ASX Announcement
21 May 2026

Avecho completes treatment phase for interim analysis in Phase III insomnia trial

Key Highlights

- Avecho has successfully completed the treatment phase for the last patient required for the planned interim analysis of its pivotal Phase III insomnia trial
- 244 participants have now been successfully recruited and completed treatment for the upcoming interim analysis
- Interim analysis results remain on track for late June 2026,
- and will provide the first indication of the product's efficacy profile, inform the final trial size and support ongoing licensing discussions
- Avecho CEO Dr Paul Gavin will host an investor update webinar at 11am AEST on Monday 25 May. Register: https://us02web.zoom.us/webinar/register/WN_un03u7nDS9G_fsKlhqlQlw

Melbourne, Australia, 21 May 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to announce that the last patient required for the planned interim analysis of its pivotal Phase III clinical trial evaluating its TPM®-enhanced cannabidiol (CBD) capsule for insomnia has successfully completed the treatment phase.

The interim analysis cohort comprises 244 participants randomized across three treatment groups to receive nightly doses of either 150mg CBD, 75mg CBD or placebo in a TPM enhanced capsule. Completion of the treatment phase represents the final clinical milestone prior to the planned interim analysis, with results remaining on track for late June 2026.

The interim analysis represents a major inflection point for Avecho's pivotal Phase III insomnia program. The analysis is expected to provide the first indication of the product's efficacy profile, inform the total number of participants required for the final study population and support the progression of ongoing licensing discussions.

With the treatment phase now complete for all participants in the interim analysis cohort, the clinical database will be locked and the data cleaned ahead of statistical analysis. An independent blinded statistics team will conduct the interim analysis and provide the results to Avecho's independent Data Monitoring Board (DMB), which will review the outcomes and provide recommendations in accordance with the study protocol.

Avecho has already secured significant commercial validation for the CBD TPM capsule, having licensed the commercial rights for Australia to Sandoz AG in 2025. Under the agreement, Avecho received an upfront payment of US$3 million, is eligible for up to US$16 million in development and commercial milestone payments and will receive tiered royalties of 14–19% on net sales..

Avecho's Phase III trial has been 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 to be the first to capitalise on the TGA's unique over-the-counter (OTC) CBD registration pathway, with early forecasts for over-the-counter CBD in Australia estimated at more than US$125 million per year[1]. Subsequent overseas regulatory submissions would target entry into the global insomnia market, which was valued at US$5.22 billion in 2024[2].

Avecho CEO Dr Paul Gavin said:
"Completion of the treatment phase for the interim analysis cohort is a major milestone for Avecho and brings us significantly closer to the first efficacy readout from our pivotal Phase III insomnia trial.
"With 244 participants now recruited and having completed treatment, the interim analysis remains on track for late June and is expected to provide important insight into the product's efficacy profile and the pathway forward for the program.
"With Sandoz already established as our Australian commercial partner, a positive interim analysis outcome has the potential to materially de-risk the program and strengthen Avecho's position in discussions relating to commercialisation opportunities outside Australia."

Investor Webinar

Avecho CEO Dr Paul Gavin is hosting an investor webinar to provide an update ahead of the Phase III interim analysis.

The webinar will be held on **Monday 25 May 2026 at 11am AEST**.

Register to attend the presentation at the following link:
https://us02web.zoom.us/webinar/register/WN_un03u7nDS9G_fsKlhqlQlw

A recording will be available at the above link shortly after the conclusion of the live session, and the replay will also be available via the Company's website and social media channels.

Participants attending the Webinar may submit questions during the session, or email them in advance to matt@nwrcommunications.com.au

For enquiries, please contact
Dr Paul Gavin
Chief Executive Officer
Avecho Biotechnology Limited
+61 3 9002 5000

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.

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

[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

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.