

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.



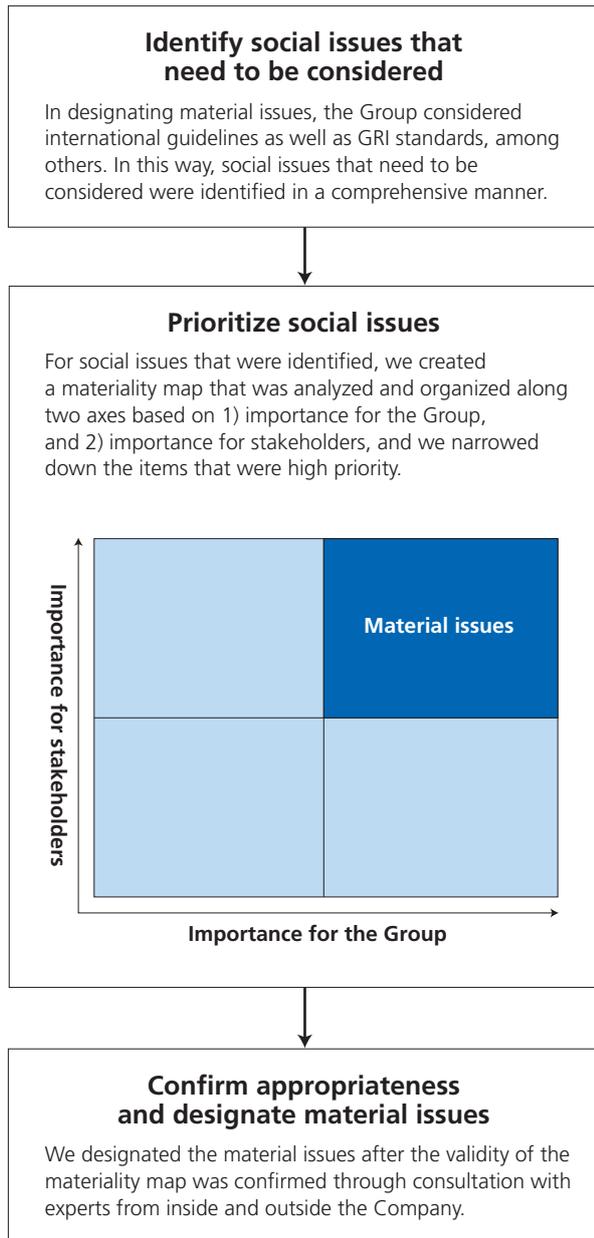


S Strength

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 	<p>23 (Global)</p> <p>13 (Global)</p> <p>18 (Global)</p> <p>17 million (Japan)</p> <p>100,000 (Global)</p>	 	<p>H-1 Contribute to medical treatment</p> <p>H-2 Contribute to the prevention and early detection of diseases</p>
	<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 	<p>1ppm³ (Global)</p> <p>92.4% (Japan)</p>	 	<p>C-1 Endeavor to earn greater recognition of corporate trust from society</p>
	<ul style="list-style-type: none"> Number of external presentations on clinical research (papers / academic conferences, etc.) Instances of safety information collected by MRs 	<p>56 (Global)</p> <p>7,419 (Japan)</p>	 	<p>C-1 Endeavor to earn greater recognition of corporate trust from society</p>
	<ul style="list-style-type: none"> Compliance training participation rate Employee compliance awareness (Perfect score: 5 points) 	<p>97.7% (Japan)</p> <p>4.34 points (Japan)</p>	 	<p>C-1 Endeavor to earn greater recognition of corporate trust from society</p>
	<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.) 	<p>198 (Global)</p> <p>3.68 points (Japan)</p> <p>10 (Japan)</p>		<p>C-2 Promote communication and work in concert with stakeholders</p>
	<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 	<p>153.9 hours (Japan)</p> <p>68% (Japan)</p> <p>19.8% (Japan)</p> <p>3.72 points (Japan)</p> <p>20.2% (Global)</p> <p>29 (Global)</p>	  	<p>C-2 Promote communication and work in concert with stakeholders</p>
	<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 	<p>7.29 million (Global)</p> <p>42.3% (Japan)</p> <p>91 (Japan)</p> <p>12,236 meals (Japan) vaccine 14,500 doses (Japan)</p>	  	<p>C-2 Promote communication and work in concert with stakeholders</p>

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

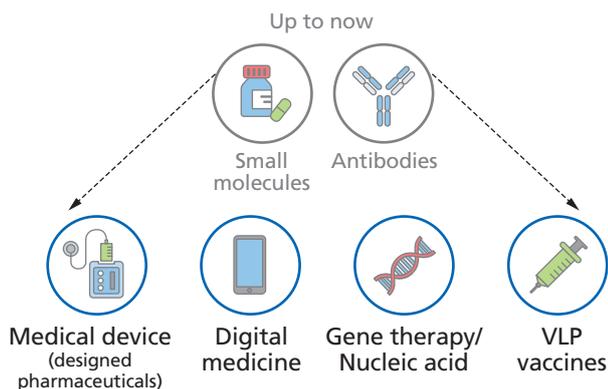
1. Medical needs for which there are no effective treatments or drugs
2. Acronym for Proof of Concept. Confirmation of the efficacy and safety of new drug candidate substances in humans at the R&D stage
3. Fast track designated by the FDA

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.

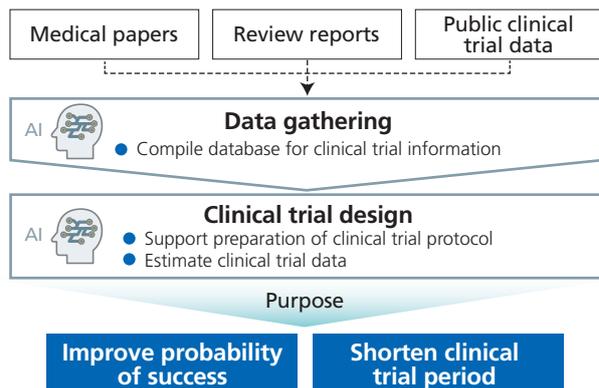
Using modalities

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



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Achieving a healthy and sustainable society through medical care

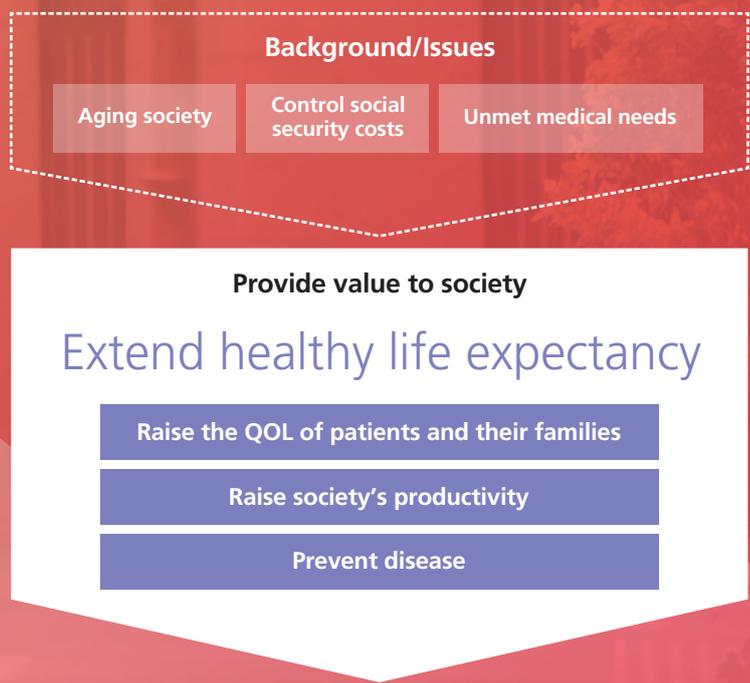
In Japan and other developed countries, social security spending has increased dramatically due to the rapid aging of the population and declining birthrates, so a balance between reducing medical costs and providing high-quality medical care is needed. The key to solving this issue is to extend the 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.



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.

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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](#)

Note: Figures before fiscal 2014 are based on Japanese GAAP.

Revenue / Operating margin



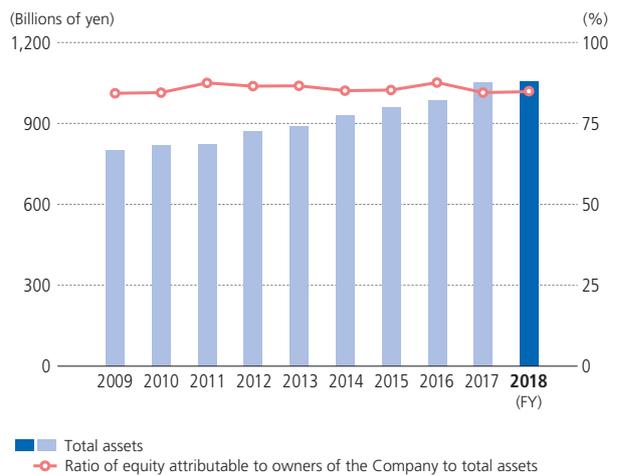
Operating profit / R&D expenses



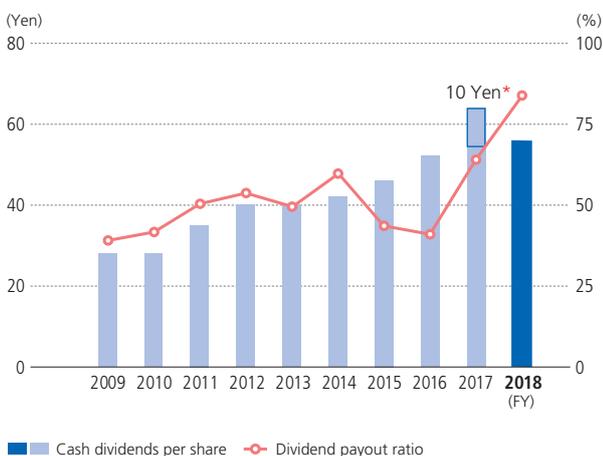
Profit attributable to owners of the Company / ROE



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.