

Quarterly Activities Report for the Period Ended 30 September 2023

Operational Highlights

- 'Last patient, last visit' milestone reached with all patients completing Phase IIB Can-Rest Insomnia trial
- Bod's becomes the only company with an advanced Schedule 3 Cannabidiol (CBD) product candidate for the Australian market
- Schedule 3 Clinical Trial CBD 100mg displays statistical significance over placebo for the primary endpoint of relief from short term insomnia with a p-value of 0.04 in the per protocol group
- Pharmacokinetic (PK) analysis showed that Aqua Phase CBD statistically outperformed CBD oil demonstrating 6 times greater bioavailability
- Bod completes acquisition of Aqua Phase following satisfaction of all conditions precedent
- Completion of a A\$1.9 million placement at an offer price of A\$0.08

Financial Highlights

- Net cash used in operating activities of \$1,918k
- Quarterly receipts from customers were \$499k
- The Group reported \$196k in quarterly sales revenue
- The Group held \$115k in cash as at 30 September 2023

Sydney, Australia – 31 October 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 activities for the three-month period ended 30 September 2023 (Q1 FY2024).

Operational Overview:

Phase IIB Clinical Trial of Schedule 3 CBD^{i,ii,iii}

During the quarter, the Company made significant advancements on its phase IIB clinical trial for a new Schedule 3 (Pharmacist Only) CBD product for the Australian market. The double blind, randomised and placebo-controlled trial was undertaken by Australia's leading sleep research organisation, the Woolcock Institute of Medical Research, assessing the efficacy of a uniquely developed CBD formulation on symptoms associated with insomnia in 208 participants over 8 weeks; 194 completed the study and 208 were included in the intent to-treat study population.

The study design randomised patients to receive daily doses of double-blind study medication of either CBD 50mg, CBD 100mg, or placebo. The statistically powered primary endpoint compared Insomnia Severity Inventory (ISI) scores for each dose compared to placebo. ISI is a patient questionnaire completed at baseline (before study medication), then at week 4 and week 8, with an objective to measure sleep using actigraphy data gathered from a smart watch worn by patients for 7 days before taking study medication, and then again for the final 7 days of study medication at Week 8. 'Last patient, last visit' milestone was reached in July 2023, with all patients completing the Can-Rest Insomnia trial, deemed as the final step in R&D for this new product.

Preliminary topline results were returned in September 2023, with CBD 100mg showing statistical significance over placebo for the primary endpoint from short term insomnia when tested at the 0.05 statistical significance level. A significance level of 0.05 indicates a 5% risk that the results occurred by chance. Safety and tolerability of both CBD doses were also assessed, with no safety concerns identified.

The clinical trial elevated Bod as a cannabis focussed drug development innovation company, with its unique CBD formulation in soft gel format considered as the only advanced Schedule 3 CBD product candidate for the Australian market. Schedule 3 products can be sold to Australian consumers over-the-counter (OTC) without a prescription. The Company will undertake pre-submission meetings with the TGA during Q2 FY23.

Acquisition of Aqua Phase Technology^{iv,v,vi}

Pharmacokinetic (PK) studies for the Aqua Phase delivery technology were completed during the quarter, with an initial PK study of 10 healthy volunteers conducted to evaluate the bioavailability of CBD in capillary blood samples.

A condition of the acquisition of the technology required successful proof in a human PK Study that Aqua Phase had a 30% or greater improved bioavailability as determined by the area under the curve compared with CBD oil. The results from the PK study were that bioavailability improved by **311% (over 4 times)**, statistically outperforming CBD oil. The maximum concentration (C_{max}) was statistically significantly higher at **277% (almost 4 times)** more than CBD oil. Aqua Phase as a technology applied to CBD, conferred enhanced absorption and bioavailability.

The second PK study used venous blood samples from 12 healthy volunteers, which returned consistent results with **6 times** greater bioavailability than CBD in oil. Importantly, it also showed that Aqua Phase is faster-acting, reaching its maximum concentration in two and a half hours versus six hours for CBD in oil. This significantly enhances its absorption and tolerability for users, with no taste or smell, with the potential to substantially improve existing oil-based drugs which are used to assist a number of health conditions.

The findings support the commercialisation of the Aqua Phase technology, concluding the research and development phase of work.

Following completion of all precedent conditions, Bod successfully acquired 'Aqua Phase' in August 2023, providing multiple opportunities to expand Bod's business. The initial payment was made under the acquisition agreement and Bod now holds the rights to use the 'Aqua Phase' invention. The Company has the potential to licence the technology to industries looking to solve absorption issues of drugs and ingredients for pharmaceutical companies, beverage manufacturers and consumer healthcare companies globally. Benefits offered by Aqua Phase are multi-dimensional, including lower-cost manufacturing, reduced dose and hence cost of medicines, reduction in adverse side effects, and improved therapeutic outcomes.

Placement to Raise \$1.9m^{vii,viii}

During the quarter, the Company announced firm commitments for an A\$1.9 million Placement of new, fully paid ordinary shares, at an offer price of A\$0.08. The Placement was backed by professional and sophisticated investors, with proceeds put towards research and development, as well as working capital.

In conjunction with the capital raising announcement, the Company held a live webinar and released an updated Investor Presentation discussing near-term value drivers.

Financial Overview:

Net cash used in operating activities of \$1,918k increased by \$288k (18%) on Q4 FY2023 (\$1,630k). Cash outflows during Q1 FY2024 were impacted by prepayments for new products which will commence selling during Q2 FY2024. The Q1 FY2024 net cash outflow was \$155k (9%) higher than the PCP (Q1 FY2023: \$1,763k) due to increased research and development payments of \$413k as two major clinical trials near completion, partially offset by reduced manufacturing payments due to timing differences of \$211k and reduced staff payments of \$81k.

Quarterly receipts from customers were \$499k, an increase of \$93k (23%) on the last quarter (Q4 FY2023: \$406k) and up \$32k (7%) on the previous corresponding period ("PCP") (Q1 FY2023: \$467k).

The Group reported \$196k in sales revenue for the quarter, a decrease of \$110k (36%) on the last quarter. Medical sales of \$131k decreased 21% on the prior quarter (\$165k), with volumes continuing to be impacted by the market's move towards THC dominant products. There were no sales to H&H during the quarter and this was down \$12k on the last quarter.

Bod's exclusive relationship with H&H has now expired which allows it to explore supplementary global distribution arrangements in upcoming periods. Bod is actively engaged in progressing a number of new or enhanced supply arrangements domestically and internationally. The acquisition of Aqua Phase process technology also provides additional potential to secure further global distribution partnerships in broader food and beverage market segments given exclusive limitations are no longer applicable. During the quarter, Bod entered into a new supply agreement with Burleigh Heads Cannabis (a Vitura group company) with an expanded product range that is expected to substantially increase revenue in H2 FY2024.

Expenses associated with key clinical trials (Phase IIB clinical trial of unique Schedule 3 CBD product) and associated PK studies are mostly complete and the Group expects that R&D cash outflows will reduce after Q2 FY2024. Of the research and development payments during the quarter of \$837k, \$421k (50%) related to the Phase IIB clinical trial of unique Schedule 3 CBD product while \$211k (25%) related to the Aqua Phase PK studies. These two clinical trials represent 17% and 9% respectively of total expense payments of \$2,420k for the quarter. The Group continues to manage its cashflows closely.

During the quarter, Bod made an initial payment of \$1,917k for the acquisition of Aqua Phase, a process technology and related assets (Invention). Bod now holds the rights to use the Invention, together with all intellectual property (including a patent application), confidential information, records, goodwill and the right to use the name "Aqua Phase" going forward.

The Group raised proceeds from an equity placement of \$1,676k (net of fees) and also received proceeds of \$183k (net of fees) from a loan against its eligible June 2023 R&D spend, which provides early access to a portion of Bod's FY23 R&D tax incentive rebate.

The Group made payments totalling \$162k to related parties during the quarter, representing remuneration paid to directors of \$123k, a retainer paid to a director for commercial support in contract negotiations of \$20k, legal fees paid to an associate of a director of \$11k and the cost of printing materials paid to an associate of a director of \$8k.

Outlook:

Following the successful completion of significant R&D activities, the Company moves into Q2 FY2024 focused on a number of value-driving opportunities, including:

- Launching an expanded medical portfolio of products under MediCabilis including THC Flower;
- Finalising all results from the Phase IIB Can-Rest trial into a data pack which becomes part of the dossier submission to the TGA;
- Organising a pre-submission meeting with the TGA on our Phase IIB Can-Rest trial and discussing the final results;
- Discussions with suppliers, distributors and strategic partners to expand the business - with the focus on commercialisation of both key assets being soft gel capsule (from the Schedule 3 trial) and Aqua Phase; and
- Continue discussions and investigations with Kings College into how Aqua Phase could enhance several lipophilic orphan drugs; specifically Clozapine, a highly regarded CNS medication with a very poor side effect profile and Atorvastatin, a generic cholesterol-lowering drug.

Management commentary:

CEO Ms Jo Patterson said: *"This has been an important quarter for Bod as we completed a number of large research projects and reported on the successful outcomes on both Schedule 3 Can-Rest trial and the PK results for Aqua Phase. Our focus now turns towards the commercialisation of Schedule 3 and Aqua Phase as we take advantage of our leading downstream position within the cannabis market and beyond."*

"We greatly appreciate the ongoing support of our shareholders as we seek to capitalise on our expanding asset base."

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

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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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ⁱ ASX Announcement – 3 July 2023: Updates on Phase IIB clinical trial on Schedule 3 CBD

ⁱⁱ ASX Announcement – 10 July 2023: Phase IIB Clinical Trial of Schedule 3

ⁱⁱⁱ ASX Announcement – 6 September 2023: Schedule 3 CBD trial preliminary results

^{iv} ASX Announcement – 25 July 2023: Completion of Pivotal Aqua Phase PK Studies

^v ASX Announcement – 27 September 2023: Aqua Phase CBD PK Study Results

^{vi} ASX Announcement – 10 August 2023: Bod completes acquisition of Aqua Phase

^{vii} ASX Announcement – 3 August 2023: Bod announces placement to raise \$1.9m

^{viii} ASX Announcement – 13 July 2023: Investor Presentation