



AusBiotech Invest 2025

Developing the first pharmaceutical
cannabidiol product for insomnia

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

Avecho

Insomnia is a major problem worldwide¹

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.

Existing medications have safety issues and significant impairment to next day function

10-30%

of people across the world experience insomnia

Based on the current global populations up to

237 million

people are affected

Insomnia costs the US economy

\$63 billion

each year

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



Avecho's TPM increases oral CBD absorption

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

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

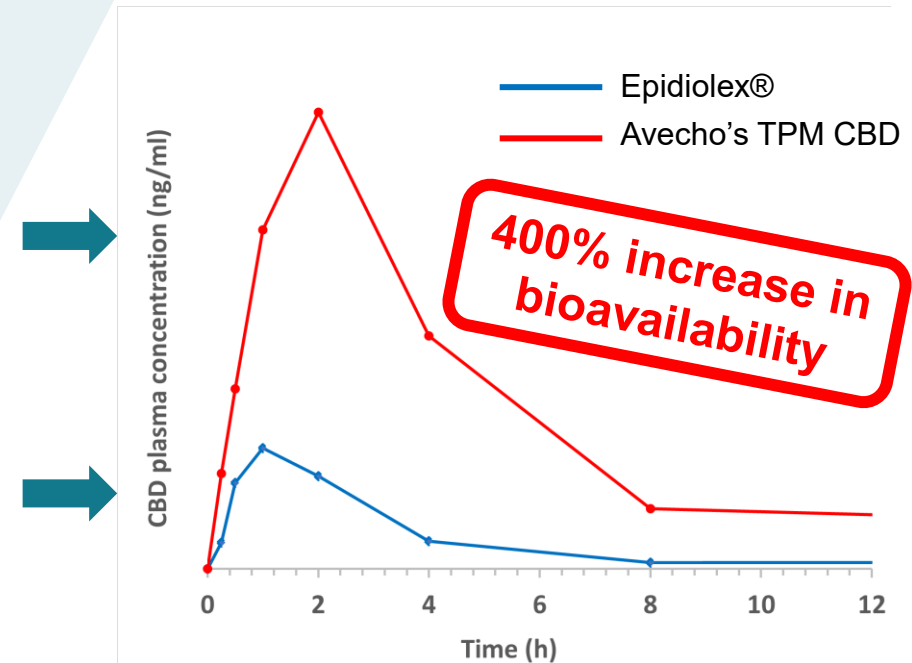
- Epidiolex was developed by GW Pharma
- Approved for rare childhood epilepsy conditions² – rarely prescribed
- GW Pharma was acquired for **\$7.2Bn USD** by Jazz Pharma (2021) to obtain Epidiolex³
- One of the **side effects of Epidiolex is sleepiness**¹



Epidiolex® Oil



Avecho's TPM CBD capsule



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 products⁴

¹Sources:

1. <https://www.epidiox.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

Australian TGA Opportunity

- › TGA now allows oral CBD products to be registered as over-the-counter (OTC) medicines¹
- › OTC medicines are available from a pharmacist without a prescription, a significant commercial advantage
- › Australians spend ~\$5B per year on OTC medicines²
- › Avecho met with TGA in 2024 to discuss our Phase III protocol and future submission plans. TGA had no requested changes.

Ongoing phase 3 Trial

- › Largest randomized, placebo-controlled trial in the world assessing CBD for insomnia
- › Developed using **FDA and EMA** guidance documents
- › Targeting **519 patients; 210 to interim analysis**
- › **160** patients on study medication: **~50** required
- › Interim read-out expected **H1 2026**

Major inflection point for Avecho

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)



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 year³

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



Globally

Big Business: Global insomnia market
was valued at \$US 5.22B in 2024⁴

Global mental health market valued at
\$US 375.2B in 2022⁵

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 26Bn)

- Global presence
- Portfolio of **~1,500 approved** medicines
- Annual revenues **>\$US 10Bn**
- **>800 million** patient treatments annually

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

Licensing Deal

- Sandoz acquired exclusive rights to Avecho's pharmaceutical cannabidiol capsule for insomnia in Australia (ROFR ROW) March 2025²
- 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

- Sandoz to purchase the product from Avecho for commercial sale

Sources:

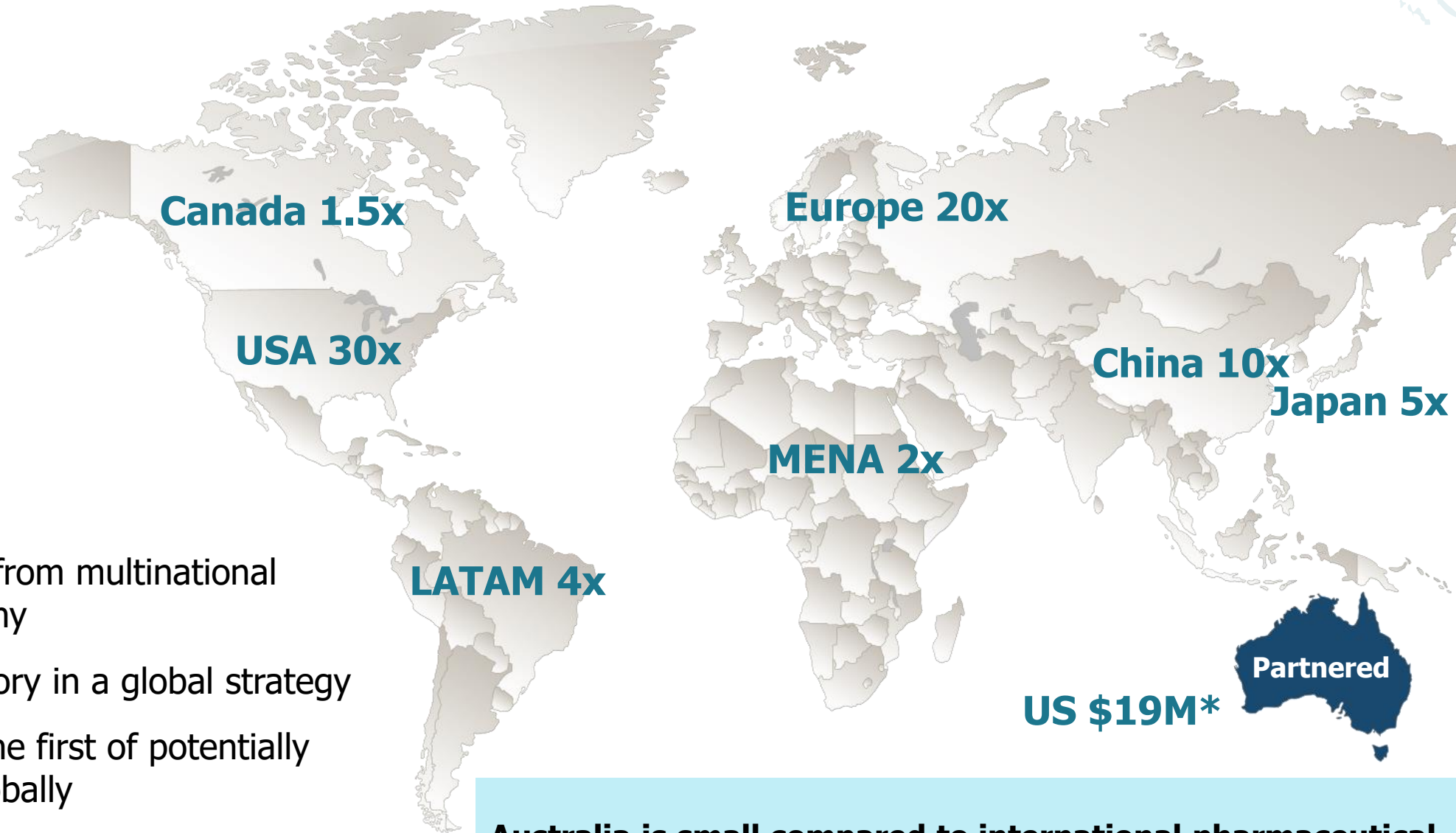
2. <https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02920239-3A663194&v=undefined>



Commercial Growth

- › Commercial validation from multinational pharmaceutical company
- › 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 sales¹



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

The path ahead

Significant re-rate anticipated with positive interim results

Major stackable inflection points



Pharma deal for Australia

Complete



Phase III Interim Analysis

H1 2026

Phase III Completion

26/27



Deals for global territories

Discussions ongoing



TGA Submission and Approval

27/28*



Commercial Launch Australia

2028*



Development/submission for ROW (FDA, EMA, etc)

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



Avecho

Questions Welcome



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