

# Turning Dramatic Changes in the Business Aiming for Sustainable Growth as We

President,  
Representative Director

*M. Sawai*



# Environment into Opportunities; Enter the 100th Year Since Our Founding

## Looking Back on Fiscal 2018

The dramatic overhaul of the drug pricing system in April 2018 was a systemic reform that brought the prices of long-term listed drugs and generic drugs closer together. As a result, the patient copayment gap has become narrower than ever, leading to industry-wide concern as to whether the switch to generic drugs would actually occur.

However, when looked at more carefully, the impact of these systemic reforms was negligible, and as

before, the switch from long-term listed drugs to generic drugs proceeded smoothly. In this environment, solid sales of core products such as Oseltamivir and Capecitabine, which are new exclusive products brought to market (as of January 2019), as well as successful efforts to enhance cost competitiveness through more efficient production and multiple purchases, enabled us to achieve higher than expected sales revenues and operating income.

### Consolidated Financial Highlights

Millions of yen

	FY2017		FY2018		Year on year	
	Amount	Composition of sales	Amount	Composition of sales	Amount	Growth rate
Net sales	168,068	100.0%	<b>184,341</b>	100.0%	16,273	9.7%
Core operating income	31,118	18.5%	<b>37,738</b>	20.5%	6,620	21.3%
Operating income	22,209	13.2%	<b>25,798</b>	14.0%	3,588	16.2%
Profit before tax	20,251	12.0%	<b>25,666</b>	13.9%	5,415	26.7%
Profit attributable to owners of the parent	14,017	8.3%	<b>19,376</b>	10.5%	5,359	38.2%

## Solid Core Product Sales Lead to Higher than Expected Sales Revenues and Operating Income

## Future Outlook

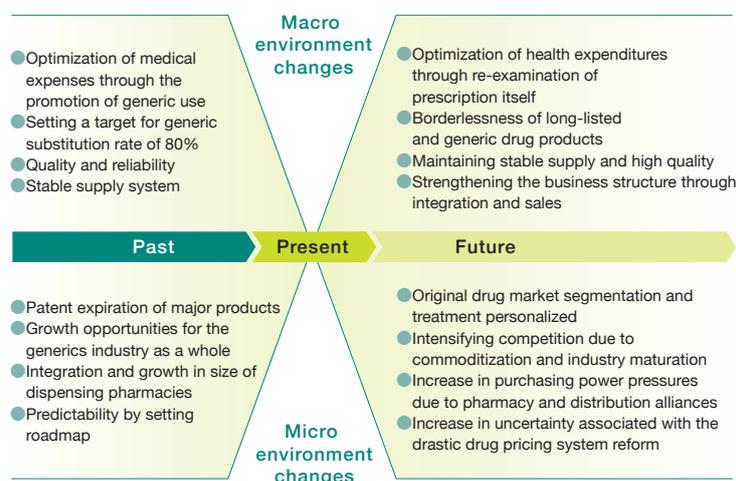
Fiscal 2019 is expected to be quite challenging for the industry. Drug price revisions are expected after the consumption tax hike in October 2019, and further drug price revisions are planned in April 2020. This is the first time that two drug price revisions will occur in such a short period of time. If these challenging conditions persist, some companies will leave the market, making it a near certainty that market share will be concentrated among major generic drug makers. As these conditions provide us with an opportunity to further demonstrate our strengths, Sawai sees a silver lining among even these dark clouds.

While we are also focused on “regional comprehensive care systems” and other government initiatives, this does not change the fact that, ultimately, it is the physician who prescribes generic drugs dispensed to patients at pharmacies. Thus, even if the system changes, we believe the impact will be minor as long as we continue to build relationships of trust with medical institutions as we have up to now.

In Japan, it is thought that the goal for generic drugs is an 80% share. The share of generic drugs in the United States is 90%. In Japan, which is becoming a super-aged society, the share of generic drugs will not stop at 80% given the trend up to now. Even if it is

difficult to reach a 90% share, I think it will naturally rise to more than 85%. Furthermore, up to now generic drug makers have grown overall due to national policy protections, but going forward, we are entering a period in which the capabilities of individual companies will be tested. In other words, there will still be a large growth market for Sawai, and we believe that opportunities to further expand market share will arise as competitors are eliminated.

### Changes in the Micro/Macro Environment



## Synergies with Upsher-Smith

From the very beginning, we have engaged in ongoing discussions regarding synergies with Upsher-Smith Laboratories, LLC (Upsher-Smith), which we acquired in 2017. One of those is expanding the pipeline

through collaborations with Sawai, but it will take three to four years until we can bring a product to market, making it difficult to see any immediate effects of these efforts. As Upsher-Smith was also originally involved in new drug production, they have new drug development capabilities, new drug production equipment, and personnel that we think can be used to create new synergies.

This fiscal year, the U.S. market appears extremely challenging. We will steadily increase our product lineup and number of pipeline assets to continue uncovering more opportunities for new synergies and pipelines than previously planned.

### Financial Highlights of U.S. Business

Millions of yen

	FY2017*	FY2018
Net sales	33,347	40,242
Core operating income	6,730	9,563
Operating income	303	1,568

\*June 1, 2017 to March 31, 2018

## Sustainable Development Goals (SDGs) and Social Contributions

Sawai is aware that its business of providing generic drugs is in itself something that gives hope to people burdened by illness. As a manufacturer of products that affect human life, we conduct our work with sincerity and in good faith so as not to cause anxiety to patients on the basis of supporting the SDGs so that no one is left behind. However, we cannot

address all SDGs, so we focus on Goal 3 (see below) and tackle them one by one. Recently, our Minodronic Acid Tablets won an award\* for their patient-friendly packaging at a global contest. Efforts such as these are born from consideration for how we can make patients happy.

\* See P.20

### Measures Relating to the U.N. SDGs



several of the SDGs through its business activities. We have a particular focus on Goal 3: "Ensure healthy lives and promote well-being for all at all ages," and we are implementing measures that target 13 individual items.

The 17 Sustainable Development Goals (SDGs) and 169 individual targets that were adopted by the United Nations General Assembly as part of "Transforming our World: the 2030 Agenda for Sustainable Development" in 2015 offer important recommendations on the kinds of action we need to take to safeguard humanity's future. Sawai contributes toward the realization of



## Supply Stability: Our Commitment to the Social Infrastructure

Recent discontinuation of the sales and manufacturing of high-profile generic drug products and recalls are shaking the confidence in supply stability. There are various reasons for this, including profitability and active pharmaceutical ingredients (APIs) origin issues. In an era in which generic drugs account for 80% of the market, and market share is becoming concentrated among major companies due to industry reorganization and other factors, Sawai recognizes its tremendous responsibility of ensuring a stable supply of products as part of social infrastructure.

Furthermore, the appropriate preparation is required when accepting G1\* long-term listed drugs. Thus, in addition to quality control, including APIs, and capital investment, we must organize our portfolio and

respond with the collective wisdom of our employees to fulfill our responsibilities regarding supply stability.

### \*G1 Rule

This rule incrementally lowers prices of original drugs ("long-term listed drugs") to the same price as generic drugs over a period of six years for products having a generic replacement of 80% and more (G1) among long-term listed drugs for which 10 years have passed since the initial generic listing. Under this rule, long-term listed drugs can be withdrawn from the market, in which case the generic drug manufacturer who wants to be a successor is responsible for increased production and information provision.

## Corporate Governance Enhancements

With regard to corporate governance, up to now our founder had been responsible for managing the company. We recognize that we had lagged somewhat behind current trends, but we have now arrived at a point where we are able to establish and operate a Governance Committee for Nomination and Compensation. Discussions pertaining to corporate

executive appointments, dismissals and evaluations are led mainly by external directors from an objective perspective. We designed a system that works as an incentive taking compensation levels in the industry into consideration, enabling us to recruit talented human resources from outside the Company. We expect this to contribute to the enhancement of our corporate values.

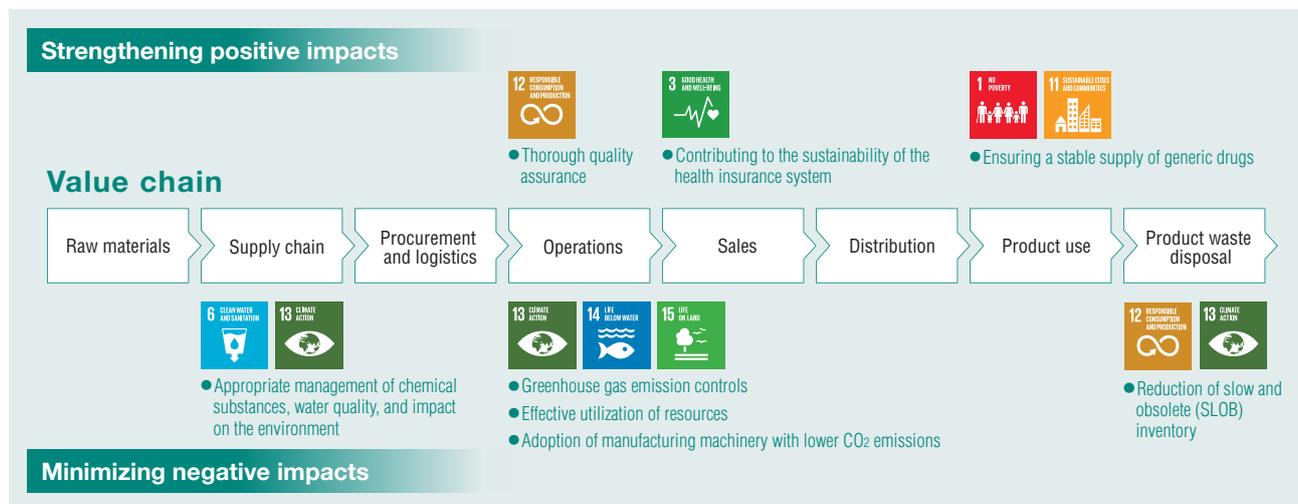
## Environmental Contributions

While we have long engaged in environmental measures at our factories in Japan, we are also constantly thinking about the API manufacturing process.

The pharmaceutical supply chain is extremely long,

and at present, environmental costs are increasing in each process, leading to higher costs. However, we cannot use APIs without this kind of environmental investment. We also engage in green procurement, which includes disclosing information on country of origin. \*

\* As of July 1, 2019



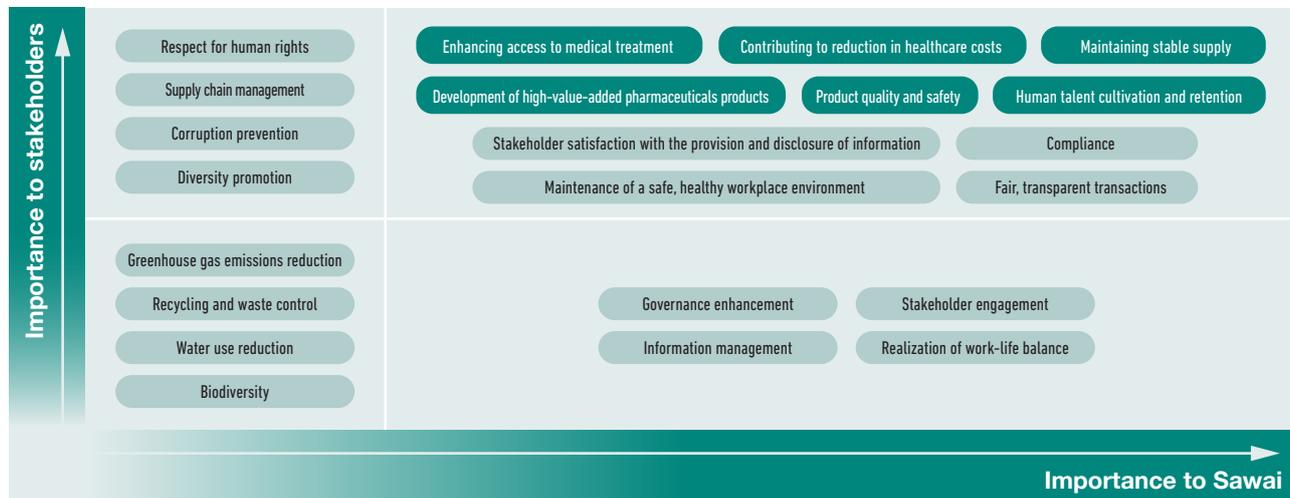
## Sound Management and Employee Diversity

In addition to being recognized under the Ministry of Economy, Trade and Industry's Health & Productivity Management Outstanding Organizations Recognition Program (Large Enterprise Category) for two years straight, Sawai was selected for inclusion in the MSCI Japan Empowering Women (WIN) Select Index, one of the indices used by the GPIF\*, and in 2019, we were selected for inclusion in the FTSE4Good Index Series, the global standard for ESG investment. These accomplishments reflect high esteem for our efforts toward the promotion of health and women's participation

in the workplace. However, we must strive to accomplish further innovations and improvements with regard to employee health, an improved work-life balance, employee workstyles and the creation of workplace environments amid a decline in the workforce. Also, from the perspective of diversity, we must move forward with the recruitment of foreigners. As many APIs exist overseas, we must welcome talented foreigners into our ranks to build out our international capabilities.

\* Japan's Government Pension Investment Fund, the largest government pension fund in the world.

## Identification of Materiality



## Human Resource Development

The “Guidelines Regarding Sales Information Provision Activities” were announced in April 2019 and will go into effect in October. These guidelines substantially restrict the information that Medical Representatives (MRs) are able to provide, which is why now more than ever we need MRs that can build relationships of trust with customers. We are entering an era in which

Artificial Intelligence(AI) will replace half of all human work, yet some work is valuable precisely because humans perform it—I think MRs are one example of this. Thus, if we make human resource development one of Sawai’s strengths, I believe we will be able to further enhance our brand power and organizational capabilities.

## Toward Sustainable Growth

Thanks to all our stakeholders, in 2019 we commemorated 90 years since our founding. Everything Sawai has done up to now has been an embodiment of our belief in “Always Putting Patients First” by viewing the world through the eyes of the end user.

I believe that, as a pharmaceutical manufacturing and sales company, continuing to constantly create products that we put our hearts into will lead to sustainable growth for the next 100 years—and the 100 years after that. Fortunately, Upsher-Smith has also always been managed from the patient’s perspective.

We must strive to ensure that this belief is steadily passed on to the next generation. To this end, I myself, and all employees going forward will pay meticulous attention to our work as we carefully manufacture pharmaceutical products. We will make consumers

happy and never betray their trust and confidence in us. We must be consumed by this simple honesty in all our endeavors.

