

# Japanese generics business

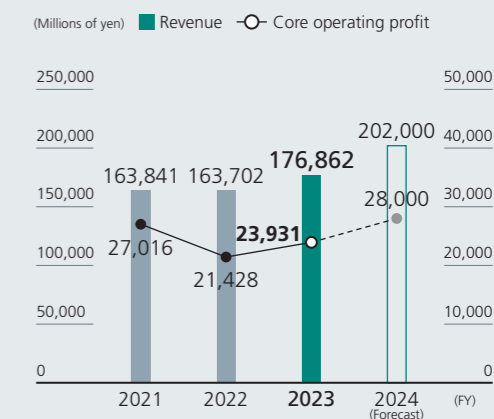


**Motohiko Kimura**  
Senior Managing Executive Officer  
Representative Director and President of  
Sawai Pharmaceutical Co., Ltd.

### SWOT analysis

<p><b>Strengths</b></p> <ul style="list-style-type: none"> <li>• Brand strength as top manufacturer</li> <li>• Stable financial base</li> <li>• Strengthened production capacity following quick investments</li> <li>• Development of capabilities that enabling us to launch products first and exclusively</li> <li>• Growing share of high value-added products</li> </ul>	<p><b>Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Securing and developing talent that can handle growing production capacity</li> <li>• Constraints on productivity due to high-mix, low-volume production</li> </ul>
<p><b>Opportunities</b></p> <ul style="list-style-type: none"> <li>• Chance to reorganize the generic drug industry</li> <li>• Growing demand due to advance of aging society</li> <li>• Growing healthcare and medical needs</li> <li>• Generic drugs as social infrastructure</li> <li>• Company scoring system that promotes sales at reasonable prices</li> </ul>	<p><b>Threats</b></p> <ul style="list-style-type: none"> <li>• Increase in launch of AGs</li> <li>• Lower reliability due to generic drug supply instability</li> <li>• Growing raw material and utility costs</li> <li>• Lower NHI drug prices due to annual drug price revisions</li> <li>• Changes in various systems</li> </ul>

### Revenue / Core operating profit



### Medium- and long-term quantitative targets (Generic drug business)

	FY2023 results	Beyond 2027 targets	Sawai Group Vision 2030 targets*
Revenue	¥176.9 billion	<b>¥ 219.0 billion</b>	¥300.0 billion
Generics market share/Sales volume	17.1% / 15.7 billion tablets	<b>20.5% / 19.0 billion tablets</b>	25.0% or more / 24.0 billion tablets
In-house production capacity	18.5 billion tablets	<b>22.0 billion tablets</b>	25.0 billion tablets or more

\* Revised June 2024

## Striving to build a system for achieving both a stable supply of generic drugs and our own sustainable growth

### Review of the first year as president Simultaneously addressing inappropriate testing and strengthening production capacity

I would like to express my deepest apologies to all related parties for the substantial problems caused by the inappropriate stability monitoring dissolution testing of Teprenone Capsules 50mg "Sawai" at Sawai Pharmaceutical's Kyushu Factory that was discovered in April 2023.

This incident came to light just as I took up the position of president, and since then, I have addressed it through such steps as conducting an in-house investigation, disclosing the results of the investigation outside the Company, providing explanations to business

partners and other parties, and holding dialogues with employees. We are now making steady progress in implementing recurrence prevention measures in order to regain trust as soon as possible.

At town hall meetings held as part of recurrence prevention measures, I communicated my honest opinion to employees in the various departments and answered numerous questions. Since moving from Senior Vice President of the Manufacturing Division to President, I have uncovered issues related to conditions at several divisions, including the Reliability Assurance Division, Research & Development Division, and Marketing Division, by gathering information, and I am working to resolve those problems while incorporating ideas from the workplace into management.

At the same time, we worked to enhance production capacity to eliminate the generic drug supply shortage through two initiatives. The first was the launch of Trust Pharmatech, which was planned since I was Senior Vice President of the Manufacturing Division and involved the transfer of Kobayashi Kako production facilities and 400 employees. The second was the construction of a new

solid dosage form facility at Daini Kyushu Factory. Because both projects progressed as planned, we increased our production capacity by 5.0 billion tablets. However, as of May 13, 2024, there continued to be limited shipments of 249 items, and thus we still have a responsibility to meet the expectations placed on Sawai Pharmaceutical to dramatically improve the situation and provide a stable supply.

### Bright signs as pricing policy and interdepartmental collaboration boost business results

In fiscal 2023, our Japan generic drug business revenue rose 8.0% year on year due to growth in sales of products launched since fiscal 2022. In addition, core operating profit increased 11.7% year on year despite the impact of higher energy and sales costs.

The improved business results are due to increased revenue, the revised distribution pricing policy, and implementation of a pricing policy that reflects increased costs into the wholesale acquisition cost, particularly for low-priced items.

As for the pricing policy, the Marketing Division has spearheaded earnest negotiations to win the understanding

of business partners. On the other hand, even after the inappropriate testing was discovered, the Manufacturing Division not only conducted normal production but also worked hard on future-oriented activities, including collaborating on the launch of Trust Pharmatech and addressing construction of the new solid dosage form facility at the Daini Kyushu Factory. Furthermore, with the 2024 drug pricing reforms, there were special increases in the price of unprofitable drugs\* based on requests by companies for recalculation in response to the sudden rise in raw material prices and stable supply problems. Our head office tenaciously negotiated with government authorities regarding the recalculated prices and the Manufacturing Division compiled and provided the data necessary for those negotiations. In this way, the Marketing Division, Manufacturing Division, and head office departments were able to work together, just like a well performing orchestra, and I think this facilitated the fiscal 2023 business results.

However, one issue that we face is the increase in raw material prices, which is likely to continue for a while. There are limits to the extent that cost increases can be

covered by cost cuts through increased productivity, which means we will have to continue to implement pricing policies. Furthermore, we will work to ensure earnings by increasing production capacity and launching better products at the right time.

\* These are prescription drugs for which the Ministry of Health, Labour and Welfare determines it is appropriate to raise or maintain the current NHI drug price because its price is clearly low despite its importance for healthcare.

**Steadily implementing recurrence prevention measures and focusing on talent and system development to restore trust**

It is important to reform our corporate culture to ensure that recurrence prevention measures take root and avoid such incidents as inappropriate testing from occurring again. One such recurrence prevention measure is the Corporate Culture Reform Project, a project directly under the supervision of the President. Project-related information, including its progress, is also available on the Sawai Pharmaceutical website at all times. Furthermore, I explain to all business partners and other stakeholders I meet the progress we have made in implementing recurrence prevention measures.

At town hall meetings, a venue for direct dialogue with employees, I have explained to MRs, who communicate with medical institutions, our progress with production workplace improvements and recurrence prevention measures. MRs use this information to answer questions from medical institutions.

It is necessary to properly develop talent and systems to prevent recurrences. As for system development, the R&D Division is moving forward with optimizing high-mix, low-volume production and further improving quality, starting with high-priority products.

In my opinion, one of the reasons for the inappropriate testing was that work and knowledge depended on particular individuals. Therefore, we are moving forward

with digital transformation both to prevent incidents such as the inappropriate testing from occurring by ensuring work does not become dependent on a particular individual, and to improve production and quality efficiency. For example, in the new facility of the Daini Kyushu Factory, we introduced a system that automatically enters data from analysis equipment and makes necessary calculations, eliminating human involvement as much as possible. We will gradually introduce this system into other factories. At the Kanto factory, where it has already been introduced, this system has eliminated mistakes and improved test efficiency, leading to stable operations. A similar DX is underway in the Quality Assurance Department, and we plan to quickly introduce a quality control system that makes it possible to visualize progress with such operations as deviation management and CAPA in fiscal 2024.

We will only restore trust when our efforts have won the praise of outside stakeholders. As we are now still on the path to restoring trust, we must make our efforts to



Webpage to check progress [https://www.sawai.co.jp/important\\_news/detail/17](https://www.sawai.co.jp/important_news/detail/17) (Available only in Japanese)



Townhall meeting

continue to firmly implement recurrence prevention measures and communicate those results to parties outside the Company. In an emergency, what you do in normal times will come into play. After returning to normal times, it is important to continue to maintain our determination to prevent such an incident from ever occurring again.

**Taking the lead to establish a trusted corporate foundation and generate business growth**

At the start of the Medium-Term Business Plan START 2024 in 2021, the generic drug business was in a precarious position because of annual drug price revisions. Looking back at that time, we made progress with enhancing the production system as planned, and we were able to boost earnings to a certain extent. Furthermore, we saw positive signs for the future in the final year for various reasons, including having introduced pricing policies to achieve a long-term stable supply and having our opinions reflected in price recalculations for unprofitable items.

In the new Medium-Term Business Plan Beyond 2027, which was announced in June 2024, we position the period of the plan as a time to concentrate management resources to ensure quality and expansion of production capacity, and to establish a system for growth in the current Medium-Term Business Plan and great strides in the next. We will make the next round of investments to improve productivity at Trust Pharmatech and respond to further increases in demand at the Daini Kyushu Factory with an eye toward increased production capacity of 3.5 billion tablets, compared to the initially planned 3.0 billion tablets, resulting in overall production capacity of 22.0 billion tablets. It is necessary, however, to enhance production capacity even more in order to increase our share of the Japan generic drug market from the current approximate 17% to our target of 25% or more by fiscal 2030. In addition to our own production, we will likely examine flexibly partnering and collaborating with other generic drug companies.

Another important topic is the steady development and launch of new products. A medium- and long-term



strategy that includes a patent strategy for R&D is critical, as the usage ratio of generic drugs has reached more than 80% and development of new products is becoming more difficult. When it comes to decisions regarding what to develop and launch, rather than having individuals make them, I believe that it is important that we make them systematically by sharing and organizing our development portfolio within the organization.

To achieve that, the most important measure is securing and developing talent, and in the new Medium-Term Business Plan, we have positioned "creating talent that supports sustainable growth" as a key theme. We are focusing on securing talent by strengthening recruiting, as well as making efforts to retain employees, including introducing a mentor system and reviewing personnel allocations at factories. To raise the level of young employees, it is important to improve compensation. We must also be thorough about providing education, particularly GMP and compliance education.

The period of the new Medium-Term Business Plan is an important one for putting us on the path to achieve our long-term vision, the Sawai Group Vision 2030. With myself leading the way, we will raise the morale of employees and move forward to both establish a trusted corporate foundation and generate business growth.

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Senior Managing Executive Officer  
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**Generic drug industry environment**

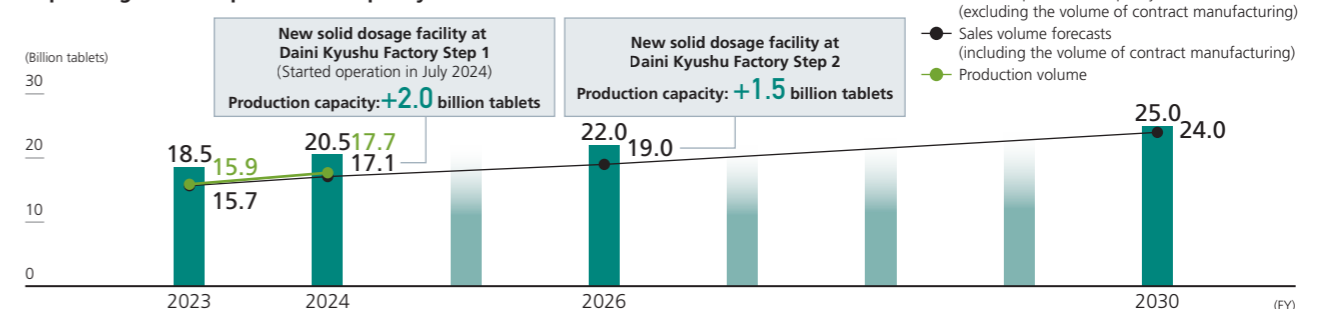
**Social issues**

<b>Rising medical expenses</b> Medical expenses ¥45.0 trillion (FY2021)	<b>Hyper-aging society</b> Percentage of Japanese population aged 65 or older 29.1% (September 2023)	<b>Need for affordable and safe drugs</b>	<b>Drug shortage</b>
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**Quantitative targets and outline of the drug pricing system reform in April 2024**

<b>Quantitative targets</b>	<b>Raising NHI drug prices of unprofitable drugs</b>
<b>Primary</b> — To achieve a volume share of <b>80% or more for generics in all prefectures</b> by the end of FY2029	<b>Repricing of unprofitable products</b> — To raise NHI drug prices of unprofitable products as requested by companies exceptionally in response to soaring costs and supply issues
<b>Secondary</b> — • To have the number of components replaced over 80% by biosimilars constitute <b>more than 60% of the total components</b> by the end of FY2029	<b>Essential medicines</b> — To relax requirements for eligible products from 25 years to <b>15 years</b> after listing
• To achieve a value share of <b>65% or more</b> for generics by the end of FY2029	
<b>Company scoring system</b>	<b>Selective treatment</b>
A system to enhance transparency in companies' supply systems, etc., and to provide preferential treatment in drug pricing to companies with capability and track record	A system under which a patient pays a portion (one-fourth) of the difference in drug price between a generic drug and a long-listed drug when choosing a long-listed drug that is eligible for selective treatment.

**Expanding in-house production capacity toward FY2030**



Note: For the current number of items, it is assumed that the machines are kept running in two shifts per day on weekdays for the current number of items. Contract manufacturing is not included.