ASX Announcement
24 June 2026

Positive interim analysis advances Avecho Phase III insomnia program

Key Highlights

- Independent Data Monitoring Board (DMB) unanimously recommends Avecho's pivotal Phase III insomnia trial continue to its originally planned enrolment of 519 participants, having successfully met the pre-specified criteria at the interim analysis
- Continuation with the originally planned sample size, rather than an increased number, is highly encouraging and consistent with the treatment effect and data variability assumed in the trial's design
- No serious adverse events identified across the 244 participants assessed to date with 75mg or 150mg CBD or placebo
- Additional clinical sites already identified to accelerate recruitment of the second patient cohort
- Importantly, this positive outcome materially de-risks Avecho's CBD TPM® insomnia product, supports continued regulatory and commercial development, and strengthens Avecho's position for ongoing licensing discussions for territories outside Australia

Melbourne, Australia, 24 June 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to announce that the independent Data Monitoring Board (DMB) has completed its review of the unblinded interim analysis data from the Company's pivotal Phase III clinical trial evaluating its TPM®-enhanced cannabidiol (CBD) capsule for insomnia.

The DMB is comprised of independent experts in sleep medicine, clinical safety and biostatistics and is the only body with access to unblinded trial data. Following review of the interim data, the DMB has unanimously recommended the trial continue to the full planned enrolment of 519 participants. The recommendation is highly encouraging as it confirms the study has satisfied the pre-specified criteria established in the trial protocol to progress beyond the interim analysis and continue recruitment of a second patient cohort.

The interim analysis represents a major value-inflection point for the program, reducing clinical development risk and providing a defined pathway toward completion of the pivotal study.

Avecho CEO Dr Paul Gavin said: "This is an important and major milestone for Avecho, and exactly the outcome we designed this trial to achieve. The independent DMB has recommended we continue at the originally planned size of 519 participants, without the need to dose additional participants.

"That recommendation carries a clear message: the treatment effect and the variability in the data are tracking closely with the assumptions this study was built around. We have always said the trial's design — its two independent endpoints, stringent inclusion and exclusion criteria, and controls on the placebo effect — was its greatest strength in giving the product the best chance to show its effect, and the positive DMB recommendation vindicates that approach.

"Although we remain blinded and the study is not complete, so final outcomes cannot be determined until then, we are more confident than ever that our CBD capsule works as a treatment for insomnia."

The interim analysis was conducted on data from 244 participants randomised across three treatment groups receiving nightly doses of either 150mg CBD, 75mg CBD or placebo in a TPM®-enhanced capsule over an eight-week treatment period.

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Safety data reviewed at the interim analysis further supported the program, with no serious adverse events (SAEs) recorded across the 244 participants. Tolerability is central to the commercial rationale for the product.

Avecho CEO Dr Paul Gavin added: "For three years, our central question has been whether this product works. The interim analysis has changed how we approach it — from here, we are planning the business on the assumption that it does.

"That shifts our focus toward commercialisation, and how this product is positioned against the medicines people currently rely on for sleep. Many existing prescription treatments carry well-documented limitations, including next-day impairment and the risk of overdose — concerns that cannabidiol's safety profile does not share.

"A treatment that can improve sleep without that safety burden has a clear place in the market and will be central to our ongoing licensing discussions."

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Regulatory and Commercial Progress

In 2025, Avecho licensed Australian commercial rights to the CBD TPM capsule to Sandoz under an agreement that included a US$3 million upfront payment, potential development and commercial milestones of up to US$16 million and tiered royalties on future sales.[1]

The positive interim analysis strengthens Avecho's commercial position and adds momentum to ongoing licensing discussions covering territories outside Australia.

The Company believes the interim outcome enhances the attractiveness of the program to potential commercial partners and strengthens the product's positioning against existing sleep medications. Accordingly, progressing additional regional licensing agreements will be a key strategic priority as Avecho seeks to fund continued development while maximising shareholder value.

The Company will also now look to engage with the FDA and other international regulatory agencies to determine the path forward for the product in specific geographies.

Clinical Completion Strategy

Following the positive interim outcome, Avecho will immediately commence preparations for recruitment of the second patient cohort required to complete the study using its existing clinical site network.

The Company has already engaged with additional clinical sites to support accelerated recruitment and intends to activate these sites as rapidly as possible. Recruitment protocols, site activation procedures and patient management processes refined during the interim phase have been incorporated into the completion plan.

Consistent with the commercial priorities outlined above, Avecho intends to fund this next stage primarily through regional licensing agreements, and the positive interim outcome is expected to support those discussions. Once the additional sites are active, the Company currently expects recruitment of the remaining participants to take approximately 12 months.

[1] https://announcements.asx.com.au/asxpdf/20250303/pdf/06g5xlzjwc3h7z.pdf

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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[2]. 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[3]. 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[4]. 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[5].

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

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

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[6].

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