ASX Announcement
23 September 2026

Avecho to present at the ASX SMIDcaps Conference

Melbourne, Australia, 23 September 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to advise that CEO Dr Paul Gavin will present at the ASX SMIDcaps Conference on Wednesday, 23 September 2026.

The Company's presentation, which is attached to this announcement, provides an update on Avecho's Phase III CBD insomnia trial, which has passed the independent interim analysis, and outlines the Company's planned activities over the next 12 to 18 months.

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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].

[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

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 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.

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

ASX SMIDcaps Conference
September 2026

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Developing the first pharmaceutical cannabidiol product for insomnia

www.avecho.com.au | ASX:AVE

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Safe Harbour Statement

This presentation, and any representations made before, during or after the presentation, may include forward-looking statements that are inherently subject to risks and uncertainties. These statements relate to, but are not limited to: (1) the safety or efficacy of, or potential applications for, Avecho's TPM® platform technology; (2) the strength of Avecho's intellectual property; (3) the timelines for Avecho's clinical trials and regulatory processes for its different products; (4) the scalability and efficiency of manufacturing processes; (5) revenue projections, market share expectations, share price expectations and capital requirements.

Actual results may differ from the expectations expressed in these forward-looking statements, and the differences may be material (whether positive or negative). The risks that may cause Avecho's actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements, include but are not limited to: (1) risks inherent in the development, approval and commercialization of potential products; (2) uncertainty of clinical trial results or regulatory approvals or clearances; (3) changes to market trends or government laws or regulations; (4) the potential need for future capital; (5) dependence upon collaborators; and (6) protection of intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements.

Where Avecho sits today

Proprietary product

- TPM-enhanced synthetic cannabidiol (CBD) capsule; IP protection to ~2043. A registered pharmaceutical, not a medicinal-cannabis product.

De-risked in pivotal Phase III trial

- Pivotal Phase III passed its independent interim analysis — the largest risk for the study. Good safety profile. Dosing recommenced to conclude study.

Commercially validated

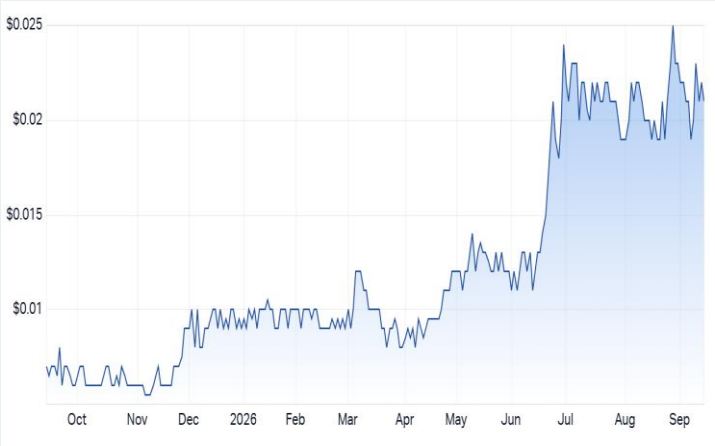
- Sandoz — a global pharma major — licensed exclusive Australian rights after extensive due diligence.

First-mover market

- Australia's Schedule 3 pathway lets a registered CBD product sell through pharmacies. No product registered yet – the market is open.

AVE CORPORATE SUMMARY

Shares on issue	**3.86 Bn**
Cash (end June 2026)	**A$6.6 M**
Market capitalization[1]	**A$81.14 M**
Broker coverage	**Euroz Hartleys**



1. At COB 17th September, 2026

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Insomnia is a major problem worldwide[1]

Broadly defined as difficulty initiating or maintaining sleep

Insomnia can be a symptom of a range of other disorders, particularly mental health and psychiatric disorders, and can contribute to their onset or exacerbation.

10-30%
of people across the world experience insomnia symptoms

Insomnia market worth
$US 5.2 billion
In 2024[2]

Mental Health worth
$US 375 Bn[3]

>850 million
people have clinically significant insomnia

1. https://www.thegoodbody.com/insomnia-statistics/
2. https://www.marketresearchfuture.com/reports/insomnia-market-545#:~:text=How%20much%20is%20the%20insomnia,forecast%20period%2C%202024%2D2032
3. https://finance.yahoo.com/news/532-billion-mental-health-market-144800771.html

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Pivotal Phase III Trial passed the interim analysis

UNANIMOUS **Independent DMB recommends the trial continue to 519 patients — sample size unchanged**

EFFICACY · on track?

- By recommending continuation at the original sample size — not a larger one — the independent Board signalled that assumptions on effect size and variability are tracking at least in line with expectation.
- The study was powered on the assumption the product performs comparably to approved insomnia medicines.

Take-away performance to date is tracking in line with approved insomnia medications.

SAFETY · is it tolerable?

Approved insomnia medicines carry real burdens:

- Overdose toxicity, next-day impairment, dependence & tolerance

CBD-TPM interim cohort — benign.

No serious adverse events reported across the 244 participants dosed, at both dose levels.

Take-away safety profile to date is competitive with approved sleep drugs.

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The Australian Opportunity

Australia – First Mover Market

- A **registered CBD medicine can sell over the counter** in Australia — through pharmacies, no prescription
- No such product is registered yet — **the market is open to the first mover**
- 9.5 million Australians experience insomnia symptoms
- Australians spend ~A$5 billion a year on OTC medicines; initial forecasts for OTC CBD **exceed US$125 million** a year[1]

Licensed to Sandoz – Key Terms[2]

- Exclusive Australian rights
- **US$3M** upfront — received on signing
- **US$16M** in development milestones (pre-commercial)
- **14–19%** tiered royalties on net sales
- Right of first refusal on ex-Australia territories

The first deal is always the hardest. Focus now on licensing the CBD capsule in larger global markets

Sources:
1. Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021
2. https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02920239-3A663194&v=undefined

Completing the trial — and the value ahead

~320
patients to complete
(includes spares)

~10 sites
identified & ready

~12 months
to trial completion
(once all sites open)

H2 2026 — Recommence Trial

- Recommence dosing - Activate additional sites
- Pursue ex-Australia licensing deal(s)
- Commence engagement with overseas regulators (e.g. FDA, EMA)
- Manufacturing scale-up continues

2027 — Complete Trial

- Pursue further licensing deals
- Complete Phase III dosing to the final patient
- Complete manufacturing work required for TGA submission
- Compile TGA submission dossier
- Develop product with partners in international territories (specific territories may have their own requirements)

Take-away: A de-risked asset, operationally executing a pivotal Phase III, already partnered with further commercial deals ahead — the next 12–18 months is a sequence of value inflections for shareholders.

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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 remained.

Preclinical	US, EU & Japan Patent Office	TGA	Sandoz	Market	Interim analysis
validated that	*validated that*	*validated that*	*validated that*	*validated that*	*validated that*
TPM Increased CBD absorption	**Product is unique**	**Trial design & submission strategy are sound**	**Data, trial design, commercial case are compelling**	**Story is good, value will follow**	**Effect tracking in line with expectations**
					

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Questions Welcome

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