January 31, 2020

Consolidated Financial Results for the First Nine Months of the Year Ending March 31, 2020 (Fiscal 2019) <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: February 6, 2020
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, 2020 (from April 1, 2019 to December 31, 2019)

(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, 2019	757,032	7.7	155,581	60.3	159,978	63.3	134,199	70.3
Nine months ended December 31, 2018	703,080	-5.1	97,082	4.1	97,957	0.2	78,814	9.3

	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, 2019	134,281	70.4	125,595	-14.9	207.25	206.82
Nine months ended December 31, 2018	78,799	8.5	147,583	47.3	121.65	121.37

(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, 2019	2,089,754	1,330,286	1,329,795	63.6	2,052.27
As of March 31, 2019	2,088,051	1,249,705	1,249,642	59.8	1,928.80

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, 2019	–	35.00	–	35.00	70.00
Year ending March 31, 2020	–	35.00	–		
Year ending March 31, 2020 (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, 2020

(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	970,000	4.3	135,000	61.3	135,000	57.3	110,000	17.7	110,000	17.8	169.76

Note: Revision of the forecast from most recently announced figures: Yes

*Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): Yes

Excluded from consolidation: One company Japan Vaccine Distribution Co., Ltd.

Note: Please see *"2. Condensed Interim Consolidated Financial Statements with Primary Notes, (5) Notes to Condensed Interim Consolidated Financial Statements, (Changes in Significant Subsidiaries during the Period)"* on page 23.

(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 23.

(3) Number of ordinary shares issued

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

As of December 31, 2019	709,011,343 shares
As of March 31, 2019	709,011,343 shares

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

As of December 31, 2019	61,049,104 shares
As of March 31, 2019	61,124,702 shares

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

Nine months ended December 31, 2019	647,925,691 shares
Nine months ended December 31, 2018	647,759,180 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 13 for matters related to the above forecasts.

Attached Material

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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, 2018	Nine months ended December 31, 2019	YoY change
Revenue	703,080	757,032	53,952 7.7%
Operating profit	97,082	155,581	58,499 60.3%
Profit before tax	97,957	159,978	62,020 63.3%
Profit attributable to owners of the Company	78,799	134,281	55,482 70.4%
Total comprehensive income	147,583	125,595	-21,987 -14.9%

<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, 2018	Nine months ended December 31, 2019	YoY change
Edoxaban anticoagulant	87,407	116,387	28,979 33.2%
Olmesartan antihypertensive agent	80,867	76,976	-3,891 -4.8%
Prasugrel antiplatelet agent	18,812	14,315	-4,496 -23.9%

<Selling, general and administrative expenses>

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

	Nine months ended December 31, 2018	Nine months ended December 31, 2019	YoY change
Selling, general and administrative expenses	198,513	208,232	9,718 4.9%
Ratio of Selling, general and administrative expenses to revenue	28.2%	27.5%	-0.7%

<Research and development expenses>

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

	Nine months ended December 31, 2018	Nine months ended December 31, 2019	YoY change
Research and development expenses	142,582	136,937	-5,644 -4.0%
Ratio of research and development expenses to revenue	20.3%	18.1%	-2.2%

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

(Yen)

	Nine months ended December 31, 2018	Nine months ended December 31, 2019
USD/Yen	111.15	108.67
EUR/Yen	129.49	121.05

a. Revenue

- Revenue in the first nine months of the year ending March 31, 2020 increased by ¥54.0 billion, or 7.7% compared to the same period of the previous fiscal year (year on year), to ¥757.0 billion.
- The increase of revenue is mainly due to the growth in sales of mainstay products such as *edoxaban*, and the revenue recognition of upfront payment for the global development and commercialization collaboration, and regulatory milestone payment of *trastuzumab deruxtecan* (HER2-targeting ADC, development code: *DS-8201*) with AstraZeneca (¥8.0 billion).
- The negative effect on revenue from foreign exchange was ¥12.2 billion in total.

b. Operating profit

- Operating profit increased by ¥58.5 billion, or 60.3% year on year, to ¥155.6 billion.
- Gross profit increased by ¥62.6 billion, or 14.3%, to ¥500.8 billion mainly due to a decrease in cost of sales as a result of a change in the product mix and the recording of a gain on sale of subsidiary (¥18.8 billion) in association with the transfer of Takatsuki plant, in addition to an increase in revenue.
- Selling, general and administrative expenses increased by ¥9.7 billion, or 4.9%, to ¥208.2 billion mainly due to an increase in expenses accompanied by the establishment of oncology business structure in the U.S.
- Research and development expenses decreased by ¥5.6 billion, or 4.0% year on year, to ¥136.9 billion mainly due to the effect of sharing the costs related to *trastuzumab deruxtecan* with AstraZeneca.
- The negative effect on operating profit from foreign exchange was ¥3.1 billion in total.

c. Profit before tax

- Profit before tax increased by ¥62.0 billion, or 63.3% year on year, to ¥160.0 billion.

d. Profit attributable to owners of the Company

- Profit attributable to owners of the Company increased by ¥55.5 billion, or 70.4% year on year, to ¥134.3 billion.
- The rate of increase of profit attributable to owners of the Company exceeded that of profit before tax, mainly due to lower income taxes as a result of the introduction of consolidated taxation system.

e. Total comprehensive income

- Total comprehensive income decreased by ¥22.0 billion, or 14.9% year on year, to ¥125.6 billion.
- Total comprehensive income decreased mainly because the tax liabilities related to business restructuring of Daiichi Sankyo and its consolidated subsidiaries (“the Group”), which was carried out in the past fiscal year, were reversed in the same period of the previous fiscal year.

[Revenue by Geographic Area]

Primary revenue by geographic area is as follows.

a. Japan

- Revenue in Japan increased by ¥26.5 billion, or 5.9% year on year, to ¥475.1 billion.

<Prescription drug business>

- Revenue from prescription drug business increased by ¥26.6 billion, or 6.7% year on year, to ¥422.3 billion. The increase was mainly due to the growth in sales of mainstay products *LIXIANA, Inavir, Tarlige* and others, and the contribution to sales from authorized generic[*1] products. This revenue also includes revenue generated by the vaccine business and revenue generated by the generic pharmaceutical business of Daiichi Sankyo Espha Co., Ltd.
- In April 2019, Daiichi Sankyo launched *Tarlige* (generic name: *mirogabalin besilate*) for the indication of peripheral neuropathic pain.
- In May 2019, Daiichi Sankyo launched *MINNEBRO* (generic name: *esaxerenone*) for the indication of hypertension.
- In October 2019, Daiichi Sankyo launched *VANFLYTA* (generic name: *quizartinib*) for the indication of relapsed or refractory FLT3-ITD acute myeloid leukemia.
- In June 2019, Daiichi Sankyo decided that it will return the exclusive development and marketing rights in Japan for four diagnostic imaging agents (*Omnipaque*, *Omniscan*, *Visipaque* and *Sonazoid*) to U.S. company GE Healthcare and transfer marketing authorization rights in Japan to GE Healthcare Pharma Limited, an entity of GE Healthcare to run its business in Japan.

*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 was ¥52.9 billion, approximately the same level as the same period of the previous fiscal year (decreased year on year by 0.1%).

<Primary revenue composition in Japan>

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

	Nine months ended December 31, 2018	Nine months ended December 31, 2019	YoY change
Prescription drugs*	395.7	422.3	26.6 6.7%
Healthcare (OTC) products	52.9	52.9	-0.1 -0.1%

* 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, 2018	Nine months ended December 31, 2019	YoY change
LIXIANA anticoagulant	49.3	65.6	16.3 33.1%
NEXIUM ulcer treatment	61.0	62.3	1.3 2.2%
Memary Alzheimer's disease treatment	39.5	40.2	0.7 1.7%
PRALIA treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	21.0	24.3	3.3 15.6%
TENELIA type 2 diabetes mellitus treatment	19.9	19.7	-0.2 -1.1%
Loxonin anti-inflammatory analgesic	24.3	22.7	-1.6 -6.4%
Inavir anti-influenza agent	4.5	11.5	7.1 157.9%
RANMARK treatment for bone complications caused by bone metastases from tumors	12.7	14.0	1.3 10.5%
Efient antiplatelet agent	10.9	11.1	0.2 2.0%
Rezaltas antihypertensive agent	12.2	11.6	-0.6 -4.5%
Canalia type 2 diabetes mellitus treatment	6.9	9.8	3.0 43.3%
Vimpat anti-epileptic agent	4.8	8.5	3.7 77.0%
Omnipaque contrast agent	9.5	8.4	-1.1 -11.9%
Olmetec antihypertensive agent	11.9	9.4	-2.5 -21.0%

b. North America

- Revenue in North America increased by ¥4.8 billion, or 4.1% year on year, to ¥123.6 billion. Revenue in local currency terms increased by US$69 million, or 6.4%, to US$1,137 million. This revenue includes revenue generated by Daiichi Sankyo, Inc., and American Regent, Inc.
- At Daiichi Sankyo, Inc., sales of *Welchol* declined.
- In August 2019, Daiichi Sankyo, Inc. launched *TURALIO* (generic name: *pexidartinib*) for the indication of tenosynovial giant cell tumor.
- 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, 2018	Nine months ended December 31, 2019	YoY change
*Olmesaratan** antihypertensive agent	71	72	0 0.5%
Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	99	79	-20 -19.9%

* *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, 2018	Nine months ended December 31, 2019	YoY change
Injectafer treatment for iron deficiency anemia	303	362	59 19.5%
Venofer treatment for iron deficiency anemia	217	215	-2 -1.1%

c. Europe

- Revenue in Europe increased by ¥1.7 billion, or 2.6% year on year, to ¥67.7 billion. Revenue in local currency terms increased by EUR50 million, or 9.7%, to EUR559 million.
- Sales of *LIXIANA* increased despite sales of *Olmesartan* and its combination drugs and *Efient* declined.

<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, 2018	Nine months ended December 31, 2019	YoY change
LIXIANA anticoagulant	258	362	105 40.7%
*Olmesaratan** antihypertensive agent	162	140	-22 -13.7%
Efient antiplatelet agent	36	16	-20 -55.1%

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

d. Asia, South & Central America

- Revenue in Asia, South & Central America increased by ¥10.4 billion, or 16.5% year on year, to ¥73.5 billion. This revenue includes revenue to overseas' licensees.
- Mainstay products such as synthetic antibacterial agent *Cravit* and *Olmesartan* and its combination drugs grew in China.
- In August 2019, *LIXIANA* was launched in China.

2) Status of R&D

- The Group has established its 2025 Vision of being a "Global Pharma Innovator with Competitive Advantage in Oncology."
- Toward the realization of 2025 Vision, the Group is working on research and development in accordance with the "3 and Alpha" Strategy, which focus research and development resources to 3 ADCs[*1] (*DS-8201*, *DS-1062* and *U3-1402*) for maximizing its product value and aim to discover medicines that change SOC[*2] (Alpha) for realization of sustainable growth.
- While striving to strengthen its drug discovering capabilities by active utilization of partnering and technology research of new modalities[*3], the Group focuses on accelerating global clinical development.
  In the medium- to long-term, the Group aims to develop therapeutic drugs for diseases by utilizing its competitive science and technology, not limited to specific therapeutic area.

*1 ADC (Antibody Drug Conjugate): Drug 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 SOC (Standard of Care): Universally applied best treatment practice in today's medical science.

*3 New modalities: New medical treatment such as ADC, nucleic acid drugs, viruses for treatment, and cell therapy.

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

【3 ADCs】

a. Trastuzumab deruxtecan (DS-8201): HER2-targeting ADC

- To maximize the value of *DS-8201*, which was created using Daiichi Sankyo's proprietary ADC technology, Daiichi Sankyo is jointly developing *DS-8201* with AstraZeneca, a company with a wealth of global experience in oncology.

<Breast cancer>

- DESTINY-Breast01 trial
  In December 2019, the U.S. Food and Drug Administration (FDA) approved *trastuzumab deruxtecan* for the treatment of adult patients with unresectable or metastatic HER2 positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.
  This indication is approved under accelerated assessment based on the results of global Phase II clinical trial presented at the San Antonio Breast Cancer Symposium (SABCS) in December 2019.
  Based on the result of this clinical trial, an application was filed in Japan for manufacturing and marketing approval of *DS-8201* for the treatment of HER2-positive breast cancer in September 2019.
- DESTINY-Breast02 trial
  The global Phase III clinical trial designed to compare the efficacy and safety of *DS-8201* versus the investigator's choice for the patients with HER2-positive recurrent and/or metastatic breast cancer previously treated with anti-HER2 ADC *T-DM1* (the third or later line treatment) is underway.
- DESTINY-Breast03 trial
  The global Phase III clinical trial designed to directly compare the efficacy and safety of *DS-8201* versus *T-DM1* in patients with HER2-positive recurrent and/or metastatic breast cancer previously treated with anti-HER2 antibody *trastuzumab*, etc. (the second line treatment) is underway.
- DESTINY-Breast04 trial
  The global Phase III clinical trial designed to compare the efficacy and safety of *DS-8201* versus the investigator's choice (chemotherapy) for the patients with HER2 low expressing metastatic breast cancer is underway.

<Gastric cancer>

- DESTINY-Gastric01 trial
  The Group is conducting Phase II clinical trials in Japan and South Korea for patients with HER2-positive recurrent and/or advanced gastric cancer.
  DS-8201 has been granted SAKIGAKE Designation[*4] by the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of the above patients.

*4 SAKIGAKE Designation: 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>

- The Group is conducting global Phase II clinical trials for patients with HER2-positive and HER2-mutated, 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, etc.>

- Daiichi Sankyo is conducting a collaborative clinical trial with Bristol-Myers Squibb Company, to evaluate the combination of *DS-8201* and *nivolumab*, the immune checkpoint inhibitor (brand name: *Opdivo*) in patients with HER2-positive breast cancer.

b. DS-1062: TROP2-targeting ADC

- Phase I clinical trials for patients with recurrent and/or advanced non-small cell lung cancer are underway in Japan and the U.S. The Group presented the preliminary results concerning safety and efficacy in the dose escalation part of the trial at the 2019 American Society of Clinical Oncology (ASCO) held in May to June 2019, and at the 2019 World Conference on Lung Cancer (WCLC) held in September 2019.

c. U3-1402: HER3-targeting ADC

<Breast cancer>

- The Group is conducting Phase I/II clinical trials in patients with HER3-positive recurrent and/or metastatic breast cancer in Japan and the U.S.

<Non-small cell lung cancer>

- The Group is conducting Phase I clinical trials in Japan and the U.S. for patients with epidermal growth factor receptor (EGFR)-mutated NSCLC whose disease has progressed while taking an EGFR tyrosine kinase inhibitor (TKI). The Group presented the preliminary results concerning safety and efficacy in the dose escalation part of the trial at the 2019 American Society of Clinical Oncology (ASCO) held in May to June 2019, and at the 2019 World Conference on Lung Cancer (WCLC) held in September 2019.

【Alpha】

1) Oncology Area

a. Quizartinib: FLT3 Inhibitor

- In June 2019, Daiichi Sankyo obtained approval for manufacturing and marketing in Japan for the treatment of adults with relapsed or refractory FLT3-ITD acute myeloid leukemia (AML). *Quizartinib* has been marketed since October 2019 under the brand name *VANFLYTA*.
- In June 2019, Daiichi Sankyo received a Complete Response Letter (CRL), which is issued when a product is not approved as is, from the FDA for the New Drug Application (NDA) for marketing approval of *quizartinib* for the treatment of adults with relapsed or refractory AML with FLT3-ITD mutations.
- In October 2019, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on marketing authorization application for *quizartinib* for the treatment of adults with relapsed or refractory AML with FLT3-ITD mutations.
- Currently, the Group is conducting global Phase III clinical trials (QuANTUM-First) to obtain approval for the indication as a first-line treatment of AML.
- *Quizartinib* has been granted Orphan Drug designation by the MHLW, the FDA and the EMA for the treatment of AML.

<Combination, etc.>

- The Group is conducting global Phase I trials to evaluate the combination of *quizartinib* and *milademetan*[*5], 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, who are not tolerant to intensive chemotherapy.

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

b. Pexidartinib: CSF-1R/KIT/FLT3 Inhibitor

- In August 2019, Daiichi Sankyo obtained approval for marketing from the FDA for the treatment of tenosynovial giant cell tumor (TGCT). *Pexidartinib* has been marketed since August 2019 under the brand name *TURALIO*.
- In April 2019, the EMA accepted the application for approval for marketing based on the results of Phase III clinical trials (ENLIVEN study) for TGCT patients in Europe and the U.S.
- *Pexidartinib* has been granted Orphan Drug designation by the EMA for the treatment of TGCT.

c. Valemetostat (DS-3201): EZH1/2 Dual Inhibitor

- In December 2019, the first patient has been dosed in Phase II clinical trial for patients with adult T-cell leukemia-lymphoma in Japan.
- The Group is conducting Phase I clinical trials for patients with non-Hodgkin lymphomas including peripheral T-cell lymphoma (PTCL) in Japan and the U.S.
- In April 2019, *DS-3201* has been granted SAKIGAKE Designation by the MHLW for the treatment of PTCL.
- The Group is conducting Phase I clinical trials for patients with AML, acute lymphocytic leukemia (ALL) and small cell lung cancer in the U.S.

d. DS-7300: B7-H3 targeting ADC

- In October 2019, the first patient has been dosed in Phase I/II clinical trials evaluating *DS-7300* for the treatment of patients with recurrent and/or advanced solid tumors (head and neck cancer, esophageal cancer, non-small cell lung cancer, etc.) in Japan and the U.S.

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

- In April 2019, Daiichi Sankyo exercised its option for a commercial license for proprietary immuno-oncology bispecific antibodies based on a collaboration and cross-licensing agreement with Zymeworks Inc. regarding bispecific antibodies[*6]. Daiichi Sankyo will continue to effectively use the technology platforms of manufacturing bispecific antibodies developed by Zymeworks Inc. with the aim of providing novel therapeutic options for patients with cancer.

*6 Bispecific antibodies: An antibody that can bind different antigens to the two antigen binding sites of one antibody molecule.

2) Areas Other than Oncology

a. Edoxaban: Factor Xa-inhibitor

- *Edoxaban* has been on the Japanese market under the brand name *LIXIANA* with indications such as 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 over 30 countries and regions.
- The safety and efficacy data in ENTRUST-AF PCI study for patients with atrial fibrillation (AF) following successful percutaneous coronary intervention (PCI) was presented at the ESC Congress in September 2019.

- Currently, the Group is conducting Phase III clinical trials in Japan for 80 years of age or older patients with non-valvular atrial fibrillation with the targeted indication of the prevention of stroke and systemic embolism.

b. Mirogabalin: α2δ ligand

- *Mirogabalin* has been marketed in Japan since April 2019 under the brand name *Tarlige* with indication for peripheral neuropathic pain.
- Currently, the Group is conducting Phase III clinical trials for patients with post-spinal cord injury neuropathic pain, etc. in Japan and other countries in Asia.

c. Esaxerenone: Mineralocorticoid receptor blocker

- *Esaxerenone* has been marketed in Japan since May 2019 under the brand name *MINNEBRO* with indication for hypertension.
- The Phase III clinical trial in Japan for patients with diabetic nephropathy met its primary endpoint and key secondary endpoints. In November 2019, the result of this clinical trial was presented in the annual meeting of the American Society of Nephrology (ASN).

(2) Analysis of Financial Position as of December 31, 2019

- Total assets as of December 31, 2019 are ¥2,089.8 billion, an increase of ¥1.7 billion from the previous fiscal year-end, mainly due to an increase in cash and cash equivalents, which was partially offset by a decrease in trade and other receivables.
- Total liabilities as of December 31, 2019 are ¥759.5 billion, a decrease of ¥78.9 billion from the previous fiscal year-end, mainly due to decreases in trade and other payables and bonds and borrowings (non-current liabilities), which were partially offset by an increase in other financial liabilities (non-current liabilities).
- Total equity as of December 31, 2019 is ¥1,330.3 billion, an increase of ¥80.6 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 3.8 points from the previous fiscal year-end to 63.6%.

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

- The differences from the forecasts of consolidated financial results for the year ending March 31, 2020, which were publicly announced on October 31, 2019, are shown below.

1) Revisions to the forecasts of consolidated financial results for the year ending March 31, 2020 (from April 1, 2019 to March 31, 2020)

	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
Previous forecasts (A)	955,000	125,000	125,000	90,000	90,000	138.90
Revised forecasts (B)	970,000	135,000	135,000	110,000	110,000	169.76
Change (B-A)	15,000	10,000	10,000	20,000	20,000	
Percentage of change (%)	1.6%	8.0%	8.0%	22.2%	22.2%	
(Reference) Year ended March 31, 2019	929,717	83,705	85,831	93,422	93,409	144.20

* Assumed exchange rate since the fourth quarter: USD/Yen = 110 EUR/Yen = 130

2) Reason for the revision

- The forecast for revenue has been revised upward from the previous forecast by ¥15.0 billion to ¥970.0 billion taking into account the strong performance, including new products in Japan and the U.S.
- The forecasts for operating profit and profit before tax have been revised upward from the previous forecasts by ¥10.0 billion to ¥135.0 billion based on the projection for an increase in gross profit resulting from growth in revenue.
- Profit attributable to owners of the Company has been revised upward by ¥20.0 billion from the previous forecast to ¥110.0 billion in light of an increase of profit before tax and a decrease in income taxes resulting from the introduction of consolidated taxation system.

Note: The forecasted statements shown above 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 2, 2019. The year-end dividend for the year ending March 31, 2020 is forecasted at ¥35 per share, and, accordingly, the annual dividend for the year ending March 31, 2020 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, 2019	As of December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	243,155	326,400
Trade and other receivables	419,609	351,862
Other financial assets	536,880	526,991
Inventories	176,067	172,700
Other current assets	15,471	13,809
Subtotal	1,391,183	1,391,764
Assets held for sale	2,000	–
Total current assets	1,393,184	1,391,764
Non-current assets		
Property, plant and equipment	229,085	242,458
Goodwill	77,851	77,120
Intangible assets	169,472	164,608
Investments accounted for using the equity method	2,200	1,004
Other financial assets	114,895	101,667
Deferred tax assets	94,809	104,891
Other non-current assets	6,551	6,238
Total non-current assets	694,866	697,989
Total assets	2,088,051	2,089,754

(Millions of yen)

	As of March 31, 2019	As of December 31, 2019
LIABILITIES AND EQUITY		
Current liabilities		
Trade and other payables	312,660	224,021
Bonds and borrowings	40,000	40,388
Other financial liabilities	530	9,154
Income taxes payable	10,451	25,762
Provisions	7,837	5,557
Other current liabilities	12,715	17,757
Subtotal	384,195	322,643
Liabilities directly associated with assets held for sale	349	–
Total current liabilities	384,544	322,643
Non-current liabilities		
Bonds and borrowings	220,585	183,903
Other financial liabilities	5,680	36,198
Post-employment benefit liabilities	10,384	10,456
Provisions	4,985	2,589
Deferred tax liabilities	17,166	16,439
Other non-current liabilities	195,000	187,236
Total non-current liabilities	453,802	436,824
Total liabilities	838,346	759,468
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,633	94,724
Treasury shares	(162,964)	(162,788)
Other components of equity	115,166	97,892
Retained earnings	1,152,806	1,249,967
Total equity attributable to owners of the Company	1,249,642	1,329,795
Non-controlling interests		
Non-controlling interests	62	490
Total equity	1,249,705	1,330,286
Total liabilities and equity	2,088,051	2,089,754

(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, 2018	Nine months ended December 31, 2019
Revenue	703,080	757,032
Cost of sales	264,902	256,280
Gross profit	438,178	500,751
Selling, general and administrative expenses	198,513	208,232
Research and development expenses	142,582	136,937
Operating profit	97,082	155,581
Financial income	6,064	8,398
Financial expenses	5,537	4,082
Share of profit (loss) of investments accounted for using the equity method	348	79
Profit before tax	97,957	159,978
Income taxes	19,142	25,778
Profit for the period	78,814	134,199
Profit attributable to:		
Owners of the Company	78,799	134,281
Non-controlling interests	15	(81)
Profit for the period	78,814	134,199
Earnings per share		
Basic earnings per share (Yen)	121.65	207.25
Diluted earnings per share (Yen)	121.37	206.82

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2018	Nine months ended December 31, 2019
Profit for the period	78,814	134,199
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	59,607	(1,067)
Remeasurements of defined benefit plans	(145)	(130)
Items that are or may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	9,306	(7,405)
Other comprehensive income for the period	68,768	(8,604)
Total comprehensive income for the period	147,583	125,595
Total comprehensive income attributable to:		
Owners of the Company	147,567	125,677
Non-controlling interests	15	(81)
Total comprehensive income for the period	147,583	125,595

(3) Condensed Interim Consolidated Statement of Changes in Equity

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 for the period	–	–	–	–	9,306	59,607
Total comprehensive income 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 for the period	(145)	68,768	–	68,768	–	68,768
Total comprehensive income 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

Nine months ended December 31, 2019

(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, 2019	50,000	94,633	(162,964)	1,805	66,628	46,732
Changes in accounting policies	–	–	–	–	–	–
Adjusted balance as of April 1, 2019	50,000	94,633	(162,964)	1,805	66,628	46,732
Profit for the period	–	–	–	–	–	–
Other comprehensive income for the period	–	–	–	–	(7,405)	(1,067)
Total comprehensive income for the period	–	–	–	–	(7,405)	(1,067)
Purchase of treasury shares	–	–	(65)	–	–	–
Cancellation of treasury shares	–	90	241	(61)	–	–
Dividends	–	–	–	–	–	–
Changes associated with obtaining control of subsidiaries	–	–	–	–	–	–
Changes associated with losing control of subsidiaries	–	–	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(8,739)
Total transactions with owners of the Company	–	90	176	(61)	–	(8,739)
Balance as of December 31, 2019	50,000	94,724	(162,788)	1,744	59,222	36,924

(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, 2019	–	115,166	1,152,806	1,249,642	62	1,249,705
Changes in accounting policies	–	–	(375)	(375)	–	(375)
Adjusted balance as of April 1, 2019	–	115,166	1,152,431	1,249,267	62	1,249,329
Profit for the period	–	–	134,281	134,281	(81)	134,199
Other comprehensive income for the period	(130)	(8,604)	–	(8,604)	–	(8,604)
Total comprehensive income for the period	(130)	(8,604)	134,281	125,677	(81)	125,595
Purchase of treasury shares	–	–	–	(65)	–	(65)
Cancellation of treasury shares	–	(61)	–	270	–	270
Dividends	–	–	(45,354)	(45,354)	–	(45,354)
Changes associated with obtaining controls of subsidiaries	–	–	–	–	576	576
Changes associated with losing control of subsidiaries	–	–	–	–	(67)	(67)
Transfer from other components of equity to retained earnings	130	(8,608)	8,608	–	–	–
Total transactions with owners of the Company	130	(8,670)	(36,745)	(45,148)	509	(44,639)
Balance as of December 31, 2019	–	97,892	1,249,967	1,329,795	490	1,330,286

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2018	Nine months ended December 31, 2019
Cash flows from operating activities		
Profit before tax	97,957	159,978
Depreciation and amortization	34,294	39,198
Impairment losses	68	4,547
Financial income	(6,064)	(8,398)
Financial expenses	5,537	4,082
Share of (profit) loss of investments accounted for using the equity method	(348)	(79)
(Gain) loss on sale and disposal of non-current assets	(4,131)	(9,914)
(Increase) decrease in trade and other receivables	(73,549)	69,937
(Increase) decrease in inventories	(4,989)	(4,878)
Increase (decrease) in trade and other payables	8,173	(85,546)
Others, net	(9,791)	(10,570)
Subtotal	47,156	158,356
Interest and dividends received	4,548	5,183
Interest paid	(1,140)	(1,584)
Income taxes paid	(29,870)	(21,155)
Net cash flows from (used in) operating activities	20,694	140,799
Cash flows from investing activities		
Payments into time deposits	(382,905)	(737,016)
Proceeds from maturities of time deposits	335,582	731,858
Acquisition of securities	(99,662)	(122,336)
Proceeds from sale of securities	101,563	151,334
Acquisition of property, plant and equipment	(21,541)	(24,970)
Proceeds from sale of property, plant and equipment	7	112
Acquisition of intangible assets	(13,070)	(17,525)
Acquisition of subsidiaries	－	463
Proceeds from sale of subsidiary	－	37,128
Payments for loans receivable	(514)	(201)
Proceeds from collection of loans receivable	703	340
Others, net	4,386	14,197
Net cash flows from (used in) investing activities	(75,449)	33,384

	Nine months ended December 31, 2018	Nine months ended December 31, 2019
Cash flows from financing activities		
Proceeds from bonds and borrowings	–	3,981
Repayments of bonds and borrowings	(20,000)	(40,290)
Purchase of treasury shares	(35)	(65)
Proceeds from sale of treasury shares	0	0
Dividends paid	(45,377)	(45,391)
Others, net	(688)	(7,260)
Net cash flows from (used in) financing activities	(66,101)	(89,026)
Net increase (decrease) in cash and cash equivalents	(120,856)	85,158
Cash and cash equivalents at the beginning of the period	357,702	243,155
Effect of exchange rate changes on cash and cash equivalents	2,321	(1,913)
Cash and cash equivalents at the end of the period	239,167	326,400

(5) Notes to Condensed Interim Consolidated Financial Statements

Going Concern Assumption

Not applicable.

Changes in Significant Subsidiaries during the Period

Japan Vaccine Distribution Co., Ltd. has been excluded from the scope of consolidation since the liquidation procedures of the company were completed during the second quarter ended September 30, 2019.

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 accounting standard.

[IFRS 16 “Leases”]

The Group adopted IFRS 16 “Leases” (issued in January 2016; hereafter “IFRS 16”) since the first quarter of the year ending March 31, 2020. In adopting IFRS 16, the Group did not restate the comparative information and recognized the cumulative effect from initial application as an adjustment to the opening balance of retained earnings.

Regarding the determination of whether a contract is or contains a lease on transition to IFRS 16, the Group elected the practical expedient prescribed in IFRS 16 paragraph C3 and continued to apply the assessment under IAS 17 “Leases” (hereafter “IAS 17”) and IFRIC 4 “Determining whether an Arrangement Contains a Lease”. From the date of initial application, this assessment is determined based on the provisions of IFRS 16.

The Group recognizes a right-of-use asset and a lease liability at the lease commencement date.

A right-of-use asset is initially measured at cost and is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of the equivalent tangible fixed assets. In addition, a right-of-use asset is reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

A lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group’s incremental borrowing rate. Lease payments are allocated to financial expenses and repayments of lease liabilities so that the interest expenses in each period during the lease term will result in a constant interest rate on the outstanding lease liability. A lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, or if the Group changes its assessment of whether it will exercise a purchase, extension or termination option.

As for leases as lessee which the Group previously classified as operating leases applying IAS 17, right-of-use assets and lease liabilities were recognized at the date of initial application. Lease liabilities were measured at the present value of the remaining lease payments discounted using the lessee’s incremental borrowing rate at the date of initial application. The weighted average lessee’s incremental borrowing rate is 0.61%. Right-of-use assets were measured at either:

・carrying amounts as if IFRS 16 had been applied since the commencement date of the leases, but discounted using the lessee’s incremental borrowing rate at the date of initial application; or

・amounts equal to lease liabilities as adjusted for prepaid or accrued lease payments.

As for leases as lessee which the Group previously classified as finance leases applying IAS 17, the carrying amounts of right-of-use assets and lease liabilities at the date of initial application are measured respectively as the carrying amounts of lease assets and lease liabilities based on IAS 17 immediately before the date of initial application.

As a result, compared to the application of the previous accounting standards, at the beginning of first quarter of the year ending March 31, 2020, right-of-use assets included in “Property, plant and

equipment", "Trade and other receivables", "Other financial assets", "Deferred tax assets" and lease liabilities included in "Other financial liabilities" increased by 28,698 million yen, 2,881 million yen, 2,884 million yen, 46 million yen and 40,874 million yen, respectively, and "Intangible assets", "Other non-current liabilities", "Provisions" and "Retained earnings" decreased by 479 million yen, 3,424 million yen, 3,040 million yen and 375 million yen, respectively.

The Group applied following practical expedients in adopting IFRS 16:

- Right-of-use assets and lease liabilities for short-term leases and leases of low-value assets are not recognized;
- Leases for which the lease term will end within 12 months from the date of initial application are accounted for in the same way as short-term leases;
- Initial direct costs are excluded from the measurement of right-of-use assets at the date of initial application.