

## ASX Announcement

30 July 2025

### Avecho Quarterly Activities Report and Appendix 4C

#### Key Highlights

- Expansion of Avecho's Phase III insomnia trial with three new clinical sites activated in Sydney and the Gold Coast.
- Acceleration of trial recruitment, with 131 participants on study medication ahead of an interim readout expected in early 2026.
- Strategic planning commenced for Therapeutic Goods Administration ("TGA") registration and commercialisation following joint Avecho-Sandoz meetings.
- TPM®-enhanced CBD capsule remains positioned to be the first registered over-the-counter ("OTC") cannabidiol product for insomnia in Australia.
- Cash balance of A\$5.9 million as at 30 June 2025.
- Receipt of \$1.66 million under the Australian Government's R&D Tax Incentive Scheme.

**Melbourne, Australia, 30 July 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 June 2025. The Company continues to advance the clinical development and commercialisation of its TPM®-enhanced cannabidiol ("CBD") soft-gel capsule, currently under evaluation in a pivotal Phase III clinical trial for the treatment of insomnia.

#### Operational Update

In March 2025, Avecho entered into a licensing agreement with Sandoz AG for the exclusive commercialisation rights of its TPM®-enhanced CBD product in Australia. Avecho and Sandoz met in April 2025 to commence planning the path toward TGA registration and commercialization, with an initial focus on increasing the rate of recruitment on the Phase III clinical trial.

Several initiatives are now underway which have accelerated recruitment as the trial proceeds towards an interim analysis. The interim readout, targeted for early 2026, will be a key milestone in Avecho's commercial strategy.

These efforts are aimed at positioning Avecho as the first company to secure over-the-counter registration of a CBD product for insomnia in Australia and build a leadership position globally as the market evolves, with significant opportunity in overseas territories.

Australia's 2020 regulatory reforms allowing over-the-counter sales of registered low-dose CBD products present a significant commercial opportunity, with the local market projected to exceed US\$125 million annually. Avecho is well positioned to be first to market with an over-the-counter CBD pharmaceutical, commercialized by Sandoz, with no other successful Phase III CBD trials in Australia to date.

#### Phase III Trial Progress

In May 2025, Avecho provided an update on its Phase III program – the largest CBD insomnia trial ever conducted in Australia. The trial is a multi-centre, randomised, double-blind, placebo-controlled study assessing nightly doses of 75 mg and 150 mg of CBD against placebo over an eight-week period. Primary endpoints assess validated measures of sleep quality and duration.



Approximately 70 participants had been dosed by the end of 2024. Following a seasonal recruitment pause, participant enrolment resumed in March 2025. Three new trial sites commenced operations during the quarter – two in Sydney and one on the Gold Coast – contributing to an accelerated pace of recruitment. As announced on 29 July 2025, a total of 131 patients have received study medication, with a target of 210 required to complete the planned interim analysis.

The Company anticipates completing enrolment for the interim analysis cohort in the second half of calendar year 2025, with interim results expected in early 2026. Avecho continues to work closely with Sandoz on planning and execution activities to ensure timely trial delivery and regulatory readiness.

### **Licensing expansion**

Following the successful licensing of Australian rights to Sandoz, Avecho has broadened its business development efforts to target additional international markets. During the quarter, CEO Dr Paul Gavin attended the BIO International Convention in the United States and conducted follow-up meetings across Europe to engage with a range of potential commercial partners. Licensing discussions remain active across multiple jurisdictions as the Company seeks to secure further agreements beyond Australia.

### **Corporate**

Avecho received \$1.66 million for the year ended 31 December 2024 under the Australian Government's Research and Development ("R&D") Tax Incentive Scheme.

The R&D Tax Incentive Scheme is an Australian Government program developed to assist businesses recover some of the costs of undertaking research and development. The funds were used to repay \$1.04 million R&D tax advances obtained from Endpoint Capital over the last year, support the ongoing Phase III insomnia clinical trial, Company operations, and to advance the Company's commercialisation strategy to bring innovative medicines to patients globally.

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\$67K.

### **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 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)

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### **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. 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.

## 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 June 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	588	6,116
1.2 Payments for		
(a) research and development	(1,005)	(1,570)
(b) product manufacturing and operating costs	(5)	(191)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	(226)	(387)
(f) administration and corporate costs	(647)	(945)
(g) patent portfolio costs	(37)	(78)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	5
1.5 Interest and other costs of finance paid	(1)	(2)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	652	652
1.8 Other (EMDG)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(680)</b>	<b>3,600</b>
<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	-	-

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

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 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)	(41)
<b>3.9(b)</b> Others	-	-
<b>3.10</b> <b>Net cash from / (used in) financing activities</b>	<b>(21)</b>	<b>(41)</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	6,635	2,375
<b>4.2</b> Net cash from / (used in) operating activities (item 1.9 above)	(680)	3,600

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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)	(41)
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>5,934</b>	<b>5,934</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	5,934	6,635
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>5,934</b>	<b>6,635</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.*

7. <b>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 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	

8. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(680)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,934
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,934
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>8.73</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: 30 July 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.