



**sawai**

# **Long-Term Vision for 2030 and Medium-Term Business Plan**

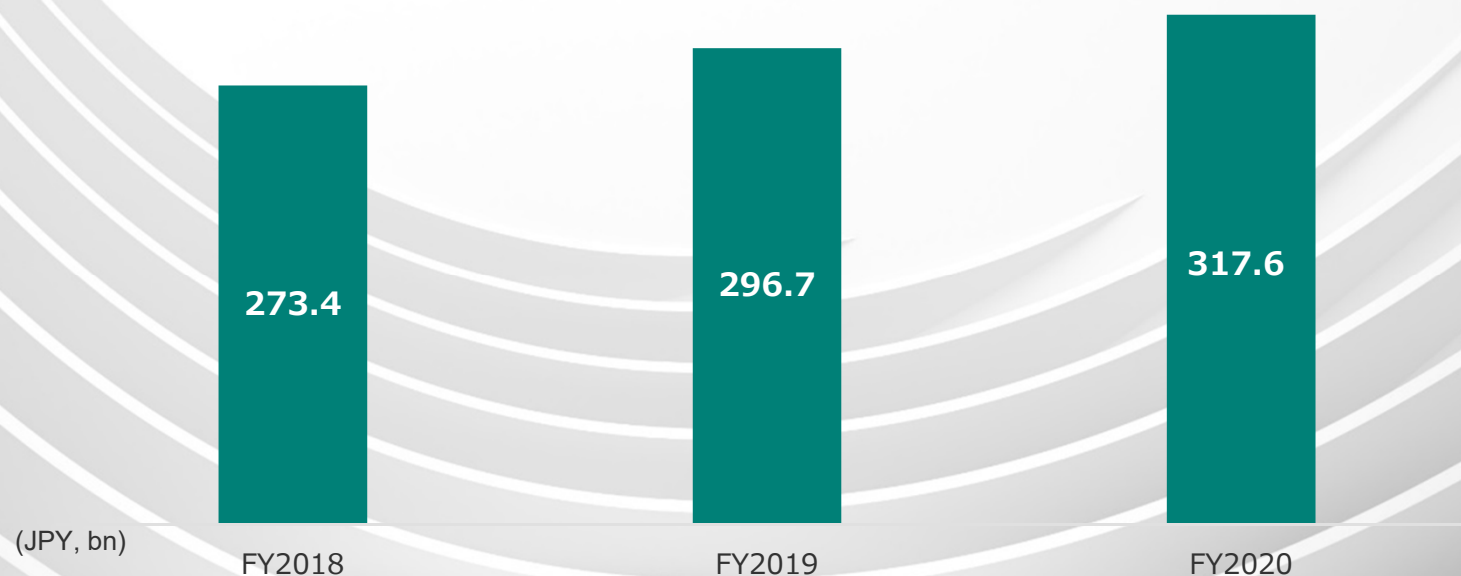
- FY2021 to FY2023 -

Sawai Group Holdings Co., Ltd.

May 2021

## Addressing social issues through Sawai Pharmaceutical's long-time businesses

### Medical cost-saving impact from Sawai Pharmaceutical products



**Sawai Pharmaceutical's business model is to create a growth cycle through realizing healthy lives for patients and reduced medical expenses, contributing to a sustainable society.**

**Sawai Pharmaceutical also achieves growth through working to resolve social issues under its corporate philosophy, "Always Putting Patients First."**

# Always Putting Healthier Lives First

## Working to resolve social issues through Sawai Group Holdings' businesses

- Realizing a sustainable society through the generics business
- Contributing to the extension of healthy lifespans through new businesses

**We will strive to contribute to the health of as many people as possible as a healthcare corporate group developing sustainably alongside society, with the generic drugs as our core business.**

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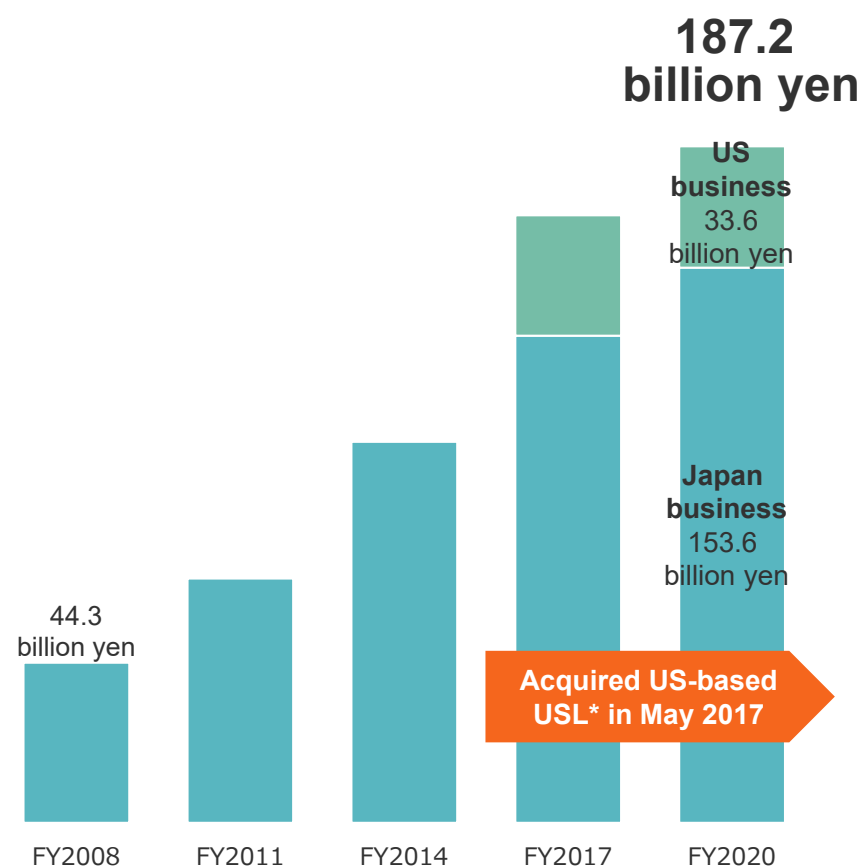
# **Review of the Medium-Term Business Plan M1 TRUST 2021**



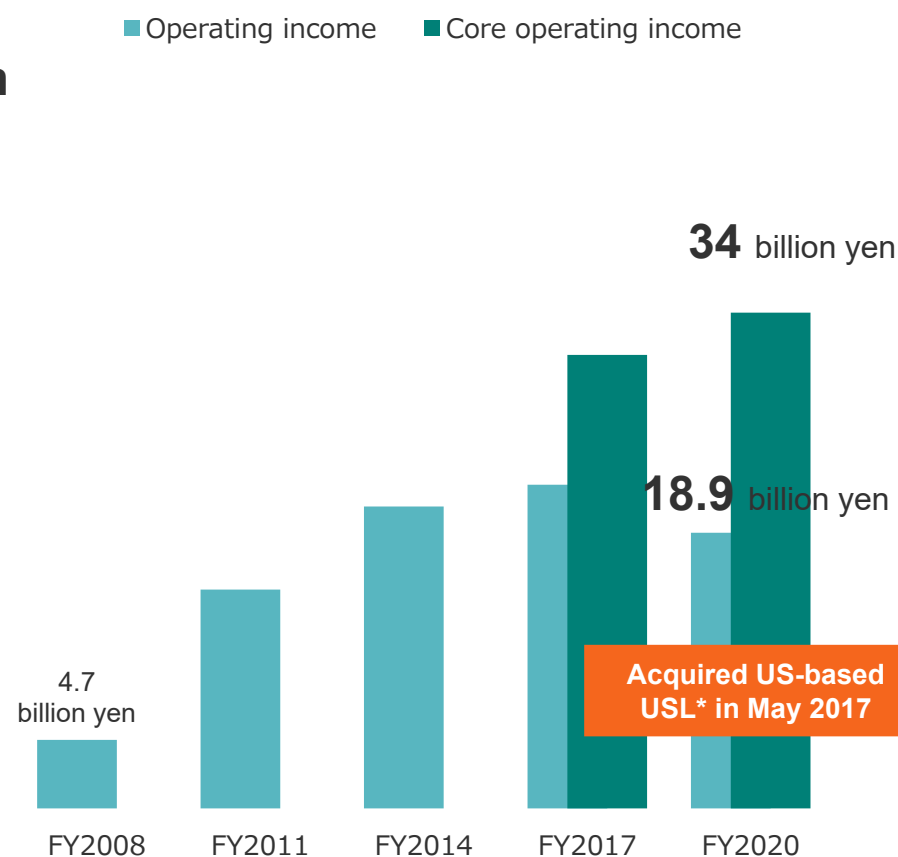
# Historical Growth Trajectory

- Successful upfront investment made in anticipation of policy impact (increasing demand for generic drugs) has achieved steady growth
- Acquired USL\* in May 2017, making a full-scale entry into the US market

## Revenue



## Operating Income / Core Operating Income



\*USL: Upsher-Smith Laboratories, LLC

(Note) IFRS standards applied as of FY2018

## Matters Achieved

### Japan business

- Ranked No. 1 and No. 2 in generics in new product sales share
- Improve production efficiency by consolidating manufacturing sites through plant transfers, etc.
- Launch of single-market and competitive-superior new products
- Develop proprietary technologies

### US business

- Expansion of pipelines and product lineups
- Started construction of a new factory to strengthen manufacturing capacity via factory consolidation



## Future Issues

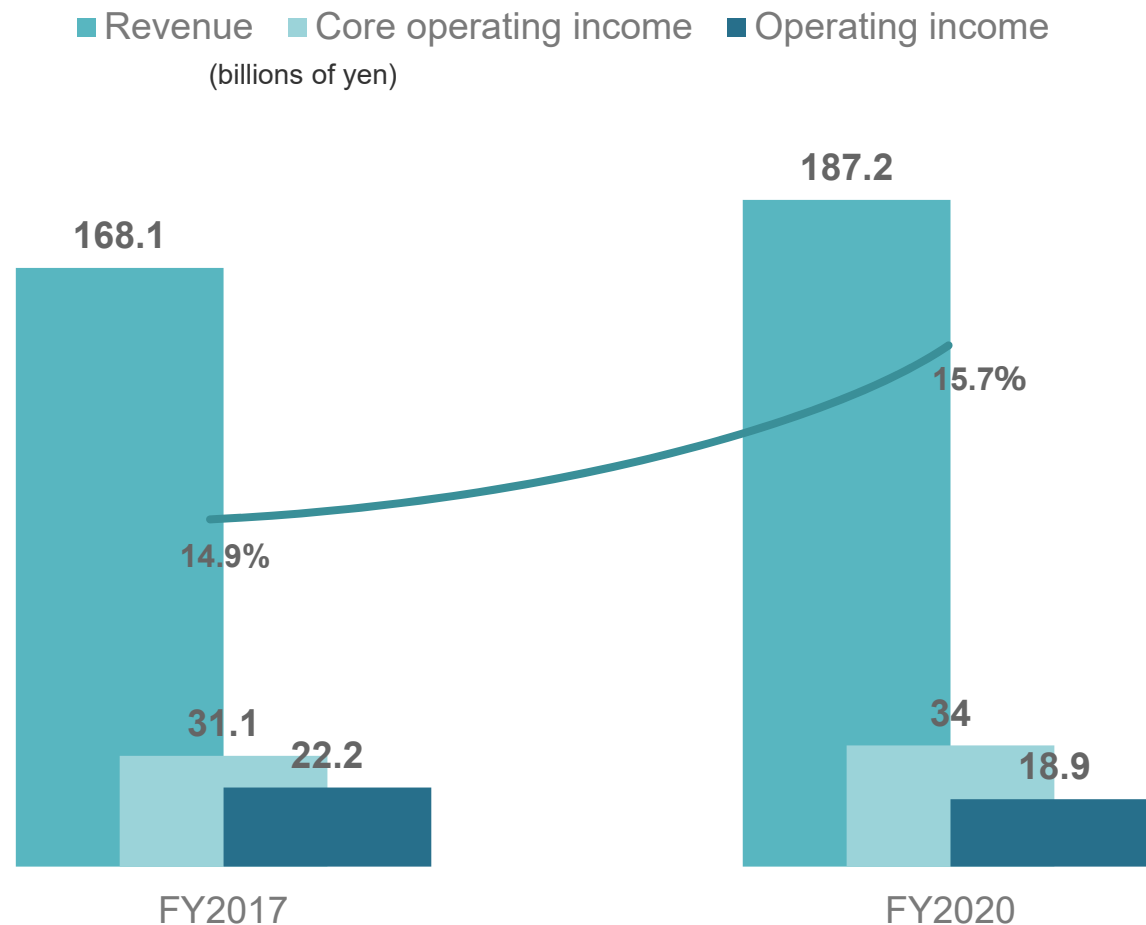
### Japan business

- To further expand market share

### US business

- To realize growth in US business

- Despite the severe business environment, both revenue and core operating income increased by 10% during the previous medium-term business plan
- Generics volume share in Japan rose 0.8 points to 15.7%

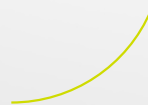






# Recognizing the Business Environment

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# Changes in the External Environment: Trends and Technologies

## Changes in Trends

A more aging society, changes in values for prevention/pre-symptomatic illness

**Era of 100-year lifespans**

**Emphasis on prevention of disease and pre-symptomatic illness state**

**Increasing medical costs**

**Increasing home care**

## Evolution of Technology

Advances in technological innovations such as new modalities, AI, and robots

**New modalities**



**AI**



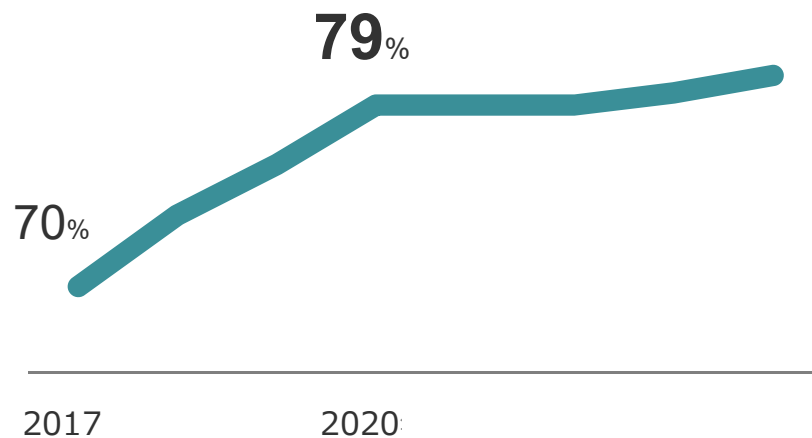
**Digital**



**Robotics**



Generics volume share\* in Japan



- Generic drugs volume share has reached almost 80% for the three years since 2017
- Although growth is expected to slow down in the future, the demand is expected to grow to some extent

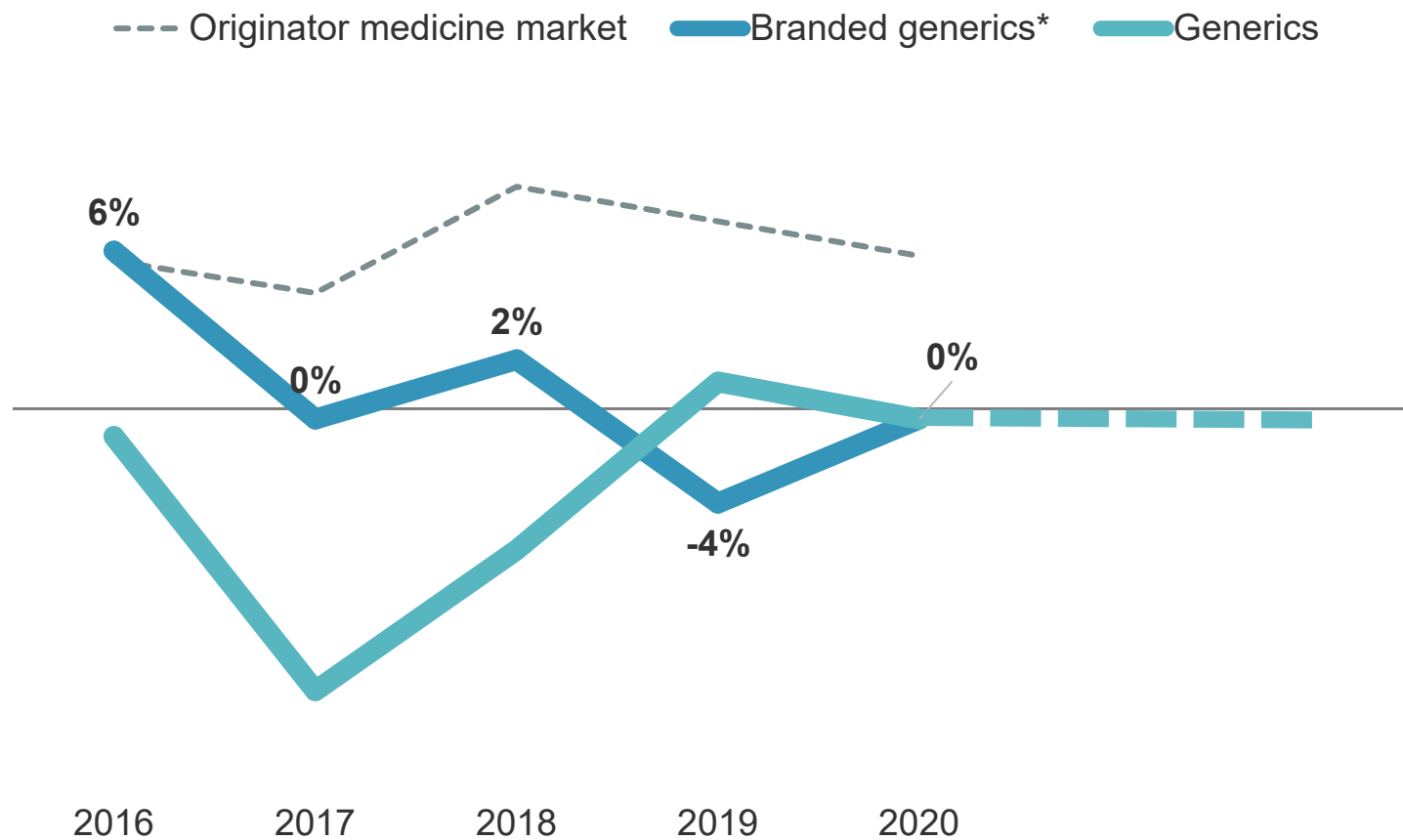


**Potential for accelerating industry reorganization due to falling drug prices driving deteriorating profitability**

\* Volume shares are Sawai estimates

## Changes in the External Environment: Current Situation of the US Generics Market

- US generics market grew negatively in 2017 and 2018
- The latest figures have remained almost flat



\* ANDA-approved branded generic drugs

Source : IQVIA, national Sales Perspectives, November 2020

Note : Limited to Rx and OTC Insulins; Includes Retail, Non-Retail and Mail



# Our Vision for 2030



## Sawai Group Vision 2030



### The World We Want to Build

**A world where more people can receive healthcare services and live a full life with peace of mind among society**



### Our Ideal State

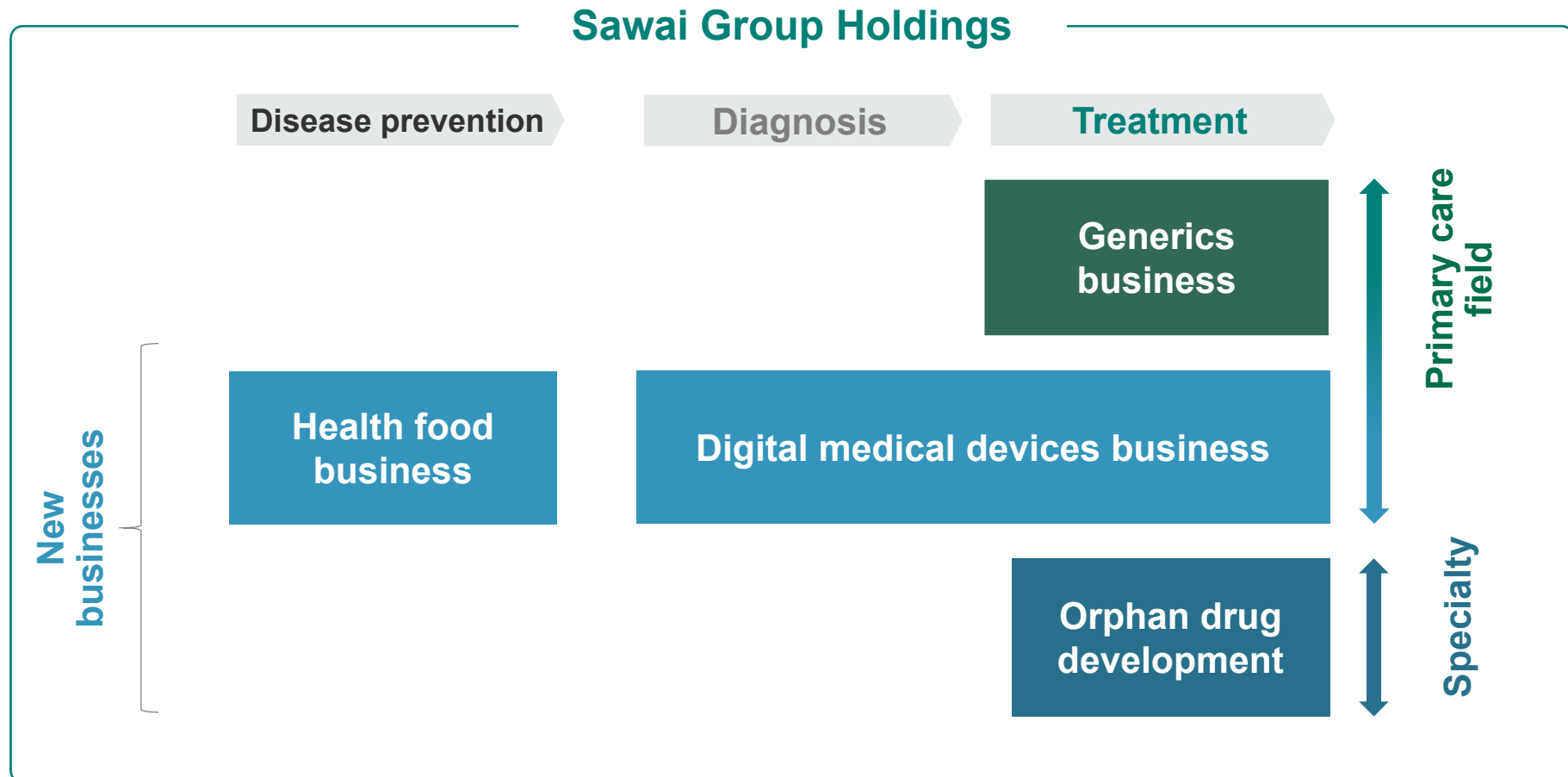
**A company with a strong presence that continues to contribute to people's health by providing a multifaceted mix of products and services based on scientific evidence that meets individual needs**

# Sawai Group Vision 2030: Business Development

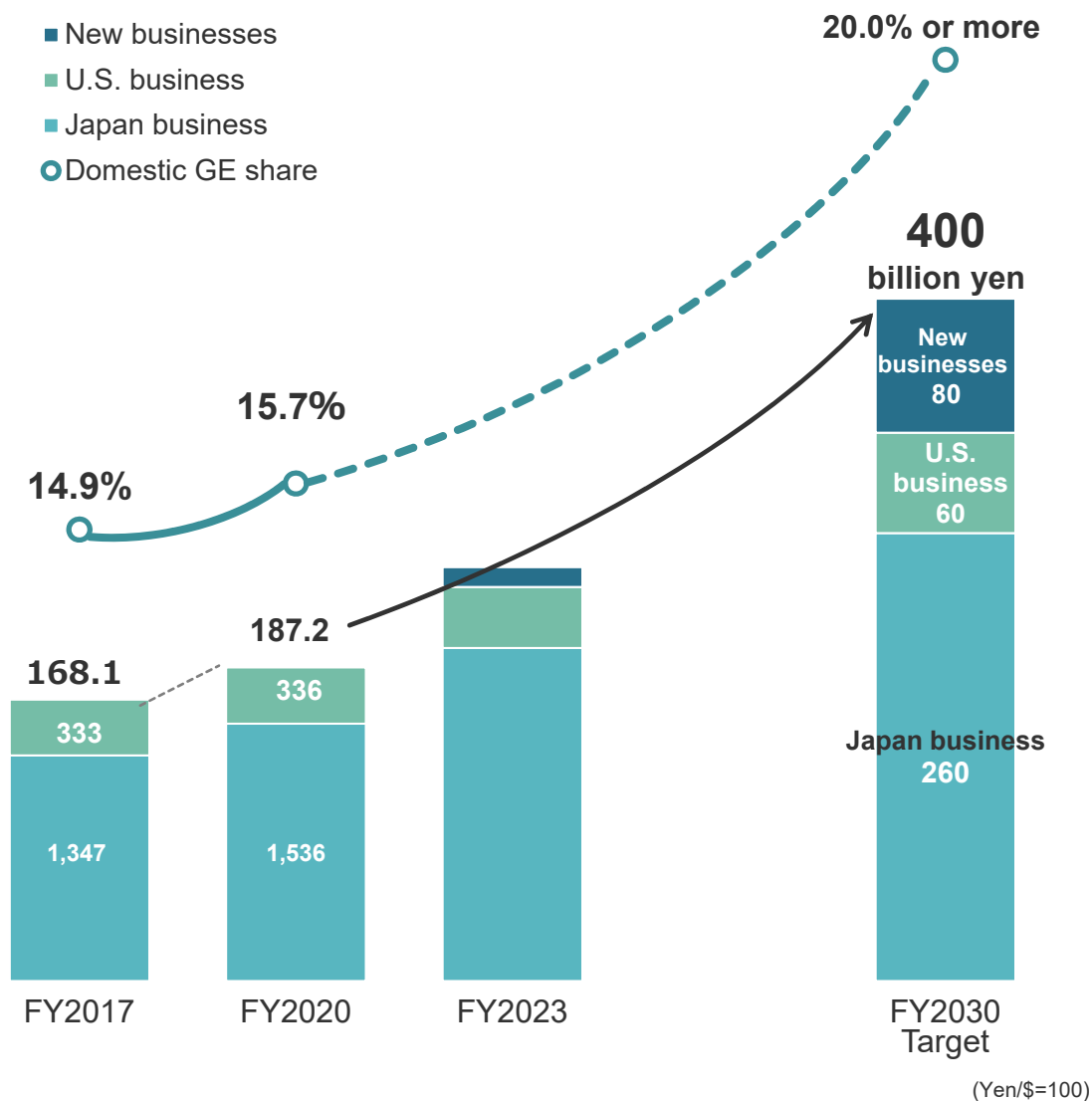
**Fostering new businesses with generics as our core business**

**Providing a wide-range of options, not limited to drug treatment,  
from prevention to treatment in the primary care field**

**Entering the new drug development business in the orphan diseases field  
in order to provide unprecedented treatment opportunities**



# Sawai Group Vision 2030: Quantitative Targets



Targets and Prerequisite Values

		As of FY2020	FY2030 under Vision 2030
Japan business	Revenue	153.6 billion yen	260 billion yen
	Sales volume	13.3 billion tablets	20 billion tablets
	Share of sales	15.7%	20.0% or more
	Production capacity	15.5 billion tablets	23 billion tablets or more
New businesses	Revenue	—	80 billion yen
US business	Revenue	33.6 billion yen	60 billion yen
Total revenue		187.2 billion yen	400 billion yen
ROE		5.8%	10% or more



# Medium-Term Business Plan, START 2024



# Three Categories for Growth 2024 Onward

## Generics business

### 1) Expanding share in the Japanese generics market

- Increasing sales of new products
- Strengthening stable supply capabilities

### 2) Business investment for future growth in the US



## Entry into new businesses

### 3) Cultivating new growth areas

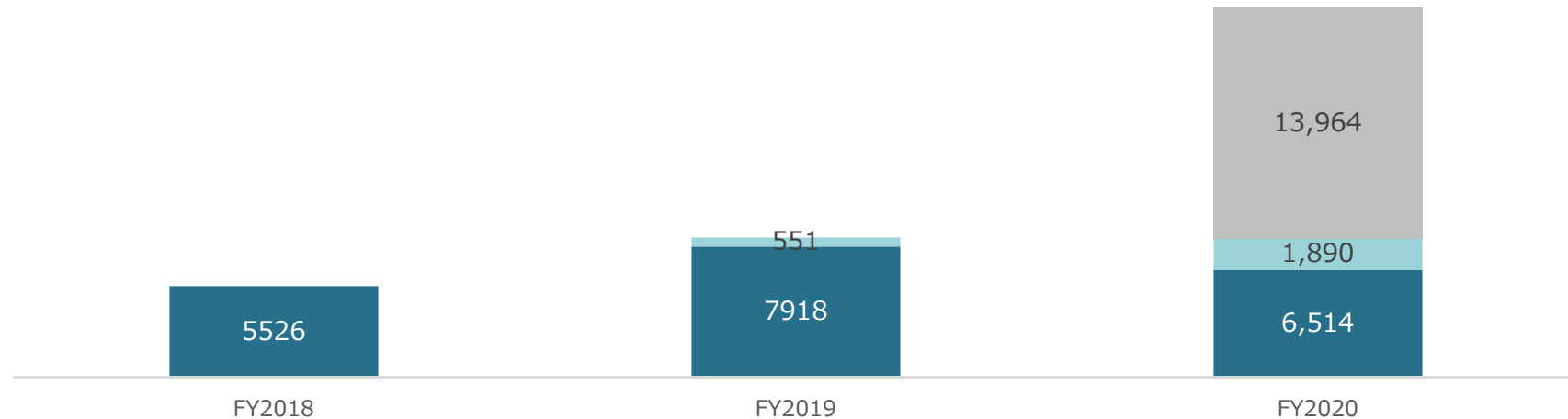
- Digital medical devices business
- Orphan drug business (ALS, etc.)
- Health food business

## (1) Expanding Generics Market Share in Japan: Increasing Sales of New Products

**Launched 89 products in three years**  
**Strongly competitive products (including single-market products)**  
**serve as core drivers for sales**

Revenue from products launched in the past three years

■ Products launched in FY2018 ■ Products launched in FY2019 ■ Products launched in FY2020 (Unit: millions of yen)



Numbers of products launched in the past three years and strongly competitive products

	FY2018	FY2019	FY2020
Number of products	33	14	42
Single-market and strongly competitive products (included in above)	3	7	9
Major products released (generic name)	Capecitabine Oseltamivir	Micafungin sodium (for IV infusion) Tadalafil CI Aprepitant	Eldecalcitol Bazedoxifene Fexofenadine hydrochloride / Hydrochloride pseudoephedrine (Pusofeki combination tablets) Repaglinide Vardenafil

## (1) Expanding Generics Market Share in Japan : Increasing Sales of New Products

**Planning for launch of over 85 products in the next three years**

**Going forward, we will continue to outperform industry peers through our strategy of leveraging our intellectual property strengths and aiming to expand profits in the generics business in Japan as a whole**

### New product launch plan

	FY2021	FY2022	FY2023
Number of ingredients	14	11	14
Number of products	32	27	26
Original drug market (billions of yen)	250.7	288.0	274.4
Original drugs for first-listed Generic drugs	Cymbalta capsule / Patanol ophthalmic solution / Samsca OD tablets / Nexium capsules / Azilva tablets		

**Also planning launch of single launch products  
other than those listed above**

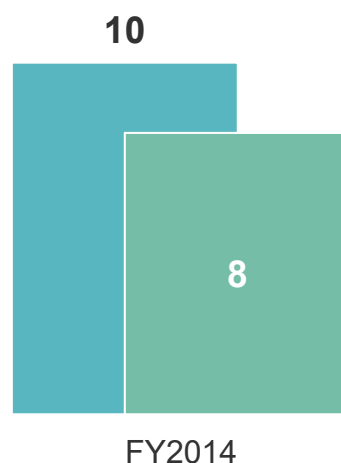
## (1) Expanding Generics Market Share in Japan : Strengthening Stable Supply Capabilities

Aiming to further improve supply capacity by taking all reasonable measures in anticipation of industry reorganization and consolidation, e.g., building new factories, acquiring factories, and securing high-quality production contractors

Industry-leading production capacity, sales volume

■ Production capacity  
■ Sales volume

(billions of tablets)



Aiming to establish an in-house production system for more than

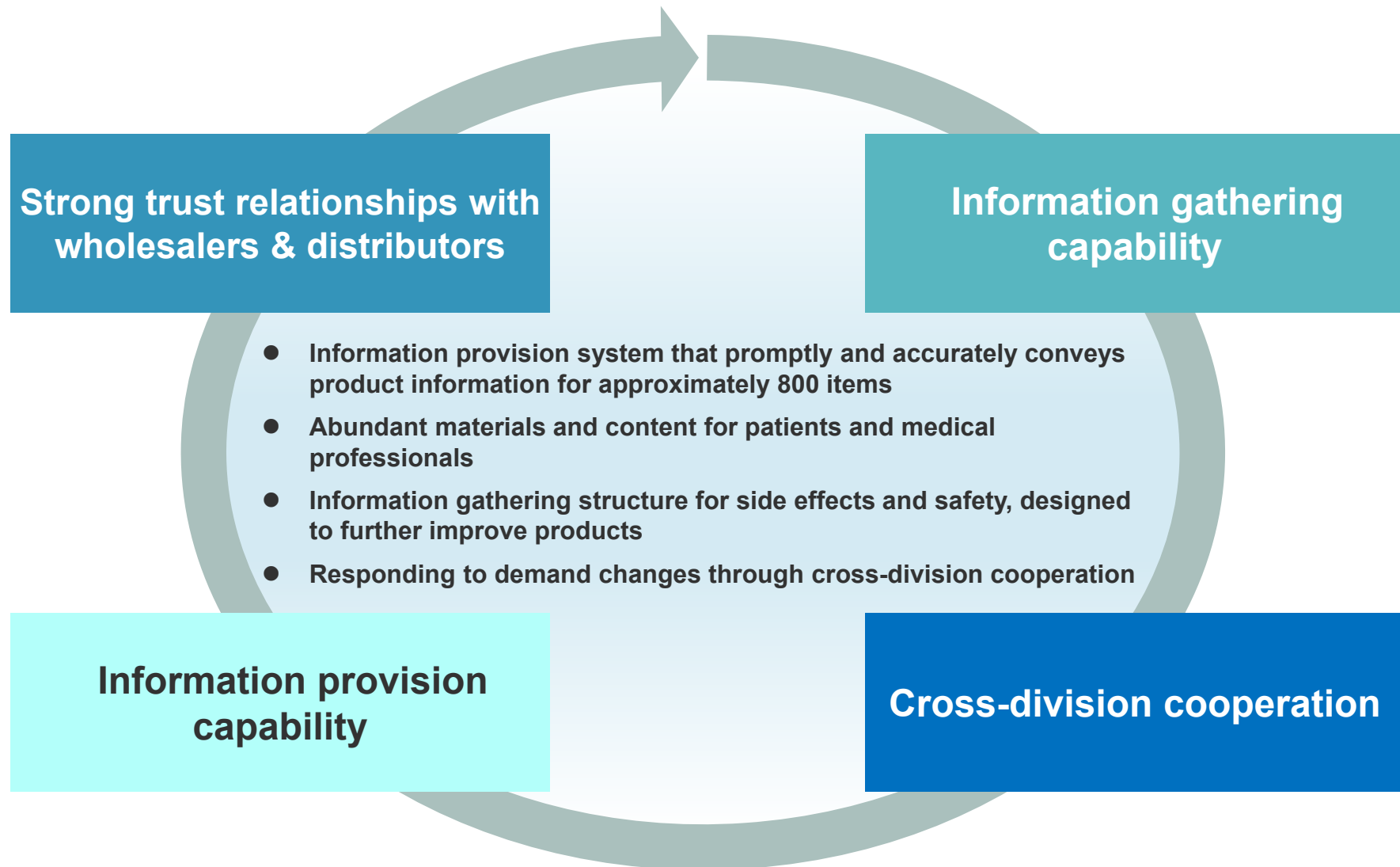
**20 billion tablets**



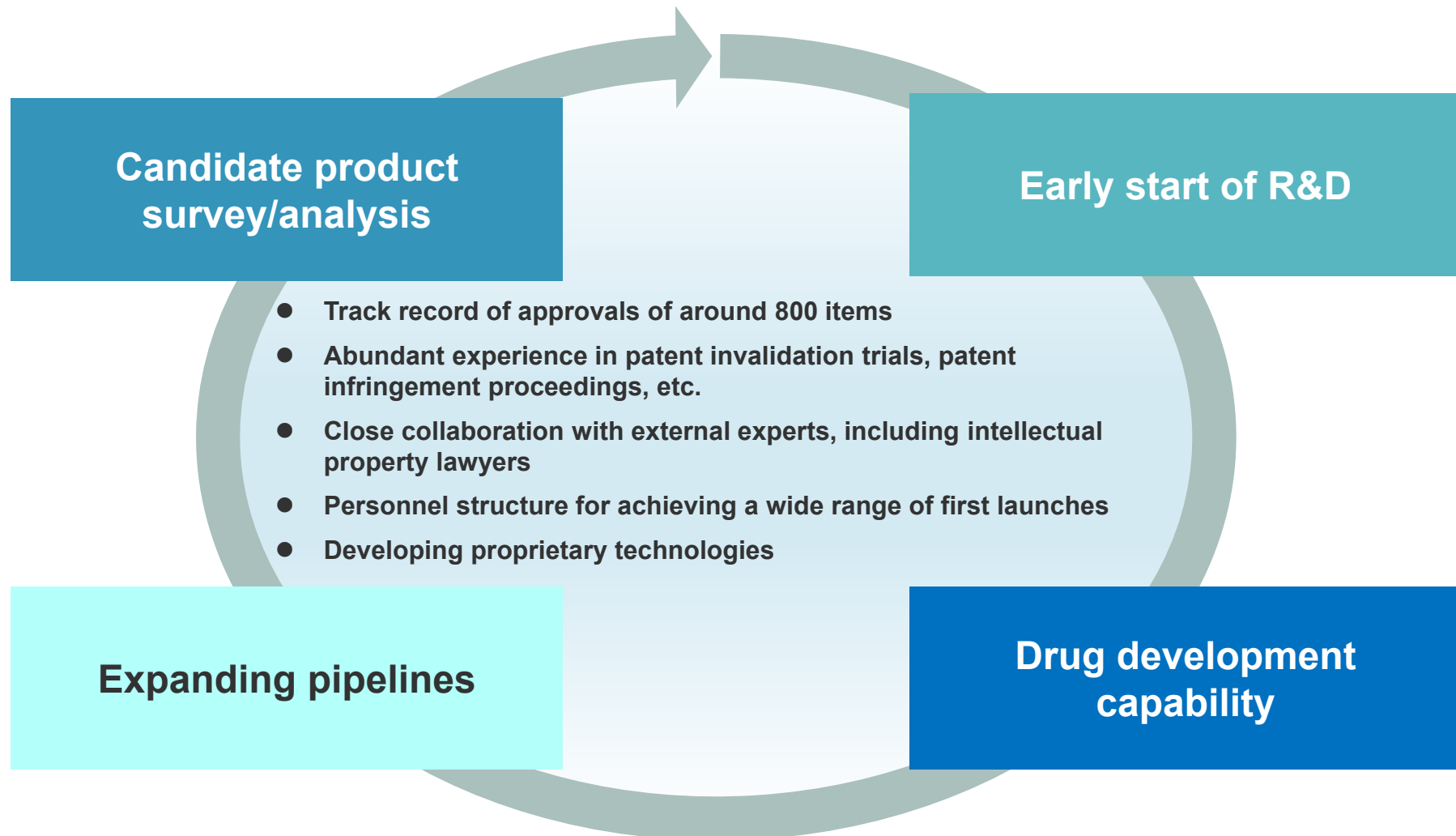
**Aiming to further expand share in the Japanese generics market by leveraging Sawai Pharmaceutical's strengths**



## Building the Sawai brand through a steady track record of activities

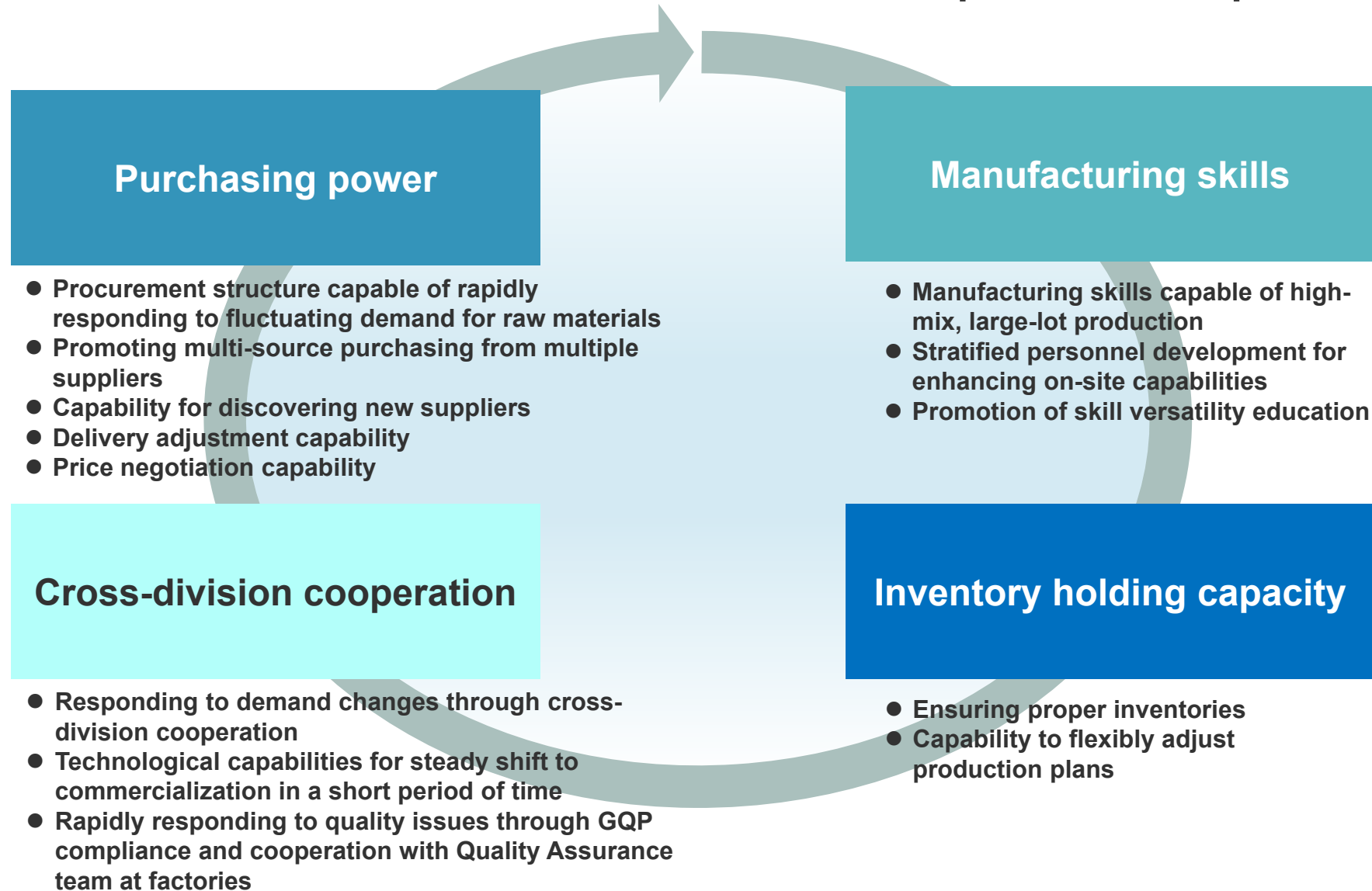


## Achieving first new product launch through R&D and drug formulation development capabilities

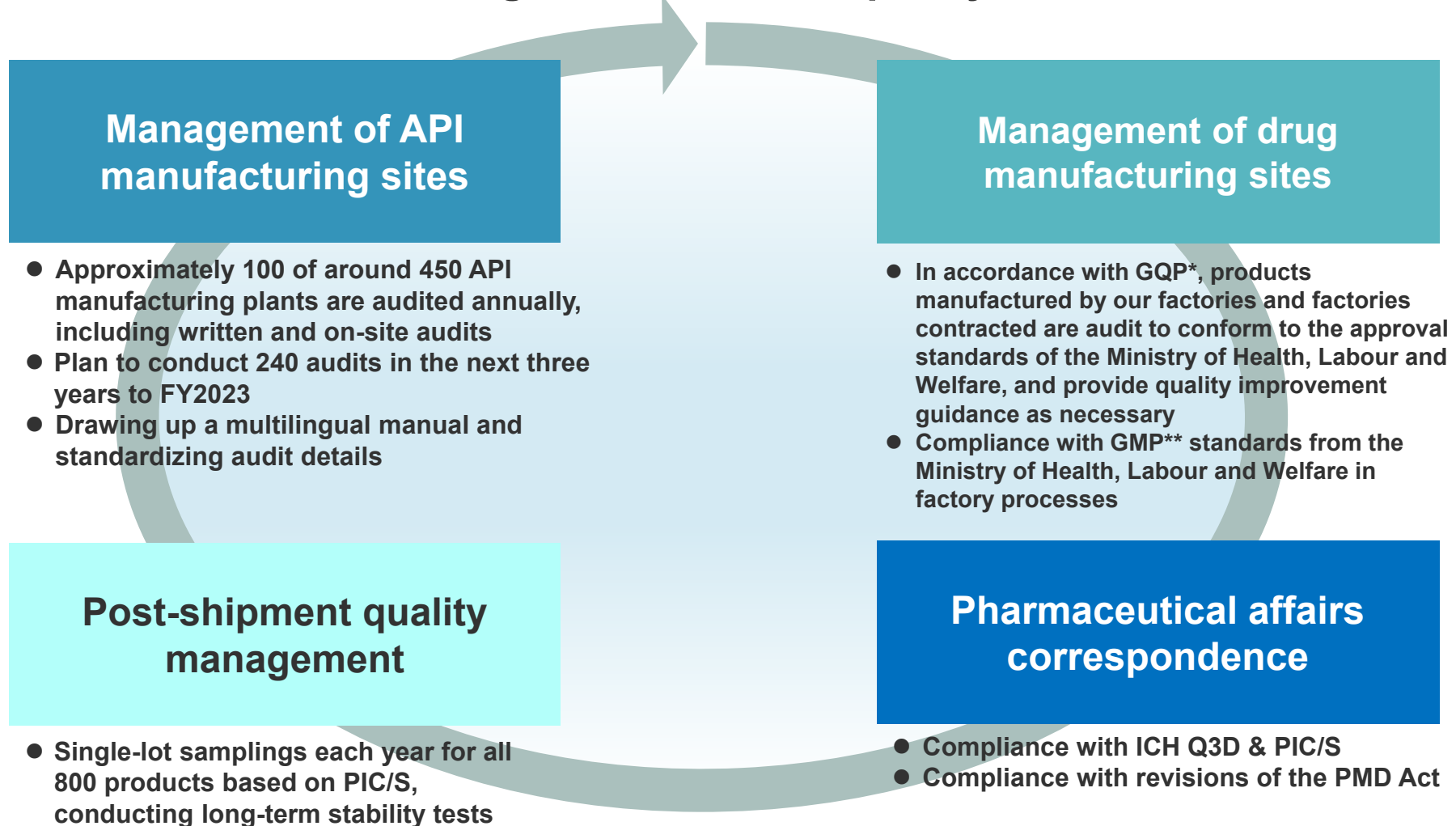




**Achieving stable supply by making full use of expertise as a generics-dedicated manufacturer and internal and external production capabilities**



## Implementing a variety of initiatives to provide a higher standard of quality

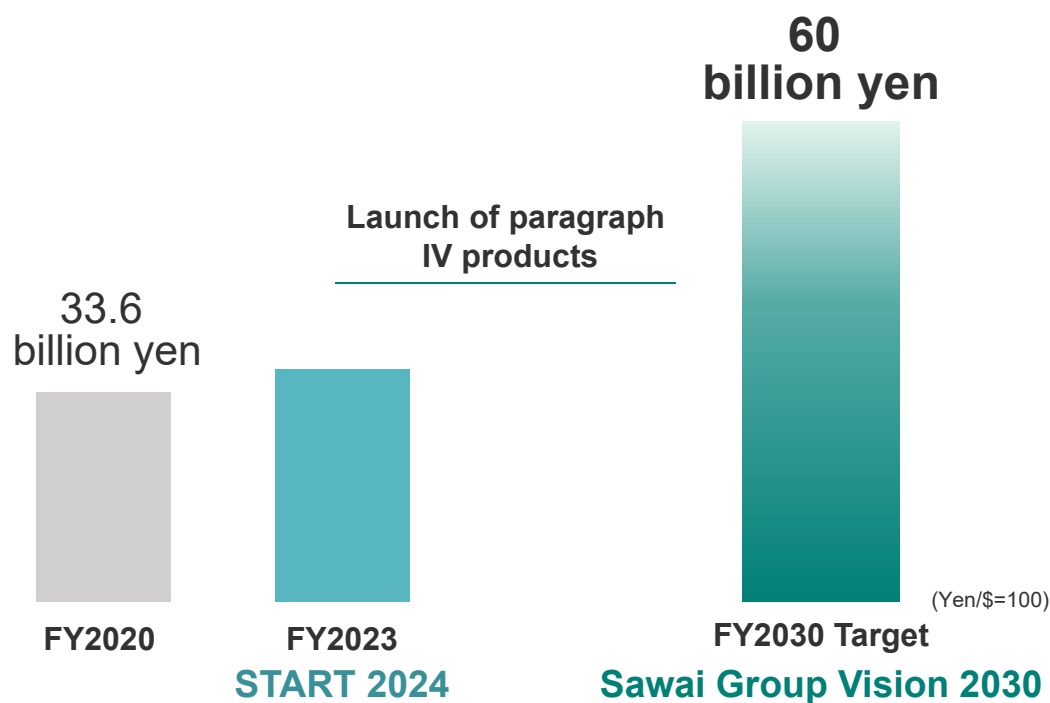


\* GQP (Good Quality Practice): Criteria for checking whether the company's manufacturing factory or contracted manufacturer is conducting proper manufacturing control/quality control

\*\*GMP (Good Manufacturing Practice): Standards for pharmaceutical manufacturing control and quality control by the Ministry of Health, Labour and Welfare

## (2) Business investment for future growth in the US business

Future earnings image



Planning upfront investment  
in facilities and R&D, etc. for improving  
profitability in the future during the three-  
year period ending in FY2023



**Aiming for growth from  
2024 onward**

# Strategy and Growth Drivers for US Business (USL)

## Desired State

**Upsher-Smith will drive sustainable long-term growth as a specialty generic company focused on generics and small brands that leverage its unique commercial capabilities**

## Growth Driver

**Contribute to sales by promoting sales of existing brand drugs and generics**

**Further expansion of product lineup mainly in niche generics**

**Strengthen product pipeline with high complexity and product lineup in cooperation with Sawai Pharmaceutical**

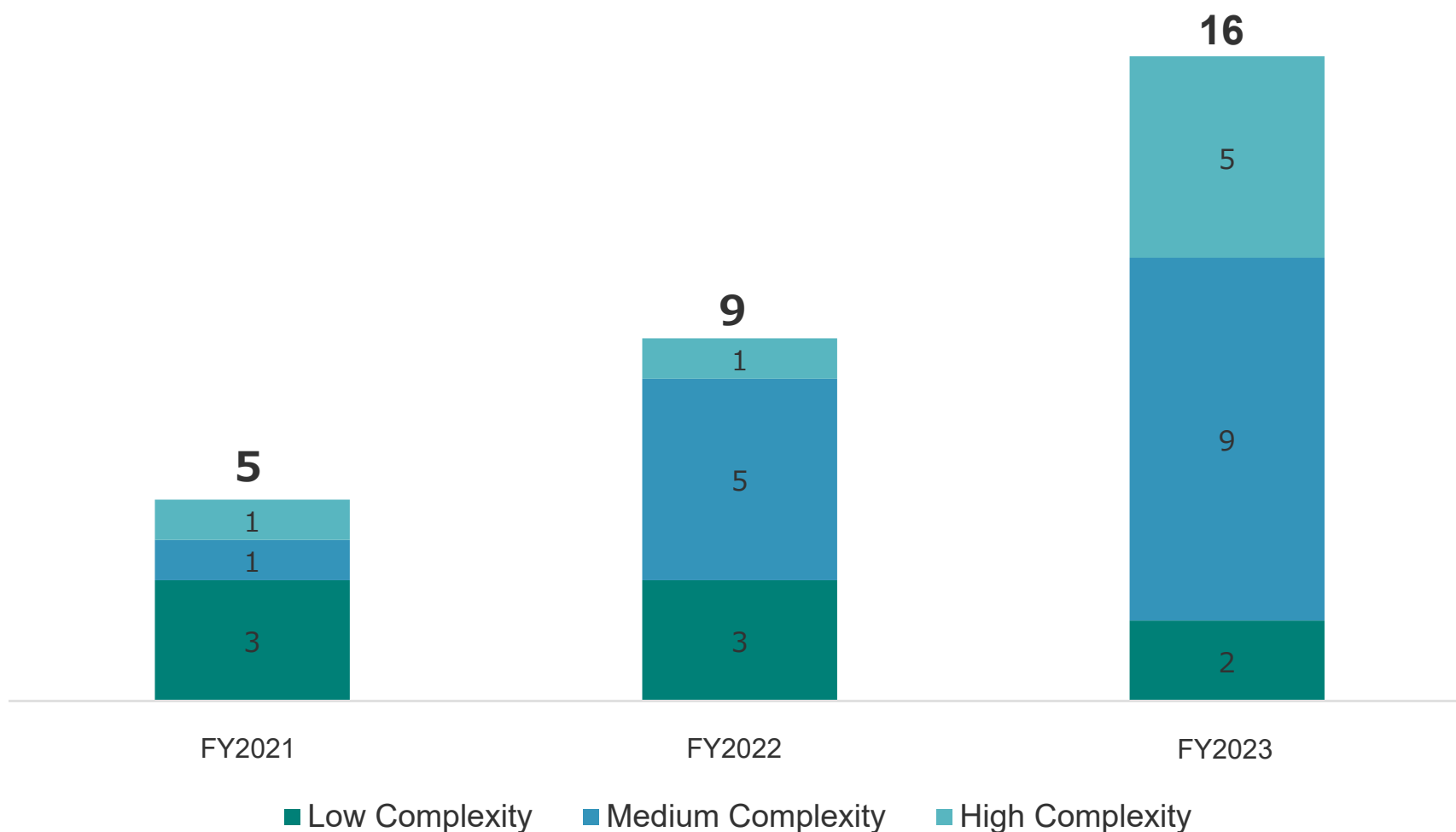
# Outline of Strategies for US Operations (USL)

Products Strategy	Existing products	<div>Focus on key products</div> <ul style="list-style-type: none"><li>• Zembrace, Tosymra: Utilize specialty pharmacy, reduce the use of Platinum Pass to improve ASP, actively visit doctors, and undertake other measures to expand sales channels</li><li>• Vigadrone: Aim to increase the revenue</li><li>• Qudexy: Aim to retain sales of Topiramate, which is the authorized generic of Qudexy, utilizing specialty pharmacy</li></ul>
	New products Pipeline	<div>Generic Drugs</div> <p>Currently 42 development pipeline items with a total market size of \$4.5 billion Subsequent addition of pipeline with focus on niche generics</p>
		<div>505(b)(2)</div> <p>Developing corticotropin injection, a drug for infantile spasms, multiple sclerosis and other indications, in collaboration with AmbioPharm Pre-IND meeting with the FDA for product development scheduled in May</p>
		<div>Paragraph IV</div> <p>Aim to sell pitavastatin tablets and mirabegron tablets in the US in the future Additions to Paragraph IV products</p>
		<div>Orphan drugs</div> <p>Sawai Pharmaceutical, in cooperation with Neugen Pharma, is developing a drug for amyotrophic lateral sclerosis (ALS). Launch the clinical study in the US in 2021</p>
Cost control measures		<p>Capital expenditures to improve production efficiency</p> <p>Review overall costs</p>

## US business (USL): Planned launches of generic drugs

Planning for launches of over 30 products in the next three years  
Total market size for these product is approximately 430 billion yen

Expected number of generic drugs launch in the next 3 years



# Project to create a new factory in the US business (USL)

## Overview

- Consolidating all marketed products into a single manufacturing plant
- Consolidation to a single manufacturing plant to lower operating expenses and improve quality and efficiency
- Planned total investment amount for the construction and Denver product transfer: \$13 billion yen

## Expected benefit

1. Expected annual manufacturing cost reduction of approx. 1 billion yen from 2023 onward through consolidation of facilities and repatriation of CMO products
2. Improved efficiencies driven by the long-term benefit of consolidating operations into modernized facility
3. Improved quality through electronic batch records, better material and manufacturing flow and improved equipment



## Key Milestones

**Jul 2022**

Qualification & validation complete

**Dec 2022**

Denver product transfer complete

### (3) Cultivating New Growth Areas: **Entry Into New Businesses**

- Focusing resources on three areas: new drug businesses (orphan diseases), Digital medical devices business, and Health food business
- In addition to investing in existing businesses, setting an investment budget of 30 billion yen in new business areas during the period of the Medium-Term Business Plan

Specialty Drugs		Primary Care	
New drug businesses		Digital medical devices business	Health food business
Orphan diseases (e.g., ALS)		Depression/psychosis treatment	Pre-symptomatic illness measures
		Diabetes/lifestyle-related disease management	Longer healthy lifespans



### (3) Cultivating New Growth Areas: **New Businesses: Orphan Diseases**



#### **ALS treatment WN1316/SW007**

Jointly develop WN1316, a drug for amyotrophic lateral sclerosis (ALS) treatment, which was discovered by Neugen Pharma, targeting global markets including North America, Europe, Asia, and Japan, for all indications applicable as an ethical drug. (announced in June 2020)

Advance the development optimizing each company's expertise - Neugen Pharma's knowledge on ALS and Sawai's clinical R&D capability including drug development

#### **Target markets, numbers of ALS patients**

The United States is the main target market for the time being  
Between around 20,000 to 30,000 ALS patients in the US

#### **Future plans**

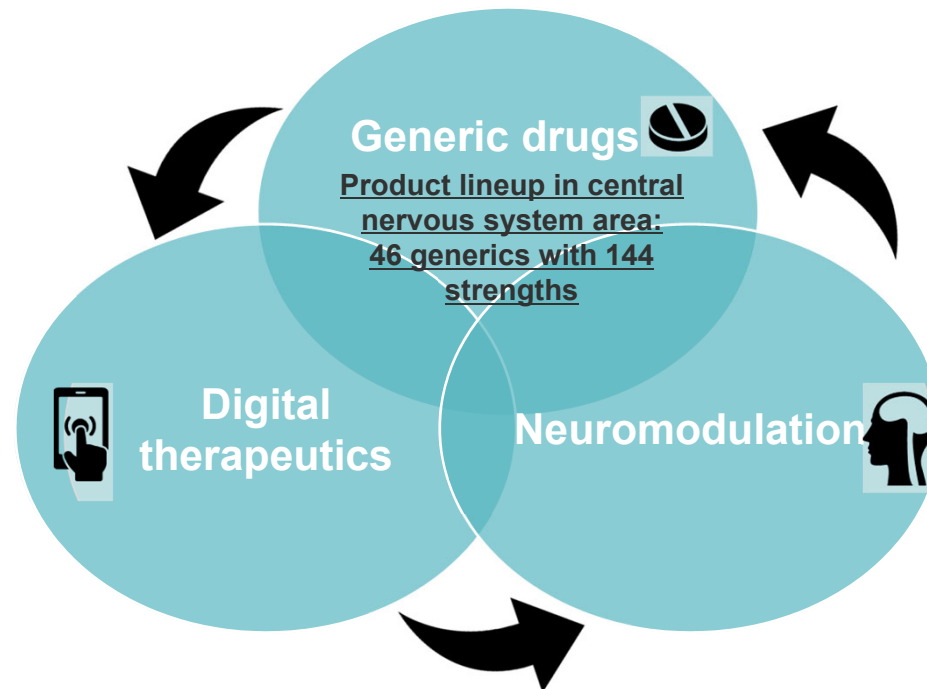
To launch Phase I clinical studies in the US in FY2021  
Market launch target: 2025 or thereafter



Aiming to expand the pipeline targeting orphan diseases in the future

**Aiming to be the only player in the industry  
who can provide a trifecta solution**

In the central nervous system area, recent years have seen increasing needs for device therapy and cognitive behavioral therapy in addition to drug therapy.  
On the other hand, the development and provision of solutions are still limited.



**In addition to drug treatment with generic drugs, we are aim  
to provide services utilizing cognitive behavioral  
therapy applications (DTx) and neuromodulation**

### (3) Cultivating New Growth Areas: New Businesses - Digital Medical Devices Business

#### Capital and business alliance with SUSMED

Through the investment in SUSMED, a digital therapeutic company with applications for treating insomnia, collaborations that can blend and optimize SUSMED's technology and knowledge in the digital healthcare field and Sawai Pharmaceutical's generic business are under consideration (announced September 2020)

#### Looking ahead

We continuously consider improving operational efficiency, such as reduction of R&D costs using SUSMED's blockchain technology, and collaboration in the areas of depression and psychiatry

#### Medical devices for migraines/depression

We have entered into an exclusive development and marketing agreement with Neurolief, targeting the Japanese market. Neurolief's non-invasive neuromodulation device allows patients to use it at home, and can share treatment data with their physician, in addition to uploading the data to the cloud database through a dedicated app. It is also designed to self-learn and analyze the treatments using AI technology in order to optimize the treatments for patients according to their symptoms. (announced January 2021)

Proposed as a new treatment method to patients who are receiving drug treatment but feel no effect.

#### Number of target patients

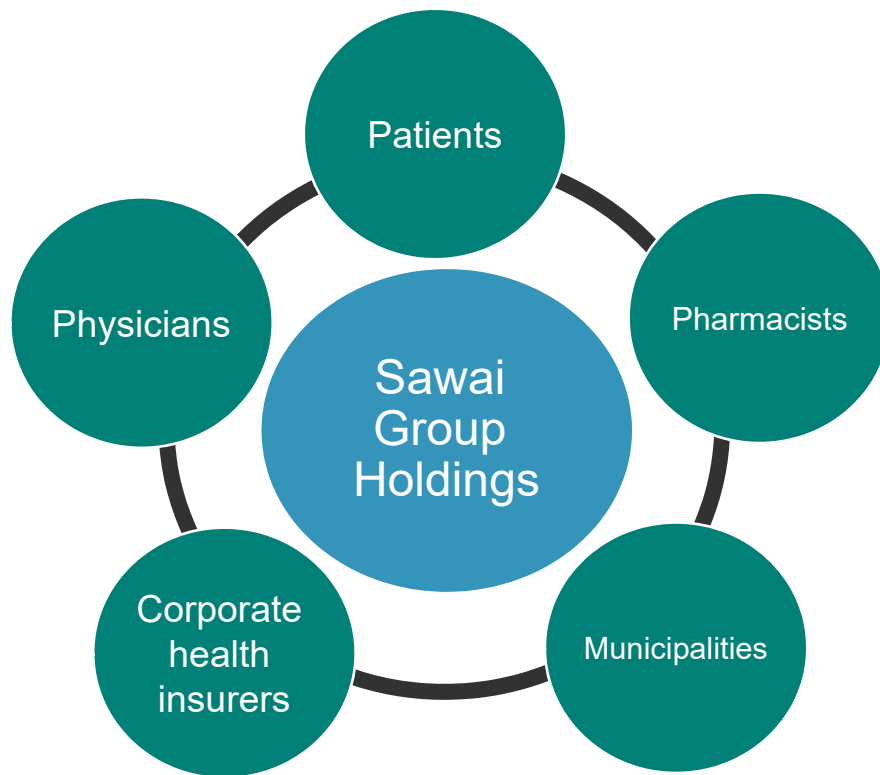
392,000 (Patients with migraines who are non-responsive to drug treatment)  
174,000 (Patients with acute depression who are non-responsive to drug treatment)

#### Future plans

For migraine - Application: 2022, Launch target: 2023  
For depression - Application: 2023, Launch target: 2024

### (3) Cultivating New Growth Areas: **New Businesses - Digital Medical Devices Business**

Contributing to improving people's lifestyles, health, and quality of life by providing and utilizing medical and health information, not only pharmaceuticals



Through strategic alliances with various companies, we broadly contribute to medical care by providing solutions that utilize IT technologies

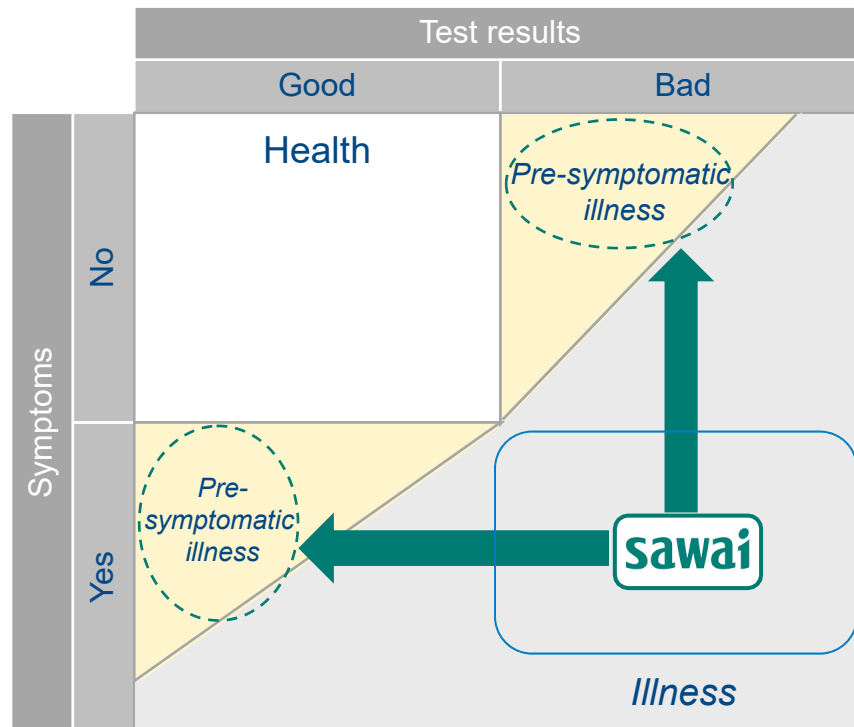
- Support from prevention to treatment for lifestyle-related diseases and chronic diseases using PHR\* data
- Support for addressing diversifying medical treatment styles
- Support for health activities of companies and local governments
- Support for regional medical cooperation

**Aiming to play a role in connecting various stakeholders,  
e.g., patients and medical professionals**

\*PHR (Personal Health Record) is a mechanism for patients to collect and centrally store their own medical/health information

### (3) Cultivating New Growth Areas: New Businesses - Health Food Business

- Considering entry into the health food business, where we would support longer healthy lifespans in the areas of pre-symptomatic illness and prevention (e.g., locomotive syndrome/frailty measures, and dementia/lifestyle-related disease prevention)



#### Target markets

2.3 trillion yen scale of total health food market

The market for extending healthy lifespans, including a number of areas such as locomotive syndrome/frailty/dementia covers 18% of the market

In addition, the market covers many people receiving insurable medical treatment

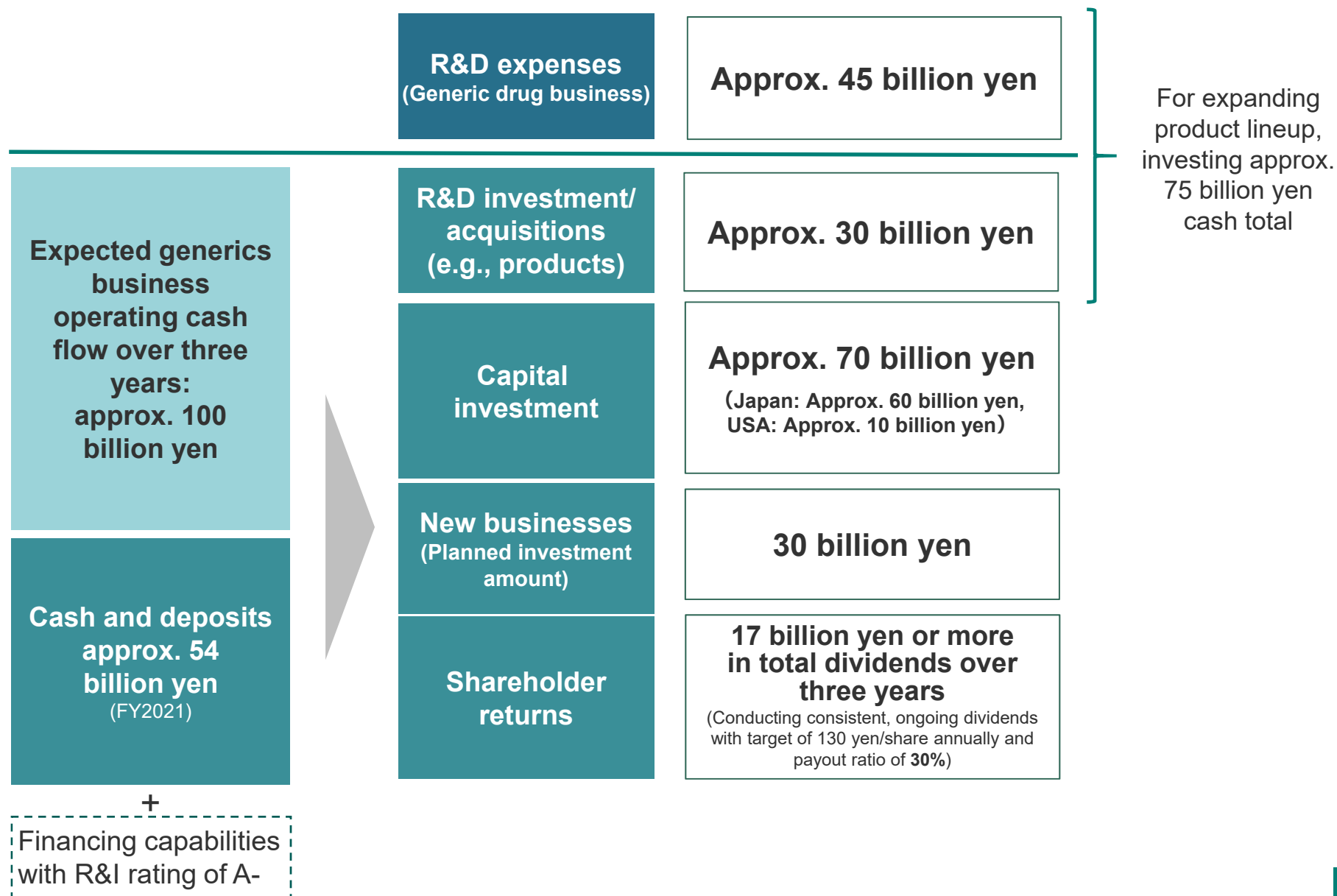
#### Future plans

We plan to proceed with a balanced exploration, including whether to proceed in-house or in partnership with other companies

**Searching for development centered on the intermediate value theme of medical care and health**

# Investment Plan and Shareholder Returns

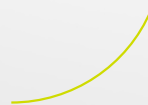
Investment Plan and Expected Shareholder Returns in the Medium-Term Business Plan Period



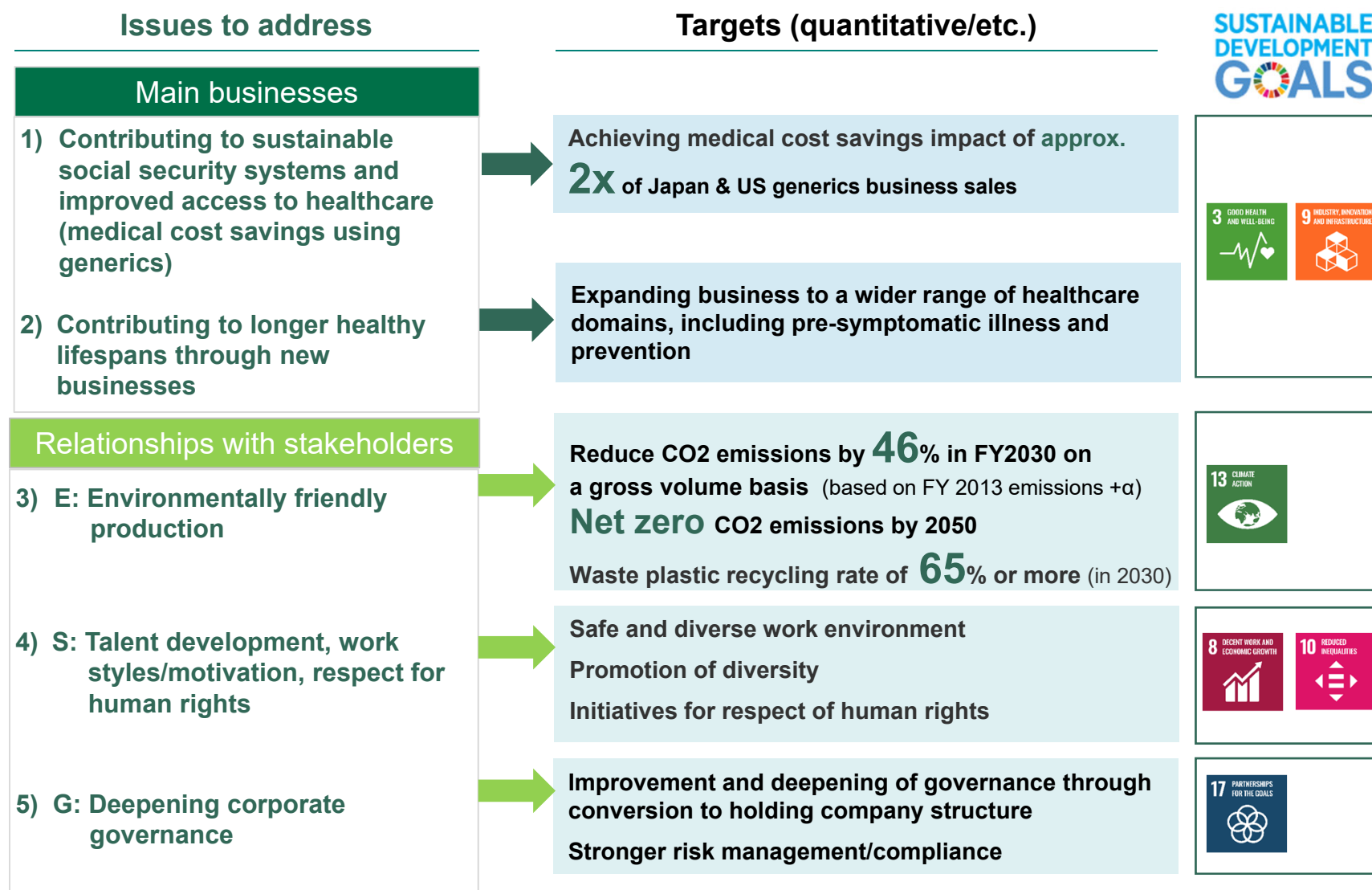


# Initiatives Resolving Social Issues

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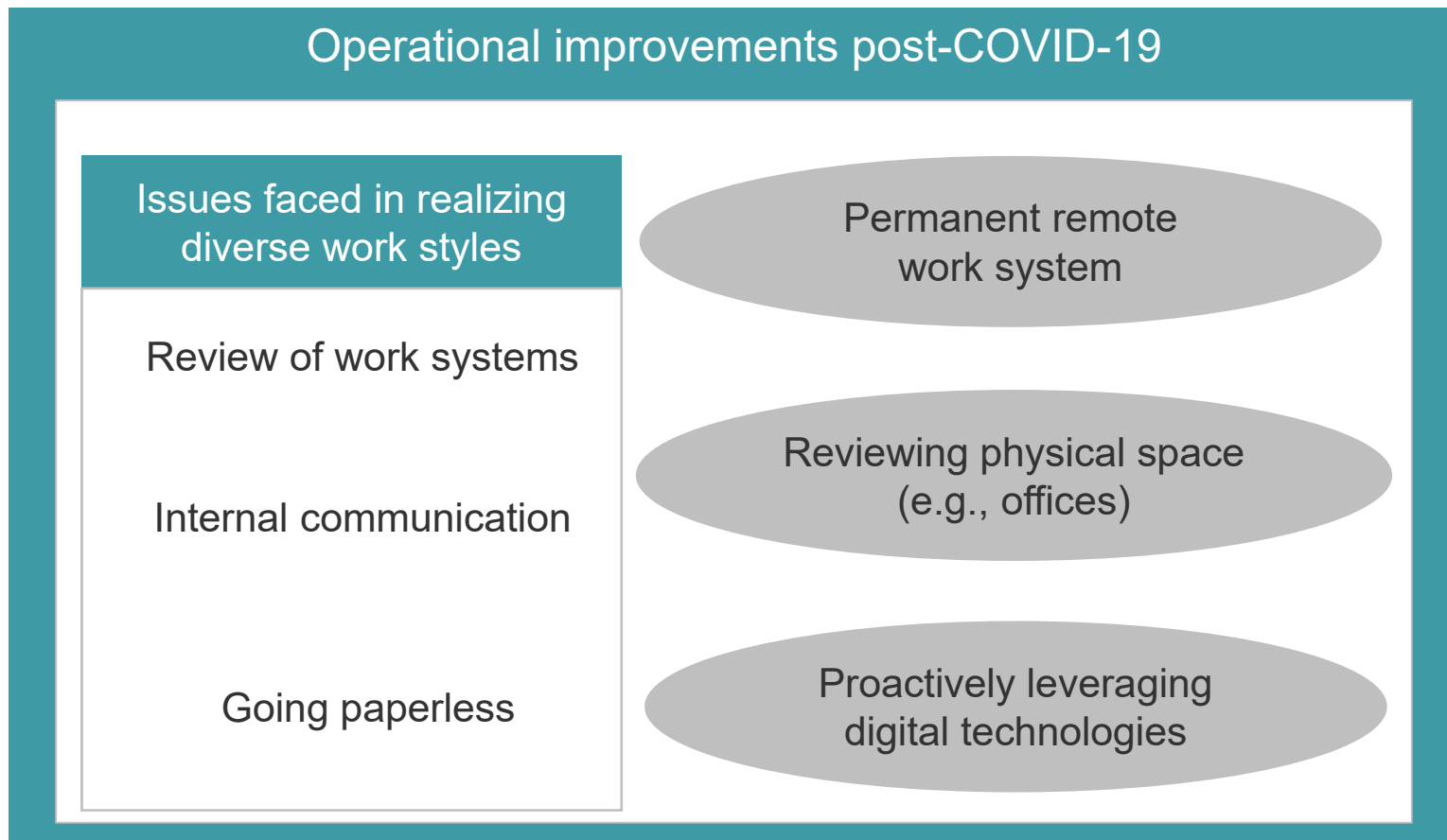
# Initiatives Resolving Social Issues





### Clean slate review of traditional ways of doing business

**Achieving efficiency gains worth over 1 billion yen  
in the Medium-Term Business Plan period by  
improving operations**



## Caution Regarding Future Outlooks

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The information in this document is based on a variety of assumptions, and do not constitute a guarantee or promise of the execution of measures or future planning or target figures described.

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