2.3 Risk Management

Risk Governance Unit:

The Board of Directors serves as the highest supervisory and decision-making body for risk management, endorsing the overall objectives and policies for risk management and continuously overseeing the effective operation of risk management mechanisms. The Audit Committee, the Audit Office, and the Corporate Governance Director are established under the Board to manage both existing and potential risks, thereby strengthening internal control mechanisms to reduce risks, proactively mitigate negative impacts, and prevent financial losses.

Risk Management Policies and Practices:

The company has established internal risk management policies, procedures, and control systems in accordance with relevant standards, managing all risk issues, impacts, and corresponding significant topics properly. Annually, the overall risk management objectives and policies are ratified by the Board of Directors. Board of Directors assigns the senior management responsible for the major issues management and continues to ensure the effective operation of the risk management mechanisms through the regular supervision.

Risk Identification and Classification:

PharmaEssentia adopts the 2018 COSO Enterprise Risk Management (ERM) framework, along with the biotech industry-specific requirements, to classify risks into nine categories. For each category of risk, different mitigation strategies are employed to reduce their impact on the company.

Risk Category	Definition	Mitigation Strategy
Industry Risk	High-risk industry due to the high investment and uncertainty in drug development timelines.	• Besremi is already on the market; ongoing development using PEGylation technology platform to develop other long-acting protein drugs, expanding new indications to maximize R&D efficiency, and reducing single product market risk.
Market Risk	New drug development is time-consuming and has a low success rate. If successful, the product must compete with existing or alternative products.	• Develop new products focusing on orphan drugs, which typically have fast-track review benefits, potential for free pricing, and market exclusivity upon market entry. • Collaborate with external companies to diversify product offerings.
R&D Risk	Includes risks from clinical trial progress or results differing from expectations, competitors' advancements, difficulty in retaining/ developing R&D talent, and heavy reliance on CRO/CMO.	• Develop drugs for various indications to diversify risk. • Recruit biotech industry talent to create and maintain conducive R&D environment. • Select cooperative trial organizations to foster long-term partnerships.
Financial Risk	Risks involving exchange rates, inflation, R&D investments, and operational capital requirements causing financial losses.	• Financial unit interacts closely with forex banks, monitors market trends, and strictly manages financial resources and budget execution.

Risk Category	Definition	Mitigation Strategy
Legal Risk	Risks from international arbitration that could lead to reputational damage or financial loss.	• Engage a professional legal team to handle international arbitration issues to protect and maximize shareholder interests.
Policy Risk	Risks from geopolitical situations or changes in national policies.	• Stay updated with international political and economic news, monitor impacts on production supply chains, and adjust business strategies swiftly. • Establish a regulatory affairs department to keep track of drug approvals and changes in health insurance policies.
Technology Change Risk	Risks including information security, digital transformation, talent skills, supply chain disruptions, or regulatory changes affecting operations.	• Establish an information security management team responsible for promoting, governing, and monitoring information security, continually strengthening information security management to protect trade business secrets and stakeholder interests.
Environmental Risk	Risks from climate change, natural disasters, or pandemics.	• Implement the TCFD framework to enhance climate risk management, pass ISO 14064-1 inspections at Taichung plant, and implement various energy-saving and carbon-reduction measures. • Strengthen SCM to maintain safety stock and develop alternative material sources.
Other Risks	Risks not categorized above that could cause significant losses.	• Implement corresponding emergency measures based on the severity of the situation.

Remediation of Negative Impacts GRI 2-25, 2-26

The company has established a comprehensive remediation process for negative impacts, structured in three phases: prevention, grievance, and corrective action. This approach ensures effective responses to both potential and emergent issues.

1. Prevention

Strict Policy Formulation

Implementing detailed policies requiring employees and suppliers to strictly adhere to standards related to business integrity, pharmaceutical marketing ethics, human rights, and environmental protection to prevent any violations.

Robust Information Security Control

Enforcing stringent information security management and control measures to ensure data security and protect privacy rights.

Comprehensive Risk Management

Utilizing the COSO ERM framework to perform thorough assessments coupled with conducting numerous educational trainings to ensure all employees are aware of the preventive measures against risks.

2. Establishment of Grievance Mechanisms

Multiple Internal and External Reporting and Grievance Channels
(Create diversified two-way communication channels for colleagues and listen to the voices of employees)

Internal Communication Channels

- Labor-management meetings
- Welfare committee meetings
- Employee suggestion e-mail box: voice@pharmaessentia.com

External Grievance Channels

- ESG dedicated web portal for disclosures and contact: includes updates, downloads, newsletters, interactive sections, and contact information.
- Reporting of workplace legal violations: hr@pharmaessentia.com

3. Review and Improvement

Case Handling: Complaint cases are forwarded by the receiving units to the responsible departments based on the nature of the issues. Proposed corrective measures are discussed with employees or external stakeholders.

Documentation and Compliance: The audit office maintains records of the outcomes to ensure compliance and reasonableness. These are disclosed timely in the sustainability report to enable stakeholders to have complete access to the company's information.