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ASX Announcement
27 May 2025

Chair's Address & CEO Presentation

Melbourne, Australia, 27 May 2025: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") attaches the Chair's Address and the Chief Executive Officer's presentation for the Annual General Meeting of 27 May 2025 to be held at Grant Thornton Offices, Collins Square, Tower 5, Level 22, 727 Collins Street, Melbourne VIC 3008 at 1.00pm (AEST).

For enquiries, please contact
Melanie Leydin
Company Secretary
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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

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Chair's Address

Dear Shareholders,

I am delighted to share an update on behalf of Avecho Biotechnology Limited for our Annual General Meeting ("AGM") today.

Earlier this year, global pharmaceutical company Sandoz AG ("Sandoz") made a significant upfront investment in Avecho's proprietary TPM®-enhanced cannabidiol ("CBD") soft-gel capsule, licensing the commercial rights to the product in Australia.

Sandoz is a strong, global partner for our Company – and sets us up for success, providing tangible resources, expertise and established commercial distribution networks.

We remain on track to become the first first company to bring an approved CBD sleep treatment to the Australian over the counter ("OTC") pharmacy market, strengthened by this validation from a global pharmaceutical leader.

Key Achievements

> Sandoz AG Deal

In March 2025, we secured financial backing from one of the world's most well-established pharmaceutical companies, Sandoz – a Swiss-based multinational with a portfolio of over 1500 approved medicines and annual revenues greater than US $10Bn.

Partnerships with pharmaceutical companies of this calibre are not formed lightly—particularly when the product involves molecules derived from cannabis, which carries significant investor relations and public perception considerations for any global player.

However, the commercial potential of our CBD capsule is substantial, and the strength of the business case behind it was compelling. So much so that Sandoz, after thorough deliberation, could not afford to ignore the opportunity. With this agreement, Sandoz has become the largest pharmaceutical company globally to publicly commit to the development and future commercialization of a pharmaceutical-grade cannabinoid product.

Securing this partnership required passing months of rigorous due diligence by the Sandoz team. They scrutinised our science, our trial design, our preliminary data, and our team. Their willingness to commit significant resources prior to the availability of Phase III data should provide shareholders with immense confidence.

Sandoz has now provided an upfront payment US $3M, with a further US $16M plus royalites committed in development milestones prior to commercial sales. This immediate injection of capital ensures that our Trial is now fully funded through to the critical interim analysis.

Successful registration of a pharmaceutical CBD product for sleep will provide access to the global insomnia market estimated at more than US $5.22Bn[1] – with Sandoz first in line to capitalise on this opportunity with us. The commercial framework we have established with Sandoz creates an excellent benchmark for future licensing across international markets with other major players too.

Avecho remains the only company positioned to register an over-the-counter cannabidiol product with the TGA in Australia. With the backing of a major international pharmaceutical company, we now have the regulatory expertise and distribution capabilities to maximise this opportunity.

[1] https://www.marketresearchfuture.com/reports/insomnia-market-545#:~:text=How%20much%20is%20the%20insomnia,forecast%20period%2C%202024%2D2032.

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Australia is just the start and the commercial validation of a deal with Sandoz has already piqued the interest of additional pharmaceutical companies for the territories available overseas.

> Phase III Clinical Program: CBD Soft-Gel Capsule

Avecho is currently navigating the final stages of clinical validation and patient recruitment for our CBD soft-gel capsule for the treatment of insomnia.

The Trial is the largest sleep study of its kind, recruiting 519 patients across sites around Australia**.** As of December 2024, approximately 70 participants had received medication – but soon after, we received ethics approval to revise the inclusion/exclusion criteria. This has broadened the recruitment criteria to include previously ineligible participants who had expressed interest in the study.

Our Company also added three new trial sites to the study, one on the Gold Coast and two in Sydney, which were activated with the signing of Sandoz. These sites have now begun screening and recruitment of patients.

In addition to these measures, Sandoz has volunteered to aid recruitment by using pharmacy access and patient advocacy groups with whom they are closely affiliated with. This is the final sprint to our interim analysis – and an exciting time.

Conclusion

On behalf of the Avecho team I would like to express our gratitude for your ongoing support – and patience too, as we have executed these important commercial milestones.

It is remarkable for a small Australian company to have licensed our product to one of the largest pharmaceutical companies in the world, prior to phase III results being available. We hope you appreciate the significance of this deal and the endorsement it represents of both our product, our trial, its commercial potential, and our team.

As Chairman I am enormously proud of the focus and determination of the Avecho team to deliver for our valued shareholders.

With thanks,

Dr Gregory Collier
Chairman of Avecho Biotechnology Limited

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CEO Presentation

27th May 2025

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Safe Harbour Statement

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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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Summary

Phase 3 Opportunity

Drug Product

- TPM-enhanced cannabidiol (CBD) capsule for insomnia
- In a pivotal Phase III clinical trial

Insomnia indication

- Difficulty falling or staying asleep
- Affects 10-30% of the population, with 10-15% classified as chronic

Market Opportunity

- Unique Australian OTC opportunity: Market potential >$US 125M per annum
- 3.6M Australians with chronic insomnia; 9.5M with symptoms of insomnia
- 237M people worldwide suffering from insomnia

Commercial Validation

- Commercial licensing deal with Sandoz for Australia
- Attractive terms: substantial revenue upon commercialization

Upcoming Milestones

- Interim Analysis
- Potential licensing deals in new territories
- Phase III completion

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SANDOZ

Swiss-based multinational pharmaceutical company spun out of Novartis
(Market Cap ~$US 22Bn)

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

SANDOZ

Strong Australian presence to efficiently and effectively execute

Australia's 2nd largest generics and biosimilars company with a dedicated team focussed on driving OTC medicines

Nationwide presence and strong partnerships with major pharmacy banner groups

Robust distribution network already in place, with the capability to supply every pharmacy nationally

47 person strong face-to-face sales team, nationally located to cover the vast Australian geography

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Avecho | SANDOZ Partnership

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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.

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Forecast market size

Insomnia is broadly defined as difficulty initiating or maintaining sleep

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]

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

Up to **237M** people are affected[4]

Global insomnia market was valued at **$US 5.22B** in 2024[5]

Global mental health market valued at $US 375.2B in 2022[6]

4. https://www.thegoodbody.com/insomnia-statistics/
5. https://www.marketresearchfuture.com/reports/insomnia-market-545#:~:text=How%20much%20is%20the%20insomnia,forecast%20period%2C%202024%2D2032.
6. https://finance.yahoo.com/news/532-billion-mental-health-market-144800771.html

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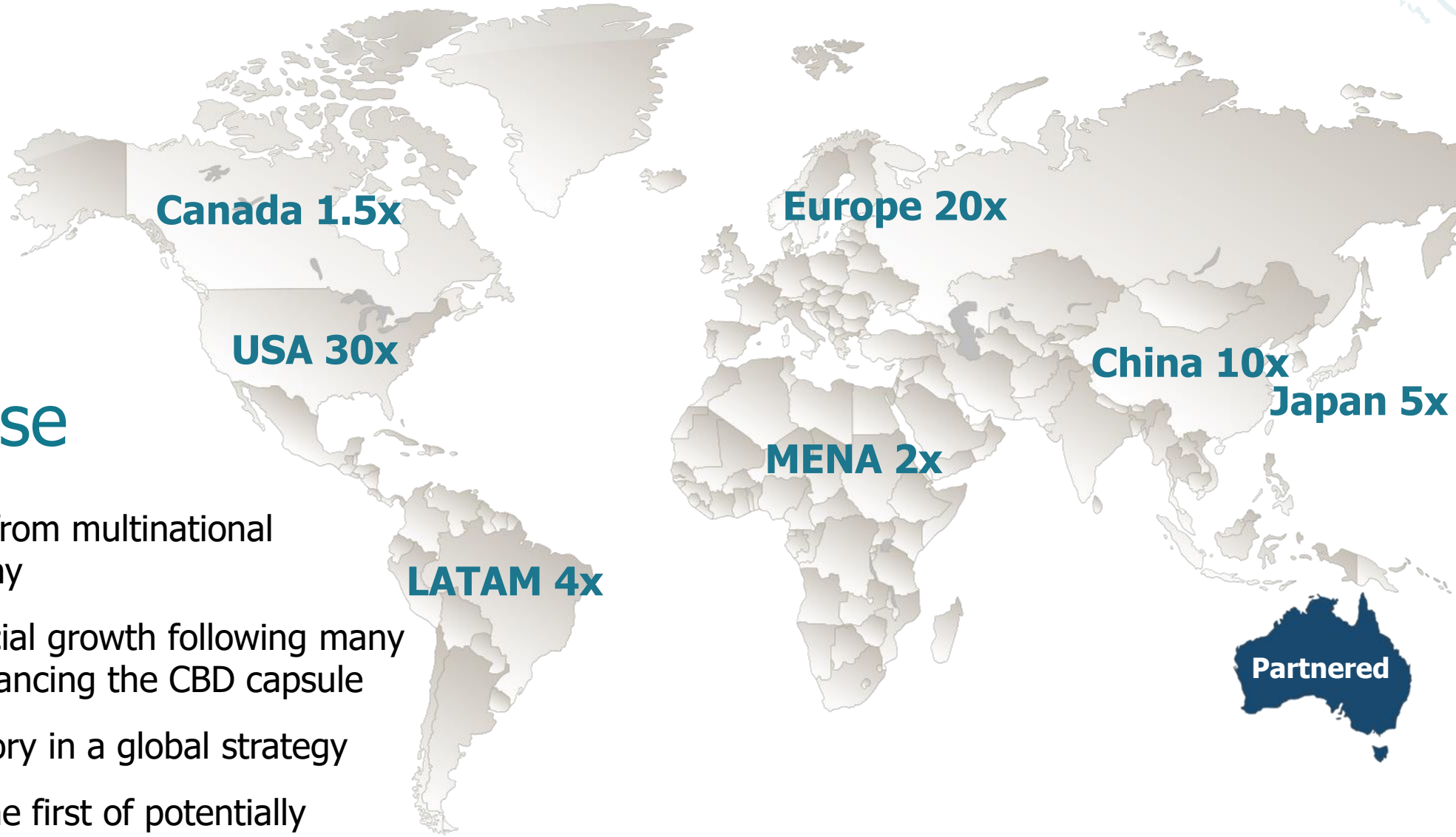
Commercial Growth Phase



- 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

Australian deal the benchmark for further territories

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Phase III Trial

Path Forward

⟵ 8-week treatment period ⟶

Treatment A – Placebo before bed

Treatment B – 75 mg CBD before bed

Treatment C – 150 mg CBD before bed

Enrolment Targets

519 patients in total; 210 to interim analysis

1st patient dosed

First patient dosed April 2024

Progress

70 patients on study medication by end Dec 2024; need further ~150

Lessons Learnt

Inclusion/Exclusion criteria

Types of clinical trial sites

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Next Major Milestone: Interim Analysis

Faster recruitment in 2025

- 70 patients on study medication by end Dec 2024; need further ~150
- Inclusion/Exclusion criteria revised - Previously ineligible patients now eligible
- Three new sites added: existing database (>400) of insomnia patients
- Sandoz to assist in patient recruitment

Interim Analysis Completion

- Aiming to complete all patients required for interim by end 2025
- Interim analysis result available early 2026
- Sandoz to help position interim analysis for TGA – early completion?

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Increasing shareholder value

Dimerix Case Study

Dimerix (ASX:DXB) are in a Phase III clinical trial for Focal Segmental Glomeruloscelosis (FSGS)

Orphan indication (<200,000 patients in the US)

1. **Phase III trial underway**: ~$26M market cap
2. **First licensing deal** (ANZ, EU, UK, Canada): ~$89M market cap (Increased 3.42x)
3. **Positive interim analysis**: ~$130M market cap (Further increased 1.46x)
4. **Capital raise**: ~$180M market cap (Further increased 1.38x)
5. **Second licensing deal** (MENA): ~$336M market cap (Further increased 1.86x)

Market cap increased **12.92x within 12 months**

Two subsequent licensing deals (Japan/USA)

Avecho entering similar window of opportunity on our Phase III trial

Company Snapshot

AVE Corporate Summary	
Total shares	3.17 Bn
Total options[1]	2.15 Bn
Cash (end Q1 2025)	A$6.6 M
MCAP[2]	A$12.69 M

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

[2] As of COB 23rd May 2025

AVE ASX Chart – Last 6 months

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The year in front of us

Partner

Complete

- Sign commercial partner for CBD insomnia product in Australia

Complete Trial

- Complete Phase III trial to interim analysis
  - Discuss results with TGA. Study completed?
  - Dosing further patients to completion

Partner

- Partner discussions for CBD product in further territories

Partnerships for further products

TGA

- Commence build of TGA submission dossier

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Questions Welcome

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