

## 2023 AGM

### Chair's Address and CEO's Presentation

Microba Life Sciences Limited (ASX:MAP) ("Microba" or "the Company") is pleased to attach the Chair's Address and CEO's Presentation to be delivered at the 2023 Annual General Meeting of Shareholders of the Company to be held today at 11.00 am Brisbane time.

Shareholders wishing to attend the Annual General Meeting in person can find the details in the Notice of Meeting as lodged with the ASX on 30 October 2023 and available at the Company's website at [ir.microba.com](http://ir.microba.com).

*This announcement has been authorised for release by the Chair and CEO.*

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#### About Microba Life Sciences Limited

Microba Life Sciences is a precision microbiome company driven to improve human health. With world-leading technology for measuring the human gut microbiome, Microba is driving the discovery and development of novel therapeutics for major chronic diseases and delivering gut microbiome testing services globally to researchers, clinicians, and consumers. Through partnerships with leading organisations, Microba is powering the discovery of new relationships between the microbiome, health and disease for the development of new health solutions.

not subject to, the registration requirements of the US Securities Act and applicable securities laws of any state or other jurisdiction of the United States

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

Microba encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.

## Chair's Address to Annual General Meeting

Welcome to the 2023 AGM of Microba Life Sciences. Professor Ian Frazer has been unable to join today, so Dr. Luke Reid and I will address the meeting.

Microba has now entered its second year as a publicly listed company and continues to maintain its steadfast vision of the human gut microbiome representing one of the biggest untapped opportunities to improve human health. Unfortunately, it has been a second difficult year for the globally listed biotechnology companies. After beginning a gradual recovery from the low enterprise level in June 2022, the global biotechnology sector fell again in 2023. Valuations of many listed biotechnology companies are down significantly since the peak. This is important to note, but more importantly the team at Microba believes more than ever in the long-term fundamentals of biotechnology innovation and is continuing to advance both our testing services and therapeutic development activities to unlock the health and commercial opportunity from the human microbiome.

Microba commenced operations in 2018 providing gut microbiome profiling to consumers, clinicians and researchers in Australia. Fast forward to today, the Company and the microbiome sector have made several significant advances. In October 2022, we announced an expansion and extension of our testing services distribution agreement with SYNLAB, Europe's largest pathology company. In December 2022, we were delighted to also announce a strategic shareholding and commercial testing services partnership with global medical diagnostics leader Sonic Healthcare. The partnerships align the intent of the companies to bring microbiome testing into the hands of clinicians and patients across the globe.

In February 2023, we launched the most comprehensive gastrointestinal testing solution available to healthcare professionals, **MetaXplore**. The test is currently available to clinicians in Australia. Furthermore, Microba announced the upcoming launch of the advanced infectious disease test, **MetaPanel** with Sonic Healthcare in Australia. Following the domestic launch, we intend to take the technology into the United States.

FY23 was a year of significant advancement for the Microba therapeutic division and the microbiome sector. In November 2022, the FDA approved Reboyta, the first ever faecal microbiome product and in April 2023, the FDA approved Vowst, the first oral microbiome therapeutic. These approvals have confirmed a regulatory pathway for the approval of live bio-therapeutic drug candidates for the microbiome sector. For Microba, FY23 is the year that the Company became a clinical stage drug development company, three years after the establishment of the therapeutic division. In June 2023 we commenced a Phase 1 clinical trial for Microba's Inflammatory Bowel Disease program with lead candidate MAP 315. The trial has completed dosing, with the final read out expected in December 2023. The Company has also used its pre-clinical research capability to progress microbiome candidates from discovery to generation of pre-clinical data in Immuno-oncology and Autoimmune diseases.

Post the completion of FY23 year, the Company announced the acquisition of Invivo Clinical, a commercial stage microbiome testing and product company based in the United Kingdom, one of the key countries for Microba Life Sciences international growth strategy. The Company would like to welcome the thirty-three employees from Invivo to the Microba group and we will have more to say about Invivo post expected completion in December 2023.

30 November 2023



As mentioned earlier, despite the negative performance of the global biotechnology sector in 2023, Microba is well positioned to accelerate growth in FY24 both domestically and in international markets. The Company has strategically positioned itself at the forefront of microbiome testing and the continued growth in testing revenues. In Therapeutics, the Company has a clinical stage drug candidate for IBD, is advancing its Immunology program and on track to soon complete its two-year pre-clinical Autoimmune discovery program with Gingo Bioworks.

Professor Frazer and I would like to thank our fellow board members, executives, and employees for their hard work during the year. We would also like to say thank you to our customers and shareholders for their significant support in FY23. Microba Life Sciences will have a positive impact on human lives globally when we are successful in achieving our goals.

**MICROBA™**

# Transforming health through the human microbiome

Microba Annual General Meeting 2023

30 November 2023

# | Achievements & Upcoming catalysts

## Recent Achievements

- Next generation healthcare test, MetaXplore™ launched in Australia with strong uptake
- First agreement executed to deliver Microba's advanced infectious disease testing technology MetaPanel™ into Australia
- Phase I trial commenced for IBD lead drug candidate transitioning Microba to a clinical stage drug development Company
- Positive first animal model data generated under the Company's Immuno-Oncology Program
- Stage 1 activity screening complete under the Company's Autoimmune Disease Program

## Therapeutic Catalysts

### Inflammatory Bowel Disease Program

Dec 2023 MAP315 Phase I clinical trial data readout

### Immuno-Oncology Program

H1 2024 Pre-clinical biology and lead candidate selection complete

### Autoimmune Disease Program

H1 2024 Stage 2 activity screening complete

## Testing Services Catalysts

Sonic distribution agreements for UK and US

Major international launches for MetaXplore™ and MetaPanel™

- United Kingdom
- Europe
- United States

Invivo Healthcare integration and growth

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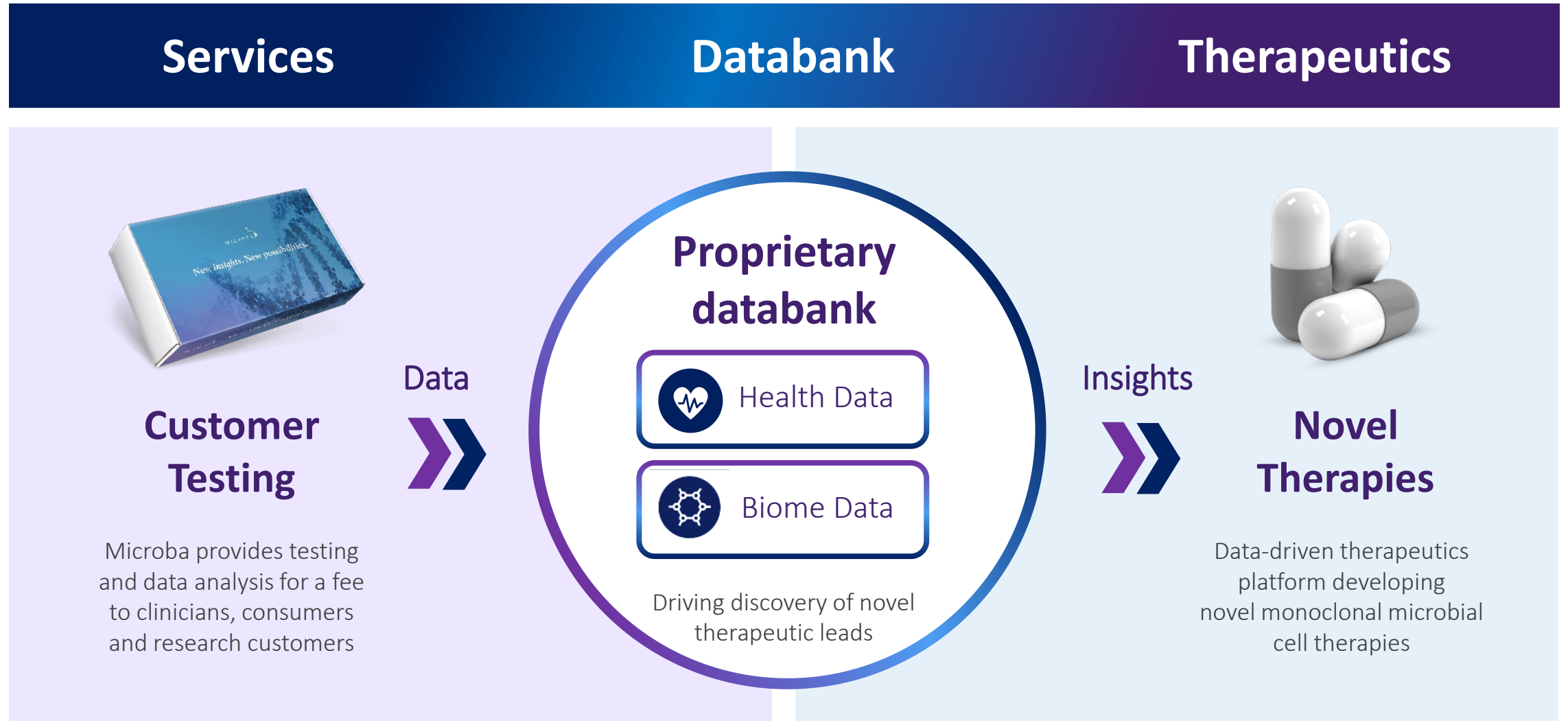
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# Two core business segments driven by a proprietary databank



# Company Snapshot



**Continuous YoY revenue growth** over 5 years of operations



Partnerships with market leaders incl. **Sonic Healthcare** (ASX: SHL), **Ginkgo Bioworks** (NYSE: DNA), **SYNLAB** (GR:SYAB) + more



**Large, unique, proprietary** microbiome databank



3 key therapeutic programs with lead IBD drug candidate **in Phase I trial** read out expected Dec 23



World-leading technology in the emerging and rapidly growing **US\$4.9 billion** microbiome sector<sup>1</sup>



Globally **leading microbiome expertise** complemented by drug discovery experts including Prof. Ian Frazer





# Microbiome Services

## Driving global revenues and data growth

# | Recent Highlights – Testing Services



## MetaXplore launch and growth in Australia

Strong uptake and continued growth of MetaXplore™ sales in Australia following its launch.



## MetaPanel progressing to launch in Australia

Microba's advanced infectious disease testing technology MetaPanel™ progressing to launch in Australia with Sonic Healthcare (ASX: SHL) targeting first test delivery before end of Q2 FY24.



## Further European expansion

New agreement executed with SYNLAB to deliver Microba's testing into Norway, Serbia and additional European countries.

# Advanced microbiome testing addressing large markets in healthcare

## Addressable Healthcare Markets

### Gastrointestinal disorders

#### MetaXplore™

Is the microbiome contributing to the patients DGBI and how can they manage?

**150M est.** addressable patients worldwide<sup>1</sup>

Well established out of pocket private pay market

### Gastrointestinal infection

#### MetaPanel™

Does the patient have a pathogen and how can I selectively treat it?

**16M est.** addressable patients worldwide<sup>2</sup>

Well established hospital direct-bill and path to reimbursement

<sup>1</sup>Estimated based on the prevalence of specific Disorders of the Gut-Brain Interaction across 26 countries (Av prevalence of 32.8% DOI: [10.1111/nmo.14594](https://doi.org/10.1111/nmo.14594)), and the proportion regularly seeking medical support with one or more doctor visit per month (Average 15.4% - DOI: [10.1053/j.gastro.2020.04.014](https://doi.org/10.1053/j.gastro.2020.04.014))

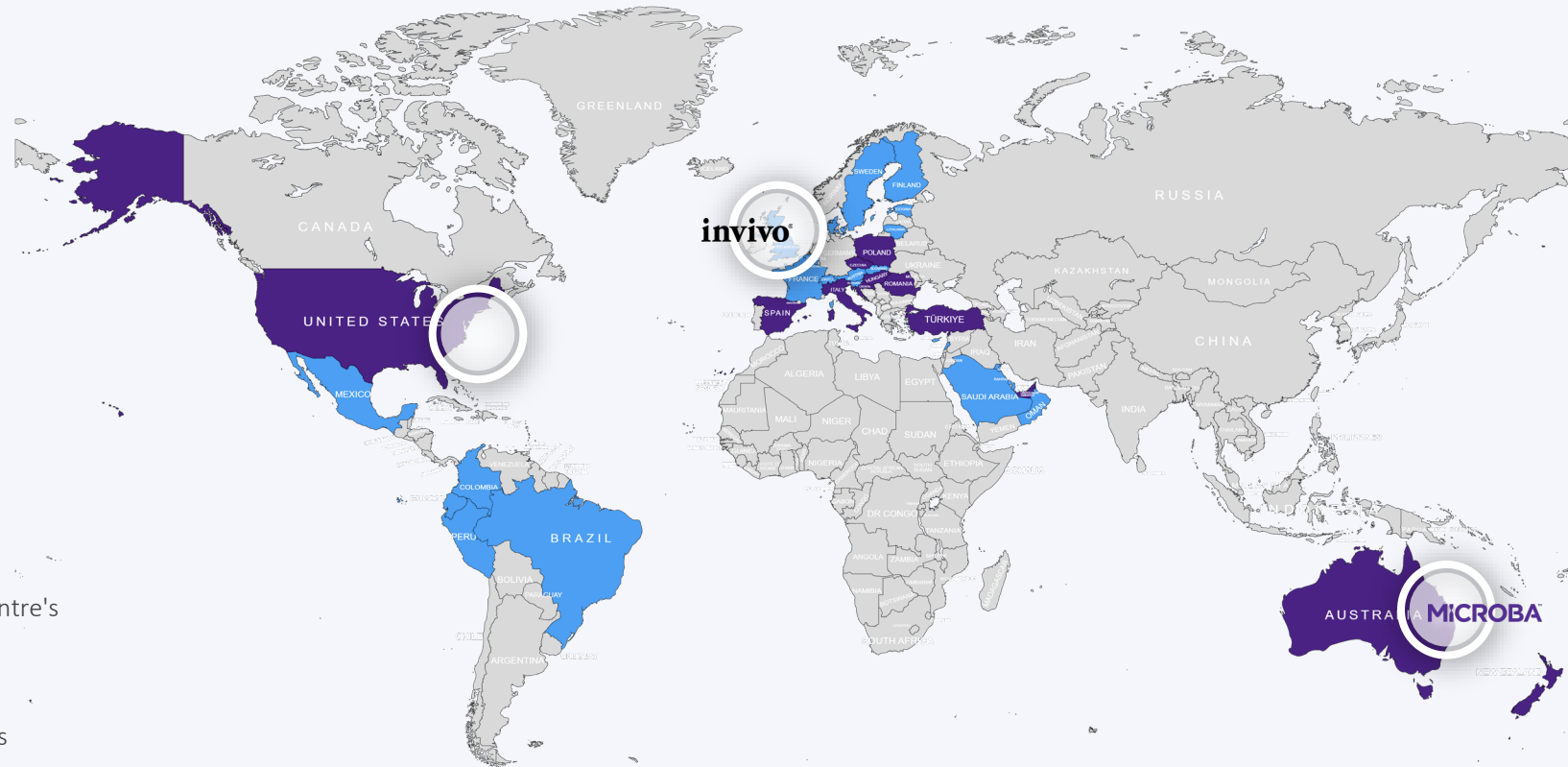
<sup>2</sup> Estimated based on the global number of immuno-compromised patients and other patients at high risk for gastrointestinal infection (>8.1m chemotherapy treated solid tumor cancer patients and >1.1m haematological cancer patients DOI: [https://doi.org/10.1016/S1470-2045\(19\)30163-9](https://doi.org/10.1016/S1470-2045(19)30163-9)), (>3m dialysis patients DOI: 10.1038/s41581-022-00542-7), (>140k Organ Transplant patients per year <https://www.transplant-observatory.org/>), (>3.5m long stay ICU patients – estimate based on data from <https://ourworldindata.org/grapher/intensive-care-beds-per-100000>)

# Significant international distribution

Partners provides access into 35 countries with 16 now operational



Strategic acquisition unlocking a geographical base and laboratory in the UK, supporting the next phase of Microba's international growth strategy.



- Operating Team and/or Laboratory Centre's
- Contracted partner/s operational
- Access via current distribution partners

A scientist in a white lab coat and gloves is working in a laboratory. They are holding a black multi-well plate in their left hand and a blue circular component in their right hand, which is positioned near a Fisherbrand Bead Mill 24. The machine has a digital display and control buttons. The background shows a typical laboratory environment with white cabinets and electrical outlets.

# | UK Strategic Aquisition

# | Invivo has a strong brand, reputation, and team

- Pioneer in UK microbiome testing services
- Established a strong brand with healthcare professionals
- Self-funded with positive operating cashflow
- Positioned for growth acceleration
- Experienced and well-credentialed team

## Laboratory - Bristol

- 10 staff
- PCR laboratory
- CL2 laboratory

## Headquarters - Stroud

- 23 staff
- Finance, sales and marketing
- Customer service & clinical support



## Multiple growth opportunities exist before introducing Microba synergies

- Continued growth acceleration in Vaginal microbiome testing revenue with 40% growth in FY23.
- New targeted interventions are in late-stage development to address clinician and patient needs.
- The integrative healthcare market is expanding as clinicians move to private practice due to pressure on the NHS.
- Small sales team which is positioned for expansion with significant opportunity to accelerate growth.

# Taking a leading position in the UK market

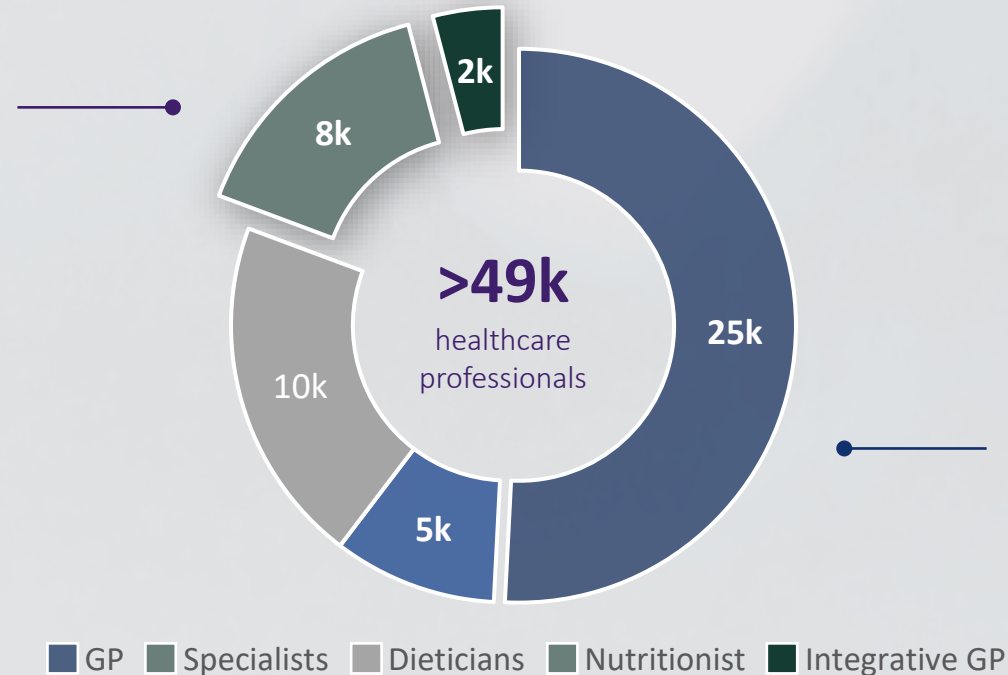
Invivo together with our Sonic Healthcare partnership provides Microba with deep access to the entire UK healthcare market spanning private practice and the public NHS environment

## invivo®

### Capturing the integrative healthcare market

- Leading microbiome testing company targeting integrative healthcare practitioners
- Est. 10k integrative healthcare professionals in the UK\*
- Growth market – more people seeking out private health services in the UK
- Customers positioned to adopt Microba's MetaXplore testing

### UK TARGET HEALTHCARE MARKET



### Driving broad adoption into general practice, specialists & hospitals

- Leading medical diagnostics company in the UK
- Preparing to deliver MetaXplore and MetaPanel
- Addressable UK target practitioners:
  - 25k General Practitioners<sup>^</sup>
  - 10k Clinical dieticians<sup>^</sup>
  - 4.7k Specialists positioned to adopt microbiome testing<sup>^</sup>

# | Invivo acquisition provides strong UK customer base

**FY23**

## Key metrics

**7,300+** tests sold

**1,700+** ordering HCPs<sup>^</sup>

**A\$8.9m** revenue<sup>\*</sup>

**10,000+** sample biobank

## Engaged customer base

17% penetration into the UK integrative healthcare professional market and well positioned to accelerate growth

 **94%**

of revenue driven by repeat customers<sup>#</sup>



□ Remaining market   □ Invivo customer   □ Invivo engaged lead

 **51%**

Gross Profit Margin



# | Strengthening Invivo's position in GI microbiome testing

A platform for UK market entry and growth of Microba's MetaXplore™ test

 **79%**

of Invivo's **testing revenue** is through their GI products\*.

 **19%**

growth in GI testing revenue in FY23^

*“From our leading position in market, we expect Microba’s world leading MetaXplore™ will become the most favoured microbiome test for healthcare professionals in the UK”* Debbie Cotton – Head of Clinical Innovation, Invivo

- **Current leading GI testing product for UK** healthcare professionals
- Featuring 7 host markers, 62 microbial markers
- Microbiome analysis via multiplex PCR
- Offers static PDF reports



- **Next generation advanced GI test** using Microba's world leading metagenomic technology
- Includes 7 host markers, 28,000 microbial markers, 19 microbiome functions
- Offers both static PDF and interactive digital reports.



# Microbiome Therapeutics

Developing novel monoclonal  
microbial cell therapies

# A therapeutic revolution.

## Novel, precision microbiome therapeutics

### Precision Microbiome Therapeutics

- **Precision microbiome analysis platform** delivering unparalleled accuracy, coverage & depth.
- Data driven discovery platform utilising one of the worlds **most advanced & highly curated microbiome datasets**.
- Next generation approach to microbiome drug development **identifying single keystone species and their biology to develop Live Biotherapeutics**.



### Innovative Pipeline

- ✓ Excellent safety profile
- ✓ Scalable GMP manufacturing for high dose oral delivery
- ✓ Potent and novel biology mediated by Live Biotherapeutic strategy

### Strong Corporate Profile

- ✓ US Pharmaceutical Executive leadership
- ✓ Technically robust multi-disciplinary team
- ✓ Global partners

### Microba Partners



### Team Experience



# Rapid progress tapping the therapeutic potential of the human microbiome for major chronic diseases

## Inflammatory Bowel Disease



### PHASE I IN PROCESS

#### Recently Completed

- ✓ Phase I HREC approval
- ✓ cGMP manufacturing complete
- ✓ Phase I trial commenced
- ✓ Phase I participant dosing complete

#### Upcoming milestones

- Phase I complete



## Immuno-Oncology Program



### PRECLINICAL

#### Recently Completed

- ✓ Leads discovered
- ✓ Leads isolated
- ✓ First animal model results

#### Upcoming milestones

- Immunological pre-clinical results
- Lead candidate selection



## Autoimmune Diseases



### SCREENING

#### Recently Completed

- ✓ Program commenced
- ✓ Strains provided to Ginkgo
- ✓ First in vitro screening results
- ✓ Stage 1 activity screening complete

#### Upcoming milestones

- Stage 2 activity screening complete



# | Recent Highlights



## **Inflammatory Bowel Disease Program**

MAP315 Phase I all patients dosed. Positive MOA data generated.

Dosing and all patient visits successfully completed. Preliminary blinded data indicates that MAP315 is well tolerated. Multi-modal mechanism of action (MOA) data generated for MAP315. Results remain on track for Dec 2023.



## **Immuno-Oncology Program**

Confirmed potent anti-tumour activity.

Second mouse model demonstrated again that Microba's therapeutic leads significantly reduce tumour burden. Further, immunological studies demonstrated activity consistent with induction of a specific and targeted immune response. Additional animal studies and immune profiling experiments are continuing with further data expected in Q2 FY24.

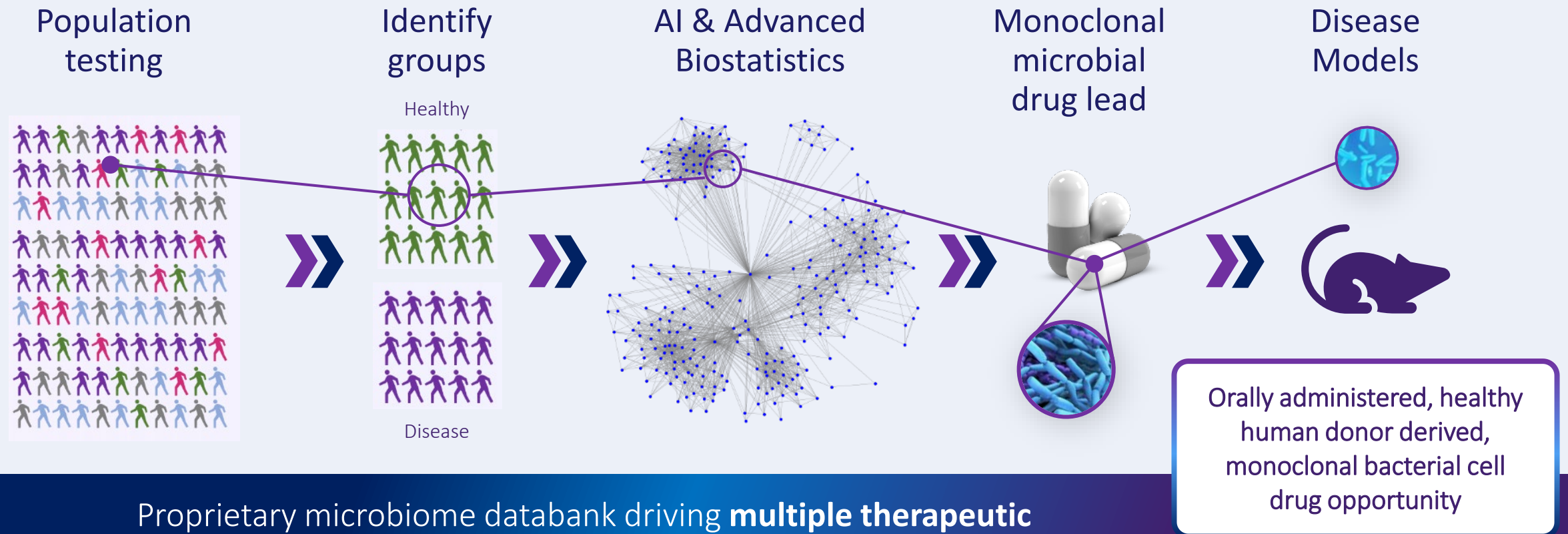


## **Autoimmune Disease Program**

Primary screening 100% complete.

Stage 1 activity screens complete with 62% of strains demonstrating significant immunomodulatory activity and a further 18% significantly impacting the inflammasome. 36 strains have now progressed into Stage 2 functional screening for expected completion in Q4 FY24 to enable lead candidate selection.

# Repeatable, scalable, data-driven platform **discovering novel monoclonal microbial cell therapies**



Proprietary microbiome databank driving **multiple therapeutic opportunities through a capital light platform**

# The start of a therapeutic revolution

## 1 First Generation



Fecal Doner Derived



**FDA approval Nov 30 2022**  
Fecal doner derived enema drug product



**FDA approval April 27 2023**  
Fecal doner derived oral capsule drug product

## 2 Second Generation



Bacterial Consortia



**Vedanta Biosciences**  
Vedanta Biosciences Raises \$106.5M in Funding



**SER-155**  
Phase 1b showing engraftment reduction in pathogens

## 3 Next Generation













Single Strain & Small Molecule



**MAP315**  
Phase I – Ongoing, readout expected December 2023

# Executing towards pharmaceutical out-licensing transactions

## Recent IBD and microbiome deals

Licensee / Acquiror	Licensor / Target	Date	Type	Deal size	Indication / clinical stage
 <b>MERCK</b>	 <b>Prometheus</b> Biosciences	Apr 2023	Acquisition	Total deal size: US\$10.8b	Ulcerative Colitis (phase 2) Crohn's disease (phase 2A) Autoimmune diseases (phase I or pre clinical)
 <b>Nestlé</b> HealthScience®	 <b>Enterome</b>	July 2022	R&D collaboration and license agreement	Total deal size: Undisclosed Upfront: €40m Sales / regulatory milestones: Undisclosed	Food allergies and IBD (pre clinical)
 <b>Pfizer</b>	 <b>ARENA</b> PHARMACEUTICALS	Mar 2022	Acquisition	Total deal size: US\$6.7b	Ulcerative Colitis (FDA Approved, 2023), Crohn's disease (phase2/3), Atopic dermatitis (phase 2 complete)
 <b>Roche</b> <b>Genentech</b> <small>A Member of the Roche Group</small>	 <b>NOVOME</b> BIOTECHNOLOGIES	Nov 2021	R&D collaboration and license agreement	Total deal size: US\$605m Upfront: US\$15m Additional payments: US\$590m	IBD (Discovery)
 <b>Nestlé</b> HealthScience®	 <b>SERES</b> THERAPEUTICS	Jul 2021	Licensing agreement in US/Canada	Total deal size: US\$525m Upfront: US\$175m Sales / regulatory milestones: Up to US\$225m	Recurrent Clostridioides difficile infection (Phase 3)

<https://www.merck.com/news/merck-strengthens-immunology-pipeline-with-acquisition-of-prometheus-biosciences-inc/>  
<https://www.enterome.com/news-events/enterome-signs-major-strategic-rd-collaboration-with-nestle-health-science-to-develop-and-commercialize-new-allermimics-and-endomimics-immunotherapies-for-food-allergies-and-inflamm/>  
<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-arena-pharmaceuticals>  
<http://novomebio.com/wp-content/uploads/2021/11/Novome-and-Genentech-Enter-into-Strategic-Collaboration.pdf>  
<https://ir.serestherapeutics.com/news-releases/news-release-details/seres-therapeutics-nestle-health-science-announce-ser-109-co>



# Outlook



# Milestones for 2023

2023 JAN – MAR	2023 APR - JUN	2023 JUL - DEC
<p><b>Services</b> New healthcare product full launch </p>	<p><b>Services</b> New international distribution deals </p>	<p><b>Services</b> New country expansion </p>
<p><b>Services</b> New international distribution deals </p>	<p><b>Therapeutics - IBD MAP 315 program</b> HREC Approval for Phase I trial </p>	<p><b>Services</b> First Sonic partners operational</p>
<p><b>Therapeutics - IBD MAP 315 program</b> Phase I HREC Submission </p>	<p><b>Therapeutics - IBD MAP 315 program</b> GMP manufacture complete Phase I </p>	<p><b>Therapeutics - IBD MAP 315 program</b> Phase I participant dosing complete </p>
<p><b>Therapeutics - IBD MAP 315 program</b> FDA Pre-IND meeting outcome </p>	<p><b>Therapeutics - IBD MAP 315 program</b> Phase I trial commencement </p>	<p><b>Therapeutics - IBD MAP 315 program</b> Phase I complete</p>
<p><b>Therapeutics - IO Program</b> Pre-clinical results </p>		<p><b>Therapeutics – IO Program</b> Immunological pre-clinical results</p>
<p><b>Therapeutics – Autoimmune Program</b> First <i>in vitro</i> screening results </p>		<p><b>Therapeutics - Autoimmune Program</b> Stage 1 activity screening complete </p>



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