicating that sleep health should be considered a national priority as important as fitness and nutrition<sup>3</sup>.

### **About Avecho's Phase III Trial Program**

The Company is currently conducting a pivotal (Phase III), multi-centre, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of CBD TPM soft-gel capsules in adults for use in the reduction of insomnia severity. The trial is the largest of its kind testing cannabidiol, taking place at multiple sites around Australia. Aided by advice from international sleep and regulatory experts, the trial has been designed to meet the requirements of the Australian Therapeutic Goods Administration ("TGA"), US Food and Drug Agency and the European Medicines Agency. Trial Participants will be randomly assigned to one of three groups to receive nightly doses of either 75mg or 150mg of CBD, or a placebo for eight weeks. Participants will use validated questionnaires and daily sleep diaries over the course of the study to record the duration and quality of their sleep.

Further information about the study can be found at ClinicalTrials.gov (Study Identifier: NCT05840822)

A successful Phase III trial is Avecho's final clinical step in support of a submission to the TGA for pharmaceutical registration of the CBD TPM soft-gel capsule for the management of insomnia. This opportunity is particularly significant in Australia, where regulatory changes in 2020 allow for over-the-counter sales of CBD products direct from pharmacy without a prescription, provided they gain appropriate approvals. Avecho has an opportunity to be the first in this area as no other Phase III CBD trials in Australia have succeeded. Initial projections estimated the Australian over-the-counter CBD market would grow to over US\$125M per annum<sup>2</sup>.

### **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 Avecho 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, Avecho 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, Avecho 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.

<sup>1</sup><https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html>

<sup>2</sup><https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html>

<sup>3</sup><https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf>

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Nothing in these materials shall under any circumstances create an implication that there has been no change in the affairs of Avecho since the date of the announcement.

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.

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## 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 September 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	28	6,144
1.2 Payments for		
(a) research and development	(877)	(2,447)
(b) product manufacturing and operating costs	(109)	(300)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	(129)	(516)
(f) administration and corporate costs	(198)	(1,143)
(g) patent portfolio costs	(44)	(122)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	3	8
1.5 Interest and other costs of finance paid	(1)	(3)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	652
1.8 Other (EMDG)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,327)</b>	<b>2,273</b>

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

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(h) entities	-	-
(i) businesses	-	-
(j) property, plant and equipment	-	-
(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	-	-
<b>2.2</b> Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
<b>2.3</b> Cash flows from loans to other entities	-	-
<b>2.4</b> Dividends received (see note 3)	-	-
<b>2.5</b> Other (provide details if material)	-	-
<b>2.6</b> <b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b> <b>Cash flows from financing activities</b>		
<b>3.1</b> Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
<b>3.2</b> Proceeds from issue of convertible debt securities	-	-
<b>3.3</b> Proceeds from exercise of options	-	-
<b>3.4</b> Transaction costs related to issues of equity securities or convertible debt securities	-	-
<b>3.5</b> Proceeds from borrowings	-	-
<b>3.6</b> Repayment of borrowings	-	-
<b>3.7</b> Transaction costs related to loans and borrowings	-	-
<b>3.8</b> Dividends paid	-	-
<b>3.9(a)</b> Other – Payment of principal element of lease liabilities	(21)	(62)
<b>3.9(b)</b> Others	-	-
<b>3.10</b> <b>Net cash from / (used in) financing activities</b>	<b>(21)</b>	<b>(62)</b>

<b>4.</b> <b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
<b>4.1</b> Cash and cash equivalents at beginning of period	5,934	2,375
<b>4.2</b> Net cash from / (used in) operating activities (item 1.9 above)	(1,327)	2,273

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)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(21)	(62)
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>4,586</b>	<b>4,586</b>

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	4,586	5,934
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
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>4,586</b>	<b>5,934</b>

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	(67)
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.*

<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.</i>		
<i>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 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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		

<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)	(1,327)
8.2 Cash and cash equivalents at quarter end (item 4.6)	4,586
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	4,586
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>3.45</b>
<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: 31 October 2025

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.