2.3 Risk Management

Risk Governance Unit

The board of directors is the highest supervision and decision-making unit for risk management, and is responsible for approving risk management targets and policies, and for ensuring effective operations of management mechanisms. The Audit Committee, auditing department, and corporate governance officer has been established under the Board to assist supervision of current and potential risk issues, strengthening internal monitoring mechanisms while reducing negative impacts and financial losses.

Risk Management Guidelines and Implementations

We have established internal risk management policies, procedures, and internal control systems for appropriate management of risk issues, impacts, and corresponding material topics in accordance with related regulations. Every year, the board approves corporate risk management targets and policies, and also assigns senior managers to oversee promotion and execution of various issues, and ensure that risk management mechanisms are operating effectively through regular monitoring.

Risk Issues and Responses

PharmaEssentia referenced the 2018 COSO Enterprise Risk Management guidelines and biopharmaceutical industrial characteristics and requirements to classify risks into 9 categories, and adopted response measures for different risks to reduce corporate impacts.

Risk categories	Risk causes	Response measures
Industrial risks	New drug R&D is a high-risk endeavor with low success rates, high investments, and high levels of uncertainty during product R&D processes	• BESREMi has obtained marketing authorizations and we are continuing to use our PEGylation technology platform to develop other long-acting protein-based drugs, as well as expand into new indications to maximize R&D investment benefits and reduce market risks from single products
Market risks	New drug R&D is time-consuming and has a low success rate, and products that obtain marketing authorization still need to compete with existing market products or other alternative products	• Independently develop new drugs and use medicines for rare diseases (orphan drugs) as a foundation for development; approval processes for products that have obtained orphan drug status are often fast-tracked, and these products usually enjoy freedom in pricing, monopoly markets, and other preferential conditions after receiving marketing authorization • Collaborate with external companies on developing new products with good potential to expand product diversification
R&D risks	Risks include underperformance in clinical progress or trial outcomes, being outpaced by competitors on R&D progress, challenges in cultivating and retaining research talent, and over-reliance on CROs and CMOs for clinical trials	• Simultaneously develop new drugs for different indications to disperse the risks from only developing a single drug • Recruit talents with backgrounds in the biotechnology industry to create and maintain sound R&D environments and employee welfare, and provide employees with training opportunities to retain talent • Choose trial institutes that offer optimal collaboration conditions and develop long-term collaborative relations
Financial risks	Risks from exchanges rates, rising prices caused by inflation, R&D investments, and operating capital requirements during all corporate financial activities, which may incur additional costs for the company	• Our finance department is the dedicated unit responsible for closely interacting with foreign banks; tracking exchange rates, market information, and future trends; and rigorously controlling capital utilization, budget implementations, and other management processes for all business units
Legal risks	Risks from international arbitration and litigation cases, which may lead to reputational damage or financial losses	• Commissioned a professional legal team which is responsible for handling international arbitration and litigation cases to maintain corporate and shareholder interests, and to maximize benefits
Policy risks	Risks from geopolitical conditions or changes in national policies	• Closely monitor international political and economic information and news as well as supply chain impacts that could be caused by international trade conflicts to quickly adjust overall business strategies and ensure supply chain stability • Established a dedicated regulatory department to keep abreast of policy changes associated with new drug applications, health insurance, and reimbursement policies in various countries
Technological change risks	Risks from information security, digital transformation, talent capabilities, supply chain disruptions, or regulatory changes which may impact corporate operations	• Established the information security management team, which is responsible for information security executions, governance, and supervision, and continued strengthening in management of information security to comprehensively enhance information security awareness, as well as to protect trade secrets and stakeholder interests
Environmental risks	Climate change, natural disasters, infectious diseases, and other uncontrollable external risks	• Introduced the TCFD framework to strengthen climate risk management. Our Taichung Plant has passed ISO 14064-1 verifications and implemented multiple energy and carbon reduction measures to mitigate climate change impacts • In light of lessons learned from the coronavirus pandemic, we have reinforced supply chain management (SCM) practices by securing safety stock and identifying alternative material sources to reduce supply shortage risks
Other risks	Other risks not listed above which may cause the company to suffer major losses	• Adopt corresponding emergency measures based on the severity of each situation

Countermeasures for Risks and Impacts GRI 2-25 GRI 2-26

PharmaEssentia responds to negative impacts from risks using three steps: Prevention, grievance reporting, and review and improvement. We established complete remedial processes for negative impacts to effectively respond to potential or emergency impacts.

1. Prevention

Formulation of rigorous policies

Formulate various policies and require compliance from employees and suppliers to prevent violations of regulatory requirements or corporate policies related to ethical management, drug marketing ethics, human rights, and environmental protection.

Robust information security controls

Adopt rigorous information security management measures to ensure information security and protection of personal privacy.

Comprehensive risk management

Conduct comprehensive assessments based on the COSO ERM framework, and host multiple education and training sessions to ensure that our colleagues are aware of various risk prevention measures.

2. Establish grievance and communication channels

We have established diverse internal and external grievance reporting channels as well as two-way communication channels for our colleagues so we can listen to employee suggestions.

Internal communication channels

- Labor-management meetings
- Employee welfare committee
- Employee suggestion email: voice@pharmaessentia.com

External grievance channels

- Dedicated ESG portal for information disclosures and contact: Includes latest news, download section, newsletters, interactive section, and contact section
- Reports of unlawful infringements in the workplace: hr@pharmaessentia.com

3. Review and improvement

Receiving units transfer all grievance cases to responsible units for review of case content and proposal of improvement measures, and communication with employees or external stakeholders to ensure compliance and disclose content in sustainability reports as appropriate so stakeholders can fully grasp information about our company.