

# Biome Australia The Microbiome Health Company







#### **ASX ANNOUNCEMENT**

6 July 2023

# Biome Lift™ Probiotic trial update: positive results received.

- Biome Lift clinical trial completed and pre-publication results received
- Self-report questionnaire responses, results of faecal, saliva and blood samples and anthropometric and dietary intake data analysed
- Results provide evidence on the effectiveness of Biome Lift™ Probiotic in reducing the severity of depressive symptoms in patients with subthreshold depression
- Webinar on clinical trial results to be held on Wednesday 12 July at 9.30am
   AEST register <u>here</u>

Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the Company') has received the pre-publication results of the Biome Lift<sup>TM</sup> Probiotic clinical trial (the "trial") taking place at La Trobe University in Melbourne (Ref announcements 21 February 2022, 29 June 2022 and 1 September 2022).

This trial investigated the effect of the Company's product Biome Lift<sup>™</sup> Probiotic compared to placebo on the severity of depressive symptoms in 39 patients with subthreshold depression over a 12-week intervention period.

Biome Lift<sup>™</sup> Probiotic is currently sold within the community pharmacy and healthcare practitioner channels across Australia, New Zealand and the United Kingdom. The formulation found in Biome Lift<sup>™</sup> Probiotic has been the subject of two previous studies, and this latest study builds upon their findings and further strengthens this product's supporting clinical evidence.

According to the researchers, these latest results provide evidence on the effectiveness of Biome Lift™ Probiotic in reducing the severity of depressive symptoms in patients with subthreshold depression. These findings, which are the culmination of a strategic research partnership with La Trobe University, reinforce the positive impacts this product can have and highlight additional benefits it can offer.

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Biome has now received results of the:

- **Self-report questionnaire-based assessment tools**, which were used to assess the depression, mood, anxiety, stress and quality of life scores of participants before, during and after the intervention period
- **Blood samples**, which were used to assess changes in biochemical markers of the glycemic profile, inflammation and oxidative stress of participants before, during and after the intervention period
- **Saliva samples**, which were used to assess the change in a biochemical marker of stress before, during and after the intervention period
- **Faecal samples**, which were used to assess compositional and metagenomic changes in the gut microbiota of participants before, during and after the intervention period
- **Anthropometric and dietary intake data** recorded before, during and after the intervention period, which were used to monitor for confounding effects on the study outcomes

The full data set of results for all outcome measures can be found in a presentation to be lodged after this announcement.

According to the findings of the self-report questionnaire-based assessment tools, there were several within-group improvements that were primarily in favour of the probiotic group. There were no differences observed between the two groups within the questionnaire results. The researchers stated that these results provide evidence on the effectiveness of the Biome Lift<sup>TM</sup> intervention in reducing the severity of depressive symptoms in patients with subthreshold depression. Results from the blood and saliva samples supported the favourable changes observed in the probiotic group's questionnaire results.

A clear reduction in inflammation (i.e., through the reduction in hs-CRP levels) in the probiotic arm, as well as an improvement in brain antioxidant capacity (i.e., through the increases observed in total glutathione levels) both at 6 and 12 weeks of treatment was apparent, according to the researchers, following analysis of the blood sample results. The researchers stated that the significant differences that were observed between the probiotic compared to the placebo arm support anti-inflammatory and antioxidant properties (especially in the brain cells) of the probiotic supplement, which further support the favourable changes observed in the questionnaire results.

They also noted a clear reduction in stress levels (i.e., through the reduction in 30-minutes post-awakening cortisol and cortisol awakening response levels) in the probiotic arm, compared to the placebo at the end of the 12-week intervention period.

There were no changes observed between timepoints or treatment arms in measures of gut microbiome diversity from analysis of faecal samples.



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The questionnaire-based assessment tools were also completed by 19 participants six weeks after the end of the trial. The researchers highlighted that data from these follow-up results demonstrated that improvements seen in the probiotic group's depressive and anxiety symptoms also remained 6 weeks after supplementation was ceased (as measured by the Beck Depression Inventory and Hospital Anxiety and Depression Scale).

#### -ENDS-

Approved for release by the Biome Australia board of directors.

#### **About Biome Australia Limited**

Biome Australia develops, licenses, 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<sup>®</sup>.

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, <u>Activated Nutrients</u> and a sports performance and recovery range, <u>Activated X Performance</u>, which is made exclusively for professional athletes.

For more information visit: www.biomeaustralia.com

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