



ASX Announcement

30 April 2025

Avecho Quarterly Activities Report and Appendix 4C

Key Highlights

- Avecho and Sandoz sign an exclusive ten-year development and license agreement ("Agreement") for Avecho's pharmaceutical cannabidiol capsule for insomnia in Australia.
- Avecho to receive upfront, milestone and royalty payments:
 - US\$3M (~A\$4.8M¹) in upfront payment
 - US\$16M in development milestones prior to commercial sales
 - Tiered royalties ranging from 14% to 19% on net sales
 - Sandoz to purchase the product from Avecho for commercial sale
- Avecho retains the rights to commercialise the product in all other territories, with Sandoz granted a right of first refusal to exceed any commercial offers Avecho receives.
- New clinical trial sites opening on pivotal Phase III insomnia study
- Targeting completion of required patients for the interim analysis in 2025
- 5.4 Tonnes of Vital-ET manufactured for Ashland generating ~A\$560K in revenue. A further 3.6 Tonnes scheduled for later 2025
- Cash balance of A\$6.6M on 31 March 2025

Melbourne, Australia, 30 April 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 31 March 2025.

During the period, the Company achieved a significant milestone by entering into an exclusive ten-year development and licensing agreement with Sandoz Group AG ("Sandoz") for the commercialisation of Avecho's Phase III cannabidiol ("CBD") capsule for insomnia in the Australian market. This agreement represents a key step in Avecho's strategy to bring the first pharmaceutical-grade CBD product to market as an over-the-counter medicine, registered with the Therapeutic Goods Administration ("TGA"). Market forecasts estimate the product could generate annual sales exceeding US\$125 million² in Australia. This partnership marks a major commercial milestone in Avecho's growth trajectory.

With Sandoz secured as the ideal commercial partner, the Company concentrated its efforts on enhancing the infrastructure supporting its ongoing pivotal Phase III clinical trial (the "Trial") to accelerate patient recruitment. The Trial remains on schedule to complete dosing of participants required for the interim analysis in 2025—an important inflection point in the Company's development program.

In addition, Avecho successfully completed a major manufacturing campaign on behalf of its U.S. partner, Ashland. Further details are outlined in the following sections below.

SANDOZ LICENSING AGREEMENT

Avecho has spent considerable time over the last three years engaging with potential partners for its CBD product in Australia. This business development effort culminated in a landmark licensing and development agreement with Sandoz AG, finalized in February 2025.

¹ Avecho received the US\$ 4.8m upfront payment from Sandoz AG for license on 28 March 2025.

² Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021.



Sandoz, a Swiss-based multinational pharmaceutical company, is a global leader in generic pharmaceutical and biosimilar medicines. With a portfolio of approximately 1,500 products, Sandoz delivers more than 800 million patient treatments each year, addressing a broad spectrum of conditions ranging from the common cold to cancer.

Under the terms of the agreement, Sandoz paid Avecho an upfront licensing fee of US\$3M (approx. A\$4.8M) for the exclusive commercial rights to the CBD product for insomnia in Australia for a period of ten years, with a first right of refusal to additional international territories. Avecho will continue to fund and oversee the ongoing Phase III clinical trial. Upon successful completion, Avecho and Sandoz will collaborate to secure TGA regulatory approval. Sandoz will purchase finished product from Avecho and assume responsibility for the product's commercialisation, including marketing and distribution in Australia. Avecho is eligible for development milestone payments totalling US\$16M prior to commercialisation and will receive tiered royalties ranging from 14% to 19% on net sales once on market.

Avecho CEO, Dr Paul Gavin, said: "The upfront licensing fee from Sandoz strengthens our financial position, providing the necessary support to accelerate ongoing research and commercial activities. With ample capital to complete our pivotal Phase III trial through to the interim analysis, our primary focus is to advance the study to this key inflection point as swiftly as possible".

PHASE III INSOMNIA STUDY PROGRESSING TOWARD INTERIM ANALYSIS

Following the execution of the Sandoz agreement, Avecho initiated a series of steps to accelerate recruitment for its pivotal Phase III clinical trial for insomnia.

Insights gained during the 2024 recruitment phase identified key opportunities to optimize enrolment strategies for 2025. In response, the Company implemented targeted changes, including revised inclusion/exclusion criteria and the expansion of trial sites.

In December 2024, Avecho submitted an amendment to the Human Research Ethics Committee (HREC) to broaden participant eligibility by refining the inclusion/exclusion criteria. These changes were subsequently approved, enabling the participation of previously ineligible individuals who had expressed interest in the trial.

The approved amendment also included the addition of two new trial sites—one on the Gold Coast and another in Sydney. A third site, also located in Sydney, received ethics approval in Q1 2025.

Following the Sandoz agreement, regulatory preparations commenced for activating these new sites. This work is almost complete, with all three new sites on track to initiate patient recruitment activities in early May 2025.

As of December 2024, approximately 70 participants had received study medication. Recruitment activities were temporarily paused during the summer holiday period but have since resumed. Notably, each of the newly added sites maintains its own database of insomnia patients, providing an immediate and valuable pool of prospective participants.

The trial is targeting the enrolment of approximately 210 subjects to reach the planned interim analysis—a critical milestone in the program's development. Avecho aims to complete dosing for this cohort within 2025.

INCREASED MANUFACTURING FOR VITAL-ET

Avecho continues to support its U.S. partner, Ashland LLC, in the production and supply of Vital-ET® for the global personal care market. In Q1 2025, the Company completed a major manufacturing campaign, delivering 5.4 tonnes of Vital-ET to Ashland, resulting in approximately A\$560K in revenue. Additional campaigns are already scheduled to produce a further 3.6 Tonnes later in the year.



CORPORATE

During the quarter ended 31 March 2025, the Company invested ~A\$565K in Research and Development ("R&D") activities and incurred employment, administration and corporate costs of ~A\$686K. At 31 March 2025, the Company held ~A\$6.64M 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\$67K.

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®). 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

32 056 482 403

Quarter ended ("current quarter")

31 March 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	5,528	5,528
1.2 Payments for		
(a) research and development	(565)	(565)
(b) product manufacturing and operating costs	(186)	(186)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	(161)	(161)
(f) administration and corporate costs	(297)	(297)
(g) patent portfolio costs	(41)	(41)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	4	4
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (EMDG)	-	-
1.9 Net cash from / (used in) operating activities	4,280	4,280

*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	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
	(k) investments	-	-
	(l) 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	-	-

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)	(20)
3.9(b)	Others	-	-
3.10	Net cash from / (used in) financing activities	(20)	(20)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	2,375	2,375
4.2	Net cash from / (used in) operating activities (item 1.9 above)	4,280	4,280
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)	(20)	(20)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	6,635	6,635

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	6,635	2,375
5.2	Call deposits	-	-
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)	6,635	2,375

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	-
<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)	4,280
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,635
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	N/A
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
	<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 April 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.