July 31, 2020

Consolidated Financial Results for the First Three Months of the Year Ending March 31, 2021 (Fiscal 2020) <under IFRS>

Listed company name: Daiichi Sankyo Company, Limited
Listed exchange: First Section of the Tokyo Stock Exchange
Stock code number: 4568
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Scheduled date of Quarterly Report filing: August 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 Three Months of the Year Ending March 31, 2021 (from April 1, 2020 to June 30, 2020)

(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	%
Three months ended June 30, 2020	236,947	-4.9	34,122	-40.1	41,378	-27.5	31,823	-26.5
Three months ended June 30, 2019	249,239	10.4	56,993	90.5	57,067	92.6	43,322	80.9

	Profit attributable to owners of the Company		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Three months ended June 30, 2020	31,857	-26.5	32,528	17.4	49.15	49.07
Three months ended June 30, 2019	43,347	81.0	27,699	-72.8	66.91	66.77

(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 June 30, 2020	2,063,186	1,316,108	1,315,678	63.8	2,029.36
As of March 31, 2020	2,105,619	1,306,274	1,305,809	62.0	2,014.93

2. Dividend

	Annual dividend per share				
	First quarter	Second quarter	Third quarter	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Year ended March 31, 2020	–	35.00	–	35.00	70.00
Year ending March 31, 2021	–				
Year ending March 31, 2021 (Forecast)		40.50	–	13.50	–

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

Note: Effective Thursday, October 1, 2020, Daiichi Sankyo Company, Ltd. (hereinafter, Daiichi Sankyo) has resolved to implement a three-for-one share split of its ordinary shares. The dividend forecast for the fiscal year ending March 31, 2021 presents the amount prior to the share split for the end of the second quarter and the amount after the share split for the end of the fiscal year. The annual dividend per share forecast is not presented because the amounts cannot be simply combined due to the implementation of the share split. When calculated based on the assumption of no share split, the annual dividend per share is ¥81 for the year ending March 31, 2021. For further details, please refer to "1. Qualitative Information about Consolidated Results for the First Three Months (4) Information about Return to Shareholders" on page 12 and "2. Condensed Interim Consolidated Financial Statements with Primary Notes, (5) Notes to Condensed Interim Consolidated Financial Statements (Additional Information)" on page 21 of the attached material.

3. Forecast of Consolidated Financial Results for Year Ending March 31, 2021

(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	-1.2	80,000	-42.4	80,000	-43.3	56,000	-56.6	56,000	-56.6	86.38

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

Note: As it is difficult to accurately estimate the impact of the spread of new corona virus infection (COVID-19) at the present time, the above forecasts do not reflect any adjustments in relation to it. However, Daiichi Sankyo expects there will be no significant changes as compared to the forecast announced in April 2020. Specifically, if global activity restrictions continue until the fourth quarter, Daiichi Sankyo expects a negative impact of 2% to 4% (¥20.0 to ¥40.0 billion) on revenue. In that case, however, Daiichi Sankyo also expects a decrease in expenses due to the influence on business activities. Therefore, the impact on operating income is estimated to be insignificant. Daiichi Sankyo assumes the impact on the forecast consolidated financial results for the year ending March 31, 2021 due to the strategic alliance related to DS-1062 is limited. Daiichi Sankyo will promptly disclose any necessary revisions to its earnings forecasts in the future. Please see "1. Qualitative Information about Consolidated Results for the First Three Months (3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements" on page 11 for details of the above forecasts.

***Notes**

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in a change in scope of consolidation): No

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

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

(3) Number of ordinary shares issued

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

As of June 30, 2020	709,011,343 shares
As of March 31, 2020	709,011,343 shares

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

As of June 30, 2020	60,689,158 shares
As of March 31, 2020	60,943,592 shares

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

Three months ended June 30, 2020	648,220,255 shares
Three months ended June 30, 2019	647,887,006 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 Daiichi Sankyo 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 Three Months (3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements"* on page 11 for matters related to the above forecasts.

Attached Material

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

	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
Revenue	249,239	236,947	-12,291 -4.9%
Cost of sales	87,899	82,211	-5,688 -6.5%
Selling, general and administrative expenses	63,161	71,790	8,629 13.7%
Research and development expenses	41,184	48,823	7,638 18.5%
Operating profit	56,993	34,122	-22,870 -40.1%
Profit before tax	57,067	41,378	-15,688 -27.5%
Profit attributable to owners of the Company	43,347	31,857	-11,489 -26.5%
Total comprehensive income	27,699	32,528	4,828 17.4%

<Revenue of global mainstay products>

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

Generic name *(Main brand name)*	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
Trastuzumab deruxtecan *(ENHERTU)* antitumor agent (HER2-targeting antibody drug conjugate)	2,455	7,894	5,438 221.5%
Edoxaban *(LIXIANA)* anticoagulant	37,235	38,726	1,490 4.0%
Olmesartan antihypertensive agent	27,484	25,731	-1,753 -6.4%
Prasugrel antiplatelet agent	5,019	4,442	-576 -11.5%

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

(Yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
USD/Yen	109.90	107.62
EUR/Yen	123.49	118.47

a. Revenue

- Revenue in the first three months of the year ending March 31, 2021 decreased by ¥12.3 billion, or 4.9% compared to the same period of the previous fiscal year (year on year), to ¥236.9 billion.
- Revenue decreased despite having achieved growth with global mainstay products such as *ENHERTU* (generic name: *trastuzumab deruxtecan*, development code: *DS-8201*) and *LIXIANA*, due to factors that include American Regent, Inc. having become subject to effects of the spread of novel coronavirus infection (hereinafter, COVID-19), and also due to NHI drug price revision in Japan and termination of vaccine sales cooperation.
- The negative effect on revenue from foreign exchange was ¥4.0 billion in total.

b. Operating profit

- Operating profit decreased by ¥22.9 billion, or 40.1% year on year, to ¥34.1 billion.
- Cost of sales was ¥82.2 billion, a decrease of ¥5.7 billion, or 6.5% year on year due to a decrease in revenue.
- Selling, general and administrative expenses increased by ¥8.6 billion, or 13.7%, to ¥71.8 billion despite a decrease in sales promotion expenses due to the impact of the spread of COVID-19, as a result of having recorded a gain on sale of property, plant and equipment of ¥10.6 billion in the previous year, in addition to an increase in expenses associated with *ENHERTU* (sales promotion expenses and profit sharing).
- Research and development expenses increased by ¥7.6 billion, or 18.5% year on year, to ¥48.8 billion despite lower expenses brought about by an increase in cost sharing with AstraZeneca pertaining to *trastuzumab deruxtecan*, mainly due to R&D investment in 3 ADCs (*DS-8201*, *DS-1062* and *U3-1402*) as well as higher expenses associated with enhancing the oncology project development structure.
- The negative effect on operating profit from foreign exchange was ¥1.6 billion in total.

c. Profit before tax

- Profit before tax decreased by ¥15.7 billion, or 27.5% year on year, to ¥41.4 billion.
- The decrease in profit before tax was modest compared to the decrease in operating profit due to improvement of ¥7.2 billion in Daiichi Sankyo's financial balance mainly resulting from improvement of loss (gain) on exchange differences.

d. Profit attributable to owners of the Company

- Profit attributable to owners of the Company decreased by ¥11.5 billion, or 26.5% year on year, to ¥31.9 billion.

e. Total comprehensive income

- Total comprehensive income increased by ¥4.8 billion, or 17.4% year on year, to ¥32.5 billion.
- Total comprehensive income increased year on year due to improvements both in valuation difference on

financial assets and in currency translation difference pertaining to net assets of overseas subsidiaries.

[Revenue by Geographic Area]

Primary revenue by geographic area is as follows.

a. Japan

- Revenue in Japan decreased by ¥9.9 billion, or 6.4% year on year, to ¥144.5 billion.

<Prescription drug business>

- In the prescription drug business, revenue decreased by ¥8.8 billion, or 6.3%, to ¥130.2 billion mainly due to NHI drug price revision in Japan and termination of vaccine sales cooperation despite growth in sales of *Tarlige*.
  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 May 2020, Daiichi Sankyo launched *ENHERTU* for the treatment of patients with HER2-positive unresectable or recurrent breast cancer after prior chemotherapy (limit the use to patients who are refractory or intolerant to standard treatments).

<Healthcare (OTC) products business>

- Revenue from the healthcare (OTC) products business decreased by ¥1.1 billion, or 7.3% year on year, to ¥14.3 billion due to the impact of the spread of COVID-19.

<Primary revenue composition in Japan>

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

	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
Prescription drugs*	139.0	130.2	-8.8 -6.3%
Healthcare (OTC) products	15.4	14.3	-1.1 -7.3%

* 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.)

Brand name	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
NEXIUM ulcer treatment	21.9	19.9	-2.0 -9.2%
LIXIANA anticoagulant	21.6	19.8	-1.8 -8.2%
PRALIA treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	8.2	8.7	0.5 6.2%
Memary Alzheimer's disease treatment	13.7	12.8	-1.0 -6.9%
TENELIA type 2 diabetes mellitus treatment	6.9	6.6	-0.3 -5.0%
Loxonin anti-inflammatory analgesic	7.8	6.2	-1.6 -20.7%
RANMARK treatment for bone complications caused by bone metastases from tumors	4.7	5.0	0.3 6.2%
Inavir anti-influenza agent	0.0	0.6	0.6 –
Tarlige pain agent	2.0	4.3	2.3 118.5%
Canalia type 2 diabetes mellitus treatment	3.2	3.9	0.8 23.5%
Vimpat anti-epileptic agent	2.7	3.8	1.1 41.8%
Efient antiplatelet agent	3.8	3.8	-0.0 -0.5%
Rezaltas antihypertensive agent	4.2	3.6	-0.5 -13.0%
Olmetec antihypertensive agent	3.5	2.7	-0.8 -23.4%
ENHERTU antitumor agent (HER2-targeting antibody drug conjugate)	–	0.2	0.2 –

b. North America

- Revenue in North America decreased by ¥5.8 billion, or 13.2% year on year, to ¥38.0 billion. Revenue in local currency terms decreased by US$45 million, or 11.3%, to US$353 million. This revenue includes revenue generated by Daiichi Sankyo, Inc., and American Regent, Inc.
- At Daiichi Sankyo Inc., sales increased due to contributions of *ENHERTU* upon its sales launch in January 2020.
- At American Regent, Inc., sales of *Injectafer* and *Venofer,* etc. decreased due to the impact of the spread of COVID-19.

<Revenue of Daiichi Sankyo, Inc. mainstay products>

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

Brand name	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
ENHERTU antitumor agent (HER2-targeting antibody drug conjugate)	–	46	46 –
*Olmesartan** antihypertensive agent	28	35	6 22.9%
Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	23	5	-18 -77.0%

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

<Revenue of American Regent, Inc. mainstay products>

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

Brand name	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
Injectafer treatment for iron deficiency anemia	125	88	-37 -29.9%
Venofer treatment for iron deficiency anemia	85	64	-20 -23.9%

c. Europe

- Revenue in Europe increased by ¥5.6 billion, or 25.3% year on year, to ¥27.7 billion. Revenue in local currency terms increased by EUR55 million, or 30.6%, to EUR234 million.
- Revenue increased due to steady growth in sales of *LIXIANA* and as a result of having recorded a gain from transfer of the long-listed products of Daiichi Sankyo France SAS.

<Revenue of Daiichi Sankyo Europe GmbH mainstay products>

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

Brand name	Three months ended June 30, 2019	Three months ended June 30, 2020	YoY change
LIXIANA anticoagulant	109	139	29 26.9%
*Olmesartan** antihypertensive agent	52	44	-8 -14.5%
Efient antiplatelet agent	6	3	-4 -58.3%

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

d. Asia, South & Central America

- Revenue in Asia, South & Central America decreased by ¥1.8 billion, or 7.3% year on year, to ¥22.5 billion. This revenue includes revenue to overseas' licensees.
- Sales of *Cravit* and other products declined 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 focuses research and development resources to 3 ADCs[*1] (*DS-8201*, *DS-1062* and *U3-1402*) for maximizing its product value and aims 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 small 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.

【3 ADCs】

The following describes the Group's clinical development of 3 ADCs projects as of June 30, 2020.

a. Trastuzumab deruxtecan (DS-8201, Japanese and U.S. brand name: *ENHERTU*): HER2-targeting ADC

DS-8201 has been marketed in Japan and the U.S. under the brand name *ENHERTU*. To maximize the product value, Daiichi Sankyo is jointly developing *DS-8201* with AstraZeneca, a company with a wealth of global experience in oncology.

<Breast cancer>

DESTINY-Breast01 trial

- The global Phase II clinical trial 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) has been completed.
- *DS-8201* has been approved and marketed 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 in the U.S., and for the treatment of patients with HER2 positive unresectable or recurrent breast cancer after prior chemotherapy (limited to the use to patients who are refractory or intolerant to standard treatments) in Japan.
- In June 2020, the European Medicines Agency (EMA) accepted the application for approval for the treatment of unresectable or metastatic HER2 positive breast cancer.

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* for the 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.

BEGONIA trial

- AstraZeneca is conducting Phase Ib/II clinical trials in the U.S., Europe, and Asia to evaluate the combination of *DS-8201* and *durvalumab*, the immune checkpoint inhibitor (brand name: *IMFINZI*) in patients with triple negative breast cancer (TNBC).

<Gastric cancer>

DESTINY-Gastric01 trial

- Phase II clinical trial in Japan and South Korea for the patients with HER2 positive unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma that had progressed following two or more treatment regimens including *trastuzumab* has been completed in the fiscal year ending March 31, 2020.
- In April 2020, Daiichi Sankyo submitted an application in Japan for the treatment of patients with HER2 positive metastatic gastric cancer, based on the result of this clinical trial.
- The Group presented the primary analysis results at the 2020 American Society of Clinical Oncology (ASCO) held in May 2020.
- *DS-8201* has been granted SAKIGAKE Designation[*4] for the treatment of HER2-overexpressing unresectable advanced and/or recurrent gastric cancer that has progressed after cancer chemotherapy by the Japan Ministry of Health, Labour and Welfare (MHLW).
- In May 2020, *DS-8201* has been granted Breakthrough Therapy Designation[*5] for the patients with HER2-positive recurrent and/or metastatic gastric cancer, and Orphan Drug Designation[*6] for the treatment of patients with gastric cancer, including gastroesophageal junction cancer by the U.S. Food and Drug Administration (hereinafter, FDA).

*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.

*5 Breakthrough Therapy Designation: Designation in the U.S. designed to expedite the development and review of medicines that may demonstrate substantial benefit over currently available treatments in order to ensure that patients with serious diseases have access to new treatments as soon as possible.

*6 Orphan Drug Designation: Designation to medicines intended for the treatment, diagnosis or prevention of rare diseases of disorders that affect fewer than 200,000 people in the U.S.

DESTINY-Gastric02 trial

- The Group is conducting Phase II trials in the U.S. and Europe for patients with HER2 positive unresectable or metastatic gastric cancer.

<Non-small cell lung cancer>

DESTINY-Lung01 trial

- The Group is conducting global Phase II clinical trials for patients with HER2-positive and HER2 mutant, recurrent and/or advanced non-small cell lung cancer (NSCLC).
- In May 2020, *DS-8201* has been granted Breakthrough Therapy Designation by the FDA for the treatment of patients with HER2 mutant unresectable and/or metastatic non-squamous NSCLC.
- The Group presented the preliminary results for the patients with HER2 mutant unresectable and/or metastatic NSCLC at the 2020 American Society of Clinical Oncology (ASCO) held in May 2020.

HUDSON trial

- AstraZeneca is conducting Phase II clinical trials in the U.S., Europe and Asia to evaluate the combination of *DS-8201* and *durvalumab*, the immune checkpoint inhibitor (brand name: *IMFINZI*) for patients with NSCLC whose disease progressed on an anti-PD-1/PD-L1 containing therapy.

<Colorectal cancer>

DESTINY-CRC01 trial

- The Group is conducting global Phase II clinical trials for patients with HER2-positive, recurrent and/or advanced colorectal cancer.
- The Group presented the primary analysis results at the 2020 American Society of Clinical Oncology (ASCO) held in May 2020.

<Other>

Combination study of *DS-8201* and *nivolumab,* the immune checkpoint inhibitor

- Daiichi Sankyo is conducting Phase I clinical trials in the U.S. and Europe 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 and bladder cancer.

Combination study of *DS-8201* and *pembrolizumab*, the immune checkpoint inhibitor

- Daiichi Sankyo is conducting Phase I clinical trials in the U.S. and Europe with Merck & Co., Inc., to evaluate the combination of *DS-8201* and *pembrolizumab*, the immune checkpoint inhibitor (brand name: *KEYTRUDA*) in patients with HER2-positive breast cancer and NSCLC.

b. DS-1062: TROP2-targeting ADC

Daiichi Sankyo entered into a strategic collaboration agreement for *DS-1062* with AstraZeneca. To maximize the product value, Daiichi Sankyo is jointly developing *DS-8201* with AstraZeneca, a company with a wealth of global experience in oncology.

<Non-small cell lung cancer>

- Phase I clinical trials for patients with recurrent and/or advanced NSCLC are underway in Japan and the U.S.
- The Group presented data from the trial at the 2020 American Society of Clinical Oncology (ASCO) held in May 2020.

<Other>

Combination study of *DS-1062 and pembrolizumab*, the immune checkpoint inhibitor

- In June 2020, Daiichi Sankyo entered into a clinical trial collaboration agreement with Merck & Co., Inc., to evaluate the combination of *DS-1062* and *pembrolizumab*, the immune checkpoint inhibitor (brand name: *KEYTRUDA*) in patients with advanced or metastatic NSCLC without actionable genomic alterations.

c. Patritumab deruxtecan (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, the U.S. and Asia for patients with epidermal growth factor receptor (EGFR)-mutated NSCLC whose disease has progressed while taking an EGFR tyrosine kinase inhibitor (TKI).

【Alpha】

The following describes the clinical development and progress made in each project other than 3 ADCs projects as of June 30, 2020.

1) Oncology Area

a. DS-6157: GPR20-targeting ADC

- In May 2020, Phase I clinical trials for patients with advanced gastrointestinal stromal tumor (GIST) initiated in Japan and the U.S.

2) Areas Other than Oncology

a. Strategic partnership with Ultragenyx Pharmaceutical Inc. for use of gene therapy manufacturing technology

- In April 2020, Daiichi Sankyo has entered into a strategic partnership with Ultragenyx Pharmaceutical Inc. for the non-exclusive use of Ultragenyx Pharmaceutical Inc.'s proprietary adeno associated virus (AAV) vector based gene therapy manufacturing technology.

b. Commencement of open innovation research with Mitsubishi UFJ Capital Co., Ltd. and Nagoya Institute of Technology

- In April 2020, Daiichi Sankyo has commenced open innovation research concerning a gene therapy for restoring vision with Mitsubishi UFJ Capital Co., Ltd. and Nagoya Institute of Technology.

3) Efforts to Address the Novel Coronavirus Infection

- Daiichi Sankyo is proactively involved in the establishment of prevention and treatment methods in the fight against COVID-19, for which there is an urgent global social need. In April 2020, Daiichi Sankyo established a task force to promote company-wide R&D on vaccines and therapeutic agents for COVID-19; moreover, in our role as a pharmaceutical company, by leveraging our research properties, technologies and knowledge to the maximum extent, and through partnerships with other organizations, Daiichi Sankyo is proceeding with the following R&D.

a. DS-5670: genetic (mRNA) vaccine

- For the prevention of COVID-19, Daiichi Sankyo is currently participating in "Fundamental Research on the Control of the Novel Coronavirus (2019-nCoV[*1]),"[*2] an initiative supported by the Japan Agency for Medical Research and Development (AMED). In addition, using novel nucleic acid delivery technology[*3] developed by Daiichi Sankyo itself, Daiichi Sankyo is taking part in a basic research project on a genetic (mRNA) vaccine with the title "Development of a Genetic Vaccine for 2019-nCoV."

- In a pharmacological evaluation using animal models, Daiichi Sankyo achieved an increase in antibody titers to the COVID-19 in June 2020. Leveraging this result, Daiichi Sankyo has positioned the development of the mRNA vaccine as a priority project and start to consider an increase in scale toward establishing a supply system. At the same time, Daiichi Sankyo aims to proceed to clinical studies around March 2021.

*1 2019-nCoV is synonymous with SARS-CoV-2.

*2 A vaccine development initiative determined for support by AMED under urgent government-wide efforts against the worldwide spread of COVID-19.

*3 Technology focusing on forming lipid nanoparticle structures, stabilizing pharmaceutical active ingredients and delivering nucleic acids into immune cells. Compared to conventional vaccine technology, it has been demonstrated to induce a more optimal immune response.

b. DS-2319: Nafamostat inhalation formulation

- In June 2020, Daiichi Sankyo entered into a Basic Agreement on Collaborative R&D on Nafamostat Inhalation Formulation with the University of Tokyo, RIKEN, and Nichi-Iko Pharmaceutical Co., Ltd. on Nafamostat inhalation formulation for the treatment of COVID-19.
- Daiichi Sankyo will carry out R&D on the Nafamostat inhalation formulation using technology gained in the development of its anti-influenza virus agent, *Inavir*. Non-clinical studies have begun in July 2020 and after consultation with authorities with the aim of proceeding to clinical studies by March 2021.

c. Start of discussions with AstraZeneca regarding supply in Japan of novel coronavirus vaccine

- In June 2020, Daiichi Sankyo agreed to proceed with discussions with AstraZeneca for the stable supply in Japan of a potential novel coronavirus vaccine being developed by AstraZeneca and Oxford University in the U.K. Daiichi Sankyo will advance discussions with AstraZeneca to formulate the vaccine, including vial filling, packaging, and storage in Japan.

(2) Analysis of Financial Position as of June 30, 2020

- Total assets as of June 30, 2020 were ¥2,063.2 billion, a decrease of ¥42.4 billion from the previous fiscal year-end, mainly due to decreases in cash and cash equivalents and trade and other receivables, which were partially offset by an increase in other financial assets.
- Total liabilities as of June 30, 2020 were ¥747.1 billion, a decrease of ¥52.3 billion from the previous fiscal year-end, mainly due to decreases in trade and other payables and other non-current liabilities.
- Total equity as of June 30, 2020 was ¥1,316.1 billion, an increase of ¥9.8 billion from the previous fiscal year-end, mainly because of the profit for the period, which was partially offset by dividend paid.
- The ratio of equity attributable to owners of the Company to total assets was 63.8%, an increase of 1.8 points from the previous fiscal year-end.

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

- There are no changes from the forecasts of consolidated financial results for the year ending March 31, 2021 publicly announced on April 27, 2020.
- It is difficult to accurately estimate the effects of the potential impact of the COVID-19 pandemic at the present time. However, Daiichi Sankyo assumes there will be no major changes with respect to the forecasts Daiichi Sankyo released in April. More specifically, if global activity restrictions

continue until the fourth quarter, Daiichi Sankyo expects a negative impact of 2% to 4% (approximately ¥20.0 billion to ¥40.0 billion) on revenue. In that case, however, Daiichi Sankyo also expects a decrease in expenses due to the influence on business activities. Therefore, the impact on operating income is estimated to be insignificant.

- Daiichi Sankyo assumes the impact on the forecast consolidated financial results for the year ending March 31, 2021 due to the strategic alliance related to DS-1062 is limited.
- Daiichi Sankyo will promptly disclose any necessary revisions to its earnings forecasts in the future.

Note: The forecasted statements shown above are based on information currently available and certain assumptions that Daiichi Sankyo 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*[1] of 100% or more during the period, and in terms of dividend payments, to distribute ordinary dividend to ¥70 or more yearly, to pay stable dividend, and to exercise the agile purchase of treasury shares.

  *[1] Total return ratio = (Total amount of dividend + Total acquisition costs of treasury shares) / Profit attributable to owners of the Company
- Under this policy, Daiichi Sankyo paid a year-end dividend of ¥35 per share on June 16. Accordingly, the annual dividend for the year ended March 31, 2020, together with the interim dividend of ¥35 per share paid on December 2, 2019, is ¥70 per share in total.
- For the fiscal year ending March 31, 2021, Daiichi Sankyo intends to pay an interim dividend of ¥40.5 per share and a year-end dividend of ¥13.5 per share (on a post-share split*[2] basis). The annual dividend will be increased by ¥11 from the fiscal year ended March 31, 2020 to ¥81 per share (on a pre-share split basis).

  *[2] At a meeting on April 27, 2020, the Board of Directors passed a resolution to "implement a three for-one share split of ordinary shares with an effective date of October 1, 2020."

2. Condensed Interim Consolidated Financial Statements with Primary Notes

(1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2020	As of June 30, 2020
ASSETS		
Current assets		
Cash and cash equivalents	424,184	382,102
Trade and other receivables	309,363	243,887
Other financial assets	466,528	495,977
Inventories	173,362	183,663
Other current assets	10,546	12,037
Subtotal	1,383,984	1,317,668
Assets held for sale	134	136
Total current assets	1,384,119	1,317,804
Non-current assets		
Property, plant and equipment	247,053	247,867
Goodwill	76,760	76,215
Intangible assets	172,499	182,801
Investments accounted for using the equity method	383	289
Other financial assets	97,974	109,020
Deferred tax assets	114,748	116,845
Other non-current assets	12,079	12,343
Total non-current assets	721,499	745,381
Total assets	2,105,619	2,063,186

(Millions of yen)

	As of March 31, 2020	As of June 30, 2020
LIABILITIES AND EQUITY		
Current liabilities		
Trade and other payables	270,867	223,449
Bonds and borrowings	40,389	40,390
Other financial liabilities	9,490	10,647
Income taxes payable	9,937	13,262
Provisions	5,367	4,628
Other current liabilities	15,019	12,272
Total current liabilities	351,071	304,649
Non-current liabilities		
Bonds and borrowings	183,811	183,719
Other financial liabilities	37,118	37,925
Post-employment benefit liabilities	5,263	5,189
Provisions	10,597	10,574
Deferred tax liabilities	15,641	15,281
Other non-current liabilities	195,840	189,737
Total non-current liabilities	448,273	442,428
Total liabilities	799,344	747,077
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,633	94,633
Treasury shares	(162,519)	(161,849)
Other components of equity	82,094	82,137
Retained earnings	1,241,600	1,250,757
Total equity attributable to owners of the Company	1,305,809	1,315,678
Non-controlling interests		
Non-controlling interests	464	430
Total equity	1,306,274	1,316,108
Total liabilities and equity	2,105,619	2,063,186

(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)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Revenue	249,239	236,947
Cost of sales	87,899	82,211
Gross profit	161,339	154,736
Selling, general and administrative expenses	63,161	71,790
Research and development expenses	41,184	48,823
Operating profit	56,993	34,122
Financial income	4,003	8,044
Financial expenses	3,935	798
Share of profit (loss) of investments accounted for using the equity method	6	9
Profit before tax	57,067	41,378
Income taxes	13,744	9,555
Profit for the period	43,322	31,823
Profit attributable to:		
Owners of the Company	43,347	31,857
Non-controlling interests	(24)	(34)
Profit for the period	43,322	31,823
Earnings per share		
Basic earnings per share (Yen)	66.91	49.15
Diluted earnings per share (Yen)	66.77	49.07

Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Profit for the period	43,322	31,823
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(1,783)	4,045
Remeasurements of defined benefit plans	(44)	118
Items that are or may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(13,794)	(3,459)
Other comprehensive income for the period	(15,623)	704
Total comprehensive income for the period	27,699	32,528
Total comprehensive income attributable to:		
Owners of the Company	27,724	32,562
Non-controlling interests	(24)	(34)
Total comprehensive income for the period	27,699	32,528

(3) Condensed Interim Consolidated Statement of Changes in Equity

Three months ended June 30, 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	–	–	–	–	(13,794)	(1,783)
Total comprehensive income for the period	–	–	–	–	(13,794)	(1,783)
Purchase of treasury shares	–	–	(15)	–	–	–
Cancellation of treasury shares	–	–	17	(7)	–	–
Dividend	–	–	–	–	–	–
Changes associated with obtaining control of subsidiaries	–	–	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(1,730)
Total transactions with owners of the Company	–	–	1	(7)	–	(1,730)
Balance as of June 30, 2019	50,000	94,633	(162,962)	1,798	52,833	43,218

(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	–	–	43,347	43,347	(24)	43,322
Other comprehensive income for the period	(44)	(15,623)	–	(15,623)	–	(15,623)
Total comprehensive income for the period	(44)	(15,623)	43,347	27,724	(24)	27,699
Purchase of treasury shares	–	–	–	(15)	–	(15)
Cancellation of treasury shares	–	(7)	(9)	0	–	0
Dividend	–	–	(22,676)	(22,676)	–	(22,676)
Changes associated with obtaining controls of subsidiaries	–	–	–	–	576	576
Transfer from other components of equity to retained earnings	44	(1,685)	1,685	–	–	–
Total transactions with owners of the Company	44	(1,693)	(20,999)	(22,691)	576	(22,114)
Balance as of June 30, 2019	–	97,850	1,174,778	1,254,299	614	1,254,914

Three months ended June 30, 2020

(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, 2020	50,000	94,633	(162,519)	1,611	51,218	29,264
Profit for the period	–	–	–	–	–	–
Other comprehensive income for the period	–	–	–	–	(3,459)	4,045
Total comprehensive income for the period	–	–	–	–	(3,459)	4,045
Purchase of treasury shares	–	–	(12)	–	–	–
Cancellation of treasury shares	–	–	682	(325)	–	–
Dividend	–	–	–	–	–	–
Transfer from other components of equity to retained earnings	–	–	–	–	–	(218)
Total transactions with owners of the Company	–	–	670	(325)	–	(218)
Balance as of June 30, 2020	50,000	94,633	(161,849)	1,285	47,759	33,092

(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, 2020	–	82,094	1,241,600	1,305,809	464	1,306,274
Profit for the period	–	–	31,857	31,857	(34)	31,823
Other comprehensive income for the period	118	704	–	704	–	704
Total comprehensive income for the period	118	704	31,857	32,562	(34)	32,528
Purchase of treasury shares	–	–	–	(12)	–	(12)
Cancellation of treasury shares	–	(325)	(355)	0	–	0
Dividend	–	–	(22,682)	(22,682)	–	(22,682)
Transfer from other components of equity to retained earnings	(118)	(336)	336	–	–	–
Total transactions with owners of the Company	(118)	(662)	(22,701)	(22,693)	–	(22,693)
Balance as of June 30, 2020	–	82,137	1,250,757	1,315,678	430	1,316,108

(4) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Cash flows from operating activities		
Profit before tax	57,067	41,378
Depreciation and amortization	12,941	14,120
Impairment losses (reversal of impairment losses)	–	0
Financial income	(4,003)	(8,044)
Financial expenses	3,935	798
Share of (profit) loss of investments accounted for using the equity method	(6)	(9)
(Gain) loss on sale and disposal of non-current assets	(10,611)	13
(Increase) decrease in trade and other receivables	63,630	64,949
(Increase) decrease in inventories	(12,467)	(10,429)
Increase (decrease) in trade and other payables	(23,942)	(30,295)
Others, net	(363)	(7,119)
Subtotal	86,181	65,362
Interest and dividend received	2,160	1,134
Interest paid	(532)	(224)
Income taxes paid	(10,235)	(10,395)
Net cash flows from (used in) operating activities	77,574	55,877
Cash flows from investing activities		
Payments into time deposits	(249,603)	(235,017)
Proceeds from maturities of time deposits	261,010	235,549
Acquisition of securities	(38,901)	(69,215)
Proceeds from sale and redemption of securities	31,681	37,311
Acquisition of property, plant and equipment	(8,311)	(8,968)
Proceeds from sale of property, plant and equipment	80	2
Acquisition of intangible assets	(5,224)	(30,028)
Acquisition of subsidiaries	463	–
Payments for loans receivable	(24)	(21)
Proceeds from collection of loans receivable	113	110
Others, net	14,299	(569)
Net cash flows from (used in) investing activities	5,583	(70,848)

	Three months ended June 30, 2019	Three months ended June 30, 2020
Cash flows from financing activities		
Proceeds from bonds and borrowings	3,981	–
Repayments of bonds and borrowings	(40,097)	(97)
Purchase of treasury shares	(15)	(12)
Proceeds from sale of treasury shares	–	0
Dividend paid	(22,711)	(22,794)
Others, net	(2,457)	(3,170)
Net cash flows from (used in) financing activities	(61,300)	(26,074)
Net increase (decrease) in cash and cash equivalents	21,857	(41,044)
Cash and cash equivalents at the beginning of the period	243,155	424,184
Effect of exchange rate changes on cash and cash equivalents	(4,112)	(1,037)
Cash and cash equivalents at the end of the period	260,900	382,102

(5) Notes to Condensed Interim Consolidated Financial Statements

Going Concern Assumption

Not applicable.

Changes in Significant Subsidiaries during the Period

Not applicable.

Changes in Accounting Policies

The significant accounting policies adopted in preparing the condensed interim consolidated financial statements of the Group have not changed from the prior year.

Additional Information

At the meeting of the Board of Directors held on Monday, April 27, 2020, a share split and partial amendment to Daiichi Sankyo's articles of incorporation was resolved as follows:

1) Purpose of the share split

The share split aims to increase the liquidity of the shares by reducing the investment unit price for Daiichi Sankyo's share, and to further expand the investor base.

2) Outline of the share split

(a) Method

Fixing Wednesday, September 30, 2020 as the record date, Daiichi Sankyo will split its ordinary shares, owned by shareholders listed or recorded in the shareholder registry, three-for-one.

(b) Number of shares to be increased by the share split

(i) Total number of shares issued before the share split	709,011,343
(ii) Increase in the number of shares upon the share split	1,418,022,686
(iii) Total number of shares issued after the share split	2,127,034,029
(iv) Total number of shares issuable after the share split	8,400,000,000

(c) Schedule

(i) Announcement of record date	Friday, September 11, 2020
(ii) Record date	Wednesday, September 30, 2020
(iii) Effective date	Thursday, October 1, 2020

(d) Others

The share split will not change the amount of stated capital.

3) Effect of the share split on per share information

Per-share information calculated as if the share split had taken place at the beginning of the three months ended June 30, 2019 is as follows:

	Three months ended June 30, 2019	Three months ended June 30, 2020
Basic earnings per share (Yen)	22.30	16.38
Diluted earnings per share (Yen)	22.26	16.36

4) Partial amendment to the articles of incorporation

(a) Reason for the amendment

In line with the share split, pursuant to the Article 184.2 of the Companies Act of Japan, Daiichi Sankyo will amend, as of Thursday, October 1, 2020, the total number of shares issuable set by Article 6 in the Articles of Incorporation of Daiichi Sankyo.

(b) Details of the amendment to the articles of incorporation

Details are as follows.

(Underlined points indicate changes)

Before the amendment	After the Amendment
(Total Number of Shares Issuable) Article 6. The total number of shares issuable by the Company shall be 2.8 billion shares.	(Total Number of Shares Issuable) Article 6. The total number of shares issuable by the Company shall be 8.4 billion shares.

(c) Schedule for the amendment to the articles of incorporation

Date resolved at the Board of Directors meeting : Monday, April 27, 2020

Effective date of the amendment to the articles of incorporation : Thursday, October 1, 2020

Subsequent Events

On July 27, 2020, Daiichi Sankyo entered into a global development and commercialization agreement with AstraZeneca (Headquarters: Cambridge, United Kingdom) for Daiichi Sankyo's DS-1062, a TROP2 directed antibody drug conjugate (ADC).

Daiichi Sankyo and AstraZeneca will jointly develop and commercialize monotherapies and combination therapies for DS-1062 worldwide, except in Japan, where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will manufacture and supply DS-1062.

Under the agreement, Daiichi Sankyo will receive an upfront payment of $1 billion from AstraZeneca, of which $350 million is due upon execution of the agreement, $325 million 12 months later and $325 million 24 months later. In addition, Daiichi Sankyo will receive up to $1 billion for achievement of regulatory milestones, and up to $4 billion for sales-related milestones. If all regulatory and sales milestones are achieved, Daiichi Sankyo's total receipts will be $6 billion.

Daiichi Sankyo and AstraZeneca will share equally development and commercialization costs as well as profits from DS-1062 worldwide, except in Japan, where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo is expected to book sales in Japan, U.S. and certain countries in Europe and certain other countries and markets where Daiichi Sankyo has affiliates. AstraZeneca is expected to book sales in other markets worldwide, including China, Australia, Canada and Russia.

The upfront payment and regulatory milestones will be booked as revenue over the period in which Daiichi Sankyo satisfies the performance obligations under the agreement. Daiichi Sankyo expects to book approximately 4 billion yen as revenue for the fiscal year ending March 31, 2021.