

CONSOLIDATED FINANCIAL REPORT [IFRS] for the Three-Month Period Ended June 30, 2022

August 5, 2022
Eisai Co., Ltd.

Stock exchange listing: Tokyo Stock Exchange (TSE)

TSE Code: 4523

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Expected date of quarterly report submission: August 5, 2022

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, 2022

(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, 2022	184,262	-7.4	7,434	-86.6	9,722	-82.6	27,970	-33.8	26,897	-36.1	79,702	88.1
Three-month period ended June 30, 2021	198,894	20.1	55,339	72.5	55,715	71.9	42,253	70.9	42,110	72.6	42,365	78.9

	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, 2022	(¥) 93.81	(¥) 93.81
Three-month period ended June 30, 2021	146.89	146.86

(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, 2022	1,272,871	828,349	804,545	63.2	2,806.07
As of March 31, 2022	1,239,315	771,534	748,821	60.4	2,611.82

2. Dividends

	Annual dividend per share				
	End of Q1	End of Q2	End of Q3	End of FY	Total
	(¥)	(¥)	(¥)	(¥)	(¥)
FY 2021	—	80.00	—	80.00	160.00
FY 2022	—				
FY 2022 (Forecast)		80.00	—	80.00	160.00

(Note) Revisions to the latest dividend forecast: No

3. Consolidated Financial Forecast for Fiscal 2022 (April 1, 2022 – March 31, 2023)

(Percentage figures show year on year change)

Fiscal Year	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)	(%)	(¥)
	700,000	-7.4	55,000	2.3	56,500	3.7	58,000	26.9	57,000	18.9	197.80

(Note) Revisions to the latest financial forecast: No

* 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, 2022	296,566,949	As of March 31, 2022	296,566,949
2) Number of treasury shares	As of June 30, 2022	9,736,635	As of March 31, 2022	9,801,133
3) Weighted average number of shares outstanding	For the three-month period ended June 30, 2022	286,707,490	For the three-month period ended June 30, 2021	286,671,064

The Company's shares held through a trust (113,830 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 the page 9 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 Friday, August 5, 2022. The handouts from the disclosure meeting will be made available on the Company's website after the event.

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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, 2022.

	Three-month period ended June 30, 2021	Three-month period ended June 30, 2022	Year on year change (%)
Revenue	198.9	184.3	92.6
Cost of sales	39.2	47.4	120.8
Gross profit	159.6	136.9	85.7
Selling, general and administrative expenses	74.8	92.3	123.4
Research and development expenses	41.8	38.5	92.1
Operating profit	55.3	7.4	13.4
Profit before income taxes	55.7	9.7	17.4
Income taxes	13.5	(18.2)	—
Profit for the period	42.3	28.0	66.2
Profit for the period attributable to owners of the parent	42.1	26.9	63.9

(¥billion)

- While revenue of pharmaceutical business came to ¥181.3 billion (123.2% year on year) increasing significantly due to the continuous growth of global brands such as anticancer agent Lenvima, the Group’s revenue decreased due to the impact caused by the recording of an upfront payment (¥49.6 billion) from Bristol Myers Squibb (the U.S.) in the same period of the previous fiscal year.
- Regarding revenue from global brands, revenue for Lenvima, anticancer agent Halaven, antiepileptic agent Fycompa and insomnia treatment Dayvigo was ¥66.3 billion (150.0% year on year), ¥11.1 billion (109.7% year on year), ¥9.9 billion (133.1% year on year) and ¥6.5 billion (247.1% year on year), respectively.
- Selling, general and administrative expenses increased significantly mainly due to the depreciation of the Japanese yen, in addition to increase in shared profit paid to Merck & Co., Inc., Rahway, NJ, USA following Lenvima’s revenue growth, despite decrease in expenses related to Alzheimer’s disease (AD) treatment ADUHELM (aducanumab).
- Research and development expenses decreased mainly due to controlling of expenses through the partnership model including the recording of regulatory milestone payments for Lenvima from Merck & Co., Inc., Rahway, NJ, USA as reimbursement, despite aggressive resource investment in anti-amyloid beta protofibril antibody lecanemab, jointly developed with Biogen Inc. (the U.S., hereinafter “Biogen”).

- As a result of the above, although operating profit decreased, segment profit of pharmaceutical business increased significantly achieving ¥90.6 billion (133.1% year on year).
- Profit for the period increased compared to profit before income taxes following recording of a credit of income taxes due to the Company's recognition of losses on transferring of investments in subsidiaries for tax purposes following a repayment of paid-in capital from a consolidated U.S. subsidiary to the Company in order to collect capital from the consolidated U.S. subsidiary as part of the Company's capital policy to optimize the global allocation of cash in the Group.

[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, India, ASEAN, Central and South America), and OTC and others (Japan). Effective from this fiscal year, Hong Kong has been changed from the "Asia and Latin America" segment to the "China" segment. Also, as the co-development and co-promotion agreements with Biogen regarding ADUHELM were amended in March 2022, expenses related to ADUHELM (selling, general and administrative expenses) which the Company should share have been included in the "Group headquarters' management costs and other expenses". In addition, gains and losses on sale of non-current assets have been included in the "Group headquarters' management costs and other expenses". The year on year changes in the segment performance for this report are based on this new segmentation.

<Japan pharmaceutical business>

- Total revenue came to ¥57.5 billion (115.8 % year on year), with a segment profit of ¥21.6 billion (138.9% year on year).
- Regarding revenue by products, from neurology products, revenue for Dayvigo came to ¥5.3 billion (285.2% year on year), achieving significant growth. Revenue for Fycompa came to ¥1.6 billion (126.0% year on year) achieving growth. Among oncology products, revenue for Lenvima came to ¥3.6 billion (144.3% year on year) achieving significant growth due to impact of additional indications. Revenue for Halaven came to ¥2.2 billion (113.6% year on year). Fully human anti-TNF- α monoclonal antibody Humira earned revenue of ¥12.6 billion (110.1% year on year). Revenue for chronic constipation treatment Goofice came to ¥1.7 billion (115.3% year on year).

<Americas pharmaceutical business>

- Total revenue came to ¥53.1 billion (138.5% year on year), with a segment profit of ¥31.3 billion (144.0% year on year).

- Regarding revenue by products, from neurology products, revenue for Fycompa and Dayvigo came to ¥4.6 billion (132.6% year on year) and ¥1.1 billion (147.4% year on year), respectively. Among oncology products, Lenvima earned ¥38.5 billion (157.8% year on year) achieving significant growth due to impact of additional indications. Revenue for Halaven came to ¥4.1 billion (124.7% year on year) achieving growth.

<China pharmaceutical business>

- Revenue totaled ¥34.8 billion (127.1% year on year), with a segment profit of ¥20.8 billion (126.4% year on year).
- Regarding revenue by products, revenue for Lenvima and peripheral neuropathy treatment Methycobal both achieved significant growth coming to ¥13.9 billion (128.5% year on year) and ¥4.4 billion (132.8% year on year), respectively. Proton pump inhibitor Pariet earned ¥2.3 billion (100.6% year on year). Liver disease and anti-allergy agents Stronger Neo-Minophagen C and Glycyron Tablets together recorded ¥2.0 billion (85.9% year on year).

<EMEA pharmaceutical business>

- Revenue totaled ¥18.1 billion (128.1% year on year). A segment profit totaled ¥10.2 billion (127.1% year on year).
- Regarding revenue by products from neurology products, revenue for Fycompa came to ¥2.8 billion (129.2% year on year) achieving growth. Among oncology products, revenue for Lenvima/Kispplx achieved significant growth recording ¥8.1 billion (167.1% year on year). Revenue for Halaven came to ¥3.5 billion (103.4% year on year).

<Asia and Latin America pharmaceutical business>

- Revenue totaled ¥12.0 billion (95.0% year on year), with a segment profit of ¥5.3 billion (94.0% year on year) due to ending of development and supply agreement for Humira in South Korea in March 2022.
- Regarding revenue by products, Lenvima achieved growth, recording revenue of ¥2.3 billion (134.3% year on year). Revenue for Aricept, a treatment for Alzheimer's disease dementia, came to ¥3.3 billion (109.9% year on year).
- Dayvigo was launched in India and Singapore in April 2022, and in Taiwan in May of the same year.

< OTC and others business>

- Revenue totaled ¥6.0 billion (115.3% year on year), with a segment profit of ¥1.4 billion (207.8% year on year).
- Revenue for Chocola BB Group came to ¥3.9 billion (111.3% year on year) achieving growth.

(2) Financial Position

[Assets, Liabilities, and Equity]

- Total assets as of the end of the period amounted to ¥1,272.9 billion (up ¥33.6 billion from the end of the previous fiscal year). Assets of overseas consolidated subsidiaries increased due to the depreciation of the Japanese yen. In addition, deferred tax assets of the Company increased.
- Total liabilities as of the end of the period amounted to ¥444.5 billion (down ¥23.3 billion from the end of the previous fiscal year). This was mainly due to a decrease in accounts payable-other to partners.
- Total equity as of the end of the period amounted to ¥828.3 billion (up ¥56.8 billion from the end of the previous fiscal year). Exchange differences on translation of foreign operations increased following the depreciation of yen.
- As a result of the above, the ratio of equity attributable to owners of the parent was 63.2% (up 2.8 percentage points from the end of the previous fiscal year).

[Cash Flows]

- Net cash from operating activities amounted to an inflow of ¥3.9 billion (outflow of ¥14.5 billion in the same period of the previous fiscal year).
- Net cash used in investing activities amounted to an outflow of ¥16.8 billion (inflow of ¥0.3 billion in the same period of the previous fiscal year). There were capital expenditures following the expansion of research facilities and production facilities.
- Net cash used in financing activities amounted to an outflow of ¥25.2 billion (up ¥2.7 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 ¥287.8 billion (down ¥21.8 billion from the end of the previous fiscal year). Free cash flow (cash flow from operating activities less capital expenditures) for the period was an outflow of ¥12.6 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., Rahway, NJ, USA)
 - ◇ Approved for use in the treatment of thyroid cancer (monotherapy) in over 80 countries including Japan, the United States, in Europe, China and in Asia.
 - ◇ Approved for use in the treatment of hepatocellular carcinoma (first-line, monotherapy) in over 80 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 65 countries, including the United States and in Europe.
 - ◇ Approved in combination with the anti-PD-1 therapy pembrolizumab from Merck & Co., Inc., Rahway, NJ, USA for use in the treatment of renal cell carcinoma (first-line) in over 40 countries including Japan, the United States, in Europe and in Asia.
 - ◇ The agent obtained approval (including conditional approval) in combination with

pembrolizumab for use in the treatment of endometrial carcinoma (following prior systemic therapy) in over 45 countries including Japan, the United States, in Europe and in Asia.

- ◇ In August 2022, a Phase III trial investigating the combination therapy with pembrolizumab versus Lenvima monotherapy as a first-line treatment in patients with hepatocellular carcinoma did not meet its dual primary endpoints of overall survival (OS) and progression-free survival (PFS). There were trends toward improvement in OS and PFS for patients who received the combination therapy versus Lenvima monotherapy; however, these results did not meet statistical significance per the pre-specified statistical plan. The median OS of the Lenvima monotherapy arm in the trial was longer than that observed in previously reported clinical trials evaluating Lenvima monotherapy in hepatocellular carcinoma. The safety profile of Lenvima plus pembrolizumab was consistent with previously reported data on the combination. These data will be presented at an upcoming medical conference.
 - ◇ Regarding studies of the agent in combination with pembrolizumab, respective Phase III studies for endometrial carcinoma (first-line), melanoma (first-line), nonsquamous non-small cell lung cancer (first-line, in combination with chemotherapy), non-small cell lung cancer (second-line), head and neck cancer (first-line), hepatocellular carcinoma (first-line, in combination with transcatheter arterial chemoembolization), esophageal carcinoma (first-line, in combination with chemotherapy), gastric cancer (first-line, in combination with chemotherapy), and colorectal cancer (non-MSI-H / mismatch repair proficient [pMMR], third-line) are underway in the United States, Europe and other countries.
 - ◇ 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 80 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 80 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, the United States and China. 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.
 - ◇ 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 in more than 10 countries including Japan, the United States and countries in Asia.
 - ◇ A Phase III study for insomnia is underway in China.
 - ◇ 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.
- Anti-amyloid beta protofibril antibody lecanemab (development code: BAN2401, jointly developed with Biogen)
- ◇ In July 2022, a Biologics License Application (BLA) under the accelerated approval pathway for the treatment of early AD (mild cognitive impairment due to AD or mild AD) based on Study 201 (Phase II study) was accepted by the U.S. Food and Drug Administration (FDA) in the United States. This application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of January 6, 2023. The agent was granted Breakthrough Therapy designation and Fast Track designation for AD treatment in the United States.
 - ◇ A submission of application data to the Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system has been initiated in Japan.
 - ◇ Clarity AD (Phase III study) in patients with early AD is underway in Japan, the United States, Europe and China.
 - ◇ AHEAD 3-45 (Phase III study) for preclinical (asymptomatic) AD is underway in countries including Japan, the United States and in Europe. In this study, the agent has been selected by the Alzheimer's Clinical Trials Consortium (ACTC) as a treatment to be evaluated.
 - ◇ Development of subcutaneous dosing is underway with aim of increasing convenience.
- In May 2022, ultrahigh-dose mecobalamin received orphan drug designation with a prospective indication for delaying the progression of disease and functional impairment of amyotrophic lateral sclerosis (ALS), by the Ministry of Health, Labour and Welfare (MHLW) in Japan. With the result of an investigator-initiated Phase III trial, Eisai plans to submit a new drug application during the fiscal year 2023.
- A Phase II part of Phase I/II clinical trial of E7386 in combination with pembrolizumab for solid tumors has been initiated in Japan, the United States and Europe.

- Phase III REMAP-COVID study of eritoran, a Toll-Like Receptor (TLR) 4 antagonist, for suppression for increasing of severity of COVID-19 in Japan and the United States was discontinued.

[Major Alliances, Agreements and Other Events]

- In April 2022, Centers for Medicare and Medicaid Services (CMS) announced the finalized National Coverage Determination (NCD) for monoclonal antibodies directed against amyloid for the treatment of AD and decided to cover treatments receiving accelerated approval based upon evidence of efficacy from a change in a surrogate endpoint only if patients are enrolled in CMS-approved randomized controlled clinical trials. At the same time, CMS has committed to quickly reconsider the NCD for treatments which have obtained full approval with quality evidence on clinical benefit.
- In May 2022, Eisai established pharmaceutical sales company EISAI PHARMACEUTICALS AFRICA (PTY) LTD as its subsidiary in Republic of South Africa.
- In May 2022, EA Pharma Co., Ltd. (Tokyo, hereinafter EA Pharma) launched a high dose formulation which is a new dosage form of MOVICOL, a chronic constipation treatment, in Japan. Eisai will co-promote the product with EA Pharma.
- In June 2022, Eisai announced that a brain health check utilizing “NouKNOW”, a digital tool (non-medical device) for self-assessment of brain performance (brain health) developed by Eisai, will be promoted as part of the FY2022 dementia examination project conducted by Bunkyo City, Tokyo.
- In June 2022, Eisai signed the Kigali Declaration on neglected tropical diseases (NTDs) and expressed its continued support for the elimination of NTDs towards the achievement of the road map for NTDs 2021-2030 launched by the World Health Organization (WHO).
- In June 2022, Eisai entered into a business alliance agreement with E.design Insurance Co., Ltd. (Tokyo), a direct non-life insurance company of the Tokio Marine Group, aiming to realize a society where people can safely enjoy driving for a longer period of their lives under the theme of “Improving Brain Health for Safe Driving.”
- In July 2022, partnership was ended due to expiration of co-promotion agreement in Japan with Pfizer Inc. (U.S.) for Lyrica, a pain treatment.
- In July 2022, under the concept of Deep Human Biology Learning (DHBL), Eisai transitioned to a new DHBL drug discovery that is based on Eisai’s R&D with creating synergy of “C&I” (Collaboration & Incubation) and “A&I” (Academia/ Industry Alliance). The functions for clinical development and establishment of a solid launch structure for next-generation AD treatments and dementia-related disease treatments were reorganized as Alzheimer's Disease and Brain Health (ADBH) under the Global AD Officer. Eisai plans to integrate H3 Biomedicine Inc., an R&D subsidiary in the United States, into its parent company, Eisai Inc. (U.S.) in this year.

**(4) Information on Outlook for the Future including Financial Forecast
(April 1, 2022 – March 31, 2023)**

[Consolidated Financial Forecast]

- There are no changes to the consolidated financial forecast announced on June 8, 2022.

	FY2021	FY2022 Forecast	Year on year change
Revenue	¥756.2 billion	¥700.0 billion	92.6%
Operating profit	¥53.7 billion	¥55.0 billion	102.3%
Profit before income taxes	¥54.5 billion	¥56.5 billion	103.7%
Profit for the year	¥45.7 billion	¥58.0 billion	126.9%
Profit for the year attributable to owners of the parent	¥48.0 billion	¥57.0 billion	118.9%
Earnings per share attributable to owners of the parent (basic)	¥167.27	¥197.80	118.3%

(Assumptions: 1 USD = ¥125.0, 1 EUR = ¥130.0, 1 GBP = ¥151.5, 1 RMB = ¥19.0)

[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 Concept, risks related to maximization of the value of next-generation AD treatments, 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 trends to contain medical costs, risks related to succession, risks related to acquiring and developing human resources, 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, 2022	Three-month period ended June 30, 2021
Revenue	184,262	198,894
Cost of sales	(47,404)	(39,250)
Gross profit	136,857	159,644
Selling, general and administrative expenses	(92,306)	(74,812)
Research and development expenses	(38,499)	(41,796)
Other income	2,460	13,444
Other expenses	(1,077)	(1,141)
Operating profit	7,434	55,339
Financial income	2,694	749
Financial costs	(407)	(374)
Profit before income taxes	9,722	55,715
Income taxes	18,248	(13,461)
Profit for the period	27,970	42,253
Profit for the period attributable to		
Owners of the parent	26,897	42,110
Non-controlling interests	1,072	144
Earnings per share		
Basic (yen)	93.81	146.89
Diluted (yen)	93.81	146.86

(2) Condensed Interim Consolidated Statement of Comprehensive Income

(Millions of yen)

	Three-month period ended June 30, 2022	Three-month period ended June 30, 2021
Profit for the period	27,970	42,253
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)	2,746	(1,177)
Subtotal	2,746	(1,177)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations (loss)	48,988	1,269
Cash flow hedges	(2)	19
Subtotal	48,986	1,289
Total other comprehensive income (loss), net of tax	51,732	112
Comprehensive income (loss) for the period	79,702	42,365
Comprehensive income (loss) for the period attributable to		
Owners of the parent	78,603	42,222
Non-controlling interests	1,098	144

(3) Condensed Interim Consolidated Statement of Financial Position

(Millions of yen)

	As of June 30, 2022	As of March 31, 2022
Assets		
Non-current assets		
Property, plant and equipment	172,902	169,926
Goodwill	213,775	191,758
Intangible assets	93,919	95,451
Other financial assets	49,213	44,033
Other assets	20,720	20,919
Deferred tax assets	101,395	76,622
Total non-current assets	651,924	598,709
Current assets		
Inventories	103,510	99,008
Trade and other receivables	198,940	207,950
Other financial assets	2,640	432
Other assets	28,041	23,584
Cash and cash equivalents	287,815	309,633
Total current assets	620,947	640,606
Total assets	1,272,871	1,239,315

(Millions of yen)

	As of June 30, 2022	As of March 31, 2022
Equity		
Equity attributable to owners of the parent		
Share capital	44,986	44,986
Capital surplus	77,600	77,605
Treasury shares	(33,894)	(33,936)
Retained earnings	513,310	506,583
Other components of equity	202,544	153,584
Total equity attributable to owners of the parent	804,545	748,821
Non-controlling interests	23,804	22,712
Total equity	828,349	771,534
Liabilities		
Non-current liabilities		
Borrowings	84,905	94,893
Other financial liabilities	38,348	39,213
Provisions	1,512	1,473
Other liabilities	17,133	18,386
Deferred tax liabilities	730	483
Total non-current liabilities	142,627	154,449
Current liabilities		
Borrowings	9,997	—
Trade and other payables	96,106	108,065
Other financial liabilities	42,336	40,865
Income taxes payable	9,034	6,877
Provisions	21,923	17,949
Other liabilities	122,497	139,576
Total current liabilities	301,894	313,333
Total liabilities	444,521	467,782
Total equity and liabilities	1,272,871	1,239,315

(4) Condensed Interim Consolidated Statement of Changes in Equity

For the three-month period ended June 30, 2022

(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, 2022	44,986	77,605	(33,936)	506,583	—
Profit for the period	—	—	—	26,897	—
Total other comprehensive income (loss)	—	—	—	—	2,746
Comprehensive income (loss) for the period	—	—	—	26,897	2,746
Dividends	—	—	—	(22,941)	—
Share-based payments	—	(27)	—	—	—
Acquisition of treasury shares	—	—	(1)	—	—
Disposal of treasury shares	—	23	43	—	—
Reclassification	—	—	—	2,746	(2,746)
Other changes	—	—	—	25	—
Total transactions with owners (loss)	—	(4)	41	(20,169)	(2,746)
As of June 30, 2022	44,986	77,600	(33,894)	513,310	—

	Equity attributable to owners of the parent			Total equity attributable to owners of the parent	Non-controlling interests	Total equity
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity			
As of April 1, 2022	153,584	—	153,584	748,821	22,712	771,534
Profit for the period	—	—	—	26,897	1,072	27,970
Total other comprehensive income (loss)	48,962	(2)	51,706	51,706	26	51,732
Comprehensive income (loss) for the period	48,962	(2)	51,706	78,603	1,098	79,702
Dividends	—	—	—	(22,941)	(7)	(22,948)
Share-based payments	—	—	—	(27)	—	(27)
Acquisition of treasury shares	—	—	—	(1)	—	(1)
Disposal of treasury shares	—	—	—	65	—	65
Reclassification	—	—	(2,746)	—	—	—
Other changes	—	—	—	25	—	25
Total transactions with owners (loss)	—	—	(2,746)	(22,879)	(7)	(22,886)
As of June 30, 2022	202,545	(2)	202,544	804,545	23,804	828,349

For the three-month period ended June 30, 2021

(Millions of yen)

	Equity attributable to owners of the parent				
	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity Financial assets measured at fair value through other comprehensive income (loss)
As of April 1, 2021	44,986	77,628	(34,049)	506,403	—
Profit for the period	—	—	—	42,110	—
Total other comprehensive income (loss)	—	—	—	—	(1,177)
Comprehensive income (loss) for the period	—	—	—	42,110	(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)	524,405	—

	Equity attributable to owners of the parent					Non-controlling interests	Total equity
	Other components of equity			Total equity attributable to owners of the parent			
	Exchange differences on translation of foreign operations	Cash flow hedges	Total other components of equity				
As of April 1, 2021	106,702	(69)	106,633	701,601	24,759	726,360	
Profit for the period	—	—	—	42,110	144	42,253	
Total other comprehensive income (loss)	1,269	19	112	112	0	112	
Comprehensive income (loss) for the period	1,269	19	112	42,222	144	42,365	
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	107,971	(49)	107,922	720,919	24,802	745,721	

(5) Condensed Interim Consolidated Statement of Cash Flows

(Millions of yen)

	For the three-month period ended June 30, 2022	For the three-month period ended June 30, 2021
Operating activities		
Profit before income taxes	9,722	55,715
Depreciation and amortization	9,803	9,304
(Increase) decrease in working capital	(1,065)	(63,316)
Interest and dividends received	663	700
Interest paid	(296)	(281)
Income taxes paid	(4,542)	(2,270)
Other	(10,339)	(14,342)
Net cash from (used in) operating activities	3,945	(14,491)
Investing activities		
Purchases of property, plant and equipment	(11,614)	(12,118)
Purchases of intangible assets	(4,275)	(2,538)
Proceeds from sale of property, plant and equipment and intangible assets	215	13,288
Purchases of financial assets	(889)	(477)
Proceeds from sale and redemption of financial assets	4	2,229
Proceeds from redemption of time deposits exceeding three months	(0)	(0)
Other	(272)	(40)
Net cash from (used in) investing activities	(16,832)	344
Financing activities		
Net increase (decrease) in short-term borrowings	—	2,782
Repayments of long-term borrowings	(1)	—
Repayments of lease liabilities	(2,372)	(2,532)
Dividends paid	(22,941)	(22,938)
Other	74	156
Net cash from (used in) financing activities	(25,240)	(22,533)
Effect of exchange rate change on cash and cash equivalents	16,309	1,021
Net increase (decrease) in cash and cash equivalents	(21,818)	(35,658)
Cash and cash equivalents at beginning of period	309,633	248,740
Cash and cash equivalents at end of period	287,815	213,082

(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. 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
IAS 16 Property, Plant and Equipment	January 1, 2022	Fiscal year ending March 31, 2023	Amendments to proceeds before intended use of property, plant and equipment
IAS 37 Provisions, Contingent Liabilities and Contingent Assets	January 1, 2022	Fiscal year ending March 31, 2023	Clarifying cost of fulfilling onerous contracts
IFRS 3 Business Combinations	January 1, 2022	Fiscal year ending March 31, 2023	Amendments to reference to the Conceptual Framework

The Group changed its accounting policies related to "Configuration or customization costs in a cloud computing agreement (related to IAS 38)" in the previous fiscal year. The changes in accounting policies are applied retroactively. The condensed interim consolidated financial statements for the three-month period ended June 30, 2021 have been restated to reflect the changes. As a result of applying the changes, compared to the amounts prior to the retroactive application, in the condensed interim consolidated statement of income for the three-month period ended June 30, 2021, selling, general and administrative expenses increased by ¥87 million. Research and development expenses decreased by ¥19 million. Both operating profit and profit before income taxes decreased by ¥68 million. Profit for the period decreased by ¥52 million.

(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, India, ASEAN, Central and South America), and OTC and others (Japan).

Hong Kong has been changed from the "Asia and Latin America pharmaceutical business" to the "China pharmaceutical business" since April 1, 2022. This change has been reflected on "Revenue" and "Segment profit (loss)" for the three-month period ended June 30, 2021 provided in Segment Information.

As the co-development and co-promotion agreements on Alzheimer's disease treatment ADUHELM (aducanumab) with Biogen Inc. (the U.S.) were amended in March 2022, expenses related to ADUHELM (selling, general and administrative expenses) which the Company should share based on the agreements have been included in the "Group headquarters' management costs and other expenses" since April 1, 2022. In addition to that, in order to more accurately reflect the condition of the business, gains and losses on sale of non-current assets have been included in the "Group headquarters' management costs and other expenses". The above changes of the three-month period ended June 30, 2021 have been reflected in Segment Information.

(Millions of yen)

	Three-month period ended June 30, 2022		Three-month period ended June 30, 2021	
	Revenue	Segment profit (loss)	Revenue	Segment profit (loss)
Pharmaceutical business				
Japan	57,462	21,618	49,629	15,568
Americas	53,069	31,273	38,304	21,723
China	34,810	20,753	27,394	16,415
EMEA	18,058	10,240	14,096	8,058
Asia and Latin America	11,952	5,319	12,579	5,657
OTC and others	5,993	1,428	5,198	687
Reporting segment total	181,343	90,631	147,200	68,109
Other business (Note 1)	2,918	514	51,694	49,843
Total	184,262	91,145	198,894	117,952
R&D expenses (Note 2)	—	(38,499)	—	(41,796)
Group headquarters' management costs and other expenses (Note 3)	—	(45,212)	—	(20,817)
Operating profit in the condensed interim consolidated statement of income	—	7,434	—	55,339

(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 (the U.S.) 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 other income and expenses, and the amount of profits and expenses shared under strategic collaborations with partners. For the three-month period ended June 30, 2022, shared profit of ¥31,728 million (¥19,780 million for the three-month period ended June 30, 2021) for anticancer agent Lenvima paid by the Group to Merck & Co., Inc., Rahway, NJ, USA 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.

Three-month period ended June 30, 2022

(Millions of yen)

	Revenue from pharmaceutical goods sales	License revenue	Other revenue	Total
Pharmaceutical business				
Japan	54,202	1,431	1,829	57,462
Americas	52,942	127	—	53,069
China	34,810	—	—	34,810
EMEA	18,058	—	—	18,058
Asia and Latin America	11,644	307	—	11,952
OTC and others	5,993	—	—	5,993
Reporting segment total	177,649	1,865	1,829	181,343
Other business (Note 1)	—	383	2,536	2,918
Total	177,649	2,248	4,365	184,262
Revenue recognized from contracts with customers	177,649	1,248	4,365	183,262
Revenue recognized from other sources (Note 2)	—	1,000	—	1,000

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

(Note 2) Revenues recognized from other sources are not from contracts with customers, but from partner companies that share the risks and benefits of co-promotion activities.

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	27,394	—	—	27,394
EMEA	14,096	—	—	14,096
Asia and Latin America	12,455	123	—	12,579
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”.

(Note 2) All revenue for the three-month period ended June 30, 2021 is recognized based on contracts with customers.

(2) Selling, general and administrative expenses

For the three-month period ended June 30, 2022, the Group recognized shared profit of ¥31,728 million (¥19,780 million for the three-month period ended June 30, 2021) for anticancer agent Lenvima paid by the Group to Merck & Co., Inc., Rahway, NJ, USA 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.

(4) Income taxes

For the three-month period ended June 30, 2022, as part of the Company’s capital policy to optimize the global allocation of cash in the Company, the Company received a repayment of paid-in capital of ¥63,622 million from its consolidated U.S. subsidiary, Eisai Corporation of North America. As a result, the Company recognized losses on transferring of investments in subsidiaries for tax purposes and income taxes decreased by ¥21,287 million.

(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