

**2024 2<sup>nd</sup> on-line Investor Conference**

**Corporate Presentation**

**2024.12.27**

# Disclaimer

- The forward-looking statements mentioned in the presentation may include operating forecasts, financial status and marketing forecasts, based on information obtained from internal and external resources.
- There are numerous factors could cause actual results to be different from the implicit and explicit forecasts. The factors include, but are not limited to market risks, supply chain, market demand and our capability of launching high-quality products and services.
- Further, certain forward-looking statements are based on the company's forecast of future events as of the date of this presentation. Oneness Biotech does not undertake any obligation to update or revise the forward-looking statements.

# Financial Report

# 2024 / 2023 Q3 Operation Status

## Financial Reports For the Nine Months Ended September 30, 2024 & 2023

| Item              | 2024.Q3    | 2023.Q3     | Difference |
|-------------------|------------|-------------|------------|
| Revenue           | 1,247,964  | 1,157,441   | 90,523     |
| Operating loss    | (358,665)  | (419,507)   | 60,842     |
| Net loss          | (938,980)  | (1,257,886) | 318,906    |
| Total Assets      | 14,541,515 | 14,613,099  | (71,584)   |
| Total Liabilities | 2,039,322  | 1,136,751   | 902,571    |
| Total Equity      | 10,896,308 | 11,720,500  | (824,192)  |

Unit: NT\$ thousand

## 2023-2024 Stock price chart



Closing Price

33.70

Year' s Range

73.3~32.95

Market Value

19.8bn

Unit: NT\$

# Consolidated Statements of Comprehensive Income

Unit: NT\$ thousand except EPS

| Item                                | 2024.Q3          | 2023.Q3            |
|-------------------------------------|------------------|--------------------|
| Operating revenue                   | 1,247,964        | 1,157,441          |
| Operating costs                     | 763,599          | 717,383            |
| Operating gross profit              | <u>484,365</u>   | <u>440,058</u>     |
| Selling expenses                    | 404,471          | 391,339            |
| Administrative expenses             | 142,461          | 143,896            |
| R&D expenses                        | 296,370          | 324,330            |
| Total operating expenses            | <u>843,302</u>   | <u>859,565</u>     |
| Other operating income and expenses | 272              | -                  |
| Loss from operations                | <u>(358,665)</u> | <u>(419,507)</u>   |
| Non-operating income                | (579,927)        | (838,379)          |
| Income tax (profit) expense         | 388              | -                  |
| Net loss                            | (938,980)        | <u>(1,257,886)</u> |
| Loss per share (NT\$)               | (1.34)           | (1.86)             |

# Consolidated Balance Sheet

Unit: NT\$ thousand

| Item   | 2024.09.30        | 2023.12.31        | 2023.09.30        |
|--|-------------------|-------------------|-------------------|
| Cash /Cash equivalents /<br>Financial assets-current                             | 3,910,649         | 3,660,231         | 3,812,953         |
| Other current assets   | 536,993           | 350,982           | 303,627           |
| Financial assets-noncurrent/<br>Investments accounted for using equity<br>method | 7,792,147         | 8,382,044         | 8,252,855         |
| Property, plant and equipment  | 1,163,718         | 1,174,366         | 1,186,553         |
| Right-of-use Asset   | 659,384           | 683,241           | 590,143           |
| Intangible assets  | 177,476           | 180,254           | 186,181           |
| Other assets   | 301,148           | 303,966           | 280,787           |
| <b>Total assets</b>  | <b>14,541,515</b> | <b>14,735,084</b> | <b>14,613,099</b> |
| <b>Total liabilities</b>   | <b>2,039,322</b>  | <b>1,234,689</b>  | <b>1,136,751</b>  |
| Share capital  | 5,881,706         | 5,601,625         | 5,601,625         |
| Capital surplus  | 4,978,477         | 6,372,870         | 6,367,069         |
| Retained earnings<br>(Accumulated deficit)                                       | (790,296)         | (1,124,217)       | (1,041,973)       |
| Other equity   | 826,421           | 960,666           | 793,779           |
| Non Controlling Interests  | 1,605,885         | 1,689,451         | 1,755,848         |
| <b>Total equity</b>  | <b>12,502,193</b> | <b>13,500,395</b> | <b>13,476,348</b> |

# Summary of Financial Statements for the 2024 Q3 (A)

- For the Nine Months Ended September 30, the consolidated net loss after tax is 938,980 thousand NTD, and the main changes are as follows :

1) Net Revenue : 1,247,964 thousand NTD ; Gross Profit : 484,365 thousand NTD

Operating income mainly comes from sales of medicines, health supplements, and revenue from Cotton Field Organic. It increased of 90,523 thousand NTD compared with 2023 Q3 · increase ratio 7.8% · was mainly because the adjustment of sales strategy and the growth in revenue of Cotton Field Store.

2) Operating expenses : 843,302 thousand NTD :

A total of 404,471 thousand NTD is from sales and marketing expense for medicines, health supplements and Cotton Field Organic, and 296,370 thousand NTD for research and development. The operating expenses of this period decreased by 16,623 thousand NTD compared with 2023 Q3 was mainly because the decreased of research and development expenses according to the RD progress.

3) Net non-operating expense : 579,927 thousand NTD :

It is mainly the Investment Loss Recognized by Using the Equity Method of 638,374 thousand NTD which mainly attributed to unrealized valuation losses arising from the fluctuation in stock prices of investment targets held by biotech venture capital companies and Interest Income 64,574 thousand NTD.

# Summary of Financial Statements for the 2024 Q3 (B)

- Financial situation stable , important financial ratio :

| Current ratio | Quick ratio | Debts ratio |
|---------------|-------------|-------------|
| 863.33%       | 818.49%     | 14%         |

- Major changes in balance sheets :

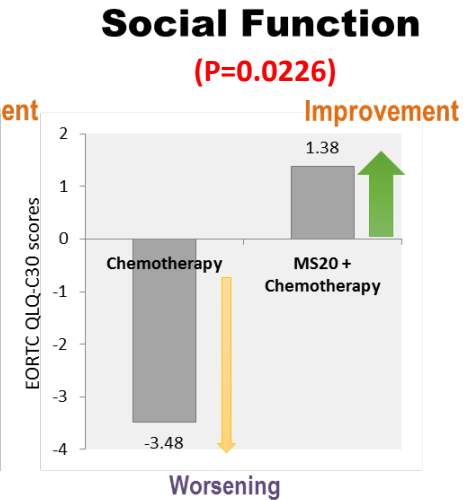
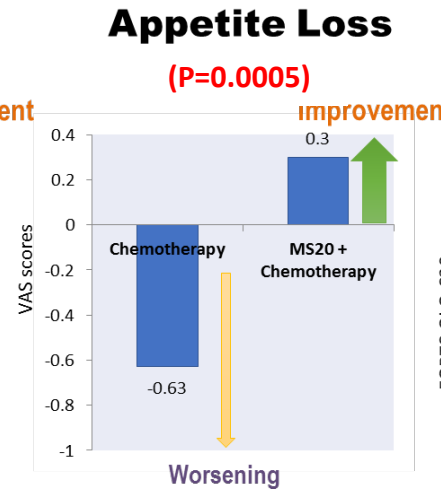
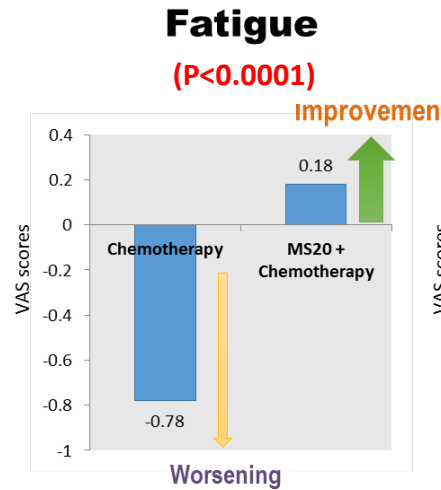
Unit: NT \$ thousand

| Item   | 2024.9.30 | 2023.12.31  | Explanations  |
|--|-----------|-------------|---|
| Cash /Cash equivalents /<br>Financial assets-current                             | 3,910,649 | 3,660,231   | The main reason for the change is that Microbio (Shanghai) received the first installment of the authorization payment for Fespixon from CR Double-Crane. Microbio also recorded net cash changes from increased investments in related enterprises and various business activities of consolidated entities. |
| Financial assets-noncurrent/<br>Investments accounted for using<br>equity method | 7,792,147 | 8,382,044   | It is mainly the Investment Loss Recognized by Using Equity Method.   |
| Total liabilities  | 2,039,322 | 1,234,689   | Microbio (Shanghai) has entered into an exclusive agreement of Fespixon commercialization with CR Double Crane Pharmaceutical Co.,Ltd. According to the contract, an estimated contract liability of RMB 200 million (equivalent to approximately NT\$900 million) is recorded.                               |
| Capital surplus  | 4,978,477 | 6,372,870   | The main reason is that the 2024 shareholders' meeting decided to use the capital reserve to cover accumulated losses. °  |
| Accumulated deficit  | (790,296) | (1,124,217) | The accumulated losses of 2023 were fully offset by the surplus reserve and capital reserve as resolved by the 2024 shareholders ' meeting. 2024.9.30 The accumulated loss is the current period net loss of the parent company. °  |

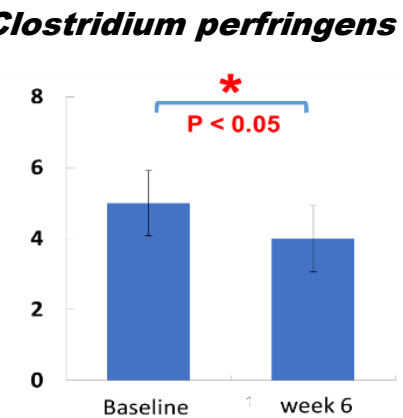
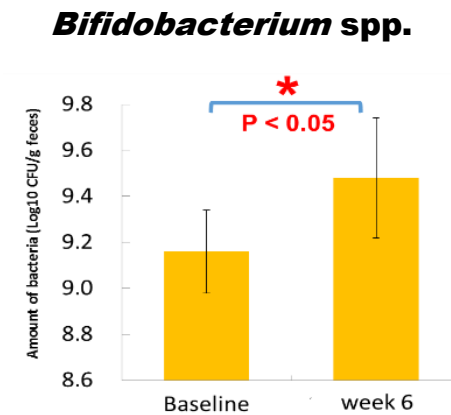
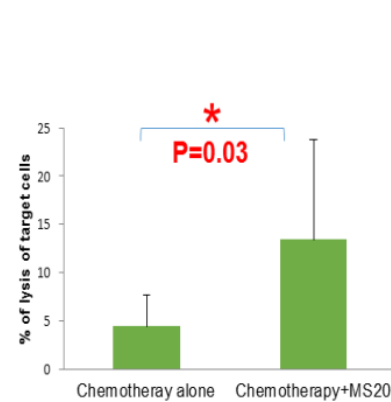
# Key operating reports

# MS-20

## The first new drug alleviating cancer therapy-related side effects in Taiwan (2011)



Drug license : 015926



# MS-20

## New indication development

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1. Immune checkpoint combination therapy
2. Inflammatory bowel disease combination therapy

# The Enormous Market Value for Cancer Immunotherapy

- The global cancer immunotherapy market was valued at USD 240 billion in 2023.
- The compound annual growth rate (CAGR) is 18.4%.
- The market is expected to reach around USD 1.3 trillion in 2033.

**2033 1.3 Trillion**

**2024 284 Billion**

**2023 240 Billion**

**CAGR 18.4%**

NOVA ADVISOR Immunotherapy Drugs Market Size 2023 to 2033 (USD Billion)



<https://www.biospace.com/immunotherapy-drugs-market-size-to-reach-usd-1-30-trillion-by-2033>

# Keytruda (anti-PD1 immunotherapy) is the best selling drug globally

- The sales of Keytruda generate more than USD 25 billion of revenue in 2023, which accounted for one-tenth of cancer immunotherapy market.
- In 2024, the sales of Keytruda is expected to reach USD 30 billion.



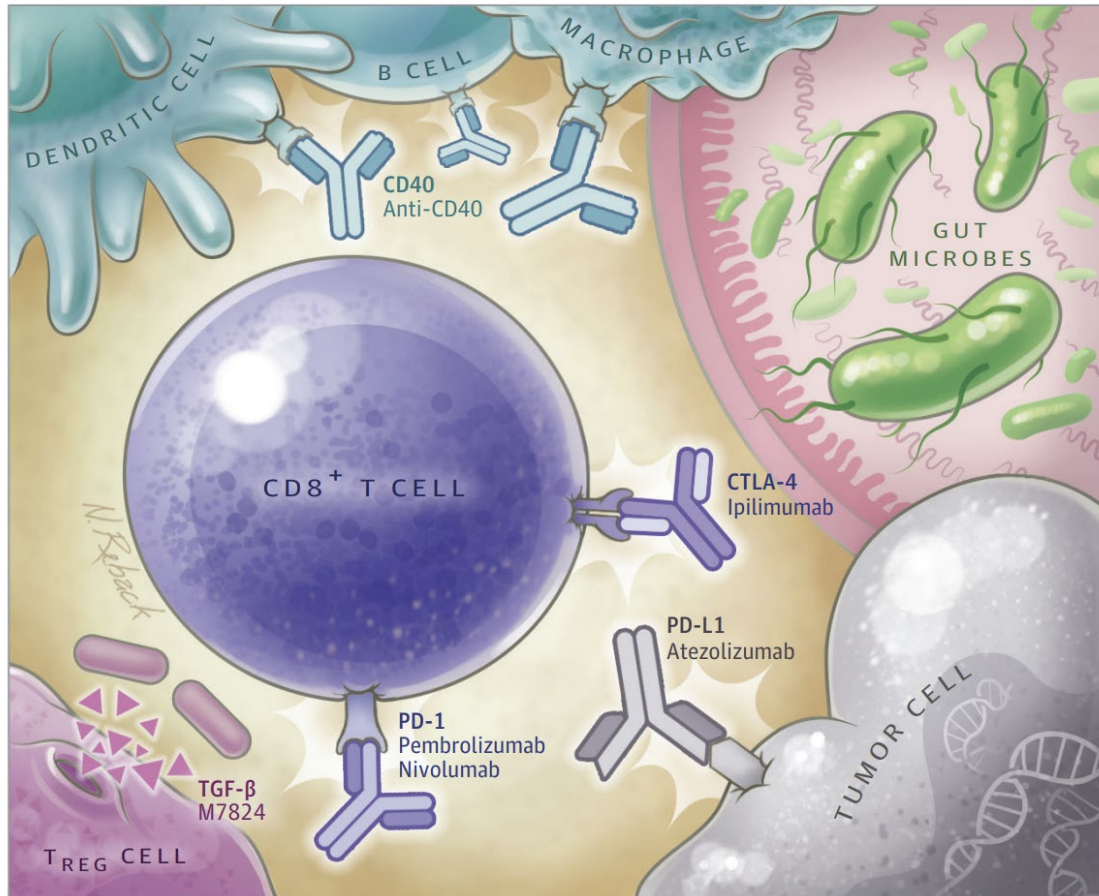
Merck's Keytruda rolled to \$25 billion in sales in 2023, which likely made it the world's top-selling drug in 2023. (Merck & Co.)

# Unmet needs of anti-PD1 in NSCLC

- The objective response rate (ORR) is greatly varied in patients. In addition, low response rate and the median PFS with **3.8 months** were also observed.
- Immunotherapy was also found to **overactivate the host immune system**, leading to the occurrence of immune-related adverse events. For example, dermatological, gastrointestinal, and endocrine side effects, which can range from mild to severe and even life-threatening conditions.
- US FDA launch “**The Immuno-Oncology Therapeutics Program (IOTP)**” to develop therapeutic strategies on harnessing the immune system to engage new, more efficacious treatment paradigms.

# Aim of immunotherapy 2.0

## Improve response, reduce side effect and overcome drug resistance



### Ways to improve response

- Combination therapy

(e.g., dual immunotherapy, cytokine modulation, anti-CD40 antibody etc)

- Using biomarker to identify responder

- Modulation of gut microbiota

# MS-20

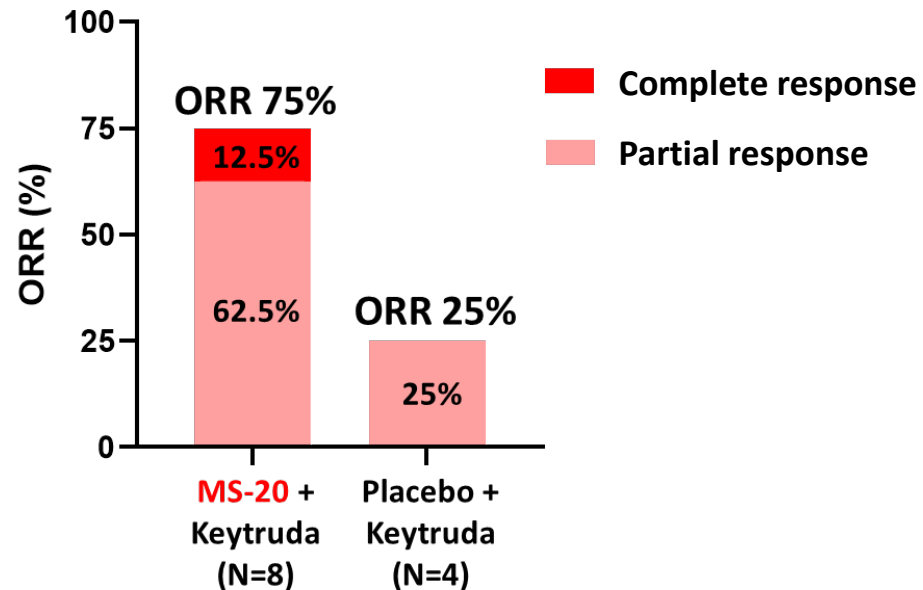
Exploratory clinical trial

Improve the efficacy of immunotherapy  
in advanced NSCLC

# MS-20 + Keytruda for treatment of advanced NSCLC

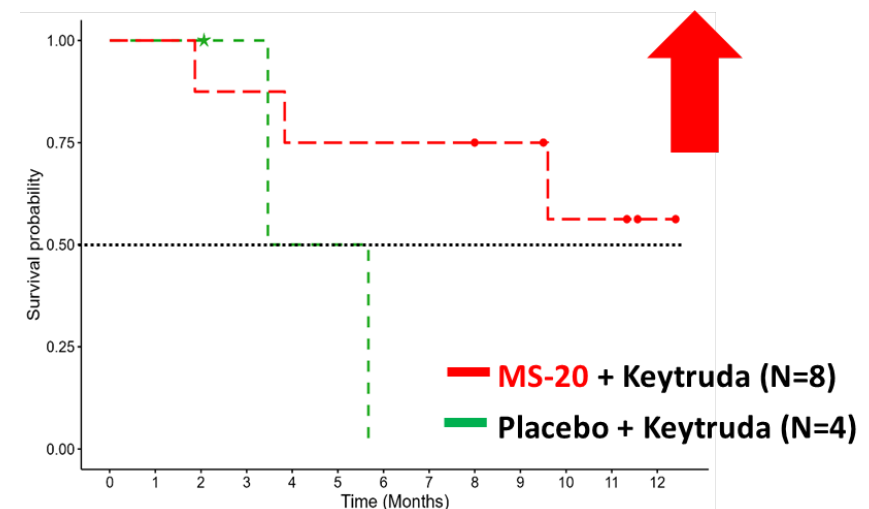
- Placebo + Keytruda · ORR=25%
- MS-20 + Keytruda · ORR=75% · complete response rate=12.5%

## Object response rate (ORR)



- Placebo + Keytruda · mPFS=4.5 months
- MS-20 + Keytruda · in 1 year of observation period, the median PFS has yet to be reached.

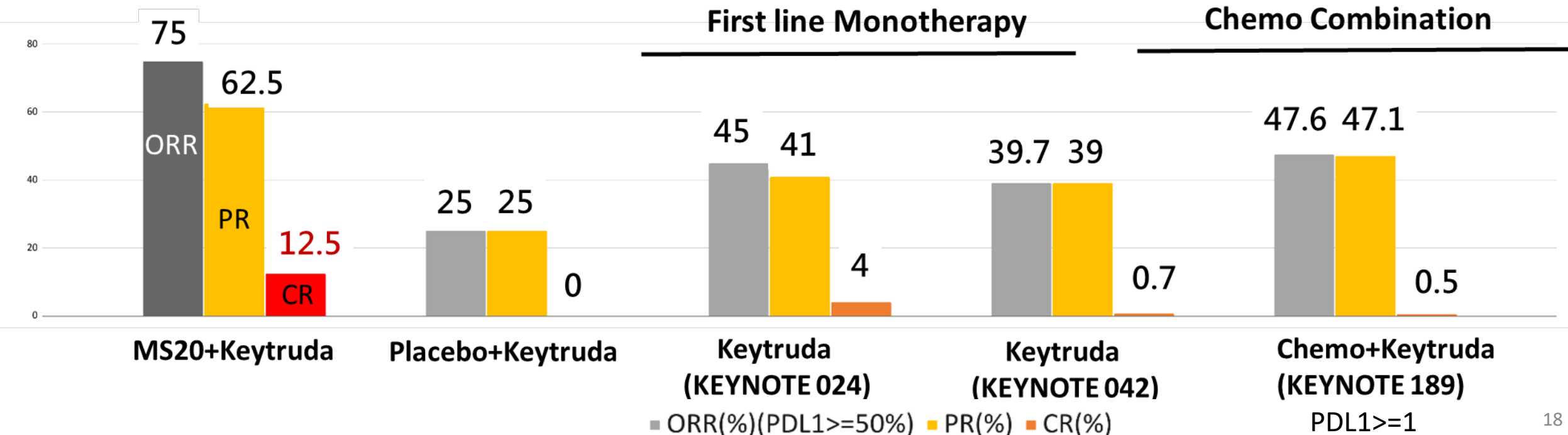
## Progression free survival (PFS)



# MS-20

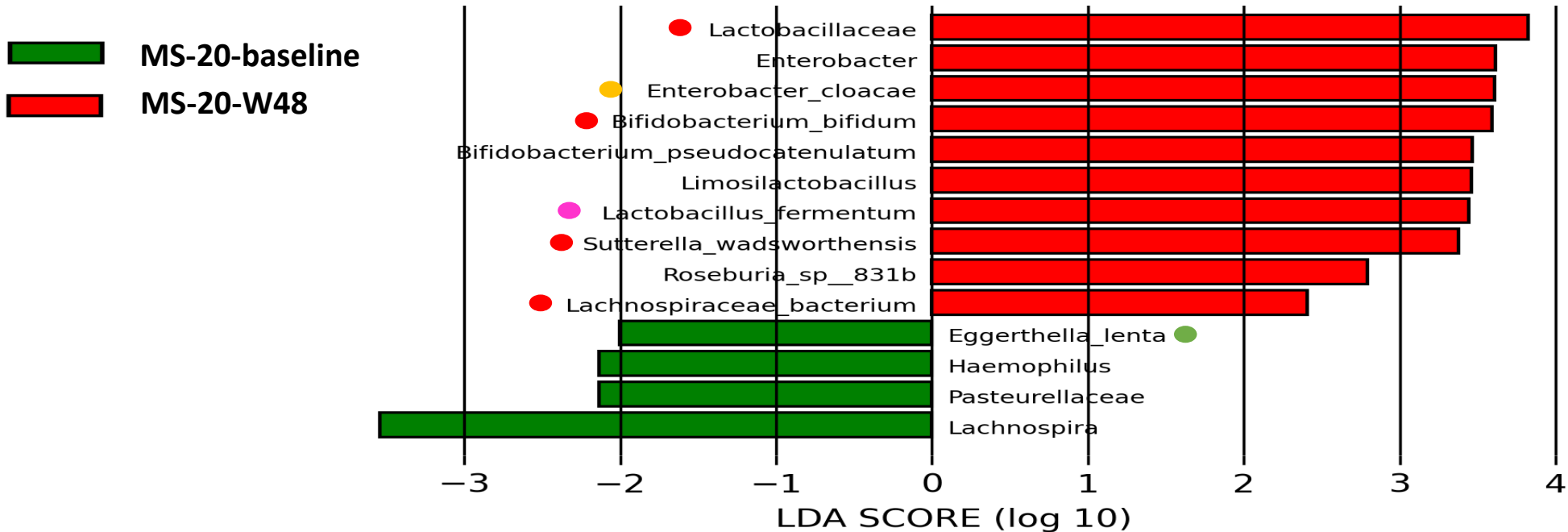
## Improve response rate of immunotherapy

- The object response rate of Keytruda alone is 39.7-45% and the complete response (CR) rate is 0.7-4%.
- The object response rate of Keytruda +chemotherapy is 47.6% and the complete response (CR) rate is 0.5%.



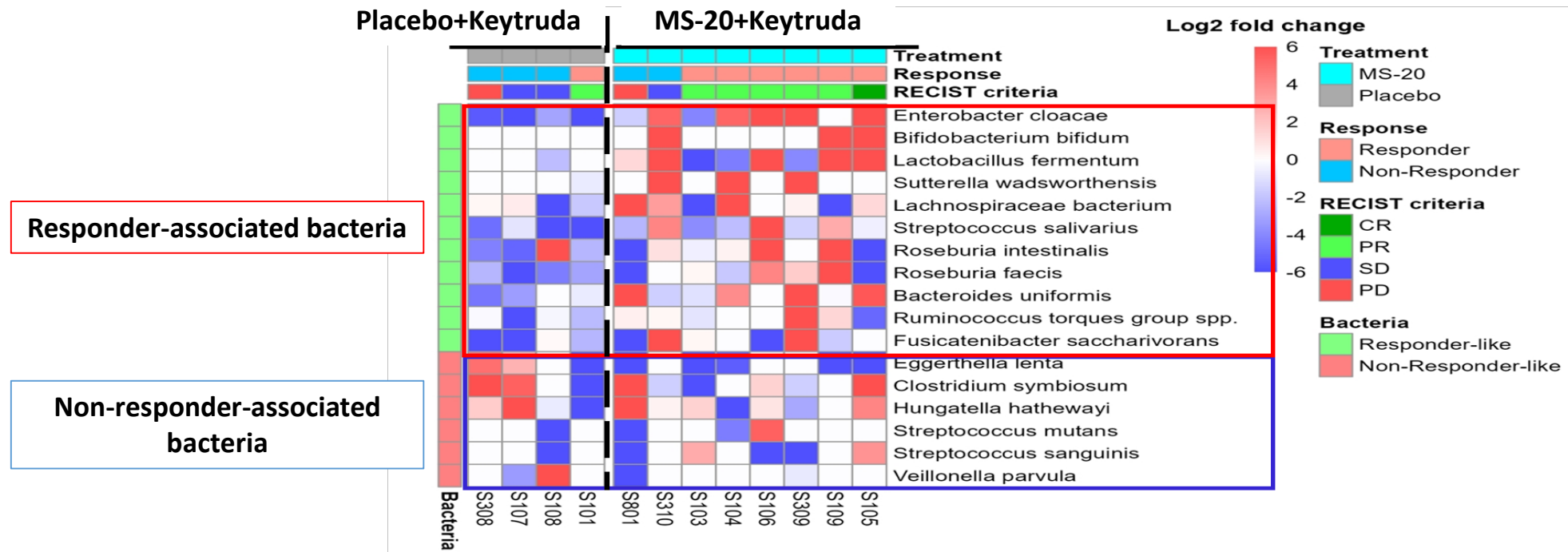
# MS-20 regulates the gut microbiota of NSCLC

- Increased Immunotherapy responder associated bacteria
- Inhibited Immunotherapy non-responder associated bacteria
- Increased DC activation associated bacteria
- Increased Gut barrier associated bacteria



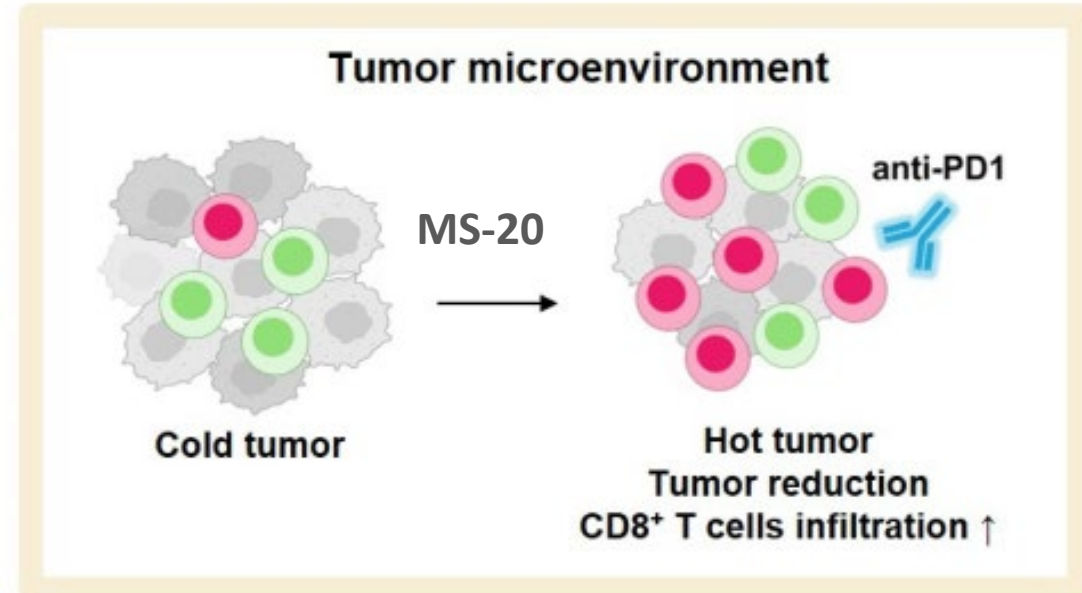
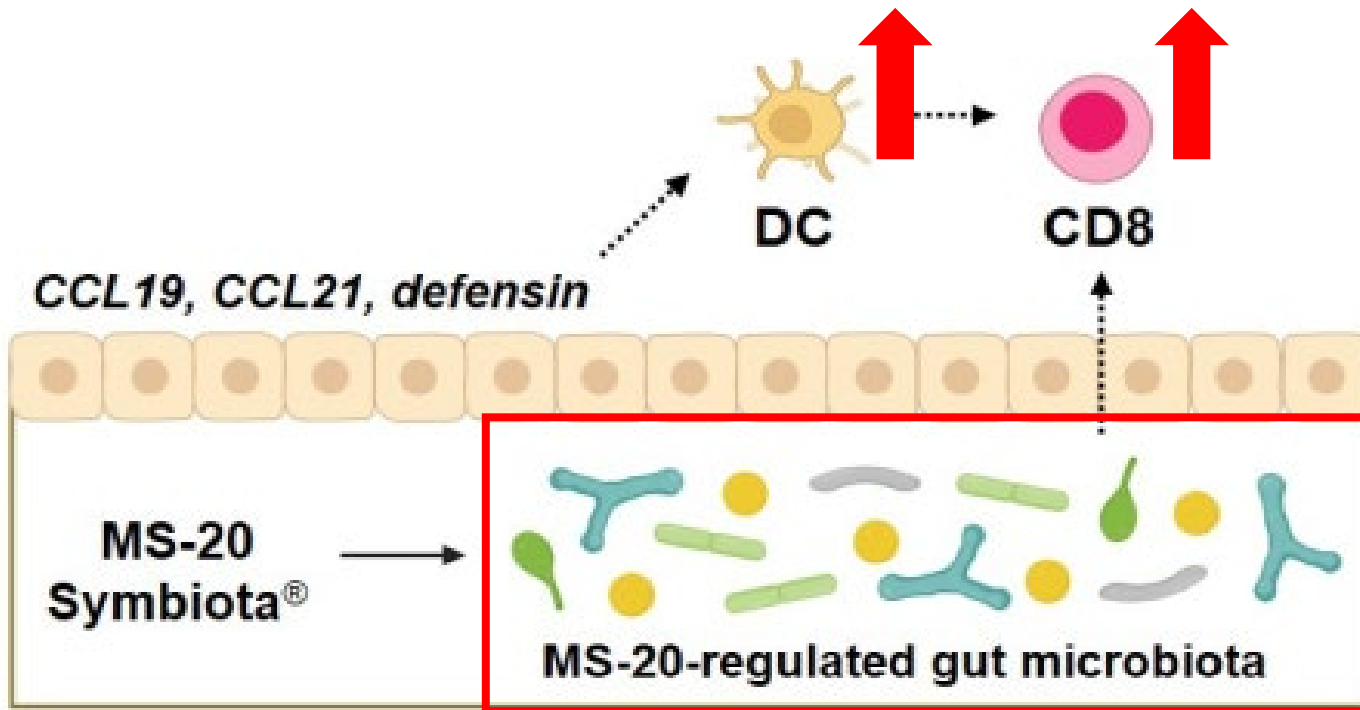
# MS-20 reverses the gut microbiota of patient from non-responder to responder

MS-20 + Keytruda increased responder-associated bacteria;  
inhibited non-responder-associated bacteria.



# MS-20

Reshape Microbiome - DC - CD8 T cell  
Turn Cold tumor to **Hot Tumor**



# Summary of MS-20+Keytruda clinical trial

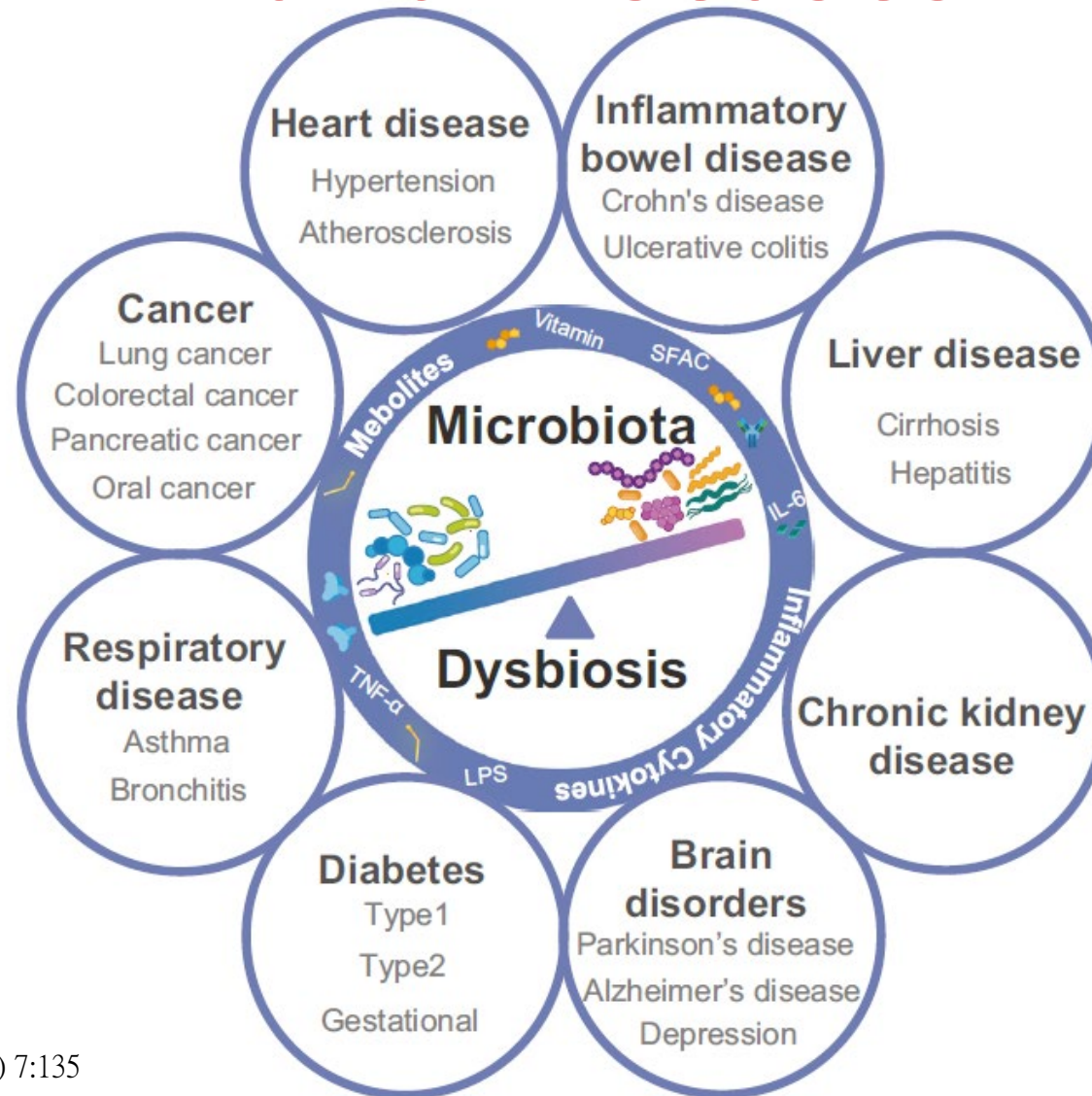
- Increase 3-fold **object response rate** compared to placebo+Keytruda (ORR is 75% in MS-20+ Keytruda; ORR is 25% in placebo+Keytruda).
- One participant who achieved an ongoing CR >22 months in MS-20 and Keytruda combination group with a CR of 12.5% was observed, which increasing **the complete response rate by 20 times** in comparison to the 0.6% complete response rate observed in a clinical trial of 299 patients treated with Keytruda
- During the 1 year observation period, the median PFS of MS-20 + Keytruda has yet to be reached. The median PFS of Placebo + Keytruda is 4.5 months.
- It suggested that "MS-20" modulating the gut microbiome and increasing DC and effector CD8 T cells in the tumor microenvironment, leading to an improvement of the treatment efficacy in advanced lung cancer.

# MS-20

## The progress of IBD clinical trial

- Ex vivo fecal culture platform proved that MS-20 can inhibit IBD-associated harmful bacteria and promote beneficial bacteria for gut
- Animal studies showed MS-20 effectively alleviated the severity of DSS-induced colitis and restored normal villi structure
- Exploratory trial has completed the enrollment of 30 patients, and the results will be unblinded in 2025Q1

# Relationships between Microbiome and Diseases

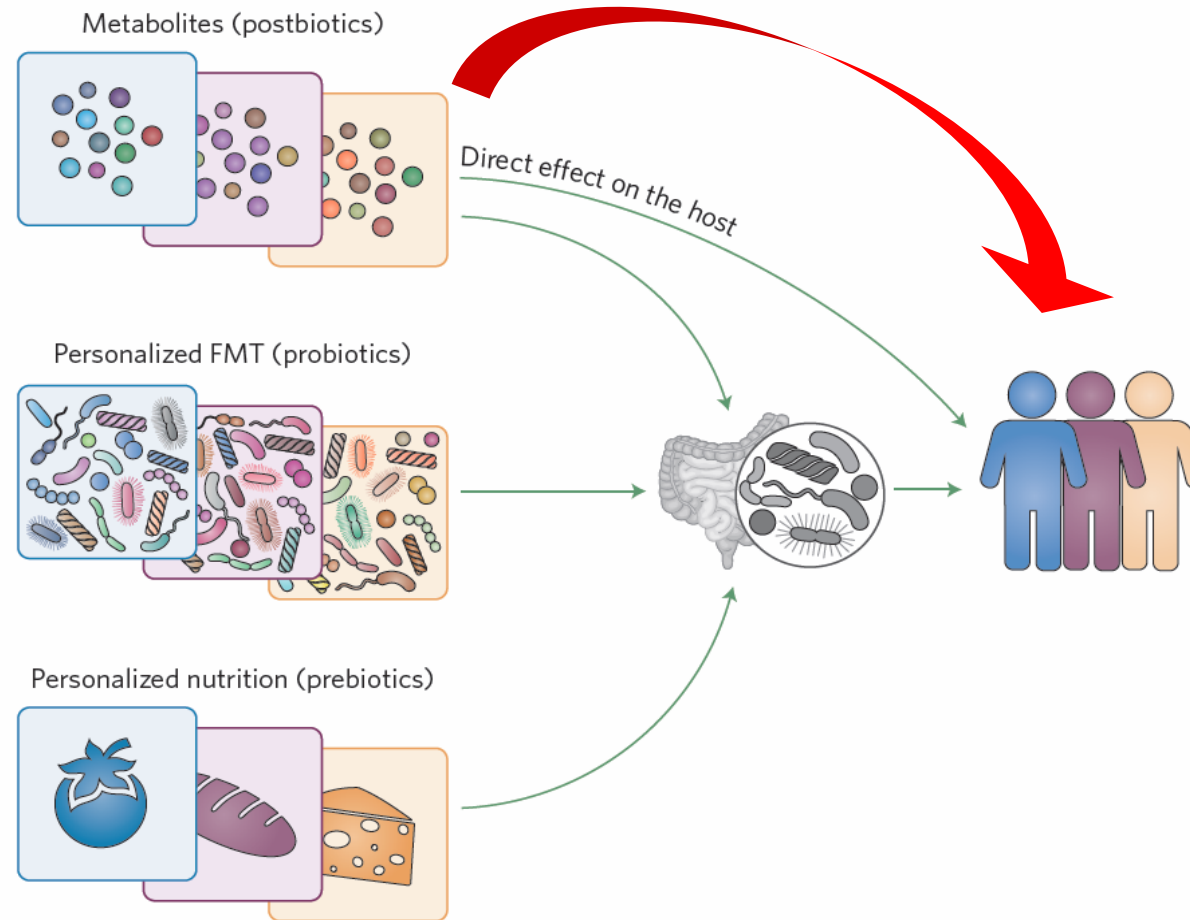


# Direct effect of metabolites on human

Metabolites from gut microbes

Fecal microbiota transplant (FMT)

Prebiotics



# Microbio' s microbiome product, Symbiota<sup>®</sup>-1

## What is Symbiota<sup>®</sup>?

- Symbiota<sup>®</sup> microbiome-based products successfully developed by Microbio' s proprietary symbiotic anaerobic fermentation technology using multi-strain probiotics.
- Microbio' s Symbiota<sup>®</sup> microbiome product has a significant physiological mechanism of action, which is different from that of other postbiotics from single bacteria on the market.
- It contains no live bacteria, so it doesn' t need to colonize the gut to have effects with high stability and good safety profile
- The core technology of Microbio is through regulating specific bacteria (increase certain beneficial ones and inhibit certain harmful bacteria) to achieve symptom improvement or disease treatment.

# Microbio' s microbiome product, Symbiota<sup>®</sup>-2

- Evaluate the international commercialization model of microbiome products and maximize opportunities and value of Symbiota<sup>®</sup> products.
- Symbiota<sup>®</sup> according to the regulations of different countries will adopt a diverse regulatory strategies to reduce time-to-market.
- Aim for international licensing by initiating Symbiota<sup>®</sup> product launches into global markets and creating value.

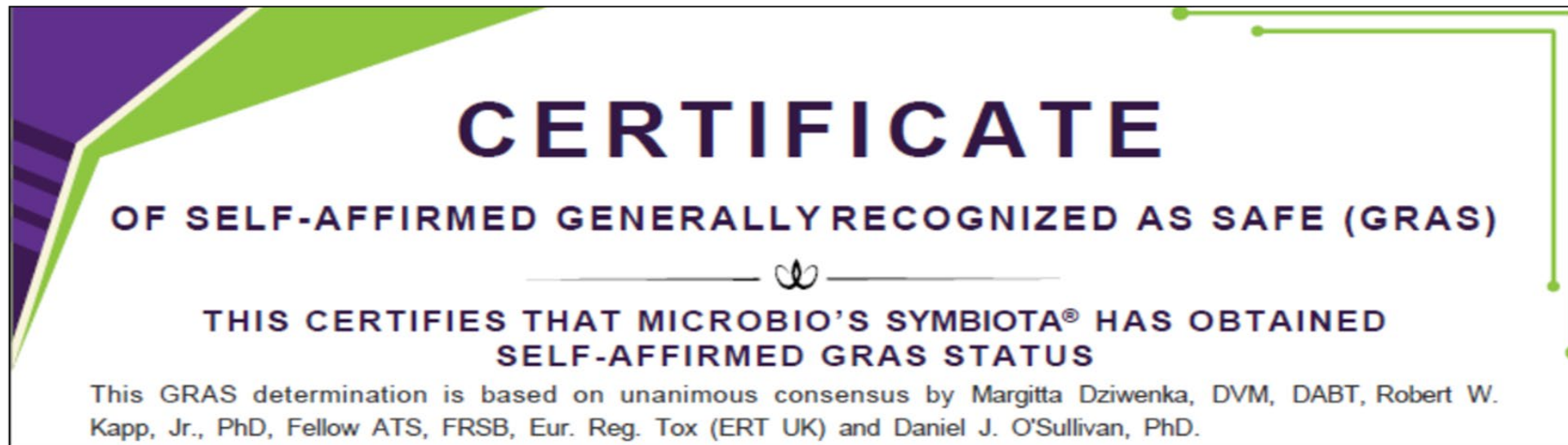
Medical  
food

Medical  
device

New drug

# Microbio' s microbiome product, Symbiota<sup>®</sup>-3

Obtain US **GRAS** (Generally Recognized as Safe)Independent/Self-affirmed conclusion



## Global Commercialization Strategy

# Business opportunities for Symbiota®

## through obtaining GRAS status

- Symbiota® Library has been created with more 1200 candidates, including the products for cancer adjuvant therapy, preventing precocious puberty, alleviating liver function, type-2 diabetes, irritable bowel syndrome, allergy, etc, which contain multi-faceted functions and valuable for the development of new drugs, medical devices, medical foods, and functional foods.
- Obtaining GRAS conclusion will significantly shorten product development time, gain international market access approval from regulatory authorities, and accelerate product launches.

# Global Commercialization Strategy

- **Market positioning:** 1. In medical foods, focusing nutritional adjuvant therapy for cancer and IBD 2. Functional foods: for the consumers who need to boost their immunity and gut health.
- **Business model:** 1. Medical nutrition sales: connect with international nutrition companies to apply MS-20 (GRAS) medical food to entering cancer immunotherapy market 2. Licensing and co-development with global pharma.
- **Marketing:** 1. Increase the exposure of products through international conferences 2. LinkedIn 3. Elevate the recognition by collaborating with scientific and clinical research institutes

# Microbio's Symbiota<sup>®</sup> Medical food

## Clinical trials

| Product | Use                                       | Trial sites | Expected completion date |
|---------|---|-------------|--------------------------|
| MBS-217 | Non-alcoholic fatty liver disease (NAFLD) | NTUH, TMUH  | 2025Q2                   |

# Microbio Symbiota® Medical Device-1 MB107

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**Skin Microbiota-Regulating  
AhR Agonist**

# Atopic Dermatitis & Plaque Psoriasis

- **Atopic dermatitis (AD) 及 Plaque Psoriasis (PsO):** These are chronic inflammatory diseases with complex and variable pathogenesis, often characterized by recurrent episodes. Symptoms include itching, a burning sensation, and redness of the skin. They significantly impact the patient's quality of life throughout their lifetime and place a long-term burden on healthcare systems.
- **Global Market Value** : The global treatment market was valued at approximately US\$37.1 billion (AD) and US\$35.8 billion (PsO) in 2034.
- **Corticosteroid cream treatment:** Long-term use can lead to skin atrophy and thinning, making the skin more fragile, among other side effects. Additionally, individuals who are allergic to corticosteroid creams may experience increased skin irritation, which can worsen the condition.
- **Preclinical results:** MB107 cream, when applied to atopic dermatitis and psoriasis, shows similar efficacy to the *FDA-approved new drug Tapinarof*, indicating its strong market potential.

# New Topical Treatments Drug for Atopic Dermatitis and Psoriasis (Tapinarof Cream)

Tapinarof cream became the preferred topical treatment for plaque psoriasis within just two months of its launch. Organon agreed to acquire Dermavant for a total of up to approximately \$1.2 billion, highlighting the market potential of AhR mechanism-based products.

Healthcare

M&A

## Organon to acquire Roivant company Dermavant for \$1.2B



Sep. 18, 2024 7:44 AM ET | **Organon & Co. (OGN) Stock, ROIV Stock** | By: Sinchita Mitra, SA News Editor

### Dermavant: Plaque Psoriasis to Atopic Dermatitis

Dermavant Sciences ([DRMT](#)) is a biopharmaceutical company that develops innovative therapies in immuno-dermatology. It is a Roivant Sciences Ltd. ([ROIV](#)) [subsidiary](#) with a VANT model for generating biotech firms that address specific medical needs. Dermavant's flagship product is VTAMA cream, which treats mild, moderate, and severe plaque psoriasis in adults with a submitted sNDA for atopic dermatitis [AD]. The firm quickly established itself in the dermatology field and had strong success after launching the VTAMA cream.

# Preclinical Trial Results for Atopic Dermatitis and Psoriasis

The efficacy endpoints of MB107 are comparable to those of the FDA-approved new drug Tapinarof

| Indicator   | MB107   | Tapinarof  |
|---|---|------------|
| Atopic Dermatitis<br>Investigator Global Assessment<br>(vIGA-AD 0 or 1) | 62.5%    | 45.4%      |
| Psoriasis<br>Investigator Global Assessment<br>(PGA-AD 0 or 1)          | 50.0%  | 35.4/40.2% |

# MB107 R&D Summary

- **FDA 510(k) Application Status :**
  - 2024.11.26 Clinical Trial Pre-Submission Inquiry
  - The goal is to **obtain 510(k) certification** by 2025.
- **Manufacturing License Application :**
  - 2024.12.02 ISO 13485 audit has been completed, and the manufacturing license is expected to **be obtained in Q1 2025**, which will help **accelerate entry into the European market**.

# Commercial Strategy of MB107

- MB107 has the same mechanism of action as the FDA-approved new drug Tapinarof and demonstrates comparable efficacy.
- Achieving U.S. market entry through medical device regulations.
- The medical device is priced lower than existing drugs (Tapinarof \$1,531/60 grams), offering a pricing advantage, while also providing superior efficacy compared to current atopic dermatitis medical products.
- Initiating a U.S. market strategy assessment and engaging in discussions with potential international partners or licensing candidates.

# **Microbio Symbiota® Medical Device-2**

## **MB828**

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**Novel multi-effect microbiota Nasal Spray  
Allergic Rhinitis and Chronic Rhinosinusitis**

# Chronic sinusitis - unmet medical need

- Four key treatment targets for AR and CRS
  - Immune control (steroids), Nasal flora (antibiotics), Nasal epithelium integrity, Inhibition of Nasal polys growth
- Current treatments: topical and oral corticosteroid therapy and endoscopic sinus surgery
- Existing treatments cannot effectively control the disease. The medicine has short-term beneficial effects, but will relapse quickly

# MB828 innovative medical device

## Comprehensive solution to allergic rhinitis and chronic sinusitis

- Suppresses Th2 immune responses, as effective as steroids.
- Effectively inhibits the growth of opportunistic pathogens and inhibits the formation of pathogenic biofilms
- Repair the integrity of nasal epithelial tissue
- Inhibit the formation of nasal polyps

## MB828 R&D progress

- 2024 H2 Preliminary trial mass production test successful
- 2024 H2 Completed U.S. FDA Pre-sub and confirmed comparable products
- It is expected to apply for US 510(K) approval in 2025

# MB828 competitive advantage

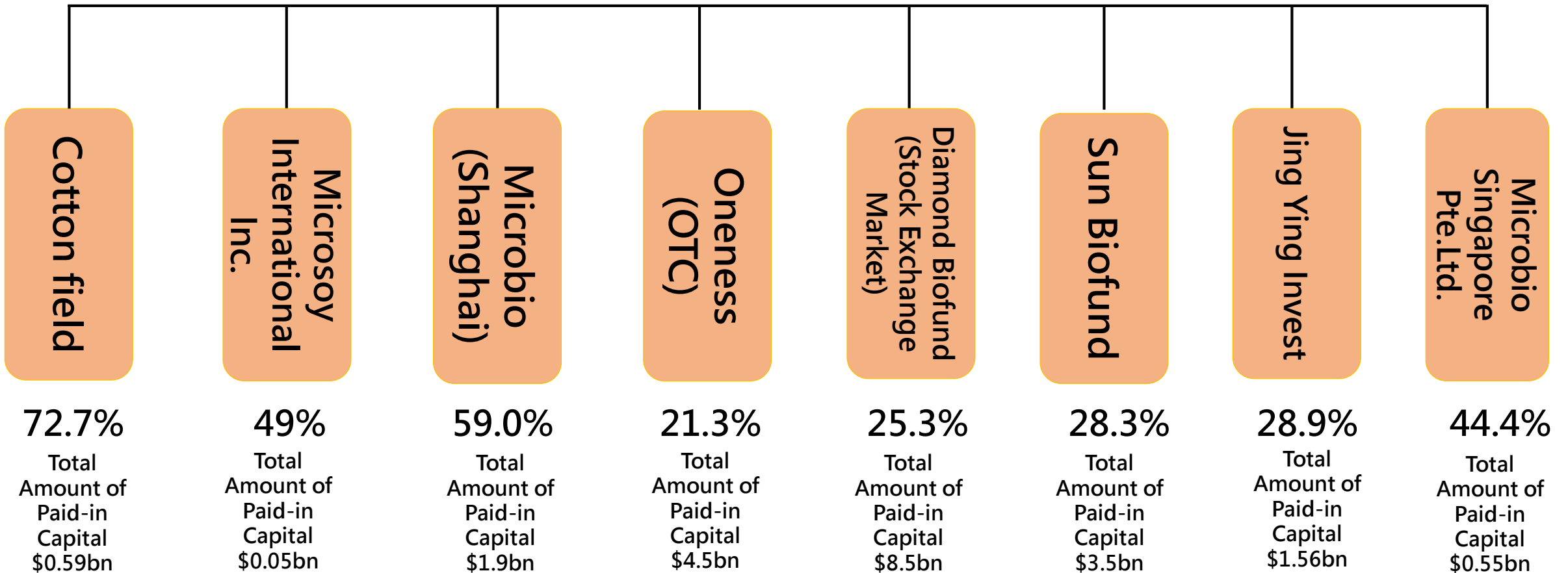
| Treatment options | MB828  | Steroid<br>(tropical and systemic)  | Antibiotics  | ESS  | Biologics   |
|-------------------|--|---|--|--|---|
| Shortcoming       | The taste and color are not well accepted by some people   | <ul style="list-style-type: none"> <li>Systemic side effects</li> <li>Symptom improvement disappears rapidly</li> </ul> | <ul style="list-style-type: none"> <li>Lack of clinical data to support effectiveness</li> <li>GI side effect</li> <li>Drug resistant</li> </ul> | <ul style="list-style-type: none"> <li>Surgical complication</li> <li>Expensive</li> </ul> | <ul style="list-style-type: none"> <li>Side effect</li> <li>Requires continuous use</li> <li>Expensive</li> </ul> |
| Advantage         | <ul style="list-style-type: none"> <li>Comprehensive MOA</li> <li>Repair epithelial cells</li> <li>Inhibit nasal polyps</li> <li>Convenient administration</li> <li>High security</li> </ul> | <ul style="list-style-type: none"> <li>Cheap</li> <li>Effective in 20% of patients</li> </ul>                           | <ul style="list-style-type: none"> <li>Cheap</li> <li>Easy to admin.</li> </ul>  | Usually a one-time treatment that is effective in patients                                 | Effective for patients with specific endotypes and need to be treated every two months or every month             |
| Estimated cost    | NT 1,000-5,000/course  | NT 320-16,000/course  | NT 320-1,600/course  | NT 160,000-480,000/time  | NT 320,000-1,280,000/year   |

Modified from *J Allergy Clin Immunol.* 2022 August ; 150(2): 287–290.

# MB828 Commercialization Advantages and Strategies

- Steroid and antibiotic drugs have limited efficacy, while antibody drugs are effective for some people but are expensive and require continuous use.
- MB828' s new mechanism has the opportunity to cure allergic rhinitis and chronic sinusitis
- Initiate US market strategy assessment and negotiate international cooperation or licensing partners

# Investment



# Reinvestment Valuation

## Book Value and (loss) Gain from Investment Accounted under the Equity Method

(Currency in thousand TWD)

| Company                      | 2024.09.30<br>Share<br>holding ratio | Original<br>Investment  | 2024.09.30<br>Book value | For the Nine Months<br>Ended September 30 |
|------------------------------|--------------------------------------|-------------------------|--------------------------|---|
| Oneness (4743)               | 19.67%                               | 1,564,909               | 2,625,818                | (151,996)                                 |
| Diamond Biofund (6901)       | 25.34%                               | 845,327                 | 2,821,512                | (444,136)                                 |
| Jing Ying Invest             | 28.88%                               | 450,739                 | 487,947                  | 5,462                                     |
| Sun Biofund                  | 28.32%                               | 987,725                 | 1,085,620                | (17,739)                                  |
| Microbio Singapore Pte. Ltd. | 44.44%                               | 244,878                 | 268,976                  | 152                                       |
| Cotton field Organic Farm    | 49.00%                               | 147,000                 | 179,007                  | (30,117)                                  |
| <b>Total</b>                 |                                      | <b><u>4,240,578</u></b> | <b><u>7,468,880</u></b>  | <b><u>(638,374)</u></b>                   |

Above statement excludes subsidiaries: Cotton field , Microsoy and Microbio (Shanghai)

# 2024 Operating Summary

- Completed the exploratory trial in advanced NSCLC to demonstrate MS-20 can change human microbiota, modulate immune cells, and increase the efficacy of current therapy.
- Completed the enrollment of 30 patients for the exploratory trial of MS-20 in IBD, and the results will be unblinded in 2025Q1
- Symbiota portfolio, including MS-20, has obtained a GRAS conclusion, thus enabling the international market entry
- Two medical devices, MB107 and MB828, will be submitted to FDA for market approval next year

# 2025 Annual Operating Goals

- MS20/TB90010- Medical food launch in US, Novel food application for the EU market
- Medical devices, MB107/MB828, are aimed for market approval in 2025
- Microbio product is ready for entering the global market to generate revenue, which is the key goal of next year.

**Medical  
food**

**Medical  
device**

**New drug**

**Q & A**

# Thank You



**Globalization by Innovation**