ASX Announcement
31 August 2026

Avecho recommences recruitment for final stage of pivotal Phase III insomnia trial

Key Highlights

- Recruitment has recommenced for the final stage of Avecho's pivotal Phase III trial evaluating its TPM®-enhanced cannabidiol (CBD) capsule for insomnia
- Approximately 320 additional participants will be enrolled in the second cohort to bring the trial to its originally planned size of 519 participants completing the study
- Recommencement of recruitment follows the Company's positive interim analysis announced in June 2026, whereby the independent Data Monitoring Board unanimously recommended that the trial continue without any increase to the originally planned sample size
- Existing clinical sites have now recommenced recruitment, and additional sites will be progressively activated to accelerate enrolment
- Once the additional sites are operational, Avecho expects recruitment of the remaining participants to be completed within approximately 12 months

Melbourne, Australia, 31 August 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to announce that recruitment has recommenced for the final stage of its pivotal Phase III clinical trial evaluating its TPM®-enhanced cannabidiol (CBD) soft-gel capsule for the treatment of insomnia.

The commencement of the trial's second and final patient cohort follows the Company's recently announced successful interim analysis of its Phase III insomnia trial. Following its review of the unblinded interim data, the independent Data Monitoring Board (DMB) unanimously recommended that the trial continue to its originally planned size of 519 participants.

Importantly, the DMB did not recommend increasing the number of participants. A trial's size is set from assumptions about how well the treatment is expected to work and how much patients naturally vary, and a weaker or more variable interim result would typically call for more participants. That the DMB recommended continuing at the planned size, rather than expanding the trial, indicates the study is appropriately sized and tracking in line with its original design, while Avecho remains blinded to all treatment and efficacy data.

Approximately 320 additional participants will be enrolled in this second cohort so that 519 participants complete the study as originally targeted, with sufficient additional participants to replace any who withdraw over the course of the trial. The final number will be confirmed as recruitment progresses. Recruitment has recommenced through Avecho's existing clinical site network, with additional sites being progressively activated to support and accelerate enrolment.

Avecho Chief Executive Officer Dr Paul Gavin said:

"The interim analysis was the most significant milestone in this program and, in our view, the single biggest risk to the study. With that risk now behind us and the trial materially de-risked, we are recommencing dosing of the final cohort of patients, confident we are on the path to a successful completion of this pivotal Phase III study.

"We are now applying the recruitment strategies, site-management processes and operational improvements developed during the first stage of the study to complete enrolment efficiently.

"Our existing sites have recommenced recruitment, and we will progressively bring additional sites online to accelerate enrolment as we drive this pivotal study through to completion."

Study Design

The Phase III study is a multi-centre, randomised, double-blind and placebo-controlled trial evaluating the efficacy and safety of Avecho's CBD TPM® soft-gel capsule in adults with insomnia.

Participants are randomly assigned to receive a nightly dose of either 75mg CBD, 150mg CBD or placebo over an eight-week treatment period. The study uses validated questionnaires and daily sleep diaries to assess changes in insomnia severity and sleep quality.

The interim analysis was conducted using data from 244 participants. The DMB, comprising independent experts in sleep medicine, clinical safety and biostatistics, is the only body with access to the trial's unblinded data.

The DMB unanimously recommended that the study continue to its full planned enrolment after determining that it had satisfied the pre-specified criteria established in the trial protocol.

Safety data reviewed as part of the interim analysis identified no serious adverse events among the 244 participants assessed across the trial's three treatment groups.

Avecho remains blinded to the treatment allocations and efficacy results, which will not be available until the study has been completed and the final data have been analysed.

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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 chronic[1]. 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[2]. 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[3]. 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[4].

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[5].

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.

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[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

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.