

**BIOME** | AUSTRALIA  
GROUP

September 2024

# **Vision 27**

# **Strategic Plan**

Blair Norfolk, CEO & Managing Director

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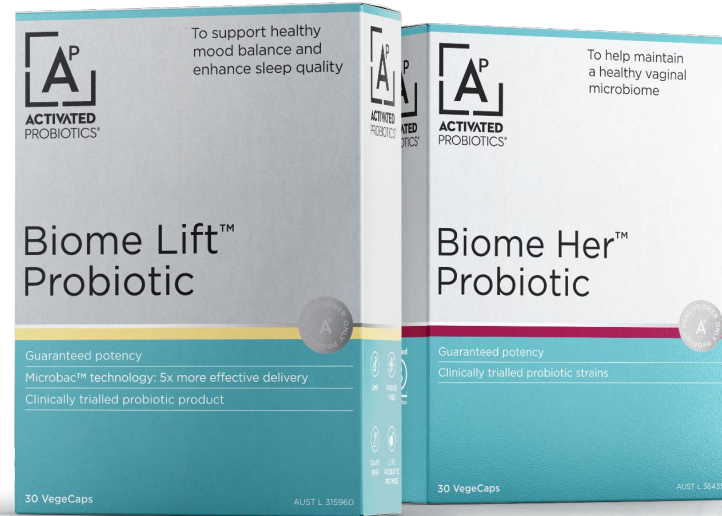
# About Biome Australia

Biome Australia (ASX: BIO) is focused on becoming a global leader in the complementary medicine industry, offering clinically-proven, condition-specific probiotic products fueled by novel clinical research programs to cement and extend the evidence base of its probiotic products.

Activated Probiotics, Biome's flagship range of novel live-biotherapeutics (probiotics), was created in partnership with world leading organisations in microbiome research and utilises innovative delivery technologies that improves their stability and efficacy.

Biome has a B Corporation certification, a designation that a business is meeting high standards of verified performance, accountability and transparency.

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## Our mission

To prevent disease, improve health outcomes and quality of life, and make our products accessible to all



# Biome Underlying Business

## Growth & Development

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- Biome became both **cash flow and EBITDA positive** in the second half of FY24
  - **International market expansions** are well underway after successful test market was completed in the UK and Ireland, Biome recently launched Activated Probiotics into Health Retail, including community pharmacy and health food stores.
  - **Intellectual Property agreement** was completed in FY24 and accompanying project to develop novel biological IP is well underway (Reference ASX Announcement 11 Dec 2023)
    - There is a substantial opportunity for probiotic IP to add value to Biome's balance sheet once developed.
    - An industry example, *Lactobacillus rhamnosus* GG, protected under the trademark LGG®, was acquired by Chr. Hansen in 2016 for EUR €73M (AUD \$120M).
  - **Practitioner only** – premium distribution model (behind the counter S3 in health retail)
    - Products recommended by health professionals to their patients and customers
    - Professional brand, is not based on deals or discounts significantly reducing marketing spend and leading to strong customer retention and repeat purchase
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# Biome Underlying Business

## Growth & Development

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- **Ongoing clinical research and development pipeline** (low cost) which drives product development, additional trust and support of health professionals
  - **Activated Probiotics** is the highest growth practitioner only brand in Australian pharmacy, based on IQVIA retail scan data for 12 months to May 2024\*.
  - Biome Pharmacy wholesalers, Symbion and API, the two largest pharmaceutical wholesalers in Australia have shared that **Biome's Activated Probiotics is the highest growth complementary medicine brand** in their respective businesses.
  - **5000+ Existing distribution points** in Australia
    - Addressable distribution market is 40% penetrated
    - Existing accounts ~30% developed with large opportunity for business development
  - Significant opportunity within the **adjunct medication market. There are 330m prescriptions a year in Australia**, each of which is an opportunity for an Activated Probiotic product to be recommended alongside at the discretion of a qualified health professional.
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# Vision 27

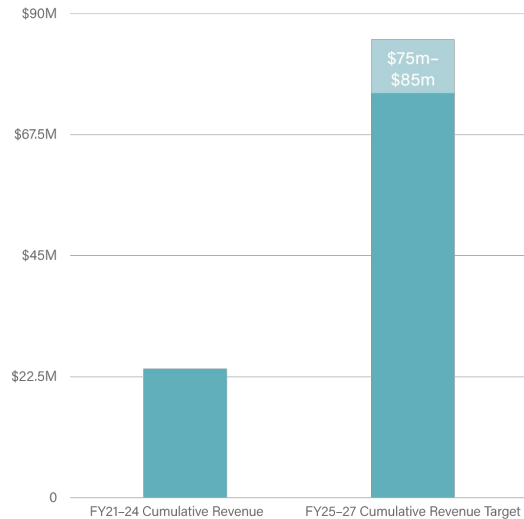
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## Vision 27

Bring Activated Probiotics to the mainstream market as a significant probiotic brand locally and abroad.



*Vision 27* – Biome’s strategic plan is to grow from a successful ASX microcap company to a major player in the Australian and global complementary medicine markets. Biome will look to maintain cash flow positivity and reinvest a portion of profits to continue its rapid growth through the Vision 27 period, FY25 to FY27.

### Revenue Growth

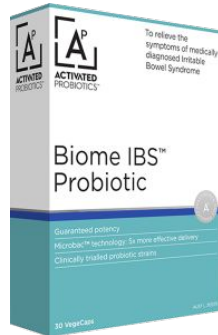
Biome has a three year cumulative sales revenue target of up to \$85m. (\$75m-\$85m for FY25-FY27)

#### 1. Distribution Growth & Business Development (Australian Market)

- Grow the existing 5000 (40% TAM for distribution) Australian distribution points (Pharmacy and Practitioner) to 8000 (~67% TAM for distribution)
- Business development in underdeveloped accounts
- Co-prescribing / adjunct prescribing dispensary opportunity in developed accounts (330m prescriptions or opportunities in pharmacy per year in 2024)

# Vision 27

Bring Activated Probiotics to the mainstream market as a significant probiotic brand locally and abroad.



## 2. International Market Acceptance and Growth

- Gain traction and brand recognition as well as meaningful sales volume in both European and North American markets
  - Further European geographies are under review for future launches
  - North America (Canada) is set for test market launch in FY25 after Biome received initial Health Canada approvals in Q4 FY24

## 3. Supply Chain

- Identification and viability analysis of a novel probiotic strain that will be proprietary to Biome
  - *Lactobacillus plantarum* XXXX (final name pending)
  - Supporting new product development and further protection from competition
- Actively reviewing opportunities to optimise production run and production timing

## 4. New Brand and Product Range

- *Activated X* (final name pending) and Product Range Launch in H2 FY25

## Distribution growth &amp; Business Development

# Australian Market



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## Pharmacy & Health Food Distribution Channel

- Distribution growth
  - Develop the existing 5000 Australian distribution points (Pharmacy and Practitioner) to 8000 by the close of FY27 (67% of the total distribution in Pharmacy and Practitioner markets)
  - Business development in underdeveloped accounts
    - Biome aims to develop *Activated Probiotics* to be a strong performing brand in each health retail account through higher levels of service and support.
  - Co-prescribing / adjunct prescribing dispensary opportunity in developed accounts
    - 330m prescriptions per year in Australia in 2024, each an opportunity for a health professional to recommend a condition specific *Activated Probiotics* product alongside.

## Practitioner Distribution Channel

- Strong foundation business (25% of current Australian sales revenue)
  - Key driver of brand trust and loyalty
  - Active recommendation to patients comes with trust and high repeat use
  - Independent practitioners are a key driver of foot traffic into the health retail channel
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# International Markets

Maintain High Growth

Minimal OPEX Increase

Funded by existing operating cash flow

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**In FY24 revenue in international markets grew 95% to reach ~\$895k**

Biome looks for markets outside Australia that have a number of specific traits:

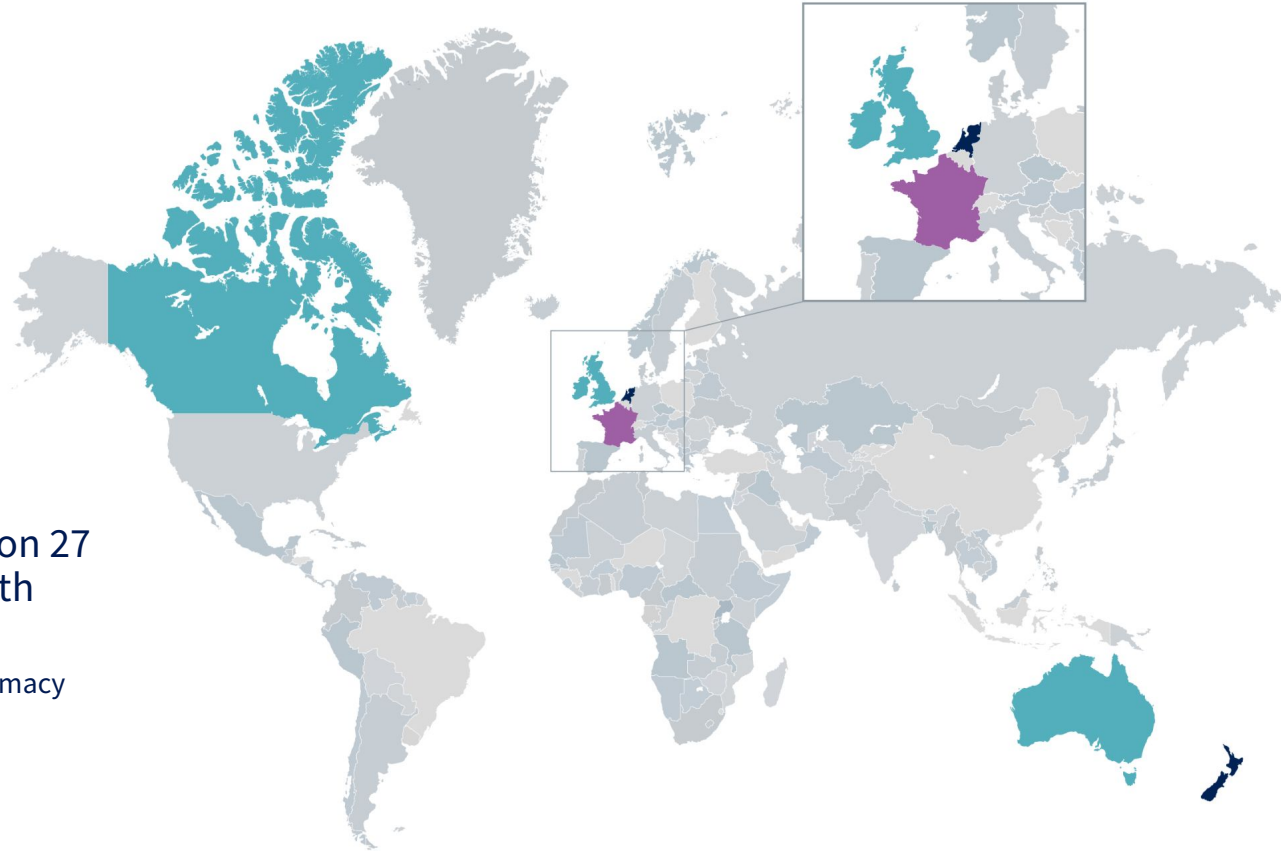
- Strong health and service based pharmacy market
- Established integrative practitioner market
- Cultural and language similarities
- Appropriate regulatory environment

**Vision 27 strategy (international) – Carefully grow international business:**

- Cost effective conservative expansion
  - Targeting positive cash flow within the period
  - Tight cost control
  - Work to contain international expansion funding from within operating profit
  - International expansion provides Biome a larger total addressable market (TAM)
-

## Biome existing footprint and Vision 27 distribution growth

- Practitioner & Pharmacy
- Practitioner only
- Pharmacy only



# International Markets

## Test markets & markets under review



Canada



France



Benelux

## Developing early stage markets



United kingdom



Ireland



New Zealand

## Established markets in growth



Australia

## Biome has several markets at various stages of development

Biome takes a conservative and considered approach to each market and channel within each market and only invests once a review is complete and a test market is successful

- Established Markets in Growth
  - Australia
- Developing Early Stage Markets
  - United Kingdom
  - Ireland
  - New Zealand
- Test Markets and markets under review
  - Canada
  - France
  - Benelux (Netherlands, Belgium and Luxembourg)

## International Markets

# Europe



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### Biome Australia Trading UK (Europe)

Biome has established a base of operations out of the United Kingdom over the past 3 years to support the company's future growth and development plans throughout Europe. The existing UK based team is lead by a General Manager reporting directly to Biome's CEO and a regional sales manager leading a team of high value sales and education resources across Europe reporting directly to Biome's Commercial Manager in Australia

### Practitioner Market (Europe)

- Strong growth in both sales and distribution expected (UK and Ireland)
- Biome trained Practitioner Education and Territory managers already in the field (UK and Ireland)
- Plans to review the opportunity in the **Benelux** region that has pre-existing thriving independent practitioner market and captive consumers who understand professional probiotics and natural medicines

## International Markets

# Europe



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### Heath Retail

- Community Pharmacy and Health Food stores launched in FY25
- Strong growth expected and strategy in place to grow rate of sales in health retail market (UK & Ireland)
  - Significant growth expected through signing new accounts and key account development during Vision 27
- Team well resourced and foundations set with support from local health retail distributors
- Biome has commenced an exploratory review of the **French** pharmacy market, as high value full service pharmacy opportunity. Subject to a successful outcome of the market review, Biome would then consider a test market supported by the recruitment of a French sales team of three practitioner education consultants (PECs) reporting to the European Sales manager



## International Markets

# New Zealand



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### Practitioner

- Strong sales growth - in excess of 100% in FY24
- Biome trained Practitioner Education Consultant and Territory manager recruited in FY24, now working to develop local accounts
- Significant growth expected through signing new accounts and key account development during the Vision 27 period

### Health Retail

- Carefully selected integrative community Pharmacy and Health Food stores being launched in FY25, with an ongoing review of the wider health retail market continues
  - Significant growth expected through signing new accounts and key account development during Vision 27
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## International Markets

# North America Canada



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### Pre Test Market Launch

- Health Canada Product Registrations and approvals received in H2 FY24
  - **Distribution deal signed with Ecotrend**, a leading wholesaler to healthcare practitioners and independent health retailers
    - Ecotrend has professional sales and education staff on the ground to support Biome's Activated Probiotics. This team will work alongside Biome's future team of Canadian Practitioner Education Consultant & Territory Managers (PECs)
  - Biome Australia team presented Activated Probiotics at Canada's largest Complementary Medicine Industry exhibition, *CHFA NOW* (Toronto) in September 2024
  - Initial orders are now being placed with Ecotrend for new Canadian practitioner customers.
  - Canada has high barriers to entry, has a regulatory model based on the Australian TGA and is seen by Americans to have the highest quality products in the region
  - Canada has thriving community pharmacy and independent practitioner channels for Biome to develop
  - Biome will aim to conclude its test market in 2025, establishing a base for North American operations though this strategic period and beyond
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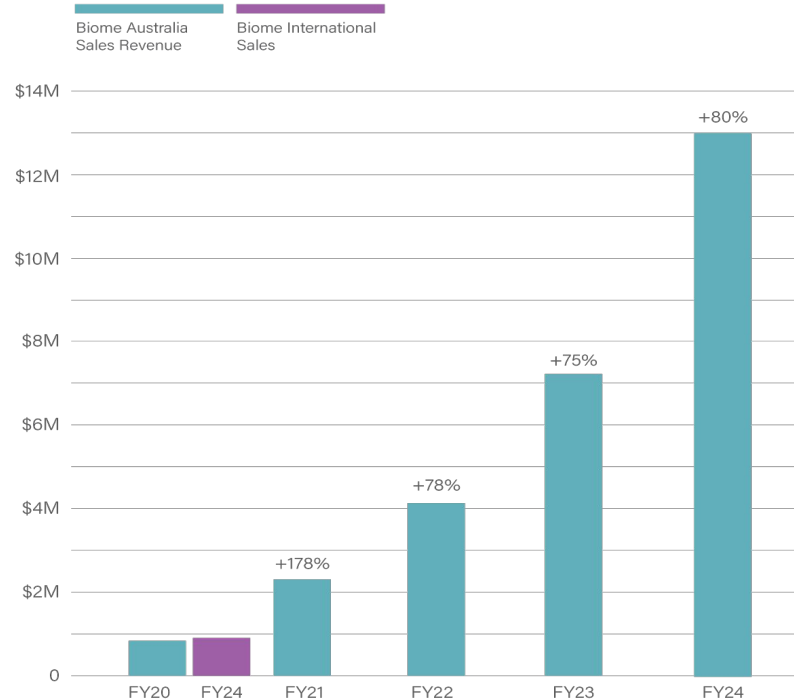
## International Markets

# Staffing and Growth Model

- Biome will seek to replicate its Australian success with a lean operational model, heavily weighted towards sales and education human resourcing
- Each territory has existing team members (UK & Ireland) or Biome is in the process of recruitment of a small number of health qualified Practitioner Education Consultants (Sales Reps) in new territories. These staff are supported in their local timezone by the existing UK management support office and local distributors for logistics
- Biome Australia head office in Melbourne will provide the required support for our international teams, including educational training resources, product development, IT, finance and strategy

# Replicating the Australian success with a fraction of the investment

- Australia grew from \$830K to \$12.1M (ex International) between FY20 and FY24
- Biome plans to leverage its skilled Australian team, to support cost effective international market expansion
- Targeting strong growth profile for international markets



\* Illustrative example of Biome’s FY20 sales revenue vs FY24 international sales revenue. This graphical illustration is not intended as a forecast.

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# Supply Chain

## IP Development of Novel Probiotic Strain & Probiotic Production

Biome has executed an agreement to develop a Biome owned novel probiotic strain

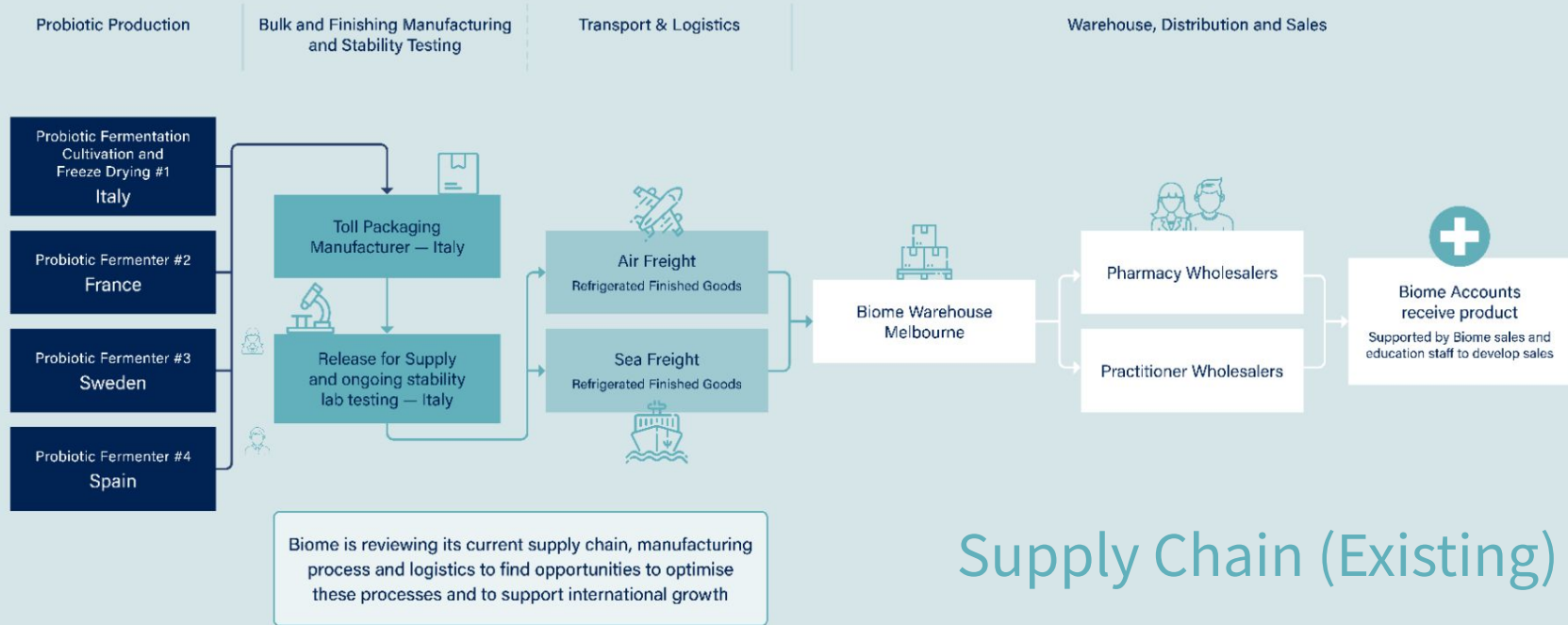
The strain is well under way in development. The current steps for this process are commercial validation, genetic sequencing and characterisation which is expected to be completed within FY25:

- *Lactobacillus plantarum* XXXX (final name pending)

This program will support Biome in new product development, provide further protection from competition and if successful secure a significant asset for the company

## Actively reviewing opportunities to optimise production run and production timing

- Biome is reviewing its current manufacturing and supply chain processes and looking for new opportunities to support growth
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# New brand and product range launch



Example only

## Activated X Brand

Biome has identified a gap in the market between its existing clinically proven range of targeted probiotics, *Activated Probiotics*, and other professional offerings in the complementary medicine market

Over the past two years, Biome has been working in research and development in support of this new offering

Biome plans to launch a second professional brand and range of products under the “*Activated*” brand masthead beyond probiotics. The new brand *Activated X* (final name pending), will operate within Biome’s successful existing practitioner-only distribution channel. The brand will be driven by education and professional recommendation

Biome has secured a number of novel products for this brand that we feel will meet unmet needs for both practitioners and their patients.

- A detailed update and overview of this brand and products will be shared nearer to launch date in H2 FY25
- Biome expects to secure distribution for the new brand soon after launch through its network of distributors and independent healthcare practitioners

# Vision 27

## Summary

### Revenue Growth

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  - Distribution deal signed with Ecotrend Ecologics (Canada)

### 3. Supply Chain

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# Risk statement

## 1. Early stage risk

Whilst the Company became Biome became both cash flow and EBITDA positive in the second half of FY24, it nonetheless remains subject to risks common to early stage companies, including increasing market share and brand recognition, developing its product pipeline, competition risk and satisfying regulatory requirements.

## 2. Uncertainty of future revenue

Biome's future profitability is contingent on its ability to continue to enter into appropriate supply, distribution and partner arrangements, maintain certainty of supply, to set favourable prices for its products, market demand for products being sold, general economic conditions, the results of further research and clinical trials in relation to microbial genomics.

## 3. Effectively managing growth

The Company's future success depends on its ability to effectively manage expected growth, and the Company may require effective support from its supply partners for expansion into new jurisdictions. Otherwise, Company's ability to achieve its growth objectives by geographic expansion may be materially impaired.

## 4. Loss of adoption by independent practitioners

The Company is reliant in some jurisdictions on independent practitioners accepting, recommending and purchasing its products. They play a significant role in influencing the types of products used by patients, in addition to being purchasers themselves. While the Company has strong relationships with healthcare practitioners, and provides education, training and marketing support, these do not guarantee sufficient adoption of its products to achieve the targeted growth metrics.

## 5. Loss of key management personnel

There is substantial competition for personnel in the Company's industry, and there is a limited number of persons with the necessary knowledge and experience in this industry. An inability to attract or maintain a sufficient number of requisite personnel could have a material adverse effect on the Company's performance.

## 6. Access to sufficient manufacturing capability

The Company's products are dependent on the availability of raw materials, packaging and production capacity with contract manufacturers at a viable cost. Failure to maintain such availability, including due to global logistics issues outside of the Company's control could adversely impact the Company's supply chain or cost of goods sold and require the Company to source and engage new providers for the above or new goods and services.

## 7. Intellectual property risks

The Company depends on its ability to register, protect and commercially exploit its intellectual property, and accordingly there is a risk that unauthorised use or copying of intellectual property could occur and lead to the reverse engineering of product formulas. A breach of the Company's intellectual property may remain undetected, and if detected may require legal action which could be costly and time consuming. There is also a risk that intellectual property developed by the Company by way of clinical trials, works or studies permitted under a supply agreement will be forcefully acquired upon termination of that supply agreement.

## 8. Regulatory risks

The Company is subject to a number of regulatory regimes, including the Australian Therapeutic Goods Administration, Food Standards Australia and New Zealand, Medsafe New Zealand, the United Kingdom Medicines and Healthcare Products Regulatory Agency, and Food Standards Scotland.

There are further regulatory regimes that will require compliance under new jurisdictions that the Company plans to expand into. Securing, maintaining and complying with the necessary regulatory approvals and licences is a key requirement for the Company to maintain and grow its operations in all markets, and there is a risk that regulatory approvals will fail to be obtained or maintained in some or all of the markets in which the Company operates.

## 9. Product risks and liability

There is no assurance that unforeseen adverse events or manufacturing defects will not arise in respect of the Company's products, which could expose the Company to product liability claims, litigation, withdrawal of regulatory approvals and reputational damage.

# Risk statement

## 10. Sufficiency of funding

There is a risk that the costs of operations may be higher than anticipated by the Company or increase as a result of unforeseen circumstances.

The Company may also be required to raise additional equity or debt capital in the future, and there is no guarantee that it will be able to raise that capital on such terms satisfactory or favourable to the Company. If Biome Australia is unsuccessful in obtaining funds when required, it may need to delay or cease its research and development, commercialisation, manufacturing activities, or other components of its business. In the event of insufficient capital, the Company may also have to licence or sell its technologies on unfavourable terms, or scale down or cease operations. No assurance can be given that future funding will be available to the Company, on any particular terms, or at all.

## 11. Litigation risk

In the ordinary course of business, the Company may be involved in litigation disputes from time to time. Litigation disputes brought

by third parties, including but not limited to, customers, suppliers, business partners, and employees may adversely impact the financial performance and industry standing of the Company.

## 12. Changes in strategy

The Company's plans and strategies (including those set out in this presentation as the Vision 27 plan) may evolve over time due to review and assessment of, amongst other things, trial results and data, market trends, the outcome of its intellectual property registrations and applications, changes in policy or regulations, the level of market acceptance in particular markets and the emergence of new technologies or improvements in existing technology. Any such changes have the potential to expose the Company to additional risks.

## 13. General risks

The Company is subject to a number of business risks applicable to most publicly listed companies in Australia, which include risks in relation to:

- general economic conditions and macro-economic factors such as financial market volatility, interest rate fluctuations and foreign currency and exchange rate fluctuations;
- general corporate regulatory risks applying to all corporations in Australia in respect of compliance with the Corporations Act and the ASX Listing Rules;
- potential changes in taxation laws and policies in Australia (particularly in respect of the rules regarding the R&D tax offset);
- risks associated with future acquisitions; and
- force majeure risks such as labour unrest, civil disorder, war, extreme weather conditions and natural disasters and pandemics or epidemics.

# BIOME | AUSTRALIA GROUP

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