

ASX ANNOUNCEMENT

15 December 2025

Biome Launches First Human Clinical Trial on Proprietary BMB18 Strain

- Ethics approval submitted and study registered with the [ANZCTR](#) for Biome's first human clinical trial on proprietary probiotic strain *Lactobacillus plantarum* BMB18
- Trial planned to commence in February 2026 in partnership with La Trobe University
- Randomised, double-blind, placebo-controlled trial recruiting 240 participants across two active dosage levels and placebo, providing robust data for multiple product development opportunities
- Study follows successful completion of in vitro research demonstrating strong positive outcomes for its ability to modulate immune responses and inflammation, reduce oxidative stress, and maintain intestinal barrier integrity (Ref announcement 30 January 2025)
- Trial targeting patients with digestive symptoms (e.g. bloating, discomfort) and/or sleep or mood disturbances
- A positive outcome is expected to support significant growth in gut health sales, *Biome's* largest volume category
- *Lactobacillus plantarum* BMB18 represents valuable intellectual property and product innovation that adds to *Biome's* competitive advantage

Microbiome health company *Biome Australia Limited* (ASX: *BIO*) ('*Biome*' or '*the Company*') is pleased to announce that the first human clinical trial on its proprietary probiotic strain, *Lactobacillus plantarum* BMB18 (BMB18), has been submitted for ethics approval and registered with the Australia New Zealand Clinical Trials Registry (ANZCTR) (registration number: ACTRN12625001338459p). This marks a significant milestone in *the Company's* research, intellectual property (IP) and product development strategy.

Trial Overview

The human clinical trial will investigate the efficacy of BMB18 in patients 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.

This next-generation probiotic strain has demonstrated strong positive outcomes in recently completed in vitro studies conducted by the cell culture lab of one of Biome's key research partners (Ref announcement 30 January 2025).

The randomised, double-blind, placebo-controlled trial will recruit 240 participants across two active dosage levels and placebo to identify multiple use cases in new product development with Biome-owned IP.

Ethics approval has been submitted, with the trial scheduled to commence in February 2026. The 12-month study will be conducted for approximately \$140k and managed within Biome's existing R&D budget, representing excellent value for this critical validation of BMB18's clinical benefits and advancement of Biome's proprietary strain technology.

In Vitro Validation

The strain demonstrated an ability to effectively modulate immune responses and inflammation, reduce oxidative stress, and maintain intestinal barrier integrity. The findings from this report were used to help inform clinical research opportunities and potential health applications and targets for this strain.

Strategic Significance

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. Successful clinical validation of BMB18 will:

- Strengthen *Biome's* competitive position through proprietary strain ownership



- Support new product development across the *Activated Probiotics* and *Activated Therapeutics* ranges
- Provide additional protection from competition
- Drive innovation in next-generation probiotic formulations
- Expand addressable market opportunities in gastrointestinal health

Cut disorders and targeted gut health remain *Biome*'s largest volume category, with significant growth potential as consumer awareness of the gut-health connection continues to expand. Clinical validation of BMB18 is expected to support substantial sales growth across existing products while enabling new product innovation.

Partnership with La Trobe University

The clinical trial continues *Biome*'s successful research partnership with La Trobe University, following the *Biome Lift™ Probiotic* clinical trial collaboration which resulted in several publications supporting the product's application for patients with mental health concerns.

This partnership ensures the trial meets rigorous scientific standards and reinforces *Biome*'s commitment to evidence-based product development.

***Biome* Managing Director and Founder Blair Norfolk said:**

"The registration of our first human clinical trial on L.P. BMB18 represents years of dedicated research and development work by the Biome team. The strong positive outcomes from our in vitro studies provided the foundation for this next critical phase of clinical validation.

L.P. BMB18 is a proprietary strain that will differentiate Biome in the marketplace and support our ongoing product innovation. Gastrointestinal symptoms affect millions of Australians, and developing clinically validated solutions for these common health concerns is central to our mission of improving health outcomes through evidence-based microbiome science.

This trial advances our Vision 27 strategic plan and strengthens our competitive advantage in technology, science and innovation. The clinical validation of BMB18 will enable new product development opportunities and is expected to



drive significant growth in our gut health category, which represents our largest sales volume.

Our partnership with La Trobe University continues to deliver meaningful research outcomes, and we look forward to commencing this exciting trial in February 2026."

—ENDS—

This announcement has been authorised for release by the Board of Biome Australia Limited.

About Biome Australia Limited

Biome Australia develops, licenses, commercializes and markets innovative, evidence-based live biotherapeutics (probiotics) and complementary medicines supported by clinical research. Biome aims to improve health outcomes and quality of life, making products accessible through professional health channels.

Incorporated in Australia in 2018, Biome distributes locally and internationally. In partnership with leading microbiome research organizations, Biome produces unique live biotherapeutic products with innovative delivery technologies improving stability and efficacy for its flagship Activated Probiotics® range.

Supported by randomized double-blind placebo-controlled clinical trials, Activated Probiotics® and Activated Therapeutics® help prevent and support management of various health concerns including low mood and sleep, bone health, iron malabsorption, mild eczema and IBS. Through practitioner-recommended distribution, Biome educates health professionals on gut microbiota's systemic health effects, providing evidence-based natural medicines for prevalent chronic health concerns.

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Forward Looking Statements

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