



October 31, 2019

Consolidated Financial Results for the First Six 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>
 Representative: Dr. Sunao Manabe, Representative Director, President and CEO
 Contact: Mr. Junichi Onuma, Vice President of Corporate Communications Department
 Telephone: +81-3-6225-1125

Scheduled date of Quarterly Report filing: November 6, 2019
 Scheduled date of dividend payments: December 2, 2019
 Preparing supplementary material (Reference Data) on quarterly financial results: Yes
 Holding quarterly information meeting: Yes (for institutional investors, analysts and the press)

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

1. Consolidated Financial Results for the First Six Months of the Year Ending March 31, 2020 (from April 1, 2019 to September 30, 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	%
Six months ended September 30, 2019	479,573	7.3	86,163	48.6	87,040	48.4	64,377	46.2
Six months ended September 30, 2018	446,850	-4.8	57,984	18.9	58,635	14.5	44,020	30.4

	Profit attributable to owners of the Company		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Six months ended September 30, 2019	64,426	46.4	45,575	-66.9	99.44	99.23
Six months ended September 30, 2018	44,014	28.4	137,880	168.3	67.95	67.80

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets	Equity per share attributable to owners of the Company
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of September 30, 2019	2,043,400	1,272,964	1,272,441	62.3	1,963.79
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	955,000	2.7	125,000	49.3	125,000	45.6	90,000	-3.7	90,000	-3.7	138.90

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 September 30, 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 September 30, 2019	61,060,141 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)

Six months ended September 30, 2019	647,909,862 shares
Six months ended September 30, 2018	647,717,922 shares

* This quarterly financial results summary is not subject to quarterly review procedures by Certified Public Accountants or audit firm

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

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

Please see “1. Qualitative Information about Consolidated Results for the First Six Months (3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements” on page 13 for matters related to the above forecasts.

Attached Material

Index

1. Qualitative Information about Consolidated Results for the First Three Months.....	2
(1) Information about Operating Results.....	2
1) Overview	2
[Consolidated Financial Results]	2
[Revenue by Geographic Area].....	5
2) Status of R&D	8
(2) Analysis of Financial Position as of June 30, 2019	13
(3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements	13
(4) Information about Return to Shareholders.....	14
2. Condensed Interim Consolidated Financial Statements with Primary Notes	15
(1) Condensed Interim Consolidated Statement of Financial Position.....	15
(2) Condensed Interim Consolidated Statement of Profit or Loss and Condensed Interim Consolidated Statement of Comprehensive Income	17
Condensed Interim Consolidated Statement of Profit or Loss.....	17
Condensed Interim Consolidated Statement of Comprehensive Income.....	18
(3) Condensed Interim Consolidated Statement of Changes in Equity	19
(4) Condensed Interim Consolidated Statement of Cash Flows	21
(5) Notes to Condensed Interim Consolidated Financial Statements	23
Going Concern Assumption.....	23
Changes in Significant Subsidiaries during the Period.....	23
Changes in Accounting Policies.....	23

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

(1) Information about Operating Results

1) Overview

[Consolidated Financial Results]

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

	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
Revenue	446,850	479,573	32,723 7.3%
Operating profit	57,984	86,163	28,179 48.6%
Profit before tax	58,635	87,040	28,404 48.4%
Profit attributable to owners of the Company	44,014	64,426	20,411 46.4%
Total comprehensive income	137,880	45,575	-92,305 -66.9%

<Revenue of global mainstay products>

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

Product name	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
<i>Edoxaban</i> anticoagulant	54,138	73,758	19,620 36.2%
<i>Olmesartan</i> antihypertensive agent	53,500	50,725	-2,775 -5.2%
<i>Prasugrel</i> antiplatelet agent	13,529	9,392	-4,136 -30.6%

<Selling, general and administrative expenses>

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

	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
Selling, general and administrative expenses	128,561	130,454	1,892 1.5%
Ratio of Selling, general and administrative expenses to revenue	28.8%	27.2%	-1.6%

<Research and development expenses>

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

	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
Research and development expenses	93,657	85,850	-7,807 -8.3%
Ratio of research and development expenses to revenue	21.0%	17.9%	-3.1%

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

(Yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
USD/Yen	110.27	108.63
EUR/Yen	129.84	121.41

a. Revenue

- Revenue in the first six months of the year ending March 31, 2020 increased by ¥32.7 billion, or 7.3% compared to the same period of the previous fiscal year (year on year), to ¥479.6 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 payments for the global development and commercialization collaboration of *DS-8201* (HER2-targeting ADC) with AstraZeneca (¥4.9 billion).
- The negative effect on revenue from foreign exchange was ¥7.2 billion in total.

b. Operating profit

- Operating profit increased by ¥28.2 billion, or 48.6% year on year, to ¥86.2 billion.
- Gross profit increased by ¥22.3 billion, or 7.9%, to ¥302.5 billion due to an increase in revenue.
- Selling, general and administrative expenses were ¥130.5 billion, approximately the same level as the same period of the previous fiscal year (increased year on year by 1.5%).
- Research and development expenses decreased by ¥7.8 billion, or 8.3% year on year, to ¥85.9 billion due to the effect of sharing the costs related to *DS-8201* by partnering with AstraZeneca.
- The negative effect on operating profit from foreign exchange was ¥2.3 billion in total.

c. Profit before tax

- Profit before tax increased by ¥28.4 billion, or 48.4% year on year, to ¥87.0 billion.

d. Profit attributable to owners of the Company

- Profit attributable to owners of the Company increased by ¥20.4 billion, or 46.4% year on year, to ¥64.4 billion.

e. Total comprehensive income

- Total comprehensive income decreased by ¥92.3 billion, or 66.9% year on year, to ¥45.6 billion.
- Total comprehensive income decreased significantly 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 ¥16.5 billion, or 5.9% year on year, to ¥295.1 billion.

<Prescription drug business>

- Revenue from prescription drug business increased by ¥17.2 billion, or 7.1% year on year, to ¥261.0 billion. The increase was mainly due to the growth in sales of mainstay products *LIXIANA, Tarlige, PRALIA, Vimpat, Canalia* 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 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 ¥34.1 billion, approximately the same level as the same period of the previous fiscal year (decreased year on year by 2.1%).

<Primary revenue composition in Japan>

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

	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
Prescription drugs*	243.7	261.0	17.2 7.1%
Healthcare (OTC) products	34.8	34.1	-0.7 -2.1%

* 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	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
<i>LIXIANA</i> anticoagulant	30.1	41.8	11.7 38.7%
<i>NEXIUM</i> ulcer treatment	38.6	40.2	1.6 4.2%
<i>Memary</i> Alzheimer's disease treatment	25.2	25.7	0.5 1.9%
<i>PRALIA</i> treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	13.0	15.4	2.4 18.8%
<i>TENELIA</i> type 2 diabetes mellitus treatment	12.6	12.8	0.1 1.2%
<i>Loxonin</i> anti-inflammatory analgesic	15.6	14.8	-0.8 -5.3%
<i>Inavir</i> anti-influenza agent	0.1	1.0	0.9 -
<i>RANMARK</i> treatment for bone complications caused by bone metastases from tumors	8.1	9.2	1.1 13.5%
<i>Effient</i> antiplatelet agent	7.0	7.1	0.1 1.6%
<i>Rezaltas</i> antihypertensive agent	7.8	7.5	-0.2 -3.2%
<i>Canalia</i> type 2 diabetes mellitus treatment	4.1	6.1	2.0 49.2%
<i>Vimpat</i> anti-epileptic agent	2.8	5.2	2.4 84.1%
<i>Omnipaque</i> contrast agent	6.2	5.6	-0.6 -10.3%
<i>Olmetec</i> antihypertensive agent	7.9	6.2	-1.6 -20.4%

b. North America

- Revenue in North America increased by ¥2.8 billion, or 3.5% year on year, to ¥83.2 billion. Revenue in local currency terms increased by US\$37 million, or 5.1%, to US\$766 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	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
<i>Olmesartan</i> * antihypertensive agent	53	51	-2 -3.6%
<i>Welchol</i> hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	79	44	-35 -43.8%

* *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	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
<i>Injectafer</i> treatment for iron deficiency anemia	200	239	40 19.8%
<i>Venofer</i> treatment for iron deficiency anemia	150	151	1 0.5%

c. Europe

- Revenue in Europe was ¥43.2 billion, approximately the same level as the same period of the previous fiscal year (increased year on year by 0.5%). Revenue in local currency terms increased by EUR25 million, or 7.5%, to EUR356 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	Six months ended September 30, 2018	Six months ended September 30, 2019	YoY change
<i>LIXIANA</i> anticoagulant	160	226	66 41.2%
<i>Olmesartan</i> * antihypertensive agent	111	92	-19 -17.1%
<i>Efient</i> antiplatelet agent	25	11	-14 -55.0%

* *Olmotec*/*Olmotec Plus*, *Sevikar* and *Sevikar HCT*

d. Asia, South & Central America

- Revenue in Asia, South & Central America increased by ¥8.8 billion, or 22.1% year on year, to ¥49.0 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.”
- In setting out to achieve our 2025 Vision, the Group established ADC^{*1} franchise, AML^{*2} franchise and Breakthrough Science^{*3} as three pillars for oncology which is the primary focused area, and is working on strategic research and development.
- The Group is accelerating research activities in areas other than oncology, particularly for rare diseases and immune diseases.
- The Group is also working on research and development based on innovative drug discovery technology through technical research on new modalities^{*4}.
- The Group is trying to continuously generate innovative medicine that transforms standards of care (SOC) by actively utilizing partnering, open innovation^{*5} and other activities.

*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 AML: Acute myeloid leukemia

*3 Breakthrough Science: New treatment that brings radical innovation to cancer treatment methods through the practical application of innovative science and technology.

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

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

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

【Oncology Area】

a. [Fam-] 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>

- The Group has conducted 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). Based on the result of this clinical trial, an application was filed in Japan for manufacturing and marketing approval in September 2019.
- The global Phase III clinical trial (DESTINY-Breast02) designed to compare the efficacy and safety of *DS-8201* versus the investigator's choice for the above-mentioned patients is also underway.
- *DS-8201* has been granted Fast Track designation*6 and Breakthrough Therapy designation*7 by the U.S. Food and Drug Administration (FDA) for the treatment of the above patients.
- The global Phase III clinical trial (DESTINY-Breast03) 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 *trastuzumab*, etc. (the second line treatment) is underway.
- The global Phase III clinical trial (DESTINY-Breast04) 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.

*6 Fast Track designation: System that is designed in the U.S. to accelerate the development and review of promising medicines for the treatment of severe disease with high unmet medical needs.

*7 Breakthrough Therapy designation: System that is designed in the U.S. 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.

<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*8 by the Japan Ministry of Health, Labour and Welfare (MHLW) for the treatment of the above patients.

*8 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, 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 the U.S. company, 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. 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 non-small cell lung cancer (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) in May 2019, and at the 2019 World Conference on Lung Cancer (WCLC) in September 2019.

c. 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) in June 2019, and at the 2019 World Conference on Lung Cancer (WCLC) in September 2019.

d. Quizartinib: FLT3 Inhibitor

- In June 2019, manufacturing and marketing approval in Japan was received for the treatment of adults with relapsed or refractory FLT3-ITD AML.
- In June 2019, Daiichi Sankyo received a Complete Response Letter (CRL)*⁹ from the U.S. Food and Drug Administration (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 November 2018, the application for approval for marketing was accepted by the European Medicines Agency (EMA) 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 Japan Ministry of Health, Labour and Welfare (MHLW), the FDA and the EMA for the treatment of AML.

*⁹ Complete Response Letter: Notice issued upon completion of the review of an approval application when it was not approved in its present content.

<Combination, etc.>

- The Group is conducting global Phase I trials to evaluate the combination of *Quizartinib* and *milademetan*^{*10}, 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.

*10 *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.

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

- 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 Japan Ministry of Health, Labour and Welfare (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.

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

- In August 2019, approval for marketing was received from the FDA for the treatment of tenosynovial giant cell tumor (TGCT).
- 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.

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

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

- In September 2016, Daiichi Sankyo entered a cross-licensing and collaboration agreement with Zymeworks Inc. in Canada regarding bispecific antibodies^{*11}. In April 2019, based on this agreement, Daiichi Sankyo has exercised its option for a commercial license to proprietary immuno-oncology bispecific antibodies. Daiichi Sankyo will continue to effectively use the technology platforms of manufacturing bispecific antibodies with the aim of providing novel therapeutic options for patients with cancer.

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

【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: $\alpha 2\delta$ 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 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.
- Currently, the Group is conducting Phase III clinical trials in Japan for patients with diabetic nephropathy.

(2) Analysis of Financial Position as of September 30, 2019

- Total assets as of September 30, 2019 are ¥2,043.4 billion, a decrease of ¥44.7 billion from the previous fiscal year-end, mainly due to a decrease in trade and other receivables, which was partially offset by an increase in cash and cash equivalents.
- Total liabilities as of September 30, 2019 are ¥770.4 billion, a decrease of ¥67.9 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 September 30, 2019 is ¥1,273.0 billion, an increase of ¥23.3 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 2.4% from the previous fiscal year-end to 62.3%.

(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 April 25, 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)	940,000	100,000	100,000	72,000	72,000	111.13
Revised forecasts (B)	955,000	125,000	125,000	90,000	90,000	138.90
Change (B-A)	15,000	25,000	25,000	18,000	18,000	
Percentage of change (%)	1.6%	25.0%	25.0%	25.0%	25.0%	
(Reference) Year ended March 31, 2019	929,717	83,705	85,831	93,422	93,409	144.20

* Assumed exchange rate since the third 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 ¥955.0 billion taking into account the strong performance in Japan and the U.S.
- The forecasts for operating profit and profit before tax have been revised upward from the previous forecasts by ¥25.0 billion to ¥125.0 billion taking into account factors including the effect of sharing the costs related to *DS-8201* by partnering with AstraZeneca in addition to the projection for an increase in gross profit resulting from growth in revenue.

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
- The meeting of the Board of Directors held on October 31, 2019 approved a resolution to pay an ordinary dividend of ¥35 per share as an interim dividend, which will be paid on December 2 to shareholders as of September 30, 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 in total.

2. Condensed Interim Consolidated Financial Statements with Primary Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2019	As of September 30, 2019
ASSETS		
Current assets		
Cash and cash equivalents	243,155	297,578
Trade and other receivables	419,609	342,495
Other financial assets	536,880	510,316
Inventories	176,067	177,359
Other current assets	15,471	11,136
Subtotal	1,391,183	1,338,886
Assets held for sale	2,000	19,723
Total current assets	1,393,184	1,358,610
Non-current assets		
Property, plant and equipment	229,085	241,948
Goodwill	77,851	76,325
Intangible assets	169,472	157,478
Investments accounted for using the equity method	2,200	977
Other financial assets	114,895	106,651
Deferred tax assets	94,809	95,062
Other non-current assets	6,551	6,346
Total non-current assets	694,866	684,790
Total assets	2,088,051	2,043,400

(Millions of yen)

	As of March 31, 2019	As of September 30, 2019
LIABILITIES AND EQUITY		
Current liabilities		
Trade and other payables	312,660	245,834
Bonds and borrowings	40,000	40,388
Other financial liabilities	530	8,759
Income taxes payable	10,451	19,409
Provisions	7,837	5,722
Other current liabilities	12,715	11,944
Subtotal	384,195	332,059
Liabilities directly associated with assets held for sale	349	1,118
Total current liabilities	384,544	333,178
Non-current liabilities		
Bonds and borrowings	220,585	183,995
Other financial liabilities	5,680	36,342
Post-employment benefit liabilities	10,384	10,167
Provisions	4,985	2,504
Deferred tax liabilities	17,166	16,486
Other non-current liabilities	195,000	187,760
Total non-current liabilities	453,802	437,258
Total liabilities	838,346	770,436
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,633	94,737
Treasury shares	(162,964)	(162,805)
Other components of equity	115,166	90,327
Retained earnings	1,152,806	1,200,181
Total equity attributable to owners of the Company	1,249,642	1,272,441
Non-controlling interests		
Non-controlling interests	62	523
Total equity	1,249,705	1,272,964
Total liabilities and equity	2,088,051	2,043,400

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

Condensed Interim Consolidated Statement of Profit or Loss

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Revenue	446,850	479,573
Cost of sales	166,646	177,105
Gross profit	280,203	302,468
Selling, general and administrative expenses	128,561	130,454
Research and development expenses	93,657	85,850
Operating profit	57,984	86,163
Financial income	4,447	5,279
Financial expenses	3,643	4,455
Share of profit (loss) of investments accounted for using the equity method	(151)	53
Profit before tax	58,635	87,040
Income taxes	14,614	22,663
Profit for the period	44,020	64,377
Profit attributable to:		
Owners of the Company	44,014	64,426
Non-controlling interests	6	(49)
Profit for the period	44,020	64,377
Earnings per share		
Basic earnings per share (Yen)	67.95	99.44
Diluted earnings per share (Yen)	67.80	99.23

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Profit for the period	44,020	64,377
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	73,427	(1,459)
Remeasurements of defined benefit plans	(175)	(87)
Items that are or may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	20,607	(17,255)
Other comprehensive income for the period	93,859	(18,801)
Total comprehensive income for the period	137,880	45,575
Total comprehensive income attributable to:		
Owners of the Company	137,874	45,624
Non-controlling interests	6	(49)
Total comprehensive income for the period	137,880	45,575

(3) Condensed Interim Consolidated Statement of Changes in Equity
Six months ended September 30, 2018

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Capital surplus	Treasury shares	Other components of equity		
				Subscription rights to shares	Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance as of April 1, 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	-	-	-	-	20,607	73,427
Total comprehensive income for the period	-	-	-	-	20,607	73,427
Purchase of treasury shares	-	-	(24)	-	-	-
Cancellation of treasury shares	-	52	296	(40)	-	-
Dividends	-	-	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	(71,404)
Others	-	-	-	-	-	-
Total transactions with owners of the Company	-	52	272	(40)	-	(71,404)
Balance as of September 30, 2018	50,000	94,686	(163,259)	1,952	77,946	63,195

(Millions of yen)

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

Six months ended September 30, 2019

(Millions of yen)

	Equity attributable to owners of the Company					
	Share capital	Capital surplus	Treasury shares	Other components of equity		
				Subscription rights to shares	Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance as of April 1, 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	-	-	-	-	(17,255)	(1,459)
Total comprehensive income for the period	-	-	-	-	(17,255)	(1,459)
Purchase of treasury shares	-	-	(45)	-	-	-
Cancellation of treasury shares	-	103	204	(37)	-	-
Dividends	-	-	-	-	-	-
Changes associated with obtaining control of subsidiaries	-	-	-	-	-	-
Changes associated with losing control of subsidiaries	-	-	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	(6,087)
Total transactions with owners of the Company	-	103	159	(37)	-	(6,087)
Balance as of September 30, 2019	50,000	94,737	(162,805)	1,768	49,373	39,185

(Millions of yen)

	Equity attributable to owners of the Company					
	Other components of equity			Total equity attributable to owners of the Company	Non-controlling interests	Total equity
	Remeasurements of defined benefit plans	Total other components of equity	Retained earnings			
Balance as of April 1, 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	-	-	64,426	64,426	(49)	64,377
Other comprehensive income for the period	(87)	(18,801)	-	(18,801)	-	(18,801)
Total comprehensive income for the period	(87)	(18,801)	64,426	45,624	(49)	45,575
Purchase of treasury shares	-	-	-	(45)	-	(45)
Cancellation of treasury shares	-	(37)	-	270	-	270
Dividends	-	-	(22,676)	(22,676)	-	(22,676)
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	87	(6,000)	6,000	-	-	-
Total transactions with owners of the Company	87	(6,037)	(16,675)	(22,450)	509	(21,940)
Balance as of September 30, 2019	-	90,327	1,200,181	1,272,441	523	1,272,964

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Six months ended September 30, 2018	Six months ended September 30, 2019
Cash flows from operating activities		
Profit before tax	58,635	87,040
Depreciation and amortization	22,628	26,378
Impairment losses	-	4,469
Financial income	(4,447)	(5,279)
Financial expenses	3,643	4,455
Share of (profit) loss of investments accounted for using the equity method	151	(53)
(Gain) loss on sale and disposal of non-current assets	(4,721)	(10,233)
(Increase) decrease in trade and other receivables	(36,100)	77,027
(Increase) decrease in inventories	(12,072)	(11,698)
Increase (decrease) in trade and other payables	3,837	(59,000)
Others, net	(9,163)	(2,491)
Subtotal	22,392	110,613
Interest and dividends received	2,761	3,404
Interest paid	(736)	(1,390)
Income taxes paid	(17,767)	(10,345)
Net cash flows from (used in) operating activities	6,649	102,282
Cash flows from investing activities		
Payments into time deposits	(394,705)	(424,270)
Proceeds from maturities of time deposits	330,828	426,996
Acquisition of securities	(78,118)	(70,764)
Proceeds from sale of securities	72,202	99,651
Acquisition of property, plant and equipment	(14,760)	(18,741)
Proceeds from sale of property, plant and equipment	84	103
Acquisition of intangible assets	(9,945)	(6,369)
Acquisition of subsidiaries	-	463
Payments for loans receivable	(253)	(101)
Proceeds from collection of loans receivable	505	209
Others, net	4,609	14,145
Net cash flows from (used in) investing activities	(89,552)	21,321

	Six months ended September 30, 2018	Six months ended September 30, 2019
Cash flows from financing activities		
Proceeds from bonds and borrowings	–	3,981
Repayments of bonds and borrowings	(20,000)	(40,194)
Purchase of treasury shares	(24)	(45)
Proceeds from sale of treasury shares	0	0
Dividends paid	(22,662)	(22,671)
Others, net	(533)	(4,950)
Net cash flows from (used in) financing activities	(43,220)	(63,878)
Net increase (decrease) in cash and cash equivalents	(126,123)	59,725
Cash and cash equivalents at the beginning of the period	357,702	243,155
Effect of exchange rate changes on cash and cash equivalents	5,273	(5,301)
Cash and cash equivalents at the end of the period	236,852	297,578

(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.