Positive 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

Independent Data Monitoring Board (DMB)

- External sleep, safety and biostatistical experts
- Independent of Avecho and trial investigators

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 was continuing the trial to 519 patients.

VERDICT

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Positive – DMB recommends trial continues to 519 patients

What does the recommendation tell us - *Efficacy*

1. Interim analysis met the pre-specified criteria to continue for efficacy — a treatment effect for the CBD TPM capsule versus placebo on at least one of the two primary endpoints
2. Observed data variability is in line with the assumptions used to power the study
3. If the second cohort performs consistently with the first, the completed 519-participant trial is well positioned to meet its primary endpoint
4. By recommending continuation at the originally planned sample size — rather than a larger one — the independent DMB has signalled that Avecho's original assumptions on effect size* and variability are tracking at, or better than, expectation

***Original assumptions were that the product performs as well as approved insomnia drugs**

Take Away - So far, product performance appears in line with approved insomnia medications

VERDICT

Positive – DMB recommends trial continues to 519 patients

What does the recommendation tell us - *Safety*

1) **CBD TPM® capsule** — no serious adverse events across 244 participants at two doses in the interim analysis. Safety profile looks good.

Safety burdens of currently approved insomnia medicines

- Dependence, tolerance and withdrawal
- Next-day impairment
- Overdose toxicity
- Complex sleep behaviours
- Risk in older adults

Take Away - So far, the product safety profile is competitive with approved insomnia drugs

Global insomnia: a large, growing market underserved by current therapies

Market context for Avecho's TPM®-enhanced CBD capsule for insomnia

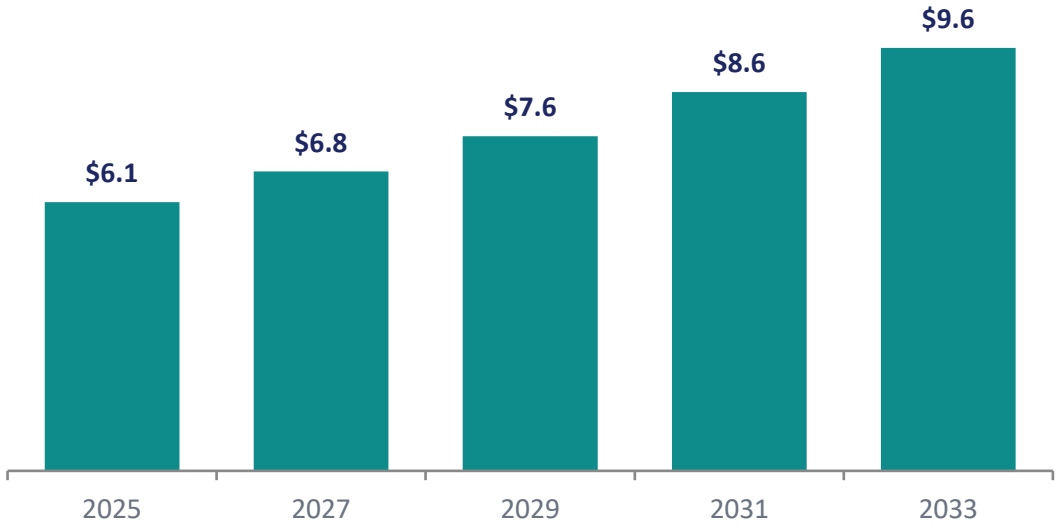
~850M
adults live with chronic insomnia worldwide — 16.2% of the adult population

~1 in 3
adults experience insomnia symptoms at some point

~US$9.5bn
forecast global insomnia treatment market by 2033

~6% CAGR
projected annual market growth, 2025–2033

Insomnia treatment market — global revenue (US$bn)



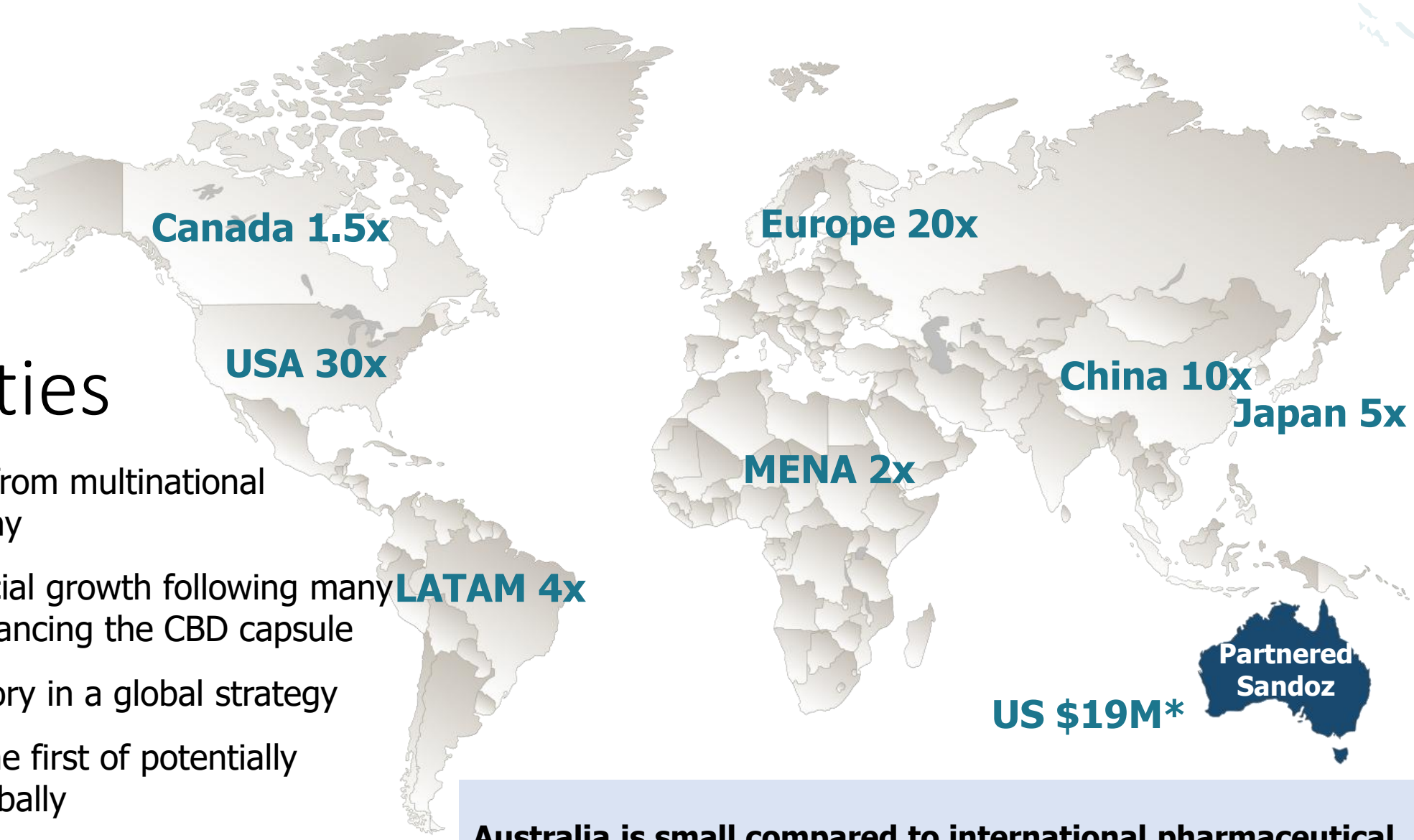
Why this is Avecho's opportunity

- **A safety-driven gap.** Benzodiazepines, Z-drugs and sedating antihistamines carry dependence, next-day impairment and overdose risk — shifting demand to safer, non-scheduled options. The newest class, orexin antagonists, is the fastest-growing at ~12% CAGR.
- **An open OTC pathway in Australia.** Since Feb 2021 the TGA permits low-dose CBD (≤150 mg/day) to be sold pharmacist-only, over the counter — but no product has yet met the efficacy bar required for ARTG registration.
- **First-mover potential.** A successful Phase III is the registration-enabling dataset — positioning Avecho's CBD TPM capsule to be first to that OTC market, with Sandoz as Australian commercial partner.

Sources: Market size — consensus of MarketDataForecast, DataBridge & Straits Research (2025–26), figures vary by provider; prevalence — systematic analysis, Sleep Medicine Reviews 2025 (852M adults, 16.2%); OTC pathway — TGA, low-dose CBD down-scheduled to Schedule 3, Feb 2021.

Licensing Opportunities

- Commercial validation from multinational pharmaceutical company
- New phase of commercial growth following many years of hard work advancing the CBD capsule
- Australia the first territory in a global strategy
- Licensing deal marks the first of potentially several agreements globally



Australia is small compared to international pharmaceutical markets. Huge opportunity for overseas territories

*For upfront and potential milestone payments prior to commercial sales

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

Trial completion 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.
- Pro-forma $6.25M in the bank already

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

MILESTONES AND TRIGGERS

Next 12-18 months

H2 2026

Trial Continuation

- Pursue multiple licensing deals
- Open additional trial sites and recommence dosing
- Engagement with overseas regulators (e.g. FDA)
- Scale up and manufacturing

2027

Trial completion and submission readiness

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

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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 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**	**Evidence the product works for the indication**
VALIDATED	VALIDATED	VALIDATED	VALIDATED	VALIDATED	VALIDATED

INVESTMENT CASE DE-RISKED

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Positive Interim Analysis in Phase III insomnia trial

Positive signal for efficacy and safety after 244 patients — de-risks remaining Phase III trial to completion.

Significant Commercial Partner for Australia

Sandoz, world's largest generics pharma — US$3M upfront, US$16M in milestones, 14–19% tiered royalties.

Clear registration pathway with the TGA

Unique Australian OTC pathway for CBD; trial designed and conducted for TGA submission.

Global licensing potential

Large commercial opportunity in numerous jurisdictions allows for potentially multiple licensing transactions

Significant commercial potential in Australia

9.5M Australians experience insomnia; addressable market potential >US$125M per annum. Global opportunity larger

Money in the bank

Proforma cash position of $6.25M , provides strong position to execute deals following a positive interim readout

Stop thinking if this will work – start thinking what this could be

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Questions Welcome

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