

4.4 Risk Management

With risk management being the key to an enterprise's operations, Microbio incorporates the spirit of risk management into the operation strategy. The Board of Directors resolved and approved the "Risk Management Policies and Procedures". As the highest unit of risk management policy, the Board of directors is responsible for approving, reviewing and monitoring the Company's risk management policy to ensure the effectiveness of risk management. The Audit Committee routinely listens to the reports given by the risk management team and monitors the implementation of risk management of the Company and its major subsidiaries. At the same time, the Company advocates that risk management is not just the responsibility of certain units; all employees should acknowledge the idea that responsibilities should be shared.

- **Risk Management Policies and Procedures**

In order to manage the various risks that may be faced during operations, we have created business strategies and an organizational culture that emphasize risk management. We also adopt the "Risk Management Policies and Procedures" as the highest guiding principle for the Company's risk management. The Board of Directors, personnel, and employees of the Company and significant subsidiaries work together to promote the execution. The Risk Management Task Force reports the status of risk management to the Audit Committee and the Board of Directors at least once a year.



» Risk Management Practices

Drawing from the "Enterprise Risk Management" frameworks published by COSO (Committee of Sponsoring Organizations of the Treadway Commission) and the BCSD Taiwan, the processes include identification, assessment, monitoring, reporting, and response. From the perspective of the enterprise's overall operations, the responsible unit identifies related risk factors and measures and analyzes the impact of each risk on the enterprise's operation. Risk control measures are also planned to control risks that may be faced in operating activities within the tolerable range of the enterprise. In order to continuously improve the risk management system, climate change and environmental protection issues related to sustainable business operation, and regulatory compliance, market competition, drugs, health products and food safety, intellectual property management, and cyber security are incorporated in the risk management system to ensure better risk management and sustainable operation.



- **Risk Identification**

The Company identifies key risk events through SWOT analysis, global risk reports, analysis of industry trends within and outside our field, stakeholder engagement, and the ESG significance process. We establish response plans to maintain operational resilience in the face of these identified risks. In 2024, a total of 22 risks were identified for risk measurement.

• Risk Measurement

The probability of occurrence and degree of impact of risk events was used as the factors to quantify risk

Rating	Explanation of the Probability of Occurrence	Definition
1	It almost never happens	Expected to occur almost never within the next 10 years
2	Low probability of occurrence	Expected to occur once within the next 10 years
3	Possible occurrence	Expected to occur once within the next 5 years
4	Likely to occur	Expected to occur once within the next 3 years
5	Almost certain to occur	Expected to occur once within the next year



Rating	Explanation of Impact Level	Financial Impact	Operational Impact	Personnel Impact (including employees, test subjects, and patients)	Impact on Human Resources	Impact on R&D Progress
1	Negligible	Loss or additional expenses under NTD 1 million	No damage to plant, buildings, or equipment, or impact on operations	Temporary discomfort or no impact	Less than 10% of the human resource vacancy or personnel recruitment cycle time less than a month	Does not affect the R&D progress
2	Slight Impact	Losses or additional expenses in the range of NTD 1.01 million to NTD 5 million	Partial damage to plant, building, or equipment that can be restored within one day of business interruption.	Temporary damage that does not require follow-up medical treatment or surgery	10% to 20% of human resource vacancy or personnel recruitment cycle time exceeding over a month	R&D was significantly impacted, with project progress delayed for less than half a year
3	Medium Impact	Losses or additional expenses in the range of NTD 5.01 million to NTD 10 million	Partial damage to plant, building, or equipment that can be restored within three day of business interruption.	Temporary damage that requires follow-up medical treatment or surgery	20% to 30% of human resource vacancy or personnel recruitment cycle time exceeding over two months	R&D was significantly impacted, with project progress delayed for more than half a year
4	Significant Impact	Loss or additional expenses over NTD 10 million	Partial damage to plant, building, or equipment that can be restored within one week of business interruption.	Cause permanent or irreversible damage	30% to 50% of human resource vacancy or personnel recruitment cycle time exceeding over three months	R&D was significantly impacted, with project progress delayed for more than a year
5	Serious Impact	Loss or additional expenses over NTD 50 million	The plant, building, or equipment severely damaged, and operations are interrupted for more than a week.	Causing death	Over 50% of human resource vacancy or personnel recruitment cycle time exceeding over six months	Suspended project due to significant impact on R&D

• Risk monitoring and reporting

Based on the risk management, an enterprise-level risk matrix is compiled. Control measures are formulated for each unit. The Risk Management Task Force reports the implementation results to the Audit Committee and the Board of Directors at least once a year. Enhancing risk awareness mindset and culture through continuous education training.

		Risk Impact					
		Low	1	2	3	4	High
Likelihood	Low		1	2	3	4	5
	1	1	2	3	4	5	
	2	2	4	6	8	10	
	3	3	6	9	12	15	
	4	4	8	12	16	20	
High	5	5	10	15	20	25	

Score	Risk Level	Risk Response
13 ~25	High	Risk avoidance and/or risk reduction
6~12	Moderate	Risk Spreading
1~5	Low	Risk bearing

Example

Risk Factor	Risk Event	Incidence Rate	Degree of Impact	Risk Rating	Risk Level
Innovation Management	1. The R&D results were not as expected and the R&D progress was delayed. 2. Lack of experience in cooperating with international pharmaceutical companies, making it difficult to cultivate and accumulate professional experience.	4	5	20	High
Intellectual Property Management	Intellectual property (including patents, trade secrets, copyrights, and trademarks) is not managed properly, affecting the Company's operations or business interests.	3	5	15	High

Material topics in 2024 and corresponding mitigation and response strategies

Significant Risk Factors	Risk Description	Company's Response
Regulatory Compliance	<ul style="list-style-type: none"> Penalties given for violating the laws and regulations, resulting in financial losses and damage to the corporate image when performing duties. Laws and regulations for the biotechnology industry are highly intensive and the development prospect of the industry is uncertain. 	<ul style="list-style-type: none"> We reinforce the competencies of the Board of Directors and functional committees; implement corporate governance and the internal control system; strengthen the promotion of internal ethics regulations and laws and regulations the future business may possibly be involved at the training of new employees; enhance the training of employees on domestic and international laws and regulations; take the initiative to participate in professional seminars or training courses organized by the government or the industry, or recruit professional talent with experience in new drug R&D and laws and regulations to reduce adverse effects on new drug R&D due to laws and regulations; ensure all colleagues comply with laws and regulations and the internal rules of the Company when performing duties through audits. Management keeps a close eye on changes of important domestic and foreign policies and laws to fully grasp changes and to respond to market conditions. In the most recent year, important domestic and foreign policies and laws did not pose a significant impact on the Company's financial operations.
Innovation Management	<ul style="list-style-type: none"> It takes a long time to develop new drugs, with uncertainty whether or not the development will be successful. There are risks of the result of the development being unpredictable, or development cannot be completed or it fails, leading to high research and development costs and much time invested. Possible risks brought by technological changes and industry changes. 	<ul style="list-style-type: none"> We put government resources to good use; when a new drug enters the clinical stage, we apply for the Technology Project subsidy initiated by the Ministry of Economic Affairs to reduce R&D costs and expenditures. In addition, through substantial incentives and support for biotechnology enterprises, the government provides clear incentives for the research and development, financing, and high-end professional talent recruitment of new drug enterprises under the "Act for the Development of Biotech and New Pharmaceuticals Industry". Thanks to the Act, the Company is able to have access to professional talent and funding for investments. In addition, stable sales of our proprietary health supplements provide internal funding, which in turn reduces the risks associated with new drug development. We have adequate capital to reduce the risk of failure of new drugs; we carefully review and evaluate the opportunities and benefits of each new drug under development; new drug development and biosimilars are developed at the same time; we enforce cost-saving and expense rationalization; and we strictly implement the budget management system to reduce unnecessary expenditures, while at the same time cooperating with the government's industrial policies and applying for subsidies for R&D programs.
Drugs, health products and food safety	<ul style="list-style-type: none"> As drugs and food are vital to human health and safety, and most Chinese medicines are natural plants or minerals, complex factors such as botanical origin, place of origin, and harvest season will cause differences in quality. Safety issues of adverse reactions to drugs, health products, or foods cause serious damage to the Company's corporate image, further affecting the sales of products. 	<ul style="list-style-type: none"> We strictly abide by domestic food/drug regulations and international GMP standards of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). We have established stringent standards from raw material selection and supply evaluation to product quality control at all stages. In the second year after the Company was founded, we established the Longtan GMP pharmaceutical plant and food plant for strictly controlling quality to be in compliance with the Chemistry, Manufacturing and Controls (CMC) operating procedures, ensuring consistent product quality and stability. At present, our Longtan Plant has mature technology and research and development and is ISO 9001:2015, ISO 22000/HACCP, and Chinese medicine GMP certified. In addition, the inspection laboratory of the Longtan Plant has attained the ISO 17025 laboratory certification by the Taiwan Accreditation Foundation (TAF) to strictly enforce quality control to reduce the risk of product quality control. In addition to the strict quality control described above, our healthcare products have attained many health food certifications. Our product labels are clear and easy to understand, enabling users to correctly use them and understand possible side effects and warnings. We have also formulated operating procedures to handle healthcare product/drug complaints. Records of customer feedback are recorded for routine follow-up and improvement. The subsidiary Cotton Field Organic has established a Food Safety Department to strictly control quality, ensuring all sold products meet national standards and hygiene regulations. Products are clearly labeled with grades, allowing customers to understand the product standards and request inspection certificates. The laboratory conducts daily self-inspections on pesticide residues in fruits and vegetables as well as self-made products to ensure consumer safety.

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Intellectual Property Management	<ul style="list-style-type: none"> The biotechnology industry is a knowledge-intensive and technology-intensive industry. If trade secrets are leaked, the Company will suffer significant losses. As the research and development of new drugs involves an extensive range of scientific fields, to avoid concerns of infringement and to protect intellectual property rights from being infringed, related development technologies or products must be protected by patents. 	<ul style="list-style-type: none"> In accordance with the Taiwan Intellectual Property Management System (TIPS, 2016 version), we have compiled an Intellectual Property Management Manual as the guiding principle for IP management and related procedures. Using the Plan-Do-Check-Act (PDCA) cycle, we ensure the effective operation of the IP management system and the achievement of our IP policy and objectives. In November 2024, the Company passed TIPS (A-level) re-certification; the scope covers patents and trade secrets, and the certificate is valid through December 31, 2026. With breakthrough technology being closely linked to patent acquisition, the Company has formulated internal management procedures for employees to follow. In addition, employees are reminded of the importance of trade secrets through education and training as well as signing a confidentiality contract. At the same time, employees are encouraged to apply for patent acquisition if there is new R&D technology to ensure the advantage of the Company's competitiveness. As of December 31, 2024, we have filed 67 patent applications domestically and internationally (61 granted; 6 under examination). We have also filed 165 trademark applications (152 registered; 13 under examination). At the early R&D stage and prior to patent filing, we conduct detailed prior-art searches and benefit assessments under our internal R&D lifecycle control and patent rights management rules to ensure applications are supported by comprehensive searches and evaluations, thereby avoiding infringement of others' IP rights.
Cyber Security	<ul style="list-style-type: none"> Data leakage and damage Cyberattacks, computer viruses and phishing scam letters 	<ul style="list-style-type: none"> We passed the ISO 27001:2013 certification in Q2 2022 and have undergone annual surveillance audits since. The transition to the latest version is expected to be completed in Q1 2025 to further strengthen the information security management system. We have introduced a file encryption system so that encrypted files cannot be opened in external environments; we conduct irregular audits of user behaviors on encrypted files (such as adding, modifying, deleting, and copying); the system can apply watermarks to files as alerts and control printing permissions, and supports retrospective audits; computers are prohibited from writing to portable media; we have introduced a network management system to monitor network behaviors and control the use of cloud storage; an IP management system has been implemented to block external devices from accessing the Company's internal network; a backup system has been introduced to back up critical hosts and files; and disaster recovery drills are conducted on a regular basis. We have introduced firewall and anti-virus software to block malicious cyberattacks and computer viruses; introduced an anti-spam system to block malicious emails; and conduct information security awareness promotion for employees on a regular or ad-hoc basis. In order to enhance colleagues' information security concepts and strengthen self-protection awareness, an information security management review meeting is held at least once a year to supervise and control relevant information security systems and events during the year. Each year we also hold at least 3 hours of information security education and training, 1 incident notification drill, and 1 email social engineering drill, and promote security concepts through internal email from time to time. In 2024, a total of 1 company-wide information security training session, 1 incident notification drill, and 4 email social engineering drills were carried out to raise information security awareness among employees. We have joined the TWCERT/CC Information Security Alliance and Cyber Security Executive Association of Information Service Industry Association of R.O.C., and exchanged cyber hacking information through the above platforms from time to time. It is expected to expand the breadth of company information security defense, and strengthening information security resilience by the joint defense mechanism and sharing of cyberattack information.

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Talent Recruitment, Cultivation and Retention	<ul style="list-style-type: none"> Inability to attract talent, reduce R&D power, and affect the Company's long-term sustainable development 	<ul style="list-style-type: none"> The remuneration system is defined reflective of industrial characteristics, market conditions, and future developments and suitable rewards are provided to employees who have made contributions according to the fulfillment of operational goals and performance review results of departments and employees. Incentives such as employee share subscription warrants are adopted to motivate employees to improve operational performance and long-term value together with the Company. We provide comprehensive welfare, equal job opportunities for both genders, and assist colleagues in improving their professionalism and self-growth through a well-developed education and training system and employee development plans.
Climate Strategies	<ul style="list-style-type: none"> Extreme weather causes shortages of resources, rising costs of raw materials, and shutdowns of plant operations. 	<ul style="list-style-type: none"> We have attained the ISO 14001:2015 environmental management system certification, which will effectively reduce the negative impact on the environment. We have alternative suppliers for key raw production materials, and evaluate raw material production, synthesis and mass production processes to reduce raw material shortages and production delays. We also research the financial impact on climate change risks. As the Company is not in a traditional energy-consuming industry, it does not have facilities that generate large amounts of GHGs. At the same time, we have formulated an air pollution prevention policy and, each year, we take the initiative to convert electricity to GHG emissions to set future reduction targets. Also, the air quality of the laboratory is regularly monitored and filters replaced to reduce the impact of laboratory exhaust on the environment. Heavy oil boilers have been replaced with gas boilers to reduce the production of sulfur and nitrogen compounds by a wide margin, and carbon emission. Also, replace the water-cooled chiller to achieve the objective of energy-conservation and carbon reduction. Targets for wastewater discharge reduction are set to reduce wastewater pollution of the local environment. Waste is thoroughly classified and resources recycled, which are disposed of by qualified professional vendors according to the characteristics of the waste. From 2022, we began to introduce "Task Force on Climate-Related Financial Disclosures" (TCFD) architecture has been introduced to identify how the risks/chances of climate change may affect the operation and finance of the Company, and the response strategies and solutions have been formulated.

• **Emerging Risks**

In order to strengthen the management, control, and response to future risks, the Company not only identifies the aforementioned risks based on past experience, but also refers to the literature published by domestic and foreign institutions to assess emerging risks to understand their possible impacts and formulate countermeasures. After reporting the relevant risks, the Company will continue to monitor the effectiveness of its management, control, and mitigation measures for emerging risks.

Emerging Risk Assessments

Emerging Risk Factors	Risk Description	Risk Response
Geopolitical Risk	Taiwan is listed as one of the high geopolitical risk regions in the world. It is expected that geographical conflicts will lead to higher commodity prices and affect the availability of raw materials, resulting in increased operating costs and instability.	<ol style="list-style-type: none"> 1. For raw materials required for production, safety stocks will be maintained according to the delivery deadline to ensure that production can make up product stocks at any time, and to reduce the problem of material shortages caused by political factors. 2. Diversify the supply chain and market, diversify supply chain and market risks, and reduce the dependency on a single region or country to cope with the impact of geopolitical events.
Market Competition in the Post-pandemic Era	<ul style="list-style-type: none"> • The Covid-19 pandemic has affected global social and economic development, and human health risks have become one of the focuses of future risks. The pandemic has also prompted the transformation and promotion of the biotechnology and pharmaceutical industry, resulting in more fierce market competition in the industry. • The development time of new drugs is long and the uncertainty of successful development is high. A great deal of manpower, material resources, funds, and time are required to be invested during the development period. 	<ol style="list-style-type: none"> 1. Utilizing government resources and support for biotech and pharmaceutical enterprises, for example, the "Act for the Development of Biotech and Pharmaceutical Industry" has specified the rewards for R&D, fundraising, and recruitment of top executives of pharmaceutical enterprises. At the same time, the stable sales of the Company's own healthcare products are also used to fund the capital, which in turn reduces the risks associated with new drug development. 2. As the R&D of new drugs enters the clinical trial stage, applying to the technology development subsidy program for the industry with the Ministry of Economic Affairs to reduce the R&D costs. 3. Preparing sufficient funds to minimize the risk of new drug failure and carefully evaluate opportunities and benefits of each new drug under development. Committed to cost saving and rationalization, rigorously implementing budget management policy to reduce unnecessary expenses, and applying to R&D subsidy programs backed by the governmental industrial policy. 4. Aggressively expanding physical channels and building cross-industry alliances, and at the same time, focusing on the development of online channels. Through the online-to-offline strategy, increasing the opportunities and width of product sales. Strengthening online-merge-offline to raise customer number and enhancing customer stickiness.
Implementation of Artificial Intelligence (AI) in the Biopharmaceutical Industry	<ul style="list-style-type: none"> • Competition and market risks: Other pharmaceutical companies' earlier or more effective application of AI technology in new drug research and development may have an impact on market competition. In addition, the application of AI in the pharmaceutical industry may change the industry structure and market landscape, affecting the Company. • Technology and talent risk: There may be challenges in AI technology when introducing AI into drug discovery and R&D, such as algorithmic instability or lack of interpretability. In addition, the company also needs talents with professional knowledge of AI and new drug R&D. AI talents or professionals with both AI and new drug R&D may be scarce in a short time. 	<ol style="list-style-type: none"> 1. Remaining sensitive to the market and competitive environment, adjusting strategies and business models in a timely manner. 2. Actively invest in R&D and innovation to maintain competitive advantages and continuously improve product value. 3. Establish cooperative relationships with other companies to jointly cope with industry changes and market challenges. 4. Invest in talent development and recruitment to ensure that the Company has sufficient technical expertise and capabilities. 5. Establish partnerships with higher academic institutions and research institutions to stay abreast of new technologies and innovations.