



## **ASX Announcement**

29 July 2025

### **Phase III CBD Clinical Trial Recruitment Update**

#### **Highlights:**

- A total of 131 patients dosed with study medication
- On track to complete recruitment of all 210 patients required for the interim analysis in the second half of 2025
- Results of the interim analysis are anticipated early 2026

**Melbourne, Australia, 29 July 2025:** Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to provide a progress update 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.

In March 2025, Avecho entered into an agreement with Sandoz AG ("Sandoz") to license the Australian commercial rights to the Product. Following this partnership, three new clinical trial sites – two in Sydney and one on the Gold Coast - were activated and commenced patient recruitment in May and June 2025. The activation of these sites has significantly accelerated recruitment, with patients now being recruited in Melbourne, Perth, Sydney and the Gold Coast.

To date, 131 patients have received study medication. A total of 210 randomized patients is required for the planned interim analysis. Based on anticipated recruitment rates, Avecho expects to complete enrolment for the interim analysis cohort in the second half of CY2025, enabling results from the interim analysis to be available in early CY2026.

**Avecho CEO, Dr Paul Gavin, said:** "The changes we made to our inclusion and exclusion criteria late 2024, coupled with the addition of new trial sites, have had a measurable impact on recruitment. We now have a clear line of sight to our interim analysis, a key milestone for the Company. Our focus remains on advancing the Trial efficiently toward this important inflection point, and I look forward to keeping the market updated as we make continued progress."

Individuals interested in participating in the trial are encouraged to register interest with the clinical trial sites nearest to them (details below).

#### **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](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>1</sup>. 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 2032<sup>2</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>3</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>4</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).

### Contact details for insomnia participation enquiries

#### Melbourne

Monash Health - <https://trials.mlsi.org.au/trials/avecho-ave047-cbd-insomnia-study>

#### Sydney

Pioneer - <https://www.pioneerclinicaltrials.com/our-clinical-trials>

Key Health - <https://www.keyhealth.com.au/clinical-trials/2025-sleep-insomnia>

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

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

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

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

## Queensland

Griffith University Clinical Trial Unit - <https://www.griffith.edu.au/griffith-health/clinical-trial-unit/current-trials/insomnia-trial>

## Perth

Captain Stirling Medical Centre - <https://csmc.net.au/services/medical-studies-and-clinical-trials>

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>5</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. 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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<sup>5</sup> Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021