



Boldly taking on challenges in new fields that leverage Sawai's strengths while firming up our foothold

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Review of the first year since transitioning to new structure

Moving forward with management in line with Sawai Group Vision 2030

Having started on a new path as a holding company in 2021, the Sawai Group undertakes management in line with Sawai Group Vision 2030, its long-term vision for the future.

While the market for existing generic drugs continues to grow and will account for 80% of volume in the future, healthcare and medicine-related needs are growing more diverse and sophisticated at a quicker and quicker pace. We view this as a business opportunity and aim to create a "world where more people can receive healthcare services and live a full life with peace of mind among society" and to continue to contribute to people's health, which we have set as our ideal state.

Let's look back at the first year since we transitioned to this new structure. We started on this path with many employees who work in both holding company operations and business company operations learning how things have changed. Employees have struggled with switching between the perspective they should adopt and what they should communicate depending on which operations they are working in, but it seems that they are gradually figuring things out and moving forward.

One of the results of transitioning to a holding company structure was the founding of a new subsidiary that contributes to the stable supply of generic drugs. We founded the company Trust Pharmatech Co., Ltd., and acquired the production facilities and human resources of Kobayashi Kako Co., Ltd. I am sure that we were able to add Trust Pharmatech as a sibling company, not a subsidiary of Sawai Pharmaceutical Co., Ltd. and respect the numerous people who have worked with pride for many years because we created an entity to handle that task, a holding company. Of course, when manufacturing Sawai Pharmaceutical products, it will be necessary to thoroughly spread various elements, including the Sawai Pharmaceutical corporate culture and awareness of legal compliance.

Summary of business results for fiscal 2021

Year-on-year growth in revenue but massive operating loss because of impairment loss for U.S. business

In fiscal 2021, despite the impact of drug price revisions and limited shipments as a result of suspension of supplies from other companies and other developments, the Japan business saw an increase in sales in part because of new products. Both revenue and operating profit rose year on year even though core operating profit fell due to an increase in R&D expenses.

On the other hand, for the U.S. business, revenue contracted year on year for several reasons, including a dramatic decline in sales of its main generic drugs as competitors entered the market. An operating loss was also recorded as a result of a massive impairment loss.

Therefore, the Group recorded consolidated revenue of ¥193,816 million (+3.5% YoY), consolidated core operating profit of ¥26,321 million (-22.7% YoY), and a consolidated operating loss of ¥35,888 million (consolidated operating profit of ¥18,888 million for fiscal 2020).

Overview of FY2021

(Millions of yen)

	FY2020 Actual		FY2021 Actual		YoY		
	Japan	US	Japan	US			
Revenue	187,219	153,584	33,635	193,816	163,841	29,975	+3.5% (+6,597)
Core operating profit	34,043	30,258	3,765	26,321	27,016	(708)	(22.7)% (7,722)
Operating profit	18,888	26,284	(7,396)	(35,888)	32,361	(68,249)	- (54,776)
Profit before tax	18,460	-	-	(36,214)	-	-	- (54,674)
Profit attributable to owners of the Company	12,340	-	-	(28,269)	-	-	- (40,609)
Average rate	US\$1= ¥106		US\$1= ¥112				

* Results by segment in Japan and the U.S. are not consistent with the overall figures, as each segment profit includes inter-segment transactions.

* Core operating profit is calculated by excluding profits and losses attributed to non-recurring factors from operating profit.

Recording impairment loss

Recording an impairment loss refers to lowering the carrying amount of fixed assets. For fixed assets, the purchase price is normally expensed (depreciated/amortized) over the useful life of the asset, but if it is not expected that an amount equivalent to the investment will be recovered for any number of various reasons, including a decline in profitability due to changes in the business environment, such as changes in the market or technology, an impairment loss is recorded when necessary. The size of the decline in the asset value is a loss, but there is no corresponding cash outflow.

As a result of examining how to generate sustainable growth for the U.S. business, which operates in a harsh environment that rivals continue to enter, and revising future plans, we expect sales to decline and growth to slow and determined that the recoverable amount of U.S. business assets was less than their carrying amount. Therefore, we posted an impairment loss of ¥68.8 billion, which consisted primarily of ¥39.9 billion for goodwill, ¥26.0 billion for intangible assets, such as trademarks, and ¥2.9 billion for property, plant, and equipment.

As a result, depreciation of intangible assets is expected to fall from the previously given ¥5.0 billion level to ¥1.9 billion for the current fiscal year. (See message from Mr. Rich Fisher on page 28 for concrete future efforts.)



Rebuilding the U.S. business

Aiming to provide high value added and quickly return to profitability by cutting costs, etc.

As discussed previously, a massive impairment loss was recorded for the U.S. business because of not only a dramatic decline in sales of its main generic drugs on account of the entry of competitors but also a review of future plans for the U.S. segment. As the person in charge of this business, I would like to apologize to all stakeholders, particularly shareholders. It is my responsibility to implement a strategy to rebuild the business and make it profitable.

The Sawai Group fully entered the world's largest generic drug market with the 2017 purchase of Upsher-Smith, a U.S. generic drug manufacturer that is more than one hundred years old. Since then, Upsher-Smith has contributed to the global expansion of the Sawai Group as a member of the Group.

In recent years, however, three major purchasing groups, which were formed by the merger of wholesalers, pharmacies, and similar entities, have captured approximately 90% of the U.S. generic drug market. Furthermore, at the same time that the U.S. Food and Drug Agency (FDA) has approved a large number of abbreviated new drug applications (ANDAs), price competition with India-based generic drug companies has grown fiercer. When rebuilding the business, therefore, we will not only shift to a business model and high value added products to avoid direct competition with those companies but also reorganize the various divisions, including the research, manufacturing, and marketing ones, and cut costs. In this way, we are aiming to quickly return the business to profitability.

For the Manufacturing Division, progress is being made in transferring products from the Denver Factory in Colorado to the new factory that is next to the company's headquarters in Maple Grove, Minnesota. Reducing operating costs by centralizing manufacturing at the new factory and further improving quality and efficiency is expected to contribute to profits. Efforts are also being made to reduce costs by reviewing API suppliers.

As for launching products, we are planning on conducting even stricter examinations of cost effectiveness and narrow down candidates to those that will definitely boost profit. For development, too, we have shifted our focus away from in-house development to collaborations with companies throughout the world that are already developing products for the U.S. and created success-based deal structures. This is how we are working to reduce development risks.

Corporate officer Taku Nakaoka, who previously worked at a trading company and has a long career overseas, took up the position of CEO as part of the new management team. We will not simply value the know-how of Upsher-Smith but demonstrate leadership by becoming more integrally involved in strategy and plans. Serious debates regarding the direction of new product development and other issues will be held with the company's management team under our leadership, and we will move forward while clarifying responsibility for decisions and results.

Progress with new businesses

Efforts to develop new growth fields for the Group to continue to develop

For the Group to continue to grow in the future, we must build and develop not only the generic drug business, which has grown because of the health insurance system, but also new businesses that go beyond the pharmaceutical industry while using the generic drug business as our core business. After reviewing opinions collected within the Company regarding what business fields to expand into when transitioning to a holding company, we came up with the three fields of digital medical devices, new drugs, and health foods, which leverage Sawai's knowledge and know-how. To create a society with health longevity through pre-symptomatic approaches, preventive measures, and data health reforms, which the government is aiming for, we are focusing the investment of resources into these three fields. I would like to explain the progress we have made and the future growth strategy for each field.

The digital medical device business is steadily moving toward commercialization. In January 2021, Sawai Pharmaceutical concluded an exclusive development and marketing agreement with Israel-based Neuro Relief Ltd. regarding a non-invasive neuromodulation device for migraines and depression for the Japanese market. The medical device, which treats migraines with electromagnetic waves, offers a new treatment method for patients when drug therapies are not effective. Although already available in the U.S., the device has never been used in Japan before, and it has drawn high expectations from physicians in the field of central nervous system. We will apply for approval in 2022, and if approval is obtained, it will be the only neuromodulation device in Japan that can be used at home. We plan to launch the product in 2024.

Furthermore, in October 2021, we released the personal health record (PHR) management app SaluDi, which offers functions for recording and managing daily state of health, making online appointments for doctor visits, and viewing information on pre-symptomatic and preventive measures. This has already drawn strong interest from a broad range of customers, including hospitals and pharmacies. There have also been inquiries from numerous medical institutions regarding whether it can be used for a broad range of businesses, including making appointments online and providing guidance on taking medications. Local governments, too, have commented that they would like to use the app for maintaining the health of residents. Since April 2022, in partnership with several entities, including Tokyo University, we have been moving forward with a verification test for building a business model linked to the flow from metabolic syndrome-specific health checkups to recommended general checkups and changes in behavior.

One activity that leverages Sawai efforts to differentiate the Company is the provision of information. It is now possible to access the health information site Sawai Kenko Suishinka,

Personal Health Record Business Management app, "SaluDi"

Personal health record, PHR, management app, "SaluDi" was launched in October 2021 with the functions of recording and managing daily health conditions, linkage with telemedicine and its reservation, and access to information on pre-symptomatic illness and disease prevention.

Main functions

1. Provision of health-related information

- Disease information.
•Information from one of the popular websites run by Sawai Pharmaceutical which offers health-related information.



2. Record and visualization of PHR data

- Automatically input PHR data linking with healthcare devices.
•Manage dietary photos, check-up result data, and prescription record books.



3. Communication features

- Messaging functions between medical institutions and patients.
•Medical institutions can cooperate to support patients.

Messaging function

It is possible to communicate shared data with physicians and patients.

PDF/CSV output

If the diabetes record book and blood pressure record book are saved in PDF format, they can be attached to e-mails, printed out, and carried around, making them more convenient.

4. Linkage with telemedicine

- Recorded PHR data can be used when using telemedicine as well as seeing doctors in person.



* SaluDi is an OEM app of Smart One Health provided by Integrity Healthcare.
* SaluDi is available only in Japan.



which Sawai Pharmaceutical has operated since 2008. Sawai Kenko Suishinka is an informational website that meets a wider range of needs by not only providing information on actual illnesses and symptoms but also offering suggestions on ways to improve routine health problems, beauty tips, and diets. The website is visited by many people and boasts an average monthly PV of more than 2.50 million. Furthermore, it can be used to help manage blood pressure by uploading blood pressure record book data, which is provided to parties such as pharmacies free of charge.

With SaluDi, it is possible to share data with family pharmacies and medical institutions, and if it becomes possible to also use the app for making appointments online and providing guidance on taking medications, medical institutions will feel that it is even more beneficial. The basic functions are now provided free of charge, but we would like to introduce it as a new business by further expanding services and content.

As for the new drug business that targets rare diseases, we are currently preparing for clinical trials in order to introduce an ALS medicine in the U.S. Furthermore, we have strengthened the in-house evaluation system and are continuing to examine expanding the pipeline.

Turning to health foods, we have already completed product development and filed a registration of “product with functional claims” to the Consumer Affairs Agency, and the filing has been accepted. We are moving forward with preparations for test marketing through the Internet, which offers high cost performance, as a channel. Although we are late to this field, drug treatments for life-style diseases is a field that Sawai Pharmaceutical is strong in. Therefore, we would like to introduce products using the trust that “if Sawai developed it, I am not worried” as a strength.

Investment decisions

Investment decisions and business management based on capital costs and improving corporate value

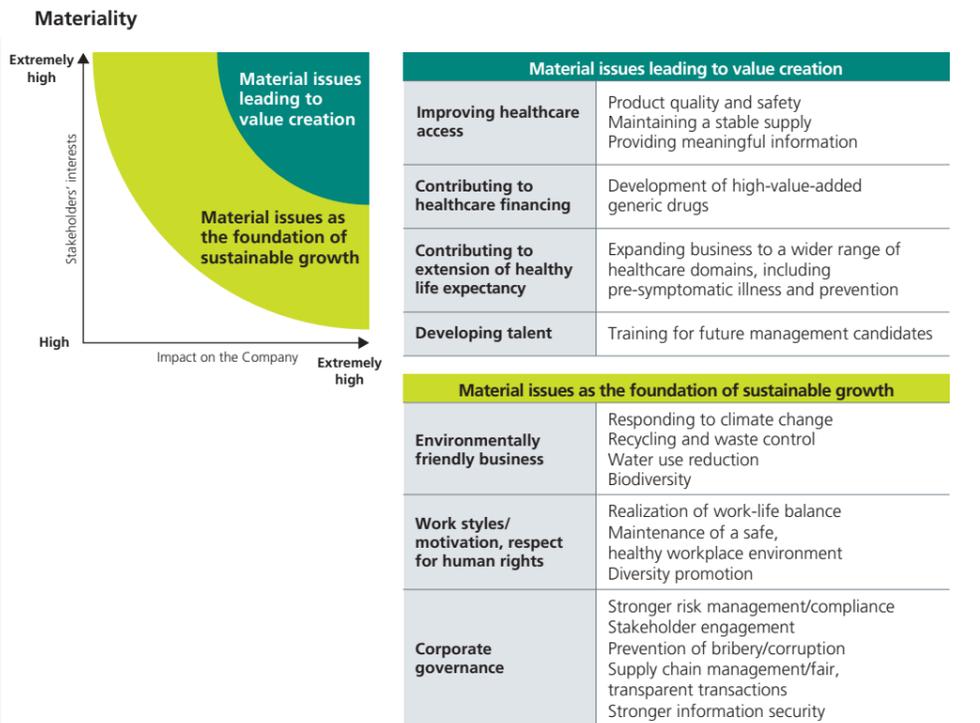
For the Japan business, we have made various growth investments, including constructing a solid dosage form facility at the Daini Kyushu Factory and acquiring assets from Kobayashi Kako Co., Ltd. These investments can be expected to result in greater future profits and ROE for the Company. Investment decisions are made taking into consideration capital efficiency.

For investments of a certain amount or greater, the Board of Directors makes the decision after the Group Investment Committee carefully reviews the proposal based on the general rule that ROI, which uses NPV and IRR as indicators, surpasses the cost of capital. In order to make use of not only shareholder capital but also liabilities, we employ WACC (currently about 4%) when calculating the cost of capital. However, if an investment will contribute to an increase in corporate value in the medium and long term considering not only capital efficiency but also the corporate philosophy and social nature, it may be decided to make the investment. In addition, the cost of capital and state of various investments are regularly reviewed, and if investments fall short of original expectations, a strict investment decision, which includes the possibility of withdrawing from the investment, is made for not only the Japan business but also U.S. and new businesses.

Sustainability efforts

Promoting materiality-based sustainability and building long-term trust with various stakeholders

By providing generic drugs, the Group lessens the burden of healthcare costs and contributes to solutions to social issues, such as growing healthcare costs. In fiscal 2021, this contributed to healthcare cost savings of ¥338.2 billion in Japan and ¥99.4 billion in the U.S. In Japan, the volume of drugs sold by Sawai Pharmaceutical accounts for about 8% of total prescription drugs



(our analysis), making Sawai Pharmaceutical an indispensable part of the social infrastructure for Japan’s healthcare.

As for our relationship with stakeholders, which is centered on value creation through the business, our earnest efforts to tackle environmental, social, and governance (ESG) issues form a foundation for the Group’s sustainable growth. For the Group, we have identified improving access to medical treatment, contributing to healthcare financing and the extension of healthy life expectancy, and similar topics as material issues leading to value creation and environmentally friendly production, work styles / motivation, respect for human rights, corporate governance, and similar topics as material issues as the foundation of sustainable growth.

Within the field of sustainability, we particularly stress aspects related to people. This is because people are a company’s greatest assets and are one of our strengths. What I have valued since taking up the position of president of the Company is creating a company at which employees can put their all into their work and can feel their dreams in their work. When creating the long-term vision with an eye toward 2030, we had both mid-career and young employees take part in the project to set the vision and conducted lively discussions that started from scratch. While undertaking two-way communication as much as possible, I want to create mechanisms that make it possible for anyone to volunteer for work they want to do and take on challenges related to interesting work. To do this, I think that we must implement measures that promote diversity so that we can break free of the current situation when women account for only below 8% of management and most employees in Japan are Japanese.

A company can only achieve sustainability by building long-term relations of trust with various stakeholders. We aim to jointly generate innovation with stakeholders and create a “healthcare corporate group which develops sustainably alongside society” by communicating Sawai’s open corporate culture that values integrity to various stakeholders and working with those stakeholders.

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