



January 31, 2022

## Consolidated Financial Results for the First Nine Months of the Year Ending March 31, 2022 (Fiscal 2021) <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

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 Preparing supplementary material (Reference Data) on quarterly financial results: Yes  
 Holding quarterly information meeting: Yes (for institutional investors, analysts and the press)

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

### 1. Consolidated Financial Results for the First Nine Months of the Year Ending March 31, 2022 (from April 1, 2021 to December 31, 2021)

#### (1) Consolidated Financial Results

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

	Revenue		Operating profit		Profit before tax		Profit for the period	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended December 31, 2021	810,967	9.8	123,772	38.3	125,886	26.4	94,318	24.6
Nine months ended December 31, 2020	738,791	(2.4)	89,463	(42.5)	99,568	(37.8)	75,678	(43.6)

	Profit attributable to owners of the Company		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Nine months ended December 31, 2021	94,318	24.4	110,638	49.2	49.21	49.16
Nine months ended December 31, 2020	75,806	(43.5)	74,149	(41.0)	38.99	38.94

Note: Effective Thursday, October 1, 2020, Daiichi Sankyo Company, Limited (hereinafter, "Daiichi Sankyo" or "the Company") implemented a three-for-one share split of its ordinary shares. "Basic earnings per share" and "Diluted earnings per share" are calculated as if the share split had taken place at the beginning of the year ended March 31, 2021.

## (2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the Company	Ratio of equity attributable to owners of the Company to total assets	Equity per share attributable to owners of the Company
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of December 31, 2021	2,163,472	1,331,220	1,331,220	61.5	694.53
As of March 31, 2021	2,085,178	1,272,053	1,272,053	61.0	663.85

## 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, 2021	–	40.50	–	13.50	–
Year ending March 31, 2022	–	13.50	–		
Year ending March 31, 2022 (Forecast)				13.50	27.00

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

Note: Effective Thursday, October 1, 2020, Daiichi Sankyo implemented a three-for-one share split of its ordinary shares. The dividend for the first six months of the fiscal year ended March 31, 2021 presents the amount prior to the share split. The annual dividend per share for the fiscal year ended March 31, 2021 is not presented because the amounts cannot be simply combined due to the implementation of the share split. For further details, please refer to “1. Qualitative Information about Consolidated Results for the First Nine Months (4) Information about Return to Shareholders” on page 10 of the attached material.

## 3. Forecast of Consolidated Financial Results for Year Ending March 31, 2022

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

	Revenue		Core operating profit		Operating profit		Profit before tax		Profit for the year	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Full year	1,030,000	7.0	90,000	14.1	92,000	44.2	92,000	24.1	64,000	(15.6)

	Profit attributable to owners of the Company		Basic earnings per share
	Millions of yen	%	Yen
Full year	64,000	(15.7)	33.39

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

Note: Regarding the forecast of consolidated financial results for the fiscal year ending March 31, 2022, Daiichi Sankyo discloses core operating profit, which excludes temporary income and expenses from operating profit, as an indicator of ordinary profitability. For the definition of core operating profit, please refer to “1. Qualitative Information about Consolidated Results for the First Nine Months (1) Information about Operating Results” on page 2 of the attached material.

## \*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 December 31, 2021	1,947,034,029 shares
As of March 31, 2021	2,127,034,029 shares

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

As of December 31, 2021	30,309,866 shares
As of March 31, 2021	210,868,203 shares

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

Nine months ended December 31, 2021	1,916,549,230 shares
Nine months ended December 31, 2020	1,944,131,938 shares

Note: Effective Thursday, October 1, 2020, Daiichi Sankyo implemented a three-for-one share split of its ordinary shares. "Number of ordinary shares issued" is calculated as if the share split had taken place at the beginning of the year ended March 31, 2021.

\* This quarterly financial results summary is not subject to quarterly review procedures by Certified Public Accountants or an 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 Nine Months (3) Information about Forecasts of Consolidated Financial Results and Other Forward-Looking Statements" on page 10 for matters related to the above forecasts.

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## 1. Qualitative Information about Consolidated Results for the First Nine Months

### (1) Information about Operating Results

#### 1) Overview

#### [Consolidated Financial Results]

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

	Nine months ended December 31, 2020	Nine months ended December 31, 2021	YoY change
Revenue	738,791	810,967	72,175 9.8%
Cost of sales*	256,414	263,208	6,794 2.6%
Selling, general and administrative expenses*	229,265	255,679	26,413 11.5%
Research and development expenses*	163,749	169,083	5,334 3.3%
Core operating profit*	89,362	122,995	33,633 37.6%
Temporary income*	114	2,120	2,006 -
Temporary expenses*	13	1,343	1,330 -
Operating profit	89,463	123,772	34,309 38.3%
Profit before tax	99,568	125,886	26,318 26.4%
Profit attributable to owners of the Company	75,806	94,318	18,512 24.4%
Total comprehensive income	74,149	110,638	36,489 49.2%

\* Daiichi Sankyo discloses core operating profit, which excludes temporary income and expenses from operating profit, as an indicator of ordinary profitability. Temporary income and expenses include gains/losses on sale of non-current assets, gains/losses associated with business restructuring (excluding gains/losses on sales of developed products and products on the market), impairment losses on property, plant and equipment, intangible assets, and goodwill, compensation for damages or settlement, and non-recurring and large gains/losses.

This table shows the actual results of cost of sales, selling, general and administrative expenses, and research and development expenses, exclusive of temporary income and expenses. The adjustment table from operating profit to core operating profit is stated in the reference data.

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

	(Yen)	
	Nine months ended December 31, 2020	Nine months ended December 31, 2021
USD/Yen	106.11	111.10
EUR/Yen	122.37	130.62

**a. Revenue**

- Revenue in the first nine months of the year ending March 31, 2022 increased by ¥72.2 billion, or 9.8% compared to the same period of the previous fiscal year (year on year), to ¥811.0 billion.
- Revenue increased year on year due to the achieved growth with Injectafer affected by the spread of COVID-19 in the previous fiscal year and others, in addition to the achieved growth with global mainstay products such as Lixiana (generic name: edoxaban) and Enhertu (generic name: trastuzumab deruxtecan, T-DXd/DS-8201) and others.
- The positive effect on revenue from foreign exchange was ¥20.6 billion in total.

**b. Core operating profit**

- Core operating profit increased by ¥33.6 billion, or 37.6% year on year, to ¥123.0 billion.
- Cost of sales increased only by ¥6.8 billion, or 2.6% year on year, to ¥263.2 billion due to an improvement in cost-to-sales ratio as a result of a change in the product mix.
- Selling, general and administrative expenses increased by ¥26.4 billion, or 11.5%, to ¥255.7 billion due to the cost increase by an increase in profit sharing with AstraZeneca pertaining to Enhertu.
- Research and development expenses were ¥169.1 billion which was about the same level year on year.
- The positive effect on core operating profit from foreign exchange was ¥5.3 billion in total.

**c. Operating profit**

- Operating profit increased by ¥34.3 billion, or 38.3% year on year, to ¥123.8 billion.
- Gain on sale of property, plant and equipment (¥2.1 billion) was recorded as temporary income, and impairment losses (¥1.3 billion) on intangible assets were recorded as temporary expenses.

**d. Profit before tax**

- Profit before tax increased by ¥26.3 billion, or 26.4% year on year, to ¥125.9 billion.
- The amount of increase in profit before tax was smaller compared to operating profit due to worsening loss (gain) on exchange differences.

**e. Profit attributable to owners of the Company**

- Profit attributable to owners of the Company increased by ¥18.5 billion, or 24.4% year on year, to ¥94.3 billion.

**f. Total comprehensive income**

- Total comprehensive income increased by ¥36.5 billion, or 49.2% year on year, to ¥110.6 billion.
- The amount of increase in total comprehensive income increased compared to profit attributable to owners of the Company due to improvement in the currency translation difference pertaining to net

assets of overseas subsidiaries, despite a worsening in the valuation difference on financial assets.

## **[Revenue by Business Unit]**

Revenue by business unit in the first nine months of the year ending March 31, 2022 is as follows. In addition, revenue by product is stated in the reference data.

### **a. Japan Business Unit**

- Revenue from Japan Business Unit includes revenue generated by the innovative pharmaceuticals business, the vaccine business and revenue from products generated by the generic pharmaceutical business of Daiichi Sankyo Espha Co., Ltd.
- Revenue from the Unit increased by ¥7.3 billion, or 1.9% year on year, to ¥393.7 billion due to growth in sales of Lixiana, Tarlige, Enhertu, Emgality and others, despite the impact of NHI drug price revision, decline in sales of Nexium which was terminated co-promotion and decline in sales of Memary caused by generic entries following the loss of exclusivity, and others.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In April 2021, the migraine prevention drug Emgality was launched.
- In May 2021, adalimumab biosimilar, a fully human anti-TNF- $\alpha$  monoclonal antibody, was launched.
- In August 2021, a supplemental application was approved for partial changes in usage and dosage for Lixiana tablets 15 mg and Lixiana OD tablets 15 mg.
- In August 2021, a collaborative agreement was concluded to commercialize lasmiditan succinate in Japan for the treatment of migraines.
- In November 2021, Delytact oncolytic virus G47 $\Delta$  was launched.
- In December 2021, a supplemental application was approved for partial changes in usage and dosage for antiplatelet agents Efient 3.75 mg Tablets and Efient 2.5 mg Tablets.

### **b. Daiichi Sankyo Healthcare Unit**

- Revenue from Daiichi Sankyo Healthcare Unit decreased by ¥1.8 billion, or 3.5% year on year, to ¥49.7 billion caused by decline in sales of the drugs for common cold such as Lulu.

### **c. Oncology Business Unit**

- Revenue from Oncology Business Unit includes revenue from products generated by Daiichi Sankyo, Inc. (the U.S.) and revenue generated from cancer treatment products sold by Daiichi Sankyo Europe GmbH.
- Revenue from the Unit increased by ¥13.8 billion, or 39.0% year on year, to ¥49.2 billion due to increase of Enhertu in the U.S. and Europe. Revenue in local currency terms increased by US\$109 million, or 32.7%, to US\$443 million.

### **d. American Regent Unit**

- Revenue from American Regent Unit increased by ¥24.6 billion, or 27.0% year on year, to ¥115.6 billion due to an increase in sales of Injectafer and others affected by the spread of COVID-19 in the previous fiscal year. Revenue in local currency terms increased by US\$183 million, or 21.3%, to US\$1,041 million.

#### e. EU Specialty Business Unit

- Revenue from EU Specialty Business Unit includes revenue from products other than from cancer treatment products generated by Daiichi Sankyo Europe GmbH.
- Revenue from the Unit increased by ¥15.0 billion, or 18.1% year on year, to ¥97.9 billion due to steady growth in sales of Lixiana. Revenue in local currency terms increased by EUR72 million, or 10.6%, to EUR750 million.

#### f. ASCA Business Unit

- Revenue from ASCA<sup>\*1</sup> Business Unit includes sales to overseas licensees.
- Revenue from the Unit increased by ¥8.4 billion, or 11.3% year on year, to ¥82.9 billion due to increase of olmesartan and others in China.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In April 2021, Esperion's bempedoic acid, the hypercholesterolemia treatment, was licensed in for Asia and South America.

<sup>\*1</sup> Asia, South & Central America

## 2) Status of R&D

- The Daiichi Sankyo Group (hereinafter, "the Group") is working on research and development including active collaboration with the outside in accordance with the "3 and Alpha" Strategy, which intensively allocates resources to 3ADCs<sup>\*1</sup> (trastuzumab deruxtecan: T-DXd/DS-8201, datopotamab deruxtecan: Dato-DXd/DS-1062 and patritumab deruxtecan: HER3-DXd/U3-1402) for maximizing their product values, and aims to deliver medicines that change SOC<sup>\*2</sup> for realization of sustainable growth (Alpha). In addition, the Group focuses on accelerating global clinical development.
- In the medium to long term, the Group aims to develop therapeutic drugs for various diseases in addition to oncology by utilizing its competitive science and technology, and strives to strengthen drug discovering capabilities by technology research of new modalities<sup>\*3</sup>.

<sup>\*1</sup> 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.

<sup>\*2</sup> Standard of Care: Universally applied best treatment practice in today's medical science.

<sup>\*3</sup> New medical treatment such as ADC, nucleic acid drugs, viruses for treatment, and cell therapy.

### **【3ADCs】**

The following describes the Group's clinical development of 3ADCs projects in the first nine months of the year ending March 31, 2022 (from April 1, 2021 to December 31, 2021). The status of each clinical trial is stated in the reference data.

#### a. Trastuzumab deruxtecan (T-DXd/DS-8201: HER2-directed ADC, brand name: Enhertu)

- The product is marketed under the brand name Enhertu. Daiichi Sankyo is jointly developing Enhertu with AstraZeneca, a company with a wealth of global experience in oncology.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In June 2021, data was presented at the 2021 American Society of Clinical Oncology (ASCO) from the Phase Ib/II clinical trial for patients with triple negative breast cancer (TNBC) (trial name:



BEGONIA) and the Phase II clinical trial for the third line treatment for patients with HER2 expressing colorectal cancer (trial name: DESTINY-CRC01).

- In June 2021, a Phase III clinical trial for the first line treatment for patients with HER2-positive breast cancer (trial name: DESTINY-Breast09) was initiated.
- In June 2021, the top line results (the outline of trial results) of the Phase II clinical trial for the second line treatment for patients with HER2-positive gastric cancer (trial name: DESTINY-Gastric02) were obtained.
- In June 2021, the top line results of the Phase II clinical trial for the second or later line treatment for patients with HER2-overexpressing or HER2 mutant, non-small cell lung cancer (NSCLC) (trial name: DESTINY-Lung01) were obtained.
- In July 2021, a Phase III clinical trial for the second line treatment for patients with HER2-positive gastric cancer (trial name: DESTINY-Gastric04) was initiated.
- In August 2021, the primary endpoint in interim analysis of the Phase III clinical trial for the second line treatment for patients with HER2-positive breast cancer (trial name: DESTINY-Breast03) was achieved, and Real-Time Oncology Review (RTOR<sup>\*4</sup>) designation was obtained from the U.S. Food and Drug Administration (FDA).
- In September 2021, a Phase II clinical trial for the third line treatment for patients with HER2-positive gastric cancer (trial name: DESTINY-Gastric06) was initiated in China.
- In September 2021, data was presented at the European Society for Medical Oncology Congress 2021 (ESMO Congress 2021) from the Phase II clinical trial for the third line treatment for patients with HER2-positive breast cancer (trial name: DESTINY-Breast01), the DESTINY-Breast03 clinical trial, the DESTINY-Gastric02 clinical trial, and the DESTINY-Lung01 clinical trial.
- In October 2021, Breakthrough Therapy Designation<sup>\*5</sup> was obtained from the FDA for the second or later line treatment for patients with HER2-positive breast cancer.
- In November 2021, the Type II Variation application for the second line treatment for patients with HER2-positive gastric cancer was validated by the European Medicines Agency (EMA).
- In November 2021, a Phase III clinical trial for neoadjuvant therapy for patients with HER2-positive early-stage breast cancer (trial name: DESTINY-Breast11) was initiated.
- In December 2021, the analysis results of the DESTINY-Breast03 clinical trial for patient subgroups with brain metastases were presented at the 2021 San Antonio Breast Cancer Symposium (#SABCS2021) in the U.S.
- In December 2021, a supplemental new drug application was submitted in Japan and the Type II Variation application was validated by the EMA for the second line treatment for patients with HER2-positive breast cancer.
- In December 2021, a Phase III clinical trial for the first line treatment for patients with HER2 mutant NSCLC (trial name: DESTINY-Lung04) was initiated.

<sup>\*4</sup> The Real-Time Oncology Review (RTOR) program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible. Under the program, the FDA allows for accelerated screening of large amounts of data prior to an applicant formally submitting the complete application.

<sup>\*5</sup> The Breakthrough Therapy Designation is designed to expedite the development and review of medicines that may demonstrate substantial benefit over currently available treatments in order to ensure that patients with serious diseases have access to new treatments as soon as possible.

#### **b. Datopotamab deruxtecan (Dato-DXd/DS-1062: TROP2-directed ADC)**

- Daiichi Sankyo is jointly developing the product with AstraZeneca, a company with a wealth of global experience in oncology.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In May 2021, data was presented at the European Society for Medical Oncology Breast Cancer Virtual Congress 2021 (ESMO Breast Cancer 2021) for TNBC patients in the Phase I clinical trial for solid tumors (trial name: TROPION-PanTumor01).
- In June 2021, data was presented at the 2021 American Society of Clinical Oncology (ASCO) for NSCLC patients in the TROPION-PanTumor01 clinical trial.
- In September 2021, data was presented at the 2021 World Conference on Lung Cancer (WCLC) and the European Society for Medical Oncology Congress 2021 (ESMO Congress 2021) for NSCLC patients in the TROPION-PanTumor01 clinical trial.
- In October 2021, an agreement was entered into with Merck & Co., Inc. to conduct a Phase III clinical trial for the first line treatment for NSCLC patients to evaluate the combination with pembrolizumab, the immune checkpoint inhibitor (trial name: TROPION-Lung08).
- In November 2021, a Phase III clinical trial for the second line treatment for patients with hormone receptor-positive, HER2-negative metastatic breast cancer (trial name: TROPION-Breast01) was initiated.
- In December 2021, data was presented at the 2021 San Antonio Breast Cancer Symposium (#SABCS2021) in the U.S. for TNBC patients in the TROPION-PanTumor01 clinical trial.

### **c. Patritumab deruxtecan (HER3-DXd/U3-1402: HER3-directed ADC)**

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In June 2021, data was presented at the 2021 American Society of Clinical Oncology (ASCO) from the Phase I clinical trial for patients with epidermal growth factor receptor (EGFR)-mutated NSCLC.
- In June 2021, a Phase I clinical trial was initiated to evaluate the combination with osimertinib, a tyrosine kinase inhibitor, in patients with EGFR-mutated NSCLC.
- In December 2021, Breakthrough Therapy Designation was obtained from the FDA for patients with metastatic EGFR-mutated NSCLC.

### **【Alpha】**

The following describes the major progress in clinical development for each project other than 3ADCs in the first nine months of the year ending March 31, 2022. The status of each clinical trial is stated in the reference data.

- In April 2021, a Phase I/II clinical trial for DS-1594 (Menin-MLL interaction inhibitor) was initiated for patients with acute myeloid leukemia (AML) and acute lymphocytic leukemia.
- In April 2021, a Phase II clinical trial for pexidartinib (PLX3397: CSF-1R inhibitor, brand name in the U.S.: Turalio) was initiated in Japan for patients with tenosynovial giant cell tumor.
- In April 2021, a Phase I clinical trial for DS-6016 (anti-ALK2 antibody) was initiated for patients with fibrodysplasia ossificans progressiva.
- In May 2021, a supplemental new drug application was submitted for the pain agent mirogabalin (DS-5565:  $\alpha\delta$  ligand, brand name: Tarlige) for an additional indication related to central neuropathic pain in Japan.
- In June 2021, approval for manufacturing and marketing in Japan was received for the oncolytic virus tesorpaturev (DS-1647: G47 $\Delta$ , brand name: Delytact).
- In June 2021, data was presented at the annual congress of the European Hematology Association (EHA) from the Phase I clinical trial of valemestostat (DS-3201: EZH1/2 dual inhibitor) for patients with non-Hodgkin lymphoma.

- In June 2021, a Phase II clinical trial of valemestostat was initiated for patients with relapsed/refractory peripheral T-cell lymphoma (PTCL) and adult T-cell leukemia-lymphoma (ATL) (trial name: VALENTINE-PTCL01).
- In June 2021, a Phase I clinical trial for VN-0200 (RS virus vaccine) was initiated with healthy Japanese adults including elderly individuals.
- In August 2021, the primary endpoint of the ENVISAGE-TAVI AF clinical trial involving the anticoagulant edoxaban (brand name: Lixiana) for patients with atrial fibrillation (AF) who have undergone transcatheter aortic valve implantation (TAVI) was achieved, and results were presented at the European Society of Cardiology Congress 2021 (ESC Congress 2021).
- In September 2021, data was presented at the European Society for Medical Oncology Congress 2021 (ESMO Congress 2021) from the Phase I/II clinical trial of DS-7300 (B7-H3-directed ADC) for solid tumors.
- In November 2021, the primary endpoint of the Phase III clinical trial of quizartinib (AC220: FLT3 inhibitor, brand name in Japan: Vanflyta) for the first line treatment for patients with AML (trial name: QuANTUM-First) was achieved.
- In December 2021, data was presented at the meeting of the American Society of Hematology (ASH) from the Phase II clinical trial of valemestostat in Japan for relapsed/refractory ATL patients for the treatment of ATL, Orphan Drug Designation<sup>\*6</sup> was obtained from Japan's Ministry of Health, Labour and Welfare (MHLW), and an application for manufacturing and marketing in Japan was submitted.
- In December 2021, Orphan Drug Designation<sup>\*7</sup> for valemestostat was obtained from the FDA for the treatment of PTCL.

<sup>\*6</sup> A system under which designation is granted in order to support and expedite development under the conditions that there are fewer than 50,000 patients in Japan and there is a particularly high medical need for it.

<sup>\*7</sup> A system under which designation is granted in order to support and expedite development for medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S.

### 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. The Company is leveraging our research properties, technologies and knowledge to the maximum extent, and through partnerships with other organizations, we are proceeding with the following R&D.

#### a. DS-5670 (COVID-19 mRNA vaccine)

- For the prevention of COVID-19, the Company is currently participating in “Fundamental Research on the Control of the Novel Coronavirus (2019-nCoV<sup>\*1</sup>),”<sup>\*2</sup> an initiative supported by the Japan Agency for Medical Research and Development (hereinafter, AMED). In addition, using novel nucleic acid delivery technology<sup>\*3</sup> developed inhouse, the Company is taking part in a basic research project on a genetic (mRNA) vaccine with the title “Development of a Genetic Vaccine for 2019-nCoV.”
- The Company has been selected by the MHLW to be a provider for the Japanese Government's “Emergent Initiative to Build Production Capacity for COVID-19 Vaccines<sup>\*4</sup> (First Round)” as well as by AMED to be a company for the AMED's Drug Discovery Support Program “Development of COVID-19 Vaccines<sup>\*5</sup> (Second Round).”
- The Company is conducting Phase I/II clinical trials in Japan with healthy adults including elderly individuals.

<sup>\*1</sup> 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 demonstrated to induce a more optimal immune response.
- \*4 The project aims to swiftly develop an actual (large-scale) production system for biologics, including vaccines, in order to ensure that the vaccines necessary for the prevention of the spread and severity of unexpected epidemics, including COVID-19, are produced as soon as possible, and that their supply is secured for the Japanese people.
- \*5 The project aims to support the development of a vaccine against COVID-19, for which R&D is already underway, and aims to ensure the early commercialization of safe and effective vaccines.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In November 2021, a Phase II clinical trial was initiated using a batch of DS-5670 from the optimized manufacturing process to evaluate the safety and determine the recommended dose of DS-5670.

#### **b. DS-2319 (Nafamostat inhalation formulation)**

- Daiichi Sankyo was carrying out a collaborative R&D on nafamostat inhalation formulation for the treatment of COVID-19 with the University of Tokyo, RIKEN, and Nichi-Iko Pharmaceutical Co., Ltd.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In June 2021, the Company decided to discontinue the development of DS-2319 as a result of examining the data of ongoing nonclinical studies and Phase I clinical trial.

#### **c. Supply of AstraZeneca's novel coronavirus vaccine, Vaxzevria**

- Based on the agreement which Daiichi Sankyo entered into with AstraZeneca to manufacture the vaccine, Daiichi Sankyo Biotech Co., Ltd., a subsidiary of the Company, has been manufacturing the vaccine (including vial filling and packaging, etc.) since March 2021.

The following describes the major progress in the first nine months of the year ending March 31, 2022.

- In June 2021, through the Japanese government, Vaxzevria was supplied to Southeast Asia and other regions.

## **(2) Analysis of Financial Position as of December 31, 2021**

- Total assets as of December 31, 2021 were ¥2,163.5 billion, an increase of ¥78.3 billion from the previous fiscal year-end, mainly due to increases in cash and cash equivalents and trade and other receivables, which were partially offset by decreases in other financial assets (current assets).
- Total liabilities as of December 31, 2021 were ¥832.3 billion, an increase of ¥19.1 billion from the previous fiscal year-end, mainly due to increases in other non-current liabilities, which were partially offset by decreases in trade and other payables and bonds and borrowings (non-current liabilities).
- Total equity as of December 31, 2021 was ¥1,331.2 billion, an increase of ¥59.2 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 61.5%, an increase of 0.5 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, 2022 publicly announced on October 29, 2021.

## **(4) Information about Return to Shareholders**

- In order to secure sustainable growth in corporate value, one of the fundamental business strategies 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.
- For the fiscal year ended March 31, 2021, the Company paid a year-end dividend of ¥13.5 per share on June 22, 2021. Accordingly, the annual dividend for the fiscal year, together with the interim dividend of ¥40.5 per share (on a pre-share split basis<sup>\*1</sup>) paid on December 1, 2020, was ¥81.0 per share in total, which was an increase of ¥11.0 from the previous fiscal year on a pre-share split basis.
- For the fiscal year ending March 31, 2022, the Company intends to pay an interim dividend of ¥13.5 per share, a year-end dividend of ¥13.5 per share and an annual dividend of ¥27.0 per share.
- The Board of Directors meeting held on October 29, 2021 approved to pay an ordinary dividend of ¥13.5 per share as an interim dividend, and the Company paid it on December 1, 2021 to shareholders as of September 30, 2021.

<sup>\*1</sup> Effective October 1, 2020, the Company implemented a three-for-one share split of its ordinary shares.

## 2. Condensed Interim Consolidated Financial Statements with Primary Notes

### (1) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of March 31, 2021	As of December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	380,547	577,295
Trade and other receivables	232,036	282,879
Other financial assets	444,368	221,962
Inventories	200,860	211,606
Other current assets	10,607	16,899
Total current assets	1,268,420	1,310,643
Non-current assets		
Property, plant and equipment	265,281	296,423
Goodwill	77,706	79,857
Intangible assets	172,822	168,715
Investments accounted for using the equity method	1,440	1,361
Other financial assets	139,991	131,650
Deferred tax assets	128,525	134,824
Other non-current assets	30,990	39,995
Total non-current assets	816,757	852,829
Total assets	2,085,178	2,163,472

(Millions of yen)

	As of March 31, 2021	As of December 31, 2021
<b>LIABILITIES AND EQUITY</b>		
Current liabilities		
Trade and other payables	297,499	274,949
Bonds and borrowings	20,391	20,393
Other financial liabilities	9,359	9,998
Income taxes payable	6,096	24,248
Provisions	6,051	4,939
Other current liabilities	14,173	20,666
Total current liabilities	353,571	355,195
Non-current liabilities		
Bonds and borrowings	163,441	143,161
Other financial liabilities	36,983	42,224
Post-employment benefit liabilities	3,929	4,396
Provisions	8,741	8,819
Deferred tax liabilities	17,516	14,533
Other non-current liabilities	228,941	263,919
Total non-current liabilities	459,553	477,055
Total liabilities	813,125	832,251
Equity		
Equity attributable to owners of the Company		
Share capital	50,000	50,000
Capital surplus	94,494	-
Treasury shares	(261,252)	(37,558)
Other components of equity	111,479	127,346
Retained earnings	1,277,332	1,191,432
Total equity attributable to owners of the Company	1,272,053	1,331,220
Total equity	1,272,053	1,331,220
Total liabilities and equity	2,085,178	2,163,472

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

**Condensed Interim Consolidated Statement of Profit or Loss**

(Millions of yen)

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Revenue	738,791	810,967
Cost of sales	256,412	264,498
Gross profit	482,379	546,468
Selling, general and administrative expenses	229,275	253,573
Research and development expenses	163,640	169,121
Operating profit	89,463	123,772
Financial income	12,135	4,882
Financial expenses	2,108	2,833
Share of profit (loss) of investments accounted for using the equity method	77	65
Profit before tax	99,568	125,886
Income taxes	23,889	31,568
Profit for the period	75,678	94,318
Profit attributable to:		
Owners of the Company	75,806	94,318
Non-controlling interests	(127)	-
Profit for the period	75,678	94,318
Earnings per share		
Basic earnings per share (Yen)	38.99	49.21
Diluted earnings per share (Yen)	38.94	49.16



## Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Profit for the period	75,678	94,318
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	9,511	(5,220)
Remeasurements of defined benefit plans	29	(144)
Items that are or may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(11,069)	21,684
Other comprehensive income for the period	(1,528)	16,319
Total comprehensive income for the period	74,149	110,638
Total comprehensive income attributable to:		
Owners of the Company	74,277	110,638
Non-controlling interests	(127)	-
Total comprehensive income for the period	74,149	110,638

### (3) Condensed Interim Consolidated Statement of Changes in Equity

Nine months ended December 31, 2020

(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, 2020	50,000	94,633	(162,519)	1,611	51,218	29,264
Profit for the period	-	-	-	-	-	-
Other comprehensive income for the period	-	-	-	-	(11,069)	9,511
Total comprehensive income for the period	-	-	-	-	(11,069)	9,511
Purchase of treasury shares	-	(57)	(40,047)	-	-	-
Disposal of treasury shares	-	-	1,189	(523)	-	-
Dividend	-	-	-	-	-	-
Changes associated with losing control of subsidiaries	-	-	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	(805)
Total transactions with owners of the Company	-	(57)	(38,857)	(523)	-	(805)
Balance as of December 31, 2020	50,000	94,576	(201,377)	1,087	40,149	37,970

(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, 2020	-	82,094	1,241,600	1,305,809	464	1,306,274
Profit for the period	-	-	75,806	75,806	(127)	75,678
Other comprehensive income for the period	29	(1,528)	-	(1,528)	-	(1,528)
Total comprehensive income for the period	29	(1,528)	75,806	74,277	(127)	74,149
Purchase of treasury shares	-	-	-	(40,104)	-	(40,104)
Disposal of treasury shares	-	(523)	(393)	272	-	272
Dividend	-	-	(48,946)	(48,946)	-	(48,946)
Changes associated with losing control of subsidiaries	-	-	-	-	(336)	(336)
Transfer from other components of equity to retained earnings	(29)	(835)	835	-	-	-
Total transactions with owners of the Company	(29)	(1,358)	(48,505)	(88,778)	(336)	(89,115)
Balance as of December 31, 2020	-	79,207	1,268,901	1,291,308	-	1,291,308

Nine months ended December 31, 2021

(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, 2021	50,000	94,494	(261,252)	1,038	70,024	40,416
Profit for the period	-	-	-	-	-	-
Other comprehensive income for the period	-	-	-	-	21,684	(5,220)
Total comprehensive income for the period	-	-	-	-	21,684	(5,220)
Purchase of treasury shares	-	-	(12)	-	-	-
Disposal of treasury shares	-	-	697	(191)	-	-
Cancellation of treasury shares	-	(94,494)	223,009	-	-	-
Dividend	-	-	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	(405)
Total transactions with owners of the Company	-	(94,494)	223,694	(191)	-	(405)
Balance as of December 31, 2021	50,000	-	(37,558)	847	91,708	34,790

(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, 2021	-	111,479	1,277,332	1,272,053	-	1,272,053
Profit for the period	-	-	94,318	94,318	-	94,318
Other comprehensive income for the period	(144)	16,319	-	16,319	-	16,319
Total comprehensive income for the period	(144)	16,319	94,318	110,638	-	110,638
Purchase of treasury shares	-	-	-	(12)	-	(12)
Disposal of treasury shares	-	(191)	(221)	285	-	285
Cancellation of treasury shares	-	-	(128,514)	-	-	-
Dividend	-	-	(51,744)	(51,744)	-	(51,744)
Transfer from other components of equity to retained earnings	144	(260)	260	-	-	-
Total transactions with owners of the Company	144	(452)	(180,218)	(51,471)	-	(51,471)
Balance as of December 31, 2021	-	127,346	1,191,432	1,331,220	-	1,331,220

**(4) Condensed Interim Consolidated Statement of Cash Flows**

(Millions of yen)

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Cash flows from operating activities		
Profit before tax	99,568	125,886
Depreciation and amortization	42,868	43,199
Impairment losses (reversal of impairment losses)	12	1,339
Financial income	(12,135)	(4,882)
Financial expenses	2,108	2,833
Share of (profit) loss of investments accounted for using the equity method	(77)	(65)
(Gain) loss on sale and disposal of non-current assets	324	(1,286)
(Increase) decrease in trade and other receivables	44,785	(46,584)
(Increase) decrease in inventories	(11,194)	(5,982)
Increase (decrease) in trade and other payables	(19,142)	(23,432)
Others, net	6,184	28,998
Subtotal	153,301	120,023
Interest and dividend received	2,671	2,489
Interest paid	(1,033)	(962)
Income taxes paid	(22,687)	(20,413)
Net cash flows from (used in) operating activities	132,252	101,137
Cash flows from investing activities		
Payments into time deposits	(410,875)	(162,070)
Proceeds from maturities of time deposits	626,323	254,873
Acquisition of securities	(207,378)	(241,636)
Proceeds from sale and redemption of securities	150,788	378,813
Acquisition of property, plant and equipment	(21,798)	(46,873)
Proceeds from sale of property, plant and equipment	18	2,804
Acquisition of intangible assets	(32,380)	(13,010)
Payments for loans receivable	(24)	-
Proceeds from collection of loans receivable	324	298
Others, net	(140)	(678)
Net cash flows from (used in) investing activities	104,854	172,520

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
<b>Cash flows from financing activities</b>		
Repayments of bonds and borrowings	(40,292)	(20,293)
Purchase of treasury shares	(40,104)	(12)
Proceeds from sale of treasury shares	2	0
Dividend paid	(48,988)	(51,774)
Others, net	(9,517)	(10,558)
Net cash flows from (used in) financing activities	(138,900)	(82,637)
Net increase (decrease) in cash and cash equivalents	98,206	191,019
Cash and cash equivalents at the beginning of the period	424,184	380,547
Effect of exchange rate changes on cash and cash equivalents	(2,316)	5,728
Cash and cash equivalents at the end of the period	520,074	577,295

**(5) Notes to Condensed Interim Consolidated Financial Statements**

**Going Concern Assumption**

Not applicable.

**Changes in Significant Subsidiaries during the Period**

Not applicable.