

Quarterly Activities Report for the Period Ended 30 June 2023

Operational Highlights

- ‘Last patient, last visit’ milestone reached with all patients completing Phase IIB Can-Rest Insomnia trial. Bod’s Phase IIB clinical trial is the only advanced Schedule 3 Cannabidiol (CBD) product candidate for the Australian market
- Significant progress in Aqua Phase PK Studies and final Acquisition Asset Deed milestone
- Advanced collaboration discussions underway for use of the Aqua Phase Technology in multiple treatment areas including those outside of cannabis
- Bod and Antah Group sign Letter of Intent (LOI) to collaborate to identify, develop and commercialise medical cannabis products in Malaysia, with the opportunity to be the first to explore the use of cannabidiol (CBD) in the Malaysian healthcare industry

Financial Highlights

- Net cash used in operating activities of \$1,630k, a \$559k increase on Q3 FY2023, reflecting final stage expenditure on the Can-Rest trial
- Quarterly receipts from customers were \$406k, a marginal increase on the last quarter (excluding a one-off receipt in the last quarter of \$500k from Arrotex Pharmaceuticals under Bod’s Licencing and Supply Agreement)ⁱ
- The Group reported \$306k in quarterly sales revenue, a 17% increase on the last quarter
- The Group held \$2,031,041 in cash as at 30 June 2023

Sydney, Australia – 31 July 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 June 2023 (Q4 FY2023).

Operational Overview:

Investor Presentation

Subsequent to the end of the quarter, the Company held a live webinar and released an updated Investor Presentationⁱⁱ discussing near-term value drivers, including the imminent completion of Aqua Phase studies comparing it with CBD in oil, the anticipated completion of Phase IIB study for Insomnia for TGA ARTG registration, the Company’s expansion into the Malaysian market through collaboration with Antah Pharma and the expansion of Bod’s medical cannabis product portfolio.

Phase IIB Clinical Trial of Schedule 3 CBD

During the quarter, the Company reached a significant milestone in its Phase IIB Can-Rest Insomnia trial, with all patients completing ‘last patient, last visit’, indicating conclusion of the clinical studies for Bod’s Phase IIB clinical trial being undertaken by Australia’s leading sleep research organisation, the Woolcock Institute of Medical Researchⁱⁱⁱ. The trial has assessed the efficacy of a uniquely developed Schedule 3 CBD formulation on symptoms associated with insomnia in 198 participants over an 8-week period. The clinical studies are the final step in R&D for Bod’s new product - a unique CBD formulation presented in a unique soft gel format and which utilises a patent protected encapsulation technology that improves the bioavailability of the CBD extract. A revised Product Schedule as part of the agreement with Arrotex Pharmaceuticals (who will have the exclusive distribution rights for Bod’s Schedule 3 product), was executed to vary the In-Licensing and Supply Agreement between Arrotex Pharmaceuticals and Bod, by changing the sunset clause for the successful completion of the study from 30 June 2023 to 31 October 2023 to accommodate receipt of top line clinical trial results.

Analysis of clinical trial results continued through July 2023, with top line results expected in late August 2023 and dossier submission for TGA ARTG registration anticipated in the final quarter of the calendar year. The trial remains the only advanced Schedule 3 cannabidiol (CBD) product candidate for the Australian market. Schedule 3 products can be sold to Australian consumers over-the-counter without a prescription.

Aqua Phase Delivery Technology PK Studies Progress and Updates

Bod continued its R&D evaluation of the Aqua Phase delivery technology as part of the key conditions precedent to complete the acquisition from the inventors, with ethics approval received in March 2023 from Bellberry for a definitive PK Study to compare the bioavailability of Aqua Phase Cannabidiol (CBD) and CBD in Medium Chain Triglycerides (MCT) oil^{iv}. Bod actioned an amendment to the date by which the final milestone (Phase I PK Studies) was to be completed under the Aqua Phase Acquisition Asset Purchase Deed to 31 July 2023^v, noting that on satisfactory completion of the final conditions precedent, Bod's initial acquisition consideration of GBP 1 million would be triggered. Successful completion of a PK study was the final condition for the acquisition of the Aqua Phase delivery technology^{vi}. A condition of the acquisition 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.

Bod has been focused on two PK studies to satisfy this CP and demonstrate the enhanced bioavailability of CBD using Aqua Phase technology compared with CBD in MCT oil. The first PK study assessed bioavailability in capillary blood, using microsampling technology, and the second PK study, a Phase I study has investigated bioavailability in venous blood on 12 participants, who were dosed with either Aqua Phase CBD 100mg or CBD 100mg in oil.

The results from the first PK study were released subsequent to the quarter, triggering the acquisition consideration, and confirming that bioavailability improved by 311% (over 4 times)^{vii}. The study, using micro sampling technology with capillary blood instead of blood taken from the vein in 10 volunteers, demonstrated the amount of the drug that can penetrate organs and the extremities, which is a key factor in the efficacy of most drugs. Pharmacokinetic analysis showed that Aqua Phase CBD statistically outperformed CBD oil. Total exposure (AUC) showed that Aqua Phase CBD was 311% (4.1x) greater than CBD oil. The maximum concentration (C_{max}) was statistically significantly higher at 277% (3.8x) more than CBD oil. Time to peak concentration (T_{max}) was consistent across both presentations. In summary, Aqua Phase as a technology applied to CBD, conferred enhanced absorption and bioavailability. When comparing the same dose of CBD (100mg), Aqua Phase CBD achieved higher CBD concentrations, and greater overall bioavailability than CBD in oil. The results provided additional confirmation that capillary blood sampling for CBD concentrations is a viable and cost-effective alternative to venous blood sampling and may be utilised in future studies^{viii}.

These results have been further supported by the second PK study using venous blood samples. Whilst these results are still in draft form, the results demonstrate a consistent trend. Final results will be reported to market when they have been finalised imminently.

Additional R&D into Aqua Phase was undertaken in parallel at a UK University to support Bod's commercialisation discussions, via Ultraviolet (UV) analysis accessing the solubility of Aqua Phase CBD using UV-Vis Spectrophotometry compared with standard CBD preparations. This analysis confirmed that Aqua Phase CBD solubility ranges from 1.6 millimolar (mM) to 2.7mM under various conditions, whereas standard CBD solubility is 0.2 micromolar(μM)^{ix}. This increase in solubility (approaching 10,000 times) is remarkable. Aqueous solubility is a key rate-limiting parameter influencing biological activity and gastrointestinal absorption of a drug from solid lipophilic dosage forms. As such, solubility is one of the main considerations studied during the pre-formulation of any drug's dosage form.

The benefits presented by Aqua Phase are multi-dimensional: low-cost manufacturing (scalable with off the shelf equipment), reduced cost of medicines and reduction in adverse side effects, thereby improving numerous therapeutic outcomes. Most common encapsulations are lipids or nano emulsification technologies which are expensive to manufacture, limited by dose load, restricted to liquid formats and often still present constraints on solubility and, as such, side effects.

Advanced collaboration discussions are underway with Kings College London for use of the Aqua Phase delivery technology in multiple treatment areas including those outside of cannabis, where enhanced solubility for established drug therapies has significant potential.

Bod is working with a number of other lipophilic cannabinoids and expects the solubility and bioavailability benefits to be the same or similar.

Aqua Phase is widespread in its application opportunities, enabling Bod to explore other ingredients or drugs outside the cannabis sector, including pharmaceutical markets, beverages and more generally consumer healthcare markets. The technology is a unique, proprietary process that produces a colourless, odourless tasteless powder format which can then be presented in multiple formats including creams, liquids, capsules, tablets, liquids and gummies. These characteristics are also expected to provide Bod with exposure to the global cannabis beverage market in circumstances where cannabis beverages may begin to compete with alcohol as the social elixir of choice, especially given the low-calorie profile of the active ingredient and absence of deleterious effects (such as organ damage and weight gain).

Bod and Malaysian Antah Group Sign Letter of Intent^{ix}

Bod and Antah Group (one of the largest investment holding companies based in Malaysia), which has diverse business interests in industries such as healthcare, power generation and property development), signed a Letter of Intent (LOI) during the quarter to collaborate to identify, develop and commercialise medical cannabis products in Malaysia, with the first and exclusive opportunity to explore the use of cannabidiol (CBD) in the Malaysian healthcare industry. Bod's unique delivery platforms for medical cannabis and patented products would provide the base for a clinical trial program, which is now under development with Antah. On successful completion of clinical trials, Antah will have exclusive use of Bod's investigational medical product for sales and distribution. Bod and Antah anticipate benefitting from first mover advantage in the Malaysian market. Bod and Antah intend to identify need states that are expected to benefit from medical cannabis therapy upon the establishment of a regulated medical cannabis market in Malaysia. These need states include autism spectrum disorder, anxiety disorders and major depression. To date, there have been no clinical trials or opportunity to explore the use of medical cannabis in the Malaysian healthcare industry, however Antah is positive that such opportunity will be presented in the near future.

Financial Overview:

Net cash used in operating activities of \$1,630k increased by \$559k (52%) on Q3 FY2023 (\$1,071k). Cash outflows during Q4 were negatively impacted compared to Q3 by a reduction of \$407k in customer receipts and an increase of \$157k (8%) in expense payments. The Q4 FY2023 net cash outflow was \$804k higher than the PCP (Q4 FY2022: \$826k) due to increased research and development payments of \$590k as two major clinical trials near completion and due to additional staff costs of \$185k from the filling of key roles to ensure the Company is adequately resourced to capture and convert a range of commercial opportunities, as generally summarised in the report.

Quarterly receipts from customers were \$406k, a decrease of \$407k (50%) on the last quarter (Q3 FY2023: \$813k) and down \$664k (62%) on the previous corresponding period ("PCP") (Q4 FY2022: \$1,070k). Receipts during the last quarter included an amount of \$500k representing an initial cash payment for exclusive supply of a unique Pharmacist Only (Schedule 3) CBD product to Arrotex Pharmaceuticals, while receipts in the PCP included \$562k from Health and Happiness (H&H) compared to \$1k in the current quarter.

The Group reported \$306k in sales revenue for the quarter, an increase of \$45k (17%) on the last quarter. Medical sales of \$165k decreased 13% on the prior quarter (\$190k), with volumes continuing to be impacted by the market's move towards THC dominant products. Sales to H&H remained minimal during the quarter.

Bod remains cognisant that the exclusive relationship with H&H has now expired which allows it to explore supplementary global distribution arrangements in the upcoming period. 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.

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 Q1 FY2024. Of the research and development payments during the quarter of \$788k, 72% related to the Phase IIb clinical trial of unique Schedule 3 CBD product and Schedule 3 payments represent 28% of total expense payments of \$2,044k for the quarter. The Group continues to manage its cashflows closely and non-R&D payment categories are mostly consistent with or lower than previous quarters.

The Group received proceeds of \$500k from a loan against its eligible R&D spend from January to May 2023, which provides early access to a portion of Bod's FY23 R&D tax incentive rebate.

The Group made payments totalling \$191k to related parties during the quarter, representing remuneration paid to directors of \$141k, a retainer paid to a director for commercial support in contract negotiations of \$20k, legal fees paid to an associate of a director of \$28k and the cost of printing materials paid to an associate of a director of \$2k.

Board & Management:

During the quarter, the Company's chairman David Baker assumed an additional advisory role to support management to progress a number of commercial initiatives. David is expected to stay in this commercial support role on an ongoing basis until the end of 2023.

Outlook:

Bod moves into Q1 FY2024 with imminent completion of significant near-term value drivers that have been the key focus of the business as a biotech company. Progress made in R&D of these value drivers have enabled Bod to advance a number of discussions with suppliers, distributors and strategic partners to expand the business - with the focus on commercialisation of both the two key assets being Schedule 3 and Aqua Phase, including pharmaceutical markets, beverages and more generally consumer healthcare markets.

The Company has noted that 28% of expenditure for the quarter was attributed to the costs of the Schedule 3 Clinical Trial. With R&D activities into Bod's key assets almost finalised, Bod will move its attention to amplifying the value and prospects associated with results and products coming from these studies. Progress throughout the quarter enabled Bod to advance discussions regarding collaboration and opportunities to take Bod's key assets into additional markets and commercialisation pathways beyond the biotech space.

Of significant priority to Bod is exploring how Aqua Phase's enhanced solubility can be applied across platforms and sectors beyond cannabis, as noted earlier in this report. Solubility is a crucial gateway factor in the formulation of drugs: low solubility results in the active pharmaceutical ingredient (API) sitting in the gut for longer, resulting in side effects and requiring higher dosing rates to achieve the same therapeutic outcome, impacting the tolerability of the drug.

Bod will 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. Both drugs are existing and available generic drugs, so Bod sees the opportunity for competitive interest from drug manufacturers.

The Company anticipates various avenues for commercialisation of Aqua Phase, including:

- Bod as manufacturer (scalable, off-the-shelf equipment) focussed on Bod's medicinal cannabis products – differentiating those products both by price (reduced API, lower production costs) and efficacy; and
- Bod as licensor to global pharma companies – technology transfer to licensees to incorporate Aqua Phase into their drug production. Bod is developing trial protocols with these drugs to demonstrate the transformational effects of the process technology during the next few months.

The next quarter will also see the launch of the soft gels commercialised through the SAS-B pathway and other medical cannabis products including Cannabigerol (CBG). CBG is derived from young cannabis plants, which contain higher amounts of this cannabinoid than fully developed plants. Both CBD and THC start as CBGA, an acidic form of CBG. This is why younger cannabis plants contain higher concentrations^x. CBG is particularly effective for inflammation and as an antioxidant and has been deployed in the treatment of inflammatory bowel disease, Crohn's disease, ulcerative colitis, bladder dysfunction and a range of other conditions

Management commentary:

CEO Ms Jo Patterson said: *"We are thrilled to be able to move into the next quarter with our focus on commercialising Bod's two key assets – Schedule 3 and Aqua Phase. The R&D activities associated with both assets have been extensive with results 18 months in the making."*

"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.

-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.

The Australian Securities Exchange ("ASX") granted the company a waiver from ASX Listing Rule 7.3.4. The waiver, which is at the option of the Company, permits the Company to issue Deferred Consideration Securities under a binding acquisition agreement between the Company and the vendors of Aqua Phase later than 3 months from the date of the shareholder meeting which approved the issue of the Deferred Consideration Securities. In accordance with that waiver, the company is required to disclose the following information in relation to the deferred consideration shares for the Aqua Phase acquisition. The deferred consideration shares will be issued on the following conditions:

- The shares are issued immediately upon satisfaction of the relevant milestones and in any event no later than 31 March 2024 in respect of the Milestone 1 tranche and no later than 31 March 2025 in respect of the Milestone 2 tranche. Milestone 1 requires successful manufacture to pharmaceutical GMP standards of two batches of the milestone product to specified criteria no later than 24 months after the completion date. Milestone 2 requires successful production of the first commercial pharmaceutical GMP (100,000-500,000 capsule run) batch of milestone product, where "successful production" means the milestone product has been manufactured in accordance with necessary specifications and regulations and will be able to be offered for commercial use no later than 36 months after the completion date.
- The maximum number of shares to be issued is capped at 70 million.

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ⁱ ASX Announcement – 2 December 2022: Exclusive licensing and five-year supply agreement secured with Australia's largest generic pharmaceutical and private label OTC medicines company

ⁱⁱ ASX Announcement – 13 July 2023: Investor Presentation

ⁱⁱⁱ ASX Announcement – 3 July 2023: Bod Science provides significant updates on Phase IIB clinical trial of Schedule 3 CBD product for Australian market

^{iv} ASX Announcement – 23 March 2023: Bod Science announces significant updates regarding Aqua Phase Delivery Technology

^v ASX Announcement – 30 June 2023: Bod Science announces significant progress in Aqua Phase PK Studies and remaining Acquisition Asset Deed milestone

^{vi} ASX Announcement – 30 August 2022: Bod to acquire Aqua Phase

^{vii} ASX Announcement – 25 July 2023: Bod Science completes pivotal Aqua Phase PK studies demonstrating 311% (over 4 times) improved bioavailability

^{viii} UV-Vis Spectrophotometry is a quantitative technique used to measure how much a chemical substance absorbs light. Solubility of that compound can then be calculated using an equation where $y = mx + b$ where y is absorbance, x is concentration, m the slope and b the intercept

^{ix} ASX Announcement – 21 June 2023: Bod Science and Malaysian powerhouse Antah Group sign Letter of Intent in milestone collaboration

^x <https://www.verywellmind.com/cannabigerol-cbg-uses-and-benefits-5085266>