ASX Announcement
5 February 2026

Avecho CEO Dr Paul Gavin to present at Euroz Hartleys Healthcare Forum

Melbourne, Australia, 5 February 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to advise that CEO Dr Paul Gavin will present at the Euroz Hartleys Healthcare Forum on Thursday 5 February 2026.

The Company's presentation (attached below) provides an update on Avecho's Phase III CBD insomnia trial, which is nearing completion of recruitment ahead of the interim analysis, and the Company's broader outlook for 2026.

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

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

2026 Euroz Hartleys Healthcare Forum

Avecho

Developing the first pharmaceutical cannabidiol product for insomnia

www.avecho.com.au | ASX:AVE

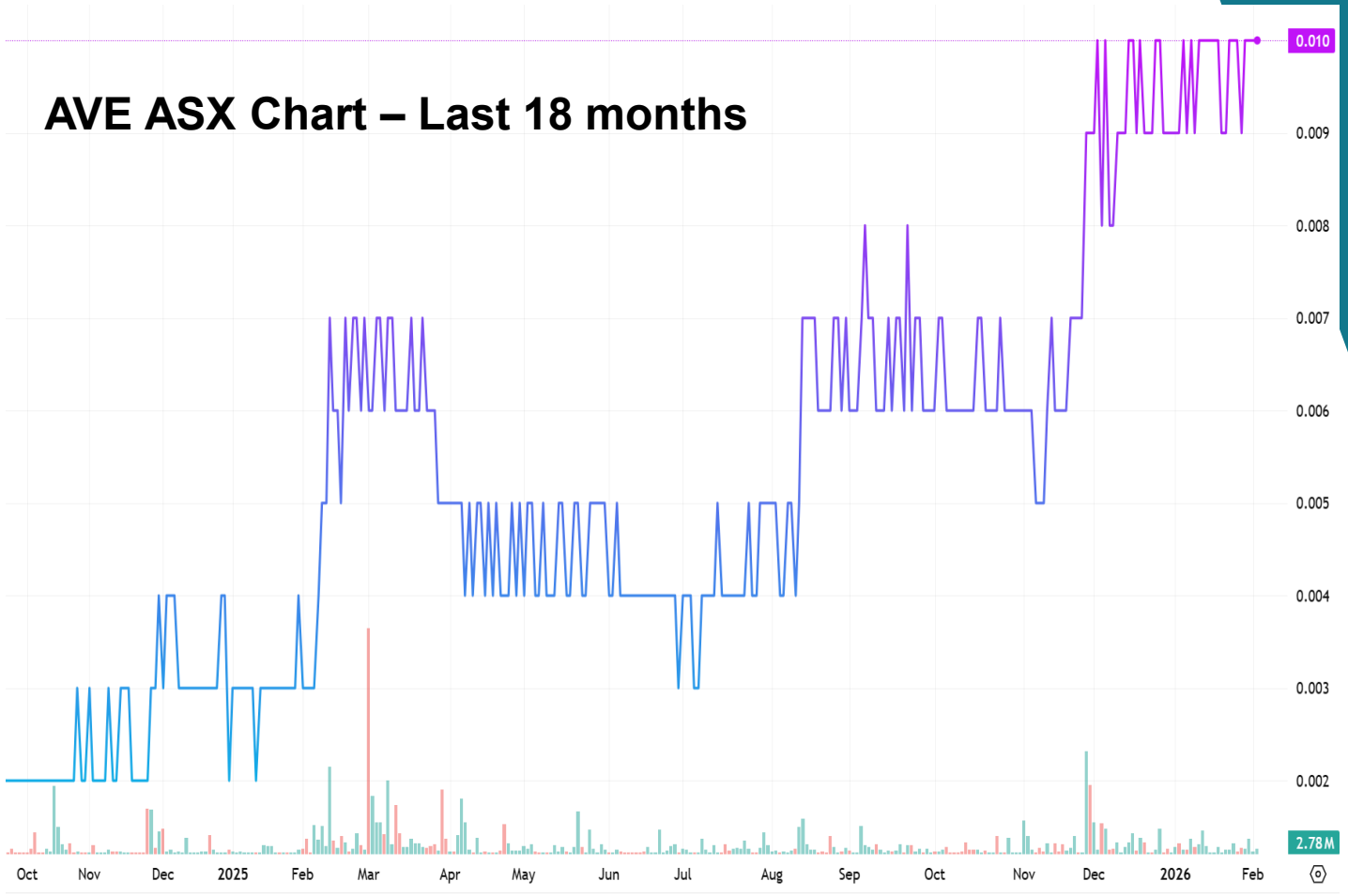
Company Snapshot

AVE Corporate Summary	
Total shares[1]	3.67 Bn
Total options[2]	2.29 Bn
Cash (end Q4 2025) **+ R&D tax credits Q2 2026**	A$4.7 M $1.8M
MCAP[3]	A$36.73 M

[1] Top 20 Shareholders = 36.20%

[2] Various exercise price and expiry dates – AVEOA (2.15B; price 1.2c) expire 10th May 2026

[3] As of February 3rd 2026



Management and Board

Dr Paul Gavin
Chief Executive Officer

An inventor of the TPM delivery platform

Developed multiple TPM enhanced products to pharma license

Dr Greg Collier
Chairman

Taken drug from discovery to approval

Multiple commercial transactions

Sold Chemgenex to Cephalon for $230M

Dr Ross Murdoch
Non-Exec Director

CEO of Extractas

Held Executive & Senior Management roles at Shire Pharmaceuticals, Avecho and Prana

Matt McNamara
Non-Exec Director

CIO of Biotech Fund Horizon 3 Healthcare

Previous Executive roles at BioScience Managers, SciCapital.

Kathy Connell
Non-Exec Director

Led ANZ External Innovation at Johnson and Johnson, Sanofi

Executed over $US1B worth of deals in ANZ

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Summary

Phase 3 Opportunity

Drug Product

- Cannabidiol (CBD) capsule for insomnia enhanced with TPM
  - TPM increases drug absorption
- CBD capsule in a pivotal Phase 3 clinical trial

Insomnia indication

- Difficulty falling or staying asleep
- Affects 10-30% of the population

Market Opportunity

- Unique Australian over-the-counter approval pathway with TGA
- 9.5M Australians with insomnia; Market potential >$US 125M pa
- 237M people worldwide suffering from insomnia

Commercial Validation

- Licensing deal with Sandoz AG for Australia
- Attractive terms: substantial revenue upon commercialization

Upcoming Milestones

- Phase 3 interim analysis
- Licensing deals in further territories
- Phase 3 study completion

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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

Insomnia costs the US economy
$63 billion
each year

Based on the current global populations up to
237 million
people are affected

1. https://www.thegoodbody.com/insomnia-statistics/

Pharmaceutical cannabidiol is valuable

Cannabidiol (CBD) is the major non-psychoactive component of medicinal cannabis

Only one pharmaceutical CBD product is approved by the FDA (Epidiolex®)[1]

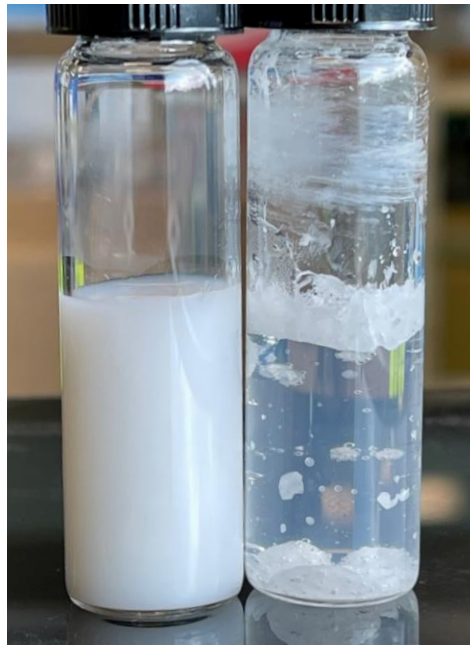
- Epidiolex was developed by GW Pharma
- Approved for rare childhood epilepsy conditions[2] – rarely prescribed
- GW Pharma was acquired for **$7.2Bn USD** by Jazz Pharma (2021) to obtain Epidiolex[3]
- One of the **side effects of Epidiolex is sleepiness**[1]

No pharmaceutical CBD products are approved for sleep, but insomnia remains one of the most prevalent indications targeted globally by medical cannabis and consumer CBD products[4]

Sources:
1. https://www.epidiolex.com/
2. https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms
3. https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-acquire-gw-pharmaceuticals-plc-creating
4. Suraev, A.S., et al.. Cannabinoid therapies in the management of sleep disorders: A systematic review of preclinical and clinical studies. Sleep Medicine Reviews 2020b (53); 101339

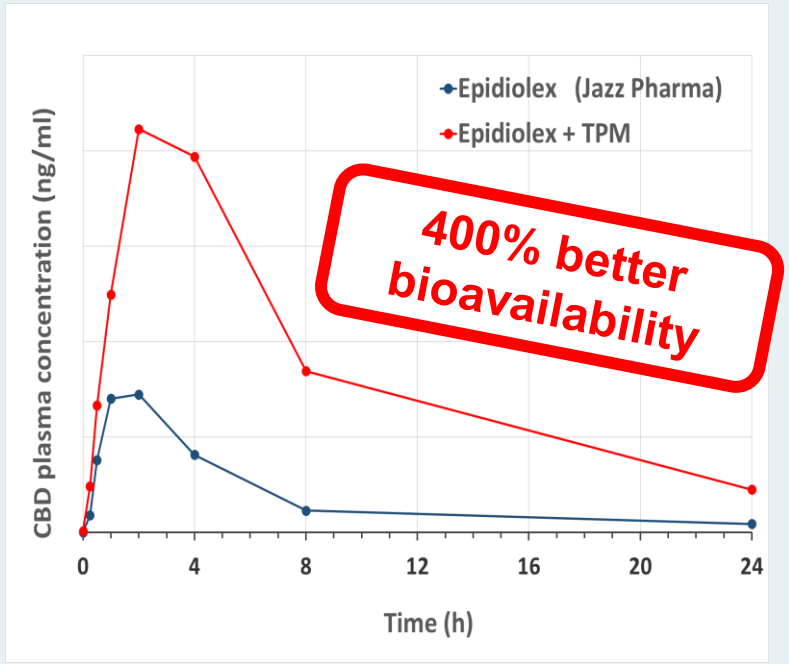
Avecho's TPM increases CBD absorption

TPM increases CBD Solubility



With TPM Without TPM

TPM increases oral CBD absorption



- Single dose of Epidiolex or Epidiolex + TPM
- CBD in blood quantified over time

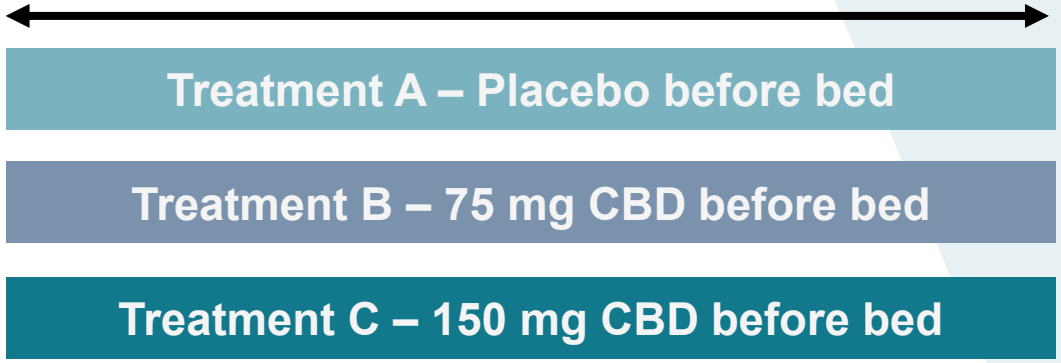
- Avecho developed CBD TPM capsule
- Pharmaceutically preferred dosage form
- Increased absorption
- GMP manufacture – stable for 3 years
- Patent protection to ~2040

Phase 3 Study Design

Two **independent** primary endpoints (only need one to work) measuring improvement in insomnia;

- Improvement measured by insomnia severity index (ISI)
- Improvement in subjective sleep efficiency (sSE)

8 week treatment period



Assessments include

- Daily sleep diary to record nightly sleep.
- Sleep questionnaire every two weeks.
- Secondary endpoints related to anxiety

Study Protocol

- Developed using EMA and FDA guidance documents
- Based upon recently approved insomnia medications
- Targeting 519 patients; 210 to interim analysis
- Interim read-out expected H1 2026

Compared to recent studies, Avecho's trial uses;

- **The maximum dose allowed for OTC (150mg)**
- **Larger patient numbers (519 patients)**
- **Higher insomnia scores required for inclusion**
- **Longer dosing period (8 weeks)**
- **An interim analysis (after 210 patients) to calculate required patient numbers**
- **Methods to minimise the placebo effect**

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Australian TGA Opportunity

- Australia's TGA now allows oral CBD products to be registered as over-the-counter medicines[1]
- OTC medicines are available from a pharmacist without a prescription, a significant commercial advantage
- Australians spend ~$5B per year on OTC medicines[2]
- Avecho met the TGA to discuss the Phase 3 protocol and future submission
- New Zealand has adopted the same approach and Canada is considering a similar pathway

Avecho met with the TGA in 2024 to discuss the Phase III protocol and future submission plans. The TGA had no requested changes

Sources:
1. https://www.tga.gov.au/news/media-releases/over-counter-access-low-dose-cannabidiol
2. Medicines in the health system, Australian Institute of Health and Welfare (2022)

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Forecast market size

It affects 10-30% of the population, with 10-15% of the population classified as chronic[1,2]

9.5M
people in Australia experience symptoms of insomnia

3.6M
people in Australia classified as chronic insomniacs

Initial forecasts for OTC CBD in Australia are

>$US 125M per year[3]

Globally

Big Business: Global insomnia market was valued at $US 5.22B in 2024[4]

Global mental health market valued at $US 375.2B in 2022[5]

1. https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
2. The societal and economic burden of insomnia in adults: An international study, RAND, 2023
3. Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021
4. https://www.marketresearchfuture.com/reports/insomnia-market-545#:~:text=How%20much%20is%20the%20insomnia,forecast%20period%2C%202024%2D2032.
5. https://finance.yahoo.com/news/532-billion-mental-health-market-144800771.html

SANDOZ

Swiss-based multinational pharmaceutical company spun out of Novartis
(Market Cap ~$US 34Bn)

Global presence with a portfolio of ~1,500 approved medicines and annual revenues >$US 10Bn

Focus on driving access to make a real difference for patients worldwide[1]

Purpose

Pioneering access for patients

Vision

To be the world's leading and most valued biosimilars and generics company

Estimated Global Impact

>800 million*
Patient treatments provided annually

>$US 18Bn savings
Generated annually in EU & US ^

~$US 400Bn#
Estimated annual social impact of key medicines

1. Sandoz Integrated Annual Report 2023. Available from: https://prod.cms.sandoz.com/sites/spare53_sandoz_com/files/Media%20Documents/2023-Integrated-Annual-Report.pdf. P.3365. (accessed April 2024)

* Calculated based on volumes sold, the daily dose as defined by the World Health Organisation, the treatment duration and certain adjustments from internal medical experts

^. AAM as data source for US healthcare system savings; IQVIA Midas data source for EU healthcare system savings

#. Based on 2023 WifOR Institute analysis

Avecho | SANDOZ Partnership

Key Terms[1]

- Sandoz acquires exclusive rights to Avecho's pharmaceutical cannabidiol capsule for insomnia in Australia.
- Avecho to receive upfront, milestone and royalty payments:

$US 3M
(~A$4.8M) up front payment received upon signing

$US 16M
(~A$24.4M) in development milestones **prior to** commercial sales

Tiered royalties ranging from **14% to 19%** on net sales

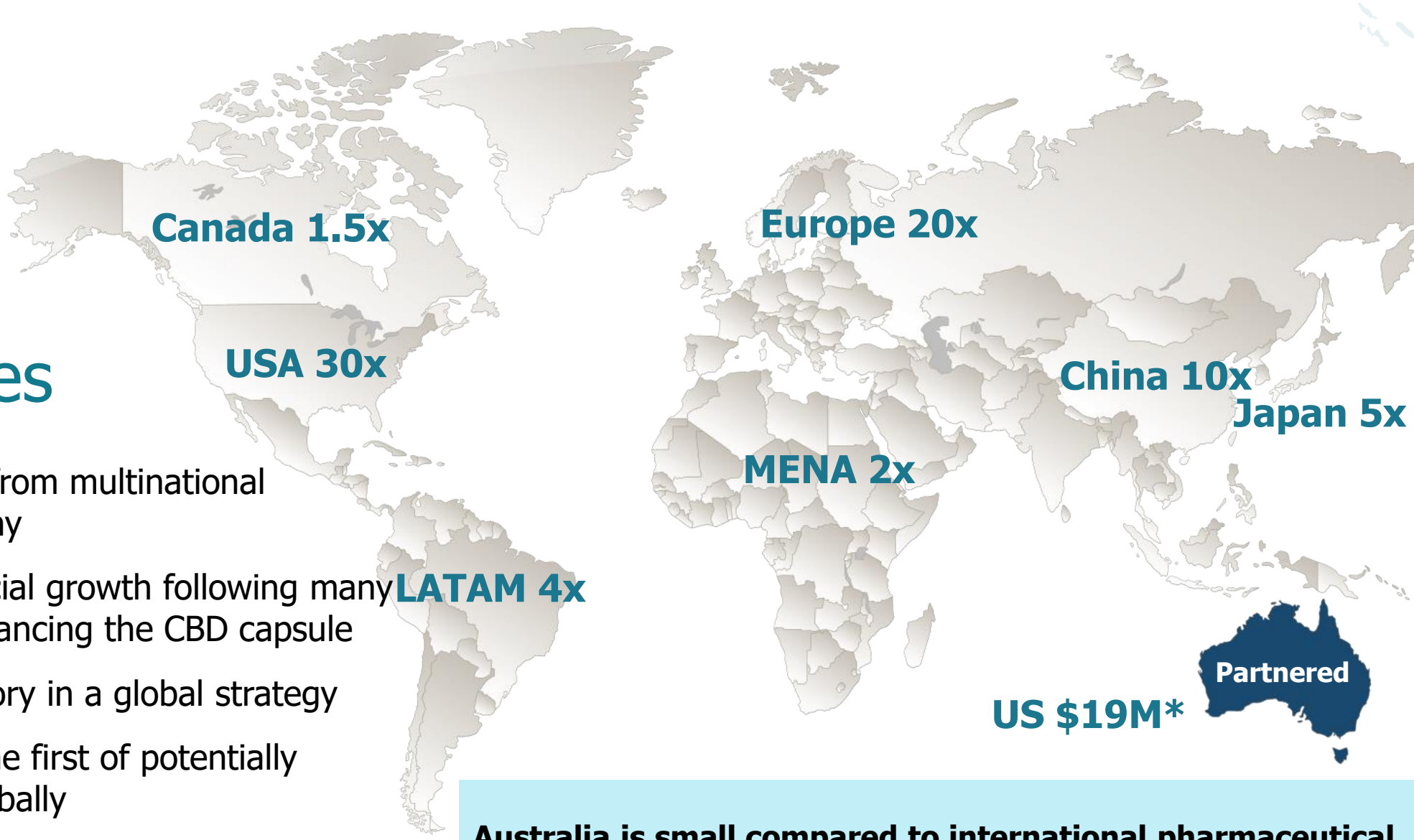
- Avecho responsible for the completion of the Phase III trial and supporting development activities
- Sandoz responsible for the sales, marketing and commercialization of the product in Australia.
  - Sandoz to purchase the product from Avecho for commercial sale
- Sandoz granted a right of first refusal for commercial rights to territories outside Australia and/or new clinical indications for the CBD capsule.

Sources:
1. https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02920239-3A663194&v=undefined

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

*For upfront and potential milestone payments prior to commercial sales



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

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Next Major Milestone: Interim Analysis

Enrolment Targets

519 patients in total; ~210 to interim analysis

Progress

190 patients on study medication by December 18th 2025, needed a further ~20

Interim Analysis Completion

On track to recruit all patients required for interim by end Feb 26

Interim analysis result available H1 2026

Interim analysis to show either:

1. Phase III study isn't working – stop the trial
2. Phase III study is working - requires X number of patients to complete

The path ahead

Significant re-rate anticipated with positive interim results

Major stackable inflection points

Pharma deal for Australia	Complete
Phase III - Complete Recruitment Interim Analysis	Feb 2026
Phase III - Complete Patient Dosing	Apr 2026
Phase III - Result Interim Analysis!	Jun 2026
Phase III Completion	26/27
Deals for multiple global territories	Discussions ongoing
TGA submission and Approval	27/28*
Commercial Launch Australia	2029*

*Indicative timeline estimates, reliant on time to Phase 3 completion and duration of TGA review

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Questions Welcome

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