



# *Open Up* *the Future*

Mitsubishi Tanabe Pharma Corporate Report 2018



Mitsubishi Tanabe Pharma

## Corporate Communications Tools

To foster a deeper understanding of the Group among stakeholders, Mitsubishi Tanabe Pharma prepares a variety of communications tools in addition to disclosure materials.

### Providing Information about Initiatives Targeting Sustained Growth

#### MITSUBISHI TANABE PHARMA CORPORATE REPORT 2018

Mitsubishi Tanabe Pharma prepares this report to provide information to its shareholders, investors, and other stakeholders about the Group's initiatives targeting sustained growth. This report, which was prepared with reference to the framework released by the International Integrated Reporting Council (IIRC)\*, is positioned as the Group's integrated report. Its principal sections comprise reports on value creation over the short, medium, and long term. The business model for value creation is explained in the business overview section, initiatives to create value are covered in the business strategy section, and initiatives to support value creation are described in the ESG section.

\* Private-sector organization established in 2010 by private-sector companies, investors, accountants' organizations, and government institutions to develop an international corporate reporting framework.



### Providing Information about Initiatives Targeting the Sustainable Development of Society

#### WEB CSR WEBSITE (CORPORATE WEBSITE)

Mitsubishi Tanabe Pharma provides information on the CSR website to a wide range of stakeholders, including patients, health care professionals, shareholders and investors, local communities, and employees, about the principal CSR activities implemented in fiscal 2017 (initiatives targeting the sustainable development of society). This website includes information about specific initiatives based on the corporate philosophy, presented in accordance with the ISO 26000 core subjects. Other sections on the website include the VOICE section, which contains messages from employees and outside parties related to those initiatives, and the data section, which contains related data.



#### Inclusion in SRI Indexes\*

Mitsubishi Tanabe Pharma's initiatives in the area of CSR activities have been highly evaluated, and we have been included in the following SRI indexes.

\* Indicators of socially responsible investment, which utilizes evaluation / selection standards that consider not only corporate financial matters but also social responsibility.



### Other Communications Tools

To foster a better understanding of the Group's businesses among a wide range of stakeholders, Mitsubishi Tanabe Pharma has created a corporate website and prepared a corporate profile in pamphlet form.

#### WEB CORPORATE WEBSITE

In addition to corporate information, the Group has prepared a variety of specialized sites, such as an investor relations site for shareholders and investors and a health support site.



#### CORPORATE PROFILE

The corporate profile is a digest version of Mitsubishi Tanabe Pharma Corporate Report 2018.



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This section explains the business strategies that play the central role in initiatives to create value.



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This section includes ESG-related information as initiatives to support value creation.

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In fiscal 2017, the second year of Medium-Term Management Plan 16–20, which concludes in fiscal 2020, Mitsubishi Tanabe Pharma made significant progress in accelerating U.S. business development, such as the launch of Radicava, an ALS treatment agent, in the U.S. In this section, President Masayuki Mitsuka explains the Company's results and challenges in fiscal 2017 as well as the outlook going forward.

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#### Application of IFRS

To improve the international comparability of financial information in the capital markets, the Company has adopted IFRS effective from fiscal 2016. Figures for fiscal 2015 are also presented in accordance with IFRS.

#### Forward-Looking Statements

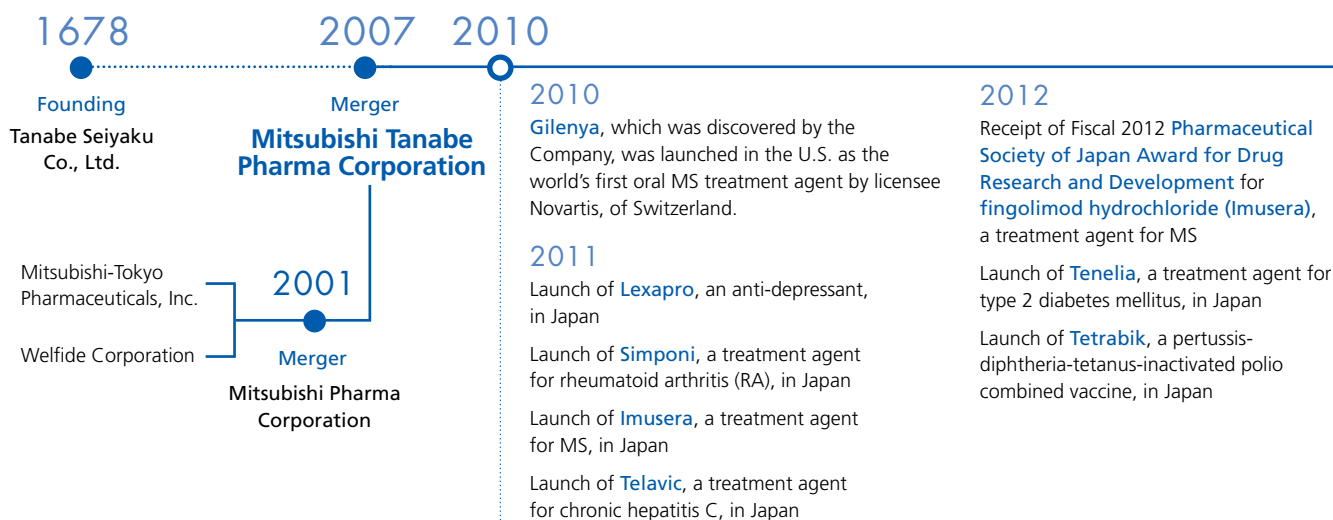
Statements contained in this corporate report that are not historical facts are forward-looking statements that reflect the Company's plans and expectations. These forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the Company's actual results, performance, or achievements to differ materially from those anticipated in these statements.

# Creation

Mitsubishi Tanabe Pharma was established in October 2007. However, Tanabe Seiyaku, one of our predecessor companies, was founded 340 years ago. Throughout our long history, we have continually taken on the challenge of creating pharmaceuticals that are useful to society, and we have discovered a large number of innovative drugs. We currently have four priority disease areas—autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. Centered on these areas, we are aiming to discover new drugs that address unmet medical needs (see the “Explanation of Terms” section). To realize that objective, our researchers are doing their utmost each day to achieve results.



## Our History of Drug Discovery





## 2015

### 2013

Launch of **Invokana**, a treatment agent for type 2 diabetes mellitus that was discovered by the Company, was launched as the first SGLT2 inhibitor in the U.S. by licensee Janssen Pharmaceuticals, of the U.S.

### 2014

Receipt of Fiscal 2014 **Pharmaceutical Society of Japan Award for Drug Research and Development for SGLT2 inhibitor canagliflozin (Canaglu)**, a new treatment agent for type 2 diabetes mellitus

Launch of **Canaglu**, a treatment agent for type 2 diabetes mellitus, in Japan

### 2015

Receipt of **commendation** at the Fiscal 2015 National Commendation for **Invention for discovery of diabetes treatment agent teneligliptin (Tenelia)**

### 2016

Receipt of **METI Minister's Award** at the Fiscal 2016 National Commendation for **Invention for discovery of diabetes treatment agent canagliflozin (Canaglu)**

### 2017

Receipt of **Okochi Memorial Technology Prize** at the 63rd Okochi Prize awards for  **fingolimod hydrochloride, a treatment agent for MS**

Launch of **Radicava**, an amyotrophic lateral sclerosis (ALS) treatment agent, in the U.S.

Launch of **Canalia (Tenelia-Canaglu combination drug)**, a treatment agent for type 2 diabetes mellitus that was Japan's first combination drug including a DPP-4 inhibitor and an SGLT2 inhibitor

Launch of **Rupafin**, a treatment agent for allergic disorders, in Japan

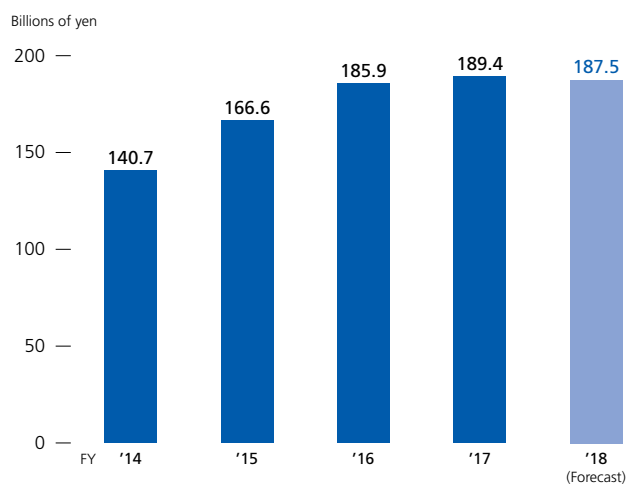
### 2018

Receipt of Technology Award **Grand Prize** at the 50th Japan Chemical Industry Association (JCIA) Awards for **diabetes treatment agent Canagliflozin, which has a revolutionary treatment concept**

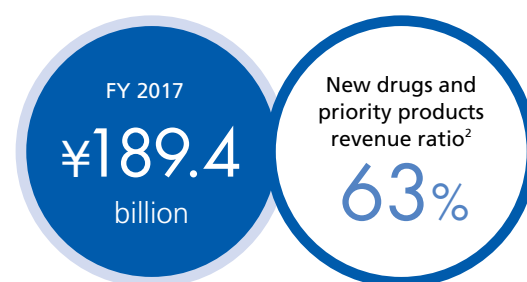
# Provision

The Company's MRs (see the "Explanation of Terms" section) play a central role in the Company's provision of pharmaceuticals to as many patients as possible. In Japan, we are conducting information provision activities for health care professionals. These activities, which are related to the appropriate use of pharmaceuticals (see the "Explanation of Terms" section), are centered on new drugs and priority products (see below). Overseas, in addition to Europe (U.K., Germany) and Asia (China, South Korea, Taiwan, Indonesia), following the launch of Radicava we started information provision activities through MRs in the U.S. in 2018. Moreover, to provide drugs discovered by the Company to a wide range of patients around the world, we are taking steps to actively leverage collaboration with global companies.

## New Drugs and Priority Products Revenue



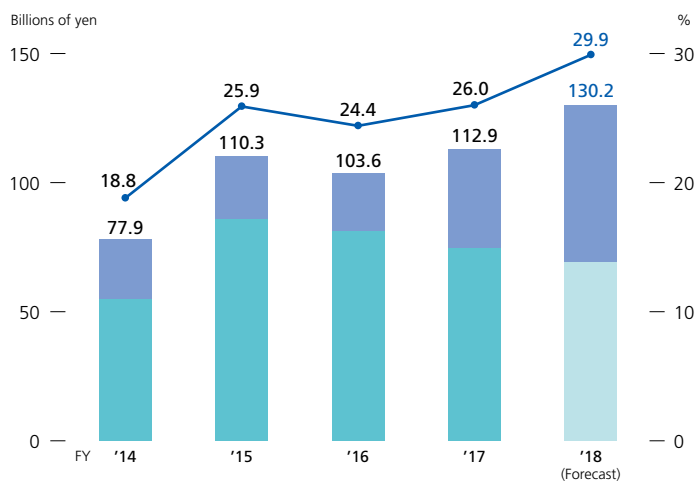
In Japan, steady growth of revenue from new drugs and priority products<sup>1</sup>



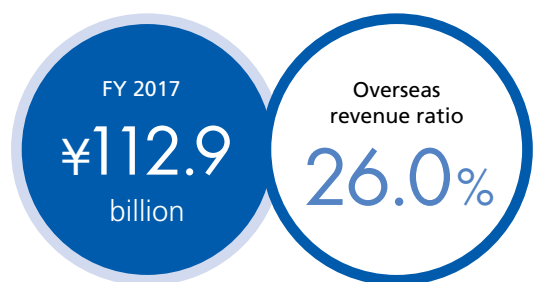
1. Priority products in fiscal 2017 (Remicade, Simponi, Tenelia, Talion, Lexapro, Canaglu, and Imusera), vaccines, and new drugs
2. Ratio of revenue from new products and priority products to revenue from domestic ethical drugs



## Overseas Revenue



Royalty revenue from Gilenya and Invokana as well as full-sale acceleration of U.S. business development with the launch of Radicava



■ Royalty revenue, etc. (overseas) 
 —●— Overseas revenue ratio 
 ■ Overseas ethical drugs

# Contributi

The Mitsubishi Tanabe Pharma corporate philosophy is to “contribute to the healthier lives of people around the world through the creation of pharmaceuticals.” This philosophy expresses how we have returned to the basics of the discovery of pharmaceuticals and puts our fundamental purpose into words. In line with this philosophy, we strive to be a global research-driven pharmaceutical company that is trusted by society. Going forward, in accordance with the Group’s shared values that “everything we do is for the patients,” we will work to fulfill our social mission as a life sciences company by creating pharmaceuticals that are useful to people around the world and delivering those pharmaceuticals to patients.



## For Patients

Our brand mark takes the form of hands gently enfolding the health of people around the world, symbolizing Mitsubishi Tanabe Pharma’s future growth and unlimited potential as a global research-driven pharmaceutical company.



## Imusera (Gilenya)

Contributing to the treatment of MS in more than **80 countries** as the world’s first oral MS treatment agent



In 1997, we transferred exclusive development and sales rights worldwide, except for Japan, to Novartis. This drug was launched by Novartis in the U.S. in 2010, and is now prescribed in more than 80 countries and regions around the world. As a replacement for injections, it contributes to addressing unmet medical needs by reducing the mental and physical burden on patients.





on



Vision

We strive to be a global research-driven pharmaceutical company that is trusted by society.



Philosophy

We contribute to the healthier lives of people around the world through the creation of pharmaceuticals.



### Tenelia, Canaglu (Invokana)

Contributing to the treatment of diabetes, which affects **1 out of 11** adults worldwide, with two drugs that have entirely different mechanisms of action



The global population of people with diabetes is increasing each year, and in 2017 this disease was said to affect 8.8% of people between the ages of 20 and 79, or 1 out of 11 adults (Source: IDF Diabetes Atlas, 8th Edition, 2017). Mitsubishi Tanabe Pharma has Tenelia, a DPP-4 inhibitor, and Canaglu, an SGLT2 inhibitor, both of which were originated in-house. In 2017, we launched Canalia, Japan's first combination drug of this type, and we are contributing to further progress in the treatment of diabetes.

### Radicava (Radicut)

Contributing to ALS patients around the world as the first new drug for ALS launched in the U.S. in approximately **20** years



ALS is an idiopathic disease in which motor neurons selectively degenerate and die. Muscle strength declines throughout the entire body, including the extremity, facial, and respiratory muscles, and muscular atrophy progresses. This drug was approved in Japan and South Korea in 2015, and subsequently it was approved as the first new drug in the U.S. in approximately 20 years that limits the progress of ALS. We have also filed applications in Canada, Switzerland, and Europe, and moving forward we will work to see that this drug can contribute to the treatment of as many patients as possible.

## Business Portfolio

Mitsubishi Tanabe Pharma meets a wide range of medical needs through the provision of distinctive ethical drugs, including drugs for autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines.

Revenue (FY 2017)

¥433.8 billion

Note: Tanabe Seiyaku Hanbai was a sales subsidiary of the Company that sold generic drugs (see the "Explanation of Terms" section) and long-listed drugs (see the "Explanation of Terms" section) transferred from the Company. On October 1, 2017, the Company transferred all of its shares of Tanabe Seiyaku Hanbai to Nipro. Tanabe Seiyaku Hanbai's fiscal 2017 revenue was ¥6.6 billion.

Domestic ethical drugs ¥309.3 billion

Priority Products in Fiscal 2017

### Remicade

**Indications** RA (including the prevention of structural joint damage), Behcet's disease with refractory uveoretinitis, psoriasis vulgaris, psoriasis arthropathica, pustular psoriasis, erythrodermic psoriasis, ankylosing spondylitis, entero-Behcet's disease, neuro-Behcet's disease, vasculo-Behcet's disease, Kawasaki disease, Crohn's disease, ulcerative colitis



Revenue  
¥64.6 billion

### Talion

**Indications** Allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, prurigo, cutaneous pruritus)



Revenue  
¥16.9 billion

### Lexapro

**Indications** Depression, depressive symptoms, social anxiety disorder



Revenue  
¥12.7 billion

### Simponi

**Indications** RA (including the prevention of structural joint damage), ulcerative colitis



Revenue  
¥32.1 billion

### Canaglu

**Indication** Type 2 diabetes mellitus



Revenue  
¥5.6 billion

### Tenelia

**Indication** Type 2 diabetes mellitus



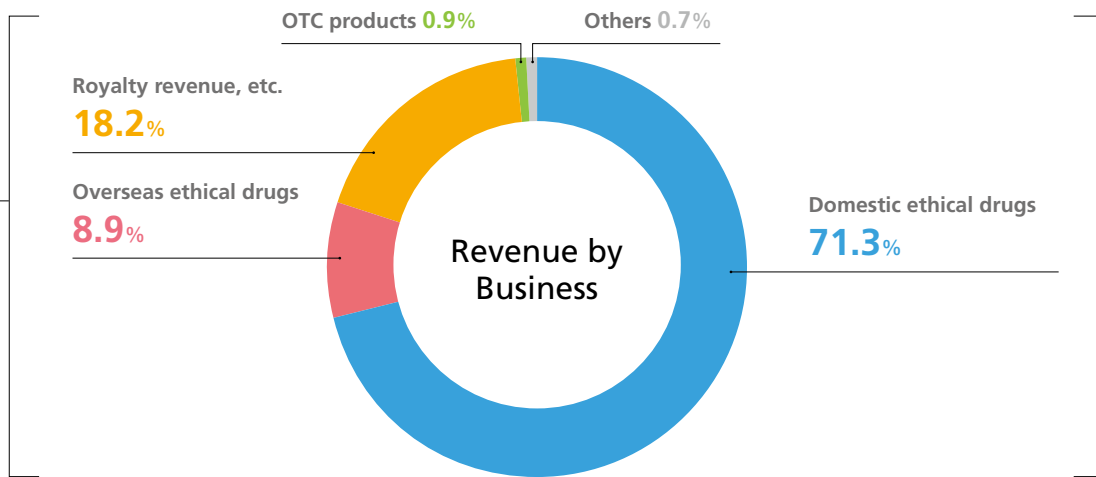
Revenue  
¥17.5 billion

### Imusera

**Indication** Multiple sclerosis (MS)



Revenue  
¥4.7 billion



### Vaccines

#### Influenza vaccine

**Indication** Prevention of influenza

Revenue

¥9.9 billion

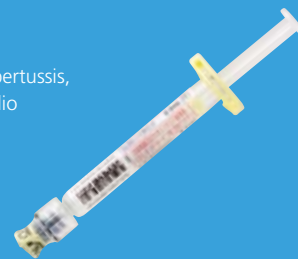


#### Tetrabik

**Indications** Prevention of pertussis, diphtheria, tetanus, and polio

Revenue

¥8.7 billion



#### Varicella vaccine

**Indications** Prevention of chickenpox and herpes zoster in subjects aged 50 years or older

Revenue

¥5.2 billion



#### JEBIK V

**Indication** Prevention of Japanese encephalitis

Revenue

¥5.2 billion



#### Mearubik

**Indications** Prevention of attenuated measles and rubella

Revenue

¥5.0 billion



Overseas ethical drugs **¥38.5 billion**

Major Out-Licensed Products

Royalty revenue, etc. **¥79.1 billion**

#### Radicava

**Indication** Amyotrophic lateral sclerosis (ALS)

Revenue

¥12.3 billion



#### Gilenya

**Indication** Multiple sclerosis (MS)

Royalty Revenue

¥57.7 billion

#### Invokana

**Indication** Type 2 diabetes mellitus

Royalty Revenue

¥13.9 billion

OTC products **¥3.7 billion**

- 1 Flucort f
- 2 Tanabe Ichoyaku Urso
- 3 Aspara Drink α

- 1
- 2



Others **¥3.0 billion**

Contract manufacturing of other companies' products, etc.

## Financial and Non-Financial Highlights

Note: Figures for fiscal 2014 and previous fiscal years are presented in accordance with Japanese GAAP.

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
Years ended March 31, 2018 (FY 2017), 2017 (FY 2016), and 2016 (FY 2015)

	Billions of yen			% Change
	FY 2015	FY 2016	FY 2017	FY 2017 / 2016
Revenue	¥425.7	¥423.9	¥433.8	+2.3%
Core operating profit	106.9	94.5	78.5	-16.9
Operating profit	81.8	94.0	77.2	-17.9
Profit attributable to owners of the Company	59.3	71.2	57.9	-18.7
R&D expenses	64.6	64.7	79.0	+22.1
Capital expenditures <sup>1</sup>	12.1	14.4	6.0	-58.3
Total assets	958.4	984.5	1,047.6	+6.4
Total equity	826.3	871.4	894.8	+2.7
Net cash provided by operating activities	80.8	59.7	66.9	—
Net cash used in investing activities	(42.2)	(10.5)	(19.1)	—
Net cash used in financing activities	(22.2)	(24.4)	(32.5)	—

### Financial indicators

	%			
Overseas revenue ratio	25.9	24.4	26.0	—
Operating margin	19.2	22.2	17.8	—
R&D expenses ratio	15.2	15.3	18.2	—
Ratio of equity attributable to owners of the Company to total assets	85.1	87.4	84.3	—
ROE	7.4	8.5	6.6	—
Dividend payout ratio	43.5	40.9	63.9	—

### Per share amounts

	Yen			
Profit attributable to owners of the Company	¥105.72	¥127.03	¥103.35	-18.6%
Cash dividends	46.00	52.00	66.00 <sup>4</sup>	—

### Non-financial data

Number of employees	8,125	7,280	7,187	-1.3%
Number of clinical trials started <sup>2</sup>	1	4	6	—
Energy used (TJ) <sup>3</sup>	1,919	1,789	1,697	-5.1
CO <sub>2</sub> emissions (thousands of tons-CO <sub>2</sub> ) <sup>3</sup>	112	102	95	-6.9
Amount of waste generated (domestic) (thousands of tons)	9	6	12	+106.0
Final waste disposal rate (%)	0.55	0.33	0.37	—

1. Property, plant and equipment and intangible assets on an accrual basis.

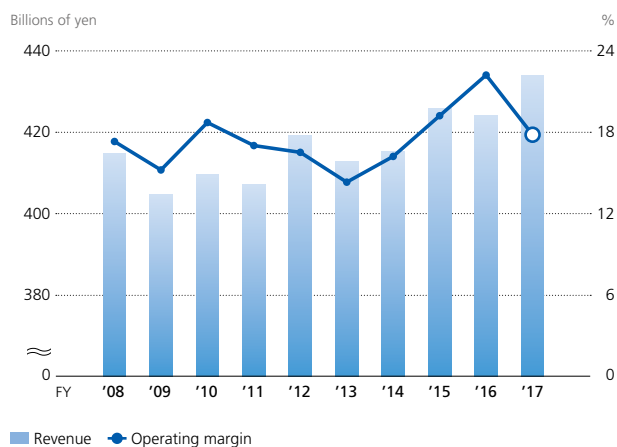
2. Phase 2 clinical trials and thereafter. Including in-licensed products.

3. Domestic and overseas production and research bases. The amount of fuel used in sales vehicles is not included in the total.

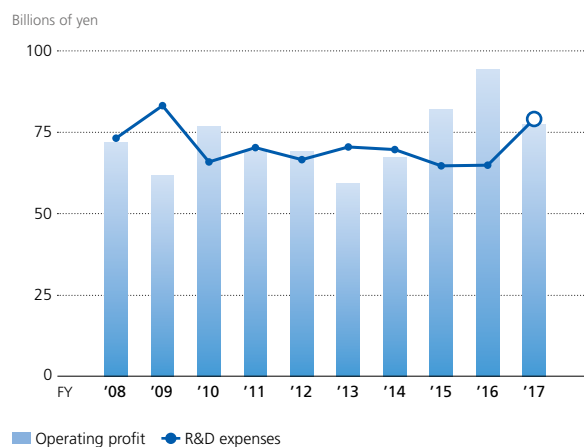
4. In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

For further information about financial data, please refer to "10-Year Financial Summary." > P68

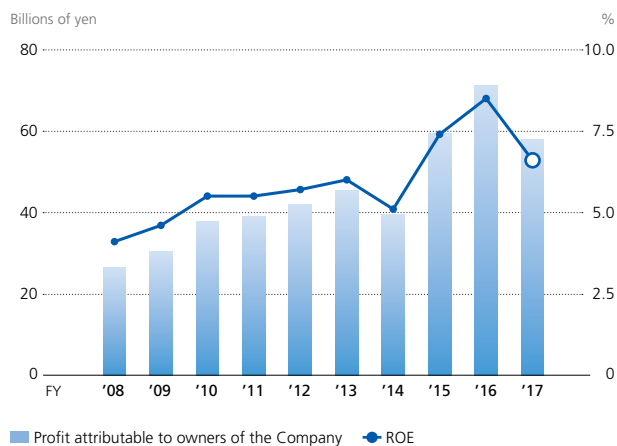
### Revenue / Operating Margin



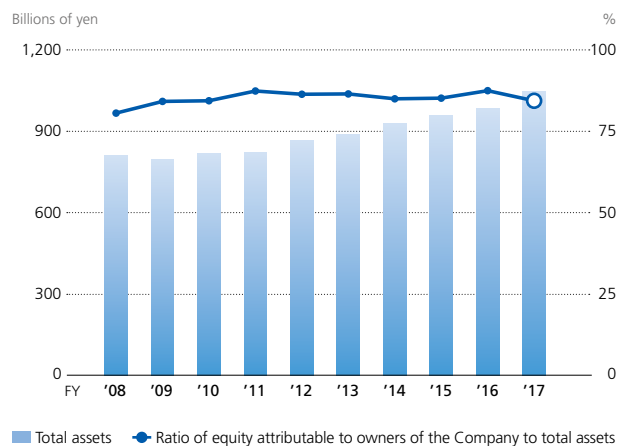
### Operating Profit / R&D Expenses



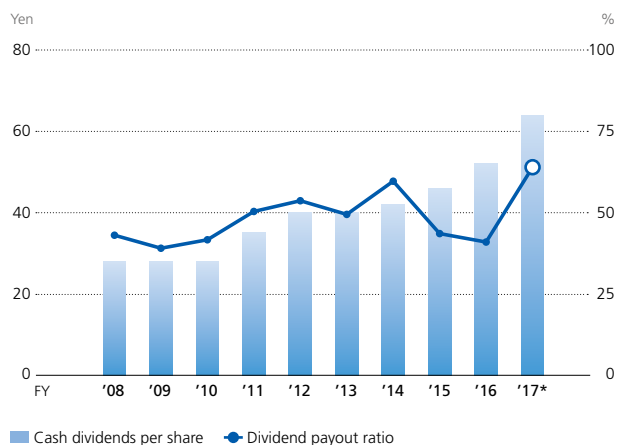
### Profit Attributable to Owners of the Company / ROE



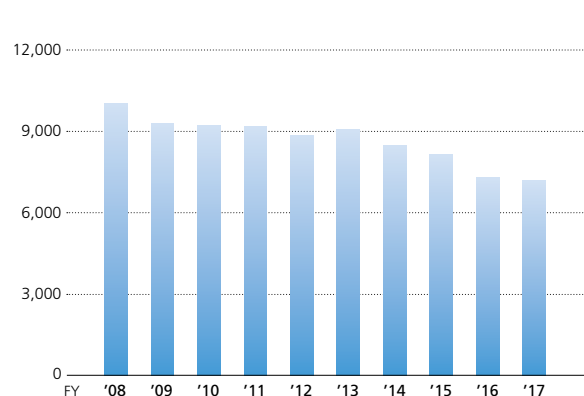
### Total Assets / Ratio of Equity Attributable to Owners of the Company to Total Assets



### Cash Dividends per Share / Dividend Payout Ratio



### Number of Employees



\* In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

# Pipeline (Status of Drug Candidates)

As of July 27, 2018

## Status of Drug Candidates

Disease area: ■ Autoimmune diseases ■ Diabetes and kidney diseases ■ Central nervous system diseases ■ Vaccines ■ Other

Development code / product name (Generic name)	Category	Expected indications	Region	Stage			NDA filed	Origin (Remarks)
				1	2	3		
MT-5547	Fully human anti-NGF monoclonal antibody	Osteoarthritis	Japan	■	■	■	Phase 2/3	US: Regeneron
MT-1303	S1P receptor functional antagonist	Multiple sclerosis	Europe	■	■			In-house
		Psoriasis	Europe	■	■			
		Crohn's disease	Japan, Europe	■	■			
MT-7117	Dermatologicals, etc.	Erythropoietic protoporphyria	US	■	■			In-house
MT-2990	Inflammatory diseases, autoimmune diseases, etc.		—	■				In-house
TA-7284 (canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus	Indonesia	■	■	■	Aug. 2017	In-house
		Diabetic nephropathy	Global clinical trial	■	■	■		In-house (Sponsor: Janssen Research & Development)
MP-513 (teneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus	Indonesia	■	■	■	Apr. 2015	In-house
			China	■	■	■		
			Europe	■	■			
MT-6548	Hypoxia inducible factor prolyl hydroxylase inhibitor	Renal anemia	Japan	■	■	■		US: Akebia Therapeutics
MT-3995	Selective mineralocorticoid receptor antagonist	Diabetic nephropathy	Europe	■	■			In-house
			Japan	■	■			
		Non-alcoholic steatohepatitis: NASH	Japan	■	■			
MCI-186 (edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis	Switzerland	■	■	■	Dec. 2017	In-house
			Canada	■	■	■	Apr. 2018	
			Europe	■	■	■	May 2018	
MP-214 (cariprazine)	Dopamine D3/D2 receptor partial agonist	Schizophrenia	Korea	■	■	■	Dec. 2017	Hungary: Gedeon Richter
			Taiwan	■	■	■	Dec. 2017	
			Singapore	■	■	■	Jun. 2018	
MT-5199	Vesicular monoamine transporter type 2 inhibitor	Tardive dyskinesia	Japan	■	■	■	Phase 2/3	US: Neurocrine Biosciences
MT-8554	Nervous system, etc.	Painful diabetic peripheral neuropathy	Europe	■	■			In-house
		Vasomotor symptoms associated with menopause	US	■	■			
ND0612 (levodopa / carbidopa)	Continuous SC pump/ patch pump	Parkinson's disease	US, Europe	■	■			In-house
MP-124	Nervous system		—	■				In-house
ND0701 (apomorphine)	Continuous SC pump	Parkinson's disease	—	■				In-house
MT-1186 (edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis / new administration route	—	■				In-house

Development code / product name (Generic name)	Category	Expected indications	Region	Stage				Origin (Remarks)
				Phase			NDA filed	
				1	2	3		
MT-2355	Combined vaccine	Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants	Japan	■	■	■		Japan: BIKEN Foundation (The Research Foundation for Microbial Diseases of Osaka University) (Co-developed with BIKEN Foundation)
MT-2271	Plant-based VLP vaccine	Prophylaxis of seasonal influenza	US, Europe, Canada, and others	■	■	■		In-house
MT-8972	Plant-based VLP vaccine	Prophylaxis of H5N1 influenza	Canada	■	■			In-house
MT-7529	Plant-based VLP vaccine	Prophylaxis of H7N9 influenza	—	■				In-house
MT-5625	Plant-based VLP vaccine	Prophylaxis of rotavirus gastroenteritis	—	■				In-house
Valixa (valganciclovir)	Anti-cytomegalovirus chemotherapeutic agent	Prevention of cytomegalovirus disease in pediatric organ transplant patients	Japan	■	■	■	Feb. 2018	Switzerland: F. Hoffmann-La Roche
GB-1057 (recombinant human serum albumin)	Blood and blood forming organs		—	■				In-house
MT-0814	Ophthalmologicals		—	■				In-house
MT-4129	Cardiovascular system, etc.		—	■				In-house
MP-2765	Cardiovascular system, etc.		—	■				In-house (Co-researched with Shanghai Pharmaceuticals Holding (China))

## Licensing-Out

Development code / product name (Generic name)	Category	Expected indications	Region	Stage				Origin (Remarks)
				Phase			NDA filed	
				1	2	3		
FTY720 Gilenya (fingolimod)	S1P receptor functional antagonist	Pediatric multiple sclerosis	Europe	■	■	■	Nov. 2017	Switzerland: Novartis (Co-developed with Novartis Pharma K.K. in Japan)
TA-7284 Invokana (canagliflozin)	SGLT2 inhibitor	Reduce the risk of death in type 2 diabetes with established, or risk for, cardiovascular disease (CANVAS/CANVAS-R)	US Europe	■	■	■	Nov. 2017 Nov. 2017	US: Janssen Pharmaceuticals
MT-210	5-HT2A / Sigma 2 receptor antagonist	Schizophrenia	US, Europe	■	■	■		US: Minerva Neurosciences
Wf-516	Multiple mechanisms on several receptors*	Major depressive disorder	US, Europe	■	■			US: Minerva Neurosciences
MT-4580 Orkedia (evocalcet)	Ca sensing receptor agonist	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	Japan	■	■	■		Japan: Kyowa Hakko Kirin
MCC-847 (masilukast)	Leukotriene D4 receptor antagonist	Asthma	Korea	■	■			Korea: SAMA Pharma
Y-803	Bromodomain inhibitor	Cancer	Europe, Canada	■	■			US: Merck

\* SSRI, 5-HT1A, dopamine transporter, and alpha-1A and B

# Business Strategy Section

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This section explains the business strategies that play the central role in initiatives to create value.

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## Transcending Limits and Fully Achieving Our Goals to the End

Mitsubishi Tanabe Pharma Is Taking the Next Step

Overview of Medium-Term Management Plan 16–20

# Open Up *the Future*

## Fiscal 2020 Objectives

**Revenue**      ¥**500.0** billion

**Core operating profit**      ¥**100.0** billion

**Period:** April 2016 to March 2021 (five years)

## Fiscal 2020 Quantitative Plans

	Fiscal 2015 results	Fiscal 2017 results	Fiscal 2020 objectives Announced Nov. 30, 2015
<b>Revenue</b>	¥425.7 billion	¥433.8 billion	¥500.0 billion
<b>Core operating profit</b>	¥106.9 billion	¥78.5 billion	¥100.0 billion
<b>Profit attributable to owners of the Company</b>	¥59.3 billion	¥57.9 billion	¥70.0 billion
<b>R&amp;D expenses</b>	¥64.6 billion	¥79.0 billion	¥80.0 billion
<b>Overseas revenue ratio</b>	25.9%	26.0%	40%

## Overview of Fiscal 2017

Our revenue reached a record high due to growth in sales of fiscal 2017 priority products and to a major contribution from the launch of Radicava in the U.S. However, due to our aggressive strategic investment, we recorded declines in core operating profit, operating profit, and profit attributable to owners of the Company.

Mitsubishi Tanabe Pharma is currently implementing Medium-Term Management Plan 16–20: Open Up the Future, which was commenced in fiscal 2016. In fiscal 2017, the second year of the plan, we recorded revenue of ¥433.8 billion, up 2.3%; core operating profit of ¥78.5 billion, down 16.9%; operating profit of ¥77.2 billion, a decrease of 17.9%; and profit attributable to owners of the Company of ¥57.9 billion, a decline of 18.7%.

First, I will explain the factors affecting revenue. Domestic sales of ethical drugs decreased 1.5%, to ¥309.3 billion. Simponi, Tenelia, Canaglu, and other priority products registered growth, and excluding vaccines, revenue from fiscal 2017 priority products increased ¥7.4 billion year on year, to ¥154.4 billion. However, revenue from vaccines declined ¥3.8 billion, to ¥35.0 billion. Furthermore, revenue from long-listed drugs declined, and the transfer of the generic drugs business to Nipro in October 2017 had the effect of reducing revenue by ¥7.5 billion.

In royalty revenue, etc., we recorded growth in royalty revenue from Gilenya, which is licensed to Novartis, of Switzerland, but we registered a decline in royalty revenue from Invokana and its fixed-dose combination with metformin, which are licensed to Janssen Pharmaceuticals, of the U.S. As a result, royalty revenue, etc., declined 3.8% year on year, to ¥79.1 billion.

In this way, revenue from domestic ethical drugs and royalty revenue, etc., recorded declines. Nonetheless, revenue from overseas ethical drugs registered a significant increase, rising 70.0%, to ¥38.5 billion. The principal reason for this gain was the contribution made by Radicava, which was launched in the U.S. in August 2017. Radicava has gotten off to a strong start, with revenue of ¥12.3 billion in fiscal 2017.

As a result of the above factors, revenue reached a record high. However, SG&A expenses rose as a result of the launch of Radicava and other factors, and R&D expenses increased significantly due to development candidates moving to late-stage development and to the acquisition of NeuroDerm, of Israel. Due to this aggressive advancement of strategic investment, we recorded declines in core operating profit, operating profit, and profit attributable to owners of the Company.

## Strategic priority 1 Maximizing Pipeline Value

Late-stage drug candidate objective  
**10** candidates  
(including in-licensed candidates)

R&D investment  
**¥400.0** billion

In fiscal 2017, we were able to advance four drug candidates to late-stage development. We currently have five late-stage drug candidates, and our highest priority task is to launch these candidates as soon as possible.

During the period of the current medium-term management plan, the domestic business environment will become increasingly challenging, and royalty revenue from Gilenya is expected to decline as it goes off patent in the U.S. Accordingly, we do not anticipate substantial growth in our results. The period of the current medium-term management plan is positioned as a time for steadily securing revenue and gathering our strength in preparation for dramatic growth in fiscal 2020 and thereafter.

To that end, we have established four strategic priorities as milestones, and for each of these priorities we have formulated specific quantitative objectives. If we can achieve these objectives, I believe that we will be able to accumulate the strength that will drive dramatic growth.

First, in maximizing pipeline value, we will invest ¥400.0 billion in R&D expenses, centered on the priority disease areas of autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. We have established a numerical target of 10 late-stage drug candidates.

In fiscal 2017, we were able to advance four drug candidates to late-stage development. We started late-stage clinical trials in Japan for MT-5547 (expected indication: osteoarthritis) in autoimmune diseases; MT-6548 (expected indication: renal anemia) in diabetes and kidney diseases; and MT-5199 (expected indication: tardive dyskinesia) in central nervous system diseases. In addition, in vaccines, in the U.S., Europe, and Canada, and other regions we started late-stage clinical trials for adults for MT-2217 (expected indication: prophylaxis of seasonal influenza).

As a result, together with MT-2355 (expected indications: prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis, and Hib infection in infants), a combined vaccine for five diseases that started late-stage clinical trials in Japan in fiscal 2016, we now have five late-stage drug candidates. Furthermore, we are preparing for late-stage clinical trials in the U.S. and Europe for ND0612 (expected indication: Parkinson's disease) from NeuroDerm, which we acquired in October 2017. In February 2018, we acquired Stelic Institute & Co., thereby strengthening our pipeline in the field of autoimmune diseases with the acquisition of a nucleic acid drug (STNM01) in the field of inflammatory bowel disease.

In this way, we have achieved a certain degree of success in advancing drug candidates, and our highest priority will be to launch late-stage drug candidates as rapidly as possible. Also, in

regard to the overall composition of our pipeline, over the next two years the leading role in development will be shifted from Japan and Asia to a global basis. R&D expenses were ¥64.7 billion in fiscal 2016, the first year of the plan and ¥79.0 billion in fiscal 2017. We are forecasting R&D expenses of ¥84.5 billion in fiscal 2018.

➤ In regard to specific initiatives for Maximizing Pipeline Value, please refer to "Business Strategies by Process: Drug Discovery." → Page 22

## Strategic priority 2 Strengthening IKUYAKU and Marketing

Domestic revenue objective  
**¥300.0** billion  
(fiscal 2020)

New drugs and priority products revenue ratio  
**75%**

**We made generally favorable progress with each of our initiatives, but the NHI drug price revisions implemented in April 2018 will have a significant influence on the achievement of our fiscal 2020 revenue target.**

In strengthening IKUYAKU and marketing, our target for revenue from domestic ethical drugs in fiscal 2020 is ¥300.0 billion. This target takes into account the revision of the NHI drug price system during the period covered by the current management plan as well as further market penetration by generic drugs. To sustain the current level of revenue, we will replace a large portion of our product portfolio and raise the new drugs and priority products revenue ratio<sup>1</sup> from 55% in fiscal 2015 to 75% in fiscal 2020.

In autoimmune diseases, through a sales alliance with Janssen Pharmaceutical K.K., we are recording favorable growth in revenue from Simponi. The combined share of Remicade and Simponi in the market for biologics (see the "Explanation of Terms" section) used in the treatment of autoimmune diseases was approximately 37% in fiscal 2017. These drugs are maintaining a dominant position as the top brand. Furthermore, in May 2017 we commenced a sales alliance for Stelara, a treatment agent for Crohn's disease developed by Janssen Pharmaceutical K.K., and in June 2018 we concluded an agreement to update the sales framework. In these ways, with a lineup of biologics that includes Remicade, Simponi, and Stelara, I believe that we have further reinforced our strengths in the field of autoimmune diseases.

In diabetes and kidney diseases, Tenelia, a DPP-4 inhibitor, and Canaglu, an SGLT2 inhibitor, are demonstrating synergies through a sales alliance with Daiichi Sankyo, and revenue from these products continues to increase. In addition, in September 2017 we launched a new product, Canalia. This is Japan's first combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor. We are also marketing Canalia through a sales alliance with Daiichi Sankyo and it has gotten off to a smooth start.

Furthermore, in central nervous system diseases, Lexapro is recording solid growth. In addition, in vaccines, the Company and The Research Foundation for Microbial Diseases of Osaka University

## Message from the President

established BIKEN Co., a joint venture for vaccine manufacturing that began operations in September 2017. In this way, the Company and the research foundation will aim to achieve a more stable supply and increase production of vaccines by combining our pharmaceutical production-related systems and management methods and accelerating the reinforcement of our production foundation.

As a result of these initiatives, the total revenue from fiscal 2017 priority products and vaccines increased 1.9%, to ¥189.4 billion, and the new drugs and priority products revenue ratio was 63%.

In this way, we have made generally favorable progress with each of the initiatives that we have implemented to strengthen IKUYAKU and marketing. However, the NHI drug price revisions implemented in April 2018 will have a significant influence on the achievement of our fiscal 2020 revenue target of ¥300.0 billion. When we formulated the current plan, we anticipated the NHI drug price revision, but the details of the revision are more severe than we envisioned. Basically, we cannot expect future growth of the domestic ethical drug market.

During the period covered by the current plan, it will be difficult to follow up Canalia with the launch in Japan of a product developed in-house. However, in November 2017 we commenced a sales alliance for Rupafin, an anti-allergy agent discovered by Teikoku Seiyaku. In a range of disease areas, by aggressively pursuing opportunities for sales alliances with other companies in this way, we will work to enhance domestic sales and make progress toward the achievement of our numerical targets.

1. Ratio of revenue from new products and priority products to revenue from domestic ethical drugs

➤ In regard to specific initiatives for Strengthening IKUYAKU and Marketing, please refer to “Business Strategies by Process: IKUYAKU and Marketing.” → Page 26



**Through the launch of Radicava, we were able to open a door to the future. To achieve our U.S. revenue target of ¥80.0 billion, as well as subsequent growth in the years ahead, we must open the second and third doors.**

In accelerating U.S. business development, we have set a numerical target of ¥80.0 billion in U.S. revenue in fiscal 2020. In addition, to establish our business foundation in the U.S., we plan to implement strategic investment of more than ¥200.0 billion over the period of the current medium-term management plan.

Fiscal 2017 was a year in which we took a big step forward in our U.S. business. MCI-186 (Japan product name: Radicut) received approval in the U.S. in May 2017 for an indication of ALS, and sales

were started in August under the product name Radicava. As I mentioned, Radicava has gotten off to a strong start, and by the end of August 2018 the number of patients treated with Radicava had surpassed 3,000. Moving forward, in addition to the treatment of new patients, we will also leverage Searchlight Support<sup>2</sup> and focus on initiatives to increase the treatment continuation rate. As a result of these initiatives, we are forecasting fiscal 2018 revenue of ¥31.5 billion, more than 2.5 times the level in fiscal 2017. For many years, we continued to take on challenges with the aim of launching new drugs in the U.S. With the launch of Radicava, I believe that we have achieved that objective and opened a door to the future.

However, this is only the first step. Realizing the achievement of our U.S. revenue target of ¥80.0 billion, as well as subsequent growth, we must open the second and third doors. One key will be MT-2271 and other plant-based Virus-Like Particle (VLP) vaccines, which are being developed by Group subsidiary Medicago, of Canada. If MT-2271 makes favorable progress, we expect to file applications in North America within fiscal 2018 for the prophylaxis of seasonal influenza, and we anticipate the acquisition of approval in fiscal 2019. In addition, to enhance the product value, we will move forward with development initiatives for applications for children and the elderly. Moreover, to expand the business after the launch, we also plan to start construction of a full-scale manufacturing facility for plant-based VLP vaccines in Quebec, Canada.

Another key will be NeuroDerm. NeuroDerm has a pipeline that includes ND0612 and other drugs for central nervous system diseases, such as Parkinson's disease. Through combinations of formulation technologies and devices, NeuroDerm is advancing the development of innovative drugs that address unmet medical needs. Up to this point, we have implemented strategic investments totaling approximately ¥120.0 billion, such as the acquisition of NeuroDerm. Moving forward, we will further advance investment to strengthen our business in the fields of neurological disorders and vaccines, and will search for new disease areas that have a high degree of synergy with existing areas.

In addition, we also intend to roll-out Radicava, MT-2271, and ND0612 in other markets, including Europe. We are already making progress on these initiatives. For Radicava, we filed applications in Switzerland in December 2017, Canada in April 2018, and Europe in May 2018. We will also consider initiatives in the ASEAN region and other markets.

We have started full-fledged business initiatives in the U.S., which is the world's largest pharmaceutical market. To develop these operations into our second pillar of business after Japan, we will continue to move forward without slackening our efforts.

2. Information support service for ALS patients provided by Mitsubishi Tanabe Pharma America, a pharmaceutical sales subsidiary in the U.S. Through a portal site, we will provide detailed support for patients, such as addressing questions from patients regarding insurance, offering support programs for patients, and providing introductions to institutions that administer Radicava.

➤ In regard to specific initiatives for Accelerating U.S. Business Development, please refer to “Business Strategies by Process: U.S. Business.” → Page 36



Strategic priority **4** **Reforming Operational Productivity**

Cost of sales / SG&A expense reduction objective  
**¥20.0 billion**  
 (fiscal 2020; compared to fiscal 2015)

Number of consolidated domestic employees  
**5,000 employees**  
 (As of the end of September 2015; 6,176 employees)

**We are making strong progress, but the business environment in the domestic ethical drugs market is increasingly challenging, and there is a growing sense of uncertainty about the future. In this setting, we will implement initiatives that aim one level higher.**

In reforming operational productivity, we have set numerical targets of reducing the total of cost of sales and SG&A expenses by ¥20.0 billion in comparison with fiscal 2015 by fiscal 2020 and of having a domestic workforce of less than 5,000 employees on a consolidated basis. In fiscal 2017, our initiatives were centered on controlling labor costs by optimizing the workforce and reducing procurement costs for active pharmaceutical ingredients and other items. As a result, we were able to reduce cost of sales by ¥3.0 billion and SG&A expenses by ¥3.0 billion. Consequently, the total of cost of sales and SG&A expenses was reduced by ¥14.0 billion in comparison with fiscal 2015, substantially exceeding the fiscal 2017 plan of ¥10.0 billion in reductions. In fiscal 2018, we expect to achieve ¥19.0 billion in reductions. In addition, the domestic consolidated workforce was 5,158 employees as of the end of fiscal 2017. Accordingly, we expect to achieve our numerical targets ahead of schedule.

In these ways, we are making strong progress in our initiatives in the area of reforming operational productivity. However, the business environment in the domestic ethical drugs market is increasingly challenging, and there is a growing sense of uncertainty about the future. In this setting, we will implement initiatives that aim one level higher. To that end, we have two key phrases. The first is leading-edge “digital technologies,” such as robotic process automation (RPA). The second is business “sharing,” including sharing within the same industry and with other industries. To fully leverage these key phrases, we will strive to consider all possibilities, foster working-style reforms, and secure resources for investment in future growth.

➤ In regard to specific initiatives for Reforming Operational Productivity, please refer to “Business Strategies by Process: Supply Chain” and “Message from the Financial and Accounting Officer” → Page 40 and Page 42

## Working to Resolve Social Issues

**Mitsubishi Tanabe Pharma wants to be a company that continues to provide value to important stakeholders—including patients, society, and employees.**

There is a clear trend toward the consideration of non-financial elements, such as ESG (Environment, Society, Governance), in making decisions about investing in companies. In addition, there is growing interest in the Sustainable Development Goals (SDGs) that were adopted by the United Nations in 2015, and corporate activities that support the resolution of social issues are increasingly important.

Mitsubishi Tanabe Pharma wants to be a company that continues to provide value to important stakeholders—including patients, society, and employees—through its business activities.

In particular, we want to do more for patients than just helping in the treatment of diseases through the provision of pharmaceuticals. We want to contribute to health from a wide-ranging viewpoint. This includes helping people to restore their ability to enjoy daily life and to enjoy dynamic lifestyles in society as they look forward to bright futures. To assist as many people as possible in this way, Mitsubishi Tanabe Pharma will strive to open up the future of medicine.

Furthermore, the MCHC Group, of which Mitsubishi Tanabe Pharma is a member, believes that, through our business activities, we must address environmental and social issues and contribute to increases in people’s health and the sustainability of society. Accordingly, the MCHC Group has established the *KAITEKI* concept and the MOS (Management of Sustainability) Indexes, which are *KAITEKI* indexes. The MOS Indexes are divided into three groups—sustainability indexes, for contributions to the sustainability of the natural environment; health indexes, for contributions to people’s health; and comfort indexes, for contributions to people’s comfort. In this way, we are evaluating the extent of contributions to sustainability.

Among the MOS Indexes, we play a central role in contributing through the health indexes. In regard to the health indexes, quantitative objectives have been set for the categories of “contribute to medical treatment,” “contribute to improvements of QOL” (see the “Explanation of Terms” section), and “contribute to early detection and prevention of disease.” Currently, elements related to product sales are a significant part of the basis for the calculation of these indexes. It is difficult to evaluate the resolution of social issues simply by considering sales of pharmaceuticals. Moving forward, we will strive to increase corporate value by clarifying what we consider to be important social issues (material issues) and by incorporating the SDGs adopted by the United Nations.

**WEB** For further information about *KAITEKI* and the MOS Indexes, please see the MCHC website.

[http://www.mitsubishichem-hd.co.jp/english/kaiteki\\_management/](http://www.mitsubishichem-hd.co.jp/english/kaiteki_management/)  
<http://www.mitsubishichem-hd.co.jp/english/sustainability/mos/>

## Corporate Governance

**As we accelerate our strategic investment initiatives, our three outside directors offer extremely valuable opinions in regard to investment decisions.**

To strengthen corporate governance, we have steadily advanced measures from a variety of perspectives since we introduced outside directors in 2011. These measures have included increasing the number of outside directors, implementing evaluations of the effectiveness of the Board of Directors, establishing the Compensation Committee and the Nomination Committee, and introducing a performance-linked stock compensation plan. In particular, as we accelerate our strategic investment initiatives, our three outside directors offer extremely valuable opinions in regard to investment decisions. Each outside director actively participates in meetings of the Board of Directors, and we are receiving advice from their wide-ranging perspectives, backed by their extensive experience and knowledge as corporate executives.

On the other hand, we recognize that we will need to enhance diversity in regard to the operation of the Board of Directors. Currently, we have three outside directors, each of whom is from a different industry. In addition, our outside corporate auditors include specialists in law and finance. In these ways, the composition of our Directors and Corporate Auditors reflects consideration for diversity. However, in consideration of demands from the capital markets, I believe that we also need to increase diversity from the perspectives of gender and nationality. We must also consider how the composition of our Directors and Executive Officers will lead to the reinforcement of our corporate governance, and then move to the stage of implementation.

➤ For further information about ESG, please refer to “Corporate Governance and Internal Control” and “Social and Environmental Activities.” → Page 49 and Page 62

## Shareholder Return

**In fiscal 2017, looking at our results, we recorded declines in core operating profit, operating profit, and profit attributable to owners of the Company. However, we set annual dividends at ¥66.0 per share, an increase of ¥14.0 per share (including the 10th anniversary commemorative dividend).**

Our basic policy calls for providing a stable and continuous return to shareholders while striving to increase enterprise value by aggressively implementing strategic investment and R&D investment to achieve sustained growth.

Under the current medium-term management plan, we will work to enhance shareholder return, with a basic aim of a dividend payout ratio of 50% under IFRS. On October 1, 2017, the Company marked the 10th anniversary of its founding. To commemorate this milestone, the Company implemented a commemorative dividend of ¥10 per share at the time of the interim dividend in fiscal 2017. Also, looking at our results, we recorded declines in

core operating profit, operating profit, and profit attributable to owners of the Company. However, in accordance with the basic policy on shareholder return, the Company set annual dividends at ¥56.0 per share, an increase of ¥4.0 per share (not including the commemorative dividend). Including the commemorative dividend, the annual dividend was ¥66.0 per share, and the dividend payout ratio was 63.9%, compared with 40.9% in the previous fiscal year.

In fiscal 2018, due to the NHI drug price revision in Japan and to measures to promote the use of generics and biosimilars, our operating environment will become more challenging. Nonetheless, we will step up initiatives to bolster sales of fiscal 2018 priority products and to increase sales of Radicava in the U.S. Accordingly, we are forecasting increased revenue for fiscal 2018. However, targeting strong growth in fiscal 2020 and subsequent years, we will accelerate R&D investment in late-stage drug candidates, resulting in a record-high level of R&D expenses in fiscal 2018. Accordingly, in profits we anticipate continued declines in core operating profit operating profit, and profit attributable to owners of the Company. In accordance with these results forecasts and the dividend policy, the Company plans to pay annual dividends for fiscal 2018 of ¥56.0 per share, the same as in the previous fiscal year (excluding the commemorative dividend), for a consolidated dividend payout ratio of 66.8% under IFRS.

Dividends	Announced May 9, 2018	
	Fiscal 2017	Fiscal 2018 (forecast)
Dividends per share (excluding commemorative dividend)	¥56	¥56
Commemorative dividend per share	¥10	—
Dividend payout ratio	63.9%	66.8%

Note: In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

## Looking Ahead to the Next 10 Years

**Looking ahead to the next 10 years and beyond, everyone at Mitsubishi Tanabe Pharma will work together to “transcend limits” and “fully achieve our goals to the end.” In this way, we will take the next step.**

Mitsubishi Tanabe Pharma reached the 10th anniversary of its founding in 2017. During 2017, in accelerating U.S. business development, which is positioned as our greatest challenge under the current medium-term management plan, we were able to achieve our longstanding goal of launching a new drug in the U.S. and to open a door to the future. I believe that we made a strong start for the next 10 years. As I explained, we are also making overall progress in line with our plans for the other three strategic priorities.

However, our operating environment is undergoing dramatic change. In Japan, the effect on the Company of the April 2018 NHI drug price revision will be greater than expected. Moreover, in overseas operations, royalty revenue, etc., has been the driver of the Company’s revenue over the past several years, but intensified

competition has reduced the earnings power of Invokana, and royalty revenue, etc., is not expected to reach the planned level.

In consideration of this situation, we recognize that we will need to implement additional measures moving forward. However, we will not be able to take the next step if we limit ourselves to traditional working styles and to simply extend existing concepts. For example, in the U.S., Radicava has already opened one door, and the advanced technologies of Medicago and NeuroDerm are about to open other doors. But in the world beyond those doors, the functions and knowledge that Mitsubishi Tanabe Pharma has cultivated to date will not be sufficient. In other words, we must cultivate new capabilities.

To that end, we need to take on the challenge of new initiatives that transcend limits without being restricted by previous values and experience. Furthermore, we need to do more than just “take action” in a vague manner. We need to “fully achieve our

goals to the end.” I believe that this approach will foster innovation and lead to growth that opens doors to the future, as individuals and as organizations. Looking ahead to the next 10 years and beyond, everyone at Mitsubishi Tanabe Pharma will work together to “transcend limits” and “fully achieve our goals to the end.” In this way, we will take the next step. I would like to ask our shareholders and investors for their support of Mitsubishi Tanabe Pharma in the years ahead.

#### Fiscal 2018 Results Forecast

Announced May 9, 2018

	Fiscal 2017	Fiscal 2018 (forecast)	% change
Revenue	¥433.8 billion	¥435.0 billion	+0.3%
Core operating profit	¥78.5 billion	¥70.0 billion	-10.9%
Profit attributable to owners of the Company	¥57.9 billion	¥47.0 billion	-18.9%



September 2018

*Masayuki Mitsuka*

**Masayuki Mitsuka**  
President & Representative Director

# Drug Discovery

## Basic Policy

Mitsubishi Tanabe Pharma strives to continually discover new drugs that address unmet medical needs around the world. The Company's four priority disease areas are autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. Centered on these areas, we are aiming to become a "pharmaceutical company that works with a sense of speed and is the first to deliver original value." On that basis, we are focusing on the discovery of new drugs. Moreover, as we move forward we will expand discovery resources by aggressively leveraging open shared business through the in-licensing of discovery seeds as well as collaboration with other companies. We will also utilize the optimal discovery and development methods for each candidate, thereby shortening the period required until acquisition of POC (see the "Explanation of Terms" section).

## Fiscal 2017 Initiatives

In fiscal 2017, we aimed for rapidly obtain POC for drug candidates, and focused on initiatives to promote the continued discovery of new drug candidates in the future. We reviewed the allocation of resources to discovery projects, from initial exploratory trials to late pre-clinical trials, and implemented the principles of selection and concentration. In addition, to achieve further gains in the quality and quantity of drug candidates that have newly entered clinical trials, we actively strengthened translational research<sup>1</sup>, which involves the connection from pre-clinical trials to clinical trials.

As a result of these initiatives, in line with our plans, we initiated clinical trials to obtain POC in the U.S. and Europe for multiple drug candidates, such as MT-8554 (expected indications: vasomotor symptoms associated with menopause, etc.) and MT-7117 (expected indication: erythropoietic protoporphyria). We also made progress with the follow ups to those candidates. We are also conducting clinical trials for drug candidates in early stages, such as MT-4129 (expected indications: cardiovascular system, etc.), MT-0814 (expected indications: ophthalmologicals), and MT-2990 (expected indications: inflammatory diseases, autoimmune diseases, etc.). We are moving ahead with the expansion of drug discovery modalities<sup>2</sup> for drug candidates.

1. Research conducted with the objective of applying the results of basic research to clinical trials and on the medical front lines.
2. Physical classification of treatment agents. Treatment methods, such as small molecule compounds; protein drugs, including peptide (middle molecule) drugs and therapeutic antibodies; nucleic acid drugs; cell therapy drugs; and regenerative medicine.



### Hiroaki Ueno

Managing Executive  
Officer  
Division Manager of  
Sohyaku. Innovative  
Research Division



This section explains our initiatives in the area of business processes leading to product launch, from clinical research and basic research to the identification of candidate compounds (discovery seeds) that will become pharmaceuticals and the demonstration of superior medical value through the conduct of a variety of pre-clinical trials and clinical trials.

## Fiscal 2017 Results and Fiscal 2018 Initiatives

Product	Fiscal 2017 Results	Fiscal 2018 Initiatives
<b>Autoimmune Diseases</b>		
MT-1303 (S1P receptor functional antagonist)	Reevaluated the development plan for in-house development	Promotion of activities for cooperation with other companies
MT-5547 (anti-NGF antibody)	Phase 2/3 trials initiated in Japan for osteoarthritis	Promotion of Phase 2/3
MT-7117 (dermatologicals, etc.)	Phase 1 completed	Phase 2 initiated overseas Plan to achieve POC
MT-2990 (inflammation, autoimmune diseases, etc.)	Phase 1 initiated	Phase 2 initiated overseas Plan to achieve POC
<b>Diabetes and Kidney Diseases</b>		
MT-6548 (HIF-PH inhibitor)	Phase 3 initiated in Japan for renal anemia	Promotion of phase 3 (Targeting approval in fiscal 2020)
TA-7284 (SGLT2 inhibitor)	Promoted global clinical trial (CREDENCE study) in Japan, the U.S., Europe, etc., for diabetic nephropathy * Clinical trial client: Janssen Research & Development	Targeting end of CREDENCE study in June 2019 Under consideration for acquisition of approval for diabetic nephropathy
MT-3995 (selective mineralocorticoid receptor antagonist)	Promoted phase 2 in Japan, with a focus on NASH (non-alcoholic steatohepatitis)	Promotion of activities for cooperation with other companies
<b>Central Nervous System Diseases</b>		
MT-5199 (VMAT2 inhibitor)	Phase 2/3 initiated in Japan for tardive dyskinesia	Promotion of phase 2/3 (Targeting approval in fiscal 2021)
MT-8554 (nervous system, etc.)	Phase 2 initiated for painful diabetic peripheral neuropathy in the EU and for vasomotor symptoms associated with menopause in the U.S.	Promotion of phase 2 Targeting acquisition of POC in third quarter of fiscal 2018
ND0612 (levodopa / carbidopa)	NeuroDerm became wholly owned subsidiary (October 2017) Promoted long-term safety study	Phase 3 initiated in the U.S. and Europe for Parkinson's
MT-1186 (edaravone / new administration route)	Considered new dosage form with the aim of increasing convenience for ALS patients	Phase 1 initiated
<b>Vaccines</b>		
MT-2355 (combined vaccine for five diseases)	Promoted phase 3 in Japan	Promotion of phase 3
MT-2271 (plant-based VLP vaccine)	Initiated phase 3 (for adults) in the U.S., Europe, Canada, etc., for seasonal influenza	Filing in North America in fiscal 2018 (Targeting approval in fiscal 2019)

### ■ Bolstering Our Drug Discovery Capabilities

Through aggressive collaboration with academic institutions and venture companies in the top ranks worldwide, we are now taking steps to strengthen our platform for innovative drug discovery and our drug discovery advancement capabilities. In particular, we are establishing discovery research bases in locations close to the medical front lines and reinforcing our system for the promotion of discovery research together with MDs in order to accurately understand unmet needs on the medical front lines and to leverage that knowledge in discovery research.

Furthermore, we are now working to implement translational research with a global viewpoint from the initial stages of discovery research. We have taken steps to build that type of system in cooperation with our pharmaceutical development subsidiaries in the U.S. (Mitsubishi Tanabe Pharma Development America) and Europe (Mitsubishi Tanabe Pharma Europe). We have strengthened the functioning of our drug discovery system, which is integrated

from pre-clinical trials to acquisition of POC, and expect to see results from these initiatives in fiscal 2018.

### ■ Leveraging Alliances

Our basic policy is to utilize alliances with academia for basic research activities, such as identifying discovery targets and acquiring new technologies, as well as alliances with venture companies and other pharmaceutical companies for the acquisition of new drug discovery projects and joint research. In addition, drug discovery research for new modalities is an area of special focus. We are working together with multiple partners, such as academic institutions and venture companies, to implement initiatives in this area while advancing the formation of a drug discovery ecosystem<sup>3</sup>.

As one part of those initiatives, in fiscal 2017 three companies—Astellas Pharma, Daiichi Sankyo, and Mitsubishi Tanabe Pharma—cooperated in the launch of a new drug discovery program called JOINUS. Through this project, the partners will build a

## Stepping Up to the Future

### Studying diligently each day to increase expertise

Modality Laboratory,  
Sohyaku, Innovative Research Division  
Yuichi Imura



Since joining the Company, I have worked in discovery research, centered on physical property analysis of new drug candidate compounds. For the first two years, I worked with small-molecule pharmaceuticals, and since that time I have been working with biologics. For biologics, the manufacturing process is complex, and in addition to efficacy and safety, it is difficult to identify substances that are appropriate for manufacturing other than small-molecule pharmaceuticals. In this setting, it is my job as a researcher to use a variety of analyses to discover new drug candidate substances that proceed to clinical trials.

In 2017, I had the opportunity to visit Tanabe Research Laboratories U.S.A., in the U.S., and for about six months, I was able to gain experience on the front lines of discovery research in the U.S. The first thing I noticed was a difference in speed. I was very impressed with the approach of the researchers, who boldly take risks and push forward to the launch of a new drug while striving to ensure safety.

The biggest benefit I reaped was once again realizing the importance of expertise. In the U.S., if you do not have expertise, then your value as a researcher will not be recognized. The reason is that a high level of expertise is indispensable in order to reach the

final objective of launching a new drug. Furthermore, discovery research covers a wide range of fields, and accordingly researchers can increase their expertise through active collaboration and mutual encouragement, not only internally but also externally.

The group at which I worked implemented study sessions and other initiatives so that we could increase our own expertise in such areas as analyzing, cultivating, and refining in order to facilitate the rapid achievement of results in the discovery of pharmaceuticals. Moreover, looking at the Company overall, we have a large number of researchers with high levels of expertise in the field of small-molecule pharmaceuticals. If we bolster collaboration among biologics researchers and small-molecule pharmaceuticals researchers and leverage various areas of expertise, I believe that we have the potential to rank with the world's major players in the areas where those technologies overlap.

Accordingly, I first of all want to increase my own expertise. The quality needed for new drug candidate substances changes continually, and accordingly the required analyses also change. I will do my utmost each day so that I can continually gather and leverage the latest information.

drug repositioning library comprising compounds for which development was halted after the implementation of clinical trials or pre-clinical trials. We will provide this library to domestic research institutions selected for this program, and they will make evaluations using their own *in vitro*<sup>4</sup> assays. In this way, we will aim to foster drug discover projects that individual companies would not be able to come up with on their own.

As another initiative to establish the drug discovery ecosystem, we participated in the launch of the Immune-Mediated Inflammatory Diseases Consortium for Drug Development with the objective of promoting discovery research targeting immune-mediated inflammatory diseases. The participants in this consortium include three academic institutions, Keio University, Kochi University, and the National Institutes of Biomedical Innovation, Health and Nutrition, as well as three pharmaceutical companies, Mitsubishi Tanabe Pharma, Daiichi Sankyo, and Ono Pharmaceutical. A high-quality database will be constructed based on the various data accumulated by the consortium, and this database will be shared by the participating academic institutions and pharmaceutical companies. The pharmaceutical companies will be able to use this database in their own discovery research. On the other hand, the participating academic institutions will be able to use the database in order to make further progress with basic and applied research. Through the use of this unique new concept for industry-academia cooperation, we will aim to establish a new drug discovery ecosystem for the treatment of immune-mediated inflammatory diseases and the discovery of innovative drugs.

3. System to increase efficiency in the discovery process.

4. Testing in which drug reactions are detected in an artificial environment similar to that in the living organism, using human or animal tissue in test tubes, culture vessels, etc.

## Outlook for Fiscal 2018 and Thereafter

The operating environment for pharmaceutical companies is undergoing dynamic change. In this setting, the Company must continuously launch innovative drugs. The “Sohyaku. Innovative Research Division” employees will strive to transcend previous frameworks and to become a standard-bearer for reforms. At the same time, the entire division will work to implement future-oriented reforms while maintaining a focus on results. In this way, we will aim for a system that can continually discover pharmaceuticals with true value. We will form a drug discovery ecosystem comprising the best partners. This initiative will include partners inside and outside of the Group as well as those in Japan and overseas. We will aggressively leverage a variety of drug discovery opportunities, build a global R&D system, and strive to achieve steady results in fiscal 2018 and thereafter.

WEB

For further information about initiatives to support value creation in drug discovery, please use the following URL.

### CSR Website



### | Consumer Issues → Research & Development

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer\\_issues/index.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer_issues/index.html)



**Seiichi Murakami**

Board Director  
Managing Executive  
Officer  
In charge of Ikuyaku,  
Integrated Value  
Development Division

# IKUYAKU and Marketing

## Basic Policy

Mitsubishi Tanabe Pharma is strengthening its initiatives to maximize product value as rapidly as possible, centered on our priority disease areas—autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. In addition, to strengthen our sales promotion activities we are further enhancing our special expertise in our priority disease areas, and are also promoting area marketing and digital marketing.

## IKUYAKU

### Fiscal 2017 Initiatives

Since April 2017, the “Ikuyaku. Integrated Value Development Division” has been responsible for operations from late-stage development through to post-launch activities. These operations are handled through the clinical research & development, medical affairs, and pharmacovigilance sections.

In Japan, we commenced late-stage development of three candidates—MT-5199 (expected indication: tardive dyskinesia), MT-5547 (expected indication: osteoarthritis), and MT-6548 (expected indication: renal anemia). For products that have already been launched, such as Canaglu and Tenelia, we worked to enhance product information. In addition, looking overseas we established a global pharmacovigilance system accompanying the start of overseas sales activities for Radicava, an ALS treatment agent that originated in-house.

### Outlook for Fiscal 2018 and Thereafter

In fiscal 2018, in Japan, in addition to the abovementioned MT-5199, MT-5547, and MT-6548, we will advance the clinical trial for MT-2355, a combined vaccine for five diseases. In addition, we will aim for an additional indication of diabetic nephropathy for Canaglu. For each of these products, we will strive to advance clinical trials while maintaining quality without losing speed. Currently, after the implementation of POC trials overseas for two compounds that originated in-house—MT-7117 (expected indication: erythropoietic protoporphyria) and MT-8554 (expected indications: painful diabetic peripheral neuropathy, and vasomotor symptoms associated with menopause)—we plan to advance development in Japan as well. Moreover, clinical trials in China for MP-513 (teneligliptin), a diabetes treatment agent originated in-house, have reached phase 3, and we expect MP-513 to contribute to our China business in the future.

This section explains our initiatives in post-marketing business processes, such as sales promotion activities by the MRs and life-cycle management to increase product value.

The medical affairs sections have a special focus on activities to increase product value after launch. For our priority products, such as Remicade, Canaglu, Tenelia, and Canalia, we will further clarify the product profile through the use of overseas information and post-marketing clinical trials (safety and efficacy). In this way, we will make it easy to understand the positioning of our products in treatment. On the other hand, the pharmacovigilance sections collect safety information and clarify in-depth product safety profiles. Moving forward, we will continue working to develop the capabilities of our staff members so that they improve the knowledge required to engage in disease-related discussions with health care professionals, and will work to further enhance their understanding of product safety. Also, in collaboration with the medical affairs sections, for Canaglu and other products, we are reporting data regarding clinical safety in Japanese patients at academic conferences, etc., and moving forward we intend to continue to

actively communicate with healthcare professionals regarding safety information.

Since the Ikuyaku. Integrated Value Development Division was established, through collaboration among the clinical research & development sections, which develop products; the pharmacovigilance sections, which work to thoroughly understand safety; and the medical affairs sections, which provide scientific, well-balanced explanations of efficacy and safety, we have been working to increase product value and communicate information about our products to related parties. Currently, we are further advancing this initiative. We will strive to build a system that can provide information in a more effective and efficient manner from an earlier phase, i.e., from the late-stage development phase. In this way, we will work to support the use in patient treatment of highly anticipated new drugs for which launches are planned.

## Advancing New Drug Development and Life-Cycle Management Strategy

In fiscal 2017, we made progress with initiatives to maximize the value of drugs, as follows.

### Acquisition of Approval

#### ■ Remicade

Approval was received for a partial change in administration / dosage (shortened administration interval) for Crohn's disease in Japan.

#### ■ MT-2412

Approval was received for type 2 diabetes mellitus in Japan (launched under the product name Canalia).

#### ■ MCI-186 (Japan product name: Radicut)

Approval was received for ALS in the U.S. (launched under the product name Radicava).

#### ■ Novastan

Approval was received for acute cerebral thrombosis in China.

Note: In June 2018, Jublia was approved for tinea unguium in Taiwan.

### Application Filed

#### ■ TA-7284 (Japan product name: Canaglu)

An application was filed in Indonesia for type 2 diabetes mellitus.

#### ■ MP-214

An application was filed in South Korea and Taiwan for schizophrenia.

Note: An application for MP-214 for schizophrenia was filed in Singapore in June 2018.

#### ■ MCI-186 (Japan product name: Radicut)

An application was filed in Switzerland for ALS.

Note: For MCI-186, applications were filed for ALS in Canada in April 2018 and in Europe in May 2018.

#### ■ Valixa

An application was filed in Japan for the prevention of cytomegalovirus disease in pediatric organ transplant patients.

### Out-Licensed Products

#### ■ FTY720 (product name: Gilenya)

Licensee Novartis, of Switzerland, filed applications for pediatric multiple sclerosis in the U.S. and Europe.

Note: In May 2018, approval was received in the U.S. for FTY720 for pediatric multiple sclerosis.

#### ■ TA-7284 (product name: Invokana)

Licensee Janssen Pharmaceuticals, of the U.S., filed applications in the U.S. and Europe for reduction of the risk of cardiovascular death in type 2 diabetes patients at risk for or with a history of cardiovascular disease (CANVAS/CANVAS-R).

#### ■ MT-210

Licensee Minerva Neurosciences, of the U.S., started phase 3 clinical trials for schizophrenia in the U.S. and Europe.

#### ■ MT-4580

Licensee Kyowa Hakko Kirin obtained approval in Japan for secondary hyperparathyroidism in patients on maintenance dialysis. In addition, phase 3 clinical trials were started in Japan for an indication of hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism.

Disease area: ■ Autoimmune diseases ■ Diabetes and kidney diseases ■ Central nervous system diseases ■ Other

Marketing

Fiscal 2017 Initiatives

Medium-Term Management Plan 16–20 includes the numerical objectives of domestic revenue of ¥300.0 billion and a new drugs and priority products revenue ratio of 75%. Targeting the achievement of these objectives, we implemented initiatives to strengthen area marketing, leverage digital marketing, and bolster prescription proposal capabilities. In these ways, we worked to enhance our marketing productivity.

We have assigned area marketing planners (AMPs) to all of our sales offices. The AMPs play a central role in the formulation of area marketing plans for their areas, and they promote the reinforcement and implementation of area strategies. In addition, the AMPs work to support the realization of efficient sales promotion activities. To that end, we implement multichannel information provision

utilizing real and digital initiatives, such as making prescription proposals in face-to-face meetings with health care professionals while also operating exclusive websites for those professionals.

Initiatives Centered on Priority Disease Areas

In the field of autoimmune diseases, Janssen Pharmaceutical K.K. obtained approval of an indication of Crohn's disease for Stelara, and in May 2017 Mitsubishi Tanabe Pharma and Janssen Pharmaceutical K.K. started co-promotion. Sales are handled by Janssen Pharmaceutical K.K., and the provision of information to health care professionals is implemented jointly by both companies. Up to this point, Mitsubishi Tanabe Pharma has sold Remicade as a treatment agent for Crohn's disease. Moving forward, we will also conduct information provision activities for Stelara, which has a different mechanism of action. In this way, the Company is now able to provide a new treatment option for patient's with Crohn's disease.

In addition, Mitsubishi Tanabe Pharma now offers Remicade, Simponi, and Stelara, making us the only pharmaceutical company that offers three biologics in this field. We have received high evaluations from health care professionals as a pharmaceutical company that can provide the optimal treatment option to many patients who are suffering from autoimmune diseases, and as a pioneer in biologics. In fiscal 2017 our share of the market for biologics used to treat autoimmune diseases was 37%, and we have established a position as a leading brand in this market. Janssen Pharmaceutical K.K. received approval for an additional indication of ulcerative colitis in March 2017, and in fiscal 2017, the first year, Simponi earned a share of 10% of the market for ulcerative colitis. In this way, Simponi has gotten off to a favorable start.

Next, in the field of diabetes, the demand for combination tablets is increasing due to the need to control health care expenditures and address the harmful effects of polypharmacy and other health care issues. In this setting, in September 2017 we were able to launch Canalia, a type 2 diabetes mellitus treatment agent, as Japan's first combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor. Canalia has gotten off to a favorable start, and we are demonstrating synergies resulting from our ability to offer three diabetes treatment agents—Tenelia, Canaglu, and Canalia.

In vaccines, the operating environment is undergoing drastic change, and we are moving ahead with the establishment of a system that facilitates the realization of a stable vaccine supply. In fiscal 2017, there was concern about a shortage of influenza vaccine in Japan, and we worked to offer a stable supply in order to avoid any disorder in the market. As a result, we were able to maintain the No. 1 share among sales companies in the domestic market. The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation) and Mitsubishi Tanabe Pharma established BIKEN Co., a joint venture for vaccine manufacturing that began operations in September 2017.

In addition, in November 2017 the Company and Teikoku Seiyaku, began co-promotion of Rupafin, an anti-allergy agent developed by Teikoku Seiyaku. Rupafin is Japan's first anti-histamine that has anti-PAF\* action.

\* Platelet Activating Factor. Closely involved in the pathology of allergies.



**Yoshiaki Ishizaki**  
Board Director  
Managing Executive  
Officer  
In Charge of Sales &  
Marketing Division

## Outlook for Fiscal 2018 and Thereafter

We took steps to produce results at a speed exceeding the pace of change in the market environment. To that end, the AMPs played the central role in the formulation of the area marketing plan for each area, and the MRs and employees responsible for area marketing promotion worked together to implement these plans and increase unit sales. In addition, we have assigned digital marketing planners (DMPs) to all sales offices. The DMPs support approaches to health care professionals through the optimal channel. Moving forward, we will work to generate synergies through mutual collaboration between AMPs and DMPs.

In fiscal 2018, to increase the quantity and quality of the sales promotion activities conducted by our MRs, we will implement initiatives in the fields of area marketing, digital marketing, and training to strengthen prescription proposal capabilities. Moreover, with a view to future launches of new products, we will work to enhance our presence in priority disease areas.

Furthermore, the ways in which health care professionals acquire information are diversifying, and in response we will accelerate digital marketing and advance the implementation of area

marketing plans. In these ways, we will strive to achieve growth in unit sales through the efficient, effective provision of information that is truly needed on the medical front lines.

WEB

For further information about initiatives to support value creation in IKUYAKU and Marketing, please use the following URLs.

### CSR Website



#### | Consumer Issues → Information Provision

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer\\_issues/information.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer_issues/information.html)

#### | Consumer Issues → Quality and Reliability Assurance

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer\\_issues/reliability.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer_issues/reliability.html)

## Stepping Up to the Future

### Taking the initiative for patients

Chuo Sales Office Manager, Tokyo Branch  
**Sachiko Yayama**

I originally joined the Company as an MR. As I confronted the various issues that MRs typically face, I began to think that I would like to work in a position that offers support from the perspective of MR development. That ambition was fulfilled, and in 2010 I was assigned to the Sales Force Training Office. I subsequently worked in MR development, including both operations and knowledge. In particular, my work in the formulation and adoption of solution maps\* has been an extremely valuable experience.

In April 2018, I became the manager of this sales office, and MR development is still an important part of my responsibilities as manager. In regard to MR development, I believe that it is important to foster independent action. I am working to ensure that we share common objectives as a sales office, and at the same time I am also encouraging all employees to think for themselves about specific measures to achieve those objectives. In this way, I believe that each individual MR will focus on sustained success rather than being satisfied with short-term results.

However, promoting independence does not mean simply leaving things up to the individual. Follow-up is also important. For example, as a new initiative at this sales office we are strengthening the provision of information to medical institutions that account for only a small share of our sales but nonetheless have a high degree of potential. To that end, we are conducting strategy meetings in which participants share their insights and discuss effective measures. In this way, we are supporting the activities of individual MRs.

In regard to the independent action of MRs, I believe that the most important point is to give serious consideration to how our actions benefit patients. I also believe that acting for the benefit of patients is connected to the implementation of the solution maps that I mentioned above. Moving forward, I will continue to emphasize working for the benefit of patients, so that all of our MRs can have confidence that they are contributing to patients and society as they strive to carry out their duties each day.

\* A systematic approach to processes that are models for the provision of information to health care professionals, based on analyses of the actions of Company MRs with superior results.

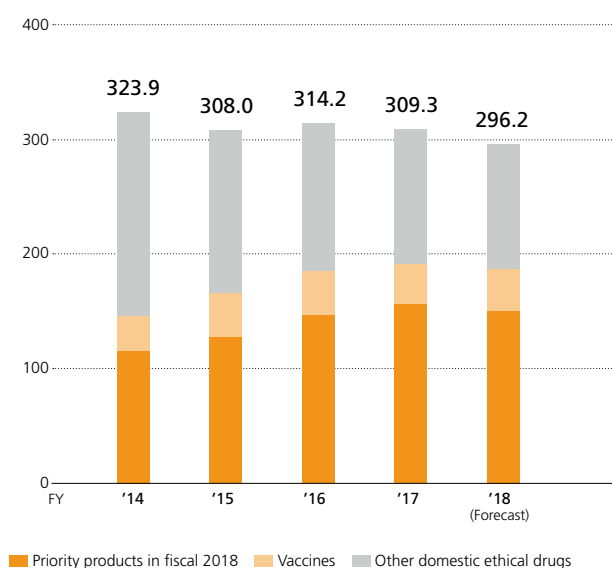
## Overview and Sales Trends of Priority Products in Fiscal 2018

The sales forecasts in this section were announced on May 9, 2018.



### Domestic Revenue of Ethical Drugs

Billions of yen



### Revenue of Priority Products in Fiscal 2018

Billions of yen	'14	'15	'16	'17	Forecast '18
Remicade	70.6	69.4	66.8	64.6	55.5
Simponi	10.4	12.9	24.9	32.1	35.0
Tenelia	6.2	14.1	16.5	17.5	17.0
Talion	15.9	16.8	18.9	16.9	7.3
Lexapro	7.9	9.5	11.2	12.7	13.1
Canaglu	1.1	0.5	3.4	5.6	7.6
Imusera	3.2	4.1	4.9	4.7	4.9
Canalia (new product)	—	—	—	1.8	3.2
Rupafin (new product)	—	—	—	0.4	6.8
<b>Vaccines:</b>					
Influenza vaccine	7.3	13.7	12.7	9.9	11.2
Tetrabik	7.5	9.5	9.9	8.7	9.1
Varicella vaccine	7.1	6.3	5.4	5.2	5.5
JEBIK V	3.5	3.6	3.9	5.2	4.3
Mearubik	3.9	4.9	5.9	5.0	5.5

Note: From fiscal 2016, the Company has voluntarily applied IFRS instead of Japanese GAAP. Figures for fiscal 2015 are also presented in accordance with IFRS, but figures for fiscal 2014 are before the application.



## Remicade

Infliximab

Domestic Revenue

¥64.6 billion



### Indications

RA (including the prevention of structural joint damage), Behcet's disease with refractory uveoretinitis, psoriasis vulgaris, psoriasis arthropathica, pustular psoriasis, erythrodermic psoriasis, ankylosing spondylitis, entero-Behcet's disease, neuro-Behcet's disease, vasculo-Behcet's disease, Kawasaki disease, Crohn's disease, ulcerative colitis

<b>Launch</b>	May 2002
<b>Origin</b>	Janssen Biotech (U.S.)
<b>Development</b>	Mitsubishi Tanabe Pharma

### Overview

Remicade is the world's first anti-TNF monoclonal antibody. It targets TNF, an inflammatory cytokine. Administered through IV infusion, it is very fast-acting and its efficacy is sustained for eight weeks with a single administration. In Japan, it was launched as a treatment agent for Crohn's disease in 2002 and received an additional indication for RA in 2003. In 2009, approval was received for a change of dosage / administration for RA (increased dosage, shortened administration interval). Furthermore, additional indications for a wide range of inflammatory autoimmune diseases, such as psoriasis and ulcerative colitis, have contributed to growth in sales. In 2012, it became possible to shorten the IV infusion time from the 4th administration if there are no problems with safety. Also, in fiscal 2017 approval was received for a partial change in administration / dosage (shortened administration interval) for Crohn's disease.

### Sales Trend

In fiscal 2017, revenue was down 3.2%, to ¥64.6 billion. NHI drug prices were revised in April 2018, and the third biosimilar is expected to be launched during fiscal 2018. The circumstances will remain difficult, including competing products. However, in the treatment of RA, we will work to enhance original value by facilitating contributions to the optimization of treatment through the use of blood concentration measurement kits. The forecast for revenue in fiscal 2018 is ¥55.5 billion, a decline of 14.1%.

## Simponi

Golimumab

Domestic Revenue

¥32.1 billion



### Indications

RA (including the prevention of structural joint damage), ulcerative colitis

<b>Launch</b>	September 2011
<b>Origin</b>	Janssen Biotech (U.S.)
<b>Development</b>	Co-development with Janssen Pharmaceutical K.K.

### Overview

Simponi is a human TNF $\alpha$  monoclonal antibody that targets TNF $\alpha$ , an inflammatory cytokine. With simple administration—subcutaneous injection once every four weeks—it has superior efficacy that continues for an extended period of time. Its efficacy and safety are higher than other subcutaneous injections, and it is expected to contribute to raising the percentage of patients who continue treatment. In regard to indications, in addition to RA (including the prevention of structural joint damage), in 2017 Janssen Pharmaceutical K.K., with which we are conducting joint development, added an indication for ulcerative colitis.

### Sales Trend

In fiscal 2017, revenue rose 29.0%, to ¥32.1 billion. The convenience of a single administration for a four-week period has been highly evaluated, and Simponi is increasing its share in the RA market. In addition, in the ulcerative colitis market, it is used by a growing number of institutions as the third biologic. In April 2018, insurance coverage was extended to include self-administered injections for the treatment of RA, which provides a new treatment option for patients who face difficulties in commuting to medical facilities. In fiscal 2018, new competing products are expected to be launched, and the market environment will be challenging. However, we will leverage our collaborative alliance with Janssen Pharmaceutical K.K. and work to promote the further use of Simponi. The forecast for revenue in fiscal 2018 is ¥35.0 billion, an increase of 9.2%.

## Tenelia

### Teneligliptin

Domestic Revenue

¥17.5 billion



#### Indication

Type 2 diabetes mellitus

**Launch** September 2012  
**Origin** Mitsubishi Tanabe Pharma  
**Development** Mitsubishi Tanabe Pharma

#### Overview

Tenelia is the first dipeptidyl peptidase-4 (DPP-4) inhibitor originating in Japan that has ever been launched. Due to the strength and duration of its action, it can improve post-prandial blood glucose, after three meals, with once-a day oral administration. Furthermore, because it is eliminated from the body via two routes—through the kidneys and the liver—it is not necessary to adjust the dosage for patients with impaired kidney function. In 2013, approval was received for an indication of additional combination for type 2 diabetes mellitus, making it possible to use Tenelia in combination with all oral diabetes mellitus treatment agents and insulin.

#### Sales Trend

In fiscal 2017, revenue rose 5.8%, to ¥17.5 billion. Competition in the DPP-4 inhibitors market is intense, but we have implemented joint promotional activities with Daiichi Sankyo and achieved solid increases in the number of administrations. From 2015, to increase efficiency we changed from a joint sales scheme to solo marketing by Daiichi Sankyo. However, we continue to implement joint promotions, and are emphasizing its ease-of-use and strong effectiveness, such as for senior citizens and patients with impaired kidney function. Accompanying the change in the sales scheme, the total of the amount of the Company's sales to Daiichi Sankyo, and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of revenue from Tenelia. The forecast for revenue in fiscal 2018 is ¥17.0 billion, a decrease of 2.8%.

## Talion

### Bepotastine

Domestic Revenue

¥16.9 billion



#### Indications

Allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, prurigo, cutaneous pruritus)

**Launch** October 2000  
**Origin** Ube Industries  
**Development** Co-development with Ube Industries

#### Overview

Talion has rapid onset of histamine H1 receptor antagonist effects and quickly displays a high degree of effectiveness for allergic rhinitis, urticaria, and pruritus accompanying dermatitis. It has a low frequency of sedation, which is a side effect of anti-histamines. An orally disintegrating tablet formulation, which makes it easier for patients to take the drug, has been sold since 2007, and a pediatric indication (ages 7 to 15) was approved in 2015.

#### Sales Trend

In fiscal 2017, sales declined 10.7%, to ¥16.9 billion. In March 2018, an authorized generic was launched. (An authorized generic is a product that is sold through a subsidiary, affiliate, etc., when that company receives patent usage rights from the pharmaceutical company that manufactures and sells the original product.) In addition, a generic drug was launched in June. However, during the reexamination period we will focus on pediatric applications (ages 7 to 15). The forecast for revenue in fiscal 2018 is ¥7.3 billion, a decrease of 56.6%.

## Lexapro

Escitalopram

Domestic Revenue

¥12.7 billion



### Indications

Depression, depressive symptoms, social anxiety disorder

**Launch** August 2011  
**Origin** H. Lundbeck (Denmark)  
**Development** Mochida Pharmaceutical

### Overview

Lexapro is a selective serotonin reuptake inhibitor (SSRI). It was launched in 2002 in Europe and the U.S., and is currently approved in approximately 100 countries and regions.

Among SSRIs, it has the highest serotonin transporter selectivity. Its superior efficacy for depression and depressive symptoms and good tolerability have been confirmed. In addition, it has simple administration, and as a result it is expected to contribute to the improvement of medication adherence, which is especially important in patients with depression. We have been conducting joint sales activities with Mochida Pharmaceutical since 2011. In 2015, it received an additional indication for social anxiety disorder (SAD).

### Sales Trend

In fiscal 2017, revenue rose 13.2%, to ¥12.7 billion.

Recognition of Lexapro's efficacy and tolerability has begun to achieve further market uptake, and Lexapro has secured the top share in the SSRI market. With an additional indication for SAD, we will work to promote its use by patients with anxious depression. In addition, for consideration of the pediatric dosage the re-examination period was extended by two years. The forecast for revenue in fiscal 2018 is ¥13.1 billion, an increase of 3.1%.

## Canaglu

Canagliflozin

Domestic Revenue

¥5.6 billion



### Indication

Type 2 diabetes mellitus

**Launch** September 2014  
**Origin** Mitsubishi Tanabe Pharma  
**Development** Mitsubishi Tanabe Pharma

### Overview

Canaglu is an SGLT2 inhibitor that originated in Japan. It has been approved in more than 80 countries around the world, including the U.S., European countries, and Australia. It is based on the SGLT inhibitor T-1095, which was discovered by the Company and is the world's first orally administered SGLT inhibitor. SGLT2 inhibitors promote urinary glucose excretion and blood glucose reduction. In this way, SGLT2 inhibitors have a new mechanism of action that was not previously available and does not work through insulin. In addition to a strong blood glucose lowering effect, SGLT2 inhibitors are expected to have a low hypoglycemia risk in monotherapy. SGLT2 inhibitors also have a weight reduction effect that is not seen with other oral diabetes treatment drugs. In overseas markets excluding Asia, licensee Janssen Pharmaceuticals, of the U.S., received approval in the U.S. in 2013, making this drug the first SGLT2 inhibitor approved in the U.S., and this drug is sold under the brand name Invokana.

### Sales Trend

In fiscal 2017, revenue was up 60.8%, to ¥5.6 billion.

Moving forward, we will work to see that Canaglu rapidly catches up to SGLT2 inhibitors that were launched earlier by securing accounts at hospitals and by differentiating it from other drugs in the private practitioner and small hospital market. On a base of abundant evidence for Canaglu, which is the world's most prescribed SGLT2 inhibitor, we will advance appropriate information provision activities and work to promote the appropriate use of SGLT2 inhibitors while fostering an understanding of the usefulness of this drug. The forecast for revenue in fiscal 2018 is ¥7.6 billion, an increase of 36.5%.

## Imusera

Fingolimod

Domestic Revenue

¥4.7 billion



### Indication

Multiple sclerosis (MS)

### Launch

November 2011

### Origin

Mitsubishi Tanabe Pharma

### Development

Co-development with Novartis Pharma K.K.

### Overview

Imusera is a first-in-class drug that controls inflammation in the brain and spinal cord in MS. It inhibits the receptor function of the sphingosine-1-phosphate (S1P) receptor on the lymphocyte, and prevents auto-aggressive lymphocytes from invading the central nervous system. Unlike previous drug treatments for MS, which are limited to injections, it can be administered orally (once daily), thereby lowering the burden on patients. Imusera was discovered by Mitsubishi Tanabe Pharma and developed jointly by Mitsubishi Tanabe Pharma and Novartis Pharma K.K. in Japan. We are marketing this product under the name Imusera, while Novartis Pharma K.K. is marketing it under the name Gilenya. Overseas, Novartis, of Switzerland, which licensed the product, has obtained approval in more than 80 countries and regions, including countries in Europe and the U.S.

### Sales

In fiscal 2017, revenue was down 3.5%, to ¥4.7 billion.

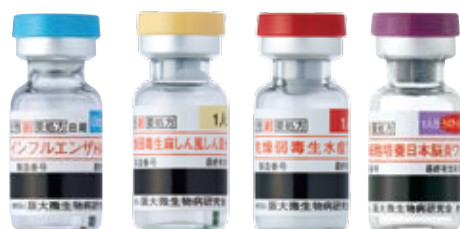
### Trend

New competing product was launched in February 2017, but based on their combined results Imusera and Gilenya have maintained the No. 1 share in the market. Moving forward, we anticipate a shift from injections toward oral drugs, and patients will have a choice of two oral drugs in accordance with their condition. The forecast for revenue in fiscal 2018 is ¥4.9 billion, an increase of 5.4%.

## Vaccines

Domestic Revenue

¥35.0 billion



### Overview

The Company sells vaccines developed and produced by The Research Foundation for Microbial Diseases of Osaka University (BIKEN Foundation). In May 2017, aiming for a stable supply of high-quality vaccines that are competitive in Japan and overseas, the BIKEN Foundation and the Company established a joint venture company, BIKEN Co., based on the BIKEN Foundation's vaccine manufacturing business. On a base of the BIKEN Foundation's vaccine manufacturing technologies, BIKEN Co., will leverage Mitsubishi Tanabe Pharma's pharmaceutical production-related systems and management methods and accelerate the reinforcement of the production foundation. In this way, BIKEN Co., will aim to achieve a more stable supply of vaccines.

### Sales

In fiscal 2017, overall revenue from vaccines was down 10.0%, to ¥35.0 billion. The Company maintained the top share of the domestic vaccine market in fiscal 2017. For the seasonal influenza vaccine, which accounts for the largest

### Trend

share of the Company's sales of vaccines, intradermal and cell-culture vaccines have been developed, but their influence on the market is not clear and it is not possible to make specific market forecasts. For the varicella vaccine, the number of children receiving periodic vaccination and the supply both stabilized. Accordingly, from fiscal 2017 we focus on promotions to prevent shingles in people 50 or older. However, the effect on the market has been small because this is a voluntary vaccination. The forecast for overall revenue of vaccines in fiscal 2018 is ¥36.5 billion, an increase of 4.2%.

## New Products Launched in Fiscal 2017

### Canalia

Teneligliptin/canagliflozin



#### Indication

Type 2 diabetes mellitus

**Launch** September 2017  
**Origin** Mitsubishi Tanabe Pharma  
**Development** Mitsubishi Tanabe Pharma

#### Overview

Canalia is a type 2 diabetes mellitus treatment agent that combines Canaglu and Tenelia. It is the first combination drug launched in Japan that includes a DPP-4 inhibitor and an SGLT2 inhibitor. Canalia has two different mechanisms of action, with the DPP-4 inhibitor promoting the secretion of insulin in accordance with blood glucose level and the SGLT2 inhibitor promoting the excretion of glucose into urine. Accordingly, it is expected to offer good blood glucose control with a single tablet administered once per day. In addition, in clinical trials in Japan targeting patients for whom monotherapy with Tenelia or Canaglu is not sufficiently effective, favorable results have been confirmed in regard to efficacy and safety.

#### Sales Trend

In fiscal 2017, revenue was ¥1.8 billion. Since its launch in September 2017, product recognition and intention to prescribe have been high, and sales have followed a favorable trend. In fiscal 2018, a competing product is expected to be launched, and domestic needs for combination tablets are increasing against a background of declines in the number of tablets taken and in the NHI drug price burden. Accordingly, we will work to foster further uptake in the market by providing information about the characteristics of Canalia. The total of the amount of the Company's sales to Daiichi Sankyo and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of the Company's revenue. The forecast for revenue in fiscal 2018 is ¥3.2 billion, an increase of 79.6%.

### Rupafin

Rupatadine fumarate



#### Indications

Allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, cutaneous pruritus)

**Launch** November 2017  
**Origin** J. Uriach Y COMPANIA (Spain)  
**Development** Teikoku Seiyaku

#### Overview

Rupafin is an oral allergy treatment agent that has a new mechanism of action. In addition to anti-PAF (platelet activating factor) action, it also has anti-histamine action. Launched in 2001 in Spain, it is currently approved in more than 80 countries and regions. Like histamine, PAF is a chemical transmitter that is closely involved in the pathology of allergic disorders. PAF induces vasodilation, vascular permeability enhancement, sensory nerve stimulation, and white blood cell activation. As a result, it brings about such symptoms as sneezing and runny nose. By simultaneously controlling PAF and histamine, Rupafin offers strong effectiveness and controls the symptoms of allergic disorders.

#### Sales Trend

Sales commenced in November 2017, and in fiscal 2017 revenue was ¥0.4 billion. The number of patients with hay fever and other allergic disorders is increasing each year. By simultaneously controlling both PAF and histamine, Rupafin offers dual action that is not available from existing anti-histamine products. Rupafin is a highly effective product, and on that basis we will work to increase its share by implementing sales activities to promote a switch from existing anti-histamine products. The forecast for revenue in fiscal 2018 is ¥6.8 billion, a substantial increase.



**Eiji Tanaka**

Executive Officer, General Manager of U.S. Operations, General Manager of Global Business Development

President of Mitsubishi Tanabe Pharma Holdings America

# U.S. Business

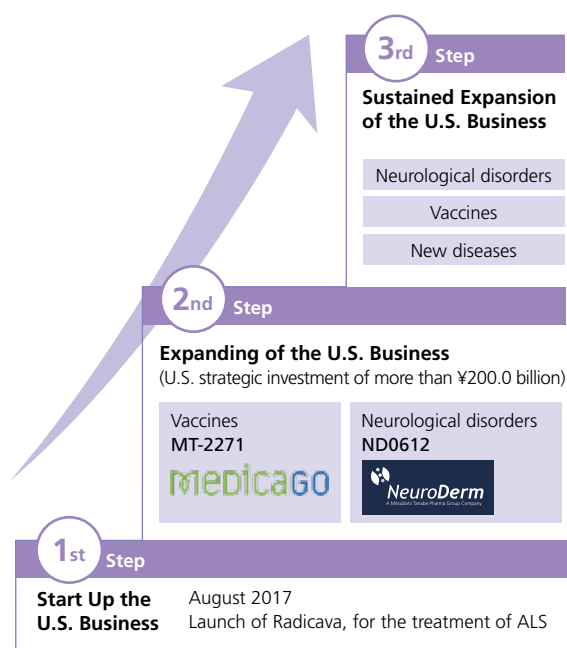
## Basic Policy

“Accelerating U.S. Business Development” is one of the four strategic priorities in Medium-Term Management Plan 16–20, and the Company has set a numerical target of ¥80.0 billion in U.S. revenue in fiscal 2020. We have outlined three steps for the roadmap toward the achievement of that target as well as sustained growth in fiscal 2021 and subsequent years.

The first step was getting the U.S. business under way with the launch of Radicava. The second step will be a focus on expanding the U.S. business through the active use of strategic investment and other measures. The current medium-term management plan calls for the implementation of more than ¥200.0 billion in strategic investment. The third step will be the continued growth of the U.S. business through initiatives in new disease areas in addition to neurological disorders and vaccines. These initiatives will be implemented on the business foundation that the Company establishes with the first and second steps.

## Smooth Launch for Radicava

We took the first step in August 2017 with the launch of Radicava. In the U.S. business, we use the term “the three Ps” to refer to our key stakeholders—Patients, Physicians, and Payers. We have been working with these stakeholders to foster an understanding of Radicava’s product value, and have been taking steps to enhance the treatment



In August 2017, Mitsubishi Tanabe Pharma took the first step in the development of its U.S. business with the launch of Radicava, an ALS treatment agent. This section explains our business strategy for developing the U.S. business into the Company's second operational pillar following Japan, as well as our initiatives with Medicago and NeuroDerm.

environment, such as measures to provide and expand information regarding medical institutions that prescribe Radicava.

As a result of these efforts, the number of patients who have taken Radicava surpassed 3,000 in August 2018. Radicava has gotten off to a strong start, and revenue in fiscal 2017 reached ¥12.3 billion. Moving forward, we will continue working to promote appropriate usage and to increase recognition of Radicava through the provision of information to health care professionals. In addition, we will focus on measures to enhance Radicava's accessibility and take steps to improve the ALS treatment environment, including support for at-home care. In these ways, we will advance a range of measures for the three Ps.

Moreover, at the same time we will implement Companywide initiatives to maximize the product value of Radicava. We filed an application in Switzerland in December 2017, followed by applications in Canada in April 2018 and Europe in May 2018. In the future, we will consider extending these measures to ASEAN markets and other regions. Furthermore, we are also working to advance life-cycle management strategies, such as the development of dosage forms for new administration routes. We are forecasting Radicava revenue in the U.S. of ¥31.5 billion in fiscal 2018. Going forward, we will continue working to achieve growth for Radicava and to deliver this treatment agent to as many ALS patients as possible around the world.

### Taking On the Challenge of Achieving Numerical Targets through Strategic Investment

Targeting the second step—expanding our U.S. business—we will work to follow up Radicava by enhancing our pipeline in the area of neurological disorders. To that end, in October 2017 we acquired NeuroDerm, of Israel, for approximately ¥124.0 billion (approximately US\$1.1 billion), and made it a wholly owned subsidiary. NeuroDerm is a pharmaceutical company with excellent capabilities in the development of technologies that combine drugs and medical devices. It is advancing the development of new drugs, centered on ND0612, a treatment agent for Parkinson's disease. In addition, in fiscal 2017 Medicago, of Canada, started phase 3 trials for MT-2271, a plant-based VLP vaccine. Plans call for an application to be filed in fiscal 2018, and this product is expected to be launched during the period of the current medium-term management plan.

We will continue to implement strategic investment, and will obtain products, drug candidates, etc., from external sources. In these ways, we will work to expand our U.S. business and achieve ¥80.0 billion in U.S. revenue in fiscal 2020.

> For further information about the specific initiatives of Medicago and NeuroDerm, please refer to Page 38–39.

### Building a Foundation for Sustained Growth

First-step and second-step initiatives—such as maximizing sales of Radicava and rapidly developing and launching ND0612 and MT-2271—are issues that we will have to address in order to achieve the numerical targets in the medium-term management plan. On the other hand, to realize sustained expansion in our U.S. business, which is positioned as the third step, we need to further enhance our pipeline and steadily advance development of in-house products.

We believe that the most important issue in accelerating U.S. business development is the implementation of measures and the establishment of systems to foster sustained growth in fiscal 2021 and thereafter, while at the same time pursuing short-term results, including the achievement of our numerical targets. To that end, we will need to implement the principles of selection and concentration in our R&D investment, with an early-stage focus on products developed in-house. Currently, at Mitsubishi Tanabe Pharma Holdings America (MTHA), we are working to strengthen the market analysis function in order to appropriately address the needs of patients and health care professionals. We will work to maximize pipeline value, including accelerating the development of in-house products, by seamlessly linking the creation of products that meet market needs and the formulation of sales strategies. We will also strive to rapidly nurture products that have been launched and to maximize their sales.

Furthermore, in fiscal 2017 the administrative functions of Group companies in the U.S., including human resources, legal affairs, accounting and finance, IT, and general affairs, were transferred to MTHA. Going forward, we will also simultaneously advance measures to reinforce defensive functions in the U.S. business, such as further bolstering governance and compliance through changes in the organizational system.

Our role will be to make full use of the Company's management resources and to achieve a balance between proactive initiatives (strategic investment and function reinforcement) and defensive initiatives (bolstering governance and compliance).

We will take steps to ensure sustained growth in the U.S. business while also pursuing results in the short term. With the launch of Radicava, the U.S. business is expanding rapidly. I believe that society's expectations of our business, as well as the duties and responsibilities that are our obligations to society, are expanding on a daily basis. To develop the U.S. business into Mitsubishi Tanabe Pharma's second operational pillar following Japan, we will steadily complete the three steps.

## Opening Up the Future with Innovative Vaccine Production Technologies

Medicago Inc.

medicago

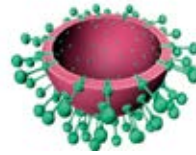


Medicago was established in Canada in 1997—the result of a collaboration between Laval University and the Ministry of Agriculture. The Quebec-based company was publicly funded until late 2013, when Japan’s Mitsubishi Tanabe Pharma Group and Switzerland’s Philip Morris International (PMI) made a joint venture agreement to support its future development.

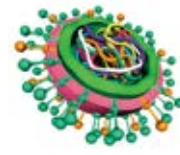
Medicago is a biopharmaceutical company specializing in the research and development of new vaccines and other therapeutic proteins. To produce vaccines, Medicago has developed an innovative technology that uses plant as mini factories to produce VLPs. VLPs have the same external structure as viruses; when administered as a vaccine, they stimulate the human immune system and are expected to provide strong protection against the viruses they imitate. However, because VLPs do not include any genetic material, there are no risks of replication and infectious disease. Medicago’s proprietary technology uses transient gene expressions in non-genetically modified plants. The plant species used is *Nicotiana benthamiana*.

Typically, in the case of producing the influenza pandemic, egg-based vaccines take around five to six months to manufacture a vaccine with this technique. In contrast, Medicago’s plant-based

Plant-Based VLP Vaccine



VLP



Influenza virus

VLPs (virus-like particles) have the same external structure as viruses, so VLP vaccines are expected to provide high levels of immunization effectiveness.

VLP methods require just five to six weeks. With such a short production timeline, Medicago could make a real difference if another influenza pandemic, such as the 2009 H1N1 pandemic, were to occur. The rapid availability of a vaccine during such a devastating event could help reduce the number of people infected, reduce overall morbidity and mortality, and minimize the socio-economic disruptions of a pandemic.

In addition, it is well known that the chicken-egg manufacturing process can cause the virus to mutate suddenly, meaning that the strain in the vaccine no longer exactly matches the target strain. When that happens, the effectiveness of the seasonal egg-based vaccine is reduced and the risk of infection increases. The social and economic losses can be substantial. This problem does not exist in plant-based vaccines; the VLP produced by Medicago’s manufacturing process always matches the circulating strain.

Under its current medium-term management plan, Mitsubishi Tanabe Pharma has positioned the vaccine business as a priority disease area, both in Japan and overseas. Moving forward, we will take steps to advance new vaccine development through Medicago’s VLP vaccine technology, with a focus on the U.S.

### MESSAGE

To achieve the launch of plant-based VLP vaccines, we want to make sure that all employees have a clear view and understanding of Medicago’s short- and long-term goals.

In the short term, we need to begin preparing for the early New Drug Application for MT-2271, which will be Medicago’s first product. This involves maintaining focus and motivation across all departments. We will also encourage a culture of entrepreneurship and efficient decision-making at all management levels to maximize effort and minimize distractions.

Medicago’s technology platform represents a truly disruptive approach not only to vaccine development and production, but also to many biologics. The VLP platform is incredibly versatile and efficient. Our goal at Medicago is to become the global leader in innovative product development using plant-based technology. We initially intend to demonstrate our capability through our VLP vaccine development program. However, our platform also has the potential to develop new therapies that combine vaccines and antibodies, both of which can be produced with the same VLP technology.



Bruce D. Clark  
President & CEO  
Medicago



## Opening Up the Future with a Combination of Pharmaceuticals and Devices

### NeuroDerm Ltd.



NeuroDerm, a pharmaceutical company that was established in Israel in 2003, has joined the Mitsubishi Tanabe Pharma Group. NeuroDerm has proprietary production technology for liquefying insoluble compounds, and through combinations of pharmaceuticals and devices, the company is developing treatment agents with high clinical value that offer increased effectiveness in addressing unmet medical needs and reduced side effects.

ND0612, for example, is under development in the U.S. and Europe with an expected indication of Parkinson's. Parkinson's is a progressive neurodegenerative disorder, with the onset of symptoms typically occurring when patients are in their 40s, 50s, or thereafter. The number of patients is said to be approximately 1 million in the U.S., 1.4 million in Europe, and 0.1 million in Japan. Furthermore, accompanying the aging of society, the number of patients is increasing.

Parkinson's disease occurs due to a deficiency of dopamine, a neurotransmitter that works in the brain. Accordingly, drug therapy is widely used to compensate for the dopamine deficiency through the administration of levodopa as an oral preparation. Patients are generally prescribed a combination

### ND0612 Pump Formulation



ND0612, which is administered through subcutaneous injection, realizes stabilization of the blood levodopa concentration.

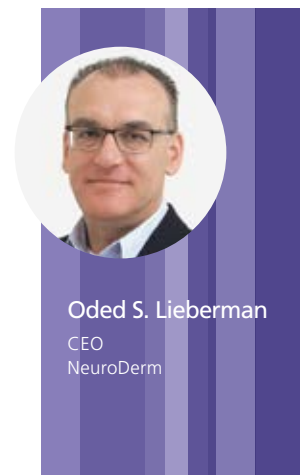
drug that includes carbidopa, which inhibits the breakdown of levodopa. However, oral levodopa has a short half-life and, as Parkinson's disease progresses, it becomes difficult to stabilize the blood levodopa concentration, and as a result the number of administrations per day has to be increased while the clinical effect of the treatment deteriorates. In addition, as the disease progresses to moderate and severe stages, treatment with drug therapy becomes difficult, and treatment methods that involve surgical intervention and place a larger physical burden on patients must be selected.

Through proprietary formulation technology, NeuroDerm achieved a world first with the successful liquefaction of levodopa and carbidopa, which are oral treatment agents. ND0612 is a treatment agent that can be administered through subcutaneous injection in a sustained manner for 24 hours through the combination of liquified levodopa and carbidopa with a mobile pump. There are high expectations for ND0612 as a new drug that addresses unmet medical needs for Parkinson's by making it possible to stabilize the blood concentration of levodopa in patients with moderate to severe symptoms.

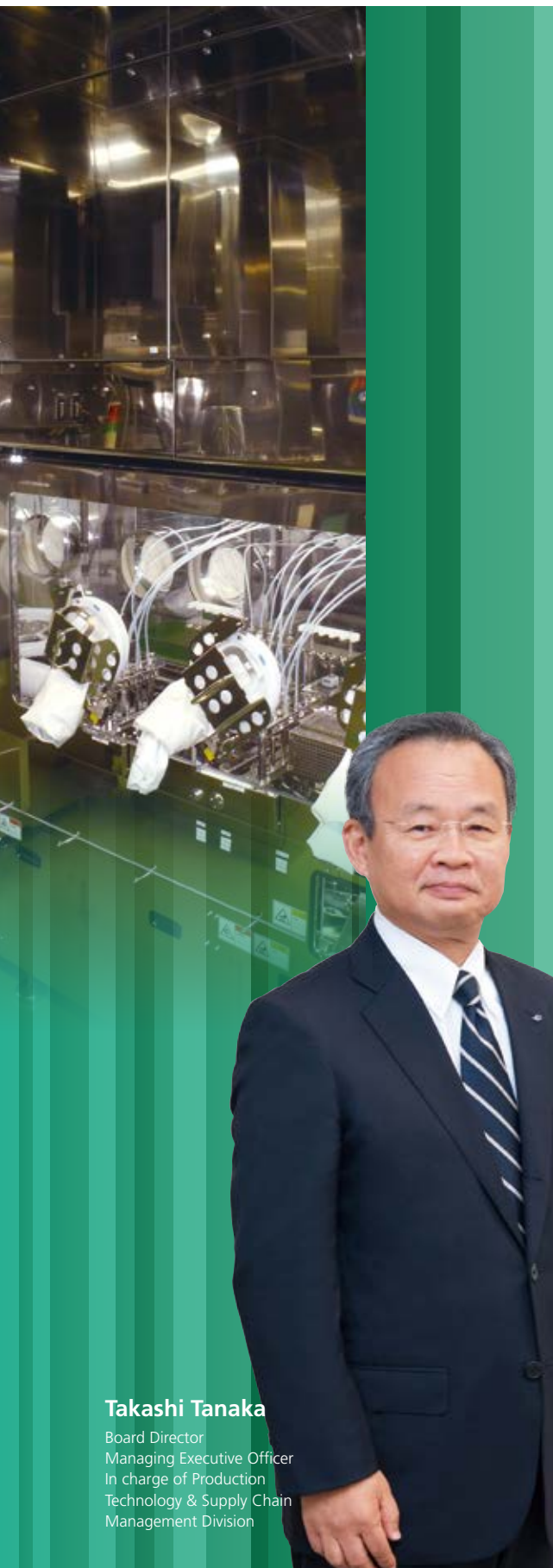
### MESSAGE

The acquisition of NeuroDerm by Mitsubishi Tanabe Pharma marks an important milestone in NeuroDerm's long road to develop a new pharmaceutical product, a road that involves hard work, dedication, ingenuity, creativity, and above all, integrity and commitment to do good in this world. But we are not there yet, we have a lot more to do. And now we will do it as part of a large, global group that shares our values.

Mitsubishi Tanabe Pharma has shown incredible vision and courage when deciding to add NeuroDerm to the Group. We will do our best to prove that we can make a big change in the lives of Parkinson's patients; that we can generate new combination "Designed Pharmaceuticals" drug-device combination products, more rapid and less risky to develop, that have great impact on the lives of patients; and that we can change the world for the better. Wishing all of us the best of success in our mutual journey!



Oded S. Lieberman  
CEO  
NeuroDerm



**Takashi Tanaka**

Board Director  
Managing Executive Officer  
In charge of Production  
Technology & Supply Chain  
Management Division

# Supply Chain

## Establishment of the Production Technology & Supply Chain Management Division

In April 2018, the Company consolidated the CMC Division (CMC: see the “Explanation of Terms” section) and the *monozukuri* functions of the Production Division to establish the new Production Technology & Supply Chain Management Division. The new division’s role will be to advance the entire range of *monozukuri* activities more smoothly and flexibly, from the investigational drug products used in the initial stages of clinical trials to post-marketing product manufacturing and supply.

There are two major reasons for the establishment of the Production Technology & Supply Chain Management Division. The first is steady progress for development projects. We will contribute to maximizing pipeline value by shortening the development period and implementing other initiatives. The second is the establishment of production technology and supply chain management that is able to adjust to changes in the business environment. To that end, we will advance a range of measures, such as global supply chain management and CMC organization maintenance, optimization of manufacturing bases, reduction in cost of goods sold, and reinforcement of *monozukuri*.

## Steady Progress for Development Projects

The domestic market environment is challenging, and in this setting we will need to launch products as rapidly as possible in the U.S., Europe, and other overseas markets. This is an important issue for the entire Company. In addition, R&D targets have expanded to include a wider range of modalities<sup>1</sup>, from small-molecule drugs to biologics, cell therapy drugs, nucleic acid drugs, etc. In comparison with small-molecule pharmaceuticals, it is more difficult to develop these types of products to the point where they are suitable for commercial production, and the ability to quickly set a target for commercial production is significantly connected to development speed. Accordingly, the role of *monozukuri* is increasingly important in drug development. Previously, the CMC Division was positioned upstream (R&D) in the drug development value chain and the Production Division was positioned downstream (production and supply). However, in consideration of these business environment changes, we decided that we would need to implement structural reforms to our *monozukuri* organization, with a view extending from upstream to downstream. Accordingly, we established the Production Technology & Supply Chain Management Division. Furthermore, the CMC Division had strengths in active pharmaceutical ingredients and pharmaceutical technologies, while the Production Division had strengths in commercial production technologies. The Production Technology & Supply Chain Management Division

This section explains our initiatives regarding the entire range of *monozukuri* (manufacturing with production technology and supply chain management) activities, from the investigational drug products used in the initial stages of clinical trials to post-marketing product manufacturing and supply.

combines the knowledge and know-how of the employees from these two divisions. Moving forward, we will strive to leverage these strengths not only to achieve shorter development times but also to realize the development of products with higher value for patients.

1. In drug development, treatment methods are classified by molecule, such as small molecule compounds; protein drugs, including peptide (middle molecule) drugs and therapeutic antibodies; nucleic acid drugs; cell therapy drugs; and regenerative medicine.

### Supply Chain Management and CMC Organization Maintenance that Is Able to Adjust to Changes in the Business Environment

In August 2017, we launched Radicava in the U.S. We are also advancing initiatives for this product in Europe and other markets. In addition, new drug development is shifting to an overseas focus, centered on the U.S. In this setting, we believe that we will need to devote resources to the maintenance of a global supply chain management and CMC organization. However, it will be difficult for us to do everything in-house, and accordingly we will strengthen collaboration with external subcontractors.

With modalities expanding, it will be increasingly important to select external subcontractors that are suitable for such factors as product characteristics. We are continually working to gather information, and when necessary we visit local regions to select the external subcontractor. In addition, production processes are becoming more complex, and it is not a simple matter to transfer production technologies to external subcontractors. Previously, we addressed this issue through collaboration between the CMC Division and the Production Division. However, going forward we will aim to realize smoother technology transfers by consolidating our response through the Production Technology & Supply Chain Management Division.

In addition, reduction in the cost of goods sold is also an urgent issue. To reduce fixed costs, such as facilities and labor costs, in 2007 we optimized manufacturing bases from the system that we had utilized since the merger. Mitsubishi Tanabe Pharma Factory, a domestic production subsidiary, had five manufacturing bases, which have been consolidated into two bases, the Onoda Plant and the Yoshitomi Plant. On the other hand, to reduce variable costs, such as for raw materials, we are taking steps to strengthen our production technologies, such as developing technology for low-cost production of intermediates for active pharmaceutical ingredients. In addition, we are working to reduce procurement and distribution costs. Furthermore, we have consolidated *monozukuri* functions into the Production Technology & Supply Chain Management Division. As a result, in addition to these types of post-marketing initiatives, I believe that we will be able to conduct highly cost competitive product development from the initial stages of clinical trials.

### Outlook for Fiscal 2018 and Thereafter

In fiscal 2018, we will advance initiatives targeting the rapid start-up of a *monozukuri* system suitable for the launch of Radicava in countries and regions outside the U.S. and for the launch drug candidates in late-stage clinical trials, such as ND0612 and MT-2271. Moreover, for MT-8554, MT-7117, MT-2990, and other drug candidates that are in early stage clinical trials, we will promote steady yet rapid development, and will take on the challenge of developing future technologies, such as continuous manufacturing technologies<sup>2</sup>.

As a unit created through the consolidation of two divisions, the Production Technology & Supply Chain Management Division must leverage its unique capabilities to take on a variety of challenges while continuing to move forward with the initiatives that were being implemented by its two predecessors, such as the Production Division's measures targeting stable supply and quality.

I believe that the key to making the whole greater than the sum of the parts is to develop supply chain managers who are globally active and well versed in technology. In other words, it is the nurturing of human resources who have multifaceted capabilities that cover all *monozukuri* activities. To that end, we will need to promote communication among employees that clears away walls between divisions. Moreover, by ensuring that they gain experience in various departments, we will develop a large number of employees with careers extending across a wide range of areas in *monozukuri*. Human resources development is not something that is completed in a short period of time. We need to take the time that is required and work persistently. I believe that this is essential in order for the Production Technology & Supply Chain Management Division to demonstrate its true value. I will lead the promotion of initiatives to move beyond unit boundaries and take the next step in *monozukuri*. As a dedicated supply chain unit, we will strive to give concrete shape to a variety of measures addressing the global market.

2. Technology under which raw materials and reactants are continuously introduced, reactions occur continuously, and products are manufactured successively.

**WEB** For further information about initiatives to support value creation in the supply chain, please use the following URL.

#### CSR Website



#### | Consumer Issues → Manufacturing and Supply Chain

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer\\_issues/manufacturing.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/consumer_issues/manufacturing.html)



**Eizo Tabaru**  
Board Director  
Managing Executive Officer  
In charge of Finance & Accounting Department

## Pharmaceutical Market Trends

Looking at growth rate estimates for pharmaceutical markets around the world, the markets in the U.S., Europe, China, and ASEAN are expected to record annual growth in the range of 3% to 8% over the period from 2017 to 2022. In other words, continued growth is anticipated in global markets.

On the other hand, the level of growth in our home market of Japan is approaching zero. One major reason is that the Japanese government is taking steps to control the increases in social security expenses resulting from expansion in the population of senior citizens. To that end, the government is rapidly reducing NHI drug prices, which are the official prices of ethical drugs, and promoting the use of generic drugs, etc. We do not expect this trend to change in the short term.

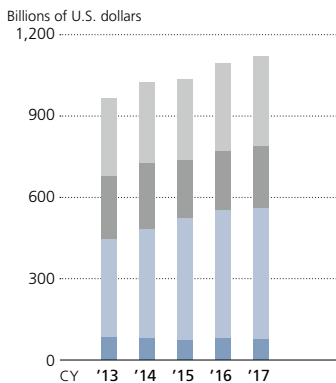
In general, NHI drug prices are revised once every two years, and the effect of those revisions differs in accordance with each company's product portfolio. An NHI drug price revision was implemented in April 2018, and we estimate the effect on our fiscal 2018 revenue will be approximately ¥21.0 billion. In particular, the Company will be significantly affected by the new G1/G2 rules. These rules are for long-listed drugs for which 10 years have passed since the launch of generic drugs. G1 products are defined as long-listed drugs for which the generic drug substitution rate is 80% or more, while G2 products are long-listed drugs for which the generic drug substitution rate\* is less than 80%. Drug prices are to be lowered in stages, with G1 drug prices reduced to the level of the generic drug prices after 6 years and G2 drug prices reduced to approximately 1.5 times the generic drug prices after 10 years.

In addition, the government is considering the implementation of an NHI drug price revision accompanying an increase in the consumption tax rate in 2019. We believe that we need to consider our future business operations based on the assumption that the government will carry out increasingly severe NHI drug price revisions on an annual basis.

\* Substitution rate = Number of generic drugs / (Number of original drugs for which there are generic competitors + Number of generic drugs)

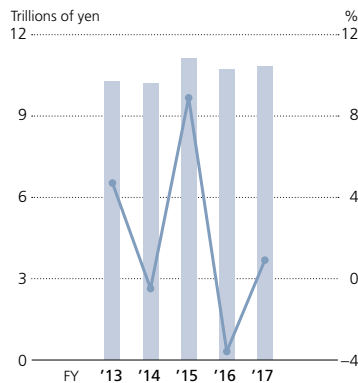
## Market Data

### Worldwide Pharmaceutical Market (including OTC products)



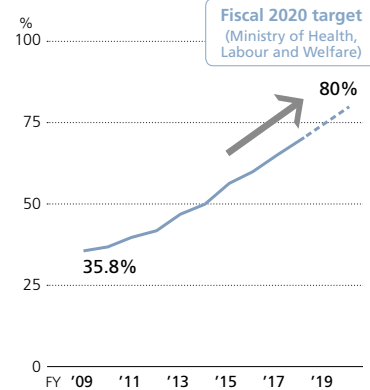
Legend: Japan (dark blue), North America (light blue), Europe (grey), Others (white).  
Note: OTC drugs are included.  
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Source: IQVIA (World Review Analyst 2018), January 2013–December 2017, Reprinted with permission

### Domestic Ethical Drugs Market (including OTC products)



Legend: Amount of sales (grey bars), Growth rate (blue line).  
Note: OTC drugs are included.  
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Source: IQVIA (Pharmaceutical Market), April 2013–March 2018, Reprinted with permission

### Market Share of Generic Drugs (Volume basis)



Source: Ministry of Health, Labour and Welfare

## Advancing Operational Productivity Reforms

“Reforming operational productivity” is one of the four strategic priorities in Medium-Term Management Plan 16–20. For fiscal 2020, the final year of the plan, we have established a numerical objective calling for reducing cost of sales by ¥8.0 billion and SG&A expenses by ¥12.0 billion, for a total of ¥20.0 billion in cost reductions in comparison with fiscal 2015.

In working to reform our operational productivity, we have focused on securing the resources for SG&A expenses and R&D expenses, which are increasing due to the acceleration of U.S. business development and the increase in late-stage drug candidates. However, as described above, the domestic market environment is becoming increasingly challenging at a pace exceeding expectations. Furthermore, our business environment is worsening to a greater extent than we envisioned when we formulated the current medium-term management plan. For example, Invokana royalty revenues are slowing down. Accordingly, we face an urgent issue, and need to do more than simply achieve the initial objectives.

In this setting, in fiscal 2017 we were able to achieve cost reductions of ¥14.0 billion, versus our target of ¥10.0 billion. In addition, for fiscal 2018 we have set an objective of ¥19.0 billion, and are on track to accelerate the achievement of that numerical objective. This is the result of the success of the measures that we have implemented. However, we will not be satisfied with these results. Rather, we will step up our efforts.

## Reforming Employee Awareness

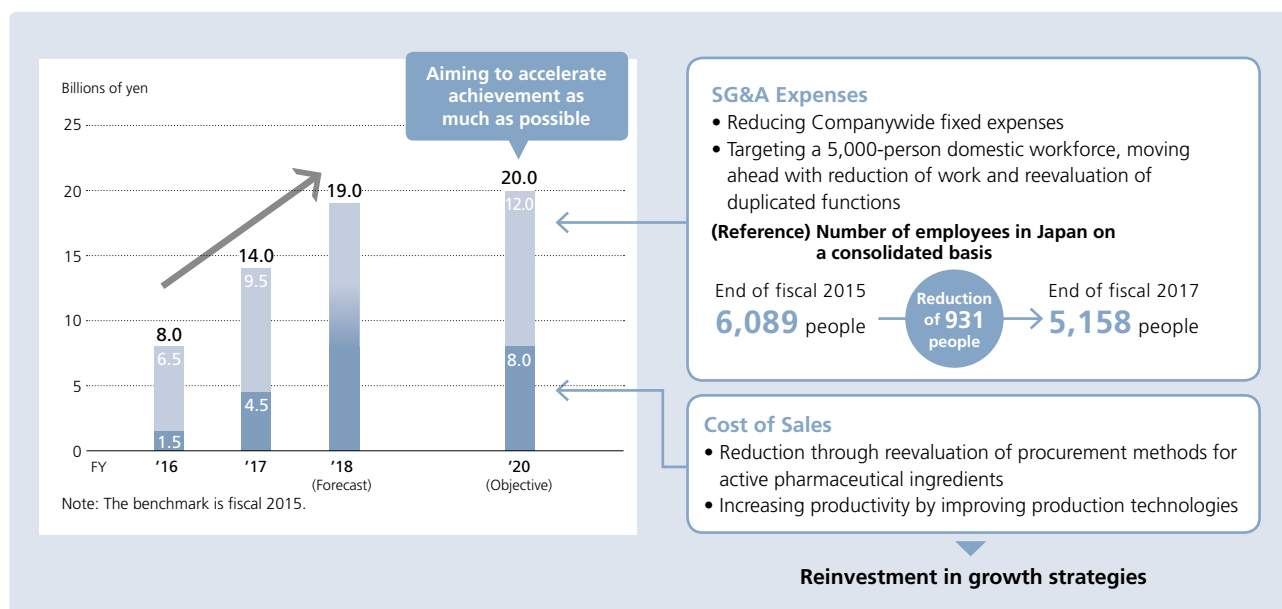
To overcome this challenging business environment and record growth in fiscal 2021 and thereafter, I believe that we need to foster a change in the ideas and awareness of each employee in regard to

the manner in which we move our work forward. Previously, work was generally handled at the department level and then passed on to the next department. With that style of working, however, it will be difficult to survive in business environments where the speed of change has increased, including not only Japan but also the U.S. and Europe. To survive we must evolve. In this type of environment, we need to shift to a system under which all employees and organizational units advance their work in a way that is suitable for the business environment. We have to transition to a system that enables us to address increasing speed and intensifying competition.

There are always competitors in the market. Unless we advance our work at the same speed as our competitors, or even faster, we will not be able to compete successfully. We must continually ask ourselves to what extent we will complete our work and when we will finish it. I would like to see the Company achieve true reforms in operational productivity by leveraging the experience of employees and organizations in order to rapidly achieve objectives and resolve issues.

Moreover, when our attitudes change, our actions and statements will change. I also believe that it will be extremely important to foster a change in attitudes so that the objectives and issues of individual employees are approached from a Companywide viewpoint. We need to visualize issues from a Companywide perspective and strive to foster collaboration inside and outside the Group. In this way, we can implement measures that fully leverage the Company's potential and always act with consideration for speed. We need to “transcend limits” and “fully achieve our goals to the end” I believe that these types of changes among individual employees will lead to changes in Mitsubishi Tanabe Pharma and will become the driving force that enables the Company to overcome the current challenging business environment and record sustained growth in the years ahead.

## Advancing Operational Productivity Reforms



## Fundamental Approach to Human Resources

Mitsubishi Tanabe Pharma is working to further enhance its competitiveness and achieve sustained growth by giving individual employees the opportunity to demonstrate their full potential. To that end, we focus on our people as a management resource, and we operate the Comprehensive Management System for Human Resources. Furthermore, we are aiming to develop human resources who act in accordance with the guidelines of pride and sense of mission, challenge and innovation, trust and collaboration, and harmonious coexistence with society. In addition, under Medium-Term Management Plan 16–20 we are aiming to implement reforms to become a “pharmaceutical company that works with a sense of speed and is the first to deliver original value,” and on that basis we are working to “realize a corporate culture with a sense of speed and a profitable business structure.”

We are implementing a range of human resources development initiatives that address the ongoing globalization of our business. To that end, we are implementing not only on-the-job training but also various off-the-job measures to help employees learn about foreign cultures and develop business English skills. These measures include a variety of group training and language study programs. In fiscal 2017, we began to recruit volunteers for overseas training and to assign them to work at overseas bases.

## Enhancing Personnel Training

To strengthen our corporate vitality and competitiveness, we must work to enhance the capabilities of our human resources, who are the source of that vitality and competitiveness. Aiming to develop people with key attributes, we support the development and demonstration of the capabilities of employees through the smooth coordination of four frameworks: employing diverse human resources, on-the-job and off-the-job training through management by objectives (MBO), transfers and rotations, and fair evaluations. To that end, we are enhancing individual capabilities through daily on-the-job and in-house training programs and through the assignment of the right person to the right place. The Company is also working to provide support for autonomous employee career management and individual skill development and to develop next-generation leaders and global human resources who will be future managers. In fiscal 2017, we started career consultations with the objective of enhancing career management support, and revised our training systems and self-education support programs in order to further expand our viewpoints and establish independent study habits. We entered the second year of MT-VIVID, a management rapid development program for the development of the next-generation of leaders, and will continue working to strategically develop managers. In addition, to develop global human resources, which is an increasingly urgent task, we commenced OJTO, a training program that particularly emphasizes on-the-job training initiatives overseas.

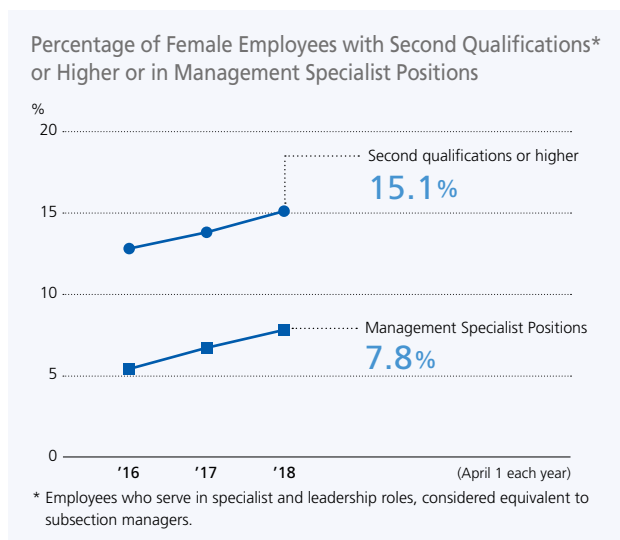
## Actively Utilizing Diverse Human Resources

The Group has positioned its approach to diversity and inclusion as one of its management strategies. With the objective of leveraging diverse human resources and maximizing results, the Company is conducting human resources development to draw on the skills of diverse employees, establishing systems and frameworks that make it easy for diverse employees to do their jobs, and providing opportunities for a diverse range of people. Managers will implement diversity management to leverage diverse employees and maximize results, which will lead to the generation of synergies by each employee.

In regard to diversity, we take into account both visible diversity (gender, gender identity (including LGBT), age, career background, nationality, disability status, time restrictions due to childcare, nursing care, etc.) and non-visible diversity (knowledge, skills, experience, values, ways of thinking, etc.). Moving forward, we will enjoy these differences and strive to realize a corporate culture that can draw on differences as strengths.

In fiscal 2017, we conducted training for all managers on the implementation of diversity management. In addition, we took steps to enhance understanding of LGBT issues through lectures by LGBT people, and distributed ally stickers, which show understanding of and support for LGBT people. Furthermore, we offered nursing care seminars to deepen understanding of nursing care for those with an interest in this issue.

In regard to the enhancement of career opportunities for women, we continued to implement www28 training (www: abbreviation for Win-Win-Woman), which considers the careers of women who have not yet experienced such life events as marriage and childbirth. In addition, we provided free e-learning and online English conversation classes for employees on childcare leave in order to enable them to quickly enjoy active careers after they return to work. We also introduced external study sessions for employees on childcare leave, and started childcare support through babysitters as a measure to support both work and childcare. Moreover, we established consultation hotlines for childcare, nursing care, and LGBT issues.



## Initiatives to Raise Human Rights Awareness

The Mitsubishi Chemical Holdings (MCHC) Group signed the United Nations Global Compact (UNGC) in May 2006. As a member of the MCHC Group, the Mitsubishi Tanabe Pharma Group also respects the 10 principles of the UNGC, which address human rights, labor, the environment, and anticorruption, and upholds these principles in its business activities in line with its Corporate Behavior Charter. The Company's Human Rights Awareness Promotion Committee, chaired by the president, plays a key role in advancing human rights education as one facet of the promotion of diversity. These measures include internal training for officers and employees. In addition, we are implementing Companywide human rights education initiatives, including collaboration with outside experts and participation in outside lectures.

## Securing Occupational Health and Safety

Aiming to promote environmentally friendly activities and to realize workplaces where employees can work in a healthy, enthusiastic, safety, and comfortable manner, the Group is strengthening its initiatives in the areas of Environment, Health, and Safety (EHS).

Securing the safety of employees in business activities is our highest priority, and to that end we are implementing a range of initiatives. In particular, in regard to the prevention of disasters, we are maintaining and strengthening our environmental management capabilities. In addition, it is important to enhance the risk sensitivity of all employees in regard to safety in their work, and accordingly we are implementing a wide range of safety training. To eliminate workplace disasters, we will continue to implement highly effective training and activities to reduce risks related to facilities and operations. We will work to realize *KAITEKI*, which is being advanced by the entire Mitsubishi Chemical Holdings Group.

**WEB** For further information about *KAITEKI*, please see the MCHC website.  
[http://www.mitsubishichem-hd.co.jp/english/kaiteki\\_management/kaiteki/](http://www.mitsubishichem-hd.co.jp/english/kaiteki_management/kaiteki/)

## Employee Health Management

The Group considers health management to be an important issue for corporate management. In April 2016, to effectively and appropriately advance activities related to employee health, we formulated the MTPC Group Health Policy in accordance with our Philosophy, Vision, and Corporate Behavior Charter. We are striving to promote awareness of work-life balance, improve mental and physical health, and implement varied working styles.

The Group will further strengthen activities related to the promotion of employee health, including its approach to working-style reforms. From fiscal 2017, we have highlighted the issues of promoting working-style reforms, strengthening our mental health measures, bolstering measures to prevent lifestyle-related diseases,

and cultivating health awareness among employees, and are already implementing initiatives to address these areas.

## Implementation of Employee Survey

Since fiscal 2011, the Mitsubishi Tanabe Pharma Group has implemented employee surveys to provide a comprehensive understanding of employee attitudes toward their jobs and of the Company's workplace environments in order to improve management initiatives. In fiscal 2017, many items recorded year-on-year gains, and in particular improvement was recorded in the item regarding how the Company values its employees. The overall indicator for management philosophy, management policies, and corporate culture reached a record-high level. On the other hand, a number of issues were identified. In consideration of these issues, we will strive to establish a work environment that facilitates dynamic managers and to implement career formation measures for professionals. In addition, we will take steps to establish workplaces in which diverse employees are able to work in a healthy, energetic, and active manner.

**WEB** For further information about initiatives to activate human resources, please use the following URL.

### CSR Website



### | Labor Practices → Human Resources Development

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/labor\\_practices/index.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/labor_practices/index.html)

### | Human Rights → Initiatives for Employees

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/human\\_rights/index.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/human_rights/index.html)



## Advancing Health Management Measures

To increase labor productivity, Japanese companies are implementing working-style reforms, which are the focus of increasing attention. In this environment, there is growing activity in the area of promoting active careers for human resources through “employee health management.” In this section, the Company’s initiatives in this area are introduced by Kazumi Kuroda and Michiko Shigematsu from the Human Resources Department’s Health Promotion Group, which is in charge of health management measures for Mitsubishi Tanabe Pharma.



### Health Promotion Group, Human Resources Department

#### Kazumi Kuroda

Ms. Kuroda is certified as an occupational health nurse, and worked in occupational health after joining the Company. Since 2010, she has worked in the Human Resources Department to advance overall health management operations.

#### Michiko Shigematsu

Ms. Shigematsu has experience working as a hospital nurse and as a local government public health nurse. From 2010, she worked in health affairs for the Company health insurance association, and in 2017 she joined the Human Resources Department’s Health Promotion Group.

#### — Please describe the specific initiatives of the Health Promotion Group.

**Kuroda** The operating environment for domestic pharmaceutical companies is increasingly challenging. In this setting, a significant role is played by human resources support initiatives, such as promoting active careers for diverse human resources and implementing working-style reforms. Health is indispensable for the achievement of maximum performance with limited human resources. Taking steps to ensure that employees are able to work in a healthy and energetic manner has a number of benefits. It increases their individual quality of life by enhancing their work lives, and it also bolsters the Company’s overall productivity and competitiveness. For the Company to achieve sustained growth, our role in implementing health management measures will be increasingly important.

The Human Resources Department’s Health Promotion Group was established in fiscal 2017 as a unit specialized in health management, centered on health care professionals. Over the short period since its establishment, the group has already rolled out a number of new measures. For example, we have introduced the *i*<sup>2</sup> Healthcare (*i*<sup>2</sup> HC) program and a three-year smoking cessation program. We also started a blood pressure management program

by risk level. In addition, we introduced an external Employee Assistance Program\* (EAP) to strengthen our mental health measures, and prepared a health white paper with the objectives of verifying the effectiveness of measures and understanding health issues.

\* Program to support stress countermeasures and issue resolution initiatives for individual employee stress and to increase workplace productivity.

**Shigematsu** I will explain in more detail about *i*<sup>2</sup> HC, which is an original platform developed by the MCHC Group with the objective of supporting employee and workplace health. When employees access a dedicated website, they can confirm a wide range of information on their personal page. In addition to employee health examination data and working-style data, this also includes data obtained from wristwatch-style wearable devices, such as numbers of steps, activity levels, and sleep data. In addition, with the information accumulated on this platform, we can understand health management issues that were previously difficult to monitor, facilitating a health management PDCA cycle, such as for the formulation of measures and the confirmation of results.

**Kuroda** Within the MCHC Group, the Company took the lead in implementing *i*<sup>2</sup> HC initiatives, which have gotten off to a good start. The Company lends wearable devices to employees after



obtaining their consent in regard to the provision of the acquired data to i<sup>2</sup> HC. As of the end of 2017, 75% of employees had already given their consent. The major reason is that managers have actively taken the lead and given their consent. Also, as one of the events to commemorate the 10th anniversary of the Company, we worked together with the health insurance association to hold a charity walk using wearable devices. There were about 1,000 participants. Wearable devices were used to measure the number of steps taken by the employees, and the Company and the health insurance association jointly donated funds to ALS patient organizations, etc., with the amount of the donations based on the number of steps. I think that this was a successful example of initiatives to motivate employees to use i<sup>2</sup> HC.

— **The Company was selected for two consecutive years under the Health & Productivity Management Outstanding Organizations (White 500) program, which is promoted by the Ministry of Economy, Trade and Industry. In what areas was the Company highly evaluated?**

**Shigematsu** This system recognizes companies, medical corporations, and others that have done a particularly good job at health management. In fiscal 2018, 541 companies, including Mitsubishi Tanabe Pharma, were recognized in the large enterprise category (White 500). A number of evaluation items have been established in accordance with a framework that includes management philosophy (awareness of leaders), organizational structure, systems / policy implementation, evaluation / improvement, and observance of laws and regulations / risk management. In evaluation / improvement, the Company received the highest evaluation in the industry for the item regarding understanding indicators for work hours / leave, etc.

**Kuroda** This recognition system looks at initiatives to build a platform for health management, and short-term initiatives alone are not highly evaluated. In 2013, Mitsubishi Tanabe Pharma commenced full-scale efforts to build a health management administration system, with a focus on the alignment of labor management and health management. In addition, in the same year we introduced a health management system with integrated control extending from health management to labor management. In 2016, with the objective of advancing activities related to employee health in an effective and appropriate manner, we formulated the MTPC Group Health Policy and the Health Management Rules, which give concrete shape to the policy. In these ways, we steadily advanced the establishment of a platform for the implementation of health management.

**Shigematsu** In addition, as feedback following this recognition, we received a comment that there was still room for improvement in regard to the prevention of lifestyle diseases, etc. In particular, in regard to the high smoking rate, we recognize smoking as a challenge. In fiscal 2017, we set specific numerical targets and

launched a three-year smoking cessation program, and are advancing a variety of initiatives to achieve those targets. For example, in the first year we made every Friday a no-smoking day, with the smoking rooms in our offices closed all day. Next, in the second year smoking was prohibited during working hours, and the smoking rooms were closed outside of break time. In these ways, we are advancing in stages. In the final year, fiscal 2019, we will aim to completely prohibit smoking in buildings.

In implementing this program, at the end of the first year we asked employees to fill out a questionnaire. As a result, we understood that, overall, 86% of employees approved of the program, including smokers. In addition, it is clear that more than 60% of smokers want to quit at some point. I believe that the extent to which we can encourage these employees to quit smoking will serve as a demonstration of our abilities.

— **Finally, what would the Health Promotion Group like to see people focusing on going forward?**

**Shigematsu** The Health Promotion Group cannot implement all of the health management measures by itself. Moving forward, we will actively step up cooperative initiatives both inside and outside the Company. This collaboration will include not only related departments inside the Company but also the health insurance association and subcontractors, as well as joint research with external research institutions. Moreover, the Company has not appointed a chief industrial physician, and the current system handles health management for more than 5,000 employees with nine nurses, including the two of us. In this setting, in order to advance health management measures for employees who are temporarily reassigned and those who are posted overseas, as well as for the families who support the employees, we will need to take on the challenge of new initiatives that extend beyond current frameworks. To that end, we will implement various initiatives, such as establishing systems that utilize ICT to provide health support even in distant locations. The entire nine-person nursing staff will work together to contribute ideas and strive to realize them.

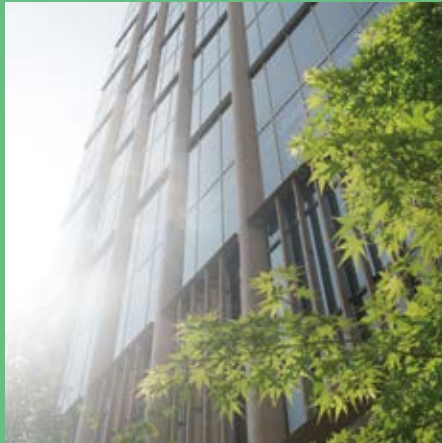
**Kuroda** Fiscal 2018 will be the second year since the establishment of the Health Promotion Group, and it will be a year for seeing the results of initiatives implemented to date. However, health management is something that will always continue, and accordingly not all initiatives will generate results in the short term. To help employees to enjoy healthy, more fulfilling lifestyles after they retire, I believe that the mission of the Health Promotion Group is to encourage them to deepen their understanding of health and to develop healthy habits. To that end, we will work to leverage a health management PDCA cycle as we pursue results one by one. In this way, we will strive to further enhance a range of health management measures as we move forward.

## ESG Section

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This section includes ESG-related information as initiatives to support value creation.

- 49 Corporate Governance and Internal Control
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- 62 Social and Environmental Activities



Corporate Governance (As of June 22, 2018)

Fundamental Approach

The Mitsubishi Tanabe Pharma corporate philosophy is to “contribute to the healthier lives of people around the world through the creation of pharmaceuticals,” and our vision is “to be a global research-driven pharmaceutical company that is trusted by society.” To realize this philosophy and vision, the Mitsubishi Tanabe Pharma Group places the highest priority on fulfilling its responsibilities to all of its stakeholders, including shareholders, and working to achieve the sustainable growth of the Group and increases in its corporate value over the medium- to long-term. To that end, the Group works to ensure the transparency and objectivity of management by ensuring efficiency and promptness in management decision-making, enhancing monitoring and supervision through

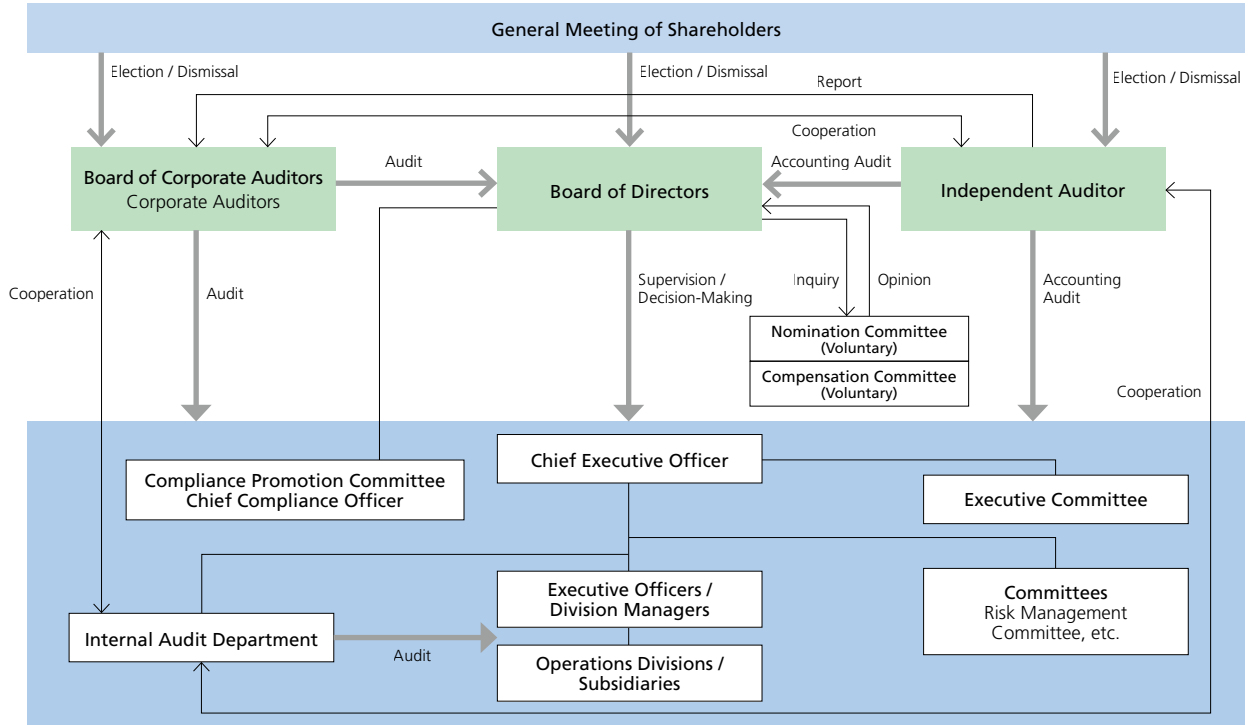
the outside directors, and enhancing the auditing system through the corporate auditors.

In accordance with this approach, the Group has formulated the Corporate Governance Policy of Mitsubishi Tanabe Pharma, and based on this policy the Group will continue working to realize an optimal corporate governance system.

In addition, although the Company is a consolidated subsidiary of Mitsubishi Chemical Holdings, the Company will continue its listing status and maintain independence in its management.

➤ The following URL provides further information about the corporate governance policy.  
[https://www.mt-pharma.co.jp/e/company/pdf/cg\\_policy\\_e.pdf](https://www.mt-pharma.co.jp/e/company/pdf/cg_policy_e.pdf)

Corporate Governance System (As of June 22, 2018)



■ Corporate Governance System

The Company has adopted the Company with Corporate Auditors system. In addition to the General Meeting of Shareholders and the Directors, the Company has established the Board of Directors, Corporate Auditors, and the Board of Corporate Auditors, and employs an independent auditor. In addition, as advisory bodies to the Board of Directors, the Company has established voluntary committees related to officer nomination and compensation.

Organizational form	Company with Corporate Auditors
Maximum number of directors stipulated in Articles of Incorporation	10
Term of office stipulated in Articles of Incorporation	1 year
Chairperson of the Board	President
Number of directors	10
Appointment of outside directors	3

■ Overview

To secure transparency and objectivity in management decision-making and supervision, the Board of Directors has 10 members (10 men, 0 women), including three outside directors. Regular meetings of the Board of Directors are held once a month, and additional meetings are held as needed. Decisions on important matters related to business execution are made in a flexible manner. In addition, the Company has adopted the executive officer system, thereby clarifying the division of roles between the decision-making / supervision function and the business execution function. In this way, management is conducted in a prompt and efficient manner. In regard to the business execution function, the Executive Committee, which includes the President and CEO and other managing executive officers, meets two or more times per month as a general rule. The committee discusses in advance the agenda of the meetings of the Board of Directors and deliberates on matters in order to assist in the decision-making of the President and CEO.

The Company implements an analysis and evaluation of the effectiveness of the Board of Directors once per year. In accordance with the results, in fiscal 2017, with consideration for the functions and roles of the Board of Directors and the Executive Committee, we revised decision-making and reporting standards. In this way, we worked to speed up management by delegating authority to the Executive Committee to the greatest extent possible. In addition, we took steps to increase the effectiveness of the Board of Directors, such as holding director seminars regarding the duties of directors in Group management, implementing information exchange between the President and Outside Directors, and, as needed, holding meetings of the Outside Directors Council to deepen shared understanding.

The Board of Corporate Auditors has four members (4 men, 0 women; of whom, 2 are outside corporate auditors). The Board of Corporate Auditors, as an entity independent from the Board of Directors, makes appropriate decisions from an objective standpoint in fulfilling its roles and responsibilities, which include the auditing

of business execution of directors, accounting audits, and exercising its authority with respect to the selection and dismissal of independent auditors and audit compensation.

Furthermore, in an effort to strengthen the independence, objectivity, and accountability of the functions of the Board of Directors with respect to the nomination and compensation of its executives, the Company has established and operates voluntary committees that are chaired by an independent outside director and have independent outside officers (directors and corporate auditors) as a majority of the members. In line with inquiries from the Board of Directors, the Nomination Committee and the Compensation Committee hold transparent, objective discussions. The Nomination Committee holds these discussions regarding the selection/nomination standards for candidates for director, corporate auditor, and executive officer as well as the selection/nomination of each candidate. The Compensation Committee holds these discussions regarding revision of the compensation system for directors and executive officers as well as decisions on plans for individual amounts of compensation. Reports are then made to the Board of Directors.

Pursuant to Article 427, Paragraph 1 of the Companies Act, the Company has entered into liability limitation contracts with outside directors and outside corporate auditors that limit their liability for damages under Article 423, Paragraph 1 of the Companies Act, within the limits stipulated by laws and regulations.

■ Reasons for Adoption of the Current Corporate Governance System

The Company is a pharmaceutical company in an industry that is regulated based on the health care system. As such, management decision-making requires deep knowledge and experience related to pharmaceutical regulatory and business affairs. In this setting, the Board of Directors includes not only directors with abundant operational experience and knowledge in the pharmaceutical industry but also independent outside directors with abundant experience and wide-ranging knowledge as managers. In this way, the Company has established a system that secures transparency and objectivity in management decision-making and supervision. In addition, the Board of Corporate Auditors includes not only corporate auditors with abundant operational experience and knowledge in the pharmaceutical industry but also independent outside corporate auditors with experience and expertise in such fields as finance, accounting, and law. In this way, the Company has established a system that facilitates appropriate auditing from an objective viewpoint by the Board of Corporate Auditors, as an institution independent from the Board of Directors.

Accordingly, Mitsubishi Tanabe Pharma believes that the Company with Corporate Auditors system is the most effective form of corporate governance for the Company at present.

■ Auditing System

Corporate Auditors attend important meetings, such as meetings of the Board of Directors and the Executive Committee. In addition, they conduct interviews on the execution of duties with Directors, Executive Officers, and members of each Company division, review

documents relating to major decisions, and investigate the operations and assets of principal worksites and subsidiaries (including internal control systems, such as those for compliance and risk management). In these ways, the Corporate Auditors audit the execution of Company business. Furthermore, we hold meetings of a Corporate Auditors liaison committee for subsidiaries in Japan and are working to strengthen information sharing and collaboration,

In regard to the relationship with the independent auditor, while monitoring the independence and appropriateness of audits, the Corporate Auditors receive explanations from the independent auditor of audit plans and policies as well as quarterly reports on audit implementation and results. The Corporate Auditors also regularly exchange opinions with the independent auditor. When necessary, the Corporate Auditors witness on-site work and review work by the independent auditor. At the end of each period, the Corporate Auditors receive explanations concerning measures to ensure the proper execution of the independent auditor's duties. Also, in regard to the audit plans of the internal auditing divisions and the progress and results of those plans, the Corporate Auditors exchange opinions with internal auditing divisions on a regular monthly basis. At the same time, the Corporate Auditors receive reports on the results of the evaluation of internal control systems for financial reporting.

In addition, the Company is working to build an auditing system that is highly independent and specialized, and a lawyer, who is a legal specialist, and a certified public accountant, who is an expert in finance and accounting, have been nominated to be Outside Corporate Auditors.

Furthermore, to provide support for the Corporate Auditors in the execution of their duties, the Company has established the Corporate Auditors' Office, which is independent from business execution. The Corporate Auditors' Office has three full-time staff.

For internal auditing, the Company has established the Internal Audit Office, which is independent from the executive divisions and audits the internal control systems in operations divisions. The Internal Audit Office has 12 employees as of June 2018.

The Company has appointed Ernst & Young ShinNihon LLC as its independent auditor. There are three certified public accountants

who are in charge of the account auditing activities. Assisting in the account auditing activities are 18 certified public accountants and 16 other people.

### ■ Nomination of Outside Officers

In selecting directors and corporate auditors, the fundamental requirements are superior character, knowledge, and ability; abundant experience; and high ethical standards as well as the ability to work proactively to help the Group achieve sustained growth and increases in corporate value over the medium to long term.

In regard to outside directors, in addition to the above requirements, to secure greater transparency and objectivity in management and to strengthen the Board of Directors' oversight function, the Company has three outside directors who are well versed in corporate management. In selecting these outside directors, the Company selects people who meet the Company's Criteria for Independence of Outside Board Directors and Outside Corporate Auditors and who can secure the time needed to fulfill the functions and roles expected of outside directors. The specific reasons for the selection of each outside director are shown on pages 60 and 61.

In regard to outside corporate auditors, the Company selects two people who meet the Company's Criteria for Independence of Outside Board Directors and Outside Corporate Auditors and who have knowledge in such fields as finance, accounting, and law for the purpose of conducting audits of the legality and appropriateness of management from an independent viewpoint. The table below shows the specific reasons for the selection of each outside corporate auditor.

Moreover, in addition to the Company's Criteria for Independence of Outside Board Directors and Outside Corporate Auditors, these five outside officers also meet the requirements of the Tokyo Stock Exchange (TSE) for independent Directors / Corporate Auditors, and the Company has reported these five officers as independent Directors / Corporate Auditors to the TSE.

➤ In regard to the Company's Criteria for Independence of Outside Board Directors and Outside Corporate Auditors, please refer to the Mitsubishi Tanabe Pharma Corporate Governance Report.  
[https://www.mt-pharma.co.jp/e/company/pdf/gr\\_mtpc180625\\_e.pdf](https://www.mt-pharma.co.jp/e/company/pdf/gr_mtpc180625_e.pdf)

## Names of Outside Corporate Auditors, Relationships between Outside Officers and the Company, and Reason for Nomination

	Relationships between Outside Corporate Auditors and the Company	Reason for nomination
<b>Tadashi Fukuda</b> Outside Corporate Auditor	Tadashi Fukuda works as Executive Partner of Daiichi Law Office and as Outside Corporate Auditor of EXEDY. There are no special conflicts of interest between the Company and Tadashi Fukuda or these companies.	Tadashi Fukuda has abundant experience and highly sophisticated knowledge as an attorney. The Company believes that he will utilize this experience and knowledge in appropriately executing his duties as an Outside Corporate Auditor and be able to contribute to the sustainable growth of the Group and to the establishment of a corporate governance system, and thus has nominated him as an Outside Corporate Auditor.
<b>Hiroshi Enoki</b> Outside Corporate Auditor	There are no special interests between Hiroshi Enoki and the Company.	Hiroshi Enoki, as a certified public accountant, has abundant experience in accounting audit and professional service to companies that are going to be listed on a stock exchange. As a consultant in areas related to enhancing corporate governance to increase corporate value, he also has professional expertise and experience, including ESG. The Company believes that he will, as an Outside Corporate Auditor, be able to contribute to the sustainable growth of the Group and to the establishment of a corporate governance system, based on his experience and knowledge, and thus has nominated him as an Outside Corporate Auditor.

■ Compensation of Directors and Corporate Auditors

The Company's basic policy is to have an appropriate and balanced compensation plan for the Board Directors that can be tied to medium- and long-term performance and also improve corporate value. The Company reviews the level of compensation by taking into consideration objective data, such as compensation surveys conducted by outside professionals, and the balance with the level of salaries of the Company's employees.

The compensation plan for the Board Directors (excluding part-time directors) is comprised of "base compensation," "bonuses" that are tied to short-term performance, and "stock compensation" that is tied to medium- to long-term performance. This is a compensation plan with a high degree of linkage with the Company's performance and stock value. "Bonuses" will be paid in the range of 0% to 200% depending on position and on the evaluation of company performance and individual performance in the relevant fiscal year. "Stock compensation" will be paid in the range of 0% to 200% depending on the degree of achievement of revenue and net profit as performance indicators.

Policy concerning the compensation of Board Directors and the content of the compensation of individual Board Directors are determined by the Board of Directors through deliberation of the Compensation Committee, which is chaired by an Independent Outside Board Director and for which a majority of members are Independent Outside Board Directors.

In fiscal 2017, basic compensation for directors and corporate auditors was as shown in the table below. The Company and consolidated subsidiaries paid ¥91 million and ¥8 million, respectively, to Ernst & Young ShinNihon LLC as compensation for auditing and verification.

	Basic compensation	Number of people
Directors (excluding outside directors)	¥309 million	7
Corporate auditors (excluding outside corporate auditors)	¥74 million	3
Outside officers	¥55 million	5

■ Guidelines Related to Measures to Protect Minority Shareholders in the Event of Transactions, etc., with Controlling Shareholder

Mitsubishi Chemical Holdings (MCHC), which is Mitsubishi Tanabe Pharma's parent company, is a holding company. To leverage the human and tangible resources held by the MCHC Group, MCHC and the Company share know-how; jointly use assets and facilities, including IT systems, and Group networks; and exchange human resources, and the Company deposits funds with MCHC. However, there are no transactions that have the potential to significantly influence the results of the Company, and there are no plans to engage in such transactions in the future. In regard to transactions between the Company and MCHC or other companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Mitsubishi Tanabe Pharma Group in order to maximize the benefit to all of the Company's shareholders.

In regard to transactions between the Company and MCHC or other companies in the MCHC Group, the Company verifies the appropriateness and economic rationality of the transactions, such as whether the terms and conditions are equivalent to those of general transactions. Significant transactions are subject to sufficient deliberations and approval by the Board of Directors, which includes two or more independent outside directors, from the perspective of ensuring the common interests of the Mitsubishi Tanabe Pharma Group and shareholders.

■ Other Special Matters that May Have a Significant Impact on Corporate Governance

In regard to the independence of the Company from its parent company, MCHC, both companies have agreed that the Company will remain listed and that, in principle, for 10 years from October 1, 2007, MCHC would maintain its shareholding ratio in the Company. Both companies have also agreed that the Company will be operated based on the principle of independent decisions and judgment as a publicly listed company. The abovementioned time limit was reached at the end of September 2017, but at this point in time MCHC has no plans to increase or decrease the shareholding ratio. The Company believes that it has secured its independence from its parent company.

■ Disclosure of Information to Stakeholders

In order to promote understanding of the Company and to obtain fair evaluations of the Company, Mitsubishi Tanabe Pharma strives to disclose in a fair, timely, and appropriate manner important Company information related to its activities, such as its management policies, management objectives, and financial situation, to all of its stakeholders, including shareholders, investors, patients and health care workers, and local communities. We adhere to the Financial Instruments and Exchange Law and other Japanese laws and regulations relating to information disclosure and stock exchange regulations for listed securities. Also, based on our information disclosure regulations, and in accordance with the relevant internal systems, we are working to ensure that both the content and timing of our information disclosure are fair to all stakeholders.

We give a range of presentations to explain the Company's financial situation, describe the development of new products, and explain important management policies and business developments. These presentations include results briefings for institutional investors and business presentations. To enable individual and overseas investors to access presentations, the audio and video for presentations are distributed via the Company's website, and the content of Q&A sessions is also released. In addition, in fiscal 2017 we held seven presentations for individual investors. Furthermore, as an initiative related to corporate social responsibility, the Company has established a CSR website on the corporate website, where the Company's CSR activities are published and updated in a timely manner, and the CSR Activities Report for fiscal 2017 (PDF version) is also published.

## Discussion with an Outside Director

In June 2017, Tsutomu Kamijo, who became an Outside Director of Mitsubishi Tanabe Pharma in June 2017, and Takashi Kobayashi, who is Representative Director, Senior Managing Executive Officer, and Chief Compliance Officer of the Company, met to discuss measures to strengthen corporate governance as well as future governance-related issues. This section introduces their discussion.



### Tsutomu Kamijo

Outside Director  
Chairman and Representative Director,  
Sapporo Holdings

### Takashi Kobayashi

Representative Director,  
Senior Managing Executive  
Officer

**Kobayashi** It has been a year since you became an Outside Director of the Company. Over that period, we were able to achieve our longstanding goal of taking the first step in accelerating U.S. business development with the launch of Radicava in the U.S. In addition, the Board of Directors has engaged in multiple discussions of important matters, such as the investment of ¥124.0 billion for the acquisition of NeuroDerm, of Israel, in October 2017. The Company is highly appreciative of the valuable opinions that we received from you and the other Outside Directors.

**Kamijo** As a company executive, I have had to make decisions on important matters, and at those times I understood the value and significance of opinions from outside directors and outside corporate auditors, who can speak from different viewpoints. Based on this experience, as an outside director I am striving to directly communicate my opinion on important matters.

For example, in regard to M&A and other large investments, I am working to confirm the extent to which the Company is anticipating legal risks and if the investment offers value that is commensurate with the amount of the investment.

However, I think that the most important point is to focus on whether or not the project is aligned with the vision of Mitsubishi Tanabe Pharma.



**Kobayashi** That is an excellent point. For matters like the recent NeuroDerm investment, the Board of Directors conducts repeated discussions and offers answers to the various questions asked by the outside directors. Through this process, our vision is further clarified as we ask ourselves what kind of value we want to provide to society, in what markets and what fields.

**Kamijo** In particular, the business environment has been changing at a rapid pace in recent years, and there have been many cases in which companies have taken too long to make decisions on M&As and related projects and as a result opportunities were lost. Accordingly, it is important that the Company clarify its vision. If we do so, then as we determine the pros and cons of a particular project, we will naturally identify the highest priority items that need to be confirmed, and we should be able to make decisions in a rapid yet reasonable manner.

To that end, it is important to always hold discussions, exchange information, and ensure that we are all in agreement on the Company's objectives. In that sense, I think that the Company's Board meetings are dynamic and that the level of communication is excellent.

**Kobayashi** Thank you. We are working to foster good communications on a Companywide basis. Next, I would like to ask your opinion about current issues in regard to the Company's corporate governance.

It is important to always hold discussions, exchange information, and ensure that we are all in agreement on the Company's objectives.

**Kamijo** As the Company expands its focus from domestic business to overseas business, I think that one issue will be the establishment of a global governance system, including overseas subsidiaries. This is an issue that I have also encountered in my career. Looking at compliance, there are certain matters that do not involve any legal issues in Japan but do present legal conflicts overseas, and of course there are also matters that are the reverse. In addition, there are major differences among countries and regions in regard to what is considered to be conventional wisdom.

However, even if they are located in a different country or region, they are still members of the Mitsubishi Tanabe Pharma Group. It is essential that overseas Group employees also share a common understanding of what must be done to maintain good relationships with the Group's stakeholders. I believe it will be necessary to focus on building systems and frameworks to support that understanding.

**Kobayashi** Until a few years ago, the Company's ability to implement clinical trials in the U.S. was limited to following instructions from Japan. Now, however, our U.S. operations can take the lead in advancing clinical trials. Moreover, with the launch of Radicava we also have our own in-house sales capability in the U.S. In this setting, I fully realize the importance and necessity of the types of initiatives that you mentioned.

In 2017, in order to help Group employees around the world to realize the corporate philosophy and vision, we formulated the Code of Conduct as a guide to behavior based on the Corporate Behavior Charter and the Declaration of Compliance. In addition, as needed, we have begun to establish global policies aligned with business activities. If the actions of employees, including employees of overseas subsidiaries, depart from those policies, then we request that those actions be corrected. This process is repeated, and through this cycle we are working to promote the adoption of these policies.



**Kamijo** Some time will be necessary for the adoption of those policies. Based on my own experience, the most effective approach for obtaining the understanding of employees is to explain the risks associated with damage to the Mitsubishi Tanabe Pharma brand, as well as what types of actions could end up damaging the brand. I would definitely like to see this implemented.

**Kobayashi** The scope of employee actions that enhance the corporate brand should not be changed, even if there are differences among countries. Finally, I would like to hear your thoughts about further reinforcing corporate governance.

**Kamijo** Since the introduction of the Corporate Governance Code in 2015, Japanese companies have strengthened their corporate governance systems. I believe that Mitsubishi Tanabe Pharma has also made steady progress, such as implementing evaluations of the effectiveness of the Board of Directors, establishing the Compensation Committee and the Nomination Committee as voluntary committees, introducing a performance-linked stock compensation plan, and increasing the number of outside directors.

However, strengthening corporate governance will always be an ongoing task. The reason is that corporate governance entails earning the trust of stakeholders. It is only natural that the things that stakeholders want from the Company will change. In response, I believe it is important to continue to have an approach of enhancing and advancing corporate governance.

**Kobayashi** I agree. Measures to address the Corporate Governance Code were principally static in the sense that they focused on adjusting the form. However, to earn the trust of stakeholders it is necessary to focus on dynamic initiatives appealing to stakeholders, including communications. In particular, in advancing its business activities the Company places the highest priority on earning the trust of patients, who are important stakeholders.

In particular, in advancing its business activities the Company places the highest priority on earning the trust of patients, who are important stakeholders.

**Kamijo** That is a good point. Corporate management is not something that always proceeds according to plan. In particular, pharmaceuticals are a business that requires long-term initiatives over periods of 5 years or 10 years, and accordingly there are delays in plans that exceed expectations. However, I believe that if Mitsubishi Tanabe Pharma clearly shares its direction with stakeholders through communications, then that trust will be maintained.

Moving forward, I think we should continue working to foster an understanding of the Company's direction and the concepts incorporated into it, while holding repeated discussions with Directors. In addition, we should ask whether we are making the decision that is truly best for patients and other stakeholders.

**Kobayashi** Beginning with the acceleration of our U.S. business development, we are moving forward into a world in which we have no experience. In consideration of your own experience in starting up a business in the U.S., I would like to request that you continue to provide your frank opinion as we go forward. Thank you for participating in today's discussion.



## Risk Management and Compliance

### Risk Management

#### ■ Business Activity Risk Management

With the objective of appropriately managing the risks resulting from its business activities, the Company has formulated risk management regulations. We ascertain the areas and types of risks that we face in our business activities and ensure that the necessary countermeasures are implemented by the relevant department. To handle risks at the Companywide level, we established the Risk Management Committee, which is led by the President and CEO and, as a general rule, meets twice per year. The committee has overall responsibility for risk management, such as consideration of the progress of the Group's risk reduction measures, and has established and operates a system to advance risk management.

#### ■ Preparation for Large-Scale Disasters

To secure a stable supply of pharmaceuticals, which is the mission of a pharmaceutical manufacturing and sales company, we have formulated disaster regulations, such as Business Continuity Management Rules for Large-Scale Disaster. The Company is advancing a variety of countermeasures to large-scale disasters, such as an earthquake, tsunami, pandemic, or terrorist incident, and related risks. In this way, the Company is working to increase its disaster resilience. In an emergency, we will work to accomplish our mission with a Companywide system based on collaboration among the head office and each base, with our highest priority being the stable delivery of pharmaceuticals to patients.

### Compliance

#### ■ Compliance Promotion System

To ensure sound business activities, Mitsubishi Tanabe Pharma has formulated the Corporate Behavior Charter, which identifies the top priorities for directors and employees in the implementation

of business activities, and the Mitsubishi Tanabe Pharma Group Declaration of Compliance, which provides specific behavioral guidelines. In accordance with the code, members of the Board of Directors and Board of Corporate Auditors take the lead in strictly adhering to laws, regulations, and the Company's Articles of Incorporation. Also, the Company is taking steps to create a Companywide compliance system, including Group companies, centered on the Compliance Promotion Committee, which is chaired by the Chief Compliance Officer. A total of 136 compliance implementation personnel, including managers and staff, meet semiannually (overall / individually). These meetings are held to facilitate coordination among individual workplaces, heighten sensitivity to risk associated with compliance and potential scandals, share information on related problems, and enhance the capacity of workplaces to address compliance issues.

#### ■ Compliance Training

Once per year, we are implementing Companywide compliance training and department-level compliance training. The objectives of this training are to cultivate a high level of ethical standards and awareness of norms and to further foster compliance awareness. In addition, through e-learning we perform a compliance understanding check twice per year to confirm understanding of such matters as laws, regulations, and internal rules. This enables officers and employees to act in accordance with consistent evaluation standards.

#### ■ Establishment of Hotlines

The Company has established internal and external hotlines as systems for reports and consultation regarding actual or possible violations of laws, regulations, and social rules. The use of the hotlines leads to the prevention or reduction of scandals, etc., before major problems develop. Also, through regular compliance training and other means, we are reporting the most recent trends and examples worthy of special mention.

Corporate Behavior Charter

**We maintain the highest ethical standards, place top priority on fairness and integrity in all activities, and act in accordance with the following guidelines.**

**Pride and Sense of Mission**

As people involved in the creation of pharmaceuticals, we work with pride and a sense of mission as we endeavor to research and develop pharmaceuticals that are needed by society and to ensure product safety and quality.

**Challenge and Innovation**

With acute sensitivity and a broad perspective, we focus on our future direction, decisively take on the challenge of meeting higher goals, and strive to create innovative value.

**Trust and Collaboration**

We promote free and open communication to understand and respect each other, and collaborate with mutual trust to maximize our results.

**Harmonious Coexistence with Society**

We work to achieve harmonious coexistence with society by acting with consideration for local communities and the environment.

### ■ Compliance at Overseas Group Companies

The Group consults regularly with relevant departments in the Group concerning action programs to strengthen compliance and risk management systems at Group companies outside Japan. The Group has bases in North America, Europe, China, Asia, ASEAN, and the Middle East. We are sharing policies that are important in Group management while considering the values of each country, such as the cultures, laws, and business practices. In this way, we are advancing the compliance and risk management of Group companies.

### ■ Implementation of Employee Survey

We conduct an employee survey once a year with the objective of tracking employee motivation. This survey includes compliance awareness. In this way, we are tracking and periodically observing awareness on a Companywide level. We are utilizing the results to advance compliance by providing them to each division as feedback. In addition, we will work to continue to increase compliance awareness among employees through such means as Companywide compliance training.

### ■ Prevention of Bribery and Corruption

With the objective of strengthening measures to prevent bribery and corruption in business, the Group has formulated the Mitsubishi Tanabe Pharma Group Global Anti-Bribery and Corruption Policy, which has been adopted by all Group companies. Moreover, to further clarify the content of this policy, we formulated corruption prevention guidelines in Japan, China, South Korea, Taiwan, Indonesia, and Thailand, and we are implementing appropriate responses in line with the laws, regulations, and business practices of each country.

### ■ Exclusion of Antisocial Elements / Checking Of Suppliers for Relationships with Antisocial Forces

In regard to antisocial elements, as an organization, in the face of unreasonable demands the Group follows a resolute approach that is unyielding and uncompromising. Furthermore, in accordance with the Company's business conduct guidelines, all executives and employees are required to adhere strictly to relevant laws and ordinances in all of their day-to-day business activities, avoid relationships with antisocial elements, and act in accordance with social ethics. Also, the Group cooperates closely with specialized external specialist institutions, such as the police, etc. In addition, prior to starting transactions with new business partners, the Company checks for affiliations between the supplier and antisocial elements. In this way, the Company is working to exclude relationships with antisocial elements.

### ■ Personal Information Protection

In regard to the important personal information of customers, we have formulated and announced the Privacy Policy: Personal Information Protection Policies. In accordance with the basic policy of suitable and secure handling of personal information, we gather personal information through appropriate means and use personal information within the scope necessary to fulfill the purpose of use.

### ■ Appropriate Relationships with Medical Institutions and Patient Organizations

In accordance with guidelines formulated by the Japan Pharmaceutical Manufacturers Association (JPMA), in July 2011 the Company formulated its guidelines for transparency in relationships with medical institutions, etc. In accordance with these guidelines, from fiscal 2012 we have followed a policy of releasing related information on the Company's website. This information includes payments to medical institutions as research and development expenses, etc., academic research support expenses, manuscript / writing fees, etc., information provision-related expenses, and hospitality and other expenses. The purpose of these initiatives is to secure a broad understanding from society in regard to the contribution made by the Company's business activities to progress in medicine, pharmacology, and the other life sciences and in regard to the Company's high ethical standards in its business activities. In addition, in August 2014 the Company formulated guidelines for managing conflicts of interest with medical and research institutions, etc. We have established principles for avoiding problems with conflicts of interest and a system for managing conflicts of interest, and are working to operate this system in an appropriate manner.

In particular, in regard to scholarships and donations to domestic medical institutions, which are included in research and development expenses, to secure transparency in April 2016 the Company started a system of publicly inviting applications on the Internet. Funding is provided after screening is conducted by a third-party unit.

In addition, in regard to relationships with patient organizations, first it is important for corporate activities to be based on a high level of ethical standards and mutual understanding with respect for the independence of patient organizations. On that basis, to secure a broad understanding from society in regard to our contribution to the activities and development of patient organizations, in accordance with the guidelines of the JPMA, in April 2013 we formulated our guidelines for transparency in relationships with patient organizations. From fiscal 2013, information regarding the funds and labor provided to these patient organizations is provided on the Company's website.

Furthermore, in regard to the provision of compensation or funds to doctors or to health care-related institutions or organizations in Europe or the U.S., we are conducting information disclosure in an appropriate manner in accordance with guidelines and laws formulated in Europe and the U.S.



For further information about corporate governance and internal control, please refer to the Company's CSR website.

#### CSR Website

<https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/index.html>

#### CSR Activities Report 2018 (PDF version)

[https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/csr\\_pdf/index.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/csr_pdf/index.html)

## Board of Directors and Corporate Auditors

As of August 1, 2018

### Board of Directors



#### Masayuki Mitsuka

President & Representative Director,  
Chief Executive Officer

1982 Entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical)  
1999 General Manager of Pharmaceuticals Discovery Laboratory of Yokohama Research Center of Mitsubishi-Tokyo Pharmaceuticals  
2004 President and Board Director of ZOEGENE  
2007 Associate Director, General Manager of Product Strategy Department of Mitsubishi Pharma  
Associate Director, General Manager of Global Product Strategy Department of the Company  
2008 Executive Officer, General Manager of Global Product Strategy Department of the Company  
2009 Board Director, Executive Officer, General Manager of Global Product Strategy Department of the Company  
2012 Board Director, Managing Executive Officer, Division Manager of Development Division of the Company  
2014 Representative Director, Senior Managing Executive Officer of the Company  
President & Representative Director, Chief Executive Officer of the Company (current)  
Board Director of Mitsubishi Chemical Holdings  
Board Director of The KAITEKI Institute (current)

Masayuki Mitsuka entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical) in 1982. He worked as a researcher in the Pharmaceutical Research Department. After studying as a research student overseas, in 1999 he became General Manager of Pharmaceuticals Discovery Laboratory of Yokohama Research Center of Mitsubishi-Tokyo Pharmaceuticals. In 2000, he became Assistant Manager of the Corporate Strategic Planning Office and the Life Science Business Promoting Office at Mitsubishi Chemical, and he was responsible for the reform of the R&D system. In addition, he worked on the merger of Mitsubishi-Tokyo Pharmaceuticals and Welfide. Subsequently, in 2002 he moved to ZOEGENE, a bio-related subsidiary established by Mitsubishi Chemical, and in 2004 he became President and Board Director of ZOEGENE. After Mitsubishi Tanabe Pharma was established, he worked in such positions as Board Director, Executive Officer, General Manager of Global Product Strategy Department, and Managing Executive Officer, Division Manager of Development Division. In 2014, he became President & Representative Director, Chief Executive Officer, and since then he has worked to speed up decision-making and reform the corporate constitution. Under Medium-Term Management Plan 16-20: Open Up the Future, which started from fiscal 2016, those policies have been continued, and the Company is implementing its four strategic priorities. In addition, he also works as Board Director of The KAITEKI Institute.



#### Takashi Kobayashi

Representative Director,  
Senior Managing Executive Officer

In charge of Internal Control Office,  
Future Design Department, Global Quality Assurance Department, Global Regulatory Affairs Department, Clinical, Research & PV Quality Assurance Department, and Medway Business Management Office

1980 Entered the Company  
2004 General Manager of Pharmaceuticals Sales & Marketing Department of Marketing Planning Division of the Company  
2007 Executive Officer, General Manager of Corporate Management Department of the Company  
2009 Board Director, Executive Officer, General Manager of Corporate Strategic Planning Department of the Company  
2012 Board Director, Managing Executive Officer, in charge of Business Unit, responsible for Special Assignments from the President of the Company  
2014 Board Director, Managing Executive Officer, Division Manager of Research Division of the Company  
2015 Board Director, Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division of the Company  
2016 Representative Director, Senior Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division of the Company  
2017 Representative Director, Senior Managing Executive Officer, Division Manager of CMC Division of the Company (current)  
2018 Representative Director, Senior Managing Executive Officer, in charge of Internal Control Office, Future Design Department, Global Quality Assurance Department, Global Regulatory Affairs Department, Clinical, Research & PV Quality Assurance Department, and Medway Business Management Office of the Company (current)  
Chief Compliance Officer (current)

Takashi Kobayashi entered Tanabe Seiyaku in 1980. He worked as a researcher in the Safety Research Laboratories. In 1997, he moved to the Human Resources Division, where he was engaged in the operation of the personnel system. He worked as General Manager of Secretary's Office of Administrative Division and as General Manager of Pharmaceuticals Sales & Marketing Department of Marketing Planning Division. After Mitsubishi Tanabe Pharma was established, he worked as Executive Officer, General Manager of Corporate Management Department, and in 2009 he became Board Director, Executive Officer, General Manager of Corporate Strategic Planning Department. Subsequently, he became Board Director, Managing Executive Officer, in charge of Business Unit, responsible for Special Assignments from the President, and he worked to implement structural reforms and to resolve quality control issues and other issues in sales and corporate divisions. Subsequently, as Division Manager of Research Division and as Division Manager of "Sohyaku. Innovative Research Division," he implemented reforms of the research system, and in 2016, he became Representative Director, Senior Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division. In 2017, he became Division Manager of CMC Division (Chemistry, Manufacturing, and Control), and started up the Future Design Department. Together with employees, he is working to identify the form of the pharmaceuticals of the future.



#### Yoshiaki Ishizaki

Board Director,  
Managing Executive Officer

In charge of Sales & Marketing Division,  
OTC Business Department, and Tokyo Head Office

1978 Entered Yoshitomi Pharmaceutical Industries  
2006 General Manager of Distribution Management & Wholesalers Relations Department of Sales & Marketing Division of Mitsubishi Pharma  
2007 General Manager of Tokyo Branch of Sales & Marketing Division of the Company  
2008 Associate Director, General Manager of Tokyo Branch of Sales & Marketing Division of the Company  
2009 Executive Officer, General Manager of Tokyo Branch of Sales & Marketing Division of the Company  
2011 Executive Officer, Division Manager of Pharmacovigilance & Quality Assurance Division of the Company  
2012 Managing Executive Officer, Division Manager of Pharmacovigilance & Quality Assurance Division of the Company  
2014 Managing Executive Officer, Division Manager of Pharmacovigilance & Quality Assurance Division of the Company, Chief Compliance Officer of the Company  
Board Director, Managing Executive Officer, Division Manager of Pharmacovigilance & Quality Assurance Division of the Company  
2015 Board Director, Managing Executive Officer, Division Manager of Sales & Marketing Division of the Company (current)  
2018 Board Director, Managing Executive Officer, in charge of Sales & Marketing Division, OTC Business Department, and Tokyo Head Office of the Company (current)

Yoshiaki Ishizaki entered Yoshitomi Pharmaceutical Industries in 1978. He worked in the sales and marketing department of Yoshitomi Pharmaceutical Industries, and in 1994 he became General Manager of Tokyo Johoku Office I. In 2006, he became General Manager of Distribution Management & Wholesalers Relations Department of Sales & Marketing Division of Mitsubishi Pharma. After Mitsubishi Tanabe Pharma was established, he became General Manager of Tokyo Branch of Sales & Marketing Division, and in 2009 he became Executive Officer, General Manager of Tokyo Branch of Sales & Marketing Division of the Company. After joining Yoshitomi Pharmaceutical Industries, he contributed to the Company's results on the front lines of sales. Subsequently, he worked in such positions as Managing Executive Officer, Division Manager of Pharmacovigilance & Quality Assurance Division. In 2014, he became Board Director, and in 2015 he became Division Manager of Sales & Marketing Division. Leveraging the wide-ranging experience he acquired through many years on the front lines of sales, he is taking steps to build a strong sales system suitable for the future market environment, such as strengthening area marketing and reforming MR activities through the use of digital marketing.



### Seiichi Murakami

Board Director,  
Managing Executive Officer

In charge of Ikuyaku. Integrated Value Development Division and Vaccine Business Development Office

- 1980 Entered the Company
- 2003 General Manager of Remicade Department of Pharmaceuticals Sales & Marketing Division of the Company
- 2006 Executive Officer, Deputy Division Manager of Pharmaceuticals Sales & Marketing Division of the Company
- 2009 Executive Officer, Division Manager of Development Division of the Company
- 2012 Managing Executive Officer, in charge of Management Strategy of the Company
- 2014 Managing Executive Officer, Division Manager of Sales & Marketing Division of the Company
- 2015 Board Director, Managing Executive Officer, Division Manager of Sales & Marketing Division of the Company
- Board Director, Managing Executive Officer, Division Manager of Ikuyaku. Integrated Value Development Division of the Company
- 2018 Board Director, Managing Executive Officer, in charge of Ikuyaku. Integrated Value Development Division and Vaccine Business Development Office of the Company (current)

Seiichi Murakami entered Tanabe Seiyaku in 1980. He worked in the area of in-licensing in the global development group at Tanabe Seiyaku. In 1983, he worked on the development of Maintate in the domestic development group, and subsequently he worked in sales and marketing on the launch of new products. After working as Manager in Corporate Strategic Planning Department, in 2003 he became General Manager of Remicade Department of Pharmaceuticals Sales & Marketing Division and Manager of Corporate Strategic Planning Department. He supported the development of Remicade and contributed to Remicade's growth into a major drug. In 2006, he became Executive Officer, Deputy Division Manager of Pharmaceuticals Sales & Marketing Division. After Mitsubishi Tanabe Pharma was established, he worked in such positions as Executive Officer, Division Manager of Development Division and Managing Executive Officer, Division Manager of Sales & Marketing Division. In 2015, he became a Board Director. Also in 2015, he became Division Manager of "Ikuyaku. Integrated Value Development Division." Leveraging the experience that he acquired in nurturing products in the Sales & Marketing Division and the Development Division, he is working to strengthen IKUYAKU in order to maximize product value.



### Eizo Tabaru

Board Director,  
Managing Executive Officer

In charge of Corporate Strategic Planning Department, NeuroDerm Office, Finance & Accounting Department, and Corporate Communications Department

- 1981 Entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical)
- 2010 General Manager of Finance and Accounting Department of Mitsubishi Chemical (currently, Mitsubishi Chemical)
- Associate Director, General Manager of Finance and Accounting Department of Mitsubishi Chemical
- 2012 Executive Officer, General Manager of Finance and Accounting Department of Mitsubishi Chemical
- 2014 Executive Officer, General Manager of Finance & Accounting Department of the Company
- 2015 Board Director, Executive Officer, General Manager of Finance & Accounting Department of the Company
- 2016 Board Director, Managing Executive Officer, General Manager of Finance & Accounting Department of the Company
- 2018 Board Director, Managing Executive Officer, in charge of Corporate Strategic Planning Department, NeuroDerm Office, Finance & Accounting Department, and Corporate Communications Department of the Company (current)

Eizo Tabaru entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical) in 1981. In the General Affairs Department at the Kurosaki Plant of Mitsubishi Chemical, he worked in finance and accounting. In 1985, he moved to the Accounting Department at Mitsubishi Chemical, and he worked on a companywide cost system unification project. Subsequently, he worked on overseas projects, and was in charge of local plant construction in such countries as Indonesia and Thailand. In 1998, he started a new job as CFO at MCC PTA India Corp. He worked in accounting, finance, and IT for a plant construction project in Calcutta. Subsequently, he became Associate Director, General Manager of Finance and Accounting Department of Mitsubishi Chemical in 2010, Executive Officer of Mitsubishi Chemical in 2012, and Executive Officer, General Manager of Finance & Accounting Department of the Company in 2014. Since he became a Board Director in 2015, he has contributed to increasing the corporate value of the Company as the person responsible for corporate strategic planning, finance and accounting, and other areas.



### Takashi Tanaka

Board Director,  
Managing Executive Officer

In charge of Production Technology & Supply Chain Management Division

- 1985 Entered the Company
- 2002 General Manager of Production Planning Department of Production Division of the Company
- 2005 General Manager of Onoda Plant of Production Division of the Company
- Director of TANABE YAMAGUCHI SEIYAKU (currently, Mitsubishi Tanabe Pharma Factory)
- 2008 General Manager of Production Strategy & Coordination Center of Production Division of the Company
- 2010 General Manager of Production Strategy & Coordination Department of Production Division of the Company
- President and Representative Director of Mitsubishi Tanabe Pharma Factory
- 2013 Associate Director, Deputy Division Manager of CMC Division (Chemistry, Manufacturing and Control) of the Company
- 2014 Executive Officer, Deputy Division Manager of CMC Division (Chemistry, Manufacturing, and Control) of the Company
- 2015 Executive Officer, Division Manager of Production Division of the Company
- 2017 Managing Executive Officer, Division Manager of Production Division of the Company
- Board Director, Managing Executive Officer, Division Manager of Production Division of the Company
- 2018 Board Director, Managing Executive Officer, in charge of Production Technology & Supply Chain Management Division of the Company (current)

Takashi Tanaka entered the Company in 1985. He worked as a researcher in the Toda Research Center of the Company. After he became General Manager of Production Planning Department of Production Division in 2002, he worked in a variety of important manufacturing-related positions, including positions on the frontlines, such as in positions related to production, technology, and plants. These positions included General Manager of Onoda Plant of Production Division and President and Representative Director of Mitsubishi Tanabe Pharma Factory. In addition, he helped to resolve the quality-related problems that arose in 2011. Subsequently, in 2015 he became Division Manager of Production Division, and in 2017 he became a Board Director of the Company. Leveraging his experience and knowledge, he is leading initiatives in the area of Reforming Operational Productivity through manufacturing supply chain management reforms. From 2018, he is in charge of Production Technology & Supply Chain Management Division, which was created through the consolidation and reorganization of the CMC Division and the Production Division.



**Takeshi Matsumoto**

Board Director

- 1983 Entered the Company
- 2002 General Manager, Discovery Research Laboratory of Research and Development Division of the Company
- 2003 General Manager of Discovery & Pharmacology Research Laboratories of Research Division of the Company
- 2004 General Manager of Discovery Research of Research Division of the Company
- 2007 General Manager of Research Strategy & Planning Department of Research Division of the Company
- 2008 Associate Director, General Manager of Research Strategy & Planning Department of Research Division of the Company
- 2010 Associate Director, General Manager of Discovery Screening Center of Research Division of the Company
- 2012 Executive Officer, General Manager of Discovery Screening Center of Research Division of the Company
- 2014 Executive Officer, Division Manager of Development Division of the Company
- 2015 Executive Officer, General Manager of Corporate Strategy Office of Mitsubishi Chemical Holdings (healthcare)
- 2018 Managing Executive Officer, General Manager, Healthcare Strategy Office, Corporate Strategy Division of Mitsubishi Chemical Holdings (current)  
Board Director of Life Science Institute (current)  
Board Director of the Company (current)

Takeshi Matsumoto entered the Company in 1983. From 2002, he held important positions in discovery research, including, in the Research Division, General Manager of Discovery & Pharmacology Research Laboratories and General Manager of Research Strategy & Planning Department. Subsequently, in 2012 he became Executive Officer, General Manager of Discovery Screening Center of Research Division, and in 2014 he became Division Manager of Development Division. In 2015, he became Executive Officer, General Manager of the Corporate Strategy Office of Mitsubishi Chemical Holdings, which is the parent company of Mitsubishi Tanabe Pharma. In 2018, he became Managing Executive Officer, General Manager of Healthcare Strategy Office in Corporate Strategy Division of Mitsubishi Chemical Holdings. In this position, he is responsible for business execution in the health care businesses. In 2018, he became a Board Director of Mitsubishi Tanabe Pharma. He is working to contribute to the business of Mitsubishi Tanabe Pharma by reflecting the management strategy of Mitsubishi Chemical Holdings. In addition, he is also a Board Director of Life Science Institute.



**Shigehiko Hattori**

Board Director (Outside)

- 1964 Entered Shimadzu
- 1993 Board Director of Shimadzu
- 1997 Managing Board Director of Shimadzu
- 2003 President & Representative Director of Shimadzu
- 2009 Chairman of the Board and Representative Director of Shimadzu
- 2011 Outside Board Director of the Company (current)
- 2012 Outside Board Director of Sapporo Holdings (current)  
Outside Board Director of BROTHER INDUSTRIES (current)  
Outside Board Director of Meiji Yasuda Life Insurance (current)
- 2015 Senior Corporate Adviser of Shimadzu (current)

**Relationship with the Company**

Shigehiko Hattori is Senior Corporate Adviser of the Board of Shimadzu and Outside Board Director of Sapporo Holdings, BROTHER INDUSTRIES, and Meiji Yasuda Life Insurance. There are no special conflicts of interest between the Company and Shigehiko Hattori or these companies.

**Reason for nomination**

Since his appointment in June 2011, Shigehiko Hattori has fulfilled his duties as an Independent Outside Board Director on the Company's Board of Directors, based on his abundant experience as a top executive and wide-ranging knowledge in science and technology. He has made pointed comments and opinions on the growth strategy, and given advice and proposals considering the balance of interests among stakeholders, from an independent and objective perspective. In addition, as the chair of the Nomination Committee and the Compensation Committee, which are discretionary advisory bodies, in regard to nomination and compensation, has contributed to appropriate judgments by the Board of Directors and to the enhancement of accountability of the Company. The Company believes that he will contribute to growth in the Group's corporate value through the continued supervision of the management of the Company as an Independent Outside Board Director, and thus has nominated him as an Outside Board Director.



**Shigeki Iwane**

Board Director (Outside)

- 1976 Entered The Kansai Electric Power
- 2005 Senior Officer and Office Head of Nuclear Power Maintenance and Innovation Promotion Office of The Kansai Electric Power
- 2007 Executive Officer, General Manager of Corporate Planning Office of The Kansai Electric Power
- 2010 Managing Director of The Kansai Electric Power
- 2012 Representative Director, Executive Vice President & Director of The Kansai Electric Power
- 2013 Representative Director, Executive Vice President of The Kansai Electric Power  
Outside Corporate Auditor of Kinden
- 2016 Outside Board Director of the Company (current)  
President and Director of The Kansai Electric Power (current)

**Relationship with the Company**

Shigeki Iwane works as President and Director of The Kansai Electric Power. There are no special conflicts of interest between the Company and Shigeki Iwane or this company.

**Reason for nomination**

Since his appointment in June 2016, Shigeki Iwane has fulfilled his duties as an Independent Outside Board Director on the Company's Board of Directors, based on his abundant experience as a top executive and wide-ranging knowledge in corporate governance. He has made pointed comments and proposals in regard to rationality in management, ensuring profitability in business as well as consistency between strategy and business execution, from an independent and objective perspective. In addition, he has, as a member of the Nomination Committee, which is a discretionary advisory body, been engaged in establishing the criteria for the selection of Board Directors, Corporate Auditors, and Executive Officers as well as the selection and appointment of each candidate. The Company believes that he will contribute to growth in the Group's corporate value through the continued supervision of the management of the Company as an Independent Outside Board Director, and thus has nominated him as an Outside Board Director.



**Tsutomu Kamijo**  
Board Director (Outside)

- 1976 Entered Sapporo Breweries (currently, Sapporo Holdings)
- 2001 Board Director of Sapporo Beverage
- 2003 Board Director and Managing Executive Officer of Sapporo Beverage
- 2007 Board Director of Sapporo Holdings
- 2009 Managing Director (Member of the Board) of Sapporo Holdings
- 2011 President and Representative Director of Sapporo Holdings and CEO of the Sapporo Holdings Group
- 2017 Chairman and Representative Director of Sapporo Holdings (current)  
Outside Director of the Company (current)

**Relationship with the Company**

Tsutomu Kamijo works as Chairman and Representative Director of Sapporo Holdings. There are no special conflicts of interest between the Company and Tsutomu Kamijo or this company.

**Reason for nomination**

Since his appointment in June 2017, Tsutomu Kamijo has fulfilled his duties as an Independent Outside Board Director on the Company's Board of Directors, based on his abundant experience as a top executive and wide-ranging knowledge in business globalization. He has given advice and proposals, especially on the expansion of overseas business and the operation thereof, and has made pointed comments on risk management, from an independent and objective perspective. In addition, he has, as a member of the Compensation Committee, which is a discretionary advisory body, been engaged in the revision of the compensation plan and the determination of compensation for Board Directors and Executive Officers. The Company believes that he will contribute to growth in the Group's corporate value through continued supervision of the management of the Company as an Independent Outside Board Director, and thus has nominated him as an Outside Board Director.

## Corporate Auditors



**Koji Kudo**  
Corporate Auditor (Standing)

- 1981 Entered Mitsubishi Petrochemical (currently, Mitsubishi Chemical)
- 2006 General Manager of Finance & Accounting Department of Japan Polychem
- 2010 General Manager of Finance & Accounting Department of Mitsubishi Plastics (currently, Mitsubishi Chemical)
- 2012 Associate Director, General Manager of Finance & Accounting Department of Mitsubishi Plastics
- 2014 Executive Officer, General Manager of Finance & Accounting Department of Mitsubishi Plastics
- 2016 Corporate Advisor of the Company  
Corporate Auditor (Standing) of the Company (current)



**Tadashi Fukuda**  
Corporate Auditor (Outside)

- 1986 Entered Daiichi Law Office
- 2015 Outside Corporate Auditor of EXEDY (current)
- 2016 Executive Partner of Daiichi Law Office (current)  
Outside Corporate Auditor of the Company (current)



**Matsuo Kikuchi**  
Corporate Auditor (Standing)

- 1984 Entered the Company
- 2010 General Manager of Development Quality Management Department of Development Division of the Company
- 2012 General Manager of Pharmacovigilance & Quality Planning and Coordination Department of Pharmacovigilance & Quality Assurance Division of the Company
- 2014 Associate Director, General Manager of Pharmacovigilance & Quality Planning and Coordination Department of Pharmacovigilance & Quality Assurance Division of the Company  
Associate Director, General Manager of Pharmacology Research Laboratories I of Research Division of the Company
- 2015 Executive Officer, General Manager of Pharmacology Research Laboratories I of Research Division of the Company
- 2016 Executive Officer, Division Deputy Manager of Ikuyaku, Integrated Value Development Division of the Company
- 2017 Corporate Auditor (Standing) of the Company (current)



**Hiroshi Enoki**  
Corporate Auditor (Outside)

- 1984 Entered Tohmatsu Awoki & Co.
- 1999 Representative Director of Tohmatsu Environmental Quality Research Institute
- 2006 Representative Director of Tohmatsu Consulting  
Managing Partner of Tohmatsu & Co.
- 2009 Partner of Deloitte ToucheTohmatsu
- 2018 Outside Corporate Auditor of the Company (current)  
Representative of Hiroshi Enoki Certified Public Accountant Office (current)

### Corporate Citizenship Activities

#### Declaration on Corporate Citizenship

We have formulated the Mitsubishi Tanabe Pharma Group Declaration on Corporate Citizenship, and are actively advancing corporate citizenship activities, targeting the realization of a “KAITEKI society.”

**WEB** For further information about KAITEKI, please see the MCHC website.  
[http://www.mitsubishichem-hd.co.jp/english/kaiteki\\_management/kaiteki/](http://www.mitsubishichem-hd.co.jp/english/kaiteki_management/kaiteki/)

#### Support for Medical Treatment and Welfare

##### ■ Implementing Donation and Assistance Activities

In 2012, we established the Mitsubishi Tanabe Pharma Tenohira Partnership Program, which provides aid for the activities of associations and support groups for patients with intractable diseases. These organizations work to improve patients' medical treatment, education, and career prospects and to enhance their quality of life. In fiscal 2017, aid was provided to a total of 17 organizations.

Meetings were held on October 19, 2017 (Head Office) and October 25 (Tokyo Head Office) to report on the fiscal 2016 activities of organizations receiving assistance under the Tenohira Partnership Program (15 organizations, 19 people). At these meetings, participants shared know-how about the possibilities of cooperation that transcends disease, shared challenges, asking for outside volunteers, etc.

In addition, on two occasions, in June and October 2017, Group company employees and family members from Japan and the U.S. participated in walking events sponsored by the ALS Association, a U.S. organization for patients with ALS. The ALS Association is a leading ALS patient organization in the U.S., and sponsors more than 150 charity events throughout the U.S.

Mitsubishi Tanabe Pharma America, cooperates in the walking events. Donations that were raised through the events will be used for medical treatment, for research and development, and for patients and their families.

##### ■ Contributing to Developing Countries

The Global Health Innovative Technology Fund (GHIT Fund) is a public-private partnership, originating in Japan, that advances the discovery of new drugs for infectious diseases that afflict people in the developing world, such as malaria, tuberculosis, and neglected tropical diseases (NTDs). In 2015, through the GHIT Fund, the Company provided its pharmaceutical compound library (50,000 compounds) to Medicine for Malaria Venture, a research institution for anti-malaria drugs. Three types of promising compounds that have the potential to become pharmaceuticals have been identified. Moving forward, we will continue to advance joint research targeting the discovery of new anti-malaria drug candidate compounds.

In addition, we have introduced the TFT Program at the employee cafeterias of the Head Office and the Kashima Office. TFT is an abbreviation for Table for Two, a social contribution activity that originated in Japan. This activity is aimed at simultaneously resolving the problems of hunger in developing countries and the problems of obesity and lifestyle-related diseases in industrially developed countries. At the employee cafeterias, when employees eat low-calorie meals that help prevent obesity, through TABLE FOR TWO International, ¥20 of the price is allocated to the cost of school meals in developing countries, such as in Africa. ¥20 is the amount of money needed to provide 1 meal in a developing country.

Furthermore, since 2014 the Group has been participating in vaccine support activities for children in developing countries. Through this program, when unneeded books, CDs, DVDs, etc.,

#### The Mitsubishi Tanabe Pharma Group Declaration on Corporate Citizenship

The Mitsubishi Tanabe Pharma Group will strive to contribute to society through its pharmaceutical operations in accordance with its Philosophy, Vision, and Corporate Behavior Charter. In addition, as a good corporate citizen, the Mitsubishi Tanabe Pharma Group will proactively implement the following activities to contribute to the resolution of problems related to health and living environments in the countries and regions where the Group conducts business.

#### Activities to Contribute to the Resolution of Problems Related to Health and Living Environments

- 1 Activities to promote medical research and nurture human resources
- 2 Activities to help patients and families find more joy and satisfaction in their lives
- 3 Activities to improve health and welfare in developing countries
- 4 Activities to activate communities and develop more-comfortable living environments
- 5 Other activities

**WEB** For further information about corporate citizenship activities, please see the URLs on the below.

**CSR Website** <http://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/index.html>

**CSR Activities Report 2018 (PDF version)** [http://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/csr\\_pdf/index.html](http://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/csr_pdf/index.html)



are sent to BOOKOFF Online, 10% is added to the assessed amount and the total is donated to Authorized NPO Japan Committee Vaccines for the World's Children. This international contribution activity uses those donations to deliver vaccines to children in developing countries, such as vaccines for six major infectious diseases. In fiscal 2017, as a result of aggressive initiatives at each worksite, the amount of donations reached ¥223,056, about 1.4 times the level in the previous fiscal year and equivalent to polio vaccines for 11,153 people. Moreover, from fiscal 2017, in addition to donations from employees, the Company is also participating in vaccine support through matching gifts. (Same amount: ¥223,056 donation).

### ■ Initiatives to Support Active Lifestyles for People with Disabilities

At the Kashima Office, as an activity to help patients and families find more joy and satisfaction in their lives, we have been supporting CP Soccer (soccer played by seven people with cerebral palsy) since fiscal 2013. The Kashima Office makes the office grounds available for the CP soccer tournament and other events.

### Advances in Medicine and Pharmacology

We are making donations to the SENSIN Medical Research Foundation and to the Japan Foundation for Applied Ezymology. In this way, through the activities of these foundations we are working to contribute to the promotion of research and the dissemination of knowledge in a broad range of fields, such as medicine, pharmacology, agriculture, and the physical sciences, as well as to the treatment and health of people. In fiscal 2017, we provided a total of approximately ¥200 million to these foundations.

### Contributing to the Environment

The Group is aggressively implementing greening and beautification activities at each domestic and overseas worksite. Employees clean worksite surroundings and actively participate in other neighborhood cleaning activities. In these ways, we are working to contribute to environmental conservation and to foster harmonious coexistence with local communities.



Osaka Marathon Clean-Up Operation



Seashore cleaning volunteer activity (Hsinchu Plant, Taiwan Tanabe Seiyaku)

### Advancement of local communities

#### ■ Mitsubishi Tanabe Pharma Historical Museum

In 2015, the Company opened the Mitsubishi Tanabe Pharma Historical Museum on the second floor of the Head Office in Doshomachi, Osaka, which is known as the "pharmaceutical district." More than 20,000 people have visited the museum over the three years since its opening. Through the Mitsubishi Tanabe Pharma Historical Museum, the Company is cooperating in regional



Mitsubishi Tanabe Pharma Historical Museum

events and contributing to the development of the next generation, such as with school off-campus learning activities.

**WEB** For further information about the Mitsubishi Tanabe Pharma Historical Museum, please visit the following website. <http://www.mtpc-shiryokan.jp/en/>

### Activities Addressing Other Social Needs

#### ■ Developing the Next Generation

As a measure to develop the next generation, the Group offers lessons and company tours at worksites, which are used as venues for pharmaceutical-related lectures and comprehensive learning initiatives that leverage the knowledge of a pharmaceutical company.



Company employee wears a lab coat to deliver a lecture during an off-site educational activity

#### ■ Support for Disaster Reconstruction

The Company is providing ongoing support to regions affected by the Great East Japan Earthquake and the Kumamoto Earthquake and working to support recovery and reconstruction initiatives for regions damaged by national disasters in Japan and overseas.

The Company has made a variety of donations to help people who were affected by the torrential rains in northern Kyushu in July 2017, the earthquake in northern Osaka Prefecture in June 2018, and the torrential rains in western Japan in July 2018, and to assist in the reconstruction of the disaster-stricken regions. In addition, as one part of initiatives to support reconstruction in Tohoku and Kumamoto, we held events to sell products, with the objective of fostering knowledge about and support for the regions affected by the disasters. Moving forward, we will continue to support the regions affected by the disasters by encouraging purchases in order to ensure that memories of the earthquakes do not fade away.

## Initiatives Related to Environmental Conservation

### Environmental Management

In accordance with its environmental policy, in order to help protect the global environment and create a sustainable society, in every aspect of its business operations Mitsubishi Tanabe Pharma is working to reduce resource consumption, energy consumption, and

waste and to achieve sustained reductions in the environmental burden. Moreover, we work proactively to ensure that our operations are environmentally friendly. Furthermore, the Group appropriately discloses information related to the environment and promotes dialogue with the public in its initiatives aimed at contributing to the environment and society.

#### Environmental and Safety Policy

Mitsubishi Tanabe Pharma and its Group companies (“MTPC Group”) aim to be global research-driven pharmaceutical companies that are trusted by communities, and actively strive to protect global environment and ensure people’s safety.

- 1 We assess our corporate activities for their environmental impact in order to continuously reduce environmental burden.
- 2 We give priority to safety considerations for all of our workers to prevent occurrence of occupational accidents.
- 3 We set clear targets for our environmental and safety activities, and we effectively maintain and improve our system to achieve such targets.
- 4 We pursue activities in compliance with not only laws and regulations relating to environment and safety, but also more rigorous corporate management standards.
- 5 We systematically conduct training to enhance each and every employee’s awareness on the environment and safety.
- 6 We proactively disclose information relating to environment and safety so that we can deepen communication with communities.
- 7 By proactively participating in and cooperating with environment management and disaster reduction activities organized by local communities, we prepare against unforeseen contingencies such as accidents and disasters, so as to minimize their impact.

### Environmental Action Plan

In consideration of changes in the status of our business activities in Japan and overseas, changes in capital investment and other business plans, the demands of external stakeholders, etc., we revised the details of the Medium-Term Environmental Action Plan (2016–2020). The major revisions were as follows.

- In “energy conservation and global warming mitigation,” we increased our target for CO<sub>2</sub> emission reductions. We also included offices and expanded the scope.
- We added “effective use of water resources” as a new theme and established domestic and global numerical targets for water usage volume (production and research bases).

#### Medium-Term Environmental Action Plan (2016–2020): Principal Objectives and Progress

Area	Objectives	Principal initiatives and results in fiscal 2017
Energy conservation and global warming mitigation	<ul style="list-style-type: none"> <li>• CO<sub>2</sub> emissions by fiscal 2020 (production and research bases, offices)</li> <li>Domestic group: Reduce by at least 40% compared to the fiscal 2010 level</li> <li>Global: Reduce by at least 35% compared to the fiscal 2010 level</li> <li>• Advance tracking of supply chain CO<sub>2</sub> emissions</li> </ul>	<ul style="list-style-type: none"> <li>• CO<sub>2</sub> emissions volume (excluding CO<sub>2</sub> emissions from the use of fuel in sales vehicles)</li> <li>Domestic group: 37% reduction (vs. fiscal 2010)</li> <li>Global: 29% reduction (vs. fiscal 2010)</li> <li>• Scope 3 emissions in categories 1, 2, 3, 4, 5, 6, 7, and 12 were CO<sub>2</sub> calculated.</li> </ul>
Reduction of waste / effective use of water resources	<ul style="list-style-type: none"> <li>• Domestic group: Reduce the amount of waste generated, maintain zero emissions (final waste disposal rate of less than 0.5%)</li> <li>• In comparison with fiscal 2010, reduce water usage volume (production and research bases) by 15% or more, both in Japan and overseas, by fiscal 2020.</li> </ul>	<ul style="list-style-type: none"> <li>• Domestic group: Final waste disposal rate: 0.37%</li> <li>• Water usage volume</li> <li>Domestic group: 40% reduction (vs. fiscal 2010)</li> <li>Global: 41% reduction (vs. fiscal 2010)</li> </ul>
Chemical substance emissions reductions	<ul style="list-style-type: none"> <li>• Reduce emissions of toluene into the environment by 30% or more by fiscal 2020 in comparison with fiscal 2010</li> </ul>	<ul style="list-style-type: none"> <li>• Emissions of toluene into the environment: Decrease of 34% (vs. fiscal 2010)</li> </ul>
Preservation of biodiversity	<ul style="list-style-type: none"> <li>• Understand the relationship between business activities and biodiversity, advance initiatives for the preservation of biodiversity</li> </ul>	<ul style="list-style-type: none"> <li>• Advanced environmental conservation activities, such as planting at Ikoma Mountain (Osaka Prefecture) and natural woodland conservation in the Hachioji Takiyama Area (Tokyo Prefecture)</li> </ul>
Enhancement of environmental management	<ul style="list-style-type: none"> <li>• Rigorously implement environmental compliance, enhance environmental risk management</li> <li>• Maintain zero environmental accidents</li> </ul>	<ul style="list-style-type: none"> <li>• Environmental audits by environment-related departments</li> <li>Subject: 6 domestic production and research bases, 1 overseas production base</li> <li>• No environmental accidents, record of zero accidents maintained</li> </ul>

The Environmental Safety Committee, which is led by the president and has members from the Executive Committee, etc., deliberates environmental safety action policies and plans as well as important measures and other matters. In addition, to further strengthen collaboration with Group companies, the Liaison Council for Environmental Safety formulates and implements measures to address issues related to environmental safety. Moreover, in the General Affairs Department we have established the Environment & Safety Management Office as a unit that oversees environmental safety management. The office is promoting environmental management on a Groupwide basis in Japan and overseas.

In recent years, climate change has become more apparent and there are growing calls around the world for measures to address climate change risk. In addition, water risk, such as water depletion, flooding, and water pollution, is susceptible to the influence of climate change. Moving forward, the Group will track and analyze the relationship between its business activities and climate risk and water risk. We will organize information regarding risks that affect operations and other aspects of management as well as available opportunities and move forward with initiatives.

## Greenhouse Gas Emissions in the Supply Chain

We are working to track greenhouse gas emissions from business activities in the supply chain and to expand the data that is disclosed.

### Greenhouse Gas Emissions Calculation in Fiscal 2017 (tons-CO<sub>2</sub>)

<b>Scope 1</b> Direct emissions of greenhouse gases from the business itself		35,777
<b>Scope 2</b> Indirect emissions from the consumption of electricity supplied by other companies		65,343
<b>Scope 3</b> Indirect emissions other than those covered in scope 2	Purchased goods and services	517,342
	Capital goods	17,504
	Fuel- and energy-related activities not included in Scope 1 and 2	10,273
	Transportation and distribution (upstream)	3,330
	Waste generated from operations	3,289
	Business travel	934
	Employee commuting	1,166
	Disposal of sold products	439

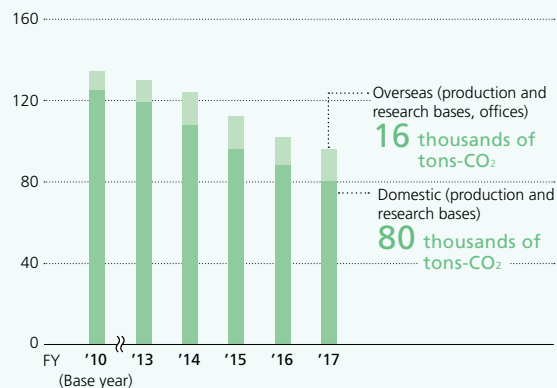
#### WEB

For further information about environmental activities, please use the following URL. In regard to major environmental performance indicators, we obtain third-party assurance with the objective of increasing the reliability of the information disclosed to stakeholders.

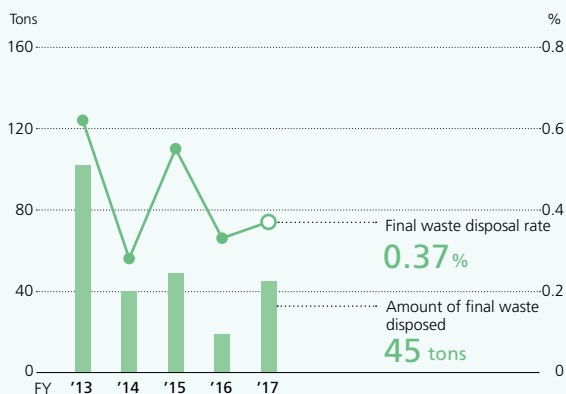
<https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/environment/index.html>

## CO<sub>2</sub> Emissions

Thousands of tons-CO<sub>2</sub>

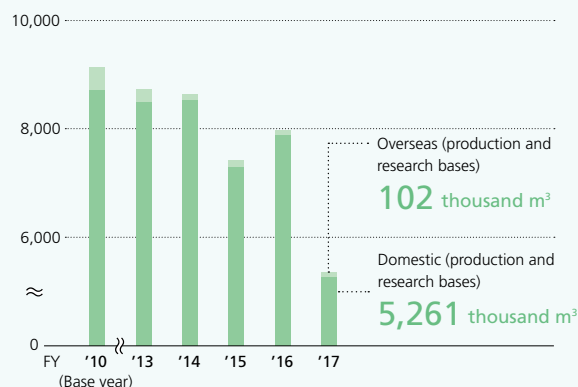


## Amount of Final Waste Disposed / Final Waste Disposal Rate (Domestic)



## Water Usage

Thousand m<sup>3</sup>



## Initiatives for the Preservation of Biodiversity

In accordance with the concept that a variety of environmental initiatives are connected with biodiversity, the Group is advancing biodiversity initiatives through a wide range of environmental activities. These include environmental burden reductions, appropriate usage of inherited resources, harmonious coexistence with nature and society, and increased awareness within the Group.

Over the entire life-cycle, from research and development to production, distribution, sales, use, and disposal, we will work to track the connections between our business activities and biodiversity, understand our influence and dependence on biodiversity, and enhance our understanding.

### ■ Environmental Conservation Activities in Local Communities

As environmental conservation activities that support biodiversity conservation, Group employees and their family members continue to participate each year in woodland conservation activities with Tokyo Greenship Action (Tokyo Prefecture) and planting activities with the Ikoma Mountain Range “Folding Screen of Flowers” Project (Osaka Prefecture).

In addition, as one part of its corporate citizenship initiatives, the Group is supporting regional environmental events through the provision of Aspara Drink.



Ikoma Mountain Range  
“Folding Screen of Flowers”  
Project



Woodland conservation  
activity

## Promoting Environmental Communications

### ■ Participation in Environmental Information Disclosure Program

In evaluating companies, the importance of ESG (Environment, Society, Governance) information is increasing. In this setting, the Ministry of the Environment is implementing an environmental information disclosure program with the aim of establishing a society in which companies that aggressively implement environmental activities receive appropriate evaluations from investors, etc., as well as appropriate funding.

The Company has continually participated in this program since fiscal 2014. In fiscal 2017, we updated our environmental information and engaged in dialogue with investors using the systems and tools that are provided.

### Receipt of Award Under Kansai Eco-Office Encouragement Awards Program

The Company’s Head Office won the Fiscal 2017 Kansai Eco-Office Award under the Kansai Eco-Office Encouragement Awards program. The Kansai Eco-Office Award is sponsored by the Union of Kansai Governments, which comprises multiple prefectures and ordinance-designated cities in the Kansai region. Under this award system, worksites that are conducting superior environmentally friendly activities are selected from among worksites that are participating in the Kansai Eco Office Declaration movement.

We received high evaluations for the achievement of CO<sub>2</sub> emissions volume reductions through the introduction of advanced energy-saving facilities in the Head Office building and the greening of the grounds and rooftop, as well as for aggressive CSR activities that contribute to the prevention of global warming through planting activities in the suburbs.



### Receipt of Excellence Award in the Environmental Report Section of the Environmental Communication Awards

The Company’s Corporate Report 2017 and CSR Activities Report 2017 received the Excellence Award in the Environmental Report Section of the 21st Environmental Communication Awards, which are sponsored by the Ministry of the Environment and the Global Environmental Forum.

The Company provides an overview of its major environmentally friendly initiatives in Corporate Report 2017. In addition, in CSR Activities Report 2017 we provide detailed disclosure of the results of our environmental management system and our activities targeting the achievement of the objectives in the Medium-Term Environmental Action Plan. We have also worked to ensure reliability by acquiring third-party assurance in regard to principal environmental performance indicators. These initiatives were highly evaluated, and as a result we received this award.



# Financial Section

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**WEB**

For the CONSOLIDATED FINANCIAL STATEMENTS AND INDEPENDENT AUDITOR'S REPORT, please use the following URL.  
<https://www.mt-pharma.co.jp/shared/show.php?url=../e/ir/annual/index.html>

## 10-Year Financial Summary

Note: Figures for fiscal 2014 and previous fiscal years are presented in accordance with Japanese GAAP.  
Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

	FY 2008	FY 2009	FY 2010	FY 2011
<b>Financial figures (billions of yen):</b>				
Revenue	¥414.7	¥404.7	¥409.5	¥407.1
Cost of sales	158.1	147.8	154.5	152.2
SG&A expenses	184.8	195.4	178.3	185.8
Operating profit	71.6	61.4	76.5	69.0
Profit attributable to owners of the Company	26.5	30.2	37.7	39.0
R&D expenses	73.1	83.0	65.7	70.2
Capital expenditures <sup>1</sup>	13.8	9.1	11.0	8.3
Depreciation and amortization	15.6	13.2	12.4	12.4
<b>Total assets</b>	<b>810.7</b>	<b>796.8</b>	<b>818.7</b>	<b>819.9</b>
<b>Total equity</b>	<b>666.2</b>	<b>676.8</b>	<b>695.9</b>	<b>721.4</b>
Net cash provided by operating activities	50.5	23.9	59.0	37.2
Net cash used in investing activities	(74.5)	(61.2)	(7.6)	(63.2)
Net cash used in financing activities	(15.9)	(17.1)	(15.4)	(17.1)
Cash and cash equivalents at the end of the year	116.9	62.9	97.8	54.3
<b>Per share amounts (yen):</b>				
Profit attributable to owners of the Company	47.28	53.91	67.27	69.54
Equity attributable to owners of the Company	1,162.69	1,194.79	1,230.16	1,275.85
Cash dividends	28.00	28.00	28.00	35.00
<b>Financial indicators (%):</b>				
Cost of sales ratio	38.1	36.5	37.7	37.4
SG&A expenses ratio	44.6	48.3	43.6	45.6
Operating margin	17.3	15.2	18.7	17.0
R&D expenses ratio	17.6	20.5	16.1	17.3
Ratio of equity attributable to owners of the Company to total assets	80.5	84.1	84.3	87.3
ROE	4.1	4.6	5.5	5.5
Dividend payout ratio	43.0 <sup>2</sup>	39.0 <sup>2</sup>	41.6	50.3
<b>Others:</b>				
Number of employees	10,030	9,266	9,198	9,180
Number of common stock issued (thousands)	561,417	561,417	561,417	561,417

1. Property, plant and equipment and intangible fixed assets on an accrual basis.

2. Dividend payout ratio is calculated using net income less amortization of goodwill.

3. In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
¥419.1	¥412.6	¥415.1	¥425.7	¥423.9	¥ 433.8
166.4	169.3	169.5	155.8	164.3	169.7
183.8	184.1	178.3	96.3	98.3	104.0
68.9	59.1	67.1	81.8	94.0	77.2
41.8	45.3	39.5	59.3	71.2	57.9
66.5	70.4	69.6	64.6	64.7	79.0
11.4	14.7	17.3	12.1	14.4	6.0
8.4	9.1	9.0	10.3	10.4	11.5
866.7	886.4	929.3	958.4	984.5	1,047.6
752.9	777.8	800.4	826.3	871.4	894.8
60.5	69.8	68.1	80.8	59.7	66.9
(34.9)	(24.3)	(59.8)	(42.2)	(10.5)	(19.1)
(23.6)	(21.0)	(21.8)	(22.2)	(24.4)	(32.5)
58.7	84.9	73.3	88.9	113.2	127.0
74.67	80.92	70.41	105.72	127.03	103.35
1,333.22	1,365.52	1,406.41	1,453.71	1,533.91	1,574.26
40.00	40.00	42.00	46.00	52.00	66.00 <sup>3</sup>
39.7	41.0	40.9	36.6	38.8	39.1
43.9	44.6	43.0	22.6	23.2	24.0
16.5	14.3	16.2	19.2	22.2	17.8
15.9	17.1	16.8	15.2	15.3	18.2
86.3	86.4	84.9	85.1	87.4	84.3
5.7	6.0	5.1	7.4	8.5	6.6
53.6	49.4	59.6	43.5	40.9	63.9
8,835	9,065	8,457	8,125	7,280	7,187
561,417	561,417	561,417	561,417	561,417	561,417

# Management's Discussion and Analysis

## Results of Operations (amounts less than ¥100 million are rounded down)

### Revenue

In fiscal 2017, revenue increased by ¥9.8 billion year on year, to ¥433.8 billion. The pharmaceuticals segment, which is the Company's only segment, comprises domestic ethical drugs, overseas ethical drugs, royalty revenue, etc., OTC products, and others in pharmaceuticals.

Revenue from domestic ethical drugs decreased by ¥4.8 billion year on year, to ¥309.3 billion. Revenue from Simponi, Tenelia, Canaglu, and other priority products in fiscal 2017 increased ¥7.4 billion year on year, to ¥154.4 billion. However, overall revenue from vaccines declined ¥3.8 billion, to ¥35.0 billion, and revenue from long-listed drugs also declined. In addition, in October 2017 the Company transferred the generic drugs business to Nipro, and this transfer had the effect of reducing revenue by ¥7.5 billion. On the other hand, revenue from overseas ethical drugs increased ¥15.8 billion, to ¥38.5 billion, with a strong contribution from Radicava, which was launched in the U.S. in August 2017.

Royalty revenue, etc., was down ¥3.0 billion year on year, to ¥79.1 billion. Royalty revenue from Gilenya, which is licensed to Novartis, of Switzerland, increased ¥3.9 billion, to ¥57.7 billion. However, royalty revenue from Invokana and its fixed-dose combination with metformin, which are licensed to Janssen Pharmaceuticals, of the U.S., declined ¥4.8 billion, to ¥13.9 billion. Furthermore, in the previous fiscal year, the license agreement with Biogen, of the U.S., related to MT-1303 (expected indication: autoimmune diseases) was terminated, and as a result the balance of the upfront payment, which had been recorded in liabilities as deferred revenue, was recognized as revenue in a lump sum. Non-recurring revenue declined.

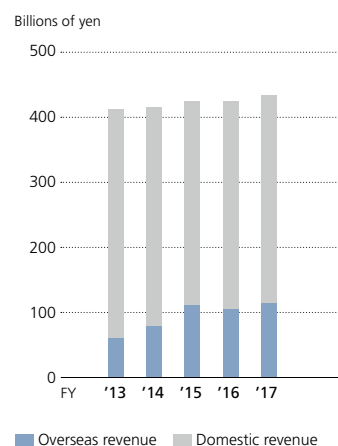
In addition, revenue from OTC products was up ¥0.3 billion, to ¥3.7 billion, and revenue from the others category of pharmaceuticals operations increased ¥1.6 billion, to ¥3.0 billion.

Overseas revenue rose ¥9.3 billion, to ¥112.9 billion, and the overseas revenue ratio was up 1.6 percentage points, to 26.0%.

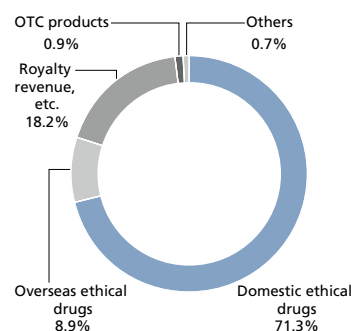
### Core Operating Profit

In applying IFRS, the Company has introduced "core operating profit" as a major profit item showing recurring profitability and has positioned it as an important management indicator. Core operating profit is operating profit after the deduction of non-recurring income and loss items (non-recurring items) as defined by the Company. The Company assumes that non-recurring items will include such items as income and losses associated with business transfers, restructuring expenses, impairment losses on intangible assets associated with products, and losses on disasters.

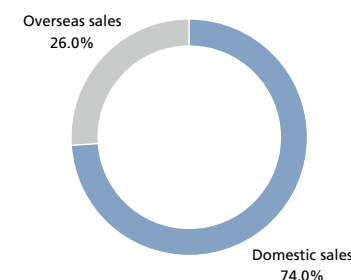
### Revenue



### Percentage of Revenue by Business



### Percentage of Revenue by Region



	FY 2016	FY 2017	Change	% Change
Revenue	¥423.9	¥433.8 (100.0%)	¥+ 9.8	+ 2.3%
Domestic ethical drugs	314.2	309.3 (71.3 )	- 4.8	- 1.5
Overseas ethical drugs	22.6	38.5 (8.9 )	+ 15.8	+ 70.0
Royalty revenue, etc.	82.2	79.1 (18.2 )	- 3.0	- 3.8
OTC products	3.4	3.7 (0.9 )	+ 0.3	+ 9.3
Others	1.4	3.0 (0.7 )	+ 1.6	+ 113.9
Revenue by region:				
Domestic	320.3	320.8 (74.0 )	+ 0.5	+ 0.2
Overseas	103.6	112.9 (26.0 )	+ 9.3	+ 9.0

Note: Figures in parentheses are percentages of revenue.



## Revenue of Major Ethical Drugs

	Billions of yen		Change	% Change
	FY 2016	FY 2017		
Domestic ethical drugs				
Priority Products in Fiscal 2017	¥146.9	¥154.4	¥+ 7.4	+ 5.1%
Remicade	66.8	64.6	- 2.1	- 3.2
Simponi	24.9	32.1	+ 7.2	+ 29.0
Tenelia	16.5	17.5	+ 0.9	+ 5.8
Talion	18.9	16.9	- 2.0	- 10.7
Lexapro	11.2	12.7	+ 1.4	+ 13.2
Canaglu	3.4	5.6	+ 2.1	+ 60.8
Imusera	4.9	4.7	- 0.1	- 3.5
Vaccines	38.9	35.0	- 3.8	- 10.0
Influenza vaccine	12.7	9.9	- 2.8	- 22.2
Tetrabik	9.9	8.7	- 1.1	- 12.0
Varicella vaccine	5.4	5.2	- 0.1	- 3.2
JEBIK V	3.9	5.2	+ 1.2	+ 30.4
Mearubik	5.9	5.0	- 0.8	- 15.0
Overseas ethical drugs				
Radicava	—	12.3	12.3	—
Royalty revenue, etc.				
Royalty from Gilenya	53.7	57.7	3.9	+ 7.4
Royalty from Invokana	18.8	13.9	- 4.8	- 25.8

In fiscal 2017, core operating profit decreased ¥15.9 billion year on year, to ¥78.5 billion. Priority products in fiscal 2017 recorded growth, and the launch of Radicava in the U.S. made a major contribution. However, revenue from long-listed products and royalty revenue declined, and R&D expenses increased significantly due to such factors as the advancement of candidates to late-stage development and the acquisition of NeuroDerm, of Israel. SG&A expenses increased ¥5.7 billion, to ¥104.0 billion. In addition, R&D expenses increased ¥14.3 billion, to ¥79.0 billion, and the R&D expenses ratio was up 2.9 percentage points year on year, to 18.2%.

The cost of sales ratio was up 0.3 percentage point, to 39.1%, but gross profit rose ¥4.5 billion, to ¥264.1 billion, due to the increase in revenue.

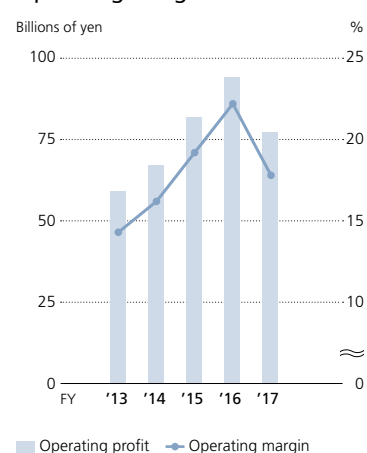
## Operating Profit

In fiscal 2017, operating profit was down ¥16.7 billion year on year, to ¥77.2 billion. Core operating profit declined, and in non-recurring items, impairment loss and restructuring and other expenses exceeded the proceeds from transfer of business and gain on sales of property, plant and equipment. Non-recurring items in fiscal 2017 were a loss of ¥1.2 billion, compared with a loss of ¥0.4 billion in the previous fiscal year. The operating margin declined 4.4 percentage points, to 17.8%.

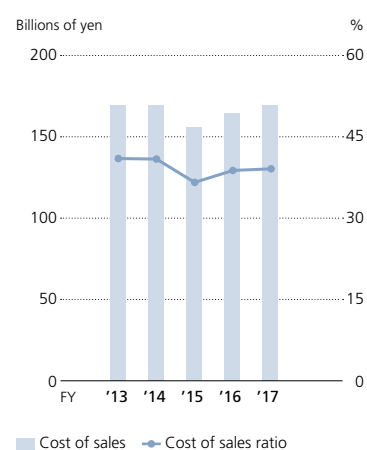
	Billions of yen		Change	% Change
	FY 2016	FY 2017		
Cost of sales	¥164.3	¥169.7 (39.1%)	¥+ 5.3	+ 3.3%
Gross profit	259.5	264.1 (60.9 )	+ 4.5	+ 1.7
SG&A expenses	98.3	104.0 (24.0 )	+ 5.7	+ 5.9
R&D expenses	64.7	79.0 (18.2 )	+ 14.3	+ 22.1
Core operating profit	94.5	78.5 (18.1 )	- 15.9	- 16.9
Operating profit	94.0	77.2 (17.8 )	- 16.7	- 17.9

Note: Figures in parentheses are percentages of revenue.

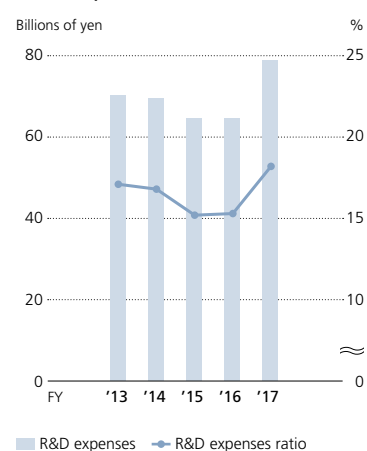
## Operating Profit / Operating Margin



## Cost of Sales / Cost of Sales Ratio



## R&D Expenses / R&D Expenses Ratio



### Profit Attributable to Owners of the Company

As a result of the decrease in operating profit, in fiscal 2017 profit attributable to owners of the Company was down ¥13.3 billion year on year, to ¥57.9 billion.

### Financial Position (amounts less than ¥100 million are rounded down)

#### Total Assets, Total Liabilities, and Total Equity

Total assets at the end of the fiscal year were ¥1,047.6 billion, an increase of ¥63.0 billion from the previous fiscal year-end.

Total non-current assets increased ¥161.3 billion year on year, to ¥462.0 billion. Due to such factors as the acquisition of NeuroDerm, intangible assets increased ¥139.7 billion and goodwill rose ¥9.9 billion. Investments in associates and joint ventures accounted for using equity method increased ¥16.2 billion due to the acquisition of shares of BIKEN Co., as an equity-method affiliate.

Total current assets declined ¥98.2 billion year on year, to ¥585.5 billion. Other financial assets declined ¥107.5 billion due to the implementation of strategic investment, as described above.

Total liabilities were up ¥39.6 billion from the end of the previous fiscal year, to ¥152.7 billion. Deferred tax liabilities increased ¥30.7 billion, and income taxes payable rose ¥13.2 billion.

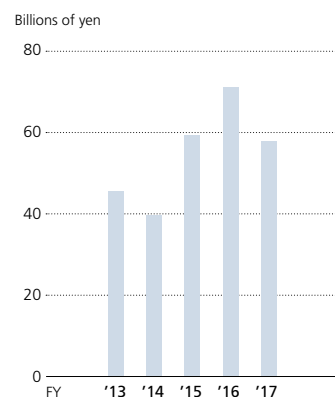
Total equity at the end of the period was up ¥23.3 billion from the end of the previous fiscal year, to ¥894.8 billion. Profit attributable to owners of the Company was ¥57.9 billion, while dividends paid was ¥37.0 billion. As a result, retained earnings increased ¥28.6 billion.

Consequently, the ratio of equity attributable to owners of the Company to total assets declined 3.1 percentage points, to 84.3%.

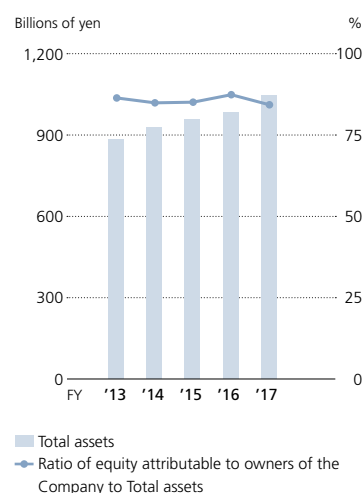
	FY 2016	FY 2017	Change	% Change
Total assets	¥984.5	¥1,047.6 (100.0%)	¥+ 63.0	+ 6.4%
Non-current assets	300.7	462.0 (44.1 )	+ 161.3	+ 53.6
Current assets	683.7	585.5 (55.9 )	- 98.2	- 14.4
Total liabilities	113.1	152.7 (14.6 )	+ 39.6	+ 35.1
Non-current liabilities	24.7	55.4 (5.3 )	+ 30.7	+ 124.4
Current liabilities	88.4	97.3 (9.3 )	+ 8.9	+ 10.1
Total equity	871.4	894.8 (85.4 )	+ 23.3	+ 2.7

Note: Figures in parentheses are percentages of total assets or percentages of the total of liabilities and equity.

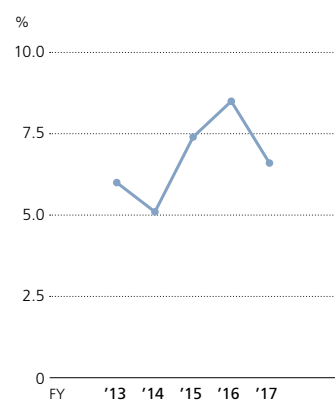
### Profit Attributable to Owners of the Company



### Total Assets / Ratio of Equity Attributable to Owners of the Company to Total Assets



### ROE



## Cash Flows

Net cash provided by operating activities was ¥66.9 billion. Inflows, which included profit before income tax of ¥78.7 billion, exceeded outflows, which included income taxes paid of ¥13.8 billion.

Net cash used in investing activities was ¥19.1 billion. Principal items included the acquisition of NeuroDerm and the purchase of intangible assets.

Net cash used in financing activities was ¥32.5 billion. Dividends paid was ¥37.0 billion.

As a result, net cash inflows for the fiscal year were ¥13.8 billion, and the balance of cash and cash equivalents at fiscal year-end was ¥127.0 billion.

	FY 2016	FY 2017	Change
Net cash provided by operating activities	¥59.7	¥+ 66.9	+ 7.1
Net cash used in investing activities	(10.5)	(19.1)	- 8.6
Net cash used in financing activities	(24.4)	(32.5)	- 8.0
Cash and cash equivalents at the end of the year	113.2	127.0	+13.8

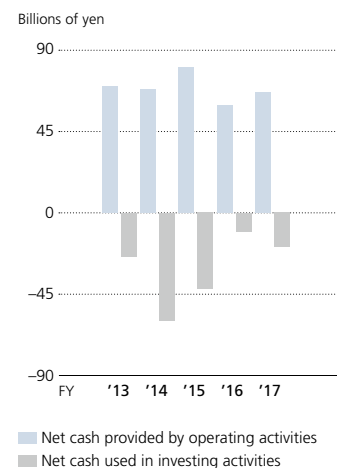
## Dividends

Mitsubishi Tanabe Pharma's basic policy calls for providing a stable and continuous return to shareholders while striving to increase enterprise value by aggressively implementing strategic investment and R&D investment to achieve sustained growth.

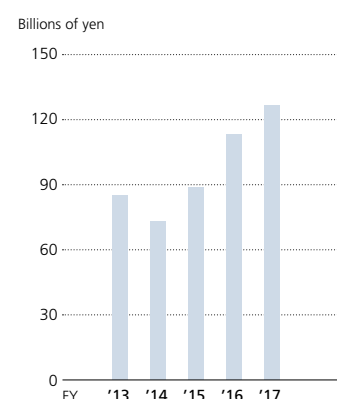
Under Medium-Term Management Plan 16–20, for which fiscal 2016 was the first year, the Company is working to enhance return to shareholders, aiming for a dividend payout ratio of 50% under the application of IFRS.

On October 1, 2017, the Company marked the 10th anniversary of its founding. To commemorate this milestone, the Company implemented a commemorative dividend of ¥10 per share at the time of the interim dividend in fiscal 2017. In fiscal 2017, core operating profit, operating profit, and profit attributable to owners of the Company all declined, but in accordance with the basic policy on shareholder return, the Company set annual dividends at ¥56.0 per share, an increase of ¥4.0 per share (not including the commemorative dividend). Including the commemorative dividend, the annual dividend was ¥66.0 per share, and the dividend payout ratio was 63.9%, compared with 40.9% in the previous fiscal year.

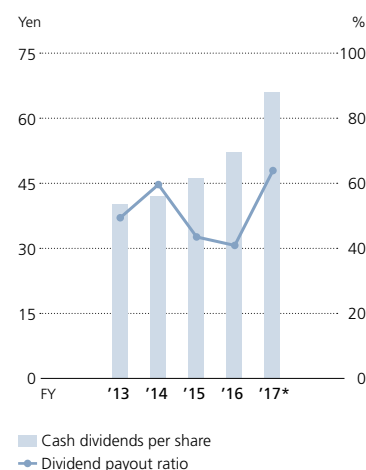
## Net Cash Provided by Operating Activities / Net Cash Used in Investing Activities



## Cash and Cash Equivalents at the End of the Year



## Cash Dividends per Share / Dividend Payout Ratio



\* In commemoration of the 10th anniversary of its founding, the Company implemented a commemorative dividend of ¥10 per share in fiscal 2017.

## Operational Risks

The following are major risks that have the potential to significantly influence the financial position or performance of the Mitsubishi Tanabe Pharma Group. In recognition of these risks, the Mitsubishi Tanabe Pharma Group works to prevent the occurrence of risk events and to implement responses in the event of their occurrence. Items in this document relating to the future are based on the judgment of the Mitsubishi Tanabe Pharma Group as of the end of fiscal 2017 (March 31, 2018).

### 1 Risks Related to R&D

The R&D of drugs requires lengthy investment and the commitment of substantial resources. In addition, pharmaceuticals cannot be sold if approval is not obtained under the legal and regulatory system of each country. Accordingly, it is difficult to accurately predict whether or not products will be launched and the timing of those launches. Furthermore, if problems with effectiveness or safety are found, or if a drug candidate is not expected to have economic value, development could be halted. Due to these types of factors, it is possible that R&D investment will not lead to the launch of new drugs, or that the initially-projected level of sales will not be achievable.

### 2 Risks Related to Adverse Drug Reactions

In the event of the appearance of serious adverse drug reactions or safety problems with a pharmaceutical, there could be a sales suspension, recall, etc.

### 3 Risks Related to Insurance Systems

The sale of pharmaceuticals is significantly influenced by various health insurance systems, such as medical fees, drug price standards, etc. In the event of revisions to the drug price standard that is the official price of pharmaceuticals or to the drug price system; revisions to medical fees or revisions to various health insurance systems that influence trends in the use of pharmaceuticals by medical institutions; or similar revisions to the standards and systems employed overseas, there could be an influence on the Mitsubishi Tanabe Pharma Group's business activities.

### 4 Risks Related to Changes in the Market Environment

Due to the launch of competing products or generic drugs, the launch of new methods of treatment or new technologies, the announcement of new evidence, etc., there could be a relative change in the position of the Company's pharmaceutical products in clinical use.

### 5 Risks Related to Intellectual Property

If the Mitsubishi Tanabe Pharma Group's business activities conflict with the intellectual property rights of other parties, it is possible that there could be a legal dispute or that the activities could be suspended. Also, in the event that the Mitsubishi Tanabe Pharma Group believes that its intellectual property rights have been infringed upon by another party, it is possible that the Mitsubishi Tanabe Pharma Group might file lawsuits.

### 6 Risks Related to Alliances with Other Companies

The Mitsubishi Tanabe Pharma Group works with other companies in joint research and development, product in-licensing and out-licensing, joint promotion and marketing, and the performance of various operations on a contract basis. In the future, if contracts with alliance partners are changed or canceled, if the management environment of alliance partners worsens, if the management policies of alliance partners change, or if the supply of products from these companies is delayed or suspended, there could be an adverse influence on the Mitsubishi Tanabe Pharma Group's business activities.

### 7 Risks Related to Business Acquisitions, Etc.

The Mitsubishi Tanabe Pharma Group conducts business development activities for sustained growth, and business acquisitions, etc., are implemented as a means to that end. It is possible that the expected acquisition effects, etc., will not be achieved due to such factors as changes to laws or regulations of various countries, political instability, uncertainty of economic trends, differences in business practices, changes in the economic environment or businesses of acquired businesses, etc.

### 8 Risks Related to Stable Supply

Due to the emergence of technical or legal / regulatory problems in the Mitsubishi Tanabe Pharma Group's internal or external production, distribution sales, etc., or to operational stoppages, etc., resulting from fires or other disasters, there could be a suspension of or substantial delay in the supply of products.

## 9 Risks Related to Financial Market Conditions and Exchange Rate Fluctuations

The Mitsubishi Tanabe Pharma Group receives and delivers money related to exports and imports of certain pharmaceuticals and raw materials and also receives from overseas patent-right usage fees related to out-licensed pharmaceuticals. In addition, the Mitsubishi Tanabe Pharma Group has overseas assets, including overseas consolidated subsidiaries. Accordingly, substantial fluctuations in financial market conditions or exchange rates could lead to declines in revenue, increases in procurement costs, the generation of foreign exchange losses, etc., declines in the assets of overseas consolidated subsidiaries, and the recording of loss on sales or valuation loss due to declines in the market prices of stocks, bonds, etc.

## 10 Risks Related to the Environment

In the event that chemical substances, etc., used in business activities have a serious influence on the environment, expenses required for environmental improvement could arise, social trust could decline, or liability for damages, etc., could arise.

## 11 Risks Related to Lawsuits

- (1) The Mitsubishi Tanabe Pharma Group could face lawsuits in regard to adverse drug reactions, product liability, labor problems, fair trade, etc.
- (2) For “the Special Relief Law Concerning the Payment of Benefits to Relieve the Patients of Hepatitis C Infected through Specified Fibrinogen Preparations and Specified Blood-Coagulation Factor IX Preparations Contaminated by Hepatitis C Virus,” which was put into effect in January 2008, the time limit for filing a claim for benefits was extended to January 2023. Accordingly, there could be an increase in the number of people who receive payment of benefits, etc.

## 12 Risks Related to Information

In the event of a leakage of the confidential information of the Mitsubishi Tanabe Pharma Group or of obstruction of business due to inappropriate handling of information, system deficiencies, cyberattacks, etc., the Mitsubishi Tanabe Pharma Group could experience a loss of its competitive strength, a decline in social trust, etc.

## 13 Risks Related to Overseas Business Development

Substantial investment is necessary to expand and advance overseas operations, and it is possible that, due to changes in the laws and systems of various countries, the worsening of diplomatic relations, or natural disaster, etc., operations under development might be affected and the opportunity to recover that investment might be lost.

## 14 Risks Related to Major Disasters, Etc.

Due to a major disaster, pandemic, terrorist incident, or secondary disaster, there could be a suspension or significant delay in the supply of products, a delay in R&D plans, etc.

## 15 Relationship with Parent Company and Other Group Companies

In regard to transactions between the Company and its parent company, Mitsubishi Chemical Holdings (MCHC), or companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Mitsubishi Tanabe Pharma Group in order to maximize the benefit to all of the Company's shareholders. Transactions with a high degree of importance are implemented after the Board of Directors conducts sufficient deliberations and gives its approval.

In the event that there is a change in the capital relationship with the MCHC Group, the Mitsubishi Tanabe Pharma Group's business activities could be affected.

## Consolidated Statement of Income

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

Millions of yen

	FY 2016	FY 2017
<b>Revenue</b>	¥423,977	¥433,855
<b>Cost of sales</b>	164,397	169,750
<b>Gross profit</b>	259,580	264,105
Selling, general and administrative expenses	98,302	104,055
Research and development expenses	64,783	79,083
Amortization of intangible assets associated with products	1,528	2,451
Other income	974	6,661
Other expenses	1,882	7,915
Share of profit of associates and joint ventures accounted for using equity method	24	23
<b>Operating profit</b>	94,083	77,285
Financial income	2,212	1,881
Financial expenses	236	402
Profit before income tax	96,059	78,764
Income tax expenses	27,137	24,772
<b>Profit for the year</b>	¥ 68,922	¥ 53,992
<b>Profit attributable to:</b>		
Owners of the Company	¥ 71,263	¥ 57,963
Non-controlling interests	(2,341)	(3,971)
Profit for the year	¥ 68,922	¥ 53,992
<b>Earnings per share</b>		
Basic earnings per share (yen)	¥ 127.03	¥ 103.35
Diluted earnings per share (yen)	—	103.35

## Consolidated Statement of Comprehensive Income

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

	Millions of yen	
	FY 2016	FY 2017
<b>Profit for the year</b>	¥ 68,922	¥ 53,992
<b>Other comprehensive income</b>		
Items that will not be reclassified subsequently to profit or loss		
Net changes in financial assets measured at fair value through other comprehensive income	(2,229)	4,542
Remeasurements of defined benefit plans	3,658	5,823
Subtotal	1,429	10,365
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(1,020)	(8,798)
Effective portion of changes in fair value of cash flow hedges	(4)	1,033
Share of other comprehensive income of associates and joint ventures accounted for using equity method	(18)	28
Subtotal	(1,042)	(7,737)
Other comprehensive income (loss), net of tax	387	2,628
<b>Comprehensive income</b>	¥ 69,309	¥ 56,620
<b>Comprehensive income (loss) attributable to:</b>		
Owners of the Company	¥ 71,915	¥ 60,861
Non-controlling interests	(2,606)	(4,241)
Comprehensive income	¥ 69,309	¥ 56,620

# Consolidated Statement of Financial Position

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

Millions of yen

	FY 2016	FY 2017
<b>Assets</b>		
Non-current assets		
Property, plant and equipment	¥ 85,836	¥ 80,457
Goodwill	80,328	90,313
Intangible assets	61,209	200,940
Investments in associates and joint ventures accounted for using equity method	245	16,445
Other financial assets	51,623	46,109
Net defined benefit assets	14,769	22,711
Other non-current assets	482	379
Deferred tax assets	6,286	4,742
Total non-current assets	300,778	462,096
Current assets		
Inventories	79,168	81,998
Trade and other receivables	116,856	123,537
Other financial assets	354,255	246,733
Other current assets	9,183	6,227
Cash and cash equivalents	113,215	127,030
Subtotal	672,677	585,525
Assets held for sale	11,082	—
Total current assets	683,759	585,525
<b>Total assets</b>	<b>¥984,537</b>	<b>¥1,047,621</b>



Millions of yen

	FY 2016	FY 2017
<b>Liabilities and equity</b>		
<b>Liabilities</b>		
Non-current liabilities		
Borrowings	¥ 581	¥ 420
Other financial liabilities	2,405	2,199
Net defined benefit liabilities	1,092	868
Provisions	7,890	8,571
Other non-current liabilities	5,576	5,505
Deferred tax liabilities	7,156	37,861
Total non-current liabilities	24,700	55,424
Current liabilities		
Borrowings	127	122
Trade and other payables	35,741	35,631
Other financial liabilities	24,135	20,737
Income taxes payable	4,815	18,093
Provisions	86	1,934
Other current liabilities	20,358	20,853
Subtotal	85,262	97,370
Liabilities directly related to assets held for sale	3,145	—
Total current liabilities	88,407	97,370
Total liabilities	113,107	152,794
<b>Equity</b>		
Share capital	50,000	50,000
Capital surplus	451,187	451,228
Treasury shares	(496)	(1,045)
Retained earnings	353,427	382,122
Other components of equity	6,387	503
Total equity attributable to owners of the Company	860,505	882,808
Non-controlling interests	10,925	12,019
Total equity	871,430	894,827
<b>Total liabilities and equity</b>	¥984,537	¥1,047,621

# Consolidated Statement of Changes in Equity

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

FY 2016

Millions of yen

	Equity attributable to owners of the Company						
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity		
					Exchange differences on translation of foreign operations	Effective portion of changes in fair value of cash flow hedges	Net changes in financial assets measured at fair value through other comprehensive income
<b>Balance as of April 1, 2016</b>	¥50,000	¥451,186	¥(494)	¥304,931	¥(3,911)	¥ 4	¥13,832
Profit for the year	—	—	—	71,263	—	—	—
Other comprehensive income	—	—	—	—	(755)	(4)	(2,229)
<b>Total comprehensive income</b>	—	—	—	71,263	(755)	¥(4)	(2,229)
Acquisition of treasury shares	—	—	(2)	—	—	—	—
Disposal of treasury shares	—	1	0	—	—	—	—
Dividends	—	—	—	(26,927)	—	—	—
Share-based payments	—	—	—	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	4,160	—	—	(502)
Transfer from other components of equity to non-financial assets	—	—	—	—	—	—	—
Total contributions by and distributions to owners	—	1	(2)	(22,767)	—	—	(502)
Issuance of new shares	—	—	—	—	—	—	—
Changes in ownership interests in subsidiaries and others	—	—	—	—	—	—	—
<b>Total transactions with owners</b>	—	1	(2)	(22,767)	—	—	(502)
<b>Balance as of March 31, 2017</b>	¥50,000	¥451,187	¥(496)	¥353,427	¥(4,666)	—	¥11,101

FY 2017

Millions of yen

	Equity attributable to owners of the Company						
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity		
					Exchange differences on translation of foreign operations	Effective portion of changes in fair value of cash flow hedges	Net changes in financial assets measured at fair value through other comprehensive income
<b>Balance as of April 1, 2017</b>	¥50,000	¥451,187	¥ (496)	¥353,427	¥ (4,666)	—	¥11,101
Profit for the year	—	—	—	57,963	—	—	—
Other comprehensive income	—	—	—	—	(8,528)	¥ 1,033	4,542
<b>Total comprehensive income</b>	—	—	—	57,963	(8,528)	1,033	4,542
Acquisition of treasury shares	—	—	(549)	—	—	—	—
Disposal of treasury shares	—	0	0	—	—	—	—
Dividends	—	—	—	(37,017)	—	—	—
Share-based payments	—	41	—	—	—	—	—
Transfer from other components of equity to retained earnings	—	—	—	7,749	—	—	(1,926)
Transfer from other components of equity to non-financial assets	—	—	—	—	—	(1,033)	—
Total contributions by and distributions to owners	—	41	(549)	(29,268)	—	(1,033)	(1,926)
Issuance of new shares	—	—	—	—	—	—	—
Changes in ownership interests in subsidiaries and others	—	—	—	—	—	—	—
<b>Total transactions with owners</b>	—	41	(549)	(29,268)	—	¥(1,033)	(1,926)
<b>Balance as of March 31, 2018</b>	¥50,000	¥451,228	¥(1,045)	¥382,122	¥(13,194)	—	¥13,717

FY 2016

Millions of yen

	Equity attributable to owners of the Company					
	Other components of equity			Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Remeasurements of defined benefit plans	Share of other comprehensive income of associates and joint ventures accounted for using equity method	Total			
<b>Balance as of April 1, 2016</b>	—	¥(30)	¥ 9,895	¥815,518	¥10,798	¥826,316
Profit for the year	—	—	—	71,263	(2,341)	68,922
Other comprehensive income	¥ 3,658	(18)	652	652	(265)	387
<b>Total comprehensive income</b>	<b>3,658</b>	<b>(18)</b>	<b>652</b>	<b>71,915</b>	<b>(2,606)</b>	<b>69,309</b>
Acquisition of treasury shares	—	—	—	(2)	—	(2)
Disposal of treasury shares	—	—	—	1	—	1
Dividends	—	—	—	(26,927)	(80)	(27,007)
Share-based payments	—	—	—	—	—	—
Transfer from other components of equity to retained earnings	(3,658)	—	(4,160)	—	—	—
Transfer from other components of equity to non-financial assets	—	—	—	—	—	—
Total contributions by and distributions to owners	(3,658)	—	(4,160)	(26,928)	(80)	(27,008)
Issuance of new shares	—	—	—	—	2,813	2,813
Changes in ownership interests in subsidiaries and others	—	—	—	—	2,813	2,813
<b>Total transactions with owners</b>	<b>¥(3,658)</b>	<b>—</b>	<b>(4,160)</b>	<b>(26,928)</b>	<b>2,733</b>	<b>(24,195)</b>
<b>Balance as of March 31, 2017</b>	<b>—</b>	<b>¥(48)</b>	<b>¥ 6,387</b>	<b>¥860,505</b>	<b>¥10,925</b>	<b>¥871,430</b>

FY 2017

Millions of yen

	Equity attributable to owners of the Company					
	Other components of equity			Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Remeasurements of defined benefit plans	Share of other comprehensive income of associates and joint ventures accounted for using equity method	Total			
<b>Balance as of April 1, 2017</b>	—	¥(48)	¥ 6,387	¥860,505	¥10,925	¥871,430
Profit for the year	—	—	—	57,963	(3,971)	53,992
Other comprehensive income	¥5,823	28	2,898	2,898	(270)	2,628
<b>Total comprehensive income</b>	<b>5,823</b>	<b>28</b>	<b>2,898</b>	<b>60,861</b>	<b>(4,241)</b>	<b>56,620</b>
Acquisition of treasury shares	—	—	—	(549)	—	(549)
Disposal of treasury shares	—	—	—	0	—	0
Dividends	—	—	—	(37,017)	(138)	(37,155)
Share-based payments	—	—	—	41	—	41
Transfer from other components of equity to retained earnings	(5,823)	—	(7,749)	—	—	—
Transfer from other components of equity to non-financial assets	—	—	(1,033)	(1,033)	—	(1,033)
Total contributions by and distributions to owners	(5,823)	—	(8,782)	(38,558)	(138)	(38,696)
Issuance of new shares	—	—	—	—	5,473	5,473
Changes in ownership interests in subsidiaries and others	—	—	—	—	5,473	5,473
<b>Total transactions with owners</b>	<b>¥(5,823)</b>	<b>—</b>	<b>(8,782)</b>	<b>(38,558)</b>	<b>5,335</b>	<b>(33,223)</b>
<b>Balance as of March 31, 2018</b>	<b>—</b>	<b>¥(20)</b>	<b>¥ 503</b>	<b>¥882,808</b>	<b>¥12,019</b>	<b>¥894,827</b>

# Consolidated Statement of Cash Flows

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

Millions of yen

	FY 2016	FY 2017
<b>Cash flows from operating activities:</b>		
Profit before income tax	¥96,059	¥78,764
Depreciation and amortization	10,454	11,535
Impairment losses	185	3,791
Interest and dividend income	(1,864)	(1,238)
Share of profits of associates and joint ventures accounted for using equity method	(24)	(23)
Loss (gain) on sales of property, plant and equipment	(67)	(2,287)
Loss (gain) on sales of investments in subsidiaries	—	(3,565)
Restructuring loss	484	2,144
Decrease (increase) in trade and other receivables	(2,030)	(6,111)
Decrease (increase) in inventories	(7,842)	(2,683)
Increase (decrease) in trade and other payables	4,997	56
Increase (decrease) in provisions	(1,267)	2,529
Decrease (increase) in net defined benefit assets	(863)	1,153
Increase (decrease) in net defined benefit liabilities	(185)	(948)
Increase (decrease) in deferred income	(7,265)	(480)
Other	(331)	(2,965)
Subtotal	90,441	79,672
Interest received	1,211	522
Dividends received	737	772
Interest paid	(178)	(160)
Income taxes paid	(32,426)	(13,863)
Net cash flows provided by operating activities	59,785	66,943
<b>Cash flows from investing activities:</b>		
Payments into time deposits	(684)	(3,742)
Proceeds from withdrawal of time deposits	118,468	8,407
Purchase of property, plant and equipment	(14,271)	(6,416)
Proceeds from sales of property, plant and equipment	2,325	3,703
Purchase of intangible assets	(6,658)	(22,034)
Purchase of investments	(309,930)	(391,749)
Proceeds from sales and redemption of investments	197,454	428,741
Proceeds from withdrawal of deposits	—	70,000
Proceeds from sales of subsidiaries	—	10,803
Purchase of subsidiaries	—	(119,724)
Proceeds from transfer of business	3,056	3,000
Other	(326)	(167)
Net cash flows used in investing activities	(10,566)	(19,178)
<b>Cash flows from financing activities:</b>		
Purchase of treasury shares	(2)	(549)
Proceeds from stock issuance to non-controlling interests	2,813	5,409
Dividends paid	(26,927)	(37,017)
Other	(292)	(344)
Net cash flows used in financing activities	(24,408)	(32,501)
Effect of exchange rate changes on cash and cash equivalents	(507)	(1,457)
Net increase in cash and cash equivalents	24,304	13,807
Increase (decrease) in cash and cash equivalents resulting from transfer to assets held for sale	(8)	8
Cash and cash equivalents at the beginning of the year	88,919	113,215
Cash and cash equivalents at the end of the year	¥113,215	¥127,030

## Explanation of Terms

### ■ Appropriate usage of pharmaceuticals

A cycle under which a prescription is determined for the optimal drug and formulation with an appropriate administration / dosage in accordance with the patient's condition; the prescription is dispensed; the patient sufficiently understands the explanation of the drug; the patient takes the drug correctly; the effects and side effects are evaluated; and feedback is provided for the next prescription.

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### ■ Biologics

A general term for products that use substances of biological origin or biological functionality, including vaccines, plasma fractionation products and other protein drugs, therapeutic antibodies, nucleic acid drugs, and cells for use in regenerative medicine.

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### ■ CMC

Chemistry, manufacturing, and control research: Comprehensive research supporting pharmaceutical manufacturing and quality, such as research into manufacturing and formulation of pharmaceutical ingredients and analytical research involving the evaluation of the quality of pharmaceutical ingredients and pharmaceuticals.

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### ■ Generic drugs

Drugs that are launched after a new drug's patent expires, have the same active ingredients in the same amounts, and have equivalent effects. In Europe and the U.S., many prescriptions are written in the generic name, which is the name of the active ingredient, rather than the product name, and accordingly these products are called generic drugs.

### ■ Long-listed drugs

Original drugs that have gone off patent and for which generic drugs are on sale.

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### ■ MR (abbreviation for medical representative)

As sales representatives of pharmaceutical companies, MRs visit medical institutions and collect and provide information related to pharmaceutical quality efficacy, safety, etc., in order to promote appropriate usage of pharmaceuticals.

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### ■ POC (abbreviation for proof of concept)

Confirmation of the efficacy and safety of new drug candidate substances in humans at the R&D stage.

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### ■ QOL (abbreviation for quality of life)

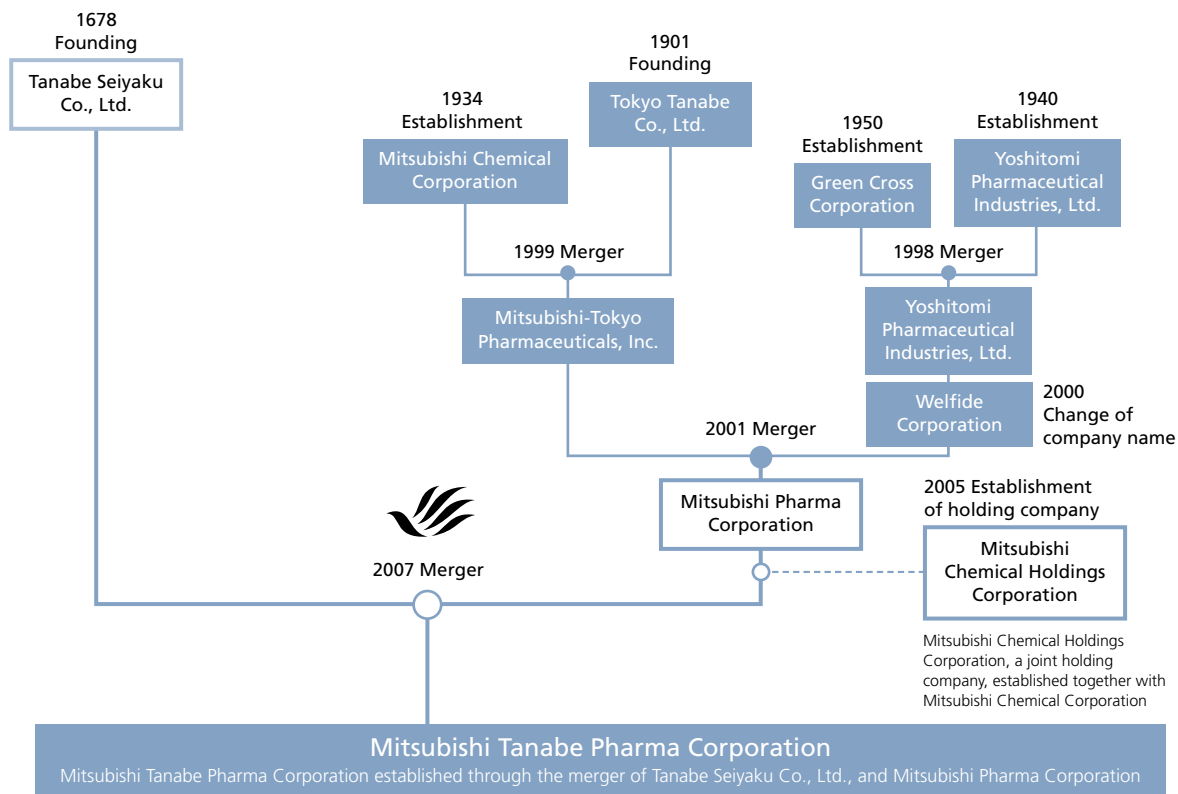
Benchmark that addresses whether patients can enjoy their daily lives with a sense of fulfillment and satisfaction, without a decline in their quality of life, including not only the effects during treatment but also after treatment is completed.

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### ■ Unmet medical needs

Medical needs for which there are no effective treatments or drugs.

## History



## Mitsubishi Tanabe Pharma's History since Its Establishment

▶ New product launches

### 2007

- October** ▶ Establishment of Mitsubishi Tanabe Pharma through the merger of Tanabe Seiyaku and Mitsubishi Pharma (President and Representative Director, Natsuki Hayama)

### 2008

- April** ▶ Establishment of Tanabe Seiyaku Hanbai, a subsidiary handling generic drugs
- May** ▶ Announcement of Corporate Behavior Charter and Medium-Term Management Plan 08–10: Dynamic Synergy for 2015
- August** ▶ Choseido Pharmaceutical became a subsidiary, start of comprehensive, equity-based alliance, centered on the generic drugs business
- October** ▶ Merger of MP-Technopharma and Tanabe Seiyaku Yamaguchi, establishment of Mitsubishi Tanabe Pharma Factory

### 2009

- June** ▶ Michihiro Tsuchiya became president and representative director
- October** ▶ Head Office relocated to Kitahama, Chuo-ku, Osaka
- November** ▶ Acquisition of domestic sales rights from Kureha for Kremezin, a treatment for chronic kidney disease

### 2010

- September** ▶ Acquisition by Novartis, of Switzerland, of approval in the U.S. for Gilenya, a treatment agent for multiple sclerosis

### 2011

- March** ▶ Acquisition by Novartis, of Switzerland, of approval in Europe for Gilenya, a treatment agent for multiple sclerosis
- April** ▶ Transfer of domestic sales of Kremezin, a treatment for chronic kidney disease, from Daiichi Sankyo to the Company

- August** ▶ Launch of Lexapro, an anti-depressant, and start of joint sales with Mochida Pharmaceutical
- September** ▶ Launch of Simponi, a treatment agent for RA, and start of joint sales with Janssen Pharmaceutical K.K.
- October** ▶ Announcement of Medium-Term Management Plan 11–15: New Value Creation
- November** ▶ Launch of Imusera, a treatment agent for MS
- ▶ Launch of Telavic, a treatment agent for chronic hepatitis C

## 2012

- March** ▶ Conclusion of strategic joint sales agreement with Daiichi Sankyo for Tenelia and Canaglu, treatments for type 2 diabetes mellitus
- ▶ Receipt of Fiscal 2012 Pharmaceutical Society of Japan Award for Drug Research and Development for fingolimod hydrochloride (Imusera), a treatment agent for MS
- May** ▶ Relocation of Tokyo Head Office to Koamicho, Nihonbashi, Chuo-ku, Tokyo
- July** ▶ Transfer of fine chemical operations to API Corporation and TAISHO TECHNOS
- September** ▶ Launch of Tenelia, a treatment agent for type 2 diabetes mellitus
- October** ▶ Establishment of Japan Blood Products Organization in joint initiative with the Japanese Red Cross Society and transfer of plasma fractionation operations
- ▶ Comprehensive consignment to Collabo-Create of distribution operations that had been handled by MP Logistics
- ▶ Dissolution of comprehensive, equity-based alliance, centered on the generic drug business, with Choseido Pharmaceutical
- ▶ Launch of Tetrabik, a pertussis-diphtheria-tetanus-inactivated polio combined vaccine

## 2013

- March** ▶ Acquisition by Janssen Pharmaceuticals, of the U.S., of approval for Invokana, a treatment agent for adult type 2 diabetes mellitus
- June** ▶ Transfer of Tanabe Europe to API Corporation
- September** ▶ Medicago, of Canada, a biopharmaceutical company, became a consolidated subsidiary

## 2014

- March** ▶ Receipt of Fiscal 2014 Pharmaceutical Society of Japan Award for Drug Research and Development for SGLT2 inhibitor canagliflozin (Canaglu), a new treatment agent for type 2 diabetes mellitus
- April** ▶ Transfer of Mitsubishi Tanabe Pharma Factory's Ashikaga Plant to CMIC HOLDINGS
- June** ▶ Masayuki Mitsuka became president and representative director
- September** ▶ Launch of Canaglu, a treatment agent for type 2 diabetes mellitus

## 2015

- March** ▶ Termination of plasma fractionation product sales agreement with Japan Blood Products Organization
- April** ▶ Relocation of Head Office to Dosho-machi, Chuo-ku, Osaka
- ▶ Transfer of Mitsubishi Tanabe Pharma Factory's Kashima Plant to Sawai Pharmaceutical
- May** ▶ Opening of Mitsubishi Tanabe Pharma Historical Museum
- ▶ Receipt of commendation at the Fiscal 2015 National Commendation for Invention for discovery of diabetes treatment agent teneligliptin (Tenelia)
- November** ▶ Announcement of Medium-Term Management Plan 16–20: Open Up the Future

## 2016

- January** ▶ Establishment of MT Pharma Singapore in Singapore
- February** ▶ Establishment of Mitsubishi Tanabe Pharma America, a pharmaceutical sales company, in the U.S.
- May** ▶ Receipt of METI Minister's Award at the Fiscal 2016 National Commendation for Invention for discovery of diabetes treatment agent canagliflozin (Canaglu)
- November** ▶ Establishment of MT Pharma (Thailand), a pharmaceutical sales company, in Thailand

## 2017

- February** ▶ Receipt of Okochi Memorial Technology Prize at the 63rd Okochi Prize awards for fingolimod hydrochloride, a treatment agent for MS
- April** ▶ Establishment of Tanabe Palm Service, which will be certified as a special subsidiary
- August** ▶ Launch of Radicava, an ALS treatment agent, in the U.S.
- September** ▶ Start of operations of BIKEN Co., a vaccine production joint venture
- ▶ Launch of Canalia (Tenelia-Canaglu combination drug), a treatment agent for type 2 diabetes mellitus
- October** ▶ Transfer of generic drugs business to Nipro
- ▶ NeuroDerm, of Israel, a pharmaceutical development company, became a consolidated subsidiary.
- November** ▶ Launch of Rupafin, a treatment agent for allergic disorders

## 2018

- February** ▶ Stelic Institute & Co., a pharmaceutical development company, became a consolidated subsidiary
- April** ▶ Establishment of Mitsubishi Tanabe Pharma Canada, a pharmaceutical sales company, in Canada
- May** ▶ Diabetes treatment agent Canagliflozin, which has a revolutionary treatment concept, won the Technology Award Grand Prize from the Japan Chemical Industry Association (JCIA)

## Corporate Data / Investor Information

As of March 31, 2018

### Corporate Data

<b>Company Name</b>	Mitsubishi Tanabe Pharma Corporation	<b>Date of Merger</b>	October 1, 2007
<b>Headquarters</b>	3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan	<b>Number of Employees</b>	7,187 (Consolidated) 4,222 (Parent company only)
<b>Incorporated</b>	December 1933		

For Further Information	Investor Relations Group	TEL: 81-6-6205-5211	FAX: 81-6-6205-5105
	Corporate Communications Department	URL: <a href="https://www.mt-pharma.co.jp/e/">https://www.mt-pharma.co.jp/e/</a>	

### Group Companies ■ Consolidated subsidiary ■ Affiliated company accounted for by the equity method

Japan			
	Paid-in Capital	% Voting Control*	Principal Business
Yoshitomiyakuhin Corporation	¥385 million	100.0%	Provision of information about pharmaceuticals
Mitsubishi Tanabe Pharma Factory Ltd.	¥1,130 million	100.0%	Manufacture and sale of pharmaceuticals
Tanabe Seiyaku Yoshiki Factory Co., Ltd.	¥400 million	100.0%	Manufacture and sale of pharmaceuticals
Tanabe Total Service Co., Ltd.	¥90 million	100.0%	Office services, etc.
Tanabe Palm Service Co., Ltd.	¥10 million	100.0% (100.0%)	Servicing office support, in-house mail and printing
Stelic Institute & Co., Inc.	¥1,136 million	100.0% (100.0%)	R&D of pharmaceuticals
BIKEN Co., Ltd.	¥100 million	33.4%	Manufacture and sale of biological products including vaccines
Overseas			
North America			
	Paid-in Capital	% Voting Control*	Principal Business
Mitsubishi Tanabe Pharma Holdings America, Inc.	USD167	100.0%	Management of Group companies in the U.S.
Mitsubishi Tanabe Pharma Development America, Inc.	USD200	100.0% (100.0%)	R&D of pharmaceuticals
Mitsubishi Tanabe Pharma America, Inc.	USD100	100.0% (100.0%)	Sale of pharmaceuticals
MP Healthcare Venture Management Inc.	USD100	100.0% (100.0%)	Investments in bio-ventures
Tanabe Research Laboratories U.S.A., Inc.	USD3 million	100.0% (100.0%)	R&D of pharmaceuticals
Mitsubishi Tanabe Pharma Canada, Inc.	CAD4 million	100.0% (100.0%)	Sale of pharmaceuticals
MTPC Holdings Canada Inc.	CAD432.4 million	100.0%	Investments in Medicago Group
Medicago Inc.	CAD569 million	60.0% (57.6%)	R&D and manufacture of vaccines
Medicago USA Inc.	USD99	60.0% (60.0%)	Manufacture of vaccines
Medicago R&D Inc.	CAD500	60.0% (60.0%)	R&D of vaccines
Asia			
Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd.	USD1 million	100.0%	R&D of pharmaceuticals
Tianjin Tanabe Seiyaku Co., Ltd.	USD16.2 million	75.4%	Manufacture and sale of pharmaceuticals
Taiwan Tanabe Seiyaku Co., Ltd.	TWD90 million	65.0%	Manufacture and sale of pharmaceuticals
Tai Tien Pharmaceuticals Co., Ltd.	TWD20 million	65.0%	Sale of pharmaceuticals
P.T. Tanabe Indonesia	USD2.5 million	99.6%	Manufacture and sale of pharmaceuticals
MT Pharma Singapore Pte. Ltd.	SGD300 thousand	100.0%	Development of pharmaceuticals
MT Pharma (Thailand) Co., Ltd.	THB103 million	100.0% (2.0%)	Sale of pharmaceuticals
Mitsubishi Tanabe Pharma Korea Co., Ltd.	KRW2,100 million	100.0%	Manufacture and sale of pharmaceuticals
Europe / Middle East			
NeuroDerm Ltd.	USD58 thousand	100.0%	R&D of pharmaceuticals
Mitsubishi Tanabe Pharma Europe Ltd.	GBP4.6 million	100.0%	R&D of pharmaceuticals
Mitsubishi Tanabe Pharma GmbH	EUR25 thousand	100.0% (100.0%)	Sale of pharmaceuticals
Synthelabo-Tanabe Chimie S.A.	EUR1.6 million	50.0%	Manufacture and sale of pharmaceuticals

\* Figures in parentheses show indirect control.

Note: Aside from the above, The Company own 5 consolidated subsidiaries. Among them, 2 companies are under the liquidation and 1 company is a dormant company. Besides, the executive compensation BIP Trust is included as one of the consolidated subsidiaries.



## Investor Information

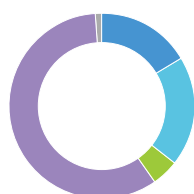
Stock Exchange Listing	Tokyo
Stock Code	4508
Paid-in Capital	¥50,000 million
Common Stock	Authorized: 2,000,000,000 shares Issued: 561,417,916 shares
Closing Date of Accounts	March 31
Number of Shareholders	19,121

### Major Shareholders

	% Voting Rights
Mitsubishi Chemical Holdings Corporation	56.3
The Master Trust of Japan, Ltd.	4.8
Japan Trustee Services Bank, Ltd.	2.3
Nippon Life Insurance Company	2.2
MSCO CUSTOMER SECURITIES	1.7
STATE STREET BANK WEST CLIENT-TREATY 505234	1.3
Japan Trustee Services Bank, Ltd. (Trust Account 9)	0.9
Japan Trustee Services Bank, Ltd. (Trust Account 5)	0.8
Japan Trustee Services Bank, Ltd. (Trust Account 7)	0.7
Nipro Corporation	0.7

Shareholder Register Agent for Common Stock in Japan	Mitsubishi UFJ Trust and Banking Corporation Osaka Corporate Agency Division 3-6-3, Fushimi-machi, Chuo-ku, Osaka 541-8502, Japan
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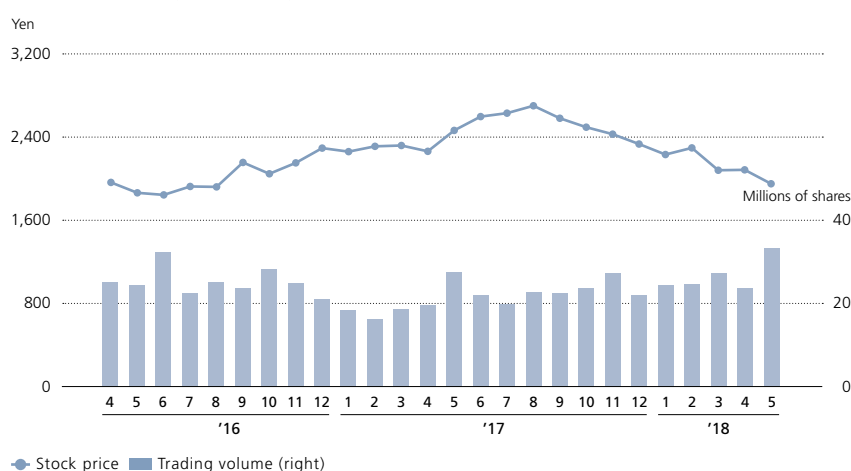
### Distribution of Share Ownership by Type of Shareholder



Japanese financial institutions	16.4%
Foreign institutions	19.4%
Japanese individuals and others*	4.5%
Other Japanese corporations	58.8%
Japanese securities firms	0.9%

\* Individuals and others includes treasury stock (431 thousand shares as of March 31, 2018)

### Stock Price Range / Trading Volume



# THE KAITEKI COMPANY

Mitsubishi Chemical Holdings Group



Mitsubishi Tanabe Pharma

[www.mt-pharma.co.jp](http://www.mt-pharma.co.jp)