ASX ANNOUNCEMENT

3 February 2026

Ethics Approval Granted for BMB18 Human Clinical Trial

- Randomised, double-blind, placebo-controlled trial recruiting 240 participants to investigate the efficacy of proprietary strain Lactobacillus plantarum BMB18 (DSM 35214) in adults experiencing digestive symptoms, sleep and mood disturbances
- La Trobe University Human Research Ethics Committee grants ethics approval, clearing the final regulatory prerequisite for the trial to commence in February 2026 as planned
- Two active dosage levels and placebo to identify multiple use cases in new product development with Biome-owned IP
- BMB18 is wholly owned by Biome, representing valuable and protectable intellectual property that strengthens the Company's competitive position and underlying asset value
- Successful clinical outcomes will unlock new product development opportunities across the Activated Probiotics and Activated Therapeutics ranges

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Microbiome health company *Biome Australia Limited* (ASX: *BIO*) ('*Biome*' or '*the Company*') is pleased to advise that the La Trobe University Human Research Ethics Committee (HREC) has granted ethics approval for the Company's first human clinical trial on its proprietary probiotic strain, *Lactobacillus plantarum* BMB18 (DSM 35214)

The approval clears the final regulatory prerequisite for the trial to commence in February 2026, consistent with the timeline outlined in *the Company's* announcement on 15 December 2025.

Trial Overview

The randomised, double-blind, placebo-controlled trial will recruit 240 participants across two active dosage levels and placebo to investigate the efficacy of BMB18 in adults experiencing digestive symptoms (e.g. bloating, discomfort) and/or occasional sleep or mood disturbances, and examine its impact on digestive function, mood, sleep and quality of life.

Two active dosage levels will be investigated alongside placebo to identify multiple use cases in new product development with *Biome*-owned IP. The 12-month study will be conducted for approximately $140k and managed within Biome's existing R&D budget.

The trial follows the successful completion of in vitro research demonstrating BMB18's ability to modulate immune responses and inflammation, reduce oxidative stress, and maintain intestinal barrier integrity (Ref announcement 30 January 2025).

Intellectual Property and Product Development

BMB18 is wholly owned by *Biome* and registered with the German culture bank DSMZ (DSM 35214), providing the Company with protectable intellectual property and future licensing opportunities.

Successful clinical validation of BMB18 will support new product development across both the *Activated Probiotics* and *Activated Therapeutics* ranges, with the potential to address multiple health applications identified during the in vitro phase. *Biome's* ownership of the strain and its clinical data provides a meaningful competitive advantage and adds to the underlying value of the business.

Gut disorders and targeted gut health remain *Biome's* largest volume category. Clinical validation of BMB18 is expected to support growth across existing products while enabling new product innovation.

Strategic Alignment

The BMB18 clinical trial aligns with *Biome's* Vision 27 strategic plan, specifically the supply chain development pillar focused on identification, characterisation and commercialisation of proprietary probiotic strains. The trial continues *Biome's* successful research partnership with La Trobe University, following the *Biome Lift™ Probiotic* clinical trial collaboration.

Biome Managing Director and Founder Blair Vega Norfolk said:

"Receiving ethics approval from La Trobe University is the final step before commencing this important trial. We are on track to begin recruiting participants this month.

BMB18 represents one of the most significant assets we have built at Biome. It is a proprietary strain that we own outright, registered internationally, and supported by strong in vitro data. Clinical validation will enable us to develop new products with IP protection that strengthens our competitive position in a growing market.

The value of owning a clinically validated, proprietary probiotic strain cannot be overstated. It provides Biome with product development opportunities, protection from competition, and potential licensing pathways that contribute to the long-term value of the Company."

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Approved for release by the Biome Australia board of directors.

Investor Hub
Biome has launched a new interactive investor hub. To view a video presentation of this announcement, ask questions or sign up for future company updates, please visit the investor hub via this link (https://investorhub.biomeaustralia.com/).

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®.

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®.
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Forward looking statements

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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.

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