Identifying and responding to opportunities and risks in the value chain

Sumitomo Pharma recognizes opportunities and risks in the value chain, which includes research and development, production and quality control, sales, marketing, corporate regulatory compliance & quality assurance and medical science, and takes measures to reduce risks, including for M&As and alliances. The direction of our responses for each area is as below.

➡ **Please see page 103 for more details on the significant risks that could negatively impact the operating results, cash flow and financial position of Sumitomo Pharma Group.**
➡ **Please see page 113 for more details on our value chain initiatives.**

Value chain	Opportunities	Risks	Direction of responses
Research and development	• There are high unmet medical needs in the three focus areas (psychiatry & neurology, oncology, and regenerative medicine/cell therapy) with significant impact on healthy life expectancy. • Open innovation with academia and biotech companies is gaining momentum. • Support from regulatory authorities, public institutions, governments and others can be actively utilized.	• The focus areas of psychiatry & neurology and oncology are areas with a higher degree of uncertainty in research and development, and there is a high degree of difficulty in research and development. As regenerative medicine/cell therapy is a new field, the rules on regulatory approval and drug price listing are not completely in place. • If clinical development fails, there are significant losses due to soaring research and development expenses. • Non-pharmaceutical disease prevention and treatment methods are emerging (which is an opportunity for Frontier business).	• We will expand our pipeline by leveraging our outstanding technology and know-how and focusing on research and development in our three research focus areas. • We will establish a strategic development plan under our global development framework, which includes coordination with our partners, to implement efficient clinical development. • We will manage our portfolio appropriately by reviewing research and development policy as is appropriate to match the timing of development stage transitions.
Production and quality control	• We are building a framework for stable supply by strengthening our global supply chains in collaboration with partners in Japan and overseas.	• The stable supply of products can be impacted by supply chain disruptions caused by natural disasters such as a major earthquake or flooding, unforeseen accidents, deterioration of social conditions, or pandemics. • Product quality issues can lead to product recalls, administrative penalties, and loss of social trust.	• To ensure stable and safe procurement, we use multiple suppliers and consider alternative products and stockpiling. We secure safe inventory of products based on risk. • We use audits of our suppliers to check on quality, the environment, and safety, and to request improvements. • We have established a global quality assurance system which complies with the laws and regulations of each country. • We are making efforts to prevent the occurrence of counterfeit pharmaceuticals.
Sales and marketing	• Unmet medical needs are increasing due to the aging of the population and responses to rare diseases. • Treatment opportunities are growing to meet the need for early detection and prevention.	• There is a global policy trend to control drug prices to reduce healthcare costs. • Changes in the competitive environment, such as the emergence of major competing products, could lead to delays in market penetration and decrease in revenue.	• We will expand our pipeline to enable contribution to revenue at an early stage. • We will commercialize healthcare solutions that provide new value to society with a focus on areas where synergies with our pharmaceutical business can be expected.
Corporate Regulatory Compliance	• We can identify unmet medical needs by collecting information from patients, their families, and healthcare professionals.	• There can be unexpected side effects after a product is launched. • There is an increasingly high level of management due to the diversifying supply chain.	• We will evaluate safety information collected from Japan and overseas through centralized database management. • We will plan the measures needed to ensure the safety and proper use of pharmaceuticals, and implement safety measures in a timely manner.
Medical Science	• Expanding usage of real-world data • Growing proliferation of digital devices • Expanding online diagnosis and treatment • Unmet medical needs are coming to light with advancements in exams and diagnosis technologies	• The needs of patients and healthcare professionals are diversifying • Society is requiring higher-quality scientific evidence • Rapid advances in science and technology shorten the period of evidence obsolescence.	• Identify the healthcare situation and identify health care needs using real-world data • Develop human resources and build systems for swiftly creating high-quality scientific evidence that satisfies healthcare needs • Identifying digital technologies and quickly utilizing digital technologies that show promise for growth
M&A and alliances	• We can maximize profit and reduce business risk by partnering on a global scale. • We can acquire pipeline products utilizing our strong marketing base.	• The development of acquired pipeline products may be delayed or terminated. • Acquired pipeline products may fall short of revenue contribution forecasts after launch.	• Through strategic investment, we will acquire pipeline products in late-stage development which can be expected to contribute to revenue at an early stage. • We will improve profitability by selling products for which the exclusive marketing period has expired and research and development assets.