

ANGLO  
NORDIC

2004 - 2024



# Mikrobiomik


rethinking microbiome

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18<sup>th</sup> April 2024





**Thousands** of people around the world suffer from many **life-threatening diseases** for which there is unmet medical needs.

Developing the therapeutic potential of the **microbiota** in the tangible form of a new biological medicine seems to be **the key.**

# We are leading the path in Europe

Founded in 2018 and headquartered in Derio (Bizkaia), a bio-pharmaceutical company born to conduct research, develop, and manufacture medicines based on the human microbiome.

- The company's aim is to market in 2025 the first biological medicine based on intestinal microbiota in Europe.
- MBK-01 is a biological medicine based on intestinal microbiota with FSPIM® technology. It consists on 4 lyophilized oral capsules and is intended for various indications.
- Production will be carried out by internal sourcing and commercialization will be managed by license agreements (currently in ongoing discussions with several pharmaceutical companies).
- A multidisciplinary team of 19 professionals to cover comprehensively all aspects of the production chain.
- Shareholding structure: 5 family offices (51%), 3 individual investors (14%), and 2 public institutions (36%). The main shareholder holds a 33% of the capital.

# Intellectual property

**Data exclusivity for 8 years and market exclusivity for 10 years <sup>(1)</sup>**

Once certified non-infringement, formulation and manufacturing/quality procedures are **protected under trade secret with block chain technology.**

We are currently **working on a patent** application for MBK-01 (confidential).

(1) Conditions if we are the first to market. +1 year of exclusivity in case of demonstrating the efficacy of the product for a new indication of significant therapeutic benefit. Intestinal microbiota is not patentable.

# One product, multiple indications

Product	Indication	Competitors	Competitive advantage	Status
<b>MBK-01</b> Oral capsules	<i>Clostridioides difficile</i>	Fidaxomicin	Non antibiotic, it is a biological therapy	Ph III completed
	Nonalcoholic Steatohepatitis (NASH)	None	First in class	Ph II ongoing (approved)
	Decompensated cirrhosis (LIVERGUT)	None	First in class	Ph III submission
	Metastatic colon cancer	Coadjuvant	Coadjuvant to other therapies in the immune response (slowing the progression)	Submission
	Recurrent diverticulitis	Rifaximin	Non antibiotic, it is a biological therapy	Submission

# Partnership

- ✓ The Company is collaborating (or has collaborated) with:
  - **Hospitals:** more than 21 national hospitals participated on the clinical trials, some of them are: University Hospital Gregorio Marañón, University Hospital Ramón y Cajal (Madrid), Clínic Barcelona, Hospital Valcecillas, Quiron Hospital, between others.
  - **Consulting firms**, to better understand aspects such as market, quality, regulatory, production scale-up and intellectual property protection;
  - **CROs** (Contract Research Organizations), such as Sermes, which monitor their different clinical trials.
  - **Public entities**, as the Basque Government, who had financed some clinical trials.
  - **Educational cooperation agreement** with the “Alfonso X el Sabio University” and the “University of Navarra”, through which students of different degrees related to biotechnology can carry out their internships at Mikrobiomik.
  - **Collaboration framework agreement with IRYCIS** (Ramón y Cajal Institute of Health Research), by which the Company will have a first option of refusal, for any research project on microbiota applied to the clinic.
  - **Members:** We are partner of the Basque Health Cluster and Asebio (Spanish association of bio companies)

Scientists and technologists from these institutions complement the knowledge and experience of Mikrobiomik in the clinical development of MBK-01.

## Hospitals



## Advisory/Collaborator companies



## Public entities/Universities



# Competitive landscape




**SERES**  
THERAPEUTICS

**VOWST**

4 capsules x 3 days  
rCDI

Antibiotic pre-treatment

**25%**  
of the  
market



**Mikrobiomik**  
*rethinking microbiome*

**MBK-01**

4 capsules x 1 day  
Primary & rCDI

**No antibiotic pre-treatment**

**100%**  
of the market



**Rebiotix**<sup>®</sup>  
Microbiota Restoration Therapy  
A FERRING COMPANY

**REBYOTA**

Enema  
rCDI

Antibiotic pre-treatment

**25%**  
of the  
market



# Scenario: Paradigm Change (First Line Treatment Positioning)

**Positioning MBK-001 as a first-line therapy could address a large population.**

## Recurrence positioning


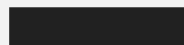





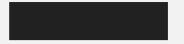

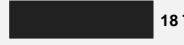
-  **First Episode CDI** MBK-001
-  **1st recurrence CDI**
-  **Multiple recurrence CDI**

## Treatment line positioning

- 1 **First line** MBK-001
- 2 **Further line**

## Severities included

-   
Mild CDI
-   
Severe CDI
-   
Fulminant CDI

	Population	Intervention	Comparator	Outcome
	 65.837	Severity patient segmentation is also considered for treatment selection	Metronidazole or Vancomycin	Clinical added benefit in comparison to Metronidazole and Vancomycin
	 22 782	First line treatment for all patients regardless of their severity	Vancomycin	Clinical added benefit in comparison to Vancomycin
	 17 897	First line treatment for all patients regardless of their severity	Vancomycin	Clinical added benefit and budget impact in comparison to Vancomycin
	 20 672	First line treatment for all patients regardless of their severity	Vancomycin	Clinical added benefit and budget impact in comparison to Vancomycin
	 18 789	First line treatment for all patients regardless of their severity	Vancomycin	Cost-effectiveness of MBK intervention in comparison to Vancomycin

## Opportunities

- ✓ First line positioning with a large addressable population.
- ✓ Vancomycin is one of the risk factors for the onset of CDI infection, a paradigm change could be applied if payers consider the value of MBK-001.

# Mikrobiomik's Competitive Advantages From Competence



## More Accurate

ICD-01 is a non-antibiotic pretreatment based on biological therapy vs. its competitors that are antibiotic pretreatments.



## First in Class

First in Class products in 2 of its 5 actual projects. It also has the first biological medicine based on intestinal microbiota to treat primary and rCDI (recurrent Clostridioides Difficile).



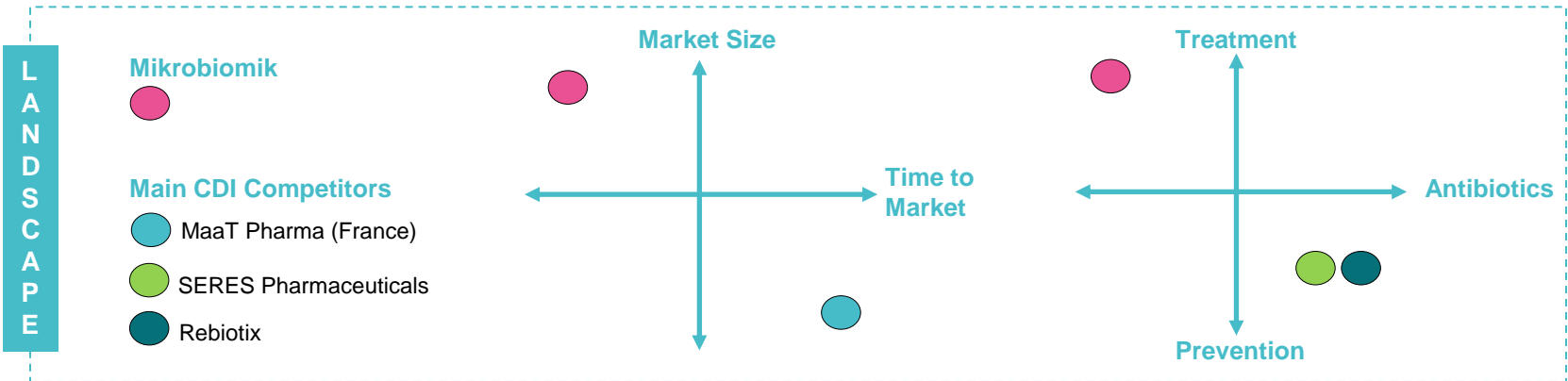
## More Affordable

Efficiency equal to or better than the competition at a much lower price for the drug against rCDI (recurrent Clostridioides Difficile).



## Efficiency

90% efficacy in the treatment of Clostridioides Difficile infection, in the absence of significant adverse effects



# INTERNATIONAL STRATEGY

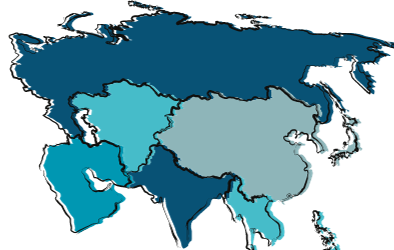
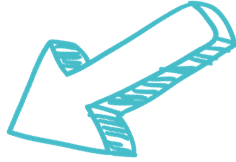
## Mikrobiomik

rethinking microbiome



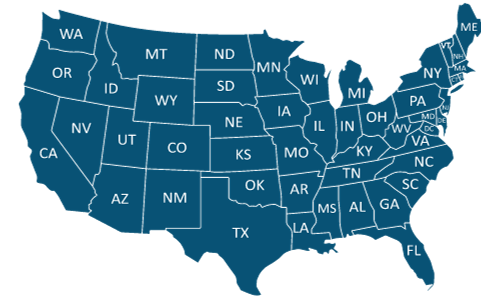
### New active substance

Centralised procedure  
CP



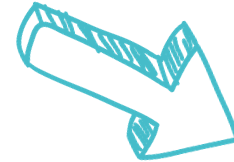
### Market opportunity

No microbiota based companies



### Investigational new drug application (IND)

Fast track  
Breakthrough therapy



# Management & Executive team



Juan Basterra  
CEO



+ 25 years of experience in the Pharmaceutical Industry



Celia Morales  
Technical Director



Experience as Head of Quality and as Researcher at Praxis Pharmaceuticals



Patricia del Río  
BD&Innovation Director



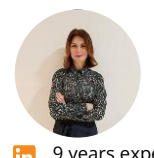
+ 10 years of experience as Researcher and Project Manager, leading the EBX R&D dept.



Leire Miñón  
CFO



+ 11 years of experience as Auditor in KPMG and PKF Attest.



Olga Shapoval  
Medical Director



9 years experience in clinical Research, experience as a medical representative in different pharmaceutical companies.



Antonio Martínez  
Board of Directors

More than 25 years in the Biotechnological industry  
CEO of Progenika (customized medicine company founded in 2000) and acquired by Grifols in 2013 (€65M).



Guillermo Marco-Gardoqui  
Board of Directors

+ 10 years as Strategic Consultant  
Vice President of Operations at Grifols Diagnostics  
Founder/Business Angel/Advisor in 3 medium-sized companies in the Health sector



Juan Pedro López Araguas  
Board of Directors

28 years at Iberdrola as Head of New Technologies  
+ 10 years in the Biotechnological Industry,  
Senior Advisor in Energy and Risk Management Sector.




# Scientific Advisory Board




Rosa del Campo   
Microbiology expert at the Ramón y Cajal Hospital.




Jesús García-Foncillas   
Head of the Oncology Department of the Jiménez Díaz Foundation.  
Director of the OncoHealth Institute.



Javier Crespo   
Chief of the Digestive and Hepatology Department at the Marqués de  
Valdecilla Hospital.  
Outgoing President of the SEPD (Spanish Society of Digestive Pathology).



Sergio Serrano   
Specialist in Internal Medicine at Ramon y Cajal Hospital (Madrid).  
Specialist in infectious diseases and interest in research and teaching.

# MAA ONE STEP FURTHER

**2023  
1Q**

Presentation  
of ICD-01  
clinical trial  
interim results

**2024  
1Q**

Final results of the  
ICD-01 clinical trial

**2024  
3/4Q**

Finalization of the  
regulatory dossier  
and MA (Marketing  
Authorization).



**Launch MBK-01  
1st semester  
2025**



**3Q 2023**  
**MBK-01: granted as new active  
sustance through centralized  
prodecure by the EMA**



# Future steps

- ▲ Ongoing new financial round (Series A).
- ▲ Find potential new partnerships to increase the supply of raw material, related with the donor phase.
- ▲ We identified a new location to expand our production space, to reach the market in 2025.
- ▲ Increase Mikrobiomik 's team from 19 to 50 professionals in the next 3 years.
- ▲ Close an upfront payment with a pharmaceutical company with the aim of licensing MBK 01 for commercialization, for CDI

The EMA has granted Mikrobiomik with the option to go through a centralized procedure considering MBK-01 as a new active substance.

**2024 1Q:** Final results of clinical trial ICD-01 are available

**2024 3Q/4Q:** We are going to completed the regulatory dossier and Marketing Authorization application

Series A  
round  
of investment  
8-10 M€

# Why Mikrobiomik?

Why invest/Partnering  
with us?

An Investor or partner will

- △ Have the potential upside of positive Phase III data without the funding burden of the trials
- △ Benefit from multiple Clinical programs (infectious diseases, antibiotic resistances, liver diseases, oncology) all at different Clinical stages
- △ Benefit from a team in-place with a stellar track record of execution- Be first in class and market MBK-01 in EU in 18 months







Let's keep saving lives  
with the microbiota!

Carlota Dopico  
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