

10th Annual Microbiome USA **Movement Summit**

The Home of Accelerating Microbiome R&D

Showcasing the Latest Biological, Preclinical & Clinical Data to Supercharge R&D for GI, Oncology, Dermatology, CNS, Women's Health, & More

40+ World-Class Speakers, Including

Chief Scientific Officer

Corundum Systems

Biology





Ken Blount Chief Scientific Officer Rebiotix Inc., a Ferring Company



Hervé Affagard Co-Founder & Chief **Executive** Officer MaaT Pharma



Nikole Kimes Denise Kelly Founder & Chief Investment Advisor **Executive Officer Seventure Partners** Siolta Therapeutics

Travis Whitfill Chief Operating Officer



Paul Carlson Principal Investigator US Food & Drug



Vivek Lal Scientific Officer



June 23-25, 2025

Boston, MA

Todd Krueger President & Chief Executive Officer AOBioa

hansonwade





2025 Partners:





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Azitra







CONFIRMED 2025 **SPEAKERS**

JOIN 80+

MICROBIOME R&D REPRESENTATIVES

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PRE-**CONFERENCE DAY**

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Realizing the Potential of Microbiome R&D in New Indications

With **Seres Therapeutics**, **Ferring Pharmaceuticals**, and **MaaT Pharma** leading the advance of microbiome therapeutics with the first approvals and current late-stage clinical trial progress; and **Microviable Therapeutics**, **Freya Biosciences**, and **Concerto Biosciences** exploring exciting new indications beyond GI–such as oncology, dermatology, and women's health–the field is poised for major breakthroughs. However, challenges in clinical translation, regulatory guidelines, and funding highlight the need for industry-wide collaboration.

The 10th Annual Microbiome Movement Summit returns to Boston, June 23-25, 2025, bringing you:

- **40+ industry-leading speakers** from discovery, preclinical, translational, regulatory, and commercial sectors.
- **Cutting-edge content** on microbiome R&D, Al-driven innovation, clinical advancements, and commercial strategies.
- **Comprehensive sessions** on GI, oncology, CNS, dermatology, and women's health, expanding conversations towards new indications and innovative research in microbiome R&D
- **The returning start-up showcase** to highlight emerging companies and breakthrough technologies shaping the future of microbiome therapeutics.
- An innovation-fuelled awards ceremony to celebrate the 10th year of this event series, and to recognize the outstanding achievements in microbiome research, innovation, and therapeutic development.

Join the #1 microbiome industry summit to advance your research, expand your network, and accelerate the next wave of microbiome-based therapeutics.

What's New This Year?



Advancing Microbiome Therapeutics in Oncology: Uncover how companies like MaaT Pharma, Microviable Therapeutics, and Kanvas Bio are driving microbiomebased strategies to enable immunomodulation by optimizing the gut microbiota balance and enhance cancer immunotherapy.



Harnessing AI & Data Science for Microbiome Drug Discovery: Learn how Pharmabiome, Jona and MD Anderson Cancer Center are leveraging Al-driven analytics, metagenomics, and spatial transcriptomics to optimize patient selection, microbiome interventions, and precision therapeutics.



Emerging Innovations in Dermatology: Explore the latest breakthroughs from **Azitra**, **Concerto Biosciences**, and **AOBiome** in microbiome-based dermatological interventions to treat Netherton Syndrome and Atopic Dermatitis.



The Rise of Consumer Microbiome Products & Their Clinical Impact: Explore how direct-to-consumer microbiome innovations are influencing therapeutic breakthroughs. Hear from Unilever, Fitbiomics, Nestlé Health Science and Florey Biosciences on navigating the regulatory landscape, ensuring scientific credibility, and bridging the gap between consumer success and clinical validation.



Microbiome-Based Respiratory & Inhaled Therapies: Discover how Pulmobiotics and Alveolus Bio are pioneering inhaled microbiome treatments for respiratory diseases, offering new approaches to lung health.



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40+ Expert Speakers for 2025

June 23-25, 2025 | Boston, MA

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40+ Expert Speakers for 2025

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Agenda at a Glance

PRE-CONFERENCE WORKSHOP DAY MONDAY, JUNE 23

Deep-Dive Networking Workshops

Bidirectional data sharing and discussion-based workshops to bring you the most current microbiome ecosystem updates, paired with networking sessions to strengthen your connections with key opinion leaders and field experts.

Workshop A

From Samples to Standards -Strengthening Microbiome Data for Clinical and Commercial Success

Lunch & Networking

Workshop B Translating Microbiome Data into Actionable Biomarkers & Regulatory Approvals

End of Pre-Conference Day

6

CONFERENCE DAY ONE CONFERENCE DAY TWO TUESDAY, JUNE 24 WEDNESDAY. JUNE 25 CONTENTS Plenary Advancing Standards, Collaboration, & Innovation in Microbiome Research Plenary Securing Funding in 2025 & Mapping the Path to the Next LBP Approval Start-Up Showcase Morning Break Morning Break & Networking Track A Track A. CONFIRMED 2025 **GI & Infectious Diseases GI & Infectious Diseases** Indication Expansion Indication Expansion AGENDA AT A Breakthroughs in Probiotics GI Therapeutics Beyond C. C. Difficile & GI Disorders Cancer Therapies & Diagnostics & DTC for Microbiome **CONFERENCE DAY** Difficile Therapeutics CONFERENCE Lunch & Networking Lunch & Networking CONFERENCE Women's Health & CNS 2025 PARTNERS Manufacturing Consistency, Skin Microbiome R&D for Driving Innovation with Data Innovation with Gut-Brain Stability, & Scalability Dermatology Axis Modulation Afternoon Refreshments & Poster Networking Session Afternoon Refreshments & Networking Plenary Plenary Bridging the Gap: Clinical Innovations in Microbiome Therapeutics Harness the Potential of Inhaled Microbiome Therapies in & The Convergence of Consumer Health with Pharmaceuticals **Respiratory Disease Treatment** 10th Anniversary Awards **End of Conference Day One End of Conference Day Two**



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Microbiome

Movement Summit

June 23-25, 2025 | Boston, MA

Pre-Conference Workshop Day | Monday, June 23

Microbiome lovement Summit June 23-25. 2025 | Boston. MA

8.30

9.00

12.00

1.00

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Morning Check-In: served with coffee + light breakfast

Workshop A

From Samples to Standards – Strengthening Microbiome Data for Clinical and

Commercial Success

To drive microbiome-based therapeutics forward, we must address the critical gaps in data collection, statistical analysis, and validation. This workshop brings together key experts to discuss:

- Standardizing Sample Collection & Processing: Learn how improved chemistry and sequencing methods can enhance reproducibility, with insights from NIST and industry leaders
- The Impact of Biostatistics on Decision-Making: Understand how inadequate statistical analysis can mislead research and drug development, and explore biostatistical solutions tailored for microbiome studies
- Resolving Discrepancies in Bioinformatics Analyses: Examine case studies demonstrating how different computational methods yield varying conclusions from the same microbiome dataset
- Validating Microbiome-Based Biomarkers: Explore successful case studies where microbiome sequencing has been validated for diagnostic and therapeutic applications
- Engage in interactive discussions and gain practical strategies for improving microbiome data reliability, ensuring stronger translational success for therapeutics

Lunch & Networking

Workshop B

Translating Microbiome Data into Actionable Biomarkers & Regulatory Approvals

As microbiome-based therapeutics move closer to regulatory pathways, overcoming data variability and establishing robust biomarkers is essential. This workshop will explore:

- Defining and Validating Microbiome Biomarkers: Discover best practices for developing clinically meaningful biomarkers and linking them to regulatory endpoints
- Al and Big Data in Microbiome Research: Learn how Al-driven analytics and spatial biology are shaping the next generation of microbiome-based therapeutics
- Regulatory Considerations for Microbiome Drug Development:
- Navigate the evolving FDA landscape and understand what it will take to translate microbiome biomarkers into approvable clinical endpoints
- Investor and Industry Perspectives: Gain insights from investors and industry leaders on which microbiome innovations hold the greatest potential for commercialization

Join this deep dive into the intersection of microbiome data science, regulatory strategy, and commercialization to accelerate your therapeutic pipeline.

Close of Pre-Conference Workshop Day



4.00



NOW

Workshop Leaders



Ken Blount Chief Scientific Officer **Rebiotix Inc..** a Ferring

Company



Advisor

Workshop Leaders





Denise Kelly

Investment Seventure Partners

Jacob Nearing

Research Fellow,

Post Doctoral

Biostatistics

Harvard

University



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	7.00 Morning Check-In: served with coffee + light breakfast	
Daniel Couto Chief Operating Officer Vedanta Biosciences	8.05 Chair's Opening Remarks	CONTENTS
	Securing Funding in 2025 & Mapping the Path to the Next LBP Approval	WHY JOIN IN 2025
Ken Blount Chief Scientific Officer Rebiotix Inc., a Ferring Company	 8.10 Pioneering the Future of Microbiome Therapeutics: Assessing Clinical Progress & Outlining Market Opportunities Evaluating clinical progress by analysing existing approvals and late-stage clinical trial candidates Unlocking new market opportunities in oncology, women's health, and metabolic disorders while navigating pharma investment trends Assessing the current progress of incorporating advanced technologies like Al-driven microbiome analysis, synthetic biology, and scalable manufacturing to accelerate innovation 	JOIN THE MICROBIOME MOVEMENT CONFIRMED 2025 SPEAKERS
Richard Ellis Business Development Director Biose Industrie	8.30 Microbiome Products (LBP & NGP) Development & Manufacturing	AGENDA AT A GLANCE
	9.00 Microbiome Clinical Landscape Review	PRE- CONFERENCE DAY
Ada Lam Researcher Analyst Beacon Microbiome	 Explore the clinical landscapes of Microbiome drug development Reveal therapeutic modalities, therapy-specific properties, and disease indications gaining traction Give an analysis of the commercial landscape driving the clinical development of the space 	CONFERENCE DAY ONE
	9.30 MaaT013: The First Phase 3 Trial for Microbiome Therapy in Hemato-Oncology	CONFERENCE
Hervé Affagard Co-Founder & Chief Executive Officer	 Discussing the ongoing pivotal Phase 3 ARES trial for MaaT013 in patients with acute Graft-versus-Host Disease (GI-aGvHD) and its significance as the first global Phase 3 trial for a microbiome-based therapy in hemato-oncology Highlighting the Orphan Drug Designation from both the FDA and EMA, and the positive outcomes from the Data Safety Monitoring Board 	DAY TWO 2025 PARTNERS
MaaT Pharma	(DSMB) review. • Exploring the positive Phase 3 ARES results, evaluating MaaT013's unprecedented efficacy as a third-line treatment for GI-aGvHD	PARTNER
00 Fireside Chat: Unlocking	Pharma & Investor Buy-In	WITHUS
 Understanding the caution Analyzing recent strategies 	bus approach of large pharma towards microbiome investments and the factors shaping their decisions c partnerships and investment trends to uncover what drives value in microbiome-based innovations cions for forging successful partnerships with big pharma and aligning biotech strategies with industry needs to drive mutual growth	PRICING
Denise Kell Investment Seventure	Advisor 🛛 🚱 Venture Lead 🛛 🖉 Executive Global Group Medical Director 🖓 🚱 Chief Scientific Officer	
	10:30 Morning Break & Networking Make the most of this morning networking session to reconnect with your industry and meet fellow microbiome pioneers. Use this opportunity effectively to connect with cross-industry stakeholders and form important connections for expediting your platform development	\ominus
		REGISTER



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Advancing GI & Infectious Diseases Track	Expanding Pipelines with New Indications Track	
Revolutionize GI Therapeutics: Pioneering Late-stage Developments & Innovative Treatments for C. Difficile and GI Disorders	Microbiome's Role in Cancer Therapy: Unveiling the Gut Microbiome's Impact on Cancer Diagnostics & Treatment Efficacy	CONTENTS
 1:30 Clinical Update on C. diff Candidate RBX2660 Discussing the pivotal Phase 3 trial results of RBX2660, demonstrating its superior efficacy in reducing recurrence of Clostridioides Difficile Infection (CDI) Explore the significance of FDA approval and breakthrough therapy designation for RBX2660, and its impact on accelerating the development and availability of this microbiome-based therapeutic Future Directions and Applications: Examine the potential expansion of RBX2660's use in other high-risk patient populations and the ongoing efforts to address unmet medical needs in gastrointestinal health Ken Blount, Chief Scientific Officer, Rebiotix Inc., a Ferring Company 	 11:30 KAN-OOl, a Complex Consortium Live Biotherapeutic Product to Augment Cancer Therapy From FMTs to LBPs: A reverse translational approach to creating an optimized and sustainable therapy to augment patients' immune systems and response to cancer immune checkpoint therapy KAN-OOl optimization and preclinical testing KAN-OOl strains in patients: assessing existing KAN-OOl strain-level clinical engraftment data de-risks development Kyle Jacoby, Vice President, Clinical Research, Kanvas Bio 	WHY JOIN IN 2025 JOIN THE MICROBIOME MOVEMENT CONFIRMED 2025 SPEAKERS AGENDA AT A GLANCE PRE- CONFERENCE DAY CONFERENCE DAY ONE CONFERENCE DAY TWO
 2:00 Beyond Antibiotics: Developing the Potential of Microbiome-Based Treatments Presenting Phase 3 efficacy and safety data for MBK-01, a non-antibiotic therapy for Clostridioides difficile infection Exploring real-world evidence findings and insights from the compassionate use program Expanding clinical research efforts into new therapeutic areas for MBK-01 Patricia del Rio, Director of Business Development, Mikrobiomik 	 12:00 Roundtable Discussion: Charting the Future of Microbiome-Driven Cancer Therapy: Integration, Innovation & Translation Reflect on key learnings from MaaT013 and KAN-001 to evaluate what defines a clinically successful and scalable microbiome-based oncology therapy Discuss the current barriers to integrating microbiome interventions with standard-of-care cancer therapies, particularly in immune-oncology and Gl cancers Identify priority areas for biomarker development, patient stratification, and regulatory clarity to accelerate clinical translation Explore what's needed to move from trial success to routine clinical practice-considering manufacturing, commercialization, and payer engagement 	
12.30 Lunch	& Networking	2025 PARTNERS
Mapping Out the Microbiome & Strategies for Manufacturing Consistency, Stability & Scalability	The Skin Microbiome Revolution for Advanced Dermatological Treatments	PARTNER WITH US
 30 A Platform for Rationally Designing and Controlled Manufacturing of Complex Consortia Products that combine the Functional Diversity and Activity of Healthy Microbiomes with Scalable, Consistent and MoA-targeted Consortia Enabling precise identification and quantification of individual strains within complex consortia, allowing for potency assessment and process control in manufacturing Addressing co-culture challenges by stabilizing microbial communities through rational product design and advanced fermentation strategies Ensuring scalability, reproducibility, and quality control of high-diversity microbial therapeutics Strategically integrating strain-specific mechanisms with host-microbiome interactions Christopher Weidenmaier, Chief Scientific Officer, Mbiomics 	 1:30 Exploring ENS-OO2: A Microbiome-Based Therapy for Atopic Dermatitis Targeting Staphylococcus aureus by using a combination of three microbial strains to restore balance to the skin microbiome without immune suppression Evaluating ENS-OO2's safety and tolerability in Phase 1 clinical trials, with a focus on its impact on S. aureus abundance and atopic dermatitis symptoms Anticipating Phase 2 trial results, which will provide further insights into ENS-OO2's efficacy and its potential to become a transformative treatment for atopic dermatitis Bernardo Cervantes, Co-Founder & Chief Operating Officer, Concerto Biosciences 	PRICING



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 2:00 Advancing Assay Development for Multi-Strain Live Biotherapeutic Products The next generation of complex live biotherapeutic products demands advanced analytical approaches beyond sequencing to accurately assess potency, efficacy, and safety Kanvas has developed a spatial imaging platform that provides unprecedented resolution in evaluating microbial interactions and the host-microbe interface This technology enhances strain isolation, refines process development by characterizing strain-strain interactions, and enables more precise potency assays to meet evolving regulatory and clinical validation requirements Philip Burnham, Chief Scientific Officer, Kanvas Biosciences 	 2:00 Development of ATR-12, an Engineered Strain of S. Epidermidis, for Netherton Syndrome Netherton syndrome is a rare, severe skin disease caused by missing LEKTI protein ATR-12 is an engineered strain that delivers LEKTI to the skin to treat Netherton syndrome Initial safety results of an ongoing Phase 1 clinical study of ATR-12 in adult Netherton syndrome patients Travis Whitfill, Chief Operating Officer, Azitra 	CONTENTS WHY JOIN IN 2025 JOIN THE MICROBIOME MOVEMENT
 2:30 Advancing Assay Development for Multi-Strain Live Biotherapeutic Products Developing assays to evaluate the potency of multi-strain LBPs Key considerations for potency assay development and validation for late-stage clinical studies of LBPs Greg Medlock, Senior Director, R&D, Vedanta Biosciences 	 2:30 Advancing Topical Therapies & Harnessing Ammonia Oxidizing Bacteria for Skin Health Exploring the therapeutic mechanism of Ammonia Oxidizing Bacteria (AOB) in regulating inflammation and immunomodulatory activity on the skin Understanding how AOB treatment supports a balanced, anti- inflammatory environment and enhances skin health Phase 2 clinical results of B244, demonstrating significant reductions in pruritus, improvements in Atopic Dermatitis (AD), and strong durability of treatment effects in patients with mild-to-moderate AD and associated itch; Preparations for Phase 3 Todd Krueger, President & Chief Executive Officer, AOBiome 	CONFIRMED 2025 SPEAKERS AGENDA AT A GLANCE PRE- CONFERENCE DAY CONFERENCE DAY ONE

Attending the Microbiome Movement meeting offers significant value by providing opportunities to learn about host-microbiome interactions and new technologies, discover and develop LBPs, form partnerships, and gain competitive insights. The conference also enables attendees to explore opportunities in various markets, such as LBP manufacturing, spatial biology, cancer immunotherapy, and inflammatory bowel disease, fostering innovation and growth in the emerging microbiome field.

Kyle Jacoby, Vice President, Clinical Research, Kanvas Biosciences



CONFERENCE DAY TWO

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3.00 Afternoon Break & Scientific Poster Session

This is an informal session to help you connect with your peers in a relaxed atmosphere to continue forging new and beneficial relationships. With an audience of preclinical, translational, and clinical scientists eager to hear the latest advancements in Microbiome therapeutic development, you will have the opportunity to display a poster presenting your own work and innovations. Get in touch to apply: info@hansonwade.com

Bridging the Gap: Clinical Innovations in Microbiome Therapeutics & The Convergence of Consumer Health with Pharmaceuticals

Panel Discussion: Scaling Up Manufacturing for Clinical Trials of LBPs 3:30

- Scaling up LBP production from preclinical to late-stage clinical trial quantities by maintaining microbial consistency, stability, and product quality at larger scales
- Managing the supply chain and logistics for late-stage trials by ensuring reliable and timelydelivery of LBPs, including temperature-sensitive storage, transportation, and distribution to multiple clinical sites
- Navigating regulatory requirements during late-stage trials by balancing manufacturing compliance with the strict demands for clinical-grade products and preparing for commercialization



Chris McChalicher

Seres Therapeutics

4:00

Senior Vice President, Head of CMC & Quality



Development of Microbiological Examination Methods for Live Biotherapeutic Products



Sarah Henning Quality Control Manager _ist Labs

Daniel Couto

Chief Operating Officer

/edanta Biosciences

- Complications with traditional methods
- Existing guidance for objectionable organism testing in LBPs
- Alternative methods for detecting and identifying objectionable organisms

4:30 Panel Discussion: From Consumer Success to Clinical Impact: How Direct-to-Consumer Microbiome Products Are Shaping Therapeutic Breakthroughs

- Evaluating clinical trial strategies for direct-to-consumer microbiome products: costs, regulatory pathways, and scientific credibility
- · Analyzing the economic viability of trial-based models in the DTC space: profitability, investor interest, and commercialization speed
- Navigating marketing and regulatory constraints for microbiome therapeutics in a consumer-driven landscape

Chair's Closing Remarks & End of Day 1

and leadership within the microbiome ecosystem.

10th Annual Microbiome Movement Awards



5:00

5:05

6:05





The 10th Annual Microbiome Movement Awards will celebrate groundbreaking achievements and exceptional contributions in microbiome research and

therapeutics. This prestigious event highlights the innovative companies, researchers, and thought leaders driving the microbiome field forward. Through a series of award categories, the ceremony will recognize advancements in microbiome-based drug discovery, novel therapeutic applications, pioneering technologies,









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End of Day 1





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7.00 **Morning Check-In**

Served with coffee and a light breakfast

Daniel Couto Chief Operating Officer Vedanta Biosciences

Chair's Opening Remarks 7.55

Advancing Standards, Collaboration & Innovation in Microbiome Research

8.00 Roundtable: Advancing Microbiome Therapeutics: Insights from the MTIG and EMIH Collaboration

- How can harmonized regulatory frameworks benefit microbiome therapeutics across different regions, and what specific steps can be taken to achieve this harmonization?
- What innovative strategies can be employed to accelerate the development of microbiome-based therapies through international collaboration, and how can these strategies be effectively implemented?
- How can expanding access to microbiome therapies benefit the economy and healthcare systems, and what measures are necessary to ensure equitable access to these innovative treatments?

Johan van Hylckama Vlieg Chief Scientific Officer & Co-Founder **Freya Biosciences**



Hervé Affagard Co-Founder & Chief Executive Officer MaaT Pharma



Nikole Kimes Founder & Chief Executive Officer Siolta Therapeutics



Regulatory Considerations for Microbiome-Based Therapeutics 8:30

- Interpreting the latest FDA guidance on LBPs, FMT-based therapies, and the shifting regulatory framework for microbiome drugs
- Addressing key hurdles in clinical trial design, potency validation, and manufacturing standards to meet FDA expectations
- Preparing for future regulatory trends with insights on accelerated approval pathways, real-world data integration, and evolving safety requirements



The Microbiome's Role in Gastrointestinal Cancers 9:00

- Exploring the Microbiome & Colorectal Cancer: How gut microbiota modulate colorectal cancer risk and progression, evaluating the influence of microbial metabolites (e.g., butyrate) on tumor microenvironment and elucidating microbiome interactions with immunotherapy and chemotherapy response
- Other GI Cancers (Pancreatic, Gastric & Esophageal): exploring key microbiome-driven mechanisms in upper GI cancers, the role of bacterial dysbiosis in inflammation and tumorigenesis, and exploring current and emerging microbiome-targeted therapeutic strategies
- Translating Microbiome Research into Oncology Practice: including strategies for microbiome modulation, the potential for microbiome-based biomarkers in GI cancer detection and challenges and future directions in integrating microbiome science into cancer care
- Matthew Henn Executive Vice President &

Chief Scientific Officer

Seres Therapeutics

- 9:30 Breakthrough in GI-Derived Bloodstream Infection Reduction: SER-155's FDA Designation
 - Highlighting the significant reduction in bacterial bloodstream infections demonstrated in Phase 1b trials of SER-155 and its impact on patient outcomes
 - Discussing the significance of FDA breakthrough therapy designation and fast track status for expedited development and regulatory collaboration
 - Exploring the future development plans for SER-155, including its potential applications in various high-risk patient populations





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10.00 Start-Up Showcase

Immerse yourself in a showcase of cutting-edge research and technologies as short-listed microbiome start-ups unveil their unique approaches to drug development. You, and a judging panel of experts, will meet the brilliant minds behind microbiome start-ups, understanding their expertise, commercial strategies for success and passion that drives their mission to revolutionize today's drug development landscape.

With prizes at stake, join us for a dynamic session where microbiome start-ups take center stage and a panel of VC's and investors decide who to award as the winner of the **Microbiome Movement Start-Up Showcase 2025!**

Expert Investment Panel Includes



Denise Kelly Investment Advisor Seventure Partners



Jessica Schneider Chief Scientific Officer Corundum Systems Biology

Start-up Showcase Finalists Announced!



Kevin Horgan Head of Research & Development Melius MicroBiomics



Zoe Watson Co-Founder & Chief Executive Officer Microvitality



Rafik Fellague-Chebra Executive Global Group Medical Director Novartis Oncology



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An opportunity to network, discuss and collaborate with like-minded leaders







Advancing GI & Infectious Diseases Track	Expanding Pipelines with New Indications Track		
Progressing Microbiome Therapeutics for GI & Infectious Diseases Beyond C.Difficile	Harnessing Probiotics to Modulate the Microbiome: Next-Gen Innovations & Engineered Solutions for Microbiome Resilience	CONTE	
1:00 KeepBio: A Microbiome-Targeted Therapy to Reduce Healthcare-Associated Infections Synbiotic approaches lead to reproducible changes in patient microbiomes	 11:00 Advancing Next-Generation Probiotics: Translating FitBiomics' Clinical & Preclinical Data into Performance and Health Innovations Harnessing the Gut Microbiome for Human Performance – Exploring FitBiomics' latest 	WHY JOI 2025	
Working to leverage glycan-microbe specificity drives decolonization in pathogendominated patients Commercializing rapidly and bringing innovation to bedsides safely Gregory McKenzie , Chief Executive Officer, KeepBio	 clinical and preclinical data on next-generation probiotics derived from elite athletes and their potential to enhance metabolism, endurance, and recovery Bridging the Gap Between Preclinical Insights and Clinical Validation – Lessons learned from translating microbiome-based discoveries into human trials, including biomarker- 	JOIN TI MICROBIO MOVEMI	
	 driven approaches to assess efficacy Mechanisms of Action: Understanding How Novel Probiotics Drive Health Benefits – Unpacking the functional impact of specific microbial strains on gut health, immune modulation, and systemic health improvements 	CONFIRME SPEAKE	
	 Regulatory & Commercialization Strategies for Microbiome-Based Interventions – Addressing the path from research to real-world applications, including regulatory considerations, consumer adoption, and future innovation in the probiotics space 	AGENDA GLANC	
	Jonathan Scheiman, Co-Founder & Chief Executive Officer, Fitbiomics	PRE- CONFEREN	
1:30 Advancing Microbiome Therapeutics: The Role of Co-cultured Therapies in Ulcerative Colitis & Beyond	 11:30 Diet & Lifestyle Factors that Influence Spore Levels & Stability Over Time Environmental factors such as diet and lifestyle influence the donor microbiota 	CONFERE	
Evaluating the promise of co-cultured microbiome therapies. Emergent function of diverse consortia	 Exploring how these factors associate with spore levels across individuals Evaluating factors that influence stability of spore levels over time within donors 	DAYO	
Exploring a case study of the development of a co-cultured therapy for ulcerative colitis Highlighting regulatory and manufacturing challenges and solutions	Sarah Tomkovich, Senior Scientist, Nestlé Health Science	CONFERI DAY TV	
Sam Costello, Chief Executive Officer & Managing Director, BiomeBank		2025 PAR	
2:00 Roundtable Session: Mission Microbiome: Designing the Next Breakthrough	12:00 Engineering Probiotics to Safeguard the Gut Microbiome During Antibiotic Therapy	PARTN	
'herapeutic for GI & Infectious Disease Participants will form small "biotech taskforce" teams. Each team's mission is to design and	 Impact of Antibiotics on the Gut Microbiome: Exploring how common antibiotic treatments can disrupt beneficial gut bacteria, leading to potential health issues 	WITH	
bitch a future-forward microbiome therapeutic concept addressing a high priority unmet need in GI or infectious diseases	 Introduction to FLR-101: Presenting FLR-101, an engineered yeast strain designed to produce enzymes that degrade specific antibiotics in the gut, thereby protecting the microbiome without compromising the systemic efficacy of the treatment 	PRICIN	
Target Prioritization: What indication or patient population should be the next focus for microbiome therapeutics, and why?	 Regulatory Strategy and Medical Food Classification: Discussing Florey's unique approach to navigating regulatory pathways by developing FLR-101 as a medical food, aiming for 		
Modality & Mechanism: Should your therapy use co-cultured consortia, synbiotics, engineered strains, or another platform? What's the core mechanism of action?	efficient market entry and broad accessibility Future Directions in Engineered Probiotics: Outlining plans for expanding the application of 		
Regulatory & Clinical Strategy: What endpoints and biomarkers will be key to regulatory success, and how do you de-risk development early on?	Florey's synthetic biology platform to develop additional probiotics targeting various health conditions influenced by the gut microbiome		
Commercial Viability: What's your plan for manufacturing, delivery (oral, capsule, etc.), and payer buy-in to make this therapy viable in real-world healthcare systems?	Andres Cubillos-Ruiz, Co-Founder & Chief Executive Officer, Florey Biosciences	(→	



12.30 Networking Lunch



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13:25 Announcing the Winner of the Start-Up Showcase!			
Using Data to Drive Innovation & Modulating Gut-Brain Axis for CNS Indications	Translating Microbiome Learnings to Women's Health & Gut-Brain Axis for CNS Indications		
 1:30 Learnings from Clinical Development with MH002 in IBD and Translation to LBP Development for Parkinson's Disease Reviewing Phase 2 clinical data of MH002, a next-generation microbiome therapy utilizing MRM Health's CORAL® Technology, combining six commensal strains for targeted action in Ulcerative Colitis (UC) and Pouchitis Lessons learned and highlights on its ability to restore gut microbiome balance and improve clinical outcomes Translation of knowhow from clinical program to develop LBPs for Parkinson's Disease; update on preclinical data Sam Possemiers, Chief Executive Officer, MRM Health 	 1:30 Impact of Vaginal Products on the Vaginal Microbiome Regulatory insights into clinical assessments during clinical trials Clinical trial data showcasing contraceptive studies and impact on the microbiome New approaches to Improving vaginal health David Friend, Chief Scientific Officer, Daré Bioscience 		
 2:00 Leveraging AI & Big Data in Microbiome Drug Discovery Analyzing gut microbiome data is incredibly challenging due to the wide variation in microbial ecosystems found in the gut and due to the incredible explosion of scientific papers linking the gut microbiome to various diseases and health conditions (now more than two thousand peer-reviewed studies per month in PubMed). For the first time, large language models (a form of AI) offer us the ability to synthesize all of the world's scientific knowledge to fully analyze gut microbiome data for an individual. The extraction of the complete published scientific knowledge of the microbiome makes it practice to device an extraction of the complete published scientific knowledge of the microbiome makes it practice to device an extraction of the complete published scientific knowledge of the microbiome makes it practice to device an extraction of the complete published scientific knowledge of the microbiome makes it practice to device and the microbiome makes it practice. 	 2:00 Leveraging Microbial Immunotherapies for Bacterial Vaginosis: Innovations with DYSCOVER Platform Developing microbial immunotherapies for Bacterial Vaginosis (BV) using the DYSCO platform to address the imbalance in the vaginal microbiome and reduce inflammat Leveraging proof-of-concept studies (DYSCOVER-1 and Dyscover II) to demonstrate efficacy of Lactobacillus strains in engrafting the vaginal tract and displacing dysbiot microbiomes Mitigating serious consequences in pregnant women by reducing the recurrence of Bacterial vagination and the present tract and the present platform of the present of the		

- than t langua knowle
- The ex it possible to develop a microbiome digital twin that can be used to digitally simulate the effects of different interventions on a trial subject with a known microbiome and predict drug therapeutic efficacy prior to treatment in the trial
- This AI technology for both analysis and digital twinning unlocks new opportunities and avenues for drug targets, therapeutic development, clinical trial design, patient recruitment and biomarker development
- Leo Grady, Founder & Chief Executive Officer, Jona

s: Innovations with the

- V) using the DYSCOVER d reduce inflammation
- er II) to demonstrate the d displacing dysbiotic
- the recurrence of BV and associated risks such as premature rupture of membranes, preterm birth, intra-amniotic infection, low birth weight, and miscarriage

Johan van Hylckama Vlieg, Chief Scientific Officer & Co-Founder, Freya Biosciences

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2:30

3:00



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P	Maria Lluch Senar Co-Founder & Chief Scientific Officer
	Pulmobiotics

Afternoon Netwokring Break

Harnessing the Potential of Inhaled Microbiome Therapies in Respiratory Disease Treatment

Engineering Microbiome-Based Inhaled Therapies for Respiratory Diseases



Vivek Lal

Alveolus Bio

Officer

- Addressing the complexities of selecting the right bacterial chassis for inhaled microbiome-based therapies to prevent rapid clearance by the immune system and respiratory physiology
- Exploring Pulmobiotics' approach to engineering bacteria to produce human proteins like cytokines and interleukins to stimulate targeted immune responses in conditions like lung cancer
- Highlighting Pulmobiotics' innovative use of microbiome-derived bacteria, such as their Mycoplasma pneumoniae-based candidate, to treat infectious diseases and disrupt biofilms in combination with standard antibiotics

Inhalation of Lactobacilli for COPD & BPD Treatment 3:30

- Targeting lung inflammation by using a Lactobacilli blend to modulate inflammatory markers and restore lung function
- Investigating preclinical results by demonstrating improvements in lung structure and function in both BPD and COPD mouse models
- Anticipating clinical trials by preparing for human safety testing and further evaluation of the therapeutic potential of this live biotherapeutic

Daniel Couto Chief Operating Officer edanta Biosciences

Founder, Executive

Chairman & Chief Scientific

Chair's Closing Remarks & End of Conference 4:00

High quality presentations, well attended by representatives of all stages of development, many opportunities for interaction **PP**

Senior Director, R&D Strategic Lead, Gastrointestinal & Microbiome, Ferring Pharmaceuticals

Take the Spotlight: Partner with Us

Maximize Opportunities in the Advancing Field of Microbiome Therapeutics

As the microbiome's role in human health continues to emerge as one of the most exciting frontiers in science, the discovery, development and commercialization of microbiome-based therapeutics must progress at an accelerated pace. With advancements spanning from discovery to clinical applications, the need for collaboration across the microbiome ecosystem is more critical than ever. This is where your expertise comes in.

The 10th Microbiome Movement USA Summit presents a unique opportunity for service providers to partner with innovators driving the future of microbiome therapeutics. By showcasing your expertise, you can help advance the field, from sequencing and bioinformatics to clinical research and manufacturing.

Key areas where you can make an impact:

Advance Microbiome Sequencing and **Bioinformatics:**

Provide innovative technologies and bioinformatics tools that enable comprehensive sequencing and data analysis of microbiome profiles, supporting the identification of novel therapeutic targets and predictive biomarkers for microbiome-related diseases

End-to-End Manufacturing Solutions for **Microbiome Therapeutics:**

Offer specialized contract 660 manufacturing and development services to scale microbiomebased drug products, ensuring the consistency, quality, and regulatory compliance needed to move therapies from bench to market

Preclinical Research Models for Microbiome Drug Discovery:

Deliver in vivo and in vitro preclinical research services, including specialized microbiome models, that enable drug developers to evaluate the therapeutic potential and safety of microbiome-based interventions prior to clinical trials

Optimize Clinical Trials for Microbiome-Based Therapies:

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Provide comprehensive clinical trial management services, including patient stratification, trial design, and data analysis, tailored to the unique challenges of microbiome drug development to ensure robust clinical evidence for therapeutic efficacy

Support Microbiome Research with High-Quality Reagents and Biobanks:

Supply essential reagents, culture systems, and $\left(- \overline{\bigcirc} \right)$ biobank services to support microbiome research, facilitating the collection, preservation, and analysis of microbiome samples for use in drug development and clinical studies

Leverage this opportunity to position your company as a leader in the microbiome space. Place your brand at the forefront of microbiome research and connect with senior-level decision-makers from across the industry. Your organization can play a pivotal role to bring innovative microbiome therapeutics to market, improve patient outcomes, and shape the future of medicine.

d The sponsor-vendor ratio was favorable and made it easy for us to have conversations with potential customers. The on-site staff were helpful in making sure we were meeting with everyone we wanted to PP

Kyle Arenofsky, Associate Director, Business Development, Catawba Research





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- BUILD a deeper understanding of the challenges and opportunities in microbiome drug discovery, from biomarker identification to clinical application with Ferring Pharmaceuticals, MaaT Pharma, and Siolta Therapeutics.
- **3 ENGAGE** with top-tier professionals from pharma, biotech, and research organizations to foster collaborations, share knowledge, and drive innovation in microbiome therapeutics

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