

## ASX ANNOUNCEMENT

21 December 2023

### Biome to launch cholesterol reducing probiotic:

- Biome to launch new cholesterol lowering probiotic, *Biome Cholesterol Probiotic*
- A double blind, placebo controlled 12 week trial reduced total cholesterol by 14% and LDL (bad cholesterol) by 15% whilst increasing HDL (good cholesterol) by 7% compared to baseline
- Potential for *Biome Cholesterol Probiotic* to be used as an adjuvant alongside statins to support increased efficacy of treatment or to reduce the dosage and side effects of this type of treatment
- For people who don't tolerate statins therapy, *Biome Cholesterol Probiotic* will provide physicians with an additional therapeutic option to help manage the cholesterol levels of these patients.
- Cardiovascular diseases are the leading cause of death globally with high total cholesterol, high LDL cholesterol and low HDL cholesterol being major risk factors
- More than 4 million Australians are reported to be living with cardiovascular diseases
- The exclusive license covers Biome practitioner only distribution channels in Australia and New Zealand and will last for an initial period of 3 years

Microbiome health company Biome Australia Limited (ASX: BIO) ('Biome' or 'the company') is pleased to announce it has signed an agreement to add a condition-specific live biotherapeutic product to the Biome Activated Probiotics product range, *Biome Cholesterol Probiotic*, which is targeted towards lowering cholesterol levels.

The product, consisting of three specific *Lactobacillus plantarum* strains (CECT7527, CECT7528, and CECT7529), has been shown to improve cholesterol levels significantly as demonstrated in four supporting human clinical trials.<sup>[1],[2],[3],[4]</sup> *Biome Cholesterol Probiotic* It is scheduled for release in Q4 FY24.



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## Burden of high cholesterol and cardiovascular disease:

Cardiovascular diseases (CVDs) are the leading cause of death globally. They are responsible for 1 in 4 deaths in Australia, and more than 4 million Australians report living with CVD<sup>[5],[6]</sup>. High total cholesterol, high LDL cholesterol (“bad” cholesterol) and/or low HDL cholesterol (“good” cholesterol) are major risk factors for the development of CVD, particularly coronary heart disease, heart attacks and strokes. Abnormal cholesterol levels contributes to atherosclerosis: the buildup of fatty deposits in artery walls, which can create blockages and prevent blood flow to the heart and brain<sup>[7]</sup>. The risk of atherosclerotic cardiovascular disease is approximately 3 times higher in individuals with severe hypercholesterolaemia (high total cholesterol and/or LDL cholesterol)<sup>[8]</sup>.

According to the World Heart Federation, high cholesterol affects approximately 39% of adults globally and is directly attributed to almost one quarter of all cardiovascular disease (CVD) related deaths<sup>[9]</sup>. In Australia, 1 in 3 adults have high levels of LDL and high total cholesterol and almost 1 in 4 have low HDL cholesterol levels<sup>[10]</sup>, making abnormal cholesterol levels a major health concern<sup>[11]</sup>.

## Statins and their limitations:

Statins are the gold-standard first-line therapy for lowering cholesterol and reducing CVD risk, and are currently taken by 2.5 million Australians. In FY22, the statins rosuvastatin and atorvastatin were the two most prescribed PBS drugs in Australia with over 15 million and 11.8 million prescriptions, respectively.

Despite this, according to Professor Nicholls (cardiologist and Director of the Victorian Heart Hospital at Monash Health and Monash University’s Victorian Heart Institute) 50% of high-risk CVD patients don’t get their cholesterol down to target levels. Up to 20% of individuals who are recommended statins demonstrate some degree of intolerance due to side effects, and 40–75% discontinue their statin therapy within 1–2 years after initiation<sup>[12]</sup>. Unfortunately, statin non-compliance is highly correlated with an increased risk for acute cardiovascular events, such as a heart attack<sup>[13]</sup>.

## Clinical Trials and Key Research:

In one double-blind, placebo controlled clinical trial, supplementation of *Biome Cholesterol Probiotic* for 12 weeks reduced total cholesterol by 14% and LDL cholesterol by 15% and improved HDL cholesterol by 7% when compared to baseline<sup>[PH1]</sup> [JB2].



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The authors of the study noted that the reductions in LDL cholesterol from this simple one-a-day capsule are similar to those shown for recommended dietary interventions such as plant sterols and viscous fibres.

In a meta-analysis of fifteen clinical trials which assessed the efficacy of various lactobacilli-containing products on cholesterol levels, Biome Cholesterol was found to demonstrate the best reduction in total cholesterol levels<sup>[14]</sup>.

### Supporting treatment with live biotherapeutic probiotics:

Biome Cholesterol has been studied as an adjuvant therapy alongside statins<sup>[15]</sup>. A 12-week observational study demonstrated that the use of Biome Cholesterol alongside statins reduced LDL cholesterol by 25%, which was greater than the 20% reduction observed in those who used Biome Cholesterol alone.

The scope of the issue and the volume of prescriptions that specifically target high cholesterol presents a significant opportunity for Biome, which will aim to promote the adjunct selling of the new product alongside statins to support increased efficacy of treatment, potentially reduce the dosage of statins to minimise the risk of side effects, and ultimately improve patient outcomes in the community.

For those who don't tolerate statins or discontinue statin therapy, Biome Cholesterol will provide physicians with an additional therapeutic option to help manage the cholesterol levels of these patients. Biome will also be able to appeal to patients with low to moderate CVD risk who have been advised to make lifestyle and dietary changes to improve their cholesterol and avoid the need for future drug therapy.

High cholesterol poses a real risk to the lives of many Australians, and there is a clear need for alternative viable options to improve the management of high cholesterol.

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<sup>[1]</sup> <https://content.iospress.com/download/mediterranean-journal-of-nutrition-and-metabolism/mnm0065?id=mediterranean-journal-of-nutrition-and-metabolism%2Fmnm0065>

<sup>[2]</sup> <https://www.mdpi.com/2072-6643/13/4/1206>

<sup>[3]</sup> [https://semipyp.es/pdf/workshop/workshop10\\_2019\\_abstracts.pdf](https://semipyp.es/pdf/workshop/workshop10_2019_abstracts.pdf)



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<sup>[4]</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8629581/>

<sup>[5]</sup> <https://www.health.gov.au/topics/chronic-conditions/what-were-doing-about-chronic-conditions/what-were-doing-about-cardiovascular-conditions>

<sup>[6]</sup> <https://www.heartfoundation.org.au/bundles/for-professionals/key-stats-cardiovascular-disease>

<sup>[7]</sup> <https://www.ncbi.nlm.nih.gov/books/NBK459188/>

<sup>[8]</sup> <https://www.ahajournals.org/doi/10.1161/JAHA.121.024379>

<sup>[9]</sup> <https://world-heart-federation.org/what-we-do/cholesterol/#:~:text=Globally%2C%20raised%20total%20cholesterol%20affects,an%20estimated%204.4%20million%20deaths.>

<sup>[10]</sup> <https://www.aihw.gov.au/reports/risk-factors/risk-factors-to-health/contents/abnormal-blood-lipids-dyslipidaemia>

<sup>[11]</sup> <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/cholesterol>

<sup>[12]</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5960491/>

<sup>[13]</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5960491/>

<sup>[14]</sup> Wu Y, Zhang Q, Ren Y, Ruan Z. Effect of probiotic Lactobacillus on lipid profile: A systematic review and meta-analysis of randomized, controlled trials. PLoS One. 2017 Jun 8;12(6):e0178868

<sup>[15]</sup> [https://semipyp.es/pdf/workshop/workshop10\\_2019\\_abstracts.pdf](https://semipyp.es/pdf/workshop/workshop10_2019_abstracts.pdf)

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## –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 [this link](https://investorhub.biomeaustralia.com/) (<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<sup>®</sup>](#).

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.



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Biome also develops, licenses and distributes a scientifically formulated, organic nutraceutical range, Activated Nutrients<sup>®</sup>.

For more information visit: [www.biomeaustralia.com](http://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. 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.*

*Nothing in this release is a promise or representation as to the future. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any Forward Looking Statements contained in this release. Except as required by law or regulation (including the ASX Listing Rules), Biome does not undertake to provide any additional or updated information whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise.*

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*Investors are strongly cautioned not to place undue reliance on Forward Looking Statements, particularly in light of the current economic climate and the significant volatility, uncertainty and disruption caused by the Covid-19 pandemic.*



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