Securities Code: 4523

FY 2023 (Ending March 31, 2024)
First Quarter Financial Results

# Reference Data

August 2, 2023

## Eisai Co., Ltd.

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**Forward-Looking Statements and Risk Factors**

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 the maximization of the value of lecanemab and next-generation AD treatments, risks related to the maximization of the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to new drug development, risks related to 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.
This English presentation was translated from the original Japanese version. In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

# Contents



**Currency Exchange Rates**

| | | US (USD/JPY) | EU (EUR/JPY) | UK (GBP/JPY) | China (RMB/JPY) |
|---|---|---|---|---|---|
| FY 2022 Q1 | Quarterly Average Rate | 129.57 | 138.11 | 162.96 | 19.57 |
| | Quarter End Rate | 136.68 | 142.67 | 165.71 | 20.38 |
| FY 2022 | Yearly Average Rate | 135.46 | 140.96 | 163.15 | 19.74 |
| | Year End Rate | 133.53 | 145.72 | 165.56 | 19.42 |
| FY 2023 Q1 | Quarterly Average Rate | 137.36 | 149.46 | 171.91 | 19.56 |
| | Quarter End Rate | 144.99 | 157.60 | 182.95 | 19.94 |
| FY 2023 | Forecast Rate | 130.00 | 140.00 | 159.00 | 19.20 |

* Eisai Co., Ltd. ("the Company") discloses its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRS).

* Eisai Group's ("the Group") business is comprised of pharmaceutical business and other business.The pharmaceutical business is organized into the following five reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia and Oceania), and Asia and Latin America (primarily South Korea, Taiwan, India, ASEAN, Central and South America). In line with the reorganization of Japan business in FY 2023, OTC and others business (Japan) has been integrated into Japan pharmaceutical business. This change has been reflected in Segment Information for the fiscal year ended March 31, 2023.

* All amounts are rounded to the nearest specified unit.

# 1. Consolidated Statement of Income

(billions of yen)

| | FY 2022 | | | | FY 2023 | | | | FY 2023 | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Q1 | Ratio (%) | Full year | Ratio (%) | Q1 | Ratio (%) | YOY (%) | Diff. | Full year forecast | Ratio (%) |
| Revenue | 184.3 | 100.0 | 744.4 | 100.0 | 196.9 | 100.0 | 106.9 | 12.7 | 712.0 | 100.0 |
| Cost of sales | 47.4 | 25.7 | 177.8 | 23.9 | 43.9 | 22.3 | 92.7 | (3.5) | 163.5 | 23.0 |
| Gross profit | 136.9 | 74.3 | 566.6 | 76.1 | 153.0 | 77.7 | 111.8 | 16.2 | 548.5 | 77.0 |
| Selling, general and administrative expenses | 92.3 | 50.1 | 358.3 | 48.1 | 86.1 | 43.7 | 93.3 | (6.2) | 353.0 | 49.6 |
| Selling expenses | 50.2 | 27.3 | 189.0 | 25.4 | 45.0 | 22.9 | 89.6 | (5.2) | — | — |
| Personnel expenses | 24.0 | 13.0 | 100.2 | 13.5 | 26.0 | 13.2 | 108.3 | 2.0 | — | — |
| Administrative and other expenses | 18.1 | 9.8 | 69.1 | 9.3 | 15.1 | 7.7 | 83.6 | (3.0) | — | — |
| Research and development expenses | 38.5 | 20.9 | 173.0 | 23.2 | 41.1 | 20.9 | 106.9 | 2.6 | 152.0 | 21.3 |
| Other income | 2.5 | 1.3 | 8.3 | 1.1 | 0.6 | 0.3 | 26.1 | (1.8) | 6.5 | 0.9 |
| Other expenses | 1.1 | 0.6 | 3.5 | 0.5 | 0.4 | 0.2 | 37.2 | (0.7) | — | — |
| Operating profit | 7.4 | 4.0 | 40.0 | 5.4 | 26.0 | 13.2 | 350.1 | 18.6 | 50.0 | 7.0 |
| Financial income | 2.7 | 1.5 | 7.2 | 1.0 | 2.8 | 1.4 | 103.5 | 0.1 | — | — |
| Financial costs | 0.4 | 0.2 | 2.3 | 0.3 | 0.5 | 0.3 | 130.3 | 0.1 | — | — |
| Profit before income taxes | 9.7 | 5.3 | 45.0 | 6.0 | 28.3 | 14.4 | 291.0 | 18.6 | 52.0 | 7.3 |
| Income taxes | (18.2) | (9.9) | (11.8) | (1.6) | 7.4 | 3.7 | — | 25.6 | — | — |
| Profit for the period | 28.0 | 15.2 | 56.8 | 7.6 | 20.9 | 10.6 | 74.7 | (7.1) | 39.0 | 5.5 |
| Profit for the period attributable to | | | | | | | | | | |
| Owners of the parent | 26.9 | 14.6 | 55.4 | 7.4 | 20.3 | 10.3 | 75.6 | (6.6) | 38.0 | 5.3 |
| Non-controlling interests | 1.1 | 0.6 | 1.4 | 0.2 | 0.6 | 0.3 | 52.4 | (0.5) | — | — |
| Comprehensive income for the period | 79.7 | 43.3 | 96.9 | 13.0 | 68.4 | 34.7 | 85.8 | (11.3) | | |

| | | | | |
|---|---|---|---|---|
| Earnings per share (EPS, yen) | 93.81 | 193.31 | 70.92 | 132.60 |
| Dividend per share (DPS, yen) | — | 160.0 | — | 160.0 |
| Return on equity (ROE, %) | — | 7.2 | — | 4.9 |
| Dividends on equity ratio (DOE, %) | — | 5.9 | — | 5.9 |

* Full year forecast for other income has had other expenses deducted from it.
* EPS: Earnings Per Share attributable to owners of the parent (basic).

Notes

| | |
|---|---|
| Revenue | - Receipt of an upfront payment of 12.3 billion yen for the transfer of future economic rights for elacestrant, a selective estrogen receptor degrader |
| | - Continuous growth of the anticancer agent Lenvima and insomnia treatment Dayvigo<br>Lenvima: 70.8 billion yen (the same period in previous fiscal year: 66.3 billion yen)<br>Dayvigo: 9.4 billion yen (the same period in previous fiscal year: 6.5 billion yen) |
| Selling, general and administrative expenses | - Recording of expenses regarding shared profit of Lenvima paid to Merck & Co., Inc., Rahway, NJ, USA: 32.3 billion yen (the same period in previous fiscal year: 31.7 billion yen) |
| | - No longer incurring expenses related to Alzheimer's disease (AD) treatment ADUHELM along with contract modification (the same period in previous fiscal year : 4.6 billion yen), while selling expenses increased for AD treatment Leqembi in the United States |
| | - Reversal of Leqembi-related expenses received from Biogen: -4.0 billion yen (the same period in previous fiscal year: -1.5 billion yen) |
| Research and development expenses | - Control of expenses through the partnership model (partner's burden: 14.1 billion yen (the same period in previous fiscal year: 17.5 billion yen)) |
| | - Recording of regulatory milestone payments of 3.2 billion yen for Lenvima from Merck & Co., Inc., Rahway, NJ, USA in the same period of the previous fiscal year |
| | - No longer incurring expenses related to Alzheimer's disease (AD) treatment ADUHELM along with contract modification (the same period in previous fiscal year : 2.3 billion yen) |
| | - Recording of impairment losses of 2.1 billion yen related to the research facilities at the U.S. consolidated subsidiary |
| Income taxes | - Decrease in corporate income taxes following a repayment of paid-in capital from the U.S. consolidated subsidiary in the same period of the previous fiscal year |
| Exchange rate effects | - Revenue: +5.43 billion yen, operating profit: +1.60 billion yen |
| Exchange rate sensitivity<br>(annual effect of 1 yen depreciation in currency value) | - Revenue (U.S. dollars: +1.92 billion yen, Euro: +0.30 billion yen, U.K. pounds: +0.08 billion yen, Chinese renminbi: +6.30 billion yen) |
| | - Operating profit (U.S. dollars: -0.55 billion yen, Euro: +0.09 billion yen, U.K. pounds: -0.04 billion yen, Chinese renminbi: +4.19 billion yen) |

# 2. Segment Information

## 1) Revenue

(billions of yen)

| | FY 2022 | | FY 2023 | | |
|---|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) | CER YOY (%) |
| Pharmaceutical Business Total | 181.3 | 684.4 | 181.7 | 100.2 | 98.0 |
| Japan pharmaceutical business | 63.5 | 238.9 | 64.5 | 101.6 | 101.6 |
| Americas pharmaceutical business | 53.1 | 212.7 | 54.3 | 102.4 | 96.7 |
| United States | 52.2 | 209.0 | 53.3 | 102.0 | 96.2 |
| China pharmaceutical business | 34.8 | 110.8 | 31.6 | 90.6 | 90.6 |
| EMEA pharmaceutical business | 18.1 | 72.2 | 18.7 | 103.4 | 100.0 |
| Asia and Latin America pharmaceutical business | 12.0 | 49.8 | 12.7 | 106.3 | 102.9 |
| Other business | 2.9 | 60.0 | 15.2 | 521.4 | 474.5 |
| Consolidated revenue | 184.3 | 744.4 | 196.9 | 106.9 | 103.9 |

* CER=Constant Exchange Rates

* Indicates revenue from external customers.

## 2) Profit by Reporting Segment

(billions of yen)

| | FY 2022 | | FY 2023 | | |
|---|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) | CER YOY (%) |
| Pharmaceutical Business Total | 90.6 | 325.6 | 93.2 | 102.8 | 100.8 |
| Japan pharmaceutical business | 23.0 | 72.9 | 22.8 | 98.9 | 98.9 |
| Americas pharmaceutical business | 31.3 | 133.4 | 35.8 | 114.4 | 108.2 |
| China pharmaceutical business | 20.8 | 55.6 | 18.6 | 89.8 | 89.7 |
| EMEA pharmaceutical business | 10.2 | 41.6 | 10.1 | 98.4 | 101.9 |
| Asia and Latin America pharmaceutical business | 5.3 | 22.1 | 5.9 | 110.8 | 106.0 |
| Other business | 0.5 | 48.5 | 13.2 | 2558.5 | 2295.2 |
| Research and development expenses | (38.5) | (173.0) | (41.1) | 106.9 | 101.6 |
| Group headquarters' management costs and other expenses | (45.2) | (161.0) | (39.1) | 86.6 | 87.6 |
| Consolidated operating profit | 7.4 | 40.0 | 26.0 | 350.1 | 328.6 |

* CER=Constant Exchange Rates

* Profits and expenses shared under strategic collaborations with partners are included in “Group headquarters' management costs and other expenses”.

# 3. Financial Results by Reporting Segment

## 1) Japan pharmaceutical business

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| Revenue | 63.5 | 238.9 | 64.5 | 101.6 |
| Japan pharmaceutical business | 57.5 | 215.4 | 58.7 | 102.2 |
| OTC and others | 6.0 | 23.5 | 5.7 | 95.3 |
| Segment profit | 23.0 | 72.9 | 22.8 | 98.9 |
| **Japan prescription medicines - revenue from major products** | | | | |
| Fully human anti-TNF-α monoclonal antibody<br>Humira | 12.6 | 47.2 | 13.3 | 105.8 |
| Insomnia treatment<br>Dayvigo | 5.3 | 24.2 | 8.1 | 154.1 |
| Anticancer agent<br>Lenvima | 3.6 | 13.7 | 4.1 | 114.4 |
| Janus kinase inhibitor<br>Jyseleca | 1.3 | 7.3 | 3.0 | 227.8 |
| Peripheral neuropathy treatment<br>Methycobal | 2.7 | 10.3 | 2.5 | 92.9 |
| Anticancer agent<br>Halaven | 2.2 | 8.5 | 2.1 | 96.1 |
| Elemental diet<br>Elental# | 1.8 | 7.0 | 1.9 | 101.5 |
| Antiepileptic agent<br>Fycompa | 1.6 | 6.1 | 1.8 | 115.7 |
| Chronic constipation treatment<br>Goofice# | 1.7 | 6.5 | 1.8 | 106.5 |
| Chronic constipation treatment<br>MOVICOL# | 1.6 | 5.8 | 1.6 | 105.4 |
| Parkinson's disease treatment<br>Equfina | 1.2 | 4.6 | 1.5 | 126.4 |
| Proton pump inhibitor<br>Pariet# | 1.6 | 5.5 | 1.2 | 72.6 |
| Alzheimer's disease / Dementia with Lewy bodies treatment<br>Aricept | 1.2 | 4.2 | 0.9 | 75.8 |
| **Japan OTC and others - revenue from major products** | | | | |
| Vitamin B2 preparation, "Chocola BB Plus," etc.<br>Chocola BB Group | 3.9 | 14.1 | 3.7 | 96.6 |

# EA Pharma product

* The revenue for Pariet includes the revenue for triple formulation packs for *Helicobacter pylori* eradication, Rabecure Pack 400/800 and Rabefine Pack.

## 2) Americas pharmaceutical business (North America)

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| Revenue | 53.1 | 212.7 | 54.3 | 102.4<br><96.7> |
| United States | 52.2 | 209.0 | 53.3 | 102.0<br><96.2> |
| Segment profit | 31.3 | 133.4 | 35.8 | 114.4<br><108.2> |
| **Americas - revenue from major products** | | | | |
| Anticancer agent<br>Lenvima | 38.5 | 161.6 | 48.1 | 125.1<br><118.0> |
| United States<br>[Millions USD] | 38.2<br>[295] | 160.5<br>[1,185] | 47.9<br>[348] | 125.2<br><118.1> |
| Anticancer agent<br>Halaven | 4.1 | 13.9 | 2.9 | 71.7<br><67.7> |
| United States<br>[Millions USD] | 4.0<br>[31] | 13.5<br>[100] | 2.8<br>[21] | 71.2<br><67.1> |
| Insomnia Treatment<br>Dayvigo | 1.1 | 4.8 | 1.0 | 91.3<br><88.1> |
| United States<br>[Millions USD] | 0.9<br>[7] | 3.5<br>[26] | 0.6<br>[4] | 63.5<br><59.9> |
| Antiepileptic agent<br>Banzel | 0.9 | 4.4 | 1.0 | 112.5<br><106.7> |
| United States<br>[Millions USD] | 0.8<br>[6] | 4.1<br>[30] | 0.9<br>[6] | 111.1<br><104.8> |

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign exchange fluctuations.

## 3) China pharmaceutical business

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| Revenue | 34.8 | 110.8 | 31.6 | 90.6<br><90.6> |
| Segment profit | 20.8 | 55.6 | 18.6 | 89.8<br><89.7> |
| **China - revenue from major products** | | | | |
| Anticancer agent<br>Lenvima | 13.9 | 32.2 | 6.9 | 49.8<br><49.7> |
| Peripheral neuropathy treatment<br>Methycobal | 4.4 | 14.5 | 3.8 | 87.2<br><87.2> |
| Vertigo and equilibrium disturbance treatment<br>Merislon | 2.5 | 9.9 | 3.7 | 147.5<br><147.6> |
| Antiepileptic agent<br>Fycompa | 0.6 | 2.4 | 2.6 | 464.9<br><464.9> |
| Proton pump inhibitor<br>Pariet | 2.3 | 8.4 | 2.6 | 109.9<br><109.8> |
| Liver disease / Allergic disease agents<br>Stronger Neo-Minophagen C and Glycyron Tablets | 2.0 | 7.9 | 1.7 | 83.7<br><83.8> |
| Alzheimer's disease treatment<br>Aricept | 1.6 | 6.1 | 1.6 | 101.0<br><100.9> |
| Anticancer agent<br>Halaven | 0.6 | 2.0 | 0.6 | 109.3<br><109.0> |

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign exchange fluctuations.

## 4) EMEA pharmaceutical business (Europe, the Middle East, Africa, Russia and Oceania)

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| Revenue | 18.1 | 72.2 | 18.7 | 103.4<br><100.0> |
| Segment profit | 10.2 | 41.6 | 10.1 | 98.4<br><101.9> |
| **EMEA - revenue from major products** | | | | |
| Anticancer agent<br>Lenvima/Kisplyx | 8.1 | 30.9 | 9.0 | 111.7<br><108.6> |
| Antiepileptic agent<br>Fycompa | 2.8 | 11.7 | 3.1 | 108.8<br><103.9> |
| Anticancer agent<br>Halaven | 3.5 | 13.6 | 3.0 | 84.2<br><83.0> |
| Antiepileptic agent<br>Inovelon | 0.7 | 3.1 | 0.8 | 109.0<br><103.8> |

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign exchange fluctuations.

## 5) Asia and Latin America pharmaceutical business

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| Revenue | 12.0 | 49.8 | 12.7 | 106.3<br><102.9> |
| Segment profit | 5.3 | 22.1 | 5.9 | 110.8<br><106.0> |
| **Asia and Latin America - revenue from major products** | | | | |
| Alzheimer's disease / Dementia with Lewy bodies treatment<br>Aricept | 3.3 | 13.0 | 3.2 | 96.7<br><94.9> |
| Anticancer agent<br>Lenvima | 2.3 | 11.1 | 2.6 | 112.2<br><106.8> |
| Proton pump inhibitor<br>Pariet | 1.1 | 4.5 | 1.3 | 121.4<br><117.7> |
| Peripheral neuropathy treatment<br>Methycobal | 0.8 | 3.9 | 1.0 | 132.6<br><129.1> |
| Anticancer agent<br>Halaven | 0.8 | 3.3 | 0.8 | 110.4<br><103.8> |
| Antiepileptic agent<br>Fycompa | 0.4 | 1.7 | 0.5 | 116.0<br><113.8> |

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign exchange fluctuations.

* Indication of Aricept for the treatment of dementia with Lewy bodies is approved only in Japan, the Philippines and Thailand.

# 4. Revenue from Major Products

## 1) Neurology Products

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| **Neurology Products Total** | 37.1 | 144.5 | 36.7 | 98.9<br><97.8> |
| **Dayvigo (Insomnia treatment)** | 6.5 | 29.4 | 9.4 | 144.6<br><144.0> |
| Japan | 5.3 | 24.2 | 8.1 | 154.1 |
| Americas | 1.1 | 4.8 | 1.0 | 91.3<br><88.1> |
| **Fycompa (Antiepileptic agent)** | 9.9 | 37.1 | 8.1 | 81.7<br><80.2> |
| Japan | 1.6 | 6.1 | 1.8 | 115.7 |
| China | 0.6 | 2.4 | 2.6 | 464.9<br><464.9> |
| EMEA | 2.8 | 11.7 | 3.1 | 108.8<br><103.9> |
| Asia and Latin America | 0.4 | 1.7 | 0.5 | 116.0<br><113.8> |
| **Methycobal (Peripheral neuropathy treatment)** | 8.2 | 30.8 | 7.8 | 94.7<br><94.3> |
| Japan | 2.7 | 10.3 | 2.5 | 92.9 |
| China | 4.4 | 14.5 | 3.8 | 87.2<br><87.2> |
| Asia and Latin America | 0.8 | 3.9 | 1.0 | 132.6<br><129.1> |
| **Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)** | 6.3 | 24.4 | 6.2 | 98.4<br><96.9> |
| Japan | 1.2 | 4.2 | 0.9 | 75.8 |
| China | 1.6 | 6.1 | 1.6 | 101.0<br><100.9> |
| Asia and Latin America | 3.3 | 13.0 | 3.2 | 96.7<br><94.9> |
| **Inovelon/Banzel (Antiepileptic agent)** | 1.8 | 8.2 | 2.0 | 110.8<br><105.7> |
| Americas | 0.9 | 4.4 | 1.0 | 112.5<br><106.7> |
| EMEA | 0.7 | 3.1 | 0.8 | 109.0<br><103.8> |
| **Other** | 4.5 | 14.6 | 3.3 | 74.5<br><74.3> |

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign exchange fluctuations.

* The Company transferred the United States commercial rights for Fycompa to Catalyst Pharmaceuticals, Inc. in January 2023.

* Indication of Aricept for the treatment of dementia with Lewy bodies is approved only in Japan, the Philippines and Thailand.

## 2) Oncology Products

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) |
| **Oncology Products Total** | 79.7 | 299.1 | 82.4 | 103.4<br><99.1> |
| **Lenvima/Kisplyx (Anticancer agent)** | 66.3 | 249.6 | 70.8 | 106.7<br><102.0> |
| Japan | 3.6 | 13.7 | 4.1 | 114.4 |
| Americas | 38.5 | 161.6 | 48.1 | 125.1<br><118.0> |
| China | 13.9 | 32.2 | 6.9 | 49.8<br><49.7> |
| EMEA | 8.1 | 30.9 | 9.0 | 111.7<br><108.6> |
| Asia and Latin America | 2.3 | 11.1 | 2.6 | 112.2<br><106.8> |
| **Halaven (Anticancer agent)** | 11.1 | 41.3 | 9.5 | 85.1<br><82.8> |
| Japan | 2.2 | 8.5 | 2.1 | 96.1 |
| Americas | 4.1 | 13.9 | 2.9 | 71.7<br><67.7> |
| China | 0.6 | 2.0 | 0.6 | 109.3<br><109.0> |
| EMEA | 3.5 | 13.6 | 3.0 | 84.2<br><83.0> |
| Asia and Latin America | 0.8 | 3.3 | 0.8 | 110.4<br><103.8> |
| **Other** | 2.2 | 8.2 | 2.2 | 99.3<br><96.6> |

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign exchange fluctuations.

# 5. Revenue Forecast by Reporting Segment (FY 2023)

(billions of yen)

| | FY 2022 | | FY 2023 | |
|---|---|---|---|---|
| | Q1 | Full year | Q1 | Full year forecast |
| **Japan** | 63.5 | 238.9 | 64.5 | 238.5 |
| **Prescription medicines** | 57.5 | 215.4 | 58.7 | 215.0 |
| Insomnia treatment Dayvigo | 5.3 | 24.2 | 8.1 | 35.0 |
| Anticancer agent Lenvima | 3.6 | 13.7 | 4.1 | 17.5 |
| Janus kinase inhibitor Jyseleca | 1.3 | 7.3 | 3.0 | 15.0 |
| Fully human anti-TNF-α monoclonal antibody Humira | 12.6 | 47.2 | 13.3 | 13.5 |
| Peripheral neuropathy treatment Methycobal | 2.7 | 10.3 | 2.5 | 10.0 |
| Anticancer agent Halaven | 2.2 | 8.5 | 2.1 | 8.5 |
| Chronic constipation treatment Goofice# | 1.7 | 6.5 | 1.8 | 8.0 |
| Antiepileptic agent Fycompa | 1.6 | 6.1 | 1.8 | 7.5 |
| Parkinson's disease treatment Equfina | 1.2 | 4.6 | 1.5 | 7.0 |
| Chronic constipation treatment MOVICOL# | 1.6 | 5.8 | 1.6 | 7.0 |
| Elemental diet Elental# | 1.8 | 7.0 | 1.9 | 7.0 |
| **OTC and others** | 6.0 | 23.5 | 5.7 | 23.5 |
| Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group | 3.9 | 14.1 | 3.7 | 16.0 |
| **Americas** | 53.1 | 212.7 | 54.3 | 205.5 |
| **United States** | 52.2 | 209.0 | 53.3 | 201.0 |
| **China** | 34.8 | 110.8 | 31.6 | 104.5 |
| **EMEA** | 18.1 | 72.2 | 18.7 | 67.0 |
| **Asia and Latin America** | 12.0 | 49.8 | 12.7 | 49.5 |
| **Other** | 2.9 | 60.0 | 15.2 | 47.0 |
| **Consolidated revenue** | **184.3** | **744.4** | **196.9** | **712.0** |
| **Global revenue from major products** | | | | |
| Lenvima/Kisplyx | 66.3 | 249.6 | 70.8 | 261.0 |
| Japan | 3.6 | 13.7 | 4.1 | 17.5 |
| Americas | 38.5 | 161.6 | 48.1 | 174.0 |
| China | 13.9 | 32.2 | 6.9 | 27.0 |
| EMEA | 8.1 | 30.9 | 9.0 | 32.0 |
| Asia and Latin America | 2.3 | 11.1 | 2.6 | 10.5 |
| Dayvigo | 6.5 | 29.4 | 9.4 | 42.5 |
| Japan | 5.3 | 24.2 | 8.1 | 35.0 |
| Americas | 1.1 | 4.8 | 1.0 | 6.5 |
| Halaven | 11.1 | 41.3 | 9.5 | 34.5 |
| Japan | 2.2 | 8.5 | 2.1 | 8.5 |
| Americas | 4.1 | 13.9 | 2.9 | 9.0 |
| China | 0.6 | 2.0 | 0.6 | 2.5 |
| EMEA | 3.5 | 13.6 | 3.0 | 11.5 |
| Asia and Latin America | 0.8 | 3.3 | 0.8 | 3.0 |
| Fycompa | 9.9 | 37.1 | 8.1 | 25.5 |
| Japan | 1.6 | 6.1 | 1.8 | 7.5 |
| China | 0.6 | 2.4 | 2.6 | 3.0 |
| EMEA | 2.8 | 11.7 | 3.1 | 12.5 |
| Asia and Latin America | 0.4 | 1.7 | 0.5 | 2.0 |

# EA Pharma product

* The development and marketing agreement for Humira in Japan with AbbVie GK was expired in June 2023.

* The Company transferred the United States commercial rights for Fycompa to Catalyst Pharmaceuticals, Inc. in January 2023.

## 6. Consolidated Statement of Comprehensive Income

(billions of yen)

| | FY 2022 | | FY 2023 | | |
|---|---|---|---|---|---|
| | Q1 | Full year | Q1 | YOY (%) | Diff. |
| Profit for the period | 28.0 | 56.8 | 20.9 | 74.7 | (7.1) |
| 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) | 2.7 | 5.5 | 3.5 | 126.4 | 0.7 |
| Remeasurements of defined benefit plans | — | 1.1 | — | — | — |
| Subtotal | 2.7 | 6.6 | 3.5 | 126.4 | 0.7 |
| Items that may be reclassified subsequently to profit or loss | | | | | |
| Exchange differences on translation of foreign operations | 49.0 | 33.4 | 43.9 | 89.6 | (5.1) |
| Cash flow hedges | (0.0) | 0.0 | 0.2 | — | 0.2 |
| Subtotal | 49.0 | 33.5 | 44.1 | 89.9 | (4.9) |
| Total other comprehensive income (loss), net of tax | 51.7 | 40.1 | 47.5 | 91.9 | (4.2) |
| Comprehensive income (loss) for the period | 79.7 | 96.9 | 68.4 | 85.8 | (11.3) |
| Comprehensive income (loss) for the period attributable to | | | | | |
| Owners of the parent | 78.6 | 95.5 | 67.8 | 86.3 | (10.8) |
| Non-controlling interests | 1.1 | 1.4 | 0.6 | 54.8 | (0.5) |

# 7. Consolidated Statement of Cash Flows

(billions of yen)

| | FY 2022 | FY 2023 | |
|---|---|---|---|
| | Q1 | Q1 | Diff. |
| Operating activities | | | |
| Profit before income taxes | 9.7 | 28.3 | 18.6 |
| Depreciation and amortization | 9.8 | 9.8 | (0.0) |
| Impairment losses | — | 2.1 | 2.1 |
| (Increase) decrease in working capital | (1.1) | (22.3) | (21.3) |
| Interest and dividends received | 0.7 | 2.2 | 1.5 |
| Interest paid | (0.3) | (0.3) | (0.0) |
| Income taxes paid | (4.5) | (2.4) | 2.2 |
| Other | (10.3) | (4.7) | 5.7 |
| Net cash from (used in) operating activities | 3.9 | 12.6 | 8.7 |
| Investing activities | | | |
| Purchases of property, plant and equipment | (11.6) | (7.0) | 4.6 |
| Purchases of intangible assets | (4.3) | (1.6) | 2.7 |
| Proceeds from sale of property, plant and equipment and intangible assets | 0.2 | 0.0 | (0.2) |
| Purchases of financial assets | (0.9) | (3.4) | (2.5) |
| Proceeds from sale and redemption of financial assets | 0.0 | 0.3 | 0.3 |
| Subtotal <Capital expenditures (cash basis)> | (16.6) | (11.6) | 4.9 |
| Payments of time deposits exceeding three months | (0.0) | (0.0) | (0.0) |
| Proceeds from redemption of time deposits exceeding three months | — | 0.0 | 0.0 |
| Other | (0.3) | 0.1 | 0.3 |
| Net cash from (used in) investing activities | (16.8) | (11.6) | 5.2 |
| Financing activities | | | |
| Net increase (decrease) in short-term borrowings | — | 20.1 | 20.1 |
| Repayments of long-term borrowings | (0.0) | (10.0) | (10.0) |
| Repayments of lease liabilities | (2.4) | (2.2) | 0.1 |
| Dividends paid | (22.9) | (23.0) | (0.0) |
| Other | 0.1 | (0.4) | (0.4) |
| Net cash from (used in) financing activities | (25.2) | (15.5) | 9.8 |
| Effect of exchange rate change on cash and cash equivalents | 16.3 | 16.4 | 0.1 |
| Net increase (decrease) in cash and cash equivalents | (21.8) | 2.0 | 23.8 |
| Cash and cash equivalents at beginning of period | 309.6 | 267.4 | (42.3) |
| Cash and cash equivalents at end of period | 287.8 | 269.3 | (18.5) |

| | | | |
|---|---|---|---|
| Free cash flows | (12.6) | 1.0 | 13.6 |

* "Free cash flows" = "Net cash from (used in) operating activities" - "Capital expenditures (cash basis)"

Notes

■Net cash from (used in) operating activities
Working capital increased mainly due to increase in inventories for Leqembi and decrease in accounts payable-other

■Net cash from (used in) investing activities
Capital expenditures occurred following the expansion of research facilities and production facilities

■Net cash from (used in) financing activities
While short-term borrowings were increased, dividends were paid and the long-term borrowings (current portion) were repaid

## 8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

| | FY 2022 | | FY 2023 | | FY 2023 |
|---|---|---|---|---|---|
| | Q1 | Full year | Q1 | Diff. | Full year forecast |
| Capital expenditures (cash basis) | 15.9 | 34.6 | 8.6 | (7.3) | 35.5 |
| Property, plant and equipment | 11.6 | 22.6 | 7.0 | (4.6) | 13.5 |
| Intangible assets | 4.3 | 12.0 | 1.6 | (2.7) | 22.0 |
| Depreciation and amortization | 9.8 | 40.0 | 9.8 | (0.0) | 40.0 |
| Property, plant and equipment | 5.6 | 22.8 | 5.5 | (0.1) | 23.0 |
| Intangible assets | 4.2 | 17.2 | 4.2 | 0.0 | 17.0 |

## 9. Consolidated Statement of Financial Position

### <Assets>

(billions of yen)

| | FY 2022 | | FY 2023 | | | |
|---|---|---|---|---|---|---|
| | March 31, 2023 | Ratio (%) | June 30, 2023 | Ratio (%) | % change | Diff. |
| Assets | | | | | | |
| Non-current assets | | | | | | |
| Property, plant and equipment | 166.6 | 13.2 | 166.0 | 12.7 | 99.6 | (0.6) |
| Goodwill | 208.8 | 16.5 | 226.4 | 17.3 | 108.4 | 17.6 |
| Intangible assets | 89.2 | 7.1 | 87.6 | 6.7 | 98.1 | (1.7) |
| Other financial assets | 52.5 | 4.2 | 61.6 | 4.7 | 117.3 | 9.1 |
| Other assets | 21.4 | 1.7 | 21.1 | 1.6 | 98.3 | (0.4) |
| Deferred tax assets | 102.6 | 8.1 | 102.4 | 7.8 | 99.8 | (0.2) |
| Total non-current assets | 641.1 | 50.7 | 665.0 | 51.0 | 103.7 | 23.9 |
| Current assets | | | | | | |
| Inventories | 140.4 | 11.1 | 149.9 | 11.5 | 106.8 | 9.5 |
| Trade and other receivables | 187.3 | 14.8 | 189.2 | 14.5 | 101.0 | 2.0 |
| Other financial assets | 0.5 | 0.0 | 1.8 | 0.1 | 336.0 | 1.3 |
| Other assets | 26.6 | 2.1 | 29.8 | 2.3 | 111.9 | 3.2 |
| Cash and cash equivalents | 267.4 | 21.2 | 269.3 | 20.6 | 100.7 | 2.0 |
| Total current assets | 622.2 | 49.3 | 640.1 | 49.0 | 102.9 | 17.9 |
| Total assets | 1,263.4 | 100.0 | 1,305.1 | 100.0 | 103.3 | 41.7 |

Notes

| | |
|---|---|
| ■ Assets | |
| (Goodwill) | Increase due to the depreciation of the Japanese yen |
| (Inventories) | Increase mainly due to proceeding the production of Leqembi |

## <Equity and Liabilities>

(billions of yen)

| | FY 2022 | | FY 2023 | | | |
|---|---|---|---|---|---|---|
| | March 31, 2023 | Ratio (%) | June 30, 2023 | Ratio (%) | % change | Diff. |
| Equity | | | | | | |
| Equity attributable to owners of the parent | | | | | | |
| Share capital | 45.0 | 3.6 | 45.0 | 3.4 | 100.0 | — |
| Capital surplus | 78.8 | 6.2 | 78.8 | 6.0 | 100.0 | 0.0 |
| Treasury shares | (33.6) | (2.7) | (33.6) | (2.6) | 100.0 | 0.0 |
| Retained earnings | 522.8 | 41.4 | 523.6 | 40.1 | 100.2 | 0.9 |
| Other components of equity | 187.0 | 14.8 | 231.0 | 17.7 | 123.5 | 44.0 |
| Total equity attributable to owners of the parent | 800.0 | 63.3 | 844.9 | 64.7 | 105.6 | 44.9 |
| Non-controlling interests | 22.6 | 1.8 | 22.8 | 1.7 | 100.8 | 0.2 |
| Total equity | 822.6 | 65.1 | 867.7 | 66.5 | 105.5 | 45.1 |
| Liabilities | | | | | | |
| Non-current liabilities | | | | | | |
| Borrowings | 84.9 | 6.7 | 84.9 | 6.5 | 100.0 | 0.0 |
| Other financial liabilities | 37.0 | 2.9 | 38.8 | 3.0 | 104.8 | 1.8 |
| Provisions | 1.3 | 0.1 | 1.3 | 0.1 | 103.6 | 0.0 |
| Other liabilities | 18.0 | 1.4 | 15.8 | 1.2 | 87.7 | (2.2) |
| Deferred tax liabilities | 0.7 | 0.1 | 0.8 | 0.1 | 115.7 | 0.1 |
| Total non-current liabilities | 141.8 | 11.2 | 141.6 | 10.8 | 99.8 | (0.3) |
| Current liabilities | | | | | | |
| Borrowings | 41.2 | 3.3 | 51.3 | 3.9 | 124.5 | 10.1 |
| Trade and other payables | 86.8 | 6.9 | 61.4 | 4.7 | 70.8 | (25.4) |
| Other financial liabilities | 34.7 | 2.7 | 37.3 | 2.9 | 107.5 | 2.6 |
| Income taxes payable | 2.2 | 0.2 | 6.6 | 0.5 | 298.5 | 4.4 |
| Provisions | 23.0 | 1.8 | 25.4 | 1.9 | 110.6 | 2.4 |
| Other liabilities | 111.0 | 8.8 | 113.8 | 8.7 | 102.5 | 2.8 |
| Total current liabilities | 298.9 | 23.7 | 295.9 | 22.7 | 99.0 | (3.1) |
| Total liabilities | 440.8 | 34.9 | 437.4 | 33.5 | 99.2 | (3.3) |
| Total equity and liabilities | 1,263.4 | 100.0 | 1,305.1 | 100.0 | 103.3 | 41.7 |

Notes

| | |
|---|---|
| ■ Equity | |
| (Other components of equity) | Increase in exchange differences on translation of foreign operations following the depreciation of the Japanese yen |
| ■ Liabilities | |
| (Borrowings - current) | Increase in short-term borrowings, decrease in long-term borrowings (current portion) |
| (Trade and other payables) | Decrease mainly in accounts payable-other |

# 10. Changes in Quarterly Results

## 1) Income Statement

(billions of yen)

| | FY 2022 | | | | FY2023 |
|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 |
| Revenue | 184.3 | 174.4 | 187.6 | 198.2 | 196.9 |
| Cost of sales | 47.4 | 45.1 | 46.7 | 38.6 | 43.9 |
| Gross profit | 136.9 | 129.2 | 140.8 | 159.6 | 153.0 |
| Selling, general and administrative expenses | 92.3 | 88.1 | 92.6 | 85.3 | 86.1 |
| Selling expenses | 50.2 | 45.3 | 48.9 | 44.5 | 45.0 |
| Personnel expenses | 24.0 | 24.7 | 25.7 | 25.8 | 26.0 |
| Administrative and other expenses | 18.1 | 18.1 | 17.9 | 14.9 | 15.1 |
| Research and development expenses | 38.5 | 43.0 | 39.9 | 51.6 | 41.1 |
| Other income | 2.5 | 0.6 | 0.4 | 4.9 | 0.6 |
| Other expenses | 1.1 | 0.9 | 0.2 | 1.4 | 0.4 |
| Operating profit | 7.4 | (2.2) | 8.6 | 26.2 | 26.0 |
| Financial income | 2.7 | 1.0 | 1.5 | 2.0 | 2.8 |
| Financial costs | 0.4 | 0.4 | 0.6 | 0.8 | 0.5 |
| Profit before income taxes | 9.7 | (1.6) | 9.5 | 27.4 | 28.3 |
| Income taxes | (18.2) | (5.4) | 0.3 | 11.5 | 7.4 |
| Profit for the period | 28.0 | 3.8 | 9.1 | 15.9 | 20.9 |
| Profit for the period attributable to | | | | | |
| Owners of the parent | 26.9 | 3.6 | 8.6 | 16.3 | 20.3 |
| Non-controlling interests | 1.1 | 0.3 | 0.5 | (0.4) | 0.6 |
| Comprehensive income for the period | 79.7 | 22.4 | (30.7) | 25.5 | 68.4 |
| Earnings per share (EPS, yen) | 93.81 | 12.44 | 30.14 | 56.92 | 70.92 |

* EPS: Earnings Per Share attributable to owners of the parent (basic).

## 2) Cash Flows

(billions of yen)

| | FY 2022 | | | | FY2023 |
|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 |
| Net cash from (used in) operating activities | 3.9 | (22.8) | (6.9) | 24.0 | 12.6 |
| Net cash from (used in) investing activities | (16.8) | 0.4 | (3.8) | (2.5) | (11.6) |
| Net cash from (used in) financing activities | (25.2) | (2.6) | 29.7 | (26.4) | (15.5) |
| Cash and cash equivalents at end of period | 287.8 | 264.5 | 268.0 | 267.4 | 269.3 |
| Free cash flow | (12.6) | (22.7) | (10.7) | 21.6 | 1.0 |

* "Free cash flow" = "Net cash from (used in) operating activities" - "Capital expenditures (cash basis)"

## 3) Capital Expenditures, Depreciation and Amortization

(billions of yen)

| | FY 2022 | | | | FY2023 |
|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 |
| Capital expenditures (cash basis) | 15.9 | 4.8 | 7.1 | 6.7 | 8.6 |
| Property, plant and equipment | 11.6 | 2.6 | 5.4 | 3.0 | 7.0 |
| Intangible assets | 4.3 | 2.3 | 1.7 | 3.7 | 1.6 |
| Depreciation and amortization | 9.8 | 9.9 | 10.2 | 10.1 | 9.8 |
| Property, plant and equipment | 5.6 | 5.6 | 5.9 | 5.7 | 5.5 |
| Intangible assets | 4.2 | 4.2 | 4.3 | 4.5 | 4.2 |

## 4) Financial Positions

(billions of yen)

| | Jun. 30, 2022 | Sept. 30, 2022 | Dec. 31, 2022 | Mar. 31, 2023 | Jun. 30, 2023 |
|---|---|---|---|---|---|
| Total assets | 1,272.9 | 1,261.3 | 1,251.1 | 1,263.4 | 1,305.1 |
| Equity | 828.3 | 850.7 | 797.1 | 822.6 | 867.7 |
| Attributable to owners of the parent | 804.5 | 828.1 | 774.0 | 800.0 | 844.9 |
| Liabilities | 444.5 | 410.6 | 454.0 | 440.8 | 437.4 |
| Borrowings | 94.9 | 94.9 | 150.1 | 126.1 | 136.2 |
| Ratio of equity attributable to owners of the parent (%) | 63.2 | 65.7 | 61.9 | 63.3 | 64.7 |
| Net debt equity ratio (times) | (0.28) | (0.24) | (0.18) | (0.21) | (0.19) |

* "Net debt equity ratio（Net DER)" = ("Interest-bearing debt" ("Borrowings") - "Cash and cash equivalents" - "Time deposits exceeding three months, etc." - "Investment securities held by the parent") / "Equity attributable to owners of the parent"

## 5) Changes in Quarterly Revenue from Major Products

### (1) Neurology Products

(billions of yen)

| | FY 2022 | | | | FY2023 |
|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 |
| **Neurology Total** | 37.1 | 37.4 | 39.7 | 30.3 | 36.7 |
| **Dayvigo (Insomnia treatment)** | 6.5 | 7.1 | 8.4 | 7.4 | 9.4 |
| Japan | 5.3 | 5.8 | 7.0 | 6.1 | 8.1 |
| Americas | 1.1 | 1.2 | 1.2 | 1.2 | 1.0 |
| **Fycompa (Antiepileptic agent)** | 9.9 | 10.2 | 10.4 | 6.6 | 8.1 |
| Japan | 1.6 | 1.5 | 1.7 | 1.3 | 1.8 |
| China | 0.6 | 0.7 | 0.6 | 0.5 | 2.6 |
| EMEA | 2.8 | 2.7 | 3.0 | 3.2 | 3.1 |
| Asia and Latin America | 0.4 | 0.4 | 0.5 | 0.4 | 0.5 |
| **Methycobal (Peripheral neuropathy treatment)** | 8.2 | 8.2 | 8.2 | 6.2 | 7.8 |
| Japan | 2.7 | 2.6 | 2.8 | 2.2 | 2.5 |
| China | 4.4 | 4.0 | 3.6 | 2.5 | 3.8 |
| Asia and Latin America | 0.8 | 1.1 | 1.2 | 0.9 | 1.0 |
| **Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)** | 6.3 | 6.4 | 6.4 | 5.3 | 6.2 |
| Japan | 1.2 | 1.1 | 1.1 | 0.8 | 0.9 |
| China | 1.6 | 1.8 | 1.8 | 0.9 | 1.6 |
| Asia and Latin America | 3.3 | 3.4 | 3.3 | 3.0 | 3.2 |
| **Inovelon/Banzel (Antiepileptic agent)** | 1.8 | 2.0 | 2.7 | 1.7 | 2.0 |
| Americas | 0.9 | 1.1 | 1.7 | 0.8 | 1.0 |
| EMEA | 0.7 | 0.8 | 0.8 | 0.8 | 0.8 |
| **Other** | 4.5 | 3.4 | 3.7 | 3.0 | 3.3 |

* The Company transferred the United States commercial rights for Fycompa to Catalyst Pharmaceuticals, Inc. on January 2023.

* Indication of Aricept for the treatment of dementia with Lewy bodies is approved only in Japan, the Philippines and Thailand.

### (2) Oncology Products

(billions of yen)

| | FY 2022 | | | | FY2023 |
|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 |
| **Oncology Total** | 79.7 | 74.0 | 75.7 | 69.7 | 82.4 |
| **Lenvima/Kisplyx (Anticancer agent)** | 66.3 | 61.8 | 63.1 | 58.3 | 70.8 |
| Japan | 3.6 | 3.3 | 3.7 | 3.1 | 4.1 |
| Americas | 38.5 | 41.7 | 43.0 | 38.4 | 48.1 |
| China | 13.9 | 6.9 | 6.7 | 4.8 | 6.9 |
| EMEA | 8.1 | 6.9 | 7.0 | 8.9 | 9.0 |
| Asia and Latin America | 2.3 | 3.1 | 2.7 | 3.0 | 2.6 |
| **Halaven (Anticancer agent)** | 11.1 | 10.3 | 10.4 | 9.6 | 9.5 |
| Japan | 2.2 | 2.1 | 2.2 | 2.0 | 2.1 |
| Americas | 4.1 | 3.6 | 3.3 | 2.9 | 2.9 |
| China | 0.6 | 0.6 | 0.5 | 0.3 | 0.6 |
| EMEA | 3.5 | 3.3 | 3.4 | 3.4 | 3.0 |
| Asia and Latin America | 0.8 | 0.7 | 0.9 | 1.0 | 0.8 |
| **Other** | 2.2 | 1.9 | 2.2 | 1.8 | 2.2 |

# 11. Major R&D Pipeline

## (1) Neurology

| Development Code: **BAN2401** Generic Name: **lecanemab** Product Name: **Leqembi** | | | | | In-license (BioArctic AB) |
|---|---|---|---|---|---|
| Indications / Drug class: Treatment for Alzheimer's disease / anti-Aβ protofibril antibody | | | | | Injection |
| Description: An IgG1 antibody that targets amyloid beta (Aβ) protofibrils. Reduces the rate of disease progression and slows cognitive and functional decline in adults with Alzheimer's disease (AD) through the elimination of neurotoxic Aβ protofibrils. In July 2023, lecanemab was granted traditional approval in the United States as a treatment for AD by the U.S. Food and Drug Administration (FDA) after an application supporting the conversion of the accelerated approval to a traditional approval based on the Phase III clinical study Clarity AD. Applications have been submitted for use in the treatment of early AD in Japan, Europe, China, Canada, Great Britain, Australia, Switzerland, South Korea and Israel. The applications have been designated for priority review in Japan, China and Israel. In Great Britain, lecanemab has been designated for the Innovative Licensing and Access Pathway, which aims to reduce the time to market for innovative medicines. Development of subcutaneous injection formulation is underway to enhance convenience for patients. In addition, a study to determine a new dosing regimen for maintenance treatment after removal of brain Aβ is also underway. The Phase III clinical study AHEAD 3-45 for preclinical (asymptomatic) AD is underway in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC). Joint development with Biogen Inc. | | | | | |
| | Early AD | Study 301<br>(Clarity AD) | US<br>EU<br>JP<br>CH<br>Asia (SK) | ◎<br><br><br><br>◎ | Traditional approval (July 2023)<br>Submission (accepted: January 2023)<br>Submission (January 2023)<br>Submission (December 2022)<br>Submission (June 2023) |
| | Preclinical AD | Study 303<br>(AHEAD 3-45) | JP/US/EU | | PIII |

| Development Code: **E2007** Generic Name: **perampanel** Product Name: **Fycompa** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Antiepileptic agent / AMPA receptor antagonist | | | | | Oral |
| Description: Selectively inhibits the AMPA receptor (a glutamate receptor subtype) activation by glutamate. Approved as an adjunctive therapy for partial-onset seizures in over 75 countries including Japan, China and countries in Europe and in Asia. Approved for monotherapy in Japan and China. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 70 countries including Japan, and countries in Europe and in Asia. An oral suspension formulation has been approved in Europe and China. A fine granule formulation has been approved in Japan. In January 2023, the commercial rights in the United States were transferred. | | | | | |
| | Injection formulation (Additional Formulation) | — | JP | | Submission (August 2022) |
| | Primary generalized tonic-clonic seizures<br>(Additional Indication) | Study 332 | CH | | Submission (March 2023) |
| | Lennox-Gastaut syndrome (Additional Indication) | Study 338 | JP/US/EU | | PIII |

| Development Code: **E2006** Generic Name: **lemborexant** Product Name: **Dayvigo** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Insomnia treatment / Orexin receptor antagonist | | | | | Oral |
| Description: An orexin receptor antagonist that blocks the receptors involved in the regulation of sleep and wakefulness. It is expected to alleviate wakefulness, thereby facilitating faster onset and maintenance of sleep. It has been approved for the treatment of insomnia in over 15 countries including Japan, the United States and countries in Asia. In addition, development for irregular sleep-wake rhythm disorder and Alzheimer's disease dementia is ongoing. | | | | | |
| | Insomnia disorder | Study 311 | CH | | PIII |
| | Irregular sleep-wake rhythm disorder and<br>Alzheimer's disease dementia (Additional Indication) | Study 202 | JP/US | | PII |

| Development Code: **E2023** Generic Name: **lorcaserin** | | | | | In-license<br>(Arena Pharmaceuticals) |
|---|---|---|---|---|---|
| Indications / Drug class: Treatment for Dravet syndrome / serotonin 2C receptor agonist | | | | | Oral |
| Description: By selectively activating serotonin 2C receptors in the brain, through the activation GABAergic inhibitory interneuron, expected to suppress seizures of Dravet syndrome by increasing synaptic suppression from GABAergic. Although approval for the obesity indication has been voluntarily withdrawn, due to the request from Dravet syndrome patient groups, the extended access program has been continued in the United States, and the Phase III clinical study is underway for this indication. FDA has designated it as an orphan drug for Dravet syndrome. | | | | | |
| | Dravet syndrome | Study 304 | US | | PIII |

JP: Japan, US: the United States, EU: Europe, CH: China, SK: South Korea, P: (Clinical trial) Phase

◎：Development progress from April 2023 onwards

| Development Code: **E2027** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Treatment for dementia with Lewy bodies, Parkinson's disease dementia / PDE9 inhibitor | | | | | Oral |
| Description: A selective phosphodiesterase (PDE) 9 inhibitor that reduces the degradation of cyclic GMP, which is critical to signal transduction among cells. Expected to be a new treatment for dementia with Lewy bodies and Parkinson's disease dementia by helping to maintain the concentration of cyclic GMP in the brain. | | | | | |
| | Dementia with Lewy bodies, Parkinson's disease dementia | Study 203 | US | | PII |

| Development Code: **E2814** | | | | | Collaboration (University College London) |
|---|---|---|---|---|---|
| Indications / Drug class: anti-MTBR tau antibody | | | | | Injection |
| Description: An anti-microtubule binding region (MTBR) tau antibody that was discovered as part of the research collaboration between Eisai and University College London. Expected to prevent the spreading of tau seeds within the brain. Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) has selected E2814 as the first investigational medicine among anti-tau drugs for their DIAN-TU tau study, and Phase Ib/II study and Phase II/III study Tau NexGen for dominantly inherited AD are underway. | | | | | |
| | AD | Tau NexGen study<br>Study103 | JP/US/EU<br>US/EU | | PII/III<br>PI/II |

| Development Code: **E2511** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Synapse regenerant | | | | | Oral |
| Description: Expected to promote recovery and synaptic remodeling of damaged cholinergic neurons, and to suppress cerebral atrophy caused by neurodegeneration. | | | | | |
| | AD | — | US | | PI |

| Development Code: **E2025** | | | | In-house | Injection |
|---|---|---|---|---|---|
| | AD | — | US | | PI |

| Development Code: **E2086** | | | | In-house | Oral |
|---|---|---|---|---|---|
| | Narcolepsy | — | US | | PI |

| Development Code: **EA4017** | | | | In-house | Oral |
|---|---|---|---|---|---|
| | Chemotherapy-induced peripheral neuropathy<br>(Development conducted by EA Pharma) | — | JP | | PI |

JP: Japan, US: the United States, EU: Europe, CH: China, SK: South Korea, P: (Clinical trial) Phase

◎：Development progress from April 2023 onwards

## (2) Oncology

| Development Code: **E7080** Generic Name: **lenvatinib** Product Name: **Lenvima** | In-house |
|---|---|
| Indications / Drug class: Anticancer agent / kinase inhibitor | Oral |

Description: An orally available multiple kinase inhibitor that selectively inhibits kinase activities vascular endothelial growth factor receptors (VEGFR): VEGFR1, VEGFR2 and VEGFR3, and fibroblast growth factor receptors (FGFR): FGFR1,FGFR2, FGFR3 and FGFR4, in addition to pathogenic angiogenesis, tumor growth and cancer progression related receptor tyrosine kinases such as the platelet derived growth factor receptor alpha (PDGFRα), KIT, and RET. Discovered and developed in-house. As monotherapy indications, approved for use in the treatment of thyroid cancer in over 80 countries including Japan, the United States, China and countries in Europe and in Asia. Approved for use in the treatment of hepatocellular carcinoma (first-line) in over 80 countries including in Japan, the United States, China and countries in Europe and in Asia. Also approved for use in the treatment of thymic carcinoma in Japan. As a combination therapy with everolimus, approved for use in the treatment of renal cell carcinoma (second-line) in over 65 countries including the United States, countries in Europe and in Asia. As a combination therapy with pembrolizumab, approved for use in the treatment of renal cell carcinoma in over 45 countries including in Japan, the United States, and countries in Europe and in Asia, and approved for use in the treatment of endometrial carcinoma in over 50 countries including in Japan, the United States, and countries in Europe and in Asia, including conditional approval. The agent is marketed under the product name Kisplyx only for renal cell carcinoma indication in Europe. Joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate.

| | | | | | |
|---|---|---|---|---|---|
| In combination with anti-PD-1 therapy pembrolizumab, joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate (Additional Indication) | | | | | |
| | Endometrial carcinoma / First-line | LEAP-001 | JP/US/EU/CH | | PIII |
| | Non-small cell lung cancer (nonsquamous) (in combination with chemotherapy) / First-line | LEAP-006 | JP/US/EU/CH | | PIII |
| | Non-small cell lung cancer / Second-line | LEAP-008 | JP/US/EU | | PIII |
| | Head and neck cancer / First-line | LEAP-010 | JP/US/EU/CH | | PIII |
| | Hepatocellular carcinoma (in combination with transcatheter arterial chemoembolization) / First-line | LEAP-012 | JP/US/EU/CH | | PIII |
| | Esophageal carcinoma (in combination with chemotherapy) / First-line | LEAP-014 | JP/US/EU/CH | | PIII |
| | Gastric cancer (in combination with chemotherapy) / First-line | LEAP-015 | JP/US/EU/CH | | PIII |
| | Colorectal cancer (non MSI-H / pMMR) / Third-line | LEAP-017 | US/EU | | PIII |
| | Melanoma / Second-line | LEAP-004 | US/EU | | PII |
| | Selected solid tumors (Gastric cancer, colorectal cancer, glioblastoma, biliary tract cancers and pancreatic cancer) | LEAP-005 | US/EU | | PII |
| | Head and neck cancer / Second-line | LEAP-009 | US/EU | | PII |
| In combination with anticancer agent everolimus, joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate (Additional Indication) | | | | | |
| | Renal cell carcinoma / First-line | Study 307 | JP/US/EU | | PIII |
| In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Indication) | | | | | |
| | Hepatocellular carcinoma | — | JP | | PI |

◎ Based on the independent Data Monitoring Committee recommendation, Phase III clinical study of LEAP-003 for melanoma / First-line in the United States, Europe and China, has been decided to be discontinued and therefore was removed from this list.

JP: Japan, US: the United States, EU: Europe, CH: China, SK: South Korea, P: (Clinical trial) Phase

◎：Development progress from April 2023 onwards

| Development Code: **E7389** Generic Name: **eribulin** Product Name: **Halaven** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Anticancer agent / microtubule dynamics inhibitor | | | | | Injection |
| Description: A synthetic analog of halichondrin B derived from the marine sponge *Halichondria okadai*. Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved in over 85 countries including Japan, the United States, China and countries in Europe and in Asia for use in the treatment of breast cancer. Approved in over 80 countries including Japan, the United States and countries in Europe and in Asia for use in the treatment of liposarcoma (soft tissue sarcoma in Japan). | | | | | |
| Monotherapy (Additional Formulation) | | | | | |
| | Liposomal formulation | — | JP/EU | | PI |
| In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Formulation) | | | | | |
| | Liposomal formulation | Study 120 | JP | | PI/II |

| Development Code: **H3B-6545** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Anticancer agent / ERα inhibitor | | | | | Oral |
| Description: An orally administered selective estrogen receptor (ER) α covalent antagonist that inhibits ERα wild type / ERα mutant. Expected to show an antitumor effect against ER positive / HER2 negative breast cancers. | | | | | |
| | Breast cancer | Study 101 | US/EU | | PI/II |
| | Breast cancer (in combination with CDK4/6 inhibitor palbociclib) | — | US/EU | | PI |

| Development Code: **E7090** Generic Name: **tasurgratinib** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Anticancer agent / FGFR1, FGFR2, FGFR3 inhibitor | | | | | Oral |
| Description: An orally administered fibroblast growth factor receptors (FGFR1, FGFR2, FGFR3) selective tyrosine kinase inhibitor. Phase II clinical study for unresectable cholangiocarcinoma (one of biliary tract cancers) with *FGFR2* gene fusion is ongoing. It has been granted the orphan drug designation with a prospective indication for unresectable biliary tract cancer with *FGFR2* gene fusion by the Ministry of Health, Labour and Welfare (MHLW) in Japan. | | | | | |
| | Cholangiocarcinoma | Study 201 | JP/CH | | PII |
| | Breast cancer | — | JP | | PI |

| Development Code: **MORAb-202** Generic Name: **farletuzumab ecteribulin (FZEC)** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Anticancer agent / Folate receptor α targeted antibody drug conjugate | | | | | Injection |
| Description: An antibody drug conjugate (ADC) with approved anticancer drug eribulin. Expected to show an antitumor effect against folate receptor α-positive tumors by concentrating eribulin on tumor; inclusive of endometrial, ovarian, lung and breast cancers. Joint development with Bristol Myers Squibb. | | | | | |
| | Non-small cell lung cancer | Study 203 | US/EU | | PII |
| | Ovarian cancer, peritoneal cancer, fallopian tube cancer | Study 205 | JP/US/EU | | PII |
| | Solid tumors | Study 201 | US/EU | | PI/II |
| | Solid tumors | — | JP | | PI |

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◎：Development progress from April 2023 onwards

| Development Code: **E7386** | | | | | Collaboration (PRISM BioLab) |
|---|---|---|---|---|---|
| Indications / Drug class: Anticancer agent / CBP/β-catenin interaction inhibitor | | | | | Oral |
| Description: A CREB-binding protein (CBP) /β-catenin inhibitor that blocks the protein-protein interaction between CBP and β-catenin, and regulates Wnt signaling-dependent gene expression. Expected inhibition of Wnt signaling-dependent tumor growth. | | | | | |
| | Solid tumors (in combination with pembrolizumab) | Study 201 | JP/US/EU | | PI/II |
| | Solid tumors | — | JP/US/EU | | PI |
| | Solid tumors (in combination with lenvatinib) | — | JP/US/EU | | PI |

| Development Code: **E7130** | | | Collaboration (Harvard University) | | Injection |
|---|---|---|---|---|---|
| | Solid tumors | — | JP | | PI |

| Development Code: **E7766** | | | In-house | | Injection |
|---|---|---|---|---|---|
| | Solid tumors | — | US/EU | | PI |

## (3) Global Health

| Development Code: **E1224** Generic Name: **fosravuconazole** | In-house |
|---|---|
| Indications / Drug class: Antifungal agent / ergosterol synthesis inhibitor | Oral |
| Description: An ongoing collaboration with the Drugs for Neglected Diseases initiative (DNDi) for a new treatment for eumycetoma, a fungal form of mycetoma with a particularly high unmet medical need, and one of the world's most neglected diseases. Eisai is mainly responsible for non-clinical studies and the provision of the investigational drug. The Phase IIb/III clinical study is being conducted in Sudan by DNDi and the Mycetoma Research Center of the University of Khartoum, Sudan. Supported by the Global Health Innovative Technology Fund (GHIT Fund). | |

| Development Code: **SJ733** | Co-development (University of Kentucky) |
|---|---|
| Indications / Drug class: Antimalarial agent / ATP4 inhibitor | Oral |
| Description: Expected to be suitable for treatment in malaria-endemic areas, with rapid efficacy and safety, and providing lasting protection against reinfection. The treatment might potentially solve the problem of increased resistance faced by current antimalarial medicines. In the ongoing collaboration with the University of Kentucky, Eisai is responsible for the provision of drug substance and formulation manufacturing. The Phase II clinical study is being conducted in Peru by the University of Kentucky. Supported by the GHIT Fund. | |

| Development Code: **AWZ1066S** | Co-development (Liverpool School of Tropical Medicine) |
|---|---|
| Indications / Drug class: Antifilarial agent / antiwolbachia mechanism | Oral |
| Description: An ongoing collaboration with the Liverpool School of Tropical Medicine and the University of Liverpool to jointly identify new drugs effective against lymphatic filariasis and onchocerciasis (river blindness), both major types of filariasis. Eisai is responsible for the provision of drug substance and formulation manufacturing. The Phase I clinical study is being conducted in the United Kingdom (UK) by the Liverpool School of Tropical Medicine. Supported by the GHIT Fund and Medical Research Council in the UK. | |

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◎：Development progress from April 2023 onwards

## (4) Gastrointestinal Disorders

| Development Code: **AJG555** Product Name: **MOVICOL** | | | | | In-license (Norgine) |
|---|---|---|---|---|---|
| Indications / Drug class: Chronic constipation treatment / polyethylene glycol preparation | | | | | Oral |
| Description: An orally available constipation treatment consisting of a polyethylene glycol preparation which facilitates bowel movement by regulating osmolality in the intestines. Approved for chronic constipation treatment for children of 2 years and above and adult patients in Japan. Development conducted by EA Pharma. | | | | | |
| ◎ | Chronic constipation in children under 2 years of age (Additional Dosage and Administration) | Study CT3 | JP | | PIII |

| Development Code: **AJM347** | | | | | In-house | Oral |
|---|---|---|---|---|---|---|
| | Inflammatory bowel disease (Development conducted by EA Pharma) | — | EU | | PI | |

| Development Code: **EA1080** | | | | | In-house | Oral |
|---|---|---|---|---|---|---|
| | Inflammatory bowel disease (Development conducted by EA Pharma) | — | EU | | PI | |

| Development Code: **EA3571** | | | | | In-house | Oral |
|---|---|---|---|---|---|---|
| | Nonalcoholic steatohepatitis (Development conducted by EA Pharma) | — | JP | | PI | |

## (5) Other

| Development Code: **FYU-981** Generic Name: **dotinurad** | | | | | In-license (FUJI YAKUHIN) |
|---|---|---|---|---|---|
| Indications / Drug class: Treatment for Hyperuricemia and Gout / selective URAT1 inhibitor | | | | | Oral |
| Description: Dotinurad selectively inhibits URAT1, one of the uric acid transporters, thus preventing reabsorption of uric acid by kidneys and promoting uric acid excretion in urine. In addition, it has a small effect on other transporters affecting uric acid secretion, so it reduces serum uric acid levels at lower doses. Therefore, dotinurad is expected to have a low risk of side effects and drug interaction. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for dotinurad in January 2020. Eisai entered into a license agreement concerning the development and distribution in China in February 2020, and in five ASEAN countries in August 2021 with FUJI YAKUHIN. | | | | | |
| | Gout | Study 301 | CH | | PIII |

| Development Code: **E6742** | | | | | In-house |
|---|---|---|---|---|---|
| Indications / Drug class: Treatment for Systemic lupus erythematosus / TLR 7/8 inhibitor | | | | | Oral |
| Description: Toll-Like Receptors (TLRs) are receptors of the innate immune system, and activated TLRs initiate an inflammatory reaction or an antiviral response. E6742 is the inhibitor of oral and selective TLR7/8 which is associated with the pathogenesis of systemic lupus erythematosus. This project has been selected by the Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) grant program. | | | | | |
| | Systemic lupus erythematosus | Study 101 | JP | | PI/II |

| Development Code: **E8001** | | | | | In-house | Injection |
|---|---|---|---|---|---|---|
| | Rejection reaction associated with organ transplantation | — | JP | | PI | |

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◎：Development progress from April 2023 onwards