ASX ANNOUNCEMENT
14 February 2022

Supplementary Announcement: Full clinical results cement product expansion plans

Highlights

- 4-arm randomized, double-blind, placebo-controlled study completed on acne patients cements viability and commercial value of new product; *Biome Acne™ Probiotic*
- Results for the probiotic arm demonstrate a 38.89% decrease in acne lesions at 8 weeks
- These results reinforce the commercial potential of *Biome Acne™ Probiotic* which is expected to launch in Q4 FY22

Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the company') is pleased to provide additional information pertaining to recently announced clinical trials results at the request of the ASX.

On the 9th of February 2022, the company announced the results from the probiotic arm of the recently published double-blind, randomised, placebo-controlled clinical trial that analysed the efficacy of specialised probiotic strains (alongside two other interventions) on mild to moderate acne which have been peer-reviewed and published in the Journal of Dermatology and Therapy, titled 'Facial Acne: A Randomized, Double-Blind, Placebo-Controlled Study on the Clinical Efficacy of a Symbiotic Dietary Supplement'[1].

The company is pleased to now release detailed results from the entire trial, encompassing each of the four arms ("Groups").

[1] Rinaldi, F., Marotta, L., Mascolo, A., Amoruso, 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*. https://doi.org/10.1007/s13555-021-00664-z

Trial overview

The trial was conducted by Giuliani S.p.A in Italy and tested the effectiveness of three different treatments on mild to moderate acne on 114 subjects over four Groups. Each of the subjects were dosed once daily for eight weeks with their corresponding Group's study treatment and results were compared with the Control Group.

Group I - 28 subjects: Placebo / Control Group

Group II - 30 subjects: A dietary supplement containing probiotics (Bifidobacterium breve BR03, Lacticaseibacillus casei LC03, and Ligilactobacillus salivarius LS03) & botanical extract (lupeol from Solanum melongena L. and Echinacea extract)

Group III - 29 subjects: A botanical extract alone containing lupeol from Solanum melongena L. and Echinacea extract

Group IV - 27 subjects: A probiotic alone containing Bifidobacterium breve BR03, Lacticaseibacillus casei LC03, Ligilactobacillus salivarius LS03

The clinical results pertinent to Biome Australia are solely those reported on Group IV vs Control Group and cement Biome's decision to proceed with the launch of *Biome Acne™ Probiotic* in Q4 2022.

The Study's endpoints were evaluated at each post-baseline visit and included the following.

- The percent change from baseline in facial comedones, papules, pustules, and nodules, measured using the global acne grading system (GAGS) score that gives a weight to each region (face and back) with a severity score
- Porphyrins, evaluated by the VISIA system
- Erythema and desquamation, measured according to a four-point qualitative scale.
- Sebum level, measured by a microcamera equipped with 200× Optic system
- Microbial dysbiosis, expressed as the relative abundance of bacterial DNA of main bacterial species on the skin: Cutibacterium acnes, Staphylococcus epidermidis, and Staphylococcus aureus

Trial results

Full results from the Trial and each Group's performance against the Study's endpoints are included in annexure A.

Group IV results (probiotics alone)

Using the global acne grading system (GAGS) score, results from Group IV vs Control Group showed that at week 4, there was a 31.11% ($p < 0.05$) decrease in the number of superficial inflammatory acne lesions in the subjects taking probiotics compared to placebo (-10%) and at 8 weeks there was a 38.89% ($p < 0.05$) decrease vs placebo (18.89% decrease).

The mean erythema score was significantly reduced after 8 weeks of treatment with probiotics (T0 1.82 ± 0.06 vs T2 0.73 ± 0.74, $p < 0.05$), while no reduction was reported in the placebo Group. 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 in Group IV at the end of the study, providing evidence for the ability of this oral probiotic to impact the skin microbiome.

Group II and Group III also reported a decrease in the number of superficial inflammatory acne lesions at 8 weeks recording -56.67% and -40% respectively. The two Groups also reported a significantly reduced sebum secretion rate and mean erythema score of 0.27 ± 0.45 ($p < 0.05$) for Group II and 0.50 ± 0.63 ($p < 0.05$) for Group III. The mean erythema score at baseline for all Groups was 1.82 ± 0.06.

Biome Acne™ Probiotic **to launch in Q4 FY22**

The results of the probiotic arm support new product opportunities that are aligned with Biome's expertise: specialised probiotic products.

This trial has helped to establish the viability, efficacy and commercial value of Biome Australia's latest product, *Biome Acne™ Probiotic,* formulated using the probiotic strains tested on the 27 subjects.

These significant clinical results cement the company's growth strategy to launch well-researched and novel probiotic products that address prevalent health concerns in new ways and expand its product portfolio.

Production and manufacturing of *Biome Acne™ Probiotic* remains on track and upon launch will be sold via the company's extensive network of over 2300 community pharmacies and independent health practitioners across Australia. It will also be launched into the UK and New Zealand markets as *Biome Derma™*.

-ENDS-

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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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ANNEXURE A

Results from Group IV (probiotics alone)

Endpoint	**Results at 4 weeks**	**Results at 8 weeks**
The percent change from baseline in the global acne grading system (GAGS) score	−31.11% ($p < 0.05$)	−38.89% ($p < 0.05$)
Erythema score	No statistically significant reductions	The mean erytheme score at baseline for all groups was 1.82 ± 0.06 and reduced to 0.73 ± 0.74 ($p < 0.05$) for group IV
Desquamation score	No statistically significant reductions	–33.30% ($p < 0.01$)
Sebum secretion rate	No statistically significant reductions	Significantly reduced
Porphyrin	No statistically significant reductions	No statistically significant reductions
Microbial dysbiosis	Significant ($p < 0.01$) decrease in C. acnes (from 26.8 to 24.2 log RA, respectively). No statistically significant changes to S. aureus or S. epidermis.	Significant ($p < 0.01$) decrease in C. acnes (21.7 log RA). No statistically significant changes to S. aureus or S. epidermis.

Results from Group II (probiotics and botanicals)

Endpoint	**Results at 4 weeks**	**Results at 8 weeks**
The percent change from baseline in the global acne grading system	−36.67% ($p < 0.05$)	−56.67% ($p < 0.05$)

(GAGS) score		
Erythema score	No statistically significant reductions	The mean erythema score at baseline for all groups was 1.82 ± 0.06 and reduced to 0.27 ± 0.45 for group II ($p < 0.05$)
Desquamation score	−33.30% ($p < 0.05$)	−55.60% ($p < 0.05$)
Sebum secretion rate	No statistically significant reductions	Significantly reduced
Porphyrin	No statistically significant reductions	−45.49% ($p < 0.05$)
Microbial dysbiosis	Significant ($p < 0.01$) decrease in C. acnes (from 29.7 to 21.4 log RA, respectively). S. aureus was significantly ($p < 0.05$) reduced (from 1.4 to 1.1 log RA) No statistically significant changes to S. epidermis	Significant ($p < 0.01$) decrease in C. acnes (8.8 log RA) S. aureus was significantly ($p < 0.05$) reduced in group II (0.2 log RA) Significant ($p < 0.05$) increase in S. epidermidis (from 0.6 to 1.2 log RA).

Results from Group III (botanicals)

Endpoint	**Results at 4 weeks**	**Results at 8 weeks**
The percent change from baseline in the global acne grading system (GAGS) score	−33.33% ($p < 0.05$)	−40.00% ($p < 0.05$)
Erythema score	No statistically significant reductions	The mean erythema score at baseline for all groups was 1.82 ± 0.06 and reduced to 0.50 ± 0.63 ($p < 0.05$) for group III
Desquamation score	No statistically significant	−43.40% ($p < 0.01$)

	reductions	
Sebum secretion rate	No statistically significant reductions	Significantly reduced
Porphyrin	No statistically significant reductions	−34.25% ($p < 0.01$)
Microbial dysbiosis	No statistically significant changes to C. acnes or S. epidermis. S. aureus was significantly ($p < 0.05$) reduced (from 1.8 to 0.9 RA)	No statistically significant changes to C. acnes S. aureus was significantly ($p < 0.05$) reduced (0.7 log RA) Significant ($p < 0.05$) increase in S. epidermidis was reported in group III (from 1.1 to 1.6 log RA)

Results from Group I (placebo)

Endpoint	**Results at 4 weeks**	**Results at 8 weeks**
The percent change from baseline in the global acne grading system (GAGS) score	No statistically significant reductions	No statistically significant reductions
Erythema score	No statistically significant reductions	No statistically significant reductions
Desquamation score	No statistically significant reductions	No statistically significant reductions
Sebum secretion rate	No statistically significant reductions	No statistically significant reductions
Porphyrin	No statistically significant reductions	No statistically significant reductions
Microbial dysbiosis	No statistically significant changes	No statistically significant changes