Overview of Business Domains

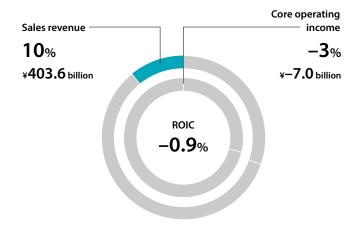
Note: The figures for each segment are based on the results for fiscal 2021.

Health Care Domain

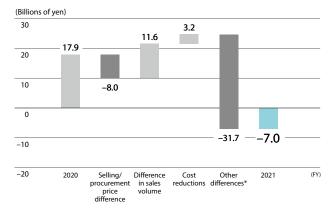
- Pharma
- Regenerative Medicine



In the Health Care domain, we not only work to provide treatments for diseases but also products and services that help people around the world live longer and healthier lives.



Health Care: Factors underlying the YoY change in core operating income (loss)



^{*} Includes differences in inventory valuation and gains/losses on equity-method investments

Health Care segment

Sales revenue amounted to ¥403.6 billion, a year-on-year increase of ¥13.0 billion, while we recorded a core operating loss of ¥7.0 billion, a decrease of ¥24.9 billion.

The pharmaceuticals business posted increased sales revenue due to growth in the sales volume of priority products, which outweighed the impact of negative factors including National Health Insurance drug price revisions in the Japanese ethical pharmaceuticals market. Core operating income

decreased, mainly due to R&D expenditures on the COVID-19 vaccine project. Note that some royalty revenue from Novartis Pharma AG for Gilenya®, a treatment agent for multiple sclerosis, has not been recognized as sales revenue in accordance with IFRS 15 (Revenue from Contracts with Customers) due to the start of arbitration proceedings in February 2019. In fiscal 2021, likewise, some royalty revenue was not recognized as sales revenue due to the ongoing arbitration proceedings.

Overview of Business Domains

Health Care Domain

Pharma business Pharma business Delayed expansion into global markets New drug creation capabilities in the pharmaceuticals business • Strong presence in priority drug markets including central nervous system and immuno-inflammation **Regenerative Medicine business** Regenerative Medicine business Labor shortage Strengths Weaknesses medicine field • Research experience with Muse cells **Pharma business Pharma business** Demand for provision of diverse healthcare Opportunities **Threats**

Unmet medical needs **Regenerative Medicine business**

due to technological advances

Increasingly diverse drug discovery activities

- Diversifying needs in healthcare and medical sectors
- Unmet medical needs
- Growing expectations for the development of regenerative medicine products

- Declining probability of success with drug discovery
- Increasing R&D expenditures
- Various government measures to control healthcare expenditures

Regenerative Medicine business

- Various government measures to control healthcare expenditures
- Risk of delay in establishing industrial structure for regenerative medicine

Finding solutions for a sustainable future

New ALS treatment option for patients in the United States



In June 2022, we released RADICAVA ORS in the United States. RADICAVA ORS is an oral suspension formulation containing the same active ingredient as Edarayone Infusion RADICUT (RADICAVA in the United States), which is a treatment for amyotrophic lateral sclerosis (ALS). RADICAVA ORS is specifically formulated for patients with ALS and provides a flexible administration option with a small, 5mL dose (taken orally or via feeding tube), a portable bottle, an oral dosing syringe, and no need for refrigeration or reconstitution.

We undertook its development with the aim of reducing burdens on ALS patients such as injection pain and outpatient visits. Previously, intravenous infusion was the only available route of administration, but now there is the option of taking the drug orally.

Focus

Contributing through vaccines to infectious disease prevention Development of a VLP vaccine to prevent COVID-19 infection

The COVID-19 vaccine COVIFENZ received approval in Canada in February 2022. We have concluded a supply contract with the Canadian government, and preparations for a swift launch of supply are underway. We are also preparing to file for approval in Japan, with Phase 1 and 2 trials launched in October 2021.

The plant-based VLP vaccine is a new type of vaccine produced using VLP manufacturing technology. VLPs have an external structure similar to that of a virus and the vaccine is expected to induce high immunogenicity. Since VLPs do not contain genetic materials, they do not proliferate in the body and are attracting attention as a promising vaccine technology with excellent safety. In addition, plant-derived VLP manufacturing technology is expected to enable mass production in a short period of time.

COVIFENZ is the world's first plant-based COVID-19 vaccine. Additionally, it can be stored and distributed under refrigerated conditions (2–8°C). By delivering the new option of a plant-based VLP vaccine, we will strengthen our contribution to the prevention of infectious diseases, which is an important social issue worldwide.

Plant-based VLP vaccine manufacturing process (utilizing transient gene expression)



Genes/plants



inserted into

the leaf tissue



products created

by the infiltrated

plant cells

accumulate

The recombinant The recombinant

products are

released into

the solution







Highly pure product is obtained

Advantages expected with VLP manufacturing technology

- The use of plants allows large-volume production in a short timespan.
- There is excellent safety, as there is no virus proliferation.





Common virus