



Pharmaceuticals

Through the Autonomous Operations of Each Company, We Pursue the Maximum Synergy between Pharmaceuticals and Chemistry.

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Primary Focus SDGs



Business Activities

Within the Pharmaceutical sector of Sumitomo Chemical Group, Sumitomo Dainippon Pharma Co., Ltd. develops and markets prescription drugs, and Nihon Medi-Physics Co., Ltd. develops diagnostic drugs, supporting people in leading healthy and active lives.

Core Competence

In the prescription drug business, our core competencies are our global business foundations, including the U.S., and our R&D capability, particularly in the areas of psychiatry & neurology, oncology, and regenerative medicine/cell therapy. In the diagnostic drug business, our core competencies are our solid experience and technologies cultivated over 50 years, and our ability to make the best use of the company's foundational technologies, including genome analysis and cell differentiation, in cooperation with the Group.

Basic Strategy

As part of our mid-term strategy, we are promoting active R&D and expanding our pipelines so that our business performance can recover quickly after the expiration of the sales exclusivity period for our main products. We are also promoting next-generation businesses, including regenerative cell medicine, frontier areas, efforts in the field of infectious diseases, and Theranostics.

Our Stance on Listing both Parent and Subsidiary

Sumitomo Dainippon Pharma is a subsidiary of Sumitomo Chemical, but it maintains managerial independence as much as possible by having a high proportion of independent officers on the Board of Directors and on the Nomination and Remuneration Committees. To improve corporate value as a Group, Sumitomo Dainippon Pharma and Sumitomo Chemical discuss important business matters in advance to align their future directions. Without abandoning minority interests, Sumitomo Dainippon Pharma is creating a system to generate synergies with Sumitomo Chemical.

Synergy of Business and Technology

Sumitomo Dainippon Pharma has strong ties with Sumitomo Chemical in terms of its technological genealogy. For instance, Sumitomo Dainippon Pharma's Regenerative Medicine/Cell Therapy business has its roots in safety research for crop protection products at Sumitomo Chemical. Sumitomo Chemical's Bioscience Institute has incorporated Sumitomo Dainippon Pharma's genome technology to increase synergy in research and to cultivate new businesses. Chemistry and pharmaceuticals are intertwined, and have the potential to generate a variety of businesses.

Long-term Vision

We aim to dedicate our efforts to better Quality of Life by making the maximum use of synergy as a Group and generating innovative medical and health care solutions.

Corporate Business Plan for FY2019-FY2021

Action Plan	Major Issues	Corporate Business Plan for FY2019-FY2021: Sector Goals FY2021 Target		
		FY2019	In Comparison to FY2018	
(Billions of yen)				
<ul style="list-style-type: none"> Strengthen innovation through new drug discovery approaches Launch new products in oncology Explore frontier fields Develop Theranostics business and strengthen the competitiveness of existing radioactive diagnostics business 	<ul style="list-style-type: none"> Enhance drug development capabilities and improve the success rate in R&D Maintain earnings power after Latuda's loss of exclusivity 	Sales revenue	515.8	+23.7
		Core operating income	75.3	-5.5
				590.0
				94.0

SWOT Analyses of the Major Businesses

- Drug research platform in the areas of psychiatry & neurology and oncology
- Development capabilities and manufacturing know-how for cellular medicine derived from allogeneic iPS cells
- Network with academia and biotech companies
- Pipeline in development for psychiatry & neurology, oncology, and regenerative medicine/cell therapy
- Strong development and manufacturing capabilities for radioactive isotope labeling agents

- Innovation in healthcare technology
- Increasing health awareness



- Limited capabilities to bear the burden of R&D costs
- Emergence of generic drugs due to the loss of exclusivity for major products

- Accelerated implementation of medical expense control measures in Japan
- Changes in the health insurance systems overseas
- Consolidation in the pharmaceutical industry

Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma Co., Ltd. is reshaping the foundations of its business by establishing growth engines and building a flexible and efficient organization as it prepares for future changes and the “post-LATUDA” era, after it loses exclusivity in the U.S.

■ Business Status

- Sumitomo Dainippon Pharma’s blockbuster, LATUDA® (atypical antipsychotic), has been selling well in the U.S., and sales for fiscal 2019 were \$1.7 billion USD. Some generic versions of LATUDA® are expected to enter the market in February 2023. Our post-LATUDA® product portfolio is under development.
- Several pipeline products were obtained through a strategic alliance with Roivant Sciences Ltd., which was completed in December 2019. Especially promising pipeline products are relugolix (uterine fibroids, prostate cancer) and vibegron (overactive bladder), which are under review for approval, and are expected to be launched after 2020.
- KYNMOBI™ (for off episodes in patients with Parkinson’s disease) was approved in the U.S. in May 2020 and is scheduled to be launched in the U.S. during this fiscal year.
- Napabucasin is under development, and is now in phase 3 clinical studies in patients with colorectal cancer. The goal is to launch it in the U.S. in fiscal 2021, and in Japan in fiscal 2022. It is expected to be a blockbuster.
- SEP-363856 (schizophrenia) is designated as a breakthrough therapy* by the US Food and Drug Administration (FDA). It is now in phase 3 clinical studies in patients with schizophrenia, and is expected to be launched in fiscal 2023 in the U.S.

* The FDA designates drug candidates as breakthrough therapies to expedite the development and review of drugs for serious or life-threatening conditions.

■ Initiatives with Cutting-edge Technology

- In addition to applying iPS cell technology in our drug discovery, we are working on R&D in regenerative and cell medicines. Working jointly with universities and research institutes, we are working to develop cell therapy products using iPS cells for the treatment of age-related macular degeneration, Parkinson’s disease, retinal pigmentary degeneration, spinal cord injuries, and renal failure.
- In cooperation with universities and research institutes, we are conducting joint research in the area of infectious diseases, concerning a treatment for antimicrobial resistant (AMR) infections, a universal influenza vaccine, and malaria vaccines.

Nihon Medi-Physics

Nihon Medi-Physics is a leading Japanese company in the highly specialized field of nuclear medicine.

■ Business Status

- Our flagship product is FDG Scan™ Injection, used in PET scans, and is considered useful in the early diagnosis of malignant tumors and the selection of a treatment policy. Its half-life is as short as about 2 hours. With 11 manufacturing sites established across Japan, we ensure a stable supply.
- We have advanced a research project adopted by the Agency for Medical Research and Development (AMED) as part of its Cyclic Innovation for Clinical Empowerment (CICLE) program in fiscal 2017, and are endeavoring to develop new radiopharmaceuticals that “integrate therapy and diagnosis (Theranostics)” by fully utilizing the characteristics of nuclear medicine. A new Theranostics research site (CRADLE facility) was completed in September 2019, and started operation in January 2020.
- We are also challenging new opportunities beyond our existing business framework, for instance through pursuing strategies to improve healthcare solution services with digital technology, and to establish business alliances to enter the wider Asian nuclear medicine market.

Value Creation Model: Sumitomo Dainippon Pharma

System for Providing Added Value

Major Management Resources (Input)

Intellectual Capital	Research and development capabilities, in order to discover new drugs, and intellectual property, such as patents and licenses, are the source of income.
Social and Relationship Capital	Besides good relationships with universities and other institutions that contribute to the development of new drugs, good relationships with authorities and healthcare professionals support global business development.
Human Capital	Outstanding personnel support all business activities, including the research and development of new drugs, production, and sales.

Value Chain



Suppliers

Chemical manufacturers
Manufacturers of drug raw materials
and intermediate materials



Sumitomo Dainippon Pharma

Sumitomo Dainippon Pharma's Competitive Advantages

■ Competitive Conditions in the Market

The global pharmaceutical market is over 1.2 trillion USD, and has grown at an annual rate of about 4% over the last five years.* Within that, significant market growth is expected in the specialty pharmaceutical market, aimed at specific illnesses and requiring a prescription from a specialist. Numerous pharmaceutical manufacturers are participating in this massive market, particularly in the U.S. and Europe, engaging in fierce competition in the development of new drugs.

■ Competitive Advantages

Sumitomo Dainippon Pharma, although small in scale compared with leading global pharmaceutical companies, has strong R&D in the psychiatry & neurology area, where it has accumulated knowledge over many years. In addition, we conduct R&D by focusing on our proprietary technology in the oncology area to discover innovative new drugs. Moreover, the company is a global leader in the commercialization of cell therapy products derived from iPS cells in regenerative medicine and cell therapy field, which is becoming prominent as a next-generation therapy.

■ Initiatives to Enhance Competitive Advantages

Sumitomo Dainippon Pharma conducts competitive drug discovery based on the foundation of our unique drug discovery platform, which has been built by incorporating cutting-edge technologies in the psychiatry & neurology area. In oncology, our company is actively involved in network-based drug discovery among Sumitomo Dainippon Pharma, our U.S. subsidiary and external institutions, taking an integrated approach to R&D. In the regenerative medicine and cell therapy field, the company aims to achieve commercialization as soon as possible with a unique growth model, pursuing advanced production technologies through open innovation, while also conducting multiple R&D projects.

Major Processes Generating Competitive Advantages

Research: Searching for compounds for new drug candidates is the first step of drug discovery, and candidate compounds are selected in preclinical studies. Sumitomo Dainippon Pharma promotes internal innovation and works to discover innovative treatments by pursuing joint research with research institutes, including universities in and outside Japan, and alliances with biotech companies.

Development: The company scientifically evaluates the efficacy and safety of new drug candidates discovered in laboratories in clinical studies. We aim to promote efficient development, and obtain speedy approval of new drugs.

Production and Quality Management: The company provides stable supplies of pharmaceuticals of reliable quality. In addition, we maintain a quality assurance system supporting the safety and security of its pharmaceuticals.

Sales and Information Provision: The company has sales locations in Japan, the U.S., and China, providing information necessary for the proper use of its pharmaceuticals.

Earnings Structure and Role in Driving Income

While pharmaceuticals discovered in-house can provide high returns in the period when exclusive sales are possible due to patents or other intellectual property, profitability deteriorates significantly once a patent has expired. For this reason, Sumitomo Dainippon Pharma hopes to maintain and improve income by continually developing and launching new drugs.

* (Source) Created based on the IQVIA World Review 2013-2018, Copyright©2020 IQVIA (unauthorized reproduction prohibited)
(Source) Japan Pharmaceutical Manufacturers Association DATA BOOK 2020

Added Value Provided to Society

Sumitomo Dainippon Pharma manufactures the pharmaceuticals it has developed using medical raw materials and intermediate materials, and then supplies them to hospitals and pharmacies via pharmaceutical wholesalers. In addition, it provides pharmaceutical information to healthcare professionals so that its pharmaceuticals will be used properly.



Pharmaceutical
wholesalers

Hospitals and
pharmacies

Patients

Customer and Consumer Needs

Healthcare professionals and patients demand pharmaceutical products that are easier to use, have higher therapeutic efficacy, and fewer adverse reactions. There is a strong demand for the development of new drugs for diseases for which no effective treatment is currently available. It is also necessary to properly use pharmaceutical products and provide information that can lead to safer and more effective treatment.

Providing Customer Value

Sumitomo Dainippon Pharma focuses its R&D resources into the areas of psychiatry & neurology, oncology, and regenerative medicine/cell therapy, where unmet medical needs are high. We also work to accelerate the development of best-in-class drugs that focus on value, and drug discovery in the field of infectious diseases. In addition, the company is engaged in business on the frontiers of healthcare beyond pharmaceuticals. We aim to contribute to better Quality of Life for patients through the creation of innovative drugs and healthcare solutions in these areas.



Contributing to the Advancement of Cutting-edge Healthcare and Better Quality of Life for Patients

Sumitomo Dainippon Pharma contributes to the treatment of patients with various diseases by providing high-quality medicine and drug information. In addition, the company contributes to the development of advanced healthcare by utilizing the technologies and knowledge cultivated over many years in Sumitomo Chemical's life science field. Through synergy between Sumitomo Dainippon Pharma and Sumitomo Chemical, we work on "contribution to solving healthcare issues," one of the material issues to be addressed as management priorities.

