Steadily advancing toward realization of the medium- to long-term vision

2005 - 2006

Maximizing Synergies from the Integration

Strategy Outline

Based on the philosophy for the integration of "aiming to become a global R&D oriented pharmaceutical company," in Japan, we will look to achieve marketing synergies for the four main products (AMLODIN®, GASMOTIN®, PRORENAL®, and MEROPEN®) and new products, and realize cost synergies by narrowing down our strategic areas and effectively utilizing resources and functions. The two companies will also integrate their capital expenditure plans, thereby reducing investments that had been planned separately.

Achievements

After the merger in October 2005, we made steady progress in achieving synergies in the three areas of business, cost, and culture, and we worked to expand our presence with a team of 1,500 MRs that emphasizes improving customer satisfaction as the basis for marketing strategy. We also worked to integrate management of R&D and consolidate sites, completing the integration as of the end of the fiscal year ended March 31, 2007.

Challenges

It is necessary to clarify the medium- to long-term vision with the aim of maximizing post-integration synergies. In addition, becoming an internationally competitive R&D oriented company and taking measures to expand overseas revenue are important in order to move away from being a business that is centered on Japan.

Main new products

Japan
- Therapeutic agent for systemic fungal infection AmBisome®

2007 - 2009

First Mid-term Business Plan

Solid Fundamentals

Strategy Outline

We established a medium- to long-term vision for the next ten years. We will aim to establish a solid foundation of our domestic business, and to expand our own overseas sales organization. In research and development, we will strengthen our drug discovery capabilities and engage in aggressive in-licensing activities aimed at enriching our R&D product pipeline to realize future vision.

Achievements

We established and expanded our North American marketing base and R&D sites through submission of our own application for approval of LATUDA®, an atypical antipsychotic, in North America, accelerated development of our own sales organization, and acquisition of U.S. pharmaceutical company Sepracor Inc. (currently Sunovion Pharmaceuticals Inc.) In Japan, we introduced a regional headquarters system in the Sales & Marketing Division aimed at developing locally-based marketing and improving profitability.

Challenges

While we were able to establish the framework for overseas business expansion, including the acquisition of Sepracor in the U.S., we were unable to achieve our profit targets due to a higher-than-expected decline in sales of long-listed products in Japan. In research and development, although we reached the target number for products to be launched during the First Mid-term Business Plan period, we did not achieve good results during the plan period regarding in-licensing of development compounds.

Main new products

Japan
- Fabry disease drug REPLAGAL®
- Atypical antipsychotic LONASEN®
- Therapeutic agent for hypertension AVAPRO®
- Therapeutic agent for Parkinson's disease TRERIEF®

2010–2012

Second Mid-term Business Plan
Take Off

Strategy Outline

Under the theme of "Creation and transformation toward a new stage of globalization," the Company set the goals of working to maximize the product value of LATUDA®, strengthening profitability in North America, structural reform in the domestic business, expansion into Europe and Asia, and pursuit of management efficiency. For future growth, the Company will aggressively invest in the expansion of its development pipeline on the Psychiatry & Neurology area as a focus area, strategic alliances and in-licensing, and the development and strengthening of human resources.

Achievements

In Japan, sales of strategic products and new products expanded, and we strengthened marketing capabilities in the Psychiatry & Neurology area, which is a focus area. In North America, sales of LATUDA® grew steadily. We acquired U.S. biotech company Boston Biomedical, Inc. (currently Sumitomo Dainippon Pharma Oncology, Inc.), making a full-scale entry into R&D in the Oncology area, and newly established the DSP Cancer Institute in Japan.

Challenges

Although sales and profit progressed in line with plans in Japan, the risk of declining revenue from long-listed products increased rapidly, necessitating acceleration in the transformation of our earnings structure. Although sales in North America grew, we did not reach our profit targets due to a variety of factors. In the midst of major changes in our business structure with our full-scale entry in the Oncology area, we faced a shortage of late-stage development compounds.

Main new products

Japan
- Therapeutic agent for hepatocellular carcinoma MIRIPLA®
- Therapeutic agent for Type 2 Diabetes METGLUCO®
- Therapeutic agent for Type 2 Diabetes SUREPOST®
- Therapeutic agent for hypertension AIMIX®

North America
- Atypical antipsychotic LATUDA®

2013–2017

Third Mid-term Business Plan
Sustained Growth

Strategy Outline

Under the theme of "Quest for further innovation," we will aspire to be a globally competitive R&D oriented company and contribute to medical care through leading edge technologies. We will aim to globally grow businesses through LATUDA® and new products in the Oncology area. In research and development, we will promote exploration of the Regenerative Medicine/Cell Therapy field in addition to the Psychiatry & Neurology area and the Oncology area. We will strengthen the business foundation through a transformation to a leaner corporate structure.

Achievements

Although we achieved growth through significant expansion in sales of LATUDA® in North America, the launch of the oncology business did not proceed according to plan. In research and development, we expanded our pipeline through acquisitions and made progress in R&D in the Regenerative Medicine/Cell Therapy field. We also achieved acceptable results in pursuit of CSR and continuous management efficiency, establishment of a corporate culture that encourages willingness to take on a challenge, and human resource development.

Challenges

The environment surrounding the pharmaceutical industry is expected to change significantly over the next 15 years. We are facing a "Time for Change" in which the establishment of non-conventional new business models is imperative. Radical reform is needed to move away from a revenue structure dependent on LATUDA® and to achieve sustained growth.

Main new products

Japan
- Therapeutic agent for pruritus REMITCH® (additional indication) Promotion alliance
- Therapeutic agent for Type 2 Diabetes Trulicity® Sales alliance

North America
- Antiepileptic APTIOM®

China
- Atypical antipsychotic LONASEN®

Revision of Mid-term Business Plan 2022 in light of changes in business environment

Revision of Mid-term Business Plan 2022

Sumitomo Dainippon Pharma believes that the pharmaceutical industry is facing a Time for Change when the establishment of non-conventional new business models is imperative to adapt to diversifying healthcare needs that include not only the creation of innovative new drugs but also making preventative medical care more widely available and contributing to global health. In April 2019, we formulated our Vision and the five-year Mid-term Business Plan 2022 (fiscal 2018 to fiscal 2022) starting in fiscal 2018 based on this belief in order to solve social issues in the changing healthcare area.

Sumitomo Dainippon Pharma set a vision of becoming a global leader in our three focus research areas of Psychiatry & Neurology, Oncology, and Regenerative Medicine/Cell Therapy, as well as working on Frontier business where we expect synergies with development of pharmaceuticals and the pharmaceutical business, with the aspiration to establish a position as a "Global Specialized Player" in 2033.

Moreover, in order to adapt to the "Time for Change" ahead of the post-LATUDA situation (after the loss of the exclusive marketing period for atypical antipsychotic LATUDA® in the U.S.), we indicated that Sumitomo Dainippon Pharma will work to rebuild the business foundation through the "establishment of growth engine" and the "building of flexible and efficient organization."

Positioning of the revision of Mid-term Business Plan 2022

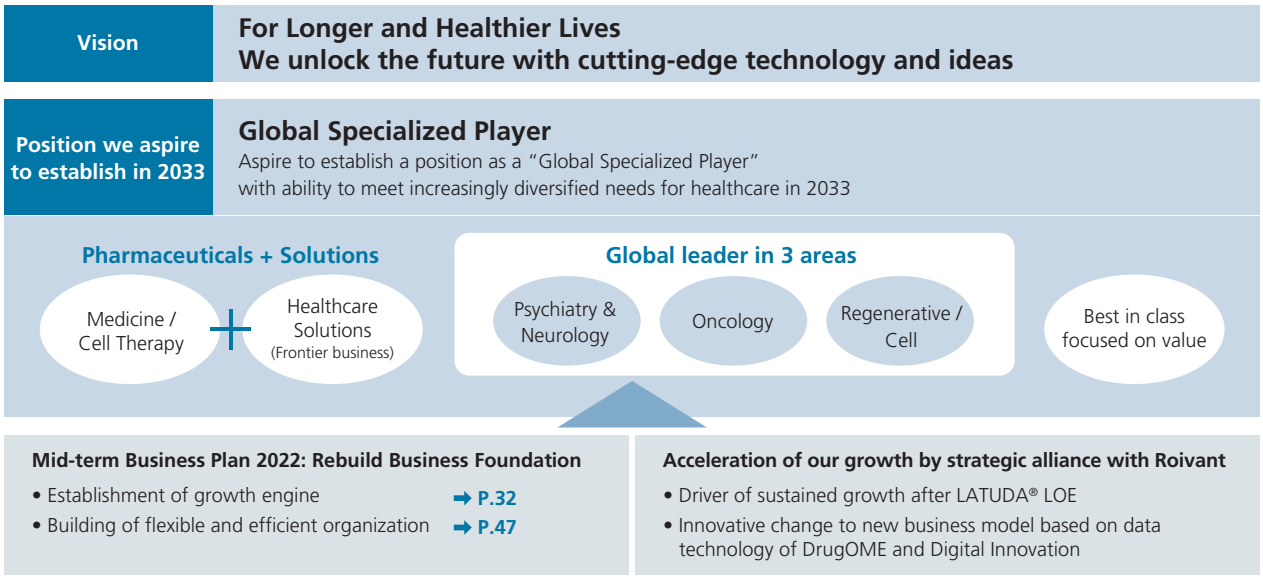
Under the Mid-term Business Plan 2022, Sumitomo Dainippon Pharma has been working to rebuild the business foundation. However, there have been significant changes in the medium- to long-term business outlook, including events such as the discontinued development of napabucasin for pancreatic cancer, which had been expected to be a revenue driver post-LATUDA. As a result of these changes, we decided to form the strategic alliance with Roivant Sciences Ltd. Through this strategic alliance, our group has acquired vibegron and an interest in Myovant which owns relugolix, which are expected to become major products as a revenue base for the time being, and we have also been working to develop the best in class* pharmaceuticals with a focus on the value of these compounds.

We also discontinued development of SB623 and dasotraline and revised sales plans downwards for new products launched in North America, including Lonhala® Magnair® for chronic obstructive pulmonary disease (COPD) and KYNMOBI® for treatment of Parkinson's Disease OFF episodes. In addition, the environment has changed significantly with acceleration of measures to curb drug costs in Japan, China, and the U.S. among other factors.

In light of these circumstances, Sumitomo Dainippon Pharma revised the financial goals of Mid-term Business Plan 2022 in May 2021.

* Best in class: There are existing drugs, but new drugs that have a clear advantage over the existing drugs.

Vision and aim for 2033 (Updated October 2019)



Revision of financial goals and future outlook

Although the discontinuation of development for napabucasin and declining revenue due to such factors as measures to curb drug costs in Japan and China will be offset by sales of new products relugolix and vibegron, core operating profit is expected to fall, partly due to the impact of sales-related expenses for the two products.

To achieve medium- to long-term growth, Sumitomo Dainippon Pharma will strive to maximize profit and reduce risk by partnering on a global scale. We will continue to invest more than ¥90 billion a year in research and development, and optimize the allocation of investment with the greatest focus on the development of compounds expected to become major products in the Psychiatry & Neurology area, the Oncology area, and the Regenerative Medicine/Cell Therapy field. We will also continue to promote management efficiency on a global basis by strengthening our foundation and structure, including the pursuit of cost synergies through enhanced collaboration between our group companies in North America.

In fiscal 2023, we expect revenue to decline due to the loss of the exclusive marketing period for LATUDA® in the U.S. However, we will minimize the impact of declining revenue with mainstay products, including vibegron and Myovant's relugolix, and aim for rapid recovery and sustained growth in business performance from fiscal 2024 onward thanks to in-house development compounds such as ulotaront (SEP-363856).

Review of financial goals

	FY2022 Financial Goals (Published in April 2019)	FY2022 Financial Goals (Revised in May 2021)	Outlook for FY2025
Revenue	¥600 billion	**¥600 billion**	**Approximately ¥750 billion**
Core operating profit	¥120 billion	**¥60 billion**	**Approximately ¥120 billion**
ROIC	10%	**3%**	**Long-term vision**
ROE	12%	**3%**	**ROE of 10% or more in latter half of the 2020s**
5-year average payout ratio	20% or higher	**20% or higher**	

Exchange rate: 110 yen to the dollar

Revenue (Diagram)