Pharmaceuticals

Businesses | Prescription Drugs | Diagnostic Drugs | CDMO (Contract Development and Manufacturing Organization) Business

Strengths of the Pharmaceuticals Sector

In the prescription drug business, we have experience and knowledge in psychiatry & neurology and oncology, which are areas of high unmet medical need, as our priority disease areas. In the diagnostic drug business, our core competencies are our solid experience and technologies cultivated over 50 years. In addition, our ability to cooperate with Sumitomo Chemical Group to make the best use of the company's foundational technologies, including genome analysis and cell differentiation, is one of our major strengths.

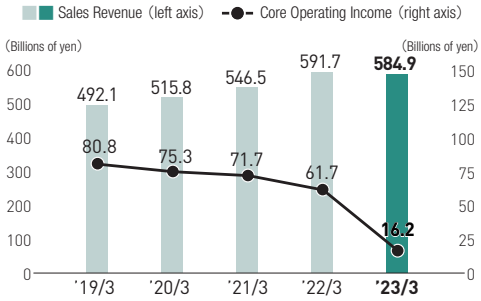
Synergy of Business and Technology

Sumitomo Pharma has strong ties with Sumitomo Chemical in terms of its technological genealogy. For instance, Sumitomo Pharma's regenerative medicine/cell therapy business has its roots in safety research for crop protection products at Sumitomo Chemical. Sumitomo Chemical's Bioscience Research Laboratory has incorporated Sumitomo Pharma's genome technology to increase synergy in research and to cultivate new businesses. Furthermore, we have recently launched a CDMO business for regenerative medicine/-cell therapy products, combining Sumitomo Pharma's knowledge of regenerative medicine/cell therapy with our knowledge of contract manufacturing. Moving forward, we will continue to generate the variety of synergy between pharmaceuticals and chemistry.

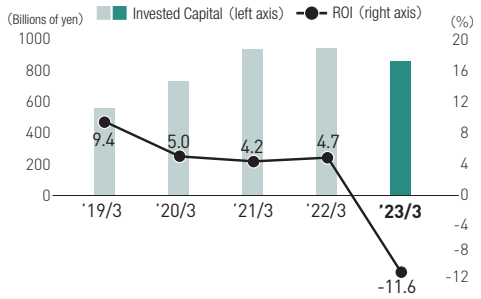
Future Initiatives

Our top priority is to establish a revenue base after the end of LATUDA® exclusivity period in the U.S. ORGOVYX® (a treatment for prostate cancer), MYFEMBREE® (a treatment for uterine fibroids and endometriosis), and GEMTESA® (a treatment for overactive bladder) are positioned as our three key products and we are aiming for sales exceeding those of LATUDA® and maximizing the potential of the agents through alliances with other companies and expansion of indications. In addition, with an eye on medium- to long-term growth, we will focus on creating new products in the psychiatry & neurology area, as well as next-generation medicine such as regenerative medicine/cell therapy and Theranostics, and further strengthen the CDMO business, which is expected to grow.

Sales Revenues and Core Operating Income



Invested Capital・ROI



Transition to date

Invested capital increased due to large acquisitions for post-Latuda, etc ROI fell to negative in FY2022 due to the impact of the loss of U.S. exclusivity for LATUDA® as well as the impact of impairment losses associated with the discontinuation of development of low-performing products and items in development.

Future Measures and Issues

We aim to achieve a V-shaped recovery toward FY2024 through further sales expansion of LATUDA® successor products and streamlining effects from the combination of subsidiaries in North America. In addition, we will expand our pipeline for future growth and build a stable earnings base by expanding peripheral businesses such as S-RACMO.

Establishment of revenue base after the end of LATUDA® exclusivity in the U.S.

As post-LATUDA agents we will maximize revenues from ORGOVYX®, MYFEMBREE®, and GEMTESA®. In addition, the Company will also promote rationalization, including improvement of management efficiency and optimization of business costs, in order to become a business entity suitable for post-LATUDA.

Progress

- Received approval for an additional indication of endometriosis for MYFEMBREE® in the U.S.
- Myovant Sciences Ltd.,(currently, Sumitomo Pharma America, Inc.) which handles ORGOVYX®, MYFEMBREE® became a wholly owned subsidiary.
- Consolidation of Sumitomo Pharma's North American subsidiaries into a single company
- Promote rationalization such as improvement of management efficiency and optimization of business costs (transfer of shares of Sumitomo Pharma's domestic subsidiaries, transfer of sales rights for respiratory drugs, etc.)

Strategies for Medium- and Long-Term Growth

Looking ahead to what comes after ORGOVYX®, MYFEMBREE®, and GEMTESA®, we will continue to create new products in the psychiatry & neurology area. In addition, we will seek to maximize product value as quickly as possible by accelerating development and reducing risk, including the active use of external resources. Furthermore, we will achieve medium- to long-term growth by taking on the challenge of developing and commercializing new therapeutic methods, such as regenerative medicine/cell therapy, and Theranostics.

Progress

- Initiated clinical trials for two additional indications for ulotaront (adjunctive major depressive disorder and generalized anxiety disorder)
- Construction begins on a cGMP-compliant cell processing center in the U.S.

Joint development and commercialization alliance with Otsuka Pharmaceutical Co., Ltd.

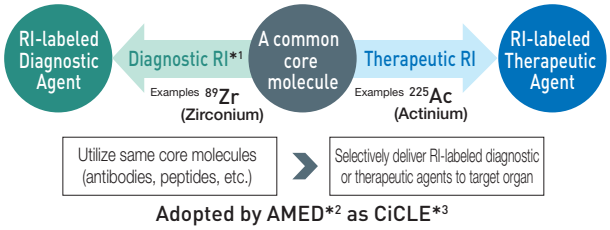
Ulotaront is a next-generation antipsychotic that has received Breakthrough Therapy*1 designation from the U.S. Food and Drug Administration(FDA). In 2021, we agreed to co-develop and co-market ulotaront and other neuropsychiatric compounds with Otsuka Pharmaceutical, which has strengths in this area. We will leverage this alliance to develop the drug into a new blockbuster for medium- to long-term growth.

Development products	Proposed indications	Scheduled to be launched
ulotaront	Schizophrenia	(U.S.) FY2024*2 (Japan) FY2027
	Adjunctive major depressive disorder	(U.S.) Late 2020s
	Generalized Anxiety Disorder	(U.S.) Late 2020s
SEP-4199	Bipolar I Depression	(U.S.) Late 2020s

*1 The U.S. FDA's program to facilitate the development and review of drugs for serious or life-threatening diseases
*2 To be revised for launch target based on consultation with the FDA, etc.

Theranostics

As a next-generation therapeutic approach, we aim to develop new radiopharmaceuticals that "integrate therapeutics and diagnostics (Theranostics)" by taking advantage of the characteristics of nuclear medicine. In the CRADLE building, our drug research facility, we are working diligently on research and development to deliver optimal medical care to patients as soon as possible.



*1 RI: Radioactive isotope
*2 AMED: Japan Agency for Medical Research and Development
*3 CiCLE: Cyclic Innovation for Clinical Empowerment

Progress

- Successfully manufactured at an investigational manufacturing scale of ^{225}Ac
- U.S. FDA accepts Clinical Trial Application for NMK89 under development as a diagnostic agent

Strengthen CDMO business

In the fields of next-generation pharmaceuticals such as regenerative medicine/cell therapy and targeted alpha-particle therapy, which are expected to show remarkable growth in the future, we will maximize the synergy between chemistry and pharmaceuticals to aggressively develop our CDMO business.

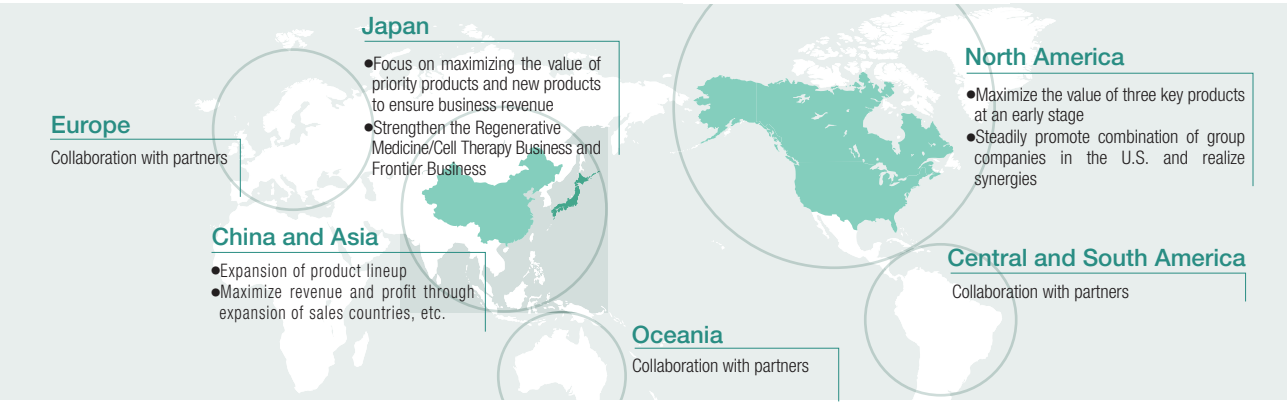
S-RACMO Co., Ltd.

S-RACMO, a joint venture of both companies, conducts CDMO business in the field of regenerative medicine/cell therapy by combining Sumitomo Chemical's fundamental technologies for iPS/ES cells and expertise in contract manufacturing of pharmaceuticals with Sumitomo Pharma's experience in advanced manufacturing method development and formulation development gained through multiple projects in the regenerative medicine/cell therapy business. Orders are steadily increasing at FORCE (Facility of Regenerative and Cellular Medicine Organization), a regenerative and cellular medicine manufacturing facility that began operations in 2022. We will continue to work to further expand our presence in this fast-growing field.

Facility of Regenerative and Cellular Medicine Organization (FORCE)

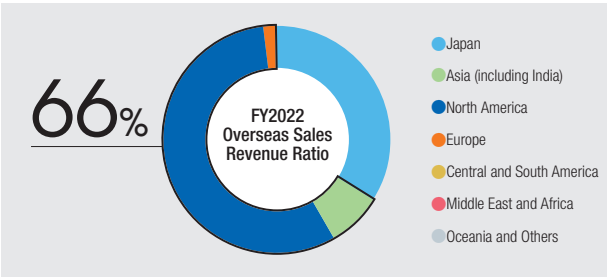
Status of Global Expansion

Regional Strategy Centering in Japan, North America and China



About 70% of the sales revenue in our Pharmaceuticals sector comes from outside Japan, and one of the features of our Pharmaceuticals sector is its global reach, centered in Japan, North America, and China. Although the ratio of overseas sales revenue is expected to decline temporarily in FY2023 due to the end of LATUDA®'s exclusive sales period in the U.S., we will not relax our efforts to achieve further growth by expanding our three key products and building new facilities for manufacturing regenerative medicine/cell therapy and we will re-grow revenue in the U.S., the country with the largest demand worldwide. In addition, growth in demand for pharmaceuticals throughout Asia has been significant, including China, which has the world's second-highest level of demand, so it is a region where we expect sustained growth going forward. Currently we are building our sales structure to increase our presence in the market, enhancing the capabilities of our subsidiaries and strengthening collaboration with local partners. For other regions, we plan to maximize revenue by collaborating with partners.

Sales Revenue Ratio by Region



Q&A

Q : Please tell us about your efforts to achieve a V-shaped recovery in FY2024.

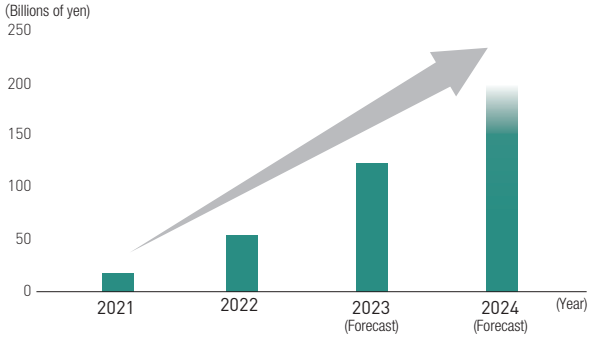
A: We will strengthen profitability through further sales expansion and rationalization of our three key products (ORGOVYX®, MYFEMBREE®, and GEMTESA®). With regard to sales expansion of the three key products, we partnered with Pfizer Inc. in 2020 to co-develop and co-market ORGOVYX® and MYFEMBREE®, and last year, MYFEMBREE® was approved in the U.S. for an additional indication for the treatment of endometriosis. In addition, we have just strengthened our revenue base and accelerated our management speed by making Myovant, which handled ORGOVYX®, MYFEMBREE®, a wholly owned subsidiary. In this year, we will focus on further increasing awareness of the strengths of our three products, and will enhance the presence of our products by promoting them to a wide range of interested parties. In this way, we aim to achieve sales revenue of 200 billion yen for the three products in total in FY2024.

In rationalization, seven of Sumitomo Pharma's U.S. subsidiaries were combined into one company in July of this year to improve profitability and strengthen the business foundation through efficiency and cost synergies. By reducing duplicated operations, simplifying the chain of command and order, etc., we expect to achieve an annual rationalization effect of approximately US$400 million by FY2024, compared to FY2022.

In addition, the Phase 3 trial of ulotaront, our next blockbuster drug candidate, is scheduled to be completed this year, and if approved, is expected to contribute from FY2024*. In the future, we also plan to launch products in regenerative medicine/cell therapy and frontier businesses. We will work to build a solid earnings base over the medium- to long-term by ensuring that our diverse pipeline leads to product launches.

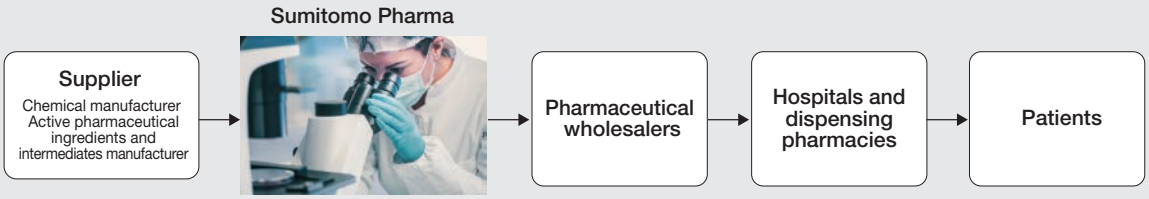
*To be revised for launch target based on consultation with the FDA, etc.

Estimation of revenues from three key products



Value Creation Model: Sumitomo Pharma

Value Chain



Sumitomo Pharma manufactures pharmaceutical products developed by itself using bulk pharmaceuticals and intermediates as raw materials and provides them to hospitals and dispensing pharmacies through pharmaceutical wholesalers. The company also provides information on the proper use of its pharmaceutical products to medical professionals and patients.

System for Providing Added Value

Sumitomo Pharma's Competitive Advantages

Although Sumitomo Pharma is smaller in scale than global major pharmaceutical manufacturers, its strength is its strong sales platform in the U.S., the region with the greatest demand for pharmaceuticals. In addition, Sumitomo Pharma is at the forefront of development of regenerative medicine/cell therapy which is expected to see market growth as cutting-edge healthcare, and is currently making progress in clinical development while also collaborating with academia and biotech companies.

Major Processes Generating Competitive Advantages

In the business of regenerative medicine/cell therapy, Sumitomo Pharma has both the Regenerative & Cellular Medicine Kobe Center, a research facility, and the SMaRT facility, the world's first commercial manufacturing facility dedicated to regenerative medicine/cell therapy products derived from allogeneic iPS stemcells and last year, construction began on a new cell product manufacturing facility in the United States. In addition, in the U.S., we received approval in October 2021 for RETHYMIC®, a regenerative medicine product for the indication of pediatric congenital atresia, and furthermore, we are currently conducting a Phase 1/2 study (investigator-initiated clinical trial) for Parkinson's disease and a clinical trial for retinal pigment epithelium tear in Japan. In this way, based on our top-runner manufacturing capabilities and the responsiveness we have cultivated in Japan and the U.S., we will further strengthen this business by expanding it globally from Japan.

Providing Customer Value

We aim to contribute to improving the quality of life of patients by providing new value globally that can only be achieved through regenerative medicine based on open innovation, utilizing its abundant pipeline, drug discovery capabilities, cutting-edge technology and know-how, and its broad scientific network.

Added Value Provided to Society

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

Sumitomo 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 by Sumitomo Chemical over many years in the life science field. Through synergy between Sumitomo Pharma and Sumitomo Chemical, we work on contributing to solving healthcare issues, one of the material issues to be addressed as management priorities.