Quarterly Activities Report: Strong progress made towards commencement of clinical trials and product commercialisation

- **Clinical Trial Authorisation for trial into medicinal cannabis efficacy on long-COVID secured from UK's Medicines & Healthcare Products Regulatory Agency (MHRA)**
- **Long-COVID focused clinical trial will provide a strong basis for the commercialisation of a CBD-based medicine used to alleviate symptoms associated with the disease - patient recruitment now underway**
- **Ethics approval awarded for phase IIB clinical trial for new low dose CBD product aiming to treat insomnia to be sold in the Australian market under Schedule 3 (pharmacist only)**
- **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[i]**
- **Bod is one of a small number of companies undertaking a clinical trial to bring a product to market and aims to be one of the first Australian companies to introduce a low dose Schedule 3 CBD product**
- **Insomnia provides a major opportunity – global market valued at US$4.3Bn in 2020 and is estimated to grow strongly to US$6.3Bn by 2030[ii]**
- **Novel Food Application accepted by UK Food Service Agency (FSA) for exclusive CBD extract – provides Bod with an ongoing legal path to sell and distribute in the UK and another competitive advantage in the growing market**
- **Submission follows ruling for CBD products to be subject to novel food standards – application follows toxicology studies, stability testing and extract analysis to highlight the high quality of Bod's products**
- **Novel Food Application provides opportunity for Bod to advance product launches in other high growth verticals in the UK including skincare, beverages, lifestyle, functional food and pet treats**
- **The UK has grown to become the world's second largest market for consumer CBD products[iii]**
- **Receipts from customers totalled $647,000 and net cash used in operating activities decreased significantly to $290,000 from $1,216,000 in the previous quarter due to the receipt of R&D tax incentives**

Sydney, Australia – 29 April 2022: Cannabis focused drug development and product innovation company Bod Australia Limited ("Bod" or "the Group") (ASX: BOD) is pleased to provide the following update on activities for the quarter ended 31 March 2022 (Q3 FY2022).

Operational overview:

Clinical Trial Authorisation secured for UK-based trial into medicinal cannabis efficacy on long-COVID:
Bod achieved a major milestone in securing its Clinical Trial Authorisation ("CTA") from the UK's Medicines & Healthcare Products Regulatory Agency (MHRA) to commence its planned open label clinical trial in association with Drug Science UK ("Drug Science"). The clinical trial will support the effectiveness of Bod's medicinal cannabis product MediCabilis® 5% ("MediCabilis") on symptoms associated with the long-term impact of SARS-CoV-2 ("COVID-19") or long-COVID.

Long-COVID is an emerging condition that refers to the ongoing or new symptoms that develop in the eight weeks following an initial COVID-19 infection. The condition may include the continuation of COVID-19 indicators from initial diagnosis, or new symptoms that arise around a month after contracting the disease. Common symptoms include shortness of breath, fatigue, ongoing chest discomfort, loss of concentration, anxiety and insomnia. Many of these are amenable to treatment with cannabis-based medicines reinforcing the significant opportunity for Bod.

The study will recruit patients over the age of 18 that are suffering from long-COVID. Under a clinical trial setting,

each patient will be administered MediCabilis on a daily basis over a six month period and undertake self-reporting assessing common long-COVID symptoms through a smartphone application. The trial will be undertaken with the UK's leading independent scientific drug body Drug Science UK and led by Principal Investigator Dr Elizabeth Iverson.

Results from the trial will provide Bod with the potential to commercialise a product which can alleviate long-COVID symptoms, as well as provide additional evidence for the use of MediCabilis. Data generated will assist in progressing potential licencing agreements with large corporate or pharmaceutical companies for the Group's unique cannabis extract.

Subsequent to the end of the quarter, Bod successfully enrolled first patients for the study (refer ASX announcement: 26 April 2022).

Ethics approval secured for phase IIB clinical trial for Schedule 3 CBD product for the Australian market:
Bod achieved another regulatory milestone following the receipt of ethics approval from national not-for-profit scientific and ethical review company Bellberry Limited for the planned phase II clinical trial which will investigate the efficacy of a new unique Schedule 3 (pharmacist only) CBD formulation on symptoms associated with insomnia. This supported the commencement of the clinical trial being undertaken with Australia's leading sleep and respiratory research organisation, the Woolcock Institute and provides Bod with the opportunity to bring another specialised product to market.

The trial is a double blind, randomised and placebo-controlled investigation of the effect of administrating a 50mg and 100mg oral CBD product per day versus a placebo over an eight-week period.

Upon completion of the trial Bod expects to have sufficient data to commence product registration for a Schedule 3 low dose CBD product with the Therapeutic Goods Administration ("TGA") and for the product to be included on the Australian Register of Therapeutic Goods ("ARTG"). It is anticipated that this process will provide Bod with a CBD product that can be commercialised and sold over-the-counter by a pharmacist to Australian consumers without a prescription.

Success in the trial and product registration will provide Bod with another channel to market and the potential to increase domestic sales and achieve substantial revenue growth. Insomnia represents a large opportunity, with a global market that is estimated to grow to US$6.3Bn in value by 2030[ii]. CBD also has the potential to disrupt the use of current pharmacological interventions for the treatment of the condition, which have major limitations including abuse and dependence, as well as questionable or uncertain efficacy.

Novel Food Application accepted by UK Food Service Agency (FSA) for Bod's exclusive CBD extract:
Bod submitted a dossier to the UK's FSA to register its cannabis extract as a novel food in the UK which was subsequently validated by the regulatory body. This marks the final step in the process for the Group to achieve registration, expected in the coming months.

Lodgement follows changes made by the FSA that required nutraceutical products containing CBD to be subjected to novel food standards. The submission and pending approval will allow for the ongoing legal sale of Bod's range of CBD products in the UK and provide the Group with the opportunity to pursue additional partnerships and introduce new products across additional lucrative verticals.

The pending approval has reinforced the quality of Bod's exclusive CBD extract and provides another significant competitive advantage. It follows a considerable amount of work including toxicology studies, stability testing and extract analysis initiatives.

The Group continues to progress the introduction of new CBD-based over-the-counter products in high growth segments including skincare, beverages, lifestyle, functional food and pet treats. The UK represents a major opportunity for Bod, as it has grown to become the world's second largest for consumer CBD products behind the US with the sale of products up to the year end April 2021 valued at £690m.

Corporate developments:

Financial overview:
Receipts from customers for the quarter were $647,000, a decrease on the previous quarter due to receipts from large orders from Health and Happiness Group Limited being collected in Q2 FY2022. Total sales for the quarter were down 8% on the previous quarter after excluding the impact of issues associated with product manufacturing of CBD wellness products for the Italian market (refer ASX announcement: 31 January 2022) during Q2 FY2022, while medical cannabis sales increased by 2% on the previous quarter.

Net cash used in operating activities decreased from $1,216,000 in the previous quarter to $290,00 during Q3 FY2022. This was due to the receipt of an R&D tax incentive relating to work undertaken towards the Group's clinical trials and ongoing R&D during the year ended 30 June 2021. The Board and management remain focused on cost management.

Bod made payments totalling $0.16m to related parties during the quarter representing remuneration paid to directors. The Group is well funded with $4.47m cash at bank at 31 March 2022 which provides financial flexibility to progress its clinical trials and product commercialisation pathway.

Appointment and resignation of Non-Executive Director:
During the quarter, Mr Simon O'Loughlin retired as a Non-Executive Director and was replaced by Mr David Baker effective 4 April 2022. Mr O'Loughlin had been a Board member since 2016 and was instrumental in Bod's ASX-listing and growth trajectory. Bod has benefitted considerably from Mr O'Loughlin's extensive expertise, guidance and advice in recent years. The Company wishes him well for his future endeavours.

Mr Baker is a commercial advisor and company director with over 40 years' experience in law, investment banking, public company leadership and corporate governance. He has deep industry knowledge across a range of sectors and a sophisticated understanding of financial markets. Mr Baker is a co-founder of Baker Cook Advisory, a boutique provider of outsourced legal, commercial and governance advice and mediation services for corporations and government agencies. He is also a longstanding Bod shareholder.

Outlook:

Bod is focused on a number of value-accretive opportunities during the current quarter and across the remainder of FY2022, including:

- Completion of the phase IIB clinical trial to bring a low dose Schedule 3 CBD product to market;
- Completion of study into the efficacy of medicinal cannabis on symptoms associated with long-COVID;
- Partnership agreements and product licencing opportunities to underpin sales growth;
- Ongoing R&D into additional uses of Bod's CBD extract to build underlying assets; and
- Securing additional binding purchase orders from H&H to drive CBD wellness product sales.

Management commentary:

CEO Ms Jo Patterson said: *"Bod has made significant progress towards the commencement of two clinical trials which have the potential to bring new products to market and disrupt the current pharmacological treatments for a number of need states. The data from these studies will be pivotal for the commercialisation journey of additional cannabis-based medicines which have the potential to underpin future licencing agreements and sales.*

"During the current quarter, we remain focused on progressing these studies towards completion, as well as the introduction of potential new products in the UK following the receipt of our novel food registration.

"We look forward to providing additional updates on clinical trial developments, licencing agreements and other growth initiatives in the coming weeks."

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.

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[i] https://www.proactiveinvestors.com.au/companies/news/950040/australian-medicinal-cannabis-market-expected-to-exceed-2021-growthexpectations-hitting-200-million-mark-950040.html
[ii] https://www.alliedmarketresearch.com/insomnia-market
[iii] https://www.foodnavigator.com/Article/2022/04/01/uk-cbd-food-sector-celebrates-as-fsa-publishes-list-of-allowable-products

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Bod Australia Limited	
ABN	**Quarter ended ("current quarter")**
89 601 225 441	31 March 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	647	2,876
1.2	Payments for		
	(a) research and development	(289)	(1,145)
	(b) product manufacturing and operating costs	(542)	(2,226)
	(c) advertising and marketing	(128)	(291)
	(d) leased assets	-	-
	(e) staff costs	(776)	(2,879)
	(f) administration and corporate costs	(412)	(1,106)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	5
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives (see note 6)	1,098	1,271
1.8	Other (royalties)	112	145
1.9	**Net cash from / (used in) operating activities**	**(290)**	**(3,350)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(4)	(18)
	(d) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
	(e) intellectual property	(74)	(186)
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(78)**	**(204)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,887	8,053
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(290)	(3,350)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(78)	(204)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(54)	(34)
4.6	**Cash and cash equivalents at end of period**	**4,465**	**4,465**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	4,465	4,887
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,465**	**4,887**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	162
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(290)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,465
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,465
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	15.4

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: Not applicable

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Not applicable

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Not applicable

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 29 April 2022

Authorised by: **The Board of Directors of Bod Australia Limited**
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

6. The amount of $1,098k disclosed at 1.7 relates to the cash receipt of the research and development tax incentive relating to the year ended 30th June 2021.