



Japan Business

(Sawai Pharmaceutical)

Continuing to offer a stable supply of high-quality drugs as a leading generic drug company

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Japan business SWOT analysis

Strengths	Weaknesses
<ul style="list-style-type: none"> One of the top supply capabilities in Japan Proprietary product development capabilities Name recognition and brand strength as top manufacturer Stable financial base Integrity of employees based on corporate philosophy 	<ul style="list-style-type: none"> Takes time to train and secure employees as demand grows Difficult for management to decide to suspend sales as many unprofitable products have top shares
Opportunities	Threats
<ul style="list-style-type: none"> Chance to restructure the generic drug industry Growing demand because of aging society Diversification and growing sophistication of healthcare and medicine needs 	<ul style="list-style-type: none"> Decline in drug prices for various reasons including annual drug price revisions General decline in trust in generic drugs Increase in AG sales Weak growth in advanced countries Increase in API and raw material costs due to changes in exchange rates and inflation

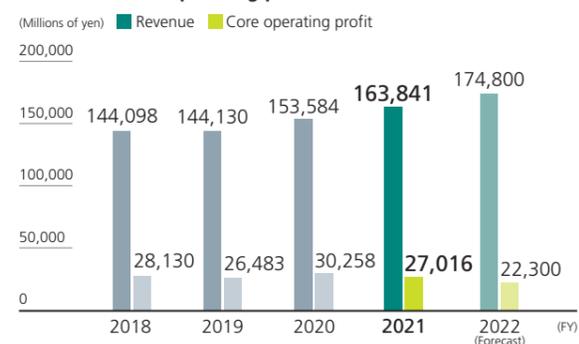
Revenue grew year on year because of increased production to meet stronger demand and contributions from new product sales

Despite drug price revisions and limited shipments due to suspended supplies from other companies and other developments, domestic revenue from the Japan generic drug business totaled ¥163,841 million (up 6.7% YoY) in fiscal 2021 for various reasons including an increase in fiscal 2020 new product sales. While the business recorded core operating profit of ¥27,016 million (down 10.7% YoY) because of an increase in R&D expenses in order to develop new products, operating profit totaled ¥32,361 million (up 23.1% YoY) since the Company acquired Kobayashi Kako Co., Ltd. assets related to production activities and recorded a gain on bargain purchase.

Production volume rose about 9% compared to fiscal 2020 to 15.1 billion tablets (including commissioned production). This was because in response to growing

market demand, we worked to increase production in various ways including introducing nighttime, weekend, and holiday work. Even so, shipments continued to be limited, making it impossible to meet all the demands of medical institutions, but in April 2022, we ended limited shipments for 57 products, which has helped market inventory

Revenue / Core operating profit



imbalances work themselves out.

In fiscal 2022, despite the impact of drug price revisions, we expect that both revenue and core operating profit will increase on account of sales of new products and other items.

Launched process for increasing production within the Group to offer a stable supply of domestic generic drugs

To meet market demand, Sawai Pharmaceutical is working to expand its share of Japan's generic drug market and reinforce its capabilities to provide a stable supply. Furthermore, the Sawai Group Vision 2030, the Group's long-term vision through fiscal 2030, includes the target of establishing an in-house production system for more than 23.0 billion tablets, and fiscal 2021 was a year in which we made major progress in achieving that goal.

Following the decision to invest in a solid dosage form facility at the Daini Kyushu Factory in October 2021, we acquired Kobayashi Kako Co., Ltd. production facilities in March 2022, and then in April, Trust Pharmatech, Co., Ltd., which employees from Kobayashi Kako joined and launched full operations. With seven production and research facilities, the company possesses the capacity to produce approximately 3.0 billion tablets annually and expects to make its first shipments in April 2023.

In 2023 or after, we expect to have created a production system with a capacity of 21.0 billion tablets annually by gradually launching operations at Trust Pharmatech and Daini Kyushu Factory, making the Group the top Japanese drug manufacturer. Trust Pharmatech is expected to manufacture as many of Sawai Pharmaceutical's large volume products as possible, and efforts are already moving forward with plans to commission the company to manufacture about seven products. Trust Pharmatech possesses not only appealing facilities and new facilities from our perspective but also many outstanding human assets. In particular, with strong develop capabilities, such

as those related to formulation development, there are probably major benefits from Trust Pharmatech joining the Group.

Regarding production plans for fiscal 2022, we plan to manufacture about 16.5 billion tablets (including commissioned production) at our six existing factories by increasing the number of employees and taking other steps while implementing ingenious measures to increase productivity such as unifying packaging units. With an eye toward restructuring and centralizing the industry, we are aiming to possess overwhelming production capacity unmatched by rivals through a wide range of measures, such as constructing our own factories, securing manufacturing subcontractors, and acquiring other companies' factories.

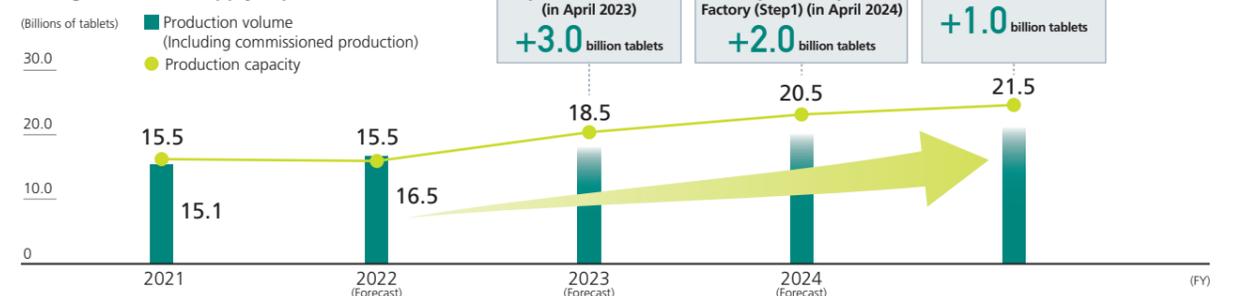
Firmly maintaining Sawai production quality and corporate culture throughout the whole Group

The main issue related to increasing supply capabilities is securing and training people. While investing money increases the production capacity of facilities, it goes without saying that people operate those facilities. Trust Pharmatech Co., Ltd., and Sawai Pharmaceutical Co., Ltd., are different companies, but as long as Trust Pharmatech manufactures Sawai products, its employees must view things from the same perspective as our factories and employees, adopt the philosophy regarding why they are producing products, and possess the same level of awareness regarding contributing to society and legal compliance.

Until the first shipments are made, we will conduct class-room and onsite training for Trust Pharmatech employees so that they can conduct manufacturing activities of the same quality as those of our factories. While undertaking actual manufacturing at factories, they will learn production methods that meet Sawai criteria.

However, unlike knowledge and skills acquired through training, a perspective of what makes work worth doing is not gained overnight. At Sawai Pharmaceutical, activities

Future production capacity to strengthen stable supply capabilities





to spread the corporate philosophy of “always putting patients first” have been undertaken for 15 years. Even individual factories have worked independently to improve operations for many years. It takes time for corporate culture to take root like this, and Trust Pharmatech will also probably have to undertake similar activities for many years.

Moving forward with new product development that employs original formulation technology

The Group’s long-term vision includes the goal of raising the Company’s share of Japan’s generic drug market from the current approximately 16% to at least 20%. To achieve that target, it is necessary to strengthen new product development. In particular, the key is to introduce competitive products, including first-of-their-kind products launched ahead of other companies.

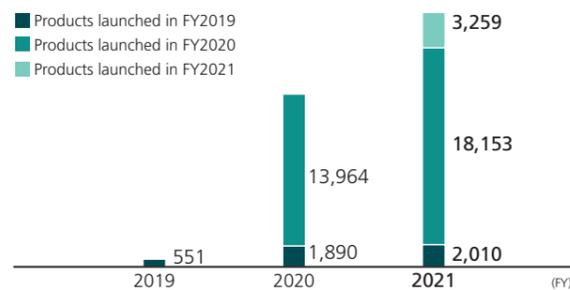
In fiscal 2021, the Company introduced 32 products, which included six competitive products. Starting in fiscal 2022, we will be sure to introduce new products that will become competitive products and continue our steady efforts to sell products at fair prices through various measures, such as undertaking difficult drug formulation that leverages Sawai R&D capabilities. The less competition there is for a product, the greater the responsibility to supply that drug becomes, and we want to continue to take on challenges while giving the greatest priority to stable supply.

Furthermore, the Company develops various technologies and acquires patents each year as it introduces numerous products to the world. We refer to the original production technology that provides value added to drugs, such as making medicines easier to take and the



SAWAI HARMOTECH®
https://www.sawai.co.jp/medicine/sawaigenerics/research/sawai_harmotech/

Revenue from products launched in the past three years (Millions of yen)



manufacturing of medicines more efficient, as SAWAI HARMOTECH®, and we have started to disclose related information through our corporate website.

To get more people, even only a few, to know about our technology, we will continue to actively disclose information on our R&D.

Taking the lead in rebuilding trust in generic drugs by stressing product and quality-related disclosure

We have traditionally focused on disclosure related to production and quality, but since fiscal 2021, we have undertaken even more extensive disclosure. In May, we added a Quality Management Disclosure page to the corporate website and started to explain our quality, GMP, and production processes. A pamphlet version has also been distributed to medical institutions. We also started to disclose information on formulation manufacturing companies and audits of API manufacturing plants through a general information site for healthcare professionals in June. We have decided to play a leading role in the industry so that healthcare professionals can use our products with peace of mind.

To restore trust in generic drugs, it is important to disclose all information, including what quality-related improvements have been implemented, what plans have been made, and what the results of these efforts have been. As a leading company in the industry, we will fulfill our duties related to disclosure.

Under the corporate philosophy of “always putting patients first,” our mission is to deliver high-quality generic drugs to patients and healthcare workers even a bit quicker. As for supply, we are building a system to increase production in the long-term, and the Manufacturing Division and Marketing Division will work together to meet the expectations of all in order to eliminate limitations.

New product launch plan for the next three years

Number of products to be released: over **70**

	FY2021	FY2022	FY2023
Number of ingredients	13	9	7
Number of products	32	21	17
Original drug market (billions of yen)	–	269.1	154.1

Original drugs for first-listed generic drugs | Cymbalta capsule / Lunesta tablets / Vesicare tablets / Adcirca tablets



My name is Rich Fisher, and I assumed the position of President and COO of Upsher-Smith Laboratories (USL) on April 7, 2022. I would like to express my sincere regret to the shareholders of Sawai Group Holdings for the significant impairment losses recorded by USL in fiscal 2021. Our USL business strategy going forward will address the following three issues in fiscal 2022:

1. Measures to stabilize revenue

The competitive environment for generic drugs in the U.S., the world’s largest pharmaceutical market, is extremely severe, and USL’s key products have been significantly affected by the entry of competitors. In order to offset the decline in sales due to falling prices of mature generics, we plan to focus on increasing sales and profits through the selling of USL brand products Zembrace and Tosymraothers. USL will also pursue increased profit and revenue for generic products with high barriers to entry such as Isotretinoin, which was introduced in fiscal 2021.

2. Cost reduction measures

With regard to the new plant built near the headquarters in Minnesota for the purpose of consolidating production functions, we expect to improve efficiency by more than 10 million dollars per year by transferring products from the Denver plant, which was sold in fiscal 2021, and by switching to in-house manufacturing for processes that were previously manufactured by outsourcing. In addition to reducing the cost ratio by reviewing and strengthening procurement sources of APIs, we will take all possible measures, including potential internal structural reforms, to reduce costs.

3. Pipeline development strategies

As part of our reforms, we have restructured our R&D function to take advantage of external expertise for drug formulation. This change, which allows us to reach market more quickly and de-risk the portfolio through utilization of success-based milestones, will be accomplished with reduced R&D expenditure.

Although USL is facing one of the most challenging

U.S. business SWOT analysis

Strengths <ul style="list-style-type: none"> Consistent high quality supply from manufacturing facilities located in the U.S. Strong relationships with major wholesalers High level of employee engagement 	Weaknesses <ul style="list-style-type: none"> Lack of in-house development capability
Opportunities <ul style="list-style-type: none"> Market where human population continues to grow, despite being a developed country The U.S. market accounts for about 40% of the world’s pharmaceuticals market Supply disruptions caused by competitors with low quality 	Threats <ul style="list-style-type: none"> Intensifying competition with India-based companies with superior cost competitiveness Continuing pricing pressures driven by consolidation of customers and buying groups

periods since our founding in 1919, we would like to ask for your patience and support as we strive to grow as a specialty generic company and make a sustainable contribution to the Sawai Group’s business performance.

Revenue / Core operating profit

