January 31, 2019

Consolidated Financial Results for the First Nine 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
Representative: Dr. Sunao Manabe, Representative Director, President and COO.
Contact: Mr. Koji Ogawa, Corporate Officer, Vice President, Corporate Communications Department
Telephone: +81-3-6225-1125

Scheduled date of Quarterly Report filing: February 6, 2019
Scheduled date of dividend payments: -
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 Nine Months of the Year Ending March 31, 2019 (from April 1, 2018 to December 31, 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	%
Nine months ended December 31, 2018	703,080	-5.1	97,082	4.1	97,957	0.2	78,814	9.3
Nine months ended December 31, 2017	741,047	0.9	93,225	-27.6	97,735	-26.2	72,129	-17.4

	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
Nine months ended December 31, 2018	78,799	8.5	147,583	47.3	121.65	121.37
Nine months ended December 31, 2017	72,602	-17.7	100,171	14.7	109.56	109.30

(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 December 31, 2018	1,893,589	1,235,019	1,234,953	65.2	1,906.25
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	84.90

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 25.

(3) Number of ordinary shares issued

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

As of December 31, 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 December 31, 2018	61,166,028 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)

Nine months ended December 31, 2018	647,759,180 shares
Nine months ended December 31, 2017	662,672,247 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 Nine Months (3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements"* on page 16 for matters related to the above forecasts.

Attached Material

Index

1. Qualitative Information about Consolidated Results for the First Nine 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.)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
Revenue	741,047	703,080	–37,967 –5.1%
Operating profit	93,225	97,082	3,856 4.1%
Profit before tax	97,735	97,957	221 0.2%
Profit attributable to owners of the Company	72,602	78,799	6,196 8.5%
Total comprehensive income	100,171	147,583	47,411 47.3%

<Revenue of global mainstay products>

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

Product name	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
Edoxaban anticoagulant	56,600	87,407	30,807 54.4%
Olmesartan antihypertensive agent	120,600	80,867	–39,733 –32.9%
Prasugrel antiplatelet agent	27,003	18,812	–8,191 –30.3%

<Selling, general and administrative expenses>

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

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
Selling, general and administrative expenses	216,743	198,513	–18,229 –8.4%
Ratio of selling, general and administrative expenses to revenue	29.2%	28.2%	–1.0%

<Research and development expenses>

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

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
Research and development expenses	175,628	142,582	–33,045 –18.8%
Ratio of research and development expenses to revenue	23.7%	20.3%	–3.4%

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

(Yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
USD/Yen	111.71	111.15
EUR/Yen	128.53	129.49

a. Revenue

- Revenue in the first nine months of the year ending March 31, 2019 decreased by ¥38.0 billion, or 5.1% compared to the same period of the previous fiscal year (year on year), to ¥703.1 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*.
- The negative effect on revenue from foreign exchange was ¥1.5 billion in total.

b. Operating profit

- Operating profit increased by ¥3.9 billion, or 4.1% year on year, to ¥97.1 billion.
- Gross profit decreased by ¥47.4 billion, or 9.8%, to ¥438.2 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 ¥18.2 billion, or 8.4%, to ¥198.5 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 ¥33.0 billion, or 18.8% year on year, to ¥142.6 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 negative effect on operating profit from foreign exchange.

c. Profit before tax

- Profit before tax was ¥98.0 billion, approximately the same level as the same period of the previous fiscal year (0.2% year on year).
- Although there was an increase of ¥3.9 billion in operating profit, profit before tax was approximately the same level as the same period of the previous fiscal year 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 ¥6.2 billion, or 8.5% year on year, to ¥78.8 billion.
- Although profit before tax was approximately the same level as the same period of the previous fiscal year, profit attributable to owners of the Company increased 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 ¥47.4 billion, or 47.3% year on year, to ¥147.6 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 ¥26.0 billion, or 5.5% year on year, to ¥448.6 billion.

<Prescription drug business>

- Revenue from prescription drug business decreased by ¥22.4 billion, or 5.4% year on year, to ¥395.7 billion. The decrease was mainly due to drug price reductions resulting from revisions to the National Health Insurance (NHI) system and the effect of a decrease in sales of Olmetec due to the loss of exclusivity, 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.
- In November 2018, Daiichi Sankyo launched the antitumor agent *trastuzumab BS for intravenous drip infusions "DAIICHI SANKYO,"* a biosimilar product to the anti-HER2 antibody, trastuzumab.

*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 ¥3.6 billion, or 6.4% year on year, to ¥52.9 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 from this fiscal year) despite growth in sales including those of the *Transino* and *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.)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
Prescription drug business*	418.1	395.7	-22.4 -5.4%
Healthcare (OTC) products business	56.6	52.9	-3.6 -6.4%

* 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	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
NEXIUM ulcer treatment	70.0	61.0	–9.0 –12.9%
LIXIANA anticoagulant	34.7	49.3	14.6 42.1%
Memary Alzheimer's disease treatment	38.1	39.5	1.4 3.8%
Loxonin anti-inflammatory analgesic	29.0	24.3	–4.7 –16.3%
PRALIA treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	17.3	21.0	3.7 21.7%
TENELIA type 2 diabetes mellitus treatment	20.9	19.9	–1.0 –4.7%
Inavir anti-influenza treatment	9.3	4.5	–4.8 –51.8%
Olmetec antihypertensive agent	40.5	11.9	–28.5 –70.5%
RANMARK treatment for bone complications caused by bone metastases from tumors	11.7	12.7	1.0 8.4%
Efient antiplatelet agent	9.9	10.9	0.9 9.4%
Rezaltas antihypertensive agent	13.1	12.2	–1.0 –7.5%
Urief treatment for dysuria	8.7	8.2	–0.5 –5.5%
Omnipaque contrast medium	11.0	9.5	–1.4 –12.9%

b. North America

- Revenue in North America decreased by ¥25.2 billion, or 17.5% year on year, to ¥118.7 billion. Revenue in local currency terms decreased by US$220 million, or 17.1%, to US$1,068 million. This revenue includes revenue generated by Daiichi Sankyo, Inc., and American Regent, Inc (formerly, Luitpold Pharmaceuticals, Inc.).
- In January 2019, the company name of former Luitpold Pharmaceuticals, Inc. was changed to American Regent, Inc. “American Regent” is a product brand been used for most of company’s products and being widely known in the U.S. market.
- At Daiichi Sankyo, Inc., sales of *Effient* and *Olmesartan* and its combination drugs declined, in addition to a decrease of sales of *Welchol* due to entry of generics in May 2018.
- At American Regent, Inc., sales of *Injectafer* increased.

<Revenue of Daiichi Sankyo, Inc. mainstay products>

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

Product name	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
*Olmesartan** antihypertensive agent	155	71	-84 -54.1%
Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	262	99	-163 -62.4%
Effient antiplatelet agent	91	22	-69 -75.8%
SAVAYSA anticoagulant	14	15	0 1.4%
MOVANTIK opioid-induced constipation treatment	33	29	-4 -11.7%

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

<Revenue of American Regent, Inc.* mainstay products>

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

Product name	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
Venofer treatment for iron deficiency anemia	215	217	2 0.9%
Injectafer treatment for iron deficiency anemia	226	303	77 34.3%

* *Formerly, Luitpold Pharmaceuticals, Inc.*

c. Europe

- Revenue in Europe increased by ¥7.8 billion, or 13.4% year on year, to ¥66.0 billion. Revenue in local currency terms increased by EUR57 million, or 12.6%, to EUR510 million.
- The increase of revenue is mainly attributable to increase in sales of *LIXIANA* despite decreases in sales of *Olmesartan* and its combination drugs and *Effient*.

<Revenue of Daiichi Sankyo Europe GmbH mainstay products>

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

Product name	Nine months ended December 31, 2017	Nine months ended December 31, 2018	YoY change
*Olmesartan** antihypertensive agent	198	162	-36 -18.2%
Efient antiplatelet agent	46	36	-11 -23.3%
LIXIANA anticoagulant	144	258	114 79.1%

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

d. Asia, South & Central America

- Revenue in Asia, South & Central America increased by ¥4.4 billion, or 7.6% year on year, to ¥63.1 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.
- Updated safety and efficacy data for patients with colorectal cancer in these trials were presented at the European Society for Medical Oncology (ESMO) congress in October 2018.
- Updated safety and efficacy data for patients with HER2 low expressing metastatic breast cancer in these trials were presented at the San Antonio Breast Cancer Symposium (SABCS) in December 2018. These most recent data suggest that *DS-8201* is also a promising treatment for patients with HER2 low expressing metastatic breast cancer.

  In addition, concerning interstitial lung disease (ILD), the first analysis of interstitial lung disease (ILD) data of all clinical trials for *DS-8201*, including adjudicated case results, was presented.
- 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.
- In October 2018, Daiichi Sankyo entered into a clinical trial collaboration agreement with German company, Merck KGaA and U.S. company Pfizer Inc., to evaluate the combination of *DS-8201* and *avelumab*, the immune checkpoint inhibitor (product name: *BAVENCIO*) and DNA damage response inhibitor (DDR) being developed by Merck KGaA, in patients with HER2-expressing or mutated solid tumors.

b. U3-1402 (HER3-targeting ADC)

- Phase I/II clinical trials in patients with HER3-positive recurrent and/or metastatic breast cancer is underway in Japan and the U.S.
- Safety and efficacy data in these trials were presented for the first time at the American Society of Clinical Oncology (ASCO) meeting in June 2018. In addition, in December 2018 updated data of these trials were presented at the San Antonio Breast Cancer Symposium (SABCS). These most recent data suggest that *U3-1402* is a promising treatment. Daiichi Sankyo considers that these data suggest that Daiich Sankyo's ADC technology could provide a new treatment approach for patients.
- 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 (FLT3 Inhibitor)

- 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, an application for manufacturing and marketing approval was filed in Japan in October 2018. In addition, in November 2018, the applications for approval for marketing were accepted for review and granted Accelerated Assessment designation*[10] and Priority Review designation*[11] at the European Medicines Agency (EMA), and the FDA, respectively.

- 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.

*10 Accelerated Assessment: A designation, that is granted by the EMA to drugs that can expect an accelerated assessment period because they are a promising treatment considered to be of major interest for public health and therapeutic innovation.

*11 Priority Review: A designation, that is granted by the FDA to drugs that would be significant improvements in the safety or effectiveness of the treatment, diagnosis or prevention of serious conditions when compared to standard applications. Under Priority Review, the FDA aims to take action on an application within six months as compared to 10 months under standard review.

<Combination, etc.>

- In December 2018, Daiichi Sankyo initiated global Phase I trials to evaluate the combination of *Quizartinib* and *milademetan*[*12], the MDM2 inhibitor (*DS-3032*), in patients with relapsed or refractory AML with FLT3-ITD mutation or patients with newly-diagnosed AML with FLT3-ITD mutation unfit for intensive chemotherapy.

*12 *Milademetan* (*DS-3032*): Phase I trials are underway targeting patients with solid and hematologic malignancies. Data from preclinical AML animal trials suggests that when combined with quizartinib, it has a synergetic effect that is greater than when used as a single agent.

d. Pexidartinib (CSF-1R/KIT/FLT3 Inhibitor）

- *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.

e. Axicabtagene ciloleucel (CD19-targeting CAR-T cell)

- In October 2018, axicabtagene ciloleucel was granted Orphan Drug designation by the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of diffuse large B-cell lymphoma (DLBCL), primary mediastinal (thymus) large B-cell lymphoma (PMBCL), high-grade B-cell lymphoma (HGBL) and transformed follicular lymphoma (TFL), which are aggressive forms of non-Hodgkin lymphoma (NHL).

f. DS-1205 (AXL Inhibitor)

- In October 2018, the Group commenced the Phase I clinical trials in Japan to evaluate the combination of *DS-1205* and *gefitinib*, epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) (product name: *IRESSA*) for patients with EGFR-mutated non-small cell lung cancer (NSCLC) whose disease has progressed while taking an EGFR TKI.

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

g. 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*[13].

*13 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.

h. 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*[14]. 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.

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

i. Worldwide licensing agreement with Glycotope GmbH for ADC

- In October 2017, Daiichi Sankyo had 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*.

j. Agreement of collaboration with Roche on the development of HER2 low companion diagnostic test

- In November 2018, Daiichi Sankyo entered into an agreement of collaboration with Roche in Switzerland on the development of a HER2 low companion diagnostic test*[15].

*15 Companion diagnostic test: It is diagnostic test that measures the efficacy and safety of a therapeutic treatment before drugs are administered. It is used to select the most suitable therapeutic treatment. It is also a clinical test that is used when monitoring the therapeutic effects of treatment.

k. Conclusion of collaboration agreement with Sarah Cannon Research Institute for the global development of the oncology field

- In December 2018, Daiichi Sankyo entered into a collaboration agreement with U.S. company Sarah Cannon Research Institute to carry out global clinical trials including Japan for the purpose of accelerating development of drugs in the oncological pipeline, including the ADC franchise held by Daiichi Sankyo.

l. Worldwide exclusive out-license agreement with AnHeart Therapeutics Inc. for DS-6051

- In December 2018, Daiichi Sankyo entered into a worldwide exclusive out-license agreement with U.S. company AnHeart Therapeutics Inc. for *DS-6051*, Daiichi Sankyo's selective ROS1/NTRK inhibitor.
- Following the conclusion of this agreement, Daiichi Sankyo will work in cooperation with AnHeart Therapeutics Inc. in the Phase I trial in patients with solid tumors and neuroendocrine tumors harboring either a ROS1 or NTRK fusion gene in the U.S. and Japan.

【Specialty Medicine Area[*16]】

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

a. Edoxaban (Anticoagulant)

- *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 30 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 expressed 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.

【Vaccine】

a. VN-100 (Intradermal seasonal influenza vaccine)

- As a result of having reviewed the influenza vaccine project within the Daiichi Sankyo Group, in October 2018, Daiichi Sankyo decided to discontinue the development of *VN-100* for strategic reasons.

(2) Analysis of Financial Position as of December 31, 2018

- Total assets as of December 31, 2018 are ¥1,893.6 billion, a decrease of ¥4.2 billion from the previous fiscal year-end, mainly due to a decrease in cash and cash equivalents, which was partially offset by an increase in trade and other receivables.
- Total liabilities as of December 31, 2018 are ¥658.6 billion, a decrease of ¥106.1 billion from the previous fiscal year-end, mainly due to a decrease in income taxes payable.
- Total equity as of December 31, 2018 is ¥1,235.0 billion, an increase of ¥102.0 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 5.5% from the previous fiscal year-end to 65.2%.

(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
- Daiichi Sankyo paid an ordinary dividend of ¥35 per share as an interim dividend on December 3, 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.

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 December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	357,702	239,167
Trade and other receivables	231,529	305,741
Other financial assets	429,380	490,379
Inventories	172,586	177,573
Other current assets	10,347	13,065
Total current assets	1,201,545	1,225,926
Non-current assets		
Property, plant and equipment	217,946	225,734
Goodwill	75,479	77,801
Intangible assets	173,537	170,370
Investments accounted for using the equity method	1,693	2,352
Other financial assets	179,177	118,687
Deferred tax assets	40,339	66,551
Other non-current assets	8,035	6,165
Total non-current assets	696,209	667,662
Total assets	1,897,754	1,893,589

(Millions of yen)

	As of March 31, 2018	As of December 31, 2018
LIABILITIES AND EQUITY		
Current liabilities		
Trade and other payables	226,164	260,204
Bonds and borrowings	20,000	40,000
Other financial liabilities	516	465
Income taxes payable	64,609	8,759
Provisions	34,015	6,814
Other current liabilities	7,800	14,459
Total current liabilities	353,105	330,703
Non-current liabilities		
Bonds and borrowings	260,564	220,580
Other financial liabilities	8,155	7,314
Post-employment benefit liabilities	10,547	9,878
Provisions	48,752	10,431
Deferred tax liabilities	18,676	19,490
Other non-current liabilities	64,911	60,172
Total non-current liabilities	411,608	327,866
Total liabilities	764,713	658,569
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,633	94,633
Treasury shares	(163,531)	(163,071)
Other components of equity	120,504	116,496
Retained earnings	1,031,376	1,136,894
Total equity attributable to owners of the Company	1,132,982	1,234,953
Non-controlling interests		
Non-controlling interests	58	65
Total equity	1,133,041	1,235,019
Total liabilities and equity	1,897,754	1,893,589

(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)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Revenue	741,047	703,080
Cost of sales	255,450	264,902
Gross profit	485,597	438,178
Selling, general and administrative expenses	216,743	198,513
Research and development expenses	175,628	142,582
Operating profit	93,225	97,082
Financial income	7,131	6,064
Financial expenses	3,020	5,537
Share of profit (loss) of investments accounted for using the equity method	398	348
Profit before tax	97,735	97,957
Income taxes	25,605	19,142
Profit for the period	72,129	78,814
Profit attributable to:		
Owners of the Company	72,602	78,799
Non-controlling interests	(473)	15
Profit for the period	72,129	78,814
Earnings per share		
Basic earnings per share (Yen)	109.56	121.65
Diluted earnings per share (Yen)	109.30	121.37

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Profit for the period	72,129	78,814
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	13,965	59,607
Remeasurements of defined benefit plans	(131)	(145)
Items that are or may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	14,208	9,306
Other comprehensive income for the period	28,042	68,768
Total comprehensive income for the period	100,171	147,583
Total comprehensive income (loss) attributable to:		
Owners of the Company	100,645	147,567
Non-controlling interests	(473)	15
Total comprehensive income for the period	100,171	147,583

(3) Condensed Interim Consolidated Statement of Changes in Equity

Nine months ended December 31, 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	–	–	–	–	14,208	13,965
Total comprehensive income (loss) for the period	–	–	–	–	14,208	13,965
Purchase of treasury shares	–	(34)	(20,023)	–	–	–
Cancellation of treasury shares	–	–	375	(41)	–	–
Dividends	–	–	–	–	–	–
Acquisition of Non-controlling interests	–	(9,064)	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(618)
Others	–	–	–	–	–	–
Total transactions with owners of the Company	–	(9,099)	(19,647)	(41)	–	(618)
Balance as of December 31, 2017	50,000	94,650	(133,599)	2,025	81,776	68,201

(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	–	–	72,602	72,602	(473)	72,129
Other comprehensive income for the period	(131)	28,042	–	28,042	–	28,042
Total comprehensive income (loss) for the period	(131)	28,042	72,602	100,645	(473)	100,171
Purchase of treasury shares	–	–	–	(20,058)	–	(20,058)
Cancellation of treasury shares	–	(41)	(30)	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	131	(486)	486	–	–	–
Others	–	–	–	–	(8)	(8)
Total transactions with owners of the Company	131	(528)	(45,974)	(75,249)	4,998	(70,250)
Balance as of December 31, 2017	–	152,003	1,038,239	1,201,293	56	1,201,350

Nine months ended December 31, 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	–	–	–	–	9,306	59,607
Total comprehensive income (loss) for the period	–	–	–	–	9,306	59,607
Purchase of treasury shares	–	–	(35)	–	–	–
Cancellation of treasury shares	–	–	495	(132)	–	–
Dividends	–	–	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(72,788)
Others	–	–	–	–	–	–
Total transactions with owners of the Company	–	–	460	(132)	–	(72,788)
Balance as of December 31, 2018	50,000	94,633	(163,071)	1,860	66,645	47,991

(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	–	–	78,799	78,799	15	78,814
Other comprehensive income (loss) for the period	(145)	68,768	–	68,768	–	68,768
Total comprehensive income (loss) for the period	(145)	68,768	78,799	147,567	15	147,583
Purchase of treasury shares	–	–	–	(35)	–	(35)
Cancellation of treasury shares	–	(132)	(53)	310	–	310
Dividends	–	–	(45,340)	(45,340)	–	(45,340)
Transfer from other components of equity to retained earnings	145	(72,642)	72,642	–	–	–
Others	–	–	–	–	(8)	(8)
Total transactions with owners of the Company	145	(72,775)	27,249	(45,066)	(8)	(45,074)
Balance as of December 31, 2018	–	116,496	1,136,894	1,234,953	65	1,235,019

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Cash flows from operating activities		
Profit before tax	97,735	97,957
Depreciation and amortization	33,487	34,294
Impairment loss	31,423	68
Financial income	(7,131)	(6,064)
Financial expenses	3,020	5,537
Share of (profit) loss of investments accounted for using the equity method	(398)	(348)
(Gain) loss on sale and disposal of non-current assets	(5,157)	(4,131)
(Increase) decrease in trade and other receivables	(46,048)	(73,549)
(Increase) decrease in inventories	(12,958)	(4,989)
Increase (decrease) in trade and other payables	(25,421)	8,173
Others, net	(7,220)	(9,791)
Subtotal	61,331	47,156
Interest and dividends received	3,803	4,548
Interest paid	(1,401)	(1,140)
Income taxes paid	(19,884)	(29,870)
Net cash flows from (used in) operating activities	43,849	20,694
Cash flows from investing activities		
Payments into time deposits	(415,393)	(382,905)
Proceeds from maturities of time deposits	482,788	335,582
Acquisition of securities	(90,090)	(99,662)
Proceeds from sale of securities	104,301	101,563
Acquisition of property, plant and equipment	(16,072)	(21,541)
Proceeds from sale of property, plant and equipment	80	7
Acquisition of intangible assets	(9,584)	(13,070)
Payments for loans receivable	(546)	(514)
Proceeds from collection of loans receivable	542	703
Others, net	8,429	4,386
Net cash flows from (used in) investing activities	64,454	(75,449)

	Nine months ended December 31, 2017	Nine months ended December 31, 2018
Cash flows from financing activities		
Repayments of bonds and borrowings	–	(20,000)
Purchase of treasury shares	(20,058)	(35)
Proceeds from sale of treasury shares	1	0
Dividends paid	(46,458)	(45,377)
Others, net	(4,657)	(688)
Net cash flows from (used in) financing activities	(71,173)	(66,101)
Net increase (decrease) in cash and cash equivalents	37,129	(120,856)
Cash and cash equivalents at the beginning of the period	246,050	357,702
Effect of exchange rate changes on cash and cash equivalents	5,444	2,321
Cash and cash equivalents at the end of the period	288,624	239,167

(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 185 million yen, 23,315 million yen and 403 million yen, respectively, and “Provisions” (current) and “Retained earnings” decreased by 23,109 million yen and 423 million yen, respectively, as of December 31, 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.