ASX Announcement
16 November 2026

Avecho presents at BIO-Europe – Europe's largest biopharmaceutical partnering event

Key Highlights

- CEO Dr Paul Gavin presented Avecho at BIO-Europe 2026 in Cologne, Germany (9–11 November 2026), one of the largest international biopharmaceutical partnering conferences.
- Avecho held 40 partnering meetings with potential licensees over the three days of the conference.

Melbourne, Australia, 16 November 2026: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") advises that CEO Dr Paul Gavin presented at BIO-Europe 2026, held in Cologne, Germany from 9 to 11 November 2026.

BIO-Europe is Europe's flagship biopharmaceutical partnering event, bringing together senior business development, licensing and investment executives from pharmaceutical and biotechnology companies around the world.

The Company's presentation (attached) provides an update on Avecho's pivotal Phase III trial of its TPM®-enhanced cannabidiol (CBD) soft-gel capsule for insomnia, which is now recruiting its final cohort following the interim analysis announced in June 2026, and the Company's strategy to license the product in territories outside Australia.

Partnering meetings

During the conference, Avecho held 40 partnering meetings with potential licensees. These included continued discussions with parties already engaged with the Company, as well as meetings with new parties.

The meetings follow the positive interim analysis of Avecho's pivotal Phase III trial announced in June 2026, in which the independent Data Monitoring Board unanimously recommended that the trial continue to its originally planned size of 519 participants without any increase, and the recommencement of recruitment for the trial's final cohort.

Avecho will continue to progress these discussions and will keep the market informed in accordance with its continuous disclosure obligations. There is no certainty that any discussion will result in a transaction.

Avecho Chief Executive Officer Dr Paul Gavin said:

"BIO-Europe was a productive three days for Avecho. With the interim analysis behind us, we came to Cologne with a materially de-risked Phase III program, and that was reflected in the level of engagement. We met with parties we have been in discussions with for some time, as well as a number of new parties, and we will now follow up on those conversations."

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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].

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-

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

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.

BIO-Europe 2026
Cologne, 9–11 November



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Developing the first pharmaceutical cannabidiol product for insomnia

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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.

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Where Avecho sits today

Proprietary product

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

Large, growing indication

- >850 million adults with clinically significant insomnia. Today's hypnotics carry dependence, next-day impairment and overdose risk

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.

Partnered for Australia

Looking for commercial partners for ROW

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Insomnia is a major problem worldwide

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.



>850 million
adults have clinically significant insomnia[1]

~1 in 3
adults report insomnia symptoms[2]

Lost productivity, US alone
$US 207bn
per year[3]

Psychiatric comorbidity, untreated insomnia **40%**[4]

1. Benjafield AV et al. Estimation of the global prevalence and burden of insomnia. Sleep Med Rev 2025;82:102121 (16.2% of adults).
2. Morin CM, Jarrin DC. Epidemiology of insomnia: prevalence, course, risk factors, and public health burden. Sleep Med Clin 2022;17:173–191.
3. RAND Europe. The societal and economic burden of insomnia in adults: an international study. 2023 (US$207.5bn).
4. Grandner M et al. The burden of untreated insomnia disorder in a sample of 1 million adults. BMC Public Health 2023;23:1481 (40.1% vs 13.2% in controls).

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]

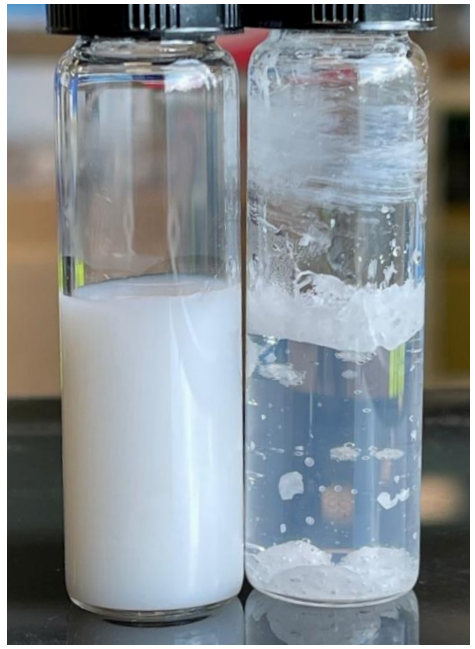


No pharmaceutical CBD products are approved for sleep, but insomnia remains one of the most prevalent indications targeted globally by medical cannabis and consumer CBD products[4]

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

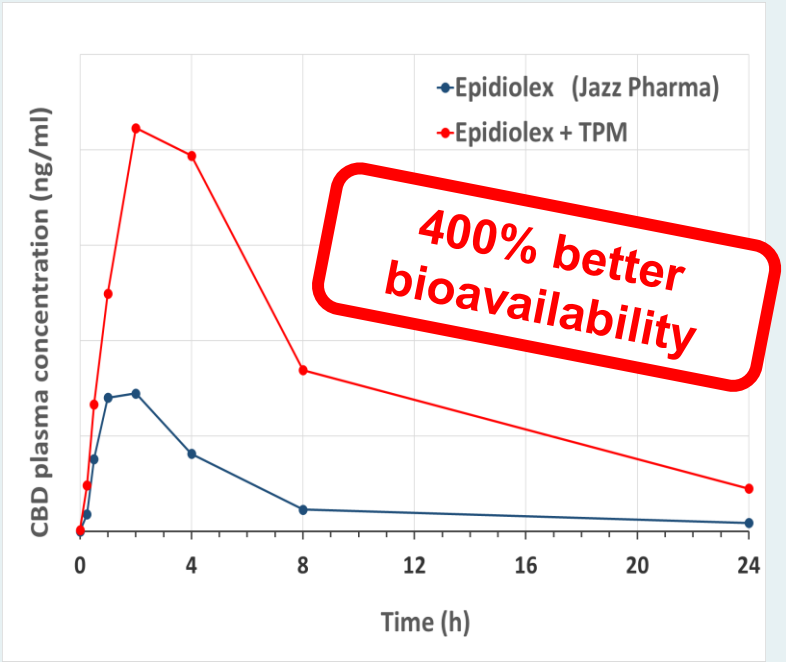
Avecho's TPM increases CBD absorption

TPM increases CBD Solubility



With TPM Without TPM

TPM increases oral CBD absorption

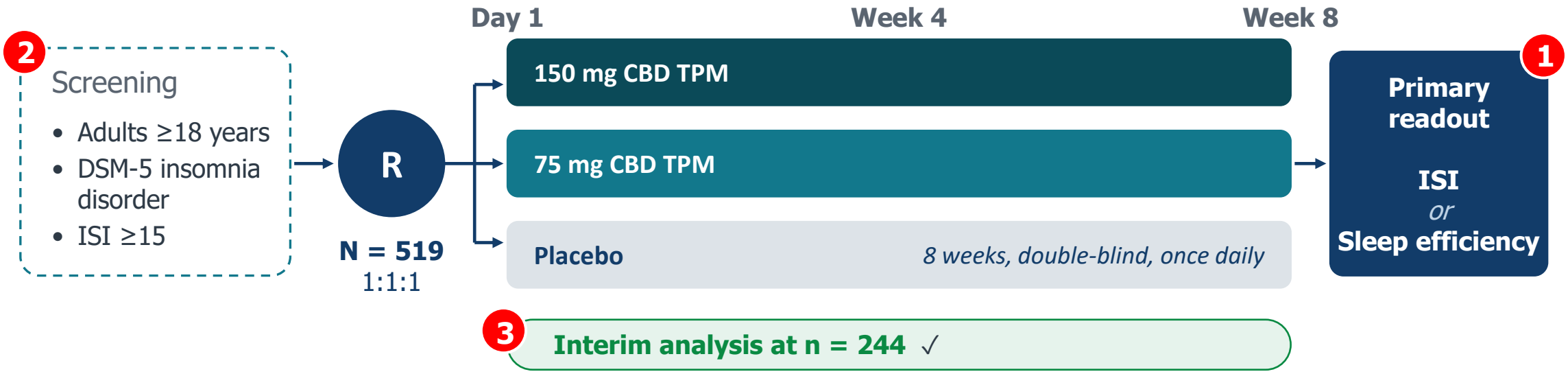


- Preclinical (dog): Single dose of Epidiolex or Epidiolex + TPM
- CBD in blood quantified over time



- Avecho developed CBD TPM capsule
- Pharmaceutically preferred dosage form
- Increased absorption
- GMP manufacture – stable for 3 years
- Patent protection to ~2043

Pivotal Phase III built 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

Placebo-effect control mechanisms

The protocol is designed to minimise the placebo effect — the most common reason for insomnia trial failure

03

Adaptive design interim analysis

Allows participant numbers to be increased mid way through the trial – ensuring we dose the optimal number of participants for success

THE DE-RISKING EVENT

Pivotal Phase III passed its interim analysis

What the independent DMB could recommend at n = 244

Stop	No worthwhile effect: futility
Continue, but enlarge	Effect smaller than assumed: more patients needed
Continue unchanged	Effect assumptions tracking at least in line with expectation **OUR RESULT**

0

serious adverse events

across all 244 participants dosed, at both dose levels

UNANIMOUS **The trial continues to 519 participants, sample size unchanged.**

A continuation recommendation is a decision to proceed, not a measure of efficacy. Efficacy is determined only at trial completion.

EMERGING PRODUCT PROFILE

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Hypnotic-range efficacy, minus the liabilities

	Prescription hypnotics, incl. orexin antagonists	CBD-TPM target profile
Efficacy	Established	**Powered on an approved-hypnotic assumption; interim tracking at least in line**
Serious adverse events	A recognised class burden	**None across the 244-participant interim cohort**
Dependence & scheduling	Benzodiazepines and Z-drugs: dependence-forming. Orexin antagonists: still US Schedule IV[3]	**WHO: no potential for abuse or dependence[1]**
Next-day impairment	Next-day and driving warnings across the class, orexin antagonists included	**Not expected mechanistically; measured prospectively in the Phase III**
Overdose & tolerability	Overdose a recognised risk for benzodiazepines and Z-drugs	**WHO: generally well tolerated, good safety profile[1]**
Anxiety	Z-drugs and orexin antagonists are not anxiolytic	**Anxiolytic potential in published human studies[2]; measured in our Phase III**

Prospective profile, contingent on the completed Phase III; efficacy is determined only at completion. No unblinded efficacy or arm-level safety data have been disclosed.

1. WHO Expert Committee on Drug Dependence, 40th meeting, June 2018: cannabidiol critical review. 2. Blessing EM et al. Cannabidiol as a potential treatment for anxiety disorders. Neurotherapeutics 2015;12:825–836.
3. US DEA proposed rule to transfer suvorexant, lemborexant and daridorexant to Schedule V, Federal Register, 11 August 2026 (pending).

A neuropsychiatric molecule, starting with sleep

01

Insomnia and anxiety travel together

In a US cohort of 1 million adults, anxiety was recorded in 29% of people with untreated insomnia, versus 9% without.[1] Sedative load and dependence risk constrain hypnotic use in these patients.

02

CBD is now approved for anxiety

July 2026: India's CDSCO approved a synthetic CBD oral solution (Leiutis Pharmaceuticals) for mild-to-moderate anxiety disorders.[2] The first regulatory approval of CBD in anxiety.

03

Anxiety is measured in our Phase III

Anxiety (Beck Anxiety Inventory) and pre-sleep arousal are secondary endpoints in AVE047-22, read out at trial completion. A data foundation for future development.

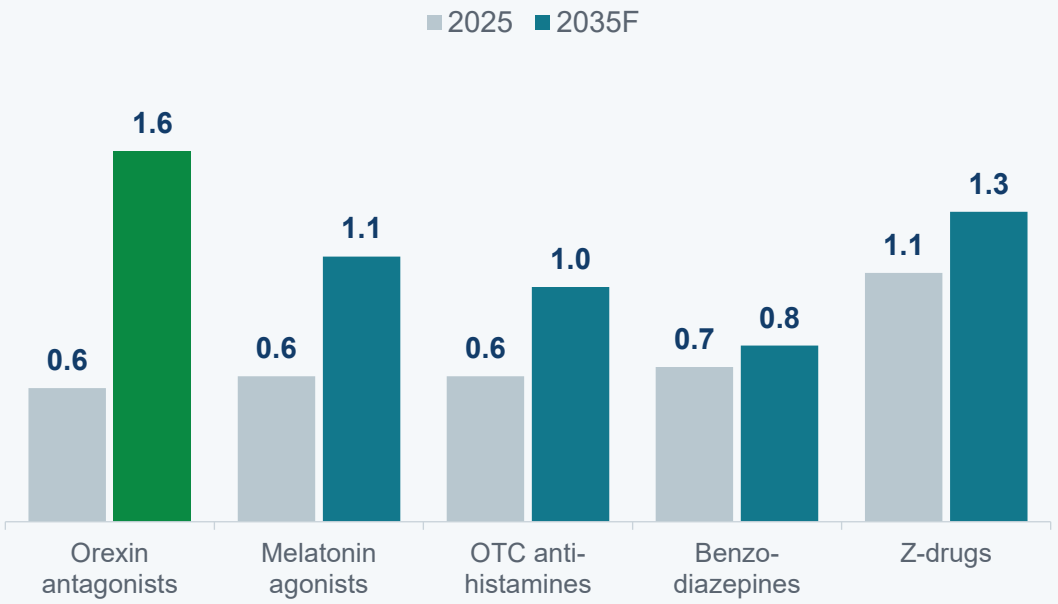
Insomnia first. Anxiety and insomnia comorbid with mental-health conditions are natural expansion paths.

AVE047-22 enrols adults with insomnia disorder; people with clinically significant anxiety or depression at screening are excluded. The DMB has provided no read on secondary endpoints.
1. Grandner M et al. BMC Public Health 2023;23:1481 (29.2% vs 8.5%). 2. CDSCO approval announced by Leiutis Pharmaceuticals, July 2026.

Growth markets: insomnia and neuropsychiatry

Insomnia drug market by class, US$bn[1]

US$4.1bn → US$6.8bn by 2035, ~5% a year. **Orexin antagonists: ~11% a year.**



2.2x QUVIVIQ, the newest orexin antagonist: sales CHF 61m → 134m in 2025[2]

US$14.6bn J&J acquires Intra-Cellular Therapies (2025)[3]

US$14bn Bristol Myers Squibb acquires Karuna Therapeutics (2024)[4]

Schedule V DEA proposes down-scheduling orexin antagonists (Aug 2026)[5]

The signal the market is moving to safer mechanisms, and big pharma is investing in neuropsychiatry.

1. Global Market Insights, Insomnia Therapeutics Market (published summary). 2025 class values from reported shares; orexin antagonist 2035 value derived from the reported 10.7% CAGR. 2. Idorsia FY2025 results. 3. J&J, January 2025. 4. BMS, announced December 2023. 5. US DEA proposed rule, Federal Register, 11 August 2026 (pending).

Layered protection around a known molecule

The molecule	CBD itself is not patentable. A well-characterised active with a known safety profile, sourced as pharmaceutical-grade synthetic API.
TPM technology	Proprietary excipient technology, manufactured and supplied by Avecho. Know-how and supply control persist beyond patent life.
CBD-TPM product	Formulation patents granted in the US (to ~2043), Europe and Japan (to ~2041).
Supply chain	Commercial supply being established now for the Sandoz launch in Australia: GMP capsule manufacture, with TPM supplied by Avecho. Partners join a supply chain already in build.
Next layer	Further, data-specific protection to be pursued once the full Phase III dataset is in hand, plus regulatory data protection on approval in each territory.

The moat **A partner licenses the product, the data and the supply chain, not just a patent.**

PARTNERING

The right partnership, territory by territory

What Avecho brings

- A pivotal Phase III, completed by Avecho
- Finished-product supply through our manufacturing chain, including proprietary TPM
- Patent protection in the major markets

What we build together

- The registration package for your territory
- Additional clinical or bridging studies as each regulator requires, e.g. polysomnography, elderly or local-population studies
- A development plan shaped with you, ahead of the pivotal readout

What the partner brings

- Regulatory leadership to register a new medicine locally
- Commercial capability to launch it and capture its full value
- A presence in insomnia, CNS or neuropsychiatry, or the ambition to use this product as the way in

Already chosen by Sandoz **Australian rights licensed after extensive due diligence: US$3M upfront, up to US$16M in milestones, 14–19% tiered royalties.**

Seeking: the right commercialisation partner for each territory, with territorial, regional or global ex-Australia rights.

Avecho



Let's talk partnering

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