ACTIVATED PROBIOTICS®

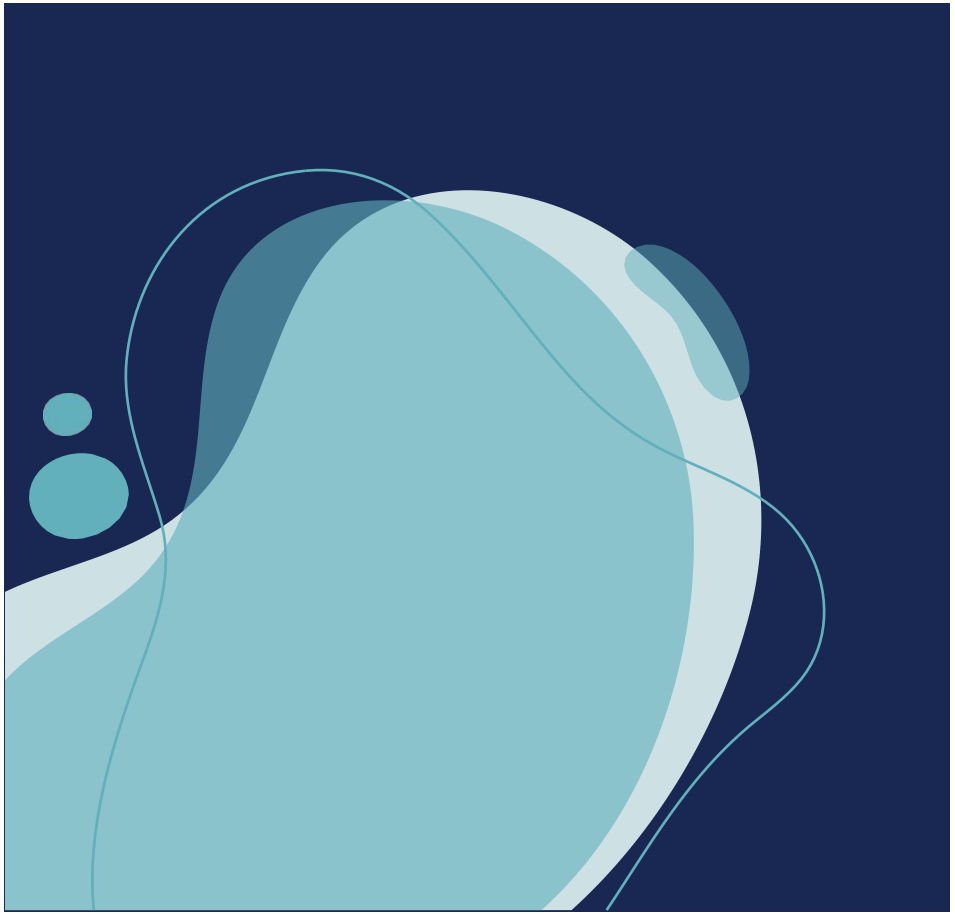
INTERNATIONAL SCIENTIFIC CONFERENCE PROBIOTICS, PREBIOTICS GUT MICROBIOTA AND HEALTH

Microbiota-Gut-Brain Psychology

Live Biotherapeutics — A new intervention for sub-threshold depression

Presented by:
Blair Vega Norfolk, CEO, Biome Australia Ltd

Certified B Corporation
This company meets the highest standards of social and environmental impact



Activated Probiotics

The next generation of live biotherapeutic products – Precision Probiotics

The range includes clinically-proven probiotics for:

Allergic asthma	Mineral absorption
Mood and sleep	Bone-density health

- Condition-specific products with targeted strains
- Supported by human clinical trials
- Practitioner-only distribution
- Practitioner-led clinical education and training
- Ongoing clinical development of products in market

Clinically trialled products | Condition specific | Gluten free | Shelf-stable live bacteria | Dairy free | One-a-day formulation

The mental health landscape in Australia

1 in 5

Australians aged 16-85 experience a mental illness in any year

3.4M

Australians saw a health professional for their mental health in 2020-2021

15%

of Australians felt lonely in the previous four weeks

61%

of Australians used at least one strategy to manage their mental health

45%

of the population will experience a mental illness in their lifetime

10%

of Australians are on an antidepressant, with 38% experiencing side effects

https://www.abs.gov.au/articles/first-insights-national-study-mental-health-and-wellbeing-2020-21

frontiers in Psychiatry

ORIGINAL RESEARCH
Published 2019 Mar 27.
doi: 10.3389/fpsyt.2019.00164

Effects of Probiotics on Cognitive Reactivity, Mood, and Sleep Quality

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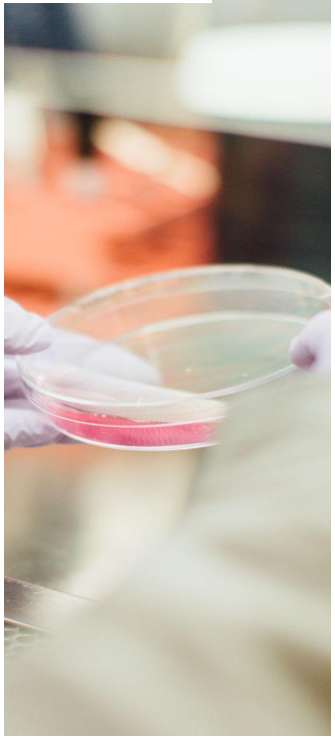
Biome Lift™ Clinical Trial

The primary aim of the trial is to assess the efficacy of Biome Lift™ compared to a placebo in reducing the severity of symptoms in patients aged 18-65 with sub-threshold depression.

The trial will be conducted at La Trobe University where 48 participants will be recruited and dosed once per day with placebo or active over a 3-month period.

Participants will:

- Take one probiotic or placebo daily, for 3 months
- Complete one brief weekly questionnaire about their mood
- Complete a set of questionnaires at 3 time points (before, during and after the probiotic or placebo)
- Collect saliva, faecal and have blood samples collected for analysis at 3 time points (before, during and after the probiotic or placebo)



Biome Lift™ Clinical Trial

The primary outcome measure will be:

Subjective assessment of depression using the following validated questionnaire weekly:

- Patient Health Questionnaire (PH9; self-report, brief specifically measures depression and has been shown to be responsive to intervention) [weekly]

The secondary outcome measures will be:

1. Subjective and clinical assessment of depression, anxiety, mood and QoL, using the following validated questionnaires:

- Structured Clinical Interview for DSM-5 (SCID 5; clinically administered; depression symptoms) [pre and post only]
- Hospital Anxiety and Depression Scale (HADS; self-report; anxiety and depression) [4 timepoints at pre, mid, post and follow-up]
- Beck Depression Inventory (BDI-II; self-report; depression) [4 timepoints at pre, mid, post and follow-up]
- Depression, Anxiety and Stress Scale (DASS-21; self-report; depression, anxiety and stress severity ratings) [4 timepoints at pre, mid, post and follow-up]
- Assessment of Quality of Life (ADoL-6D; self-report; health-related quality of life) [4 timepoints at pre, mid, post and follow-up]

2. A range of inflammatory and metabolic biomarkers assessed via blood samples including: insulin, hs-CRP, plasma GSH (glucose, TNF-a, IL-6, IL-10 – these will be analysed after the study competition with additional funding. [3 timepoints at pre, mid and post]

3. Gut microbiota composition changes assessed via fecal samples testing for microbiota genome and functional predictions of gut microbiota. [3 timepoints at pre, mid and post]

4. Salivary cortisol as a biomarker of stress assessed via saliva sample collection. [3 timepoints at pre, mid and post]

5. Subjective assessment of gastrointestinal health using the following validated questionnaire:

- Irritable bowel syndrome-severity scoring system (IBS-SSS; self-report; gut symptom severity) [4 timepoints at pre, mid, post and follow-up]

Biome Lift™

Clinically trialled product

TGA APPROVED INDICATIONS

- Supports healthy mood balance
- Enhances sleep quality
- May help reduce cognitive fatigue

The LBP Opportunity - Adjunct to Medications

Given the high level of clinical evidence and low risk profile associated with live biotherapeutic products (LBPs), Activated Probiotics has developed a program to support co-prescribing alongside medications by general practitioners and pharmacists in Australia.

When a medication is prescribed for a particular health condition that has been researched within the LBP space, a companion recommendation can be made to help improve the patient's treatment and health outcomes, if the product is commercially available.

Activated Probiotics refers to this market as "the adjunct medication market"

ATC medication category	Medication volume July 2020-June 2021	Activated Probiotics Product with adjunct opportunities within the ATC category
	**10M** Prescriptions per year	 **Biome Advanced Probiotic** To help restore the balance of beneficial gut bacteria after antibiotic use
	**48M** Prescriptions per year	 **Biome Lift Probiotic** To support healthy mood balance and enhance sleep quality

Clinical Detailing and Education Support

Unique *Education and Service* Commercialisation Model

Education-focused promotion

- An alternative model to traditional pharmaceutical *sales and education*
- Practitioner education consultants undertake education-driven engagement in key health practitioner channels
- Training and education aims to provide product and scientific knowledge to healthcare practitioners and develop stronger understanding of LBPs

Regulatory Environment

Therapeutic Goods Administration (TGA)

All medicines supplied in Australia must be included in the **Australian Register of Therapeutic Goods (ARTG).**

Medicines will be either:

- AUST L
- AUST L(A)
- AUST R

Medical Devices are categorised differently

Regulatory Environment

How types of medicine are included in the ARTG

Medicine type	Registered (AUST R)	Listed (AUST L & AUST L(A))
Complementary	Few	Most
Over-the-counter	Most	Some
Prescription	All	None

Attribute	Listed	Assessed listed	Registered
ARTG/AUST number	AUST L	AUST L(A)	AUST R
Pre-market efficacy assessment	No	Yes	Yes
Ingredients	From a list of pre-approved ingredients only	From a list of pre-approved ingredients only	Ingredients are assessed pre-market
Indications (conditions the medicine says it will treat)	From a list of pre-approved conditions only	Conditions are assessed pre-market	Conditions are assessed pre-market
Subject to post-market compliance reviews	Yes	Yes	No
Subject to post market surveillance (e.g. adverse event monitoring)	Yes	Yes	Yes
Available off-the-shelf	Yes	Yes	Some
Need for a prescription from a health professional	No	No	Some
Able to use 'TGA assessed' claim	No	Yes	Yes, for registered complementary medicines

https://www.tga.gov.au/how-we-regulate-medicines

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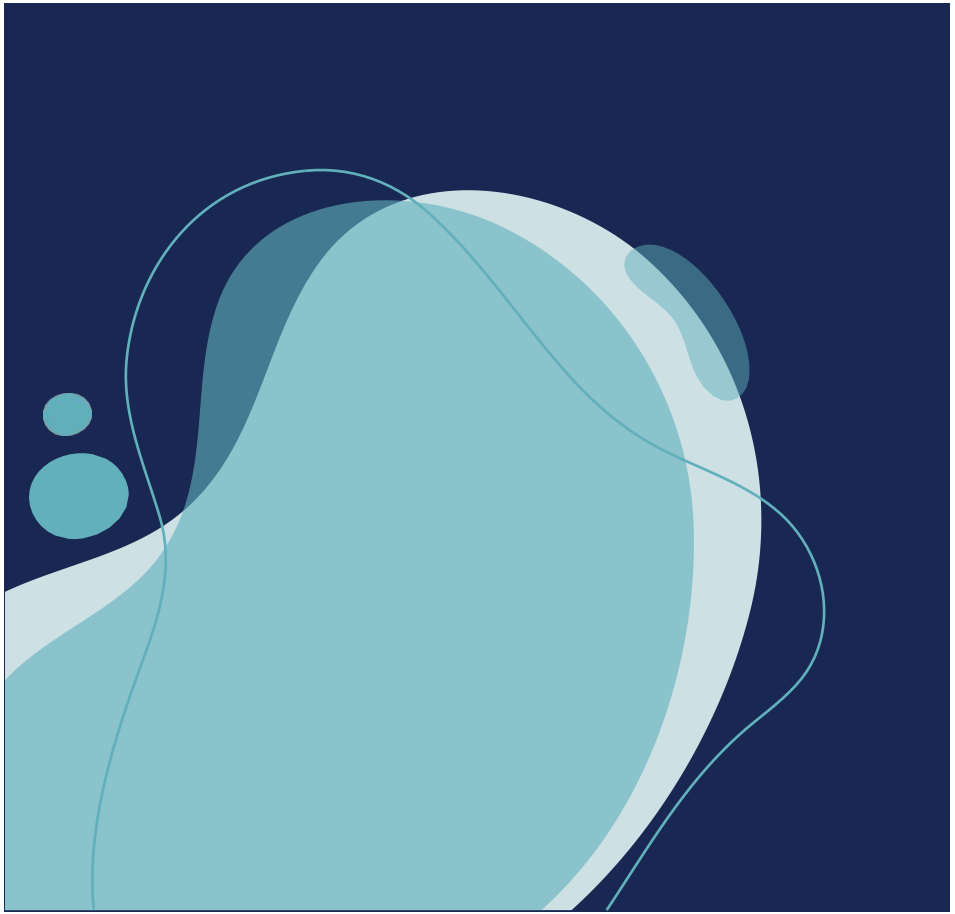
Thank You



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