

## **Bod enters into an agreement with Australia's leading respiratory and sleep institute for a Schedule 3 clinical trial of a new CBD product**

- **The study will be performed at the Woolcock Institute of Medical Research and led by Professor Ron Grunstein, Head of Sleep and Circadian Research**
- **Phase IIB clinical trial design has been finalised and will test the efficacy of Bod's unique CBD formulation over 12 week period**
- **Initiative is a crucial step to launch a product into Australia's Schedule 3 (Pharmacist Only) market – Schedule 3 CBD medicines can be sold to consumers by a pharmacist over the counter without a prescription**
- **Unlocks a large opportunity for Bod - Schedule 3 market valued at \$250m with the unregulated market estimated to be worth ~\$3.5Bn, demonstrating the potential penetration for Schedule 3 medicines**
- **Following product registration through the TGA, Bod will leverage established relationship with H&H and Swisse Wellness and other parties to drive sales growth**
- **Additional commercial opportunities underway – Bod to seek product registration with the European EMEA Union and the US FDA**

**Sydney, Australia – 22 September 2021:** Medicinal cannabis, CBD and hemp healthcare products company, Bod Australia Limited ("Bod", or "the Company") (ASX: BDA) is pleased to advise that it has entered into an agreement with leading Australian medical research group, the Woolcock Institute to undertake a phase IIB clinical trial for the development of a new CBD product. The Company will progress the development of the new product in line with Therapeutic Goods Administration (TGA) requirements, which will be made available to Australian consumers over the counter as a Schedule 3 (Pharmacist Only) medicine, as well as other key international markets.

The phase IIB clinical trial will test the efficacy of Bod's unique CBD formulation on symptoms associated with insomnia. The clinical trial is designed to be double blind, randomised and utilises both a parallel and placebo controlled group. The study will investigate the effect of the administration of a 50mg and 100mg per day oral CBD product, versus a placebo, over an 8-week period.

The study will be performed at the Woolcock Institute of Medical Research, Australia's leading sleep and respiratory research organisation, which has been ranked as the top specialist sleep and respiratory health research centre globally. The primary objective will be to investigate the effect on insomnia severity index scores in adults aged between 18 and 65 years old, who experience insomnia symptoms. As a secondary objective the trial will also determine objective sleep indices, including wake after sleep onset (WASO) as well as anxiety and stress levels. The trial will run for a total of 12 weeks, with approximately 200 participants.

The potential market opportunity for the product is significant and increasing. Critically, current pharmacological interventions for insomnia have major liabilities including abuse and dependence, questionable or uncertain efficacy, and hangover effects for a number of products.

The global insomnia market is estimated to reach \$5.48Bn by 2023, demonstrating a CAGR of 4.2% from 2017<sup>1</sup>. The estimated Australian market for Schedule 3 CBD products is \$250m and importantly, the unregulated market is estimated to be worth approximately \$3.5Bn, demonstrating the potential penetration for Schedule 3 medicines.

The finished product will be patentable, allowing Bod to progress potential licencing agreements with a number of companies involved in the schedule 3 market. The Company anticipates that the product, following all required regulatory processes, will be made available to Australian consumers and through the UK and other markets. The Company will focus on the Australian market initially, followed by registrations with the European EMEA Union and the US FDA.

Following the trial and TGA approval process, Bod will leverage its established relationship with Swisse Wellness

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parent company and exclusive global partner Health & Happiness Group Limited (“H&H”, HKSE: 1112) to progress product sales through Australian pharmacies. The Company will also progress discussions with other potential partners to ensure maximum promotional support for sales growth.

**Professor Ron Grunstein, Head of Sleep and Circadian Research at the Woolcock Institute of Medical Research said:** *“Given the need for alternative treatments for insomnia, it is critical to investigate the effect of CBD on sleep through a high-quality study.”*

**CEO Jo Patterson said:** *“We look forward to working with the Woolcock Institute and are confident that the results of the completed clinical trial will provide the required data to commercialise an over-the-counter Schedule 3 CBD product for Australian consumers. With Bod’s existing distribution networks, established partnership with H&H, relationships with other groups, and a rapidly developing market for Schedule 3 products with fewer side effects than existing offerings, the successful completion of this study will launch major opportunities for the Company.”*

**-ENDS-**

**About Bod Australia:**

Bod Australia Limited (ASX:BDA) Bod is a cannabis centric healthcare company.

With a global focus and a mission to innovate and transform the way we live and enjoy life.

Delivering premium, proven and trusted products for both the consumer markets and medicalmarkets.

Leading the way in research and development, through collaborations with research partners on clinical trial programs.

Committed to supporting the healthcare professional on Cannabinoid applications through education, research and trials.

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<sup>i</sup> <https://www.alliedmarketresearch.com/insomnia-market>

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