



ASX Announcement

18 December 2025

Phase III CBD Clinical Trial Recruitment Update

Highlights:

- Recruitment for the 210-patient interim analysis cohort approaching completion
- A total of 190 participants dosed with study medication
- Interim analysis timelines to be confirmed upon completion of recruitment

Melbourne, Australia, 18 December 2025: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to provide a progress update on recruitment for its pivotal Phase III clinical trial (the "Trial") investigating the use of its oral CBD TPM®-enhanced capsule ("the Product") for the treatment of insomnia.

Avecho continues to make steady progress toward completion of patient recruitment for the planned interim analysis. As at the date of this announcement, 190 participants have been dosed with study medication, representing the majority of the approximately 210 randomised participants required for the interim analysis cohort.

Recruitment will continue into early 2026 to recruit the remaining participants. The pace of recruitment reflects the highly specific inclusion and exclusion criteria required for participation in this Trial, which is designed to enrol a specific patient population most appropriate for assessing the Product's efficacy and safety. While this approach has extended recruitment timelines, it is critical to maximising the likelihood of a successful clinical outcome.

Upon completion of recruitment, the Company will focus on the final steps to conduct the interim analysis.

Avecho CEO, Dr Paul Gavin, said: "With 190 patients now dosed with study medication, we are approaching a major inflection point for the Company. While recruitment has extended slightly beyond earlier expectations, we are firmly focused on completing this final stage of enrolment with the appropriate patient population to maximise our chance of success. Reaching the interim analysis will be a significant milestone for Avecho, and we look forward to updating the market as we move through the final phase of recruitment."

The Company expects to announce timelines for the interim analysis once recruitment is complete, with completion of the interim analysis targeted for H1 2026.

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 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

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 chronic¹. Based on the current global population, up to 237M people are affected by insomnia, with the sleep economy and sleep aids market estimated to reach US\$950Bn by 2032². 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 billion³. In August 2023, the Australian Government issued a statement indicating that sleep health should be considered a national priority as important as fitness and nutrition⁴.

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 annum⁵.

¹ <https://www.thegoodbody.com/insomnia-statistics/>

² <https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html>

³ <https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html>

⁴ <https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf>

⁵ Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021



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.