CONSOLIDATED FINANCIAL REPORT [IFRS]
for the Three-Month Period Ended June 30, 2021

August 4, 2021
Eisai Co., Ltd.

Stock exchange listing: Tokyo Stock Exchange (TSE)
TSE Code: 4523
URL: https://www.eisai.com

Representative: Haruo Naito, Representative Corporate Officer & CEO
Contact: Sayoko Sasaki, Vice President, Chief IR Officer & Stakeholder Communications
Telephone: +81-3-3817-5120
Expected date of quarterly report submission: August 6, 2021
Expected date of dividend payment commencement: —
Preparation of quarterly supplementary explanatory material: Yes
Quarterly results briefing held: Yes

(Figures are rounded to the nearest million yen)

1. Consolidated Financial Results for the Three-Month Period Ended June 30, 2021

(1) Consolidated Operating Results

(Percentage figures show year on year change)

	Revenue		Operating profit		Profit before income taxes		Profit for the period		Profit for the period attributable to owners of the parent		Comprehensive income for the period	
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)
Three-month period ended June 30, 2021	198,894	20.1	55,407	72.5	55,783	71.9	42,305	70.9	42,161	72.6	42,417	78.9
Three-month period ended June 30, 2020	165,583	7.5	32,120	24.4	32,448	20.3	24,753	12.0	24,425	12.7	23,710	672.0

	Earnings per share attributable to owners of the parent (basic)	Earnings per share attributable to owners of the parent (diluted)
	(¥)	(¥)
Three-month period ended June 30, 2021	147.07	147.04
Three-month period ended June 30, 2020	85.23	85.20

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of the parent	Ratio of equity attributable to owners of the parent	Equity per share attributable to owners of the parent
	(¥ million)	(¥ million)	(¥ million)	(%)	(¥)
As of June 30, 2021	1,129,341	747,354	722,552	64.0	2,520.42
As of March 31, 2021	1,090,009	727,942	703,183	64.5	2,452.97

2. Dividends

	Annual dividend per share				
	End of Q1	End of Q2	End of Q3	End of FY	Total
	(¥)	(¥)	(¥)	(¥)	(¥)
FY 2020	—	80.00	—	80.00	160.00
FY 2021	—				
FY 2021 (Forecast)		80.00	—	80.00	160.00

(Note) Revisions to the latest dividend forecast: No

3. Consolidated Financial Forecast for Fiscal 2021 (April 1, 2021 – March 31, 2022)

(Percentage figures show year on year change)

	Revenue		Operating profit		Profit before income taxes		Profit for the year		Profit for the year attributable to owners of the parent		Earnings per share attributable to owners of the parent (basic)
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥)
Fiscal Year	701,000	8.5	76,000	46.8	76,500	45.6	59,000	38.9	58,500	38.9	208.00

(Note) Revisions to the latest financial forecast: Yes

* Explanatory Notes

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

(2) Changes in accounting policies and accounting estimates:
1) Changes in accounting policies required by IFRS: Yes
2) Changes in accounting policies other than 1): No
3) Changes in accounting estimates: No

(3) Number of shares issued (common shares):

1) Number of shares issued (including treasury shares)	As of June 30, 2021	296,566,949	As of March 31, 2021	296,566,949
2) Number of treasury shares	As of June 30, 2021	9,826,160	As of March 31, 2021	9,839,021
3) Weighted average number of shares outstanding	For the three-month period ended June 30, 2021	286,671,064	For the three-month period ended June 30, 2020	286,583,220

The Company's shares held through a trust (61,510 shares) are not included in the number of treasury shares as of the end of the period, but are included in the average number of shares outstanding as treasury shares that are deducted from the calculation of earnings per share.

* This financial report is not subject to the quarterly review procedures by independent auditors.

* Explanation concerning the appropriate use of results forecast and other special instructions:

(Caution concerning forward-looking statements)
Materials and information provided in this financial disclosure may contain "forward-looking statements" based on expectations, business goals, estimates, forecasts and assumptions that are subject to risks and uncertainties as of the publication date of these materials. Accordingly, actual outcomes and results may differ materially from these statements depending on a number of important factors. Please refer to pages 9-10 for details with regard to the assumptions and other related matters concerning the consolidated financial forecast.

(Methods for obtaining supplementary materials and content of financial results disclosure meeting)
Supplementary materials are attached to this financial report. The Company plans to hold a financial results disclosure meeting for institutional investors and securities analysts on Wednesday, August 4, 2021. The handouts from the disclosure meeting will be made available on the Company's website after the event.

Supplemental Materials: Table of Contents

1. Qualitative Information regarding Financial Results for the Period

(1) Operating Results

[Revenue and Profit]

○ Eisai Co., Ltd. (“the Company”) and its affiliates (collectively referred to as “the Group”) recorded the following consolidated financial results for the three-month period ended June 30, 2021.

(¥billion)

	Three-month period ended June 30, 2020	**Three-month period ended June 30, 2021**	Year on year change (%)
Revenue	165.6	**198.9**	120.1
Cost of sales	38.3	**39.2**	102.5
Gross profit	127.3	**159.6**	125.4
Selling, general and administrative expenses	64.9	**74.7**	115.1
Research and development expenses	30.5	**41.8**	137.0
Other income	0.7	**13.4**	1892.7
Operating profit	32.1	**55.4**	172.5
Profit before income taxes	32.4	**55.8**	171.9
Profit for the period	24.8	**42.3**	170.9
Profit for the period attributable to owners of the parent	24.4	**42.2**	172.6

○ The Group’s revenue increased significantly primarily due to the continuous growth of global brands such as anticancer agent Lenvima and an upfront payment of ¥49.6 billion from Bristol Myers Squibb (the U.S.) under strategic collaboration for antibody drug conjugate MORAb-202.

○ Regarding revenue from global brands, revenue for Lenvima, anticancer agent Halaven, antiepileptic agent Fycompa and insomnia treatment Dayvigo was ¥44.2 billion (127.4% year on year), ¥10.2 billion (108.5% year on year), ¥7.4 billion (116.0% year on year) and ¥2.6 billion (¥0.1 billion in the same period of the previous fiscal year), respectively.

○ Selling, general and administrative expenses increased significantly mainly due to the increase in shared profit paid to Merck & Co., Inc., Kenilworth, N.J., U.S.A. following Lenvima’s revenue growth and proactive investment for the launch of Alzheimer’s disease treatment ADUHELM (aducanumab), jointly developed and commercialized with Biogen Inc. (the U.S., hereinafter “Biogen”).

○ Research and development expenses increased significantly mainly due to aggressive resource investment in Lenvima’s combination therapy with anti-PD-1 antibody pembrolizumab of Merck & Co., Inc., Kenilworth, N.J., U.S.A., as well as ADUHELM and

anti-amyloid beta protofibril antibody lecanemab, which is also jointly developed with Biogen.

○ Other income increased significantly due to divestiture of rights for antiepileptic agent Zonegran in Europe, the Middle East, Russia and Australia to Advanz Pharma (U.K.).

○ As a result of the above, operating profit increased significantly.

[Performance by Segment]

(Revenue for each segment indicates revenue from external customers)

The Group's business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia and Oceania), Asia and Latin America (primarily South Korea, Taiwan, Hong Kong, India, ASEAN, Central and South America) and OTC and others (Japan).

<Japan pharmaceutical business>

○ Total revenue came to ¥49.6 billion (83.1 % year on year), with a segment profit of ¥15.6 billion (61.9% year on year). Revenue and profit decreased mainly due to drug price revision, launch of generics for Lyrica, a pain treatment being co-promoted with Pfizer Japan Inc., and transfer of rights for anticancer agent Treakisym which took place in December 2020 due to expiration of the business alliance.

○ Regarding revenue by products, from neurology products, revenue for insomnia treatment Lunesta and Dayvigo came to ¥2.9 billion (81.1% year on year) and ¥1.9 billion (¥0.1 billion in the same period of the previous fiscal year), respectively. Revenue for Aricept, a treatment for Alzheimer's disease dementia, totaled ¥1.8 billion (62.1% year on year). Co-promotion revenue for Lyrica totaled ¥1.6 billion (25.5% year on year). Revenue for Fycompa was ¥1.2 billion (100.6% year on year). Among oncology products, revenue for Lenvima and Halaven came to ¥2.5 billion (67.7% year on year) and ¥2.0 billion (88.5% year on year), respectively. Fully human anti-TNF-α monoclonal antibody Humira earned revenue of ¥11.4 billion (91.7% year on year).

○ Anticancer agent Remitoro was launched in May 2021.

<Americas pharmaceutical business>

○ Total revenue came to ¥38.3 billion (112.1% year on year), with a segment profit of ¥17.9 billion (104.2% year on year).

○ Regarding revenue by products, from neurology products, revenue for Fycompa came to ¥3.4 billion (112.9% year on year) achieving growth. Revenue for antiepileptic agent Banzel was ¥2.8 billion (55.1% year on year). Among oncology products, Lenvima earned ¥24.4 billion (113.1% year on year) achieving growth. Revenue for Halaven came to ¥3.3 billion (102.5% year on year).

<China pharmaceutical business>

○ Revenue totaled ¥26.9 billion (112.6% year on year), with a segment profit of ¥15.9 billion (114.9% year on year).

○ Regarding revenue by products, revenue for Lenvima totaled ¥10.5 billion (252.6% year on year) achieving significant growth following expansion of access to medicine due to listing on the National Reimbursement Drug List. Revenue for peripheral neuropathy treatment Methycobal was ¥3.3 billion (47.7% year on year) due to sales price reduction as a result of application of the government's centralized procurement system. Liver disease and anti-allergy agents Stronger Neo-Minophagen C and Glycyron Tablets together recorded ¥2.3 billion (96.8% year on year). Proton pump inhibitor Pariet earned ¥2.3 billion (132.2% year on year).

<EMEA pharmaceutical business>

○ Revenue totaled ¥14.1 billion (105.2% year on year). A segment profit totaled ¥20.8 billion (315.7% year on year) due to divestiture of rights for Zonegran.

○ Regarding revenue by products from neurology products, revenue for Fycompa came to ¥2.2 billion (125.4% year on year) achieving growth. Among oncology products, revenue for Lenvima/Kisplyx and Halaven both achieved growth, recording ¥4.8 billion (123.7% year on year) and ¥3.4 billion (108.5% year on year), respectively.

<Asia and Latin America pharmaceutical business>

○ Revenue totaled ¥13.1 billion (118.3% year on year), with a segment profit of ¥5.9 billion (137.6% year on year).

○ Regarding revenue by products, Lenvima achieved significant growth, recording revenue of ¥2.0 billion (140.6% year on year). Revenue for Aricept came to ¥3.0 billion (117.2% year on year). Revenue for Humira came to ¥2.1 billion (105.5% year on year).

○ Dayvigo was launched in Hong Kong in June 2021.

○ Bile acid transporter inhibitor Goofice was launched in Thailand in July 2021.

< OTC and others business>

○ Revenue totaled ¥5.2 billion (84.8% year on year), with a segment profit of ¥0.7 billion (49.0% year on year).

○ Revenue for Chocola BB Group came to ¥3.5 billion (113.5% year on year) achieving growth, while revenue for Etak Group including Etak Antimicrobial Spray α decreased.

(2) Financial Position

[Assets, Liabilities, and Equity]

○ Total assets as of the end of the period amounted to ¥1,129.3 billion (up ¥39.3 billion from the end of the previous fiscal year). Trade and other receivables increased due to recording of an upfront payment and reimbursement for research and development payment from Bristol Myers Squibb.

○ Total liabilities as of the end of the period amounted to ¥382.0 billion (up ¥19.9 billion from the end of the previous fiscal year). Other financial liabilities increased due to recording of reimbursement for research and development payment from Bristol Myers Squibb as deposits received.

○ Total equity as of the end of the period amounted to ¥747.4 billion (up ¥19.4 billion from the end of the previous fiscal year), increasing due to recording of profit for the period exceeding dividends paid.

○ As a result of the above, the ratio of equity attributable to owners of the parent was 64.0% (down 0.5 percentage points from the end of the previous fiscal year).

[Cash Flows]

○ Net cash from operating activities amounted to an outflow of ¥14.3 billion (inflow of ¥10.0 billion in the same period of the previous fiscal year). While profit before income taxes increased, working capital increased mainly due to recording of an upfront payment from Bristol Myers Squibb.

○ Net cash used in investing activities amounted to an inflow of ¥0.1 billion (outflow of ¥12.5 billion in the same period of the previous fiscal year). While there were capital expenditures following the expansion of research facilities and production facilities, proceeds from sale of property, plant and equipment and intangible assets were recorded due to divestiture of rights for Zonegran.

○ Net cash used in financing activities amounted to an outflow of ¥22.5 billion (down ¥2.9 billion from the same period of previous fiscal year), mainly due to dividends paid.

○ As a result of the above, cash and cash equivalents as of the end of the period stood at ¥213.1 billion (down ¥35.7 billion from the end of the previous fiscal year). Free cash flow (cash flow from operating activities less capital expenditures) for the period was outflow of ¥14.1 billion.

(3) Research & Development Pipeline, Alliances, and Other Events

[Status of Ongoing Research & Development Pipelines]

○ Anticancer agent Lenvima (product name for renal cell carcinoma indication in Europe: Kisplyx, lenvatinib, jointly developed with Merck & Co., Inc., Kenilworth, N.J., U.S.A.)

- ✧ Approved for use in the treatment of thyroid cancer (monotherapy) in over 75 countries including Japan, the United States, in Europe, China and in Asia.
- ✧ Approved for use in the (first-line) treatment of hepatocellular carcinoma (monotherapy) in over 70 countries including Japan, the United States, in Europe, China and in Asia.
- ✧ Approved for use in the treatment of unresectable thymic carcinoma (monotherapy) in Japan.
- ✧ Approved in combination with everolimus for use in the treatment of renal cell carcinoma (second-line) in over 60 countries, including the United States and in Europe.
- ✧ In July 2021, the agent was approved in combination with the anti-PD-1 antibody pembrolizumab from Merck & Co., Inc., Kenilworth, N.J., U.S.A. in the United States for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation based on Study 309 (Phase III study). The combination therapy with pembrolizumab has obtained approval (including conditional approval) for the similar indication in more than 10 countries such as Canada and Australia based on Study 111 (Phase I/II study).

- ✧ Application was submitted in Europe for an additional indication of the combination therapy with pembrolizumab as a treatment for patients with and advanced endometrial carcinoma. In April 2021, an application was submitted in Japan for an additional indication of the combination therapy with pembrolizumab as a treatment for advanced uterine body cancer and has received orphan drug designation for the indication from the MHLW in Japan.
- ✧ Applications were submitted in Japan and Europe for an additional indication of the combination therapy with pembrolizumab as a treatment for patients with advanced renal cell carcinoma. In April 2021, the FDA has accepted the application for an additional indication of the combination therapy with pembrolizumab for advanced renal cell carcinoma and granted Priority Review for the application.
- ✧ Regarding studies of the agent in combination with pembrolizumab, respective Phase III studies for endometrial carcinoma (first-line), hepatocellular carcinoma (first-line), melanoma (first-line), nonsquamous non-small cell lung cancer (first-line), non-small cell lung cancer (second-line), head and neck cancer (first-line), bladder cancer (first-line), hepatocellular carcinoma (first-line, in combination with transarterial chemoembolization), gastroesophageal adenocarcinoma (first-line), colorectal cancer (third-line) are underway in the United States, Europe and other countries. A Phase III study for squamous cell carcinoma of the esophagus (first-line) has been initiated in Japan, the United States, Europe and China. Regarding a Phase III study for PD-L1 positive non-small cell lung cancer (first-line), the study was discontinued following the recommendation of the external Data Monitoring Committee.
- ✧ Regarding studies of the agent in combination with pembrolizumab, phase II studies for melanoma (second-line) and head and neck cancer (second-line), as well as a Phase II basket trial in multiple cancer types are underway in the United States, Europe and other countries.

○ Anticancer agent Halaven (eribulin)

- ✧ Approved for use in the treatment of breast cancer in over 75 countries including Japan, the United States, in Europe, China and in Asia.
- ✧ Approved for use in the treatment of liposarcoma (soft tissue sarcoma in Japan) in over 75 countries, including Japan, the United States, in Europe and in Asia.
- ✧ A Phase I/II study for the combination therapy of the liposomal formulation of Halaven and anti-PD-1 antibody nivolumab of Ono Pharmaceutical Co., Ltd. (Osaka, Japan) is underway in Japan.

○ Antiepileptic agent Fycompa (perampanel)

- ✧ Approved in over 70 countries including Japan, the United States, in Europe, China and in Asia, as an adjunctive therapy for use in the treatment of partial-onset seizures in patients with epilepsy 12 years of age and older. The agent was approved for monotherapy and adjunctive use in the treatment of partial-onset seizures in patients with epilepsy 4 years of age and older in Japan and the United States. The agent was approved for adjunctive use in the treatment of partial-onset seizures in patients with epilepsy 4 years of age and older in Europe.

- ✧ Approved in over 70 countries including Japan, the United States, in Europe and in Asia, as an adjunctive therapy for use in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older. The agent was approved an adjunctive therapy for primary generalized tonic-clonic seizures in pediatric patients with epilepsy 7 years of age and older in Europe.
- ✧ Approved in China in July 2021 for two indications as a monotherapy for partial-onset seizures and a monotherapy / an adjunctive treatment for pediatric indication for partial onset seizures in patients with epilepsy 4 years or older.
- ✧ A Phase III study for Lennox-Gastaut syndrome is underway in Japan, the United States and Europe.

○ Orexin receptor antagonist Dayvigo (lemborexant)

- ✧ The agent was approved for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults in the United States, Canada and Hong Kong.
- ✧ The agent was approved for the treatment for insomnia in Japan and India.
- ✧ New drug applications seeking approval for the treatment of insomnia were submitted in Australia, Brazil, Asia and other countries.
- ✧ A Phase II study for irregular sleep-wake rhythm disorder associated with Alzheimer's disease dementia is finished and consideration for future development is underway.

○ Alzheimer’s disease (AD) treatment ADUHELM (aducanumab, jointly developed with Biogen)

- ✧ In June 2021, the agent was granted accelerated approval as AD treatment in the United States. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).
- ✧ New drug applications seeking approval for the treatment of AD were submitted in Japan, Europe, Australia, Brazil, Canada, Switzerland, Mexico, Israel, South Korea and the United Arab Emirates.

○ Anti-amyloid beta protofibril antibody lecanemab (development code: BAN2401, jointly developed with Biogen)

- ✧ A Phase III study (Clarity AD) in patients with mild cognitive impairment due to AD or mild AD (collectively known as early AD) is underway in Japan, the United States, Europe and China.
- ✧ A Phase III study (AHEAD 3-45) for preclinical (asymptomatic) AD is underway. In this study, the agent has been selected by the Alzheimer's Clinical Trials Consortium (ACTC) as a treatment to be evaluated.
- ✧ In June 2021, the agent was granted Breakthrough Therapy designation from the FDA for AD treatment.

○ In June 2021, anticancer agent Tazverik (tazemetostat, development code: E7438) obtained manufacturing and marketing approval for the treatment of EZH2 gene mutation-positive follicular lymphoma in Japan.

○ In May 2021, a new drug application for ulcerative colitis treatment AJM300 (development code, carotegrast methyl) was submitted in Japan. The agent has been jointly developed by EA Pharma Co., Ltd., a subsidiary of the Company, and Kissei Pharmaceutical Co., Ltd. (Nagano, Japan).

○ The development of anticancer agent MORAb-009 (development code) for mesothelioma which was at Phase I/II stage in the United States and Europe has been finished.

[Major Alliances, Agreements and Other Events]

○ In April 2021, Gilead K.K. (Tokyo) submitted an application for an additional indication for Jyseleca, a JAK (Janus kinase) inhibitor, for the treatment of ulcerative colitis with an inadequate response to conventional therapies.

○ In April 2021, Eisai entered into a business alliance agreement with Saitama Resona Bank, Limited (Saitama, Japan) for building an ecosystem with the aim of supporting people living with and preventing dementia in Saitama Prefecture.

○ In May 2021, Eisai entered into a joint research and development (R&D) agreement with the National Cancer Center Japan (Tokyo) concerning “Basic research on the drug discovery and development to accelerate development of anticancer drugs in treatment of patients with rare cancers and refractory cancers” and commenced research activities.

○ In May 2021, Eisai entered into a business alliance agreement with ITO EN, LTD. (Tokyo) concerning the initiatives for supporting people living with and preventing dementia with the aim of realizing a healthy and long-lived society.

○ In June 2021, Eisai entered into an agreement to divest its rights for antiepileptic agent Zonegran in Europe, the Middle East, Russia and Australia to Advanz Pharma (U.K.).

○ In June 2021, Eisai entered into an exclusive global strategic collaboration agreement with Bristol Myers Squibb for the co-development and co-commercialization of MORAb-202 (development code), an antibody drug conjugate developed by Eisai.

(4) Information on Outlook for the Future including Financial Forecast (April 1, 2021 – March 31, 2022)

[Consolidated Financial Forecast]

○ The consolidated financial forecast for fiscal 2021 (April 1, 2021 – March 31, 2022) have been revised from the forecasts previously announced on May 12, 2021, as follows:

	Revised forecast		Previous forecast		Increase/ Decrease	Rate of change
	(A)	YOY	(B)	YOY	(A-B)	
Revenue	¥701.0 billion	108.5%	¥681.0 billion	105.4%	up ¥20.0 billion	up 2.9%
Operating profit	¥76.0 billion	146.8%	¥58.0 billion	112.0%	up ¥18.0 billion	up 31.0%
Profit before income taxes	¥76.5 billion	145.6%	¥58.5 billion	111.3%	up ¥18.0 billion	up 30.8%
Profit for the year	¥59.0 billion	138.9%	¥45.0 billion	105.9%	up ¥14.0 billion	up 31.1%
Profit for the year attributable to owners of the parent	¥58.5 billion	138.9%	¥44.5 billion	105.7%	up ¥14.0 billion	up 31.5%
Earnings per share attributable to owners of the parent (basic):	¥208.00	141.5%	¥158.00	107.5%	up ¥50.00	up 31.6%

* Assumptions: 1 USD = ¥104.5, 1 EUR = ¥123.5, 1 GBP = ¥136.5, 1 RMB = ¥15.5

<Revenue and profit>

○ Revenue is estimated to be ¥701.0 billion, up ¥20.0 billion from the previously announced forecasts, considering factors such as progress of strategic options scheduled in business plan, including strategic collaboration agreement for MORAb-202, and recent favorable business performance. Operating profit is estimated to be ¥76.0 billion, up ¥18.0 billion from the previously announced forecasts.

○ Profit for the year is estimated to be ¥59.0 billion, up ¥14.0 billion from the previously announced forecasts due to increase in operating profit.

○ The annual dividend forecast remains unchanged at ¥160 per share (the same amount as the previous fiscal year).

[Forecasts and Risk Factors]

○ The materials and information provided in this announcement include current forecasts, targets, evaluations, estimates, assumptions that are accompanied by risks, and other matters that are based on uncertain factors. Accordingly, it is possible that actual results will deviate significantly from forecasts, etc., due to changes to a variety of factors. These risks and uncertainties include general industry and market conditions, fluctuation of interest rates and currency exchange rates, and other aspects of economic conditions in Japan and internationally.

○ Risks and uncertainties that could cause significant fluctuations in the results of the Group or have a material effect on investment decisions are as follows. However, these do not cover all of the risks and uncertainties faced by the Group, and it is possible that they will

be affected in the future by other factors that cannot be foreseen, or are not deemed to be important, at this point in time.

- ○ These are judgments as of the time of the announcement, and statements in the text regarding the future are not guarantees that they will occur or be achieved.
- ○ Risks factors include risks related to management based on the Corporate Philosophy, risks related to establishment of AD franchise, risks related to maximization of the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to uncertainties in new drug development, risks related to occurrences of side effects, risks related to product quality and stable supply, risks related to intellectual property, risks related to litigations, risks related to data reliability, risks related to medical cost containment measures, risks related to succession, risks related to information security, risks related to COVID-19, risks related to climate change, risks related to impairment of goodwill and intangible assets.
- ○ For further details on the above-mentioned risks, please refer to the “Risk Factors” section of the Annual Securities Report.

2. Condensed Interim Consolidated Financial Statements and Major Notes
(1) Condensed Interim Consolidated Statement of Income

(Millions of yen)

	Three-month period ended June 30, 2021	Three-month period ended June 30, 2020
Revenue	198,894	165,583
Cost of sales	(39,250)	(38,282)
Gross profit	159,644	127,301
Selling, general and administrative expenses	(74,725)	(64,924)
Research and development expenses	(41,815)	(30,530)
Other income	13,444	710
Other expenses	(1,141)	(437)
Operating profit	55,407	32,120
Financial income	749	651
Financial costs	(374)	(323)
Profit before income taxes	55,783	32,448
Income taxes	(13,477)	(7,695)
Profit for the period	42,305	24,753
Profit for the period attributable to		
Owners of the parent	42,161	24,425
Non-controlling interests	144	328
Earnings per share		
Basic (yen)	147.07	85.23
Diluted (yen)	147.04	85.20

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three-month period ended June 30, 2021	Three-month period ended June 30, 2020
Profit for the period	42,305	24,753
Other comprehensive income (loss)		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income (loss)	(1,177)	1,100
Subtotal	(1,177)	1,100
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations (loss)	1,269	(2,174)
Cash flow hedges	19	31
Subtotal	1,289	(2,143)
Total other comprehensive income (loss), net of tax	112	(1,043)
Comprehensive income (loss) for the period	42,417	23,710
Comprehensive income (loss) for the period attributable to		
Owners of the parent	42,273	23,378
Non-controlling interests	144	332

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of June 30, 2021	As of March 31, 2021
Assets		
Non-current assets		
Property, plant and equipment	159,074	160,933
Goodwill	171,625	171,783
Intangible assets	110,889	108,641
Other financial assets	40,467	43,817
Other assets	19,272	19,567
Deferred tax assets	65,506	66,923
Total non-current assets	566,833	571,665
Current assets		
Inventories	89,852	85,118
Trade and other receivables	236,336	160,310
Other financial assets	492	267
Other assets	22,746	23,909
Cash and cash equivalents	213,082	248,740
Total current assets	562,507	518,344
Total assets	1,129,341	1,090,009

(Millions of yen)

	As of June 30, 2021	As of March 31, 2021
Equity		
Equity attributable to owners of the parent		
Share capital	44,986	44,986
Capital surplus	77,619	77,628
Treasury shares	(34,013)	(34,049)
Retained earnings	526,030	507,976
Other components of equity	107,930	106,641
Total equity attributable to owners of the parent	722,552	703,183
Non-controlling interests	24,802	24,759
Total equity	747,354	727,942
Liabilities		
Non-current liabilities		
Borrowings	49,913	49,908
Other financial liabilities	38,867	39,825
Provisions	1,449	1,386
Other liabilities	13,548	14,420
Deferred tax liabilities	276	511
Total non-current liabilities	104,053	106,050
Current liabilities		
Borrowings	42,770	39,985
Trade and other payables	80,776	94,548
Other financial liabilities	39,718	16,992
Income taxes payable	9,520	2,522
Provisions	15,594	17,850
Other liabilities	89,555	84,119
Total current liabilities	277,934	256,017
Total liabilities	381,987	362,067
Total equity and liabilities	1,129,341	1,090,009

(4) Condensed Interim Consolidated Statement of Changes in Equity

For the three-month period ended June 30, 2021

(Millions of yen)

	Equity attributable to owners of the parent				
					Other components of equity
	Share capital	Capital surplus	Treasury shares	Retained earnings	Financial assets measured at fair value through other comprehensive income (loss)
As of April 1, 2021	44,986	77,628	(34,049)	507,976	—
Profit for the period	—	—	—	42,161	—
Other comprehensive income (loss)	—	—	—	—	(1,177)
Comprehensive income (loss) for the period	—	—	—	42,161	(1,177)
Dividends	—	—	—	(22,938)	—
Share-based payments	—	(14)	—	—	—
Acquisition of treasury shares	—	—	(13)	—	—
Disposal of treasury shares	—	5	49	—	—
Reclassification	—	—	—	(1,177)	1,177
Other changes	—	—	—	8	—
Total transactions with owners (loss)	—	(9)	36	(24,108)	1,177
As of June 30, 2021	44,986	77,619	(34,013)	526,030	—

	Equity attributable to owners of the parent					
	Other components of equity					
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity	Equity attributable to owners of the parent	Non-controlling interests	Total equity
As of April 1, 2021	106,710	(69)	106,641	703,183	24,759	727,942
Profit for the period	—	—	—	42,161	144	42,305
Other comprehensive income (loss)	1,269	19	112	112	0	112
Comprehensive income (loss) for the period	1,269	19	112	42,273	144	42,417
Dividends	—	—	—	(22,938)	(101)	(23,039)
Share-based payments	—	—	—	(14)	—	(14)
Acquisition of treasury shares	—	—	—	(13)	—	(13)
Disposal of treasury shares	—	—	—	54	—	54
Reclassification	—	—	1,177	—	—	—
Other changes	—	—	—	8	—	8
Total transactions with owners (loss)	—	—	1,177	(22,904)	(101)	(23,005)
As of June 30, 2021	107,980	(49)	107,930	722,552	24,802	747,354

For the three-month period ended June 30, 2020

(Millions of yen)

	Equity attributable to owners of the parent				
					Other components of equity
	Share capital	Capital surplus	Treasury shares	Retained earnings	Financial assets measured at fair value through other comprehensive income (loss)
As of April 1, 2020	44,986	77,609	(34,338)	505,359	—
Profit for the period	—	—	—	24,425	—
Other comprehensive income (loss)	—	—	—	—	1,100
Comprehensive income (loss) for the period	—	—	—	24,425	1,100
Dividends	—	—	—	(22,933)	—
Share-based payments	—	(8)	—	—	—
Acquisition of treasury shares	—	—	(7)	—	—
Disposal of treasury shares	—	(0)	85	—	—
Reclassification	—	—	—	1,100	(1,100)
Other changes	—	—	—	6	—
Total transactions with owners (loss)	—	(8)	79	(21,827)	(1,100)
As of June 30, 2020	44,986	77,601	(34,260)	507,957	—

	Equity attributable to owners of the parent					
	Other components of equity					
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity	Equity attributable to owners of the parent	Non-controlling interests	Total equity
As of April 1, 2020	84,704	(192)	84,511	678,127	24,503	702,630
Profit for the period	—	—	—	24,425	328	24,753
Other comprehensive income (loss)	(2,177)	31	(1,047)	(1,047)	4	(1,043)
Comprehensive income (loss) for the period	(2,177)	31	(1,047)	23,378	332	23,710
Dividends	—	—	—	(22,933)	(172)	(23,105)
Share-based payments	—	—	—	(8)	—	(8)
Acquisition of treasury shares	—	—	—	(7)	—	(7)
Disposal of treasury shares	—	—	—	85	—	85
Reclassification	—	—	(1,100)	—	—	—
Other changes	—	—	—	6	—	6
Total transactions with owners (loss)	—	—	(1,100)	(22,856)	(172)	(23,029)
As of June 30, 2020	82,527	(162)	82,365	678,648	24,663	703,311

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	For the three-month period ended June 30, 2021	For the three-month period ended June 30, 2020
Operating activities		
Profit before income taxes	55,783	32,448
Depreciation and amortization	9,455	8,681
(Increase) decrease in working capital	(63,316)	(22,885)
Interest and dividends received	700	731
Interest paid	(281)	(267)
Income taxes paid	(2,270)	(7,118)
Other	(14,342)	(1,542)
Net cash from (used in) operating activities	(14,271)	10,049
Investing activities		
Purchases of property, plant and equipment	(12,118)	(8,841)
Purchases of intangible assets	(2,758)	(3,235)
Proceeds from sale of property, plant and equipment and intangible assets	13,288	13
Purchases of financial assets	(477)	(610)
Proceeds from sale and redemption of financial assets	2,229	38
Payments of time deposits exceeding three months	(0)	(1)
Proceeds from redemption of time deposits exceeding three months	—	74
Other	(40)	65
Net cash from (used in) investing activities	124	(12,497)
Financing activities		
Net increase (decrease) in short-term borrowings	2,782	—
Repayments of lease liabilities	(2,532)	(2,369)
Dividends paid	(22,938)	(22,933)
Other	156	(89)
Net cash from (used in) financing activities	(22,533)	(25,391)
Effect of exchange rate change on cash and cash equivalents	1,021	(97)
Net increase (decrease) in cash and cash equivalents	(35,658)	(27,935)
Cash and cash equivalents at beginning of period	248,740	254,244
Cash and cash equivalents at end of period	213,082	226,308

(6) Notes to Condensed Interim Consolidated Financial Statements

(Going Concern)

Not applicable

(Changes in Accounting Policies)

With the exception of the following, all significant accounting policies that are applied to these condensed interim consolidated financial statements for this period are the same as those that were applied to the consolidated financial statements for the previous fiscal year.

(1) Accounting standards and interpretations the Group applied from the fiscal year ending March 31, 2022

None of the following accounting standards and interpretations applied by the Group has any major impact on the condensed interim consolidated financial statements for this period.

Accounting standards and interpretations		Mandatory application (Date of commencement)	To be applied by the Group	Description
IFRS 4 IFRS 7 IFRS 9 IFRS 16 IAS 39	Insurance Contracts Financial Instruments: Disclosures Financial Instruments Leases Financial Instruments: Recognition and Measurements	January 1, 2021	Fiscal year ending March 31, 2022	Amendments to the effects on financial statements when replacing the old interest rate benchmark with an alternative benchmark rate as a result of IBOR reform
IFRS 16	Leases	April 1, 2021	Fiscal year ending March 31, 2022	Amendments to the extension of the application period concerning rent concessions related to COVID-19

(2) Co-development and co-promotion

The Group has signed co-development and co-promotion agreements on its developing or developed products with its alliance partners. Pharmaceutical goods sales (goods sales) are recorded on revenue and the relevant expenses are recorded in total on cost of sales, selling, general and administrative expenses (SG&A expenses) and research and development expenses (R&D expenses), respectively. The Group records the partners' proportionate share of revenue generated from its pharmaceutical goods sales on SG&A expenses as co-promotion expenses.

Based on the above agreements and the economic conditions, the Group allocates the received considerations (upfront payments, milestone payments, etc.) from the alliance partners to license grant, co-development activity and co-promotion activity.

a) License grant

License grant is recognized as revenue in accordance with "5. Financial Information, 1. Consolidated Financial Statements, etc., (1) Consolidated Financial Statements, Notes to Consolidated Financial Statements, 3. Significant Accounting Policies, (4) Revenue, b) License revenue" described in the Group's securities report for the fiscal year ended March 31, 2021. Based on the above agreements and the economic conditions, revenue, which does not fall under the category of revenue from contracts with customers, is classified as revenue arising from other sources.

b) Co-development activity

Considerations allocated as co-development activity are recorded as reversal of R&D expenses according to the progress of co-development activity.

c) Co-promotion activity

Considerations allocated as co-promotion activity are recorded as reversal of other income or the relevant expenses (cost of sales and SG&A expenses) according to the progress and results of co-promotion activity.

Global Strategic Collaboration for Alzheimer's disease treatment ADUHELM between Eisai Co., Ltd. and Biogen Inc. (the U.S.)

In June 2021, the U.S. Food and Drug Administration granted accelerated approval for Alzheimer's disease treatment ADUHELM (aducanumab) in the U.S. The Company has signed co-development and co-promotion agreements on Alzheimer's disease treatment with Biogen Inc., and the Company and Biogen Inc. co-develop and co-promote ADUHELM based on the agreements. The Group markets ADUHELM in Japan and Asia (excluding China and South Korea), while Biogen Inc. markets ADUHELM in the U.S., Europe and the rest of the world. The profit or loss related to ADUHELM generated by the Group and Biogen Inc. is aggregated, and the aggregated profit or loss is shared between the Group and Biogen Inc. in proportion to the profit-sharing ratio by region. The following profit or loss is shared with the Group: 45% share of potential profit or loss in the U.S., 31.5% share of potential profit or loss in Europe, 80% share of potential profit or loss in Japan and Asia (excluding China and South Korea), and 50% share of potential profit or loss in the rest of the world. The Group also incurs the milestones paid by Biogen Inc. to Neurimmune (Switzerland), which out-licensed the rights for ADUHELM to Biogen Inc., in proportion to the above-mentioned profit-sharing ratio by region.

The Group's accounting procedures regarding the agreement are as follows:

- Biogen Inc. recognizes revenue on sales of ADUHELM in the U.S., where Biogen Inc. started to market ADUHELM, and in the other regions where Biogen Inc. markets ADUHELM. The Group recognizes the amount of the expenses recognized by the Group in co-promotion activities (SG&A expenses) plus its portion of operating profit or loss (excluding R&D expenses) as revenue. If this amount is negative, it is recognized as SG&A expenses.
- Regarding R&D expenses on ADUHELM, the Group recognizes its portion of the incurred R&D expenses based on the agreement as R&D expenses. Regarding the expenses on the co-commercialization in the regions before obtaining approval, the Group recognizes its portion of the expenses incurred from the co-commercialization as SG&A expenses.
- Regarding the milestones which Biogen Inc. pays to Neurimmune, the Group recognizes its portion of the milestones incurred as intangible assets. Amortization of the intangible assets is recognized as cost of sales.

Global Strategic Collaboration for antibody drug conjugate MORAb-202 between Eisai Co., Ltd. and Bristol Myers Squibb (the U.S.)

In June 2021, the Company entered into an exclusive global strategic collaboration agreement for the co-development and co-commercialization of antibody drug conjugate MORAb-202 (development code) with Bristol Myers Squibb. Under this agreement, the Company and Bristol Myers Squibb will co-develop and co-commercialize MORAb-202 in collaboration territories. Bristol Myers Squibb will be solely responsible for developing and commercializing MORAb-202 in regions outside of the collaboration territories.

Bristol Myers Squibb paid the Group an upfront payment of $650 million including $200 million as payment toward R&D expenses of the Group. In addition, the Group will receive a maximum of up to $2,450 million for the achievements of development, regulatory and sales milestones. Assuming the achievement of all development, regulatory and sales goals, the total amount of payments to the Group, including the upfront payment at the time of agreement, has the potential to reach up to $3,100 million.

The Group's accounting procedures regarding the agreement are as follows:

- After the time of agreement, R&D expenses on MORAb-202 are jointly shared between the Group and Bristol Myers Squibb. Based on the agreement, the Group recognizes its portion of the incurred R&D expenses on MORAb-202 as R&D expenses.
- At the time of agreement, the Group receives $200 million as reimbursement for R&D expenses from Bristol Myers Squibb and recognizes it as deposits received. On each occasion that R&D expenses related to MORAb-202 occur in the Group, the Group withdraws these deposits received and recognizes them as reversal of R&D expenses.
- Under this agreement, the Group allocates the upfront payment (excluding reimbursement for R&D expenses) and sales milestone payments to the consideration of the license grant. According to the development and regulatory milestone payments applied, the Group allocates them to the considerations of the license grant and co-development activity, respectively.

(Segment Information)

Reporting segments are units for which the Group can obtain independent financial information and for which top management undertakes periodic reviews in order to determine the allocation of management resources and evaluate performance.

The Group's business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia and Oceania), Asia and Latin America (primarily South Korea, Taiwan, Hong Kong, India, ASEAN, Central and South America), and OTC and others (Japan).

(Millions of yen)

	Three-month period ended June 30, 2021		Three-month period ended June 30, 2020	
	Revenue	Segment profit (loss)	Revenue	Segment profit (loss)
Pharmaceutical business				
Japan	49,629	15,637	59,725	25,270
Americas	38,304	17,901	34,182	17,181
China	26,855	15,905	23,841	13,847
EMEA	14,096	20,803	13,404	6,590
Asia and Latin America	13,118	5,862	11,088	4,259
OTC and others	5,198	687	6,127	1,402
Reporting segment total	147,200	76,795	148,366	68,550
Other business (Note 1)	51,694	49,843	17,217	15,136
Total	198,894	126,638	165,583	83,686
R&D expenses (Note 2)	—	(41,815)	—	(30,530)
Group headquarters' management costs and other expenses (Note 3)	—	(29,416)	—	(21,035)
Operating profit in the condensed interim consolidated statement of income	—	55,407	—	32,120

(Note 1) "Other business" mainly includes the license revenue and pharmaceutical ingredient business of the parent company. For the three-month period ended June 30, 2021, an upfront payment of ¥49,649 million from Bristol Myers Squibb under the strategic collaboration for antibody drug conjugate MORAb-202 was included in "Revenue" and "Segment profit (loss)."

(Note 2) "R&D expenses" are not allocated to any particular segment as the Group manages such expenses on a global basis.

(Note 3) "Group headquarters' management costs and other expenses" are the costs and expenses covering Group-wide operations which include the amount of profits and expenses shared under strategic collaborations with partners. For the three-month period ended June 30, 2021, shared profit of ¥19,780 million (¥16,497 million for the three-month period ended June 30, 2020) for anticancer agent Lenvima paid by the Group to Merck & Co., Inc., Kenilworth, N.J., U.S.A. was included in Group headquarters' management costs and other expenses.

(Consolidated Statement of Income)

(1) Revenue

The Group disaggregates revenue by type of goods or services. Disaggregation of revenue by reporting segment is as follows. All revenue for the three-month periods ended June 30, 2021 and June 30, 2020 is recognized based on contracts with customers.

Three-month period ended June 30, 2021

(Millions of yen)

	Revenue from pharmaceutical goods sales	License revenue	Other revenue	Total
Pharmaceutical business				
Japan	47,006	495	2,128	49,629
Americas	38,241	―	63	38,304
China	26,855	―	―	26,855
EMEA	14,096	―	―	14,096
Asia and Latin America	12,994	123	―	13,118
OTC and others	5,198	―	―	5,198
Reporting segment total	144,390	619	2,191	147,200
Other business (Note 1)	―	49,785	1,909	51,694
Total	144,390	50,404	4,100	198,894

(Note 1) “Other business” mainly includes the license revenue and pharmaceutical ingredient business of the parent company. For the three-month period ended June 30, 2021, an upfront payment of ¥49,649 million from Bristol Myers Squibb under the strategic collaboration for antibody drug conjugate MORAb-202 was included in “License revenue.”

Three-month period ended June 30, 2020

(Millions of yen)

	Revenue from pharmaceutical goods sales	License revenue	Other revenue	Total
Pharmaceutical business				
Japan	52,790	282	6,653	59,725
Americas	34,182	―	―	34,182
China	23,841	―	―	23,841
EMEA	13,404	―	―	13,404
Asia and Latin America	11,066	22	―	11,088
OTC and others	6,127	―	―	6,127
Reporting segment total	141,409	304	6,653	148,366
Other business (Note 1)	―	14,806	2,411	17,217
Total	141,409	15,110	9,064	165,583

(Note 1) “Other business” mainly includes the license revenue and pharmaceutical ingredient business of the parent company.

(2) Selling, general and administrative expenses

For the three-month period ended June 30, 2021, the Group recognized shared profit of ¥19,780 million (¥16,497 million for the three-month period ended June 30, 2020) for anticancer agent Lenvima paid by the Group to Merck & Co., Inc., Kenilworth, N.J., U.S.A. as SG&A expenses.

(3) Other income

For the three-month period ended June 30, 2021, the Group recognized gains on sale of non-current assets of ¥13,286 million as other income. The gains on sale of non-current assets consisted mainly of the gains arising from the divestiture of its rights for the antiepileptic agent Zonegran in Europe and other regions.

(Consolidated Statement of Cash Flows)

For the three-month period ended June 30, 2021, proceeds from sale of property, plant and equipment and intangible assets of ¥13,288 million consisted mainly of the proceeds from the divestiture of the Group's rights for the antiepileptic agent Zonegran in Europe and other regions.

(Significant Subsequent Events)

Not applicable