

Navigating a turning point in the generic drug industry and providing a stable supply of high quality drugs

Motohiko Kimura

Senior Managing Executive Officer Representative Director and President of Sawai Pharmaceutical Co., Ltd.

SWOT analysis

Strengths

- One of the top supply capabilities in Japan
- Proprietary product development capabilities
- Brand strength as top manufacturer
- Stable financial base
- Integrity of employees based on corporate philosophy

Opportunities

- Chance to restructure the generic drug industry
- Growing demand because of aging societyDiversification and growing
- Diversification and growing sophistication of healthcare and medicine needs

- 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

Threats

Weaknesses

- Decline in drug prices for various reasons
- including annual drug price revisionsDecline in trust in generic drugs
- Increase in launch of AGs
- Increase in launch of AGs
 Weak growth in advanced countries
- Increase in raw material costs

Revenue / Core operating profit



Sawai Group Vision 2030 quantitative targets

	FY2020 (actual)	FY2022 (actual)	FY2030 (target)
Revenue	¥153.6 billion	¥163.7 billion	¥260.0 billion
Sales volume	13.3 billion tablets	15.0 billion tablets	20.0 billion tablets
Share of sales	15.7%	16.0%	20.0% or more
Production capacity	15.5 billion tablets	18.5 billion tablets	23.0 billion tablets or more

On assuming the position of Sawai Pharmaceutical President—responding to change by melding the strengths of each in-house divisions

My name is Motohiko Kimura and I am the new Representative Director and President of Sawai Pharmaceutical. Before entering the Company in 2016, I worked in the department responsible for coordinating production at Sumitomo Pharmaceuticals (currently Sumitomo Pharma). Before that, I worked on biopharmaceutical research and gained experience in various divisions, including ones involved in the launch of a commercial cell cultivation plant, sales and purchase of intellectual property, business development, and purchasing. When I was stationed in Europe, I also helped launch an English corporation. At Sawai Pharmaceutical, as the Senior Vice President of the Manufacturing Division since 2017, I pushed forward efforts related to restructuring and strengthening the production system at each factory and increasing their production capacity. I was appointed president in order to leverage these experiences and contribute to guick solutions to problems related to guality and stable supply, which are demanded of the generic drug industry.

The Company is now approaching a turning point. In addition to annual drug price revisions, increases in raw material costs, and a duty to provide a stable supply of our GE new products, development is growing more difficult due to the growing complexity of formulation. Despite releasing new products, we have been unable to halt the increase in the number of unprofitable products. AGs are also growing in number, making it an extremely difficult time. Furthermore, this is a period of numerous expected changes, including the Ministry of Health, Labour and Welfare launching a working group on system reforms, and we must properly respond to these changes.

Under these conditions, the management and marketing strategies are important, and it is time for each

division to collaborate even closer with each other and for us to rebuild our system so that we can quickly respond to change.

Because we produce an extremely large number of generic drugs, we face different production difficulties than those of drug manufacturers that produce a small number of new drugs, and these difficulties include having to routinely change production equipment.

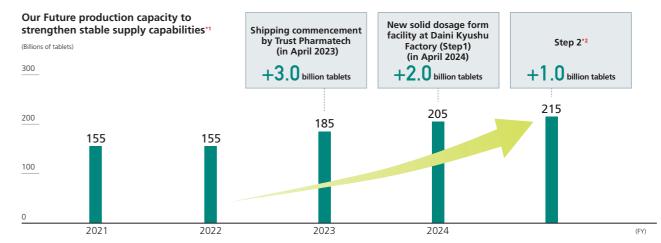
One of my responsibilities is to link not only research to production but also marketing to production by formulating a strategy and leading them like an orchestra conductor. This makes it possible for work to progress smoothly both inside and outside the Company. I would like to leverage my skillful footwork, one of my strengths, for that.

Taking on the challenge of implementing various measures to transform difficulties into opportunities

In fiscal 2022, we recorded revenue of ¥163,702 million from the Japan generic drug business because despite the impact of drug price revisions, sales of new products grew, and we lifted limits on shipments. On the other hand, core operating profit fell year on year to ¥21,425 million because of upfront investments and higher costs.

Furthermore, we project a decline in profit for fiscal 2023. The main reason for this decline is higher costs. Although we have lowered production costs each year after I became the Senior Vice President of the Manufacturing Division, fiscal 2022 was the first year that it was not possible to cover drug price revisions with lower production costs. This was because of the impact of the war in Ukraine, and higher labor and heating and lighting costs. For example, products that cost ¥100 in the previous year cost ¥105 this year, an overall 5% increase in costs.

In response to this increase in costs, we worked to further raise productivity and reflect the impact of those higher costs in prices. We have requested the understanding



- *1 Production capacity assumptions: Assumes continued operation of machinery using two shifts on weekdays for current number of products. Does not include outsourcing.
- *2 Step 2: Timing undecided

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of wholesalers and retailers in fiscal 2023, too.

Under these conditions, we must take these kinds of steps so that we can fulfill our responsibility to continue to deliver required drugs, even unprofitable ones, to patients. In this type of situation, what is important is properly fulfilling our responsibility to be accountable to business partners. In my previous position as Manager of the Purchasing Department, the most important thing was to fully explain the Company's current situation before requesting cooperation. Greater understanding not only raises the level of cooperation but also leads to trust. I consider it my role as head of the Company to continue this type of dialogue.

Furthermore, there previously were few exchanges among companies in the generic drug industry. I think that we can build a relationship of mutual prosperity beneficial to all through even deeper collaboration with stakeholders, including business partners and suppliers. Fortunately, there are extremely high expectations for the Company, which boasts the largest market share in the industry, and I want to examine what type of collaboration is possible through consultations with the Chairman of the Board and Vice Chairman.

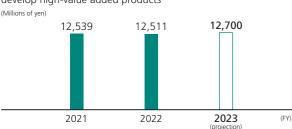
Moving forward with both increasing production capacity and securing and training people in order to further increase our share

Following an almost yearlong preparatory period, Trust Pharmatech started to ship products fully produced in-house in June 2023 as scheduled in order to eliminate supply shortages and increase production capacity. Furthermore, at the Daini Kyushu Factory, construction of a new solid dosage form facility is moving with the goal of launching production activities in April 2024. This will make it possible to increase our production capacity to more than 20.0 billion tablets in fiscal 2024.

There is a need to improve the capabilities of production facilities, which would also resolve the issue of it being more difficult to commercialize new products. This is because it is necessary to possess spare production capacity and launch commercial production-scale tests at

R&D expenses

More than ¥10.0 billion annually in R&D expenses to develop high-value added products



the factory as quickly as possible so that we can swiftly transition to stable production. First of all, we will focus on launching full production at Trust Pharmatech and completing the new facility at the Daini Kyushu factory.

While our current share of the Japanese generic drug market is about 16% on a volume basis, the long-term vision for 2030 includes a target market share of 20% or more. It is, however, my opinion that the mission of the Company is to increase our market share beyond that.

To do that, it is important to recruit and train people. We not only stress the turnover rate as a KPI, but have also introduced a system in which more senior employees close to the age of new recruits are assigned as mentors, who serve as advisors and pass on their experience along with work guidance. Through these efforts, we lowered the employee turnover rate to 3.1% in fiscal 2022 from 4.8% in fiscal 2017. Having employees remain at the Company will also increase the capabilities of each and every employee. In addition to a system in which a single employee handles multiple operations, we are introducing KPI and a numerical scale for work skill ranks.

Because of these efforts, since 2017, the year I became the Senior Vice President of the Manufacturing Division, our production volume has increased 1.6-fold without substantially increasing the number of employees.

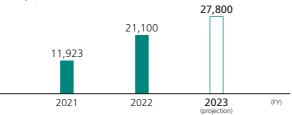
Creating a "company that continues to contribute to society far into the future" by leveraging our strengths

One of Sawai Pharmaceutical's strengths is its corporate philosophy of "always putting patients first." We are proud of the fact that we are all moving in the same direction under this philosophy and are unsurpassed in the speed of our response. My goal is to transform the Company into a "company that continues to contribute to society far into the future." While consulting with everyone regarding what should be done to achieve that and deliberating with stakeholders both in and outside the Company, we will move forward with management so that we can win people's trust.

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Capital expenditures

¥60.0 billion in capital expenditures over three years from fiscal 2021 to increase production capacity (Millions of ven)



U.S. business (Upsher-Smith)

FY2022 Marks a turning point for **Upsher-Smith**

-looking to build on momentum from strong FY2022 performance-

Rich Fisher

President & COO, Upsher-Smith Laboratories

SWOT analysis

Strenaths

- Consistent high quality supply from manufacturing facilities located in the U.S.
- Strong relationships with major
- High level of employee engagement
- Strong development partnerships with outside partners

Opportunities

- High population growth rate for an advanced country
- Size of the market, which accounts for about 40% of the global market
- Supply disruptions of competitors that struggle to comply with regulations and raise funds

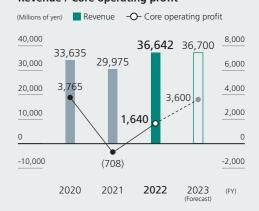
Weaknesses

 Lower relative price competitiveness compared to Indian companies

Threats

- Excessive decline in selling price due to competition with new
- Continuing pricing pressures driven by consolidation into three major purchasing groups

Revenue / Core operating profit



FY2022 performance

My name is Rich Fisher and I assumed the role of President and COO of Upsher-Smith Laboratories (USL) approximately one year ago. Despite the continuation of challenging conditions in the U.S. generic market, USL had an outstanding year. FY2022 marked USL's first year-over-year revenue increase in nearly a decade and USL also achieved substantive improvements in profitability. We expect additional revenue and profitability growth in FY2023. Growth in FY2023 will be driven primarily by a significant number of new product launches, which will more than offset expected revenue declines for mature products. USL's external R&D model, which was implemented over a year ago, has been a spectacular success, leading to a dramatic decrease in expense and an increase in pipeline products, submissions to FDA, and new product launches.

Investing in human resources for future growth

Shortages of workers in production areas continue to be a challenge, with unemployment in MN remaining at historic lows of approximately 3%. USL continues to aggressively recruit and work on initiatives important to employees such as Diversity, Equity and Inclusion. In FY2022, USL increased the diversity pool of candidates for new jobs, implemented

new training tools, and expanded activities associated with Employee Resource Groups. Despite worker shortages, significant milestones were achieved in FY2022.

Outlook for FY2023

USL's new 25,000 square meter manufacturing facility was approved by the FDA late in 2022 and began commercial manufacturing in February of 2023. The outlook for FY2023 and beyond looks promising. USL has a strong reputation in the U.S. for consistently delivering quality products. Some of USL's competitors have stumbled due to 1) lack of regulatory compliance, leading to importation bans into the U.S. 2) Financial difficulties, leading to bankruptcy filings and inability to continue to market their products 3) Insufficient investments in operations, leading to potential non-compliance with pending serialization and aggregation requirements. It is possible that these developments mark a turning point in the U.S. generic industry, and USL is very well-positioned to capitalize on competitor's failures.

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