

## First patients enrolled for Schedule 3 CBD clinical trial for Australian Pharmacy Market

- Phase IIB clinical trial will investigate the efficacy of a uniquely developed CBD formulation on symptoms associated with insomnia in 200 participants over 8 weeks
- Trial is being undertaken with Australia's leading sleep research organisation, the Woolcock Institute of Medical Research
- Upon successful completion of the trial, Bod will have sufficient data to bring a new product to market, designed for Australia's Schedule 3 (pharmacist only) market
- Schedule 3 products can be sold over-the-counter by a pharmacist to consumers without a prescription – schedule 3 CBD market expected to reach \$250m capturing ~2m customers<sup>i</sup>
- Bod is one of a small number of companies advancing a clinical trial and aims to be one of the first Australian companies to introduce a low dose Schedule 3 CBD product
- Insomnia is also a lucrative opportunity – global market valued at US\$4.3Bn in 2020 and is estimated to grow strongly to US\$6.3Bn by 2030<sup>ii</sup>
- Trial also provides data for product registration with US FDA and European regulatory bodies

**Sydney, Australia – 10 May 2022:** Cannabis focused drug development and product innovation company Bod Australia Limited (“Bod” or “the Group”) (ASX: BOD) is pleased to advise that it has successfully enrolled first patients for its Australian-based planned Phase IIB clinical trial to investigate the efficacy of a new, unique Schedule 3 (pharmacist only) CBD formulation on symptoms associated with insomnia.

The clinical trial is being undertaken at the Woolcock Institute of Medical Research, Australia's leading sleep and respiratory research organisation and is one of the first registered in Australia for a Schedule 3 product. The Woolcock is continuing to actively recruit participants and interest can be expressed via the following link: <https://canrest.com.au/>

Bod's trial is a double blind, randomised and placebo-controlled investigation of the effect of administering a 50mg and 100mg oral CBD product per day, versus a placebo, over an 8-week period with over 200 participants (refer ASX announcement: 22 September 2021).

Upon completion of the study, Bod is confident that it will have sufficient data to progress product registration for Schedule 3 low dose CBD product with the Therapeutic Goods Administration (TGA) and for the final product to be added to the Australian Register of Therapeutic Goods (ARTG).

Expected to be one of the first companies in Australia to do so, the completion of this process provides Bod with a unique CBD product that can be sold over-the-counter by a pharmacist to Australian consumers who are seeking to alleviate symptoms of insomnia, without the requirement of a prescription. With a potential market valued at \$250m, the new product will unlock another channel for Bod to significantly increase domestic sales.

Importantly, the clinical trial has the potential to unlock opportunities in the growing global insomnia market, which is expected to reach US\$6.38Bn in value by 2030<sup>ii</sup>.

**CEO Ms Jo Patterson said:** *“We have achieved very strong interest from a number of interested participants and are excited to have successfully qualified and enrolled our first patients. Patient recruitment is ongoing and we look forward to providing additional updates in the coming months.*

*“This clinical trial is an important milestone for Bod. We expect that it will provide us with sufficient data to progress product registration and commercialise a new, low dose CBD product for the Australian market that does not have the major liabilities associated with current pharmacological interventions for insomnia, including abuse,*

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*dependence and hangover effects.*

*“Data generated from the initiative will also allow Bod to progress product registrations with the US FDA and European EMEA Union, significantly broadening Bod’s international footprint.”*

**This announcement has been approved by the Board of Bod Australia Limited.**

**-ENDS-**

**About Bod Australia:**

Bod Australia Limited (ASX:BOD) Bod is a cannabis focused drug development and product innovation company.

Bod is focused on progressing R&D and a defined clinical trial pathway to commercialise and deliver premium, scientifically proven and trusted products for the consumer and medical markets.

The company has a number of existing partnerships with large corporate groups and collaborations with leading research partners to advance the use of CBD.

**For more information please contact:**

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<sup>i</sup> <https://www.proactiveinvestors.com.au/companies/news/950040/australian-medicinal-cannabis-market-expected-to-exceed-2021-growthexpectations-hitting-200-million-mark-950040.html>

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