

# Bod Science completes pivotal Aqua Phase PK studies demonstrating 311% (over 4 times) improved bioavailability

- Pharmacokinetic (PK) analysis showed that Aqua Phase CBD statistically outperformed CBD oil
- Total CBD availability (as measured by area under the curve, AUC) showed that Aqua Phase CBD was statistically significantly greater than CBD oil by 311%
- The maximum concentration (Cmax) was also statistically significantly higher at 277% (3.8 times) more than CBD oil
- The PK Study satisfies the condition associated with the acquisition of Aqua Phase which required improved bioavailability of greater than 30%
- Bod expects interest from commercial parties to license the technology for new and existing drugs

**Sydney, Australia – 25 July 2023:** Cannabis focused drug development and product innovation company Bod Science Limited ("Bod" or "the Company") (ASX: BOD) is pleased to announce the completion of their Pharmacokinetic (PK) studies evaluating the bioavailability of Cannabidiol (CBD) in capillary blood samples. Successful completion of a PK study is the final condition for the acquisition of the Aqua Phase delivery technology<sup>1</sup>. 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. The results from the PK study were that bioavailability improved by 311% (over 4 times).

These results have been further supported by a 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 in the coming weeks.

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 (Cmax) was statistically significantly higher at 277% (3.8x) more than CBD oil. Time to peak concentration (Tmax) 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.

Capillary blood samples were taken from 10 healthy volunteers who took a single dose of Aqua Phase CBD 100mg and CBD oil 100mg, separated by a washout period of at least 2 weeks. CBD absorption was measured by area under the curve (AUC).

CBD and cannabinoids have intrinsically poor biological absorption which limits their commercial opportunities for reasons relating to manufacturing, side effects and costs. Oral CBD compounds in oil are estimated to only have 6 to 8% bioavailability. Aqua Phase technology uses a modified starch combined with a lipophilic compound (in this case CBD) made under specific conditions to deliver a stable, highly soluble and bioavailable complex.

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. Most common encapsulations are lipids or nano emulsification technologies which are expensive to manufacture, limited by dose load and stability issues.

As part of due diligence for this transaction, Bod conducted Ultraviolet (UV) absorbance spectroscopy<sup>2</sup> testing on the aqueous solubility of Aqua Phase compared with CBD isolate and other CBD formulations using modified starch technologies. The study 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( $\mu$ M). This increase in solubility (exceeding 10,000 times) is remarkable. Aqueous solubility is a key rate-limiting parameter influencing biological activity and gastrointestinal absorption of a drug from lipophilic dosage forms.

Solubility is a key gateway issue in the formulation of drugs: low solubility can lead to delayed absorption causing a range of side effects and can require higher doses to achieve the desired therapeutic outcomes, thereby



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exacerbating the tolerability of the drug.

As Aqua Phase can complex with most lipophilic compounds, Bod is exploring multiple opportunities outside the cannabis sector. This includes pharmaceuticals, functional beverages, and consumer healthcare markets. The technology is patent protected and offers a completely unique process that delivers a colourless, odourless, flavourless complex which can be presented in multiple stable formats including capsules, creams, liquids, tablets and gummies.

Collaborations currently underway include Kings College London. Bod is exploring how Aqua Phase could enhance a widely used psychiatric drug, Clozapine, a highly regarded medication with a very poor side effect profile. In the cardiovascular space Bod is exploring Atorvastatin, a cholesterol lowering drug. Both drugs are genericised. Complexing these drugs to Aqua Phase, can add proprietary features and extend the drugs lifecycle. As such, competitive interest from incumbent drug manufacturers is expected.

The commercialisation of Aqua Phase provides multiple opportunities to expand Bod's business - including the potential establishment of an advanced manufacturing facility, where Bod will manufacture the high value complex with lipophilic compounds, initially focussing on medicinal cannabis applications. This will allow Bod to differentiate its product range both by price (reduced active ingredient, lower production costs) and efficacy. The process technology is readily scalable, utilising mainly off-the-shelf equipment (vats and agitation, heating and drying equipment).

In addition, opportunities exist 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.

Bod looks forward to updating its shareholders as these opportunities develop.

### Management commentary:

**CEO Ms Jo Patterson said:** "We are very pleased to have completed this extensive body of work and obviously delighted by the results that substantiates the value proposition of Aqua Phase. We are at the precipice of an exciting chapter where we will be talking to potential collaborators across vast industries on the value of Aqua Phase its application and the solution it can provide.

"It can unlock the potential of many existing drugs that have been limited by their poor absorption, cost and safety profile. We are also excited to continue the work we have been doing with the inventors over the last 12 months to commercialise Aqua Phase to its full potential."

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.

### For more information please contact:

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<sup>&</sup>lt;sup>1</sup> ASX Announcement – 30 August 2022: Bod to acquire Aqua Phase

<sup>&</sup>lt;sup>2</sup> 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