



#### **ASX ANNOUNCEMENT**

30 April, 2025

#### **Activated Probiotics New Product Launches**

- Biome to release two new Products into the Activated Probiotics range in Q4 FY25
- Biome Her<sup>™</sup> Pessary
  - Featuring a clinically-trialled combination of probiotic strains shown to support healthy vaginal microbiome balance<sup>1</sup>
- Biome Perinatal™ Probiotic
  - Featuring a clinically-trialled probiotic strain shown to support healthy pregnancy outcomes and improve postpartum mood balance<sup>2-5</sup>

Microbiome health company **Biome Australia Limited** (ASX: BIO) ('Biome' or 'the company') is pleased to provide an update on two new product launches supporting women's health through our flagship brand, Activated Probiotics.

Women's health is the number one vitamin and dietary supplements category by sales volume in Australia<sup>6</sup>. With over 75% of Australian households using complementary medicines<sup>6</sup>, demand for female-focused products– including those targeting vaginal health, fertility, pregnancy, and overall well-being–continues to rise. Female customers and patients are the leading demographic of complementary medicine consumers, often being the main purchaser of probiotics and complementary medicines. With two new product offerings, Biome is aiming to better support this demographic at earlier life stages and through their child-bearing years.



#### Biome Her™ Pessary

Biome Her<sup>TM</sup> Pessary will complement Biome Her<sup>TM</sup> Probiotic, an oral probiotic for vaginal microbiome balance, by providing targeted support through a new vaginally-inserted probiotic pessary. This product includes clinically-trialled probiotic strains<sup>1</sup> and will include 10 vaginal capsules designed to be recommended for short-term use to women with acute vaginal health concerns, and has been listed on the Australian Register of Therapeutic Goods to maintain/support vaginal healthy flora/microflora.

#### Biome Perinatal™ Probiotic

Biome has also identified an opportunity in the Australian and international markets for a high-quality evidence-based probiotic for use before, during and after pregnancy including throughout breastfeeding.

Biome Perinatal+ Probiotic, Biome's upcoming offering in this category, includes clinically-trialled probiotic strains which have demonstrated clinical evidence of efficacy for their ability to support the health needs of women before, during and after pregnancy<sup>2-5</sup>, and has been listed on the Australian Register of Therapeutic Goods with the following health claims:

- Maintain/support healthy pregnancy
- Helps enhance/promote maternal health
- Helps enhance/promote maternal postnatal health
- Support healthy emotional/mood balance in post-partum women

Alongside women's products being number one in the industry, there were \$98.6 million prenatal multivitamin supplement sales in 2024, a key co-prescribing opportunity for Biome Perinatal™ Probiotic.<sup>6</sup>

#### Lactobacillus acidophilus LA02 and Lactobacillus fermentum LF10

Biome has worked with its research partners to identify key probiotic strains that have been found in human clinical trials to support vaginal microbiota balance. In women with recurrent vaginal thrush, *Lactobacillus acidophilus* LAO2 and

Lactobacillus fermentum LF10 have been found to reduce relapse rates to 27.6% when administered after standard treatment<sup>1</sup>. Current standard treatment approaches alone are not particularly effective, with post-treatment relapse rates as high as 57%<sup>7</sup>.

#### Lactobacillus rhamnosus HN001

Similarly, probiotic strains which help to improve health outcomes during pregnancy and into motherhood have also been an area of focus. *Lactobacillus rhamnosus* HN001 is one such strain that was identified as a well-researched probiotic intervention indicated for this application, with reductions in the rate of gestational diabetes<sup>5</sup>, improved postpartum mood balance<sup>2</sup>, and protection against eczema development<sup>4</sup> in future children\* observed when supplemented during pregnancy and throughout breastfeeding (\*when the children were also supplemented with this probiotic strain in the first two years of life).

#### References

- 1. Murina F, Graziottin A, Vicariotto F, De Seta F. Can Lactobacillus fermentum LF10 and Lactobacillus acidophilus LA02 in a slow-release vaginal product be useful for prevention of recurrent vulvovaginal candidiasis?: A clinical study. J Clin Gastroenterol. 2014;48(December):S102–5.
- 2. Slykerman, R. F., Hood, F., Wickens, K., Thompson, J. M. D., Barthow, C., Murphy, R., ... & Mitchell, E. A. (2017). Effect of Lactobacillus rhamnosus HN001 in pregnancy on postpartum symptoms of depression and anxiety: a randomised double-blind placebo-controlled trial. EBioMedicine, 24, 159-165.
- 3. Kalliomäki, M, Salminen, S, Poussa, T, et al. (2007) Probiotics during the first 7 years of life: a cumulative risk reduction of eczema in a randomised, placebo-controlled trial. J Allergy Clin Immunol 119, 1019–1021.
- 4. Wickens, K., Black, P. N., Stanley, T. V., Mitchell, E., Fitzharris, P., Tannock, G. W., ... & Probiotic Study Group. (2008). A differential effect of 2 probiotics in the prevention of eczema and atopy: a double-blind, randomized, placebo-controlled trial. Journal of Allergy and Clinical Immunology, 122(4), 788-794.
- 5. Wickens, K. L., Barthow, C. A., Murphy, R., Abels, P. R., Maude, R. M., Stone, P. R., ... & Crane, J. (2017). Early pregnancy probiotic supplementation with Lactobacillus rhamnosus HN001 may reduce the prevalence of gestational diabetes mellitus: a randomised controlled trial. British Journal of Nutrition, 117(6), 804-813.
- 6. Complementary Medicines Australia. (2024). 2024 Industry Snapshot. Available from: https://cmaustralia.org.au/wp-content/uploads/CMA-Snapshot-2024.pdf
- 7. Bradfield Strydom M, Walpola RL, Khan S, Ware RS, Tiralongo E. Evidence-based update on Australasian pharmaceutical prescribing approaches for recurrent vulvovaginal candidiasis. Aust N Z J Obstet Gynaecol. 2021 Aug;61(4):496-499.

Women's Health

# Biome Her™ Pessary



## A new vaginal pessary to support women re-establish a healthy vaginal microbiome

Biome Her™ Pessary is more suitable for short-term use for women with acute vaginal health concerns, and includes clinically trialled probiotic strains that help women re-establish and maintain a healthy vaginal microbiome.



#### Practitioner-only product

## Biome Her<sup>™</sup> Pessary

• To help maintain a healthy vaginal microbiome

#### Formulation

Total live bacteria	3 BLB*
Lactobacillus acidophilus LA02 (DSM 21717)	1 BLB*
Lactobacillus fermentum LF10 (DSM 19187)	1 BLB*
Lactobacillus crispatus LCR01 (DSM 24619)	1 BLB*

Education Team Master Presentation



#### Biome Her<sup>™</sup> Pessary

## Market analysis

The global women's probiotic market is growing at a compound annual growth rate (CAGR) of 18.1% from 2024 to 2034.

The women's probiotic market in Australia and New Zealand is projected to grow at a CAGR of 8.2% from 2024 to 2034.<sup>1</sup>

With over 75% of Australian households using complementary medicines, demand for female-focused products—including those targeting vaginal, fertility and pregnancy—continues to rise.<sup>2</sup>

<sup>1.</sup> Future Market Insights. (2024). Women's Probiotic Market Report. Retrieved from https://www.futuremarketinsights.com/reports/women-probiotic-market

<sup>2.</sup> Complementary Medicines Australia. (2024). CMA Snapshot 2024. Retrieved from https://cmaustralia.org.au/wp-content/uploads/CMA-Snapshot-2024.pdf



#### Biome Her<sup>™</sup> Pessary

### Consumer needs

Approximately 70% of women will develop vaginal thrush in their lifetime

Recurrent vaginal thrush affects up to 10% of Australian women<sup>1</sup>

It has debilitating effects on the physical and emotional well-being of these women<sup>1</sup>

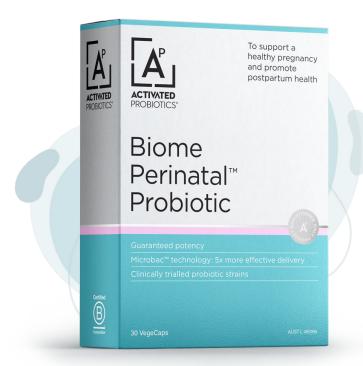
Standard treatment is not particularly effective with post-treatment relapse rates as high as 57%<sup>1</sup>

1. Bradfield Strydom M, Walpola RL, Khan S, Ware RS, Tiralongo E. Evidence-based update on Australasian pharmaceutical prescribing approaches for recurrent vulvovaginal candidiasis. Aust N Z J Obstet Gynaecol. 2021 Aug;61(4):496-499.

 Murina F, Graziottin A, Vicariotto F, De Seta F. Can Lactobacillus fermentum LF10 and Lactobacillus acidophilus LA02 in a slow-release vaginal product be useful for prevention of recurrent vulvovaginal candidiasis?: A clinical study. J Clin Gastroenterol. 2014;48(December):5102–5.

Women's Health

## Biome Perinatal™ Probiotic



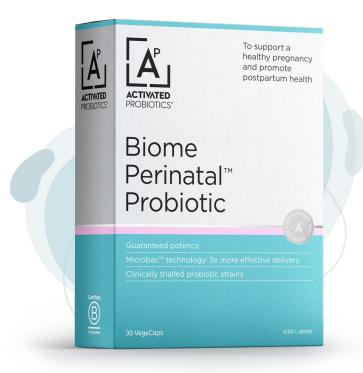
Practitioner-only product

### Biome Perinatal™ Probiotic

- Supports a healthy pregnancy
- Helps promote maternal health
- Supports healthy postpartum mood balance

#### Formulation

Total live bacteria (BLB=Billion Live Bacteria)	20 BLB*
Bifidobacterium animalis subsp. lactis BA05 (DSM 18352)	3 BLB*
Bifidobacterium breve BR03 (DSM 16604)	5 BLB*
Lactobacillus crispatus LCR01 (DSM 24619)	1 BLB*
Lactobacillus rhamnosus HN001 (ATCC SD5675)	6 BLB*
Lactobacillus rhamnosus GG (ATCC 53103)	5 BLB*



## A new probiotic formulation to support women before, during and after their pregnancy journey

Biome Perinatal™ is formulated with clinically-trialled probiotic strains that have evidence to support a healthy pregnancy, promote maternal health and support healthy postpartum mood balance.



## Biome Perinatal™ Probiotic Market analysis

According to the Australian Institute of Health and Welfare, there were nearly 300,000 pregnant women in Australia in 2022¹. Biome Perinatal™ offers targeted probiotic support to this group of women prior to, during and in the one year period following their pregnancy journey, compounding into a total market size of approximately 1 million+.

Biome Perinatal™ offers a streamlined co-prescribing opportunity for the highly engaged customer purchasing prenatal supplements.

1. Australian Institute of Health and Welfare. (2024). Australia's mothers and babies: State and territory. Retrieved from

https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-babies/contents/overview-and-demographics/state-and-territory

2. Complementary Medicines Australia. (2024). CMA Snapshot 2024. Retrieved from https://cmaustralia.org.au/wp-content/uploads/CMA-Snapshot-2024.pdf

#### -ENDS-

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 <a href="mailto:this.link">this link</a> (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,  $\underline{\text{Activated Nutrients}}^{\underline{\mathbb{R}}}$ .

For more information visit: www.biomeaustralia.com

#### **Investor Relations**

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#### Forward looking statements

This release may contain forward looking statements, including but not limited to projections, guidance on future revenues, earnings, other potential synergies and estimates and the future performance of Biome (**Forward Looking Statements**).

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.

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.

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