



April 27, 2018

## Consolidated Financial Results for Year Ended March 31, 2018 (Fiscal 2017) <under IFRS>

Listed company name: Daiichi Sankyo Company, Limited  
 Listed exchange: First Section of the Tokyo Stock Exchange  
 Stock code number: 4568  
 URL: <https://www.daiichisankyo.com>  
 Representative: Dr. Sunao Manabe, Representative Director, President and COO.  
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Scheduled date of Ordinary General Meeting of Shareholders: June 18, 2018  
 Scheduled date of dividend payments: From June 19, 2018  
 Scheduled date of Annual Securities Report filing: June 18, 2018  
 Preparing supplementary material (Reference Data) on financial results: Yes  
 Holding information meeting: Yes (for institutional investors, analysts and the press)

(All amounts have been rounded down to the nearest million yen.)

### 1. Consolidated Financial Results for Year Ended March 31, 2018

#### (1) Consolidated Financial Results

(Percentages indicate changes from the previous fiscal year.)

	Revenue		Operating profit		Profit before tax		Profit for the year	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Year ended March 31, 2018	960,195	0.5	76,282	-14.2	81,021	-7.7	59,811	26.0
Year ended March 31, 2017	955,124	-3.2	88,929	-31.8	87,788	-28.3	47,479	-40.9

	Profit attributable to owners of the Company		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Year ended March 31, 2018	60,282	12.7	61,890	91.4	91.31	91.10
Year ended March 31, 2017	53,466	-35.0	32,332	29.5	79.63	79.44

	Return on equity attributable to owners of the Company	Ratio of profit before tax to total assets	Ratio of operating profit to revenue
	%	%	%
Year ended March 31, 2018	5.2	4.3	7.9
Year ended March 31, 2017	4.4	4.6	9.3

Reference: Share of profit or loss of investments accounted for using the equity method:

Year ended March 31, 2018: 320 million yen  
 Year ended March 31, 2017: 162 million yen

## (2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets	Equity per share attributable to owners of the Company
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of March 31, 2018	1,897,754	1,133,041	1,132,982	59.7	1,749.33
As of March 31, 2017	1,914,979	1,171,428	1,175,897	61.4	1,772.99

## (3) Consolidated Cash Flows

	Net cash flows from operating activities	Net cash flows from investing activities	Net cash flows from financing activities	Cash and cash equivalents at the end of year
	Millions of yen	Millions of yen	Millions of yen	Millions of yen
Year ended March 31, 2018	108,439	108,568	-101,766	357,702
Year ended March 31, 2017	136,234	-96,792	-15,022	246,050

## 2. Dividends

	Annual dividends per share					Total dividends (Total)	Dividend payout ratio (Consolidated)	Ratio of dividends to equity attributable to owners of the Company (Consolidated)
	First quarter	Second quarter	Third quarter	Fiscal year-end	Total			
	Yen	Yen	Yen	Yen	Yen			
Year ended March 31, 2017	–	35.00	–	35.00	70.00	46,591	87.9	3.9
Year ended March 31, 2018	–	35.00	–	35.00	70.00	45,885	76.7	4.0
Year ending March 31, 2019 (Forecast)	–	35.00	–	35.00	70.00		82.4	

### 3. Forecast of Consolidated Financial Results for Year Ending March 31, 2019

(Percentages indicate changes from the same period in the previous fiscal year.)

	Revenue		Operating profit		Profit before tax		Profit for the year		Profit attributable to owners of the Company		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Full year	910,000	-5.2	78,000	2.3	78,000	-3.7	55,000	-8.0	55,000	-8.8	84.92

#### \*Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates

- 1) Changes in accounting policies required by IFRS: Yes
- 2) Changes in accounting policies due to other reasons: No
- 3) Changes in accounting estimates: No

Note: Please see "4. Consolidated Financial Statements with Primary Notes, (5) Notes to Consolidated Financial Statements, (Changes in Accounting Policies)" on page 33

(3) Number of ordinary shares issued

1) Number of shares issued at the end of the period (including treasury shares)

As of March 31, 2018	709,011,343 shares
As of March 31, 2017	709,011,343 shares

2) Number of treasury shares at the end of the period

As of March 31, 2018	61,343,747 shares
As of March 31, 2017	45,783,623 shares

3) Average number of shares during the period

Year ended March 31, 2018	660,161,874 shares
Year ended March 31, 2017	671,422,557 shares

**(Reference)**

**Non-Consolidated Financial Results**

**Non-Consolidated Financial Results for Year Ended March 31, 2018**

**(1) Non-Consolidated Financial Results**

(Percentages indicate changes from the previous fiscal year.)

	Net sales		Operating income		Ordinary income		Net income	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Year ended March 31, 2018	630,954	0.3	17,177	-7.1	90,136	120.0	83,729	699.0
Year ended March 31, 2017	629,151	-2.2	18,483	-34.7	40,976	-12.2	10,479	-0.7

	Basic net income per share	Diluted net income per share
	Yen	Yen
Year ended March 31, 2018	126.83	126.53
Year ended March 31, 2017	15.61	15.57

**(2) Non-Consolidated Financial Position**

	Total assets	Net assets	Equity ratio	Net assets per share
	Millions of yen	Millions of yen	%	Yen
As of March 31, 2018	1,472,669	872,659	59.1	1,344.31
As of March 31, 2017	1,463,461	888,519	60.6	1,336.57

Reference: Equity:

As of March 31, 2018: 870,666 million yen  
As of March 31, 2017: 886,452 million yen

\* This financial results report is not subject to audit procedures by Certified Public Accountants or audit firm

\*Disclaimer regarding forward-looking information including appropriate use of forecast financial results

The forecast information included in these materials is based on information currently available and certain assumptions that the Company regards as reasonable. Actual performance and results may differ from those forecast due to various factors.

Please see "1. Financial Results (3) Future Outlook" on page 16 for matters related to the above forecasts.

## Attached Material

### Index

1. Results of Operations .....	2
(1) Operating Results for Year ended March 31, 2018.....	2
(2) Analysis of Financial Position as of March 31, 2018.....	14
(3) Future Outlook.....	16
(4) Basic Policy on Profit Distribution and Dividends for the Years Ended March 2018 and Ending March 2019.....	16
(5) Prospective Challenges.....	17
(6) Other Information.....	20
2. Corporate Governance .....	21
(1) Systems and Policies on Corporate Governance .....	21
(2) Basic Policy Regarding Moves toward Large-Scale Acquisition of Company's Stock.....	23
3. Rationale for the Selection of Accounting Standards .....	24
4. Consolidated Financial Statements with Primary Notes.....	25
(1) Consolidated Statement of Financial Position.....	25
(2) Consolidated Statement of Profit or Loss and Consolidated Statement of Comprehensive Income .....	27
(3) Consolidated Statement of Changes in Equity .....	29
(4) Consolidated Statement of Cash Flows .....	31
(5) Notes to Consolidated Financial Statements .....	33
Going Concern Assumption .....	33
Changes in Accounting Policies .....	33
Operating Segment Information .....	33
Earnings per Share.....	36
Subsequent Events.....	36

# 1. Results of Operations

## (1) Operating Results for Year ended March 31, 2018

### 1) Overview

#### [Consolidated Financial Results]

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
Revenue	955,124	960,195	5,070 0.5%
Operating profit	88,929	76,282	-12,647 -14.2%
Profit before tax	87,788	81,021	-6,766 -7.7%
Profit attributable to owners of the Company	53,466	60,282	6,815 12.7%
Total comprehensive income	32,332	61,890	29,557 91.4%

#### <Revenue from global mainstay products>

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

Product name	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
<i>Olmesartan</i> antihypertensive agent	218,017	149,672	-68,344 -31.3%
<i>Edoxaban</i> anticoagulant	37,332	77,089	39,756 106.5%
<i>Prasugrel</i> antiplatelet agent	41,609	32,815	-8,793 -21.1%

#### <Selling, general and administrative expenses>

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
Selling, general and administrative expenses	302,475	301,845	-629 -0.2%
Ratio of selling, general and administrative expenses to revenue	31.7%	31.4%	-0.2%

<Research and development expenses>

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
Research and development expenses	214,347	236,046	21,699 10.1%
Ratio of research and development expenses to revenue	22.4%	24.6%	2.1%

<Yen exchange rates for major currencies (average rate for year)>

(Yen)

	Year ended March 31, 2017	Year ended March 31, 2018
USD/Yen	108.42	110.86
EUR/Yen	118.84	129.70

#### **a. Revenue**

- Revenue in the year ended March 31, 2018 (fiscal 2017) increased by ¥5.1 billion, or 0.5% year on year, to ¥960.2 billion.
- The positive effects from growth in sales of mainstay products such as *Edoxaban* and ongoing yen depreciation (¥14.0 billion) led to an increase in revenue, despite a decrease in sales of *Olmесartan* due to the loss of exclusivity.

#### **b. Operating Profit**

- Operating profit decreased by ¥12.6 billion, or 14.2% year on year, to ¥76.3 billion.
- Gross profit increased by ¥8.4 billion, or 1.4% year on year, to ¥614.2 billion. Although the increase in cost of sales arising from changes in the product mix did have an effect, the historical factor of impairment losses for property, plant and equipment and intangible assets in the vaccine business (¥20.6 billion) getting recorded as cost of sales in the previous fiscal year led to the net increase in gross profit.
- Selling, general and administrative expenses were ¥301.8 billion, nearly flat compared to the previous fiscal year.
- Research and development expenses increased by ¥21.7 billion, or 10.1% year on year, to ¥236.0 billion mainly because an impairment loss (¥27.8 billion) on intangible assets related to *CL-108*, a combination drug for the treatment of pain and opioid-induced nausea and vomiting (OINV), was recorded.
- The positive effects on operating profit stemming from yen depreciation were ¥1.9 billion in total.

#### **c. Profit before Tax**

- Profit before tax decreased by ¥6.8 billion, or 7.7% year on year, to ¥81.0 billion.
- The decrease in profit before tax was modest compared to the decrease in operating profit mainly due to an improvement of loss (gain) on exchange differences relating to assets denominated in foreign currencies.

#### **d. Profit Attributable to Owners of the Company**

- Profit attributable to owners of the Company increased by ¥6.8 billion, or 12.7% year on year, to ¥60.3 billion.
- Profit attributable to owners of the Company increased mainly from the impact of a decrease in income taxes resulting from the reduction of tax rates in the U.S.

#### **e. Total comprehensive income**

- Total comprehensive income increased by ¥29.6 billion, or 91.4% year on year, to ¥61.9 billion.
- Total comprehensive income increased significantly year on year mainly due to improvements in valuation difference on financial assets.



## [Revenue by Geographic Area]

Primary revenue by geographic area is as follows.

### a. Japan

Revenue in Japan increased by ¥39.7 billion, or 6.9% year on year, to ¥612.9 billion.

[Prescription drug business]

- Revenue from prescription drug business increased by ¥33.5 billion, or 6.6% year on year, to ¥540.0 billion. The increase is attributable to growth in sales of mainstay products such as *LIXIANA*, *Inavir*, *PRALIA*, *NEXIUM*, *Efient*, *TENELIA*, *Memary* and *RANMARK*, and contributions to sales from newly launched authorized generic\*<sup>1</sup> products, despite a decline in sales of *Olmotec* and negative effects on sales of long-listed products as a result of the growing numbers of prescriptions of generic drugs. This revenue also includes revenue generated by the generic pharmaceutical business of Daiichi Sankyo Espha Co., Ltd., and revenue generated by the vaccine business of companies that include Kitasato Daiichi Sankyo Vaccine Co., Ltd., Japan Vaccine Co., Ltd., etc.
- In June 2017, Daiichi Sankyo launched *Narurapid* tablets (immediate release formulation) and *Narusus* tablets (extended release formulation) for cancer pain treatment, whose principal ingredients are hydromorphone hydrochloride.
- In September 2017, Daiichi Sankyo launched *CANALIA* (combination drug of *TENELIA* and *CANAGLU*), a type 2 diabetes mellitus treatment agent.
- In November 2017, Daiichi Sankyo launched oral anticoagulant *Lixiana OD* tablets (orally disintegrating tablets).
- The antiepileptic drug *VIMPAT* was approved, in August 2017, for monotherapy for partial-onset seizures in patients with epilepsy. Furthermore, in September 2017, the Ministry of Health, Labour and Welfare issued a notification announcing the lifting of the restriction on the prescription period for *VIMPAT*.
- Since June 2017, Daiichi Sankyo Espha Co., Ltd. has successively launched multiple authorized generic products including *Olmecartan OD* tablets.

\*1 Authorized generic: Generic drug manufactured after receiving consent from the manufacturer of the original drug.

[Healthcare (OTC) products business]

- Revenue from the healthcare (OTC) products business increased by ¥6.2 billion, or 9.3% year on year, to ¥72.9 billion. The increase is attributable to growth in sales including those of the *MINON* series handled by Daiichi Sankyo Healthcare Co., Ltd.

<Primary revenue composition in Japan>

(Billions of yen; all amounts have been rounded off to the nearest single decimal place.)

	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
Prescription drug business*	506.6	540.0	33.5 6.6%
Healthcare (OTC) products business	66.7	72.9	6.2 9.3%

\* Includes generic pharmaceutical business and vaccine business.

<Domestic revenue from mainstay prescription drugs>

(Billions of yen; all amounts have been rounded off to the nearest single decimal place.)

Product name	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
<i>NEXIUM</i> ulcer treatment	84.0	86.5	2.6 3.0%
<i>Memary</i> Alzheimer's disease treatment	46.9	48.6	1.7 3.6%
<i>Olmetec</i> antihypertensive agent	69.4	44.6	-24.8 -35.8%
<i>LIXIANA</i> anticoagulant	25.0	45.3	20.3 81.4%
<i>Loxonin</i> anti-inflammatory analgesic	37.4	36.5	-1.0 -2.6%
<i>TENELIA</i> type 2 diabetes mellitus treatment	24.2	26.3	2.1 8.8%
<i>PRALIA</i> treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	18.0	23.2	5.2 29.1%
<i>Rezaltas</i> antihypertensive agent	17.5	16.8	-0.8 -4.4%
<i>RANMARK</i> treatment for bone complications caused by bone metastases from tumors	13.9	15.4	1.5 10.6%
<i>Efient</i> antiplatelet agent	10.4	12.8	2.4 23.2%
<i>Inavir</i> anti-influenza treatment	19.6	25.3	5.7 29.2%
<i>Cravit</i> synthetic antibacterial agent	15.1	12.7	-2.4 -16.1%
<i>Urief</i> treatment for dysuria	11.4	11.1	-0.3 -2.7%
<i>Omnipaque</i> contrast medium	14.2	14.0	-0.2 -1.6%
<i>Mevalotin</i> antihyperlipidemic agent	10.4	8.6	-1.8 -17.6%

**b. North America**

- Revenue in North America decreased by ¥50.2 billion, or 21.8% year on year, to ¥180.2 billion. Revenue in local currency terms decreased by US\$500 million, or 23.5%, to US\$1,625 million. This revenue includes revenue generated by Daiichi Sankyo, Inc., and Luitpold Pharmaceuticals, Inc.
- At Daiichi Sankyo, Inc., sales of *Olmesartan* and its combination drugs, *Welchol* and *Efient* declined.
- Daiichi Sankyo, Inc. signed a license agreement with Inspirion Delivery Sciences LLC, which has given Daiichi Sankyo, Inc. an exclusive license in the U.S. to commercialize two abuse-deterrent opioid analgesics in October 2016.

Based on the contract, Daiichi Sankyo, Inc. launched *MorphaBond*, morphine extended-release tablets, in October 2017. Moreover, Daiichi Sankyo, Inc. has determined the commercialization of *RoxyBond*, FDA-approved oxycodone hydrochloride immediate-release tablets, in May 2017 and its launch preparation is underway.

- Daiichi Sankyo Inc., after giving careful thought to the drug product group in the United States and the pipeline (group of new drug candidates) for oncology, decided in March 2018 reorganization including reduction of the number of personnel at its sales departments by 280 people as part of efforts to gain further efficiency improvements from the sales organization operations so that it can prepare for the future new drug market for oncology.
- At Luitpold Pharmaceuticals, Inc., sales of *Injectafer* and *Venofer* increased.

<Revenue of Daiichi Sankyo, Inc. mainstay products>

(Millions of US\$; all amounts have been rounded off to the nearest million US\$.)

Product name	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
<i>Olmesartan</i> * antihypertensive agent	612	192	-420 -68.5%
<i>Welchol</i> hypercholesterolemia treatment/ type 2 diabetes mellitus inhibitor	420	306	-114 -27.1%
<i>Effient</i> antiplatelet agent	205	96	-109 -53.0%
SAVAYSA anticoagulant	17	20	2 13.0%
MOVANTIK opioid-induced constipation treatment	38	42	4 9.9%

\* *Benicar/Benicar HCT, AZOR, TRIBENZOR* and authorized generics for *Olmesartan*

<Revenue of Luitpold Pharmaceuticals, Inc. mainstay products>

(Millions of US\$; all amounts have been rounded off to the nearest million US\$.)

Product name	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
<i>Venofer</i> treatment for iron deficiency anemia	263	279	17 6.3%
<i>Injectafer</i> treatment for iron deficiency anemia	221	310	89 40.1%

### c. Europe

- Revenue in Europe increased by ¥8.5 billion, or 12.0% year on year, to ¥79.4 billion. Revenue in local currency terms increased by EUR15 million, or 2.6%, to EUR613 million.
- The increase of revenue is mainly attributable to increase in sales of *LIXIANA* despite of decrease in sales of *Olmесartan* and its combination drugs.

<Revenue of Daiichi Sankyo Europe GmbH mainstay products>

(Millions of euro; all amounts have been rounded off to the nearest million euro.)

Product name	Year ended March 31, 2017	Year ended March 31, 2018	YoY change
<i>Olmесartan</i> * antihypertensive agent	363	258	-105 -28.9%
<i>Efient</i> antiplatelet agent	67	62	-5 -7.6%
<i>LIXIANA</i> anticoagulant	81	208	127 155.7%

\* *Olmetec/Olmetec Plus, Sevikar and Sevikar HCT*

### d. Asia, South & Central America

- Revenue in Asia, South & Central America increased by ¥8.2 billion, or 11.4% year on year, to ¥80.4 billion. This revenue includes revenue to overseas' licensees.
- Mainstay products such as synthetic antibacterial agent *Cravit* grew in China.
- Mainstay products such as anticoagulant *LIXIANA* grew in South Korea.

## 2) R&D Activities

- Daiichi Sankyo Group (the Group) has established its 2025 Vision of being a “Global Pharma Innovator with Competitive Advantage in Oncology.”
- In setting out to achieve our 2025 Vision, the Group established antibody drug conjugates (ADC)\*<sup>1</sup> franchise, acute myeloid leukemia (AML) franchise and Breakthrough Science\*<sup>2</sup> as three pillars for oncology which is the primary focused area, and is working on strategic research and development activities.
- In addition, the Group positioned pain, central nervous system diseases, heart and kidney diseases, and rare diseases as new horizon areas, and is accelerating research activities.
- The Group is trying to generate innovative medicine that transforms standards of care (SOC) utilizing partnering\*<sup>3</sup>, open innovation\*<sup>4</sup> and translational research\*<sup>5</sup> in the research and early-stage of development.
- As for the late-stage of development, the Group is developing drugs in oncology, cardiovascular-metabolics and other fields.
- The Group is continuously undertaking life cycle management activities\*<sup>6</sup> particularly in the field of cardiovascular-metabolics.
- In April 2017, Biologics Division was newly established which has integrated functions for biologics' modality research\*<sup>7</sup> and production technology research and development.
- As part of initiatives to improve R&D functions, Daiichi Sankyo made the decision to carry out an absorption-type merger with its domestic subsidiary Asubio Pharma Co., Ltd., on April 1, 2018.

\*1 Antibody drug conjugate (ADC): Drugs composed of an antibody drug and a payload (a low molecule drug) linked via appropriate linker. By using a monoclonal antibody that binds to a

specific target expressed on cancer cells, a cytotoxic payload is delivered to cancer cells effectively with reducing systemic exposure.

- \*2 Breakthrough Science: New treatment modality that brings radical innovation to cancer treatment methods through the practical application of innovative science and technology.
  - \*3 Partnering: Cooperation between companies, universities and research institutions utilizing their own strengths mutually to generate new values.
  - \*4 Open innovation: Development method in which external development capabilities and ideas are used to overcome internal development challenges and create innovative new value.
  - \*5 Translational research: Research process that translates basic scientific results obtained in preclinical studies into new drugs or medical technologies for practical application via testing at clinical settings, or applies the efficacy and safety confirmed at clinical settings to new basic researches.
  - \*6 Life cycle management: Initiatives to bring the value of pharmaceuticals to the healthcare fields over a long period by further enhancing its product value through expanding indications and improving dosage and administration.
  - \*7 Modality research: Drug discovery technology research for all compounds excluding small molecules, such as antibodies, ADC, peptides, and nucleic acid etc.
- The following section describes the Group's major development projects and progresses made in each project.

## [Oncology Area]

### a. DS-8201 (HER2-targeting ADC)

- The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to *DS-8201* for the treatment of HER2-positive metastatic breast cancer in December 2016. Furthermore, the FDA has granted Breakthrough Therapy designation\*8 to *DS-8201*, for the treatment of HER2-positive, recurrent and/or metastatic breast cancer in August 2017. In addition, *DS-8201* has granted SAKIGAKE Designation\*9 for the treatment of HER2-overexpressing unresectable recurrent and/or advanced gastric cancer that has progressed after cancer chemotherapy by the Japan Ministry of Health, Labour and Welfare (MHLW) in March 2018.
  - Second part (expansion study) of Phase I clinical trial for patients with HER2-positive cancer is underway in Japan and the U.S. The preliminary results were presented at the American Society of Clinical Oncology (ASCO) in June 2017 and the European Society for Medical Oncology (ESMO) in September 2017. Furthermore, updated safety and efficacy data from patients with HER2-positive and HER2 low-expressing breast cancer was presented at the San Antonio Breast Cancer Symposium in December 2017 and updated safety and efficacy data from patients with HER2-positive gastric cancer was presented at the ASCO Gastrointestinal Cancers Symposium (ASCO-GI) in January 2018.
  - In August 2017, the Group initiated global Phase II clinical trials for patients with HER2-positive, recurrent and/or metastatic breast cancer.
  - In November 2017, the Group initiated Phase II clinical trials in Japan and South Korea for patients with HER2-positive, recurrent and/or advanced gastric cancer.
  - In February 2018, the Group initiated global Phase II clinical trials for patients with HER2-positive, recurrent and/or advanced colorectal cancer.
- \*8 Breakthrough Therapy designation is designed to expedite the development and review of medicines that may demonstrate substantial benefit over currently available treatments in order to ensure that patients with serious diseases have access to new treatments as soon as possible.

\*9 SAKIGAKE Designation System: System that promotes R&D in Japan by providing prioritized access to clinical trials and approval procedures aiming at early practical application for innovative pharmaceutical products.

[Research and development collaboration relating DS-8201]

- Daiichi Sankyo concluded an agreement with the U.S. company, Bristol-Myers Squibb Company, in August 2017 concerning a collaborative clinical trial to evaluate the combination of *DS-8201* and *nivolumab*, the immune checkpoint inhibitor (product name: *Opdivo*) in patients with HER2-positive breast cancer and bladder cancer.
- Daiichi Sankyo concluded an agreement with the U.S. company, Puma Biotechnology, Inc. and Memorial Sloan Kettering Cancer Center, in December 2017 concerning a collaborative preclinical trial to evaluate the combination of *DS-8201* and tyrosine kinase inhibitor *neratinib* (product name in the U.S.: *NERLYNX*) in cancer patients with HER2-mutated solid tumors.

**b. U3-1402 (HER3-targeting ADC)**

- A Phase I/II clinical trial is being conducted in Japan and the U.S. in patients with HER3-positive metastatic and/or unresectable breast cancer.
- In February 2018, the Group initiated Phase I clinical trials in the U.S. for patients with epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) whose disease has progressed while taking an EGFR tyrosine kinase inhibitor (TKI).

**c. DS-1062 (TROP2-targeting ADC)**

- In February 2018, the Group initiated Phase I clinical trials in Japan and the U.S. for patients with recurrent and/or advanced NSCLC.

**d. Quizartinib**

- Phase III clinical trials are underway in Europe, the U.S. and Asia to obtain approval for indication as second-line treatment and first-line treatment in AML patients with FLT3-ITD mutations.

**e. DS-3201**

- Phase I clinical trials are being conducted in Japan in patients with relapsed or refractory non-Hodgkin lymphomas, and the preliminary results were presented at the ASH Annual Meeting in December 2017.
- Phase I clinical trials are being conducted in the U.S. in patients with relapsed or refractory AML and acute lymphocytic leukemia (ALL).

**f. Pexidartinib**

- *Pexidartinib* was granted Breakthrough Therapy designation by the FDA for the treatment of tenosynovial giant cell tumor (TGCT) in October 2015.
- In October 2017, Daiichi Sankyo announced that Phase III clinical trial in TGCT patients in Europe and the U.S. met its primary endpoints.

**g. DS-1647**

- The oncolytic virus *G47Δ* (*DS-1647*), for which the Group is jointly conducting Phase II clinical trials in Japan with Dr. Tomoki Todo, Professor at the Institute of Medical Science, the University of Tokyo, was granted SAKIGAKE Designation for the treatment of glioblastoma in February 2016.

Furthermore, *DS-1647* was designated as an orphan drug for the treatment of glioblastoma in July 2017.

#### **h. Denosumab**

- *Denosumab* has been on the Japanese market under the brand name *RANMARK*, since 2012 with indications for the treatment of bone complications stemming from multiple myeloma or bone metastases from solid tumors, and since 2014 with indications for the treatment of giant cell tumors of bone (GCTB). In 2013, manufacturing and marketing approval was received for the treatment for osteoporosis in Japan, where it has been on the market under the brand name *PRALIA*.
- As for *PRALIA*, the Group obtained approval for an additional indication for inhibition of the progression of bone erosion associated with rheumatoid arthritis in July 2017.
- In February 2018, the Group and Amgen Inc., in the U.S. made an announcement regarding the top-line results from their global Phase III clinical trials for *RANMARK* as a postoperative adjuvant breast cancer therapy which the companies jointly have conducted. The trial did not meet its primary endpoint of prolonged bone metastasis-free survival. Adverse events observed in patients treated with *RANMARK* were generally consistent with the known safety profile.

#### **[Major R&D Alliances, etc.]**

##### **a. Option agreement for ADC strategic collaboration and licensing with Glycotope GmbH**

- In October 2017, Daiichi Sankyo has signed an option agreement with the German company, Glycotope GmbH (Glycotope), for future strategic collaboration and licensing to develop an ADC by combining Daiichi Sankyo's proprietary ADC technology with Glycotope's investigational tumor-associated TA-MUC1 antibody *PankoMab-GEX*.
- Under the agreement, once a feasibility study has been successfully completed, Daiichi Sankyo has the worldwide exclusive rights to develop and commercialize *PankoMab-GEX ADC*.

##### **b. Conclusion of agreement with MD Anderson Cancer Center regarding research and development collaboration relating to therapies for AML**

- In September 2017, Daiichi Sankyo's U.S. subsidiary Daiichi Sankyo Inc., together with Plexxikon Inc., concluded an agreement with the U.S. university, the University of Texas MD Anderson Cancer Center, regarding research and development collaboration relating to therapies for AML.
- Under the agreement, the collaboration will conduct translational research, including preclinical development and exploration of novel biomarkers\*<sup>10</sup>, while assessing the concomitant effects (concomitant effects among Daiichi Sankyo's drugs and those with other companies' drugs) of the multiple compounds under development in Daiichi Sankyo's AML Franchise.

\*<sup>10</sup> Biomarker: An indicator for patient stratification, discovery of modes of action of pharmaceuticals, and efficacy and safety thereof.

##### **c. Conclusion of cancer R&D collaboration agreement with Max Planck Innovation GmbH**

- In July 2017, Daiichi Sankyo, Max Planck Innovation GmbH (Max Planck) and its exploratory research center the Lead Discovery Center GmbH (LDC) signed an agreement providing Daiichi Sankyo with the option to receive the exclusive rights to a new lead compound\*<sup>11</sup> for the treatment of cancer to be discovered and developed at the LDC.
- Under the agreement, Daiichi Sankyo, Max Planck researchers and the LDC will now closely cooperate to further optimize these novel compounds that target cancer cell transcription and proliferation.

\*11 Lead compound: A compound that marks the starting point for a drug discovery process. Modifications of its chemical structure may lead to improvements in its activity, toxicity and pharmacokinetics.

**d. Conclusion of *DS-5010* licensing agreement with Boston Pharmaceuticals Inc.**

- In August 2017, Daiichi Sankyo concluded an agreement with the U.S. company, Boston Pharmaceuticals Inc., granting that company worldwide rights for the research, development, manufacturing and commercialization of Daiichi Sankyo's *DS-5010*, a highly selective and potent RET (ret proto-oncogene) kinase inhibitor.

**e. Commencement of open innovation research on a new cancer hyperthermia therapy**

- In March 2018, Daiichi Sankyo commenced open innovation research on a new cancer hyperthermia therapy with Public University Corporation Nagoya City University, Chubu University, Incorporated Educational Institution Chubu University, and Mitsubishi UFJ Capital Co., Ltd. (Mitsubishi UFJ Capital).
- To carry out the research, a new company called OiDE RYO-UN, Inc. was established. OiDE RYO-UN, Inc. was wholly funded by the OiDE Fund Investment Limited Partnership, a fund jointly set up by Daiichi Sankyo and Mitsubishi UFJ Capital in 2013.
- Daiichi Sankyo will promote industry-university collaboration of new drug discovery fundamentals research and aim to develop new treatment methods.

**[Specialty Medicine Area\*12]**

\*12 Specialty Medicine Area: Cardiovascular-metabolics, pain, central nervous system diseases, heart and kidney diseases, and rare diseases

**a. Edoxaban**

- *Edoxaban* has been on the Japanese market since 2011 under the brand name *LIXIANA* with indication for the prevention of venous thromboembolism (VTE) after major orthopedic surgery. In 2014, the product also received approval in Japan for additional indications for the prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF), and for the treatment and prevention of recurrence of VTE (deep vein thrombosis (DVT) and pulmonary embolism (PE)).
- As for overseas, *Edoxaban* has received marketing approval in over 20 countries including the U.S., Europe and Asia regions.
- The Group initiated randomized controlled trials (ENVISAGE-TAVI AF study) in patients with AF undergoing transcatheter aortic valve implantation in Europe and the U.S. in April 2017.
- The results from the Hokusai-VTE CANCER study for patients with VTE associated with cancer in Europe and the U.S. were presented during the late-breaker session at the American Society of Hematology (ASH) Annual Meeting in December 2017.

**b. Esaxerenone**

- The Group initiated Phase III clinical trial in Japan for patients with diabetic nephropathy in September 2017.
- The top-line results that the primary efficacy endpoint was met in Phase III clinical trials for patients with essential hypertension in Japan were announced in September 2017.
- Based on the result, an application was filed in Japan for manufacturing and marketing approval for the treatment of hypertension in February 2018.



### c. Mirogabalin

- The top-line results of two Phase III clinical trials to evaluate the efficacy of *mirogabalin* in patients with pain were announced in June 2017. As for clinical trial in patients with postherpetic neuralgia (PHN) in Japan and Asia, *mirogabalin* met the primary efficacy endpoint. On the other hand, with regards to clinical trial in patients with fibromyalgia (FM) in Europe and the U.S., *mirogabalin* did not meet the primary efficacy endpoint.
- The top-line results that the primary efficacy endpoint was met in Phase III clinical trials for patients with diabetic peripheral neuropathic pain (DPNP) in Japan and Asia were announced in August 2017.
- Based on the result of Phase III clinical trials in Japan and Asia, an application was filed in Japan for manufacturing and marketing approval for the treatment of peripheral neuropathic pain in February 2018.

### d. DS-5141

- Duchenne muscular dystrophy treatment drug, *DS-5141*, whose Phase I/II clinical trial is jointly underway in Japan with Orphan Disease Treatment Institute Co., Ltd., was granted SAKIGAKE Designation in April 2017.

### e. CHS-0214

- In July 2017, the Group decided to discontinue the joint development being carried out with the U.S. company, Coherus BioSciences, Inc., in Japan of *CHS-0214*, an etanercept biosimilar for autoimmune disease treatment mainly of rheumatoid arthritis, because a manufacturing process to enable stable supply cannot be established at this time.

## [Major R&D Alliances, etc.]

### a. Termination of *TS23* licensing agreement with Translational Sciences, Inc.

- In October 2017, Daiichi Sankyo decided to return all rights to develop and commercialize Translational Sciences, Inc.'s thrombus dissolving agent, *TS23*, due to the re-prioritization and re-focusing of the R&D pipeline.

### b. Termination of development and commercialization agreement with Charleston Laboratories Inc. regarding *CL-108*

- Daiichi Sankyo and U.S. subsidiary Daiichi Sankyo Inc. decided in August 2017 to terminate a development and commercialization agreement with the U.S. company, Charleston Laboratories Inc., regarding *CL-108*, a combination drug for the treatment of pain and opioid-induced nausea and vomiting (OINV) as a result of a revaluation of the U.S. pain market and the Group's portfolio.

### c. Conclusion of agreement with Cuorips Inc. regarding commercialization of iPS-derived cardiomyocyte (iPS-CM) sheet

- In August 2017, Daiichi Sankyo signed an investment contract with Cuorips Inc. (Cuorips), an Osaka University spin-off venture to receive an option right concerning the worldwide commercialization of iPS-CM sheet developed by Cuorips.
- Under the agreement, Daiichi Sankyo and Cuorips are aiming to commercialize iPS-CM sheets as a pioneering treatment for severe heart failure.

### 3) Production and Logistics

- The Group is working on transforming its production platform toward the establishment of an oncology business.
- Daiichi Sankyo made capital investments for ADC, including *DS-8201*, at its three domestic plants to expand its production platform.
- With regard to its global product *Edoxaban*, preparations have been made for establishing the product supply system that will accommodate sales growth in Japan and Europe as well as market launches in China and Brazil in the future.
- In Japan, Daiichi Sankyo has built the system to increase production of *Inavir* Dry Powder Inhaler, which has been designated as a product for governmental stockpile against novel influenza, and preparations of production platform have been made for market launches of *Esaxerenone* and *Mirogabalin*. Furthermore, the production system for *Olmesartan OD* tablets, which has been newly released in the current fiscal year, has been developed.
- In China, the construction of a new building for pharmaceutical processing at Daiichi Sankyo Pharmaceutical (Shanghai) Co., Ltd.'s Shanghai Factory has completed, securing the Group's increase in its production capacity in conjunction with future growth of the China business.

### 4) Corporate Social Responsibility (CSR) Activities

- The Daiichi Sankyo Group Corporate Conduct Charter commits the Group to working as a whole to carry out CSR activities based on medium- and long-term business activities and corporate social responsibility. The Group aims to achieve sustained growth in corporate value by following through on this commitment.
- Daiichi Sankyo has defined its six domains for CSR activities as promoting compliance management, mutual growth of employees and the Company, enhancement of communication with stakeholders, promoting environmental management, improving access to healthcare, and social contribution activities, and works on its activities in each of these domains on an ongoing basis.
- For working on these activities, Daiichi Sankyo also seeks to upgrade its stakeholder communications by improving disclosure of information related to environmental, social and governance (ESG) issues.

## (2) Analysis of Financial Position as of March 31, 2018

### 1) Assets, Liabilities and Capital Position

- Total assets as of the fiscal year-end are ¥1,897.8 billion, a decrease of ¥17.2 billion from the previous fiscal year-end, mainly due to a decrease in intangible assets which was partially offset by an increase in other financial assets (non-current assets).
- Total liabilities as of the fiscal year-end are ¥764.7 billion, an increase of ¥21.2 billion from the previous fiscal year-end, mainly due to an increase in provisions (non-current liabilities) which was partially offset by a decrease in deferred tax liabilities.
- Total equity as of the fiscal year-end is ¥1,133.0 billion, a decrease of ¥38.4 billion from the previous fiscal year-end, mainly because of dividends paid and acquisition of treasury shares (15,729 thousand shares, ¥50.0 billion) which were partially offset by the profit for the year.
- The ratio of equity attributable to owners of the Company to total assets decreased by 1.7% from the previous year-end to 59.7%.

### 2) Status of Cash Flows

Cash and cash equivalents increased by ¥111.7 billion during the year ended March 31, 2018 to ¥357.7

billion. The cash flow status and the contributing factors are summarized as follows:

- Net cash flows provided by operating activities totaled ¥108.4 billion (previous year: ¥136.2 billion). Besides profit before tax (¥81.0 billion) and non-cash items such as depreciation and amortization (¥46.7 billion) and impairment loss (¥36.7 billion), this reflected cash outflows from the payments of income taxes.
- Net cash flows provided by investing activities totaled ¥108.6 billion (previous year: ¥96.8 billion outflow) mainly provided by proceeds from maturities of time deposits, which was partially offset by capital expenditures and acquisitions of intangible assets.
- Net cash flows used in financing activities totaled ¥101.8 billion (previous year: ¥15.0 billion), which reflected spending on acquisition of treasury shares and dividend payments.

(Reference) Cash flow-related indicators

***Principal Cash Flow Indicators***

	Year ended March 31, 2017	Year ended March 31, 2018
Ratio of equity attributable to owners of the Company to total assets (%)	61.4	59.7
Ratio of equity attributable to owners of the Company to total assets (at market value) (%)	86.8	120.3
Interest-bearing debt to cash flow ratio (years)	1.69	2.13
Interest coverage ratio (times)	111.2	65.1

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

Ratio of equity attributable to owners of the Company to total assets (at market value): total market capitalization/total assets

Interest-bearing debt to cash flow ratio: interest-bearing debt/cash flows

Interest coverage ratio: cash flows/interest paid

(Notes)

1. All indicators are calculated on a consolidated basis.
2. Total market capitalization is calculated based on the number of outstanding ordinary shares (net of treasury shares).
3. Cash flows equal the amount of net cash provided by operating activities in the consolidated statement of cash flows less the amounts of "interest paid" and "income taxes paid." Interest paid equals the "interest paid" included in the consolidated statement of cash flows.
4. Interest-bearing debt includes all liabilities reported on the consolidated statement of financial position which are subject to interest payments.

### (3) Future Outlook

#### The Group

(Millions of yen; all amounts have been rounded down to the nearest million yen.)

	Year ended March 31, 2018	Year ending March 31, 2019	Amount change	Percentage change
Revenue	960,195	910,000	-50,195	-5.2
Operating profit	76,282	78,000	1,717	2.3
Profit before tax	81,021	78,000	-3,021	-3.7
Profit for the year	59,811	55,000	-4,811	-8.0
Profit attributable to owners of the Company	60,282	55,000	-5,282	-8.8

- Regarding revenue, the Company is working toward rapid growth of Edoxaban both in Japan and overseas, and growth of *Injectafer*, a product of Luitpold Pharmaceuticals, Inc. in the U.S. However, we are expecting a 5.2% decrease in revenue year on year, to ¥910.0 billion due to the decrease of units sold that will accompany the domestic expiration of the patent period for Olmesartan and the effect of the large decrease in pharmaceutical prices accompanying Japan's NHI Drug Price Reform.
- Although an increase in expenses is expected due to the future concentrated injection of resources into the oncology business, operating profit is expected to be ¥78.0 billion, a 2.3% increase year on year mainly due to enhancing profit generation and ongoing cost reductions.
- Profit attributable to owners of the Company is expected to be ¥55.0 billion, which is an 8.8% decrease year on year.
- Forecasts are based on assumption of foreign exchange rates at ¥110 against U.S. dollar and ¥130 against euro.

#### (4) Basic Policy on Profit Distribution and Dividends for the Years Ended March 2018 and Ending March 2019

- In order to secure sustainable growth in corporate value, one of the fundamental business policies of Daiichi Sankyo is to decide profit distributions based on a comprehensive consideration of the investments essential for implementing its growth strategy and returning profits to shareholders.
- In the 5-Year Business Plan, Daiichi Sankyo introduced policy to pay a total return ratio\* of 100% or more during the period, and in terms of dividend payments, to distribute ordinary dividends to ¥70 or more yearly, to pay stable dividends, and to exercise the agile purchase of treasury shares.

\* Total return ratio = (Total amount of dividends + Total acquisition costs of treasury shares) / Profit attributable to owners of the Company

- During the fiscal year under review, under this policy, to increase shareholder returns and enhance capital efficiency, Daiichi Sankyo acquired approximately 15,730 thousand of its own shares for approximately ¥50.0 billion from November 1, 2017 to March 22, 2018.
- Daiichi Sankyo paid an interim dividend of ¥35 per share to shareholders on December 1, 2017. The year-end dividend for the fiscal year ended March 31, 2018 is forecast at ¥35 per share, and, accordingly, the annual dividend for the fiscal year ended March 31, 2018 is forecast at ¥70 per share.
- Daiichi Sankyo intends to pay a dividend of ¥70 per share for the fiscal year ending March 2019.

## (5) Prospective Challenges

### 1) 2025 Vision

The Group has established its 2025 Vision of being a “Global Pharma Innovator with Competitive Advantage in Oncology.”

Specifically, the Group aspires to be a Company having a specialty area business centered on oncology as its core business, having enriched regional value products aligned with each regional market, and having innovative products and pipeline changing the SOC in each market. At the same time, the Company aims to realize high shareholder value through highly efficient management in 2025.

### 2) 5-Year Business Plan

- The fourth medium-term plan for the period covering fiscal 2016 through fiscal 2020 is designated as the 5-Year Business Plan to realize the transformation towards the 2025 Vision. Under this plan, we are taking action on two challenges: growing beyond the patent cliff<sup>\*4</sup> for antihypertensive agent *Olmесartan* and establishing foundations for ensuring sustainable growth thereafter.
- Furthermore, we strive to achieve revenue of ¥1,100.0 billion, operating profit of ¥165.0 billion, and ROE of 8% or above in fiscal 2020. Moreover, as of fiscal 2020, we aim to hold three to five late-stage pipeline products that can be commercialized within five years and are expected to achieve respective peak revenues exceeding ¥100.0 billion.
- The six strategic targets put up to establish foundations for ensuring sustainable growth, key efforts to attain the targets and the results in fiscal 2017 are as follows.

\*4 Patent cliff (LOE: loss of exclusivity): Decreases in sales and profits brought by the patent expiration of certain products.

#### i. Strategic Targets

##### 1. Grow *Edoxaban*

- With *Edoxaban*, we will forge ahead with efforts that involve consistently deploying our market launch strategy globally, continually promoting the appeal of the product’s established attributes, and generating new evidence with the aim of enhancing its product strengths. We will accelerate growth of *Edoxaban* and develop it into a mainstay product that generates more than ¥120.0 billion in revenues in fiscal 2020. To such ends, in Japan we will draw on its product strengths and our high-quality marketing capabilities in order to make it a top-selling product, and in Europe we will bring about full-scale launch of the product across Europe by taking advance of collaborative initiatives with an alliance partner.

[Key Efforts and Results in Fiscal 2017]

- Orally disintegrating tablets (product name: *Lixiana OD* tablets) was launched in Japan.
- Market share and revenues in Japan, Germany, and South Korea were expanded substantially.
- Countries in Europe, Asia and South & Central America in which products are approved or brought to market were expanded.
- Started a new randomized study of ENVISAGE-TAVI AF. Also, Hokusai-VTE CANCER study results were announced at the American Society of Hematology (ASH) Annual Meeting.

##### 2. Grow as No. 1 Company in Japan

- We aim to grow into Japan’s leading pharmaceutical company as the No. 1 company. We will leverage the strengths of our innovative pharmaceuticals business, while precisely addressing various social needs and medical needs such as prevention, self-medication and medical treatment with the innovative business as well as our vaccines, generics and OTC drug businesses.

[Key Efforts and Results in Fiscal 2017]

- Revenue in 6 mainstay products (*NEXIUM*, *Memary*, *PRALIA*, *RANMARK*, *Efient* and *TENELIA*) grew.
- Received approval for *PRALIA* for an additional indication for inhibition of the progression of bone erosion associated with rheumatoid arthritis.
- Started sales of *CANALIA* combination tablets, a type 2 diabetes mellitus treatment agent and several authorized generic products, including *Olmесartan OD* tablets, an antihypertensive agent.
- Applied for approval to manufacture and sell *Esaxerenone*, an antihypertensive agent and *Mirogabalin*, a neuropathic pain agent.
- Received No. 1 MR evaluation for the sixth year in a row from medical practitioners.

### 3. Expand U.S. Businesses

- Daiichi Sankyo Inc. (DSI) will pursue expansion of the pain franchise business with the aim of revenue of more than ¥100.0 billion in fiscal 2020.
- With Luitpold Pharmaceuticals, we aim to achieve revenue of ¥150.0 billion in fiscal 2020 by facilitating growth of its business through increased sales of the *Injectafer* iron franchise and the generic injectable franchise.

[Key Efforts and Results in Fiscal 2017]

<Daiichi Sankyo Inc.>

- In addition to starting sales of *MorphaBond* (morphine extended-release tablets) abuse-deterrent opioid analgesic, decided to commercialize *RoxyBond* (oxycodone hydrochloride immediate-release tablets) abuse-deterrent opioid analgesic.
- Stopped development of *CL-108*, a combination drug for the treatment of pain and opioid-induced nausea and vomiting (OINV), which had been positioned as a central item in the expansion of the pain treatment business. Also, gave up on applying for manufacture and sale approval for *Mirogabalin* for the treatment of fibromyalgia (FM) patients due to not reaching primary endpoint in the clinical study of *Mirogabalin* for fibromyalgia (FM) patients.
- <Luitpold Pharmaceuticals>Expanded *Injectafer*'s revenue and share in iron injectable market.

### 4. Establish Oncology Business

- We will develop our oncology business to the point where such operations generate revenue of more than ¥40.0 billion in fiscal 2020, and ¥300.0 billion in fiscal 2025. Efforts to that end will involve getting oncology business off the ground by bringing late-stage products to market, steadily developing products in the early stage of the pipeline, and enriching the product-line and the pipeline by acquiring external assets.

[Key Efforts and Results in Fiscal 2017]

- *DS-8201* received breakthrough designation from the U.S. FDA for recurrent and/or metastatic breast cancer, and also received SAKIGAKE Designation from the Ministry of Health, Labour and Welfare for recurrent and/or advanced gastric cancer.
- *DS-8201* received good clinical study results and they were announced at American/European conferences of Clinical Oncology.
- Started several new clinical studies for ADC franchise. (*DS8201* Phase II clinical studies for breast cancer, gastric cancer, and colorectal cancer, and Phase I studies for both *U3-1402* and *DS-1062* for non-small cell lung cancer patients).
- Promoted investment in ADC production facilities, aiming to enhance the production platform.
- Promoted strategic alliance activities regarding the ADC and AML franchises (commencements of R&D Alliances on combination therapies with other companies, etc.)

### 5. Continuously Generate Innovative Medicine Changing SOC

- With the aim of transforming operations of the research organization to a bioventure model\*<sup>5</sup>, we will make oncology the Primary Focused area with respect to target disease, while categorizing pain

treatments, central nervous system disease, heart and kidney disease, and rare disease in the New Horizon area, while also generating innovative medicine changing standards of care (SOC) by drawing on initiatives that involve partnering, open innovation and translational research. In addition, we will forge ahead in bringing about clinical applications for nucleic acid, cell therapies and other advanced technologies.

- \*5 Bioventure model: A business form similar to that of a venture company in which the organization actively collaborate with external organizations, advance research themes based on openly produced ideas, and make decisions within the organization.

[Key Efforts and Results in Fiscal 2017]

- Obtained an option right concerning the commercialization of iPS-derived cardiomyocyte (iPS-CM) sheet, a treatment for heart failure.
- Oncolytic virus *G47Δ* (*DS-1647*) received designation as an orphan drug for regenerative health care from the Ministry of Health, Labour and Welfare.
- *DS-5141*, a Duchenne muscular dystrophy treatment drug, received SAKIGAKE Designation.

## 6. Enhance Profit Generation Capabilities

- In addition to initiatives taken up through fiscal 2015 to enhance our capacity for generating profits, for the duration of the business plan we will also forge ahead with efforts that involve optimizing our manufacturing systems on a global level and strengthening procurement functions. At the same time, we will enhance our ability to generate profits by drastically cutting costs and streamlining operations across the entire Group, while also conducting reviews with respect to cost of sales, selling, general and administrative expenses, and research and development expenses.

[Key Efforts and Results in Fiscal 2017]

- Decided restructuring of the U.S. commercial organization (decision to reduce headcount at Daiichi Sankyo Inc.).
- Implemented domestic R&D platform restructuring. (absorption-type merger of Asubio Pharma Co., Ltd.)

## ii. Cash Generation and Allocation in Investment for Future Growth

- During the 5-Year Business Plan, we will prioritize growth investments while enhancing shareholder returns.
- As of March 31, 2016, cash-on-hand totaled roughly ¥700.0 billion. Our activities over the five years of the plan will be funded by this cash as well as the approximately ¥2,200.0 billion to be generated in the form of free cash flow before R&D expenses (Profit before R&D, depreciation and amortization), and cash recovered through asset downsizing. As for specific allocations, we plan to conduct growth investments of ¥900.0 billion in R&D expenses and ¥500.0 billion in business development investments. The remainder of the funds will be used for shareholder returns, capital expenditure and working capital.

[Key Efforts and Results in Fiscal 2017]

- Sold cross-held shares creating cash of ¥14.4 billion.
- Made preferential R&D investments in oncology, promoted the acceleration of starting up and establishment of the oncology business.

## iii. Shareholder Return Policy

- We will seek a total return ratio<sup>\*6</sup> of 100% or more over the period of the plan and annual ordinary dividends of more than ¥70 per share. While continuing stable dividend payments, we will conduct flexible acquisition of our own shares.

\*6 Total return ratio = (Total amount of dividends + Total acquisition costs of treasury shares) / Profit attributable to owners of the Company

[Key Results in Fiscal 2017]

- Issued an interim dividend of ¥35 per share. With a ¥35 per share year-end dividend, expecting a ¥70 annual dividend per share.
- Obtained approximately 15.73 million treasury shares for approximately ¥50 billion.

## **(6) Other Information**

### **1) Strategic Targets and Forward-Looking Statements**

- Strategic targets, forward-looking statements and other information disclosed in this material are all determined by the Company based on information obtained at the time of disclosure of this material with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, actual results of the Company may diverge materially from the content of this material.
- Various risks and uncertainties are included in these, such as manufacture and sales of rival products and generic drugs, lawsuits, laws and regulations, regulatory trends to restrain healthcare expenditures, corporate acquisitions and other such initiatives, R&D and alliances with other companies, manufacturing and procurement, emergence of side effects, intellectual property, developing business overseas, operations related to occurrence of disasters, environmental problems, financial market and currency fluctuation, IT security and information management, and maintenance of internal control related to financial reporting.



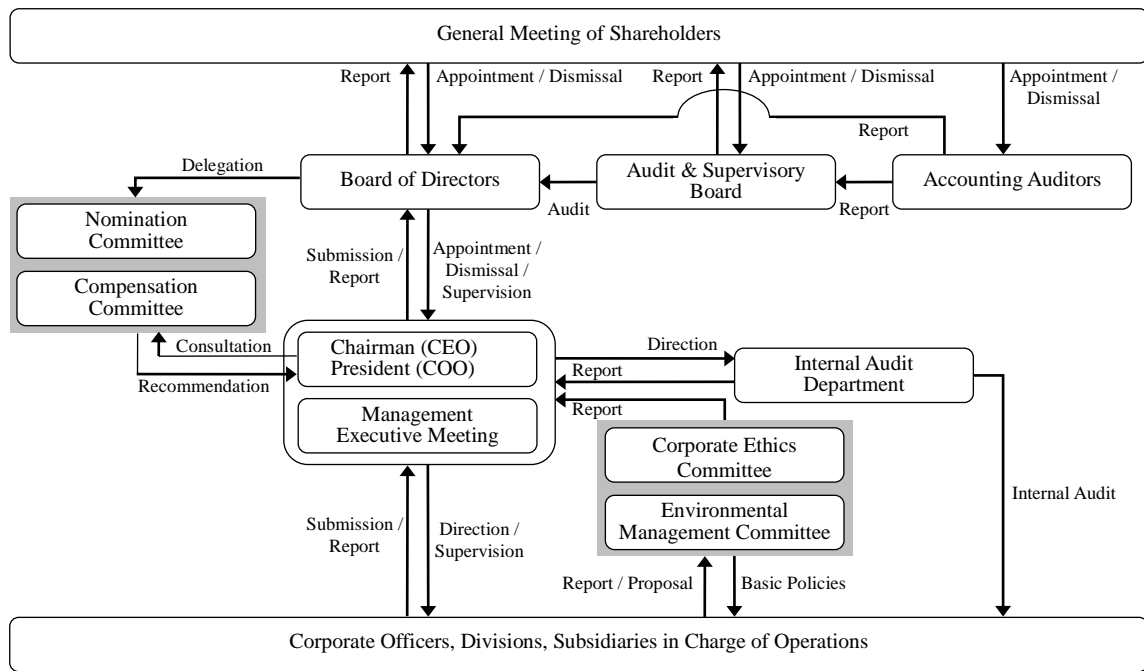
## **2. Corporate Governance**

### **(1) Systems and Policies on Corporate Governance**

- In addition to creating a management structure that can respond speedily and flexibly to changes in the business environment, the Daiichi Sankyo is working to secure legal compliance and management transparency and to strengthen oversight of management and the conduct of operations. We place great importance on building up a corporate governance structure that is responsive to the trust of our stakeholders, especially our shareholders.

### **1) Corporate Governance Structure**

- a. To clarify Members' of the Board management responsibility and reinforce their oversight of management and the conduct of operations, their terms of office are set at one year, and four out of our ten Members of the Board are Members of the Board (Outside).
- b. To ensure management transparency, nomination of candidates for Member of the Board and Corporate Officer and compensation thereof are deliberated on by a Nomination Committee and a Compensation Committee, respectively, which are established as voluntary committees. These Committees consist of at least three Members of the Board, of whom Members of the Board (Outside) form a majority, and are chaired by a Member of the Board (Outside). Currently, these Committees consist only of Members of the Board (Outside).
- c. For audits of legal compliance and soundness of management, the Company has adopted an Audit & Supervisory Board system and established the Audit & Supervisory Board comprising five members, the majority of which are Members of the Audit & Supervisory Board (Outside).
- d. The Company prescribes specific criteria on the judgment of independence of Members of the Board (Outside) and Members of the Audit & Supervisory Board (Outside) and basic matters regarding execution of duties by Members of the Board and Members of the Audit & Supervisory Board.
- e. The Company employs a Corporate Officer System which contributes to appropriate and swift management decision-making and the conduct of operations.



(Notes) In addition to relations shown in the Corporate Governance Structure, coordination between relevant departments such as report to Audit & Supervisory Board by Internal Audit Department etc. is made appropriately.

## 2) Policies and Procedures for Appointment and Nomination of Candidates for Members of the Board and Members of the Audit & Supervisory Board

- The candidates for Members of the Board shall meet the requirement of being personnel of excellent character and insight who contribute to maximizing the corporate value of the Group.
- The candidates for Members of the Board shall meet the requirements of being appropriate candidates with respect to term of office and age, and of being suitably competent of performing timely and accurate judgment, looking at the changes in the business environment while giving importance to the continuance of management policies, etc.
- The candidates for Members of the Board shall meet the requirements that there shall always be Members of the Board (Outside) included to strengthen the decision-making functions based on various perspectives and to strengthen the function of supervising conduct of operations.
- When appointing the candidates for Members of the Board, the Board of Directors shall appoint the candidates after they have been sufficiently deliberated by the Nomination Committee, of which Members of the Board (Outside) form a majority.
- The candidates for Members of the Audit & Supervisory Board shall be examined prudently concerning their suitability as Members of the Audit & Supervisory Board, such as whether they can fulfil their duties, ensuring their independence from the representative directors, members of the board, and corporate officers.
- The candidates for Members of the Audit & Supervisory Board (Outside), in addition to meeting the aforementioned requirements, shall be confirmed to have no problems according to specific criteria on the judgment of independence.
- When appointing the candidates for Members of the Audit & Supervisory Board, the Board of Directors shall appoint the candidates after the relevant proposal has been sufficiently verified and agreed to by the Audit & Supervisory Board.

### **3) Policy and Determination Methods on Remuneration Amounts or Related Calculation Methods to Members of the Board and Members of the Audit & Supervisory Board**

- a. Basic design of remuneration to Members of the Board and Members of the Audit & Supervisory Board
  - Remuneration to Members of the Board is designed to provide remuneration that contributes to maximize corporate value. Specifically, in addition to a basic, fixed remuneration, performance based bonuses serving as short-term incentive and restricted share-based remuneration serving as long-term incentive are adopted.
  - Performance based bonuses serving as short-term incentives are determined by the degree of achievement of a single fiscal year measured by adopting revenue, operating profit margin and profit attributable to owners of the Company as the relevant indices.
  - As long-term incentives, the Company grants, every year in principle, restricted stocks with 3-5 years of transfer restriction to the eligible Members of the Board. The objective of the scheme is to provide Member of the Board an incentive to sustainably increase the Company's corporate value and to further promote shared value between shareholders and them by having the restricted stocks.
  - The level of remunerations is set aiming to provide medium to high level remunerations in the industrial sector, referring to the levels of other companies learned from the surveys of external specialist institutions.
  - In order to ensure that Members of the Board (Outside) and Members of the Audit & Supervisory Board adequately perform their role, which is oversight of management, short-term and long-term incentives are not provided and only basic remuneration is granted.
- b. Procedures for deciding remuneration of Members of the Board and Members of the Audit & Supervisory Board
  - The General Meeting of Shareholders has approved a basic remuneration of Members of the Board at a maximum limit of 450 million yen per fiscal year and a total amount of restricted share-based remuneration to be granted to Members of the Board at a maximum limit of 140 million yen per fiscal year. Performance based bonuses are approved by the General Meeting of Shareholders for the relevant fiscal year.
  - The General Meeting of Shareholders has approved a basic, fixed remuneration of Members of the Audit & Supervisory Board, which shall be the only remuneration they receive, at a maximum limit of 120 million yen per fiscal year.
  - Establishment of the remuneration system and criteria for Members of the Board and Corporate Officers, examination and review of the remuneration level for each position, confirmation of the results of performance based bonuses, and allotment of restricted stocks have been thoroughly deliberated at the Compensation Committee, in which the majority of members are Members of the Board (Outside).

### **(2) Basic Policy Regarding Moves toward Large-Scale Acquisition of Company's Stock**

- The Company believes that it is the shareholders to decide whether or not to respond to any moves toward large-scale acquisition of Company stock. The Company does not deny the potentially significant impact that transfers of management control may have in terms of stimulating business enterprise. In line with this thinking, the Company has not prepared any specific takeover defenses.
- Nonetheless, the Company would consider it a self-evident duty of the Company management to oppose any takeover plans whose aims were generally considered inappropriate (such as schemes to ramp up

the share price) or that would otherwise be deemed detrimental to the value of the Company or the mutual interests of shareholders. Accordingly, the Company will continue monitoring closely share transactions and changes in shareholders. In the event any moves toward large-scale acquisition of Company stock are noticed, the Company would evaluate any takeover proposal with outside experts and determine carefully the impact of such on the value of the Company and the mutual interests of shareholders. If any proposal were deemed detrimental to such interests, the Company would institute appropriate anti-takeover measures in response to individual cases.

### **3. Rationale for the Selection of Accounting Standards**

Daiichi Sankyo and its consolidated subsidiaries (“the Group”) have adopted International Financial Reporting Standards as issued by the International Accounting Standards Board (“IFRS”) starting in the fiscal year ended March 31, 2014. Having considered what accounting and financial reporting standards would be best to contribute to growth in corporate value through a concerted global business development program, Daiichi Sankyo made this move (1) to improve the international comparability of the Group’s financial statements with global capital markets, (2) to unify the accounting treatments applied across the Group, and (3) to contribute to diversification of the Group’s methods of fund procurement in global markets.

## 4. Consolidated Financial Statements with Primary Notes

### (1) Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2017	As of March 31, 2018
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	246,050	357,702
Trade and other receivables	231,867	231,529
Other financial assets	552,896	429,380
Inventories	153,138	172,586
Other current assets	10,461	10,347
Subtotal	1,194,414	1,201,545
Assets held for sale	3,374	–
Total current assets	1,197,788	1,201,545
Non-current assets		
Property, plant and equipment	217,772	217,946
Goodwill	78,446	75,479
Intangible assets	217,044	173,537
Investments accounted for using the equity method	1,424	1,693
Other financial assets	140,856	179,177
Deferred tax assets	53,502	40,339
Other non-current assets	8,143	8,035
Total non-current assets	717,190	696,209
Total assets	1,914,979	1,897,754

(Millions of yen)

	As of March 31, 2017	As of March 31, 2018
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Trade and other payables	219,759	226,164
Bonds and borrowings	–	20,000
Other financial liabilities	535	516
Income taxes payable	57,955	64,609
Provisions	41,223	34,015
Other current liabilities	6,285	7,800
Subtotal	325,758	353,105
Liabilities directly associated with assets held for sale	1,058	–
Total current liabilities	326,817	353,105
Non-current liabilities		
Bonds and borrowings	280,543	260,564
Other financial liabilities	9,069	8,155
Post-employment benefit liabilities	11,381	10,547
Provisions	16,350	48,752
Deferred tax liabilities	32,294	18,676
Other non-current liabilities	67,093	64,911
Total non-current liabilities	416,733	411,608
Total liabilities	743,550	764,713
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	103,750	94,633
Treasury shares	(113,952)	(163,531)
Other components of equity	124,489	120,504
Retained earnings	1,011,610	1,031,376
Total equity attributable to owners of the Company	1,175,897	1,132,982
Non-controlling interests		
Non-controlling interests	(4,469)	58
Total equity	1,171,428	1,133,041
Total liabilities and equity	1,914,979	1,897,754

**(2) Consolidated Statement of Profit or Loss and Consolidated Statement of Comprehensive Income****Consolidated Statement of Profit or Loss**

(Millions of yen)

	Year ended March 31, 2017	Year ended March 31, 2018
Revenue	955,124	960,195
Cost of sales	349,373	346,021
Gross profit	605,751	614,173
Selling, general and administrative expenses	302,475	301,845
Research and development expenses	214,347	236,046
Operating profit	88,929	76,282
Financial income	6,406	8,642
Financial expenses	7,710	4,223
Share of profit (loss) of investments accounted for using the equity method	162	320
Profit before tax	87,788	81,021
Income taxes	40,309	21,210
Profit for the year	47,479	59,811
Profit attributable to:		
Owners of the Company	53,466	60,282
Non-controlling interests	(5,987)	(471)
Profit for the year	47,479	59,811
Earnings per share		
Basic earnings per share (Yen)	79.63	91.31
Diluted earnings per share (Yen)	79.44	91.10

## Consolidated Statement of Comprehensive Income

(Millions of yen)

	Year ended March 31, 2017	Year ended March 31, 2018
Profit for the year	47,479	59,811
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(9,366)	10,688
Remeasurements of defined benefit plans	1,840	1,616
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(7,626)	(10,229)
Share of other comprehensive income of investments accounted for using the equity method	6	3
Other comprehensive income (loss) for the year	(15,146)	2,078
Total comprehensive income for the year	32,332	61,890
Total comprehensive income attributable to:		
Owners of the Company	38,309	62,361
Non-controlling interests	(5,976)	(471)
Total comprehensive income for the year	32,332	61,890



### (3) Consolidated Statement of Changes in Equity

Year ended March 31, 2017

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Capital surplus	Treasury shares	Other components of equity		
				Subscription rights to shares	Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance as of April 1, 2016	50,000	103,927	(64,155)	1,935	75,195	69,586
Profit for the year	-	-	-	-	-	-
Other comprehensive income (loss) for the year	-	-	-	-	(7,626)	(9,366)
Total comprehensive income (loss) for the year	-	-	-	-	(7,626)	(9,366)
Purchase of treasury shares	-	(69)	(50,026)	-	-	-
Cancellation of treasury shares	-	-	230	(133)	-	-
Share-based payments	-	-	-	264	-	-
Dividends	-	-	-	-	-	-
Acquisition of non-controlling interests	-	(107)	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	(5,366)
Others	-	-	-	-	-	-
Total transactions with owners of the Company	-	(177)	(49,796)	131	-	(5,366)
Balance as of March 31, 2017	50,000	103,750	(113,952)	2,067	67,568	54,853

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity		Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Remeasurements of defined benefit plans	Total other components of equity				
Balance as of April 1, 2016	-	146,717	994,916	1,231,406	2,115	1,233,521
Profit for the year	-	-	53,466	53,466	(5,987)	47,479
Other comprehensive income (loss) for the year	1,835	(15,157)	-	(15,157)	10	(15,146)
Total comprehensive income (loss) for the year	1,835	(15,157)	53,466	38,309	(5,976)	32,332
Purchase of treasury shares	-	-	-	(50,095)	-	(50,095)
Cancellation of treasury shares	-	(133)	(95)	1	-	1
Share-based payments	-	264	-	264	-	264
Dividends	-	-	(43,879)	(43,879)	-	(43,879)
Acquisition of non-controlling interests	-	-	-	(107)	(600)	(708)
Transfer from other components of equity to retained earnings	(1,835)	(7,202)	7,202	-	-	-
Others	-	-	-	-	(7)	(7)
Total transactions with owners of the Company	(1,835)	(7,071)	(36,772)	(93,817)	(608)	(94,425)
Balance as of March 31, 2017	-	124,489	1,011,610	1,175,897	(4,469)	1,171,428

Year ended March 31, 2018

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Capital surplus	Treasury shares	Other components of equity		
				Subscription rights to shares	Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance as of April 1, 2017	50,000	103,750	(113,952)	2,067	67,568	54,853
Profit for the year	-	-	-	-	-	-
Other comprehensive income (loss) for the year	-	-	-	-	(10,229)	10,688
Total comprehensive income (loss) for the year	-	-	-	-	(10,229)	10,688
Purchase of treasury shares	-	(51)	(50,033)	-	-	-
Cancellation of treasury shares	-	-	453	(74)	-	-
Dividends	-	-	-	-	-	-
Acquisition of non-controlling interests	-	(9,064)	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	(4,369)
Others	-	-	-	-	-	-
Total transactions with owners of the Company	-	(9,116)	(49,579)	(74)	-	(4,369)
Balance as of March 31, 2018	50,000	94,633	(163,531)	1,993	57,339	61,171

(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	Total other components of equity	Retained earnings			
Balance as of April 1, 2017	-	124,489	1,011,610	1,175,897	(4,469)	1,171,428
Profit for the year	-	-	60,282	60,282	(471)	59,811
Other comprehensive income (loss) for the year	1,620	2,078	-	2,078	-	2,078
Total comprehensive income (loss) for the year	1,620	2,078	60,282	62,361	(471)	61,890
Purchase of treasury shares	-	-	-	(50,085)	-	(50,085)
Cancellation of treasury shares	-	(74)	(75)	304	-	304
Dividends	-	-	(46,430)	(46,430)	-	(46,430)
Acquisition of non-controlling interests	-	-	-	(9,064)	5,007	(4,057)
Transfer from other components of equity to retained earnings	(1,620)	(5,989)	5,989	-	-	-
Others	-	-	-	-	(8)	(8)
Total transactions with owners of the Company	(1,620)	(6,063)	(40,516)	(105,276)	4,998	(100,277)
Balance as of March 31, 2018	-	120,504	1,031,376	1,132,982	58	1,133,041

#### (4) Consolidated Statement of Cash Flows

(Millions of yen)

	Year ended March 31, 2017	Year ended March 31, 2018
Cash flows from operating activities		
Profit before tax	87,788	81,021
Depreciation and amortization	47,373	46,680
Impairment loss	26,459	36,672
Financial income	(6,406)	(8,642)
Financial expenses	7,710	4,223
Share of (profit) loss of investments accounted for using the equity method	(162)	(320)
(Gain) loss on sale and disposal of non-current assets	449	(5,125)
(Increase) decrease in trade and other receivables	15,148	2,535
(Increase) decrease in inventories	(10,951)	(19,394)
Increase (decrease) in trade and other payables	(16,979)	238
Others, net	13,398	(9,755)
Subtotal	163,828	128,134
Interest and dividends received	4,289	4,516
Interest paid	(1,511)	(2,038)
Income taxes paid	(30,371)	(22,173)
Net cash flows from (used in) operating activities	136,234	108,439
Cash flows from investing activities		
Payments into time deposits	(492,441)	(388,376)
Proceeds from maturities of time deposits	404,416	488,576
Acquisition of securities	(180,376)	(128,492)
Proceeds from sale of securities	219,049	165,458
Acquisition of property, plant and equipment	(24,766)	(23,399)
Proceeds from sale of property, plant and equipment	2,403	139
Acquisition of intangible assets	(28,196)	(14,609)
Payments for loans receivable	(71)	(982)
Proceeds from collection of loans receivable	1,472	753
Others, net	1,719	9,501
Net cash flows from (used in) investing activities	(96,792)	108,568

(Millions of yen)

	Year ended March 31, 2017	Year ended March 31, 2018
Cash flows from financing activities		
Proceeds from bonds and borrowings	100,000	–
Repayments of bonds and borrowings	(20,000)	–
Purchase of treasury shares	(50,095)	(50,085)
Proceeds from sale of treasury shares	1	1
Dividends paid	(43,889)	(46,420)
Others, net	(1,038)	(5,262)
Net cash flows from (used in) financing activities	(15,022)	(101,766)
Net increase (decrease) in cash and cash equivalents	24,419	115,241
Cash and cash equivalents at the beginning of the year	222,159	246,050
Effect of exchange rate changes on cash and cash equivalents	(527)	(3,590)
Cash and cash equivalents at the end of the year	246,050	357,702

## (5) Notes to Consolidated Financial Statements

### Going Concern Assumption

Not applicable.

### Changes in Accounting Policies

The significant accounting policies adopted in preparing the consolidated financial statements of the Group have not changed from the prior year except for the adoption of the following amended accounting standards. In the year ended March 31, 2018, the Group adopted the following accounting standards in accordance with their effective date. These amended accounting standards did not have a material impact on the consolidated financial statements.

IFRS		Overview
IAS 7	Statement of Cash Flows	Amendments to disclosure requirements for changes in liabilities arising from financing activities
IAS 12	Income Taxes	Amendment to clarify the recognition of deferred tax assets for unrealized losses

### Operating Segment Information

#### (1) Reportable Segments

Disclosure is omitted as the Group has a single segment, "Pharmaceutical Operation".

(2) Information about products and services

Sales by products and services were as follows:

(Millions of yen)

Item name	Year ended March 31, 2017		Year ended March 31, 2018		Increase / (decrease)	
	Amount	Ratio (%)	Amount	Ratio (%)	Amount	Ratio (%)
Prescription drugs	885,573	92.7	884,907	92.2	(665)	-0.1
Healthcare (OTC) products	66,882	7.0	72,943	7.6	6,060	9.1
Others	2,668	0.3	2,344	0.2	(324)	-12.1
Total	955,124	100.0	960,195	100.0	5,070	0.5

(3) Information by geographical area

As of and for the year ended March 31, 2017

(Millions of yen)

	Japan	North America	Europe	Other regions	Consolidated
Revenue from external customers (Note 1)	579,883	235,316	71,021	68,903	955,124
Non-current assets (Note 2)	297,805	188,120	18,877	8,459	513,263

As of and for the year ended March 31, 2018

(Millions of yen)

	Japan	North America	Europe	Other regions	Consolidated
Revenue from external customers (Note 1)	618,308	185,751	79,566	76,568	960,195
Non-current assets (Note 2)	265,787	174,969	17,806	8,400	466,963

(Notes)

1. Revenue from external customers is classified according to the geographical location of customers.
2. Non-current assets are primarily presented based on the geographical location of assets, and are comprised of property, plant and equipment, goodwill and intangible assets.

(4) Information on major customers

(Millions of yen)

Name of customer	Year ended March 31, 2017	Year ended March 31, 2018
Alfresa Holdings Corporation and its group companies	190,637	199,809
Suzuken Co., Ltd. And its group companies	88,539	98,603
McKesson Corporation	109,800	62,276

## Earnings per Share

### (1) Basis for calculation of basic earnings per share

	Year ended March 31, 2017	Year ended March 31, 2018
a. Profit Attributable to owners of the Company		
Profit attributable to owners of the Company (Millions of yen)	53,466	60,282
Profit not attributable to owners of the Company (Millions of yen)	–	–
Profit used to calculate basic earnings per share (Millions of yen)	53,466	60,282
b. Weighted-average Number of Ordinary Shares		
Weighted-average number of ordinary shares (basic) (Thousands of shares)	671,422	660,161
c. Basic Earnings per Share		
Basic earnings per share (Yen)	79.63	91.31

### (2) Diluted Earnings per Share

	Year ended March 31, 2017	Year ended March 31, 2018
a. Diluted Profit Attributable to owners of the Company		
Profit used to calculate basic earnings per share (Millions of yen)	53,466	60,282
Adjustment to profit (Millions of yen)	–	–
Profit used to calculate diluted earnings per share (Millions of yen)	53,466	60,282
b. Weighted-average Number of Diluted Ordinary Shares		
Weighted-average number of ordinary shares (basic) (Thousands of shares)	671,422	660,161
Potential effect of issue of subscription rights (Thousands of shares)	1,610	1,550
Weighted-average number of ordinary shares (diluted) (Thousands of shares)	673,033	661,712
c. Diluted Earnings per Share		
Diluted earnings per share (Yen)	79.44	91.10

## Subsequent Events

Not applicable.