ASX Announcement
30 May 2024

Chair's Address & CEO Presentation

Melbourne, **Australia, 30 May 2024**: 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 30 May 2024 to be held on Grant Thornton Offices Collins Square, Tower 5, Level 22, 727 Collins Street, Melbourne VIC 3008 at 1.00pm (AEST).

For enquiries, please contact
Ms 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 major projects include delivering TPM® enhanced injectable, oral and topical products for the human health market and is also developing TPM® to enhance the feed efficiency and health of livestock.

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.

See more here - avecho.com.au

Chair's Address

Dear Shareholders,

I am delighted to share a Company update on behalf of Avecho Biotechnology Limited to coincide with our Annual General Meeting ("**AGM**") today.

This Financial Year (FY23-24) has been a testament to our focus and perseverance as we enter our pivotal Phase III clinical trial testing our TPM®-enhanced CBD soft-gel capsule for the treatment of insomnia.

We have now begun recruitment and dosing on the study, having already screened more than 1,700 prospective patients for eligibility, and are currently referring ~150 participants to clinical trial sites for final assessments prior to dosing. This trial is the largest study of its kind assessing cannabidiol for insomnia in Australia – and is aiming to support the registration of the first **CBD product for insomnia with the Therapeutic Goods Association ("TGA").**

Leveraging our established credentials as biotechnology innovators, with deep expertise in the design and execution of clinical studies, I believe the next 12-months will see Avecho's cannabidiol product emerge as a valuable asset in the global healthcare market – primed for partnerships and meaningful commercial growth.

Key Achievements

> Phase III Clinical Program: CBD Soft-Gel Capsule

Our Company has diligently prepared for and now executing a significant clinical trial for our CBD soft-gel capsule for the treatment of insomnia. We have very specific inclusion and exclusion criteria for the study, which will necessitate screening a large number of participants to find the ones that we need for our study. We have already screened over 1,700 participants and have found approximately 150 that appear eligible after the first round of screening. These subjects are now being referred to clinical trial sites to undergo final testing and commence dosing. Our first patient was dosed in April.

Our Company successfully raised AU$8m in a tough market to kick off this trial, thanks to the support of our valued investors.

The Trial is the largest sleep study of its kind, with the intention to recruit 519 patients across sites located in Melbourne, Sydney, Central Coast, Brisbane and Perth**.** The treatment groups are comparing nightly CBD doses of 75 and 150mg CBD with placebo over an 8-week dosing period.

This trial has been intentionally designed to meet the rigorous standards of key global regulatory agencies including the TGA, FDA, and EMA. Our ambition is to prove the efficacy of our enhanced cannabidiol formulation to become the first company to commercialise a cannabidiol treatment for insomnia as a registered pharmaceutical medicine.

The global insomnia treatment market represents a significant commercial opportunity, especially as research now shows that poor sleep is a major risk factor for mental health indications including depression. A safer, relatively benign sleep medication will position Avecho to become a major player in a variety of sleep related applications and capitalise on the commercial potential of this CBD soft-gel capsule, through direct sales, distribution agreements, and/or formal commercial partnerships too.

> Expanded Board: Kathy Connell

In late April, we welcomed Kathy Connell to the Avecho Board – an internationally recognised healthcare and life sciences leader with extensive investment and licensing expertise, who is ideally qualified to support the company in our efforts to realise the commercial potential of our Phase III clinical trial.

Kathy has a solid track record of high value deals across pharmaceuticals, medtech, vaccines, and consumer and digital healthcare for some of the world's largest companies. For the past 20 years, Kathy has held senior executive leadership, including 12 years at Johnson & Johnson as Senior Director, New Ventures ANZ. She also co-founded Medicines Australia's Pharmaceutical Australia Inclusion Group ("**PAIG**"), and was awarded BioMelbourne Network's Woman of the Year in 2018 for her leadership in supporting Australia's high priority strategic growth sectors of biotech, medtech and pharmaceuticals.

Today Kathy leads Korn Ferry's Healthcare and LifeSciences practice in Australia as Senior Client Partner and she is also a Non-Executive Director of BioNSW, the peak body for Life Sciences companies and professionals in NSW.

We are delighted to welcome Kathy to the team, and you will hear from her very soon to gain insight into her vision for our shared success.

> Recreational Cannabis: Significant Revenue Opportunity

Alongside our key focus of executing the Phase III clinical trial, we are pursuing lucrative business development ("**BD**") opportunities within the North American recreational cannabis market – a market which is projected to exceed sales of US$8.4bn by next year.

Our TPM-enhanced formulations have the potential to disrupt the current market, by offering established product manufacturers a pathway to increase the absorption of THC and the other cannabinoids/terpenes to enhance their effect.

Our research shows the inclusion of TPM in THC gummies can elicit an effect within 10 minutes, which is an attractive proposition for these well-resourced companies to set their products apart in a cluttered, high-demand market. Our BD conversations are ongoing and positive, and it is hoped Avecho will secure a cornerstone TPM-supply deal in CY2024.

Financial Outlook

Following our capital raise of AU$8m, Avecho has sufficient resources to progress the first stage of the Phase III clinical trial and will be reassessing our needs as the trial progresses. This will be further supported by our ongoing manufacturing program and commercial partnerships, which are focused on revenue generation.

Conclusion

On behalf of the extended Avecho team I would like to express our gratitude for your ongoing support. We have a bright path ahead – we are part of a very small group of Australian innovators who have reach the milestone of executing a Phase III clinical trial, and this is where the journey gets exciting, and we have the capacity to positively impact the health of our community.

With thanks,

Dr Gregory Collier
Chairman of Avecho Biotechnology Limited

ANNUAL GENERAL MEETING

30TH MAY 2024

Avecho

www.avecho.com.au | ASX:AVE

SAFE HARBOUR STATEMENT

AVECHO BIOTECHNOLOGY

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.

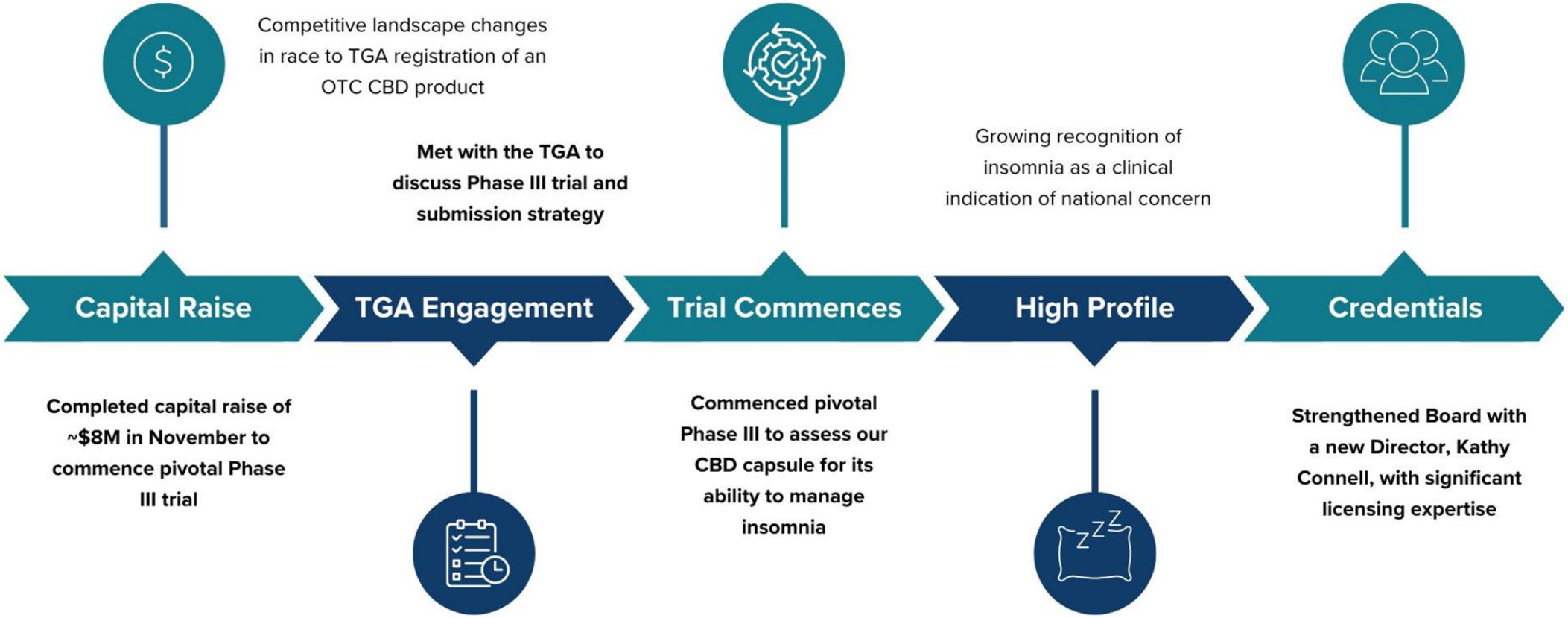
Actual results may differ from the expectations expressed in these forward-looking statements, and the differences may be material (whether positive or negative). The risks that may cause Avecho's actual results, performance or achievements to be materially different from those expressed or implied by 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.

CLEAR STRATEGIC FOCUS

1. Complete pivotal Phase III clinical trial for CBD capsule containing TPM® technology

2. License this and other TPM cannabinoid products into global markets

THE YEAR BEHIND US



COMPANY SNAPSHOT

AVE Corporate Summary	
Total shares	3.17 Bn
Total options[1]	2.37 Bn
Cash (end Q1 2024)	A$4.6 M
MCAP[2]	A$12.68 M

[1] Various exercise price and expiry dates
[2] As of COB 28th May 2024

Management Team

Dr Paul Gavin
Chief Executive Officer

Dr Roksan Libinaki
Chief Operating Officer

Melanie Leydin
Chief Financial Officer
& Co. Sec

Board

Dr Greg Collier
Chairman

Dr Ross Murdoch
Non-Executive Director

Matt McNamara
Non-Executive Director

Kathy Connell
Non-Executive Director

INSOMNIA HAS BECOME A MAJOR PROBLEM WORLDWIDE

Insomnia is broadly defined as difficulty initiating or maintaining sleep.

Insomnia affects 10-30% of the population, with 10-15% of the population classified as chronic.

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.

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[1]

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

INSOMNIA IS OF INCREASING INTEREST IN AUSTRALIA

In Australia[1]:

- **40%** of Australians getting less sleep than they need
- **59.4%** Experience symptoms 3-4 times per week
- Only **20%** report their sleep is uninterrupted
- Costs Australian economy $19.1 B per annum
- Australian insomnia market **~$250M per annum**

Avecho's CBD insomnia product is being developed at the perfect time

Bedtime Reading: Inquiry into Sleep Health Awareness in Australia[2]

Australian Government response to the Standing Committee on Health, Aged Care and Sport's report Bedtime Reading: Inquiry into Sleep Awareness in Australia.

Sources:
1. https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
2. https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf

CHANGING COMPETITIVE LANDSCAPE

Four Australian companies pursued Phase IIb/III clinicals in insomnia targeting TGA registration - three failed

Avecho is the last company in active clinical development

- Avecho's insomnia Phase III is significantly larger and more rigorous, maximizing the chance of a successful outcome.
- Recent results have validated Avecho's trial design decisions and de-risked the study
- Avecho placed to have one of the first CBD products approved by the TGA
- Without competitive products in the space, interested licensees will all need to deal with Avecho

PHASE III PROTOCOL REVIEW BY THE TGA

The TGA is yet to see a submission for OTC registration of cannabidiol

Avecho **met with the TGA** in February to discuss the Phase III protocol and future submission plans.

The TGA had **no requested changes** to the Phase III protocol, with Avecho's program described as "well thought out and robust".

Australian Government

Department of Health

Therapeutic Goods Administration

Avecho commenced Phase III trial with confidence after TGA review

PHASE III STUDY DESIGN

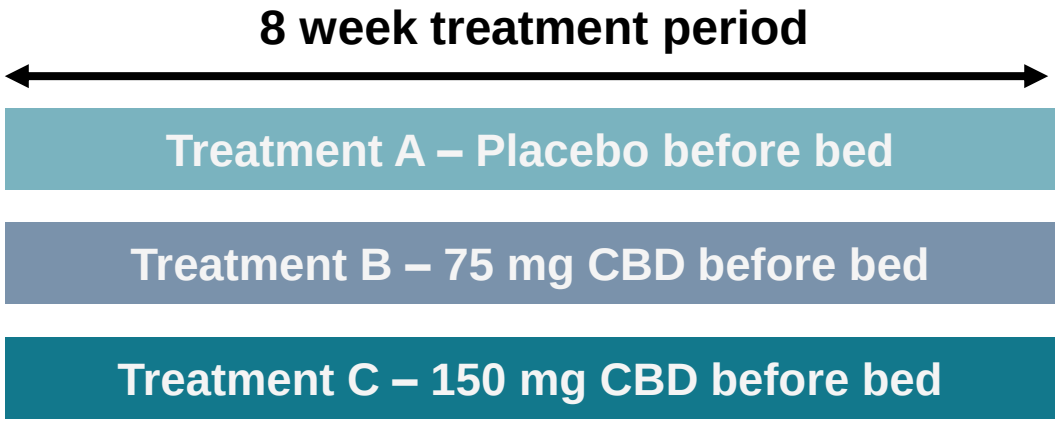
Based upon study design from FDA approved insomnia medications

Avecho's Phase III insomnia trial has been designed to maximise the chance of success. Compared to recent studies, Avecho's trial uses;

- **The maximum dose (150mg)**
- **Larger patient numbers (519 patients)**
- **Higher insomnia scores required for inclusion**
- **Longer dosing period (8 weeks)**
- **An interim analysis (after 219 patients) to calculate required patient numbers**
- **Methods to minimise the placebo effect**

Assessments include;

- Daily sleep diary to record nightly sleep.
- Sleep questionnaire every two weeks.
- Wearable device to record daily objective sleep data
- Secondary endpoints related to anxiety



PHASE III UNDER WAY

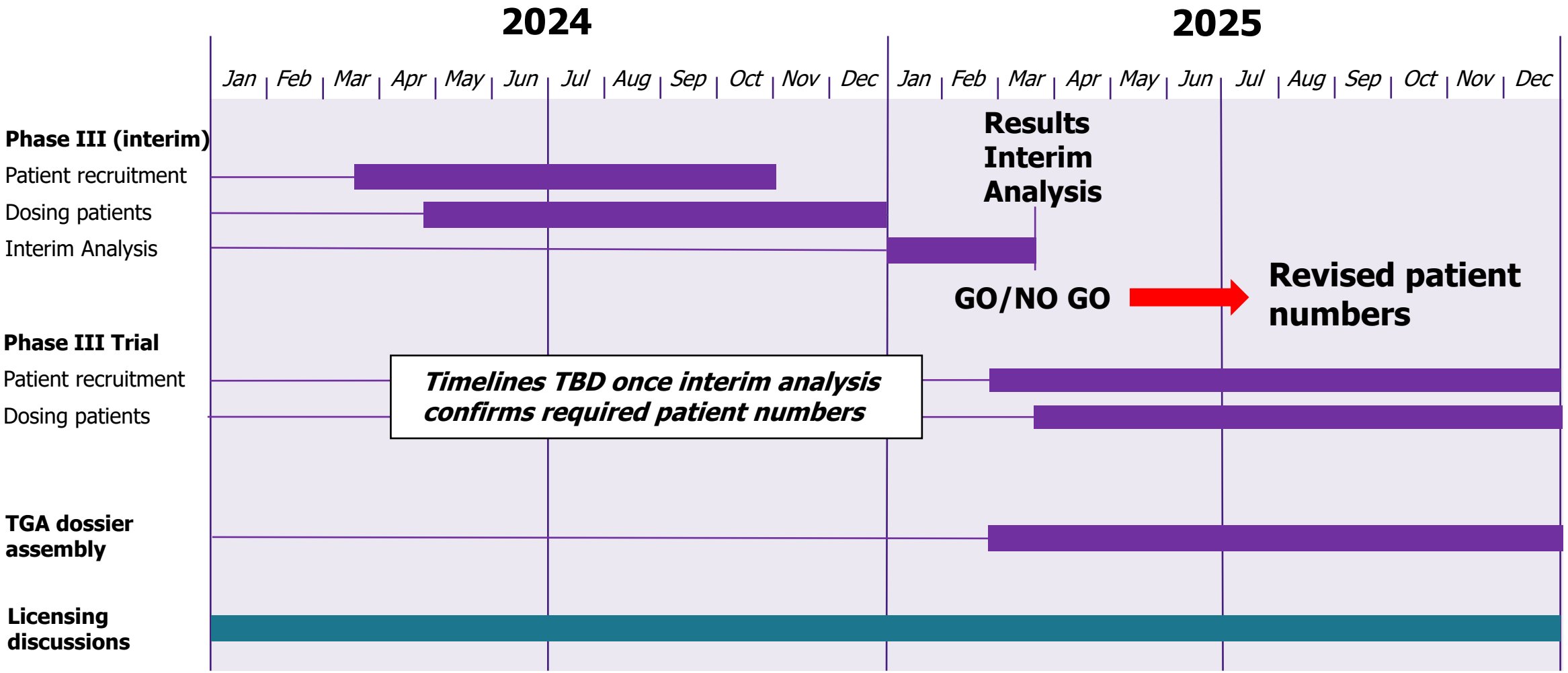
Trial Targets

- **519** patients in total
- **~219** patients complete dosing to interim analysis

- Trial commenced recruitment in March.
  - National media coverage has seen over 1750 people register interest in participating in the study
  - Of these, 151 fulfill rigorous inclusion/exclusion criteria
- 1st patient dosed in April
- Remaining patients being referred to sites now to confirm edibility and commence dosing

Eligible Patients so far

TIMELINES TO INTERIM ANALYSIS - MAJOR GO/NO GO



THE OPPORTUNITY

- De-risked Phase 3 trial underway – robust design reviewed by TGA
- Potential to be the first over-the-counter CBD sleep capsule – first mover advantage
- Outstanding partnering potential – significant interest from major pharmaceutical companies
- Avecho's TPM technology significantly increases absorption, efficacy & thus chance of success – key points of difference
- Addressing a major unmet need that costs the economy billions:
  - Insomnia costs the Australian economy $19.1 billion per annum[1]
  - Sleep economy & sleep aids market estimated to reach US$950.22 billion by 2032[2]

[1] https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
[2] https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html

NEW CANNABINOID PRODUCTS

THC TPM edibles

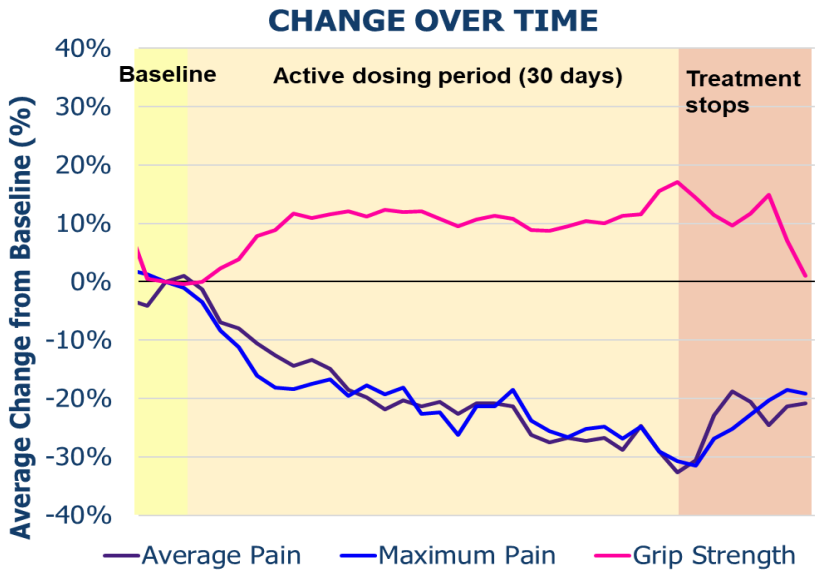
Avecho has completed the optimisation of TPM cannabinoid edibles

- Edibles have rapid onset, increased strength and longer duration
- Applications to the pharmaceutical, medicinal and recreational markets
- In discussions with partners regarding commercialisation

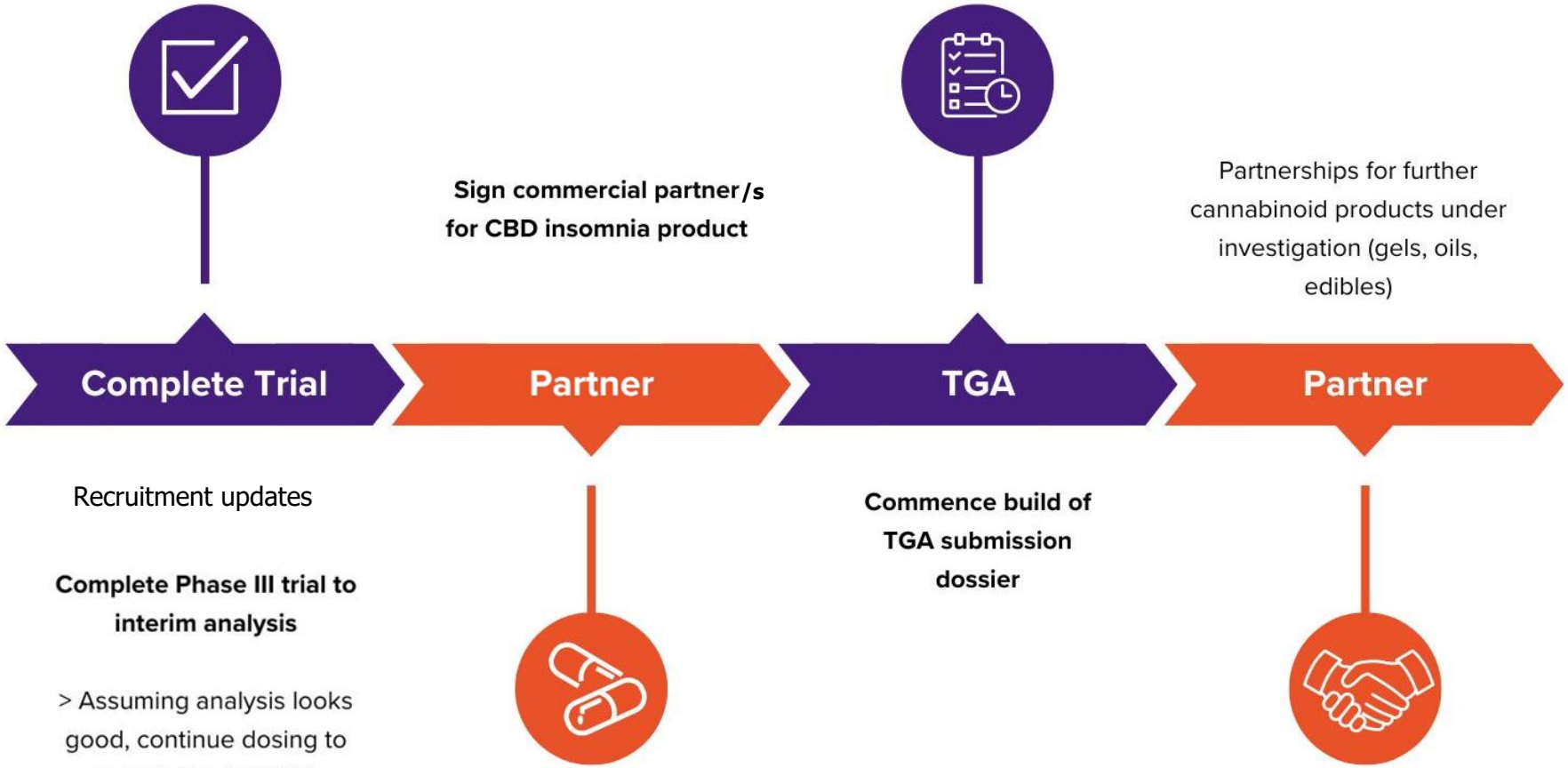
Topical Cannabinoid Gels

Avecho has completed the development of topical CBD gels tested in Phase II clinical trial for osteoarthritis

- Significant reductions in pain (*p<0.001)* over treatment period
- Significant improvements in grip strength (*p<0.001)* over treatment period



THE YEAR IN FRONT OF US



QUESTIONS WELCOME

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