

Operating Results and Data

10-Year Financial Summary	61
Management's Discussion and Analysis	63
Operational Risks	67
Overview and Sales Trends of Priority Products	69
Consolidated Statement of Income	75
Consolidated Statement of Comprehensive Income	76
Consolidated Statement of Financial Position	77
Consolidated Statement of Changes in Equity	79
Consolidated Statement of Cash Flows	81
Explanation of Terms	82
History	83
Corporate Data / Investor Information	85

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%.

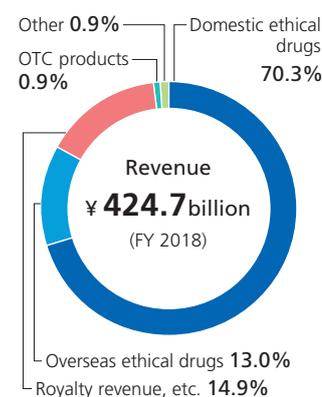
					(Billions of yen)	
	FY 2017	FY 2018		Change	% Change	
Revenue	433.8	424.7	(100.0)	-9.0	-2.1	
Domestic ethical drugs	309.3	298.7	(70.3)	-10.5	-3.4	
Overseas ethical drugs	38.5	55.1	(13.0)	+16.5	+42.9	
Royalty revenue, etc.	79.1	63.1	(14.9)	-16.0	-20.3	
OTC products	3.7	3.7	(0.9)	+0.0	+1.0	
Other	3.0	3.9	(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.

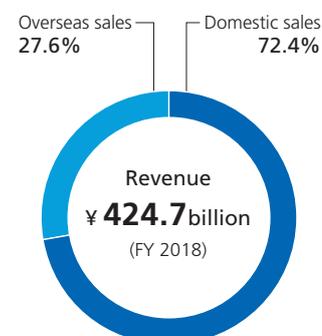
Revenue



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

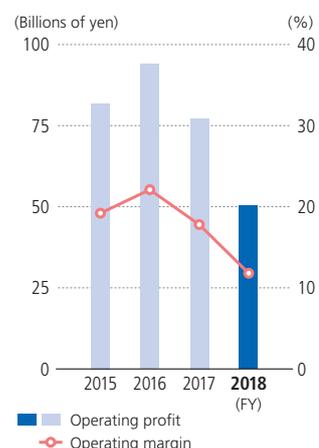
With the adoption of IFRS, the Company, its subsidiaries and its affiliates (collectively, "the Group") has introduced "core operating profit" as a major profit index to demonstrate its recurring profitability and positioned it as an important indicator of business management, etc. "Core operating profit" 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.

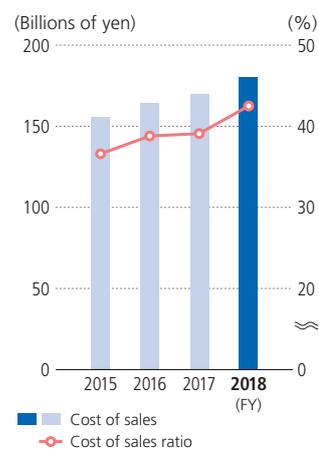
SG&A expenses decreased ¥5.8 billion, to ¥98.2 billion. In addition, R&D expenses increased ¥7.4 billion, to ¥86.5 billion, and the R&D expenses ratio was up 2.2 percentage points year on year, to 20.4%.

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.

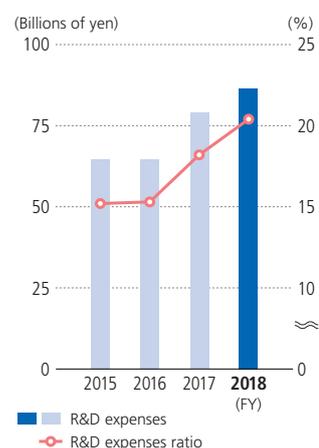
Operating profit / Operating margin



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.

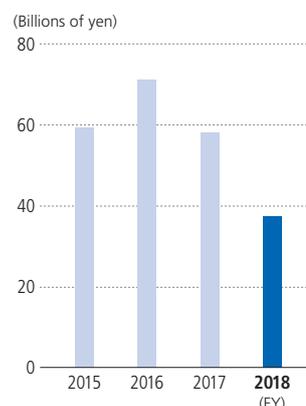
Total current assets increased ¥2.9 billion year on year, to ¥588.4 billion. Other financial assets increased ¥24.6 billion from an increase in securities, but cash and cash equivalents declined ¥15.1 billion and trade and other receivables decreased ¥6.5 billion.

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.

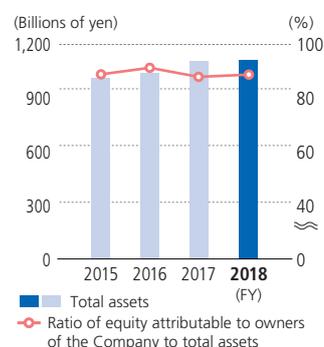
Total equity at the end of the period was up ¥15.5 billion from the end of the previous fiscal year, to ¥910.3 billion. Profit attributable to owners of the Company was ¥37.3 billion, while dividends paid were ¥31.4 billion. As a result, retained earnings increased ¥5.8 billion.

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



	At the end of FY2017	At the end of FY2018		Change	% Change
					(Billions of yen)
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.

	FY 2017	FY 2018	Change
			(Billions of yen)
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

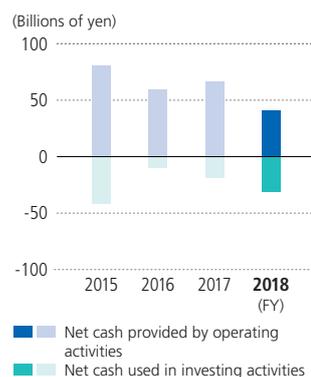
Dividends

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).

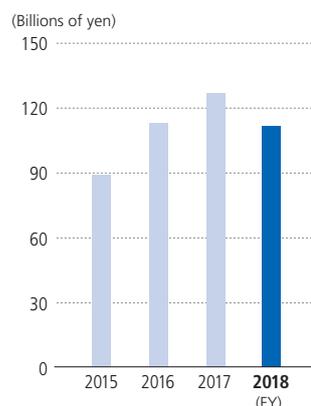
Given the arbitration proceedings with Novartis, there was a decrease in revenue in the fiscal year ended March 31, 2019 because a part of the "GILENYA Royalties" income was not recognized as sales revenue, in accordance with IFRS 15. Besides the impact of this matter, profit shifted in line with expectations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

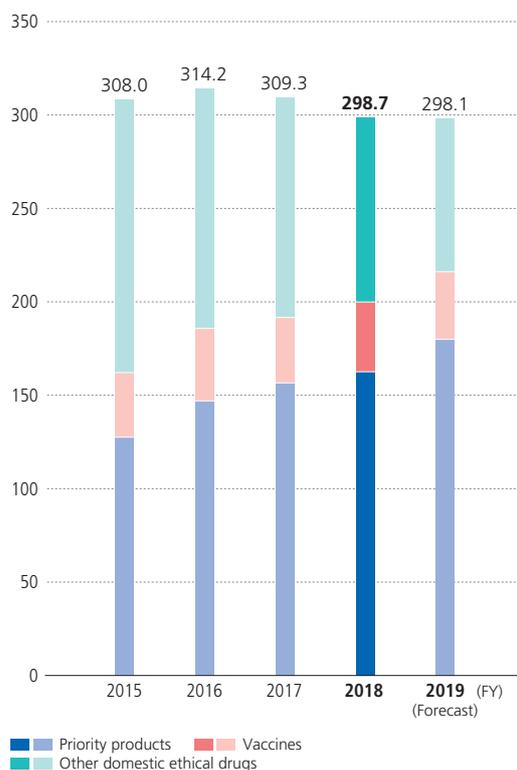
In regard to transactions between the Company and its parent company, Mitsubishi Chemical Holdings (MCHC), or companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Mitsubishi Tanabe Pharma Group in order to maximize the benefit to all 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
StoryBusiness and
Financial StrategyNon-Financial
InformationOperating 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.

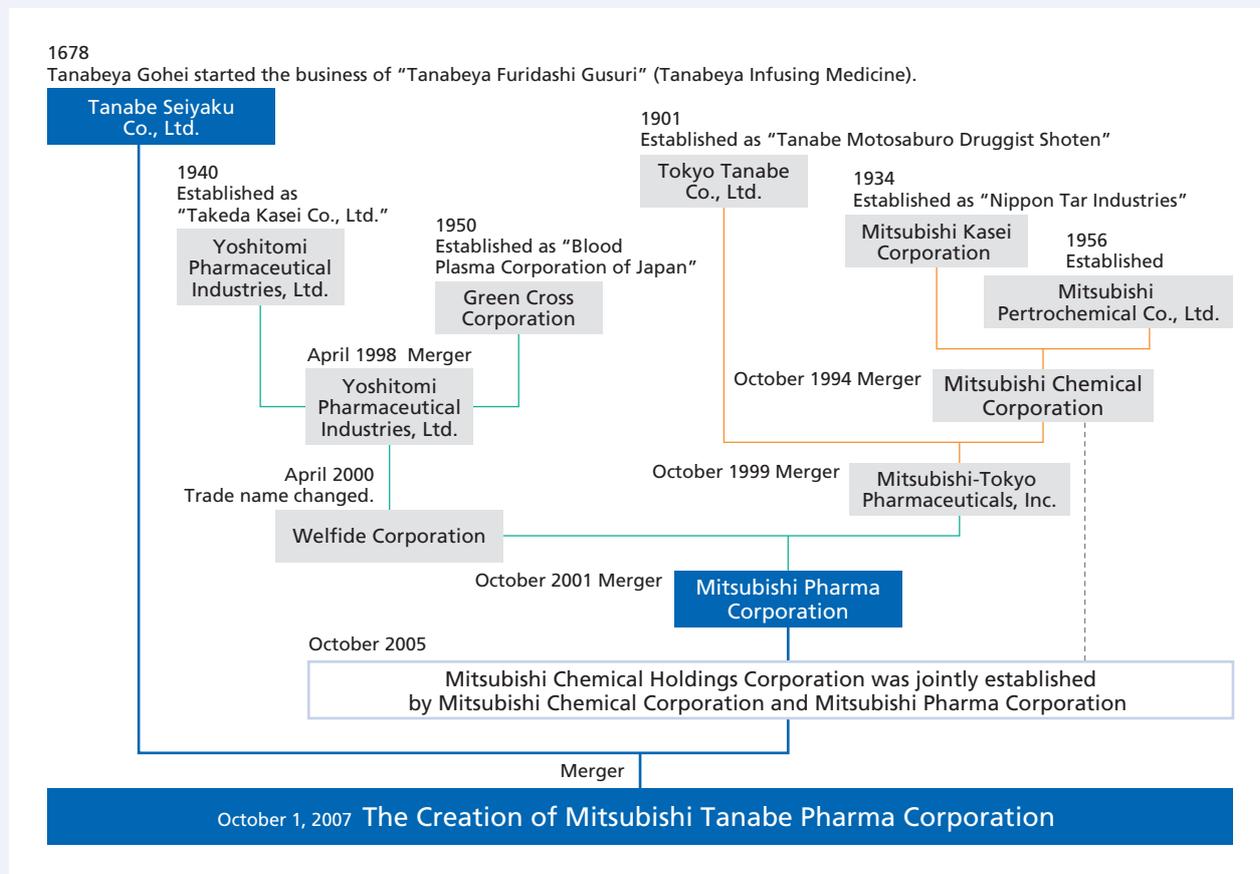
QOL (Quality of Life)

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

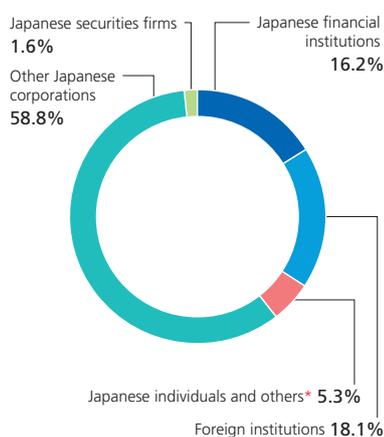
Major shareholders

	% 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

