

## ASX ANNOUNCEMENT

1 September 2022

### Biome Lift™ Trial recruitment reaches milestone; results due Q3 FY23

- Biome successfully recruits more than 40 patients to its Biome Lift™ Probiotic clinical trial with La Trobe university, surpassing recruitment target
- Biome Lift™ Probiotic is being investigated for its ability to reduce the severity of symptoms in subthreshold depression vs placebo
- Preliminary results are expected in Q3 FY23

Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the company') is pleased to announce that recruitment for the Biome Lift™ Probiotic clinical trial (the "trial") taking place at La Trobe University in Melbourne has surpassed the sample size calculation target of 40 participants

The double-blind placebo-controlled trial has successfully recruited the target 40 patients, whose successful participation in the trial will see them dosed once per day over a three-month period. Participants in the trial, who each demonstrate symptoms consistent with subthreshold depression, will be divided into two cohorts, with one cohort receiving Biome Lift™ and the other receiving a placebo. Preliminary results are expected in Q3 FY23.

The trial will be measuring a number of outcomes including (but not limited to) depression, anxiety, stress, gut microbiota composition and gastrointestinal symptoms.

Biome Lift™ Probiotic is Biome's condition-specific probiotic product which contains a formulation previously shown to assist with depressive mood state, anger, fatigue and sleep quality in a healthy adult cohort in a study published in the *Frontiers in Psychiatry* in 2019<sup>1</sup>.

<sup>1</sup> Marotta, A., Sarno, E., Casale, A. del, Pane, M., Mogna, L., Amoruso, A., Felis, G. E., & Fiorio, M. (2019). Effects of probiotics on cognitive reactivity, mood, and sleep quality. *Frontiers in Psychiatry*, 10(164), 1–11.

The undertaking of this additional clinical trial is designed to assess its ability to reduce the severity of symptoms in patients with subthreshold depression and target the growing number of people who experience mental health issues. In 2019-2020 the Australian government spent over \$566 million to subsidise the 40 million mental health related prescriptions that were filled for mental health related conditions<sup>2</sup>.

Biome Lift™ Probiotic was launched in Australia in November 2019 following the publication of evidence of its efficacy in 2019.<sup>3</sup> The product currently represents more than 6% of Activated Probiotics' sales. With the aforementioned growing number of people suffering from mental health related conditions, this creates a huge growth opportunity for Biome.

-ENDS-

Disclaimer: The information within this document is for educational purposes only, and any information or products described within are not intended to diagnose, treat, cure or prevent any disease. The information contained in this document is in no way intended to be prescriptive or replace medical advice by a healthcare physician.

Approved for release by the Biome Australia board of directors.

### About Biome Australia Limited

Biome Australia develops, licences, commercialises and markets innovative, evidence-based live biotherapeutics (probiotics) and complementary medicines, many of which are supported by clinical research. Biome aims to improve health outcomes and quality of life, and make its products accessible to all.

Incorporated in Australia in 2018, Biome distributes locally and abroad. In partnership with some of the world's leading organisations in microbiome research and development, Biome produced several unique live biotherapeutic (probiotic) products with innovative delivery technologies that improve their stability and efficacy to create its flagship range of complementary medicines: Activated Probiotics®.

---

2

<https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/expenditure-on-mental-health-related-services>

<sup>3</sup> Evidence Publication: Marotta A, Sarno E, Casale A Del, Pane M, Mogna L, Amoruso A, et al. Effects of probiotics on cognitive reactivity, mood, and sleep quality. *Front Psychiatry*. 2019;10(164):1-11.



#### Biome Australia Limited

Head Office: 16 Dover Street, Cremorne VIC 3121 AUSTRALIA



(03) 9017 5800



support@activated.co



www.biomeaustralia.com

Supported by clinical research, including randomised double-blind placebo-controlled trials, Activated Probiotics help prevent and support the management of various health concerns, including low mood and sleep, bone health, iron malabsorption, mild eczema and IBS. Through practitioner-only distribution, Biome is committed to educating health professionals on the newfound systemic health effects of the gut microbiota, helping them to provide innovative, evidence-based natural medicines for the management of some of humanity's most prevalent and chronic health concerns.

Biome also develops, licenses and distributes a scientifically formulated, organic nutraceutical range, Activated Nutrients<sup>®</sup> and a sports performance and recovery range, Activated X Performance<sup>®</sup>, which is made exclusively for professional athletes.

For more information visit: [www.biomeaustralia.com](http://www.biomeaustralia.com)

### **Investor Relations**

WE Communications

Hannah Howlett

+61 450 648 064

[hhowlett@we-worldwide.com](mailto:hhowlett@we-worldwide.com)

### **Media enquiries**

[media@activated.co](mailto:media@activated.co)

### **Forward looking statements**

*This release may contain forward looking statements, including but not limited to projections, guidance on future revenues, earnings, other potential synergies and estimates and the future performance of Biome (**Forward Looking Statements**).*

*Forward Looking Statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. Actual results, performance or achievements may differ materially from those expressed or implied in such Forward Looking Statements and any projections and assumptions on which these Forward Looking Statements are based. Such statements may assume the success of Biome's business strategies. You are cautioned not to place undue reliance on Forward Looking Statements.*

*The Forward Looking Statements are based on information available to Biome as at the date of this release. Any Forward Looking Statements containing forward looking financial information provided in this release is for illustrative purposes only and is not represented as being indicative of Biome's views on its future financial condition and/or performance. The historic financial information for the September 2021 financial quarter and revenue figures for October and November 2021 have not been audited or reviewed by Biome's auditors. Such information should not be taken as a guide for future performance.*

*Nothing in this release is a promise or representation as to the future. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any Forward Looking Statements contained in this release. Except as required by law or regulation (including the ASX Listing Rules), Biome does not undertake to provide any additional or updated information whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise.*

Certified



### **Biome Australia Limited**

Head Office: 16 Dover Street, Cremorne VIC 3121 AUSTRALIA



(03) 9017 5800



[support@activated.co](mailto:support@activated.co)



[www.biomeaustralia.com](http://www.biomeaustralia.com)

*To the maximum extent permitted by law, Biome excludes and expressly disclaims all liabilities in respect of, and makes no representation or warranty, express or implied as to the fairness, currency, accuracy, reliability or completeness of information in this release or the accuracy, likelihood of achievement or reasonableness of any Forward Looking Statements (or any event or results expressed or implied in any Forward Looking Statements) contained in, implied by, the information in this release or any part of it, or that this release contains all material information about Biome or which a prospective investor or purchaser may require in evaluating a possible investment in Biome or acquisition of securities in Biome.*

*Investors are strongly cautioned not to place undue reliance on Forward Looking Statements, particularly in light of the current economic climate and the significant volatility, uncertainty and disruption caused by the Covid-19 pandemic.*



**Biome Australia Limited**

Head Office: 16 Dover Street, Cremorne VIC 3121 AUSTRALIA



(03) 9017 5800



support@activated.co



www.biomeaustralia.com

For personal use only