

# Major Risks and Countermeasures

There are 18 major risks that ONO indicated in the Securities Report in FY2020.

Among others, the following six items were judged to have particularly high impact and risk.

We also identified risks unique to ONO and new risks in addition to the aforementioned risks.

Risk factors	Risk outline	Countermeasures
Development of new products	<ul style="list-style-type: none"> <li>Long-term and significant investment in research and development did not result in the release of inventive new drugs and development was abandoned.</li> </ul>	<ul style="list-style-type: none"> <li>Strengthening a system to engage in our drug discovery by focusing on research fields.</li> <li>Adopting the world's most advanced technologies and knowledge and promoting open innovation to increase the speed of new drug development and the probability of success.</li> </ul>
Changes in market environment	<ul style="list-style-type: none"> <li>Decreases in product competitiveness due to sales conditions of competing products and generic products.</li> </ul>	<ul style="list-style-type: none"> <li>Maximize product value by conducting proactive research and development activities, prompt cooperation between departments throughout the company.</li> <li>Review of strategy that can ensure competitive superiority for each product stage including research and development.</li> <li>Protecting resources to maximize the potential of product.</li> </ul>
Compliance	<ul style="list-style-type: none"> <li>Decreases in trust if our Group and contractors cause a critical violation of laws.</li> <li>Restriction of business activities due to amendment of laws and regulations, etc. and investment in countermeasures.</li> </ul>	<ul style="list-style-type: none"> <li>Development and practice of the compliance system based on the ONO PHARMACEUTICAL Code of Conduct.</li> <li>Establishment of the compliance promotion system.</li> <li>Thorough compliance with laws and regulations related to business activities.</li> </ul>
Product quality control	<ul style="list-style-type: none"> <li>In the event of serious quality problems or concern over the safety and security of products based on new scientific knowledge, the brand value of the product may decrease and the trust in entire our group may be damaged.</li> </ul>	<ul style="list-style-type: none"> <li>Establishment and continued improvement of the quality control system based on the original quality control manual.</li> <li>Development of the system to promptly respond to cases that concern product quality, efficacy, and safety.</li> </ul>
Acquiring and fostering human resources	<ul style="list-style-type: none"> <li>Stagnation of business activities if diverse and excellent human resources cannot be acquired and fostered in the medium- and long-term.</li> </ul>	<ul style="list-style-type: none"> <li>Development of a support system and work environment where multiple workstyles are allowed.</li> <li>Implementation of the training system based on individual growth and capability.</li> <li>Promotion of women's participation and advancement, promotion of the activities of people with disabilities, and promotion of employing mid-career individuals.</li> </ul>
Natural disasters and accidents in association with large-scale earthquakes and climate change	<ul style="list-style-type: none"> <li>Stagnation of business activities due to natural disaster in association with large-scale earthquakes and climate change, explosions and fire accidents at production plants, information and control system troubles, problems at raw materials suppliers, functional failure of society's infrastructure such as electricity, water, etc., environmental pollution by hazardous substances, terrorism, political turmoil, riot, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Establishment of disaster measures and business continuity plan (BCP) for production plants and major business bases.</li> <li>Actions for climate change risks based on the proposal of TCFD.</li> <li>Strengthening ability to handle emergency situations by development of the 2 bases system, introduction of the Safety Confirmation System, and conducting periodic disaster-drills.</li> </ul>

Part of the major risks identified in the Securities Report are extracted and indicated in the above table. For more details, please see the following Securities Report (only in Japanese) and ONO's sustainability website.

[https://www.ono.co.jp/sites/default/files/ja/ir/library/securities\\_report/ns\\_ver4\\_210618.pdf](https://www.ono.co.jp/sites/default/files/ja/ir/library/securities_report/ns_ver4_210618.pdf)