

Autoimmune Stage 1 Screening Complete with Ginkgo Bioworks

- Autoimmune disease program achieves a key milestone on schedule with completion of Stage 1 activity screening of lead strains with Ginkgo Bioworks (NYSE: DNA)
- 62% of strains demonstrated significant immunomodulatory activity and a further 18% demonstrated significant impact on the inflammasome
- 36 strains have now been selected to move into secondary functional screening in the first quarter of 2024 for expected discovery program completion in Q4 FY24

Microba Life Sciences Limited (ASX: MAP) (“Microba” or the “Company”) today announces that Stage 1 activity screening for the Company’s Autoimmune disease program has been completed on schedule together with partner Ginkgo Bioworks (NYSE: DNA). Stage 1 activity screening analysed 182¹ strains selected through Microba’s data driven drug discovery platform with 62% of strains demonstrating significant immunomodulatory activity and a further 18% significantly impacting the inflammasome. From this work, 36 strains have now progressed into Stage 2 functional screening for expected completion in Q4 FY24 to enable lead candidate selection.

Microba’s Autoimmune disease therapeutic discovery program is being conducted in partnership with synthetic biology leader Ginkgo Bioworks, and brings together Microba’s proprietary, data-driven Therapeutic Platform with the automated screening capabilities at Ginkgo’s foundry facilities in Boston. This has enabled Microba to leverage Ginkgo’s high-throughput anaerobic culturing, multi-omics data collection and analysis, functional bioassay screening, and media and fermentation optimisation capabilities to execute a robust drug discovery program. This has generated datasets that characterise the therapeutic biology of ~200 lead strains targeting autoimmune disorders identified using Microba’s data-driven platform.

Professor Trent Munro, SVP of Therapeutics at Microba said: *“Microba is at the forefront of developing precision Microbiome Therapeutics enabled by machine learning and artificial intelligence, that have the potential to help patients in need across a number of therapeutic areas. This milestone for our auto-immune disease program is a critical step as we move toward selecting potential lead candidates for future development. Our partnership with Ginkgo has allowed us to interrogate complex biology with a speed and throughput which would not be otherwise possible. We are very pleased with this data and the robustness of the primary screening assays, and are now confidently proceeding to Stage 2 deep functional screening”.*

Autoimmune Disease Program and Ginkgo Bioworks Partnership

The goal of this program is to discover and develop novel treatments for Autoimmune diseases such as lupus, psoriatic arthritis and certain Autoimmune liver diseases. In mid-2023 Microba commenced its Autoimmune disease therapeutic program in partnership with Ginkgo Bioworks. Microba first used its proprietary databank and advanced machine learning analytics to identify 200 diverse gut microbiome bacterial strains implicated in the target Autoimmune diseases. Over the past 18 months Microba in partnership with Ginkgo has screened these leads for immunomodulatory activities based on a co-designed, bioanalytical assay cascade. Ginkgo has now completed all activities related to the Stage 1 activity screen to assess immunomodulatory activity. The obtained data demonstrates that a significant number of the leads bacterial strains displayed potent anti-inflammatory and/or anti-fibrotic activities. That data completes Stage 1 and has facilitated down selection to 36 high priority strains to move into Stage 2 disease-specific functional screens expected to compete in Q4 FY24 to enable lead candidate selection.

Autoimmune diseases are a family of more than 80 chronic and often life-threatening illnesses, which occur when the body’s own immune system attacks the body’s healthy cells, tissues and organs. Autoimmune conditions now impact

¹ 200 strains selected through Microba’s data driven drug discovery platform were transferred to Ginkgo Bioworks of which 18 did not meet the growth specifications resulting in 182 strains progressing through primary screens

around 5% of the population and their prevalence is rising². In recent years, several studies have highlighted the role of the microbiome in the pathogenesis of autoimmune diseases³. The global market for autoimmune disease treatments was estimated to be US\$198b in 2023 and forecast to grow to US\$288b by 2028⁴.

Therapeutic Platform & Programs

There is a growing body of evidence that the gut microbiome plays a central role in the maintenance of health and the development of chronic disease. With microbiome-based therapeutics now in clinical development and the first FDA approvals, these novel drugs represent an exciting new opportunity for the treatment of chronic diseases that are underserved by current pharmaceuticals.

Microba is at the forefront of this field using its advanced proprietary metagenomics technology developed by leading Australian researchers in the top 1% of cited researchers globally. Using this technology, Microba has established a data-driven platform for drug discovery and development from the human gut microbiome. This platform leverages a large, growing, proprietary databank collected through the Company's Microbiome Testing Services, and is generating multiple potent therapeutic candidates to address chronic diseases. Microba has established three therapeutic programs spanning Inflammatory Bowel Disease (IBD), Immuno-Oncology and Autoimmune Diseases, with lead candidate MAP 315 under the Company's IBD program the first program to enter human clinical trials.

The Company considers that these results are material and price sensitive for the following reasons:

- The Autoimmune disease discovery program in partnership with Ginkgo Bioworks represents a significant investment from the Company of US\$7,000,000⁵, and was a key component of the use of funds from the Company's Initial Public Offering on the ASX in April 2022
- High activity hit rate (62% demonstrating immunomodulatory activity, and a further 18% impacting the inflammasome), further validates Microba's data driven therapeutic platform and would be expected to impact the valuation of Microba's therapeutic business
- The delivery of 36 lead strains demonstrating significant immunomodulatory and/or inflammasome activity, generating new therapeutic intellectual property assets for the Company
- It is estimated that the therapeutic market size in 2023 for autoimmune disease is US\$198b and forecast to grow to US\$288b by 2028, and a novel therapy for this category would be expected to be highly valued

This announcement has been authorised for release by the Board.

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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

² Fugger, L. et al. Challenges, Progress, and Prospects of Developing Therapies to Treat Autoimmune Diseases. Cell. (2020). <https://doi.org/10.1016/j.cell.2020.03.007><https://doi.org/10.1016/j.cell.2020.03.007>

³ De Luca, F. and Shoenfeld, Y. The microbiome in autoimmune diseases. Clin Exp Immunol. (2019). <https://doi.org/10.1111/cei.13158>.

⁴ <https://www.prnewswire.com/news-releases/global-autoimmune-treatment-market-soars-to-288-32-billion-by-2028--driven-by-a-7-72-cagr-from-2023--301909189.html>

⁵ Paid for by Microba in a mix of cash and equity over two years

ASX Announcement
28 November 2023



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: www.microba.com

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

MICROBA™



Unleashing the Microbiome:

Combining big data and advanced biodiscovery to identify novel Live Biotherapeutics for Autoimmune Disease

Stage 1 Activity Screening Complete

28 November 2023

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Ginkgo is a partner
with technology you
don't have in-house



Marcus Schindler (He/Him) • Following

Executive Vice President & Chief Scientific Officer at Novo Nordisk

3mo •



In Research & Early Development we are constantly evaluating our scientific processes for opportunities for innovation, enabling us to work in faster, smarter ways. We have a strong legacy of working with cutting-edge yeast expression systems, which are fundamental to the production of our drugs. But we know that there are opportunities for improvement and innovation. Therefore, we are changing the way we work and opening up to external partners who bring new and complementary expertise.

Ginkgo Bioworks, Inc. are leaders in reprogramming biology to develop novel expression hosts. These strong capabilities in synthetic biology are rooted in the ability to re-write genomes to engineer new, bespoke biological systems. In our collaboration we aspire to combine our skills to design expression systems that are tailored to our needs. This is a unique opportunity to generate next-generation expression systems, ultimately transforming how we produce our drugs.

c&en
CHEMICAL & ENGINEERING NEWS

Bayer outsources biologicals research to Ginkgo

Ginkgo absorbs a partnership, and Bayer remains an anchor customer

by **Matt Blois**

April 28, 2022 | A version of this story appeared in **Volume 100, Issue 15**

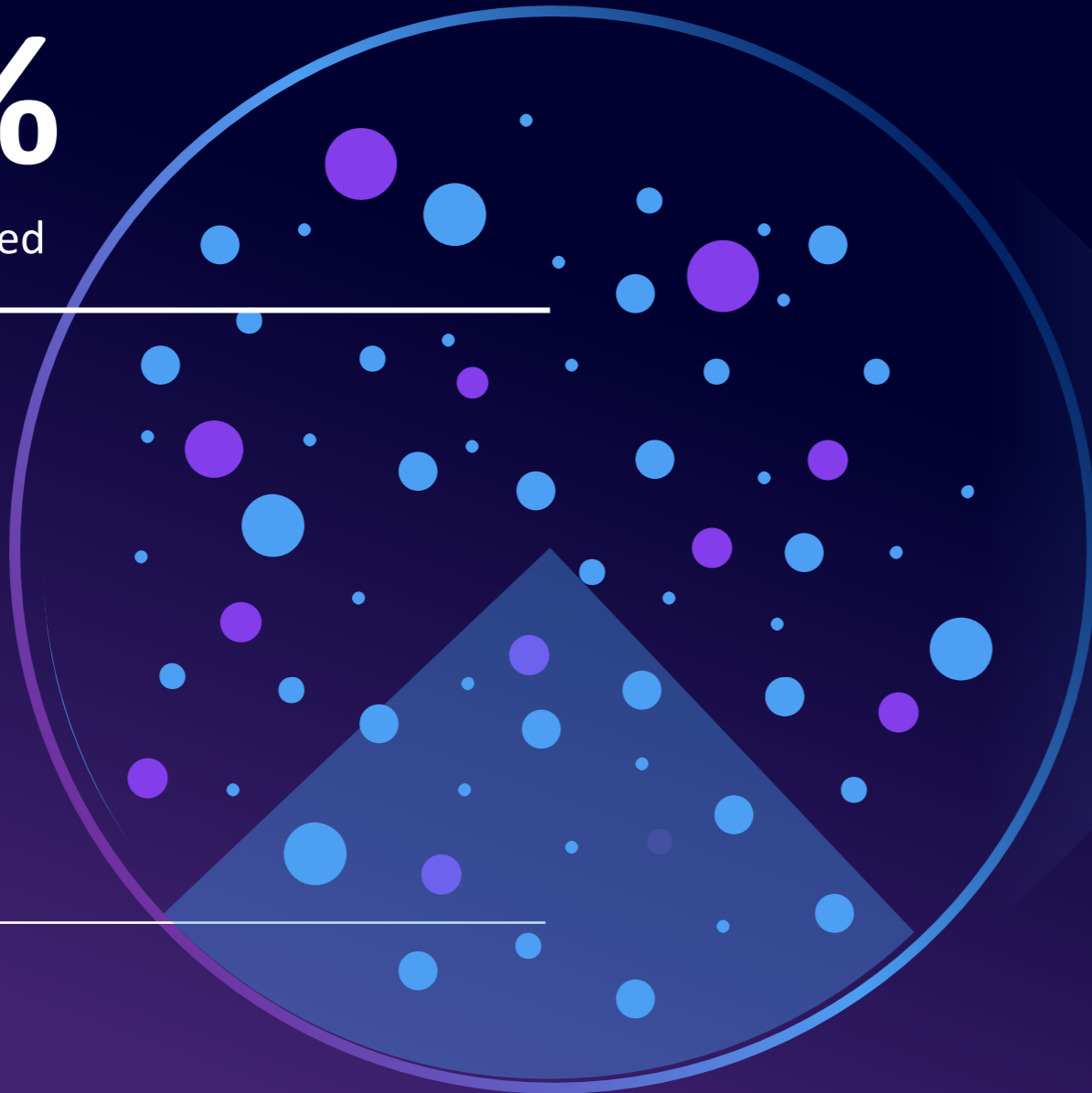
Untapped potential for drug discovery...

71%

Uncharacterized

29%

Known



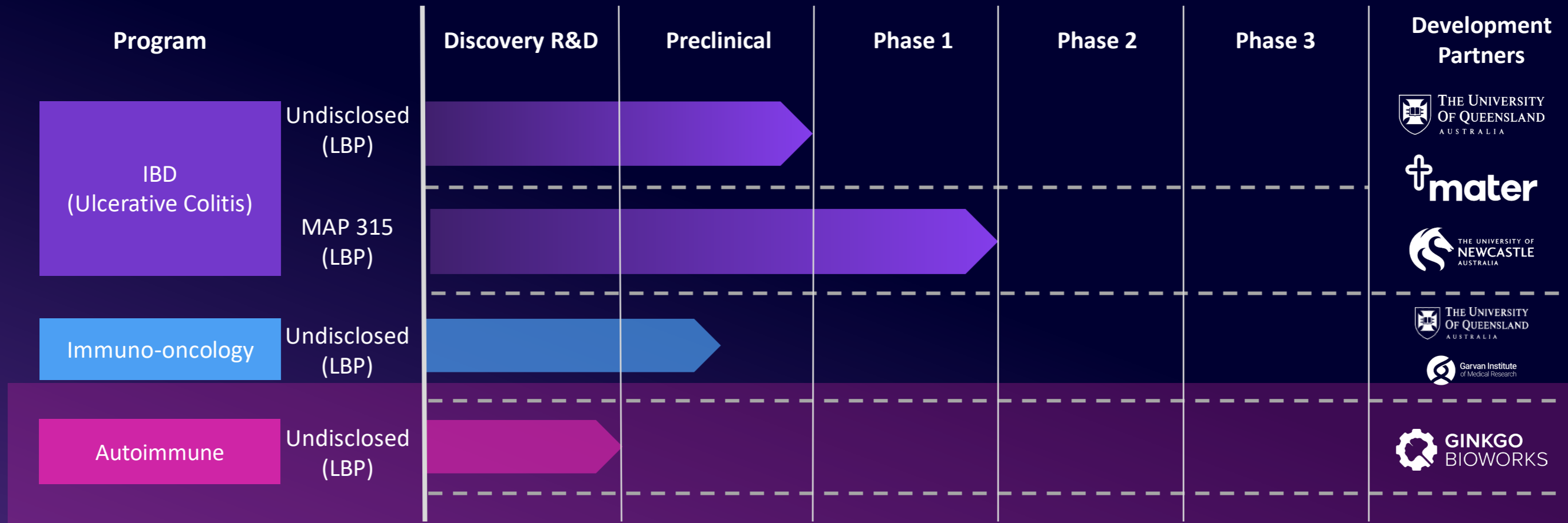
>4,800 species in gut microbiome **1**

Many species still unknown **2**

~200 species per individual **3**

The Human Microbiome

Therapeutic Pipeline

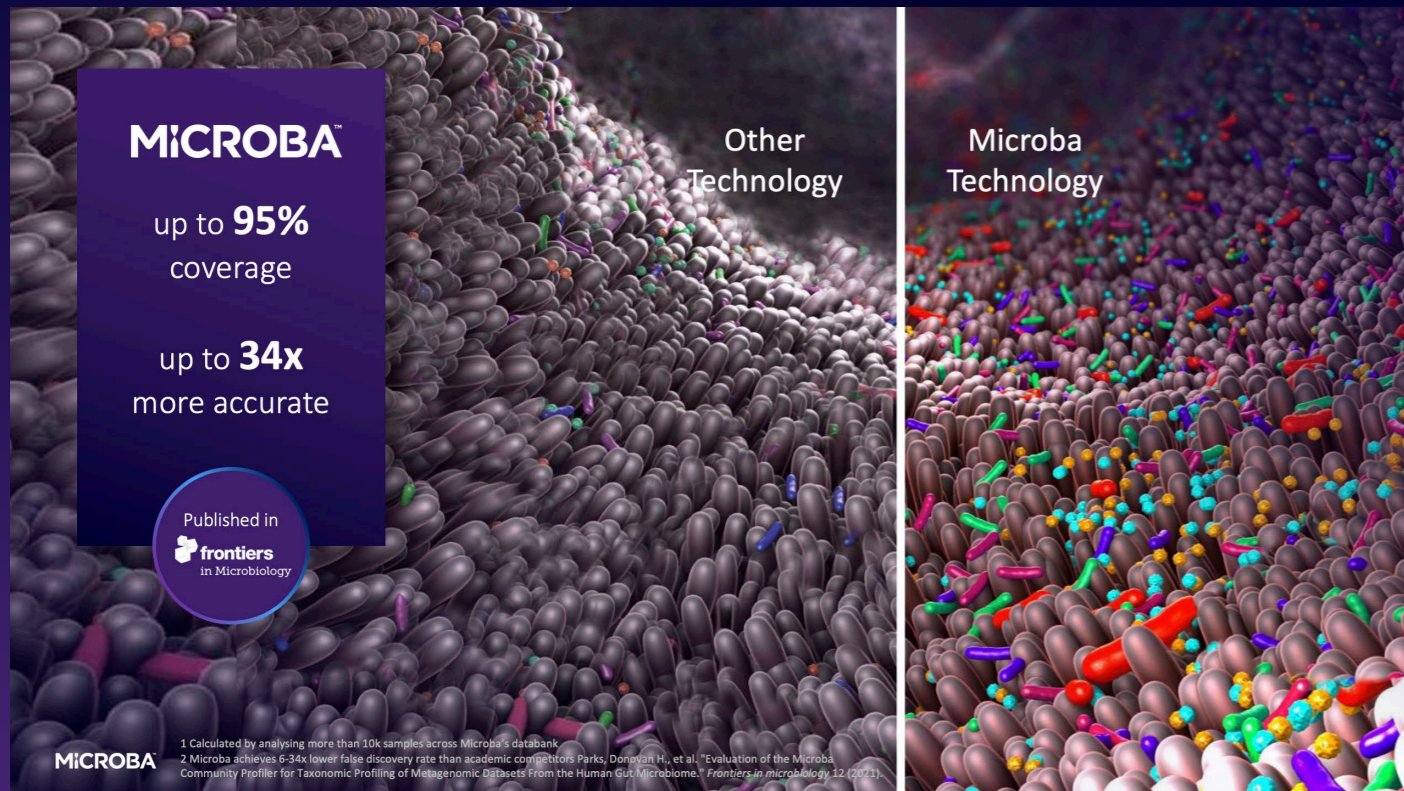


- MAP 315 Phase I clinical trial commenced first dosing in June 2023, full results to be available December 2023
- Live Biotherapeutic Product (LBP)

Microba is unlocking this opportunity

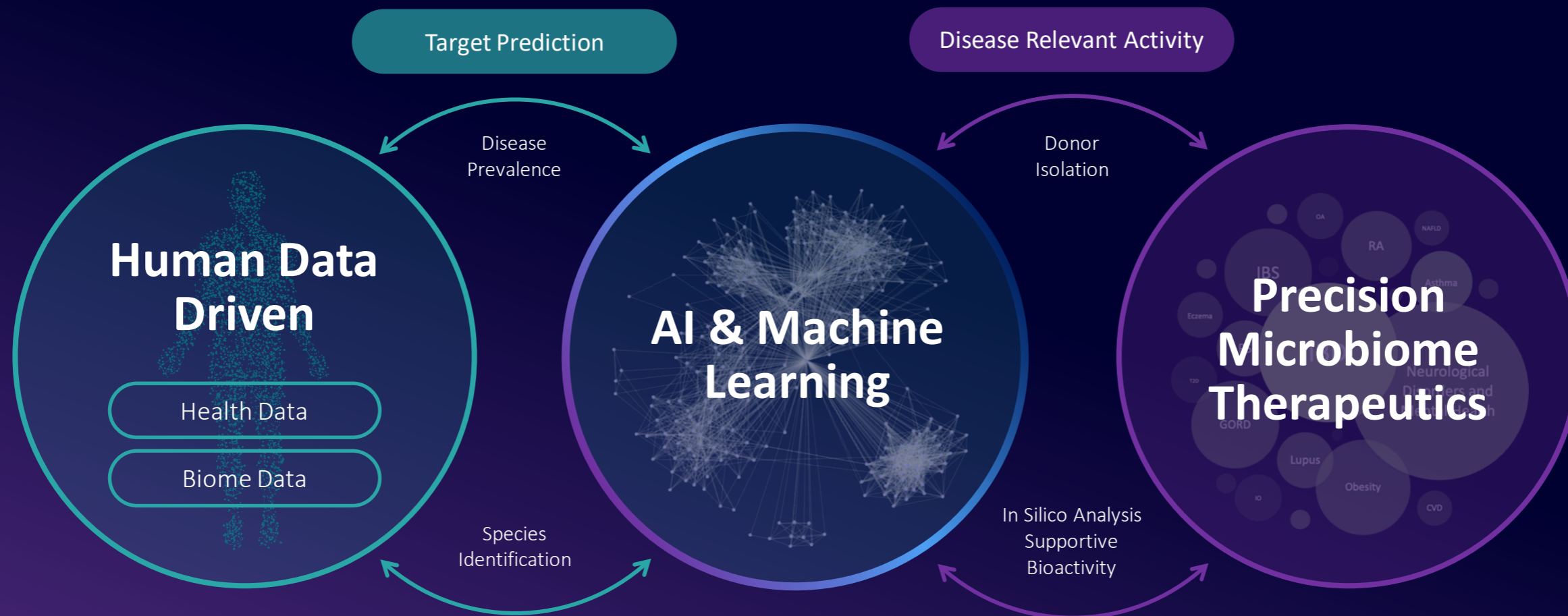
Unparalleled technology for Human Microbiome characterisation

Proprietary databank to discovery & develop Microbiome Therapeutics

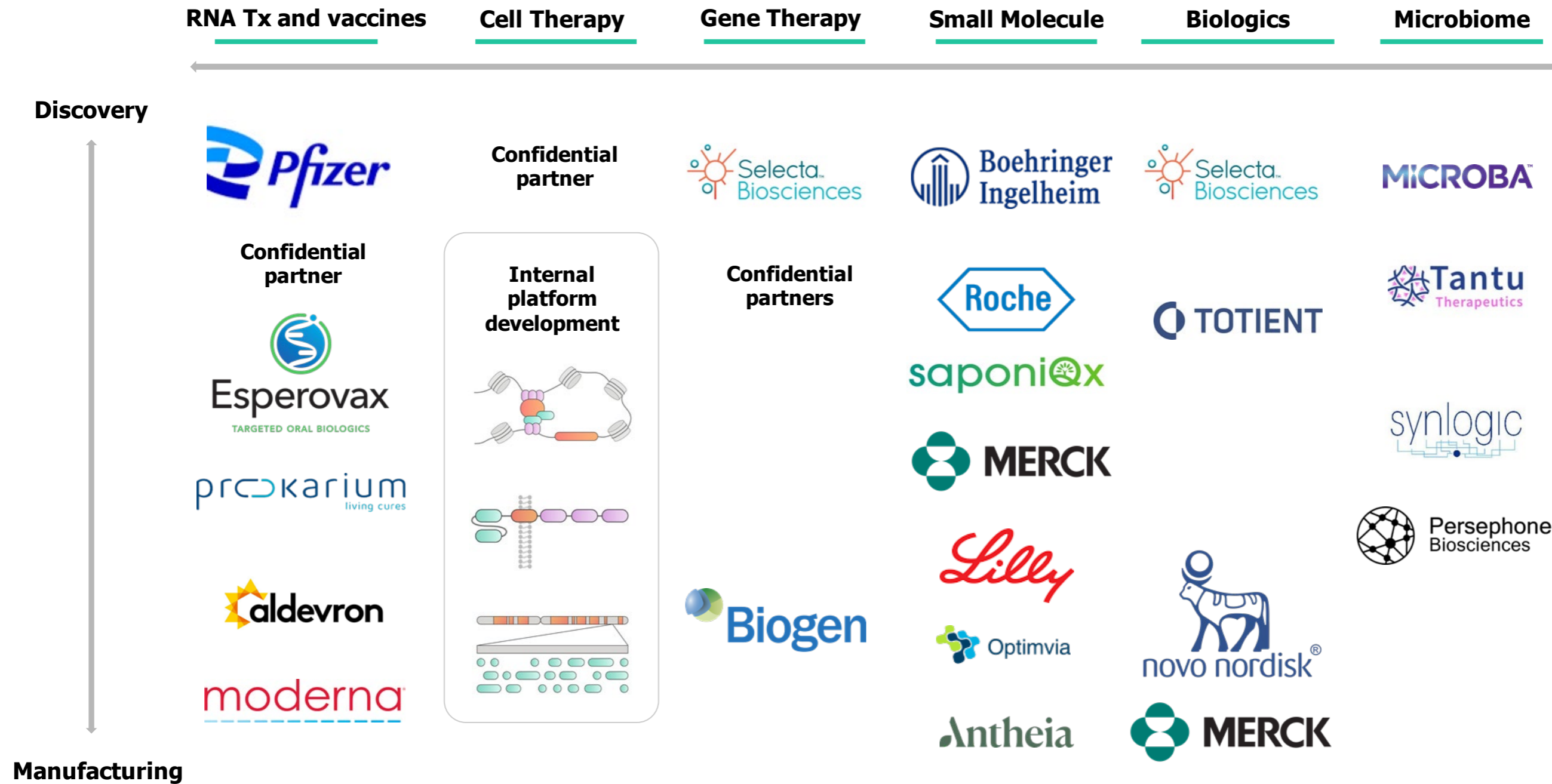


Opportunity to harness the disease modifying power of the Microbiome

Big Data Powered Therapeutics from the Human Microbiome



Ginkgo's platform can impact therapeutics discovery and manufacturing across all modalities



Gut Microbiome

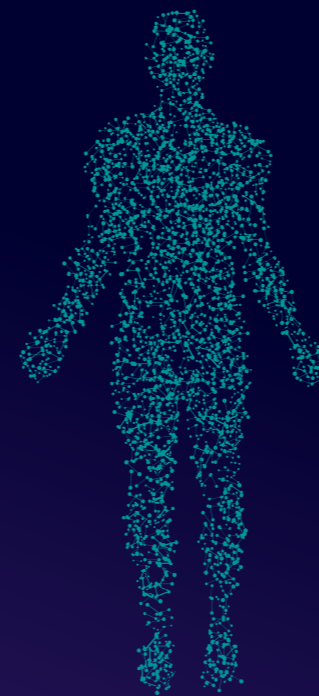


Sensor

Modulator

Translator

Autoimmune Disease



Precision Microbiome Based Intervention

MiCROBATM

 **GINKGO BIOWORKS**

Microbiome Databank

Microbiome Biobank

AI & Machine Learning Analytics

Anaerobic Foundry

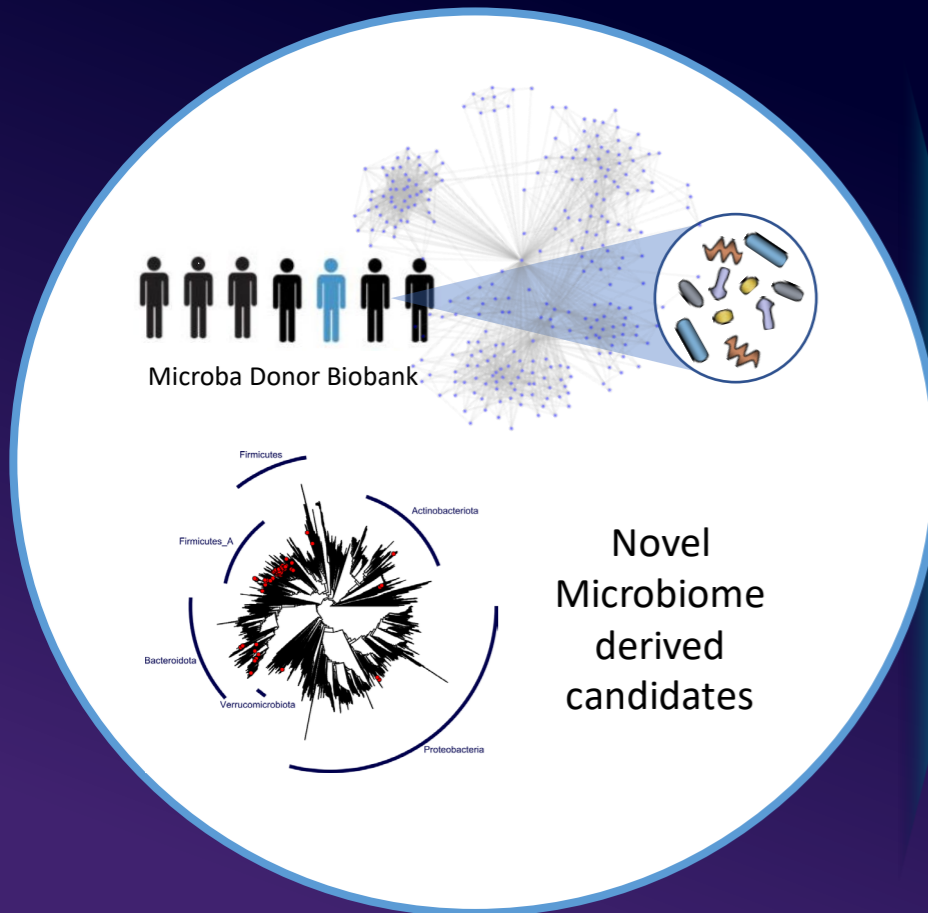
High Throughput Automated Screening

Disease Relevant Assay Development

Opportunity: Move from disease association to disease modifying activity

Autoimmune Microbiome Biodiscovery Platform

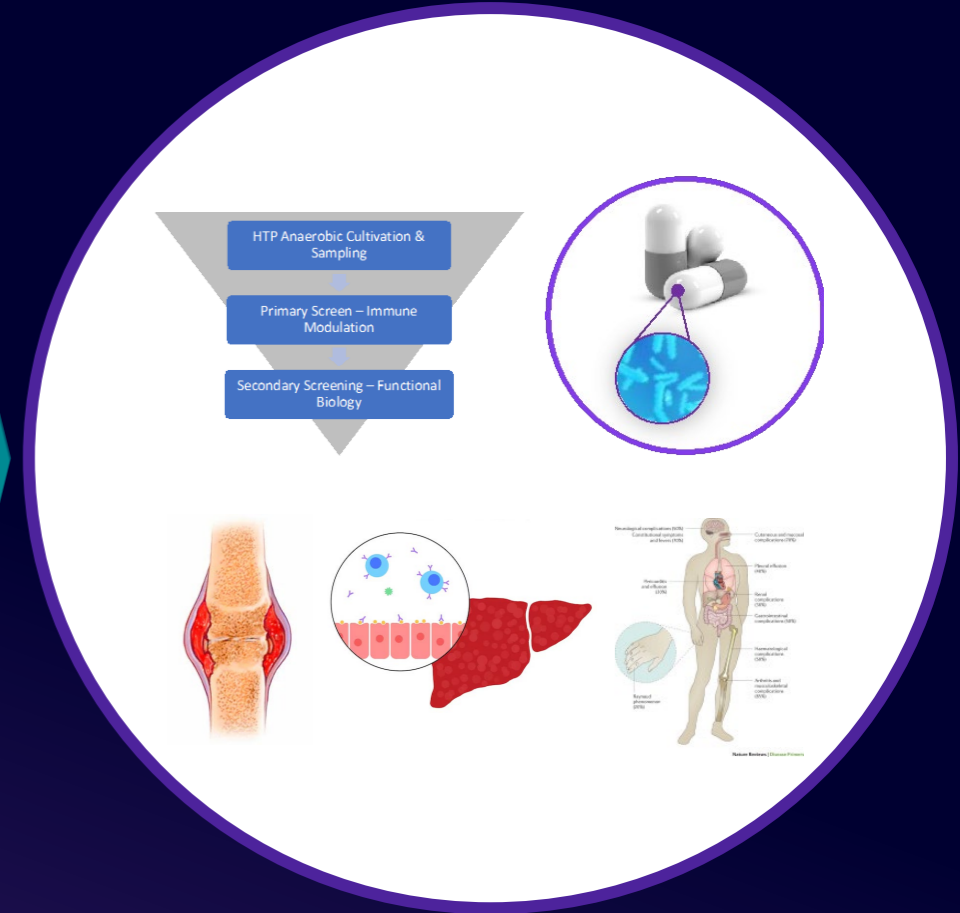
Human Data Guided Discovery Engine



Ginkgo Anaerobic Foundry



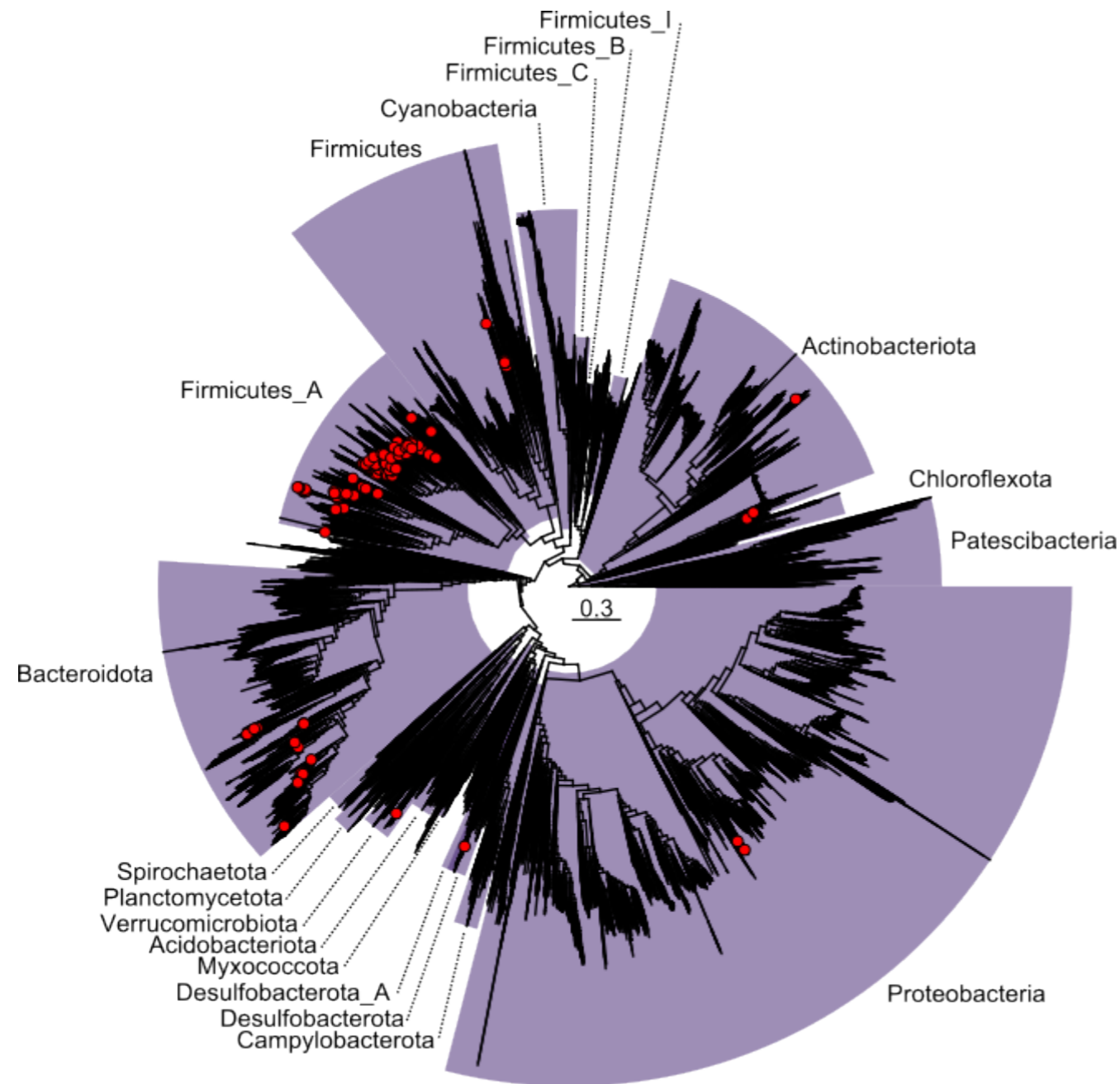
Autoimmune Bioassay Screening Cascade



Microba and Ginkgo Bioworks have established a Microbiome Drug Discovery Platform targeting Autoimmune Diseases including Psoriatic Arthritis, Autoimmune Liver Disease and Lupus.

Candidate LBPs Identified

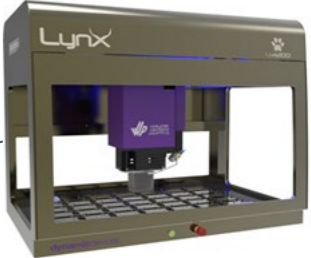
- Identification of autoimmune leads enabled by Microba's **precision microbiome measurements**
- Rationally discovered using a human first approach
- Autoimmune lead species are phylogenetically diverse and are affiliated with the predominant phyla of the gut microbiome



High throughput cultivation and real-time growth monitoring of strains at Ginkgo Bioworks Anaerobic Foundry



Microscopy

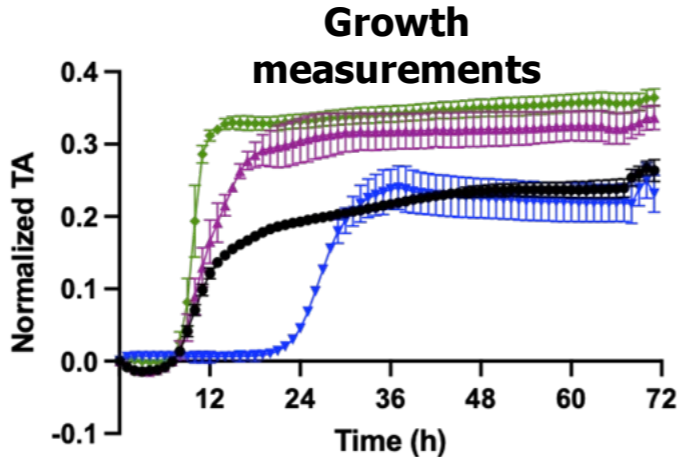


Automated liquid handling

Spectrometer



Cultivation capacity (x5)

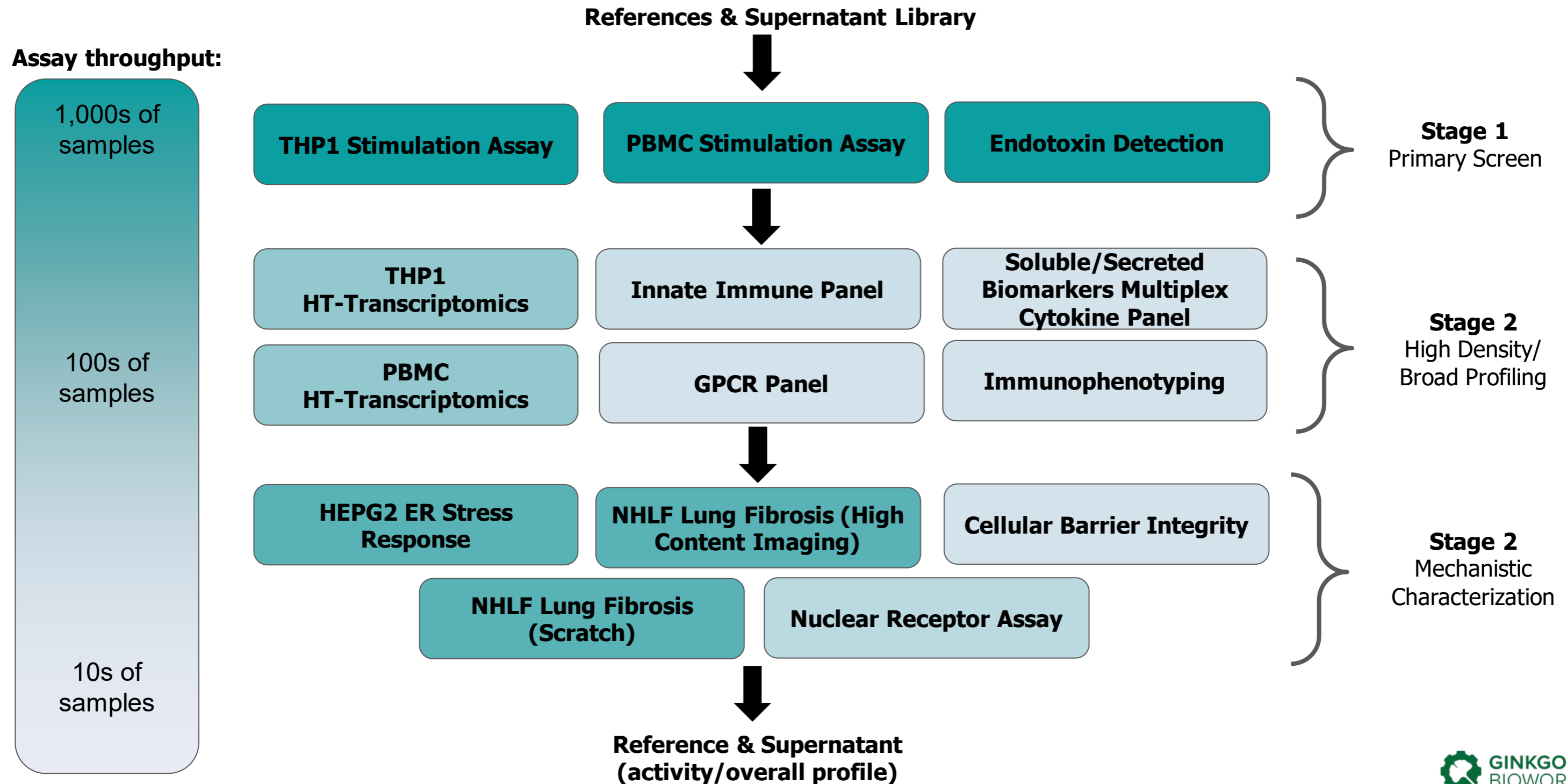


Phenotypic characterization



And more!

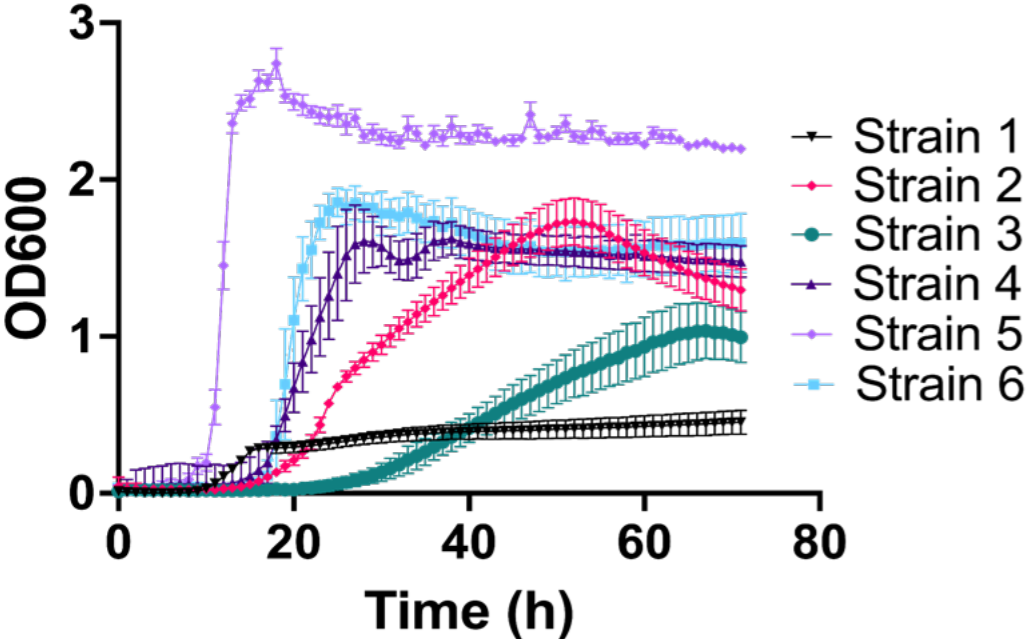
Co-Designed Biodiscovery Screening Cascade for the Microbiome



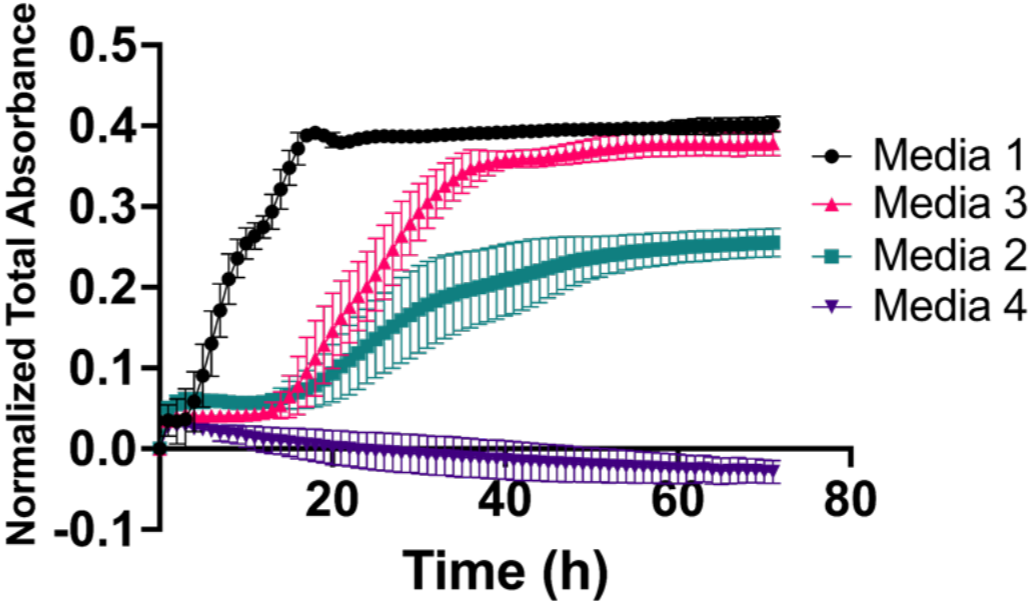
High Throughput Anaerobic Cultivation Optimization

Growth of select strains

>95% success rate in growing Microba's library, including strict anaerobes & fastidious species



12+ custom media tested for growth of strains and compatibility with downstream assays

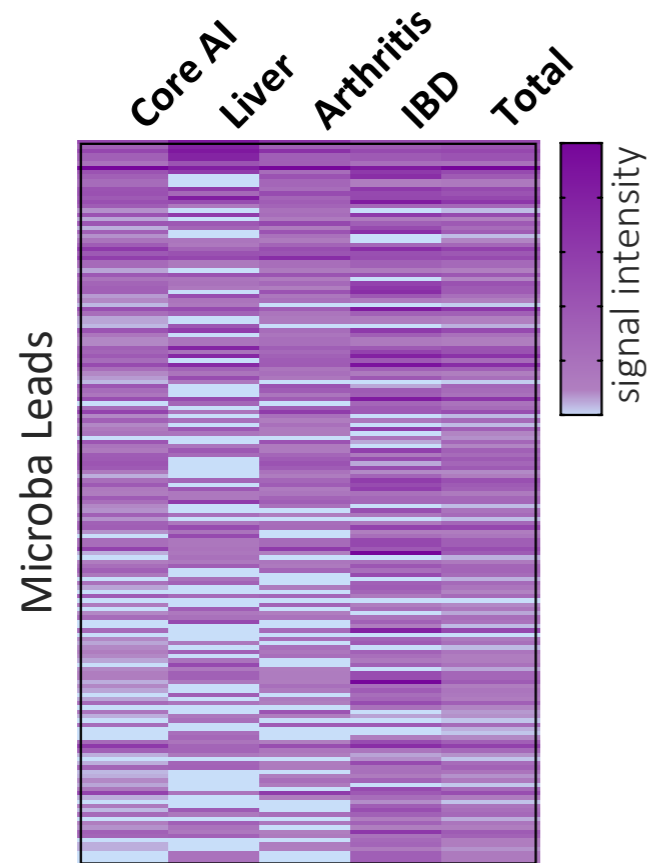


>4000 samples generated to date for downstream immune assays

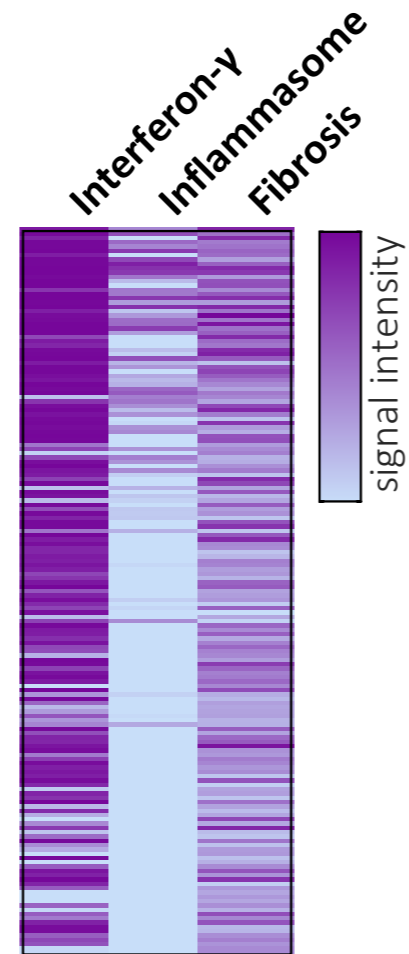


Down Selection Criteria

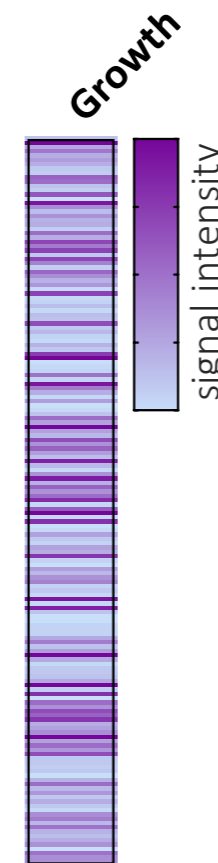
Health Association



Disease-relevant activity



Safety and Manufacturability Profile



In silico analysis of:

- AMR genes
- Virulence Factors
- Phages / Mobile Genetic Elements

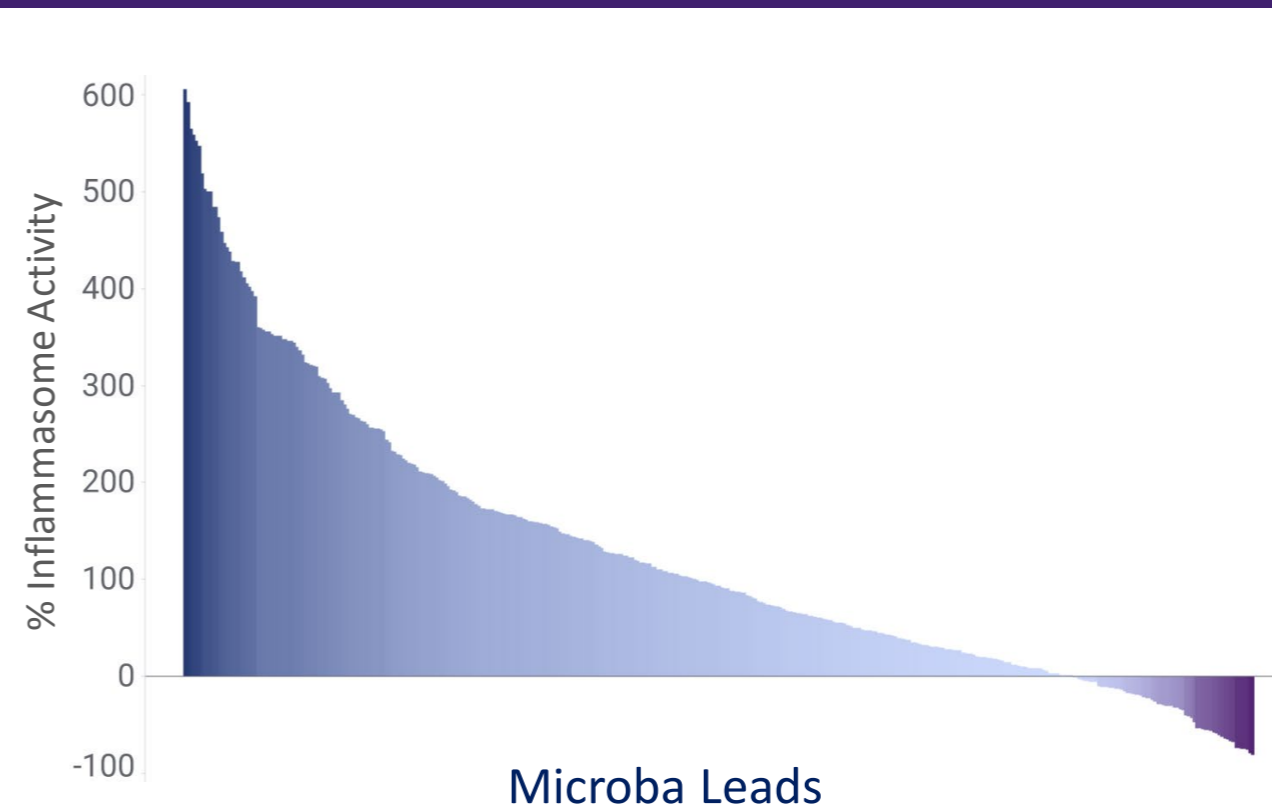
Autoimmune Program: High hit rate and potency observed in primary screens

Suppression of Th1 Immune Response



PBMC based immune suppression assay data showing suppression of IFN γ production

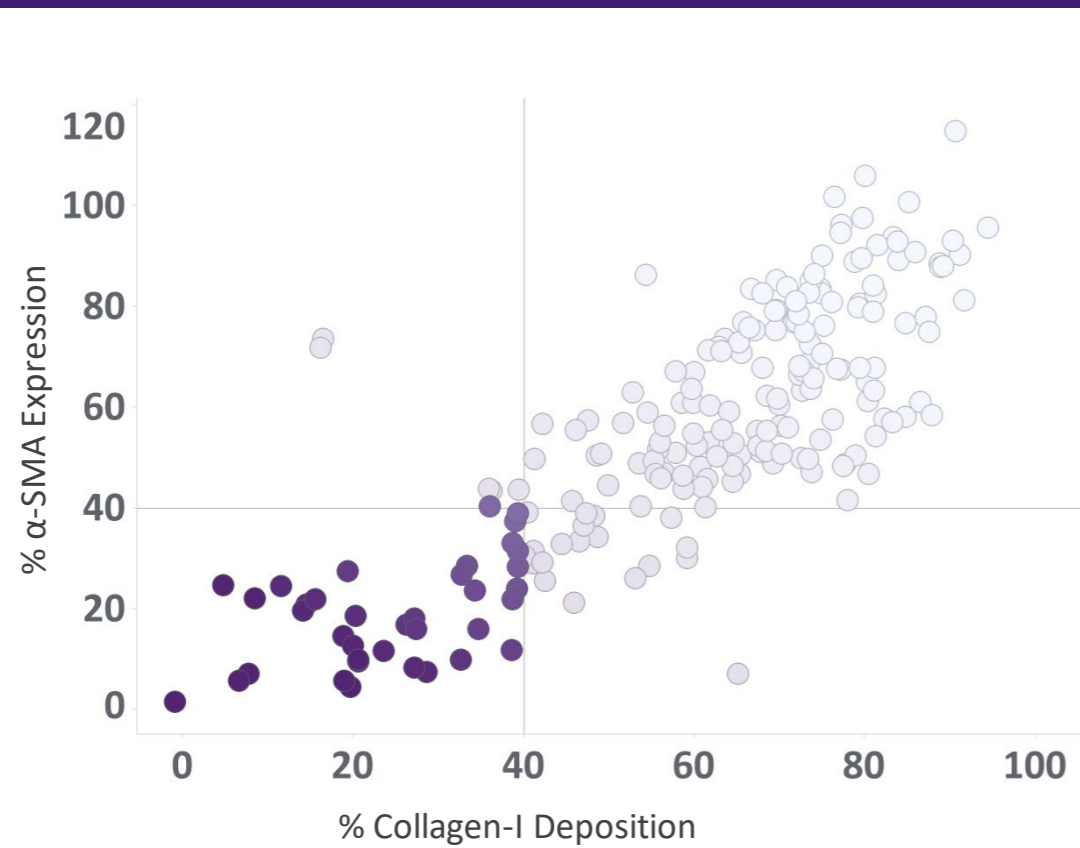
Inflammasome Suppression



Inflammasome activation assay in THP1 cells showing reduction in IL-1 β

Microba leads exhibit potent anti-fibrotic activity

Anti-fibrotic Activity

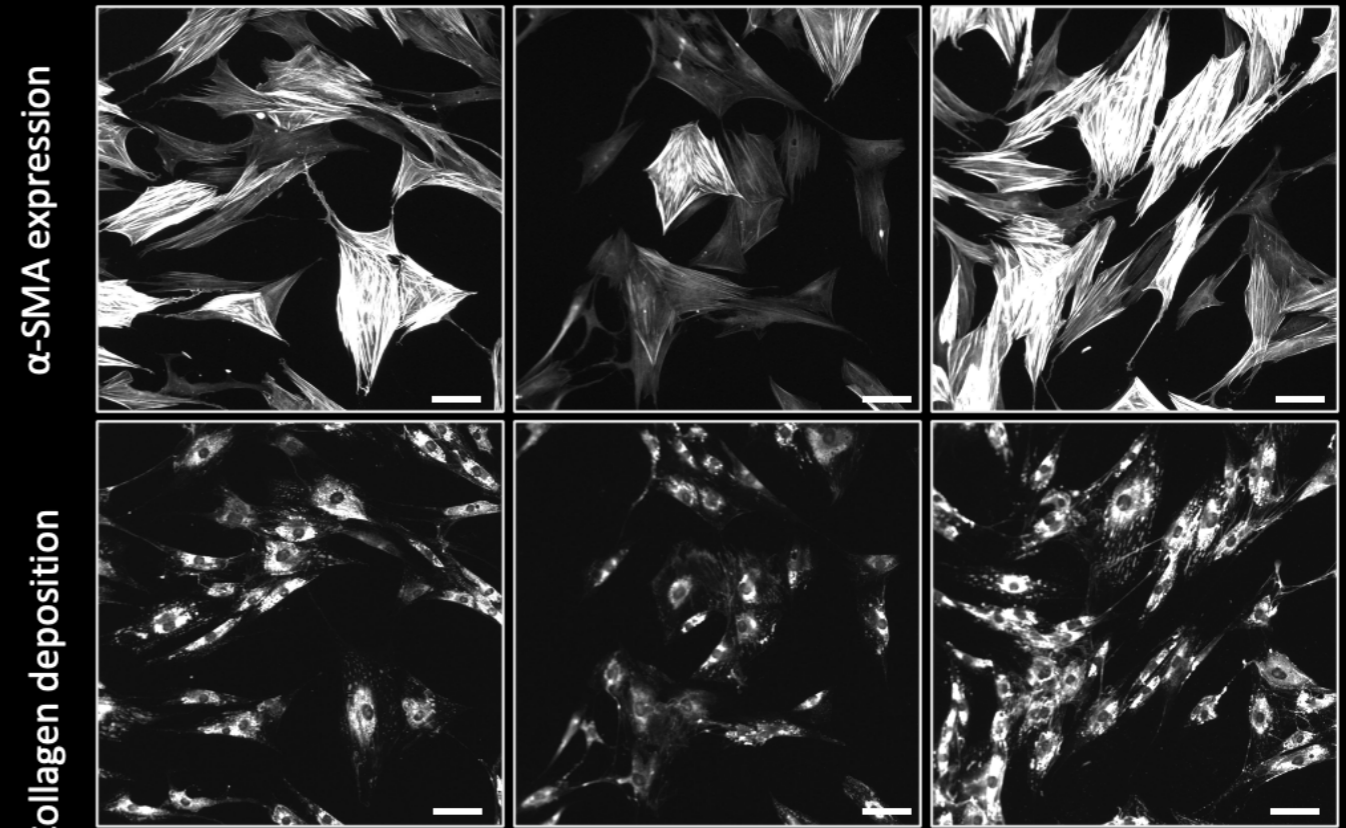


High Content Imaging of Collagen-I and α -SMA deposition in Fibroblasts shows anti-fibrotic activity

Media Control

Hit strain









Non hit strain



Images for α -SMA and for collagen were scaled identically; scale bar, 100 μ m



Upcoming Milestones for 2023

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

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