

# *Open Up* the *Future*

Mitsubishi Tanabe Pharma  
Corporate Report 2016



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 2016

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

### CSR ACTIVITIES REPORT 2016



Mitsubishi Tanabe Pharma prepares this report to provide information 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 2015 (initiatives targeting the sustainable development of society). This report includes information about specific initiatives based on the corporate philosophy, presented in accordance with the ISO 26000 core subjects. It also includes the VOICE section, which contains messages from employees related to those initiatives, and the data section, which contains related data.



### Inclusion in FTSE4Good Index Series\*

Mitsubishi Tanabe Pharma has been included in the FTSE4Good Index Series, a leading index for responsible investing (RI), for 13 consecutive years.

#### \* FTSE4Good Index Series

An index related to RI prepared by the FTSE Group. Based on FTSE Group original standards, companies that fulfill a certain level of CSR activities are selected for inclusion in the index. As of the end of March 2016, the index included 791 companies, including 176 Japanese companies.



## 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.

### 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

A corporate profile is a digest version of the Mitsubishi Tanabe Pharma Corporate Report 2016.



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



Message from the President



Special Feature:  
Accelerating U.S. Business  
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### 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.

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Michihiro Tsuchiya  
Chairman of the Board & Board Director



Masayuki Mitsuka  
President & Representative Director

# Taking a New Step in Value Creation

To become a company that can continue to provide new value, Mitsubishi Tanabe Pharma has followed a course of change over the past five years in accordance with Medium-Term Management Plan 11–15.

Over that period, we were able to launch seven new products in Japan. In addition, Remicade (indication: rheumatoid arthritis (RA) and other inflammatory autoimmune diseases<sup>1</sup>) and Simponi (indication: RA) recorded growth, and we achieved our objective for combined sales of Remicade and Simponi of ¥100.0 billion on a national health insurance (NHI) drug price basis. Moreover, Gilenya (indication: multiple sclerosis (MS)) and Invokana (indication: type 2 diabetes mellitus) were launched by licensees and grew into major drugs overseas. Both of these products are now available in dozens of countries around the world. We are pleased that we were able to deliver new value in a specific form to patients in Japan and other countries around the world. In addition, Mitsubishi Tanabe Pharma aggressively consolidated and reorganized a range of functions, including the research, manufacturing, and Head Office functions, and accelerated reforms targeting a strong management system. Through these initiatives, under Medium-Term Management Plan 11–15 Mitsubishi Tanabe Pharma was able to bolster the foundation for its future growth stage.

However, our operating environment is undergoing dramatic change. In particular, in the domestic market for ethical pharmaceuticals, government measures to promote the use of generics have progressed faster than expected. Previously, long-listed drugs<sup>2</sup> were important sources of earnings for the Company and other manufacturers of new pharmaceuticals, but the earnings capacity of these products has declined rapidly. We believe that if we simply continue to do what we have done in the past, then there is no path toward sustained growth for the Company.

Accordingly, we decided to aim to further strengthen the foundation that we established under Medium-Term Management Plan 11–15 and to take the initiative in opening up the future as we target sustained growth. On that basis, we formulated Medium-Term Management Plan 16–20, for which the final fiscal year is fiscal 2020. Moving forward, we will take a new step in value creation.

The key concept of Medium-Term Management Plan 16–20 is “Open Up the Future of Medicine” This plan incorporates our determination to “take the initiative in opening up the future,” and our shared concept regarding the starting point for our business activities, that “Everything we do is for the patients.” We believe that by opening up the future for patients and their families, we will be able to open up the future for the Company. In addition, our use of the word “medicine” in the key concept, rather than “pharmaceuticals,” expresses our commitment to contributing from a wider perspective.

In accordance with this key concept, we will strive to achieve the targets in Medium-Term Management Plan 16–20 and implement reforms to become a “company that works with a sense of speed and is the first to deliver unique value.” We would like to ask our shareholders and investors for their continued understanding and support of Mitsubishi Tanabe Pharma in the years ahead.

1. For further information about indications, please refer to “Overview and Sales Trends of Priority Products in Fiscal 2016” on page 48.

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

August 2016



**Michihiro Tsuchiya**  
Chairman of the Board & Board Director



**Masayuki Mitsuka**  
President & Representative Director

# Where We Are Now

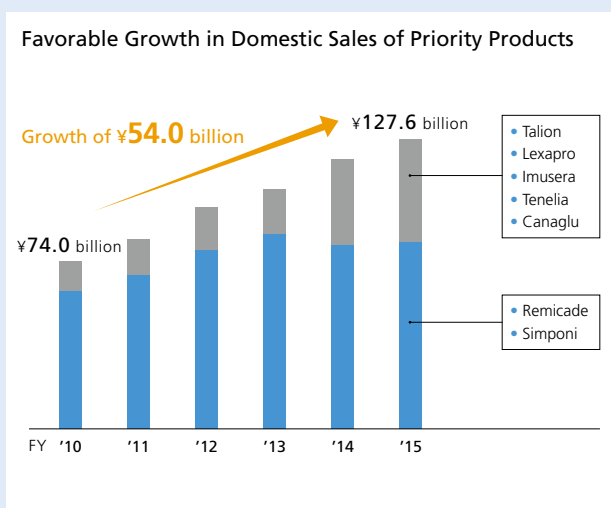
The Company has concluded the five-year Medium-Term Management Plan 11–15, which was launched in fiscal 2011. We generated clear results, and clarified the challenges that we face in a business environment that is undergoing dramatic change.

## Japan

### Our Achievements

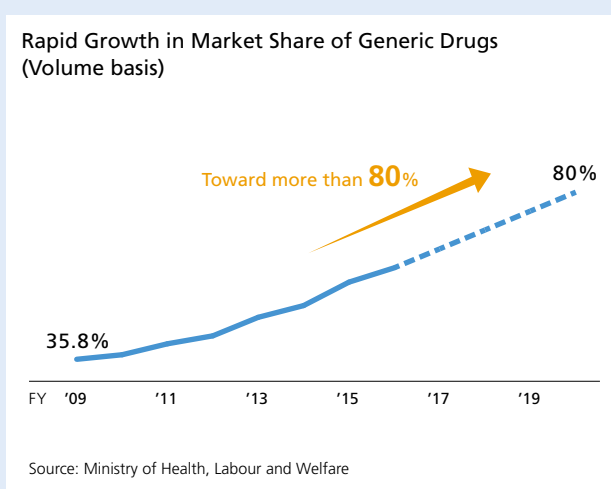
In Japan, we launched seven new products during the period of Medium-Term Management Plan 11–15. Of these, Simponi (indication: RA) and Tenelia (indication: type 2 diabetes mellitus) each recorded sales of more than ¥10.0 billion in fiscal 2015. In addition, in existing products, we focused on the nurturing of Remicade (indication: RA and other inflammatory autoimmune diseases<sup>1</sup>), and worked aggressively to obtain additional indications and changes in administration / dosage. As a result, in fiscal 2013 combined sales of Remicade and Simponi surpassed ¥100.0 billion on an NHI drug price basis for the first time. Sales of seven priority products, including Remicade, Simponi, and Tenelia, recorded favorable growth over the five-year period, increasing approximately ¥54.0 billion to reach ¥127.6 billion.

1. For further information about indications, please refer to “Overview and Sales Trends of Priority Products in Fiscal 2016” on page 48.



### Our Challenges

The Company's sales of ethical drugs in the domestic market declined from ¥361.6 billion in fiscal 2010 to ¥308.1 billion in fiscal 2015. This decline was attributable to a significant decrease in sales of long-listed drugs<sup>2</sup> during the period covered by the previous medium-term management plan. The official NHI prices for ethical drugs were revised twice, and government measures to promote the use of generics were further strengthened. The government has announced targets for the rate of substitution of generic drugs in place of long-listed drugs. The targets are the achievement of a substitution rate<sup>3</sup> of 70% in mid fiscal 2017 and 80% as rapidly as possible during the period from fiscal 2018 to fiscal 2020. During the period covered by the previous medium-term management plan, the generic drug substitution rate increased 20 percentage points, and the achievement of a 60% rate came into view. Up to this point, domestic creators of new pharmaceuticals have relied on long-listed drugs as an important source of revenues, but that earnings power is declining substantially, and in this environment business models must be changed.



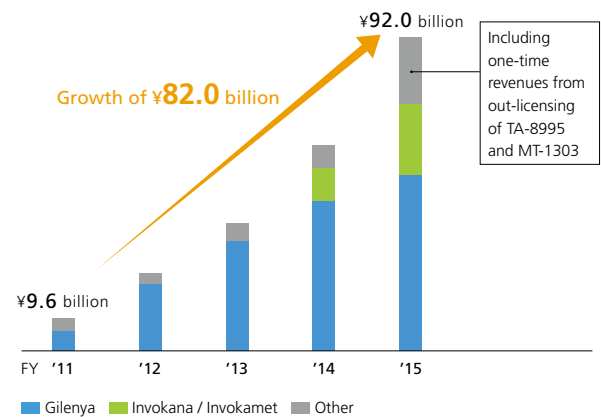
2. Original drugs that have gone off patent and for which generics are on sale.  
 3. Substitution rate = Number of generic drugs / (Number of original drugs for which there are generic competitors + Number of generic drugs)

# Overseas

## Our Achievements

Overseas sales were ¥25.7 billion in fiscal 2010, but significant growth was recorded during the previous medium-term management plan, with overseas sales reaching ¥116.9 billion in fiscal 2015. This growth was driven by royalty revenues from two drugs that were discovered in-house and out-licensed overseas to global companies — Gilenya (indication: MS) and Invokana (indication: type 2 diabetes mellitus). As the world's first oral MS treatment agent, Gilenya has grown into a blockbuster drug with annual sales of more than \$1.0 billion. In addition, in 2015, total annual sales of Invokana and Invokamet / Vokanamet, which combines Invokana and metformin hydrochloride, also surpassed \$1.0 billion. Due to the growth of these two drugs, royalty revenues, which reached a total of ¥92.0 billion in fiscal 2015, have become a pillar of the Company's revenues.

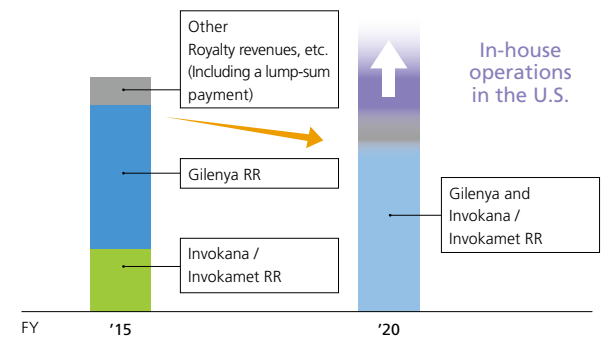
Royalty Revenues Have Grown into a Pillar of Revenues



## Our Challenges

With the domestic operating environment becoming increasingly challenging, the Company needs to achieve further gains in overseas sales. In addition, Gilenya is expected to go off patent in the U.S. during the period of Medium-Term Management Plan 16–20, and we face the urgent challenge of compensating for those revenues. Important keys to doing that will be securing royalty revenues from MT-1303 (indication: autoimmune diseases), which was out-licensed to Biogen, of the U.S., in fiscal 2015, and from other out-licensed drugs, as well as expanding our business in the U.S. The U.S. pharmaceutical market is the largest in the world and more than four times larger than the Japanese market. In addition, it is also the world's highest growth market, and over the five years from 2010 the scale of the market increased by more than \$10.0 billion<sup>4</sup>. It is expected to record continued growth over the medium to long term (5% to 8%<sup>5</sup>). To achieve sustained growth, the Company must rapidly build a business foundation in the U.S.

In regard to the decline in running royalties (RR) due to Gilenya going off patent in the U.S., we will secure revenues through RR and developing in-house operations in the U.S.



4. Source: IMS (World Review Analyst 2016)

5. Source: IMS Global Outlook for Medicines through 2018 (November 2014)



# Where We Are Heading

With the business environment undergoing significant change, we will not be able to achieve sustained growth if we simply continue to follow past business practices. In this setting, what direction should we take? With consideration for the results and issues of the previous medium-term management plan, we formulated the new Medium-Term Management Plan 16–20. Under this plan, we will strive to open up the future of medicine.

## New Value Creation

### Overview of Medium-Term Management Plan 11–15

Period: April 2011 to March 2016 (five years)

#### Objectives that Will Be Realized under Medium-Term Management Plan 11–15:

Becoming a Company that Can Continue to Create New Value

#### Building a Foundation for Future Growth

- Taking on the challenge of unmet medical needs
- Discovering drugs and building a foundation to provide them around the world
- Investing aggressively in future growth

#### Steadily Nurturing and Providing New Products and Priority Products, Centered on Remicade

#### Fiscal 2015 Quantitative Plans:

(Japanese GAAP)

	Initial Objectives Announced October 17, 2011	Revised Objectives Announced May 8, 2014	Fiscal 2015 Results
Net sales	¥500.0 billion	¥410.0 billion	¥431.7 billion
Operating income	¥100.0 billion	¥65.0 billion	¥94.9 billion
R&D expenses	¥80.0 billion	¥80.0 billion	¥75.3 billion
Overseas sales ratio	15% or more	15% or more	27.1%



# Open Up *the Future*

## Overview of Medium-Term Management Plan 16–20

Period: April 2016 to March 2021 (five years)

### Objectives that Will be Realized under Medium-Term Management Plan 16–20

- 1 Invest ¥400.0 billion in R&D, launch new drugs with the potential for worldwide roll-out
- 2 Domestic pharmaceutical sales of ¥300.0 billion  
New drugs and priority products sales ratio of 75% (ethical pharmaceuticals)
- 3 Full-scale development of U.S. business, overseas sales of ¥200.0 billion (overseas sales ratio of 40%, including running royalties and milestone payments on out-licensed drugs)
- 4 Consolidated domestic workforce of 5,000 employees\*  
Cost of sales, SG&A expenses reduced by ¥20.0 billion

\* As of the end of September 2015: 6,176 employees

### Fiscal 2020 Quantitative Plans:

(IFRS)\*

	Fiscal 2015 results (IFRS)	Fiscal 2020 objectives Announced November 8, 2015
Revenue	¥425.8 billion	¥500.0 billion
Core operating profit	¥107.0 billion	¥100.0 billion
Net profit attributable to owners of the Company	¥59.3 billion	¥70.0 billion
R&D expenses	¥64.6 billion	¥80.0 billion
Overseas sales ratio	25.9%	40%

\* The Company has voluntarily applied IFRS instead of Japanese GAAP from the first quarter of fiscal 2016.

# Four Strategic Priorities to Open Up the Future

The Group has identified four strategic priorities to open up the future of medicine in the new medium-term management plan — Maximizing Pipeline Value, Strengthening IKUYAKU and Marketing, Accelerating U.S. Business Development, and Reforming Operational Productivity. In this section, the executives responsible for advancing these strategic priorities discuss the direction of their various initiatives.

## Strategic priority 1

### Maximizing Pipeline Value

Late-stage drug candidate objective

10 candidates (including in-licensed candidates)

R&D investment

More than ¥400.0 billion

## Strategic priority 2

### Strengthening IKUYAKU and Marketing

Domestic sales objective

¥300.0 billion (fiscal 2020)

New drug and priority product sales ratio

75%

Priority disease areas

Autoimmune

Diabetes and kidney diseases

Central nervous system

Vaccines

## Strategic priority 3

### Accelerating U.S. Business Development

U.S. sales objective

¥80.0 billion (fiscal 2020)

U.S. strategic investment

¥200.0 billion

## Strategic priority 4

### Reforming Operational Productivity

Cost of sales / SG&A expense reduction objective

¥20.0 billion (fiscal 2020: compared to fiscal 2015)

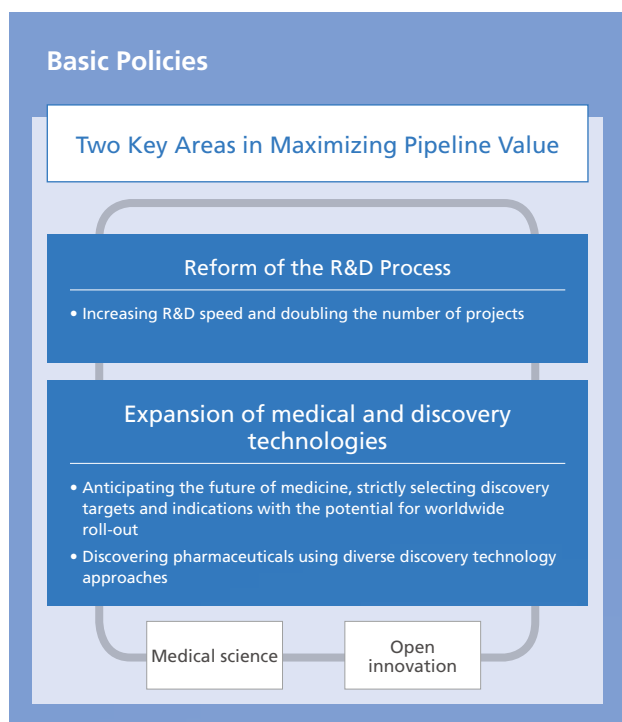
Number of employees

Consolidated domestic workforce: 5,000 employees

(As of the end of September 2015: 6,176 employees)

# Maximizing Pipeline Value

Open Up the Future of Pharmaceuticals



## Working to Increase R&D Speed and Double the Number of Projects

I believe that the value of our pipeline will be determined by the extent to which we can encourage stakeholders to have a sense of expectation. As a specific numerical target, we will work to discover 10 late-stage drug candidates during the period of the new medium-term management plan, which will be double the number discovered under the previous medium-term management plan. To increase R&D speed and double the number of projects, we are working to reform the R&D process. As one facet of those initiatives, in advance of the start of the new medium-term management plan, we reorganized the Research Division into the “Sohyaku. Innovative Research Division.” The responsibilities of the Research Division extended from basic research to the start of clinical trials, but the Sohyaku. Innovative Research Division has extended those responsibilities up to the acquisition of POC\* after the start of clinical trials. We can now seamlessly advance from pre-clinical trials to clinical trials, or what is known as “crossing the bridge.” As a result, we are aware of clinical value, in other words, what kind of drugs are needed on the medical front lines, from the pre-clinical trial stage. Consequently, the time required to advance to the clinical stage has been substantially reduced. This was one of the major aims of the reorganization. Furthermore, in addition to in-house discovery seeds, we will aggressively introduce a variety of discovery seeds from other companies. In this way, we will aim to increase the number of projects.

“Maximizing pipeline value” is positioned as an objective that we must achieve.

## Tackling Must-Achieve Objectives with Confidence

We are using the words “strategic priority” to describe “maximizing pipeline value,” which is positioned as an objective that we must achieve. Pipelines are the foundation of survival for pharmaceutical companies. They are the key to opening up both the world and the future. Without pipelines, we will not be able to obtain materials for global development or the resources that we will need to survive in the future. Drug discovery requires a variety of special skills and practical capabilities. I and all of the other employees involved with the Sohyaku. Innovative Research Division will respect each other’s specialist knowledge and will move forward with the confidence that “we can do this.” In this way, we will achieve the objective of “maximizing pipeline value.”



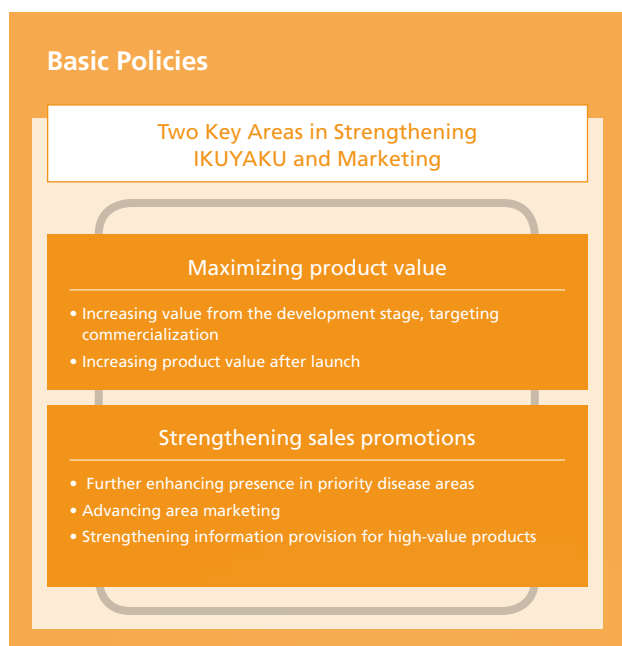
**Takashi Kobayashi**  
 Representative Director,  
 Senior Managing Executive Officer  
 Division Manager of Sohyaku.  
 Innovative Research Division

\* Proof of Concept: Confirmation of the efficacy and safety of new drug candidate substances in humans.

Strategic priority **2**

# Strengthening IKUYAKU and Marketing

Open Up the Future for Patients



## Rapidly Maximizing Product Value

I work in IKUYAKU (drug fostering and evolution). As indicated by the words “strengthening IKUYAKU and marketing,” IKUYAKU and marketing will work together as we strive to achieve domestic sales of ¥300.0 billion. IKUYAKU entails “maximizing product value.” In other words, with a focus on the post-marketing period, we plan to leverage a product’s characteristics from the post-development stage. In addition, we continue clinical research at the post-marketing stage and accumulate information about the drug’s superior aspects in a clinical database. We also strive to secure a drug price that is in line with the product value and to add safety information. Every year, we work to increase the quality of product information and to enhance ease of use. Previously, we collected feedback from clinical settings after a product was launched, so a long period of time was required to maximize value. However, we are now in an era in which the adoption of generic drugs is making rapid progress, and we cannot expect drugs that have gone off patent to generate sales. Time is limited, and we must clarify the characteristics of products as rapidly as possible.

## Developing the Concept of IKUYAKU

The “Ikuyaku. Integrated Value Development Division” was established in October 2015 with the objective of increasing product value. To fully leverage the potential of each product, it is necessary to handle efficacy and safety in a comprehensive manner. However, the necessary functions were previously distributed among other units, such as the Research Headquarters, Sales and Marketing Headquarters, Pharmacovigilance and Quality Assurance Headquarters, and Medical Affairs Department. These functions have been consolidated into the Ikuyaku. Integrated Value Development Division. It has been less than a year since the Ikuyaku. Integrated Value Development Division was established. Moving forward, we need to develop the Ikuyaku. Integrated Value Development Division itself into a strong, value-added organization so that IKUYAKU becomes a concept that is accepted around the world.

With a focus on the product lifecycle from the development stage, we will work to rapidly maximize product value.



**Seiichi Murakami**

Board Director,  
Managing Executive Officer  
Division Manager of Ikuyaku.  
Integrated Value  
Development Division

### Advancing Area Marketing in Line with the Characteristics of Each Region

Of the four strategic priorities, I believe that strengthening marketing is the most urgent because it will increase the earnings that will be allocated to growth investment. On the other hand, given the current market environment, it will not be easy to maintain domestic sales of ¥300.0 billion. To achieve our objectives, we will implement specific initiatives in three categories — area marketing, education and training system, and digital marketing.

In area marketing, in line with government policy, we expect the government to recommend the establishment of comprehensive community care systems that cover medical treatment in specific regions. As a pharmaceutical company, I believe we will need to address that trend. Accordingly, we will likely have to revise the process under which the Sales and Marketing Division determines specific initiatives, which are then communicated to the branches and sales offices. It is the branches and sales offices that understand the actual circumstances in each region, and accordingly we will shift to a method under which the Sales and Marketing Division formulates major policies while specific initiatives are determined by


the branches and sales offices. We have already commenced initiatives toward the establishment of an organization in which the front lines can think for themselves. In this way, we will advance area marketing in line with the characteristics of each region.

### Focusing on the Enhancement of Education and Training Systems and on the Reinforcement of Digital Marketing

By strengthening education and marketing systems, I would first like to enhance the skills of our MRs so that they can succeed in competition with other companies in priority disease areas. As one part of those initiatives, we will establish a framework under which we select MRs with outstanding results from around the country and have them directly teach other MRs. Competition in the field of diabetes is especially intense, and accordingly we will pay particular attention to bolstering the capabilities of individual MRs in this field so that they can reach their objectives in this competitive environment.

On the other hand, for long-listed products we will utilize digital marketing and work to increase efficiency. Also, the role of digital marketing encompasses more than simply increasing efficiency. Opportunities for MRs to meet with health care professionals are limited, and in this environment the importance of digital marketing is increasing. Through the use of IT, we will be able to enhance our approaches to health care professionals, and by working to foster two-way communications, we will identify needs in clinical settings and leverage that knowledge in sales and marketing promotional activities.

I believe that the role of MRs is currently in a transition period. By building a sales and marketing system in line with the times, we will strive to achieve our objective for domestic sales.



Speed is of the essence in our efforts to strengthen marketing.

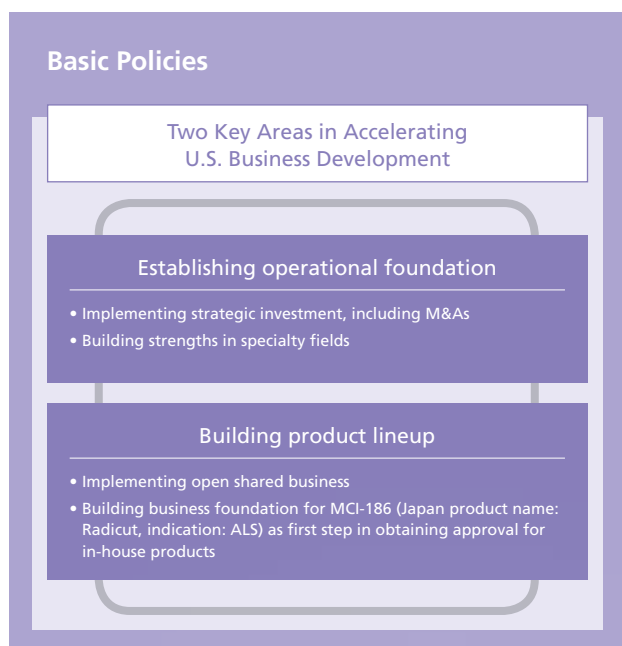
#### Yoshiaki Ishizaki

Board Director, Managing Executive Officer  
Division Manager of Sales & Marketing Division

Strategic priority **3**

# Accelerating U.S. Business Development

Open Up the Future through U.S. Business



## Making MCI-186 the First Step in Building a Foundation for U.S. Business

I think that building a business foundation in the U.S., which is on the front lines in global medicine, will lead to true globalization in which we deliver new products widely around the world. In that sense, the achievement of ¥80.0 billion in U.S. sales in fiscal 2020 is positioned as more of a transit point on the way to the next stage than as an objective.

First, MCI-186 (Japan product name: Radicut) acquired approval for an indication of amyotrophic lateral sclerosis (ALS) in Japan and South Korea in 2015, and in June 2016 we filed an application in the U.S., with the aim of acquiring approval in the U.S. within fiscal 2016. Prior to the approval of that application, in February 2016 we established MT Pharma America, a pharmaceutical sales company. We are moving forward with preparations for the start of sales. No new ALS drugs have been launched in the U.S. for more than 20 years, and patients have extremely high expectations for MCI-186. We will do our utmost to deliver this drug to patients in accordance with the plan. Our sale of MCI-186 in the U.S. through an in-house system is a specific change that is a part of our initiatives to accelerate U.S. business development, and I believe that it is a tangible step toward globalization.

## Leveraging Diverse Cooperative Initiatives

Once a business is launched, it must be continued. Accordingly, in addition to products discovered in-house, we will strengthen our product lineup through the full utilization of the global business development function. From among the diverse cooperative approaches that are possible, such as the acquisition of a certain type of rights, or the acquisition of a company itself, I think it is important to find an approach that has merits for both Mitsubishi Tanabe Pharma and our partners. Accordingly, we must understand the viewpoint from which the partner is operating the business. Moving forward, we will reinforce our business development system. In addition, I will visit our partners as often as possible and acquire up-to-date information. In this way, we will work to determine the fundamental, absolute values of the relevant compounds and collaborators. Moreover, we don't know where opportunities will arise. We will strive to acquire promising in-licensed products by always taking on the challenge of diverse business opportunities and repeating that process on a daily basis.

This will lead to true globalization, as we deliver new products to a wide range of patients around the world.

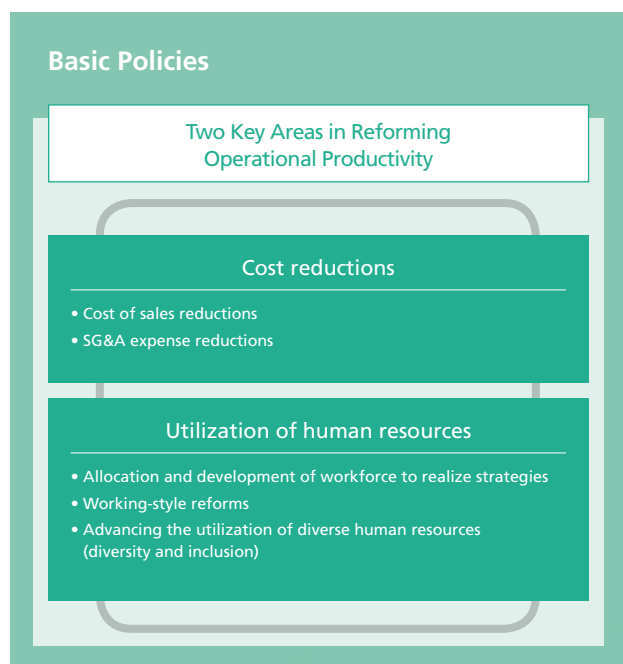


**Eiji Tanaka**  
 Executive Officer,  
 General Manager of U.S. Operations  
 Head of Global Business  
 Development  
 President of Mitsubishi Tanabe  
 Pharma Holdings America



# Reforming Operational Productivity

Opening Up a Certain Future



## Gaining the Strength Needed for Growth by Reducing Costs

Under the new medium-term management plan, our numerical objectives for fiscal 2020, the plan's final year, include reducing cost of sales by ¥8.0 billion and SG&A expenses by ¥12.0 billion, for a total reduction of ¥20.0 billion in comparison with fiscal 2015. These objectives follow the achievement of reductions of ¥9.0 billion in fiscal 2015, in comparison with fiscal 2012, through operational reforms that we started in fiscal 2013. Consequently, it will not be easy to reach the 2020 objective. Nonetheless, we must achieve this objective in order to gain the strength necessary for growth in the challenging domestic business environment. We expect to reach the objective for cost of sales through initiatives to strengthen production technologies and supply chain management and through efforts to realize low-cost operations. On the other hand, we plan to achieve the reduction in SG&A expenses through cost reductions and through the achievement of a consolidated domestic workforce of 5,000 employees.

## Strengthening Collaboration Among Departments to Enhance Organizational Performance

As we will reduce our workforce by approximately 1,000 employees, it will be important for us to reevaluate our working styles and organizations and eliminate those operations determined to be non-essential, while strengthening collaboration among departments and enhancing organizational performance. Accordingly, it is urgent that we develop human resources who can work from a viewpoint that transcends organizational boundaries. As one initiative to develop our human resources, we have already commenced the selection of employees who will support the next generation and initiatives to foster their participation in projects that extend across organizational units. I think that developing as many employees as possible with experience that extends across departmental boundaries will foster close ties among units and speed up the activities of the entire Company.

In establishing new working styles and organizational administration with a higher viewpoint and a broader field of vision, the concept of always thinking about what to change, as expressed in the phrase "Next time let's do this," will need to extend throughout the Company, from senior management to new employees.

To that end, it is my responsibility, and the responsibility of other management leaders, to continue to strongly stress this concept. I believe this will be a major prerequisite to the task of reforming operational productivity.



**We must reevaluate our working styles and organizations.**

**Eizo Tabaru**

Board Director, Managing Executive Officer  
General Manager of Finance & Accounting Department



**OUR PHILOSOPHY**

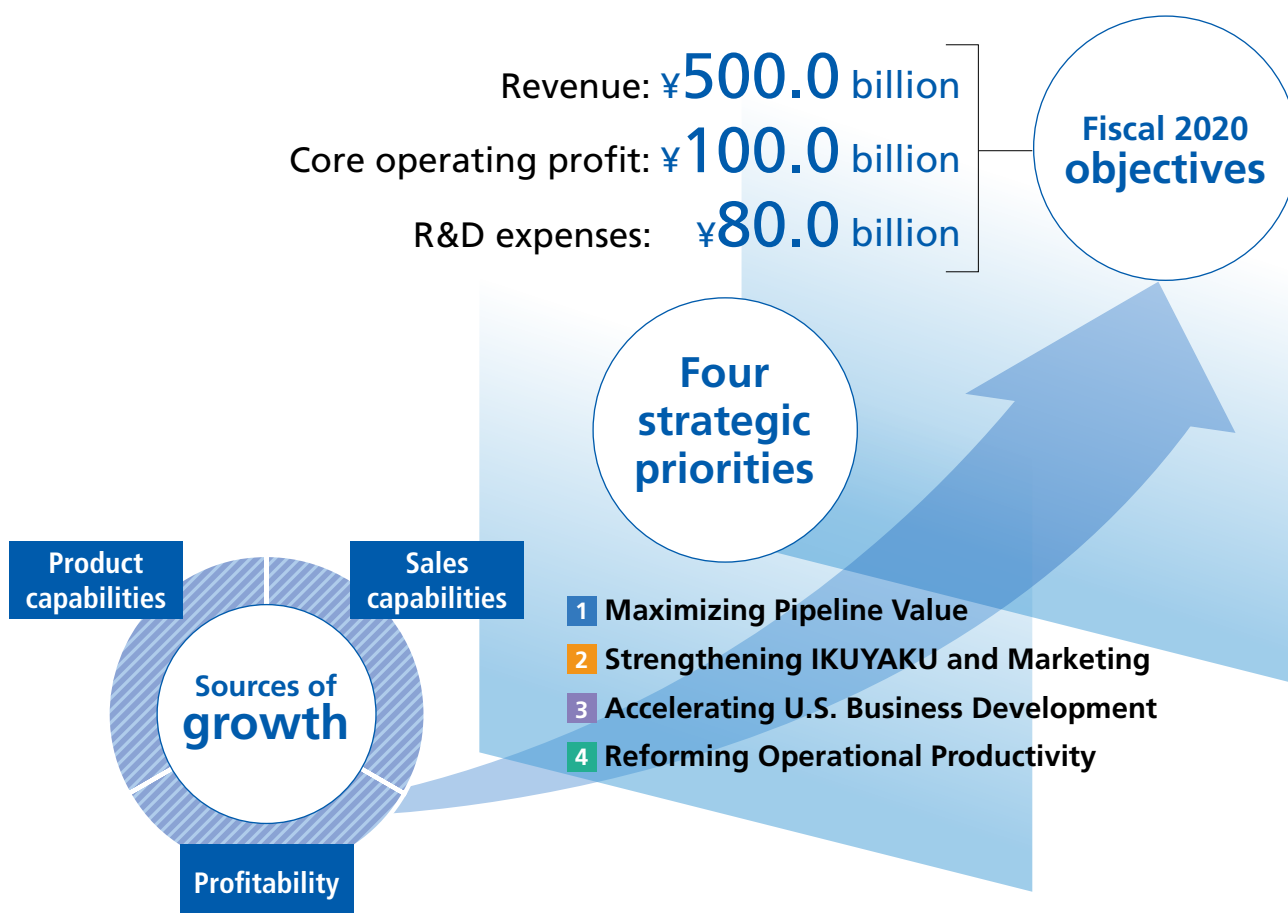
We contribute to the healthier lives of people around the world through the creation of pharmaceuticals.

**OUR VISION**

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

Mitsubishi Tanabe Pharma was established in 2007. Since that time, the Mitsubishi Tanabe Pharma corporate philosophy has been “to contribute to the healthier lives of people around the world through the creation of pharmaceuticals.” In accordance with this philosophy, we have worked to become a global research-driven pharmaceutical company that is trusted by communities.

The new medium-term management plan identifies four strategic priorities. Our efforts to address these priorities will be directed toward the realization of our vision. Moving forward, we will strive to make progress on the road toward our vision by opening up the future of medicine and contributing to the healthier lives of people around the world.





## Business Strategy Section

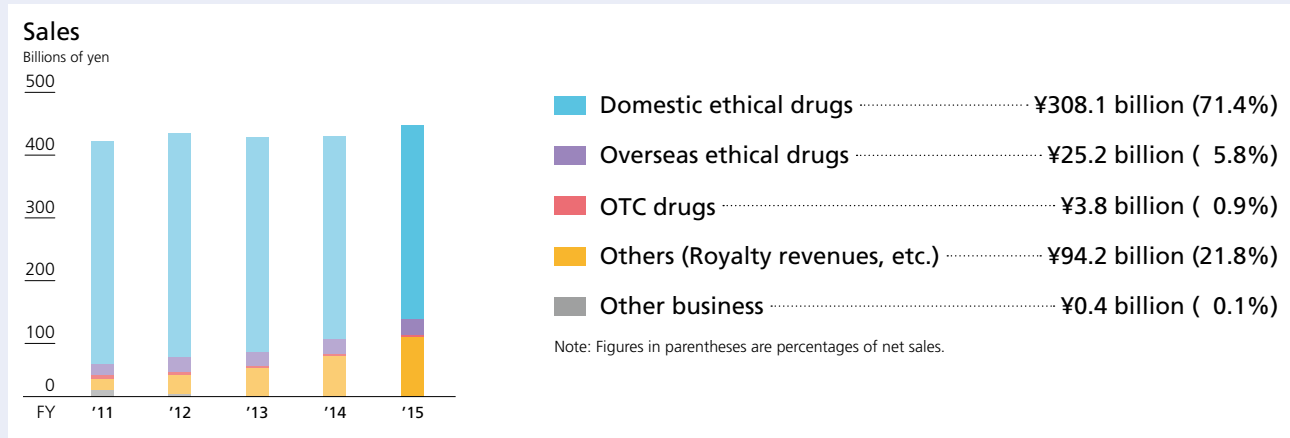
This section explains the business strategies that play the central role in initiatives to create value.

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# Mitsubishi Tanabe Pharma's Business

## Business Portfolio

Mitsubishi Tanabe Pharma provides ethical drugs, including drugs for autoimmune diseases, diabetes and kidney diseases, and central nervous system diseases. We meet a wide range of medical needs through the sale of distinctive ethical drugs, including vaccines and narcotics, as well as through the sale of generic drugs and OTC products.



## Priority Products

### Remicade [1]

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

Domestic Sales: ¥69.4 billion

Overseas Sales: ¥30 million

### Talion [2]

Indications: allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, prurigo, cutaneous pruritus)

Domestic Sales: ¥16.9 billion

Overseas Sales: ¥0.9 billion

### Tenelia [3]

Indication: type 2 diabetes mellitus

Domestic Sales: ¥14.2 billion

Overseas Sales: ¥0.3 billion

### Simponi [4]

Indication: RA (including the prevention of structural joint damage)

Domestic Sales: ¥12.9 billion

Overseas Sales: ¥1.3 billion

### Lexapro [5]

Indications: Depression, depressive symptoms, social anxiety disorder

Domestic Sales: ¥9.5 billion

### Imusera [6]

Indication: MS

Domestic Sales: ¥4.1 billion

### Canaglu [7]

Indication: type 2 diabetes mellitus

Domestic Sales: ¥0.6 billion



## Business Processes

Mitsubishi Tanabe Pharma conducts drug discovery, IKUYAKU, marketing, and production in the field of ethical drugs. To ensure that our pharmaceuticals can be used by patients with peace of mind, we have built a system to assure efficacy, safety, and quality in all of these processes.



For information about business strategies by process, please see page 32. **P32**

### Vaccines

#### Influenza vaccine <sup>8</sup>

Indication: Prevention of influenza

Domestic Sales: ¥13.8 billion

#### Tetrabik <sup>9</sup>

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

Domestic Sales: ¥9.5 billion

#### Varicella vaccine <sup>10</sup>

Indication: Prevention of chicken pox

Domestic Sales: ¥6.4 billion

#### Mearubik <sup>11</sup>

Indications: Prevention of attenuated measles and rubella

Domestic Sales: ¥5.0 billion



8

9

10

11

### Major Out-Licensed Products

#### Gilenya

Indication: MS

Royalty Revenues: ¥51.7 billion

#### Invokana

Indication: type 2 diabetes mellitus

Royalty Revenues: ¥20.6 billion



12

### Generic Drugs <sup>12</sup>

Tanabe Seiyaku Hanbai's products\*

Domestic Sales: ¥13.8 billion

\* Composed of generic drugs and the long-listed drugs (original drugs that have gone off patent and for which generic drugs are on sale) that were transferred from the Company

### OTC Drugs <sup>13</sup>

Domestic Sales: ¥3.8 billion

Overseas Sales: ¥0.1 billion



13

# Financial and Non-Financial Highlights

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

Years ended March 31, 2016 (FY 2015), 2015 (FY 2014), 2014 (FY 2013), 2013 (FY 2012) and 2012 (FY 2011)

	Billions of yen				
	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015
Net sales	¥407.2	¥419.2	¥412.7	¥415.1	¥431.7
Operating income	69.0	69.0	59.1	67.1	94.9
Net income attributable to shareholders of the Company	39.0	41.9	45.4	39.5	56.4
R&D expenses	70.2	66.5	70.4	69.6	75.3
Capital expenditures on an accrual basis	7.1	9.2	12.6	15.7	11.2
Total assets	819.9	866.8	886.5	929.3	930.2
Total net assets	721.5	752.9	777.8	800.4	816.7
Net cash provided by operating activities	37.2	60.6	69.9	68.2	65.2
Net cash used in investing activities	(63.2)	(35.0)	(24.3)	(59.8)	(26.6)
Net cash used in financing activities	(17.2)	(23.7)	(21.1)	(21.9)	(22.2)

## Financial indicators

	%				
Overseas sales ratio	7.0%	11.4%	14.4%	18.8%	27.1%
Operating margin	17.0	16.5	14.3	16.2	22.0
R&D expenses ratio	17.3	15.9	17.1	16.8	17.4
Equity ratio	87.3	86.3	86.4	84.9	86.6
ROE	5.5	5.7	6.0	5.1	7.1
Dividend payout ratio	50.3	53.6	49.4	59.6	45.7

## Per share amounts

	Yen				
Net income	¥69.54	¥74.67	¥80.92	¥70.41	¥100.60
Cash dividends	35.00	40.00	40.00	42.00	46.00

## Non-financial data

Number of employees	9,180	8,835	9,065	8,457	8,125
Number of new ethical drugs approved in Japan <sup>2</sup>	3	2	0	1	0
Energy used (TJ)	2,588	2,332	2,010	1,815	1,569
CO <sub>2</sub> emissions (thousands of tons-CO <sub>2</sub> )	126	123	115	104	92
Amount of waste generated (thousands of tons)	20	18	16	15	9

1. U.S. dollar amounts are converted from yen, for convenience only, at the rate of ¥112.68 to U.S.\$1, the prevailing exchange rate at March 31, 2016.

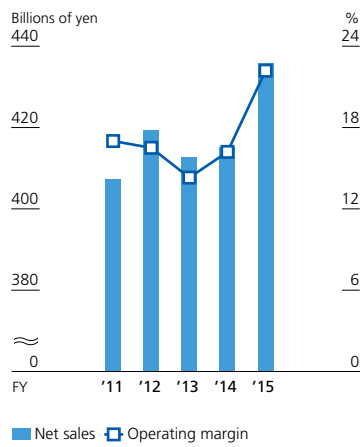
2. Number of new ethical drugs approved in Japan includes co-developed drugs.

Millions of U.S. dollars % Change

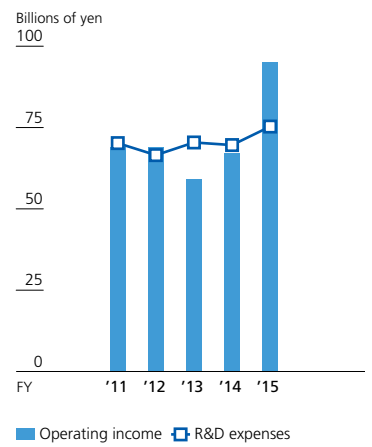
**FY 2015** FY 2015 / 2014

<b>\$3,831</b>	+ 4.0%
<b>842</b>	+ 41.4
<b>501</b>	+ 42.9
<b>668</b>	+ 8.2
<b>99</b>	- 28.7
<b>8,256</b>	+ 0.1
<b>7,248</b>	+ 2.0
<b>579</b>	—
<b>(236)</b>	—
<b>(197)</b>	—

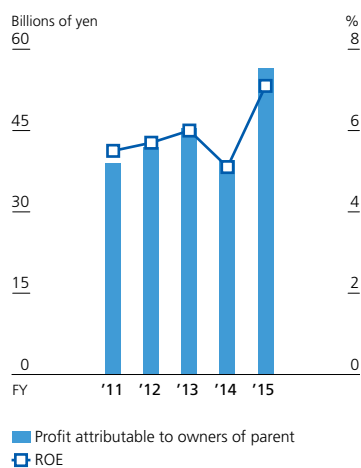
### Net Sales / Operating Margin



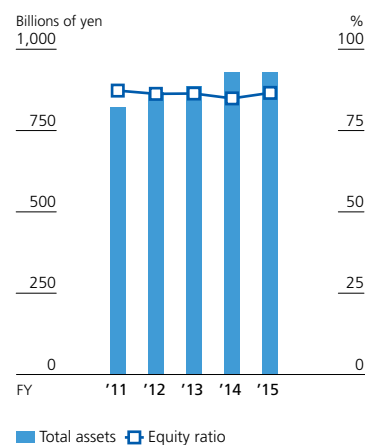
### Operating Income / R&D Expenses



### Profit Attributable to Owners of Parent / ROE



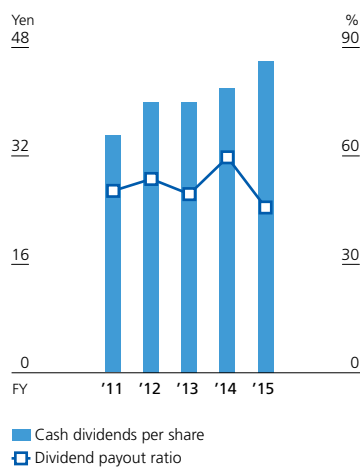
### Total Assets / Equity Ratio



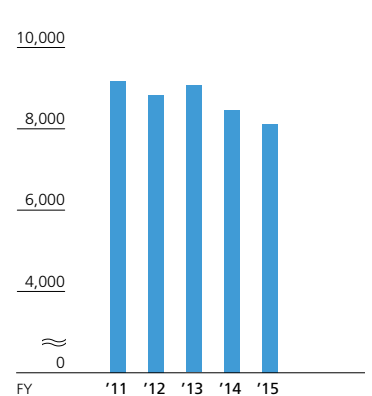
U.S. dollars

<b>\$0.89</b>	42.9%
<b>0.41</b>	—

### Cash Dividends per Share / Dividend Payout Ratio



### Number of Employees



# Pipeline (Status of Drug Candidates)

As of August 2, 2016

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

## Pipeline

Development code (Generic name)	Category	Expected indications	Region	Stage				Origin (Remarks)
				Phase 1	Phase 2	Phase 3	NDA filed	
<b>New Drugs</b>								
TA-7284 (canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus	Taiwan	■	■	■	Mar. 2015	In-house
MP-513 (teneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus	Indonesia	■	■	■	Apr. 2015	In-house
			Europe	■	■			
			US	■				
TAU-284 (bepotastine)	Selective histamine H1 receptor antagonist, antiallergic agent	Pediatric allergic rhinitis, Pediatric atopic dermatitis	China	■	■	■	Mar. 2016	Japan: Ube Industries
MCI-186 (edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis	US	■	■	■	June 2016	In-house
MT-2412 (teneligliptin, canagliflozin)	Fixed-dose combination of DPP-4 inhibitor and SGLT2 inhibitor	Type 2 diabetes mellitus	Japan	■	■	■		In-house
MP-214 (cariprazine)	Dopamine D3 / D2 receptor partial agonist	Schizophrenia	Japan, Asia	■	■	■	Phase 2b/3	Hungary: Gedeon Richter
MT-3995	Selective mineralocorticoid receptor antagonist	Diabetic nephropathy	Europe	■	■			In-house
			Japan	■	■			
			US	■				
MT-1303 (amiselimod)	S1P receptor functional antagonist	Multiple sclerosis	Europe	■	■			In-house
		Psoriasis	Europe	■	■			
		Crohn's disease	Japan, Europe	■	■			
		Inflammatory diseases, autoimmune diseases	Japan, Europe, US	■				
MT-2301	Haemophilus influenzae type b (Hib) vaccine	Prophylaxis of pediatric Hib infection	Japan	■	■			US: Nuron Biotech
Influenza vaccine	Plant-based VLP vaccine	Prophylaxis of H5N1 influenza	Canada	■	■			In-house
Influenza vaccine	Plant-based VLP vaccine	Prophylaxis of seasonal influenza	US, Canada	■	■			In-house
Influenza vaccine	Plant-based VLP vaccine	Prophylaxis of H7N9 influenza	Canada	■				In-house
GB-1057 (recombinant human serum albumin)	Blood and blood forming organs		US	■				In-house
MP-124	Nervous system		US	■				In-house
MP-157	Cardiovascular system		Europe	■				In-house
MT-0814	Ophthalmologicals		Japan	■				In-house
MT-8554	Nervous system, etc.		Europe	■				In-house
MT-5199	Nervous system		Japan	■				US: Neurocrine Biosciences
MT-7117	Dermatologicals, etc.	Inflammatory diseases, autoimmune diseases, etc.	Europe	■				In-house



Brand name (Generic name)	Category	Expected indications	Region	Stage				Origin (Remarks)
				Phase			NDA filed	
				1	2	3		

### Additional Indications & Administration

<b>Remicade</b> (infliximab)	Anti-human TNF $\alpha$ monoclonal antibody	Pediatric Crohn's disease	Japan				US: Janssen Biotech
		Pediatric ulcerative colitis					
<b>Imusera</b> (fingolimod)	S1P receptor functional antagonist	Chronic inflammatory demyelinating polyradiculoneuropathy	Global clinical trial				In-house (Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas)
<b>Canaglu</b> (canagliflozin)	SGLT2 inhibitor	Diabetic nephropathy	Global clinical trial				In-house (Sponsor: Janssen Research & Development)

Development code (Generic name)	Category	Expected indications	Region	Stage				Licensee (Remarks)
				Phase			NDA filed	
				1	2	3		

### Licensing-Out

<b>TA-7284</b> (canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus / fixed-dose combination with metformin, XR	US			Nov. 2015	US: Janssen Pharmaceuticals
		Diabetic nephropathy	Global clinical trial				
		Type 1 diabetes mellitus	US, Canada				
		Obesity / co-administration with phentermine	US				
<b>FTY720</b> (fingolimod)	S1P receptor functional antagonist	Chronic inflammatory demyelinating polyradiculoneuropathy	Global clinical trial				Switzerland: Novartis (Co-developed with Novartis Pharma in Japan)
<b>MT-4580</b>	Ca sensing receptor agonist	Secondary hyperparathyroidism in hemodialysis patients	Japan				Japan: Kyowa Hakko Kirin
<b>Y-39983</b>	ROCK (rho-kinase) inhibitor	Glaucoma	Japan				Japan: Senju Pharmaceutical
<b>MT-210</b>	5-HT2A / Sigma 2 receptor antagonist	Schizophrenia	Europe				US: Minerva Neurosciences
<b>MCC-847</b> (masilukast)	Leukotriene D4 receptor antagonist	Asthma	Korea				Korea: SAMA Pharma
<b>Wf-516</b>	Multiple mechanisms on several receptors*	Depression	Europe				US: Minerva Neurosciences
<b>Y-803</b>	Bromodomain inhibitor	Cancer	Europe, Canada				US: Merck
<b>sTU-199</b> (tenatoprazole)	Alimentary tract and metabolism		Europe				France: Negma / Sidem

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

# Plotting a Course through Uncharted Territory

We will open up the future of medicine and  
build a foundation for sustained growth.



Masayuki Mitsuka  
President &  
Representative Director

## Overview of Fiscal 2015

In fiscal 2015, Mitsubishi Tanabe Pharma recorded substantial gains in royalty revenues and achieved new record-high levels for net sales, operating income, and net income attributable to shareholders of the Company.

Net sales rose 4.0%, to ¥431.7 billion, and operating income increased 41.4%, to ¥94.9 billion. Net income attributable to shareholders of the Company was up 42.9%, to ¥56.4 billion. Each of these represented a new record high. The principal reason was a substantial gain in royalty revenues, etc., which rose 52.5%, to ¥92.0 billion.

First, we recorded continued growth in royalty revenues from Gilenya (indication: MS), which is licensed to Novartis, of Switzerland, and from Invokana (indication: type 2 diabetes mellitus), which is licensed to Janssen Pharmaceuticals, of the U.S. The combined total of royalty revenues from these two drugs was up 35% year on year, to ¥72.4 billion. Furthermore, the Company received lump-sum payments of ¥17.6 billion accompanying the out-licensing of MT-1303 (expected indication: autoimmune diseases) and TA-8995 (expected indication: dyslipidemia).

On the other hand, domestic sales of ethical drugs were down 4.9%, to ¥308.1 billion. Our sales of plasma fractionation products were ended accompanying the dissolution of our sales agreement with Japan Blood Products Organization. This had the effect of reducing the Company's sales by ¥19.7 billion. In addition, the

influence of generics expanded further, and sales of long-listed drugs<sup>1</sup> continued to decline substantially year on year. However, in our priority products<sup>2</sup>, favorable sales growth was recorded by Tenelia (indication: type 2 diabetes mellitus) and Simponi (indication: RA) as well as by vaccines. Overall sales of priority products were up 11.7% year on year, to ¥157.2 billion. Excluding the effect of the dissolution of our plasma fractionation product sales agreement, our domestic sales of ethical drugs recorded an increase.

Moreover, in regard to the structural reforms that we started in fiscal 2013, in fiscal 2015 we incurred ¥16.3 billion in restructuring expenses (including ¥15.3 billion related to subscription for an early retirement program), which we recorded as an extraordinary loss. Through the initiatives implemented over the past three years, we have achieved a reduction of ¥9.0 billion in annual cost of sales and SG&A expenses in comparison with fiscal 2012.

1. Original drugs that have gone off patent and for which generics are on sale.
2. For further information about priority products, please refer to "Overview and Sales Trends of Priority Products in Fiscal 2016" on page 46.

## Formulation of the New Medium-Term Management Plan

The period of the new medium-term management plan is positioned as a time for gathering our strength in preparation for dramatic growth in fiscal 2020 and thereafter.

In November 2015, the Company formulated Medium-Term Management Plan 16–20. This is five-year plan that will conclude in fiscal 2020.

Under Medium-Term Management Plan 11–15, our initial numerical targets were net sales of ¥500.0 billion and operating income of ¥100.0 billion. However, our operating environment underwent dramatic changes, including the expanding influence of generics on long-listed products. In consideration of these factors, in May 2014 we revised our numerical targets to net sales of ¥410.0 billion and operating income of ¥65.0 billion. As outlined above, we achieved the revised numerical targets in fiscal 2015, the final year of the previous plan, with net sales of ¥431.7 billion and operating income of ¥94.9 billion. Nonetheless, although we were able to raise operating income to a level close to the initial target, net sales were substantially lower than the initial target. This shortfall was principally attributable to the influence of the worsening of the business environment and to business restructuring initiatives, including the transfer of our fine chemical business and the dissolution of our plasma fractionation product sales agreement. However, we were not able to establish a business foundation in the U.S., which is the world’s largest pharmaceutical market. I believe that this was a more significant issue for the Company’s future growth than the shortfall in the numbers.

In addition, we were able to launch seven new drugs under the previous medium-term management plan, but we were unable to adequately secure products to follow those. This is one of our important challenges. However, we took steps to strengthen the business development function in advance of the new

medium-term management plan. As a result, in 2015 we were able to in-license MT-5199 (expected indications: tardive dyskinesia, Huntington disease), from Neurocrine Biosciences, of the U.S.; MT-5547 (expected indications: osteoarthritis and chronic low back pain) from Regeneron Pharmaceuticals, of the U.S.; and MT-6548 (expected indication: renal anemia), from Akebia Therapeutics, of the U.S. For each of these drugs, we have acquired exclusive development and sales rights in Japan and certain parts of Asia. U.S. rights are not included, but each of these drugs is a good fit for our priority disease areas. In that sense, I believe that they represent an important achievement for our new medium-term management plan.

During the period covered by the new management plan, the business environment in Japan will become more difficult due to the reevaluation of the NHI drug price system and to further progress in measures to promote the use of generics. In addition, Gilenya royalty revenues are expected to decline significantly as this drug goes off patent in the U.S. In consideration of this type of business environment and of our results and remaining challenges from the previous medium-term management plan, we set our numerical targets (IFRS<sup>3</sup>) under the new plan at revenue of ¥500.0 billion and core operating profit of ¥100.0 billion. In other words, the targets are the same as our initial targets under the previous management plan. We have positioned the period of the new plan as a time for gathering our strength in preparation for dramatic growth in fiscal 2020 and thereafter.

3. The Company has voluntarily applied IFRS instead of Japanese GAAP from the first quarter of fiscal 2016.

### Review of Medium-Term Management Plan 11–15

- |                   |  |
|-------------------|--|
| Domestic Business | <ul style="list-style-type: none"> <li>⊙ Growth of Remicade and Simponi: Sales of more than ¥100.0 billion (NHI drug price basis)</li> <li>⊙ Growth in sales resulting from the launch of new drugs and post-marketing development for existing priority products</li> <li>⊙ Cost reductions achieved through structural reforms</li> <li>✗ Lower revenues from long-listed drugs due to reevaluation of the NHI drug price system and measures to promote the use of generic drugs</li> <li>✗ Did not reach sales target for the generic drug business</li> </ul> |
| Overseas Business | <ul style="list-style-type: none"> <li>⊙ Substantial growth recorded by Gilenya and Invokana</li> <li>✗ Delay in accelerating U.S. business development due to the discontinuation of drug candidates in the field of kidney diseases</li> </ul>   |

### Fiscal 2015 Quantitative Plans (Japanese GAAP)

	Initial Objectives Announced October 17, 2011	Revised Objectives Announced May 8, 2014	Fiscal 2015 Results
Net sales	¥500.0 billion	¥410.0 billion	¥431.7 billion
Operating income	¥100.0 billion	¥65.0 billion	¥94.9 billion

## Four Strategic Priorities to Open Up the Future

For each of the four strategic priorities, we have formulated specific numerical objectives, and if we can achieve these objectives, I believe that we will accumulate strength and be capable of recording dramatic growth.

Under the new medium-term management plan, we have established four strategic priorities to open up the future — Maximizing Pipeline Value, Strengthening IKUYAKU (Drug Fostering and Evolution) and Marketing, Accelerating U.S. Business Development, and Reforming Operational Productivity. I used the phrase “accumulate strength,” and to that end we have formulated specific numerical objectives for each of the four strategic priorities. If we can achieve these objectives, I believe that we will accumulate strength and be capable of recording dramatic growth.

### Maximizing Pipeline Value

We have set an objective of 10 late-stage drug candidates during the period covered by the new medium-term management plan, and we intend to implement R&D investment of more than ¥400.0 billion. The objective for late-stage drug candidates represents a doubling of the number achieved under the previous medium-term management plan. Accordingly, I believe this is a number that we cannot achieve if we simply rely on the same methods that we used in the past.

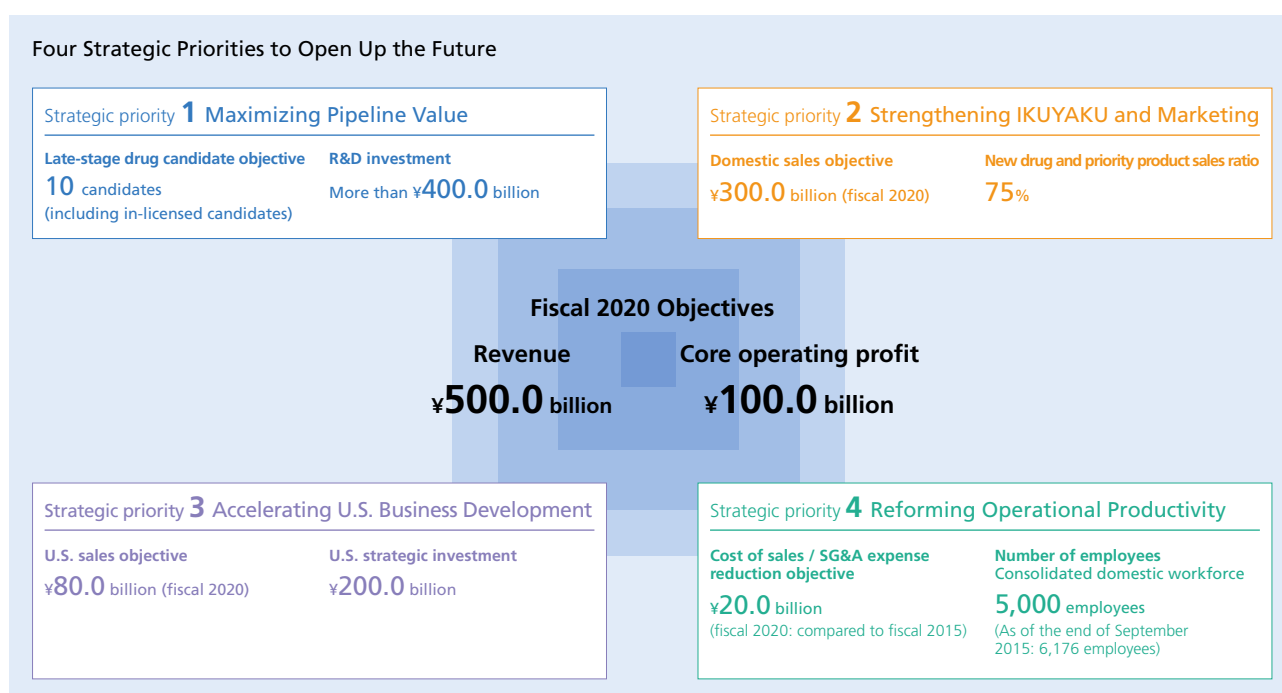
The majority of the products that we have launched originated in-house. However, looking at the drugs launched by U.S. pharmaceutical companies, more than half originate from universities or other academic institutions or from bio-ventures. Simply put, to

double the number of late stage drug candidates, I would like to double the number of projects by aggressively utilizing discovery seeds from external resources. As one measure to that end, we have posted a person responsible for business development to the U.S. since 2015, and the system will facilitate a more timely search for better projects. On the other hand, there will be no point to increasing the number of projects if the end result is a decline in the speed of R&D. In advance of the new medium-term management plan, we reorganized the Research Division and the Development Division into the “Sohyaku. Innovative Research Division,” which will seamlessly handle everything up to the acquisition of POC<sup>4</sup>. As a result, we expect that the time required to move from pre-clinical trials to clinical trials will be substantially reduced.

4. Proof of Concept: Confirmation of the efficacy and safety of new drug candidate substances in humans.

### Strengthening IKUYAKU and Marketing

We have set a target of ¥300.0 billion for domestic sales in fiscal 2020. This numerical target maintains the status quo, but we will implement substantial replacement in the product portfolio. The rate of substitution of generic drugs in place of long-listed drugs is rapidly increasing, and in this setting our domestic sales of ethical drugs have continued to decline since fiscal 2010. In the future,



## Message from the President

I believe that a business model that is dependent on long-listed drugs for revenues will not be effective. The share of domestic sales contributed by new drugs and priority products was 55% in fiscal 2015, and we will raise it to 75% in fiscal 2020.

To that end, we will work to maximize the value of priority products and enhance our presence in our priority disease areas — autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. In the autoimmune disease area, we will aim to maintain the No. 1 share through life-cycle management (LCM) initiatives for Remicade (indications: RA and other inflammatory autoimmune diseases<sup>5</sup>) and Simponi, which are priority products. In the diabetes and kidney disease area, we will aim to obtain evidence and expand sales routes for Tenelia and Canaglu (indication: type 2 diabetes mellitus), which are also priority products. Moreover, to strengthen sales promotion activities, we will further enhance our expertise in our priority disease areas and advance area marketing. In this way, we will track medical needs by region and contribute to collaboration in treatment among major hospitals and community clinics.

5. For further information about indications, please refer to “Overview and Sales Trends of Priority Products in Fiscal 2016” on page 48.

### Accelerating U.S. Business Development

Our target for U.S. sales is ¥80.0 billion in fiscal 2020. We are starting from zero, so I think this is an especially challenging target. However, I believe this is a number that we must achieve in order to record sustained growth, and we will utilize a variety of initiatives to realize it.

Our efforts to achieve this objective will have two points of focus. First, we will strive to launch drugs discovered in-house in the U.S. To begin with, in regard to MCI-186 (Japan product name: Radicut), we are aiming to acquire approval in the U.S. within fiscal 2016 for an indication of ALS. Targeting the start of sales in the U.S., in February 2016 we established MT Pharma America, a pharmaceutical sales company. In June 2016, we filed an application. With MCI-186 as our first step, we will launch in-house products.

Second, we will implement strategic investment, including M&As, in a way that will generate synergies with those in-house drugs, and will expand our U.S. business. Under the new medium-term management plan, we intend to implement more than ¥200.0 billion in strategic investment. Through a variety of collaborative arrangements with academic institutions, venture companies, and pharmaceutical companies, we will acquire products and development candidates, and build a product lineup in our fields of specialty in the U.S.

### Reforming Operational Productivity

To reduce the cost of sales and SG&A expenses, we have implemented structural reforms since fiscal 2013, and those reforms have generated results at a faster pace than planned. However, the investment needed to maximize pipeline value and accelerate U.S. business development will be secured by strengthening IKUYAKU and marketing and by reforming operational productivity. In this setting, as I mentioned, in strengthening IKUYAKU and marketing we have set numerical targets that maintain the status quo. Accordingly, we must do more with reforming operational productivity.

During the period of the new medium-term management plan, from fiscal 2016 we will work to reduce the cost of sales and SG&A expenses by a further ¥20.0 billion from fiscal 2015. In addition, to address changes in the business environment, we will streamline our organizations and workforce. Our plan calls for a consolidated domestic workforce of 5,000 employees in 2020 (6,176 as of the end of September 2015). We have set a goal of reducing cost of sales by ¥8.0 billion by strengthening manufacturing technologies and supply chain management. Reducing SG&A expenses by ¥12.0 billion will be difficult unless all employees change their ways of working. To that end, we need to step up our initiatives to determine which businesses are less essential for the Group and which new businesses we will have to launch going forward. To increase the time available for the latter, I have asked all employees to think about how we can streamline less-essential businesses. In addition, we believe that enhancing career opportunities for diverse employees (diversity and inclusion), including fostering opportunities for women, is an important management issue in regard to increasing operational productivity. Accordingly, we will step up our initiatives in this area.



## Open Up the Future of Medicine

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We do not simply provide “pharmaceuticals.” Rather, we contribute to the medical treatment of patients. I would like to ensure that all of our officers and employees share this attitude.

The key concept of the new medium-term management plan is “Open Up the Future of Medicine.” We are a pharmaceutical company, so we use the word “pharmaceutical,” but I prefer the word “medicine.” We do not simply provide “pharmaceuticals.” Rather, we contribute to the medical treatment of patients, including through the provision of information about appropriate usage methods as well as efficacy and safety. I would like to ensure that all of our officers and employees share this attitude. The purpose of our business activities is not to “provide pharmaceuticals” but rather to “contribute to medicine.”

On the front lines of drug discovery, there have been cases in which drug candidates with demonstrated efficacy and safety were unable to acquire approval because they were not able to demonstrate a difference from drugs that were already on sale. In other words, if a drug is not considered to make a contribution to medicine, it will not be approved. We must take on the challenge of drug discovery from a higher perspective.

There will be no change in the direction of our drug discovery initiatives. Our priority disease areas will be autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines, and we will focus on the discovery of drugs that are “the first to deliver unique value.” Under the new medium-term management plan, we will expand to the drugs of the future. Our drug discovery capabilities are based on organic synthetic chemistry, which is one of our strengths. Centered on these capabilities, we will use new drug discovery technologies to discover next-generation pharmaceuticals. In addition, we will expand our drug discovery fields into new types of medicine, such as regenerative medicine and preemptive medicine. For example, through collaboration with companies in the Mitsubishi Chemical Holdings (MCHC) Group, one possibility will be the fusion of chemical science and material science, such as implementing material processing to optimize the effects of a compound that will become a pharmaceutical. In addition, in October 2015 we established the New Value Creation Office, which is a specialized unit that will investigate the commercialization of the drugs of the future.

## Initiatives in ESG (Environment, Society, and Governance)

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As a member of the Mitsubishi Chemical Holdings Group, we will work to realize *KAITEKI*. In addition, we will use the results of the evaluation of the effectiveness of the Board of Directors to further strengthen our corporate governance system.

In recent years, there has been an accelerating trend toward the consideration of non-financial elements, such as ESG, in making decisions about investing in companies. One of the factors behind this trend is the idea that when companies demonstrate consideration for ESG and make contributions to the sustainable development of society, they promote their own sustained growth. Mitsubishi Tanabe Pharma is aggressively moving forward with initiatives related to these non-financial elements, and we are disclosing the details of these initiatives in a variety of ways, including on pages 57 to 76 of this report and in our CSR Activities Report, which is available on our website.

In addition, 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, the degree of contribution to sustainability is evaluated. Of these, we play a central role in contributing through the health indexes. In regard to the health indexes, we have set quantitative objectives for the categories of “contribute to medical treatment,” “contribute to improvements of QOL,” and “contribute to early detection and prevention of disease.” Looking at each of these indexes, it is clear that the results of our business activities are reflected in the health indexes. For example, in regard to “contribute to medical treatment” and “contribute to improvements of QOL,”



## Message from the President

our score increases due to the contribution of Remicade and Simponi to the treatment of patients with RA. In addition, in regard to “contribute to early detection and prevention of diseases,” the provision of vaccines that are among the best in Japan contributes to the index by controlling the onset and progression of infectious diseases. In addition, Medicago, of Canada, which became a subsidiary in 2013, is developing plant-based Virus-Like Particle (VLP) vaccines. When these vaccines are commercialized, it will be possible to produce large amounts of vaccines in less time, and it will be possible to provide them at lower prices. In fiscal 2015, we made steady progress in regard to the three quantitative objectives. Moving forward, we will continue working to quickly achieve our objectives, while reevaluating the indexes in conformance with the times.

In addition, the Company continues working to strengthen its corporate governance system, including steps to address the Corporate Governance Code formulated by the Tokyo Stock Exchange. In 2011, the Company introduced outside directors to secure management transparency and objectivity and to strengthen the oversight function of the Board of Directors. We are developing an environment in which the Company receives frank opinions about management from the outside directors and there are lively deliberations based on medium to long term viewpoints. Furthermore, in June 2016 the Company established and began

to operate the Nomination Committee and the Compensation Committee as voluntary advisory committees under the Board of Directors. This step was taken to further enhance corporate governance by strengthening the independence, objectivity, and accountability of the functions of the Board of Directors with respect to the nomination and compensation of its executives. Each of these committees is chaired by an independent outside director and has independent officers as a majority of its members. Also, to enhance the effectiveness of the Board of Directors and increase corporate value, in fiscal 2015 we conducted an evaluation of the effectiveness of the Board of Directors.

Moving forward, as a member of the MCHC Group, we will work to realize *KAITEKI*. In addition, in consideration of the evaluation of the effectiveness of the Board of Directors, we will work to further strengthen the corporate governance system.

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/>

For further information about the Nomination Committee, the Compensation Committee, and the evaluation of the effectiveness of the Board of Directors, please see page 62.



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### MOS Indexes

#### Health Index Results

	Fiscal 2015 Targets	Fiscal 2015 Results
Contribute to medical treatment	Increase the index performance derived by the degree of difficulty to treat diseases multiplied by the number of administered patients by 50% (compared with fiscal 2009)	20% increase
Contribute to improvements of QOL	Increase contribution to QOL improvements by 70% (compared with fiscal 2009)	94% increase
Contribute to early detection and prevention of disease	Increase the index of vaccine treatment by 17% (compared with fiscal 2009)	129% increase

## Shareholder Return

Under the new medium-term management plan, the basic aim is for a dividend payout ratio of 50%, which represents a real increase of 10 percentage points in comparison with the dividend policy under the previous medium-term management plan. On this basis, the Company will continue working to enhance the distribution of profits.

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 previous medium-term management plan, the Company worked to enhance the distribution of profits, with a target for the consolidated dividend payout ratio of 50% (40% consolidated dividend payout ratio prior to amortization of goodwill). In fiscal 2015, the Company set new record highs for net sales and profit at all levels. Consequently, in accordance with the basic policy on shareholder return, the Company set annual dividends at ¥46.0 per share, an increase of ¥4.0 per share. The dividend payout ratio was 45.7%, compared with 59.6% in the previous fiscal year.

Under the new medium-term management plan, the basic aim is for a dividend payout ratio of 50% under the application of IFRS<sup>6</sup>, which represents a real increase of 10 percentage points in comparison with the dividend policy under the previous medium-term management plan. On this basis, the Company will continue working to enhance the distribution of profits. For fiscal 2016, we are forecasting a decline in revenue due to the influence of the revision of NHI drug prices for domestic ethical pharmaceuticals and to the fact that in fiscal 2015 we recorded lump-sum payment revenues. We are forecasting a decline in core operating profit. In addition to the decline in revenue, the reasons include an

Since I became president, I have stated that we need to implement reforms to be a “pharmaceutical company that works with a sense of speed and is the first to deliver unique value.” I have expressed our commitment to achieving this goal inside and outside the Company, and we have incorporated this commitment into specific initiatives. The results are starting to take shape, and external evaluations of the Company are steadily shifting toward an image of Mitsubishi Tanabe Pharma as a “company that works with a sense of speed.” As the next step, we will strive to establish a reputation among shareholders and investors as a “company that takes responsibility for and achieves its objectives.” The new medium-term management plan will be the test.

We have begun to move toward our targets of revenue of ¥500.0 billion and core operating profit of ¥100.0 billion. We will plot a course through uncharted territory and open up the future. The four strategic priorities include numerical objectives as

increase in R&D expenses accompanying progress in development projects and an increase in expenses related to accelerating U.S. business development. We are also anticipating substantial improvement in non-recurring items, but are forecasting a decline in net 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 2016 of ¥48.0 per share, an increase of ¥2.0 per share, for a consolidated dividend payout ratio of 47.2% under IFRS.

6. The Company has voluntarily applied IFRS instead of Japan GAAP from the first quarter of fiscal 2016.

### Forecasts for Fiscal 2016 (IFRS) (Announced on May 11, 2016)

	Fiscal 2015 results (IFRS)	Fiscal 2016 forecasts
Revenue	¥425.8 billion	¥406.5 billion
Core operating profit	¥107.0 billion	¥77.0 billion
Net profit attributable to owners of the Company	¥59.3 billion	¥57.0 billion

milestones, and as a result it is clear that we are making steady progress. In fiscal 2020, the final year of the plan, we will have established a business foundation in the U.S., on what is a new continent for Mitsubishi Tanabe Pharma, and we will reach our target. That is my promise. I would like to ask for your support as the Company embarks on this journey.

August 2016



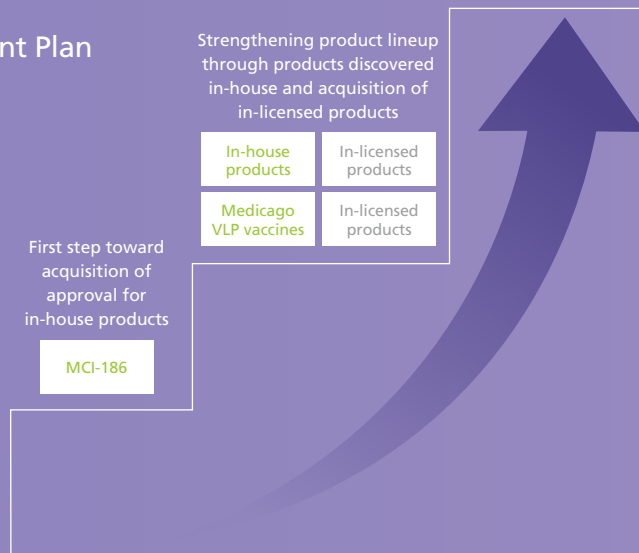
Masayuki Mitsuka  
President & Representative Director

# Accelerating U.S. Business Development

## — The Key to the New Medium-Term Management Plan

“Accelerating U.S. Business Development” is one of the four strategic priorities to open up the future under Medium-Term Management Plan 16–20. Aiming to achieve U.S. net sales of ¥80.0 billion in fiscal 2020, we are moving forward with initiatives to construct a business foundation in the U.S. As the first step in that direction, we are working to achieve a rapid launch of MCI-186, an in-house product. To achieve that goal, we will need to further strengthen our product lineup. We are taking steps to strengthen our business development function, centered on the U.S., to facilitate the acquisition of promising in-licensed products in additions to drugs discovered in-house. This section explains the results and focus of those initiatives.

U.S. sales  
(Fiscal 2020)  
**¥80.0 billion**



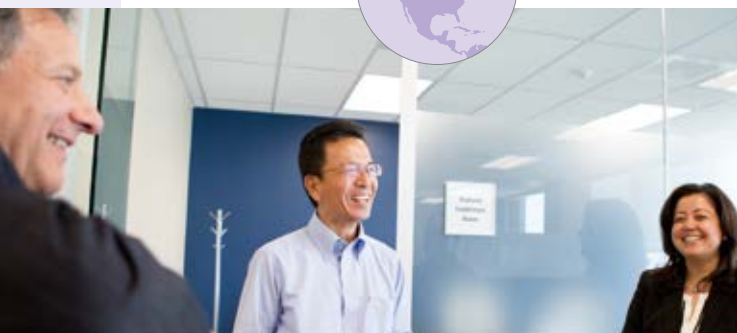
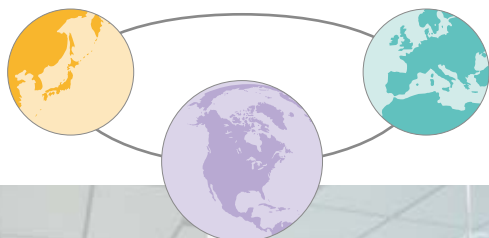
### Building a Business Development System Centered on the U.S.

Competition to acquire new drug candidates is intensifying around the world, and in this setting project acquisition has become more difficult, especially the acquisition of rights in the U.S. and Europe. In accordance with our belief that we must increase the speed of decision-making in order to lead other companies, Mitsubishi Tanabe Pharma has worked to strengthen the business development function, centered on the U.S. In December 2014, we reorganized Group companies in the U.S. in order to promote collaboration

among Group companies in the U.S. and to advance alliance activities with universities and venture companies. In addition, Mitsubishi Tanabe Pharma Holdings America (MTHA), a holding company in the U.S., has been given overall responsibility for U.S. operations, and it oversees other Group companies in the U.S. Furthermore, in July 2015, to strengthen the driving force of alliance activities, we established three business development divisions — in Japan, the U.S., and Europe — and assigned responsibility for global business development to MTHA.

#### Business Development System Centered on the U.S.

##### Establishing three business development divisions, in Japan, the U.S., and Europe



#### Assigning the global business development supervisory function to the company with overall responsibility for U.S. operations

##### U.S. Organizational System

Company with overall responsibility for U.S. operations

Mitsubishi Tanabe Pharma Holdings America

Pharmaceutical research company

Tanabe Research Laboratories U.S.A.

Pharmaceutical development company

Mitsubishi Tanabe Pharma Development America

Bio-venture investment company

MP Healthcare Venture Management

Pharmaceutical sales company

MT Pharma America

## Securing Multiple In-Licensed Products

In addition to Japanese employees, the business development divisions in the U.S. and Europe also have non-Japanese employees who are well-acquainted with local circumstances. Furthermore, substantial authority has been delegated to each division. This system emphasizes speed, with local units making decisions on everything from searching for promising alliance projects to evaluating projects and advancing negotiations with potential alliance partners. The Head Office in Japan decides only the priority ranking among the alliance projects that are ultimately forwarded to the Head Office by the responsible departments.

These initiatives have been successful, and in 2015 we were able to secure three in-licensed products. We in-licensed VMAT2 inhibitor valbenazine (expected indications: tardive dyskinesia, Huntington disease) in March 2015; fasinumab, an NGF antibody (expected

indications: osteoarthritis and chronic low back pain) in September; and vadadustat, an HIF-PH inhibitor, (expected indication: renal anemia) in December. In this way, we acquired exclusive development and sales rights in Japan and certain parts of Asia. In April 2016, we started phase 1 clinical trials for valbenazine (development code: MT-5199). We are currently in preparation for the development of the other two products, under the development codes MT-5547 and MT-6548. We are targeting a rapid launch. We do not have U.S. rights for these in-licensed products, but they do represent a major step toward the acquisition of products in the U.S. in the future.

To build a foundation for U.S. business, we will continue to in-license development seeds, technologies, drug candidates, and products that are appropriate for our business strategies. In these ways, we will strive to strengthen our product lineup by utilizing a wide array of collaborative arrangements.

### Results in 2015: Acquisition of in-licensed products

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

Development code (Generic name)	Category (Indications)	Out-licensor / Overseas development status	Mitsubishi Tanabe Pharma's development status
<b>MT-5199</b> (valbenazine)	VMAT2 inhibitor (tardive dyskinesia and Huntington disease)	<b>U.S.: Neurocrine Biosciences</b> Tardive dyskinesia: Phase 3 clinical trials (U.S.) Tourette syndrome: Phase 2 clinical trials (U.S.)	Phase 1 clinical trials (Japan)
<b>MT-5547</b> (fasinumab)	Antibody against NGF (osteoarthritis, chronic low back pain)	<b>U.S.: Regeneron Pharmaceuticals</b> Osteoarthritis: Phase 2/3 clinical trials (U.S.) Chronic low back pain: Phase 2/3 clinical trials (U.S.)	In preparation for development
<b>MT-6548</b> (vadadustat)	HIF-PH inhibitor (renal anemia)	<b>U.S.: Akebia Therapeutics</b> Renal anemia: Phase 3 clinical trials (Europe, U.S.)	In preparation for development

Close Up

## Japan-Originated ALS Treatment Agent: MCI-186 Filing an Application in the U.S.

In June 2016, we filed an application with the U.S. FDA for MCI-186 (generic name: edaravone) for an indication of ALS. If this application is approved, MCI-186 will be the first new ALS drug in the U.S. in about 20 years. There are said to be about 30,000 ALS patients in the U.S., and up to this point there has been only one type of ALS treatment agent in the world. A new type of ALS treatment agent has been eagerly awaited.

MCI-186 is a free radical scavenger discovered by the Company. It was approved in Japan in 2001 as a treatment agent for the acute stage of cerebral infarction. It is sold under the product name Radicut. MCI-186 is thought to scavenge and detoxify free radicals, which increase in ALS. In June 2015, MCI-186 was approved in Japan for an indication of controlling the progress of functional damage in ALS. In December, it also acquired approval in South Korea.

Targeting the start of sales of this drug in the U.S., in February 2016 we established MT Pharma America, a pharmaceutical sales

### ALS

- Neurological disease where motor neurons degenerate and die, leading to muscular atrophy and weakness
- Progressive disease, and many patients die within 2 to 5 years after onset of symptoms due to respiratory failure<sup>1</sup>
- There are said to be about 30,000 ALS patients in the U.S., with more than 5,600 new patients every year<sup>2</sup>

1. Source: Website of Japan Intractable Diseases Information Center  
2. Source: ALS Association website

company. To provide this drug to patients as soon as possible and take the first step toward the establishment of a foundation for U.S. business, we will continue working to acquire approval within fiscal 2016.

# Drug Discovery

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This section explains our initiatives to discover drugs with value through our business processes which leads to product launch— from the search for the candidate compounds (discovery seeds) that will become pharmaceuticals to basic research, pre-clinical trials, and clinical trials.



## Basic Policies

The Company strives to continually discover new drugs that address unmet medical needs<sup>1</sup> around the world. Under Medium-Term Management Plan 16–20, we identified four strategic priorities to open up the future. One of those priorities is “Maximizing Pipeline Value.” We have established the objective of discovering 10 late-stage drug candidates (including in-licensed candidates) during the period covered by the plan.

The Company’s priority disease areas are autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. We are focusing on the discovery of pharmaceuticals for which we can be the first to deliver unique value. In addition, we will expand discovery resources by aggressively leveraging open shared business through the in-licensing of discovery seeds and the implementation of 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<sup>2</sup>.

1. Medical needs that are not addressed adequately by existing therapies.
2. Proof of Concept: Confirmation of the efficacy and safety of new drug candidate substances in humans.

## Establishing Priority Disease Areas

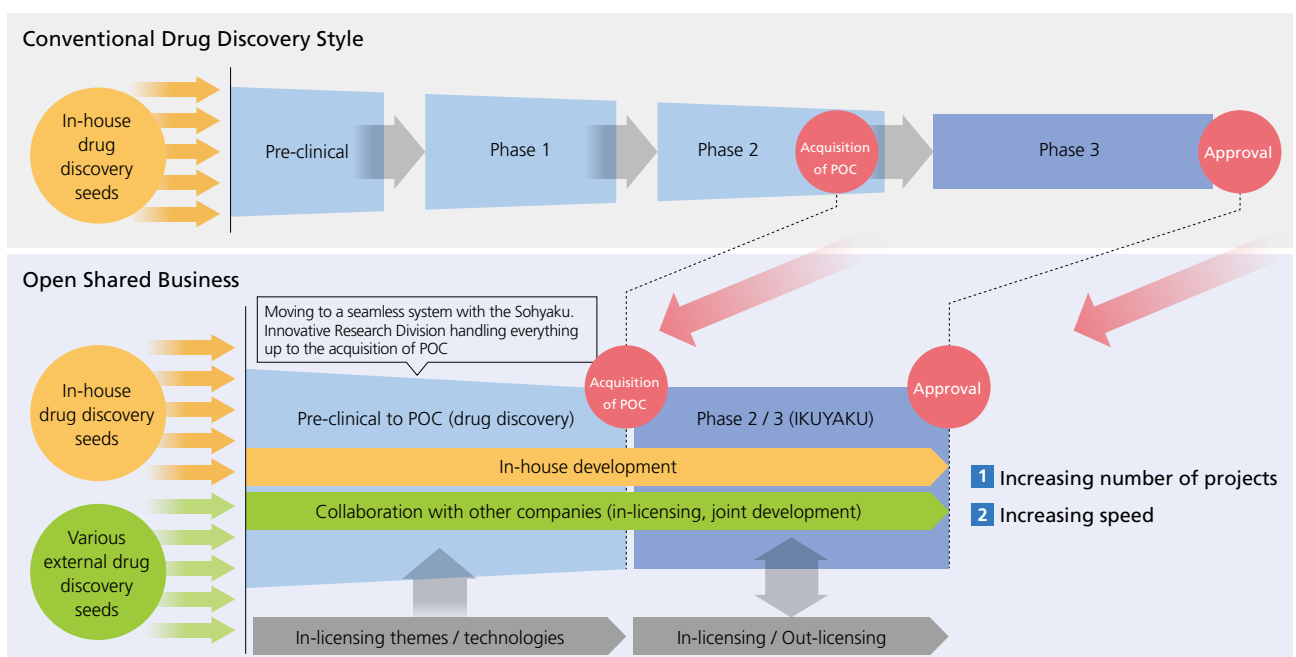
Mitsubishi Tanabe Pharma is striving to implement effective, efficient R&D activities by focusing the allocation of management resources on four priority disease areas. In these priority disease areas, there are high expectations for the use of pharmaceuticals in treatment and the markets have growth potential. In addition, the sales results of existing products have enabled the Company to

build a strong market foundation in these areas. Due to the know-how that we have accumulated in R&D and sales activities, we expect to be able to rapidly launch drug candidates and achieve quick market uptake after launch.

For further information about drug candidates in priority disease areas, please see “Status of New Product Development.” [➔ P38](#)

## R&D Process Reforms

Under the current plan, we will accelerate of the R&D process reform to increase the speed of R&D and to double the number of projects. We reevaluated the R&D system and established the “Sohyaku. Innovative Research Division” in October 2015. Under the previous system, the Research Division handled projects up to the point at which they advanced to clinical trials, and the Development Division handled projects from clinical trials to launch. That structure has been reorganized into a seamless system under which the Sohyaku. Innovative Research Division handles everything up to the acquisition of POC. This new system facilitates the fastest acquisition of POC. In addition, we established the Project Facilitation Department in the Sohyaku. Innovative Research Division. The new department will work to increase R&D speed by thoroughly reevaluating the way projects are advanced. In the same way, we established the Translational Research Department within the Sohyaku. Innovative Research Division. This department is working to strengthen the “crossing the bridge” function from pre-clinical trials to clinical trials and appropriately acquire POC. It is also working to deepen the consideration of indications from an early stage and maximize product value.





In addition, we will advance the utilization of open shared business. In-house discovery seeds previously accounted for the majority of our discovery seeds, but in the future we will increase the total number of discovery seeds by aggressively bringing in diverse discovery seeds from other companies. Furthermore, targeting the more-rapid acquisition of POC, we will work to introduce discovery themes and discovery technologies. Also, following the acquisition of POC we will implement out-licensing in line with the characteristics of drug candidates. In these ways, we will strive to collaborate with the optimal partner for all of the drug discovery processes. In July 2015, with the objective of bolstering the driving force behind alliance activities, overall responsibility for global business development was assigned to Mitsubishi Tanabe Pharma America, of the U.S. Moreover, we have established a three-part business development structure, with business development departments in the U.S., Europe, and Asia.

#### ▶ Joint Research

To identify promising discovery targets, we are engaging in joint research with academic institutions and companies. In diabetes and kidney diseases, which is a priority disease area, we are working with Kyoto University in joint research through the Basic and Clinical Research Project for Discovering Innovative Treatments for Chronic Kidney Disease. In addition, we are implementing joint research with AstraZeneca, of the U.K., with the objective of enhancing our development pipeline in diabetic nephropathy. By effectively leveraging complementary strengths—expertise and research assets related to diabetic nephropathy—through this research program the Company and AstraZeneca are aiming to

rapidly discover new low molecular weight drugs for the treatment of diabetic nephropathy.

In addition, biologics<sup>3</sup> have had a growing presence in pharmaceutical markets in recent years. In biologics research, Tanabe Research Laboratories U.S.A. (TRL), our discovery research base in the U.S., is advancing research through the use of open innovation. Together with Covagen, of Switzerland, we are conducting joint research related to the discovery of bispecific proteins using Covagen's proprietary Fynomer-antibody platform. Unlike typical therapeutic antibodies, which bind to only one type of antigen, bispecific proteins are expected to be next-generation therapeutic antibodies that bind to multiple antigens. In fiscal 2015, the Company and TRL entered into a strategic collaboration and licensing agreement with MedImmune<sup>4</sup>, of the U.S. The agreement concerns antibody-drug conjugates (ADCs) using MedImmune's anti-cancer agent pyrrolobenzodiazepine and TRL's specific cancer-targeting antibody technology. In multiple TRL cancer programs, this agreement will make it possible to conduct joint research into ADCs making exclusive use of MedImmune's technologies.

In addition, to further accelerate drug discovery research at both companies, the Company and Astellas Pharma agreed to mutually exchange and utilize approximately 250,000 compounds selected from their respective compound libraries, including a significant number of proprietary synthetic compounds.

3. 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.

4. A subsidiary of AstraZeneca. Supports global biopharmaceutical research.

## Open Up *Our* Future

### Delivering Products that Help Patients

————— **Takashi Ono** Advanced Drug Research Laboratories, Sohyaku. Innovative Research Division

Since I joined the Company, I have continued to work in evaluating effectiveness from the initial stages of drug discovery. To search for drug seeds, we utilize proteins and cells and conduct tests to verify the efficacy of compounds. The difficulty of drug discovery is steadily increasing, and previous examples of success no longer apply in the current situation. Therefore, we also conduct tests using nerve cells made from stem cells, and in recent years we have begun to do research in regenerative medicine. We have accumulated know-how in regenerative medicine through the use of stem cells, while on the other hand there are also many areas in which our know-how needs to be strengthened. To address that issue, we are aggressively advancing collaboration with universities and other academic institutions as well as

companies. Holding discussions with outside researchers brings us into contact with new ways of thinking and has become a major source of encouragement.

When we started regenerative medicine research, I was actually somewhat disoriented. The reason is that, in contrast to the previous approach, where we used cells for the purpose of evaluating drugs, in regenerative medicine we are, in a way, using cells themselves as pharmaceuticals. However, there is no doubt about our goal of helping patients. In the future, I would like to help the Company advance to the point where we can deliver regenerative medicine products around the world.





► **In-Licensing of Products and Technologies**

To continually strengthen our pipeline, we are aggressively working to in-license products and technologies. Looking at in-licensing activities in fiscal 2015, in autoimmune diseases, a priority disease area, we acquired exclusive development and commercialization rights from Regeneron Pharmaceuticals, of the U.S., for fasinumab, an NGF antibody (development code: MT-5547, expected indications: osteoarthritis and chronic low back pain), in Japan and certain parts of Asia. In addition, we acquired exclusive development and commercialization rights from Akebia Therapeutics, of the U.S., for vadadustat, an HIF-PH inhibitor (development code: MT-6548, expected indication: renal anemia), in Japan and Asia.

► **Out-Licensing Drug Candidates**

We are out-licensing drug candidates as one effective means of maximizing the value of drugs that we have discovered in-house. Through the out-licensing of drug candidates and collaboration with other companies, we can further accelerate development.

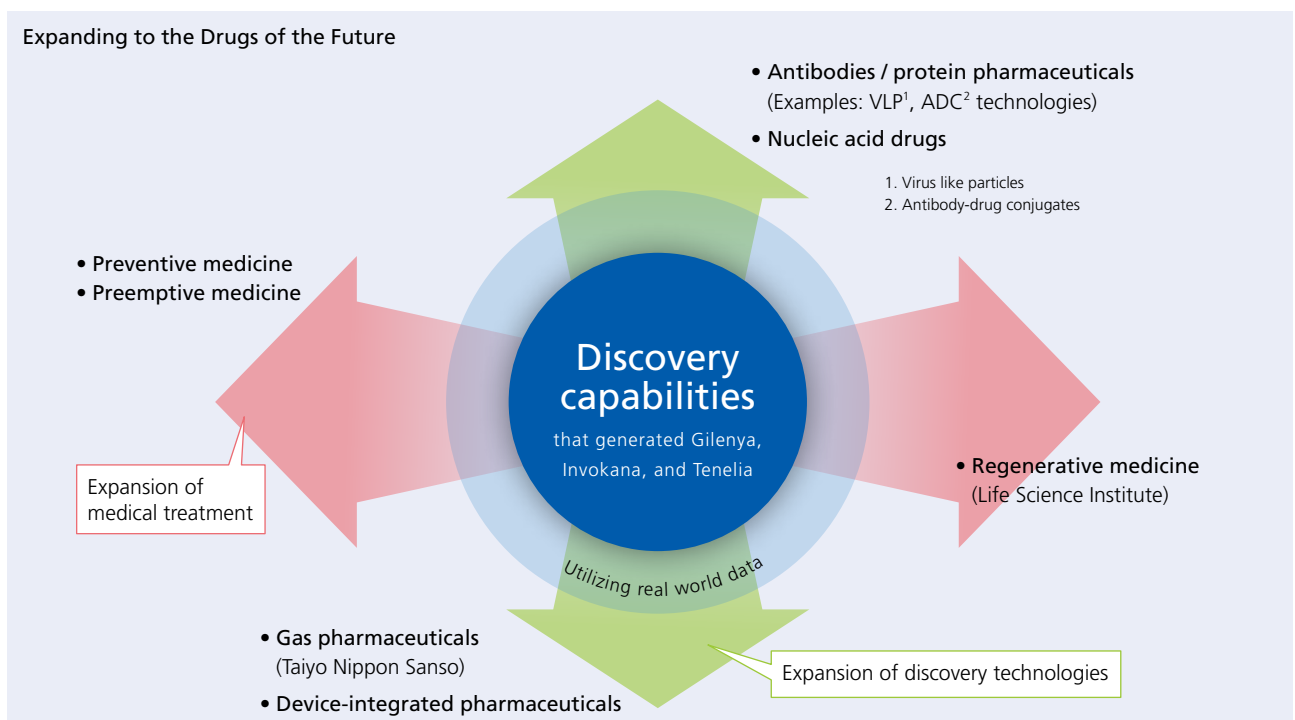
We out-licensed FTY720 (indication: MS) to Novartis, of Switzerland, and in 2011 it was launched in the U.S. under the name Gilenya. The royalty revenues from Gilenya have increased, reaching ¥51.7 billion in fiscal 2015. In addition, we out-licensed TA-7284 (indication: type 2 diabetes mellitus) to Janssen Pharmaceuticals, of the U.S. Under the brand name Invokana, TA-7284 was launched in 2013 by Janssen Pharmaceuticals as the first SGLT2 inhibitor in the U.S. Royalty revenues from Invokana reached ¥20.6 billion in fiscal 2015. In regard to out-licensing activities in fiscal 2015, the Company granted to Biogen, of the

U.S., the exclusive right to develop and market MT-1303 worldwide, except for Japan and Asia. We are advancing development of MT-1303 as a therapeutic agent for MS, Crohn's disease, and other diseases, and it is positioned to become the successor of Gilenya. Furthermore, due to the acquisition by Amgen, of the U.S., of Dezima Pharma, of the Netherlands, which is the licensee for TA-8995 (expected indication: dyslipidemia), the Company transferred worldwide TA-8995 patents and know-how to Amgen, except for Japan and certain parts of Asia.

**Expanding to the Drugs of the Future**

Centered on our ability to discover drugs in-house, we will utilize new discovery technologies in such fields as next-generation therapeutic antibodies, protein pharmaceuticals, nucleic acid drugs, vaccines, and gas pharmaceuticals. In addition, we will extend our focus into new types of medicine and discovery fields, such as regenerative medicine and preemptive medicine. To that end, we will advance collaboration with companies in the Mitsubishi Chemical Holdings Group and utilize MP Healthcare Venture Management (MPH), of the U.S., a bio-venture investment subsidiary, as well as TRL. In addition, in October 2015 we established the New Value Creation Office, which works to anticipate changes in the medical environment and find new business opportunities.

For further information about the New Value Creation Office, please see page 37. ➔ P37



## Establishment of Discovery Research Bases

When Mitsubishi Tanabe Pharma was established in 2007, the Company had five domestic discovery research bases. With the objective of increasing the efficiency and speed of discovery research activities, we subsequently made steady progress in the consolidation of functions. First, CMC<sup>5</sup> research, which includes the manufacturing and formulation of pharmaceutical ingredients and the preparation for commercial production of new drugs, was consolidated at the Kashima Office. In fiscal 2015, we closed the Kazusa Office and consolidated the research operations of the Sohyaku. Innovative Research Division into two bases — the Yokohama Office and the Toda Office.

Overseas, TRL has the role of discovery research base focusing on biologics. In addition, MPH, which handles the Group's corporate venture function in the research field, searches for companies to invest in, with a focus on development pipelines and technologies.

5. 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.

## Enhancing Our Global Development System

We are utilizing a project system that promotes global development for drug candidates with the same active ingredients, regardless of where development is being implemented. International drug development and review standards are being unified, and in this setting clinical trial data obtained outside of the country or region in which development is being conducted can now be used in application documents. Accordingly, through the management of projects by active ingredient, we can utilize clinical trial data that transcends national boundaries and increase speed and efficiency in global development.

In the future, our policy will be to transition to operations led locally so that we can implement rapid decision-making with closer ties to the development area. In accordance with this policy, we are moving forward with the establishment of decision-making system with two bases — Europe / U.S. and Japan / Asia.

In the U.S. and Europe, we are aiming to develop innovative and highly cost-competitive products that address unmet medical needs. In particular, for products discovered in-house we are aggressively advancing development in the U.S., and we will strive to link them to growth in U.S. business. In Japan, we are collaborating with development initiatives in Europe and the U.S. We are also aggressively moving forward with in-licensed products and LCM that are appropriate for the domestic market, which is our home market. Furthermore, in Asia, in line with the medical needs of each market, we are advancing the development of products that have acquired approval in Japan, the U.S., or Europe.

## Consideration for Ethics in R&D Activities

### ► Initiatives in Discovery Research

Discovery research using human tissue and cells provided by patients is increasingly important in the discovery of more-effective, safe drugs. In implementing this research, it is essential to pay careful attention to ethical issues, such as the acquisition of appropriate informed consent and the maintenance of the privacy of donors. We have established ethics review committees, which carefully examine the ethics and scientific validity of research plans. These committees include outside members to promote objectivity, impartiality, and transparency. This system facilitates balanced screening with respect for a variety of viewpoints. Furthermore, we are working to ensure transparency, and post the regulations of the ethics review committees and summaries of their proceedings on the Ministry of Health, Labour and Welfare's clinical research ethics committee reporting system.

For testing using animals, the Animal Experiment Committee deliberates the validity of testing plans based on international standards for animal testing. In addition, we carry out internal inspections and self-assessments to confirm that all animal experiments comply with our own management system and are in accordance with laws, regulations, and guiding principles. We also obtain external evaluation and certification from a third-party evaluation institution.

### ► Clinical Testing Initiatives

All of our clinical trials are conducted in strict compliance with the guidelines set by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use / Good Clinical Practices (ICH-GCP) (standards for the implementation of clinical testing of pharmaceuticals), which were formulated in accordance with the spirit of the Declaration of Helsinki. All participants give their voluntary informed consent. In implementing clinical trials, advance discussions are conducted by the Clinical Trial Protocol Review Committee, which includes members from outside the Company and medical experts who are well-versed in clinical trial ethics. Before a trial begins, the committee confirms its ethical and scientific validity.

Close Up

## Establishment of the New Value Creation Office

Becoming an organization that can anticipate the future and continue to create new value

The medical environment is undergoing dramatic change, and in this setting we anticipate significant changes in what is expected of pharmaceutical companies. Rather than chasing after those changes, we will do our utmost to anticipate them. With the objective of creating new business opportunities, in October 2015 we established the New Value Creation Office.

To anticipate change, we should not approach our business simply as the “provision of pharmaceuticals.” Rather, we need to look to the future and expand our business portfolio as we take a wide-ranging approach to our business, centered on our corporate philosophy of “contributing to the healthier lives of people around the world through the creation of pharmaceuticals.”

Accordingly, the New Value Creation Office will implement initiatives in such areas as regenerative medicine and preventive / preemptive medicine. In addition, it will work to make progress in such fields as gas pharmaceuticals and device-integrated pharmaceuticals through collaboration with Mitsubishi Chemical Holdings and MCHC Group companies. Furthermore, the New Value Creation Office will also pursue multiple future themes, such as promising ways to utilize IoT, AI, and other technologies that will find growing use in medicine in the years ahead.

I believe that the process of advancing these future themes to the commercialization stage and establishing them as one facet of medicine in the future is the reason why the New Value Creation Office was established as a new unit.

Given the nature of future themes, it is difficult to predict how long it will take to achieve a profit. However, the New Value

Creation Office will not be dealing with the types of themes that are selected out of concern about uncertainty. Accordingly, we are now considering what kind of value we can provide in future medicine. We are also returning to the corporate philosophy and considering the direction we should take as we move forward.

In selecting themes, we will consider not only the scale of a business when it is commercialized but also other viewpoints. These will include the viewpoint of providing immediate benefits and synergies, such as accelerating development or fostering differentiation in the Company’s main pharmaceutical business, as well as the viewpoint of resolving social issues, such as the realization of a sustainable society.

In addition, we will need to work with external partners in order to quickly generate results. We are already moving forward with consideration of specific initiatives together with several companies and academic institutions. In regenerative medicine and gas pharmaceuticals, there are projects for which we are making definite progress toward commercialization.

The Japanese name of the office includes the words “future creation.” I believe that the continued provision of new value is essentially “creating the future.” To continue to provide new value to people around the world who seek health and well-being, I would like the New Value Creation Office to have both exceptional sensitivity, which will act like a sensor to help us “anticipate the future,” and strength and flexibility, which will help us to “give shape to the future.”

I believe that the continued provision of new value is essentially “creating the future.”

**Rikako Yamauchi**

Section Manager of New Value Creation Office,  
Corporate Strategic Planning Department



## Status of New Product Development

If fiscal 2015, we made the following progress with new drug candidates.

For information about additional indications for existing drugs in Japan, please see page 44. [➔ P44](#)

### Acquisition of Approval

#### TA-650 (Japan product name: Remicade)

Approved for Crohn's disease, ulcerative colitis, pediatric Crohn's disease, and pediatric ulcerative colitis in Taiwan.

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

Approved for amyotrophic lateral sclerosis (ALS) in South Korea\*.

\* In Japan, approval was received in June 2015. An application was filed in the U.S. in June 2016.

### Applications Filed

#### MP-513 (Japan product name: Tenelia)

Application submitted in Indonesia for an indication of type 2 diabetes mellitus.

#### TAU-284 (Japan product name: Talion)

Application submitted in China for indications of pediatric allergic rhinitis and pediatric allergic dermatitis.

### Clinical Trials Started

#### MT-1303

Started phase 2 clinical trials in Japan and Europe for an indication of Crohn's disease.

### Newly In-Licensed

#### MT-5547

Acquired exclusive development and commercialization rights in Japan and certain parts of Asia from Regeneron Pharmaceuticals, of the U.S. (expected indications: osteoarthritis and chronic low back pain)

#### MT-6548

Acquired exclusive development and commercialization rights in Japan and Asia from Akebia Therapeutics, of the U.S. (expected indication: renal anemia).

### Out-Licensed Products

#### Fixed-dose combination of TA-7284 (product name: Invokana) with metformin (extended release preparation)

Licensee Janssen Pharmaceuticals, of the U.S., filed an application in the U.S. for an indication of type 2 diabetes mellitus.

#### MT-4580

Licensee Kyowa Hakko Kirin started phase 3 clinical trials in Japan for an indication of secondary hyperparathyroidism in hemodialysis patients.

#### Y-803

Licensee Merck (U.S.) started phase 2 clinical trials in Europe and Canada for an indication of cancer.

### Newly Out-Licensed Products

#### MT-1303

The Company granted to Biogen, of the U.S., exclusive development and marketing rights worldwide except for Japan and Asia (expected indications: ulcerative colitis, Crohn's disease, others) TA-8995

Due to Amgen's acquisition of Dezima Pharma, of the Netherlands, which is the licensee, the Company transferred worldwide patents and know-how for this product, except for Japan and certain parts of Asia, to Amgen, of the U.S. (expected indications: dyslipidemia).

## Overview of Major Drug Candidates

### Autoimmune Diseases

#### MT-1303

Like Imusera / Gilenya (indication: MS), MT-1303 is a sphingosine-1-phosphate (S1P) receptor functional antagonist. By controlling lymphocyte exit from lymph nodes, MT-1303 controls the autoimmune response. Based on the results of pre-clinical trials and clinical trials to date, it is expected to have milder cardiovascular system side effects than Imusera, and it is being developed not only for MS but also for Crohn's disease and other autoimmune diseases. In cooperation with overseas licensee Biogen, of the U.S., we will accelerate development in Japan and Asia.

### Diabetes and Kidney Diseases

#### MT-2412

MT-2412 is a fixed-dose combination of oral type 2 diabetes mellitus treatment agents Tenelia, which is a DPP-4 inhibitor, and Canaglu, which is an SGLT2 inhibitor. This combination increases convenience for patients by reducing the formulation types and the number of pills taken. Merits in treatment are thought to include the facilitation of good blood glucose control as well as the expectation that blood glucose will be controlled through both improvement of impaired insulin secretion (DPP-4 inhibitor) and elimination of glucotoxicity (SGLT2 inhibitor).

#### MT-3995

MT-3995 is a selective mineralocorticoid receptor antagonist. It inhibits the binding of aldosterone to the mineralocorticoid receptor. As a result, MT-3995 inhibits the increase of protein in the urine. It is expected that its use will then reduce renal tissue damage and treat diabetic nephropathy. In pre-clinical studies, the anti-albuminuria effect was confirmed. In addition, because it has a nonsteroid structure, side effects related to sex hormones will be avoided.

## Central Nervous System Diseases

### MP-214

MP-214 is a dopamine D3 / D2 receptor partial agonist in-licensed from Gedeon Richter, of Hungary. It is a new type of schizophrenia treatment agent that differs from existing agents. In addition to the dopamine D2 receptor, it also acts on the D3 receptor. Consequently, side effects like Parkinson's disease are limited, and it is expected to be effective not only against positive symptoms, such as hallucinations and paranoia, but also against negative symptoms, such as depression, as well as against cognitive function disorders. In the U.S., Allergan received approval and started sales in September 2015, with indications of schizophrenia and bipolar mania. In Europe, Gedeon Richter filed an application for an indication of schizophrenia. In Japan and Asia, the phase 2b/3 clinical trials that the Company was implementing failed to achieve the primary endpoint. Following further supplemental analysis and consultations with regulatory authorities, our future course is now under consideration.

## Vaccines

### MT-2301

MT-2301 is a Haemophilus influenza type b (Hib) vaccine in-licensed from Nuron Biotech, of the U.S. Invasive diseases caused by Hib include bacteremia, meningitis, acute epiglottitis, and septic arthritis. In particular, pediatric meningitis caused by Hib can be fatal or have long-lasting sequela. Accordingly, the prevention of infection through vaccination is considered to be highly important. MT-2301 is a liquid vaccine that includes avirulent mutated diphtheria toxin to increase production of antibodies to Hib constituents. Since the second half of the 1980s, it has been used in more than 50 countries overseas. In the future, we plan to move to develop a combined vaccine for five diseases by adding this vaccine to a combined vaccine for four diseases.

### Plant-based VLP vaccines

These vaccines use the plant-based VLP manufacturing technology of Medicago, of Canada, a member of the Group. VLPs have the same external structure as viruses, so VLP vaccines are expected to offer a high level of immunization effectiveness. On the other hand, because they do not include virus genes, there is no virus replication in the body, and therefore this technology is drawing attention as a promising vaccine technology that offers superior safety.

## State of Major New Product Development (As of August 2, 2016)

Development code	Expected indications	Region	Stage			NDA filed	Origin
			Phase 1	Phase 2	Phase 3		
<b>Autoimmune Diseases</b>							
MT-1303	Multiple sclerosis	Europe	■	■			In-house
	Psoriasis	Europe	■	■			
	Crohn's disease	Japan, Europe	■	■			
	Inflammatory diseases, autoimmune diseases	Japan, Europe, US	■				
MT-7117	Inflammatory diseases, autoimmune diseases, etc.	Europe	■				In-house
<b>Diabetes and Kidney Diseases</b>							
MT-2412	Type 2 diabetes mellitus	Japan	■	■	■		In-house
MT-3995	Diabetic nephropathy	Japan, Europe	■	■			In-house
		US	■				
<b>Central Nervous System Diseases</b>							
MCI-186	Amyotrophic lateral sclerosis	US	■	■	■	16.06	In-house
MP-214	Schizophrenia	Japan, Asia	■	■	■	Phase 2b/3	Hungary: Gedeon Richter
MT-8554	Nervous system, etc.	Europe	■				In-house
MT-5199	Nervous system	Japan	■				US: Neurocrine Biosciences
<b>Vaccines</b>							
MT-2301	Prophylaxis of pediatric Hib infection	Japan	■	■			US: Nuron Biotech
Influenza vaccine (Plant-based VLP vaccine)	Prophylaxis of H5N1 influenza	Canada	■	■			In-house
Influenza vaccine (Plant-based VLP vaccine)	Prophylaxis of seasonal influenza	US, Canada	■	■			In-house
Influenza vaccine (Plant-based VLP vaccine)	Prophylaxis of H7N9 influenza	Canada	■				In-house

# IKUYAKU and Marketing

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





## Basic Policies

“Strengthening IKUYAKU (Drug Fostering and Evolution) and Marketing” is one of the strategic priorities under Medium-Term Management Plan 16–20. With the objective of achieving annual domestic pharmaceutical sales of ¥300.0 billion by fiscal 2020, we will work to increase the new drugs and priority products sales ratio to 75%. To that end, we will strengthen 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 sales promotion activities, we will further enhance our special expertise in our priority disease areas. In addition, through the promotion of area marketing, we will track medical needs by region and conduct information provision activities that are appropriate for each region.

## Establishing Information Provision Systems

For efficacy to be provided safely and steadily, it is important that ethical drugs are used in an appropriate manner. If the usage of a drug, including administration and dosage, is inappropriate, then it is possible not only that sufficient effectiveness will not be obtained but also that risks, such as side effects, will increase. Mitsubishi Tanabe Pharma provides information regarding appropriate usage of ethical drugs to doctors, pharmacists, and other health care professionals. These information provision activities are centered on MRs.

To achieve increases in the quality and quantity of information provision, we have established a system under which generalist MRs, who are located throughout the country, are backed up by area-specialist MRs, who have deep levels of knowledge in specific areas. The generalist MRs conduct information provision activities

for a wide range of products and disease areas. In contrast, the area-specialist MRs offer support with highly specialized, high-quality information in each disease area. This information has been gathered from inside and outside the Company. In this way, it is possible to accurately provide information about a wide range of products with only a limited number of MRs. In addition, to conduct information provision activities that meet regional needs, we will advance area marketing. The medical environment is diversifying, and in this setting we are conducting information provision that is appropriate to the characteristics of each region and moving ahead with initiatives to support regional collaborative treatment.

In our information provision and other sales promotion activities, we are working to strictly follow the Ethical Pharmaceutical Promotion Code of the Japan Pharmaceutical Manufacturers Association. A “promotion code” is an explicitly written code of behavior and modality of promotion—the obligations that must be fulfilled as a matter of course and the moderation that naturally must be adhered to—when conducting promotion, as understood in terms of corporate ethics in the pharmaceutical industry. Moreover, in accordance with our Corporate Behavior Charter, our MRs maintain high ethical standards and awareness as appropriate for employees of a life sciences company. They place priority on fairness and integrity in all activities, and conduct information provision activities with full consideration for the rights of patients.

### ► Marketing System Centered on Priority Areas

As with our R&D activities, the priority areas for our marketing activities are autoimmune diseases, diabetes and kidney diseases, central nervous system diseases, and vaccines. On that basis, we have built a marketing system that draws on collaboration with other companies.





In autoimmune diseases, we have built a strong marketing foundation based on relationships of trust with health care professionals that we developed through our core product Remicade (indications: RA and other inflammatory autoimmune diseases<sup>1</sup>). Under the current medium-term management plan, we will offset the influence of the reduction in the NHI drug price for Remicade with growth in unit sales of Remicade and growth in sales of Simponi (indication: RA). In this way, we will work to maintain our No. 1 share in this area. For Remicade, we will continue working to increase product value through life-cycle management, and in addition we will emphasize the product's distinctive features, such as rapid onset and the possibility of increasing the dosage. On the other hand, we will work to ensure that Simponi is widely recognized as a biologic<sup>2</sup> with both efficacy and convenience. In this way, we plan to more than double sales by fiscal 2020. In April 2016, we changed the sales framework with Janssen Pharmaceutical. Previously we implemented joint sales, but now Mitsubishi Tanabe Pharma has sole responsibility for sales. Both companies continue to implement information provision. This change in the sales framework will make it possible to provide information to a wider range of facilities. In addition to these initiatives, we will also advance the launch of new products. In these ways, we will aim to achieve sales of ¥150.0 billion in the autoimmune diseases area in the future.

In the area of diabetes and kidney diseases, we have a strategic sales tie-up with Daiichi Sankyo for Tenelia (indication: type 2 diabetes mellitus) and Canaglu (indication: type 2 diabetes mellitus). For Tenelia, we had been conducting joint sales with Daiichi Sankyo, but from October 2015 Daiichi Sankyo is solely responsible for sales. On the other hand, the Company continues to handle sales of Canaglu. Moreover, both companies will continue to

provide information for both of these drugs. By having the sales for each product centralized, while information provision is conducted jointly, it will be possible to increase sales efficiency and conduct rapid yet appropriate information provision. For Tenelia, we will work to achieve growth in sales and expansion of our share, aiming to be a first-line drug in diabetes treatment. To that end, we will advance differentiation through ease-of-use and effectiveness, such as for senior citizens and patients with impaired kidney function. For Canaglu, we will leverage the abundant evidence accumulated overseas and the results of the cardiovascular outcome trials that are currently under way. In this way, we will emphasize safety and efficacy and establish a position for Canaglu in diabetes treatment. In addition, by launching a Canaglu / Tenelia combination drug, we will expand the options available to patients. Moving forward, we will aim to achieve sales of ¥100.0 billion in the diabetes and kidney diseases area by establishing a presence in this area for both of these drugs and by advancing the launch of new drugs.

1. For further information about indications, please refer to "Overview and Sales Trends of Priority Products in Fiscal 2016" on page 48.

2. 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.

► **Advancing Efficient Sales Promotion Activities**

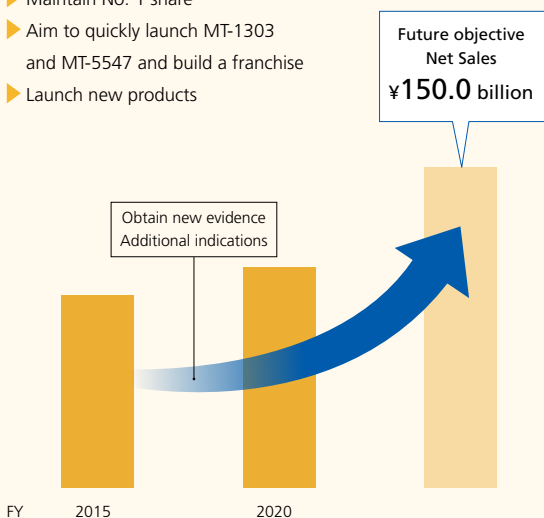
The influence of generics is increasing, and the revenues and profits from long-listed drugs<sup>3</sup> are rapidly declining. However, these long-listed drugs include many drugs that make a strong contribution to medical treatment, such as highly evaluated drugs that are widely used on the medical front lines and drugs for which there are no substitutes. Accordingly, we are moving forward with initiatives to maintain earnings from these products.

**Future Targets in Priority Disease Areas**

**Autoimmune diseases**

**Priority products: Remicade, Simponi, and Imusera**

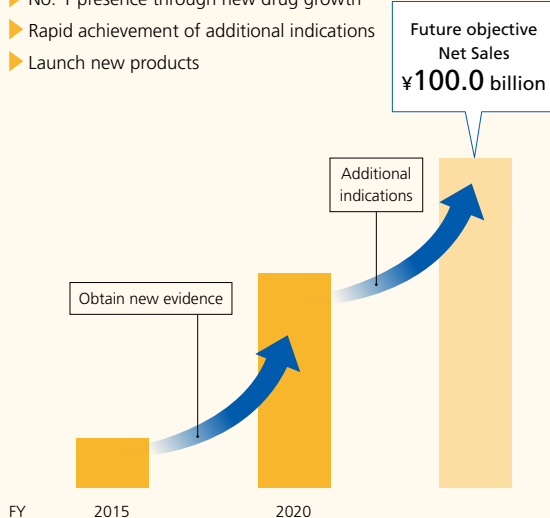
- Maintain No. 1 share
- Aim to quickly launch MT-1303 and MT-5547 and build a franchise
- Launch new products



**Diabetes and kidney diseases**

**Priority products: Tenelia and Canaglu**

- No. 1 presence through new drug growth
- Rapid achievement of additional indications
- Launch new products



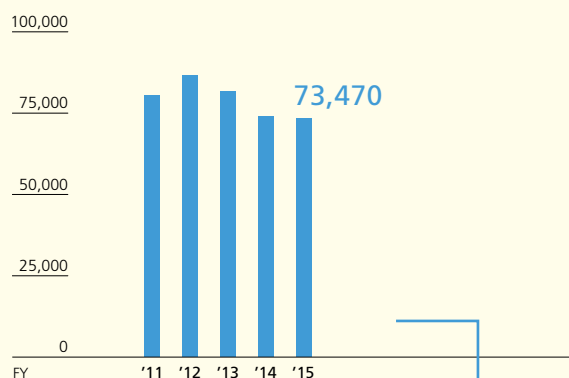
Specifically, we are working to implement effective sales promotion activities for these long-listed drugs, such as conducting information provision activities through a multichannel approach that does not rely on MRs. We have established a specialized medical website for the exclusive use of doctors, pharmacists, and other health care professionals. This website introduces pharmaceutical information, the latest pharmacotherapy evidence, and other information. In addition, through such measures as the use of IT and the establishment of two-way networks, we will strengthen our on-demand information provision system in line with the individual needs of health care professionals.

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

### ▶ Establishing the Medical Information Center

We established the Medical Information Center to respond directly to inquiries from patients, consumers, and health care professionals. For patients and consumers, this is the only product information center, and we are working to provide information that is easy to understand while at the same time making certain not to disperse the type of medical advice that should only come from a physician. In response to more than 70,000 inquiries a year, we work to promote appropriate usage of our products by sharing objective facts and data based on drug approval documents and scientific evidence. Furthermore, the center tracks information about side effects and other safety- and quality-related information obtained through inquiries and then communicates that information to related departments. In this way, the center helps us to improve products and ensure reliability.

Number of Inquiries to the Medical Information Center



Principal Subjects of Inquiries

Product distribution	15.6%
Usage and dosage	13.3%
Safety (precautions for use)	12.9%
Stability	10.2%
Requests for printed materials	7.1%

## Open Up *Our* Future

We will identify needs and link that understanding to customer happiness.

**Mai Oka** Osaka East Sales Office, Osaka Branch, Sales and Marketing Division

For me, the real joy of being an MR is to contribute to patients through products. When we meet with health care professionals, we work to be able to propose treatments from the patient's perspective. To that end, it is important to first understand the needs in each clinical setting. We conduct our conversations with a focus on understanding what is needed.

Also, in differentiating Mitsubishi Tanabe Pharma from other companies, it is essential to provide information in line with needs. However, needs are diversifying, and accordingly there are limits to what a single MR can do. I believe that it will be increasingly necessary to work in teams as well as on a Companywide basis. For example, my team proactively shares examples of successes and

failures, and everyone considers the next step. We become aware of things that we did not notice on our own, and we learn about different viewpoints. This has been very useful.


On the other hand, I think we need to make further efforts in the area of working with a sense of speed. The information that is necessary in clinical settings is continually changing, and we are striving to gather information, focus on anticipated changes, and implement rapid responses. Moving forward, my team and I will continue working tenaciously so that we are seen as a true partners of health care professionals. In the end, I believe that our efforts will ultimately lead to the happiness of patients.



► **Overseas Sales Promotion Activities**

Mitsubishi Tanabe Pharma also has sales bases overseas. We have Group companies with sales functions in Europe (the U.K. and Germany) and in Asia (China, South Korea, Taiwan, and Indonesia). While drawing on alliances with other companies, we are conducting pharmaceutical information provision activities for local health care professionals. Specific activities include the implementation of initiatives that support the diagnosis and treatment activities of health care professionals, such as visiting medical institutions and doctors, participating in related academic conferences, exchanging opinions with opinion leaders, implementing academic research, and creating and distributing information materials. In addition, MRs involved in drug information provision activities need advanced levels of knowledge, information, and skills in order to conduct discussions with doctors and pharmacists. Accordingly, we are working to enhance the quality of information provision activities through periodic training.

In February 2016, in preparation for sales of MCI-186 (Japan product name: Radicut) in the U.S., we established MT Pharma America, a pharmaceutical sales company, as a subsidiary of Mitsubishi Tanabe Pharma Holdings America, which has overall responsibility for U.S. business. Our first step will be the launch of MCI-186, and on that basis we will advance collaboration with outside partners in a variety of forms. In this way, we will work to strengthen our product lineup and build a business foundation in our fields of specialty in the U.S.

For further information about "U.S. Operations Reforms," please see page 30  P30

**Advancing Product Life-Cycle Management**
























































Product life-cycle management operations have been unified by the "Sohyaku. Innovative Research Division," which was established in October 2015. Through integrated advancement, from the product development stage to post-marketing strategy, we will aim to maximize post-marketing product value in a short period of time.

To maximize product value, we continue to implement development activities targeting additional indications. In fiscal 2015, Talion (indications: allergic rhinitis, urticaria, and pruritus accompanying dermatitis) received additional pediatric indications in Japan. In addition, Radicut (indications: neurological symptoms at the acute stage of cerebral infarction, interference with activities of daily living, and improvement of functional disability) received an additional indication in Japan for ALS. Furthermore, BIKEN, our joint development partner, acquired approval in Japan for Tribik for an indication of prophylaxis of pertussis, diphtheria, and tetanus (stage 2 vaccination).

Remicade, which plays a central role in our life-cycle management strategy, has received approval in Japan for additional indications for entero-Behcet's disease, neuro-Behcet's disease, vasculo-Behcet's disease, and Kawasaki disease, as well as a change in administration / dosage for psoriasis (increased dosage). In addition, we are implementing phase 3 clinical trials in Japan for additional indications for pediatric Crohn's disease and pediatric ulcerative colitis.

**Status of Life-cycle Management Strategy (As of August 2, 2016)**

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

Development code (Generic name)	Expected indications	Region	Stage					Origin (Remarks)	
			Phase 1	Phase 2	Phase 3	NDA filed	Approved		
Talion (bepotastine)	Pediatric allergic rhinitis	Japan						15.05	Japan: Ube Industries
	Pediatric atopic dermatitis							15.05	
Radicut (edaravone)	Amyotrophic lateral sclerosis*	Japan						15.06	In-house
Remicade (infliximab [recombinant])	Behcet's disease with special lesions*	Japan						15.08	US: Janssen Biotech
	Refractory Kawasaki disease*							15.12	
	Psoriasis: Increased dosage							16.05	
	Pediatric Crohn's disease								
	Pediatric ulcerative colitis								
Tribik (adsorbed diphtheria– purified pertussis– tetanus combined vaccine)	Prophylaxis of pertussis, diphtheria, and tetanus (Stage 2 vaccinations)	Japan						16.02	Japan: BIKEN (BIKEN acquired approval, Co-development by the Company and BIKEN)
Imusera (fingolimod)	Chronic inflammatory demyelinating polyradiculoneuropathy	Global clinical trial							In-house (Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas)
Canaglu (canagliflozin)	Diabetic nephropathy	Global clinical trial							In-house (Sponsor: Janssen Research & Development)

\* Orphan drug designated

## Establishment of a Quality Assurance System

To ensure that our pharmaceuticals can be used with peace of mind, we have built a system to assure quality, efficacy, and safety at each business process, such as discovery, IKUYAKU, marketing, and production. Divisions related to the various business processes must implement their operations in rigorous compliance with the Pharmaceuticals and Medical Devices Law<sup>4</sup> as well as other laws, regulations, and guidelines. Independent supervisory units—the Quality Audit Section and the Product QA Section—provide objective appraisals of compliance and offer suggestions and instructions on improvement, as appropriate. These initiatives help to assure the reliability of the efficacy and safety data obtained through discovery research, clinical trials, and post-marketing surveillance, as well as the quality of investigational drugs, which are used in clinical trials, and of post-marketing products.

4. The formal name is the "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics."

### ► Implementing Post-Marketing Surveillance

Based on the results of clinical trials and other trials, product sales begin after the receipt of manufacturing and sales approval from the regulatory authorities. Clinical trials are conducted with the number of patients that are needed to scientifically verify pharmaceutical efficacy and safety. However, clinical trials are implemented under restricted conditions, and consequently there are limits to the information that can be obtained in the period up to approval.

Accordingly, adverse reactions that were not discovered in clinical trials are sometimes discovered after the drug is marketed. We start to collect safety information as soon as products are launched, and in addition we are implementing a variety of post-marketing surveillance activities. Through these surveillance activities, we gather data related to new products that are actually prescribed on the medical front lines. We repeatedly examine the safety and efficacy of drugs, and the resulting information is rapidly and accurately provided as feedback to the medical front lines. In this way, the Company is working to support the appropriate use of pharmaceuticals. The Company believes that by advancing these types of proactive safety management measures, the prevention of adverse reactions from new drugs and the promotion of appropriate usage will support the use of new drugs on the medical front lines.

As mentioned above, in 2015 Radicut received approval in Japan for an indication of inhibiting the progression of functional disability in patients with ALS. Radicut was launched in Japan in 2001 as a treatment agent for the acute stage of cerebral infarction, and it has been used for many years. With the new indication, it is now used for patients with ALS, an entirely different disease, and the patients, medical environment, and usage / dosage are substantially different than before. Accordingly, it is necessary to carefully conduct safety measures, and from October 2015, with the cooperation of medical institutions, we commenced a long-term, seven-year post-marketing survey of patients who are using this drug in the treatment of ALS.

Through proactive safety management activities that we have implemented to date, we have acquired valuable experience in advancing appropriate usage. Making full use of that experience, we will work to provide information to foster the appropriate, safe use of Radicut and to contribute to improvement in the treatment of ALS.

### ► Product Quality Assurance

Patient safety is the first priority of every employee, and we are implementing initiatives targeting further quality assurance with a focus not only on results but also on processes. Through management, supervision, and guidance of Group manufacturing plants in Japan and overseas, we work to improve quality through the formulation of quality targets and the implementation of quality assurance plans.

In 2014, the Japanese Ministry of Health, Labour and Welfare became a Participating Authority in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)<sup>5</sup>, and moving forward there are expected to be demands at an even higher level for the establishment of global quality assurance systems for pharmaceuticals. Based on the Quality Assurance Standards formulated by the Company and all Group manufacturing plants, we will aim to achieve further unification with global quality assurance standards.

5. A group aiming to support international harmonization in the areas of pharmaceutical Good Manufacturing Practice (GMP) standards and methods of inspecting manufacturers in regard to compliance with standards.

## Initiatives that Address a Wide Range of Medical Needs

Medical needs, which are diversifying, include not only the provision of drugs that address unmet medical needs<sup>6</sup> but also progress in the area of cost effectiveness. In response to this wide range of needs, we are working in the areas of generic drugs and OTC products.

In the generic drug business, the Group is making the most of its marketing foundation. These initiatives, which are centered on Tanabe Seiyaku Hanbai, a sales company, also include Mitsubishi Tanabe Pharma, which handles new drugs, and Yoshitomiyakuhin, which has strengths in the psychiatric field. Leveraging the rigorous quality control system and wide-ranging distribution system that we have cultivated to this point, we will provide a stable supply of high-quality generics. In addition, Tanabe Seiyaku Hanbai, which has MRs who specialize in generics, will utilize abundant experience and diverse knowledge to implement high-quality information provision activities. Through these initiatives, we will provide generic drugs that can be used with peace of mind under the slogan Reliable Generics. Measures to promote the use of generic drugs have been further strengthened, and we will work to enhance our presence in the generic drug market by responding steadily when major drugs go off patent.

6. Medical needs that are not addressed adequately by existing therapies.

## Overview and Sales Trends of Priority Products in Fiscal 2016

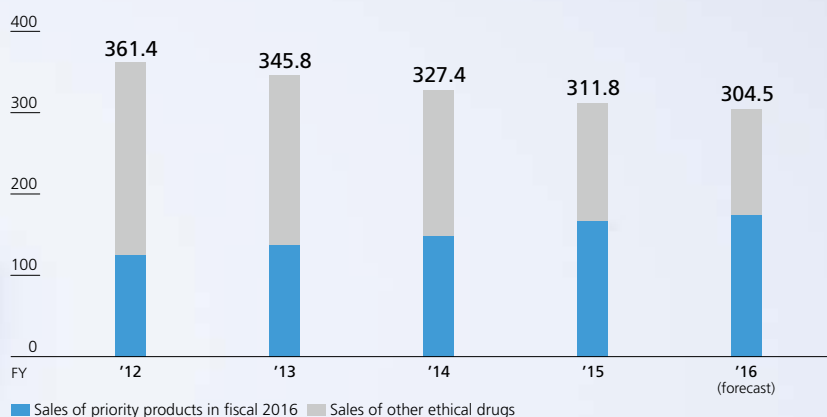
The sales forecasts in this section were announced on May 11, 2016.





## Domestic Sales of Ethical Drugs

Billions of yen



## Sales of Priority Products in Fiscal 2016

Billions of yen	'12	'13	'14	'15	Forecast '16
<b>Remicade</b>	¥73.5	¥76.3	¥70.6	¥69.4	¥62.5
<b>Talion</b>	14.3	13.7	16.0	16.9	17.3
<b>Tenelia</b>	1.2	0.8	9.2	14.2	17.5
<b>Simponi</b>	5.3	9.4	10.5	12.9	23.4
<b>Lexapro</b>	4.6	6.5	8.0	9.5	12.6
<b>Imusera</b>	1.3	2.3	3.2	4.1	4.6
<b>Canaglu</b>	—	—	1.2	0.6	3.6
<b>Vaccines:</b>					
<b>Influenza vaccine</b>	7.7	7.2	7.4	13.8	11.1
<b>Tetrabik</b>	4.5	6.7	7.5	9.5	8.6
<b>Varicella vaccine</b>	2.7	3.6	7.2	6.4	5.5
<b>Mearubik</b>	8.0	6.0	4.0	5.0	4.1
<b>JEBIK V</b>	4.8	4.1	3.5	3.7	3.6





## Business Strategies by Process

### IKUYAKU and Marketing

Overview and Sales Trends of Priority Products in Fiscal 2016

#### Remicade Infiximab

Domestic Sales: ¥ 69.4 billion (overseas sales: ¥30 million)



<b>Indications:</b>	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 $\alpha$  monoclonal antibody. It targets TNF $\alpha$ , 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 (increase of the dosage, shortening of the 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. In 2015, additional indications were received for entero-Behcet's disease, neuro-Behcet's disease, vasculo-Behcet's disease, and

Kawasaki disease. In May 2016, approval was received for an increase in the dosage and a shortening of the administration interval for psoriasis. Currently, phase 3 clinical trials are under way for pediatric Crohn's disease and pediatric ulcerative colitis.

#### ◀ Sales Trend ▶

In fiscal 2015, sales were down 1.7%, to ¥69.4 billion. NHI drug prices were revised in April 2016, and the second biosimilar is expected to be launched during fiscal 2016. The circumstances will remain difficult, including competing products, but we will emphasize Remicade's ability to contribute to a wide range of diseases. In addition, in fiscal 2016 we will continue to support education about its significance and effectiveness in the treatment of ulcerative colitis. The forecast for sales in fiscal 2016 is ¥62.5 billion, a decline of 9.9%.

#### Talion Bepotastine

Domestic Sales: ¥ 16.9 billion (overseas sales: ¥0.9 billion)

<b>Indications:</b>	Allergic rhinitis, urticaria, pruritus accompanying skin disease (eczema, dermatitis, prurigo, cutaneous pruritus)
<b>Launch:</b>	October 2000
<b>Origin:</b>	Ube Industries
<b>Development:</b>	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 2015, sales rose 5.6%, to ¥16.9 billion. In regard to competing products, generics have already been launched and sales are on a declining trend. However, Talion continues to record growth. Talion's share of pediatric patients, for which an additional indication was approved in 2015, is limited to about half of the share for adults, and accordingly we will work to increase sales, principally by increasing the share of pediatric patients. The forecast for sales in fiscal 2016 is ¥17.3 billion, an increase of 2.7%.

## Tenelia Teneligliptin

Domestic Sales: ¥ 14.2 billion (overseas sales: ¥0.3 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. DPP-4 is an enzyme that selectively breaks down glucagon-like peptide-1 (GLP-1), a hormone secreted from the gastrointestinal tract in response to food intake. By inhibiting the function of DPP-4, Tenelia promotes insulin secretion and suppresses glucagon secretion, thereby demonstrating blood glucose lowering action. In addition, in monotherapy it is less likely to cause problems associated with conventional diabetes treatments, such as hypoglycemia and weight gain. 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 2015, sales rose 53.6%, to ¥14.2 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 October 2015, to increase efficiency, we changed from the previous joint sales scheme to solo marketing by Daiichi Sankyo. We continue to implement joint promotions, and we will emphasize ease-of-use, 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 Tenelia sales. The forecast for sales in fiscal 2016 is ¥17.5 billion, an increase of 23.6%.

## Simponi Golimumab

Domestic Sales: ¥ 12.9 billion (overseas sales: ¥1.3 billion)

**Indication:** RA (including the prevention of structural joint damage)  
**Launch:** September 2011  
**Origin:** Janssen Biotech (U.S.)  
**Development:** Co-development with Janssen Pharmaceutical



### ◀ 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. We are conducting joint promotions with Janssen Pharmaceutical. In April 2016, Janssen Pharmaceutical applied for an additional indication for ulcerative colitis.

### ◀ Sales Trend ▶

In fiscal 2015, sales rose 23.5%, to ¥12.9 billion. In April 2016, we changed the sales framework with Janssen Pharmaceutical, transitioning from the previous joint sales to solo marketing by the Company. We conduct joint promotions with Janssen Pharmaceutical. In the RA market, subcutaneous injections are recording growth. Leveraging the strengthened collaboration system, we will work to achieve further market uptake. We have transitioned to solo marketing by the Company, and the forecast for sales in fiscal 2016 is ¥23.4 billion, an increase of 81.0%.

## Business Strategies by Process

### IKUYAKU and Marketing

Overview and Sales Trends of Priority Products in Fiscal 2016

#### Lexapro Escitalopram

Domestic Sales: ¥ 9.5 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 98 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 2015, sales rose 19.2%, to ¥9.5 billion. Growth in the market for anti-depressants is sluggish, but recognition of Lexapro's efficacy and tolerability has begun to achieve further market uptake. With an additional indication for social anxiety disorder, we will work to promote its use by patients with anxious depression. The forecast for sales in fiscal 2016 is ¥12.6 billion, an increase of 32.9%.

#### Imusera Fingolimod

Domestic Sales: ¥ 4.1 billion



**Indications:** Multiple sclerosis (MS)  
**Launch:** November 2011  
**Origin:** Mitsubishi Tanabe Pharma  
**Development:** Co-development with Novartis Pharma

#### ◀ 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 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 in Japan. We are marketing this product under the name Imusera, while Novartis Pharma is marketing it under the name Gilenya. Overseas, Novartis, of Switzerland, which licensed the product, has obtained approval in more than 80 countries, including countries in Europe and the U.S. It has been administered to about 150,000 patients.

#### ◀ Sales Trend ▶

Although new competing products were launched, in fiscal 2015 sales rose 27.0%, to ¥4.1 billion. The combined results of Imusera and Gilenya give them the No. 1 share in the market. The market is growing, and we expect to continue to record favorable growth in prescriptions in fiscal 2016. The forecast for sales in fiscal 2016 is ¥4.6 billion, an increase of 12.8%.

## Canaglu Canagliflozin

Domestic Sales: ¥ 0.6 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. As of May 2016, it had been approved in more than 70 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 is a type of protein that contributes to the reabsorption into the blood of glucose from the urine in the renal tubules. By inhibiting this action, urinary glucose excretion and blood glucose reduction are promoted. Canaglu has 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, Canaglu is expected to have a low hypoglycemia risk in monotherapy. It also has a weight reduction effect that is not seen with other oral diabetes treatment drugs. Overseas, licensee Janssen Pharmaceuticals, of the U.S., received approval in 2013, making this drug the first SGLT2 inhibitor approved in the U.S., and this drug is sold under the brand name Invokana. In addition, Invokana / Vokanamet, a fixed-dose combination of Invokana and metformin hydrochloride, has been approved in more than 40 countries.

### ◀ Sales Trend ▶

In fiscal 2015, sales were down 50.9%, to ¥0.6 billion. Because it has a new mechanism of action, there were concerns about safety. However, the market has gradually begun to expand due to the fact that the results of post-marketing surveillance activities for each SGLT inhibitor drug are not different from the clinical trial safety profiles and due to the results of the cardiovascular outcome studies overseas. We will work to differentiate Canaglu from other drugs and expand the number of facilities at which it is available. The forecast for sales in fiscal 2016 is ¥3.6 billion, an increase of 536.3%.

## Vaccines

Domestic Sales: ¥ 38.3 billion\*

\* Priority products in fiscal 2016  
 Total amount for vaccines (influenza vaccine, Tetrabik, Varicella vaccine, Mearubik, JEBIK V)



The Company sells vaccines developed and produced by BIKEN. In fiscal 2015, sales of the influenza vaccine (indication: prevention of influenza) and Tetrabik (indication: prevention of pertussis, diphtheria, tetanus, and polio) increased. Consequently, overall sales of vaccines rose 29.1%, to ¥39.1 billion. In fiscal 2015, there were issues such as a supply shortage for products that compete with our influenza vaccine and Tetrabik, but the supply is expected to stabilize in fiscal 2016. In regard to the Varicella vaccine, an additional

indication for prevention of shingles in people 50 or older was received in March 2016. With consideration for manufacturing capacity, we will give priority to providing a supply for periodic vaccination of children. Accordingly, for vaccines that are priority products, the forecast for sales in fiscal 2016 is ¥33.0 billion, a decline of 13.9% from ¥38.3 billion in fiscal 2015. The forecast for overall sales of vaccines in fiscal 2016 is ¥33.6 billion, a decline of 13.9%

# Production

## Basic Policy

To securely deliver drugs to patients, even in the event of a disaster or other unforeseen problem, we have built a system for the stable supply of drugs. In addition, to build an even more efficient supply system while maintaining the highest priority on quality, we are working to further strengthen a range of qualities, such as procurement, manufacturing, and distribution. Under Medium-Term Management Plan 16–20, we identified four strategic priorities to open up the future. One of those issues is “Reforming Operational Productivity.” As one facet of those initiatives, we are working to strengthen production technologies and supply chain management (SCM). In this way, we will aim to reduce cost of sales by ¥8.0 billion under the current medium-term management plan.

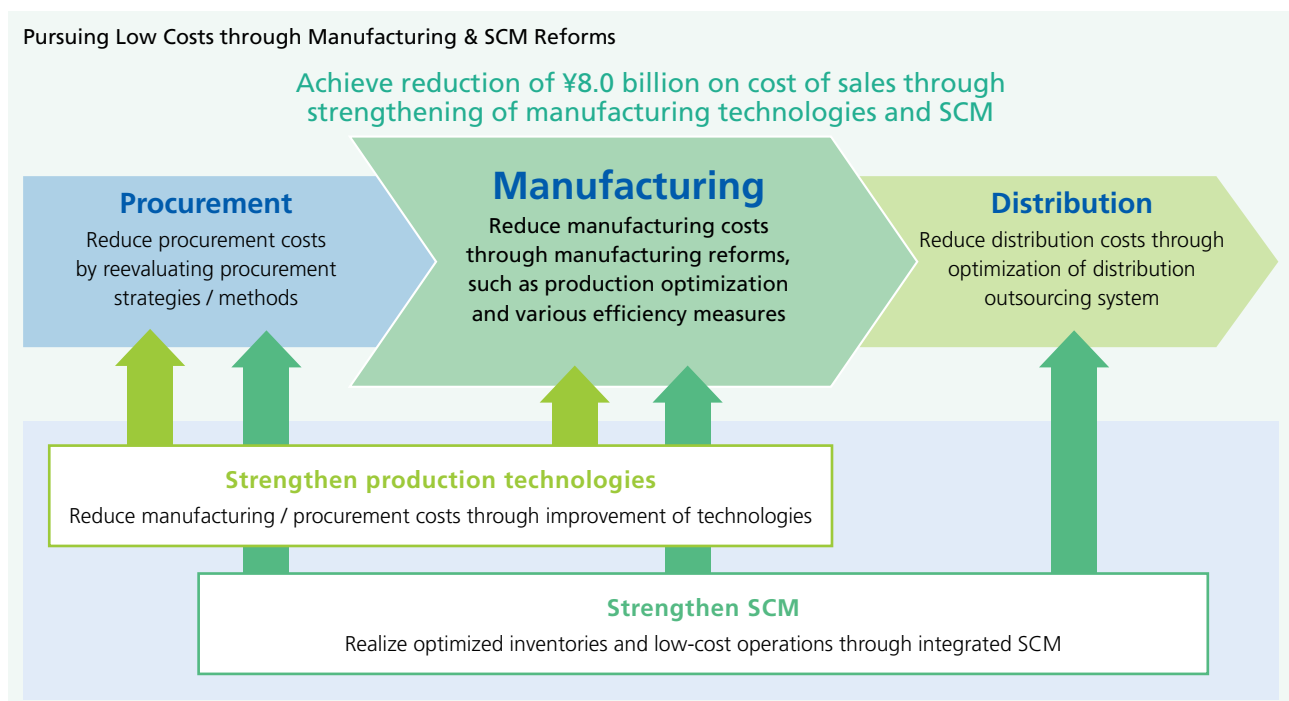
## Initiatives in Procurement

In procuring the raw materials for pharmaceuticals, we are committed to engaging in fair, transparent activities with our suppliers. In accordance with the standards that we have established—our Purchasing Principles and Purchasing Compliance Code of Conduct—we conduct purchasing activities with a strict observance of related laws and regulations, consideration for environmental conservation, and an emphasis on human rights.

In selecting (changing) raw materials for pharmaceuticals, we consider supplier selection standards developed in-house and conduct on-site confirmations of manufacturing sites prior to the selection (change) and after the start of transactions. We make decisions after evaluating such factors as the capabilities of the raw materials manufacturer, which is the supplier, in such areas as quality assurance, technical capabilities, customer focus (ability to respond flexibly), and management capabilities (continuity). In addition, with reference to the Corporate Behavior Charter of the Mitsubishi Chemical Holdings Group, we use a questionnaire for suppliers regarding areas in which we wish to work together with them. Furthermore, to deepen mutual understanding we hold explanation meetings and exchange opinions.

By establishing rules, such as inventory management standards and information cooperation standards that take into account the emergence of unusual situations, we have established a business continuity management (BCM) system. We have built a supply system that can deliver drugs to patients in a stable manner, even in the event of a disaster or other unforeseen problem.

In fiscal 2015, to further reinforce our supply chain, we consolidated supply chain-related departments into the Supply Chain Management Department.



## Production System

To manufacture drugs that can be used with peace of mind by patients, Mitsubishi Tanabe Pharma is implementing initiatives to ensure quality. We act in accordance with Good Manufacturing Practice (GMP) in all manufacturing processes—acceptance testing of raw materials procured from Japan or overseas, manufacturing of pharmaceutical ingredients, manufacturing of pharmaceutical products, and testing / inspection. The CMC Division, which conducts CMC research<sup>1</sup>, works together with the Group's production plants to develop production technologies designed to support the stable, low-cost manufacturing of high-quality products from the new drug development stage.

Currently, our global manufacturing system has five production plants in Japan and four overseas, as well as subcontracted manufacturers. Through this system, we provide a stable supply of pharmaceuticals to patients around the world. Overseas, we have manufacturing and sales bases in Asia, with Tianjin Tanabe Seiyaku manufacturing oral agents in China and Mitsubishi Tanabe Pharma Korea and Taiwan Tanabe Seiyaku handling products for their respective markets as well as products for Japan. Also, Tanabe Indonesia serves as a manufacturing base for its domestic market and other markets in Southeast Asia.

1. 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.

## Reorganization of Production Bases

We are moving ahead with initiatives targeting the establishment of a new-drug supply system that meets global standards and a shift to a flexible, efficient manufacturing system that is less susceptible to the influence of changes in the operating environment. We decided on a policy of consolidating the manufacturing bases of Mitsubishi Tanabe Pharma Factory, a domestic production subsidiary, into two bases, the Onoda Plant and the Yoshitomi Plant. In accordance with this policy, in 2014 we transferred the Ashikaga Plant to CMIC HOLDINGS, and in 2015 we transferred the Kashima Plant to Sawai Pharmaceutical. We plan to close the Osaka Plant by the end of fiscal 2017, and are moving forward with the transfer of the plant's products and other preparations. Moreover, we plan to complete the construction of a new pharmaceutical production building at the Yoshitomi Plant in fiscal 2016, and in fiscal 2015 we commenced the rebuilding of injection drug production facilities at the Onoda Plant, which are scheduled to be completed in fiscal 2016.

In addition, we are working to increase production capacity to address growth in demand in China and ASEAN markets. In fiscal 2015, we completed and placed into operation new production facilities at Tianjin Tanabe Seiyaku and Tanabe Indonesia. In the future, through the steady implementation of a range of initiatives, we will build a global system that meets QCD (quality, cost, stable delivery) standards.

## Distribution System

We have developed a dual-base supply system that ships drugs from distribution centers in eastern and western Japan. To reduce a variety of risks that could adversely affect a stable supply, both of these centers have earthquake isolation systems, in-house power generators, and redundant installations of important equipment. In this way, they will be able to maintain a supply of important drugs even in a crisis situation, such as a major disaster. In addition, if either distribution center becomes inoperable at any time, the other center will be able to provide backup distribution, thereby facilitating a continued supply of pharmaceuticals.

Furthermore, each distribution center employs an inventory control system that carefully monitors product inventory and other items. As a result, we can appropriately control products in a variety of categories, such as by product characteristics and storage temperatures, and can accurately and rapidly conduct operation in response to orders. In addition, we periodically conduct training for the employees who use these types of facilities and equipment. In this way, we aim to enhance the skills of each employee and to reduce human error. At the same time, we are heightening awareness of pharmaceutical distribution extending all the way to the patient.

## Quality Control in Distribution

In addition to conducting operations in accordance with the various conditions related to structural facilities and administrative operation as required by the Pharmaceuticals and Medical Devices Law<sup>2</sup> and other related laws and regulations, the distribution centers prepare guidelines and procedure manuals that reflect the distinctive characteristics of the products being handled. By implementing operations in strict conformance with the content of these guidelines and procedure manuals, we are maintaining both the operational and physical aspects of distribution quality. The Company is particularly vigilant about regulating the temperature at which cold storage products are stored. In addition to measures such as periodic temperature validation and thermometer calibration in cold warehouses, the Company has introduced an emergency response system, including an emergency contact system for unusual conditions and in-house power generators to maintain the power supply. In this way, it is possible to maintain an appropriate temperature 24 hours a day, seven days a week.

Products are shipped from the distribution centers by transport companies that are in compliance with transport quality standards. These companies strictly supervise the transport of this cargo in a manner that reflects the importance of pharmaceuticals. The Company takes steps to minimize any loss of quality during the distribution process, such as periodically inspecting transport companies, conducting temperature validation of transport vehicles, and using special insulated boxes. In these ways, we have built a transport system that can supply high-quality pharmaceuticals.

2. The formal name is the "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics."



# Human Resources

## Fundamental Approach to Human Resources

Mitsubishi Tanabe Pharma is working to further enhance its competitiveness by focusing on its people as a management resource and giving individual employees the opportunity to demonstrate their full potential. To further enhance its competitiveness and achieve sustained growth, the Company operates the Comprehensive Management System for Human Resources.

In addition, we endeavor to develop human resources who act in accordance with the standards of Pride and Sense of Mission, Challenge and Innovation, Trust and Teamwork, and Harmonious Coexistence with Society.

Specific initiatives include the Global Staff Training Program, which was started in fiscal 2011, foreign culture training, which was started in fiscal 2014, and English communication skill training, which was started in fiscal 2015. By combining overseas assignments with on-the-job training, we are strengthening requirements for employees who will be active in global markets.

## 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

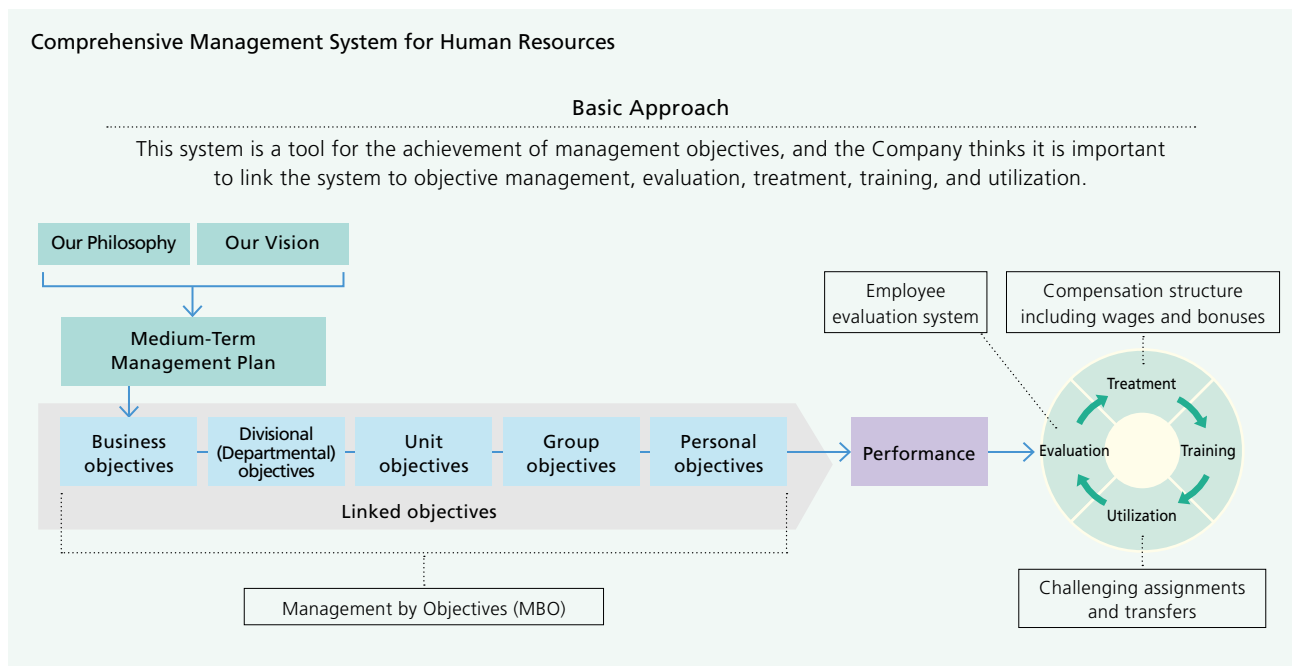
resources, on-the-job and off-the-job training through management by objectives, transfers and rotations, and fair evaluations.

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.

## Actively Utilizing Diverse Human Resources

The Group has positioned its approach to diversity and inclusion as one of its management strategies and is working to establish a work environment that provides opportunities for active careers for diverse human resources, including women, senior citizens, non-Japanese employees, and people with disabilities.

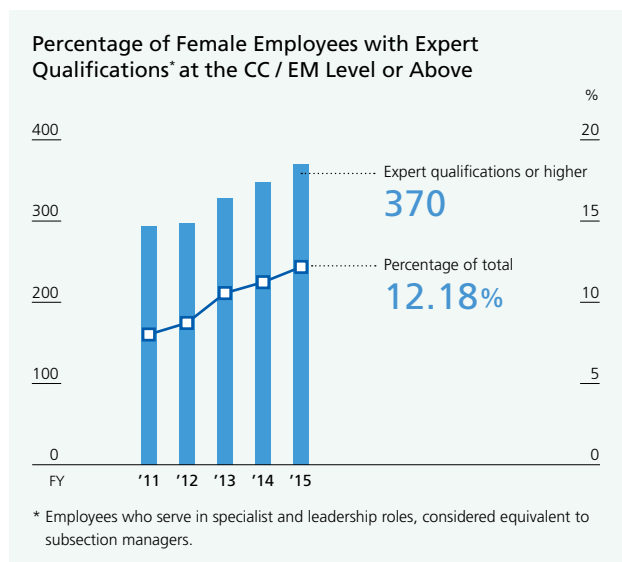
The enhancement of career opportunities for women plays a central role in these initiatives. Through discussions and analysis of the status quo under a Companywide project, we identified key issues for the Company — delays in career development accompanying life events and the further promotion of corporate culture formation. We have announced the following two points for our action plan in regard to the Act on Promotion of Women's Participation and Advancement in the Workplace, which came into effect in April 2016.



- Double the ratio of female line managers within five years, from the current level (March 2015: 5.6%)
- Introduce one or more measures to increase choices in working styles.

Moreover, in regard to the employment of non-Japanese staff, we will step up human resources exchanges with overseas affiliated companies, including opportunities for non-Japanese employees to work in Japan, and will strive to develop human resources who can work actively in the global market, without regard to nationality.

In regard to the employment of people with disabilities, as of the end of March 2016, we employed people with disabilities at a rate of 2.43%, higher than the legally required rate of 2.0%. Moving forward, we will take steps to expand the range of duties of these positions from the many types of work that are available throughout the Group, and will strive to maintain an environment that is easy to work in.



## Initiatives to Raise Human Rights Awareness

The Mitsubishi Tanabe Pharma Group respects the 10 principles of the United Nations Global Compact, which address human rights, labor, the environment, and anticorruption, and upholds these principles in its business activities as a responsible corporate citizen in line with its Corporate Behavior Charter. The Company's Human Rights Awareness Promotion Committee, chaired by the president, plays a key role in both training for officers and employees and other Groupwide human rights training programs, which include collaborating with outside experts and promoting employee participation in outside lectures.

## Securing Occupational Health and Safety

In accordance with the Mitsubishi Tanabe Pharma Environmental Safety Philosophy, the Group's approach is to give priority to consideration for the safety of everyone working and to prevent

occupational accidents. On that basis, the entire Group, centered on production departments and research departments, works to improve facilities and to operate occupational health and safety management systems.

In particular, raising the safety awareness of employees is essential for the prevention of disasters, 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.

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

## 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 corporate 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.

We are implementing a variety of health examinations so that employees do not have any physical or mental disorders. In addition, we are advancing initiatives targeting the prevention of health problems from working long hours. Furthermore, employee mental health is an important issue for the happiness of employees and their families and for the creation of lively and healthy work environments in which employees can create unique value. Accordingly, the Company is actively working in employee mental health management. Stress diagnosis initiatives have been legally required from December 2015. We have conducted these diagnoses from fiscal 2010. Our initiatives include employee self-diagnoses, evaluations of organizational units, and response measures for people with high stress.

## Surveying Employee Attitudes

Since fiscal 2011, the Mitsubishi Tanabe Pharma Group has implemented employee attitude 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 2015, many items recorded year-on-year gains, and there is an overall improvement trend in the corporate culture. On the other hand, a number of issues have been clarified. In consideration of these issues, we will strive to establish a work environment that facilitates dynamic managers, career formation measures for professionals, enhanced career opportunities for diverse human resources, reformed awareness about health, and energetic work.

Close Up

## Enhancing Career Opportunities for Women

Changing attitudes will foster progress in enhancing career opportunities for women

In April 2016, I became the general manager of the Promotion Training Department. In the Company's Sales & Marketing Division, I am the first woman to be employed at the level of general manager or above.

The enhancement of career opportunities for women is currently a major issue for Japanese companies, and Mitsubishi Tanabe Pharma is aggressively implementing initiatives to advance career opportunities for women. To provide support for life events, such as childbirth and child-rearing, the Company is moving forward with measures to test telecommuting. A framework for the provision of fair opportunities for advancement after maternity leave or child-care leave has started to take shape. The establishment of systems that enable women to demonstrate their capabilities is making considerable progress.

However, in advancing career opportunities for women, I believe that it is more important to change attitudes. By attitudes, I am referring to thoughts, intentions, and awareness. First of all, there seem to be many women who have not developed their own specific career plan. In other words, they don't have an image of women's active careers at the Company. This is due to their own attitudes as well as to their surroundings. Through my work, and through face-to-face meetings, lunches, and other opportunities to speak with women in the Company, I am striving to have discussions about how we think about our careers. I hope that these conversations encourage women to think carefully about their career plans and, in the end, contribute to changes in both their attitudes and their actions.

It is also necessary to change attitudes among men. For example, until now, there have not been any women at the level of general manager or above in the Sales & Marketing Division. This is the first time that women have attended the general manager meeting, and some people might feel a sense of discomfort about having a female supervisor. On the other hand, since I joined the Company I have worked as the only woman at meetings and on projects, and this is only natural for me. Consequently, I think that we need to expand this natural situation to other departments and change attitudes among men.

Currently, as the first step in promoting diversity, the Company is working to enhance career opportunities for women, and it is not necessary for women and men to have the exact same work and working styles. I think that the true meaning of promoting diversity involves leveraging the ideas and approaches of women, and ultimately transcending the male-female framework and becoming a company in which all employees can demonstrate their individual strengths. It is important to ensure that all employees understand that these changes will lead to growth for the Company. From my position in the Promotion Training Department, I will work to further enhance the training system so that the Company produces large numbers of role models who are admired by people in other companies and other industries and who can demonstrate their true capabilities.

In advancing career opportunities for women, I believe that it is important to change attitudes of men as well as women.

**Sachiko Nakagawa**

General Manager of  
Promotion Training Department,  
Sales & Marketing Division





田辺三菱製薬株式会社

# ESG Section

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

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# Corporate Governance and Internal Control

## Corporate Governance

### 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 communities.” 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 Corporation, 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 Corporation, the

Company will continue its listing status and maintain independence in its management.

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

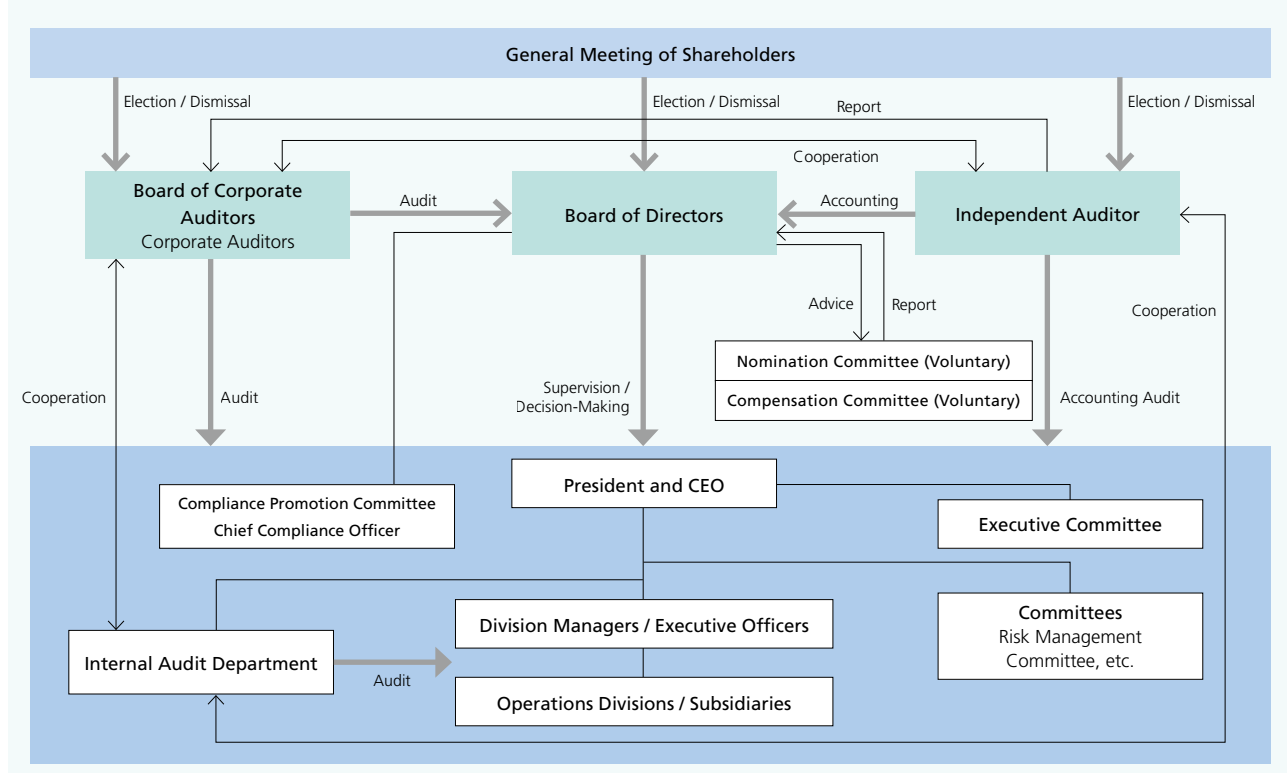
### ▶ Corporate Governance System

The Company has adopted the Company with Board of Company 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.

### ▶ Overview

To secure transparency and objectivity in management decision-making and supervision, the Board of Directors has eight members (8 men, 0 women), including two outside directors. Regular meetings of the Board of Directors are held once a month, and additional meetings are held as needed. Decisions on important

Corporate Governance System (As of June 23, 2016)



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 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. 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.

Organizational Form	Company with Board of Company 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	Chairman of the Board
Number of Directors	8
Appointment of Outside Directors	2

### ► 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 experience and knowledge in pharmaceutical industry business and management 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 Board of Company 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.

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 lawyers, who are legal specialists, and people with experience in banks or securities companies are 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 3 full-time staff.

For internal auditing, the Company has established the Internal Audit Department, which is independent from the executive divisions and audits the internal control systems in operations divisions. The Internal Audit Department has 14 employees as of June 2016.

The Company has appointed Ernst & Young ShinNihon LLC as its independent auditor. There are 3 certified public accountants who are in charge of the account auditing activities. Assisting in the account auditing activities are 12 certified public accountants and 17 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 two 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.

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

[http://www.mt-pharma.co.jp/e/company/pdf/gr\\_mtpc160623\\_e.pdf](http://www.mt-pharma.co.jp/e/company/pdf/gr_mtpc160623_e.pdf)

► **Compensation of Directors and Corporate Auditors**

The Company has adopted a performance-linked method of calculating director compensation. The compensation amount is determined by the Board of Directors within a range fixed at the General Meeting of Shareholders and as provided for by the basic formula for the calculation of compensation for the Board of Directors.

This is to ensure the transparency of compensation-related decision-making.

In fiscal 2015, basic compensation for directors and corporate auditors was as shown in the table below. The Company and consolidated subsidiaries paid ¥75 million and ¥13 million, respectively, to Ernst & Young ShinNihon LLC as compensation for auditing and verification.

	Basic compensation	Number of people
Directors (excluding outside directors)	¥326 million	8
Corporate auditors (excluding outside corporate auditors)	¥71 million	2
Outside officers	¥45 million	5

Note: Includes 3 directors (1 outside) and 1 corporate auditor (outside) who retired in fiscal 2015.

**Name of Outside Officers, Relationships between Outside Officers and the Company and Reason for Nomination**

	Relationships between outside officers and the Company	Reason for nomination
<b>Shigehiko Hattori</b> Outside Director	Shigehiko Hattori is Senior Corporate Adviser of the Board of Shimadzu and Outside 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.	Shigehiko Hattori has abundant experience as a corporate manager and wide-ranging knowledge in science and technology. The Company judged that he has fulfilled his duties in the supervision of decision-making and business execution by the Board of Directors since his appointment in June 2011 by offering valuable advice and proposals from an objective perspective on important matters at the Board of Directors' meetings, and accordingly the Company nominated him as an Outside Director.
<b>Shigeki Iwane</b> Outside Director	Shigeki Iwane works as President and Director of The Kansai Electric Power, and as outside corporate auditor at KINDEN. There are no special conflicts of interest between the Company and Shigeki Iwane or these companies.	Shigeki Iwane has abundant experience as a corporate manager and wide-ranging knowledge in corporate governance. The Company judged that he can utilize this experience and knowledge to fulfill his duties in the supervision of decision-making and business execution by the Board of Directors, and accordingly the Company nominated him as an Outside Director.
<b>Takashi Nishida</b> Outside Corporate Auditor	Takashi Nishida works as outside corporate auditor at Mitsubishi Chemical, a subsidiary of Mitsubishi Chemical Holdings, which is the parent company of Mitsubishi Tanabe Pharma. Until June 2015, Takashi Nishida worked as an outside corporate auditor at Mitsubishi Chemical Holdings and at The Bank of Tokyo- Mitsubishi UFJ, with which the Company has a business transaction relationship. There are no special conflicts of interest between the Company and Takashi Nishida.	Takashi Nishida has abundant experience in the banking and securities industries and wide-ranging knowledge in finance and accounting. The Company judged that he has used such experience and knowledge in appropriately executing his duties as Outside Corporate Auditor, and accordingly the Company nominated him as an Outside Corporate Auditor.
<b>Tadashi Fukuda</b> Outside Corporate Auditor	Tadashi Fukuda works as Executive Partner of Daiichi Law Office, as Outside Board Director of SHINYEI, 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 judged that he can utilize this experience and knowledge in appropriately executing his duties as Outside Corporate Auditor, and accordingly the Company nominated him as an Outside Corporate Auditor.

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

Mitsubishi Chemical Holdings Corporation (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, in principle, for 10 years from October 1, 2007, the Company will remain listed and MCHC will 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 Company believes that it has secured its independence from its parent company.

## Message from a New Outside Officer

Shigeki Iwane, who became an outside director in June 2016, provided the following message.



**Shigeki Iwane**  
Outside Director

I will offer my opinion from a variety of viewpoints in order to further enhance safety and security.

I have worked for many years at The Kansai Electric Power Group, where the trust of customers and society is an important foundation for business in electricity and other fields. This trust is earned through the provision of a safe, stable supply of electricity and the delivery of secure, comfortable, and convenient services. Accordingly, with the ongoing liberalization of the electric power business, we have positioned making safety our highest priority and fulfilling our social responsibilities as the foundation of management. Moving forward, we will strive to fulfill the mission of "continuing to be useful to customers and society."

Mitsubishi Tanabe Pharma is involved in the pharmaceutical business, which has a significant influence on people's lives, and accordingly earning the trust of society is an essential prerequisite for increasing corporate value. The operating environment in the pharmaceutical industry is growing increasingly challenging. The Company has the longest history in the industry. Its corporate philosophy and its vision of being a company that is trusted by communities reflect universal values, and on that basis it will be important for the Company to continue to carefully pass down its philosophy and vision. Leveraging my experience, I will strive to offer my opinion from a variety of viewpoints in order to further enhance safety and security in all of the Company's business activities. The pursuit of safety and security is an unending challenge, but I believe that working persistently to enhance safety and security will contribute to the realization of the corporate philosophy and vision. I will do my utmost to contribute to that endeavor.

## Response to the Corporate Governance Code

The Corporate Governance Code formulated by the Tokyo Stock Exchange has been applied from June 2015. As one part of its response, in June 2016 the Company established and began to operate the Nomination Committee and the Compensation Committee. As voluntary advisory committees under the Board of Directors, these committees are each chaired by an independent outside director, and the majority of their members are independent outside officers (2 inside directors, 3 independent outside officers). The purpose of this initiative is to further enhance the Company's corporate governance by strengthening the independence, objectivity, and accountability of the functions of the Board of Directors with respect to the nomination and compensation of its executives. The principal matters for discussion and reporting for each committee are as follows.

### Nomination Committee

- Selection of director candidates and corporate auditor candidates, selection of executive officers
- Matters related to selection standards for director, corporate auditor, and executive officer candidates
- Selection of candidates to succeed the CEO, matters related to development policies for successor

### Compensation Committee

- Matters related to decisions on the compensation of directors and executive officers
- Matters related to the revision or abolition of compensation systems for directors and executive officers

With the objective of enhancing the effectiveness of the Board of Directors and increasing corporate value, an evaluation of the effectiveness of the Board of Directors was conducted in fiscal 2015. Self-evaluations were conducted through questionnaires distributed to all directors and corporate auditors. In addition, the opinions of outside directors were collected. On this basis, deliberations were held by the Board of Directors. As a result, the Board of Directors confirmed that a system for supporting the supervision of management has been established, including the appropriateness of the composition, operation, and agendas of the Board of Directors and the treatment of outside officers; that discussions and deliberations that will contribute to increasing corporate value are being conducted; and that the effectiveness of the system has been secured.

From the viewpoint of securing the common interests of the Company and shareholders as an independent listed company, the Company will work to secure further management transparency, and to increase the effectiveness of the Board of Directors, the Company concluded that it needed to consider the number of independent outside directors and training for officers. Accordingly, these conclusions will be reflected in management in the next year and thereafter.

➡ In regard to response to the Corporate Governance Code, for more information please refer to the Mitsubishi Tanabe Pharma Corporate Governance Report.  
[http://www.mt-pharma.co.jp/e/company/pdf/gr\\_mtpc160623\\_e.pdf](http://www.mt-pharma.co.jp/e/company/pdf/gr_mtpc160623_e.pdf)

Also, please refer to the conversation between outside director Shigehiko Hattori and Chairperson of the Board Michihiro Tsuchiya (Chairman of the Board) regarding the Company's corporate governance system, including the status of the response to the Corporate Governance Code.



## Risk Management and Compliance

### Risk Management System

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.

In addition, the Company has formulated the Regulations on Managing Business Continuity in a Large-scale Disaster. To address the risk of a large-scale disaster, such as an earthquake, tsunami, typhoon, snowstorm, flooding, or pandemic, and related risks, the Company has established the Mitsubishi Tanabe Pharma Disaster Management Committee and Regional Disaster Management Committees and is working to implement disaster prevention and reduction measures.

Moreover, the Company has formulated a business continuity plan and established a system facilitating the implementation of activities with a focus on business continuity and rapid restoration in the event of an emergency, with the central role in the disaster countermeasures center filled by the Mitsubishi Tanabe Pharma Disaster Management Committee.

### Compliance 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 Code of Conduct, 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 the establishment of the Compliance Promotion Committee and the Internal Controls & Compliance Department, both of which are led by the Chief Compliance Officer. A total of 200 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. In addition, with the objective of strengthening measures to prevent bribery and corruption in business, the Group has formulated the Mitsubishi Tanabe Pharma Group Global Policy for the Prevention of Bribery and Corruption, which has been adopted throughout the Group. In September 2015, to further clarify the content of this policy, we formulated corruption prevention guidelines in China, South Korea, Taiwan, and Indonesia, and we are implementing

### Corporate Behavior Charter

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

<b>Pride and Sense of Mission</b>	As people involved in the creation of pharmaceuticals, we will 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.
<b>Challenge and Innovation</b>	With acute sensitivity and a broad perspective, we will focus on our future direction, decisively take on the challenge of meeting higher goals, and strive to create innovative value.
<b>Trust and Teamwork</b>	Through free and open communication, we will promote mutual understanding and respect, and we will emphasize teamwork as we strive to maximize our results based on strong relationships of trust.
<b>Harmonious Coexistence with Society</b>	We will work to achieve harmonious coexistence with society by acting with consideration for local communities and the environment.

appropriate responses in line with the laws, regulations, and business practices of each country.

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. 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. In addition, prior to starting transactions with new business partners, to the greatest extent possible, the Company checks for affiliations between the supplier and antisocial elements, which is one of the decision criteria used in deciding whether to start a new transaction relationship.

Furthermore, we have established an internal notification system that operates as an internal system for reporting on legal violations and other compliance issues. A specialized organizational unit works to resolve issues, with consideration for the protection and privacy of the person making the report. We have established internal and external hotlines for reports and consultations, and are working to respond to a wide variety of needs for consultation, including for the employees of Group subsidiaries. The number of responses is released on the intranet twice a year, and recent trends and noteworthy examples are reported through training. In fiscal 2015, 51 hotline consultations were handled.

To ensure a solid compliance foundation, the Company is conducting a range of training, including top seminars for directors and officers, Companywide training for all employees, and human rights training, as well as department-level training that deals with issues specific to the operations of each department. In fiscal 2015, Companywide training sessions were held a total of 191 times, and 6,543 people participated. For Group subsidiaries, we are taking steps to build a system to ensure appropriate operational activities are implemented in a seamless manner with the Company, such as building a system for the application of the Company's Compliance Program.

Furthermore, we conduct an employee awareness 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. Moving forward, we will work to continue to increase compliance awareness among employees through such means as Companywide compliance training.

In addition, the Group consults regularly with relevant departments concerning action programs to strengthen compliance and risk management systems at Group companies outside Japan. The Group has bases in the U.S., Europe, and Asia. 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.

### ▶ 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 March 2011, the Japan Pharmaceutical Manufacturers Association (JPMA) formulated the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions. In response, 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 after the announcement of financial results. This information includes payments to medical institutions as R&D expenses, support for academic research, manuscript writing fees, information provision-related expenses, and hospitality and other expenses.

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 we are working to operate this system in an appropriate manner.

In particular, in regard to scholarships and donations to domestic medical institutions, 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 an organization that is independent from the Sales & Marketing Division.

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 of the 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.

## Accountability to Stakeholders

### Promoting Accountability

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 ensure that both the content and timing of our information disclosure is fair to all stakeholders. Moreover, as a member of society, we take feedback from all stakeholders seriously, strive to share information with stakeholders, and work to deepen mutual understanding.

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.

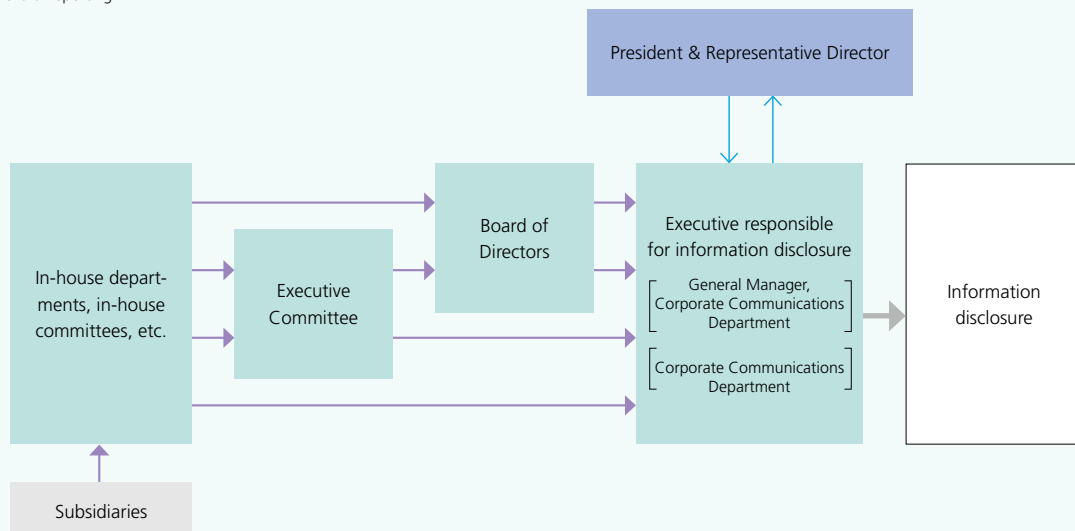
These presentations include results briefings for institutional investors and business presentations. To enable individual and overseas investors to access presentations, the audio and video for presentations are distributed via the Company's website, and the content of Q&A sessions is also released. In addition, in fiscal 2015 we held 13 presentations for individual investors. Furthermore, as an initiative related to corporate social responsibility, we make our CSR Activities Report available on the Company's website.

#### ► In-House Information Disclosure System

The Company has established an in-house system to implement Companywide disclosure of company information in a timely and appropriate manner—the Mitsubishi Tanabe Pharma In-House Information Disclosure System. The executive responsible for information disclosure will control the in-house system, which was established in accordance with information disclosure regulations; will determine whether or not disclosure of company information is appropriate; and will implement disclosure.

Mitsubishi Tanabe Pharma In-House Information Disclosure System (As of June 23, 2016)

→ Flow of information  
 → Approval / Reporting





## Discussion with an Outside Director



As an outside director, I strive to consider the viewpoints of minority shareholders when I offer my opinion.

**Shigehiko Hattori**  
Outside Director

**The application of the Corporate Governance Code formulated by the Tokyo Stock Exchange began in June 2015. The trend toward corporate governance reforms at Japanese companies is accelerating, and in this setting the role of outside directors is the focus of special attention. This section introduces a conversation between Shigehiko Hattori, who has worked as an outside director for the Company since 2011, and Chairperson of the Board Michihiro Tsuchiya (Chairman of the Board).**

**Tsuchiya:** First, how would you evaluate the Company's initiatives to strengthen its corporate governance?

**Hattori:** I think that the Company is making steady progress, including in taking steps to address the Corporate Governance Code.

The operation of the Board of Directors is improving each year, and in terms of institutional design, in June 2016 the Company established the Nomination Committee and the Compensation Committee as voluntary advisory bodies to the Board of Directors. The trend toward globalization of society continues, and the Company is working to further expand its overseas business. In this setting, we are also seeing diversification in the Company's shareholders and other stakeholders. It has become increasingly important to enhance the transparency of the decision-making processes for the nomination and compensation of directors, and accordingly the establishment of the Nomination Committee and the Compensation Committee is highly significant.

**Tsuchiya:** You mentioned institutional design. Of course it is important to take steps to change structures, but I believe that these measures have to generate "substantial results." In other words,

the most important thing is to actually increase the effectiveness of corporate governance.

**Hattori:** In that regard, I think that the recent evaluation of the effectiveness of the Board of Directors was a very good test. We were able to confirm each director's understanding of the issues, and we clarified what needs to be done to further enhance the Board's effectiveness. For example, there were a number of suggestions for increasing the quality of discussions at meetings of the Board of Directors, and those suggestions have been used to change the content of the materials that are provided at Board meetings.

For further information about the effectiveness of evaluation methodology and an overview, please refer to page 62. ➔ P62

**Tsuchiya:** Up to this point, I think that the materials have basically focused on explaining the agenda. But we must use these materials as a basis for discussion. To that end, rather than providing detailed facts about everything, it might be more useful to list the key discussion points and positioning of the issues in terms of long-term strategy.

Also, in the evaluation of the Board's effectiveness, many directors expressed the opinion that the Company should increase the number of outside directors. I think that this demonstrates how the Company's directors place great importance on the outside directors. From my position as Chairperson of the Board, I believe that the various opinions of the outside directors are playing an important role in activating discussions. And I am always grateful to receive your valuable opinions, Mr. Hattori.

**Hattori:** I think that different opinions need to be heard in order for discussions to make significant progress. To that end, I am working to offer different viewpoints and approaches. However, my background differs from those of the inside directors, and I am only able to provide frank opinions based on my experience at Shimadzu.

**Tsuchiya:** As a pharmaceutical company, Mitsubishi Tanabe Pharma is not involved in a wide range of different businesses. There is not a lot of variation in the backgrounds of our inside directors, and to a certain extent their viewpoints and approaches are similar. In that sense, I think that the outside directors play an extremely important role for the Company. In addition, if there is anything else that you have noticed as an outside director, please let me know.

**Hattori:** Mitsubishi Chemical Holdings, the parent company of Mitsubishi Tanabe Pharma, holds 56.34% of the Company's issued shares. As an outside director, I strive to consider the viewpoints of the minority shareholders when I offer my opinion. I think that it is important to always focus on ensuring that the interests of the minority shareholders are not adversely affected by the Company's decisions.

**Tsuchiya:** I believe that the viewpoint of shareholders is something that is essential for inside directors as well. However, with Japanese companies, most of the directors are former employees of that company, and I think that they need to make renewed efforts to learn how to think from the viewpoint of shareholders.

**Hattori:** I also moved from employee to director at Shimadzu, and there are many things I noticed after I became an outside director. In the evaluation of the Board's effectiveness, there were also requests for enhanced training for directors, and it might be necessary for the Company to conduct training to further reinforce awareness of the importance of doing things "for the shareholders."

**Tsuchiya:** I don't think that there are any ideal approaches to corporate governance that will work for every company. Consequently, each company needs to continually search for the best approach for its specific circumstances. I would like Mitsubishi Tanabe Pharma to move forward one step at a time while improving the issues that were clarified in the evaluation of the Board's effectiveness. To that end, the outside directors will be indispensable, and I look forward to the continued help of the outside directors in the future. Thank you for participating in today's discussion.

**Hattori:** Thank you. It was my pleasure.

Measures to improve corporate governance have to generate "substantial results." In other words, the most important thing is to actually increase the effectiveness of corporate governance.



**Michihiro Tsuchiya**  
Chairman of the Board

# Board of Directors and Auditors

As of August 1, 2016

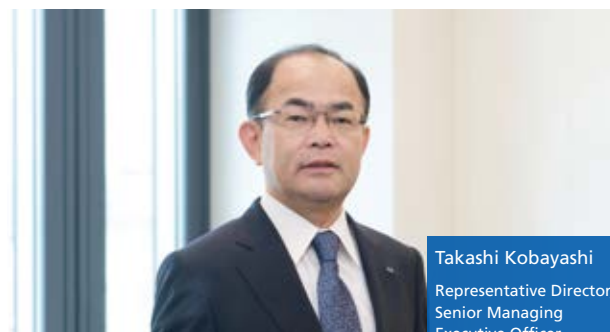
## Board of Directors



**Michihiro Tsuchiya**  
Chairman of the Board  
& Board Director



**Masayuki Mitsuka**  
President &  
Representative Director,  
Chief Executive Officer



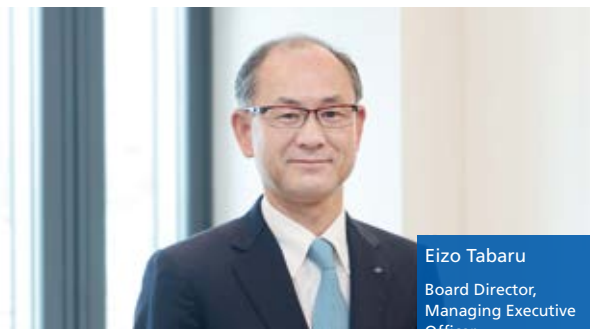
**Takashi Kobayashi**  
Representative Director,  
Senior Managing  
Executive Officer



**Yoshiaki Ishizaki**  
Board Director,  
Managing Executive  
Officer



**Seiichi Murakami**  
Board Director,  
Managing Executive  
Officer



**Eizo Tabaru**  
Board Director,  
Managing Executive  
Officer



**Shigehiko Hattori**  
Board Director  
(Outside)



**Shigeki Iwane**  
Board Director  
(Outside)

## Brief History

### Michihiro Tsuchiya

#### Chairman of the Board & Board Director

Michihiro Tsuchiya entered Tanabe Seiyaku in 1976. He worked as a researcher at the Applied Biochemistry Research Laboratories, and in 1985, he moved to the Research Planning Division, where his work included planning for new research themes and inter-departmental coordination. After working in such positions as Board Director, General Manager of Corporate Strategic Planning Department, and Managing Board Director, Division Manager of Research Division, in 2006 he became Representative Director, Senior Managing Executive Officer, and he led the merger negotiations with Mitsubishi Pharma. After Mitsubishi Tanabe Pharma was established, in 2009 he was appointed as President & Representative Director, Chief Executive Officer, and he worked to establish a corporate culture as an "inspiring company." Under Medium-Term Management Plan 11-15: New Value Creation, which was formulated in 2011, he led reforms to make Mitsubishi Tanabe Pharma a "company that can continue to create new value." He moved forward with the establishment of a business foundation for future growth, such as the launch of a large number of new products. In 2014, he became Chairman of the Board & Representative Director, and currently, as Chairman of the Board, he serves as Chairperson of the Board. In addition, he is working in such positions as Chairman in charge of health and medicine of Industrial Promotion Committee at the Kansai Economic Federation, and Chairman of the Osaka Pharmaceutical Manufacturers Association. In these ways, he is doing his utmost in activities related to the Kansai business community and the pharmaceutical industry.

1976 Entered the Company  
2001 Board Director, General Manager of Corporate Strategic Planning Department of the Company  
2003 Managing Board Director, Division Manager of Research Division of the Company  
2005 Board Director, Managing Executive Officer, Division Manager of Research Division of the Company  
2006 Representative Director, Senior Managing Executive Officer, Division Manager of Research Division of the Company  
2007 Board Director, Vice President of the Company  
2008 Board Director of Mitsubishi Chemical Holdings  
2009 President & Representative Director, Chief Executive Officer of the Company  
2014 Chairman of the Board & Representative Director of the Company  
2016 Chairman of the Board & Board Director of the Company (current)

### Masayuki Mitsuka

#### President & Representative Director, Chief Executive Officer

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 the 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 Mitsubishi Chemical Holdings and Board Director of The KAITEKI Institute.

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  
2007 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  
2014 President & Representative Director, Chief Executive Officer of the Company (current)  
Board Director of Mitsubishi Chemical Holdings (current)

### Takashi Kobayashi

#### Representative Director, Senior Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division, in charge of Tokyo Head Office

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. Leveraging the problem-resolution capabilities that he acquired in a wide range of fields, he is working to enhance the pipeline by aggressively leveraging external resources and advancing drug discovery with an emphasis on speed.

1980 Entered the Company  
2003 General Manager of Secretary's Office of Administrative Division of 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 (current)

## Board of Directors and Auditors

### Yoshiaki Ishizaki

#### Board Director, Managing Executive Officer, Division Manager of Sales & Marketing Division

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 Johoku Office I (Tokyo). 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. For more than 30 years after joining Yoshitomi Pharmaceutical Industries, he contributed to the Company 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 experience he acquired through many years on the front lines of sales, he is working to strengthen the Company's sales capabilities.

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  
2014 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)

### Seiichi Murakami

#### Board Director, Managing Executive Officer, Division Manager of Ikuyaku. Integrated Value Development Division, in charge of External Affairs Department

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.

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  
2015 Board Director, Managing Executive Officer, Division Manager of Sales & Marketing Division of the Company  
2015 Board Director, Managing Executive Officer, Division Manager of Ikuyaku. Integrated Value Development Division of the Company (current)

### Eizo Tabaru

#### Board Director, Managing Executive Officer, General Manager of Finance & Accounting Department, in charge of Procurement Management Department, Corporate Communications Department, Information Systems Department

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 Board Director in 2015, he has contributed to increasing the corporate value of the Company as the person responsible for finance and accounting.

1981 Entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical)  
2010 General Manager of Finance and Accounting Department of Mitsubishi Chemical  
2010 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 (current)

### 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)

### 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 (current)  
Outside Corporate Auditor of KINDEN (current)  
2016 Outside Board Director of the Company (current)  
2016 President and Director of The Kansai Electric Power (current)



## Auditors



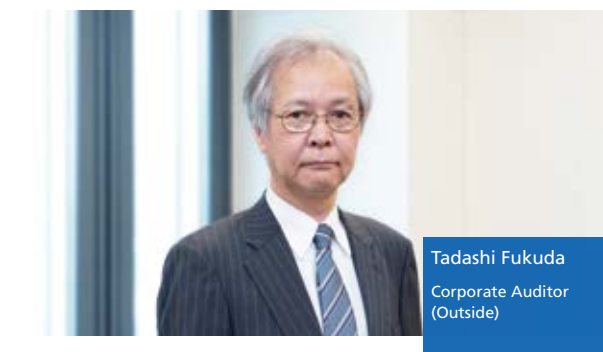
**Kenichi Yanagisawa**  
Corporate Auditor  
(Standing)



**Koji Kudo**  
Corporate Auditor  
(Standing)



**Takashi Nishida**  
Corporate Auditor  
(Outside)



**Tadashi Fukuda**  
Corporate Auditor  
(Outside)

### Brief History

#### Kenichi Yanagisawa

Corporate Auditor (Standing)

- 1973 Entered the Company
- 2000 Planning Manager of Research & Development Planning Department of the Company
- 2001 Executive Officer, Division Manager of Product Development Center of the Company
- 2003 Executive Officer, Division Manager of Development Division of the Company
- 2005 Board Director, Executive Officer, Division Manager of Development Division of the Company
- 2007 Board Director, Managing Executive Officer, Division Manager of Development Division of the Company
- 2009 Board Director, Managing Executive Officer, Division Manager of Sales & Marketing Division of the Company
- 2012 Board Director, Senior Managing Executive Officer, Division Manager of Sales & Marketing Division, in charge of Tokyo Head Office of the Company
- 2014 Board Director, Senior Managing Executive Officer, Assistant to the President of the Company
- 2014 Corporate Auditor (Standing) of the Company (current)

#### Takashi Nishida

Corporate Auditor (Outside)

- 1976 Entered The Mitsubishi Bank (currently, The Bank of Tokyo-Mitsubishi UFJ)
- 2004 Executive Officer, The Bank of Tokyo-Mitsubishi
- 2007 Outside Corporate Auditor (standing), Mitsubishi Chemical Holdings  
Outside Corporate Auditor, Mitsubishi Chemical (current)  
Outside Corporate Auditor, Mitsubishi Pharma  
Outside Corporate Auditor of the Company (current)

#### 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
- 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
- 2016 Corporate Auditor (Standing) of the Company (current)

#### Tadashi Fukuda

Corporate Auditor (Outside)

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



# Social and Environmental Activities

## Corporate Citizenship Activities

### Formulation of the Declaration on Corporate Citizenship

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

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 Health

#### ▶ Implementing Donation and Assistance Activities

In 2013, we established the Mitsubishi Tanabe Pharma Tenohira Partnership Program, which provides aid to associations and support groups for patients with incurable diseases. These organizations work to improve patients' medical treatment and career prospects and to enhance their quality of life. In fiscal 2015, a meeting was held to report on the fiscal 2014 activities of these organizations (9 organizations, 11 people). There was a lively exchange of opinion about such matters as collaboration with patients' associations, which address the same issues; the need for collaboration with companies and volunteer groups; and improvement of the medical treatment for children with incurable diseases. In addition, with the objective of contributing to medical treatment and public health in Japan, 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. In fiscal 2015, we provided a total of about ¥150 million to these foundations.

#### ▶ Contributing to Developing Countries

We have introduced the TFT Program at the employee cafeterias of the Kashima Office and the Head 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, ¥20 of the price is allocated to the cost of school meals in developing countries, such as in Africa.

In addition, as a Companywide program, we are also participating in vaccine support activities for children in developing countries. Through this program, when books, CDs, and DVDs are sold because they are no longer needed, 10% of the assessed amount is donated to Authorized NPO Japan Committee Vaccines for the World's Children. Through this international contribution activity, those financial resources are used to deliver vaccines to children in developing countries, such as vaccines for six major infectious diseases. In fiscal 2015, the total assessed amount of items collected at the Company's worksites was ¥103,701. Therefore, the donation was equivalent to 5,185 vials of polio vaccine.

### 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

For further information about corporate citizenship activities, please see CSR ACTIVITIES REPORT 2016.

 [CSR ACTIVITIES REPORT 2016](http://www.mt-pharma.co.jp/e/company/csr-report/2016/)

Furthermore, in May 2015 we endorsed the objectives of the Global Health Innovative Technology Fund (GHIT Fund) and participated in the GHIT Fund's screening program. The GHIT Fund is a public-private partnership, originating in Japan, that advances the discovery of new drugs for infectious diseases that burden the developing world, such as malaria, tuberculosis, and neglected tropical diseases (NTDs). To contribute to the treatment of infectious diseases that burden the developing world, the Company provided its original pharmaceutical compound library (50,000 compounds) to the GHIT Fund.

### ▶ 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 are supporting CP Soccer (soccer played by seven people with cerebral palsy), which is a Paralympic sport. The Kashima Office makes the office grounds available for the CP soccer tournament and other events.

## Contributing to the Environment

The Group is aggressively implementing greening and beautification activities at each domestic worksite. Employees clean worksite surroundings and actively participate in neighborhood cleaning activities. In these ways, we are working to coexist in harmony with local communities. Furthermore, overseas, Mitsubishi Tanabe Pharma Korea holds "Environment Day" one day per month and implements environmental activities at the plant and the surrounding area.



Osaka Marathon Clean-Up Operation



Beautification activities on "Environment Day" (Mitsubishi Tanabe Pharma Korea)

## Contributing to Local Communities

In May 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 8,000 people visited the museum in the first year after its opening, and it has contributed to the development of the next generation, such as with school off-campus learning activities.

In addition, we sponsor the MSC Volunteer Salon, an event held every other month that provides opportunities for people who are interested in volunteer activities to interact with people who are participating in these activities. Furthermore, since 1971 the Company has been donating OTC drugs, including Mitsubishi Tanabe Pharma products, to Kodomo-no-kuni (Children's Land), which is operated by the Kodomo-no-kuni Association, a social welfare service organization.



Mitsubishi Tanabe Pharma Historical Museum

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

## Support for Disaster Reconstruction

An earthquake struck Kumamoto Prefecture in April 2016, and to help people who were affected by the earthquake and assist in the reconstruction of the area, we made a donation of ¥10 million to the Japanese Red Cross Society. Also, in regard to support for the reconstruction initiatives related to the Great East Japan Earthquake, which struck in March 2011, the Tokyo Head Office and the Toda Office sponsored an exhibit for products from three prefectures in Tohoku (Miyagi, Fukushima, and Iwate). This was one facet of the Company's initiatives to support the reconstruction of the Tohoku region. In the future, we will continue to provide support in the affected regions through our procurement activities.

## Initiatives Related to Environmental Conservation

### Environmental Safety Management

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.

In accordance with the Mitsubishi Tanabe Pharma Environmental Safety Philosophy and the Policy on Environmental Safety Activities, which we formulated independently, we work proactively to ensure that our operations are environmentally friendly. Furthermore, the Group discloses information related to the environment and promotes dialogue with the public in its initiatives aimed at contributing to the environment and society.

In addition, as a member of the Mitsubishi Chemical Holdings Group, we are striving to realize *KAITEKI* (comfort) for the world by aiming to increase sustainability and contributing to reductions in environmental burdens, such as reductions of greenhouse gas emissions.

In environmental information collection and disclosure, the Group collects and discloses information regarding the manufacturing and research facilities of Mitsubishi Tanabe Pharma and its domestic and overseas consolidated subsidiaries.

### Establishment of an Environmental and Occupational Safety Management System

Mitsubishi Tanabe Pharma has established an environmental and occupational safety management system, overseen by the President and CEO. The Environmental Safety Committee serves as the consultative committee for this system, with members comprising representatives from the Executive Committee. The Liaison Council for Environmental Safety plans and carries out activities in response to issues relating to the environmental safety of the Mitsubishi Tanabe Pharma Group. In addition, the Environmental Safety Division has been established as a full-time specialized organization. This system promotes the management of environmental issues both in and outside Japan.

Fiscal 2015 was the final year of the Group's Medium-Term Environmental Action Plan (fiscal 2011 to 2015). Under this plan, the most important environmental objective was "energy conservation and global warming mitigation." Targeting this objective, we achieved the target for CO<sub>2</sub> emission reductions by a significant margin. In addition, during the fiscal year we made suitable progress in addressing other themes with initiatives at each Group worksite. From fiscal 2016, we will work to implement the newly formulated Medium-Term Environmental Action Plan (fiscal 2016 to fiscal 2020). In reducing CO<sub>2</sub> emissions, we have established domestic and global numerical targets. In addition, to reduce emissions of chemical substances we have set numerical targets for reducing emissions of toluene into the environment, and have established targets related to conservation of biodiversity.

#### Medium-Term Environmental Action Plan (fiscal 2011 to 2015)

Area	Objectives	Fiscal 2015 results
<b>Energy conservation and global warming mitigation</b>	<ul style="list-style-type: none"> <li>Reduce CO<sub>2</sub> emissions for fiscal 2015 by at least 30% compared to the fiscal 2005 level</li> </ul>	<ul style="list-style-type: none"> <li>Reduced CO<sub>2</sub> emissions by 52.3% compared to the fiscal 2005 level (11.5% reduction compared to the fiscal 2014 level)</li> <li>Increased number of hybrid vehicles used by sales personnel to 1,415, from 1,339 in fiscal 2014</li> </ul>
<b>Reduction of waste, reuse and recycling of resources</b>	<ul style="list-style-type: none"> <li>Promote zero emissions (final waste disposal rate of less than 0.5%) and continually reduce waste and emissions output and final waste disposal</li> <li>Fulfill the responsibility of a waste-discharging enterprise for handling waste correctly and ensuring proper treatment by contractors</li> </ul>	<ul style="list-style-type: none"> <li>Achieved a final waste disposal rate of 0.55% (0.28% in fiscal 2014)</li> <li>Promoted recycling and effective use of resources</li> <li>Performed on-site inspections of waste collection and transportation companies and intermediate and final disposal sites</li> </ul>
<b>Chemical substance emissions reductions</b>	<ul style="list-style-type: none"> <li>Properly manage chemical substances and continually reduce their discharge into the environment</li> </ul>	<ul style="list-style-type: none"> <li>Decrease in handling volumes and emissions into the atmosphere of PRTR substances and VOCs. Increase of emissions of PRTR substances and VOCs into public water bodies due to reevaluation of emission rates.</li> </ul>
<b>Enhancement of environmental management</b>	<ul style="list-style-type: none"> <li>Improve environment-related risk management at company facilities</li> <li>Maintain zero environmental accidents</li> </ul>	<ul style="list-style-type: none"> <li>Conducted environmental safety audits at seven Group worksites in and outside Japan</li> <li>Renewal of environmental audit checklist for overseas worksites</li> <li>Conducted online environmental training courses</li> <li>Implemented training for on-site confirmation at waste management contractors</li> <li>Had zero environmental accidents and one incident</li> </ul>

## Environmental Compliance

The Mitsubishi Tanabe Pharma Group is committed to proactively protecting the global environment and coexisting in harmony with society as one of its compliance activities.

At domestic plants and laboratories, we work to achieve strict observance of environment-related laws, regulations, and agreements. We have formulated more-rigorous independent management reference values for water pollution and air pollution, and we conduct our business activities in accordance with those reference values. Each year we conduct regular environmental audits at worksites, including overseas manufacturing bases, to confirm that environmental conservation activities and environmental management are being conducted in a legal, appropriate manner.

## Environmental Risk Management

The Group has formulated guidelines related to environmental safety and risk management. We are working to prevent environmental pollution, fires, etc., resulting from harmful chemical substances that are generated by natural disasters and unexpected events. In addition, to minimize damage, we have established procedures for each worksite for rapid, accurate responses in times of crisis, and we periodically plan and implement education and training in preparation for emergencies.

In particular, the Group is concerned about any influence on local communities from an accidental discharge of chemical substances to rivers or the sea, and accordingly the Group has installed equipment and systems (automation of emergency shutoff valves for wastewater and installation of water tanks for use in prevention of outflow) that can prevent outflow in case of an unforeseen contingency. In this way, the Group is working to reduce environmental pollution risk.

## ISO 14001 Certification

The Mitsubishi Tanabe Pharma Group's principal production sites have acquired either ISO 14001 certification or other certifications established by relevant local municipalities. The Group has established and operates an environmental management system and works to continually improve that system. Furthermore, in research facilities and offices we are working to implement appropriate environmental management in accordance with the location and the nature of the environmental burden associated with business activities. In this way, these facilities and offices are implementing activities that reflect consideration for the environment.

## Environmental Accounting

Mitsubishi Tanabe Pharma works to promote effective and efficient environmental management by ascertaining and analyzing the costs and effects of environmental conservation activities and the impact these activities have on economic performance.

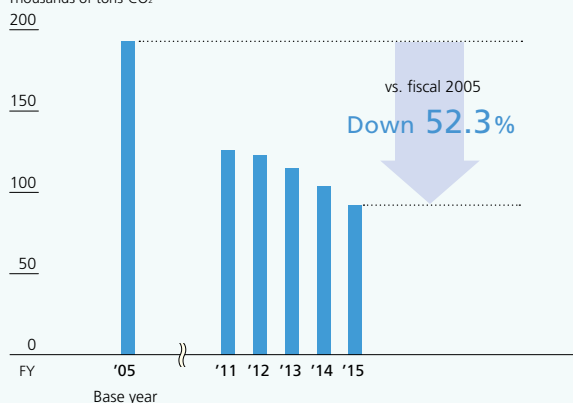
Environmental conservation costs for fiscal 2015 were ¥22 million in investments and ¥871 million in running costs. The economic benefit of environmental conservation measures was ¥5 million.

### Notes Regarding Calculations for Fiscal 2015 Data:

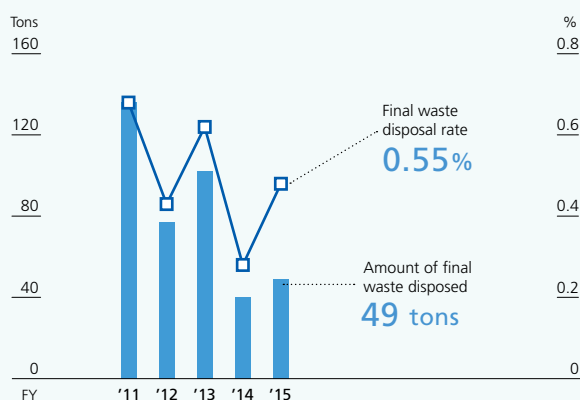
1. Data was calculated according to the Environmental Accounting Guidelines (2005 edition) published by the Ministry of the Environment of Japan.
2. Calculation period: April 1, 2015 to March 31, 2016
3. Scope: All worksites in Japan
4. Calculation methods:
  - (1) Simple method for amount invested (25%, 50%, 75%, and 100%);
  - (2) Depreciation is calculated based on the legally defined service life of applicable items; and
  - (3) The full amounts for non-depreciation costs are posted only if 100% environment related.
5. Calculation and evaluation methods for effects resulting from environmental conservation measures:
  - (1) Material effects based on conclusive grounds for each environmental measure; and
  - (2) Effects observed within the fiscal year are tallied by converting them to a period of 12 months, and evaluated by comparing them to the year before the measures were implemented (or the previous fiscal year).

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

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



### Amount of Final Waste Disposed / Final Waste Disposal Rate



Promoting Environmental Communications

The Group is working to implement environmental conservation activities. The Ikoma Mountain Range “Folding Screen of Flowers” Project has been held since 2009. In 2015, the project was held for the seventh time, and 5 Japanese maples, 3 mountain cherry trees, and 60 Japanese hydrangea were planted. In April 2015, we received a letter of appreciation from the Osaka Governor for our continued activities. In addition, since 2013 we have participated in Tokyo GreenShip Action and have implemented activities to conserve and restore natural woodlands in the Hachioji Takiyama Satoyama Conservation Area, which is designated as a conservation area by Tokyo Prefecture. Through these types of activities and environmental education, we will work to raise the awareness of environmental issues among our employees.



Ikoma Mountain Range “Folding Screen of Flowers” Project (November 2015)

Environmental Consideration at the New Pharmaceutical Production Building at the Yoshitomi Plant

In June 2016, the new pharmaceutical production building at the Yoshitomi Plant was completed. The new building addresses the latest quality assurance standards, which are becoming increasingly advanced and globalized. It will be used exclusively to efficiently manufacture a wide variety of solid dosage formulations. The new building has a base isolation structure that will enable it to continue operations when there is an earthquake, and it has an environmentally friendly design.



New pharmaceutical production building at the Yoshitomi Plant

Major Environmentally Friendly Initiatives

**1 Using LED lighting**  
 Inside, the building principally uses high-efficiency, long-life LED lighting, and human sensors are used to automatically control the lighting in the lavatories located in the common areas as well as in small rooms. As a result, we expect to reduce CO<sub>2</sub> emissions volume by 60 tons-CO<sub>2</sub> per year.

**2 Using energy-saving mode in air conditioning equipment**  
 When the production facilities are not in operation, such as evenings and holidays, the building uses a low-energy mode that reduces air conditioning air flow. As a result, we expect to be able to reduce CO<sub>2</sub> emissions by 750 tons-CO<sub>2</sub> per year due to reduced electricity usage and 110 tons-CO<sub>2</sub> per year due to reduced steam usage.

**3 Using energy-saving facilities and control systems**  
 As a result of the introduction of such energy-saving facilities as turbo refrigeration equipment with high-efficiency inverters and high-efficiency water circulation-type compressors, and the use of inverters to control pumps and fans, etc., we expect to reduce CO<sub>2</sub> emissions by 1,000 tons-CO<sub>2</sub> per year.

**4 Implementing labor-saving initiatives and increasing productivity**  
 We have installed an intermediate product warehouse in the center of the building, and introduced a system for automatically transporting stocked raw materials and intermediate products to each production room. This reduces conveyance time, increases efficiency, and saves energy, as well as raises productivity and reduces the burden on employees. In this way, a KAI/TEKI workplace has been realized.

# Financial Section

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# Six-Year Financial Summary

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
Years ended March 31

	FY 2015	FY 2014	FY 2013	FY 2012	FY 2011	FY 2010
<b>Financial figures (billions of yen):</b>						
Net sales	¥431.7	¥415.1	¥412.7	¥419.2	¥407.2	¥409.5
Cost of sales	155.8	169.6	169.4	166.4	152.3	154.6
Selling, general and administrative expenses	181.0	178.4	184.2	183.8	185.8	178.4
Operating income	94.9	67.1	59.1	69.0	69.0	76.6
Profit attributable to owners of parent	56.4	39.5	45.4	41.9	39.0	37.7
R&D expenses	75.3	69.6	70.4	66.5	70.2	65.8
Capital expenditures on an accrual basis	11.2	15.7	12.6	9.2	7.1	10.2
Depreciation and amortization	8.8	9.0	9.1	8.4	12.5	12.4
Total assets	930.2	929.3	886.5	866.8	819.9	818.7
Total net assets	816.7	800.4	777.8	752.9	721.5	696.0
Interest-bearing debt	2.6	3.0	4.1	1.2	2.2	2.9
Net cash provided by operating activities	65.2	68.2	69.9	60.6	37.2	59.1
Net cash used in investing activities	(26.6)	(59.8)	(24.3)	(35.0)	(63.2)	(7.7)
Net cash used in financing activities	(22.2)	(21.9)	(21.1)	(23.7)	(17.2)	(15.4)
Cash and cash equivalents at end of the year	88.9	73.3	85.0	58.7	54.3	97.9
<b>Per share amounts (yen):</b>						
Net income—basic	100.60	70.41	80.92	74.67	69.54	67.27
Net assets	1,436.63	1,406.41	1,365.52	1,333.22	1,275.85	1,230.16
Cash dividends	46.00	42.00	40.00	40.00	35.00	28.00
<b>Financial indicators (%):</b>						
Cost of sales ratio	36.1	40.9	41.0	39.7	37.4	37.7
SG&A expenses ratio	41.9	43.0	44.6	43.9	45.6	43.6
Operating margin	22.0	16.2	14.3	16.5	17.0	18.7
R&D expenses ratio	17.4	16.8	17.1	15.9	17.3	16.1
Equity ratio	86.6	84.9	86.4	86.3	87.3	84.3
ROA	6.1	4.4	5.2	5.0	4.8	4.7
ROE	7.1	5.1	6.0	5.7	5.5	5.5
Dividend payout ratio	45.7	59.6	49.4	53.6	50.3	41.6
<b>Others:</b>						
Number of employees	8,125	8,457	9,065	8,835	9,180	9,198
Number of common stock issued (thousands)	561,417	561,417	561,417	561,417	561,417	561,417

# Management's Discussion and Analysis

## Pharmaceutical Market Trends

The global pharmaceutical market is recording ongoing expansion against a worldwide backdrop of growing populations, aging societies, and expanding economies in emerging countries. On the other hand, growth in Japan's pharmaceutical market is slowing. For many years, Japan held the No. 2 position, after the U.S., but Japan has been surpassed by China and is currently No. 3. This sluggish growth is occurring against a background of stepped up government measures to control health care expenditures. In general, the official national health insurance (NHI) prices for ethical drugs are revised once every two years, and measures to promote the use of generics are also being implemented. These factors have restrained growth in Japan's pharmaceutical market.

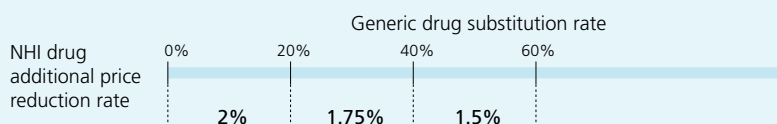
With the NHI drug price revisions implemented in April 2014, a new system was introduced to advance the substitution of generic drugs for long-listed drugs<sup>1</sup>. When NHI drug prices are revised, the prices of long-listed drugs that have had competing generics for five years or more will be subject to additional reductions, in accordance with the substitution rate, if the generic drug substitution rate<sup>2</sup> is less than 60%. In addition, under the NHI drug price revisions that were implemented in April 2016, those standards have been made stricter for long-listed drugs for which the substitution rate is less than 70%. The government has announced targets for the generic drug substitution rate of 70% in mid fiscal 2017 and 80% as rapidly as possible during the period from fiscal 2018 to fiscal 2020. The achievement of a 60% rate has already come into view. Accordingly, the business environment is expected to become increasingly challenging for manufacturers of new drugs.

On the other hand, there is an increase in new drug development in the area of unmet medical needs<sup>3</sup>, where the degree of satisfaction with existing treatments is low and new drugs are expected to drive progress in treatment. Furthermore, due to increasingly advanced drug discovery technologies and to stricter standards for drug approval, the success rate in new drug discovery is decreasing while the R&D expenses needed for new drug development are rising. As major ethical drugs go off patent, the earnings power of pharmaceutical companies declines. In this setting, companies are increasingly pursuing mergers and alliances (M&As) to expand their operational scale and reinforce their R&D capabilities.

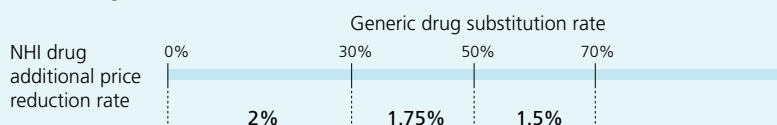
1. Original drugs that have gone off patent and for which generics are on sale.
2. Substitution rate = Number of generic drugs / (Number of original drugs for which there are generic competitors + Number of generic drugs)
3. Medical needs that are not addressed adequately by existing therapies.

### Change in the NHI Drug Price Additional Reductions for Long-Listed Drugs

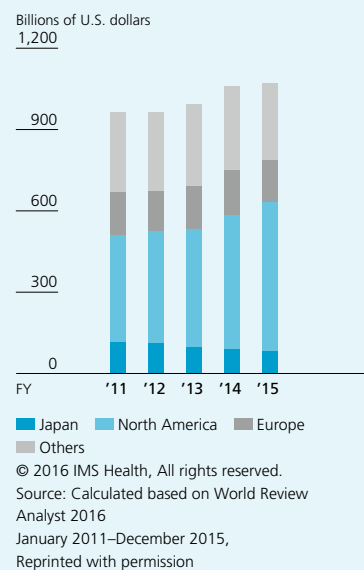
#### Before change (2014)



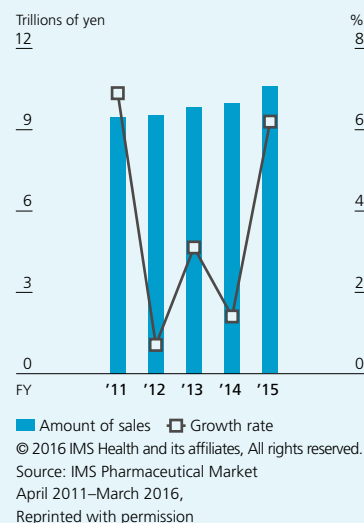
#### After change (2016)



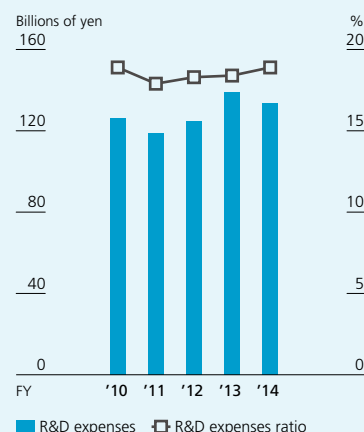
## Worldwide Pharmaceutical Market



## Domestic Pharmaceutical Market



## Average R&D Expenses of 10 Leading Pharmaceutical Companies in Japan\*



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

Net Sales

In fiscal 2015, net sales increased ¥16.6 billion year on year, to ¥431.7 billion. The pharmaceuticals segment, which accounts for the majority of the Company's net sales, comprises the domestic ethical drugs business, overseas ethical drugs business, OTC products, and others in pharmaceuticals.

Domestic sales of ethical drugs decreased ¥15.8 billion, to ¥308.1 billion. This decline was due mainly to the dissolution at the end of March 2015 of the Company's plasma fractionation product sales agreement with Japan Blood Products Organization. The end of sales of plasma fractionation products had the effect of reducing sales by ¥19.7 billion.

Excluding vaccines, seven priority products recorded sales of ¥127.6 billion in fiscal 2015, a year-on-year increase of ¥8.9 billion. Solid results were recorded by Remicade (indications: RA and other inflammatory autoimmune diseases\*) and Simponi (indication: RA), which are the Company's core products in the field of autoimmune diseases. In addition, in diabetes and kidney diseases, sales of Tenelia (indication: type 2 diabetes mellitus) increased. Sales of four vaccines rose ¥8.6 billion, to ¥34.6 billion. Overall sales of priority products were up ¥17.5 billion, to ¥162.2 billion. In addition, overall sales of vaccines rose ¥8.8 billion, to ¥39.1 billion, while sales of products handled by the Company's sales subsidiary, Tanabe Seiyaku Hanbai (including generic drugs and long-listed drugs transferred from the Company) increased ¥0.2 billion, to ¥13.8 billion.

Overseas sales of ethical drugs increased ¥2.2 billion, to ¥25.2 billion, while sales of OTC drugs were down ¥0.2 billion, to ¥3.8 billion.

In the Others category of pharmaceutical operations, the Company recorded higher royalty revenues from Gilenya (indication: MS), which is licensed to Novartis, of Switzerland. The Company also recorded increased royalty revenues from Invokana (indication: type 2 diabetes mellitus) and its fixed-dose combination with metformin (immediate release preparation), which are licensed to Janssen Pharmaceuticals, of the U.S. In addition, the Company received lump-sum payments accompanying the license agreement with Biogen, of the U.S., related to MT-1303 (expected indication: autoimmune diseases), and the patent and know-how transfer agreement with Amgen, of the U.S., and Dezima Pharma, of the Netherlands, regarding TA-8995, a CETP inhibitor (expected indication: dyslipidemia). Due primarily to these factors, sales in the Others category of pharmaceutical operations were up ¥30.5 billion, to ¥94.2 billion.

As a result, sales of pharmaceuticals increased ¥16.6 billion, to ¥431.3 billion.

Overseas sales rose ¥39.0 billion, to ¥116.9 billion, and the overseas sales ratio was up 8.3 percentage points, to 27.1%.

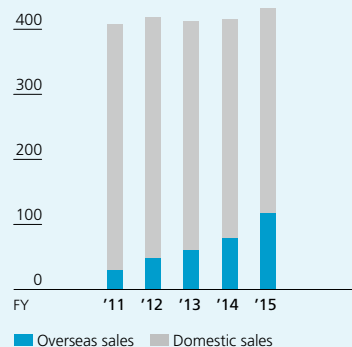
\* For further information about indications, please refer to "Overview and Sales Trends of Priority Products in Fiscal 2016" on page 48.

	Billions of yen			
	FY 2015	FY 2014	Change	% Change
Net sales	¥431.7 (100.0%)	¥415.1	¥+ 16.6	+ 4.0%
Sales by business segment:				
Pharmaceuticals	431.3 (99.9 )	414.7	+ 16.6	+ 4.0
Domestic ethical drugs	308.1 (71.4 )	323.9	- 15.8	- 4.9
Overseas ethical drugs	25.2 (5.8 )	23.0	+ 2.2	+ 9.6
OTC drugs	3.8 (0.9 )	4.0	- 0.2	- 5.8
Others	94.2 (21.8 )	63.7	+ 30.5	+ 47.8
Other business	0.4 (0.1 )	0.4	- 0.1	- 13.5
Sales by region:				
Domestic	314.8 (72.9 )	337.2	- 22.4	- 6.6
Overseas	116.9 (27.1 )	77.9	+ 39.0	+ 50.0

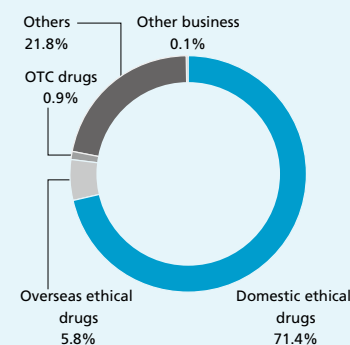
Note: Figures in parentheses are percentages of net sales.

Net Sales

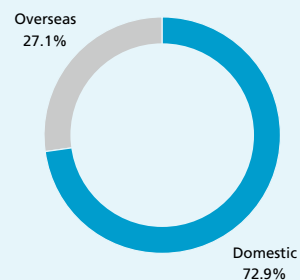
Billions of yen  
500



Sales by Business



Sales by Region



## Sales of Major Ethical Drugs

	Billions of yen			
	FY 2015	FY 2014	Change	% Change
Priority Products in Fiscal 2015 (Domestic)	¥162.2	¥144.7	¥+ 17.5	+ 12.1%
Priority Products in Fiscal 2015 (Except vaccines)	127.6	118.7	+ 8.9	+ 7.5
Remicade	69.4	70.6	- 1.2	- 1.7
Talion	16.9	16.0	+ 0.9	+ 5.6
Simponi	12.9	10.5	+ 2.5	+ 23.5
Lexapro	9.5	8.0	+ 1.5	+ 19.2
Tenelia	14.2	9.2	+ 4.9	+ 53.6
Imusera	4.1	3.2	+ 0.9	+ 27.0
Canaglu	0.6	1.2	- 0.6	- 50.9
Vaccines	34.6	26.0	+ 8.6	+ 33.1
Influenza vaccine	13.8	7.4	+ 6.4	+ 86.5
Tetrabik	9.5	7.5	+ 2.0	+ 26.5
Varicella vaccine	6.4	7.2	- 0.8	- 11.2
Mearubik	5.0	4.0	+ 1.0	+ 26.0
Royalty revenues, etc.	92.0	60.4	+ 31.7	+ 52.5
Royalty from Gilenya	51.7	43.9	+ 7.8	+ 17.7
Royalty from Invokana	20.6	9.8	+ 10.9	+ 11.2

## Operating Income

In fiscal 2015, operating income was up ¥27.8 billion, to ¥94.9 billion.

The cost of sales ratio declined 4.8 percentage points year on year, to 36.1%, due principally to the end of sales of plasma fractionation products, which have a high cost of sales ratio; to growth in royalty revenues; and to the receipt of lump-sum payments. As a result, gross profit rose ¥30.4 billion, to ¥275.9 billion.

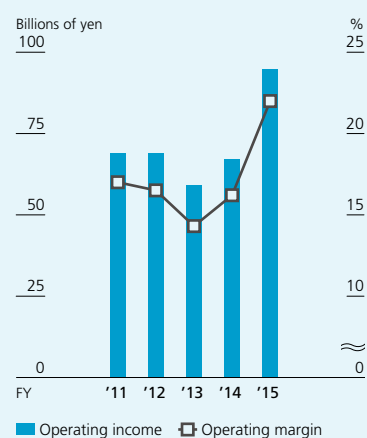
SG&A expenses increased ¥2.6 billion, to ¥181.0 billion. This increase was attributable to a rise of ¥5.7 billion in R&D expenses, to ¥75.3 billion, resulting from aggressive investment in R&D.

The R&D expenses ratio in fiscal 2015 was up 0.6 percentage point year on year, to 17.4%.

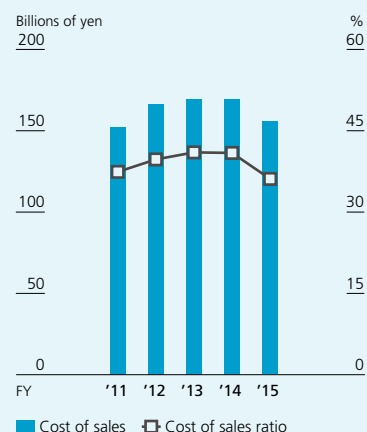
	Billions of yen			
	FY 2015	FY 2014	Change	% Change
Cost of sales	¥155.8 (36.1%)	¥169.6	¥- 13.8	- 8.1%
SG&A expenses	181.0 (41.9 )	178.4	+ 2.6	+ 1.5
R&D expenses	75.3 (17.4 )	69.6	+ 5.7	+ 8.2
Non-R&D expenses	105.7 (24.5 )	108.8	- 3.1	- 2.8
Labor costs	46.6 (10.8 )	46.8	- 0.2	- 0.4
Amortization of goodwill	10.5 (2.4 )	10.9	- 0.4	- 3.8
Other	48.6 (11.3 )	51.1	- 2.5	- 4.8
Operating income	94.9 (22.0 )	67.1	+ 27.8	+ 41.4

Note: Figures in parentheses are percentages of net sales.

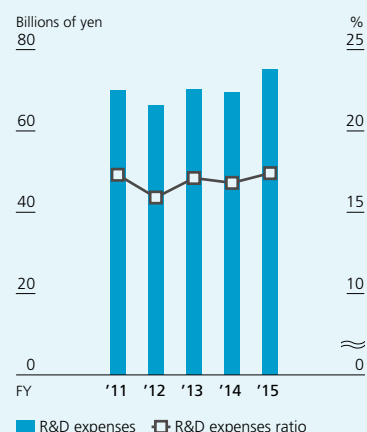
## Operating Income / Operating Margin



## Cost of Sales / Cost of Sales Ratio



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



### Net Income Attributable to Shareholders of the Company

In fiscal 2015, net income attributable to shareholders of the Company increased ¥16.9 billion, to ¥56.4 billion. A foreign exchange loss of ¥0.5 billion was recorded, compared with foreign exchange gain of ¥0.4 billion in the previous fiscal year. In addition, net extraordinary loss was ¥5.0 billion, compared with net extraordinary loss of ¥10.5 billion in the previous fiscal year. However, operating income rose substantially, leading to the increase in net income.

In extraordinary income, gain on sales of investment in securities was ¥13.4 billion, compared with ¥1.1 billion in the previous fiscal year, and total extraordinary income was up ¥0.5 billion, to ¥14.1 billion. In the previous fiscal year, extraordinary income included ¥12.0 billion in gain on sales of property, plant and equipment, such as the site of the former Nihonbashi Building.

Total extraordinary losses were up ¥6.0 billion, to ¥24.6 billion. These included restructuring expenses of ¥16.3 billion, which included ¥15.3 billion related to subscription for an early retirement program. In the previous year, restructuring expenses were ¥12.3 billion. Loss on impairment of fixed assets was ¥4.5 billion, compared with ¥2.6 billion in the previous year. In the previous fiscal year, extraordinary losses included amortization of goodwill of ¥3.5 billion.

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

#### Assets, Liabilities, and Net Assets

Total assets at the end of the fiscal year were ¥930.2 billion, an increase of ¥0.9 billion from the previous year-end. Total current assets rose ¥53.6 billion year on year, to ¥657.3 billion, due mainly to increases in cash and deposits. Total fixed assets decreased ¥52.7 billion, to ¥273.0 billion, due primarily to declines in investment in securities and in intangible fixed assets. Investments in securities declined ¥26.5 billion, due mainly to the sale of domestic listed securities. Intangible fixed assets were down ¥14.3 billion, due principally to depreciation and amortization and to amortization of goodwill.

Total liabilities were down ¥15.3 billion from the end of the previous year, to ¥113.5 billion. This decrease was principally attributable to declines in accounts payable, other and in income taxes payable.

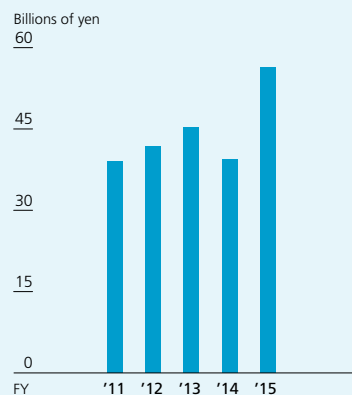
Total net assets at the end of the period were up ¥16.3 billion from the end of the previous fiscal year, to ¥816.7 billion. Remeasurements of defined benefit plans of ¥7.7 billion and translation adjustments of ¥5.0 billion had the effect of decreasing net assets, but the increase in retained earnings exceeded these factors. Net income attributable to shareholders of the Company was ¥56.4 billion, while cash dividends paid was ¥24.7 billion. As a result, retained earnings increased ¥31.8 billion.

Total accumulated other comprehensive (loss) income decreased ¥14.8 billion, and minority interests declined ¥0.7 billion. Consequently, the equity ratio was 86.6%, an increase of 1.7 percentage points from the end of the previous fiscal year.

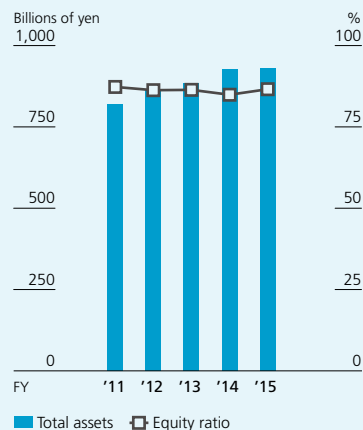
	Billions of yen			
	FY 2015	FY 2014	Change	% Change
Total assets	¥930.2 (100.0%)	¥929.3	¥+ 0.9	+0.1%
Total current assets	657.3 (70.7 )	603.6	+ 53.6	+8.9
Fixed assets	273.0 (29.3 )	325.7	- 52.7	-16.2
Total liabilities	113.5 (12.2 )	128.9	- 15.3	-11.9
Total current liabilities	91.3 (9.8 )	105.4	- 14.1	-13.4
Total long-term liabilities	22.2 (2.4 )	23.5	- 1.2	-5.3
Total net assets	816.7 (87.8 )	800.4	+ 16.3	+2.0

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

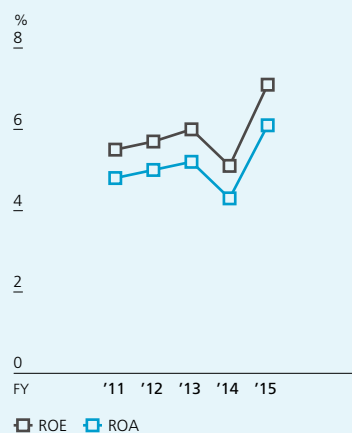
### Net Income Attributable to Shareholders of the Company



### Total Assets / Equity Ratio



### ROE / ROA



Note: Extraordinary losses were ¥6.1 billion in fiscal 2011, ¥5.9 billion in fiscal 2012, ¥4.8 billion in fiscal 2013, ¥18.6 billion in fiscal 2014, and ¥24.6 billion in fiscal 2015.

## Cash Flows

Net cash provided by operating activities was ¥65.2 billion. Inflows, which included income before income taxes and minority interests of ¥84.3 billion, exceeded outflows, which included income taxes paid of ¥33.7 billion.

Net cash used in investing activities was ¥26.6 billion. Decrease in time deposits was ¥56.4 billion, while increase in time deposits was ¥150.0 billion.

Net cash used in financing activities was ¥22.2 billion. Cash dividends paid was ¥24.7 billion.

As a result, net cash inflows for the fiscal year were ¥15.6 billion, and the balance of cash and cash equivalents at fiscal year-end was ¥88.9 billion.

	Billions of yen		
	FY 2015	FY 2014	Change
Net cash provided by operating activities	¥ 65.2	¥ 68.2	¥-3.0
Net cash used in investing activities	(26.6)	(59.8)	+33.3
Net cash used in financing activities	(22.2)	(21.9)	-0.4
Cash and cash equivalents at end of the year	88.9	73.3	+15.6

## Dividends

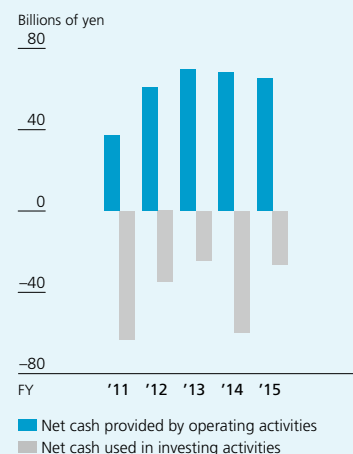
Mitsubishi Tanabe Pharma's basic policy calls for providing a stable and continuous return to shareholders while striving to increase enterprise value by aggressively implementing strategic investment and R&D investment to achieve sustained growth. Under Medium-Term Management Plan 11–15, the Company worked to enhance the distribution of profits, with a target for the consolidated dividend payout ratio of 50% (40% consolidated dividend payout ratio prior to amortization of goodwill).

In fiscal 2015, the Company made lump-sum payments accompanying in-licensing and made further progress in structural reforms. However, the Company recorded higher sales of priority products and vaccines and increased royalty revenues from Gilenya and Invokana. Moreover, a major contribution was made by lump-sum payments received from the out-licensing of MT-1303 and TA-8995. As a result, the Company set new record highs for net sales and for profit at all levels.

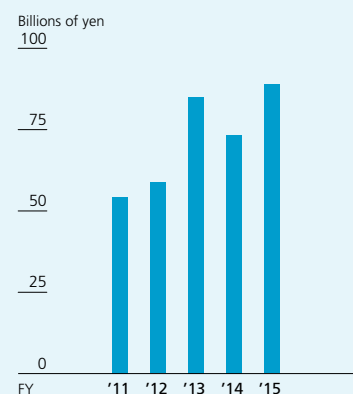
In accordance with this situation and the basic policy on shareholder return, the Company set annual dividends for fiscal 2015 at ¥46.0 per share, an increase of ¥4.0 per share. The dividend payout ratio was 45.7%, compared with 59.6% in the previous fiscal year.

In addition, under Medium-Term Management Plan 16–20, for which fiscal 2016 is the first year, the basic aim is for profit growth and a dividend payout ratio of 50% under the application of IFRS, which represents a real increase of 10 percentage points in comparison with the dividend policy under the previous medium-term management plan. On this basis, the Company will continue working to enhance the distribution of profits.

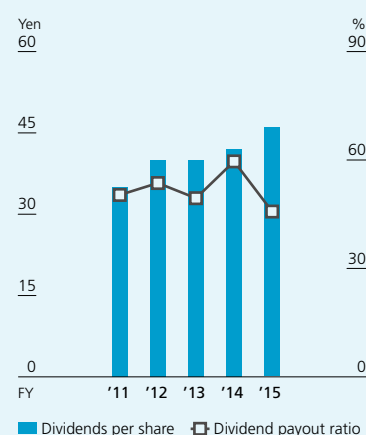
## Net Cash Provided by Operating Activities / Net Cash Used in Investing Activities



## Cash and Cash Equivalents at End of the Year



## Cash Dividends per Share / Dividend Payout Ratio





# 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 the possibility that these events could occur, the Group works to prevent their occurrence and to implement countermeasures in the event of their occurrence. Items in this document relating to the future are based on the judgment of the Group as of the end of fiscal 2015 (ended March 31, 2016).

## 1. Risks Related to New Drug R&D

The R&D of new drugs requires lengthy investment and the commitment of substantial resources, but there is no guarantee that this process will result in the creation of new products or new technologies. In addition, pharmaceuticals cannot be sold if approval is not obtained under the legal and regulatory system of each country, and it is difficult to accurately predict whether or not products will be sold and the timing of those sales. The development of current drugs in development might be halted in the event that problems with effectiveness or safety are found in non-clinical trials, clinical trials, etc., or in the event that they are determined to lack economic value due to innovation in medical treatment techniques, the launch of other drugs, etc. In the event that R&D investment does not lead to the sales of new drugs, there could be a significant influence on the Group's financial position or results.

## 2. Risks Related to Adverse Drug Reactions

Clinical trials conducted prior to the receipt of approval for a new drug are implemented with a limited number of test subjects who meet certain standards, and even in the event that approval is acquired following a rigorous safety evaluation, it is not possible to predict everything about safety in post-marketing use. Under the post-marketing use for the patients with backgrounds that are more diverse than those of the test subjects in the clinical trials, it is possible that there will be reports of new adverse drug reactions that had not been experienced previously. In the event that sales are suspended or that a large amount of compensation to victims arises, depending on such factors as the severity and frequency of those side effects, the Group's financial position and results of operations could be significantly affected.

## 3. Risks Related to the Domestic and Overseas Health Insurance System and the Revisions to National Health Insurance (NHI) Drug Price Standards

The sale of ethical drugs is significantly impacted by the various health insurance systems that relate to drug price standards as well as medical and other fees. Revisions to the drug price standard that is the official price of pharmaceuticals or its system; various health insurance systems, encompassing medical and other fees, that influence trends in the use of pharmaceuticals by medical institutions and similar revisions to the standards and systems employed overseas could substantially impact the Group's financial position and results.

#### 4. Risks Related to Product Sales

In the future, in the event of the emergence of factors—such as the launch of competing new products or generic products due to the termination of the patent, the launch of innovative new drugs or new technologies that lead to new methods of treatment, or the announcement of new evidence—that lead to a relative change in the position of the Company's pharmaceutical products in clinical use and to a decline in sales, the Group's financial position or results could be significantly affected.

#### 5. Risks Related to Intellectual Property

If the Group's business activities conflict with the patents or other intellectual property rights of other parties, it is possible that activities could be suspended or that there could be a legal dispute. Also, in the event that the Group believes that its patents or other intellectual property rights have been infringed upon by another party, the Group might file lawsuits. As a result of these actions, there could be an influence on the Group's financial position or results.

#### 6. Risks Related to Alliance with Other Companies

The Group works with other companies in joint research, joint development, product licensing and introduction, commissioned production, commissioned sales, joint promotion, and joint marketing in each business field, such as research, development, production, distribution, and marketing. However, in the future if contracts are changed or alliances dissolved, if the management environment of alliance partners worsens, if the management policies of alliance partners changes substantially, or if the supply of products suspend or delay substantially, there could be an adverse influence on the Group's financial position or results.

#### 7. Risks Related to Production and Stable Supply

In the event of the emergence of technical or legal / regulatory problems in the Group's internal or external production and distribution facilities, or in the event of operational stoppages or disorder, etc., due to fires or other disasters, a suspension of or substantial delay in the supply of products, there could be an influence on the Group's financial position or results.

#### 8. Risks Related to Legal Issues

In the research, development, distribution, production, and sale of pharmaceuticals, there is a trend toward stricter regulations regarding product quality and the environment. In the event that these regulations are further tightened, there is a possibility that corresponding additional expenses will arise, which could have an adverse influence on the Group's financial position or results.

#### 9. Risks Related to Product Liability

It is possible that the Group will be responsible for potential product liability stemming from product research, development, manufacturing, distribution, or sales activities. The Group is covered by product liability insurance, but in the event that claims exceeding the limits of this insurance coverage are approved, there could be a significant influence on the Group's financial position or results.

#### 10. Risks Related to Financial Market Fluctuations

- a) In fiscal 2015, overseas sales accounted for 27.1% of the Group's consolidated net sales. Certain raw materials for products and finished goods handled by the Group are directly imported from overseas. Substantial fluctuations in exchange rates could lead to declines in sales, increases in procurement costs, the generation of foreign exchange losses, etc., as well as declines in the assets of overseas consolidated subsidiaries, etc., and the Group's financial position and results of operations could be significantly affected.
- b) At the end of fiscal 2015, the Group held marketable securities of ¥96.5 billion and investments in securities of ¥49.8 billion, certain of which are liquid stocks and bonds, etc. Accordingly, events such as the recording of a loss on valuation due to declines in market prices could have a significant influence on the Group's financial position or results.

#### 11. Risks Related to Environmental Safety

In the event that serious damage to the environment is caused by hazardous chemical substances that are used in operating activities, it is possible that the Group could incur expenses needed for environmental improvement, face a decline in societal trust, bear responsibility for the payment of compensation, etc. In the event that one or more of these situations occurs, the Group's financial position or results could be significantly affected.

12. Risks Related to Lawsuits

- a) In regard to operational activities, in addition to adverse drug reactions, it is possible that the Group could face lawsuits regarding product liability, labor problems, fair trade, etc. As a result, there could be a significant influence on the Group's financial position or results.
- b) In January 2008, the Japanese government promulgated and put into effect "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" ("the Special Law"). In regard to the expenses associated with the relief payments, the standards for the method and the allocation of the burden of the expenses were announced on April 10, 2009. In accordance with those standards, the Company has made provisions for those expenses. For this expense burden, the cumulative total of the provisions for reserve for HCV litigation was ¥28.5 billion, of which ¥23.5 billion had already been paid out as of the end of March 2016. However, due to changes in the expected number of benefits recipients or the revision of the Special Law, the Group's financial position or results could be significantly affected.

The standards determining the Company's portion of the expense burden are shown below:

1. Portion of expense burden

Classification	The Company's portion of the burden
People infected with HCV, as stipulated in Article 2, Paragraph 3, of the Special Law, through use of specific fibrinogen products from August 21, 1985 to April 21, 1987	100%
People infected with HCV, as stipulated in Article 2, Paragraph 3, of the Special Law, through use of specific fibrinogen products from April 22, 1987 to June 23, 1988	Two-thirds
People infected with HCV, as stipulated in Article 2, Paragraph 3, of the Special Law, through the use of specific blood-coagulation factor IX products on or after January 1, 1984	100%

2. Lump-sum payment of ¥5.2 billion in addition to payments made in accordance with the portions in (1) above.

13. Risks Related to Information Management

The Group possesses large amounts of confidential information, including personal information, and in the event that information is leaked due to inappropriate handling, etc., there could be an influence on the Group's financial position or results, such as a decline in reputation.

14. Risks Related to Substantial Upfront Investment for the Purpose of Expanding Overseas Operations

Substantial upfront investment is necessary to expand and advance overseas operations, and it is possible that, due to changes in the laws and systems of each country, the worsening of diplomatic relations, or natural disaster, etc., the opportunity to recover that investment might be lost and operations under development might be affected. As a result of these actions, there could be an influence on the Group's financial position or results.

15. Major Assumptions Regarding Operational Activities

Pharmaceutical manufacturing and sales are the Group's principal business operations. In accordance with the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, the Group has obtained licenses for pharmaceutical manufacturing and sales, pharmaceutical manufacturing and wholesale pharmaceutical sales, and conducts manufacturing and sales of ethical drugs, OTC switch products, and OTC products. These activities include activities that are subject to related laws, such as the Narcotics and Psychotropic Substances Control Law.

In addition, the Group also conducts pharmaceutical manufacturing and sales activities overseas and is subject to the regulations of each country, such as laws and regulations related to pharmaceuticals. The Group acquires permissions, etc., as necessary.

In regard to these permissions, etc., they must be extended periodically, as determined by laws / regulations. Also, in the event of a violation of laws / regulations, it is possible that permissions, etc., of the Group could be cancelled or the Group could be ordered to suspend all or a portion of operations for a specified period of time. The Group is currently unaware of any reasons for the validity of its permissions, etc., to come into question. In the event that cancellation, etc., of permissions, etc., is ordered, because of the damage to the societal trust or the termination of contracts, there could be a significant influence on the Group's financial position or results.

## 16. Risks Related to Major Disasters and Other Events

In the event of a major disaster, pandemic, or secondary disaster that results in stoppages at the production or distribution bases of the Group or supplier, or damages and / or interruptions to the operations of raw material suppliers or outsourced manufacturers, the Group may be forced to suspend or incur significant delays in the supply of products. In each case, the potential exists for the Group's financial position and operating results to be substantially affected. In addition, the implementation of research and development plans may be impacted by damages to the Group's research facilities, or medical, and other institutions at which clinical testing is conducted, or by secondary disaster such as blackouts. In addition, problems with communications with the Group's production and distribution bases or with the Group's research bases, or problems with the Group's computer bases, could have a similar impact.

## 17. Relationship with Parent Company and Other Group Companies

### Transactions with Mitsubishi Chemical Holdings Corporation Group

The Company's relationship with its parent company, Mitsubishi Chemical Holdings Corporation (MCHC), and companies in that Group (MCHC Group), includes the following transactions:

- conclusion of the deposition contract of money with MCHC.
- contract for procurement of raw materials, etc.
- conclusion of leases and consignment contracts for the buildings of research facilities, etc., thereon, in Yokohama City, Kanagawa Prefecture.
- Contracts and payment as consideration for exclusive rights to intellectual property held by MCHC Group.
- conclusion of contracts for research outsourcing and information disclosure.
- consignment contracts with overseas subsidiaries.
- conclusion of the contract of the burden of operational expenses with MCHC.

Fundamentally, these transactions involve rational transaction terms decided upon following two-way negotiations conducted with reference to general market prices.

### Personnel Relationships with the MCHC Group

#### a) Concurrent service of directors and corporate auditors

As of June 22, 2016, the directors, corporate auditors, and employees of the MCHC Group include one MCHC Group corporate auditor who is concurrently serving as a corporate auditor (non-full time) of the Company.

Masayuki Mitsuka, who is a representative director of the Company, serves concurrently as a director (non-full time) of MCHC and a director (non-full time) of The KAITEKI Institute, Inc.

#### b) Acceptance of reassigned personnel

The Group has accepted the reassignment of some people from the MCHC Group with such objectives as enhancing links among each division.

### Capital Relationship with MCHC

Currently, MCHC holds 56.34% of the Company's issued shares. In regard to management decision-making, there are no matters that require the prior approval of MCHC, the Company's parent company. Also, the percentage of the Company's stock held by MCHC will, in principle, be maintained for 10 years from October 1, 2007. At this time, the Company believes that the ownership ratio remains unchanged.

However, in the future, in the event that there is a change in the transactions or the capital relationship with the MCHC Group, the Company's financial position and results of operations could be affected.

There are risks other than those described above, and the risks listed here do not include all of the risks faced by the Group.

# Consolidated Balance Sheet

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
March 31, 2016

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2016	2015	2016
<b>Assets</b>			
<b>Current assets:</b>			
Cash and deposits (Notes 4, 5 and 12)	¥ 142,674	¥ 50,203	\$ 1,266,187
Notes and accounts receivable, trade (Note 5):			
Notes	567	629	5,032
Accounts	120,721	129,702	1,071,361
Less allowance for doubtful receivables	(39)	(44)	(346)
	121,249	130,287	1,076,047
Marketable securities (Notes 5 and 6)	96,500	118,805	856,408
Inventories (Note 7)	75,631	85,091	671,202
Deferred income taxes (Note 10)	7,287	8,319	64,670
Deposits (Notes 5 and 22)	193,147	192,758	1,714,120
Other current assets	20,765	18,186	184,282
Total current assets	657,253	603,649	5,832,916
<b>Property, plant and equipment (Note 18):</b>			
Land	33,188	34,689	294,533
Buildings and structures	98,893	106,853	877,644
Machinery and vehicles	80,235	93,180	712,061
Tools, furniture and fixtures	33,641	37,306	298,553
Leased equipment	688	670	6,106
Construction in progress	5,429	4,597	48,181
	252,074	277,295	2,237,078
Less accumulated depreciation	(163,780)	(184,798)	(1,453,496)
Property, plant and equipment, net	88,294	92,497	783,582
<b>Investments, goodwill and other assets:</b>			
Investments in securities (Notes 5 and 6):			
Unconsolidated subsidiary and affiliate	265	301	2,352
Others	49,570	76,027	439,918
Goodwill	70,515	81,517	625,799
Software	3,680	4,275	32,659
Asset for retirement benefits (Note 9)	8,170	15,730	72,506
Deferred income taxes (Note 10)	6,052	763	53,710
Other assets	46,444	54,544	412,176
Less allowance for doubtful receivables	(1)	(2)	(9)
Total investments, goodwill and other assets	184,695	233,155	1,639,111
Total assets	¥ 930,242	¥ 929,301	\$ 8,255,609

See accompanying notes to consolidated financial statements.

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2016	2015	2016
<b>Liabilities and Net Assets</b>			
<b>Current liabilities:</b>			
Current portion of long-term loans (Notes 5 and 8)	¥ 125	¥ 132	\$ 1,109
Notes and accounts payable, trade (Note 5)	32,737	34,620	290,531
Accounts payable, other	19,799	25,386	175,710
Income taxes payable (Note 10)	16,449	19,189	145,980
Reserve for employees' bonuses	10,686	9,957	94,835
Reserve for sales returns	124	127	1,100
Other current liabilities (Note 8)	11,389	15,988	101,074
Total current liabilities	91,309	105,399	810,339
<b>Long-term liabilities:</b>			
Long-term loans (Notes 5 and 8)	713	894	6,328
Deferred income taxes (Note 10)	7,532	9,776	66,844
Reserve for health management allowances for HIV compensation	1,564	1,700	13,880
Reserve for health management allowances for SMON compensation	2,522	2,731	22,382
Reserve for HCV litigation (Note 27)	5,020	2,036	44,551
Liability for retirement benefits (Note 9)	1,354	2,456	12,016
Other liabilities (Note 8)	3,515	3,875	31,195
Total long-term liabilities	22,220	23,468	197,196
<b>Net assets:</b>			
Shareholders' equity (Note 11):			
Common stock:			
Authorized – 2,000,000,000 shares			
Issued – 561,417,916 shares at March 31, 2016 and 2015	50,000	50,000	443,734
Capital surplus	451,186	451,186	4,004,136
Retained earnings	307,075	275,325	2,725,195
Treasury stock, at cost	(494)	(493)	(4,384)
Total shareholders' equity	807,767	776,018	7,168,681
Accumulated other comprehensive (loss) income:			
Unrealized holding gain on securities	11,875	14,929	105,387
Deferred gain on hedges	4	105	35
Translation adjustments	(3,813)	105	(33,839)
Retirement benefits liability adjustments (Note 9)	(9,902)	(2,178)	(87,877)
Total accumulated other comprehensive (loss) income	(1,836)	12,961	(16,294)
Non-controlling interests	10,782	11,455	95,687
Total net assets	816,713	800,434	7,248,074
Total liabilities and net assets	¥930,242	¥929,301	\$8,255,609



# Consolidated Statement of Income

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
Year ended March 31, 2016

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2016	2015	2016
Net sales (Note 26)	¥431,701	¥415,124	\$3,831,212
Cost of sales (Note 13)	155,806	169,605	1,382,730
Gross profit	275,895	245,519	2,448,482
Selling, general and administrative expenses (Note 14)	180,988	178,386	1,606,212
Operating income	94,907	67,133	842,270
Other income (expenses):			
Interest and dividend income (Note 22)	2,960	2,351	26,269
Interest expense	(202)	(223)	(1,793)
Equity in earnings of affiliates	31	32	275
Foreign exchange (loss) gain, net	(463)	379	(4,109)
Donations	(1,409)	(1,522)	(12,504)
Gain on sales or disposals of fixed assets, net (Note 15)	240	11,718	2,130
Gain on sales of investments in securities, net (Notes 6 and 16)	13,425	1,558	119,143
Loss on investments in securities	(547)	(300)	(4,854)
Personnel expenses for seconded employees	-	(102)	-
Restructuring loss (Note 19)	(16,330)	(12,294)	(144,924)
Amortization of goodwill (Note 20)	-	(3,504)	-
Loss on impairment of fixed assets (Note 18)	(4,453)	(2,565)	(39,519)
Provision of reserve for HCV litigation (Note 17)	(3,521)	-	(31,248)
Loss on impairment of investments in securities (Note 6)	(279)	(130)	(2,476)
Other, net	(47)	146	(417)
Profit before income taxes	84,312	62,677	748,243
Income taxes (Note 10):			
Current	30,768	29,805	273,056
Deferred	(613)	(4,416)	(5,440)
	30,155	25,389	267,616
Profit	54,157	37,288	480,627
Loss attributable to non-controlling interests	(2,277)	(2,214)	(20,207)
Profit attributable to owners of parent (Note 25)	¥ 56,434	¥ 39,502	\$ 500,834

See accompanying notes to consolidated financial statements.

# Consolidated Statement of Comprehensive Income

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
Year ended March 31, 2016

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2016	2015	2016
<b>Profit</b>	<b>¥ 54,157</b>	<b>¥37,288</b>	<b>\$ 480,627</b>
<b>Other comprehensive (loss) income (Note 21):</b>			
Unrealized holding (loss) gain on securities	(3,054)	6,183	(27,103)
Deferred loss on hedges	(101)	(388)	(896)
Translation adjustments	(4,954)	2,385	(43,965)
Retirement benefits liability adjustments	(7,724)	5,852	(68,548)
Share of other comprehensive (loss) income of affiliates accounted for by the equity method	(30)	38	(267)
<b>Total other comprehensive (loss) income</b>	<b>(15,863)</b>	<b>14,070</b>	<b>(140,779)</b>
<b>Comprehensive income</b>	<b>¥ 38,294</b>	<b>¥51,358</b>	<b>\$ 339,848</b>
<b>Comprehensive income (loss) attributable to:</b>			
Owners of parent	¥ 41,637	¥53,688	\$ 369,516
Non-controlling interests	(3,343)	(2,330)	(29,668)

See accompanying notes to consolidated financial statements.

# Consolidated Statement of Changes in Net Assets

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
Year ended March 31, 2016

	Number of shares of common stock (Thousands)	Millions of yen									
		Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized holding gain on securities	Deferred gain on hedges	Translation adjustments	Retirement benefits liability adjustments	Non-controlling interests	Total net assets
<b>Balance at April 1, 2014</b>	561,417	¥50,000	¥451,186	¥266,575	¥(490)	¥ 8,747	¥ 493	¥(2,399)	¥(8,066)	¥11,791	¥777,837
Cumulative effects of changes in accounting policies	—	—	—	(8,313)	—	—	—	—	—	—	(8,313)
Balance at April 1, 2014, as adjusted	—	50,000	451,186	258,262	(490)	8,747	493	(2,399)	(8,066)	11,791	769,524
Profit attributable to owners of parent	—	—	—	39,502	—	—	—	—	—	—	39,502
Cash dividends	—	—	—	(22,439)	—	—	—	—	—	—	(22,439)
Increase in treasury stock	—	—	—	—	(3)	—	—	—	—	—	(3)
Net changes in items other than shareholders' equity	—	—	—	—	—	6,182	(388)	2,504	5,888	(336)	13,850
<b>Balance at April 1, 2015</b>	561,417	50,000	451,186	275,325	(493)	14,929	105	105	(2,178)	11,455	800,434
Profit attributable to owners of parent	—	—	—	56,434	—	—	—	—	—	—	56,434
Cash dividends	—	—	—	(24,684)	—	—	—	—	—	—	(24,684)
Increase in treasury stock	—	—	—	—	(1)	—	—	—	—	—	(1)
Decrease in treasury stock	—	—	0	—	0	—	—	—	—	—	0
Net changes in items other than shareholders' equity	—	—	—	—	—	(3,054)	(101)	(3,918)	(7,724)	(673)	(15,470)
<b>Balance at March 31, 2016</b>	561,417	¥50,000	¥451,186	¥307,075	¥(494)	¥11,875	¥ 4	¥(3,813)	¥(9,902)	¥10,782	¥816,713

Thousands of U.S. dollars (Note 1)

	Thousands of U.S. dollars (Note 1)									
	Common stock	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized holding gain on securities	Deferred gain on hedges	Translation adjustments	Retirement benefits liability adjustments	Non-controlling interests	Total net assets
<b>Balance at April 1, 2015</b>	\$443,734	\$4,004,136	\$2,443,424	\$(4,375)	\$132,490	\$ 932	\$ 932	\$(19,329)	\$101,660	\$7,103,604
Profit attributable to owners of parent	—	—	500,834	—	—	—	—	—	—	500,834
Cash dividends	—	—	(219,063)	—	—	—	—	—	—	(219,063)
Increase in treasury stock	—	—	—	(9)	—	—	—	—	—	(9)
Decrease in treasury stock	—	0	—	0	—	—	—	—	—	0
Net changes in items other than shareholders' equity	—	—	—	—	(27,103)	(897)	(34,771)	(68,548)	(5,973)	(137,292)
<b>Balance at March 31, 2016</b>	\$443,734	\$4,004,136	\$2,725,195	\$(4,384)	\$105,387	\$ 35	\$(33,839)	\$(87,877)	\$ 95,687	\$7,248,074

See accompanying notes to consolidated financial statements.

# Consolidated Statement of Cash Flows

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries  
Year ended March 31, 2016

	Millions of yen		Thousands of U.S. dollars (Note 1)
	2016	2015	2016
<b>Cash flows from operating activities:</b>			
Profit before income taxes	¥ 84,312	¥ 62,677	\$ 748,243
Adjustments for:			
Depreciation and amortization	8,838	9,028	78,435
Loss on impairment of fixed assets	4,453	2,565	39,519
Amortization of goodwill	10,498	14,421	93,166
Decrease in liability for retirement benefits	(803)	(510)	(7,126)
Increase in asset for retirement benefits	(4,626)	(3,887)	(41,054)
Increase (decrease) in reserve for HCV litigation	2,984	(598)	26,482
Interest and dividend income	(2,960)	(2,351)	(26,269)
Gain on sales or disposals of fixed assets, net	(240)	(11,823)	(2,130)
Restructuring loss	16,330	12,294	144,924
Gain on sales of shares of subsidiaries and affiliates	—	(560)	—
Gain on sales of investments in securities	(13,425)	(998)	(119,143)
Decrease (increase) in notes and accounts receivable, trade	8,670	(6,711)	76,944
Decrease in inventories	6,333	7,796	56,203
(Decrease) increase in notes and accounts payable, trade	(1,660)	502	(14,732)
(Decrease) increase in accounts payable, other	(4,435)	5,927	(39,359)
Other, net	(2,720)	(1,744)	(24,140)
Subtotal	111,549	86,028	989,963
Interest and dividends received	2,976	2,354	26,411
Interest paid	(323)	(241)	(2,867)
Payment for special retirement expenses	(15,282)	—	(135,623)
Income taxes paid	(33,732)	(19,974)	(299,361)
<b>Net cash provided by operating activities</b>	<b>65,188</b>	<b>68,167</b>	<b>578,523</b>
<b>Cash flows from investing activities:</b>			
Purchases of marketable securities	(142,500)	(122,300)	(1,264,643)
Proceeds from sales and redemption of marketable securities	183,800	95,871	1,631,168
Increase in time deposits	(150,027)	(25,006)	(1,331,443)
Decrease in time deposits	56,432	4,819	500,816
Increase in deposits	(389)	(20,609)	(3,452)
Purchases of fixed assets	(11,861)	(12,976)	(105,263)
Proceeds from sales of fixed assets	2,785	11,687	24,716
Purchases of intangible fixed assets	(1,153)	(1,503)	(10,233)
Purchases of investments in securities	(522)	(249)	(4,633)
Proceeds from sales and redemption of investments in securities	30,556	1,318	271,175
Proceeds from sales of investment in a subsidiary and an affiliate	—	7,600	—
Proceeds from corporate division	3,323	—	29,491
Proceeds from transfer of business	3,000	—	26,624
Proceeds from sales of investment in a subsidiary resulting in change in scope of consolidation	—	1,467	—
Other, net	(3)	47	(26)
<b>Net cash used in investing activities</b>	<b>(26,559)</b>	<b>(59,834)</b>	<b>(235,703)</b>
<b>Cash flows from financing activities:</b>			
Decrease in short-term loans, net	—	(1,216)	—
Proceeds from stock issuance to non-controlling interests	2,783	2,564	24,698
Cash dividends paid	(24,684)	(22,439)	(219,063)
Cash dividends paid to non-controlling interests	(113)	(570)	(1,003)
Other, net	(222)	(223)	(1,970)
<b>Net cash used in financing activities</b>	<b>(22,236)</b>	<b>(21,884)</b>	<b>(197,338)</b>
Effect of exchange rate changes on cash and cash equivalents	(811)	1,931	(7,197)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>15,582</b>	<b>(11,620)</b>	<b>138,285</b>
<b>Cash and cash equivalents at beginning of the year</b>	<b>73,337</b>	<b>84,957</b>	<b>650,844</b>
<b>Cash and cash equivalents at end of the year (Notes 4, 5 and 12)</b>	<b>¥ 88,919</b>	<b>¥ 73,337</b>	<b>\$ 789,129</b>

See accompanying notes to consolidated financial statements.

# Notes to Consolidated Financial Statements

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

## 1. Basis of Preparation of Consolidated Financial Statements

The accompanying consolidated financial statements of Mitsubishi Tanabe Pharma Corporation (the "Company") and its consolidated subsidiaries (collectively, the "Group") have been prepared in accordance with the provisions set forth in the Corporation Law of Japan and the Financial Instruments and Exchange Law of Japan and its related accounting regulations, and in conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards.

The accompanying consolidated financial statements have been compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Law of Japan. In preparing the accompanying consolidated financial statements, certain reclassifications and rearrangements have been made to present them in a form which is familiar to readers outside Japan. In addition, the

notes to the accompanying consolidated financial statements include information which is not required under accounting principles generally accepted in Japan but is presented herein as additional information.

Certain reclassifications of previously reported amounts have been made to conform the consolidated financial statements for the year ended March 31, 2015 to the 2016 presentation. Such reclassifications had no effect on consolidated profit or net assets.

The translation of the Japanese yen amounts into U.S. dollars is included solely for the convenience of readers outside Japan, using the prevailing exchange rate at March 31, 2016, which was ¥112.68 to U.S.\$1. The approximate rate of exchange prevailing at May 31, 2016 was ¥110.94 to U.S.\$1. This translation of convenience should not be construed as a representation that the Japanese yen amounts have been, could have been, or could in the future be, converted into U.S. dollars at this or any other rate of exchange.

## 2. Summary of Significant Accounting Policies

### (1) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its 28 significant consolidated subsidiaries for the year ended March 31, 2016.

During the fiscal year ended March 31, 2016, Tanabe U.S.A., Inc. and MP-Logistics Corporation, which were subsidiaries of the Company, were liquidated. Furthermore, in the fourth quarter of the fiscal year ended March 31, 2016, MT Pharma America, Inc. and MT Pharma Singapore Pte. Ltd. were newly included in the scope of consolidation. MT Pharma America, Inc. was newly established by Mitsubishi Tanabe Pharma Holdings America, Inc., a consolidated subsidiary of the Company, and MT Pharma Singapore Pte. Ltd. was newly established by the Company.

One affiliate, Synthelabo-Tanabe Chimies S.A., is accounted for by the equity method.

During the fiscal year ended March 31, 2016, Tanabe Seiyaku Malaysia, a non-consolidated subsidiary not accounted for by the equity method, was liquidated.

Among consolidated subsidiaries, Tianjin Tanabe Seiyaku Co., Ltd. and four other subsidiaries have fiscal years ending on December 31. Their temporary financial statements based on a provisional settlement of accounts as of March 31, are used for preparing the consolidated financial statements. However, the closing dates of the other consolidated subsidiaries are the same as the consolidated closing date.

### (2) Foreign Currency Transactions

All monetary receivables and payables denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date and gain or loss on each translation is credited or charged to income.

The balance sheet accounts of the overseas consolidated subsidiaries are translated into yen at the rates of exchange in effect at the balance sheet date, except that the components of net assets excluding non-controlling interests are translated at their historical exchange rates. Revenue and expense accounts are translated at the average rates of exchange in effect during the year. Adjustments resulting from translating foreign currency financial statements are not included in the determination of profit and are presented as translation adjustments and non-controlling interests in the accompanying consolidated balance sheets.

### (3) Cash and Cash Equivalents

In preparing the consolidated statements of cash flows, cash on hand, readily-available deposits and short-term highly liquid investments with maturities not exceeding three months at the time of purchase are considered to be cash and cash equivalents.

### (4) Allowance for Doubtful Receivables

The allowance for doubtful receivables is provided to cover possible losses on collection. With respect to normal trade accounts receivable, it is stated at an amount based on the actual rate of historical bad debts, and for certain doubtful receivables, the uncollectible amount has been individually estimated.

### (5) Marketable Securities and Investments in Securities

Marketable securities and investments in securities are classified into one of the following categories based on the intent of holding, resulting in different measurements of and method of accounting for changes in fair value. Held-to-maturity debt securities are stated at amortized cost. Available-for-sale securities with available market value are stated at market value. Unrealized holding gains and unrealized holding losses on these securities are reported, net of applicable income taxes, as a separate component of accumulated other comprehensive income (loss). Other available-for-sale securities with no available market value are stated at cost determined by the moving average method. Cost of securities sold is determined by the moving average method. Significant declines in market value or the net asset value of held-to-maturity debt securities, equity securities issued by unconsolidated subsidiaries and affiliated companies not accounted for by the equity method, and available-for-sale securities, judged to be other than temporary, are charged to income.

Investments in investment business limited liability partnerships and other similar partnerships, which are deemed to be securities under Article 2, Clause 2 of the Financial Instruments and Exchange Law of Japan, are valued at the amount of the underlying equity in their net assets based on the latest financial statements available as of the closing date stipulated in the partnership agreement. Investment gain or loss is included in other income or expenses in proportion to the ownership interests in the net asset value of the partnership. In case that such partnerships have available-for-sale securities, the difference between fair value and the carrying amount arising from holding such securities through such partnerships is included in unrealized holding gain or loss on securities in proportion to the ownership interests in the net asset value of the partnership.

#### **(6) Inventories**

Inventories are stated at the lower of cost or net selling value, cost being determined primarily by the weighted average method.

#### **(7) Property, Plant and Equipment and Depreciation (excluding leased equipment)**

Depreciation of property, plant and equipment is calculated primarily by the straight-line method. Principal estimated useful lives are as follows:

Buildings and structures	10 to 50 years
Machinery and equipment	4 to 8 years

#### **(8) Intangible Fixed Assets (excluding leased assets)**

Intangible fixed assets are amortized by the straight-line method. Amortization of software utilized internally is calculated by the straight-line method over an estimated useful life of primarily 5 years.

#### **(9) Leased Equipment**

Leased equipment arising from finance lease transactions which do not transfer ownership to the lessee are depreciated to a residual value of zero by the straight-line method using the contract term as the useful life.

Among finance lease transactions which do not transfer ownership to the lessee, those that started on or before March 31, 2008 are accounted for as operating leases.

#### **(10) Reserve for Employees' Bonuses**

Reserve for employees' bonuses is provided at the estimated amount of bonuses to be paid to the employees in the following year which has been allocated to the current fiscal year.

#### **(11) Reserve for Sales Returns**

Reserve for sales returns is estimated and recorded to provide for future losses on the return of products.

#### **(12) Reserve for Sales Rebates**

Reserve for sales rebates is estimated and recorded by multiplying the balance of accounts receivable at the year end by the rebate ratio for the current fiscal year.

#### **(13) Reserve for Health Management Allowances for HIV Compensation**

To provide for future payments of health management allowances and settlement payments (including attorney fees) in connection with a lawsuit for damages filed by plaintiffs infected with HIV, the Company has set aside an estimated amount for such future payments.

In accordance with the settlement reached in March 1996, for health management allowances, the Company has set aside the present value of the estimated amount of future payments to be made calculated with reference to the amounts actually paid to patients with AIDS who have already reached settlements; and, for settlement payments, the Company has set aside the estimated amount of payments to be made to existing plaintiffs of HIV lawsuits as of March 31, 2016 and to future plaintiffs, as patients infected with HIV through the use of antihemophilic preparations (non-heat-treated concentrated preparations), calculated with reference to settlement outcomes up to March 31, 2016.

#### **(14) Reserve for Health Management Allowances for SMON (Sub-acute Myelo-Optical-Neuropathy) Compensation**

The Company pays health management allowances and nursing expenses for plaintiffs covered under the compromise settlement reached in the SMON litigation.

The Company has made a provision in the accompanying consolidated financial statements for the estimated future medical treatment payments to be made over the remaining lives of the parties entitled to such payments under the compromise settlement.

#### **(15) Reserve for HCV Litigation**

To provide for losses that may arise in the future in accordance with "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" ("Special Law"), which was promulgated and enacted to facilitate the settlement of damage recovery lawsuits filed on behalf of people infected with HCV (hepatitis C virus), the Company has set aside the estimated amount of payments based on estimates of the people receiving relief and the amount of relief payments required under the Special Law.

#### **(16) Retirement Benefits for Employees**

The liability for retirement benefits is provided based on the amount of the projected benefit obligation reduced by the pension plan assets at fair value at the end of the year. The retirement benefits are attributed to periods corresponding to service years of eligible employees based on the benefit formula method.

Prior service cost is amortized by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

Actuarial gain or loss is amortized in the year following the year in which the gain or loss is recognized by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

#### **(17) Derivatives and Hedging Transactions**

Derivatives positions are carried at fair value with any changes in unrealized gain or loss charged or credited to income, except for those which meet the criteria for deferral hedge accounting under which unrealized gain or loss is deferred and reported as deferred gains or losses on hedges in a separate component of accumulated other comprehensive income (loss).

#### **(18) Amortization of Goodwill**

Goodwill is amortized by the straight-line method over a period of mainly 15 years.

#### **(19) Income Taxes**

Deferred income taxes are recognized with respect to the differences between financial reporting and the tax bases of the assets and liabilities. Deferred income taxes are measured at the rates which are expected to apply to the period when each asset or liability is realized, based on the tax rates which have been enacted as of the balance sheet date or are subsequently enacted.

The Company and certain consolidated subsidiaries adopt the consolidated taxation system.



### 3. Accounting Change

#### Accounting Standards for Business Combinations

From the year ended March 31, 2016, the Company has applied the "Revised Accounting Standard for Business Combinations" (Accounting Standards Board of Japan ("ASBJ") Statement No. 21 on September 13, 2013), "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22 on September 13, 2013) and "Revised Accounting Standard for Business Divestitures" (ASBJ Statement No. 7 on September 13, 2013). Under the adopted accounting standards, differences arising from changes in the Company's ownership interest in a subsidiary are recorded in capital surplus, in cases where the parent company continues to have control and acquisition expenses for business combinations are treated as expenses in the consolidated financial statements for the year in which they arise. Furthermore, effective for business combinations occurring on or after the beginning of the year ended March 31, 2016, any changes in the allocation of the

acquisition price arising from the finalization of the provisional accounting treatment are reflected in the consolidated financial statements for the year in which the business combination occurs. In addition, the previous accounting category of "net income" was changed and the category of "minority interests" was changed to "non-controlling interests." The consolidated financial statements for the previous year have been reclassified to reflect these changes in presentation.

In accordance with the provisional treatment prescribed in Clause 58-2 (4) of the "Accounting Standard for Business Combinations," in Clause 44-5 (4) of the "Accounting Standard for Consolidated Financial Statements" and in Clause 57-4 (4) of the "Accounting Standard for Business Divestitures," the aforementioned accounting standards have been applied prospectively from the beginning of the year ended March 31, 2016.

The effects of these changes on the Company's consolidated financial statements at March 31, 2016 and for the year then ended were nil.

### 4. Cash and Time Deposits

A reconciliation of cash and deposits in the accompanying consolidated balance sheets at March 31, 2016 and 2015 and cash and cash equivalents in the accompanying consolidated statements of cash flows for the years then ended is as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Cash and deposits	¥ 142,674	¥ 50,203	\$ 1,266,187
Time deposits maturing after three months	(118,004)	(25,552)	(1,047,249)
Marketable securities maturing within three months	43,000	28,000	381,612
Cash equivalents included in other current assets	1,249	686	11,085
Cash equivalents included in deposits	20,000	20,000	177,494
Cash and cash equivalents	¥ 88,919	¥ 73,337	\$ 789,129

### 5. Financial Instruments

#### Overview

##### (1) Policy for Financial Instruments

The Group manages its funds by investing in both short-term and long-term, highly stable financial assets.

The Group has introduced a cash management system ("CMS") to efficiently use capital and reduce financing costs, and enable Group companies to internally borrow and lend among themselves.

The policy with regard to derivative transactions is to limit the amount to the actual demand, and transactions are not carried out for speculative purposes.

##### (2) Types of Financial Instruments and Related Risk

Notes and accounts receivable, trade, are amounts owed to the Group, and are subject to the credit risk of customers. Marketable securities and investments in securities are mainly Japanese government bonds, bonds to be held to maturity, or shares of counterparty companies in operational or capital alliances, and are subject to risk from market price fluctuations. The deposits are funds to the parent company primarily. The deposits are exposed to its credit risks.

Notes and accounts payable, trade, are operating obligations to be paid by the Group and most are payable within one year. A portion of these are for purchases of raw materials and are denominated in foreign currencies, and are subject to risk from exchange rate fluctuations.

As necessary, however, these are netted against operating claims and forward foreign exchange contracts are used to hedge the net position.

Long-term loans are mainly used for investments in the business and have maturities of up to 8 years.

Derivative transactions involve forward foreign exchange contracts entered into in order to manage the risk arising from adverse fluctuation in foreign currency exchange rates related to operating claims and obligations denominated in foreign currencies.

##### (3) Risk Management for Financial Instruments

###### (a) Monitoring of credit risk

As to the management of credit risk (risk of non-performance by counterparty), the Group regularly monitors the status of major counterparties with regard to operating claims and manages maturity dates and outstanding amounts by transaction counterparty in accordance with its claims management regulations, while at the same time working to quickly identify and reduce concerns of repayment resulting from the weakening of a counterparty's financial position.

Japanese government bonds, bonds to be held to maturity and deposits are deemed to have minimal credit risk because the Group primarily invests only in bonds with high ratings.

To strictly minimize the credit risk related to counterparty non-performance when entering into derivative transactions, counterparties are limited to financial institutions with high credit ratings.

The maximum amount of credit risk as of the end of the fiscal year is reflected in the amounts recorded for financial assets in the consolidated balance sheets that are subject to credit risk.

#### (b) Monitoring of market risks

As to the management of market risks (risks from exchange rate or interest rate fluctuations), operating claims and obligations denominated in foreign currencies are hedged as necessary using forward foreign exchange contracts.

The market value of marketable securities and investments in securities are regularly determined and the financial position of the issuer (counterparty company) is monitored, and for securities other than Japanese government bonds and bonds to be held to maturity, the decision of whether to continue to hold the security or not is regularly reviewed taking into account for the relationship with the counterparty companies.

For derivative transactions, the authority to enter into transactions and the maximum amounts of those transactions are determined based on internal regulations, and outstanding contract amounts, and market values are regularly reported to the responsible director.

#### (c) Monitoring of liquidity risk

As to the management of liquidity risk associated with fund procurement (risk of being unable to make payment on payment date), based on reports submitted by each department, the Finance & Accounting Department prepares and updates funding plans in a timely manner, while at the same time the Group manages liquidity risk by means of maintaining sufficient liquidity on hand.

#### (4) Supplementary Explanation of the Estimated Fair Value of Financial Instruments

The market value of financial instruments is based on the market price, and when no market price exists, a rationally calculated amount is used. These calculations include variable factors, so the resulting amount may fluctuate if different underlying assumptions are applied. The notional amounts shown in Note 24 "Derivative and Hedging Transactions" do not represent the amounts of their market risk.

#### Fair value of financial instruments

The carrying value of financial instruments on the accompanying consolidated balance sheets as of March 31, 2016 and 2015, and their estimated market value are shown in the following table. The following table does not include financial instruments for which it is extremely difficult to determine the market value.

	Millions of yen		
	2016		
	Carrying value	Market value	Difference
Assets:			
Cash and deposits	¥142,674	¥142,674	¥ —
Notes and accounts receivable, trade	121,288	121,288	—
Marketable securities and investments in securities	141,786	141,952	166
Deposits	193,147	193,147	—
Total assets	¥598,895	¥599,061	¥166
Liabilities:			
Notes and accounts payable, trade	32,737	32,737	—
Long-term loans	838	832	(6)
Total liabilities	¥ 33,575	¥ 33,569	¥ (6)
Derivative transactions in other current assets or other assets:			
Derivatives for which hedge accounting is applied	7	7	—
Derivatives for which hedge accounting is not applied	1,161	1,161	—
Total derivative transactions	¥ 1,168	¥ 1,168	¥ —

## Notes to Consolidated Financial Statements

Millions of yen			
2015			
	Carrying value	Market value	Difference
<b>Assets:</b>			
Cash and deposits	¥ 50,203	¥ 50,203	¥ —
Notes and accounts receivable, trade	130,331	130,331	—
Marketable securities and investments in securities	189,743	190,073	330
Deposits	192,758	192,758	—
<b>Total assets</b>	<b>¥563,035</b>	<b>¥563,365</b>	<b>¥330</b>
<b>Liabilities:</b>			
Notes and accounts payable, trade	34,620	34,620	—
Long-term loans	1,026	1,065	39
<b>Total liabilities</b>	<b>¥ 35,646</b>	<b>¥ 35,685</b>	<b>¥ 39</b>
<b>Derivative transactions in other current assets or other assets:</b>			
Derivatives for which hedge accounting is applied	157	157	—
Derivatives for which hedge accounting is not applied	(203)	(203)	—
<b>Total derivative transactions</b>	<b>¥ (46)</b>	<b>¥ (46)</b>	<b>¥ —</b>
Thousands of U.S. dollars			
<b>2016</b>			
	Carrying value	Market value	Difference
<b>Assets:</b>			
Cash and deposits	\$1,266,187	\$1,266,187	\$ —
Notes and accounts receivable, trade	1,076,393	1,076,393	—
Marketable securities and investments in securities	1,258,307	1,259,780	1,473
Deposits	1,714,120	1,714,120	—
<b>Total assets</b>	<b>\$5,315,007</b>	<b>\$5,316,480</b>	<b>\$1,473</b>
<b>Liabilities:</b>			
Notes and accounts payable, trade	290,531	290,531	—
Long-term loans	7,437	7,383	(54)
<b>Total liabilities</b>	<b>\$ 297,968</b>	<b>\$ 297,914</b>	<b>\$ (54)</b>
<b>Derivative transactions in other current assets or other assets:</b>			
Derivatives for which hedge accounting is applied	62	62	—
Derivatives for which hedge accounting is not applied	10,304	10,304	—
<b>Total derivative transactions</b>	<b>\$ 10,366</b>	<b>\$ 10,366</b>	<b>\$ —</b>

Long-term loans include current maturities of long-term loans.

The value of assets and liabilities arising from derivative transactions are shown as the net amount, with total net obligations shown in parentheses.

The financial instruments such as cash and deposits; notes and accounts receivable, trade; deposits; and notes and accounts payable, trade; are settled within a short period of time and the market value is therefore nearly equal to the book value, so the book value is used.

As to the market value of marketable securities and investment in securities, the exchange price prevailing in the applicable stock

exchange is used for equities, and the exchange price prevailing in the applicable stock exchange or price provided by financial institutions is used for bonds. Negotiable certificates of deposit and commercial paper are settled within a short period of time and the market value is therefore nearly equal to the book value, so the book value is used.

The fair value of long-term loans with variable interest rates is nearly equal to the book value because the interest rate reflects the market rate in a short period of time. The fair value of long-term bank loans with fixed interest rates is the sum of the principal and total interest discounted by the rate that is applied if the same new loan is made.

Financial instruments for which it is deemed extremely difficult to determine the market value at March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
			Carrying value
Unlisted and unquoted stocks	¥3,969	¥4,174	\$35,224
Investments in investment business limited liability partnerships	580	1,220	5,147

Scheduled redemption amounts subsequent to March 31, 2016 for monetary claims and marketable securities with maturities are as follows:

	Millions of yen			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Current and time deposits	¥142,663	¥ —	¥—	¥ —
Notes and accounts receivable, trade	121,288	—	—	—
Marketable securities and investments in securities:				
Held-to-maturity debt securities:				
Bonds	—	2,749	—	—
Other	—	—	—	2,000
Available-for-sale securities with maturities:				
Bonds	—	4,400	—	—
Other	96,500	—	—	—
Deposits	193,147	—	—	—
Total	¥553,598	¥7,149	¥—	¥2,000

	Thousands of U.S. dollars			
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Current and time deposits	\$1,266,089	\$ —	\$—	\$ —
Notes and accounts receivable, trade	1,076,393	—	—	—
Marketable securities and investments in securities:				
Held-to-maturity debt securities:				
Bonds	—	24,396	—	—
Other	—	—	—	17,749
Available-for-sale securities with maturities:				
Bonds	—	39,049	—	—
Other	856,408	—	—	—
Deposits	1,714,120	—	—	—
Total	\$4,913,010	\$63,445	\$—	\$17,749

## 6. Marketable Securities and Investments in Securities

Held-to-maturity debt securities with available market value at March 31, 2016 and 2015 are as follows:

Millions of yen						
Held-to-maturity debt securities						
	2016			2015		
	Carrying value	Market value	Unrealized gain	Carrying value	Market value	Unrealized gain (loss)
Securities with market value exceeding carrying value:						
Bonds	¥4,759	¥4,925	¥166	¥11,450	¥11,907	¥ 457
Securities with market value not exceeding carrying value:						
Bonds	—	—	—	1,000	873	(127)
<b>Total</b>	<b>¥4,759</b>	<b>¥4,925</b>	<b>¥166</b>	<b>¥12,450</b>	<b>¥12,780</b>	<b>¥ 330</b>

Thousands of U.S. dollars		
Held-to-maturity debt securities		
	2016	
	Carrying value	Market value
Securities with market value exceeding carrying value:		
Bonds	\$42,235	\$43,708
Securities with market value not exceeding carrying value:		
Bonds	—	—
<b>Total</b>	<b>\$42,235</b>	<b>\$43,708</b>

Available-for-sale securities with available market value at March 31, 2016 and 2015 are as follows:

Millions of yen						
Available-for-sale securities with available market value						
	2016			2015		
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities with carrying value exceeding acquisition cost:						
Stocks	¥ 16,891	¥ 34,131	¥17,240	¥ 30,042	¥ 52,024	¥21,982
Bonds	4,400	4,438	38	10,400	10,450	50
Subtotal	21,291	38,569	17,278	40,442	62,474	22,032
Securities with carrying value not exceeding acquisition cost:						
Stocks	2,148	1,959	(189)	23	21	(2)
Bonds	—	—	—	3,300	3,298	(2)
Other	96,500	96,500	—	111,500	111,500	—
Subtotal	98,648	98,459	(189)	114,823	114,819	(4)
<b>Total</b>	<b>¥119,939</b>	<b>¥137,028</b>	<b>¥17,089</b>	<b>¥155,265</b>	<b>¥177,293</b>	<b>¥22,028</b>

Thousands of U.S. dollars		
Available-for-sale securities with available market value		
	2016	
	Acquisition cost	Carrying value
Securities with carrying value exceeding acquisition cost:		
Stocks	\$ 149,902	\$ 302,902
Bonds	39,049	39,386
Subtotal	188,951	342,288
Securities with carrying value not exceeding acquisition cost:		
Stocks	19,063	17,386
Bonds	—	—
Other	856,407	856,407
Subtotal	875,470	873,793
<b>Total</b>	<b>\$1,064,421</b>	<b>\$1,216,081</b>

Impairment losses on available-for-sale securities amounting to ¥279 million (\$2,476 thousand), and ¥130 million were recorded for the years ended March 31, 2016 and 2015, respectively.

Available-for-sale securities sold during the years ended March 31, 2016 and 2015 are as follows:

	Millions of yen					
	2016			2015		
	Proceeds	Gain on sale	Loss on sale	Proceeds	Gain on sale	Loss on sale
Stocks	¥25,056	¥13,425	¥—	¥1,296	¥1,069	¥—

	Thousands of U.S. dollars		
	2016	2015	
	Proceeds	Gain on sale	Loss on sale
Stocks	\$222,364	\$119,143	\$—

## 7. Inventories

Inventories at March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Finished goods and merchandise	¥52,623	¥63,566	\$467,013
Semi-finished products and work-in-process	552	582	4,899
Raw materials and supplies	22,456	20,943	199,290
Total	¥75,631	¥85,091	\$671,202

## 8. Long-Term Loans and Lease Obligations

Long-term loans and lease obligations at March 31, 2016 and 2015 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Loans, principally from banks at average interest rates ranging from 5.44% to 6.38%, due through 2024	¥ 838	¥1,026	\$ 7,437
Lease obligations due through 2026	1,743	1,945	15,469
	2,581	2,971	22,906
Less current portion	(219)	(222)	(1,944)
	¥2,362	¥2,749	\$20,962

The aggregate annual maturities of long-term loans and lease obligations recorded as other current liabilities and other liabilities subsequent to March 31, 2016 are summarized as follows:

Year ending March 31,	Millions of yen	Thousands of U.S. dollars
2017	¥ 219	\$ 1,944
2018	222	1,970
2019	261	2,316
2020	212	1,881
2021	231	2,050
2022 and thereafter	1,436	12,745
	¥2,581	\$22,906



## 9. Retirement Benefits

### 1. Outline of retirement benefits for employees

The Company and certain consolidated subsidiaries offer a choice between a defined contribution pension plan and a prepaid plan; a choice between a cash balance plan and a prepaid plan; a contract-type defined-benefit corporate pension plan; and a system of lump-sum payments at retirement.

There are also cases in which additional retirement allowances not included in the actuarial calculation as per retirement benefit accounting are paid when an employee retires.

The Company has established a retirement benefit trust. On April 1, 2011, the Company transferred a qualified pension system (closed-type) to a contract-type defined-benefit corporate pension plan in accordance with the Defined Benefit Corporate Pension Act.

Certain subsidiaries have calculated their retirement benefit obligations based on the amount which would be payable at the year-end if all eligible employees terminated their services voluntarily ("simplified method").

### 2. Information on defined benefit pension plans for the years ended March 31, 2016 and 2015

(1) The changes in retirement benefit obligation except for simplified method for the years ended March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Balance at the beginning of the year	¥157,873	¥148,049	\$1,401,074
Cumulative effects of changes in accounting policies	—	12,876	—
Balance at the beginning of the year, as adjusted	157,873	160,925	1,401,074
Service cost	2,987	3,122	26,509
Interest cost	927	1,425	8,227
Actuarial loss	4,737	2,987	42,039
Retirement benefit paid	(9,355)	(10,519)	(83,023)
Other	(11)	(67)	(98)
Balance at the end of the year	¥157,158	¥157,873	\$1,394,728

(2) The changes in plan assets except for simplified method for the years ended March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Balance at the beginning of the year	¥171,737	¥162,761	\$1,524,113
Expected return on plan assets	4,290	4,063	38,072
Actuarial (loss) gain	(7,197)	10,580	(63,871)
Contributions by the employer	4,304	4,696	38,197
Retirement benefit paid	(8,994)	(10,363)	(79,819)
Balance at the end of the year	¥164,140	¥171,737	\$1,456,692

(3) The changes in liability for retirement benefits calculated by the simplified method for the years ended March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Balance at the beginning of the year	¥ 590	¥553	\$ 5,236
Retirement benefit expenses	(144)	75	(1,279)
Retirement benefit paid	(4)	(1)	(35)
Contribution to pension plans	(299)	(64)	(2,654)
Other	23	27	205
Balance at the end of the year	¥ 166	¥590	\$ 1,473

(4) The reconciliations of the defined benefit obligations and plan assets at fair value to the asset and liability for retirement benefits including the plan based on the simplified method recognized in the consolidated balance sheet are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Funded retirement benefit obligation	¥ 157,588	¥ 157,831	\$ 1,398,545
Plan assets at fair value	(164,807)	(171,989)	(1,462,611)
	(7,219)	(14,158)	(64,066)
Unfunded retirement benefit obligation	403	884	3,576
Net amount of liabilities and assets recognized in consolidated balance sheet	¥ (6,816)	¥ (13,274)	\$ (60,490)
Liability for retirement benefits	¥ 1,354	¥ 2,456	\$ 12,016
Asset for retirement benefits	(8,170)	(15,730)	(72,506)
Net amount of liabilities and assets recognized in consolidated balance sheet	¥ (6,816)	¥ (13,274)	\$ (60,490)

(5) The components of retirement benefit expense for the years ended March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Service cost	¥ 2,987	¥ 3,122	\$ 26,509
Interest cost	927	1,425	8,227
Expected return on plan assets	(4,290)	(4,063)	(38,072)
Amortization:			
Actuarial loss	1,120	1,835	9,940
Prior service cost	(195)	(203)	(1,731)
Retirement benefit expenses calculated by the simplified method	(144)	75	(1,279)
Retirement benefit expenses	¥ 405	¥ 2,191	\$ 3,594

(Note) In addition to the above, special retirement payments of ¥15,282 million (\$135,623 thousand) as a result of the early retirement program and additional payments of ¥507 million resulting from the transfer of employees were recorded as restructuring loss for the years ended March 31, 2016 and 2015, respectively.

(6) The components of retirement benefit liability adjustments included in other comprehensive (loss) income before the deduction of the tax effect for the years ended March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Prior service cost	¥ (195)	¥ (203)	\$ (1,731)
Actuarial (gain) loss	(10,814)	9,384	(95,970)
Total	¥(11,009)	¥9,181	\$(97,701)

(7) The components of retirement benefit liability adjustments included in accumulated other comprehensive (loss) income before the deduction of the tax effect as of March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Unrecognized prior service cost	¥ (542)	¥ (737)	\$ (4,810)
Unrecognized actuarial loss	14,790	3,976	131,257
Total	¥14,248	¥3,239	\$126,447

(8) The breakdown of plan assets by major category is as follows:

	2016	2015
Bonds	28.0%	41.4%
Equities	22.3%	30.8%
Cash and deposits	20.8%	3.8%
General accounts at life insurance companies	16.8%	14.3%
Other	12.1%	9.7%
Total	100.0%	100.0%

Note: 16% of plan assets were held in the retirement benefit trust as of March 31, 2016 and 2015.

The expected long-term rate of return on plan assets is determined as a result of consideration of both the portfolio allocation at present and in the future, and long-term rate expected to earn the profit from multiple plan assets at present and in the future.

## Notes to Consolidated Financial Statements

(9) The assumptions used in accounting for the defined benefit plans for the years ended March 31, 2016 and 2015 are as follows:

	2016	2015
Discount rate	Principally 0.3%	Principally 0.6%
Expected long-term rate of return on plan assets	2.5%	2.5%
Rate of compensation increase	1.39 – 4.14%	1.39 – 4.14%

### 3. Information on defined contribution pension plans for the years ended March 31, 2016 and 2015

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Contributions to defined contribution pension plans	¥817	¥882	\$7,251

## 10. Income Taxes

The Company and certain domestic consolidated subsidiaries are subject to a number of different income taxes, which, in the aggregate, indicate statutory tax rates in Japan of approximately 33.0% and 35.5% for the years ended March 31, 2016 and 2015, respectively.

Overseas consolidated subsidiaries are subject to the income taxes of the respective countries in which they operate.

The effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2016 and 2015 differ from the above statutory tax rates for the following reasons:

	2016	2015
Statutory tax rates	33.0%	35.5%
Adjustments:		
Amortization of goodwill	4.1	8.1
Non-deductible expenses	0.5	0.8
Non-taxable dividend income, etc.	(0.9)	(1.4)
Elimination of dividends upon consolidation	0.6	1.1
Adjustment for per capita inhabitant taxes	0.2	0.3
Special deduction for R&D expenses	(6.0)	(7.0)
Valuation allowance	2.9	2.8
Effect of changes in corporation tax rate	0.6	1.3
Other	0.8	(1.0)
Effective tax rates	35.8%	40.5%

(Adjustment of deferred tax assets and liabilities due to change in the corporate tax rate)

The "Act to Partial Revision of the Income Tax Act, etc." (Act No. 15 of 2016) and "Act to Partial Revision of the Local Tax Act, etc." (Act No. 13 of 2016) were enacted during the Japanese Diet session on March 29, 2016.

As a result, the effective statutory tax rates used to measure the Company's deferred tax assets and liabilities as of March 31, 2016 were changed from 32.2% used in the previous fiscal year to 30.8% for the temporary differences expected to be realized or settled in the

years beginning April 1, 2016 and 2017 and to 30.5% for the temporary differences expected to be realized or settled in the years from April 1, 2018.

As a result of this change, net deferred tax assets, after offsetting deferred tax liabilities, decreased by ¥456 million (\$4,047 thousand), income taxes-deferred increased by ¥549 million (\$4,872 thousand), unrealized holding gain on securities increased by ¥288 million (\$2,556 thousand), and retirement benefits liability adjustments decreased by ¥195 million (\$1,731 thousand) as of and for the year ended March 31, 2016.

The significant components of deferred tax assets and liabilities of the Company and its consolidated subsidiaries at March 31, 2016 and 2015 are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Deferred tax assets:			
Reserve for employees' bonuses	¥ 3,165	¥ 3,159	\$ 28,088
Enterprise taxes	1,430	1,465	12,691
Loss on devaluation of inventories	1,455	2,036	12,913
Unrealized gain on inventories	565	1,043	5,014
Reserve for health management allowances for SMON compensation	237	268	2,103
Reserve for health management allowances for HIV compensation	478	548	4,242
Reserve for HCV litigation	1,538	661	13,649
Liability for retirement benefits	4,342	2,190	38,534
Loss on devaluation of investments in securities	482	330	4,278
Excess amortization of long-term prepaid expenses	3,530	2,518	31,328
Prepaid research expenses	6,430	7,896	57,064
Net operating loss carryforward	9,844	13,070	87,362
Excess depreciation	3,045	2,081	27,024
Loss on impairment of fixed assets	1,865	1,515	16,551
Internally generated goodwill	1,033	1,716	9,168
Other	3,137	2,019	27,840
Gross deferred tax assets	42,576	42,515	377,849
Valuation allowance	(12,430)	(13,945)	(110,313)
Total deferred tax assets	30,146	28,570	267,536
Deferred tax liabilities:			
Gain on revaluation of assets	(7,336)	(8,011)	(65,104)
Unrealized holding gain on securities	(8,667)	(12,056)	(76,917)
Deferred capital gain on fixed assets	(2,045)	(2,244)	(18,149)
Unrealized holding gain on land	(5,768)	(6,362)	(51,189)
Other	(523)	(591)	(4,641)
Total deferred tax liabilities	(24,339)	(29,264)	(216,000)
Net deferred tax assets (liabilities)	¥ 5,807	¥ (694)	\$ 51,536

The net deferred tax assets of ¥5,807 million (\$51,536 thousand) and the net deferred tax liabilities of ¥694 million as of March 31, 2016 and 2015, respectively, in the above table are analyzed as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Deferred income taxes – current assets	¥ 7,287	¥ 8,319	\$ 64,670
Deferred income taxes – non-current assets	6,052	763	53,710
Deferred income taxes – non-current liabilities	(7,532)	(9,776)	(66,844)
	¥ 5,807	¥ (694)	\$ 51,536

## 11. Shareholders' Equity

The Corporation Law of Japan (the "Law") provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the capital reserve) and retained earnings (other than the legal reserve) be transferred to the capital reserve and the legal reserve, respectively, until the sum of the capital reserve and the legal reserve equals 25% of the capital stock account. Such distributions can be made at any time by resolution of the shareholders, or by the Board of Directors if certain conditions are met.

Under the Law, upon the issuance and sale of new shares of common stock, the entire amount of the proceeds is required to be accounted for as common stock, although a company may, by resolution of the Board of Directors, account for an amount not exceeding one-half of the proceeds of the sale of new shares as additional paid-in capital.

## Notes to Consolidated Financial Statements

Common stock and treasury stock

Movements in common stock in issue and treasury stock for the years ended March 31, 2016 and 2015 are summarized as follows:

	Thousands of shares			
	Number of shares at beginning of the fiscal year	Increase during the fiscal year	Decrease during the fiscal year	2016 Number of shares at end of the fiscal year
Common stock	561,417	—	—	561,417
Treasury stock	428	0	0	428

The increase in treasury stock was due to purchases of shares of less than one unit.

The decrease in treasury stock was due to sales of shares of less than one unit.

	Thousands of shares			
	Number of shares at beginning of the fiscal year	Increase during the fiscal year	Decrease during the fiscal year	2015 Number of shares at end of the fiscal year
Common stock	561,417	—	—	561,417
Treasury stock	426	1	—	428

The increase in treasury stock was due to purchases of shares of less than one unit.

## 12. Pledged Assets

Assets pledged as collateral for opening a stand-by letter of credit at March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Cash and cash equivalents	¥7	¥8	\$62

## 13. Loss on Devaluation of Inventories

Cost of sales included a loss on devaluation of inventories of ¥574 million (\$5,094 thousand) and ¥1,617 million for the years ended March 31, 2016 and 2015, respectively.

## 14. Research and Development Expenses

Research and development expenses for improvement of existing products and development of new products, including basic research and fundamental development costs, are charged to income as incurred.

Research and development expenses included in selling, general and administrative expenses for the years ended March 31, 2016 and 2015 were ¥75,293 million (\$668,202 thousand) and ¥69,600 million, respectively.

## 15. Gain on Sales or Disposals of Fixed Assets

Gain on sales of fixed assets primarily consists of sales of vacant land after dismantling the former Nihonbashi Building for the year ended March 31, 2015.

## 16. Gain on Sales of Investments in Securities

Gain on sales of investments in securities included gains on sales of shares of CMIC CMO ASHIKAGA Co., Ltd., which had been an unconsolidated subsidiary, of ¥277 million and shares of API Corporation, which had been an affiliate accounted for by the equity method, of ¥283 million for the year ended March 31, 2015.

## 17. Provision of Reserve for HCV Litigation

Provision of reserve for HCV litigation is an additional estimated amount resulting from a re-assessment of eligible individuals receiving relief and relief payments required under the Special Law in the year ended March 31, 2016.

## 18. Loss on Impairment of Fixed Assets

The Company and its consolidated subsidiaries group their assets in association with their business and production process. Idle assets which are not anticipated to be utilized in the future and leased property are classified as individual cash-generating units.

For the year ended March 31, 2016, the book value of the impaired fixed assets was written down to the recoverable amount, and the

amount of the reduction of ¥4,724 million (\$41,924 thousand) was recorded as loss on impairment of fixed assets of ¥4,453 million (\$39,519 thousand) and restructuring loss of ¥271 million (\$2,405 thousand) under other income (expenses). The impairment loss on primary fixed assets is summarized as follows:

Location	Major use	Classification	Millions of yen	Thousands of U.S. dollars
Mitsubishi Tanabe Pharma Kashima Office No.2 Research Building and others (Yodogawa-ku, Osaka)	Idle asset	Buildings and structures	¥ 846	\$ 7,508
Mitsubishi Tanabe Pharma Kashima Office No.2 Manufacturing Building (Yodogawa-ku, Osaka)	Manufacturing facilities	Buildings and structures	184	1,633
Mitsubishi Tanabe Pharma Kazusa Office (Kisarazu-City, Chiba)	Idle asset	Buildings and structures	87	772
Bipha Headquarters and factory (Chitose-City, Hokkaido)	Manufacturing facilities	Land, buildings and structures	3,593	31,887

As the Company decided to dismantle the Kashima Office No.2 Research Building, the book value of those assets was written down to their recoverable value measured at memorandum value. Also, the Company is proceeding with the consolidation and relocation of personnel at this business site so that some facilities are expected to be classified as idle assets. The book value of those facilities was written down to their recoverable value measured at memorandum value.

As a part of its reorganization of bases, the Company is engaged in the relocation of the solid dosage production function in the Kashima Office No.2 Manufacturing Building to other bases, mainly the Onoda Plant, and CMC clinical trial drug manufacturing facilities in other bases to these manufacturing facilities. As a result of the relocation, the book value of the unused assets in these manufacturing facilities was written down to the recoverable value measured at memorandum value.

Due to the Kazusa Office closure at the end of March 2016 as a part of the reorganization of bases, the book value of the office was written down to the recoverable value measured at memorandum value.

The Group has revised the business plan of rHSA, a product which is

under the preparation for the resumption of production, due to a delay in the schedule. Since the Group decided to convert its focus from therapeutic to non-therapeutic uses in the revised plan, a substantial downsizing in the business was expected. Because estimated future cash flows are lower than the current book value of the assets as a result of this downsizing, the book value of the Bipha Headquarters and the factory was written down to the recoverable value. The recoverable value is the net selling amount based on reasonable estimates, including real estate appraisal value.

In addition, loss on impairment of the buildings and structures of the Kashima Office No.2 Manufacturing Building and the Kazusa Office is included in restructuring loss.

For the year ended March 31, 2015, the book value of the impaired fixed assets was written down to the recoverable amount, and the amount of the reduction of ¥10,936 million was recorded as loss on impairment of fixed assets of ¥2,565 million and restructuring expenses of ¥8,371 million under extraordinary losses. The impairment loss on primary fixed assets is summarized as follows:

Location	Major use	Classification	Millions of yen
Mitsubishi Tanabe Pharma Toda Dormitory (Toda-City, Saitama)	Idle asset	Land, buildings and structures	¥ 589
Mitsubishi Tanabe Pharma (Former Benesis) Former Osadano Dormitory/Housing (Fukuchiyama-City, Kyoto)	Idle asset	Land, buildings and structures	265
Mitsubishi Tanabe Pharma Chugoku Branch (Naka-ku, Hiroshima)	Idle asset	Buildings and structures	111
Mitsubishi Tanabe Pharma Hiranomachi No.1 Building (Chuo-ku, Osaka)	Administrative and sales operations	Land, buildings and structures	1,215
Mitsubishi Tanabe Pharma Factory Kashima Factory (Kamisu-City, Ibaraki)	Manufacturing facilities	Machinery, equipment and vehicles	274
Mitsubishi Tanabe Pharma and Mitsubishi Tanabe Pharma Factory Kashima Factory (Kamisu-City, Ibaraki)	Manufacturing facilities	Buildings and structures, machinery, equipment and vehicles	2,161
Mitsubishi Tanabe Pharma Kazusa Office (Kisarazu-City, Chiba)	Research facilities	Land, buildings and structures	4,432
Mitsubishi Tanabe Pharma Former Head Office (Chuo-Ku, Osaka)	Administrative and sales operations	Buildings and structures	200
Mitsubishi Tanabe Pharma Japan	Exclusive rights for sales of ethical drugs	Investment of other assets Other	1,600



## Notes to Consolidated Financial Statements

As the Company decided to sell the Toda Dormitory, the book value of those assets was written down to their recoverable value. The recoverable value is measured at the net selling value which was reasonably measured mainly by appraisal value.

As the Company decided to sell the former Osadano Dormitory/Housing, the book value of those assets was written down to their recoverable value. The recoverable value is measured at the net selling value, calculated by using sales value.

As the Company decided to transfer Chugoku Branch, the book value of these assets was written down to their recoverable value. The recoverable value is measured at the net sales amount, calculated by using estimated sales value.

The Company implemented the consolidation and relocation of the head office functions in this fiscal year ended March 31, 2015. As a result, the Hiranomachi No.1 Building was classified as an idle asset, and the book value of these assets was written down to their recoverable value. The recoverable value is measured at the net selling value based on appraisal value.

As the Company decided to liquidate unprofitable businesses, the book value of the manufacturing facilities of the Kashima Factory was written down to their recoverable value measured at memorandum value.

As the Company decided to sell the Kashima Factory, the book value of the related manufacturing facilities was written down to their recoverable value. The recoverable value is measured at the net selling value, calculated by using on estimated sales value.

As the Company decided to close down the Kazusa Office, it will be classified as an idle asset in the future. As a result, the book value of these assets was written down to their recoverable value. The recoverable value is measured at the net selling value, which was reasonably measured mainly by appraisal value.

As the Company transferred the head office and does not expect to use the former head office in the future, the book value of these assets was written down to their recoverable value measured at memorandum value.

Due to changes in the business environment, the future cash flows arising from exclusive rights for sales of ethical drugs is below its book value. As a result, the book value of the distribution rights was written down to the recoverable value measured at memorandum value.

In addition, loss on impairment of the buildings or manufacturing facilities of the Company's Hiranomachi No.1 Building, the former Head Office and the Kazusa Office, and the Kashima Factory of the Company and Mitsubishi Tanabe Pharma Factory is included in restructuring loss.

## 19. Restructuring Loss

Restructuring losses recognized as expenses for the years ended March 31, 2016 and 2015 are related to the efforts described in "Accelerating Operational and Structural Reforms", one of the strategic challenges in the "Medium-Term Management Plan 11-15 ~ New Value Creation."

The following table presents components of restructuring loss for the year ended March 31, 2016.

### Organization and human resources

#### Implementation of early retirement program

	Millions of yen	Thousands of U.S. dollars
	2016	2016
Special retirement payments incurred as a result of the early-retirement program	¥15,282	\$135,623

### Reorganization of bases

#### Reorganization of manufacturing bases

	Millions of yen	Thousands of U.S. dollars
	2016	2016
Expenses accompanying the transfer of manufacturing operations of the Kashima Office No.2 Manufacturing Building, and consolidation and relocation of CMC clinical trial drug manufacturing facilities:		
Loss on impairment of building and structures	¥ 29	\$ 257
Estimated dismantling expenses	155	1,376

#### Reorganization of research bases

	Millions of yen	Thousands of U.S. dollars
	2016	2016
Expenses accompanying closing the Kazusa Office:		
Loss on impairment of building and structures	¥ 87	\$ 772
Removal expenses	777	6,896

Details of loss on impairment included in restructuring loss are presented in Note 18 "Loss on Impairment of Fixed Assets."

The following table presents components of restructuring loss for the year ended March 31, 2015.

#### Restructuring of businesses

##### Restructuring of unprofitable businesses

	Millions of yen
	2015
Loss on withdrawal from business of subsidiary, Mitsubishi Pharma (Guangzhou) Co., Ltd.:	
Loss on liquidation of subsidiary	¥1,413
Loss on discontinuing part of overseas businesses:	
Loss on impairment of manufacturing facilities	274
Loss on disposal of inventories	690
Others	32

#### Restructuring of facilities

##### Restructuring of manufacturing facilities

	Millions of yen
	2015
Loss on sales of the Kashima Factory:	
Loss on impairment of building and manufacturing facilities	¥2,161
Estimated amount of removal expenses	335
Additional payments resulting from transfer of employees	507
Others	104

##### Consolidation and relocation of the Head Office functions

	Millions of yen
	2015
Expenses resulting from consolidation and relocation of head office functions:	
Loss on impairment of land, building and structures	¥1,415
Removal expenses	843

##### Reorganization of research facilities

	Millions of yen
	2015
Expenses of related to closing Kazusa Office	
Loss on impairment of land, building and structures	¥4,432
Others	88

Details of loss on impairment included in restructuring loss are presented in Note 18 "Loss on Impairment of Fixed Assets."

## 20. Amortization of Goodwill

The Company accelerated the amortization of goodwill and amortized the entire amount in accordance with Paragraph 32 (1) of "Practical Guidance for Consolidated Procedures Related to Equity Accounts in Consolidated Financial Statements" (JICPA Accounting Committee Report No. 7).

## 21. Other Comprehensive (Loss) Income

The following table presents reclassification adjustments and tax effects on components of other comprehensive (loss) income for the years ended March 31, 2016 and 2015:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Unrealized holding (loss) gain on securities:			
Amount arising during the year	¥ 8,478	¥ 8,367	\$ 75,240
Reclassification adjustments	(13,422)	76	(119,116)
Before tax effects	(4,944)	8,443	(43,876)
Tax effects	1,890	(2,260)	16,773
Unrealized holding (loss) gain on securities	(3,054)	6,183	(27,103)
Deferred loss on hedges:			
Amount arising during the year	180	522	1,597
Reclassification adjustments	(331)	(1,129)	(2,937)
Before tax effects	(151)	(607)	(1,340)
Tax effects	50	219	444
Deferred loss on hedges	(101)	(388)	(896)
Translation adjustments:			
Amount arising during the year	(4,954)	3,171	(43,965)
Reclassification adjustments	—	(786)	—
Translation adjustments	(4,954)	2,385	(43,965)
Retirement benefits liability adjustments, net of tax:			
Amount arising during the year	¥(11,934)	¥ 7,549	\$(105,910)
Reclassification adjustments	925	1,632	8,209
Before tax effects	(11,009)	9,181	(97,701)
Tax effects	3,285	(3,329)	29,153
Retirement benefits liability adjustments, net of tax	(7,724)	5,852	(68,548)
Other comprehensive (loss) income of equity-method companies attributable to the Company:			
Amount arising during the year	(30)	38	(267)
Other comprehensive (loss) income	¥(15,863)	¥14,070	\$(140,779)

## 22. Related Party Transactions

Principal transactions between the Company and related parties for the years ended March 31, 2016 and 2015 are summarized as follows:  
[Transactions with Mitsubishi Chemical Holdings Corporation (“MCHC”)]

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Deposits	¥389	¥20,609	\$3,452
Interest income	389	609	3,452

MCHC is the parent company.

The balances due from MCHC at March 31, 2016 and 2015 are as follows:

	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Due from MCHC	¥193,147	¥192,758	\$1,714,120

## 23. Leases

The Company and its consolidated subsidiaries accounted for the finance lease transactions which do not transfer the ownership of the leased property to the Company or its consolidated subsidiaries in the same manner as operating leases that started on or before March 31, 2008. The information of such lease transactions is omitted due to insignificance of these amounts.

Future minimum lease payments subsequent to March 31, 2016 under non-cancelable operating leases are summarized as follows:

Years ending March 31,	Millions of yen	Thousands of U.S. dollars
2017	¥1,197	\$10,623
2018 and thereafter	3,185	28,266
	¥4,382	\$38,889

## 24. Derivative and Hedging Transactions

Derivative financial instruments are utilized by the Company principally in order to manage the risk arising from adverse fluctuation in foreign currency exchange rates. The Company has established a control environment which includes policies and procedures for risk assessment, including an assessment of the effectiveness of hedging, and for the approval, reporting and monitoring of transactions involving derivatives. The Company does not hold or issue derivatives for speculative trading purposes.

The Company is exposed to certain market risk arising from forward foreign exchange contracts. The Company is also exposed to the risk of credit loss in the event of non-performance by any of the counterparties to the forward foreign exchange contracts; however, the Company does not anticipate non-performance by any of these counterparties, all of whom are financial institutions with high credit ratings.

The Company does not carry out an assessment of hedge effectiveness because of a high correlation between the hedging instruments and hedged items.

## Notes to Consolidated Financial Statements

The notional amounts and estimated fair value on the outstanding derivatives positions for which hedge accounting has not been applied at March 31, 2016 and 2015 are as follows:

			Millions of yen		
			2016		
	Notional amounts	Over one year	Estimated fair value		
Forward foreign exchange contracts:					
Selling:					
USD	¥115,689	¥—	¥1,161		
<b>Total</b>	<b>¥115,689</b>	<b>¥—</b>	<b>¥1,161</b>		

			Millions of yen		
			2015		
	Notional amounts	Over one year	Estimated fair value		
Forward foreign exchange contracts:					
Selling:					
USD	¥24,034	¥—	¥(203)		
<b>Total</b>	<b>¥24,034</b>	<b>¥—</b>	<b>¥(203)</b>		

			Thousands of U.S. dollars		
			2016		
	Notional amounts	Over one year	Estimated fair value		
Forward foreign exchange contracts:					
Selling:					
USD	\$1,026,704	\$—	\$10,304		
<b>Total</b>	<b>\$1,026,704</b>	<b>\$—</b>	<b>\$10,304</b>		

The notional amounts and estimated fair value on the outstanding derivatives positions for which hedge accounting has been applied at March 31, 2016 and 2015 are as follows:

			Millions of yen		
			2016		
	Notional amounts	Over one year	Estimated fair value		
Forward foreign exchange contracts:					
Selling:					
USD, accounts receivable–other	¥635	¥—	¥7		
<b>Total</b>	<b>¥635</b>	<b>¥—</b>	<b>¥7</b>		

			Millions of yen		
			2015		
	Notional amounts	Over one year	Estimated fair value		
Forward foreign exchange contracts:					
Buying:					
USD, accounts payable–trade	¥9,721	¥—	¥158		
<b>Total</b>	<b>¥9,721</b>	<b>¥—</b>	<b>¥158</b>		

			Thousands of U.S. dollars		
			2016		
	Notional amounts	Over one year	Estimated fair value		
Forward foreign exchange contracts:					
Selling:					
USD, accounts receivable–other	\$5,635	\$—	\$62		
<b>Total</b>	<b>\$5,635</b>	<b>\$—</b>	<b>\$62</b>		

## 25. Amounts per Share

Amounts per share as of and for the years ended March 31, 2016 and 2015 are as follows:

	Yen		U.S. dollars
	2016	2015	2016
Profit attributable to owners of parents	¥ 100.60	¥ 70.41	\$ 0.89
Cash dividends	46.00	42.00	0.41
Net assets	1,436.63	1,406.41	12.75

Diluted profit attributable to owners of parent per share has not been presented since no potentially dilutive securities have been issued.

Profit attributable to owners of parent per share is computed based on profit attributable to owners of parent available for distribution to shareholders of common stock and the weighted average number of shares of common stock outstanding during each year. The amounts

per share of net assets are computed based on the number of shares of common stock outstanding at the year end.

Cash dividends per share represent the cash dividends proposed by the Board of Directors as applicable to the respective fiscal years together with the interim cash dividends paid.

## 26. Segment Information

The Group is primarily engaged in the research and development, manufacturing, procurement and sales of pharmaceuticals, and "Pharmaceuticals" is therefore the only reportable segment.

In the Pharmaceuticals segment, the Group operates business activities related to ethical drugs and over-the-counter ("OTC") drugs in Japan and overseas.

As the Pharmaceuticals segment is the only reportable segment, the disclosure of segment information, such as calculation method of net sales, profit or loss, assets, liabilities and other items by reportable segment; information regarding amounts of net sales, profit or loss, assets, liabilities and other items by reportable segment; differences

between totals for reportable segments and amounts presented in consolidated financial statements and major details about such differences; information regarding impairment losses on fixed assets by reportable segment; and information regarding amount of amortization of goodwill and unamortized balance by reportable segment, for the years ended March 31, 2016 and 2015 has been omitted.

As sales of products and services to external customers in a single segment account for more than 90% of net sales in the consolidated statements of income, the disclosure of the information by product and service for the years ended March 31, 2016 and 2015 has been omitted.

The following table summarizes the information of the sales by region for the years ended March 31, 2016 and 2015:

Region	Millions of yen		Thousands of U.S. dollars
	2016	2015	2016
Japan	¥314,764	¥337,180	\$2,793,433
Europe	66,962	48,618	594,267
Asia	18,507	17,245	164,244
North America	31,043	11,696	275,497
Others	425	385	3,771
Total	¥431,701	¥415,124	\$3,831,212

As the amounts of property, plant and equipment located in Japan accounts for more than 90% of property, plant and equipment in the consolidated balance sheets, the disclosure of property, plant and equipment by region for the years ended March 31, 2016 and 2015 has been omitted.

The following table summarizes the information by major customers for the years ended March 31, 2016 and 2015:

Customer name	Millions of yen		Thousands of U.S. dollars	Related segment
	2016	2015	2016	
SUZUKEN CO., LTD.	¥64,121	¥69,188	\$569,054	Pharmaceuticals
Toho Pharmaceutical Co., Ltd.	61,809	66,049	548,536	Pharmaceuticals
Alfresa Corporation	46,403	51,016	411,812	Pharmaceuticals
MEDICEO CORPORATION	45,100	48,995	400,248	Pharmaceuticals



## 27. Litigation

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### **Court action for compensation by patients infected with HCV (hepatitis C virus)**

After “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” (“the Special Law” promulgated on January 16, 2008) was put into effect, in accordance with the procedures determined by the Special Law the patients allegedly suffered through HCV (hepatitis C virus) infection following use of a fibrinogen product or a blood coagulant factor IX product sold by the former Green Cross Corporation, one of the predecessors of the Company, filed a lawsuit against the government and established their eligibility for relief. Subsequently, a settlement with the government was reached, and the relief for the patients was provided through the payment of benefits. On September 28, 2008, a “basic agreement”

for the conclusion of the previous court action was signed with the nationwide plaintiff group and legal team.

In regard to the expense of relief payments under the Special Law, the burden of that expense and the method of sharing that burden were the subject of discussions with the Ministry of Health, Labour and Welfare, and those standards were announced by the Ministry of Health, Labour and Welfare on April 10, 2009, and the Company incurs the expenses in accordance with the standards. On January 16, 2013, a partial amendment was made to the Special Law and promulgated, and the period for claimants to file lawsuits was extended.

In order to reach a full resolution of the issue of HCV infection through use of specific fibrinogen products or specific coagulation factor IX products, the Company is committed to continue earnest engagement in the future.

# Independent Auditor's Report

The Board of Directors  
Mitsubishi Tanabe Pharma Corporation

We have audited the accompanying consolidated financial statements of Mitsubishi Tanabe Pharma Corporation and its consolidated subsidiaries, which comprise the consolidated balance sheet as at March 31, 2016, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information, all expressed in Japanese yen.

## Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

## Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

## Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Mitsubishi Tanabe Pharma Corporation and its consolidated subsidiaries as at March 31, 2016, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

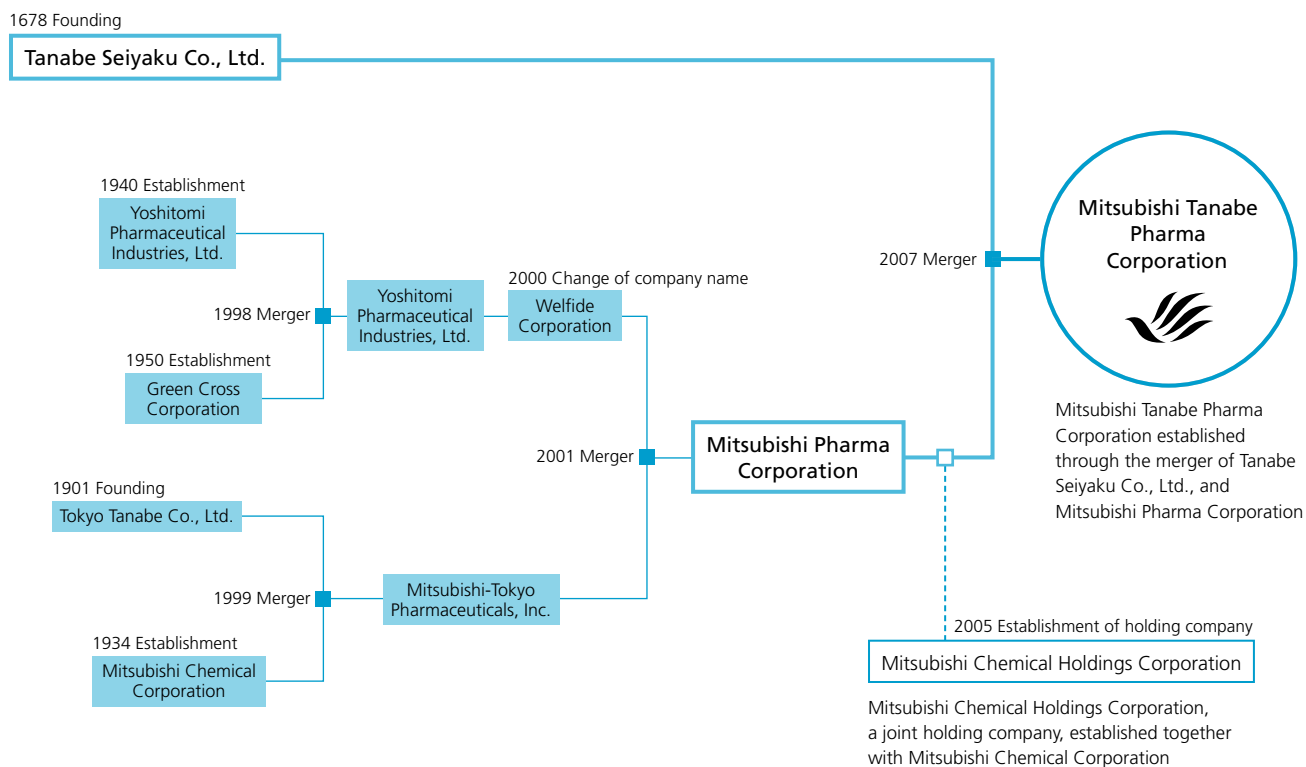
## Convenience Translation

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 1.

*Ernst & Young Shin Nihon LLC*

June 22, 2016  
Osaka, Japan

# History



## Mitsubishi Tanabe Pharma's History since Its Establishment

2007	October	Establishment of Mitsubishi Tanabe Pharma Corporation through the merger of Tanabe Seiyaku and Mitsubishi Pharma Corporation (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 drug 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 Corporation 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
	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
	November	
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
	December	
2016	February	Establishment of MT 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)

# Corporate Data / Investor Information

As of March 31, 2016

## Corporate Data

Company Name	Mitsubishi Tanabe Pharma Corporation
Headquarters	3-2-10, Doshomachi, Chuo-ku, Osaka 541-8505, Japan
Incorporated	December 1933
Date of Merger	October 1, 2007
Number of Employees	8,125 (Consolidated) 4,780 (Parent company only)

### For Further Information

Investor Relations Group  
Corporate Communications Department  
TEL: 81-6-6205-5211  
FAX: 81-6-6205-5105  
URL: <http://www.mt-pharma.co.jp/e/>

## Group Companies

■ Consolidated subsidiary □ Affiliated company accounted for by the equity method

### Japan

	Paid-in Capital	% Voting Control*	Principal Business
Yoshitomiya-kuhin Corporation ■	¥385 million	100.0%	Provision of information about pharmaceuticals
Bipha Corporation ■	¥100 million	100.0%	Manufacture and sale of 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 Seiyaku Hanbai Co., Ltd. ■	¥499 million	100.0%	Sale of generic drugs, etc.
Tanabe R&D Service Co., Ltd. ■	¥44 million	100.0%	Support of R&D regarding pharmaceuticals
Tanabe Total Service Co., Ltd. ■	¥90 million	100.0%	Real estate management, etc.

### Overseas

#### Asia

	Paid-in Capital	% Voting Control*	Principal Business
Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd. ■	USD1,000,000	100.0%	R&D of pharmaceuticals
Tianjin Tanabe Seiyaku Co., Ltd. ■	USD16,230,000	75.4%	Manufacture and sale of pharmaceuticals
Guangdong Tanabe Pharmaceutical Co., Ltd. ■	CNY7,000,000	100.0%	Sale of pharmaceuticals
Taiwan Tanabe Seiyaku Co., Ltd. ■	TWD90,000,000	65.0%	Manufacture and sale of pharmaceuticals
Tai Tien Pharmaceuticals Co., Ltd. ■	TWD20,000,000	65.0%	Sale of pharmaceuticals
P.T. Tanabe Indonesia ■	USD2,500,000	99.6%	Manufacture and sale of pharmaceuticals
MT Pharma Singapore Pte. Ltd. ■	SGD300,000	100.0%	R&D of pharmaceuticals
Mitsubishi Tanabe Pharma Korea Co., Ltd. ■	KRW2,100,000,000	100.0%	Manufacture and sale of pharmaceuticals

#### U.S.

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
MT 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. ■	USD3,000,000	100.0% (100.0%)	R&D of pharmaceuticals
MTPC Holdings Canada Inc. ■	CAD287Mn	100.0%	Investments in Medicigo Group
Medicigo Inc. ■	CAD328Mn	60.0% (56.5%)	R&D and manufacture of vaccines
Medicigo USA Inc. ■	USD99	60.0% (60.0%)	Manufacture of vaccines
Medicigo R&D Inc. ■	CAD500	60.0% (60.0%)	R&D of vaccines

#### Europe

Mitsubishi Pharma Europe Ltd. ■	GBP4,632,000	100.0%	R&D of pharmaceuticals
Mitsubishi Pharma Deutschland GmbH ■	EUR25,000	100.0% (100.0%)	Sale of pharmaceuticals
Synthelabo-Tanabe Chimie S.A. □	EUR1,600,000	50.0%	Manufacture and sale of pharmaceuticals

\* Figures in parentheses show indirect control

Note: Aside from the companies mentioned above, there are two consolidated companies under liquidation.

## 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	17,291

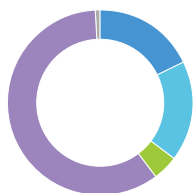
### Major Shareholders

	% Voting Rights
Mitsubishi Chemical Holdings Corporation	56.3
The Master Trust of Japan, Ltd.	4.5
Nippon Life Insurance Company	2.2
Japan Trustee Services Bank, Ltd.	2.0
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	1.3
Japan Trustee Services Bank, Ltd. (Trust Account 9)	1.1
STATE STREET BANK WEST CLIENT-TREATY 505234	1.0
STATE STREET BANK AND TRUST COMPANY 505225	0.8
Employee Stock Ownership Plan	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

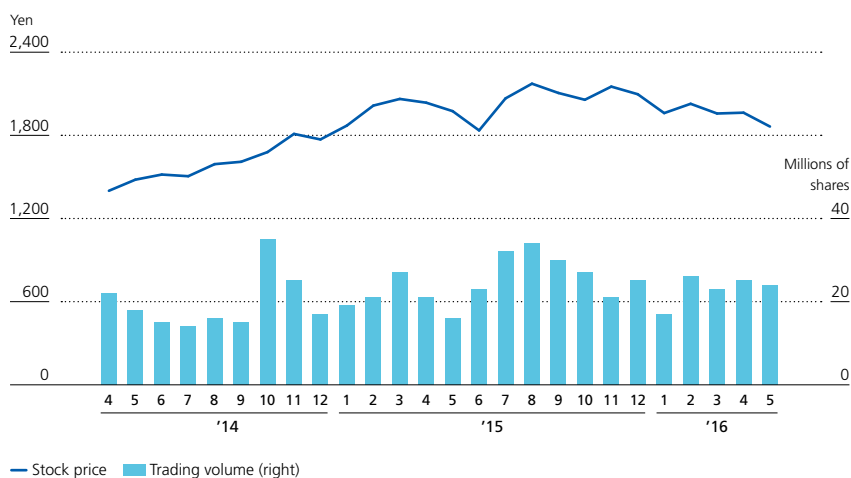
### Distribution of Share Ownership by Type of Shareholder



Japanese financial institutions	18.0%
Foreign institutions	17.4%
Japanese individuals and others*	4.5%
Other Japanese corporations	59.3%
Japanese securities firms	0.8%

\* Individuals and others includes treasury stock (428 thousand shares at March 31, 2016)

### 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)