

## Bod Science reaches major milestone in Phase IIb clinical trial of unique CBD formulation for Australia's Schedule 3 market

- Phase IIb clinical trial has reached a major study milestone with trial screening now completed and randomisation to be completed by the end of the month
- Phase IIb clinical trial examines the efficacy of a unique CBD formulation on symptoms associated with insomnia in 198 participants over 8 weeks, undertaken by Australia's leading sleep research organisation, the Woolcock Institute
- Upon successful completion of the trial, Bod will have sufficient data to support a registration package, 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>
- Insomnia is 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>

**Sydney, Australia – 13 March 2023:** Cannabis focused drug development and product innovation company Bod Science Limited ("Bod" or "the Company") (ASX: BOD) is pleased to provide the following update on their phase IIb clinical trial for a new Schedule 3 CBD product for the Australian market being undertaken by Australia's leading sleep research organisation, the Woolcock Institute.

The trial assesses the efficacy of a uniquely developed Schedule 3 (Pharmacist Only) CBD formulation on symptoms associated with insomnia in 198 participants over 8 weeks. Schedule 3 products can be sold to Australian consumers over the counter without a prescription. Bod's trial is a double blind, randomised and placebo-controlled investigation of the effect of administering 50mg and 100mg oral doses of a proprietary CBD product per day versus a placebo, (refer ASX announcement: 22 September 2021). The Phase IIb clinical trial is the final step in R&D for the new product and is expected to provide sufficient data for application to register a low dose CBD product with the TGA. Bod's unique CBD formulation is presented in a soft gel format and utilises a patent protected encapsulation technology that improves the bioavailability of the CBD extract. The clinical trial is one of the first registered in Australia for a Schedule 3 product.

Completing a major milestone in the study, the trial screening has ended with randomisation expected to be completed by the end of the month (signifying Bod are moving into the final recruitment of last patients). 370 patients have been screened in total, with the Company on track to meet their recruitment target of 198 by end of March 2023.

In order to ensure a consistent patient base for the study and minimise variation, potential patients have undergone rigorous screening. Trial results have been collected on both a qualitative and quantitative data and utilised a new technology involving smart watches to enable more efficient data collection. On completion of the data capture from this last patient, the trial focus will immediately move to the analysis of the data.

Bod is confident that it will have sufficient data to progress to a registration under Schedule 3 for a low dose CBD product with the Therapeutic Goods Administration (TGA). In preparation for this, Bod is compiling the Registration Dossier in parallel with the trial progression, and therefore is well advanced for submission to the TGA.

With a potential market valued at \$250m, the new product will unlock another channel for Bod to significantly increase domestic sales, and 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.

**Management commentary:**

**CEO Ms Jo Patterson said:** *“The trial screening ending marks a major milestone for Bod in the clinical trial for our uniquely formulated schedule 3 CBD product. The quality and uniqueness of this product is in its’ soft gel format - which utilises a patent protected encapsulation technology, enhancing the bioavailability of the CBD extract.*

*“We are feeling confident as we move toward the next phase of the study – the analysis of trial data. We anticipate it will provide us with the necessary information to progress our product registration and commercialise a new, low dose CBD product for the Australian market.”*

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

**-ENDS-**

**About Bod Science:**

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

Bod is focused on progressing research and development with a defined clinical trial pathway to commercialise and deliver premium, scientifically proven and trusted products for patients and consumers.

The company has a number of existing partnerships with large corporate companies and collaborations with leading research organisations to advance the use of Cannabis related medicines with therapeutic indications.

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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>