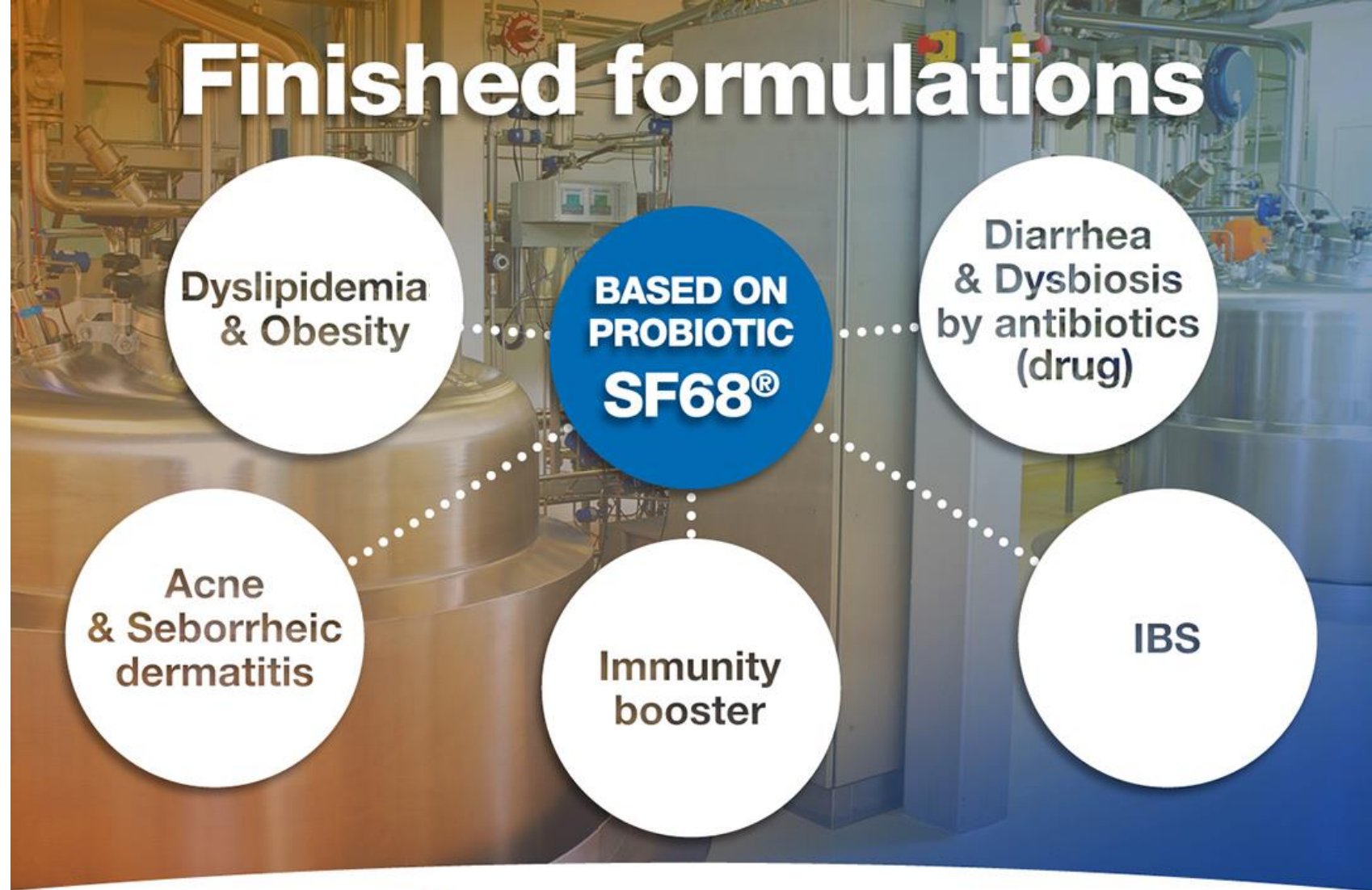




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# Who we are

With over 40 years in the pharmaceutical industry, Cerbios is a privately held company with headquarters in Lugano, Switzerland, specializing in the development and manufacture of both chemical and biological APIs for its partners worldwide.

## \$ Self financed

- Dun and Bradstreet top rated: «risk indicator factor 1» since over 10 years in a row.
- Long term investment plans for Innovation and business expansion: Capex average at 15 % of sales.

## 45+ years

of experience in development and manufacturing of APIs:

- Small molecules, including HPAPIs
- Large molecules
- Biologicals & Probiotics



## 2 manufacturing sites

- Lugano (TI) – Switzerland  
(Cerbios-Pharma SA)
- Couvet (NE) – Switzerland  
(GMT Fine Chemicals SA)



## APIs, CDMO & FP



## R&D center

At Lugano plant



## 60+ countries

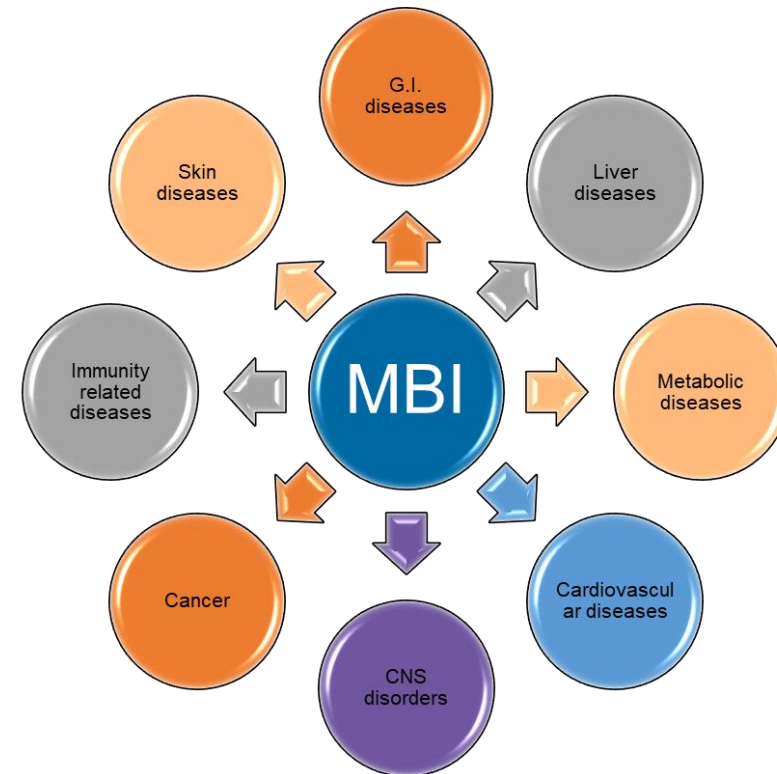
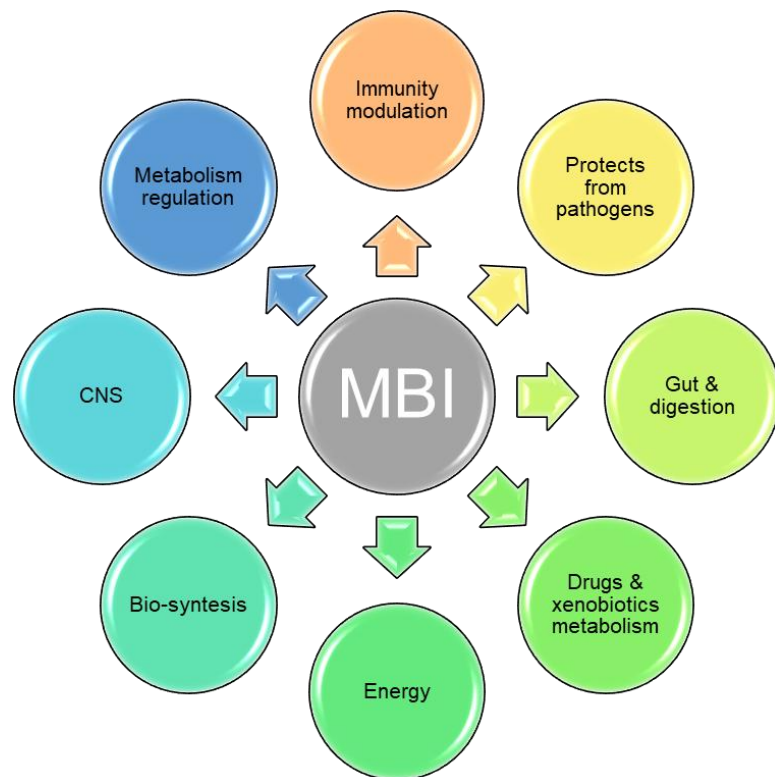
Presence in more than 60 countries.

**A sustainable strategy, intended as a balanced approach to long-term financial, social and environmental value creation, is fundamental to us and is deeply integrated into the company business model.**

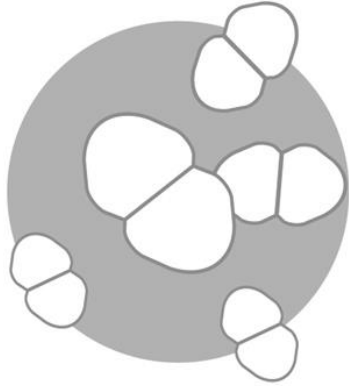


# Microbiota and its role over the gut

- Do you know that microbiota (intestinal flora, MBI) has a role over the classical gut *district*?
- Do you know that an altered microbiota (dysbiosis) is strictly linked to some pathologies?
- Do you know that some probiotics can be then functional on the management of these pathologies, with an innovative and unconventional approach?
- Cerbios is focused on R&D of new probiotic based formulations; clinically proven.



# 1 Probiotic Drug product



## SF68<sup>®</sup> CAPS

Cerbios is owner of the probiotic active ingredient ***E. lactis* SF68<sup>®</sup>** (formerly *E. faecium* (strain deposit NCIMB 10415), which is manufactured under pharmaceutical GMP's

Its formulation is registered as drug product in Switzerland, Austria, Italy, Korea, Singapore and Pakistan for treatment of acute diarrhea (adult and children), prevention of traveler's diarrhea and diarrhea by antibiotics (dysbiosis).

CTD and CPP from Switzerland available.

Cerbios is continuously searching for commercial Partners interested to distribute **SF68<sup>®</sup>** in their Country.

## Research

Cerbios supported an extensive clinical and pre-clinical research on SF68<sup>®</sup>: outcomes are the discovery of unique characteristics of this specific strain, confirmed by a significant number of publications.

Its efficacy and safety profile is confirmed more than 20 clinical trials and also by a recent review issued in 2018.

## +100 million

More than 100 million of patients treated.

## +40 years

40 years of successful commercialization.

## 2 Finished Products list (probiotic based)

Cerbios is on the market for over 40 years with its proprietary probiotic strain *Enterococcus lactis* SF68<sup>®</sup>, (formerly *E.faecium*) registered as drug product (e-CTD dossier) for the treatment of diarrhea and dysbiosis (more than 20 clinical trials published).

Given the increasing interest on microbiota and role of probiotics on prevention, diagnosis and treatment of various pathologies, Cerbios is engaged to further investigate potential applications of its strain in different areas:

- ***E. lactis* SF68<sup>®</sup>** combined with other different functional ingredients.
- Cerbios supports efficacy of its Products with clinical trials and scientific evidences.
- Regulatory status: FS or FSMPs

Pathologies	R&D & proof of concept	Industrial Validation	Clinical trial Scientific evd.	Registration file ready for submission
<b>ACNE &amp; SEBORRHEIC DERMATITIS</b>	✓	✓	✓	✓
<b>IMMUNE SYSTEM</b>	✓	✓	✓	✓
<b>DYSLIPIDEMIA OBESITY- METABOLIC SYNDROME</b>	✓	✓	✓	✓
<b>IBS (IRRITABLE BOWEL SYNDROME)</b>	✓	✓	Scheduled for Q2-2025	Scheduled for Q2 2025



# SF68<sup>®</sup> SKINActive: ACNE & SEBORRHEIC DERMATITIS



## Rationale:

Relationship between gut and skin has been supposed on 30's. Now cumulative evidences are confirming the presence of a gut-brain-skin axis that connects intestinal bacteria, stress/emotions, and diet, to acne severity and other skin conditions.

Product: *E.lactis SF68* (10<sup>9</sup> cfu/dose) in association with Niacine.

Presentation: 20 or 30 oro-dispersible sachets

## Scientific evidences:

- Literature evidence, for Niacine, as sebum production regulator, keratinocytes differentiator (cellular turnover) & anti-oxidant activity.
- Clinical trial on 25 patients with significant clinical and instrumental results on reduction of papules, pustules and seborrhea ([publication on JPD](#) vol. 17 n.3 9-2021, pp 71-77).

Status: Food Supplement ready for submission (compatibility data, formulation studies, industrialization, stabilities and clinical trial available).

# SF68<sup>®</sup> SLIPIDO: Dyslipidemia & Cardio Metabolic conditions



## Rationale:

In scientific literature is widely reported how alterations of gut microbiota (dysbiosis) are often connected to a metabolic unbalance, like dyslipidemias (cholesterol), glucose resistance, overweight and to an inflammatory status, that is predictive of a potential development of obesity.

Cerbios formulated its proprietary probiotic strain with other selected functional ingredients, targeting above mentioned conditions and acting at different levels. Efficacy of the product by preclinical and clinical tests.

**Product:** *E.lactis SF68* ( $10^9$  cfu/dose) in association with Phytosterols and 5-MTHF (folate biologically active)

**Presentation:** 20 or 30 oro-dispersible sachets

## Scientific evidences:

- Probiotics can reduce inflammatory status (acting on immuno-modulation), regulate lipids metabolism, with various mechanism of actions, maintain intestinal barrier integrity and reduce body weight/fat.
- Phytosterols reduces blood cholesterol levels (LDL).
- High blood homocysteine is linked to an increased cardiovascular risk. Folic acid is involved on homocysteine metabolism, reducing its bloody concentration. Here folic acid is present as the biologically active form of folate, 5-MTHF.
- Preclinical data available and published University of Pisa ( $\downarrow$  inflammation,  $\uparrow$  gut barrier,  $\uparrow$  microbiota on mice).

Clinical trial finalized on Q4-2024 (Florence University):  $\downarrow$  weight, lipidic profile, oxidative stress;  $\uparrow$  microbiota & gut barrier.

**Status:** Food Supplement ready for submission (with stability studies).

# **SF68® IBSoft (Irritable Bowel Disease)** (*Pipeline 2025*)



## **Rationale:**

IBS is one of most common GI disease, (constipation or diarrhea, visceral pain, swelling), representing a unmet medical need, due to unsatisfactory treatments on the market. Has been demonstrated that a dysbiosis is often associated to IBS. In prevention and treatment of IBS, some specific probiotic strains (efficacy linked to strain specificity), can be indicated for management of IBS.

Postbiotics, like butyrate (SCFA), and folic acid have an additive effect on symptoms.

**Product:** *E.lactis SF68* ( $10^9$  cfu/dose) in association with Butyrate.

**Presentation:** 30 caps

## **Scientific evidences:**

- SF68 demonstrated efficacy on prevent and treat IBS symptoms at pre-clinical level, reduce inflammatory status and increase intake of butyrate by GI cells.
- Butyrate is well known in literature for its anti-inflammatory and immunomodulant effects.
- Clinical trial planned for Q2-2025.

**Status:** Food for Special Medical Purposes.



# **SF68® IMMUNOBLASE: immunity booster**



## **Rationale:**

Intimate relationship between gut microbiota and immune system is well known since some years; is not a case that most of immune cells are located into intestine.

Several scientific evidences confirm use of probiotics to boost immune response.

**Product:** *E.lactis* SF68 ( $10^9$  cfu/dose) in association with Vitamin D, Selenium, Zinc and Folic acid as 5-MTHF (the active form of folic acid).

**Presentation:** 20 oro-dispersible sachets (1 x day).

## **Scientific evidences:**

- Literature (for vitamins and probiotics)
- Preclinical data (for SF68) on enhancing immune responses and potentiating efficacy of vaccination.

**Status:** Food Supplement ready for submission (compatibility data, formulation studies available).