October 31, 2018

Consolidated Financial Results for the First Six Months of the Year Ending March 31, 2019 (Fiscal 2018) <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
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Scheduled date of Quarterly Report filing: November 6, 2018
Scheduled date of dividend payments: December 3, 2018
Preparing supplementary material (Reference Data) on quarterly financial results: Yes
Holding quarterly 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 the First Six Months of the Year Ending March 31, 2019 (from April 1, 2018 to September 30, 2018)

(1) Consolidated Financial Results

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

	Revenue		Operating profit		Profit before tax		Profit for the period	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Six months ended September 30, 2018	446,850	-4.8	57,984	18.9	58,635	14.5	44,020	30.4
Six months ended September 30, 2017	469,397	2.5	48,758	-33.5	51,191	-28.8	33,747	-29.4

	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
Six months ended September 30, 2018	44,014	28.4	137,880	168.3	67.95	67.80
Six months ended September 30, 2017	34,278	-30.0	51,386	–	51.68	51.56

(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 September 30, 2018	1,907,941	1,248,000	1,247,943	65.4	1,926.51
As of March 31, 2018	1,897,754	1,133,041	1,132,982	59.7	1,749.33

2. Dividends

	Annual dividends per share				
	First quarter	Second quarter	Third quarter	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Year ended March 31, 2018	–	35.00	–	35.00	70.00
Year ending March 31, 2019	–	35.00			
Year ending March 31, 2019 (Forecast)			–	35.00	70.00

Note: Revision of the forecast from most recently announced figures: No

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	84.91

Note: Revision of the forecast from most recently announced figures: No

*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 *"2. Condensed Interim Consolidated Financial Statements with Primary Notes, (5) Notes to Condensed Interim Consolidated Financial Statements, (Changes in Accounting Policies)"* on page 24.

(3) Number of ordinary shares issued

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

As of September 30, 2018	709,011,343 shares
As of March 31, 2018	709,011,343 shares

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

As of September 30, 2018	61,238,015 shares
As of March 31, 2018	61,343,747 shares

3) Average number of shares during the period (cumulative from the beginning of the fiscal year)

Six months ended September 30, 2018	647,717,922 shares
Six months ended September 30, 2017	663,280,095 shares

* This quarterly financial results summary is not subject to quarterly review 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. Qualitative Information about Consolidated Results for the First Six Months (3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements"* on page 15 for matters related to the above forecasts.

Attached Material

Index

1. Qualitative Information about Consolidated Results for the First Six Months

(1) Information about Operating Results

1) Overview

【Consolidated Financial Results】

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

	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
Revenue	469,397	446,850	–22,547 –4.8%
Operating profit	48,758	57,984	9,225 18.9%
Profit before tax	51,191	58,635	7,444 14.5%
Profit attributable to owners of the Company	34,278	44,014	9,736 28.4%
Total comprehensive income	51,386	137,880	86,494 168.3%

<Revenue of global mainstay products>

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

Product name	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
Edoxaban anticoagulant	32,881	54,138	21,257 64.6%
Olmesartan antihypertensive agent	82,799	53,500	–29,299 –35.4%
Prasugrel antiplatelet agent	18,789	13,529	–5,259 –28.0%

<Selling, general and administrative expenses>

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

	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
Selling, general and administrative expenses	139,995	128,561	–11,433 –8.2%
Ratio of selling, general and administrative expenses to revenue	29.8%	28.8%	–1.1%

<Research and development expenses>

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

	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
Research and development expenses	123,586	93,657	–29,928 –24.2%
Ratio of research and development expenses to revenue	26.3%	21.0%	–5.4%

<Yen exchange rates for major currencies (average rate during the period)>

(Yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
USD/Yen	111.07	110.27
EUR/Yen	126.29	129.84

a. Revenue

- Revenue in the first six months of the year ending March 31, 2019 decreased by ¥22.5 billion, or 4.8% compared to the same period of the previous fiscal year (year on year), to ¥446.9 billion.
- The negative effect from a decrease in sales of *Olmesartan* due to the loss of exclusivity and drug price reductions resulting from revisions to the National Health Insurance (NHI) system led to the decline in revenue, despite growth in sales of mainstay products such as *Edoxaban*.
- There was an immaterial positive effect on revenue from foreign exchange.

b. Operating profit

- Operating profit increased by ¥9.2 billion, or 18.9% year on year, to ¥58.0 billion.
- Gross profit decreased by ¥32.1 billion, or 10.3%, to ¥280.2 billion due to the recording of gain on sale of property, plant and equipment (¥6.1 billion) in the same period of the previous fiscal year and an increase in cost of sales as a result of change in the product mix, in addition to a decrease of revenue.
- Selling, general and administrative expenses fell by ¥11.4 billion, or 8.2%, to ¥128.6 billion, mainly due to the recording of gain on sale of property, plant and equipment (¥3.5 billion), in addition to the effect of cost reductions in the U.S.
- Research and development expenses decreased by ¥29.9 billion, or 24.2% year on year, to ¥93.7 billion mainly because an impairment loss (¥30.2 billion) on intangible assets related to *CL-108*, a combination drug for the treatment of pain and opioid-induced nauseas and vomiting (OINV), and others was recorded in the same period of the previous fiscal year.
- There was an immaterial positive effect on operating profit from foreign exchange.

c. Profit before tax

- Profit before tax increased by ¥7.4 billion, or 14.5% year on year, to ¥58.6 billion.
- The increase in profit before tax was modest compared to the increase in operating profit mainly due to a deterioration 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 ¥9.7 billion, or 28.4% year on year, to ¥44.0 billion.
- The increase in profit attributable to owners of the Company was an increase more than the increase in profit before tax mainly due to 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 ¥86.5 billion, or 168.3% year on year, to ¥137.9 billion.

- Total comprehensive income increased significantly in comparison with the same period of the previous fiscal year mainly due to the reversal of tax liabilities related to business restructuring of the Group carried out in prior years.

【Revenue by Geographic Area】

Primary revenue by geographic area is as follows.

a. Japan

- Revenue in Japan decreased by ¥14.9 billion, or 5.1% year on year, to ¥278.6 billion.

<Prescription drug business>

- Revenue from prescription drug business decreased by ¥13.9 billion, or 5.4% year on year, to ¥243.7 billion. The decrease was mainly due to the effect of a decrease in sales of *Olmetec* due to the loss of exclusivity and drug price reductions resulting from revisions to the National Health Insurance (NHI) system, despite the growth in sales of mainstay products *LIXIANA*, *PRALIA* and others, and the contribution to sales from authorized generic[*1] products. 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 May 2018, Daiichi Sankyo launched *Naruvein Injection* for cancer pain treatment, whose principal ingredients are hydromorphone hydrochloride. In addition, Daiichi Sankyo launched the transdermal long-acting treatment for cancer pain *FENTANYL CITRATE TAPE for 1 day "DAIICHI SANKYO"* in June, thereby enhancing the lineup of opioid analgesics to better meet the various needs of cancer pain treatment.
- Daiichi Sankyo decided in July 2018 that the domestic manufacturing and sales approvals for 41 long-listed products that Daiichi Sankyo and its subsidiary Daiichi Sankyo Espha Co., Ltd. are currently manufacturing and selling will be transferred to Alfresa Pharma Corporation.

*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 decreased by ¥1.0 billion, or 2.8% year on year, to ¥34.8 billion. The decrease is mainly due to changes in the accounting for applying new accounting policy (sales incentives, previously accounted for as expenses, are treated as sales deductions effective the current fiscal year) despite 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 to the nearest single decimal place.)

	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
Prescription drug business*	257.6	243.7	–13.9 –5.4%
Healthcare (OTC) products business	35.8	34.8	–1.0 –2.8%

* Includes generic pharmaceutical business and vaccine business.

<Domestic revenue from mainstay prescription drugs>

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

Product name	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
NEXIUM ulcer treatment	44.7	38.6	–6.1 –13.7%
LIXIANA anticoagulant	19.7	30.1	10.5 53.2%
Memary Alzheimer's disease treatment	24.5	25.2	0.7 2.9%
Loxonin anti-inflammatory analgesic	18.9	15.6	–3.2 –17.2%
PRALIA treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	10.9	13.0	2.1 19.7%
TENELIA type 2 diabetes mellitus treatment	13.2	12.6	–0.6 –4.4%
Inavir anti-influenza treatment	1.1	0.1	–1.0 –94.9%
Olmetec antihypertensive agent	31.9	7.9	–24.0 –75.4%
RANMARK treatment for bone complications caused by bone metastases from tumors	7.6	8.1	0.5 7.2%
Efient antiplatelet agent	6.4	7.0	0.6 9.4%
Rezaltas antihypertensive agent	8.5	7.8	–0.8 –9.0%
Urief treatment for dysuria	5.6	5.2	–0.4 –6.9%
Omnipaque contrast medium	7.1	6.2	–0.9 –12.6%

b. North America

- Revenue in North America decreased by ¥14.0 billion, or 14.8% year on year, to ¥80.4 billion. Revenue in local currency terms decreased by US$121 million, or 14.2%, to US$729 million. This revenue includes revenue generated by Daiichi Sankyo, Inc., and Luitpold Pharmaceuticals, Inc. (Luitpold).
- At Daiichi Sankyo, Inc., sales of *Olmesartan* and its combination drugs and *Effient* declined, in addition to a decrease of sales of *Welchol* due to entry of generics in May 2018.
- At Luitpold, sales of *Injectafer* and *Venofer* increased.
- In May 2018, the decision was made to change the company name of Luitpold to American Regent, Inc. in January 2019. "American Regent" is a product brand currently making up 95% or more of Luitpold's products (on a revenue basis) and being widely known in the U.S. market.

<Revenue of Daiichi Sankyo, Inc. mainstay products>

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

Product name	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
*Olmesartan** antihypertensive agent	93	53	–40 –43.0%
Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	177	79	–99 –55.6%
Effient antiplatelet agent	72	25	–47 –65.6%
SAVAYSA anticoagulant	9	10	1 8.0%
MOVANTIK opioid-induced constipation treatment	23	20	–3 –13.5%

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

<Revenue of Luitpold Pharmaceuticals, Inc. mainstay products>

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

Product name	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
Venofer treatment for iron deficiency anemia	133	150	18 13.2%
Injectafer treatment for iron deficiency anemia	145	200	55 37.6%

c. Europe

- Revenue in Europe increased by ¥4.8 billion, or 12.5% year on year, to ¥43.0 billion. Revenue in local currency terms increased by EUR28 million, or 9.4%, to EUR331 million.
- The increase of revenue is mainly attributable to increase in sales of *LIXIANA* despite a decrease in sales of *Olmesartan* and its combination drugs.

<Revenue of Daiichi Sankyo Europe GmbH mainstay products>

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

Product name	Six months ended September 30, 2017	Six months ended September 30, 2018	YoY change
*Olmesartan** antihypertensive agent	142	111	–31 –21.9%
Efient antiplatelet agent	31	25	–6 –18.1%
LIXIANA anticoagulant	87	160	73 83.6%

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

d. Asia, South & Central America

- Revenue in Asia, South & Central America increased by ¥1.5 billion, or 4.0% year on year, to ¥40.1 billion. This revenue includes revenue to overseas' licensees.
- Mainstay products such as synthetic antibacterial agent *Cravit* grew in China.
- Products such as *LIXIANA* and *Olmesartan* and its combination drugs grew in 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)[*1] franchise, acute myeloid leukemia (AML) franchise and Breakthrough Science[*2] 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.
- Furthermore, the Group is also working on research and development activities based on innovative drug discovery technology through technical research on new modalities*[3].
- The Group is trying to continuously generate innovative medicine that transforms standards of care (SOC) utilizing partnering*[4], open innovation*[5] and translational research*[6] 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*[7] particularly in the field of cardiovascular-metabolics.

*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 that brings radical innovation to cancer treatment methods through the practical application of innovative science and technology.

*3 New modalities: New drug discovery fundamentals technology such as ADC, nucleic acid drugs, viruses for treatment, and cell therapy.

*4 Partnering: Cooperation between companies, universities and research institutions utilizing their own strengths mutually to generate new values.

*5 Open innovation: Development method in which external development capabilities and ideas are used to overcome internal development challenges and create innovative new value.

*6 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.

*7 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.

- The following section describes the Group's major development projects and progress made in each project.

【Oncology Area】

a. DS-8201 (HER2-targeting ADC)

- The second part (expansion study) of the Phase I clinical trial for multiple types of HER2-expressing cancers is underway in Japan and the U.S.

- Updated safety and efficacy data in these trials were presented at the American Society of Clinical Oncology (ASCO) meeting in June 2018. These most recent data suggest that *DS-8201* is a promising treatment, regardless of the level of HER2 expression, and for a wide variety of types of cancer.
- In September 2018, updated safety and efficacy data for patients with HER2-expressing or -mutated non-small cell lung cancer were presented at the World Conference on Lung Cancer (WCLC). These most recent data suggest that *DS-8201* is also a promising treatment for non-small cell lung cancer.
- In addition to the above clinical trials, the Group is conducting the following trials for each type of cancer.

<Breast cancer>
- Patient enrollment (approximately 230 patients) was completed in September 2018 for the global Phase II clinical trial (DESTINY-Breast01) with the primary endpoint being the overall response rate in patients with HER2-positive recurrent and/or metastatic breast cancer previously treated with medicines including T-DM1 (the third or later line treatment).

  The global Phase III clinical trial (DESTINY-Breast02) designed to compare the safety and efficacy of *DS-8201* versus the investigator's choice for the above-mentioned patients also commenced in September 2018.
- *DS-8201* has been granted Breakthrough Therapy designation*[8] by the U.S. Food and Drug Administration (FDA) for the treatment of the above patients.

  *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.
- The global Phase III clinical trial (DESTINY-Breast03) designed to compare the safety and efficacy of *DS-8201* versus T-DM1 in patients with HER2-positive recurrent and/or metastatic breast cancer previously treated with *trastuzumab*, etc. (the second line treatment) commenced in September 2018.

<Gastric cancer>
- The Group is conducting Phase II clinical trials (DESTINY-Gastric01) in Japan and South Korea for patients with HER2-positive recurrent and/or advanced gastric cancer.
- *DS-8201* has been granted SAKIGAKE Designation*[9] by the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of the above patients.

  *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.

<Non-small cell lung cancer>
- In May 2018, the Group initiated global Phase II clinical trials for patients with HER2-positive, recurrent and/or advanced non-small cell lung cancer (NSCLC).

<Colorectal cancer>
- The Group is conducting global Phase II clinical trials for patients with HER2-positive, recurrent and/or advanced colorectal cancer.

<Combination and R&D Alliances, etc.>

- Daiichi Sankyo is conducting a collaborative clinical trial with the U.S. company, Bristol-Myers Squibb Company, to evaluate the combination of *DS-8201* and *nivolumab*, the immune checkpoint inhibitor (product name: *Opdivo*) in patients with HER2-positive breast cancer.
- In September 2018, Daiichi Sankyo entered into a clinical trial collaboration agreement with a subsidiary of the U.S. company, Merck & Co., Inc., to evaluate the combination of *DS-8201* and *pembrolizumab*, the immune checkpoint inhibitor (product name: *KEYTRUDA*) in patients with HER2-expressing breast cancer and non-small cell lung cancer.

b. U3-1402 (HER3-targeting ADC)

- Safety and efficacy data from Phase I/II clinical trials being conducted in Japan and the U.S. in patients with HER3-positive recurrent and/or metastatic breast cancer were presented for the first time at the American Society of Clinical Oncology (ASCO) meeting in June 2018.
- Currently, in addition to the above trials, the Group is conducting 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. Quizartinib

- The FDA has granted Fast Track designation to *Quizartinib* for the treatment of relapsed or refractory acute myeloid leukemia (AML) with FLT3-ITD mutations. Also, it has been granted Orphan Drug designation by the FDA and the European Medicines Agency (EMA) for the treatment of AML.
  The FDA also granted *Quizartinib* Breakthrough Therapy designation for the treatment of relapsed or refractory AML with FLT3-ITD mutations in August 2018, and in September 2018 *Quizartinib* was granted Orphan Drug designation by the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of AML with FLT3 mutations.
- In the QuANTUM-R, a Phase III clinical trial being conducted in Europe, the U.S., and Asia for patients with relapsed or refractory AML with FLT3-ITD mutations, the primary endpoint was met in May 2018, and this was presented in a Late Breaking Session of the European Hematology Association (EHA) in June 2018. Based on these results, we will proceed with preparations for domestic and global approval applications.
- Currently, in addition to the above trials, we are conducting global Phase III clinical trials (QuANTUM-First) to obtain approval for the indication as a first-line treatment of AML.

d. Pexidartinib

- *Pexidartinib* was granted Breakthrough Therapy designation by the FDA for the treatment of tenosynovial giant cell tumor (TGCT). Furthermore, it has been granted Orphan Drug designation.
- In October 2017, in Phase III clinical trials for TGCT patients in Europe and the U.S., the primary endpoints were met, and this was presented at the American Society of Clinical Oncology (ASCO) meeting in June 2018. Going forward, we will apply for new drug application in the U.S. based on these results.

[Major R&D Alliances, etc. in Oncology Area]

e. Conclusion of research collaboration agreement with DarwinHealth, Inc. for identifying new cancer targets

- In April 2018, Daiichi Sankyo entered into a research collaboration agreement with DarwinHealth, Inc. in order to identify potential new targets for cancer drug development.
- Under this agreement, both companies will search for, evaluate, and verify potential targets for specific types of cancer using DarwinHealth's bioinformatics technology*[10].

*10 Bioinformatics technology: Technology to efficiently analyze and extract beneficial information that is biologically meaningful, using the computational power of computers on the vast information obtained from living bodies, such as the sequence of genes and the expression information of proteins.

f. Expansion of collaboration with Zymeworks Inc. regarding bispecific antibodies

- In September 2016, Daiichi Sankyo entered a cross-licensing and collaboration agreement with Zymeworks Inc. of Canada regarding bispecific antibodies*[11]. Under this agreement, Daiichi Sankyo obtained the right to use Zymeworks' proprietary technology platform in the manufacture of one bispecific antibody. At the same time, Daiichi Sankyo gave Zymeworks the right to research, develop and commercialize bispecific antibodies based on the immuno-oncology-related antibodies held by Daiichi Sankyo.
- In May 2018, Daiichi Sankyo entered into an agreement expanding the collaborative research with Zymeworks, and obtained the right to use Zymeworks' technology platform in the manufacture of two more bispecific antibodies.

*11 Bispecific antibodies: An antibody that can bind different antigens in the two antigen binder of one antibody molecule.

g. Worldwide licensing agreement with Glycotope GmbH for gatipotuzumab antibody drug conjugate

- 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 *gatipotuzumab*.
- In July 2018, Daiichi Sankyo exercised the option based on the results of the feasibility study and entered into an exclusive worldwide licensing agreement for the rights to develop and commercialize *gatipotuzumab*.

【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 global including Japan, *Edoxaban* has been on the market in 29 countries and regions.
- Currently, we are undertaking activities to generate new clinical and real-world data, concerning the use of *Edoxaban* in patients with AF and VTE.

b. DS-5141

- Duchenne muscular dystrophy treatment drug, *DS-5141*, whose clinical trials are jointly underway with Orphan Disease Treatment Institute Co., Ltd., has been granted SAKIGAKE Designation by the Japan Ministry of Health, Labour and Welfare (MHLW).
- The top-line results of the Phase I/II clinical trials in Japan were announced in April 2018. In these trials, although we were not able to confirm clear expression of the dystrophin protein during the trial, no safety concerns were observed, and because it was confirmed that messenger RNA was produced by skipping the gene exon 45, we are proceeding with development so as to provide a new muscular dystrophy treatment option as quickly as possible.

(2) Analysis of Financial Position as of September 30, 2018

- Total assets as of September 30, 2018 are ¥1,907.9 billion, an increase of ¥10.2 billion from the previous fiscal year-end, mainly due to an increase in other financial assets (current assets), which was partially offset by a decrease in cash and cash equivalents.
- Total liabilities as of September 30, 2018 are ¥659.9 billion, a decrease of ¥104.8 billion from the previous fiscal year-end, mainly due to a decrease in income taxes payable.
- Total equity as of September 30, 2018 is ¥1,248.0 billion, an increase of ¥115.0 billion from the previous fiscal year-end, mainly because of the profit for the period, which was partially offset by dividends paid.
- The ratio of equity attributable to owners of the Company to total assets increased by 5.7% from the previous fiscal year-end to 65.4%.

(3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements

- There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2019 publicly announced on April 27, 2018.

Note: The forecasted statements are based on information currently available and certain assumptions that the Company regards as reasonable. Actual performance and other results may differ from these forecasted figures due to various factors.

(4) Information about Return to Shareholders

- 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
- The meeting of the Board of Directors held on October 31, 2018 approved a resolution to pay an ordinary dividend of ¥35 per share as an interim dividend, which will be paid on December 3 to shareholders as of September 30, 2018. The year-end dividend for the year ending March 31, 2019 is forecasted at ¥35 per share, and, accordingly, the annual dividend for the year ending March 31, 2019 is forecasted at ¥70 per share in total.

2. Condensed Interim Consolidated Financial Statements with Primary Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2018	As of September 30, 2018
ASSETS		
Current assets		
Cash and cash equivalents	357,702	236,852
Trade and other receivables	231,529	270,773
Other financial assets	429,380	512,949
Inventories	172,586	186,591
Other current assets	10,347	13,218
Total current assets	1,201,545	1,220,385
Non-current assets		
Property, plant and equipment	217,946	224,206
Goodwill	75,479	79,137
Intangible assets	173,537	174,582
Investments accounted for using the equity method	1,693	2,013
Other financial assets	179,177	145,233
Deferred tax assets	40,339	56,143
Other non-current assets	8,035	6,238
Total non-current assets	696,209	687,556
Total assets	1,897,754	1,907,941

(Millions of yen)

	As of March 31, 2018	As of September 30, 2018
LIABILITIES AND EQUITY		
Current liabilities		
Trade and other payables	226,164	256,656
Bonds and borrowings	20,000	40,000
Other financial liabilities	516	462
Income taxes payable	64,609	10,853
Provisions	34,015	7,405
Other current liabilities	7,800	6,424
Total current liabilities	353,105	321,801
Non-current liabilities		
Bonds and borrowings	260,564	220,575
Other financial liabilities	8,155	7,225
Post-employment benefit liabilities	10,547	9,860
Provisions	48,752	10,768
Deferred tax liabilities	18,676	20,564
Other non-current liabilities	64,911	69,146
Total non-current liabilities	411,608	338,140
Total liabilities	764,713	659,941
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,633	94,686
Treasury shares	(163,531)	(163,259)
Other components of equity	120,504	143,094
Retained earnings	1,031,376	1,123,421
Total equity attributable to owners of the Company	1,132,982	1,247,943
Non-controlling interests		
Non-controlling interests	58	56
Total equity	1,133,041	1,248,000
Total liabilities and equity	1,897,754	1,907,941

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

Condensed Interim Consolidated Statement of Profit or Loss

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Revenue	469,397	446,850
Cost of sales	157,057	166,646
Gross profit	312,340	280,203
Selling, general and administrative expenses	139,995	128,561
Research and development expenses	123,586	93,657
Operating profit	48,758	57,984
Financial income	4,669	4,447
Financial expenses	2,039	3,643
Share of profit (loss) of investments accounted for using the equity method	(196)	(151)
Profit before tax	51,191	58,635
Income taxes	17,443	14,614
Profit for the period	33,747	44,020
Profit attributable to:		
Owners of the Company	34,278	44,014
Non-controlling interests	(530)	6
Profit for the period	33,747	44,020
Earnings per share		
Basic earnings per share (Yen)	51.68	67.95
Diluted earnings per share (Yen)	51.56	67.80

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Profit for the period	33,747	44,020
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	6,505	73,427
Remeasurements of defined benefit plans	(86)	(175)
Items that are or may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	11,218	20,607
Other comprehensive income for the period	17,638	93,859
Total comprehensive income for the period	51,386	137,880
Total comprehensive income (loss) attributable to:		
Owners of the Company	51,916	137,874
Non-controlling interests	(530)	6
Total comprehensive income for the period	51,386	137,880

(3) Condensed Interim Consolidated Statement of Changes in Equity

Six months ended September 30, 2017

(Millions of yen)

	Equity attributable to owners of the Company					
				Other components of equity		
	Share capital	Capital surplus	Treasury shares	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 (loss) for the period	–	–	–	–	–	–
Other comprehensive income for the period	–	–	–	–	11,218	6,505
Total comprehensive income (loss) for the period	–	–	–	–	11,218	6,505
Purchase of treasury shares	–	–	(15)	–	–	–
Cancellation of treasury shares	–	–	331	(11)	–	–
Dividends	–	–	–	–	–	–
Acquisition of Non-controlling interests	–	(6,069)	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(779)
Others	–	–	–	–	–	–
Total transactions with owners of the Company	–	(6,069)	316	(11)	–	(779)
Balance as of September 30, 2017	50,000	97,680	(113,635)	2,055	78,787	60,579

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity					
	Remeasure-ments of defined benefit plans	Total other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2017	–	124,489	1,011,610	1,175,897	(4,469)	1,171,428
Profit (loss) for the period	–	–	34,278	34,278	(530)	33,747
Other comprehensive income for the period	(86)	17,638	–	17,638	–	17,638
Total comprehensive income (loss) for the period	(86)	17,638	34,278	51,916	(530)	51,386
Purchase of treasury shares	–	–	–	(15)	–	(15)
Cancellation of treasury shares	–	(11)	(15)	303	–	303
Dividends	–	–	(23,212)	(23,212)	–	(23,212)
Acquisition of Non-controlling interests	–	–	–	(6,069)	6,069	–
Transfer from other components of equity to retained earnings	86	(693)	693	–	–	–
Others	–	–	–	–	(8)	(8)
Total transactions with owners of the Company	86	(705)	(22,535)	(28,993)	6,060	(22,932)
Balance as of September 30, 2017	–	141,422	1,023,352	1,198,820	1,061	1,199,881

Six months ended September 30, 2018,

(Millions of yen)

	Equity attributable to owners of the Company					
				Other components of equity		
	Share capital	Capital surplus	Treasury shares	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, 2018	50,000	94,633	(163,531)	1,993	57,339	61,171
Changes in accounting policies	–	–	–	–	–	–
Adjusted balance as of April 1, 2018	50,000	94,633	(163,531)	1,993	57,339	61,171
Profit for the period	–	–	–	–	–	–
Other comprehensive income (loss) for the period	–	–	–	–	20,607	73,427
Total comprehensive income (loss) for the period	–	–	–	–	20,607	73,427
Purchase of treasury shares	–	–	(24)	–	–	–
Cancellation of treasury shares	–	52	296	(40)	–	–
Dividends	–	–	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(71,404)
Others	–	–	–	–	–	–
Total transactions with owners of the Company	–	52	272	(40)	–	(71,404)
Balance as of September 30, 2018	50,000	94,686	(163,259)	1,952	77,946	63,195

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity					
	Remeasure-ments of defined benefit plans	Total other components of equity	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	Total equity
Balance as of April 1, 2018	–	120,504	1,031,376	1,132,982	58	1,133,041
Changes in accounting policies	–	–	(530)	(530)	–	(530)
Adjusted balance as of April 1, 2018	–	120,504	1,030,846	1,132,452	58	1,132,510
Profit for the period	–	–	44,014	44,014	6	44,020
Other comprehensive income (loss) for the period	(175)	93,859	–	93,859	–	93,859
Total comprehensive income (loss) for the period	(175)	93,859	44,014	137,874	6	137,880
Purchase of treasury shares	–	–	–	(24)	–	(24)
Cancellation of treasury shares	–	(40)	–	309	–	309
Dividends	–	–	(22,668)	(22,668)	–	(22,668)
Transfer from other components of equity to retained earnings	175	(71,229)	71,229	–	–	–
Others	–	–	–	–	(8)	(8)
Total transactions with owners of the Company	175	(71,269)	48,560	(22,382)	(8)	(22,391)
Balance as of September 30, 2018	–	143,094	1,123,421	1,247,943	56	1,248,000

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Cash flows from operating activities		
Profit before tax	51,191	58,635
Depreciation and amortization	21,817	22,628
Impairment loss	31,413	–
Financial income	(4,669)	(4,447)
Financial expenses	2,039	3,643
Share of (profit) loss of investments accounted for using the equity method	196	151
(Gain) loss on sale and disposal of non-current assets	(6,440)	(4,721)
(Increase) decrease in trade and other receivables	2,003	(36,100)
(Increase) decrease in inventories	(17,971)	(12,072)
Increase (decrease) in trade and other payables	(34,385)	3,837
Others, net	(11,909)	(9,163)
Subtotal	33,287	22,392
Interest and dividends received	2,274	2,761
Interest paid	(992)	(736)
Income taxes paid	(16,553)	(17,767)
Net cash flows from (used in) operating activities	18,016	6,649
Cash flows from investing activities		
Payments into time deposits	(393,912)	(394,705)
Proceeds from maturities of time deposits	458,926	330,828
Acquisition of securities	(51,223)	(78,118)
Proceeds from sale of securities	71,101	72,202
Acquisition of property, plant and equipment	(11,143)	(14,760)
Proceeds from sale of property, plant and equipment	76	84
Acquisition of intangible assets	(3,945)	(9,945)
Payments for loans receivable	(369)	(253)
Proceeds from collection of loans receivable	392	505
Others, net	8,520	4,609
Net cash flows from (used in) investing activities	78,423	(89,552)

	Six months ended September 30, 2017	Six months ended September 30, 2018
Cash flows from financing activities		
Repayments of bonds and borrowings	–	(20,000)
Purchase of treasury shares	(15)	(24)
Proceeds from sale of treasury shares	1	0
Dividends paid	(23,206)	(22,662)
Others, net	(424)	(533)
Net cash flows from (used in) financing activities	(23,644)	(43,220)
Net increase (decrease) in cash and cash equivalents	72,795	(126,123)
Cash and cash equivalents at the beginning of the period	246,050	357,702
Effect of exchange rate changes on cash and cash equivalents	5,208	5,273
Cash and cash equivalents at the end of the period	324,054	236,852

(5) Notes to Condensed Interim Consolidated Financial Statements

Going Concern Assumption

Not applicable.

Changes in Significant Subsidiaries during the Period

Not applicable.

Changes in Accounting Policies

The significant accounting policies adopted in preparing the condensed interim consolidated financial statements of the Group have not changed from the prior year except for the adoption of the following new and amended accounting standards and interpretation. In the year ending March 31, 2019, the Group is adopting the following accounting standards and interpretation in accordance with their effective dates.

IFRS		Overview
IFRS 2	Share-based Payment	Amendment to classification and measurement of share based payments
IFRS 9	Financial Instruments	Amendment to rules for general hedge accounting Limited amendment to classification and measurement of financial assets and implementation of expected loss model
IFRS 15	Revenue from Contracts with Customers	Amendment to accounting for revenue
IAS 40	Investment Property	Amendment to clarify the rules for transfers of investment property
IFRIC 22	Foreign Currency Transactions and Advance Consideration	Amendment to the exchange rate to be used on initial recognition of a related asset, expense or income when an entity has received or paid advance consideration in a foreign currency

The Group applied IFRS 15 retrospectively in accordance with the transition method and recognized the cumulative effect from initial application as an adjustment to the opening balance of retained earnings for the year ending March 31, 2019.
With the adoption of IFRS 15, from the year ending March 31, 2019, revenue from a contract with a customer is recognized by applying the following five steps.
Step 1: Identify the contract with a customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation
In addition, with the adoption of IFRS 15, from the year ending March 31, 2019, provisions for sales returns, rebates and deductions which were previously presented as “Provisions” (current), have been reclassified to refund liabilities, which are included in “Trade and other payables”.
As a result, the opening balance of “Deferred tax assets”, “Trade and other payables”, and “Other non-current liabilities” increased by 233 million yen, 22,637 million yen and 557 million yen, respectively, and “Provisions” (current) and “Retained earnings” decreased by 22,431 million yen and 530 million yen, respectively, as compared to the balances which would be reported if the previous accounting standard was applied.
Also, “Deferred tax assets”, “Trade and other payables”, and “Other non-current liabilities” increased by 201 million yen, 24,300 million yen and 454 million yen, respectively, and “Provisions” (current) and “Retained earnings” decreased by 24,094 million yen and 459 million yen, respectively, as of September 30, 2018, as compared to the balances which would be reported if the previous accounting standard was applied.

Except for the above, the new and amended accounting standards and interpretation did not have a material impact on the condensed interim consolidated financial statements.