

ASX ANNOUNCEMENT

9 February 2022

Release of successful acne clinical trial ahead of product launch

- Independent clinical trial results demonstrate the efficacy of a targeted probiotic in the treatment of acne
- Use of this probiotic led to a 31.11% reduction in acne lesions in four weeks, and a 38.89% reduction in 8 weeks
- Biome to launch a new product *Biome Acne™ Probiotic* as the world's first clinically validated probiotic for the treatment of acne
- The global acne therapeutic market was worth over USD \$6 billion in 2019, and the market is expected to reach \$7.6 billion in 2026 at a CAGR of 3.4%¹, representing a huge opportunity for commercial growth for the Company

Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the company') is pleased to announce the results of a clinical trial into the effects of specialised probiotic strains on the management of acne. The clinical trial that took place in Italy has been published in the peer-reviewed journal of *Dermatology and Therapy*².

The recently published double-blind, randomised, placebo-controlled trial analysed the efficacy of specialised probiotic strains *Bifidobacterium breve* BR03 (DSM 16604), *Lactocaseibacillus casei* LC03 (DSM 27537), and *Ligilactobacillus salivarius* LS03 (DSM 22776) versus a placebo on 55 subjects with mild to moderate acne. 27 subjects received the probiotic strains, and 28 subjects received a placebo. The subjects were dosed once per day for eight weeks.

The combination of probiotic strains demonstrated a 31.11% reduction in the number of acne lesions in just four weeks, which was statistically significant ($p < 0.05$) when compared to placebo (10% reduction).

¹<https://www.marketwatch.com/press-release/acne-therapeutics-market-share-2021-global-trend-segmentation-business-growth-top-key-players-analysis-industry-opportunities-and-forecast-to-2027-2021-12-06>

² Rinaldi, F., Marotta, L., Mascolo, A., Amoroso, A., Pane, M., Giuliani, G., & Pinto, D. (2022). Facial Acne: A Randomized, Double-Blind, Placebo-Controlled Study on the Clinical Efficacy of a Symbiotic Dietary Supplement. *Dermatology and Therapy*.

Percentage Reduction of Acne Lesions

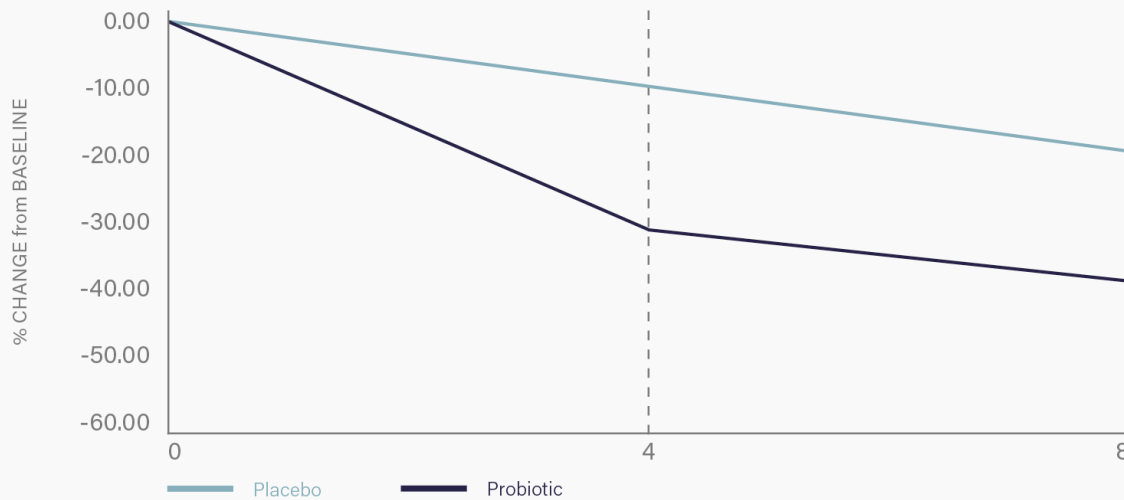


FIGURE 1

Clinical improvement of acne vulgaris expressed as Global Acne Grading System (GAGS) score. Data are expressed as % of change from baseline.

Detailed results

At week 4, there was a statistically significant ($p < 0.05$) decrease in the number of superficial inflammatory acne lesions in the subjects taking probiotics (-31.11%) compared to placebo (-10%), measured using the global acne grading system (GAGS) score (see Figure 1). This continued to improve after 8 weeks (-38.89% vs 18.89%, $p < 0.05$).

The study also examined changes in skin redness (erythema). The mean erythema score was significantly reduced after 8 weeks of treatment with probiotics ($T0\ 1.82 \pm 0.06$ vs $T2\ 0.73 \pm 0.74$, $p < 0.05$), while no reduction was reported for placebo.

There was also a significant reduction in the abundance of the main bacteria implicated in the pathogenesis of acne, *Cutibacterium acnes* (26.8 vs 21.7 log RA, $p < 0.01$), in those who received probiotics at the end of the study, providing evidence for the ability of this oral probiotic to impact the skin microbiome.

Biome Acne™ Probiotic to launch

Following these strong clinical results, the company will now commence production and manufacturing of the new product, *Biome Acne™ Probiotic*, specifically



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formulated for the treatment of acne in partnership with Probiotical S.p.A. With the support of Probiotical S.p.A.'s leading research and manufacturing facilities, the company has the ability to begin and scale production quickly. *Biome Acne™ Probiotic* is expected to launch in Q4 FY22 and will become one of the world's first clinically proven probiotics for the management of acne.

Biome Acne™ Probiotic will become available to over 2300 community pharmacies and independent health practitioners across Australia, and will also be launched into the UK and New Zealand markets as '*Biome Derma™*'.

Acne is a highly prevalent inflammatory skin disorder, affecting almost 80% of adolescents and young adults aged 11 to 30 years old³. The global acne therapeutic market was estimated to be worth over USD \$6 billion in 2019, and the market is expected to reach \$7.6 billion in 2026, representing a CAGR of 3.4%³

As well as its physical symptoms, acne is associated with significant mental health impacts, such as anxiety, depression and social inhibition, and greatly impacts the self-esteem of those suffering with this condition, all of which improve with effective treatment^{4,5}.

The product, released under a 5-year renewable exclusive license from Probiotical S.p.A., represents a large opportunity for commercial growth for the company as it diversifies its revenue generation to encompass a variety of products formulated for a range of conditions.

The trial, conducted by Giuliani S.p.A., 'Rinaldi, F., Marotta, L., Mascolo, A., Amoroso, A., Pane, M., Giuliani, G., & Pinto, D. (2022). Facial Acne: A Randomized, Double-Blind, Placebo-Controlled Study on the Clinical Efficacy of a Symbiotic Dietary Supplement. *Dermatology and Therapy*' is available from:
<https://doi.org/10.1007/s13555-021-00664-z>

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⁴ Deidda F, Amoroso A, Nicola S, Graziano T, Pane M, Mogna L. New Approach in Acne Therapy A Specific Bacteriocin Activity and a Targeted Anti IL-8 Property in Just 1 Probiotic Strain, the *L. salivarius* LS03. *J Clin Gastroenterol*. 2018 Nov 1;52:S78-81.

⁵ Dréno, B., Dagnelie, M. A., Khammari, A., & Corvec, S. (2020). The Skin Microbiome: A New Actor in Inflammatory Acne. *American journal of clinical dermatology*, 21(Suppl 1), 18-24. <https://doi.org/10.1007/s40257-020-00531-1>



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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, 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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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.

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