

ASX ANNOUNCEMENT

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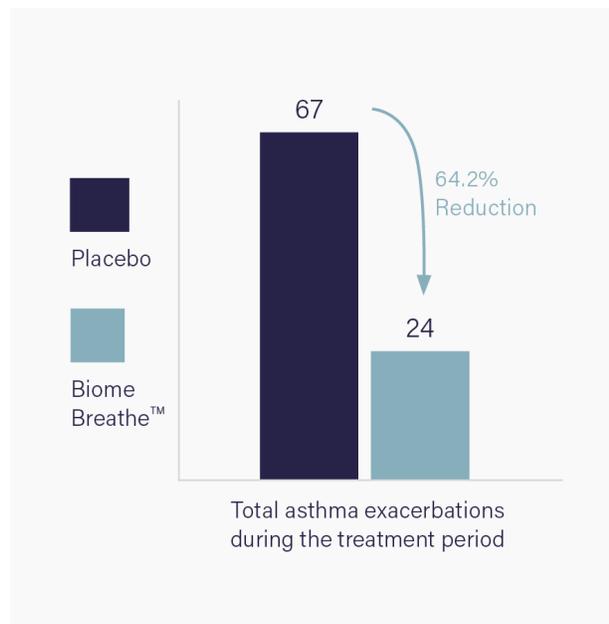
Biome Australia's independent research partners achieve groundbreaking results in clinical trial with asthma patients

- Independent clinical trial results demonstrate the efficacy of a targeted probiotic in the treatment of asthma in children
- Use of this probiotic led to a 64.2% reduction in asthma exacerbations
- Results clinically validate the company's *Biome Breathe™ Probiotic* which provides significant opportunities to support asthma patients as an adjunct to pharmaceutical intervention
- This represents one of the first probiotics globally to show an improvement in the symptoms of asthma

Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the company') is pleased to provide clinical trial results following the recent publication of a successful study completed in Italy using the probiotic strains in the company's *Biome Breathe™ Probiotic* on pediatric asthma patients.

The results of the Probiotic in Pediatric Asthma Management (PROPAM) Study have now been published in the Journal of Immunology Research and clinically validate the company's *Biome Breathe™ Probiotic* product making it one of the first probiotics globally to be scientifically proven to show an improvement in the symptoms of asthma in children.

This randomised placebo-controlled double-blind clinical trial assessed the efficacy of two specific probiotic strains in *Biome Breathe™ Probiotic*, *L. salivarius* LS01 and *B. breve* B632, in reducing the symptoms of asthma in 422 children over an eight-week period in primary care settings, such as GP clinics.



The PROPAM study found that the group of children who took the combination of probiotic strains found in *Biome Breathe™ Probiotic* experienced 64.2% fewer exacerbations of their asthma symptoms, compared to the group of children who took placebo.

The authors concluded “the finding that probiotic strains... can reduce asthma exacerbations in children provides a potential complementary therapy for primary care physicians”.

This groundbreaking clinical trial is the independent research supporting the efficacy of Biome Australia’s *Biome Breathe™ Probiotic*, which was released into the Australian market following the receipt of promising pre-publication results.

Biome Breathe™ Probiotic contains this combination of probiotic strains and is available across Australia in over 2300 community pharmacies and independent health practitioners.

Biome Australia Managing Director and Founder Blair Norfolk said: “The release of these results demonstrating that the specialised probiotic strains in *Biome Breathe™* can be used to effectively assist in the treatment of asthma in children is a major milestone for us and the health industry.”

“The clinical validation provides significant commercial opportunities for us to work closely with and expand our network of healthcare practitioners to improve the quality of life for asthma patients.”

Results in detail

In the study, fifty (23.8%) children in the placebo group experienced at least one asthma exacerbation compared to 19 (9%) in the active group. Seventeen (8.1%) children of the placebo group and 5 (2.4%) in the active group had two asthma exacerbations.



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In total, there were 67 asthma exacerbations in the placebo group and 24 in the active group, which correlates to a 64.2% reduction in asthma exacerbations in the group taking probiotics.

Children in the placebo group had a higher probability of having at least one asthma exacerbation than children in the probiotic arm, which had a statistical significance of $p < 0.001$ (OR 3.17, 95% CI 1.8–5.6). In addition, children in the placebo group were more likely to have two exacerbations than children in the active group (OR 3.65, 95% CI 1.32–10.08; $p = 0.013$).

The publication 'Drago L, Cioffi L, Giuliano M, Pane M, Amoruso A, Schiavetti I, et al. The Probiotics in Pediatric Asthma Management (PROPAM) Study in the Primary Care Setting: A Randomized, Controlled, Double-Blind Trial with *Ligilactobacillus salivarius* LS01 (DSM 22775) and *Bifidobacterium breve* B632 (DSM 24706) J Immunol Res. 2022 Jan 17;2022:1–7' is available from: www.hindawi.com/journals/jir/2022/3837418

Mechanisms of action

The authors of the PROPAM study detailed the proposed mechanisms by which the gut microbiome and probiotics may influence conditions such as asthma:

“The increase in asthma prevalence has been initially attributed to the hygiene hypothesis, especially to the imbalance of human microbiota composition, abundance, and diversity (dysbiosis) that promotes the maintenance of type-2 phenotype in the infant [3]. This gut microbiota dysbiosis appears to play a role in increasing allergy prevalence [4]. It has been proposed that a decline in biodiversity determines microbial deprivation affecting the immune response. Indeed, children with asthma display lung and intestinal dysbiosis [5] likely promote the activation of inflammatory pathways and contribute to bronchial obstruction and airway hyperresponsiveness. Thus, dysbiosis and reduced microbial diversity dysregulate the bidirectional crosstalk across the gut-lung axis [6]. This axis provides a rationale for understanding how oral supplements could improve respiratory illness [7]. These concepts have paved the way for manipulating the immune system using non-pharmacological remedies including probiotics”

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no way intended to be prescriptive or replace medical advice by a healthcare physician.

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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®](#).

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®](#) and a sports performance and recovery range, [Activated X Performance®](#), which is made exclusively for professional athletes.

For more information visit: www.biomeaustralia.com

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Forward looking statements



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