

Open Up the *Future*



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 2019

Mitsubishi Tanabe Pharma has prepared this integrated report to inform various stakeholders including shareholders and investors about the Group's initiatives targeting sustained growth. In editing this report, we referenced the framework released by the International Integrated Reporting Council (IIRC)¹. The Value Creation Story introduces our long-term value creation capability in an easy-to-understand format, and the Business and Financial Strategy, Non-Financial Information, and Management's Discussion and Analysis sections explain in detail the initiatives and data for each of our businesses that support value creation.

1. 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 Website (within the Corporate Website)

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



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

Inclusion in SRI indexes² (as of June 2019)

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

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



Other communications tools

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

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.



<https://www.mt-pharma.co.jp/e/>

Corporate Profile

The corporate profile is a digest version of Mitsubishi Tanabe Pharma Corporate Report 2019.



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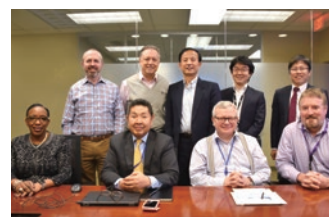
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Application of IFRS

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

Forward-Looking Statements

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

Mitsubishi Tanabe Pharma's Value Creation Model

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

Mitsubishi Tanabe Pharma was established in October 2007. To contribute to the health of people around the world, we will continue our effort of opening up the future of medical care.

The Basis of Value Creation

- Diversified human resources
- Compliance
- Corporate governance

Consideration



Contributing to the healthier lives of people around the world

Strengths

→ P.05

- Drug discovery capabilities/ Drug fostering and evolution capabilities
- Trust of patients and medical professionals
- DNA to take on challenges and change
- Core value chain as a traditional pharmaceutical company

Materiality → P.07

- Pharmaceuticals and healthcare services with differentiated value
- Reliable products and sustainable supply
- Appropriate use of products
- Ethics, fairness and sincerity in business practices
- Stakeholder engagement
- Employee health, diversity and inclusion
- Social contribution activities for health

Business/ Strategy → P.09,25

Strategy

Medium-Term Management Plan 16–20

“Open Up

- Strategic priority 1: Maximizing Pipeline Value
- Strategic priority 2: Strengthening IKUYAKU and Marketing

Business processes



Risk

- Increasing incidence rate for adult-onset diseases and rising mortality
- Increasing risk of failing health insurance systems
- Growing forays into the medical and healthcare fields from other industries

the Future''

Strategic priority 3:
Accelerating U.S. Business Development

Strategic priority 4:
Reforming Operational Productivity

Four priority disease areas

- Immuno-inflammation
- Diabetes and kidney
- Central nervous system
- Vaccines

Opportunities

- Expand market for health information services (shift from treatment to prevention)
- Realize unmet medical needs
- Progress in digitizing medical and health information using ICT

Approach to Value Creation → P.10

Development pipeline
to be the first to deliver original value

Modality and digital changes
that contribute to new medical needs

Providing Value to Society → P.11

Extension of healthy life expectancy

Raise the QOL of patients and their families

Contribute to QOL, which is to say, raise the quality of their life and living

Raise society's productivity

Contribute to increasing social productivity by providing superior pharmaceuticals and medical care services

Prevent disease

Contribute to maintaining people's health through vaccines that prevent infectious diseases and medical care to prevent the deterioration of patients' conditions

Main Stakeholders

- Patients and their families
- Healthcare professionals
- Shareholders and investors
- Employees
- Business partners
- Local communities



Strengths

Mitsubishi Tanabe Pharma's strengths backed by its achievements

The MTPC Group's strong drug discovery and drug fostering and evolution capabilities have resulted in the creation of many innovative pharmaceuticals. Underpinning this are the relationships of trust with its stakeholders. We will continue to provide society with new value based on our DNA to challenge and change backed by our more than 300 years of history.

1. Drug discovery capabilities / Drug fostering and evolution capabilities

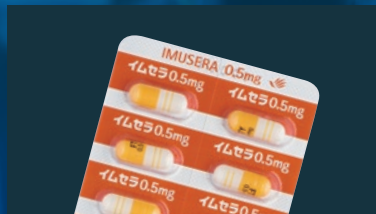
2. Trust of patients and medical professionals

3. DNA to take on challenges and change

4. Core value chain as a traditional pharmaceutical company

Imusera (Gilenya)

This drug has contributed to the treatment of MS in more than 80 countries and regions as the world's first oral MS treatment agent that is an alternative to injections.



Tenelia, Canaglu (Invokana), Canalia

We have contributed to diabetes treatment with the addition of two medicines created in-house with completely different mechanisms of action and the first combination tablets in Japan.



Radicava (Radicut)

Radicava is the first new drug in nearly 20 years in the U.S. that limits the progress of ALS and helps improve patients' QOL.



Remicade

Remicade is the first antibody in Japan with 13 indications, including rheumatoid arthritis, that contributes to the treatment of a wide range of diseases.



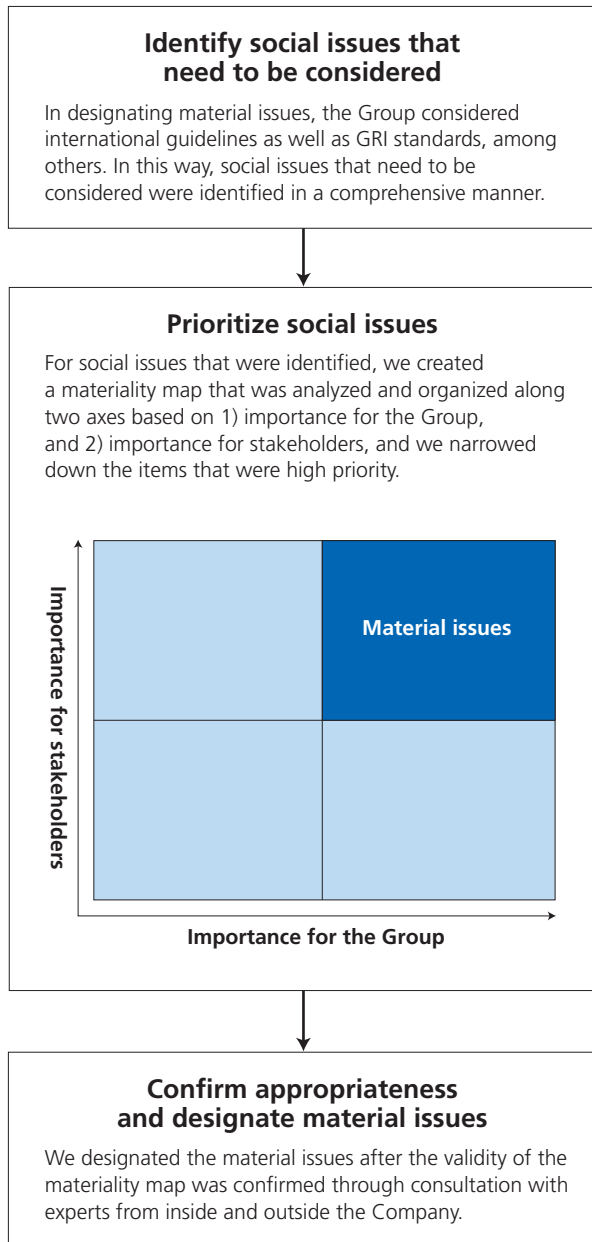


S Strength

Materiality

In accordance with the corporate philosophy of “contributing to the healthier lives of people around the world through the creation of pharmaceuticals,” the Mitsubishi Tanabe Pharma Group believes that its ability to survive and grow depends on the provision of social value and a contribution to the achievement of a sustainable society through the Group’s business activities. To clarify that idea and reinforce our initiatives, we have designated material issues that we need to address as materiality and set monitoring indicators for each of them.

Process of designating material issues



Material issues / Major initiatives / Monitoring indicators

Material issues	Major initiatives
1) Pharmaceuticals and healthcare services with differentiated value	Creating new drugs, adding indications, changing dosage and administration, adding formulations, and improving products.
2) Reliable products and sustainable supply	Building systems for a sustainable supply of reliable pharmaceuticals.
3) Appropriate use of products	Establishing a drug consultation center, collecting safety information, and providing information related to the appropriate use of products.
4) Ethics, fairness and sincerity in business practices	Working to cultivate an awareness of compliance issues, establishing and observing a variety of policies, and establishing hotlines related to compliance and harassment.
5) Stakeholder engagement	Implementing timely, appropriate information disclosure, implementing dialogue with stakeholders including investors and employees.
6) Employee health, diversity and inclusion	Taking steps to establish a work environment that enables all employees to participate actively, including promotion of health management; maternity leave, childcare leave, and nursing-care leave; and initiatives for LGBT employees.
7) Social contribution activities for health	Providing support for patient organizations and research, providing information related to diseases, the provision of vaccines in developing countries, and the GHIT Fund.

WEB

Please refer to URL below for information about KAITEKI.
https://www.mitsubishichem-hd.co.jp/english/kaiteki_management/kaiteki/



	Monitoring indicators	Fiscal 2018 results (scope of calculation)	Related SDGs	Related KAITEKI MOS indicators ¹
	<ul style="list-style-type: none"> Number of approvals (last 5 years) Number of product improvements (last 5 years) Awards received for drug discovery (total since 2007 merger) Number of vaccines shipped Number of patients using orphan drugs² provided by MTPC 	23 (Global) 13 (Global) 18 (Global) 17 million (Japan) 100,000 (Global)	 	H-1 Contribute to medical treatment H-2 Contribute to the prevention and early detection of diseases
	<ul style="list-style-type: none"> The rate of complaints attributed to manufacturing process at group manufacturing plants Satisfaction rating of responses to customer complaints 	1ppm ³ (Global) 92.4% (Japan)	 	C-1 Endeavor to earn greater recognition of corporate trust from society
	<ul style="list-style-type: none"> Number of external presentations on clinical research (papers / academic conferences, etc.) Instances of safety information collected by MRs 	56 (Global) 7,419 (Japan)	 	C-1 Endeavor to earn greater recognition of corporate trust from society
	<ul style="list-style-type: none"> Compliance training participation rate Employee compliance awareness (Perfect score: 5 points) 	97.7% (Japan) 4.34 points (Japan)	 	C-1 Endeavor to earn greater recognition of corporate trust from society
	<ul style="list-style-type: none"> Number of briefings and interviews of investors Employee understanding of management (Perfect score: 5 points) Number of next-generation educational support activities (visiting lectures, company visits, etc.) 	198 (Global) 3.68 points (Japan) 10 (Japan)		C-2 Promote communication and work in concert with stakeholders
	<ul style="list-style-type: none"> Total working hours (per employee, per month) Usage rate of paid vacation days Smoking rate Employee awareness of diversity (Perfect score: 5 points) Percentage of women in managerial positions Number of employee nationalities 	153.9 hours (Japan) 68% (Japan) 19.8% (Japan) 3.72 points (Japan) 20.2% (Global) 29 (Global)	  	C-2 Promote communication and work in concert with stakeholders
	<ul style="list-style-type: none"> Number of visitors to health support websites Rate of employee participation in social contribution activities Number of organizations supported by Tenohira Partnership Program (total since start of grant in FY2013) Number of supports provided by health contributing programs in developing countries 	7.29 million (Global) 42.3% (Japan) 91 (Japan) 12,236 meals (Japan) vaccine 14,500 doses (Japan)	  	C-2 Promote communication and work in concert with stakeholders

1. MOS indicator: Management of Sustainability (MOS) A management method unique to Mitsubishi Chemical Holdings

2. Orphan drug: Medicines for diseases that are said to be intractable disease for which there are few patients and for which no cure has been established

3. 1ppm=0.0001%

Business/Strategy

Overview of Medium-Term Management Plan 16–20

Open Up the Future

The operating environment in the pharmaceutical industry is undergoing dramatic change. In this setting, we must steer our own course and implement reforms to become a “company that works with a sense of speed and is the first to deliver differentiated value.”

Four strategic priorities to Open Up the Future

Strategic priority	1. Maximizing Pipeline Value Creating differentiated value as rapidly as possible	Implementing R&D process reforms	+	Expanding medical and drug discovery technologies
Strategic priority	2. Strengthening IKUYAKU and Marketing Delivering differentiated value to patients	Maximizing product value	+	Strengthening sales promotions
Strategic priority	3. Accelerating U.S. Business Development Build foundation for sustained growth	Establishing operational foundation	+	Building product lineup
Strategic priority	4. Reforming Operational Productivity Realizing a corporate culture with a sense of speed and profit structure	Cost reductions	+	Workforce utilization

Three growth drivers

	Features/Appeal	Goal/Strategy
MT-1186 Radicava oral suspension	<ul style="list-style-type: none"> Development of suspension agent that is easy for ALS patients to take Eliminates extended treatment time resulting from intravenous infusion administration Eliminates limits on number of administration sites 	Development plan under discussion with U.S. FDA with expected launch in fiscal 2021. Along with existing IV infusion preparations, our aim is for sales of ¥70–100 billion at peak.
MT-2271 Seasonal influenza Plant-based VLP [*] vaccine	<ul style="list-style-type: none"> Shorter time for manufacture Matches circulating strains (no egg adaptation) 	Goal is fiscal 2021 launch. Anticipating market growth based on increasing demand for non-egg-based vaccines, with peak sales target of ¥40–60 billion.
ND0612	<ul style="list-style-type: none"> Continuous subcutaneous injection stabilizes levodopa concentration in blood and improves time of onset of motor complications in Parkinson's disease patients 	Aiming for fiscal 2022 launch. The product combines device and pharmaceutical with high barriers to entry for other companies, and we expect market value to be maintained. Aiming for sales of ¥50–80 billion at peak.

* Acronym for “virus-like particle.” It is expected that a safe vaccine that is theoretically free of infection can be produced by leveraging the properties of VLP.

Approach to Value Creation

Main development pipeline

MT-1303 (amiselimod)

Concluded licensing agreement (April 2019)	<ul style="list-style-type: none"> ● MTPC grants Bausch Health Companies exclusive rights to develop and commercialize MT-1303 worldwide, except for Japan and certain other countries in Asia, in all fields, excluding neurology, rheumatology and certain rare dermatology diseases. ● Salix Pharmaceuticals Bausch Health Companies a wholly owned subsidiary of Bausch Health Companies plans to begin global development of MT-1303 with the added indication of ulcerative colitis.
Future MTPC Initiatives	<ul style="list-style-type: none"> ● MTPC will file applications for approval and sales in its territories using clinical data provided by Salix Pharmaceuticals. ● MTPC will conduct global in-house development in disease areas such as neurology and rheumatology.

Items targeted for late-stage development

Item	Target disease	Unmet medical needs ¹	Planned for fiscal 2019
MT-8554	Vasomotor symptoms	Safety issues have been reported with hormone replacement therapy and an effective and safe agent is desired.	Phase 2 study completed Under consultation with FDA for Phase 3 study
MT-3995	Non-alcoholic steatohepatitis (NASH)	A multifaceted disease that may eventually lead to cirrhosis and liver cancer, but no therapeutic agents exist.	PoC ² study results to be obtained in Q2 FY2019
MT-7117 ³	Erythropoietic protoporphyria	Neither standard treatment nor oral drug candidate has been developed in US. The only prevention is to avoid exposure to sunlight.	PoC study results to be obtained in Q3 FY 2019

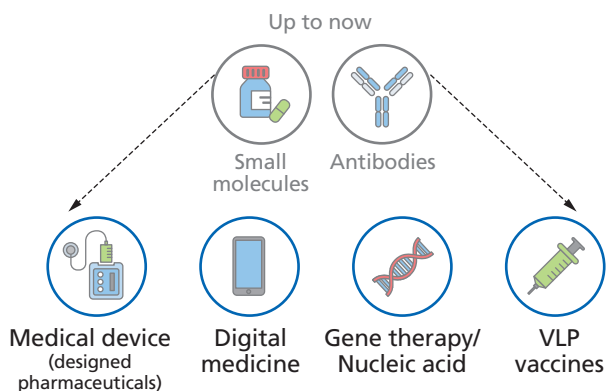
1. Medical needs for which there are no effective treatments or drugs
2. Acronym for Proof of Concept. Confirmation of the efficacy and safety of new drug candidate substances in humans at the R&D stage
3. Fast track designated by the FDA

Modality and digital changes

We will search for drug discovery targets by analyzing medical needs based on the pathway to treatment (patient journey), from diagnosis of disease to treatment period and on to prognosis. To deliver new pharmaceuticals and medical services with differentiated value as fast as possible, we will acquire new modalities in collaboration with partners and streamline clinical trial design by using AI.

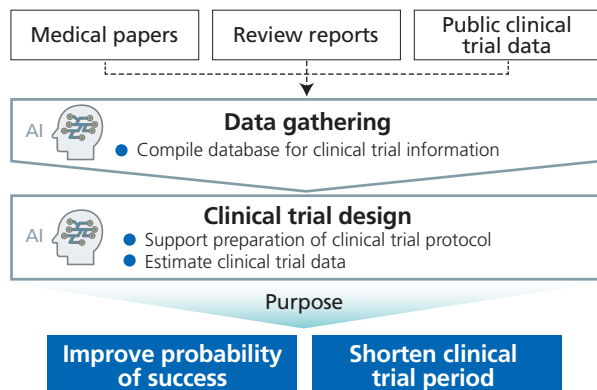
Using modalities

In addition to conventional small molecules and antibodies, we also focus on a wide range of modalities. New modalities rapidly increase satisfaction with partnering.



Using AI

We are streamlining clinical development by combining AI that supports information/data collection with AI that supports clinical trial design.



Providing Value to Society



Val

Achieving a healthy and sustainable society through medical care

In Japan and other developed countries, social security spending has increased dramatically due to the rapid aging of the population and declining birthrates, so a balance between reducing medical costs and providing high-quality medical care is needed. The key to solving this issue is to extend the healthy life expectancy of people, in other words, extend the period that people can live without their daily lives being restricted by health problems.

The Group will not only improve the QOL of patients and their families by providing pharmaceuticals and medical services that meet unmet medical needs, it will also contribute to raising society's productivity by increasing the number of people who can work in good health.

Furthermore, the Group will help to prevent disease by providing vaccines that prevent infectious diseases and medical care that prevents the deterioration of the patient's condition.

We seek to achieve a sustainable society by extending the healthy life expectancy of people through the dissemination of these values.

⇒ Please see "Message from the President" on page 16 for details.

Background/Issues

Aging society

Control social security costs

Unmet medical needs

Provide value to society

Extend healthy life expectancy

Raise the QOL of patients and their families

Raise society's productivity

Prevent disease

Achieve a healthy and sustainable society

Main contribution examples

Imusera (Gilenya)

The world's first oral treatment agent for multiple sclerosis that reduces the mental and physical burden of injections. It also contributes to the improvement of patients' QOL.

Radicava (Radicut)

A treatment agent for ALS, a rare disease. It has been approved and launched as a new drug for the first time in 20 years in the U.S. and contributes to the treatment of patients.

Remicade

As the first antibody in Japan, it controls the progress of joint destruction and pain in patients caused by rheumatism, and supports their lives.

MT-2271 (Drug candidate)

VLP vaccine for seasonal influenza. Its manufacturing time can be reduced compared with conventional egg-based vaccines.

ND0612 (Drug candidate)

It was designed to reduce the burden of everyday life during treatment by combining a medical device with the treatment of Parkinson's disease.

we

Financial and Non-Financial Highlights

Mitsubishi Tanabe Pharma Corporation and consolidated subsidiaries

	(Billions of yen)			(% Change)
	FY 2016	FY 2017 ¹	FY 2018	FY 2017/2018
Revenue	423.9	433.8	424.7	-2.1
Core operating profit	94.5	78.5	55.8	-28.9
Operating profit	94.0	77.2	50.3	-34.9
Profit attributable to owners of the Company	71.2	57.9	37.3	-35.5
R&D expenses	64.7	79.0	86.5	+9.4
Capital expenditures ²	14.4	6.0	8.5	+41.7
Total assets	984.5	1,048.4	1,056.2	+0.7
Total equity	871.4	894.8	910.3	+1.7
Net cash provided by operating activities	59.7	66.9	41.4	-
Net cash used in investing activities	-10.5	-19.1	-31.2	-
Net cash used in financing activities	-24.4	-32.5	-25.8	-

	(%)		
Financial indicators			
Overseas revenue ratio	24.4	26.0	27.6
Operating margin	22.2	17.8	11.8
R&D expenses ratio	15.3	18.2	20.4
Ratio of equity attributable to owners of the Company to total assets	87.4	84.2	85.0
ROE	8.5	6.6	4.2
Dividend payout ratio	40.9	63.9	84.0

	(Yen)			(%)
Per share amounts				
Profit attributable to owners of the Company	127.03	103.35	66.64	-35.5
Cash dividends	52.00	66.00 ³	56.00	-

	(%)			
Cost of sales				
Number of employees	7,280	7,187	7,228	+0.6
Number of clinical trials started ⁴	4	6	3	-
CO ₂ emissions ⁵ (Thousands of tons-CO ₂)	102	96	91	-5.9
Water Withdrawal (Thousand m ³)	7,980	5,375	4,913	-8.6
Waste Generation (Domestic) (t)	5,936	12,230	5,768	-52.8
Final waste disposal rate (Domestic) (%)	0.33	0.37	0.59	-

1. MTPC has finalized the purchase price allocation in connection with the acquisition of NeuroDerm Ltd. during the first six months of the fiscal year ending March 31, 2019. Hence, a retroactive adjustment of the comparative amount for previous fiscal year listed in Condensed Consolidated Statements of Financial Position was made.

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

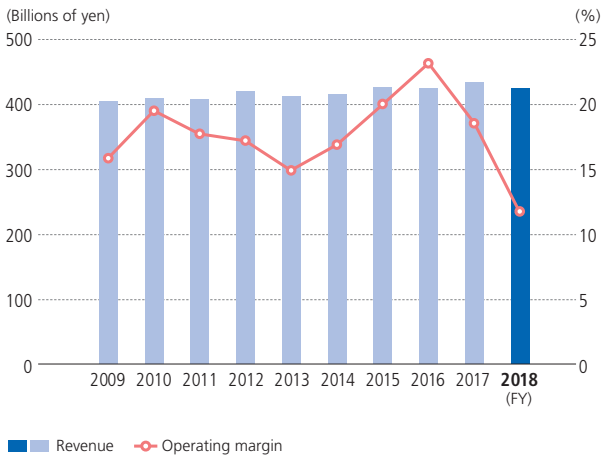
3. In commemoration of the 10th anniversary of its founding, the Company paid a commemorative dividend of ¥10 per share in fiscal 2017.

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

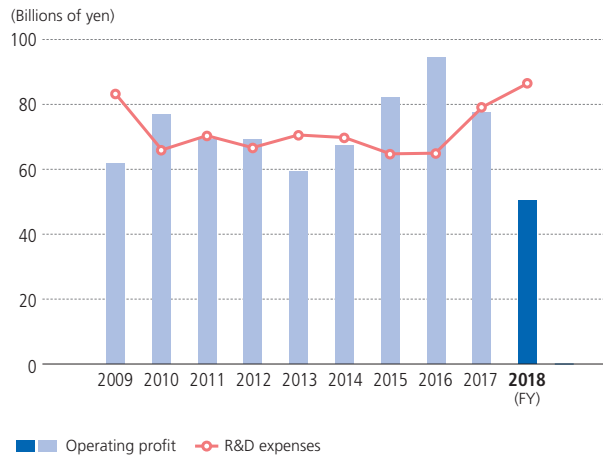
5. Domestic and overseas production and research bases, and offices (the amount of fuel used in sales vehicles is not included in the total).

For further information about financial data, please refer to "10-Year Financial Summary." [↔ Page 61](#)

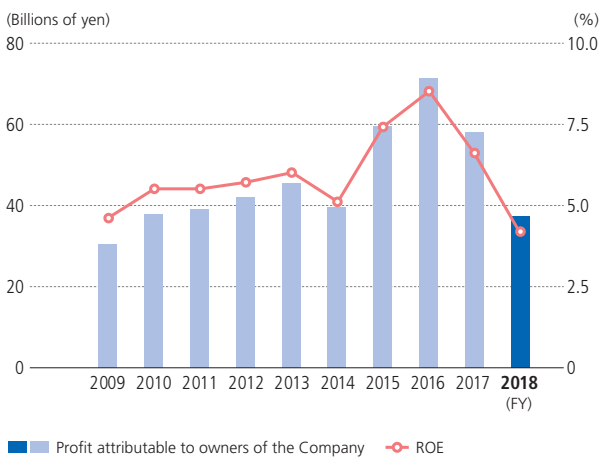
Revenue / Operating margin



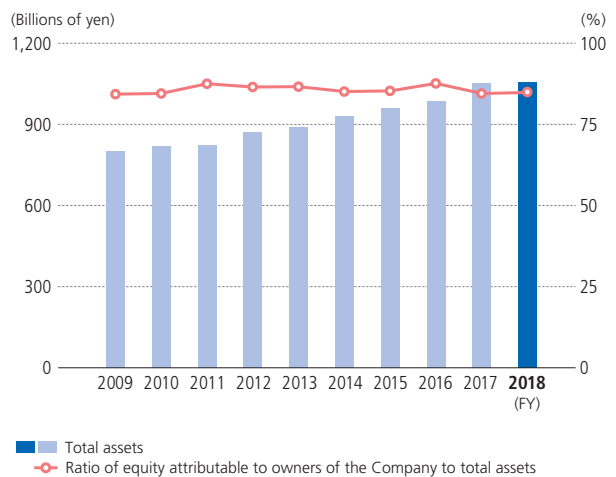
Operating profit / R&D expenses



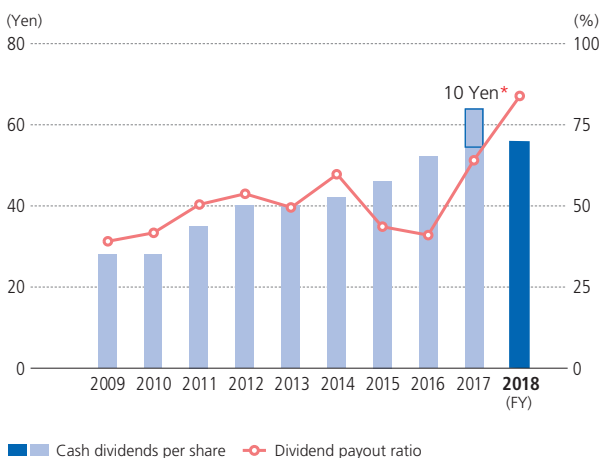
Profit attributable to owners of the Company / ROE



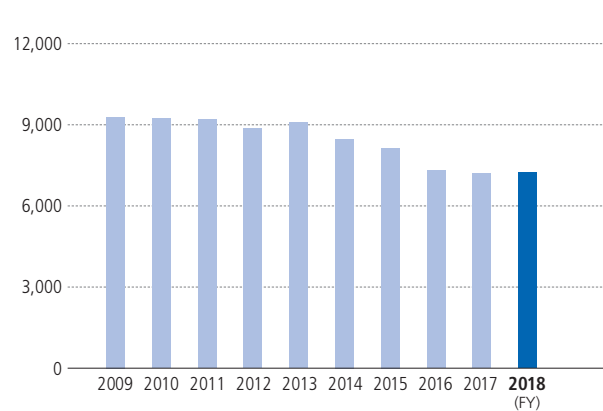
Total assets / Ratio of equity attributable to owners of the Company to total assets



Cash dividends per share / Dividend payout ratio



Number of employees



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

Business and Financial Strategy

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Message from the President



Masayuki Mitsuka
President & Representative Director

Continuing our transformation to realize long-term business growth and contribute to extending healthy life expectancy

President's Message Topics

- 1** Long-term vision for our management direction
- 2** Strengths, risks, and opportunities
- 3** Addressing ESG challenges
- 4** Short-term business conditions and outlook

Message from the President



Masayuki Mitsuka
President & Representative Director

1

Long-term vision for our management direction

Question:

What value does the Company provide to society?

Answer:

Mitsubishi Tanabe Pharma benefits society by providing treatments and preventive medicines that contribute to extending healthy life expectancy.

The rapidly aging demographics of Japan and other developed nations is leading to a crisis point for the sustainability of social security systems. I believe that this makes it incumbent for pharmaceutical companies like ours to step up and contribute to society by creating pharmaceutical products and medical services that provide higher medical value while lowering medical costs.

The Mitsubishi Tanabe Pharma Group has always considered it to be important not just for people to live long lives, but to live long and healthy lives of comfort and joy. We believe pharmaceutical companies contribute to extending healthy life expectancy in three ways. The first is to help raise the quality of life by helping treat illnesses so patients can lead productive lives. Another is to contribute to the productivity of society by increasing the number of people working with their full energy. And the final way is to stop illness before it strikes or, in a word, provide “prevention.” I believe that the products and services we offer contribute in all three of these ways and truly help people live long and healthy lives.

Remicade is an example of one of our products that helps raise the quality of life of patients and lifts the productivity of society. Remicade is the world’s first monoclonal antibody preparation against TNF-alpha, while it has also exhibited positive results for various indications. Rheumatoid arthritis is becoming increasingly common as populations age, and in Japan some 700,000–800,000 people are suffering from the inflammatory disorder. The symptoms include intense joint pain and ultimately damaged joints to the degree that regular daily activities become difficult and painful. Although there is currently no cure for rheumatoid arthritis, Remicade is able to provide relief for many patients. A doctor once told me about its effects: “Remicade enabled an elderly farmer to be able to take care of her grandchild so her son and his wife could work the fields. It helped their whole family situation.” So medicine

we developed not only relieved one person’s pain, it was also a catalyst for others to become more active and participate in the labor force. On a larger scale, I could see that medicine can have a big impact on local communities and could even bring smiles to people’s faces.

Another area where we are particularly active is developing preventive medicines, particularly vaccines. The MTPC is one of just a handful of Japanese entities that is working in all aspects from R&D through to marketing to develop vaccines with the Research Foundation for Microbial Diseases of Osaka University. We are also developing drugs for other forms of preventive treatments. Recently, clinical trials overseas found that the canagliflozin treatment (marketed as Canaglu in Japan and Invokana in the U.S.) for type 2 diabetes helps inhibit the lifestyle disease from progressing to diabetic nephropathy (diabetic kidney disease). Canagliflozin treatment therefore shows promise for blocking diabetes from progressing into nephropathy and inhibiting the development of further complications.

Living a healthy life requires more than taking care of the body. It also means taking care of the mental aspects, such as maintaining positive relations with family members and the local community. A person who is living a healthy life is active, has a positive outlook, and enjoys doing their work. Increasing the number of people living healthy lives contributes to maintaining and raising the productivity of society as a whole.

Prevention is also essential to reducing the number of people who come down with illness. In that sense, I believe our business helps individual patients but it can also contribute to resolving wider social issues.

Medicine is an accumulation of knowledge. As a business, it’s not the power of capital but the quality of a pharmaceuticals company’s patents that makes it competitive with large companies overseas. Capital might not determine success in the pharmaceuticals industry, nor does R&D or manufacturing capability. The key to success is the capabilities of a company’s people and the expertise they bring to the production site. That is why Japan is one of only a handful of countries in the world that can produce innovative medicines.

Japan’s pharmaceutical industry is going through a challenging period, and I believe we have a responsibility to transform our company so future generations can fulfill our important mission.

Message from the President

2

Strengths, risks, and opportunities

Question:

What are the company strengths that will drive its long-term growth?

Answer:

One strength is our historically proven ability to transform ourselves.

Our predecessor, Tanabe Seiyaku, was established over 300 years ago, and I believe the key to our longevity has been the ability to undergo not just one but several major transformations.

Tanabe Seiyaku originally specialized in natural remedies like Chinese herbal *kanpo* medicine but in the 1870s began offering new western medicines imported from Germany and in 1925 started mass-producing and marketing a product (salicylic acid) formulated from organic compounds. In short, the Company transformed from wholesaler of herbal medicines to a modern company offering manufactured products.

In 1974, the Company achieved its first global product through out-licensing of the hypertension treatment diltiazem (product name: Herbesser), which transformed the Company again, this time from a domestic business to a global operation. Our latest major transformation came when Tanabe Seiyaku merged with Mitsubishi Pharma Corporation in 2007. The history of our evolution makes me believe that the Group is ready for another major transformation.



I believe we need a transformation now because we are entering a whole new era with unprecedented challenges that will require the entire pharmaceutical industry in Japan to change. The government's policy to promote generic drugs has made it very difficult for pharmaceutical makers to increase profits on drugs with expired patents. On top of this economic reason, scientific advances like the advent of extremely low-cost analytic technologies, such as for the previously costly genome sequencing, and the rapid advances in digital technology, including in IoT and AI, are also compelling an industry-wide transformation.

In these conditions, whether or not we can realize our next transformation will influence the future course of the Company. In fact, we strongly feel that failing to transform the Company now will lead us to a crisis point not 30 years from now, but in just 10 years.

Transformation requires innovation. I am focusing on stimulating innovation by combining medical and digital technologies to create new hybrid medical devices. In areas where chemical expertise alone is not enough to differentiate pharmaceutical products, I believe there will be increasing opportunities to also use physic and engineering technologies, such as our devices and digital technology, to create solutions.

Consolidating our R&D bases and moving into the Shonan Health Innovation Park are two steps we have taken to stimulate innovation. The main objective of these moves is to be in contact with and integrate the latest developments arising from the explosive fusion of the computer and life sciences. We will proactively enter the open innovation space, seek promising partnerships, and form collaborations to create innovation for the medium- and long-term horizon. The pursuit of innovation will also require an internal transformation in our researchers. By expanding their sphere of contact outside traditional boundaries, our presence at the new facility will give them opportunities to broaden their perspectives.

Answer:

Another important strength is our corporate culture emphasizing trust and a desire for progress.

The core value chain for fundamental drug discovery that the Group has developed in its traditional business as a pharmaceutical company is another strength. Our drug discovery capabilities have garnered numerous awards from third-party institutions and I often receive comments that our manufacturing expertise and sales capabilities are straightforward and solid.

Upon reflection, the compliance problems we had right

after the merger are probably the reason why we are now so strong in these areas. We were adamantly determined to regain the trust that society had placed in us. Our employees should be very gratified with the results of their efforts to galvanize the whole Company to reestablish that trust. You could say that the extreme importance that we as a company place on maintaining society's trust is another of our strengths.

Another area where I think our Group stands out is the many successes we have achieved by tenaciously seeking to discover something new. For example, Remicade, which I mentioned earlier, was the first therapeutic antibody developed in Japan. We challenged ourselves to do the unprecedented: to develop an antibody drug. We didn't stop after we succeeded and marketed it. We continued our drug fostering and evolution, accumulating a growing volume of safety data and gradually adding to the indications, and it has grown into a core product with currently 13 indications.

We have also led the industry in developing drugs for incurable and rare diseases, including the Imusera (overseas: Gilenya) treatment agents for multiple sclerosis and the Radicava (in the U.S.: Radicut) treatment agent for amyotrophic lateral sclerosis (ALS). This desire to do something nobody else has done before and then to carefully see it through to the final result is in our Group's DNA.

Question:

What particularly promising opportunities does the Company see ahead?

Answer:

We believe the combination of the life sciences and digital technologies will bring major business opportunities.

As I mentioned earlier, the sharp drop in medical research costs, such as for genome sequencing, and the advances in IoT, AI, and other technologies are accelerating the integration of the life sciences and digital technology.

This fusion is behind remarkable advances in cancer treatments, and the Group wants to use it to advance treatments of immuno-inflammation. As with cancer, the effectiveness of the treatment agents changes depending on each patient's individual genetics. We believe these precision medicines whose effectiveness relies on genetic response offer a huge business opportunity. The Digital Transformation Department has been given the mission to revamp our overall business flow and also to identify and develop new business opportunities in the precision medicine field.

Question:

What major risks do you see?

Answer:

Patent expirations on new drugs present risk, but we are countering by expanding our long-tail businesses.

The new drug business carries the risk of patent cliffs, a plummet in revenue when their patents expire. We are mitigating this risk by increasing the portfolio ratio of long-tail businesses that do not rely on patents and have the potential to generate continuous revenue.

A business combining drug and a device can be a long-tail business. Insulin delivery devices are a classic example. Even after a drug patent expires, companies that market these are largely protected from competition by the barrier to developing a device, plus they generate repeat business from the need to renew the devices. Vaccines that do not have a generic alternative are another type of long-tail business. We plan to increase our weighting of drugs with devices, vaccines, and other long-tail businesses to establish a more stable revenue base.



Addressing ESG challenges

Question:

What is the Company's approach to ESG?

Answer:

We have specified seven material issues to address through our businesses.

The Group recognizes that fortifying its ESG activities is essential to its long-term growth. In fiscal 2018, we identified specific material issues (important social issues) based on the Sustainable Development Goals (SDGs) of the United Nations and the international guidelines of the Global Reporting Initiative (GRI) that we will focus on addressing with our businesses. In fiscal 2019, we instituted monitoring indicators that will enable management and outside entities to visually track the progress of our ESG initiatives.

Of the seven material issues, the one that we are particularly emphasizing as a pharmaceutical manufacturer is "pharmaceuticals and healthcare services with differentiated value." To become a company that can provide original value at all stages from disease

Message from the President

prevention to diagnosis, treatment, and post-treatment recovery, we plan to actively develop the pharmaceutical products in our core businesses while also offering devices and medical services as we pursue various channels to contribute to extending healthy life expectancy for people around the world.

We are also placing special emphasis on “employee health, diversity and inclusion.” Maintaining an atmosphere of diversity and inclusion that encourages a diverse workforce to fully apply their abilities and expertise is essential to realizing innovation. Our internal resources, including our workforce and expertise, will not be enough to create new value. We are bringing together people with various skills and ways of thinking for maximum open innovation. Our hiring activities will also be geared to stimulating innovation by actively looking for people with various backgrounds and knowledge, mainly in the electronic devices and information and communications technology fields. Management also recognizes the qualitative importance of cultivating talented personnel for generational changeover and the succession of skilled expertise. We launched MT-VIVID, a management training program designed to begin early development of the next-generation of company leaders, in fiscal 2016 and are expanding our global evaluation process and training programs.

In addition to our social activities, we are also advancing environmental measures. Although the pharmaceutical manufacturing business generally has relatively less overall environmental impact, we are steadily reducing the energy consumption and CO₂ emissions of the Group’s operations. Global warming is raising concern of an associated increase in infectious diseases, such as mosquito-borne illnesses. If infectious diseases begin to spread, the need for low-cost vaccines will also grow in all regions of the world. This has shed new light on the contribution pharmaceuticals companies that make vaccines can make to mitigating the impact of climate change, and the Group considers it to be its duty as a vaccine maker to put all our effort into developing solutions.

In the area of governance, we recognize the importance of formulating and maintaining a management structure to support our growing global business. As we prepare for full-fledged expansion of our operations in the United States, we are translating our Global Governance Policy into in multiple languages to serve our operations worldwide. We are also strengthening our compliance functions at the Group’s regional headquarters in the United States, Europe, Singapore, and China. To further reinforce compliance, we plan to deeply integrate with the governance systems of each of the worldwide regional headquarters of our parent company Mitsubishi Chemical Holdings.

4

Short-term business conditions and outlook

Question:

What is the status of the medium-term management plan?

Answer:

We lowered our numerical targets, but our four strategic priorities are unchanged.

We are currently more than midway into our Medium-Term Management Plan 16–20: Open Up the Future that we launched in fiscal 2016. The plan sets four strategic priorities for growth: maximizing pipeline value, strengthening IKUYAKU (drug fostering and evolution) and marketing, accelerating U.S. business development, and reforming operational productivity. Although we remain fully committed to implementing these strategies until we achieve our target objectives, in November 2018 we revised our numerical performance targets.

The reasons for the revisions were reduced expectations

Revised Medium-Term Performance Targets

(Billions of yen)

	Fiscal 2020		Fiscal 2023
	Initial target	Revised target	
Revenue	500	430	More than 500
(of which, U.S. sales)	(80)	(40)	–
Core operating profit	100	60	More than 100



for royalty revenue, particularly from Invokana, and the slow emergence of M&A effects in the U.S. We began developing our U.S. operations with the release of the Radicava ALS treatment agent there in August 2017. However, the royalty revenues are not contributing as much to profits as we had been expecting. Also, the development of ND0612 as a treatment agent for Parkinson's disease has not progressed as we originally anticipated.

Although we revised our numerical targets, we are continuing to direct all our energies to steadily advancing the four strategic priorities. We believe that continuing to make steady progress maximizing pipeline value will lead to significant improvement in the profit contribution from the U.S. business.

Question:

What is the business outlook and what strategies will you be implementing?

Answer:

We are accelerating our transformation to generate sustained growth.

The qualitative strategy is, as described above, to continue steadily advancing the medium-term management plan. As a pharmaceutical company our drug pipeline is the main driver of our business growth. We are therefore determined to successfully bring the drugs presently in the final stages of the development pipeline to market and will continue allocate a large proportion of funds to R&D. We expect this aggressive investment spending coupled with the results of arbitration proceedings with Novartis Pharma

AG to result in steep declines in our core operating profit, operating profit, and profit attributable to owners of the Company in fiscal 2019.

We are presently advancing two concrete strategies to transform the Group and accelerate the attainment of sustained growth. The first is revising our product structure by employing new modalities of increased ratios of new drug and long-tail businesses. The second is transforming our business model by adding a self-distribution business structure overseas, mainly in the U.S., to our domestic and royalty businesses. We deeply regret that will need more time to reach the targets in our medium-term management plan, yet we also believe it is necessary to shore up our strength to achieve the full and most expeditious results from our strategies. We intend to emerge from this period stronger than ever.

The history of our Group includes many periods when we overcame challenges and came out stronger. I am certain that the combined effort of our management and employees will propel us to success in this new transformation of the Company.

I look forward to the understanding and support of our shareholders as we set Mitsubishi Tanabe Pharma on a new path to the future.

September 2019

Masayuki Mitsuka

President & Representative Director

Message from the Financial and Accounting Officer

We will steadily make needed investments for medium- to long-term growth.



Eizo Tabaru

Member of the Board,
Managing Executive Officer

Fiscal 2018 review

In fiscal 2018, domestic sales of ethical drugs decreased ¥10.5 billion year on year due to the effects of drug price revisions, a decline in long-listed drugs, the impact of the transfer of the generic drug business, and other factors.

On the other hand, sales of Radicava increased ¥14.7 billion year on year, which contributed to a ¥16.5 billion increase in overseas ethical drug sales. However, because arbitration with Novartis over royalty income began, overseas sales of ethical drugs declined ¥16.0 billion year on year mainly due to the Company not recognizing revenue in accordance with IFRS 15 on a portion of Gilenya royalties.

Although the current situation is uncertain, we will steadily proceed with efforts to successfully invest for medium- to long-term growth from fiscal 2019 and beyond.

Acquiring the ability to win in battle

The royalty business is an effective means for maximizing product value by delivering developed drugs to patients around the world. The predecessor company before merger would have faced difficulties with rapid clinical development and global market penetration even for Gilenya and Invokana, which have become profit pillars. Radicava was successful in establishing the self-distribution business in the United States, one of the challenges of the Medium-Term Management Plan 16–20. Considering the balance and risk-balance between development costs and profits, we will continue with the growth strategy of expanding the self-distribution business globally and maintaining the royalty business.

I have worked in the financial field for a long period of time and have experience setting up plants overseas and in post-merger integration (PMI). Thanks to my extensive experience working and engaging with people overseas from diverse cultural backgrounds, I was able to develop and sharpen my negotiating and decision-making skills. We are now working Companywide to develop the “ability to win” through repeated “successful experiences” such as with self-distribution in the U.S. and development overseas. Three global products positioned as growth drivers [Radicava oral suspension (MT-1186), plant-based VLP vaccine (MT-2271), Parkinson’s disease treatment agent (ND0612)] and late-stage drug candidates all boast of being products with original value. In order to deliver these to patients around the world, we will rapidly gain the “ability to win” a wide range of business battles and take a giant leap forward.

Achieve medium- to long-term growth

Through the strengthening of priority areas such as Immuno-inflammation, diabetes and kidney as well as the pursuit of operational production reforms and base restructuring we expect to generate a total ¥600 billion over the five-year period from fiscal 2019–2023. Therefore, we anticipate we can fully cover shareholder returns and R&D investments.

R&D investment of ¥80 billion annually is planned for the aforementioned five-year period. Therefore, of the three global products under development, Radicava oral suspension and plant-based VLP vaccine (MT-2271) will be launched in fiscal 2021, and ND0612 will definitely finish launching in fiscal 2022. Moreover, we will advance our innovative drug candidates MT-8554 and MT-7117, which will be our new growth drivers, to late-stage development as quickly as possible.

To expand our business base in the U.S. and Europe and upgrade and expand our product lineup, we also flexibly conduct strategic mergers and acquisitions following those of Medicago and NeuroDerm. We are considering the acquisition of “investees with pipelines” that are developed and marketed using our knowhow, and “investees with products” that are already profitable in the market. We will continue to examine investments that can maximize synergies with existing business bases, including our sales system for specialty areas created with Radicava. We have set a limit for strategic investments, such as M&A, of ¥300 billion for the five years from 2019 to 2023. As of March 31, 2019, we have cash on hand of about ¥370 billion, an amount sufficient to cover our strategic investment allowance. However, ¥300 billion is not an upper limit,

but merely an estimate. If we decide that a project is good and matches the above strategy, we will consider additional financing by procuring new funds.

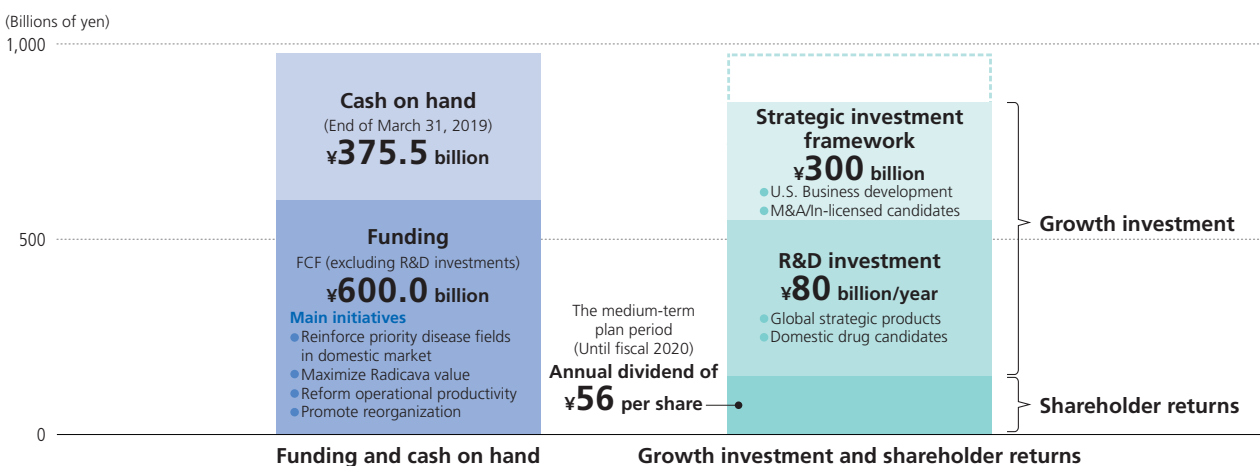
A message to shareholders and investors

The Company’s basic management policy is to secure funds for sustainable growth taking into account capital efficiency to enhance shareholder returns on a stable and continuous basis. Based on this policy, we plan to pay a dividend of ¥56 per share in fiscal 2018, which we will maintain until fiscal 2020. As for the acquisition of treasury shares as a shareholder return policy, we determine the return based on a comprehensive evaluation of stock price trends, company performance, cash flow, and management environment.

In addition to the recent difficult business performance, revenue will not be recognized during Gilenya’s arbitration period, so the impact could be even greater. However, that portion of revenue that is not recognized will be recognized in lump sum depending on the arbitration results. We will also push forward to achieve the medium-term management plan, which was revised in November 2018.

Due to the nature of arbitration, many shareholders may feel uneasy by the lack of explanation provided to everyone, but pipeline development and important strategies, including the promotion of overseas business, are steadily progressing with the aim of medium- to long-term growth. We hope you will look forward to the dramatic growth we have planned for the future, and we ask for your continued support.

Growth investments and shareholder returns (fiscal 2019 – 2023)



U.S. Business

We are implementing three deliberate steps to establish sustained growth in the world's largest pharmaceuticals market.



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

Basic policy

Expanding our business in the United States, which is by far the world's largest market for pharmaceuticals, is absolutely essential to fulfilling the goals of our Medium-Term Management Plan 16–20 and to achieving sustained growth.

The roadmap for establishing the U.S. business and generating sustained growth has three steps: launch, broaden, and sustainably grow. We will launch the U.S. business by introducing the ALS treatment agent Radicava to the market. Then we will broaden the business by aggressively investing in strategic areas. And finally, we will build on the first two steps to construct a business foundation for continual growth centered on in-house products.

We have already made progress with the first two steps under the medium-term management plan. Radicava was released in August 2017, and we invested ¥124 billion (\$1.1 billion) to acquire and make a full subsidiary of NeuroDerm in October 2017.

We are also preparing to release the MT-1186 Radicava oral suspension and MT-2271 plant-based virus-like particle (VLP) seasonal influenza vaccine in fiscal 2021, followed by NeuroDerm's ND0612 treatment for Parkinson's disease in fiscal 2022. We expect these three products to be strong growth drivers and generate accelerated growth. Through these activities we will increase our presence in the U.S. market and firmly advance us to the third stage of establishing sustained business growth centered on our proprietary products. We will continue developing the U.S. business to make it the Company's second main earnings source behind our domestic operations.



Overview of the U.S. business

Mitsubishi Tanabe Pharma America (MTPA), which handles sales and marketing functions in the United States, executed the first step of our plan to launch the U.S. business with the August 2017 sales release of Radicava. MTPA has been improving the treatment environment and conducting biomarker trials to acquire new data to pave the way for a successful market launch in fiscal 2021 and

maximize sales of Radicava. MTPA is also preparing to market the plant-based VLP vaccine being developed by Group company Medicago, of Canada, which will advance the second strategic step of broadening the U.S. business. The Parkinson's disease treatment ND0612 is also being developed by NeuroDerm.

Mitsubishi Tanabe Pharma Development America (MTDA) is also playing a central role in the Group's global aspirations. MTDA is developing the Radicava oral



Achieving success developing global pharmaceutical products

Mitsubishi Tanabe Pharma Development America (MTDA)

Hideki Kuki
President

Radicava sales in the United States have been steadily growing since the drug was introduced in August 2017. MTDA has been tenaciously supporting the Radicava business to succeed, including submitting a request after obtaining marketing approval to change a part of the approval details, managing safety information, and applying for and receiving authorization to market Radicava outside the United States. At the same time, it is leading the clinical research of the in-house developed MT-1186 oral agent.

MTDA has the important mission to follow-up the success with Radicava by developing new drug products for the global market to maximize pipeline value, which is one of the four strategic priorities in the Medium-Term Management Plan 16–20. The MTPC Group has assembled development project

teams from its member companies, which is working closely with each company's functional organizations and related departments to plan and execute drug development projects for global markets.

MTDA has a highly efficient and effective operating structure that outsources the majority of clinical study operations so it can focus primarily on forming and managing drug development plans, regulatory affairs strategies, and safety risk assessments. With the increasingly strict requirements from regulatory authorities and demand from medical society, new drug development must take medical economics into account. MTDA is also playing a crucial role constructing a network of experts in various fields in the United States, Europe, and Japan that will raise the probability of success of our drug development activities while ensuring we accurately fulfill both the medical and economic needs. We remain dedicated to the full process of bringing new drugs to market starting with combining knowledge from inside and outside the Company, establishing project proof of concept at an early stage, steadily advancing drug development to the final stages, and successfully obtaining marketing approval.



U.S. Business

suspension and is advancing the in-house production of drugs for the third step to sustainably grow the U.S. business. The company has generated several projects with global potential and is contributing to strengthening the drug pipeline for the Group's future growth.

Expanding our business in the U.S. market, which is expected to remain the world's largest pharmaceuticals market, is essential to achieving sustained earnings growth for the Group.

Progress with the three steps

As mentioned above, after the first step to establish the U.S. business by releasing Radicava, we are now moving to launch the oral preparation and implement measures to maximize sales.

The second step is to continue preparing for the release of Medicago's plant-based VLP vaccine, for which we are aiming to receive approval in fiscal 2021, while also advancing the development of NeuroDerm's Parkinson's disease treatment ND0612 for a target release date in fiscal 2022.

The key tasks for the third step will be to formulate the operating structure and implement measures to establish ongoing growth for fiscal 2021 and beyond. That will require careful selection and concentration of investment in R&D with the clear aim of bringing in-house developed products to market as swiftly as possible.

Mitsubishi Tanabe Pharma Holdings America (MTHA) conducts market analysis to accurately identify the needs of patients and healthcare professionals. The company

also contributes to developing strategies from the market's perspective by proposing market access strategies to construct compelling evidence to gain the backing of insurers and ultimately to enable access to all patients considered in need of the new drugs.

These activities are all geared to enhancing our ability to discover drugs matched to market needs and seamlessly progress to formulating marketing strategies while also accelerating in-house drug development to maximize the value in our drug development pipeline. MTHA is also strengthening the management infrastructure, including reinforcing governance and ensuring comprehensive compliance at companies doing business in the United States, which is essential to maintaining sustained business growth.

Growth drivers

(1) Radicava

Since the release of Radicava, MTPA has been providing educational opportunities about ALS and Radicava to the primary stakeholders of patients, doctors, and insurers and seeking to increase the number of medical institutions where Radicava is available to improve treatment options for ALS patients. As of June 2019, these efforts have helped increase the number of ALS patients benefiting from treatment using Radicava to over 4,000 people.

While continuing these activities, we will also seek to improve the ALS treatment environment and lay the groundwork for the release of the oral treatment in fiscal 2021 by increasing recognition of Radicava among



ALS Biomarker Research

Mitsubishi Tanabe Pharma America (MTPA)

Stephen L. Apple, MD
Senior Medical Director

Biomarkers are biological substances such as proteins or genes that may play a role in the diagnosis or prognosis of a disease. Biomarkers may also play an important role as indicators of treatment effectiveness. Biomarkers are attracting particular attention from healthcare professionals involved in amyotrophic lateral sclerosis (ALS) treatment and research as well as ALS patient communities. MTPA is collaborating in a study with Massachusetts General Hospital to identify and measure specific biomarkers in roughly 300 people using Radicava to

treat ALS. The study, which is being conducted at roughly 40 sites in the United States, will seek to create a panel of biomarkers that may be associated with Radicava treatment in ALS, including those for oxidative stress, inflammation, muscle and neuronal injury and death.

We hope this research will deepen our understanding of how Radicava affects the progression of ALS. The companies participating in the collaboration each bring unique evaluation techniques. As part of the collaboration, MTPA in the United States conducted its first clinical research of biomarkers, which was an important milestone for our business. We are proud to be leading this research and to be able to come together with members of the ALS community. In 2019, the study plans to enroll patients to participate in the biomarker study, and we plan to conduct the first interim analysis by the end of the year.

healthcare professionals to promote effective use, creating environments conducive to prescribing it, and facilitating patient accessibility to it for treatment. Because the Radicava oral suspension will be much easier to administer than the current method of intravenous drip infusion, it will widen the scope of patient eligibility, which will both address unmet medical needs and maximize the value of the treatment.

(2) VLP Vaccine

Medicago is a biopharmaceutical company specializing in the research and development of new vaccines using plant-based virus-like particle (VLP) technology. VLP vaccines have the potential to provide strong and extremely safe protection against viruses. Because the external structures of VLPs resemble viruses, they stimulate the body's immune system but carry no threat of viral transmission because they contain no viral genetic material. VLP vaccine technology also offers the significant advantages of being less costly and quicker to manufacture than current vaccines.

Medicago has proprietary technology to grow VLPs in plant cells and efficiently extract and refine the VLPs. The company completed phase 3 testing of its seasonal flu VLP vaccine for adult patients in the United States and Canada during the 2017-2018 influenza season. In fiscal

2019, the company is expecting to receive the results of phase 3 trials for administering the flu vaccine to elderly patients in the second quarter and plans to apply for approval in the United States for administering the vaccine to adults in the same year with the objective of beginning sales in fiscal 2021.

(3) ND0612

NeuroDerm has proprietary production technology for liquefying insoluble compounds. The company is using its "designed pharmaceuticals" combining pharmaceuticals and devices to increase drug effectiveness and is also advancing development of ND0612, its Parkinson's disease treatment formulated to reduce side effects. There are estimated to be over a million people with Parkinson's disease in the United States alone, and the research and development of the ND0612 treatment has high clinical value for its potential to meet a vast worldwide unmet medical need.

The development plan for ND0612 had been under review but in fiscal 2018 the company and the United States Food & Drug Administration (FDA) discussed and reached a general agreement on the design of Phase 3 study. The company plans to simultaneously submit approval applications in Europe and the United States in fiscal 2021 with the aim of beginning sales in fiscal 2022.



Business Strategies by Process

Drug Discovery

Focus on expanding the pipeline and promoting open innovation

Yoshiharu Hayashi

Executive Officer,
Head of Sohyaku,
Innovative Research Division



Basic policy

The Sohyaku, Innovative Research Division strives every day to continually discover new drugs for the world that address unmet medical needs with the aim of becoming a “pharmaceutical company working with a sense of speed to be the first to deliver original value.”

In the area of diseases, the Company is focused on the priority areas of central nervous system diseases and immune-inflammation diseases. At the same time, we are working on additional new areas and modalities for the future and will identify the ones that will become our next pillar of business.

In drug discovery activities, we are aggressively promoting cooperative business through industry-academia-government collaboration and using external drug discovery resources to expand these discovery opportunities, such as identification of novel targets and technologies.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, we sought to rapidly obtain PoC for our drug candidates and focused on strengthening translational research¹. One of the results is that we selected highly unique indications in several projects, which enabled us to advance the candidates to Phase 1. As we promote

the diversification of modalities, we seek to expand our research pipeline to achieve the continuous creation of development candidates.

In addition, with respect to our drug development project, a collaboration with our pharmaceutical development subsidiary in the U.S., Mitsubishi Tanabe Pharma Development America, and in Europe, Mitsubishi Tanabe Pharma Europe, was able to drive the PoC study for its first product as planned after the establishment of our global development system.

Meanwhile, an issue in fiscal 2018 was that we were unable to create drug candidates in priority areas, particularly central nervous system diseases and immunoinflammation diseases that lead to internal sales, especially in the U.S. following Radicava. It is necessary, more than ever before, to rigorously promote projects from a translational research perspective from the initial stage of research. Another issue was that the results of open innovation in basic research did not effectively lead to pipeline expansion.

In light of these issues, we will continue to steadily promote PoC studies and aggressively expand our pipeline focusing on priority areas in fiscal 2019. Furthermore, our policy is to focus on opening up the research environment. We created an environment where new synergies are easily produced, such as the Shonan Health Innovation Park

(see page 32), and we will collaborate with the best partners inside and outside the Company and incorporate leading-edge technologies. Moreover, we will encourage open discussions on new themes and ideas in the Sohyaku. Innovative Research Division and promote transparency in budget and human resource allocation. In addition, we will strengthen the connection between clinical practice (medical) and basic research (science) by collaborating with the Ikuyaku. Integrated Value Development Division. In cooperation with physicians inside and outside the Company, we will push forward with highly relevant project management that incorporates medical needs and a medical perspective from the early stages of research.

1. "Translational research" involves the connection from basic research to clinical practice. Its purpose is to bridge the excellent results obtained from basic research at universities with the development of innovative pharmaceuticals.

Medium- to long-term perspective

To achieve the goals of the Medium-Term Management Plan 16–20, the Sohyaku. Innovative Research Division should first focus on swift PoC confirmation of drug candidates and pipeline expansion through the continuous creation of drug candidates with a focus on priority areas. Continued discussions on the expansions of the pipeline are to be carried out, not only within the Sohyaku. Innovative Research Division, but also in joint effort with "Drug Discovery Strategy Team" set up in collaboration with the Global Portfolio Management Department and other departments.

The Sohyaku. Innovative Research Division's long-term goal is the "continuous creation of original drug candidates that meet future medical needs." Our strength lies in our drug discovery capabilities. We have a track record of creating the world's first unique pharmaceuticals leveraging our capabilities in chemical synthesis. In addition to conventional small-molecule drug discovery, we are also now expanding new modalities such as nucleic acid drugs and middle molecule drug discovery. Our ideas, creativity and tenacity for creating highly original products are also our strengths.

On the other hand, we need to accelerate drug discovery more than ever. To that end, one thing we should do is to streamline decision-making. In the initial stage of research, we need to emphasize taking on challenges and to not take too much time gathering information for streamlined decision-making. Furthermore, we believe that we can accelerate the entire drug discovery process by incorporating external knowledge and technologies through open innovation and better leveraging external assets. For example, as a new challenge that leverages open innovation, we are conducting drug discovery research on gene therapy in collaboration with Jichi Medical University.



Arisa Hisanaga

Research Unit/Neuroscience,
Sohyaku. Innovative Research Division

Develop reliable assay systems and basic technologies to challenge new themes with high medical needs

I was attracted by this work, drug discovery, that can contribute to the health of people around the world, so I studied brain and nerve functions at the faculty of pharmaceutical sciences during my university days. Since joining the company, I have been consistently engaged in central nervous system projects and primarily responsible for developing assays for compounds.

Before a new drug can be made, the cycle of (1) evaluating the compound and (2) synthesizing the compound based on those results must be repeated to improve the efficacy of the compound. Establishing an assay system that enables us to generate highly recapitulated results is critical to effectively repeat this cycle.

Recently, we created an assay utilizing iPS cell-derived neurons. iPS cells are relatively unstable and it was difficult to obtain highly reproducible results compared to the cells that we have dealt with so far. However, as a result of trial and error based on the advice from other members and my supervisors, I could successfully set up a stable assay, which now contributes significantly to the efficient progress of current drug discovery projects. Moving forward, I'd like to take part in developing functional assays that use patient-derived cells with the aim of discovering pharmaceuticals that can further help patients.

Currently, I'm investigating new projects as a member of the Neuroscience Research Unit. In the field of central nervous system, there are many serious diseases for which treatment has not yet been established despite significant needs from patients, their families, and medical professionals. To address those needs, I'm now conducting validation experiments on new concepts targeting ALS and other neurological diseases. I interact with US doctors and constantly study day after day while assimilating the latest information from domestic and overseas academic conferences and various papers.

I will continue to take on challenging themes that help us develop new pharmaceuticals while enhancing my expertise, and make every effort to improve our own drug discovery infrastructure from a long-term perspective so that I can contribute to the health and happiness of people around the world.

Business Strategies by Process Drug Discovery

It is also important to create a better environment for creating such innovations. We will create a more open research environment and promote collaboration with the best partners inside and outside the Company. The relocation of our research laboratory to Shonan Health Innovation Park in the current fiscal year is also viewed as laying the groundwork for pursuing this open innovation.

Furthermore, we also need to change researchers' way of thinking to challenge diseases with high unmet medical needs. We hope to generate new ideas by encouraging researchers who tend to stay in their own shells to break out and expand their perspectives and ideas through opportunities for dialogue and discussion with outsiders. I believe that creating a corporate culture that encourages taking on challenges is a vital mission as Head of the Sohyaku. Innovative Research Division.

Possible risks and countermeasures

Generally speaking, ideas that anticipate future needs, such as what drugs will be needed 10 years from now or ascertaining trends in diseases and technologies are highly important in drug discovery with a long development lead time, and misreading trends could be risky. Research and evaluation of disease trends is being led by three drug

discovery units, and technology trends by Modality Laboratories and the US research subsidiary Tanabe Research Laboratories U.S.A. We are proceeding with development for early commercialization of VLP vaccines, a new modality, in collaboration with Medicago and products that combine pharmaceuticals and medical devices in collaboration with NeuroDerm.

On the other hand, there are risks related to the development of new modalities and risks related to regulatory controls and drug price revisions by relevant authorities. With regard to these, we will closely monitor the international situation and industry trends, and take steps to reduce risks through prior consultations with relevant authorities.

Message to shareholders and investors

I think that many of our personnel thrive on adversity, understanding the true nature of problems and finding solutions by themselves. To create pharmaceuticals and medical services that offer new value by leveraging these personnel, we will integrate the individual strengths of each person in the Sohyaku. Innovative Research Division and continue to create original products that meet future medical needs.



Accelerate open innovation by leveraging Shonan Health Innovation Park

As initiatives for Medium-Term Management Plan 16–20 and beyond that toward fiscal 2023, we are reexamining the allocation of management resources, optimizing and streamlining our global management system, and reinforcing each function.

As part of this, to accelerate open innovation in drug discovery research, we decided to use the Shonan Health Innovation Park in Kanagawa Prefecture as one of the research centers starting from May 2019. The Company will swiftly and powerfully take on the challenge of addressing new technologies, new treatments, and new disease areas in this park.

In addition to pharmaceutical companies and drug discovery ventures, the Shonan Health Innovation

Park is occupied by companies that provide drug discovery support services, research and medical devices, and are engaged in AI and IoT business, and the park is working to attract more such companies. Approximately 250 researchers working in the Frontier Research Unit, the Modality Laboratories, and other facilities from the Yokohama Office, the Toda Office (closed in fiscal 2019) will move in to expand collaboration opportunities by building a human network with existing tenants. Above all, we will pursue initiatives based on the theme of achieving radical treatments using genetic drug discovery, which will lead to the provision of new pharmaceuticals and medical services for the prevention and cure of rare and intractable diseases.



Business Strategies by Process Pipeline

Status of drug candidates (as of July 25, 2019)

Asia: excluding Japan and China

Development code Product name <small>(Generic name)</small>	Category	Indications	Region	Stage		Origin		
				Phase			Filed	
				1	2			3
Immuno-inflammation								
MT-5547	Fully human anti-NGF monoclonal antibody	Osteoarthritis	Japan		Phase 2/3	US: Regeneron		
MT-1303	S1P receptor functional antagonist	Multiple sclerosis	Europe			In-house		
		Crohn's disease	Japan					
MT-7117	Dermatologicals, etc.	Erythropoietic protoporphyria	Global			In-house		
MT-2990	Fully human anti-interleukin-33 (IL-33) monoclonal antibody	Endometriosis	Global			In-house		
		Seasonal Allergic Rhinitis	-					
Diabetes and kidney								
TA-7284 Canaglu (Canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus	Asia			In-house		
		Diabetic nephropathy	Japan					
MP-513 Tenelia (Teneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus	Asia			In-house		
			China					
			Europe					
MT-6548 (Vadadustat)	Hypoxia inducible factor prolyl hydroxylase inhibitor	Renal anemia	Japan		19.07	US: Akebia		
MT-3995	Selective mineralocorticoid receptor antagonist	Diabetic nephropathy	Europe			In-house		
			Japan					
		Non-alcoholic steatohepatitis: NASH	Japan					
Central nervous system								
MCI-186 Radicut/Radicava (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS	China		19.04	In-house		
			Asia					
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist	Schizophrenia	Asia			Hungary: Gedeon Richter		
MT-5199	Vesicular monoamine transporter type 2 inhibitor	Tardive dyskinesia	Japan		Phase 2/3	US: Neurocrine Biosciences		
MT-8554	TRPM8 antagonist	Painful diabetic peripheral neuropathy	Europe			In-house		
		Vasomotor symptoms associated with menopause	Global					
ND0612 (Levodopa/Carbidopa)	Continuous SC pump/patch pump	Parkinson's disease	Global			In-house		
ND0701 (Apomorphine)	Continuous SC pump	Parkinson's disease	-			In-house		
MT-1186 (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis: ALS/Oral suspension	-			In-house		
MT-6345	Nervous system	-	-			Japan: Co-developed with Ube Industries		
MT-3921	Anti-RGMa antibody	Spinal cord injury	-			Japan: Co-developed with Osaka University		

Asia: excluding Japan and China

Development code Product name (Generic name)	Category	Indications	Region	Stage				Origin
				Phase			Filed	
				1	2	3		
Vaccines								
MT-2355	Combined vaccine	Prophylaxis of pertussis, diphtheria, tetanus, poliomyelitis and prophylaxis of Hib infection in infants	Japan				Japan: Co-developed with The Research Foundation for Microbial Diseases of Osaka University	
MT-2271	Plant-based VLP vaccine	Prophylaxis of seasonal influenza/adults	US, Europe				Canada: Medicago product	
		Prophylaxis of seasonal influenza/elderly	US, Europe					
MT-8972	Plant-based VLP vaccine	Prophylaxis of H5N1 influenza	Canada				Canada: Medicago product	
MT-7529	Plant-based VLP vaccine	Prophylaxis of H7N9 influenza	–				Canada: Medicago product	
MT-5625	Plant-based VLP vaccine	Prophylaxis of rotavirus gastroenteritis	–				Canada: Medicago product	
Others								
TAU-284 Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent	Allergic rhinitis, Urticaria	Asia				Japan: Licensed from Ube Industries	
MT-4129	Cardiovascular system, etc.	–	–				In-house	

Major out-licensed products

Development code Product name (Generic name)	Category	Indications	Region	Stage				licensee
				Phase			Filed	
				1	2	3		
Diabetes and kidney								
TA-7284 INVOKANA (Canagliflozin)	SGLT2 inhibitor	Diabetic nephropathy	US			19.03	US: Janssen Pharmaceuticals	
Central nervous system								
MT-210	5-HT2A/Sigma 2 receptor antagonist	Schizophrenia	US, Europe				US: Minerva Neurosciences	
Others								
MT-4580 Orkedia (Evocalcet)	Ca sensing receptor agonist	Hypercalcemia in patients with parathyroid carcinoma or primary hyperparathyroidism	Japan			19.04	Japan: Licensed to Kyowa Kirin	

Business Strategies by Process

Drug Fostering and Evolution

Maximize and optimize pharmaceutical value in global development

Yoshihiro Kobayashi

Member of the Board, Managing Executive Officer,
Head of Ikuyaku, Integrated Value Development Division



Basic policy

The Ikuyaku, Integrated Value Development Division features the development section that plans and manages clinical trials for pharmaceuticals, the medical affairs section that is responsible for medical activities such as the acquisition and dissemination of various information required in medical settings, and the pharmacovigilance (PV) section that conducts surveys and writes reports on safety information and drug side effects and also oversees a wide range of functions including the data science section that makes use of clinical trials, PV data, and RWD¹ to extract scientifically and socially useful information. With these various specialized sections collaborating together, we strive to maximize product value in various stages, from late development to post-marketing, centered on our priority disease areas of immuno-inflammation, diabetes and kidney, central nervous system, and vaccines.

¹ The acronym for Real World Data, which refers to data that is based on actual medical care practices, such as medical fee data (health insurance claim receipts) and medical exam data, or the databases of these.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, this division pursued initiatives based on the themes of "Late-stage drug development in Japan and Asia," "Medical activities for diabetes centered on Canaglu

and Tenelia," and the "Global promotion of PV activities."

Notably, in "Late-stage drug development in Japan and Asia," development of MT-6548, MT-5547, MT-5199, TA-7284 (diabetic nephropathy), and MP-513 (China) proceeded without a hitch. Of these, MT-6548 and MP-513 (China) achieved the primary endpoints anticipated in Phase 3 and are moving steadily ahead to launch as new drugs. In addition, we gave academic presentations and presented papers on the results of various clinical studies and post-marketing surveillance in collaboration with the medical affairs and PV sections. Among these, an interim report we presented on the results of Radicut use in ALS received the Excellence Award from the Japanese Society of Neurological Therapeutics.

In fiscal 2019, we will focus on "Pipeline enhancement and selection," "Acceleration of development," and "Streamlining operations" as priority issues. In our development work, we will apply for approval of MT-6548 in Japan, which obtained Phase 3 results in fiscal 2018, and approval of MP-513 in China, and move forward with other drug candidates according to plan. Since MT-8554 and MT-7117, which originated in-house, will enter the global late-stage development phase as drug candidates, in the development of these and Radicava oral suspension (MT-1186) in Japan and Asia, we will promptly cooperate with medical and PV activities to promote integrated global

activities. As for diabetes and kidney disease, Janssen Pharmaceuticals, a U.S. company, presented the excellent results of a clinical study of diabetic nephropathy (CRENCE study²) at an international conference in April 2019. Consequently, we will strengthen our development and medical activities in Japan to quickly deliver these results in Japan as well.

² Acronym for Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation.

Medium- to long-term perspective

New modalities such as regenerative medicine, gene therapy, and digital medicine are emerging in the medical world. Moreover, past rules and methods are changing, for example, “global development” now occurs simultaneously at locations around the world, and RWD and AI being used. In anticipation of these changes, as a global research-driven pharmaceutical company, we will continue to work with Sohyaku. Innovative Research Division and overseas affiliates to provide society with new drugs that patients around the world are eagerly waiting for, and we will continue to increase their value.

In maximizing and optimizing the value of pharmaceuticals, drug applications and approvals are only “waypoints.” We are carrying out our activities with greater determination to further enhance and optimize their value, including development activities such as adding indications, medical activities by providing medical information for clinical questions³, and PV activities such as collecting post-marketing safety information. We have built a system which enables the development, medical affairs, PV, and data science sections to promote strategies through this division, and with this we are steadily accumulating a wide range of knowledge and experience. Moving forward, we will continue to leverage all of these to maximize and optimize the value of pharmaceuticals not only in Japan and Asia, but globally. Furthermore, we seek to enhance our expertise and streamline operations by strengthening not only the expertise of each department’s operations, but also collaboration in disease areas including priority diseases.

³ Clinical questions and issues. There are of various types including those related to clinical condition, evaluation, treatment, risk, and prevention.

Message to shareholders and investors

One risk that is becoming apparent is the global rise in R&D costs. On the other hand, market conditions for pharmaceuticals have become increasingly harsh due to the promotion of cost control measures in Japan and other countries. We need to consider how quickly we can deliver treatment agents and treatment methods that society urgently requires without being bound by past methods.

This division will create new methods that are focused on patient-centered healthcare. I would like to create a system that enables the efficient turning of the PDCA cycle and lets us quickly determine and select those things that are certain from those that are not. For example, Japan is expected to be the first country in the world to approve and launch MT-6548, which is now under development, and post-marketing safety information that we collect will be disseminated worldwide in the future. It is important to quickly collect and analyze safety information immediately after sales and appropriately disseminate it worldwide. Since it is important that we strengthen our global system in the United States and worldwide, we will train employees to have a broad and multifaceted perspective. Recognizing that we are globally connected wherever we are, we will act based on our key message of “Think globally, Act locally.”

Along with changes in the business environment, each department of this division will increasingly require a high level of specialization. In addition to drug development activities in Japan and Asia, we will work closely with the functions of each department to expand the Group’s business presence around the world.

Business Strategies by Process

Supply Chain

Promote rebuilding of supply chain system to adapt to changes in the business environment

Ryosuke Tanabe

Executive Officer,
Head of Production Technology &
Supply Chain Management Division



Basic policy

The Production Technology & Supply Chain Management Division was established in April 2018 with the integration of the CMC¹ Division and the Production Division. It plays a role in facilitating and flexibly promoting *monozukuri* (manufacturing with production technology and supply chain management), from the manufacture of investigational drug products used in clinical trials to product design for launch, commercial product procurement, production and supply.

In fiscal 2019, we will steadily promote development projects and maximize product value through product design from the customer's point of view. At the same time, we will restructure our Japan-centered *monozukuri* system into a system capable of adapting to our U.S.-centered business development.

¹ CMC: The acronym for Chemistry, Manufacturing and Control ("the chemistry, manufacturing and quality control of drug ingredients and pharmaceuticals"). Comprehensive research that supports pharmaceutical manufacturing and quality.

Fiscal 2018 summary and fiscal 2019 initiatives

In fiscal 2018, when our division was established, we formulated a plan for restructuring our production and technology bases under our "Strategic Future Vision for Production, SCM², and CMC." In fiscal 2019, the steady

implementation of this restructuring plan will be a priority issue.

For example, this restructuring plan will include factors such as further strengthening of our capabilities in the field of global supply chain management. Leveraging the experience and know-how gained from Radicava, we will create a system that enables rapid supply of globally developed products such as MT-1186, ND0612, MT-8554, and MT-7117, from investigational drug products to commercial product supply.

In addition, we will leverage the characteristics of our domestic production bases to achieve an efficient production system. Based on the product life cycle, the Onoda Office will be responsible for everything from the manufacture of investigational drugs to the timing of their introduction and growth, while the Yoshitomi Office will promote the reallocation of production items following the restructuring of production bases, and will changeover to a system that supports *monozukuri* from growth period onward, and provides efficient and stable supply.

Furthermore, we will rebuild our production technology to create unique value and deliver it globally. To achieve a seamless connection between CMC and production functions, a new research building, CMC Innovative Laboratories (CIL), will be constructed at the site of the Onoda Office and develop it as a *monozukuri*

base. In addition, technology and know-how not located in-house will be acquired through partnering including collaboration with industry, academia, and government.

2. SCM: Acronym for Supply Chain Management. A business management method for optimizing the entire process from raw material procurement to manufacturing and supply to consumers.

Medium- to long-term strategy

The mission of our division is to grasp the needs of the market, rapidly create the products that are needed, and stably deliver products of both reliable quality and reasonable cost to customers around the world based on our high technological capabilities.

As typified by the three growth drivers, we need to shift not only investigational drugs, but also our product supply system to the U.S. to accompany the shift of development and sales areas to the U.S. Along with these changes, the functions of our division must be changed, and therefore we will build the systems that we need in the future.

To contribute to the company's global growth, we will also focus on the early development of human resources who can properly build and manage supply chains, who can manage positive relationships with various stakeholders, and who can properly respond to new modalities and markets.

A message to shareholders and investors

While raw materials suppliers, manufacturing sites, and sales regions of pharmaceuticals have globalized, global products have to be supplied according to different regulations and local requirements for each country, so it is increasingly difficult to demonstrate economies of scale by manufacturing one product together from a supply chain perspective.

In addition, manufacturing sites with special raw materials and technologies required for new modalities are limited, and there may be risks that could affect stable supply due to unexpected natural disasters and accidents. As countermeasures to these risks, we have developed rules and manuals for responding to crises with a view to business continuity, and have identified specific risks for each key business in the supply chain.

Because the market, patient needs, and required technologies are constantly changing, we will strengthen *monozukuri* from the customer's point of view and create a supply chain system that adapts to changes in the business environment so as to achieve "reliable products and sustainable supply," one of our material issues.



Takashi Nishii

Technology Department, Yoshitomi Plant
Mitsubishi Tanabe Pharma Factory Ltd.

Viewing the reorganization as an opportunity, we will introduce new technologies while ensuring quality

The Group is currently reorganizing its bases with the aim of establishing a global new drug supply system and switching to a flexible and efficient production system that is resistant to environmental changes. Accordingly, I'm in charge of transferring manufacturing technology between factories and outside the Company, and every day I feel how difficult it is to transfer manufacturing technology and continue to manufacture products of the same quality as if it were nothing. Complex factors such as raw materials, machinery, and manufacturing environment may affect quality, even in the same process and procedure. Moreover, the transfer of manufacturing technology substantially changes manufacturing conditions, so high technology is required to ensure the same quality.

For example, when the technology used to manufacture a tablet at our plant was transferred to a new plant, the brand name printed on the tablet was changed to appear on both sides instead of just one, and as a result, many technical issues needed to be solved. Therefore, working closely with the manufacturing division, we reviewed the process from the beginning and conducted repeated trial and error, such as changing the method used to polish the tablet surface. As a result, we not only ensured quality, but were able to achieve significant reductions in work time and defect rate. In a situation that requires close collaboration with other departments and related companies, we reaffirmed the importance of leading the project by having our technical staff carefully examine a wide range of information. Furthermore, viewing each change as an opportunity to achieve a higher quality, lower cost, and more stable supply than before, we review data analysis at the time of the manufacturing technology transfer. At the same time, we are actively introducing new technologies such as non-destructive and non-contact analysis technologies and continuous monitoring methods.

Also, to improve my expertise and acquire further problem-solving skills, I'm registered as a visiting researcher at a university under a work-study program. I will further enhance cooperation between the production and research divisions while combining the experience gained at the Company and the knowledge learned at the university so that we can manufacture and provide even safer and more secure pharmaceutical drugs than before.

Business Strategies by Process

Marketing

Providing high value-added information through consulting and solutions

Yasutoshi Kawakami

Executive Officer,
Head of Sale &
Marketing Division



Basic policy

The pharmaceutical market in Japan continues to face a tough environment due to drastic reform of the drug price system. Furthermore, with the introduction of "Sales Information Provision Activity Guidelines," regulations concerning MR activities have been tightened. Under these market conditions, the Sales & Marketing Division will prop up the Company's growth foundation with the goal of maintaining revenue of ¥300.0 billion in Japan.

In fiscal 2019, we will take area marketing and digital marketing to new levels and strengthen prescription proposal capabilities, which were priority policies in fiscal 2018. We will also maximize our presence in existing areas and prepare to launch new drugs.

Fiscal 2018 summary and fiscal 2019 initiatives

One of our achievements in fiscal 2018 was to raise our market share through area marketing. Area marketing planners (AMPs), who are deployed in all sales offices, played a central role to boost the market share of Canaglu, Tenelia, and Canalia for diabetes and kidney diseases by drawing up and executing strategies for each area. In digital marketing, in response to the growing number of multichannel customers, doctor assessments have

dramatically boosted our ranking¹ from No. 20 last year to No. 8 this year thanks to our healthcare professional website Medical View Point and MR activities that effectively used digital marketing tools. Finally, with regard to strengthening our prescription proposal capabilities, in the area of immuno-inflammation, Remicade, Simponi, and Stelara maintained the No. 1 market share² and MR activity evaluations boosted the Company from No. 7 last year to No. 6 this year in the area of diabetes³.

In light of the impact of the Sales Information Provision Activity Guidelines and Promotion of Working Style Reforms for Healthcare Professionals, in fiscal 2019, we recognize the need to provide appropriate high value-added information in a shorter timeframe than before. In the area of immuno-inflammation, in May of this year, we launched a new Simponi autoinjector formulation that improves patient safety and effectiveness and we are working hard to achieve its rapid market penetration. In the areas of diabetes and kidney disease, the CREDENCE study, which is the global evidence for Canaglu presented at international conferences, is being appropriately disseminated to healthcare professionals. We expect this preparatory marketing effort to facilitate sales of the HIF-PH inhibitor Vadadustat (MT-6548), which is scheduled for release in fiscal 2020.

We will also expand our points of contact in digital

marketing to ensure that these information provision activities are carried out. In order to seamlessly respond to diversifying needs, we will evolve to omnichannel, which merges digital and real world data (face-to-face information provision), and perform our industry-leading digital marketing. Further, by increasing the expertise of each MR, we will further boost our MR activities. This will be done in two ways, by accelerating consulting sales, which recommend the optimal treatment taking into account the disease's progression, and solution sales, which meet the needs of each region through the creation of regional networks such as medical facilities and nursing homes.

1. MCI Multimedia Whitepaper 2016 Winter Edition, 2018 Summer Edition.
2. IQVIA Data
3. Macromill CareNet fiscal 2018 Survey.

Medium- to long-term perspective

The greatest mission of this division from a medium- to long-term perspective is to develop growth and revenue strategies for sustainable growth.

With regard to our growth strategy, we will further increase our presence in priority areas in anticipation of the development pipeline.

Our revenue strategy will be to help secure funds for growth investments by promoting reforms to achieve an optimal organizational structure and advancing operational productivity reforms that actively utilize robotic process automation (RPA) to reform working styles and strengthen competitiveness.

Message to shareholders and investors

The business environment has changed dramatically in recent years and risks related to sales activities include drastic reform of the drug price system, promotion of generic drug and biosimilar use, and stricter regulations on visits and sales promotions to medical institutions. To deal with this sudden change, we need to create an organization in which employees have a clear awareness of goals and can quickly take on the necessary challenges. I also believe that creating this organizational culture is an important function. We want to continue to contribute to the health of as many patients as possible and to be a company trusted by society by promoting "the appropriate use of products," a material issue, strengthening our presence in priority areas, one of our strengths, and promoting information provision activities that meet market needs.



Mio Sogo

Product Marketing Department,
Sales & Marketing Division
Pediatrics West Japan
Promotion Group Team Leader

Creating a system that provides up-to-date information that matches the needs of pediatricians

Since joining the Company, I have been involved in information provision activities as an MR. After that, I was assigned to a corporate division where I examined sales policies for vaccines and created sales promotion materials. Leveraging this experience, I'm now affiliated with an MR Group specializing in pediatrics that was established in October 2018. In addition to visiting pediatricians, as a leader of a team with six members including myself, I also support these members.

Our mission is to establish an overwhelming presence in the pediatrics field by gaining the trust of not only pediatricians, but also healthcare professionals and patients. In the pediatrics field, the latest information is most important, so it is necessary to constantly raise one's expertise. Various efforts are made when providing information, so we constantly work with feelings of tension, responsibility, and good faith.

Many female employees balance work with childcare, and working style reforms are also an important mission of our team leaders. In addition to existing sales styles, we are actively pursuing efforts to establish efficient and effective approaches. One of these was the introduction of ZEUS, an email system that sends information to doctors. This system enables information to be customized to suit each pediatrician that's in charge and provide more needed information. We are also taking steps to streamline communication by leveraging IT tools to hold meetings with team members working remotely in their respective areas of responsibility.

Supporting the health of children is also about creating Japan's future. Moreover, the vaccine business that we are rolling out in the field of pediatrics contributes to society by controlling medical costs from the standpoint of disease prevention, and I am proud and satisfied to be able to play a part in this socially significant business.

Non-Financial Information

This section includes ESG-related information as non-financial approaches, strategies and major initiatives.

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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 society.” To realize this philosophy and vision, the Mitsubishi Tanabe Pharma Group places the highest priority on fulfilling its responsibilities to all of its stakeholders, including shareholders, and working to achieve the sustainable growth of the Group and increases in its corporate value over the medium- to long-term. To that end, the Group works to ensure the transparency and objectivity of management by ensuring efficiency and promptness in management decision-making, enhancing monitoring and

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

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

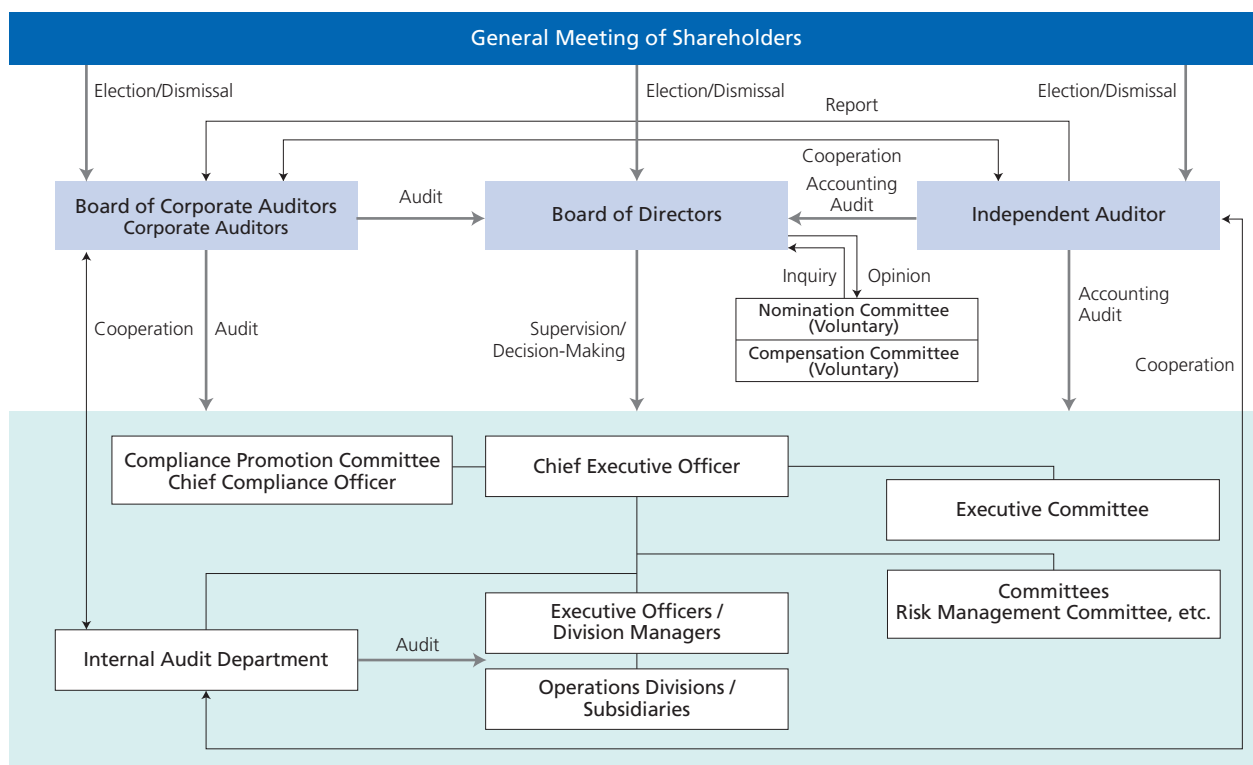
WEB

The following URL provides further information about the corporate governance policy.

https://www.mt-pharma.co.jp/e/company/pdf/cg_policy_e.pdf



Corporate Governance System (As of June 24, 2019)



Corporate governance system

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

Organizational form	Company with a Board of Corporate Auditors
Maximum number of directors stipulated in Articles of Incorporation	10
Term of office stipulated in Articles of Incorporation	1 year
Chairperson of the Board	President
Number of directors	9
Appointment of outside directors	3

Corporate Governance

■ Overview

To secure transparency and objectivity in management decision-making and supervision, the Board of Directors has nine members (9 men, 0 women), including three outside directors. Regular meetings of the Board of Directors are held once a month, and additional meetings are held as needed. Decisions on important matters related to business execution are made in a flexible manner.

The Board of Directors conducts an analysis and evaluation of the effectiveness of the Board of Directors once a year, and also conducts discussions aimed at enhancing the effectiveness of the Board of Directors and other aspects of corporate governance through meetings between Outside Members of the Board and Corporate Auditors and on other occasions, and provides advice on execution as appropriate. In fiscal 2018, the Company used these opportunities to exchange views and provide training for officers in relation to the strengthening of compliance and risk management, including at MTPC Group companies overseas, reviewing medium-term management plans, the content of reports at meetings of the Board of Directors, decision-making processes for alliances and M&A, and other matters.

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 five members (4 men, 1 women; of whom, 3 are outside corporate auditors). The Company has selected an attorney at law, a certified public accountant and a university professor. 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 election 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 the Nomination Committee and the Compensation Committee as voluntary

committees that are chaired by an independent outside director and have independent outside directors as a majority of the members.

The Nomination Committee and the Compensation Committee hold transparent, objective discussions. The Nomination Committee holds these discussions regarding the selection/nomination standards for candidates for director, corporate auditor, and executive officer as well as the selection/nomination of each candidate. The Compensation Committee holds these discussions regarding revision of the compensation system for directors and executive officers as well as decisions on plans for individual amounts of compensation. Reports are then made to the Board of Directors.

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

■ Reasons for adoption of the current corporate governance system

The Company is a pharmaceutical company in an industry that is regulated based on the healthcare system. As such, management decision-making requires deep knowledge and experience in regulatory and industry for pharmaceutical 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 operational experience and knowledge in the pharmaceutical industry as board members but also independent outside corporate auditors with experience and expertise in such fields as finance, accounting, law, and medicine. In this way, the Company has established a system that facilitates appropriate auditing from an objective viewpoint by the Board of Corporate Auditors, as an institution independent from the Board of Directors.

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

Auditing system

Corporate Auditors attend important meetings, such as meetings of the Board of Directors and the Executive Committee. In addition, they conduct interviews on the execution of duties with Directors, Executive Officers, and members of each Company division, review documents relating to major decisions, and investigate the operations and assets of principal worksites and subsidiaries (including internal control systems, such as those for compliance and risk management). In these ways, the Corporate Auditors audit the execution of Company business. Furthermore, we hold meetings of a Corporate Auditors liaison committee for subsidiaries in Japan and are working to strengthen information sharing and collaboration.

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

of internal control systems for financial reporting.

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

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

For internal auditing, the Company has established the Internal Audit Office, which is independent from the executive divisions and audits the internal control systems in operations divisions. The Internal Audit Office has 14 employees as of June 2019.

The Company has appointed Ernst & Young ShinNihon LLC as its independent auditor. There are three certified public accountants who are in charge of the account auditing activities. Assisting in the account auditing activities are 18 certified public accountants and 18 other people.

Nomination of outside officers

In selecting outside 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 independent outside directors, the

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

	Relationships between Outside Corporate Auditors and the Company	Reason for nomination
Tadashi Fukuda Outside Corporate Auditor	Tadashi Fukuda works as Executive Partner of Daiichi Law Office and as Outside Corporate Auditor of EXEDY. There are no special conflicts of interest between the Company and Tadashi Fukuda or these companies.	Tadashi Fukuda has abundant experience and highly sophisticated knowledge as an attorney. The Company believes that he will utilize this experience and knowledge in appropriately executing his duties as an Outside Corporate Auditor and be able to contribute to the sustainable growth of the Group and to the establishment of a corporate governance system, and thus has nominated him as an Outside Corporate Auditor.
Hiroshi Enoki Outside Corporate Auditor	Hiroshi Enoki serves as the president of Hiroshi Enoki Accounting Office, but there are no special interests between him and the Company or between the accounting office and the Company.	Hiroshi Enoki has extensive experience and specialized knowledge, etc. as a certified public accountant, and the Company believes that he will, as an Outside Corporate Auditor, be able to contribute to the sustainable growth of the Group and to the establishment of a corporate governance system, based on this experience and knowledge, and thus has nominated him as an Outside Corporate Auditor.
Mitsue Maru Outside Corporate Auditor	Mitsue Maru serves as a professor at Konan Women's University, but there are no special interests between her and the Company or the university and the Company.	Mitsue Maru has abundant experience and professional expertise regarding medical matters. She was selected and appointed as an Outside Corporate Auditor on account of the Company's judgment that she is capable of adequately executing her duties as an Outside Corporate Auditor by utilizing her experience and knowledge as a university professor and her perspective as a healthcare provider, and contributing to the MTPC Group's sustainable growth and the consolidation of the governance structure.

Corporate Governance

Company selects three people capable of fulfilling the roles and duties expected of outside directors. The specific reasons for the selection of each outside director are shown on page 51.

In regard to outside corporate auditors, the Company selects three people. The table on the previous page shows the specific reasons for the selection of each outside corporate auditor.

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

■ Compensation of directors and corporate auditors

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

The compensation plan for Executive Board Directors comprises "base compensation," "bonuses" which are tied to short-term performance, and "stock compensation" which is tied to medium- to long-term performance, with the ratio set at 7:2:1. The compensation plan for part-time directors and corporate auditors, who are independent of business execution, consists of base compensation only.

Bonuses are performance-linked compensation and consist of cash payments made in accordance with the degree of achievement of performance targets in the Medium-Term Management Plan. The indicator used for bonuses is consolidated core operating profit.

Stock compensation is performance-linked compensation and consists of allocations of the Company's stock in accordance with the degree of achievement of performance targets in the Medium-Term Management Plan. The indicators used for stock compensation are consolidated revenue and profit attributable to owners of the Company.

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

Board Directors. In fiscal 2018, basic compensation for directors and corporate auditors was as shown in the table below. The Company and consolidated subsidiaries paid ¥92 million and ¥8 million to Ernst & Young ShinNihon LLC as compensation for, respectively, auditing and verification.

	Basic compensation	Number of people
Directors (excluding outside directors)	¥269 million	7
Corporate auditors (excluding outside corporate auditors)	¥72 million	2
Outside officers	¥55 million	6

■ Guidelines related to measures to protect minority shareholders in the event of transactions, etc., with the corporate group of the parent company, etc.

Mitsubishi Chemical Holdings (MCHC), which is Mitsubishi Tanabe Pharma's parent company, is a holding company. To leverage the human and tangible resources held by the MCHC Group, MCHC and the Company share know-how; jointly use assets and facilities, including IT systems, and Group networks; and exchange human resources, and the Company deposits funds with MCHC. However, there are no transactions that have the potential to significantly influence the results of the Company, and there are no plans to engage in such transactions in the future.

In regard to transactions between the Company and MCHC or other companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Mitsubishi Tanabe Pharma Group in order to maximize the benefit to all of the Company's shareholders.

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.

Risk Management

■ Business activity risk management

The Company has formulated Risk Management Rules and created a system for preventing risks from materializing in the overall Group's business activities, including overseas affiliates, and for minimizing loss in the event a risk does materialize.

In addition, in order to promote effective risk management, risks are managed by categorizing them according to their characteristics into "risks in management strategy," which are intrinsic to management decision-making, "material risks," which are managed across organizational units because they affect the overall Group, and "general risks," which are addressed on the responsibility of individual divisions.

The Risk Management Committee, chaired by the Chief Executive Officer, is the body responsible for overseeing and promoting risk management for the Group overall. It deliberates on and decides risk management policies, monitors risk management and makes improvements as they are needed.

As a concrete initiative for promoting risk management, the Group conducts risk assessments each year and thereby works to raise its risk sensitivity. The results are fed back to individual divisions to further reinforce risk management.

Risk management based on risk categories

Risks in Management Strategy

Overall category overseen by Corporate Strategic Planning Department

Examples: Risks related to M&A and alliances
Risks related to new business; etc.

Material Risks

(Risks Requiring Cross-Organization Management)

Risk reduction measures devised and promoted by lead management divisions
Overall category overseen by Internal Control Office

Examples: Risks related to pharmaceutical-related laws and ordinances
Risks related to large-scale disasters
Risks related to information management
Risks related to general laws and ordinances; etc.

General Risks

(Risks Specific to Individual Divisions)

Each division devises and promotes risk reduction measures.

■ Crisis management

The Group is taking measures to prepare for the possibility of a major earthquake in the Nankai Trough and an

earthquake directly under the Tokyo metropolitan area. It has revised its regulations for crisis management, including disaster response, and strengthened its system so that pharmaceuticals continue to be stably supplied to patients even in a major disaster. The Group is also working to further improve practical capabilities through business continuity, safety confirmation and communication drills and other training.

Further, the Group maintains and regularly updates manuals on tsunami, pandemics, terrorism, conflicts and other types of incidents based on the various characteristics of its sites inside and outside Japan in order to faithfully fulfill its overarching mission of providing stable supplies of pharmaceutical products.

■ Information security

In order to accommodate overseas business expansion and the increasing complexity of IT infrastructure and to consistently utilize information and IT technologies, the Group is enhancing regulations and strengthening network security at overseas sites, strengthening security when using cloud services, and reinforcing its crisis management system for when security incidents occur.

Enhancing Global Governance

Megumi Ohtaki

Executive Officer,
Chief Compliance Officer



With the diversity of selectable modalities in the pharmaceuticals industry further accelerating due to the advance of globalization and rapid evolution of innovative science and technology, there has been increasing uncertainty in the environment surrounding the Group's management. In such an environment, full governance globally needs to be achieved for the Group to work for sustained growth and to raise corporate value while maintaining the fairness and transparency of corporate activities and to realize its corporate philosophy, "We contribute to the healthier lives of people around the world through the creation of pharmaceuticals."

All executives and employees involved in the Group are committed to acting on the basis of the Corporate Behavior Charter while maintaining awareness of the Group's ideals. The Company intends to further enhance corporate governance to prevent information from being divided by the organizational unit or region, continue working for sustainability, and endeavor to sincerely contribute to local communities and the health of people around the world in order to thereby uphold the interests of stakeholders.

A Message from an Outside Director



We are working to ensure transparency and objectivity to raise corporate value over the view to long-term.

Shigeki Iwane

Outside Member of the Board,
President and Director, The Kansai Electric Power

■ Understanding workplace issues and making recommendations

As an independent outside director, I monitor the progress of Companywide strategies from the standpoint of raising corporate value over the medium to long term, and am always conscious of ensuring transparency in this process when making decisions on important matters that affect management. I also pay close attention to the consistency between the corporate philosophy and Companywide strategy, and the state of social responsibility implementation, such as risk management, safety, quality, and compliance.

To fulfill these responsibilities, it is important to know not only Companywide issues and strategies, but the business workplace as much as one possibly can. Therefore, since becoming an outside director, I have taken the opportunity to visit research labs and plants. Knowing the front-line workplace issues and employees' thoughts about work has helped deepen my understanding of the Company significantly.

In fiscal 2018, we placed particular importance on discussions of revising the Medium-Term Management Plan 16–20. We revised numerical targets, such as profits, in light of major changes in the circumstances that the Company assumed as the basis of this plan, such as the impact of domestic drug price reductions and the progress of the US business. However, although the time for achieving the initial plan will be delayed, corporate value is expected to increase in the years ahead. I recommended that the Company increase its corporate value by reflecting this growth picture in its plan and communicate it in an easy-to-understand manner both inside and outside the Company.

■ Key points for management regardless of industry

Regardless of the industry, there are many common aspects in terms of what management's focus should be. For example, whether it be ensuring the transparency and objectivity of decision-making by revitalizing the board of directors, properly transmitting information inside and outside the company to raise corporate value, or further motivating employees, these are important management issues in any industry. I also make recommendations from this perspective at the Company's Board of Directors.

In the pharmaceutical business most of all, ensuring safety, quality, and compliance is directly connected to stakeholder trust. Viewing "safety" as a major prerequisite for all business activities, I strive to actively speak about safety management and the organizational culture that supports it.

In addition, I always express my views on revitalizing communication within the Group. Increasing employee motivation is the driving force for overcoming the difficult business environment across the Company and achieving sustainable growth. With overseas expansion accelerating, sharing the corporate philosophy is also an important challenge.

In the area of governance, we emphasize ensuring that the views of diverse stakeholders are reflected in a balanced manner in the decision-making process. In the case of the Company, in which the parent company holds the majority of shares, it is more important to ensure the transparency and objectivity of discussions so as not to harm the interests of minority shareholders.

Efforts to make the Company more attractive to shareholders and investors.

Tsutomu Kamijo

Outside Member of the Board,
Chairman of Board of Directors, Sapporo Holdings



■ Recommendations for overseas business success

In my view, the mission of an outside director is to share his opinions and recommendations after carefully examining the state of the execution of the Company's business. In that sense, as an outside director, I strive to discuss matters at the Board of Directors meeting from a wide range of viewpoints unbounded by conventional thinking and decision-making.

The major issue is not only the results of a single fiscal year, but how to advance the growth strategy from a medium- to long-term perspective, including the progress of the Medium-Term Management Plan 16–20. Given these circumstances, at the Board of Directors meeting in fiscal 2018, I paid particular attention to individual overseas businesses that are making rapid progress. The Company's overseas business is in the difficult situation of having to produce results while developing the business experience of its staff, but I want to support them as much as possible so that they succeed.

■ Emphasis on the Nomination and Compensation Committees

As an outside director, I serve on the Nomination and Compensation Committees. In discussions about officer candidates in the Nomination Committee, we evaluate them giving sufficient consideration not only to a quantitative assessment, such as age and experience, but also qualitative aspects, such as the ability required for the future growth of the Company. We also discuss succession plans. In these

discussions too, I strive to express my views from an unbiased standpoint as a third party.

In the Compensation Committee, on the other hand, since the Company's compensation system is well structured, I am particularly conscious about checking how each officer's performance is reflected in their compensation.

■ Efforts to live up to the shareholders' trust

While the business of "developing pharmaceuticals" itself may contribute substantially to society, we must also consider the fulfillment of social responsibilities associated with promoting business. For example, we can consider specific initiatives from the point of view of "how we can develop and produce safe products, while reducing our environmental impact as much as possible, and supply them to society."

In a corporate governance system, there is always room for governance improvement. In the future, it may be good to discuss governance not only in terms of transparency and fairness, but also in terms of what can we do to live up to the trust of shareholders. Efforts to make the Company more attractive to shareholders and investors are essential. To that end, we need to find ways to communicate information more openly.

Member of the Board and Corporate Auditors

Member of the Board (as of August 1, 2019)



Masayuki Mitsuka

President & Representative Director,
Chief Executive Officer

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

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



Takashi Kobayashi

Representative Director,
Senior Managing Executive Officer

In charge of Digital Transformation
Department

1980 Entered the Company
2004 General Manager of Pharmaceuticals Sales & Marketing Department of Marketing Planning Division of the Company
2007 Executive Officer, General Manager of Corporate Management Department of the Company
2009 Board Director, Executive Officer, General Manager of Corporate Strategic Planning Department of the Company
2012 Board Director, Managing Executive Officer, in charge of Business Unit, responsible for Special Assignments from the President of the Company
2014 Board Director, Managing Executive Officer, Division Manager of Research Division of the Company
2015 Board Director, Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division of the Company
2016 Representative Director, Senior Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division of the Company
2017 Representative Director, Senior Managing Executive Officer, Division Manager of CMC Division of the Company
2018 Representative Director, Senior Managing Executive Officer, in charge of Internal Control Office, Future Design Department, Global Quality Assurance Department, Global Regulatory Affairs Department, Clinical, Research & PV Quality Assurance Department, and Medway Business Management Office of the Company
Chief Compliance Officer
2019 Representative Director, Senior Managing Executive Officer, in charge of Digital Transformation Department (current)

Takashi Kobayashi entered Tanabe Seiyaku in 1980. He worked as a researcher in the Safety Research Laboratories. In 1997, he moved to the Human Resources Division, where he was engaged in the operation of the personnel system. He worked as General Manager of Secretary's Office of Administrative Division and as General Manager of Pharmaceuticals Sales & Marketing Department of Marketing Planning Division. After Mitsubishi Tanabe Pharma was established, he worked as Executive Officer, General Manager of Corporate Management Department, and in 2009 he became Board Director, Executive Officer, General Manager of Corporate Strategic Planning Department. Subsequently, he became Board Director, Managing Executive Officer, in charge of Business Unit, responsible for Special Assignments from the President, and he worked to implement structural reforms and to resolve quality control issues and other issues in sales and corporate divisions. Subsequently, as Division Manager of Research Division and as Division Manager of "Sohyaku. Innovative Research Division," he implemented reforms of the research system, and in 2016, he became Representative Director, Senior Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division, and in 2017, he became Head of CMC Division. As of 2019, he oversees the Digital Transformation Department and is responsible for accelerating business digitalization and expanding new businesses such as digital medicine using AI and IoT technologies.



Eizo Tabaru

Member of the Board,
Managing Executive Officer

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

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

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



Hiroaki Ueno

Member of the Board,
Managing Executive Officer

In charge of Human Resources Department, General Affairs Department, International Business Department, China Operations Management Office, Europe Operations Management Office, ASEAN Business, and Public Affairs & Policy Department

- 1983 Entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical)
- 2005 General Manager of Medicinal Research Laboratories IV of Research Department of Sohyaku, Division of Mitsubishi Pharma Corporation
- 2006 General Manager of Chemistry Research Laboratories of Sohyaku and Research Division of Mitsubishi Pharma Corporation
- 2007 General Manager of Chemistry Department II of Medicinal Chemistry Research Laboratories of Research Division of the Company
- 2010 General Manager of Medicinal Chemistry Research Laboratories II of Research Division of the Company
- 2012 Associate Director, General Manager of Medicinal Chemistry Research Laboratories II of Research Division of the Company
- 2014 Executive Officer, General Manager of Research Strategy & Planning Department of Research Division of the Company
- 2015 Executive Officer, Division Manager of CMC Division (Chemistry, Manufacturing and Control) of the Company
- 2017 Executive Officer, Division Manager of Sohyaku, Innovative Research Division of the Company
- 2018 Managing Executive Officer, Division Manager of Sohyaku, Innovative Research Division, in charge of Intellectual Property and Contract Department of the Company
- 2019 Member of the Board, Managing Executive Officer, in charge of Human Resources Department, General Affairs Department, International Business Department, China Operations Management Office, ASEAN Business, Europe Operations Management Office, Public Affairs & Policy Department of the Company (current)

Hiroaki Ueno entered Mitsubishi Chemical Industries (currently, Mitsubishi Chemical) in 1983 and worked as a researcher in the Pharmaceutical Research Department. In 2006, he was named General Manager of Chemistry Research Laboratories of Sohyaku and Research Division of Mitsubishi Pharma Corporation. After the Company was established, he held important positions in medicinal chemistry research, including General Manager of Medicinal Chemistry Research Laboratories II and General Manager of Research Strategy & Planning Department. After serving as Head of CMC Division in 2015, he became Head of Sohyaku. Innovative Research Division, and focused on the development of pharmaceuticals for the next generation. He was appointed Member of the Board in 2019, and, leveraging his extensive experience in technology development, product strategies and other areas based on his research background, he contributes to raising the Company's corporate value as the person responsible for general affairs, human resources and overseas business.



Yoshihiro Kobayashi

Member of the Board, Managing Executive Officer, Head of Ikuyaku, Integrated Value Development Division

In charge of Global Regulatory Affairs Department

- 1983 Entered the Company
- 2004 General Manager of Clinical Promotion Department of Clinical Operations Center of Development Division of the Company
- 2007 General Manager of Development Department III of Development Division of the Company
- 2009 General Manager of Clinical Research Planning and Coordination Department II of Development Division of the Company
- 2010 General Manager of Development Promotion Department of Development Division of the Company
- 2012 General Manager of Global Project Management Department II of Development Division of the Company
- 2014 General Manager of Global Product Strategy Department of the Company
- 2015 Associate Director, General Manager of Global Product Strategy Department of the Company
- 2016 Associate Director, General Manager of Ikuyaku Product Strategy Department of Ikuyaku, Integrated Value Development Division of the Company
- 2016 Executive Officer, General Manager of Ikuyaku Product Strategy Department of Ikuyaku, Integrated Value Development Division of the Company
- 2017 Executive Officer, Deputy Division Manager of Ikuyaku, Integrated Value Development Division, in charge of Development in Japan and Asia of the Company
- 2018 Executive Officer, Division Manager of Ikuyaku, Integrated Value Development Division of the Company
- 2019 Member of the Board, Managing Executive Officer, Head of Ikuyaku, Integrated Value Development Division, in charge of Global Regulatory Affairs Department of the Company (current)

Yoshihiro Kobayashi entered Tanabe Seiyaku in 1983. After being appointed General Manager of Clinical Promotion Department of Clinical Operations Center of Development Division of the Company in 2004, he held important positions in development-related operations, including General Manager of Global Product Strategy Department in 2014 and General Manager of Ikuyaku Product Strategy Department of Ikuyaku. Integrated Value Development Division in 2016, contributing to the Company's business on the frontlines of pharmaceutical development. In 2018, he was appointed Head of Ikuyaku, Integrated Value Development Division, where he not only devised and executed priority development products for the Japanese market but also, for overseas projects, promoted development and approval with overseas affiliates, contributing to the enhancement of the Company's product pipeline. He became a member of the Board in 2019 and draws on his high level of specialization and executive ability based on his development background to help raise the Company's corporate value.



Takeshi Matsumoto

Member of the Board

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

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

Member of the Board and Corporate Auditors

Member of the Board (as of August 1, 2019)



Shigeki Iwane
Member of the Board (Outside)

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

Relationship with the Company

There are no special conflicts of interest between the Company and Shigeki Iwane.

Reason for nomination

Since his appointment in June 2016, Shigeki Iwane has fulfilled his duties as an Independent Outside Member of the Board of the Company, based on his management perspective as a top management figure and his wide-ranging knowledge of corporate governance. He is accurate in his identification of issues and his proposals to ensure a balance between business profitability and risk as well as consistency between business execution and strategy from an independent and objective perspective. In addition, as the chair of the Compensation Committee and a member of the Nomination Committee, which are discretionary advisory bodies, he has contributed to appropriate decision making at Board meetings and enhanced the accountability of the Company in regard to management nomination and compensation. The Company believes he will contribute to improving the corporate value of the Group by continuing supervision of the management of the Company as an Independent Outside Member of the Board, and thus has selected him as an Outside Member of the Board.



Tsutomu Kamijo
Member of the Board (Outside)

- 1976 Entered Sapporo Breweries (currently, Sapporo Holdings)
- 2001 Board Director of Sapporo Beverage
- 2003 Board Director and Managing Executive Officer of Sapporo Beverage
- 2007 Board Director of Sapporo Holdings
- 2009 Managing Director (Member of the Board) of Sapporo Holdings
- 2011 President and Representative Director of Sapporo Holdings and CEO of the Sapporo Holdings Group
- 2017 Chairman and Representative Director of Sapporo Holdings
- Outside Member of the Board of the Company (current)
- 2018 Outside Member of the Board of Tohoku Electric Power (current)
- 2019 Chairman of Board of Directors of Sapporo Holdings (current)

Relationship with the Company

There are no special conflicts of interest between the Company and Tsutomu Kamijo.

Reason for nomination

Since his appointment in June 2017, Tsutomu Kamijo has fulfilled his duties as an Independent Outside Member of the Board of the Company, based on his abundant experience as a top management figure and wide-ranging knowledge of globalization of the business. He has given advice and proposals from diverse perspectives especially on strategic aspects of each business, and has accurately identified issues in risk management, from an independent and objective perspective. In addition, as a member of the Compensation Committee and the Nomination Committee, which are discretionary advisory bodies, he has contributed to appropriate decision making at Board meetings and enhanced accountability of the Company in regard to management nomination and compensation. The Company believes he will contribute to improving the corporate value of the Group by continuing supervision of the management of the Company as an Independent Outside Member of the Board, and thus has selected him as an Outside Member of the Board.



Kazutoshi Murao
Member of the Board (Outside)

- 1976 Joined NIPPON TELEGRAPH AND TELEPHONE CORPORATION (hereinafter referred to as "NTT")
- 1999 Executive Manager, Secretary Office, NTT
- 2000 General Manager, Kyoto Branch, NIPPON TELEGRAPH AND TELEPHONE WEST CORPORATION (hereinafter referred to as "NTT WEST")
- 2005 Member of the Board, Executive Manager, Corporate Strategy Planning Department, NTT WEST
- 2008 Executive Vice President, Executive Manager, Corporate Strategy Planning Department, NTT WEST
- 2009 Representative Director, Senior Executive Vice President, NTT WEST
- 2012 Representative Director, President, NTT WEST
- 2018 Counselor to the President, NTT WEST (current)
- 2019 Outside Member of the Board of the Company (current)

Relationship with the Company

There are no special conflicts of interest between the Company and Kazutoshi Murao.

Reason for nomination

Kazutoshi Murao assumed office as President of NIPPON TELEGRAPH AND TELEPHONE WEST CORPORATION in 2012, and has wide-ranging knowledge regarding the utilization of diverse human resources and the Company's value system in management for the creation of innovation, thorough compliance and the promotion of safety and health as well as health management. In addition, as a top management figure, he has abundant experience related to resolving social challenges through ICT and initiatives toward achieving SDGs. The Company believes that he can contribute to improving the corporate value of the Group by supervising the management of the Company as an Independent Outside Member of the Board, and thus has selected him as an Outside Member of the Board.

Corporate Auditors (as of August 1, 2019)



Koji Kudo
Corporate Auditor

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



Matsuo Kikuchi
Corporate Auditor

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



Tadashi Fukuda
Corporate Auditor (Outside)

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



Hiroshi Enoki
Corporate Auditor (Outside)

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



Mitsue Maru
Corporate Auditor (Outside)

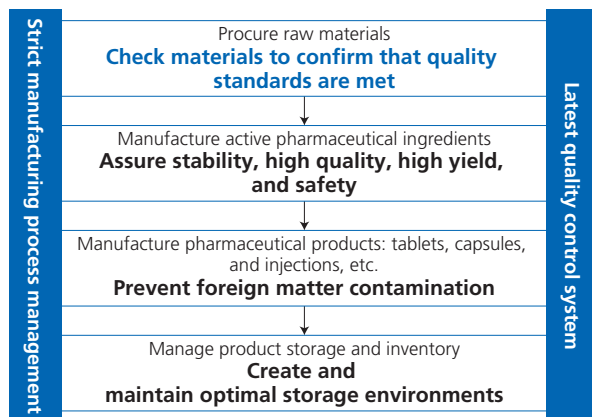
- 1987 Nurse at National Hospital Medical Center
- 1992 Assistant, Department of Nursing, Chiba University
- 1999 Completed Doctorate Course of University of Alabama at Birmingham School, and Obtained Doctorate (Mother-Child Nursing)
- 2000 Assistant Professor, Department of Nursing, Kitasato University
- 2005 Associate Professor of Development in Pediatric and Family Nursing, Graduate School of Tokyo Medical and Dental University
- 2009 Professor of International Nursing Development Graduate School of Tokyo Medical and Dental University
- 2014 Professor of International Nursing Development Department of Nursing and Rehabilitation, Konan Women's University (current)
- 2019 Outside Corporate Auditor of the Company (current)



Reliable Products and Sustainable Supply

Quality of products

Our policy is to contribute to the health and well-being of people around the world through the stable supply of high quality, reliable products which are manufactured under a world-class quality system. On that basis, we are strictly observing the ministerial ordinance on GMP (regulations regarding pharmaceutical manufacturing control and quality control) and on GQP (regulations regarding pharmaceutical quality control). 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 manufacturing sites in Japan and overseas, we are working to improve the quality of the products that we provide to the market.



Pharmaceutical manufacturing process

The Mitsubishi Tanabe Pharma Group manufactures and supplies high-quality pharmaceuticals and strictly manages

product quality from acceptance testing of raw materials procured in Japan and abroad to the manufacture of GMP-compliant pharmaceutical ingredients and preparations as well as testing and inspection, thus supplying premium quality products which patients and healthcare professionals can use safely and with peace of mind. As a global research-driven pharmaceutical company, we manufacture pharmaceuticals based on a wide range of technologies and proprietary knowhow developed over many years.

To further ensure quality, the Production Technology & Supply Chain Management Division and the Global Quality Assurance Department collaborate with the Group's manufacturing plants to develop production technologies to enhance quality, stabilize supply, and reduce costs from the early development stages of new pharmaceutical products. In addition, the Group's manufacturing plants (two in Japan and four overseas) together with manufacturing subcontractors are creating a global production system that delivers a stable supply of our products to many people around the world.

In June 2016, we built a domestic manufacturing facility within the Yoshitomi Plant for solid dosage formulations. This highly productive facility can supply pharmaceuticals in accordance with global quality standards, while further contributing to both the improvement of manufacturing technologies and the reduction of manufacturing costs.

In addition, BIKEN, a joint venture with the BIKEN Foundation's vaccine manufacturing business, began operation in September 2017. By integrating BIKEN Foundation's vaccine manufacturing technologies together with Mitsubishi Tanabe Pharma's pharmaceutical manufacturing systems and management methods, we are strengthening our platform in vaccine production in order to contribute to an even more stable supply of vaccines.



Solid dosage formulation production facility at the Yoshitomi Plant

(Related SDGs)



Appropriate Use of Products

■ New drug safety management

After the launch of a new drug, adverse reactions that were not discovered in clinical trials are sometimes reported. We quickly collect that information, analyze it, and provide feedback to the medical front lines. We are moving forward with proactive safety management activities that incorporate new safety measures. We believe that these activities help prevent the expansion of adverse reactions from new drugs and promote appropriate usage on the medical front lines.

Edaravone (Japan product name: Radicut), which was discovered by the Company, was approved as an ALS treatment agent in the U.S. in 2017 (U.S. product name: Radicava). Currently, we are advancing global initiatives with a view to other countries and regions. When Radicava is used overseas, it is used in a medical environment that is different from that in Japan, and accordingly it will be necessary to exercise caution in safety management. We have experience promoting proper use based on the abundant safety information we have accumulated. Making full use of that experience, and giving consideration to the overseas regulatory and medical environments, we will work to collect and provide safety information to foster the proper use of Radicut/Radicava and to contribute to improvement in the quality of life of ALS patients.

■ Providing comprehensive information through the Medical Information Center

Mitsubishi Tanabe Pharma has established its own Medical Information Center to respond directly to inquiries from patients and healthcare professionals (physicians,

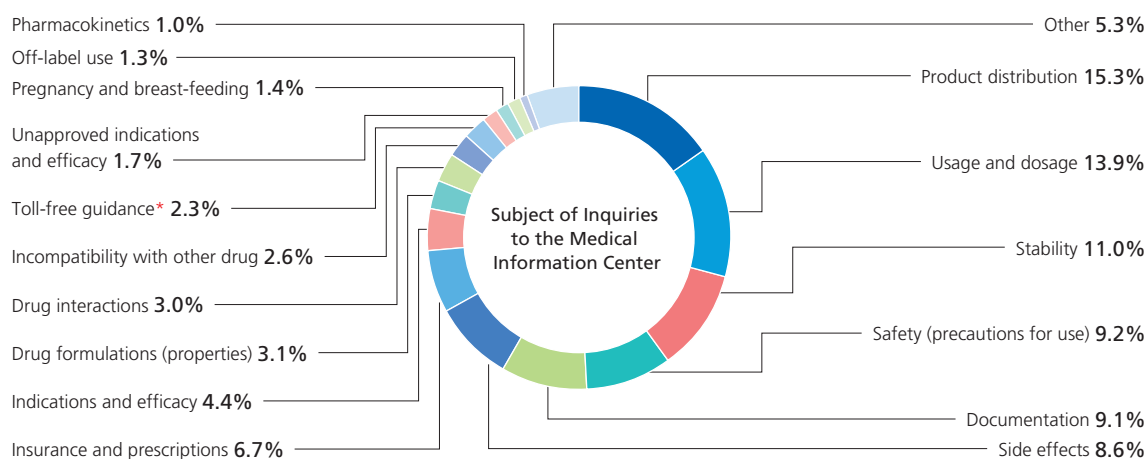
pharmacists, wholesalers, and others). For patients, this is the only company information center. With a motto of “reliable, accurate, and prompt,” the center provides information that is easy to understand while at the same time making certain not to dispense the type of medical advice that should only come from a physician. We are working each day to improve our skills so that we identify the true needs behind the inquiries and respond in a way that increases the satisfaction of the people making inquiries.

The Medical Information Center receives more than 50,000 inquiries a year on a wide range of subjects. It also provides information on the appropriate use of the Company’s products while utilizing basic pharmaceutical information and the in-house Q&A system.

Furthermore, information that the center receives about safety and quality, such as information about side effects, is shared with related departments. In this way, the center helps improve product reliability. In addition, since October 2017 we have been building a framework for effectively sharing within the Company the valuable information that is collected by the center. We are working to reflect customer feedback in product improvements and in the future discovery of new products.

From April 2019, we will be in charge of maintaining pharmaceutical information at the Medical Information Center including the creation of product Q&As provided through our website. We will reflect the needs of customers more rapidly than before, which will help us to provide valuable information. Moving forward, the center will respond flexibly to changes in the times and provide appropriate usage information for pharmaceuticals in a reliable, accurate, and prompt manner. In this way, we will work to contribute to improved health for patients.

Subject of inquiries to the Medical Information Center (FY 2018)



* Toll-free guidance to redirect consumers by providing the correct contact information

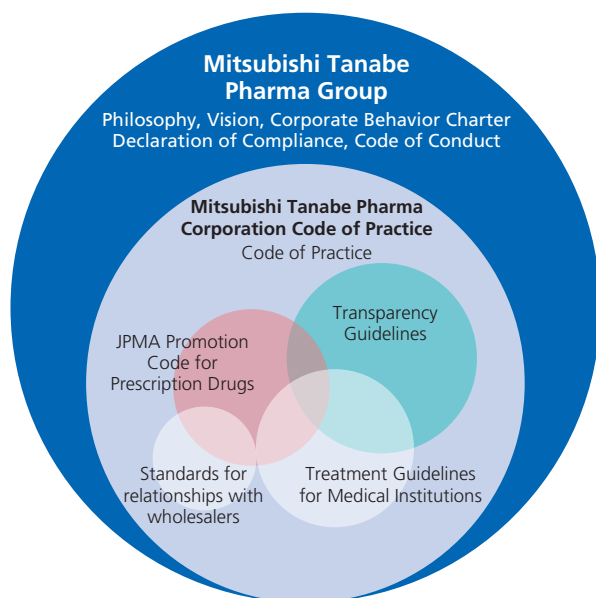


Ethics, Fairness and Sincerity in Business Practices

Code of Practice

The Japan Pharmaceutical Manufacturers Association (JPMA), of which Mitsubishi Tanabe Pharma is a member company, put the JPMA Code of Practice into effect in 2013. This establishes behavioral standards that must be observed by the executives and employees of the member companies in their interactions with researchers, healthcare professionals, patient organizations, wholesalers, etc. In response, the Company established and put into effect the Mitsubishi Tanabe Pharma Corporation Code of Practice. All executives and employees of the Company as well as its affiliated companies in Japan are required to follow this code not only in promotion endeavors designed for healthcare professionals, medical institutions, and others, but also in all other corporate activities, including testing and R&D, information provision activities, cooperation with patient organizations, and relationships with wholesalers. Overseas Group companies comply with the codes of each country based on the International Federation of Pharmaceutical Manufacturers and Associations' Code of Practice (IFPMA Code).

Positioning of the Code of Practice



Compliance training

The Group conducts the following training programs for the purpose of fostering a strong sense of ethics, raising awareness of compliance requirements, and cultivating greater awareness of compliance-related issues among all employees.

Groupwide compliance training

We implement e-learning with the aim of ensuring rigorous compliance and raising human rights awareness, which are parts of the foundation of our business operations, in order to realize the corporate philosophy and vision.

Divisional compliance training

We offer divisional training that focuses on specific topics relevant to each division, principally for compliance implementation personnel, including managers and staff.

Compliance and risk management check

Through e-learning we confirm understanding of such matters as laws, regulations, and internal rules. This enables officers and employees to act in accordance with consistent evaluation standards.

List of training sessions held in fiscal 2018

	Times held	Number of participants
Groupwide compliance training	Once a year	5,376
Divisional compliance training	Once a year	5,385
Compliance and risk management check	Twice a year	July 2018 5,300
		February 2019 5,137

Hotlines

The Mitsubishi Tanabe Pharma Group's internal and external hotlines allow employees and managers to obtain consultation and make reports about any actual or possible violation of laws, ordinances, or social conventions. The use of the hotlines leads to the prevention or reduction of scandals, etc., before major problems develop.

In addition, reports on recent trends and issues warranting special mention are included in regular compliance training sessions, which helps promote use of the hotline and prevent recurrence.

Number of hotline consultations handled in fiscal 2018

Workplace environment	Working condition/human resources	Embezzlement/misappropriation	Laws regulations, and rules	Other	Total
9	2	0	4	7	22





Stakeholder Engagement

■ Patients and their families

On its website, the Company provides a variety of disease-related information for patients and their families so that they can acquire accurate knowledge that is useful in disease prevention and treatment.



WEB	Discussions about diseases (Japanese only) https://www.mt-pharma.co.jp/shared/show.php?url=../general/index.html#n01	
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We have established the Medical Information Center to handle inquiries about the Company's products. In addition, Group company Mitsubishi Tanabe Pharma America provides information to ALS patients in the U.S. through Searchlight Support.

WEB	Medical Information Center (inquiries) https://www.mt-pharma.co.jp/e/inquiry/index.php	
WEB	Searchlight Support https://www.radicava.com/patient/support/searchlight-support/	


■ Healthcare professionals

We are actively providing pharmaceutical information through MRs. In addition, we have established information sites for healthcare professionals. In these ways, we are providing information regarding appropriate usage of ethical drugs. Furthermore, we provide information through the Community Pharmacist Support Net (CPS-net) for pharmacists and registered sales representatives who sell OTC products.

WEB	Medical View Point (for healthcare professionals) (Japanese only) https://medical.mt-pharma.co.jp/	
WEB	CPS-net (pharmacists, registered sales representatives) (Japanese only) https://cps-net.jp/	

■ Shareholders and investors

In addition to disseminating information through the Tokyo Stock Exchange's Company Announcement Disclosure Service (TDnet), the Company has opportunities for direct communication, such as the general meeting of shareholders, IR meetings for institutional investors (results briefings, business presentations, etc.), individual visits with overseas investors (U.S., Europe, and Asia), and briefings for individual investors. The Fair Disclosure rules (FD rules) have taken effect, and in response the Company has formulated Disclosure Policy for the continuation of fair, timely, and appropriate information disclosure and the implementation of constructive dialog.

WEB	Shareholders and Investors https://www.mt-pharma.co.jp/e/ir/index.php	
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■ Employees

Mitsubishi Tanabe Pharma is working to further enhance its competitiveness and achieve sustained growth by focusing on its people as a management resource and giving individual employees the opportunity to demonstrate their full potential. To that end, we have established the Comprehensive Management System for Human Resources, career interviews, and a complete training system. In addition, we are taking steps to enhance mutual understanding and communication between the Company and employees, such as holding labor consultations, operating internal and external hotlines, and implementing an employee survey. Moreover, we are providing corporate information to employees by utilizing an in-house magazine and the Company intranet.

■ Local communities

The Group has formulated its Corporate Citizenship Policy. Through educational activities at schools, company tours, local events, and the Mitsubishi Tanabe Historical Museum, we are deepening understanding of the Company, conducting active communication with people in the areas where we do business, and striving to coexist in harmony with local communities.

WEB	Promotion of Local Communities https://www.mt-pharma.co.jp/shared/show.php?url=../e/company/csr-report/community/local_communities.html	
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Employee Health, Diversity and Inclusion

(Related SDGs)



Health management initiatives

In April 2016, the Group established the MTPC Group Health Policy based on its corporate philosophy, vision, and Corporate Behavior Charter and is promoting activities related to employee health effectively and appropriately.

MTPC Group Health Policy

1. We will strive to maintain our own health so that we can contribute to the health of people around the world.
2. We will leverage our own capabilities and advance the establishment of an environment in which we can work energetically.

In fiscal 2018, we were recognized for the third consecutive year under the “Outstanding Enterprise in Health and Productivity Management White 500” (large enterprise category), a recognition system that is promoted by the Ministry of Economy, Trade and Industry. The Company’s evaluations in the categories of “systems/policy implementation” and “evaluation/improvement” improved from the previous year, and it has received the highest evaluation in the industry, particularly in the category of “measures and policies not limited to risk holders.”



Actively utilizing diverse human resources

The Group has positioned its approach to diversity and inclusion as one of its management strategies. We have organized that approach into the Diversity Promotion Circle, and we are advancing initiatives on that basis.

The Diversity Promotion Circle has the objective of leveraging diverse human resources and maximizing results and the Company develops those human resources to maximize the potential of diverse employees, establishes systems and frameworks that make it easy for diverse employees to do their jobs, and provides opportunities for a diverse range of people. Managers implement diversity management to draw on the capabilities of diverse employees and maximize results, and each employee generates synergies.

In regard to diversity, we take into account both visible diversity (gender, sexual orientation and gender identity (including LGBT¹), age, career background, nationality, disability status, time restrictions due to childcare, nursing care, etc.) and non-visible diversity (knowledge, skills,

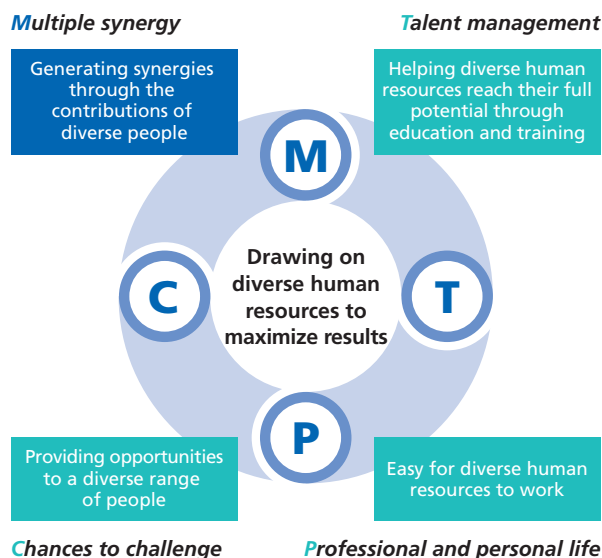
experiences, values, ways of thinking, etc.). By appreciating these differences and leveraging them, we seek to maximize our results.

In fiscal 2018, all employees undertook e-learning compliance training and departmental training based on the themes of diversity promotion and LGBT. We continued to implement nursing care seminars and www28 training (www: an abbreviation for Win-Win- Woman), which considers the careers of women who have not yet experienced such life events as marriage and childbirth. As a so-called “Ikuboss”-related measure to encourage subordinates to fulfill both work and personal matters, we fostered awareness of men’s participation in childcare and child-care leave through the distribution of folded triangular shaped signs that describe the Ikuboss Declaration and holding of the Ikuboss Award to commend the company’s best practices.

On the system side, we revised the rules of employment by adding harassment-related behavior and made them subject to disciplinary action. Specifically, the declaration clearly states that sexual harassment includes sexual orientation such as LGBT, discrimination and harassment based on sexual identity, and that maternity and paternity harassment^{2,3} are also subject to disciplinary action. The declaration was widely distributed through compliance and harassment prevention guidebooks.

- 1 LGBT is an acronym for L: lesbian, G: gay, B: bisexual, T: transgender, and is a generic term for a sexual minority.
- 2 Maternity harassment is workplace discrimination against women due to pregnancy and the need to provide childcare.
- 3 Paternity harassment is workplace discrimination against fathers who have taken paternal leave to help with childcare.

Diversity promotion circle



Social Contribution Activities for Health

(Related SDGs)



■ The Mitsubishi Tanabe Pharma Tenohira Partner Program

The Company believes in the importance of providing support for patients with diseases and their families, and in 2012 established the Mitsubishi Tanabe Pharma Tenohira Partner Program. This program provides aid for the activities of associations and support groups for patients with intractable diseases. These organizations work to improve patients' medical treatment, education, and career prospects and to enhance their quality of life. In fiscal 2018, support was provided to 21 organizations. We established "startup grants" to support organizations that do not yet have extensive track records of activity, and have made it possible to support more organizations.

At meetings held in October 2018 to report on the fiscal 2017 activities of organizations receiving assistance under the Mitsubishi Tanabe Pharma Tenohira Partner Program (14 organizations), participants shared their opinions about challenges and solutions in conducting activities that transcend each other's diseases. The Tenohira Partner Program strives to support people fighting disease, to assist them in finding more joy and satisfaction in their lives, and to help them realize their dreams and hopes for the future. On that basis, we will continue to offer support.

In fiscal 2019, we will support nine startup grants and 10 project grants, for a total of 19 organizations.

■ Participation in the Global Health Innovative Technology Fund (GHIT Fund)

The GHIT Fund aims to discover new drugs for infectious diseases that affect people in the developing world, such as malaria, tuberculosis, and neglected tropical diseases. To that end, the GHIT Fund was established as a public-private partnership from Japan. Through new drug R&D capabilities that utilize the advanced science and technology know-how of Japanese pharmaceutical companies and other institutions, the fund aims to strengthen Japan's international contribution to global health.

In May 2015, through the GHIT Fund, the Company provided its pharmaceutical compound library (50,000 compounds) to Medicines for Malaria Venture, a research institution that focuses on the discovery of new anti-malaria drugs. Three types of promising hit compounds that have the potential to become pharmaceutical products have been identified. In addition, we promoted joint research and from one of these compounds, we acquired two lead compounds as new anti-malaria drug candidates.

Further, following the provision of financial support for the GHIT Fund first phase activities (fiscal 2013 – fiscal 2017),

the Company will also provide financial support to the GHIT Fund for second phase activities (fiscal 2018 - fiscal 2022).

■ Participating in vaccine support activities

The Group has been participating in vaccine support activities for children in developing countries since 2014. Through this program, unneeded books, CDs and DVDs are donated and the proceeds from their sale are donated to Authorized NPO Japan Committee Vaccines for the World's Children. Through this international contribution activity, those donations are used to deliver vaccines to children in developing countries, such as vaccines for six major infectious diseases. The price of polio vaccine is only ¥20 per person. One book that is sitting on a shelf can save two children from polio.

In fiscal 2018, a total of ¥289,982, equivalent to polio vaccines for 14,500 children, was raised from employee donations and matching gifts from the Company.



Original poster

■ Development of science and technology support for research foundations

Mitsubishi Tanabe Pharma provides financial assistance for the activities of research foundations to promote research and provide information in a broad range of fields including medicine, pharmaceuticals, agriculture, and the physical sciences and to thereby contribute to medical treatment and public health.

SENSIN Medical Research Foundation

This foundation was established in 1968 with support from the former Yoshitomi Pharmaceutical Industries. The foundation aims to contribute to the medical treatment and health of consumers by promoting advanced research in the fields of medicine and pharmacology. In fiscal 2018 the foundation provided 102 grants with a total amount of ¥135.0 million.

Japan Foundation for Applied Enzymology

This foundation was established in 1964 with support from the former Tanabe Seiyaku. The foundation aims to contribute to the development of various fields in the life sciences in Japan by supporting research on enzymes and other molecules affecting the regulation and maintenance of biological functions. In fiscal 2018, the foundation provided 132 grants with a total amount of ¥73.0 million.

Environmental Initiatives

(Related SDGs)



■ Environmental management

Based on its Environmental and Safety Policy, the Group works to continually reduce its environmental impact and thereby help protect the global environment and realize a sustainable society by actively promoting resource and energy conservation, waste reduction and other initiatives in all its business activities. In addition, the Group voluntarily engages in environmentally conscious activities, appropriately discloses environmental information and promotes environmental communication on environmental and social contribution activities and other topics.

■ Addressing environmental risks

In recent years, climate change has become more apparent and there are growing calls around the world for measures to address climate change risk. In addition, water-related risks, such as water depletion, flooding, and water pollution, are susceptible to the influence of climate change. Moving forward, the Group will track and analyze the relationship between its business activities and climate change risk and water-related risks, and will identify risks that affect business operations and identify available opportunities.

■ Receipt of the Excellence Award in the Environmental Report Section of the 22nd Environmental Communication Awards

In February 2019, the Mitsubishi Tanabe Pharma Corporate Report 2018 and CSR Activities Report 2018 received the Excellence Award for the second consecutive year in the Environmental Report Section of the 22nd Environmental Communication Awards, which is sponsored by the Ministry of the Environment and the Global Environmental Forum. This award was presented to MTPC for its ambitious approach to environmentally friendly management and proactive information disclosure; specifically, its description of the results of taking on challenging targets to reduce CO₂ emissions and its extensive and thorough disclosure of CSR-related data.



WEB

Refer to the following URL for more details on environmental activities. Key environmental performance indicators have acquired third-party certification in order to raise the reliability of information disclosed to stakeholders.

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



■ Medium-Term Environmental Action Plan (2016 – 2020): Principal objectives and results in fiscal 2018

The Group has set four priority issues of its environmental activities as the themes of its Medium-Term Environmental Action Plan and continues to reduce its environmental impact. Specifically, as climate change measures, “energy conservation and global warming mitigation” have been positioned as the most important environmental theme.

Area	Medium-Term Action Objectives (2020)	Principal Initiatives and Results in Fiscal 2018
Energy conservation and global warming mitigation	<ul style="list-style-type: none"> ● Reduce CO₂ emissions (production/research bases, offices) for fiscal 2020 compared to fiscal 2010 <ul style="list-style-type: none"> • Japan: by at least 40% • Global: by at least 35% ● Track supply chain CO₂ discharge ● Appropriately manage fluorocarbons 	<ul style="list-style-type: none"> ● CO₂ emissions <ul style="list-style-type: none"> • Japan: 40% reduction (vs. fiscal 2010) • Global: 32% reduction (vs. fiscal 2010) ● Scope 3 emissions in categories 1, 2, 3, 4, 5, 6, 7, and 12 were tracked, calculated, and disclosed in the CSR Activities Report ● Conduct simple regular inspections ● Amount of fluorocarbon recovered and destroyed: 417kg; amount of leakage: 118kg (350t-CO₂eq), and since both are small amounts, government reporting is not required
Reduction of waste, effective use of water resources	<ul style="list-style-type: none"> ● Reduce amount of waste generated and maintain zero emissions (final waste disposal rate of less than 0.5%) (Japan Group) ● Fulfill the responsibility of a waste discharging enterprise for handling waste correctly and ensuring proper treatment by contractors ● Water usage volume: Reduce by 15% or more by fiscal 2020 compared to fiscal 2010 both in Japan and overseas (production and research bases) 	<ul style="list-style-type: none"> ● Japan: Amount of waste generated by 53% reduction (vs. fiscal 2017) ● Final waste disposal rate for Japan: 0.59% ● Advanced manifest digitalization ● Thorough internal evaluation of waste processing contractors ● Amount of water used <ul style="list-style-type: none"> • Japan: 45% reduction (vs. fiscal 2010) • Global: 46% reduction (vs. fiscal 2010)
Chemical substance emissions reductions	<ul style="list-style-type: none"> ● Properly manage chemical substances and continually reduce their discharge into the environment ● Reduce the discharge of toluene by more than 30% by fiscal 2020 in comparison with fiscal 2010 	<ul style="list-style-type: none"> ● Chemical substance environmental emissions (air and public waters) in Japan <ul style="list-style-type: none"> • PRTR-listed substances: 5.1% reduction (vs. fiscal 2017) • VOC (excluding PRTR-listed substances: 4.2% reduction (vs. fiscal 2017) ● Emissions of toluene to the environment: Decrease of 32% (vs. fiscal 2010)
Preservation of biodiversity	<ul style="list-style-type: none"> ● Understand the relationship between business activities and biodiversity and promote biodiversity initiatives 	<ul style="list-style-type: none"> ● Advanced environmental conservation activities, such as planting at Ikoma Mountain (Osaka Prefecture) and natural woodland conservation in the Hachioji Takiyama Area (Tokyo Prefecture)

Operating Results and Data

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WEB

For the CONSOLIDATED FINANCIAL STATEMENTS AND INDEPENDENT AUDITOR'S REPORT, please use the following URL.

[https://www.mt-pharma.co.jp/
shared/show.php?url=../e/ir/annual/index.html](https://www.mt-pharma.co.jp/shared/show.php?url=../e/ir/annual/index.html)



10-Year Financial Summary

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

	FY 2009	FY 2010	FY 2011	FY 2012
Financial figures (billions of yen)				
Revenue	404.7	409.5	407.1	419.1
Cost of sales	147.8	154.5	152.2	166.4
SG&A expenses	195.4	178.3	185.8	183.8
Operating profit	61.4	76.5	69.0	68.9
Profit attributable to owners of the Company	30.2	37.7	39.0	41.8
R&D expenses	83.0	65.7	70.2	66.5
Capital expenditures ²	9.1	11.0	8.3	11.4
Depreciation and amortization	13.2	12.4	12.4	8.4
Total assets	796.8	818.7	819.9	866.7
Total equity	676.8	695.9	721.4	752.9
Net cash provided by operating activities	23.9	59.0	37.2	60.5
Net cash used in investing activities	(61.2)	(7.6)	(63.2)	(34.9)
Net cash used in financing activities	(17.1)	(15.4)	(17.1)	(23.6)
Cash and cash equivalents at the end of the year	62.9	97.8	54.3	58.7
Per share amounts (yen)				
Profit attributable to owners of the Company	53.91	67.27	69.54	74.67
Equity attributable to owners of the Company	1,194.79	1,230.16	1,275.85	1,333.22
Cash dividends	28.00	28.00	35.00	40.00
Financial indicators (%)				
Cost of sales ratio	36.5	37.7	37.4	39.7
SG&A expenses ratio	48.3	43.6	45.6	43.9
Operating margin	15.2	18.7	17.0	16.5
R&D expenses ratio	20.5	16.1	17.3	15.9
Ratio of equity attributable to owners of the Company to total assets	84.1	84.3	87.3	86.3
ROE	4.6	5.5	5.5	5.7
Dividend payout ratio	39.0 ⁴	41.6	50.3	53.6
Others				
Number of employees	9,266	9,198	9,180	8,835
Number of common stock issued (thousands)	561,417	561,417	561,417	561,417

1. In the first six months of the fiscal year ended March 31, 2019, the Company finalized the purchase price allocation for the acquisition of NeuroDerm Ltd. Hence, a retroactive adjustment of the comparative amount for the previous fiscal year listed in the Condensed Consolidated Statements of Financial Position was made.

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

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

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

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

						(Billions of yen)
FY 2013	FY 2014	FY 2015	FY 2016	FY 2017 ¹	FY 2018	
412.6	415.1	425.7	423.9	433.8	424.7	
169.3	169.5	155.8	164.3	169.7	180.6	
184.1	178.3	96.3	98.3	104.0	98.2	
59.1	67.1	81.8	94.0	77.2	50.3	
45.3	39.5	59.3	71.2	57.9	37.3	
70.4	69.6	64.6	64.7	79.0	86.5	
14.7	17.3	12.1	14.4	6.0	8.5	
9.1	9.0	10.3	10.4	11.5	11.5	
886.4	929.3	958.4	984.5	1,048.4	1,056.2	
777.8	800.4	826.3	871.4	894.8	910.3	
69.8	68.1	80.8	59.7	66.9	41.4	
(24.3)	(59.8)	(42.2)	(10.5)	(19.1)	(31.2)	
(21.0)	(21.8)	(22.2)	(24.4)	(32.5)	(25.8)	
84.9	73.3	88.9	113.2	127.0	111.8	
						(yen)
80.92	70.41	105.72	127.03	103.35	66.64	
1,365.52	1,406.41	1,453.71	1,533.91	1,574.26	1,600.64	
40.00	42.00	46.00	52.00	66.00 ³	56.00	
						(%)
41.0	40.9	36.6	38.8	39.1	42.5	
44.6	43.0	22.6	23.2	24.0	23.1	
14.3	16.2	19.2	22.2	17.8	11.8	
17.1	16.8	15.2	15.3	18.2	20.4	
86.4	84.9	85.1	87.4	84.2	85.0	
6.0	5.1	7.4	8.5	6.6	4.2	
49.4	59.6	43.5	40.9	63.9	84.0	
						(%)
9,065	8,457	8,125	7,280	7,187	7,228	
561,417	561,417	561,417	561,417	561,417	561,417	

Value Creation Story

Business and Financial Strategy

Non-Financial Information

Operating Results and Data

Management's Discussion and Analysis

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

Revenue

In fiscal 2018, revenue decreased by ¥9.0 billion year on year, to ¥427.7 billion. The pharmaceuticals segment, which is the Company's only segment, comprises domestic ethical drugs, overseas ethical drugs, royalty revenue, etc., OTC products, and other in pharmaceuticals.

Revenue of domestic ethical drugs decreased by 3.4%, year-on-year, to ¥298.7 billion. There was an increase in sales, contributed to by priority products such as SIMPONI, a treatment agent for rheumatoid arthritis (RA); CANALIA, a type 2 diabetes mellitus treatment agent launched in September 2017; and STELARA, a treatment for Crohn's disease, among others, jointly promoted with Janssen Pharmaceutical K.K. following the updating of the co-promotion framework in July 2018. Yet, in spite of this, the NHI drug price revision of April 2018 and the transfer of the generic drug business in October 2017 had a net negative impact on revenue.

On the other hand, revenue from overseas ethical drugs increased 42.9%, to ¥55.1 billion, with a strong contribution from Radicava, an amyotrophic lateral sclerosis (ALS) treatment agent, which was launched in the U.S. in August 2017.

Royalty revenue, etc. was down 20.3% year on year, to ¥63.1 billion, primarily due to decreases in royalty revenue from Gilenya, a treatment agent for multiple sclerosis licensed to Novartis; from Invokana, a treatment agent for type 2 diabetes mellitus; and from the fixed dose combination of Invokana and metformin, which are both licensed to Janssen Pharmaceuticals.

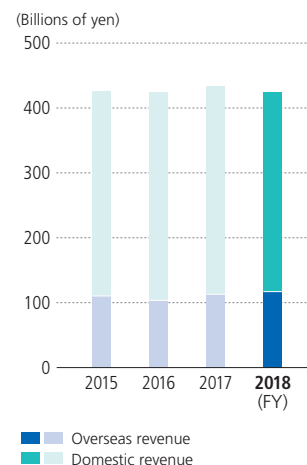
In addition, revenue from OTC products was up ¥0.0 billion, at ¥3.7 billion (the same as the previous year), and revenue from the "Other" category of pharmaceuticals operations increased ¥0.9 billion over the previous year, to ¥3.9 billion.

Overseas revenue rose ¥4.0 billion, to ¥117.0 billion, and the overseas revenue ratio was up 1.6 percentage points, to 27.6%.

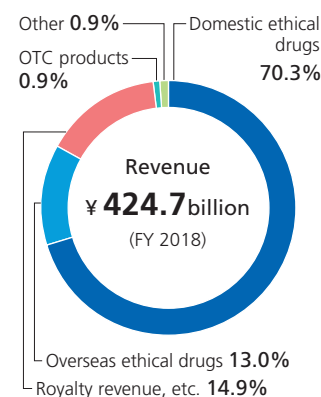
	FY 2017	FY 2018		Change	% Change
Revenue	433.8	424.7	(100.0)	-9.0	-2.1
Domestic ethical drugs	309.3	298.7	(70.3)	-10.5	-3.4
Overseas ethical drugs	38.5	55.1	(13.0)	+16.5	+42.9
Royalty revenue, etc.	79.1	63.1	(14.9)	-16.0	-20.3
OTC products	3.7	3.7	(0.9)	+0.0	+1.0
Other	3.0	3.9	(0.9)	+0.9	+30.9
Revenue by region:					
Domestic	320.8	307.7	(72.4)	-13.1	-4.1
Overseas	112.9	117.0	(27.6)	+4.0	+3.6

Note: Figures in parentheses are percentages of revenue.

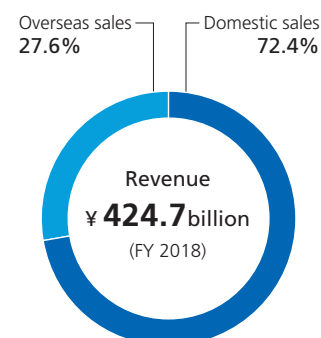
Revenue



Percentage of revenue by business



Percentage of revenue by region



Revenue from major ethical drugs

	(Billions of yen)			
	FY 2017	FY 2018	Change	% Change
Domestic ethical drugs				
Priority products in fiscal 2018	140.0	162.6	+22.6	+16.1
Remicade	64.6	58.8	-5.8	-9.1
Simponi	32.1	37.4	+5.3	+16.7
Tenelia	17.5	15.2	-2.3	-13.3
Stelara	0.3	15.2	+14.8	-
Lexapro	12.7	14.0	+1.2	+9.7
Canalia	1.8	7.4	+5.6	+310.8
Canaglu	5.6	6.7	+1.1	+19.9
Imusera	4.7	4.3	-0.3	-8.2
Rupafin	0.4	3.4	+3.0	-
Vaccines	35.0	37.3	+2.2	+6.4
Influenza vaccine	9.9	10.2	+0.3	+3.1
Tetrabik	8.7	8.5	-0.1	-2.1
Mearubik	5.0	6.8	+1.8	+37.0
JEBIK V	5.2	5.5	+0.3	+5.8
Varicella vaccine	5.2	5.1	-0.1	-3.5
Overseas ethical drugs				
Radicava	12.3	27.0	+14.7	+119.9
Royalty revenue, etc.				
Royalties from Gilenya	57.7	49.7	-7.9	-13.8
Royalties from Invokana	13.9	10.5	-3.4	-24.4

Core operating profit

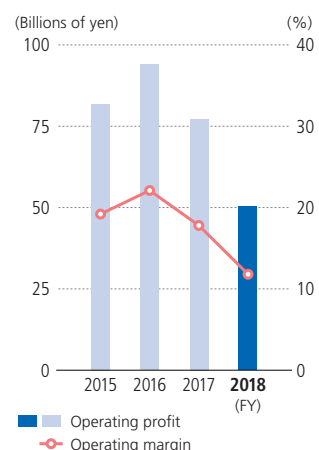
With the adoption of IFRS, the Company, its subsidiaries and its affiliates (collectively, "the Group") has introduced "core operating profit" as a major profit index to demonstrate its recurring profitability and positioned it as an important indicator of business management, etc. "Core operating profit" is profit excluding the income and loss recorded by non-recurring items specified by the Group (hereinafter "non-recurring items") from operating profit. Non-recurring items include gain or loss associated with a business transfer, restructuring loss, and impairment losses on intangible assets associated with products.

In fiscal 2018, core operating profit decreased ¥22.7 billion year on year, to ¥55.8 billion. There was sales growth from domestic priority products and Radicava in the U.S. and a decrease in SG&A expenses owing to promotion of operational productivity reforms, but NHI drug price revisions and the decline in royalty revenue had a negative impact, and R&D expenses increased with advancement to late-stage development and the acquisition of NeuroDerm Ltd. The decrease in core operating profit is attributable mainly to these factors.

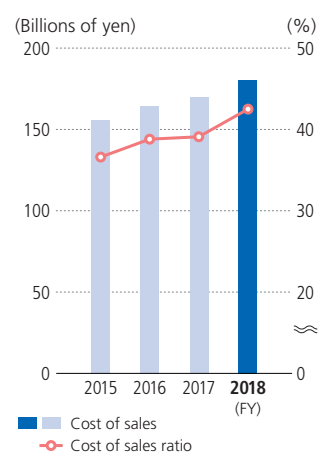
SG&A expenses decreased ¥5.8 billion, to ¥98.2 billion. In addition, R&D expenses increased ¥7.4 billion, to ¥86.5 billion, and the R&D expenses ratio was up 2.2 percentage points year on year, to 20.4%.

The cost of sales ratio was up 3.4 percentage point, to 42.5%, but gross profit was down ¥19.9 billion, to ¥244.1 billion, due to the increase in revenue.

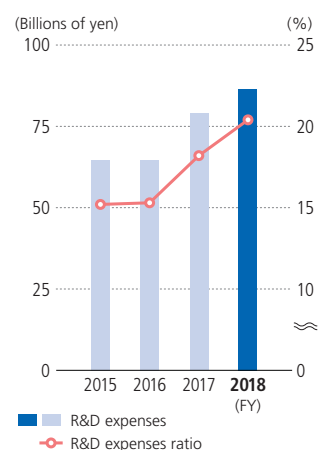
Operating profit / Operating margin



Cost of sales / Cost of sales ratio



R&D expenses / R&D expenses ratio



Management's Discussion and Analysis

Operating profit

Operating profit was down ¥26.9 billion year on year to ¥50.3 billion. In non-recurring items, restructuring expenses and impairment losses were recorded. Non-recurring items in fiscal 2018 were a loss of ¥5.5 billion, compared with a loss of ¥1.2 billion in the previous fiscal year.

The operating margin declined 6.0 percentage points, to 11.8%.

Profit attributable to owners of the Company

As a result of the decrease in operating profit, profit attributable to owners of the Company was down ¥20.5 billion year on year to ¥37.3 billion.

	(Billions of yen)				
	FY 2017	FY 2018		Change	% Change
Cost of sales	169.7	180.6	(42.5)	+10.8	+6.4
Gross profit	264.1	244.1	(57.5)	-19.9	-7.6
SG&A expenses	104.0	98.2	(23.1)	-5.8	-5.6
R&D expenses	79.0	86.5	(20.4)	+7.4	+9.4
Core operating profit	78.5	55.8	(13.1)	-22.7	-28.9
Operating profit	77.2	50.3	(11.8)	-26.9	-34.9
Profit attributable to owners of the company	57.9	37.3	(8.8)	-20.5	-35.5

Note: Figures in parentheses are percentages of revenue.

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

Total assets, total liabilities, and total equity

Total assets at the end of the fiscal year were ¥1,056.2 billion, an increase of ¥7.8 billion from the previous fiscal year-end.

Total non-current assets increased ¥4.9 billion year on year, to ¥467.8 billion. Deferred tax assets increased ¥6.9 billion, and intangible assets increased ¥5.9 billion due primarily to product-related increases from currency fluctuations. At the same time, property, plant and equipment decreased ¥7.1 billion due largely to impairment associated with the closure of the Company's Toda Office, and net defined benefit assets declined ¥1.2 billion.

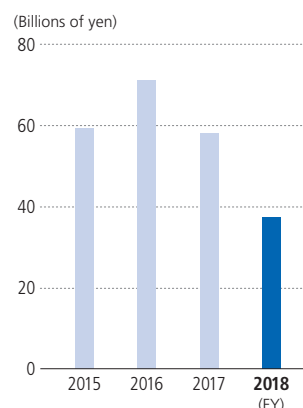
Total current assets increased ¥2.9 billion year on year, to ¥588.4 billion. Other financial assets increased ¥24.6 billion from an increase in securities, but cash and cash equivalents declined ¥15.1 billion and trade and other receivables decreased ¥6.5 billion.

Total liabilities were down ¥7.6 billion from the end of the previous fiscal year, to ¥145.9 billion. Income taxes payable were down ¥8.5 billion.

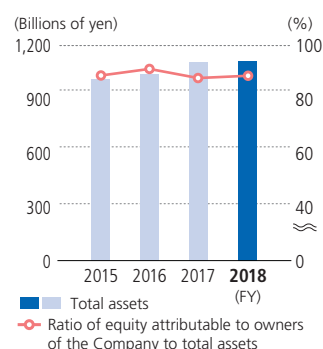
Total equity at the end of the period was up ¥15.5 billion from the end of the previous fiscal year, to ¥910.3 billion. Profit attributable to owners of the Company was ¥37.3 billion, while dividends paid were ¥31.4 billion. As a result, retained earnings increased ¥5.8 billion.

Consequently, the ratio of equity attributable to owners of the Company to total assets increased 0.8 percentage points, to 85.0%.

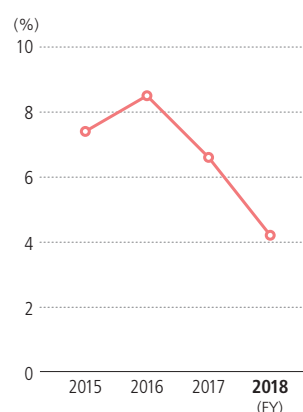
Profit attributable to owners of the Company



Total assets / Ratio of equity attributable to owners of the Company to total assets



ROE



	(Billions of yen)				
	At the end of FY2017	At the end of FY2018		Change	% Change
Total assets	1,048.4	1,056.2	(100.0)	+7.8	+0.7
Non-current assets	462.9	467.8	(44.3)	+4.9	+1.1
Current assets	585.5	588.4	(55.7)	+2.9	+0.5
Total liabilities	153.6	145.9	(13.8)	-7.6	-5.0
Non-current liabilities	55.4	54.2	(5.1)	-1.1	-2.1
Current liabilities	98.1	91.6	(8.7)	-6.4	-6.6
Total equity	894.8	910.3	(86.2)	+15.5	+1.7
Total liabilities and equity	1,048.4	1,056.2	(100.0)	+7.8	+0.7

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

Cash flows

Net cash provided by operating activities was ¥41.4 billion. Inflows, which included profit before income tax of ¥50.4 billion, exceeded outflows, which included income taxes paid of ¥35.5 billion.

Net cash used in investing activities was ¥31.2 billion mainly due to investment of cash reserves.

Net cash used in financing activities was ¥25.8 billion mainly resulting from dividends paid.

As a result, net cash outflows for fiscal 2018 were ¥15.0 billion, and the balance of cash and cash equivalents at fiscal year-end was ¥111.8 billion.

	(Billions of yen)		
	FY 2017	FY 2018	Change
Net cash provided by operating activities	66.9	41.4	-25.4
Net cash used in investing activities	-19.1	-31.2	-12.0
Net cash used in financing activities	-32.5	-25.8	+6.6
Cash and cash equivalents at the end of the year	127.0	111.8	-15.1

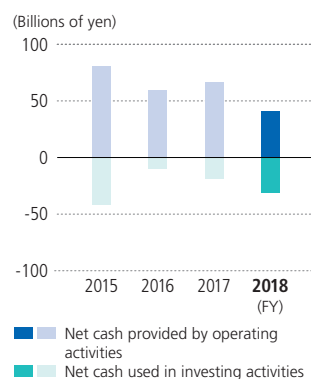
Dividends

Mitsubishi Tanabe Pharma aims to maximize corporate value through actively carrying out strategic investment and R&D investment targeting sustainable growth and provide a stable and continuous return to shareholders. In accordance with the revision of the "Medium-Term Management Plan 16-20" released in November 2018, the Company has made a basic policy of maintaining the current level of dividends distribution (annual dividend of ¥56 per share).

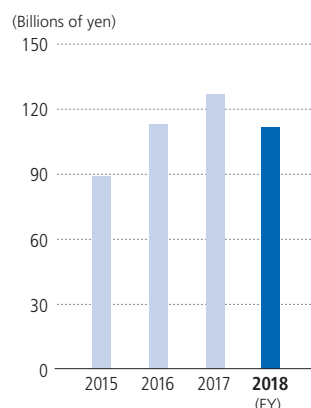
Given the arbitration proceedings with Novartis, there was a decrease in revenue in the fiscal year ended March 31, 2019 because a part of the "GILENYA Royalties" income was not recognized as sales revenue, in accordance with IFRS 15. Besides the impact of this matter, profit shifted in line with expectations following the revision of the Medium-Term Plan.

Accordingly, based on the above dividend policy, the Company paid a year-end dividend for fiscal 2018 of ¥28 per share. Combined with the interim dividend, the annual dividend was ¥56 per share, and the consolidated dividend payout ratio was 84.0%, compared with 63.9% in the previous fiscal year.

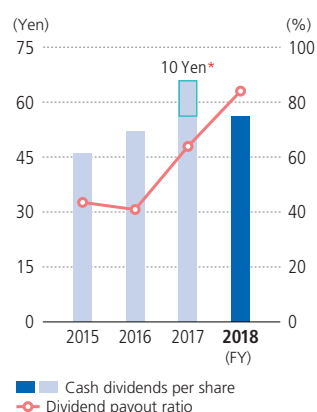
Net cash provided by operating activities / Net cash used in investing activities



Cash and cash equivalents at the end of the year



Cash dividends per share / Dividend payout ratio



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

Operational Risks

The following are major risks that have the potential to significantly influence the financial position or performance of the Mitsubishi Tanabe Pharma Group. In recognition of these risks, the Mitsubishi Tanabe Pharma Group works to prevent the occurrence of risk events and to implement responses in the event of their occurrence. Items in this document relating to the future are based on the judgment of the Mitsubishi Tanabe Pharma Group as of the end of fiscal 2018 (March 31, 2019).

1 Risks related to R&D

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

2 Risks related to adverse drug reactions

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

3 Risks related to insurance systems

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

4 Risks related to changes in the market environment

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

5 Risks related to intellectual property

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

6 Risks related to alliances with other companies

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

7 Risks related to business acquisitions, etc.

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

8 Risks related to stable supply

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

9 Risks related to financial market conditions and exchange rate fluctuations

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

10 Risks related to the environment

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

11 Risks related to lawsuits

(1) The Mitsubishi Tanabe Pharma Group could face lawsuits in regard to adverse drug reactions, product liability, labor problems, fair trade, etc.

(2) For "the Special Relief Law Concerning the Payment of Benefits to Relieve the Patients of Hepatitis C Infected through Specified Fibrinogen Preparations and Specified Blood-Coagulation Factor IX Preparations Contaminated by Hepatitis C Virus," which was put into effect in January 2008, the time limit for filing a claim for benefits was extended to January 2023. Accordingly, there could be an increase in the number of people who receive payment of benefits, etc.

12 Risks related to information

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

13 Risks related to overseas business development

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

14 Risks related to major disasters, etc.

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

15 Relationship with parent company and other group companies

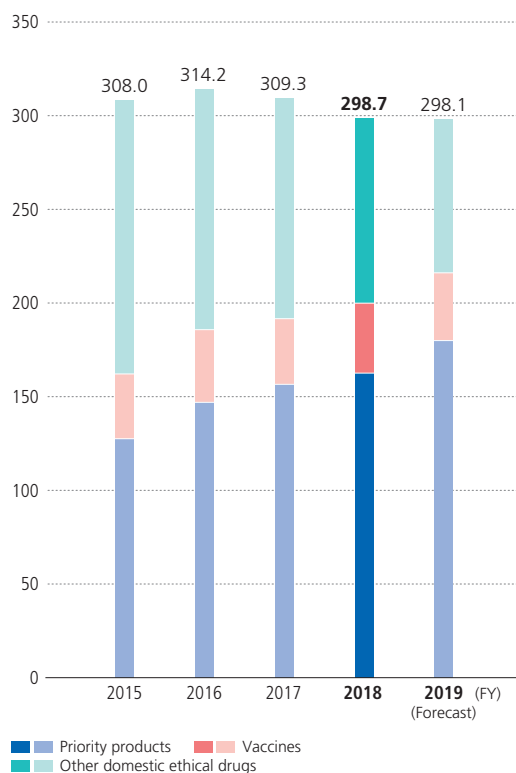
In regard to transactions between the Company and its parent company, Mitsubishi Chemical Holdings (MCHC), or companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Mitsubishi Tanabe Pharma Group in order to maximize the benefit to all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

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

Overview and Sales Trends of Priority Products



Domestic revenue of ethical drugs (Billions of yen)



Revenue of priority products (Billions of yen)

	2015	2016	2017	2018 (Forecast)	2019
Remicade	69.4	66.8	64.6	58.8	53.1
Simponi	12.9	24.9	32.1	37.4	43.0
Stelara	–	–	0.3	15.2	21.6
Tenelia	14.1	16.5	17.5	15.2	16.1
Canaglu	0.5	3.4	5.6	6.7	10.9
Canalia	–	–	1.8	7.4	7.6
Lexapro	9.5	11.2	12.7	14.0	15.2
Imusera	4.1	4.9	4.7	4.3	4.2
Rupafin	–	–	0.4	3.4	7.8
Vaccines:					
Influenza vaccine	13.7	12.7	9.9	10.2	10.7
Tetrabik	9.5	9.9	8.7	8.5	10.0
Varicella vaccine	6.3	5.4	5.2	5.1	5.1
Mearubik	4.9	5.9	5.0	6.8	4.8
JEBIK V	3.6	3.9	5.2	5.5	4.5

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

Remicade Infliximab



Domestic revenue

¥58.8 billion

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

Launch May 2002

Origin Janssen Biotech (U.S.)

Development Mitsubishi Tanabe Pharma

Overview

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

Sales trend

In fiscal 2018, revenue was down 9.1%, to ¥58.8 billion. In fiscal 2018, the third biosimilar and a new competing product for ulcerative colitis were launched and competition further intensified. However, differentiation from competitors for ulcerative colitis led to an increase in revenue in that particular market, mitigating the overall revenue decline. In fiscal 2019, competition is expected to further intensify with market penetration of biosimilars, the impact of new competing products for Crohn's disease and psoriasis, and other factors, but we will continue to collect and provide evidence on the safety and effectiveness of Remicade. The forecast for revenue in fiscal 2019 is ¥53.1 billion, a decline of 9.7% from fiscal 2018.

Simponi Golimumab



Autoinjector



Domestic revenue

¥37.4 billion

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

Launch September 2011

Origin Janssen Biotech (U.S.)

Development Co-development with Janssen Pharmaceutical K.K.

Overview

Simponi is a human TNF monoclonal antibody that targets TNF, 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 with other subcutaneous injections, and it is expected to contribute to raising the percentage of patients who continue treatment. In regard to indications, in 2017 Janssen Pharmaceutical K.K., with which we are conducting joint development, added an indication for ulcerative colitis, in addition to RA (including the prevention of structural joint damage).

Sales trend

The convenience of a single administration for a four-week period has been highly evaluated, and Simponi is increasing its share in the RA market. In fiscal 2018, revenue increased 16.7%, to ¥37.4 billion. MRs were very active, resulting in steady acquisition of hospital accounts and prescriptions, and this had a positive effect on revenue growth. In the rheumatism market, prescriptions for seniors are increasing and the scope of patients approved for self-administration is expanding. We have also achieved a steady increase in the number of administrations for ulcerative colitis cases. The forecast for revenue in fiscal 2019 is ¥43.0 billion, an increase of 14.8% from fiscal 2018. The competition will be intense, but we expect a contribution from autoinjector sales, which began in May 2019.

Overview and Sales Trends of Priority Products

Stelara Ustekinumab



Domestic revenue

¥15.2 billion

- Indications** Psoriasis vulgaris, psoriasis arthropathica, Crohn's disease
- Launch** March 2011
- Origin** Janssen Biotech (U.S.)
- Development** Janssen Pharmaceutical K.K.

Overview

Stelara is a human anti-IL12/23p40 monoclonal antibody. It shows a long acting efficacy by subcutaneous injection once every 12 weeks (initial administration, only, by intravenous drip infusion). Additional indication for Crohn's disease was approved in March 2017. Mitsubishi Tanabe Pharma and Janssen Pharmaceutical have jointly promoted STELARA as indicated for Crohn's disease in Japan since April 2017. For the indication for psoriasis, promotion is handled solely by Janssen Pharmaceutical.

Sales trend

In fiscal 2018, revenue was ¥15.2 billion. For Stelara, we achieved a steady increase in the number of cases primarily in which anti-TNF- α agents showed diminished effectiveness or that were refractory. The forecast for revenue in fiscal 2019 is ¥21.6 billion, an increase of 42.4% from fiscal 2018. A new competing product for Crohn's disease will enter the market, and competition is expected to intensify, but we intend to promote Stelara's remission maintenance benefits, low immunogenicity, safety and other characteristics and establish its position as a first bio.

Tenelia Teneligliptin



Domestic revenue

¥15.2 billion

- Indications** 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 to ever be launched. Due to the strength and duration of its action, it can improve postprandial blood glucose, after all 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 for 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

For Tenelia, the total of the amount of the Company's sales to Daiichi Sankyo and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of revenue. In fiscal 2018, revenue decreased 13.3% year on year, to ¥15.2 billion. Among DPP-4 inhibitors, Tenelia can be administered in the standard dosage; the dosage does not need to be reduced even in cases of decreased renal function, so stable treatment can be provided even for seniors and in cases of decreased renal function. In addition, when the effect is insufficient, we propose treatment by switching to Canalia or increasing the dosage to Tenelia 40 mg, and in this way, we are working for continued growth. The forecast for revenue in fiscal 2019 is ¥16.1 billion, an increase of 5.9% from fiscal 2018.

Canaglu Canagliflozin



Domestic revenue

¥6.7 billion

Indications Type 2 diabetes mellitus
Launch September 2014
Origin Mitsubishi Tanabe Pharma
Development Mitsubishi Tanabe Pharma

Overview

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

Sales trend

In fiscal 2018, revenue was up 19.9%, to ¥6.7 billion. Since the launch of Canalia, a combination drug that includes a DPP-4 inhibitor and an SGLT2 inhibitor, in September 2017, some patients have switched from Canaglu to Canalia; but the market for SGLT2 inhibitors is growing and we expect prescriptions to increase going forward. Moreover, in April 2019, a large-scale clinical trial (CREDENCE study) for Invokana for type 2 diabetes patients with renal disease was announced, so the overall market is expected to be stimulated and prescriptions of Canaglu to increase. The forecast for revenue in fiscal 2019 is ¥10.9 billion, an increase of 62.1% from fiscal 2018.

Canalia Teneligliptin/canagliflozin



Domestic revenue

¥7.4 billion

Indications Type 2 diabetes mellitus
Launch September 2017
Origin Mitsubishi Tanabe Pharma
Development Mitsubishi Tanabe Pharma

Overview

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

Sales trend

The total of the amount of the Company's sales to Daiichi Sankyo and the amount of promotion fees received from Daiichi Sankyo is disclosed as the amount of the Company's revenue. In fiscal 2018, revenue rose 310.8% year on year, a major increase, to ¥7.4 billion. Since its launch, product awareness and prescription intention have been high and sales have been steady. The revenue share of Canalia in the SGLT2 inhibitor market in fiscal 2018 has grown to approximately 10.8%. The DPP-4 inhibitor has come to be recognized as a standard drug, and the SGLT2 inhibitor market is expanding, so Canalia is expected to continue to grow going forward alongside its competitors. The forecast for revenue in fiscal 2019 is ¥7.6 billion, an increase of 3.7% from fiscal 2018.

Overview and Sales Trends of Priority Products

Lexapro Escitalopram



Domestic revenue

¥14.0 billion

Indications Depression, depressive symptoms, social anxiety disorder

Launch August 2011

Origin H. Lundbeck (Denmark)

Development Mochida Pharmaceutical

Overview

Lexapro is a selective serotonin reuptake inhibitor (SSRI). It was launched in 2002 in Europe and the U.S., and is currently approved in approximately 100 countries and regions. Among SSRIs, it has the highest serotonin transporter selectivity. Its superior efficacy for depression and depressive symptoms and good tolerability have been confirmed. In addition, it has simple administration, and as a result it is expected to contribute to the improvement of medication adherence, which is especially important in patients with depression. We have been conducting joint sales activities with Mochida Pharmaceutical since 2011. In 2015, it received an additional indication for social anxiety disorder (SAD).

Sales trend

In fiscal 2018, revenue rose 9.7%, to ¥14.0 billion. Growth in the anti-depressant market is slowing, but we propose a patient profile (patients with anxiety) to which Lexapro can contribute and a method of usage, and recognition of Lexapro's exceptional efficacy and tolerability is achieving further market uptake. It has the top share of the SSRI market. In November 2018, the shape of the 10 mg tablet was changed to make it easier to divide, and 20 mg tablets were approved as the new standard. While continuing to promote appropriate use as our basic sales activity, we will utilize the added indication for social anxiety disorder to promote Lexapro's use by patients with anxious depression and focus on its growth while differentiating it from other SSRI and SNRI drugs. The forecast for revenue in fiscal 2019 is ¥15.2 billion, an increase of 9.2% from fiscal 2018.

Imusera Fingolimod



Domestic revenue

¥4.3 billion

Indications Multiple sclerosis (MS)

Launch November 2011

Origin Mitsubishi Tanabe Pharma

Development Co-development with Novartis Pharma K.K.

Overview

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

Sales trend

In fiscal 2018, revenue was down 8.2%, to ¥4.3 billion. In March 2018, the prescription period limit for a competing product was lifted and prescriptions of it increased significantly. As a result, though Imusera (and Gilenya) maintained the top share of the market, the competing product closed the gap. The multiple sclerosis treatment market is shifting from injections (interferons) to oral drugs. In addition, in the MS and NMO Clinical Guidelines 2017 (Japanese Society of Neurology), an ideal case for fingolimod* (multiple sclerosis patients with high disease activity) is advocated. Going forward, we will continue to promote prescriptions of Imusera for this ideal case in accordance with the guidelines while promoting the convenience of oral administration. The forecast for revenue in fiscal 2019 is ¥4.2 billion, a decrease of 1.4% from fiscal 2018.

* The general name for Imusera (Gilenya)

Rupafin

Rupatadine fumarate



Domestic revenue

¥3.4 billion

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

Launch November 2017

Origin J. Uriach Y COMPANIA (Spain)

Development Teikoku Seiyaku

Overview

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

Sales trend

In fiscal 2018, revenue was ¥3.4 billion. With the limit on the dosing period lifted on December 1, 2018, we reinforced activities to position it as the drug of choice for the 2019 pollen season, and, as a result, the number of advertisements and presentations were No. 1 among all pharmaceuticals, which led to increases in both hospital accounts and prescriptions. Market share increased to 8.8% from a share of 2.0% prior to the dosing limit being lifted. In fiscal 2019, the antihistamine market is projected to contract slightly due to inroads made by generics, but we intend to achieve a share of 11% by establishing Rupafin as the drug of choice for rhinitis and dermatosis patients. The forecast for revenue in fiscal 2019 is ¥7.8 billion, an increase of 128.9% from fiscal 2018.

Vaccines



Domestic revenue

¥37.3 billion

Overview

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

Sales trend

In fiscal 2018, overall revenue from vaccines rose 6.4%, to ¥37.3 billion. The Company maintained the top share of the domestic vaccine market. In fiscal 2018, Mearubik benefited from an increase in voluntary inoculation demand due to measles and rubella outbreaks, and JEBIK V from an increase in demand for periodic vaccination for children at the end of fiscal 2017, and these both contributed greatly to revenue. For the seasonal influenza vaccine, which accounts for the largest share of the Company's vaccine sales, we worked to ensure stable supplies through the collaboration with BIKEN Foundation and the company it merged with, BIKEN. For the chickenpox vaccine, a competing product is expected to be launched this fiscal year, so while activities to promote awareness of shingles inoculation are likely to intensify, it is a voluntary vaccination, so the impact on the market is unclear. The forecast for revenue in fiscal 2019 is ¥36.2 billion, a decrease of 2.9% from fiscal 2018.

Consolidated Statement of Income

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

(Millions of yen)

	FY 2017	FY 2018
Revenue	433,855	424,767
Cost of sales	169,750	180,646
Gross profit	264,105	244,121
Selling, general and administrative expenses	104,055	98,725
Research and development expenses	79,083	86,533
Amortization of intangible assets associated with products	2,451	2,934
Other income	6,661	1,481
Other expenses	7,915	7,027
Share of profit of associates and joint ventures accounted for using equity method	23	–
Share of loss of associates and joint ventures accounted for using equity method	–	80
Operating profit	77,285	50,303
Financial income	1,881	1,253
Financial expenses	402	1,117
Profit before income tax	78,764	50,439
Income tax expenses	24,772	18,223
Profit for the year	53,992	32,216
Profit attributable to:		
Owners of the Company	57,963	37,372
Non-controlling interests	(3,971)	(5,156)
Profit for the year	53,992	32,216
Earnings per share		
Basic earnings per share	103.35	66.64
Diluted earnings per share	103.35	66.64

Consolidated Statement of Comprehensive Income

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

(Millions of yen)

	FY 2017	FY 2018
Profit for the year	53,992	32,216
Other comprehensive income		
Items that will not be reclassified subsequently to profit or loss		
Net changes in financial assets measured at fair value through other comprehensive income	4,542	4,170
Remeasurements of defined benefit plans	5,823	(780)
Subtotal	10,365	3,390
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(8,798)	5,304
Effective portion of changes in fair value of cash flow hedges	1,033	—
Share of other comprehensive income of associates and joint ventures accounted for using equity method	28	(16)
Subtotal	(7,737)	5,288
Other comprehensive income (loss), net of tax	2,628	8,678
Comprehensive income	56,620	40,894
Comprehensive income (loss) attributable to:		
Owners of the Company	60,861	46,169
Non-controlling interests	(4,241)	(5,275)
Comprehensive income	56,620	40,894

Value Creation Story

Business and Financial Strategy

Non-Financial Information

Operating Results and Data

Consolidated Statement of Financial Position

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

(Millions of yen)

	FY 2017	FY 2018
Assets		
Non-current assets		
Property, plant and equipment	80,457	73,338
Goodwill	91,136	91,640
Intangible assets	200,940	206,918
Investments in associates and joint ventures accounted for using equity method	16,445	16,294
Other financial assets	46,109	46,245
Net defined benefit assets	22,711	21,474
Other non-current assets	379	257
Deferred tax assets	4,742	11,687
Total non-current assets	462,919	467,853
Current assets		
Inventories	81,998	75,559
Trade and other receivables	123,537	116,951
Other financial assets	246,733	271,432
Other current assets	6,227	11,011
Cash and cash equivalents	127,030	111,850
Subtotal	585,525	586,803
Assets held for sale	–	1,630
Total current assets	585,525	588,433
Total assets	1,048,444	1,056,286

(Millions of yen)

	FY 2017	FY 2018
Liabilities and equity		
Liabilities		
Non-current liabilities		
Borrowings	420	150
Other financial liabilities	2,199	2,151
Net defined benefit liabilities	868	629
Provisions	8,571	6,975
Other non-current liabilities	5,505	5,116
Deferred tax liabilities	37,861	39,234
Total non-current liabilities	55,424	54,255
Current liabilities		
Borrowings	122	45
Trade and other payables	35,631	31,477
Other financial liabilities	20,737	27,032
Income taxes payable	18,093	9,576
Provisions	1,934	1,638
Other current liabilities	21,676	21,682
Subtotal	98,193	91,450
Liabilities directly related to assets held for sale	–	249
Total current liabilities	98,193	91,699
Total liabilities	153,617	145,954
Equity		
Share capital	50,000	50,000
Capital surplus	451,228	451,253
Treasury shares	(1,045)	(1,040)
Retained earnings	382,122	387,964
Other components of equity	503	9,427
Total equity attributable to owners of the Company	882,808	897,604
Non-controlling interests	12,019	12,728
Total equity	894,827	910,332
Total liabilities and equity	1,048,444	1,056,286

Consolidated Statement of Changes in Equity

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

FY 2017

(Millions of yen)

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

FY 2018

(Millions of yen)

	Equity attributable to owners of the Company						
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity		
					Exchange differences on translation of foreign operations	Effective portion of changes in fair value of cash flow hedges	Net changes in financial assets measured at fair value through other comprehensive income
Balance as of April 1, 2018	50,000	451,228	(1,045)	382,122	(13,194)	–	13,717
Profit for the year	–	–	–	37,372	–	–	–
Other comprehensive income	–	–	–	–	5,423	–	4,170
Total comprehensive income	–	–	–	37,372	5,423	–	4,170
Acquisition of treasury shares	–	–	(1)	–	–	–	–
Disposal of treasury shares	–	(8)	6	–	–	–	–
Dividends	–	–	–	(31,403)	–	–	–
Share-based payments	–	33	–	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	(127)	–	–	(653)
Transfer from other components of equity to non-financial assets	–	–	–	–	–	–	–
Total contributions by and distributions to owners	–	25	5	(31,530)	–	–	(653)
Issuance of new shares	–	–	–	–	–	–	–
Changes in ownership interests in subsidiaries and others	–	–	–	–	–	–	–
Total transactions with owners	–	25	5	(31,530)	–	–	(653)
Balance as of March 31, 2019	50,000	451,253	(1,040)	387,964	(7,771)	–	17,234

FY 2017

(Millions of yen)

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

FY 2018

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity			Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Remeasurements of defined benefit plans	Share of other comprehensive income of associates and joint ventures accounted for using equity method	Total			
Balance as of April 1, 2018	–	(20)	503	882,808	12,019	894,827
Profit for the year	–	–	–	37,372	(5,156)	32,216
Other comprehensive income	(780)	(16)	8,797	8,797	(119)	8,678
Total comprehensive income	(780)	(16)	8,797	46,169	(5,275)	40,894
Acquisition of treasury shares	–	–	–	(1)	–	(1)
Disposal of treasury shares	–	–	–	(2)	–	(2)
Dividends	–	–	–	(31,403)	(292)	(31,695)
Share-based payments	–	–	–	33	–	33
Transfer from other components of equity to retained earnings	780	–	127	–	–	–
Transfer from other components of equity to non-financial assets	–	–	–	–	–	–
Total contributions by and distributions to owners	780	–	127	(31,373)	(292)	(31,665)
Issuance of new shares	–	–	–	–	6,276	6,276
Changes in ownership interests in subsidiaries and others	–	–	–	–	6,276	6,276
Total transactions with owners	780	–	127	(31,373)	5,984	(25,389)
Balance as of March 31, 2019	–	(36)	9,427	897,604	12,728	910,332

Consolidated Statement of Cash Flows

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

(Millions of yen)

	FY 2017	FY 2018
Cash flows from operating activities:		
Profit before income tax	78,764	50,439
Depreciation and amortization	11,535	11,529
Impairment losses	3,791	17
Interest and dividend income	(1,238)	(1,144)
Share of loss (profit) of associates and joint ventures accounted for using equity method	(23)	80
Loss (gain) on sales of property, plant and equipment	(2,287)	(13)
Loss (gain) on sales of investments in subsidiaries	(3,565)	–
Restructuring loss	2,144	5,695
Decrease (increase) in trade and other receivables	(6,111)	6,567
Decrease (increase) in inventories	(2,683)	6,641
Increase (decrease) in trade and other payables	56	(4,728)
Increase (decrease) in provisions	2,529	(1,974)
Decrease (increase) in net defined benefit assets	1,153	193
Increase (decrease) in net defined benefit liabilities	(948)	(253)
Increase (decrease) in deferred income	(480)	(687)
Other	(2,965)	3,600
Subtotal	79,672	75,962
Interest received	522	555
Dividends received	772	688
Interest paid	(160)	(222)
Income taxes paid	(13,863)	(35,523)
Net cash flows provided by operating activities	66,943	41,460
Cash flows from investing activities:		
Payments into time deposits	(3,742)	(1,709)
Proceeds from withdrawal of time deposits	8,407	5,220
Purchase of property, plant and equipment	(6,416)	(5,730)
Proceeds from sales of property, plant and equipment	3,703	91
Purchase of intangible assets	(22,034)	(3,777)
Purchase of investments	(391,749)	450,669
Proceeds from sales and redemption of investments	428,741	422,367
Proceeds from withdrawal of deposits	70,000	–
Proceeds from sales of subsidiaries	10,803	–
Purchase of subsidiaries	(119,724)	–
Proceeds from transfer of business	3,000	3,000
Other	(167)	(5)
Net cash flows used in investing activities	(19,178)	(31,212)
Cash flows from financing activities:		
Purchase of treasury shares	(549)	(1)
Proceeds from stock issuance to non-controlling interests	5,409	6,276
Dividends paid	37,017	(31,403)
Other	(344)	(741)
Net cash flows used in financing activities	(32,501)	(25,869)
Effect of exchange rate changes on cash and cash equivalents	(1,457)	531
Net increase (decrease) in cash and cash equivalents	13,807	(15,090)
Increase (decrease) in cash and cash equivalents resulting from transfer to assets held for sale	8	(90)
Cash and cash equivalents at the beginning of the year	113,215	127,030
Cash and cash equivalents at the end of the year	127,030	111,850

Explanation of Terms

Precision medicine

Precision medicine is medical care with established prevention and treatment methods that takes into account individual genetic, environmental, and lifestyle differences. Its advantage is that drugs not expected to be effective do not need to be used and it avoids the risk of side effects by analyzing the patient's genetics and selecting a more precise treatment method.

Long-listed drugs

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

Digital medicine

Digital medicine combines medical devices, such as sensors, and pharmaceuticals. Pharmaceuticals with sensors embedded in the tablet that monitor medication status and activity levels are now a commercial reality.

Biologics

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

Biosimilar

Biosimilars are generic biologics (also known as follow-on biologics).

Patient journey

A process likened to a journey that includes the behavior, thought, and emotion that patient experiences from the time he or she is notified of a disease until the treatment period, full recovery, or end of life. Healthcare providers understand the patient journey and can facilitate the patient's choices and decisions by providing necessary healthcare information and measures.

Modality

Treatment methods, such as small molecule compounds, protein drugs, including peptide drugs and therapeutic antibodies, gene therapy, nucleic acid drugs, cell therapy drugs, and regenerative medicine.

MR (Medical Representative)

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

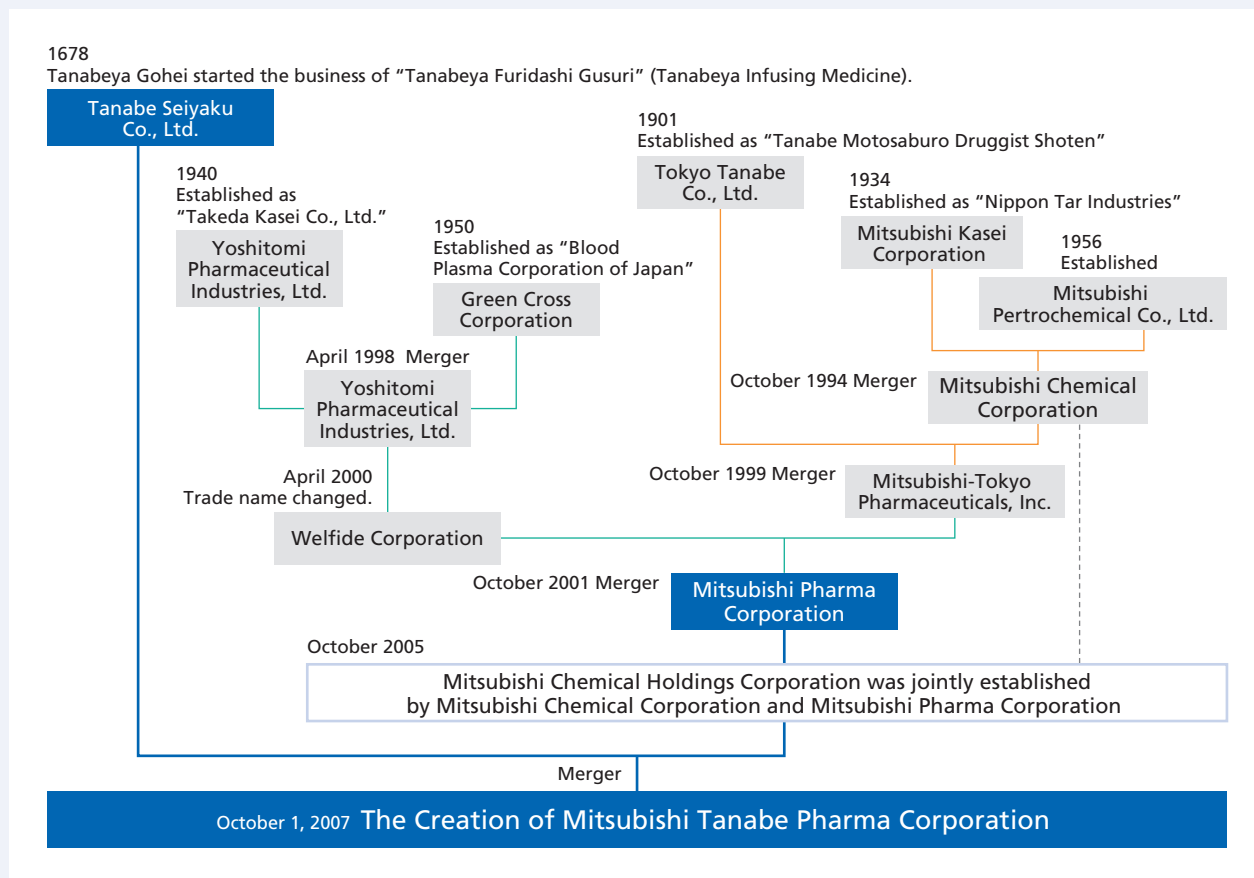
QOL (Quality of Life)

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

RPA (Robotic Process Automation)

RPA is the automation of routine desk work such as data entry using software (robots).

History



Mitsubishi Tanabe Pharma's History since Its Establishment

■ New product launches

2007

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

for Kremezin, a treatment for chronic kidney disease

2008

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

2010

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

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

2011

- March** ▶ Acquisition by Novartis, of Switzerland, of approval in Europe for Gilenya, a treatment agent for multiple sclerosis
- April** ▶ Transfer of domestic sales of Kremezin, a treatment for chronic kidney disease, from Daiichi Sankyo to the Company
- August** ■ Launch of Lexapro, an anti-depressant, and start of joint sales with Mochida Pharmaceutical
- September** ■ Launch of Simponi, a treatment agent for RA, and start of joint sales with Janssen Pharmaceutical K.K.
- October** ▶ Announcement of Medium-Term Management Plan 11–15: New Value Creation
- November** ■ Launch of Imusera, a treatment agent for MS
- Launch of Telavic, a treatment agent for chronic hepatitis C

2012

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

2013

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

2014

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

2015

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

2016

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

2017

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

2018

- February**
- ▶ Stelic Institute & Co., a pharmaceutical development company, became a consolidated subsidiary
- March**
- ▶ Closure of Mitsubishi Tanabe Pharma Factory's Osaka Plant
- April**
- ▶ Establishment of Mitsubishi Tanabe Pharma Canada, a pharmaceutical sales company, in Canada
- May**
- ▶ Diabetes treatment agent Canagliflozin, which has a revolutionary treatment concept, won the Technology Award Grand Prize from the Japan Chemical Industry Association (JCIA)
- July**
- ▶ Awarded 43rd Inoue Harushige Prize for research and development on edaravone as a novel treatment agent for amyotrophic lateral sclerosis (ALS)
- December**
- ▶ Establishment of Mitsubishi Tanabe Pharma Malaysia, a pharmaceutical sales company, in Malaysia

2019

- January**
- ▶ Establishment of Mitsubishi Tanabe Pharma Provision through a change to the name and purpose of Tanabe Total Service
- April**
- ▶ Transfer of Tanabe Seiyaku Yoshiki Factory to Nipro Pharma

Corporate Data / Investor Information

Corporate data As of March 31, 2019

Company name	Mitsubishi Tanabe Pharma Corporation	Date of merger	October 1, 2007
Headquarters	3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan	Number of employees	7,228 (Consolidated) 4,111 (Parent company only)
Incorporated	December 1933		

For further information **Investor Relations Group Corporate Communications Department**
Tel: 81-6-6205-5211 Fax: 81-6-6205-5105 URL: <https://www.mt-pharma.co.jp/e/>

Group companies As of June 30, 2019

■ Consolidated subsidiary ■ Affiliated company accounted for by the equity method

Japan

	Paid-in capital	% Voting control*	Principal business
Yoshitomiyakuhin Corporation	¥385 million	100.0%	Provision of information about pharmaceuticals
Mitsubishi Tanabe Pharma Factory Ltd.	¥1,130 million	100.0%	Manufacture and sale of pharmaceuticals
Mitsubishi Tanabe Pharma Provision Co., Ltd.	¥100 million	100.0%	Operations relating to pharmaceutical information, and operations relating to accounting, general affairs, personnel, etc.
Tanabe Palm Service Co., Ltd.	¥10 million	100.0%(100.0%)	Printing, in-house mail delivery, office support
Stelic Institute & Co., Inc.	¥1 million	100.0%(100.0%)	Pharmaceutical R&D
BIKEN Co., Ltd.	¥100 million	33.4%	Manufacture and sale of biological products including vaccines

Overseas

North America	Paid-in capital	% Voting control*	Principal business
Mitsubishi Tanabe Pharma Holdings America, Inc.	USD 167	100.0%	Management of U.S. business
Mitsubishi Tanabe Pharma Development America, Inc.	USD 200	100.0% (100.0%)	Pharmaceutical R&D
Mitsubishi Tanabe Pharma America, Inc.	USD 100	100.0% (100.0%)	Sale of pharmaceuticals
MP Healthcare Venture Management Inc.	USD 100	100.0% (100.0%)	Investments in bio-ventures
Tanabe Research Laboratories U.S.A., Inc.	USD 3 Mill.	100.0% (100.0%)	Pharmaceutical R&D
Mitsubishi Tanabe Pharma Canada, Inc.	CAD 4 Mill.	100.0% (100.0%)	Sale of pharmaceuticals
MTPC Holdings Canada Inc.	CAD 618.4 Mill.	100.0%	Investments in Medicigo Group
Medicago Inc.	CAD 828.0 Mill.	60.0% (58.1%)	Vaccine R&D and manufacture
Medicago USA Inc.	USD 99	60.0% (60.0%)	Manufacture of vaccines
Medicago R&D Inc.	CAD 500	60.0% (60.0%)	Vaccine R&D

Asia	Paid-in capital	% Voting control*	Principal business
Mitsubishi Tanabe Pharma Development (Beijing) Co., Ltd.	USD 1 Mill.	100.0%	Pharmaceutical R&D
Tianjin Tanabe Seiyaku Co., Ltd.	USD 16.2 Mill.	75.4%	Manufacture and sale of pharmaceuticals
Taiwan Tanabe Seiyaku Co., Ltd.	TWD 90 Mill.	65.0%	Manufacture and sale of pharmaceuticals
Tai Tien Pharmaceuticals Co., Ltd.	TWD 20 Mill.	65.0%	Sale of pharmaceuticals
PT Mitsubishi Tanabe Pharma Indonesia	USD 2.5 Mill.	99.6%	Manufacture and sale of pharmaceuticals
Mitsubishi Tanabe Pharma Singapore Pte. Ltd.	SGD 2 Mill.	100.0%	Management of ASEAN business
Mitsubishi Tanabe Pharma Malaysia Sdn. Bhd.	MYR 5 Mill.	100.0% (100.0%)	Sale of pharmaceuticals
Mitsubishi Tanabe Pharma (Thailand) Co., Ltd.	THB 103 Mill.	100.0% (2.0%)	Sale of pharmaceuticals
Mitsubishi Tanabe Pharma Korea Co., Ltd.	KRW 2,100 Mill.	100.0%	Manufacture and sale of pharmaceuticals

Europe / Middle East	Paid-in capital	% Voting control*	Principal business
NeuroDerm Ltd.	USD 58,000	100.0%	Pharmaceutical R&D
Mitsubishi Tanabe Pharma Europe Ltd.	GBP 4.6 Mill.	100.0%	Pharmaceutical R&D
Mitsubishi Tanabe Pharma GmbH	EUR 25,000	100.0% (100.0%)	Sale of pharmaceuticals

* Figures in parentheses show indirect control.

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

Investor information As of March 31, 2019

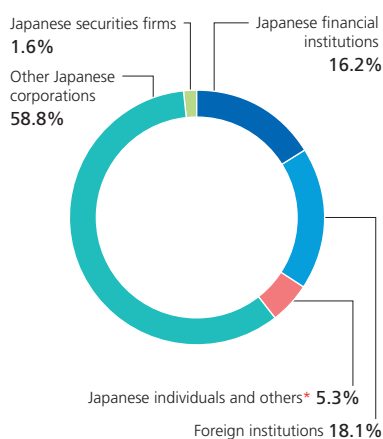
Stock exchange listing	Tokyo
Stock code	4508
Paid-in capital	¥50,000 million
Common stock	Authorized: 2,000,000,000 shares Issued: 561,417,916 shares
Closing date of accounts	March 31
Number of shareholders	25,991
Major shareholders	

	% Voting Rights
Mitsubishi Chemical Holdings Corporation	56.39
The Master Trust of Japan, Ltd.	4.74
Japan Trustee Services Bank, Ltd.	2.62
Nippon Life Insurance Company	2.15
STATE STREET BANK WEST CLIENT-TREATY 505234	1.40
Japan Trustee Services Bank, Ltd. (Trust Account 9)	0.82
Japan Trustee Services Bank, Ltd. (Trust Account 5)	0.73
STATE STREET BANK AND TRUST COMPANY 505225	0.72
STATE STREET BANK AND TRUST COMPANY 505103	0.70
Nipro Corporation	0.68

Shareholder register agent for common stock in Japan
Mitsubishi UFJ Trust and Banking Corporation
1-4-5, Marunouchi, Chiyoda-ku, Tokyo

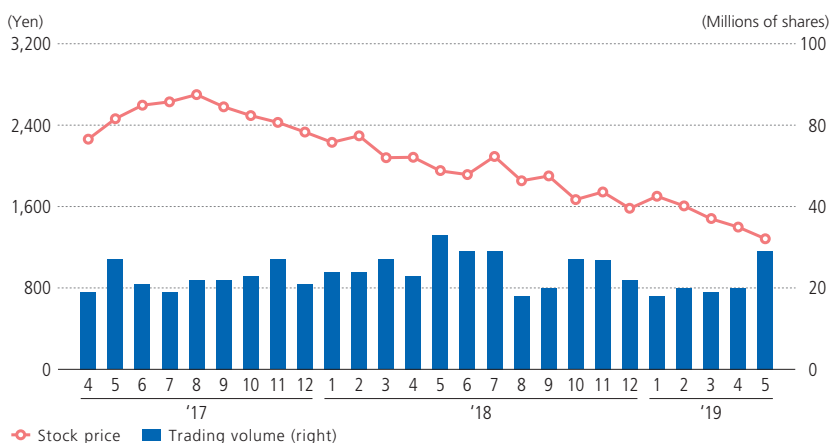
Handling office of shareholder register agent
Mitsubishi UFJ Trust and Banking Corporation
Osaka Corporate Agency Division
3-6-3, Fushimi-machi, Chuo-ku, Osaka

Distribution of share ownership by type of shareholder



* Individuals and others includes treasury stock (431 thousand shares as of March 31, 2019)

Stock price range / Trading volume





Mitsubishi Tanabe Pharma

<https://www.mt-pharma.co.jp/e/>

