ASX Announcement
2 March 2026

Avecho successfully completes recruitment for interim analysis on pivotal Phase III trial

Key Highlights

- Avecho successfully completes recruitment of the ~210-patient interim analysis cohort
- Interim analysis results anticipated in June 2026 – a major value-defining milestone for Avecho's pivotal Phase III insomnia program
- Early forecasts for over-the-counter CBD in Australia are >US$125m per year[1] with a global insomnia market valued at US$5.22B in 2024[2]
- Major commercial partner already in place for Australian market (Sandoz AG) with milestone payments and royalties on net sales
- Avecho in discussions with potential partners to license the product for countries and regions outside of Australia

Melbourne, Australia, 2 March 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to announce the completion of recruitment for the interim analysis cohort of participants for its pivotal Phase III clinical trial evaluating its TPM®-enhanced cannabidiol (CBD) capsule for insomnia.

The Company has successfully enrolled the approximately 210 participants required for the planned interim analysis, which will provide the first indication of the product's efficacy, de-risk the program moving forward and confirm the number of participants required to complete the trial.

With this initial enrolment now finalised, the Company's focus shifts to the execution of the interim analysis, which will occur after dosing of the remaining patients on trial is complete. Results of the interim analysis are anticipated in June 2026.

The interim analysis represents a major inflection point for Avecho. The Phase III study is designed to support registration of the CBD TPM® capsule with the Therapeutic Goods Administration (TGA), a necessary step for CBD to be recognised as an approved treatment for insomnia in Australia. The Company is positioned be one of the first to capitalise on the TGA's unique over-the-counter (OTC) CBD registration pathway, estimated to be worth more than US$125M per year for the Australian market. Subsequent overseas regulatory submissions will target entry into the global insomnia market valued at US$5.22B in 2024.

Avecho has already received major commercial validation for the CBD TPM capsule, having licensed the commercial rights for Australia to Sandoz AG in 2025. Avecho received an up-front payment of US$3M for the Australian rights, is eligible for US$16M of milestone payments prior to the first commercial sales and will receive tiered royalties of 14-19% on net sales. The Company's worldwide licensing strategy continues to progress, as it continues discussions with various potential partners for countries and regions outside of Australia.

[1] https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
[2] https://www.marketresearchfuture.com/reports/insomnia-market545#:~:text=How%20much%20is%20the%20insomnia,forecast%20period%2C%20

Avecho CEO, Dr Paul Gavin, said:

"Completing recruitment for the interim analysis cohort marks a significant inflection point for the Phase III program and brings us within sight of a long-anticipated result supporting the efficacy of our product. This milestone reflects the dedication of our clinical teams and the patience of our shareholders who have supported the program over the past two years.

With a commercial partnership with Sandoz already in place for Australia, the upcoming interim analysis represents a potentially transformative catalyst for Avecho that puts the Company in an excellent strategic position moving forward. A positive outcome would materially de-risk the program and increase its attractiveness to prospective partners around the world.

We look forward to updating the market as we approach the interim results expected in June."

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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[3]. 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[4]. 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[5]. 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[6].

[3] https://www.thegoodbody.com/insomnia-statistics/
[4] https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html
[5] https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
[6] https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf

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[7].

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.

[7] Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021