



ASX Announcement

25 May 2026

Phase III Interim Analysis webinar presentation

Melbourne, Australia, 25 May 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to provide the attached presentation for its investor webinar regarding the upcoming Phase III interim analysis evaluating its TPM[®]-enhanced cannabidiol (CBD) capsule for insomnia.

As previously announced, Avecho CEO Dr Paul Gavin is hosting the webinar **today, Monday 25 May 2026 at 11am AEST**.

Register to attend the presentation at the following link:

https://us02web.zoom.us/join/register/WN_un03u7nDS9G_fsKlhqIQlw

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

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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

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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 chronic¹. 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 2032². 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 billion³. In August 2023, the Australian Government issued a statement indicating that sleep health should be considered a national priority as important as fitness and nutrition⁴.

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 annum⁵.

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

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



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.



Shareholder Update

Path to the Phase III Interim Analysis Result

Dr Paul Gavin | Chief Executive Officer

THE TRIAL

Phase III design — what we're testing

244

participants randomised for the interim cohort

3 arms

75mg CBD | 150mg CBD | placebo

8 weeks

of nightly dosing per participant

2 endpoints

Insomnia Severity Index (ISI) + subjective sleep efficiency (sSE)

Blinded

patients, investigators and Avecho all blinded to allocation

Insomnia — what we're treating

Difficulty falling or staying asleep

Affects ~10-30% of Australians

No approved OTC pharmaceutical product currently available in Australia for ongoing use

Australia's unique Schedule 3 OTC pathway for CBD opens a first-mover commercial opportunity

Largest CBD insomnia trial globally; designed to support a TGA submission on positive completion.

UNDERSTANDING THE READOUT

What the interim analysis is

1

What gets tested

The interim analysis examines whether the CBD TPM[®] capsule is improving sleep in the 244 patients dosed to date — measured using two independent primary endpoints (ISI and sSE). Either endpoint succeeding is sufficient.

2

Who decides

An independent Data Monitoring Board reviews the unblinded data. The DMB is independent of Avecho and the trial investigators. Avecho remains fully blinded throughout the process.

3

What we'll learn

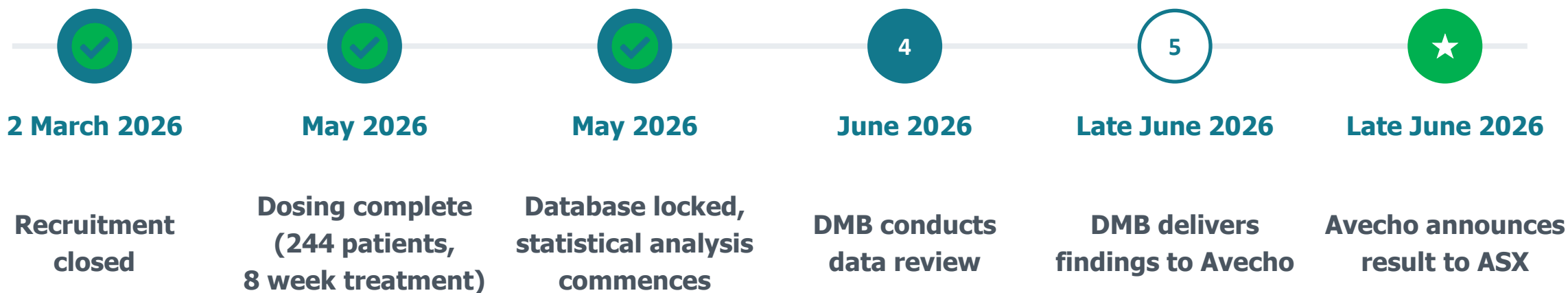
The DMB will recommend one of three outcomes:

- 1) **Positive** - Continue the trial with a second cohort of patients - confirmed sample size
- 2) **Positive** - Stop the trial for efficacy
- 3) **Negative** - stop the trial for futility

We acknowledge the interim analysis represents a binary outcome for the insomnia program — and we approach it with realistic, evidence-based confidence in the trial's design.

PROCESS TO READOUT

From recruitment closed to interim result



Independent Data Monitoring Board (DMB)

- External sleep, safety and biostatistical experts
- Independent of Avecho and trial investigators
- Met first time February 2026 to confirm charter and process

Avecho, trial sites and trial investigators remain fully blinded throughout. The DMB is the sole body with access to unblinded interim data -- standard best practice for pivotal placebo-controlled trials.

TRIAL DESIGN

Why this trial is positioned to deliver a clinical signal

Three key design features have been built into this trial specifically to maximise the probability of a successful result

01

Two independent primary endpoints

- 1) Insomnia Severity Index (ISI)
- 2) Subjective Sleep Efficiency (sSE)

Only one needs to work for trial success.

02

Adaptive design interim analysis

The interim analysis can recalibrate the trial, adjusting the required patient numbers during the study to ensure the result is conclusive.

03

Placebo-effect control mechanisms

The protocol is designed to minimise damage from the placebo response — improving the chance that genuine drug effect is detected cleanly.

Supporting design features

150mg

Maximum allowed OTC dose tested

519

Largest CBD insomnia trial globally

8 weeks

Treatment duration per patient

ISI ≥ 15

Tight inclusion criteria

FDA + EMA

Trial designed to global standards

WHAT HAPPENS AFTER THE READOUT

Three possible outcomes

Stop for futility -- negative

The drug is not showing the required effect

Dosing of further patients ceases — preserving shareholder capital. The CBD asset retains commercial value for alternative indications.

Trial continues -- positive

Base case positive outcome — this is what we are aiming for

The drug/trial is working, with an observable difference between treatment and placebo. DMB recommends continuing the trial with a confirmed sample size needed to reach statistical significance at completion.

Stop for efficacy -- positive

Upside scenario — not expected, but possible

The drug/trial is working so well results are highly statistically significant after 244 patients. The DMB can recommend stopping the trial early, declaring Phase III successful.

***The expected positive result is continuing the trial to 519 patients.
Stop-for-efficacy is upside, not the expectation.***

BASE CASE IN DETAIL

Continuing the trial — how we fund it, how we execute

The base case requires ~300 additional patients. The two questions shareholders will ask: how much, and how long?

 **How we fund it**

- Priority: pharmaceutical licensing deal for an ex-Australian territory — upfront fees from licensing would fund Phase III completion.
- Capital raise as an alternative – but plenty of time to focus on deals
- Decision driven by what's in Avecho's/shareholders' best interests at the time

 **How we accelerate**

- ~300 additional patients required to complete the trial
- Plan to open ~10 additional clinical sites — already identified
- With additional sites engaged, recruitment expected to take ~12 months
- Lessons from interim recruitment fully embedded in completion plan

 **What runs in parallel**

- TGA dossier construction (with Sandoz)
- Manufacturing scale-up continues — funded from earlier placement
- Further ex-Australia licensing conversations progress to closure
- Engagement with international regulators (e.g. FDA) for global pathway optionality

ASSUMING SUCCESS**Next 12 months — milestones and triggers****Now → Late June 2026****Interim analysis readout**

- Dosing complete; database locked
- Statistical analysis
- DMB data review
- Formal DMB meeting - results
- Avecho announces result to ASX

H2 2026**Post-readout activation**

- Pursue further licensing deals
- Open additional trial sites and recommence dosing
- Potential engagement with overseas regulators (e.g. FDA)
- Manufacturing scale-up continues

2027**Trial completion and submission readiness**

- Complete Phase III dosing to final patient
- Complete manufacturing work required for TGA submission
- Compile and finalise TGA submission dossier
- Continue international partner development

CLOSING ARGUMENT

Every part of our thesis has been independently validated

For years we have claimed big things for this product. At each step, an external body has validated those predictions. One piece of validation remains.

Preclinical	US Patent Office	TGA	Sandoz	Market	Interim analysis
<p><i>validated that</i></p> <p>TPM Increased CBD absorption</p> <p>VALIDATED</p>	<p><i>validated that</i></p> <p>Product is unique</p> <p>VALIDATED</p>	<p><i>validated that</i></p> <p>Trial design & submission strategy are sound</p> <p>VALIDATED</p>	<p><i>validated that</i></p> <p>Data, trial design, commercial case are compelling</p> <p>VALIDATED</p>	<p><i>validated that</i></p> <p>Story is good, value will follow</p> <p>VALIDATED</p>	<p><i>validated that</i></p> <p>Product works for the indication</p> <p>June 2026</p>

The next piece of validation arrives in June

Avecho

Questions Welcome



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