

# **Q4 FY24 Quarterly Investor Presentation & Webinar**

**Microba Life Sciences Limited** (ASX: MAP) ("Microba" or the "Company") is pleased to provide below its Q4 FY24 Investor Presentation and Investor Webinar with CEO Dr Luke Reid and SVP, Therapeutics Prof. Trent Munro presenting.

#### **Quarterly Investor Presentation Webinar**

Presenting: CEO, Dr Luke Reid and SVP, Therapeutics Prof. Trent Munro

**Webinar Access**: The Quarterly Investor Presentation Webinar can now be accessed on demand via Microba's Investor Hub at the following link https://ir.microba.com/link/aP3zxr

#### **Investor Q&As**

We invite investors and interested parties to submit questions on the Quarterly Investor Presentation & Webinar through the 'Ask a question' section of Microba's interactive investor platform by following this link: 'Ask a question'

This announcement has been authorised for release by the Board of Directors

#### For further information, please contact:

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https://ir.microba.com/welcome

### **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. For more information visit <a href="https://www.microba.com">www.microba.com</a>



# **MICROBA**

# Combating disease through the microbiome

Q4 FY24 Results

**ASX: MAP 25 July 2024** 

Authorised for release by the Board of Directors

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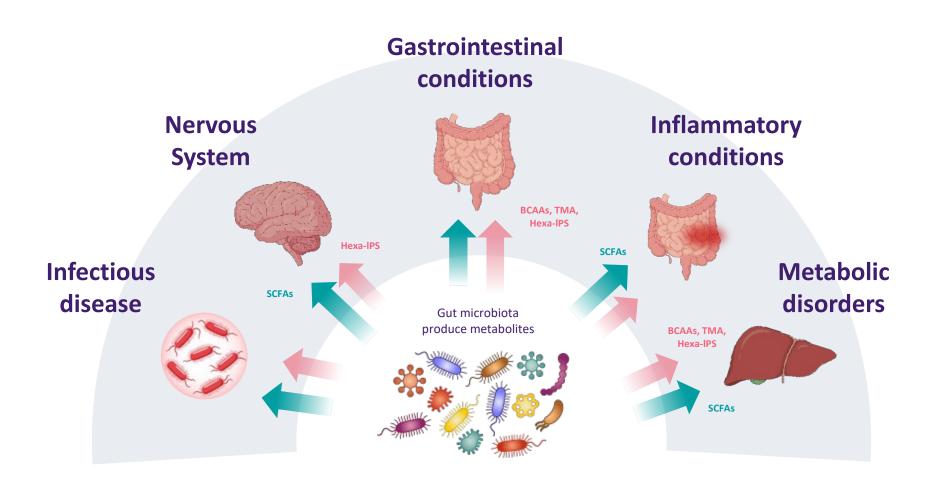
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# Unequivocal evidence demonstrates the human gut microbiome acts systemically and is a critical component of disease



>150

Clinical studies
demonstrating
that microbiome
modulation can
influence disease
outcomes and
symptoms\*

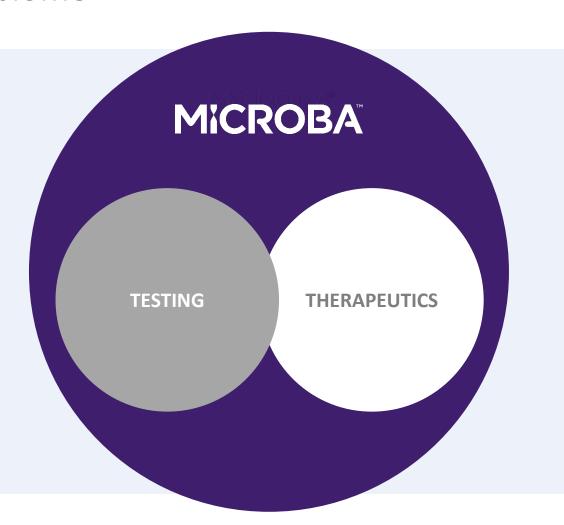
# Microba is a medical diagnostic and clinical stage therapeutics company unlocking the human microbiome

- Microba was founded in late 2017 on world-leading metagenomic microbiome analysis technology
- A clear vision for routine use of diagnostic metagenomic testing, and novel drugs developed using this technology
- Foundations and initial revenue built through non-diagnostic testing services with over 50,000 tests sold to date
- Microba's Testing business invested to develop 2 diagnostic testing products:

**MetaXplore**<sup>™</sup> Gastrointestinal disorder test – Launched Feb 2023

**MetaPanel**<sup>™</sup> Gastrointestinal pathogen test – Launched March 2024

- Microba's Therapeutics business invested in 3 programs:
  - Inflammatory Bowel Disease Phase I complete
  - Marie Marie
  - Autoimmune Disease Discovery















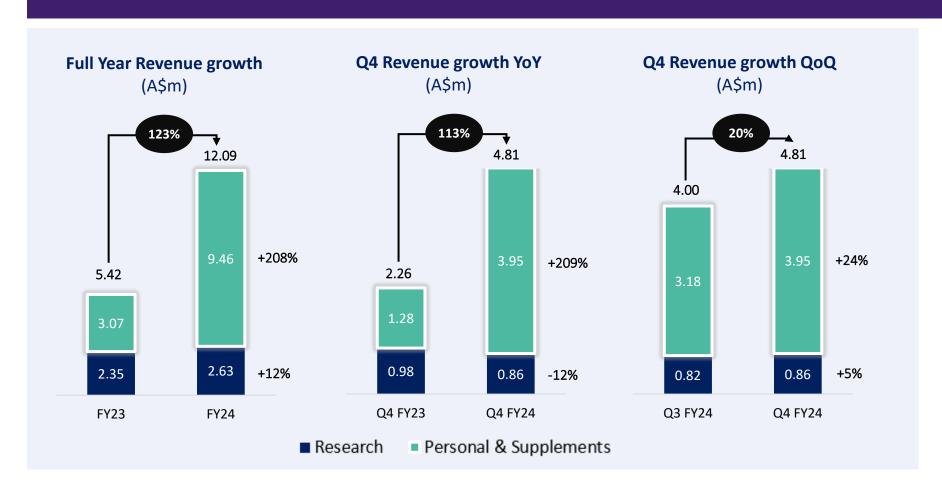


# Q4 Results Financial Highlights

# **Q4 Financial Highlights**

Record Sales and Revenue Growth in Australia, First Full Half of Revenue from Invivo Clinical in the United Kingdom

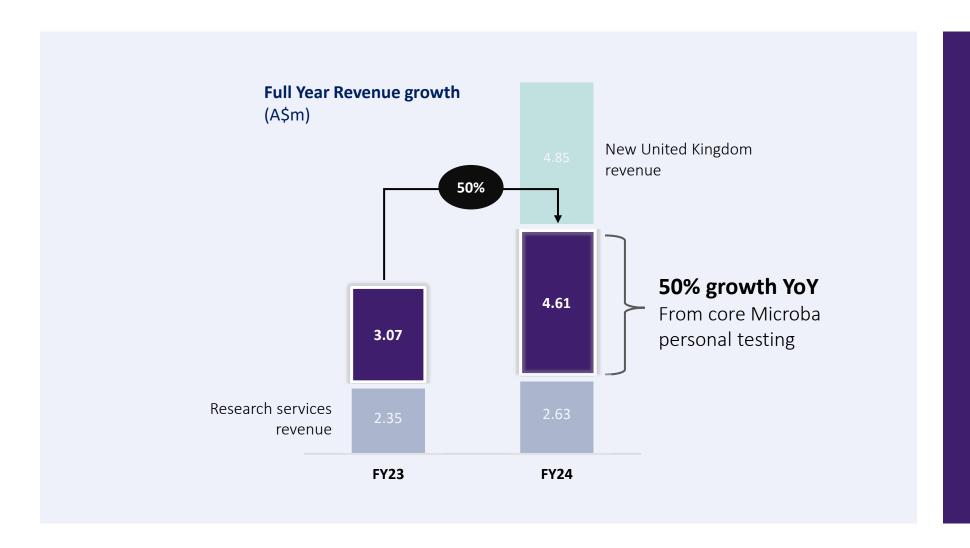
# \$12.09m full year revenue, up 123% YoY | \$4.81m Q4 revenue, up 113% YoY



- \$4.81m in Q4 FY24 unaudited revenue, up 20.2% QoQ and 113% YoY.
- \$3.95m in Q4 Personal Testing & Supplements revenue, up 24.0% QoQ and 208.8% YoY.
- \$4.66m in Q4 FY24 cash receipts, up 15.7% QoQ and up 275.4% YoY.
- \$12.44m Full Year cash receipts, up 148.1% YoY.
- \$12.09m in Full Year unaudited revenue, up 123.1% YoY.

# **Q4 Financial Highlights**

Strong growth in Microba's core personal testing revenue



# \$4.61m in revenue from core Microba personal testing, up 50% YoY

- Accelerating growth of core personal testing sales and revenue in Australia following launch of diagnostic testing products, MetaXplore and MetaPanel
- Strong growth in clinician adoption visible through retained customers, repeat test referrals and new ordering clinicians

# Q4 Results Business Highlights

# **Recent Milestones & Highlights**

# **TESTING**

- 1) Record growth for Gastrointestinal Disorder Test, MetaXplore, in Australia.
  - 1,835 tests sold during Q4 FY24, up 71% QoQ.
  - 414 ordering clinicians in Q4, up 41% from 293 in Q3 FY24.
- 2) Invivo Clinical achieved \$2.21m in sales for Q4 FY24.
  - \$2.21m in sales for Q4 FY24, and \$4.45m in sales for H2 FY24.
  - 1,934 tests and 31,833 supplements sold during Q4 FY24, consistent QoQ
  - 826 ordering clinicians in Q4
- 3) MetaPanel sales building across major states through the Sonic Healthcare (ASX: SHL) network.
  - Active KOL engagement
  - Evidence generation activities and utility publications in process.

# **THERAPEUTICS**

1) Autoimmune Program

Successful completion of world-first Autoimmune therapeutic discovery program with Ginkgo Bioworks

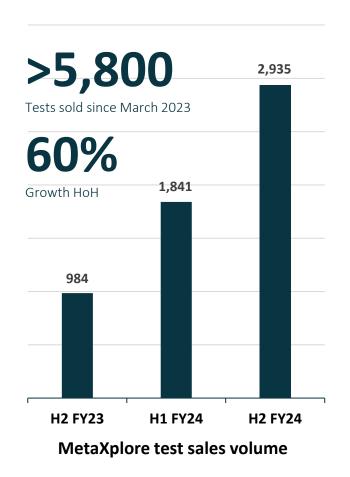
2) Inflammatory Bowel Disease Program

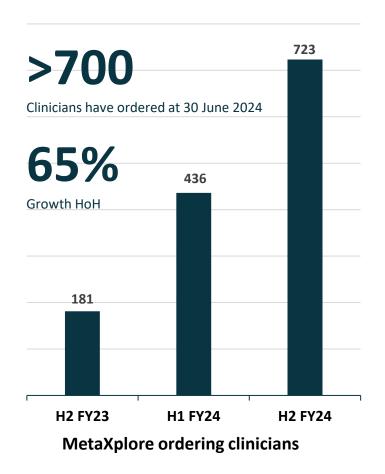
Preparing MAP 315 for Phase 2.

3) Immuno-Oncology Program

Clinical data and sample set grown to >3,500 patients supporting this program.

# Growing MetaXplore sales and clinical adoption in Australia



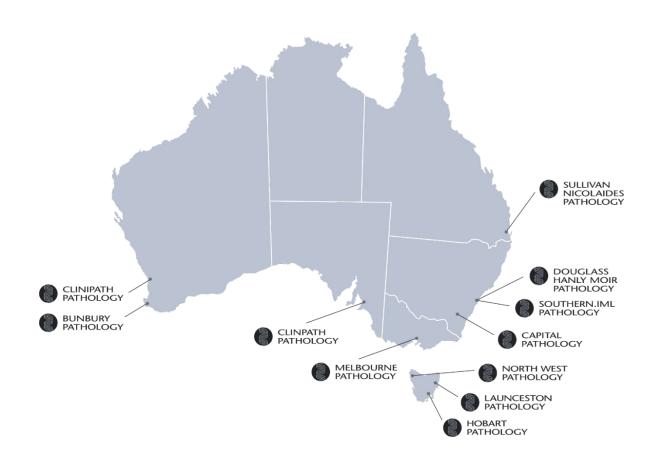


- 1,835 tests sold during Q4 FY24, up 71% QoQ.
- >300 new clinician accounts registered to access in Q3, now totals >1,700 registered
- 414 ordering clinicians in Q4, up 41% QoQ.
- Growth activities:
  - Targeted sales and marketing activities focused on high prescribing potential clinicians
  - Clinician education
  - KOL engagement
  - Utility studies and publications



**MetaXplore**<sup>™</sup>

# Growing MetaPanel sales, advancing Gl pathogen diagnosis in Australia



- Doctor referrals and sales continue to grow monthly across the country, focused around the major east coast states New South Wales, Victoria and Queensland.
- 7 clinician launch events held spanning all major states and territories
- Growth activities:
  - Targeted sales and marketing activities focused on gastroenterology specialists and general practice
  - Clinician education
  - KOL engagement
  - Utility studies and publications





# Preparing for growth in the United Kingdom

1,934

Q4 Tests Sold

31,833

Q4 Supplements Units

826

Q4 ordering clinicians

6,615

Tests Sold FY24

125,767

Supplements Units Sold FY24

6,958

Clinicians registered all time

- \$4.45m in sales generated in H2 FY24. The first full half of Invivo sales and revenue as part of the Microba group.
- Growth strategy:

# Stage 0

- Bolster sales and marketing resourcing for the UK team with recruitment of new talent to unlock latent growth potential
- Recruitment well advanced with great candidate pool

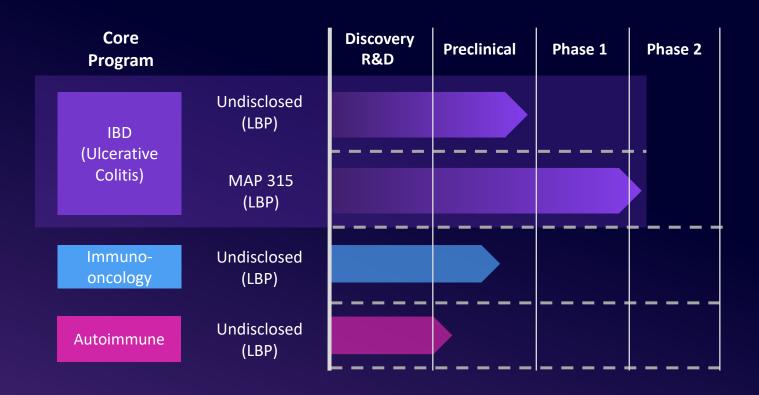
# Stage 1

- Launch Microba's MetaXplore™ product into the UK to drive testing growth
- Planning is well advanced
- Scheduled to occur in FY25.





# Therapeutic Development Programs continue to make significant advancements



# Autoimmune Program

 Successful completion of world-first Autoimmune therapeutic discovery program with Ginkgo Bioworks

# Inflammatory Bowel Disease Program

- Preparing MAP 315 for Phase 2.
- Bolstering CMC package and regulatory documentation for IND

# • Immuno-Oncology Program

Clinical data and sample set grown to
 >3,500 patients supporting this program.

# Microba Diagnostics

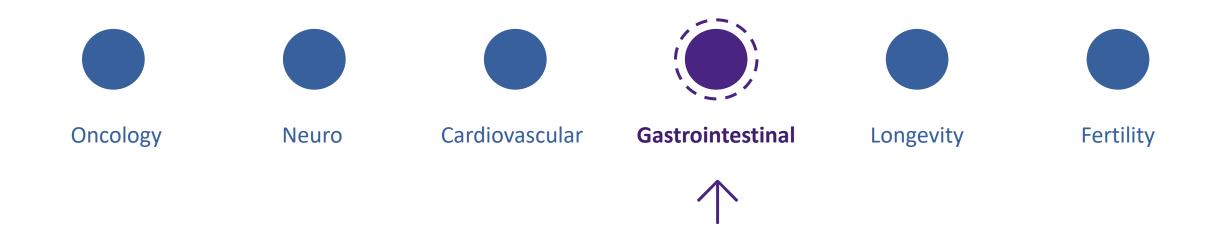
# **Our Diagnostics Vision**

To combat disease through microbiome health

Since 2023, Microba has executed the next step of its journey into a medical diagnostic company at the forefront of the medical application of microbiome testing.

# **Our Diagnostics Focus**

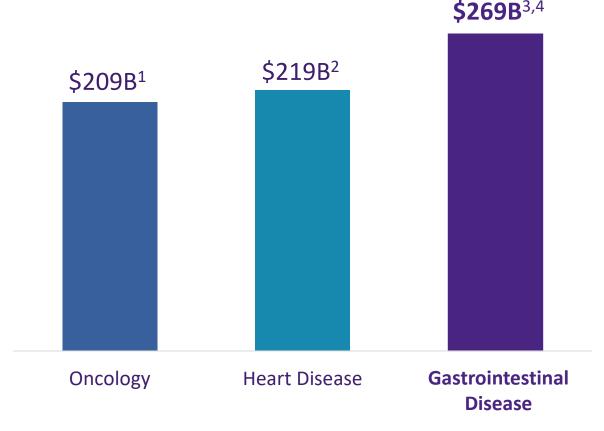
Patients suffering from Gastrointestinal Disease



# Lower Gastrointestinal Disease a leading cause of healthcare spend

37,310,000

**Patients** presenting annually in the US with lower GI abdominal symptoms\*



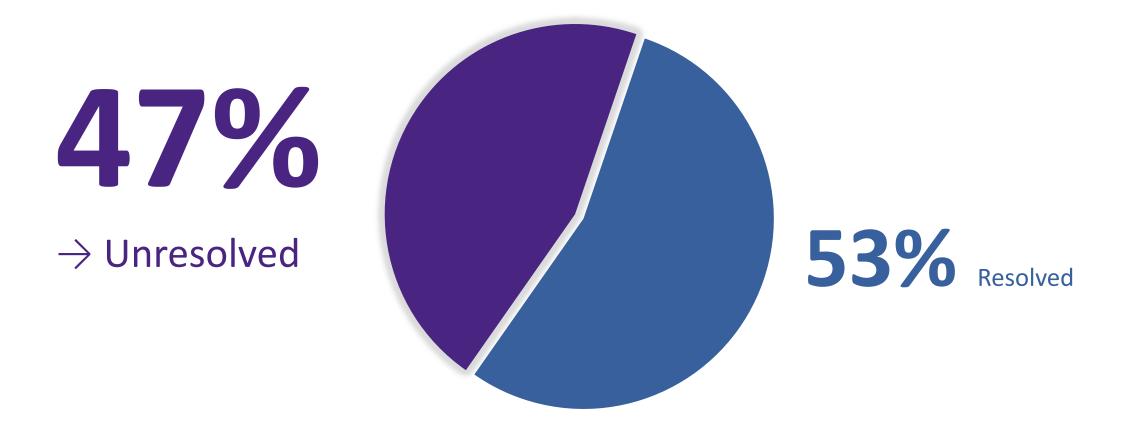
**Annual US Healthcare Spend** 

<sup>&</sup>lt;sup>1</sup>National Cancer Institute website: https://progressreport.cancer.gov/after/economic\_burden; <sup>2</sup>CDC website: https://www.cdc.gov/policy/polaris/healthtopics/heartdisease/index.html <sup>3</sup>Nyrop et al. 2007. *Alimentary Pharmacology & Therapeutics*. DOI: 10.1111/j.1365-2036.2007.03370.x. <sup>4</sup>Park et al 2019. *Inflammatory Bowel Diseases*. DOI:10.1093/ibd/izz104.

<sup>\*</sup>Assessment of Medicare claims analysis by Veranex including estimated Private and Medicaid numbers extrapolated from the Medicare claims analysis. Combined with IBS diagnosed individual data from Almario et al 2023. Gastroenterology. DOI:10.1053/j.gastro.2023.08.010 and IBD individual data from Lewis et al 2023. Gastroenterology. DOI:10.1053/j.gastro.2023.07.003 and Weisman et al 2023. Prev. Med. Rep. DOI: 10.1016/j.pmedr.2023.102173.

# Half of patients are not getting a resolution

from current standard of care



Developed with

SONIC HEALTHCARE

# Addressing the GI symptom challenge

Microba's comprehensive diagnostic products

# First line

For the detection of pathogens causing GI symptoms

# **MetaPanel**<sup>™</sup>



# Gastrointestinal pathogen test

# **Launched March 2024**

- ✓ Stool DNA test.
- ✓ 175 targets.
- ✓ Expertly curated clinical recommendations for targeted treatment.

# Second line

For identifying functional causes for non-pathogenic **GI** symptoms

# **MetaXplore**<sup>™</sup>



# Gastrointestinal disorder test

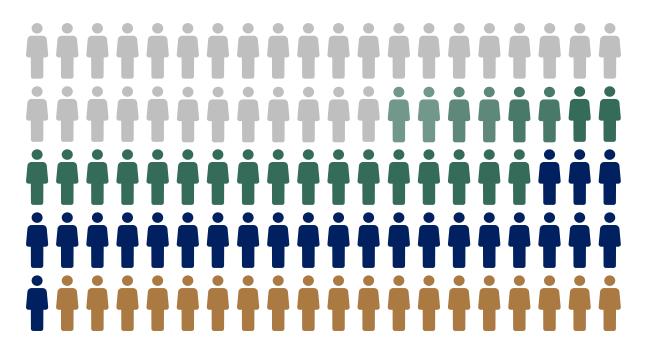
# **Launched February 2023**

- ✓ Stool DNA + targeted biomarker test.
- ✓ 7 functional GI markers. >28k microbiome markers.
- Expertly curated clinical recommendations for personalised treatment.

# Getting answers for patients in need

Closing the gap on GI symptom diagnosis and treatment

Out of 100 patients presenting with lower GI symptoms



# **MetaXplore**<sup>™</sup>

24%\*\* more diagnoses with MetaPanel™

19%\* diagnosed with
Standard of Care (PCR +MCS+OCP)

<sup>\*</sup> Large pathology company data from 70,000 tests with 19% positive pathogen detection rate

<sup>\*\*</sup> Study of first 4 months of MetaPanel test results in clinical practice in Australia

# **Transforming standard of care** A paradigm shift

"After the first 4 months using the MetaPanel test, **24% of patients have been diagnosed** with a pathogen that would have been undiagnosed or experienced delayed time to diagnosis and resolution.

This is a breakthrough in infectious disease management"









# Changing lives every day

"Before completing the MetaXplore test with my practitioner, my health was in constant distress. I looked and felt bloated all the time, to the point of appearing six months pregnant. My severe constipation led to bowel movements only every 5-6 days with trapped gas causing extreme pain. After completing the MetaXplore test and implementing my treatment plan, I have experienced remarkable improvements. My bowel movements are now regular, averaging every 2-3 days. The trapped gas and extreme pain are gone, significantly improving my daily life. With adherence to the treatment plan, I no longer suffer from bloating, pain, reflux, or indigestion"

MetaXplore patient

# **MetaXplore**<sup>™</sup>

# Changing lives every day

"I have struggled with gastrointestinal symptoms for over half my life. I have tried resolving with many specialists, restrictive eating plans and natural therapies. My MetaXplore test this year identified clear problems and a personalised treatment plan. I am grateful that through following the treatment plan I have achieved complete resolution to my symptoms and can enjoy eating unrestricted for the first time in 35 years."

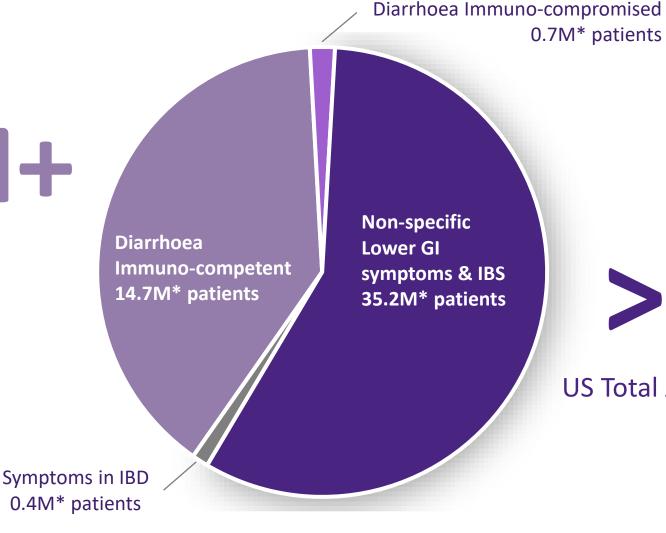
MetaXplore patient

# **MetaXplore**<sup>™</sup>

# A multi-billion dollar market opportunity



US patients\*





US Total Addressable Market\*\*



<sup>\*</sup> Assessment of Medicare claims analysis. Estimated Private and Medicaid numbers extrapolated from Medicare claims analysis.

<sup>\*\*</sup> Assumes minimum revenue per test of US \$416.78 aligned to CPT code 57507. This is viewed to be the minimum with the top pricing predicate at US \$2126.20

# Serving patients today and driving to establish a new reimbursed standard of care

# Out of pocket pay access

Driving access today where standard of care has failed.

Full out of pocket pay.



# **Evidence**

Clinical performance validation.

Case studies.

Registry driving RWE.

RCTs vs standard of care demonstrating clinical utility.

# Reimbursement & coverage



UNITEDHEALTH GROUP®







# Guidelines











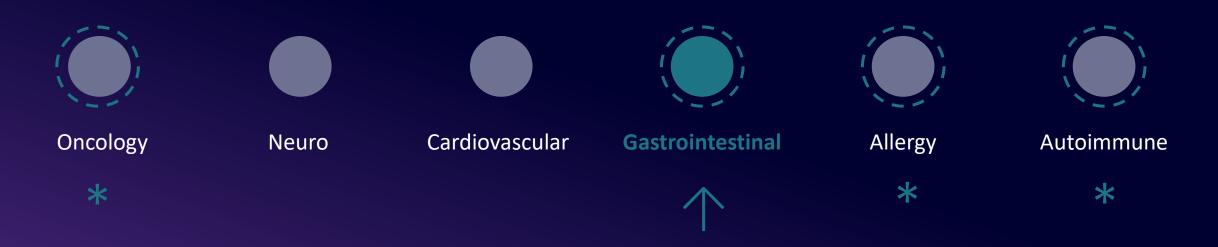
# **Our Therapeutics Vision**

To combat disease through microbiome health

Since 2020, following the establishment of the richest Microbiome data resource in the world, Microba has advanced the discovery and development of novel microbiome therapeutics at the forefront of microbiome drug development.

# **Our primary Therapeutic Focus**

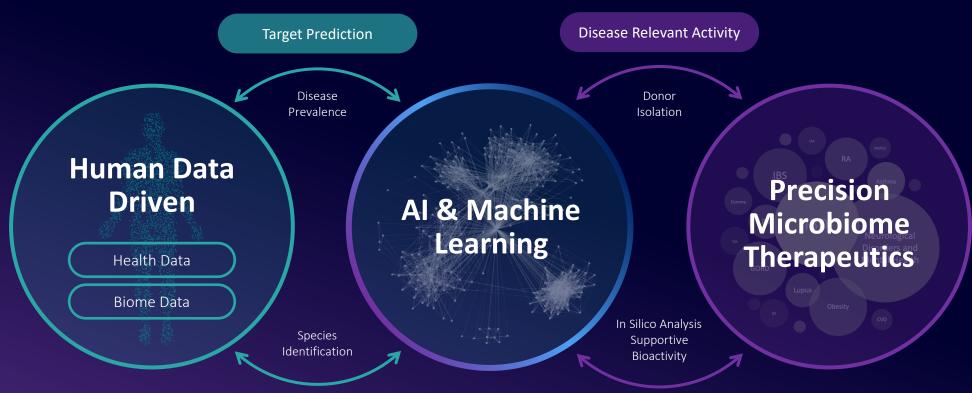
Clinical: Patients suffering from Inflammatory Bowel Disease



Preclinical: Patients suffering from autoimmune disease, allergy or undergoing cancer immunotherapy

# Microba is Pioneering an Advanced AI/ML Approach

For the Development of Next Generation Precision Live Biotherapeutics



>60,000 metagenomes\*

>1,000 health indicators/participant

>1M Genomes

**>100M** Genes

>100K species

>100TB of DNA data

**8,000B** alignments

**200M** CPU hours processing time

**20K** vCPUs, 50TB RAM

**>9,000** isolated strains





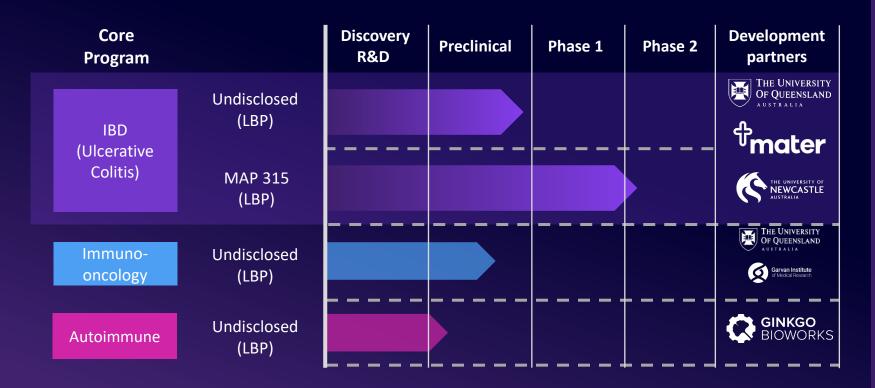
>500 species isolated in total

>200 previously uncultured species isolated

1 Phase II ready asset

Multiple pre-clinical leads

# Microba is a leader in Precision Microbiome Therapeutics



- **Precision microbiome analysis** platform delivering unparalleled accuracy, coverage & depth.
- Data driven discovery platform utilising one of the world's most advanced & highly curated microbiome datasets.
- Potent and novel biology mediated by Live Biotherapeutic strategy
- **Demonstrated scalable GMP** manufacturing process
- **Oral delivery and Excellent** safety profile

















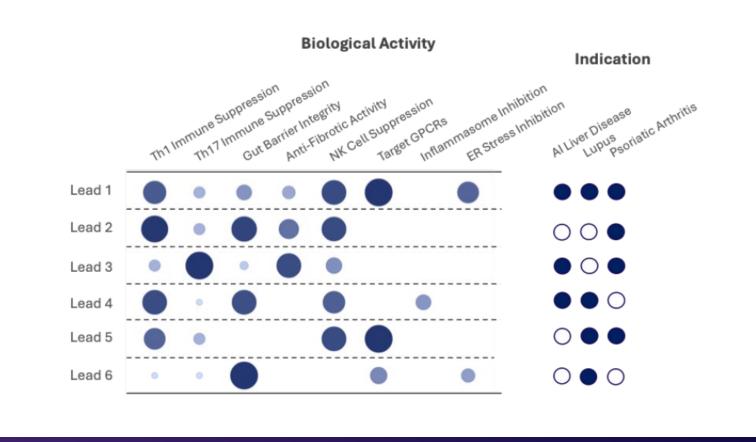
# **Autoimmune Program**



# Stage 2 Screening – Complete June 2024

- ✓ Delivered compelling biological activity enabling selection of 6 lead strains, generating new therapeutic intellectual property assets for the Company
- ✓ Data generated showing impact on fibrosis, gut barrier integrity, nuclear receptor biology, GPCRs and ER stress
- ✓ Generated more than 3 million data points in world-first microbiome therapeutic discovery effort

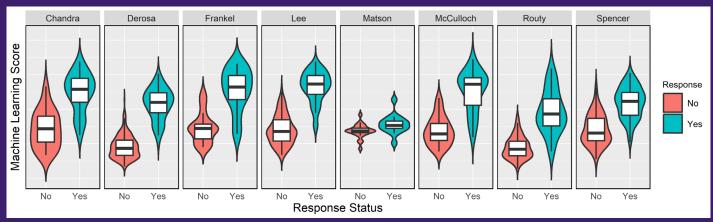
# Observed broad and potent immunomodulatory activity which is disease relevant



# **Oncology Program**

# Microba's clinical data and sample set has now grown to over 3,500 patients.

- >2,500 patient samples collected from the national PrOSPeCT study which is expected to be one of the largest clinical specimen resources with respect to the microbiome and cancer treatment expected to support the lead candidate selection decision processes and the pre-clinical package.
- >1,000 metagenomics samples already analysed from 8 internally recruited and published studies
  across multiple cancer types have been complied to discover gut microbiome signatures associated
  with patient response to checkpoint inhibitor immunotherapy
- Robust signals have been discovered spanning geography, clinical indication, and checkpoint inhibitor regimens, enabling high-throughput *in vitro* screening of potential lead species for disease-relevant activities in human immunological models



Results of integrated machine learning analysis of clinical datasets, demonstrating a consistent metagenomic signature of paient response to ICI. Models were trained on species abundances using ten-fold cross validation. Final models predict response with an accuracy of 87%.

# OMICO & PrOSPeCT study

- Microba is a collaborating partner in the landmark \$185M program, which is the largest precision oncology and cancer genomics initiative in Australia
- Microba has joined companies which as Bayer, Illumina and Sonic Healthcare to advance precision oncology

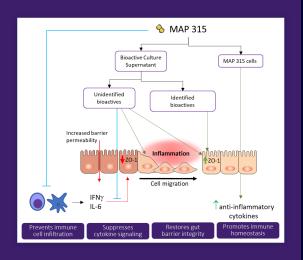




# **Inflammatory Bowel Disease Program: MAP 315**

# **Data supporting MOA**

Pre-clinical data supports that MAP 315 stimulates mucosal healing (modulation of WNT signaling, restoration of gut barrier integrity) and immune homeostasis (induction of regulatory T cells). Both critical to the etiology and pathophysiology of Ulcerative Colitis



# MAP 315 induces integrity and restores WNT pathway signaling MAP 315 induces regulatory T cells MAP 315 induces regulatory T cells MAP 315 induces regulatory T cells

## Phase II trial readiness

Study start timing actively being defined - Adaptive Patient Study, N = 140 to 200 examining induction of remission

- Phase 1 data package = complete
- Protocol development = complete
- Final CMC pack = in process
- IND filing = drafting

# Phase I trial summary – Concluded Dec 2023

- ✓ Safe and well tolerated at both low and high doses
- ✓ No clinically significant safety signals from assessments.
- ✓ Faecal kinetics assessed by metagenomic analysis indicated ability to successfully deliver live MAP 315 into the gastrointestinal tract





BACTHERA

# Therapeutic pipeline & catalysts

# Therapeutic pipeline & catalysts



# **MICROBA**



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Pasquale Rombola
Chairman
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# **CONTACT**

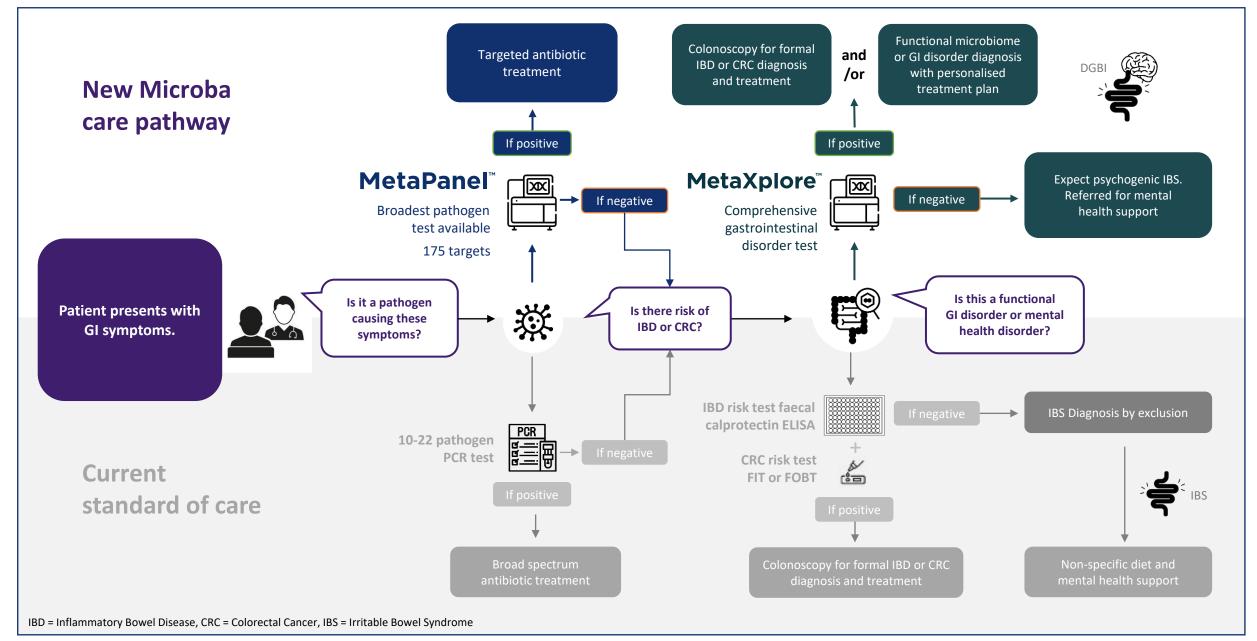
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**Laboratory**Princess Alexandra Hospital
Woolloongabba QLD Australia

# Appendix

MICROBA

# Patient pathway — Advancing the standard of care for GI symptoms



# Two core business segments driven by a world leading technology

# MICROBA®

World leading microbiome analysis technology

Proprietary databank

Advanced AI and biostatistics powering a diagnostics and therapeutics platform

# **Testing Business**

Next generation gastrointestinal diagnostics

2 clinical tests.

**GASTROINTESTINAL PATHOGEN TEST** 

**MetaPanel** 

**GASTROINTESTINAL DISORDERS TEST** 

**MetaXplore**<sup>™</sup>

2 channels to market.

#### PATHOLOGY PARTNER CHANNEL



PRIMARY TARGET CLINICIANS
Gastroenterologists
General Practitioners

Other Specialists

DIRECT TO PRACTITIONER CHANNEL

invivo CO-BIOME

**PRIMARY TARGET CLINICIANS** 

Integrative General Practitioners Integrative Specialists Dieticians Nutritionists Naturopathic practitioners

# **Therapeutics Business**

# Precision microbiome therapeutics

Data driven therapeutic development platform.

ADVANCED AI/ML APPROACH
UNDERPINNED BY WORLD LEADING
TECHNOLOGY

NOVEL PIPELINE OF MICROBIOME THERAPIES – POTENT, ORAL DELIVERY, SAFE & MANUFACTURABLE

#### 3 therapeutic programs.

# INFLAMMATORY BOWEL DISEASE PROGRAM

CLINICAL INDICATION
Mild-moderate Ulcerative

Colitis

DEVELOPMENT STAGE

Phase 1 Complete Phase 2 Readiness





# IMMUNO-ONCOLOGY PROGRAM

#### CLINICAL INDICATION

Multiple cancers to enhance check-point inhibitor treatment response

**DEVELOPMENT STAGE** 

Pre-clinical. Lead candidate selection



# AUTOIMMUNE DISEASE PROGRAM

#### CLINICAL INDICATION

Lupus, psoriatic arthritis & autoimmune liver disease

DEVELOPMENT STAGE

Discovery





# Microba is developing the 3<sup>rd</sup> Generation of Microbiome Therapeutics using a human data driven approach

# **First Generation**



**Second Generation** 



**Next Generation** 



# **Faecal Doner Derived & FMT**



FDA approval Nov 30 2022 Faecal doner derived enema

drug product



FDA approval April 27 2023

Faecal doner derived oral capsule drug product

# **Bacterial Consortia**



#### **Vedanta Biosciences**

Vedanta Biosciences Raises \$106.5M in Funding



#### SER-155

Phase Ib showing engraftment reduction in pathogens

**Single Strain & Small Molecule** 



Microba MAP 315 Phase I IBD

Advancing oncology & autoimmune pipeline