



Avecho

Bioshares

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Safe Harbour Statement

Avecho
Biotechnology

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Focus Points



- Ongoing Pivotal Phase III trial testing proprietary cannabidiol (CBD) capsule for insomnia
- Unique Australian regulatory and commercial opportunity - too good to ignore
- Licensing deal with Sandoz AG for the Australian commercial rights

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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

Australian Government (2023)²:

Prioritise sleep health as a national priority as important as fitness and nutrition

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/>
2. <https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf>



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 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



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.epidiolex.com/>

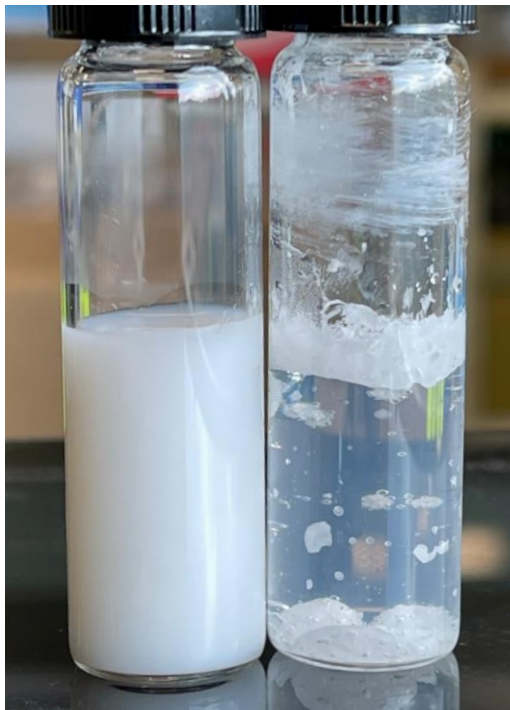
2. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms>

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

CBD Solubility



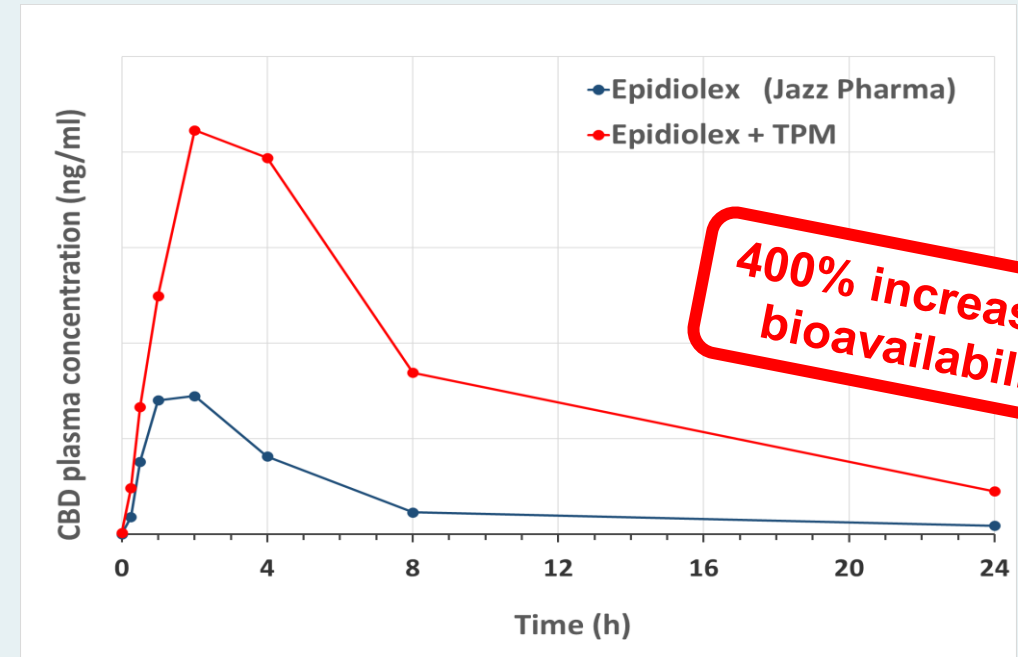
With TPM

Without TPM



20 years of learning into one product

Avecho's TPM increases oral CBD absorption



- Single oral dose of Epidiolex (FDA approved CBD oil) or Epidiolex + TPM administered to dogs
- Blood collected over time and the amount of CBD in blood quantified

Australian TGA Opportunity

- › Australia's TGA now allows oral CBD products to be registered as over-the-counter medicines¹
 - › Safety: You can't overdose on CBD
- › OTC medicines are available from a pharmacist without a prescription, a significant commercial advantage
- › Australians spend ~\$5B per year on OTC medicines²
- › New Zealand has adopted the same approach and Canada is considering a similar pathway

A large, dark blue silhouette of Australia is positioned on the right side of the slide. It is surrounded by teal-colored geometric shapes, including a large triangle at the bottom and a vertical rectangle on the right, which together form a stylized map of the region. A purple rectangular box is overlaid at the bottom right of the map.

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)



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 25Bn)

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

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

Focus on driving access to make a real difference for patients worldwide¹

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

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Partnership



Key Terms

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) in
upfront payment
upon signing



\$US 16M
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.

Extensive due diligence required to execute the deal



Phase 3 Study Design



Study Protocol

- › Largest Phase III insomnia trial using CBD in the world
- › Developed using **EMA and FDA** guidance documents
- › Based upon recently approved insomnia medications
- › Built like an adaptive design Phase II/III trial - **519 patients; 210 to interim analysis**

8 week treatment period



Treatment A – Placebo before bed

Treatment B – 75 mg CBD before bed

Treatment C – 150 mg CBD before bed



Assessments include

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

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**

Next Major Milestone: Interim Analysis



Enrolment Targets

519 patients in total; 210 to interim analysis



Progress

131 patients on study medication by July 28th, need a further ~80



Interim Analysis Completion

On track to complete all patients required for interim by end 2025

Interim analysis result available early 2026

Three possible findings of interim analysis:

1. Phase III study isn't working – stop the trial
2. Phase III study is working - requires X number of patients to complete
3. Phase III study is working so well, we can stop now and call it a completed Phase III

Summary



- We have an indication of national/global importance – insomnia/mental health
- With a product the Australian Government is desperate to get approved – OTC CBD
- With a local market anticipated to be huge
- In a pivotal Phase III trial heading toward an interim analysis
- Partnered with a global pharmaceutical company for Australia – ROW rights still to be monetized



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Questions Welcome



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