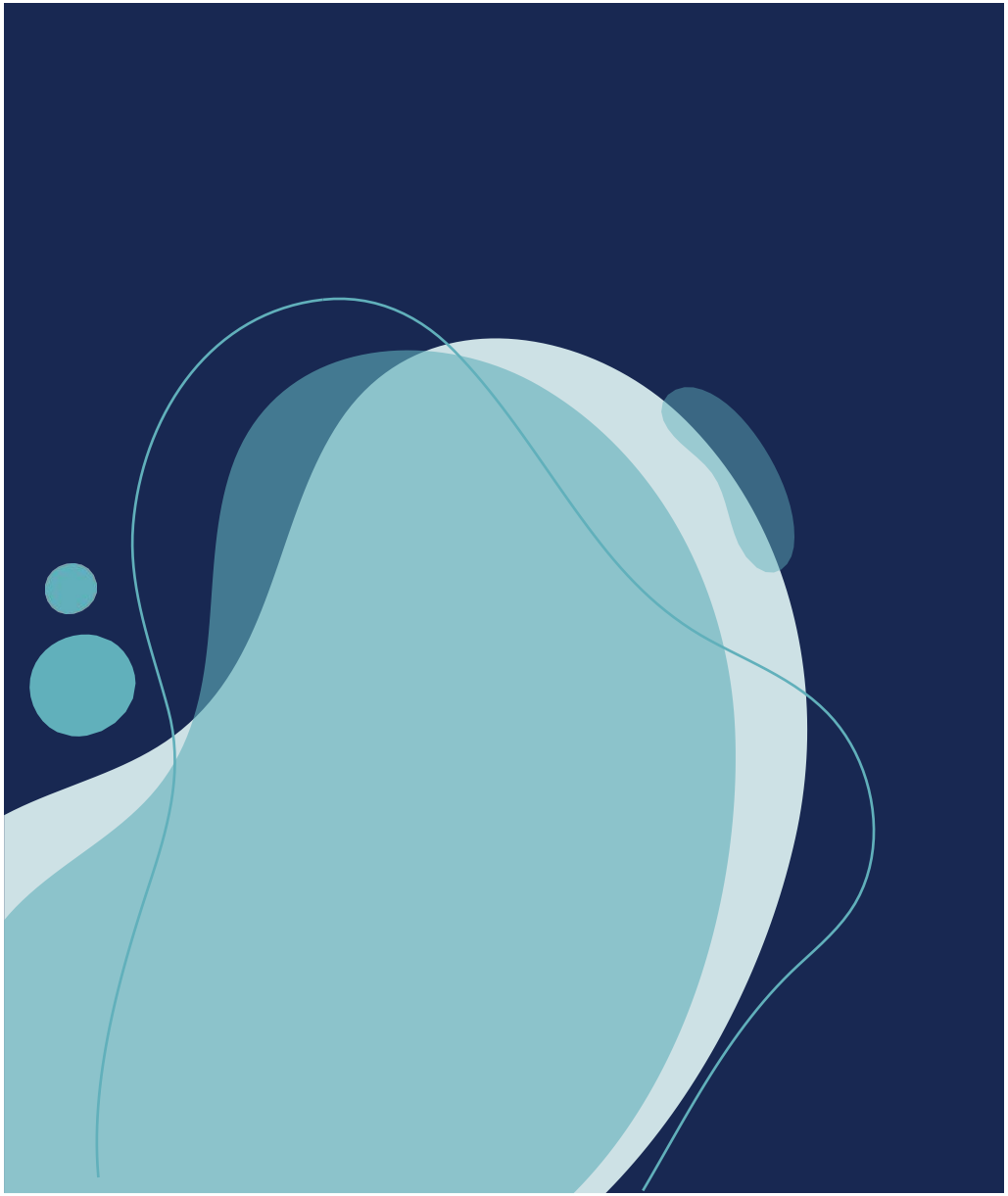
Biome Australia Limited

Clinical Development Update



Biome Australia Limited - 21 February 2022

Clinical Overview

Biome Australia (ASX: BIO) is focusing on becoming a global leader in the complementary medicine industry, offering clinically-proven condition-specific probiotic products.

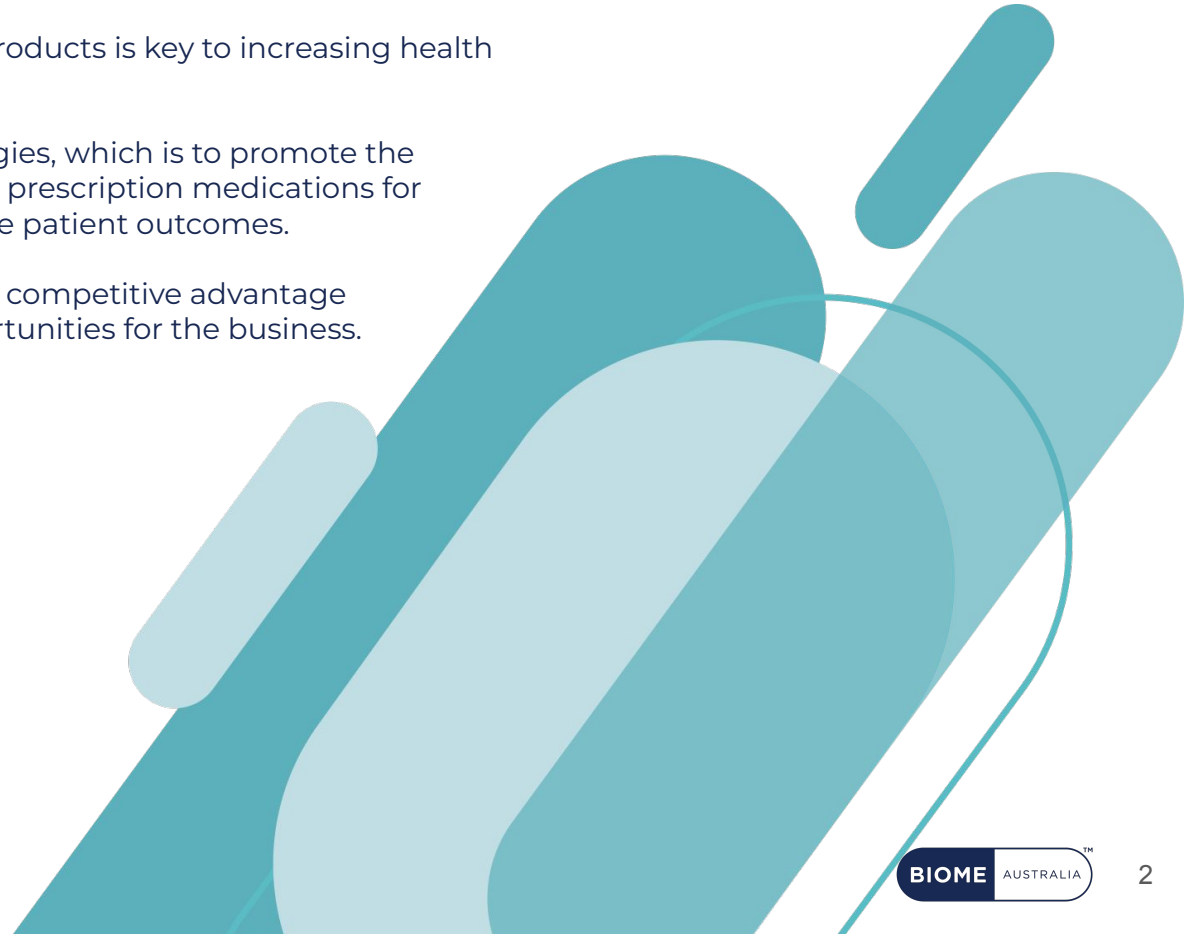
Biome is supporting novel clinical research to cement and extend the evidence base of its probiotic products.

The current ongoing clinical trials are being conducted by Biome's academic research partners La Trobe University and Federation University.

Expanding the evidence base of Biome's products is key to increasing health professional trust in product efficacy.

This strengthens one of Biome's key strategies, which is to promote the recommendation of its products alongside prescription medications for specific health concerns in order to improve patient outcomes.

This level of research also solidifies Biome's competitive advantage and will support commercial growth opportunities for the business.



Probiotics - a fast growing market

There is a strong body of literature supporting probiotic efficacy across multiple health conditions, elevating their position within conventional medicine settings. However, this evidence base requires deeper investigation which is specific to its intended application outside of general gastrointestinal health.

In 2020, probiotics were one of the top three fastest growing ingredients within complementary medicine year on year according to the CMA Industry Report 2021.

Live biotherapeutics are the next stage of development within the probiotic category, which involves the development of targeted strains of live probiotic bacteria that support specific pathological processes and disease states.

7 out of 10 Australians regularly use a complementary medicine[1]

Biome has the opportunity to access up to 80.3% of this addressable market[2]

Revenue up 100% in H1 FY22 vs PCP

2500+ distribution points and growing

(1) CMA Industry Audit 2021 p. 2

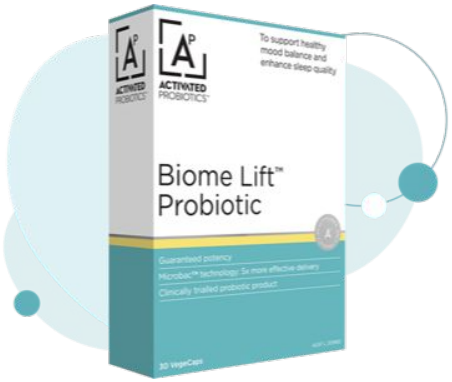
(2) CMA Industry Audit 2021 p. 5 (Biome Australia has access to 80.3% of CM market via pharmacy, health food stores, online, speciality retailers and direct selling)

Clinical Trial Programs

The clinical trial programs currently underway will expand the evidence of efficacy of existing products to support new and more specific applications.

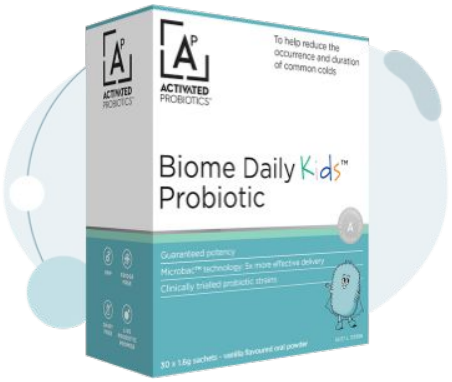
This research is helping to increase the validity of a number of non-pharmaceutical based interventions for key chronic health conditions with reduced side effects and lower risk profiles.

Biome's clinical pipeline currently includes



Study on subthreshold depression

Study on osteoporosis prevention



Study on paediatric immune health

Biome's Activated Probiotics range has 13 condition targeted probiotics ranging from eczema, bone health, asthma and other conditions that are traditionally supported by prescription medications and community pharmacies.

Current evidence of efficacy of existing products

Products undergoing additional research were previously brought to market based on the following clinical research

Product name	Evidence	Subject of the evidence
Biome Lift Probiotic	**Publication:** Marotta A, Sarno E, Casale A Del, Pane M, Mogna L, Amoruso A, et al. Effects of probiotics on cognitive reactivity, mood, and sleep quality. Front Psychiatry. 2019;10(164):1–11.	Exact combination of probiotic strains used in Biome Lift
Biome Osteo Probiotic	**Publication:** Jansson PA, Curiac D, Lazou Ahrén I, Hansson F, Martinsson Niskanen T, Sjögren K, et al. Probiotic treatment using a mix of three Lactobacillus strains for lumbar spine bone loss in postmenopausal women: a randomised, double-blind, placebo-controlled, multicentre trial. Lancet Rheumatol [Internet]. 2019;1(3):e154–62.	Exact combination of probiotic strains used in Biome Osteo
Biome Daily Kids Probiotic	**Publication:** Gawrońska A, Dziechciarz P, Horvath A, Szajewska H. A randomized double-blind placebo-controlled trial of Lactobacillus GG for abdominal pain disorders in children. Aliment Pharmacol Ther. 2007;25(2):177–84 **Publication:** Liu S, Hu P, Du X, Zhou T, Pei X. Lactobacillus rhamnosus GG supplementation for preventing respiratory infections in children: A Meta-analysis of Randomized, Placebo-controlled Trials. Indian Pediatr [Internet]. 2013 Apr 25;50(4):377–81, 3. **Publication:** Szajewska H, Canani RB, Guarino A, Hojsak I, Indrio F, Kolacek S, et al. Probiotics for the Prevention of Antibiotic-Associated Diarrhea in Children. J Pediatr Gastroenterol Nutr. 2016 Mar;62(3):495–506.	Specific probiotic ingredients within Biome Daily Kids

Clinical development timeline

Product	Ethics Approval	Recruitment and Trial Commence	Completion of Recruitment	Preliminary Results	Final Results
ASTHMA Biome Breathe Probiotic	✓	✓	✓	✓	✓
ACNE Biome Acne Probiotic	✓	✓	✓	✓	✓
SUBTHRESHOLD DEPRESSION Biome Lift Probiotic	✓	✓	Q2 2022	Q3 2022	Q4 2022
OSTEOPOROSIS PREVENTION Biome Osteo Probiotic	✓	✓	Q3 2022	Q4 2022	Mid 2023
PAEDIATRIC IMMUNE HEALTH Biome Kids Probiotic	Q1 2022	Q2 2022	TBA	TBA	TBA

✓ **Complete** **Scheduled**

Biome Lift™ Probiotic

$11b
was spent on mental health in Australia in 2019–20[1]

40.7m
prescriptions filled for mental health-related medications in Australia in 2019–20[2]

$566m
spent by the Australian government on subsidised mental health-related prescriptions 2019–20[3]

The primary aim of the trial is to assess the efficacy of the *Biome Lift™ Probiotic* compared to a placebo in reducing the severity of symptoms in patients with subthreshold depression.

The trial will be managed at La Trobe University where 48 participants will be recruited and dosed once per day with Biome Lift over a 3 month period.

The trial endpoints are as follows:

- Measures of anxiety, stress and mood
- Effects on biomarkers of inflammatory, immune, and stress responses
- The gut microbiota composition and function (via fecal samples assessing microbiota genome and functional predictions of gut microbiota)
- Body composition markers
- Gastrointestinal symptoms

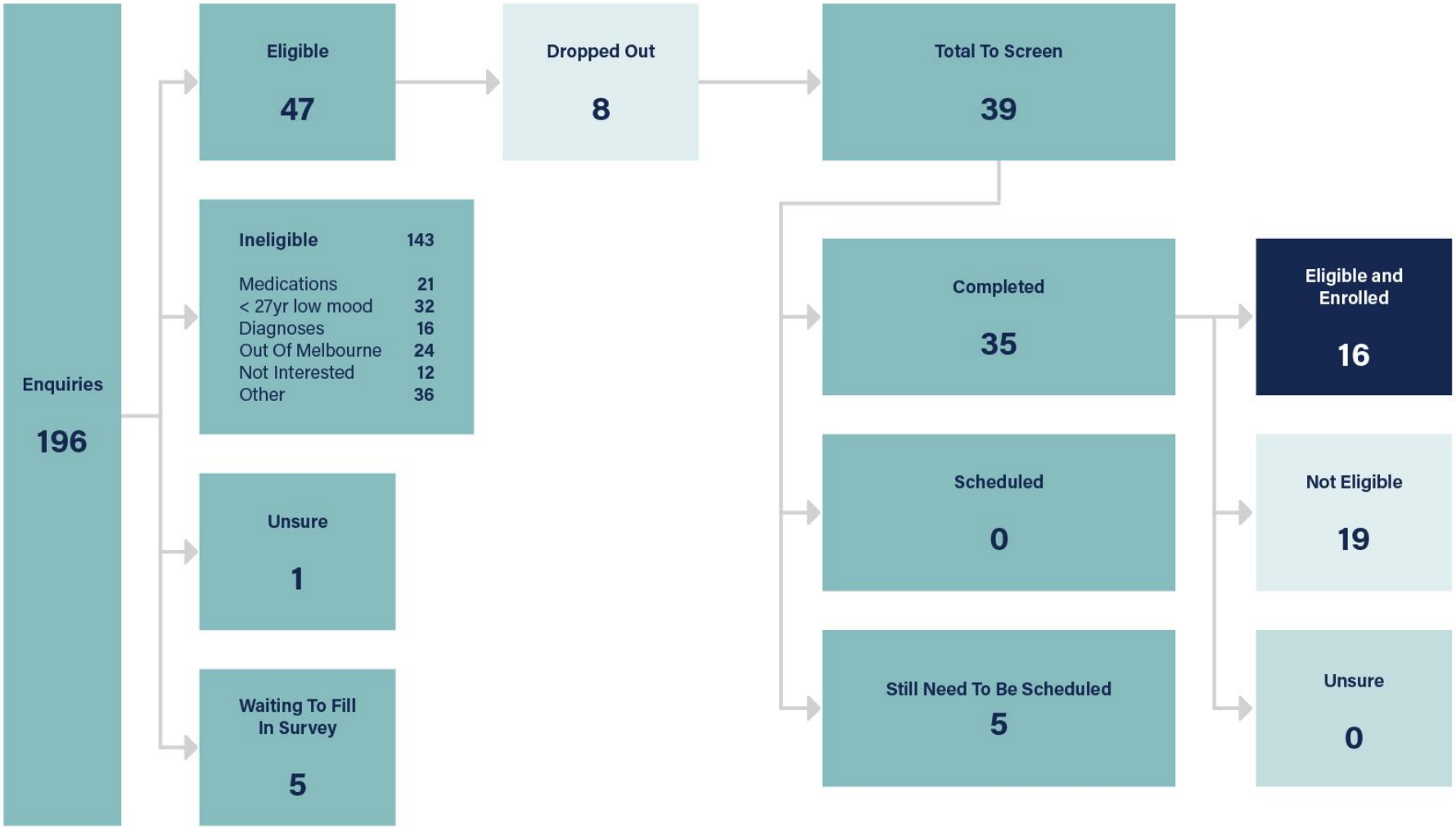
16 of the 48 participants have already been enrolled and EVRIMA, which provide support to clinical trial recruitment, has been appointed to help recruit the remaining participants.

Biome expects recruitment to be completed by Q2 2022 and final results to be available in Q4 2022.

1. https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/mental-health-related-prescriptions
2. https://www.aihw.gov.au/reports-data/health-welfare-services/mental-health-services/overview
3. https://www.aihw.gov.au/reports/mental-health-services/mental-health-services-in-australia/report-contents/expenditure-on-mental-health-related-services

Biome Lift Screening Flowchart

Last updated 03/02/2022



Probone21 Study

$3b
cost of osteoporotic fractures[1]

USD $10.74b
estimated global osteoporosis treatment market size in 2018, expected to grow to USD 15.08b by 2026 (CAGR 4.3%)[2]

The study, being conducted by La Trobe University, aims to examine the effect of 12-month supplementation with Biome Osteo on bone metabolism as well as bone mineral density.

The study aims to assess 124 postmenopausal females, aged 45-65 years, with an increased risk for osteoporosis (based on FRAX score) using high resolution peripheral quantitative computed tomography (HR-pQCT) measurements.

Study endpoints:

- DXA measurements
- Blood indices e.g. vitamin D, P1NP (collagen deposition, marker for bone formation) and CTx (marker for bone rate turnover)
- Gut microbiota composition
- Body composition

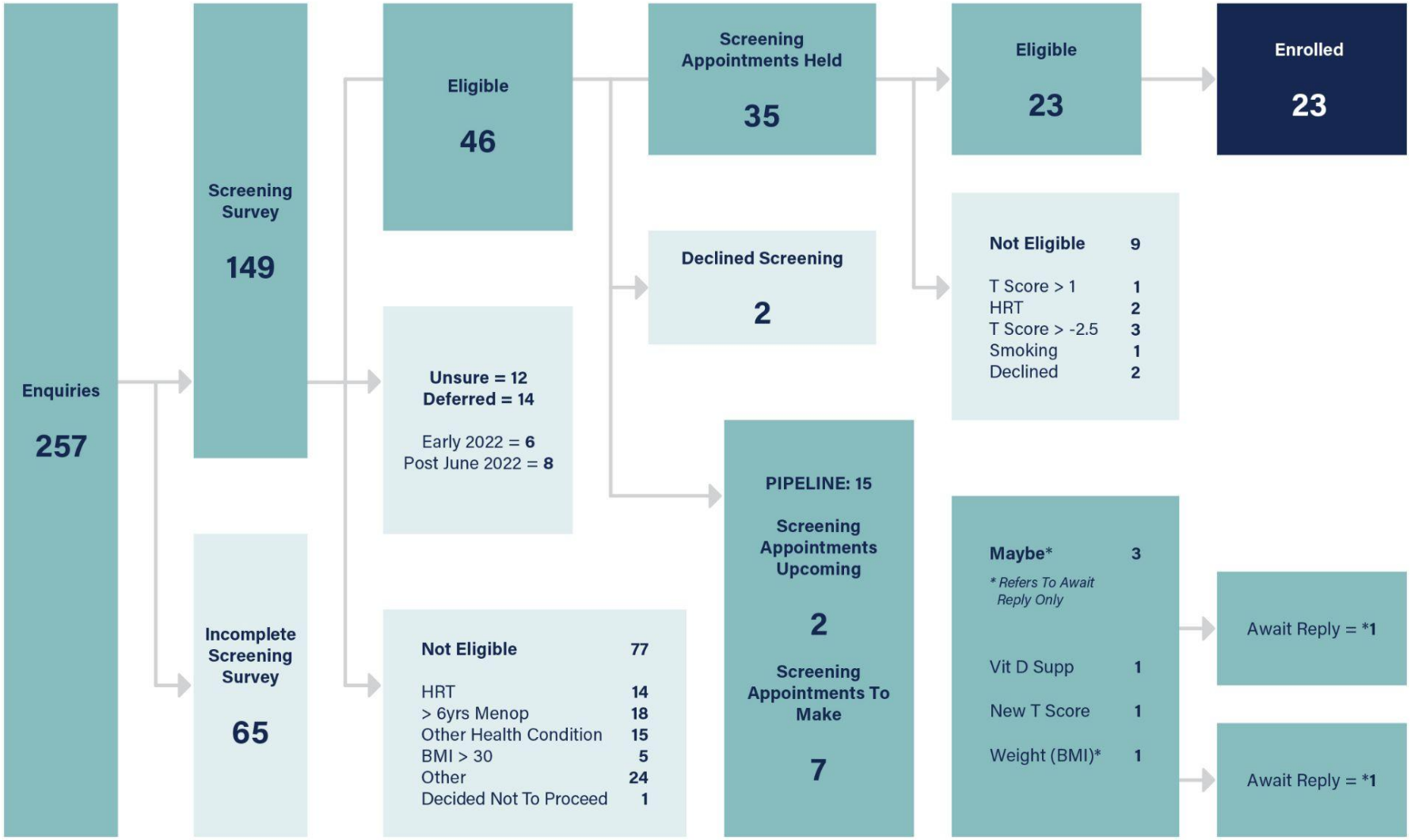
23 women have been enrolled thus far and EVRIMA has been engaged to assist with recruitment.

1. https://www1.racgp.org.au/newsgp/clinical/calls-to-prioritise-3-billion-health-problem#:~:text='Early%20diagnosis%20of%20osteoporosis%20is,than%20%243%20billion%20each%20year.
2. https://www.fortunebusinessinsights.com/industry-reports/osteoporosis-treatment-market-101034

Enquiry Tracking For Probone Study

Last updated 15/02/2022

Flowchart Of Eligibility



Biome Daily Kids Study

51%

of children aged 0-4 and 47% aged 5–9 years were dispensed at least one systemic antimicrobial (e.g. an antibiotic) in 2015[1]

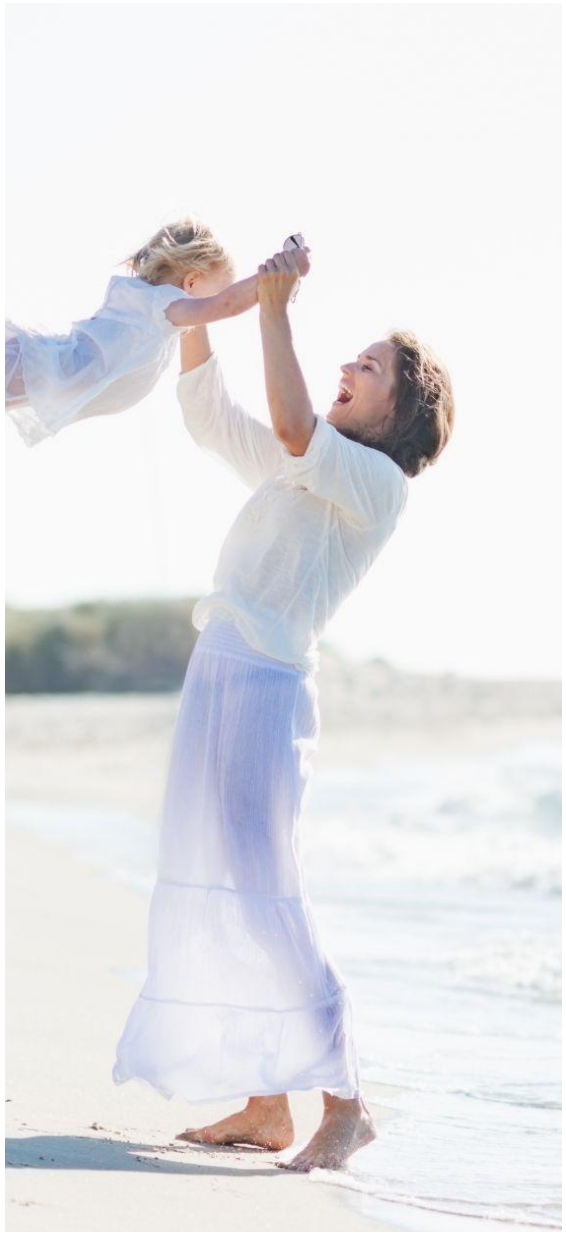
The primary aim of the trial is to examine the influence of probiotic use on absenteeism and immune health among children aged 2-5 years attending childcare centres.

192 children will be recruited into the study and will be dosed once per day over 6 months.

The study will be investigating:

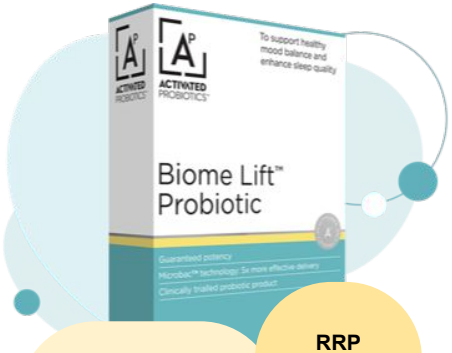
- The duration of symptoms of common infections (gastrointestinal and respiratory infections, etc)
- The number of children with different varieties of infectious diseases (gastrointestinal infections; respiratory infections; hand foot and mouth disease etc)
- Use of antibiotics or other medication related to infectious diseases
- Changes in mood and behaviour (secondary outcome)

Recruitment is expected to commence in Q2 2022



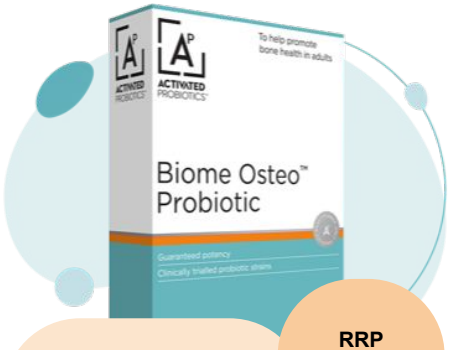
1. Rebecca Anderson, Anthea Rhodes, Noel Cranswick, Marnie Downes, Jonathan O'Hara, Mary-Anne Measey, Amanda Gwee, A nationwide parent survey of antibiotic use in Australian children, Journal of Antimicrobial Chemotherapy, Volume 75, Issue 5, May 2020, Pages 1347–1351,

Product portfolio



Biome Lift™ Probiotic

RRP $49.95



Biome Osteo™ Probiotic

RRP $59.95

Biome Daily Kids™ Probiotic

RRP $34.95

Available through over 2500 community pharmacies and healthcare practitioners and growing

Clinical backing and safety profile to be recommended alongside prescription medication

Premium products at affordable prices for consumer and patients

Strong retail margin for pharmacies and practitioners

Biome is also exploring other probiotics that address additional health concerns, which if deemed viable, will fuel the upcoming product development pipeline.

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