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

Reference Data

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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

1. Consolidated Statement of Income	-----	1
2. Segment Information	-----	2
3. Financial Results by Reporting Segment	-----	3
4. Revenue from Major Products	-----	7
5. Revenue Forecast by Reporting Segment	-----	9
6. Consolidated Statement of Comprehensive Income	-----	10
7. Consolidated Statement of Cash Flows	-----	11
8. Capital Expenditures, Depreciation and Amortization	-----	12
9. Consolidated Statement of Financial Position	-----	12
10. Changes in Quarterly Results	-----	14
11. Stock Information	-----	17
12. Number of Employees	-----	18
13. Major R&D Pipeline	-----	19

Currency Exchange Rates

		US (USD/JPY)	EU (EUR/JPY)	UK (GBP/JPY)	China (RMB/JPY)
FY 2022 Q2	Quarterly Average Rate	133.97	138.72	162.88	19.88
	Quarter End Rate	144.81	142.32	161.72	20.37
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 Q2	Quarterly Average Rate	140.99	153.38	177.49	19.74
	Quarter End Rate	149.58	158.00	182.53	20.46
FY 2023	Q3-Q4 Forecast Rate	<u>148.00</u>	<u>157.00</u>	<u>177.50</u>	<u>20.10</u>

* The full year financial forecasts for FY 2023 (April 1, 2023 – March 31, 2024) have been revised from the forecasts previously announced. Revisions are underlined.

* 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	
	Q2	Ratio (%)	Full year	Ratio (%)	Q2	Ratio (%)	YOY (%)	Diff.	Full year forecast Revised	Previous
Revenue	358.6	100.0	744.4	100.0	373.6	100.0	104.2	14.9	741.0	712.0
Cost of sales	92.5	25.8	177.8	23.9	80.3	21.5	86.8	(12.2)	154.5	163.5
Gross profit	266.1	74.2	566.6	76.1	293.2	78.5	110.2	27.1	586.5	548.5
Selling, general and administrative expenses	180.4	50.3	358.3	48.1	178.9	47.9	99.2	(1.5)	374.0	353.0
Selling expenses	95.5	26.6	189.0	25.4	95.0	25.4	99.5	(0.5)	—	—
Personnel expenses	48.7	13.6	100.2	13.5	54.6	14.6	112.2	6.0	—	—
Administrative and other expenses	36.2	10.1	69.1	9.3	29.2	7.8	80.7	(7.0)	—	—
Research and development expenses	81.5	22.7	173.0	23.2	82.8	22.2	101.5	1.3	166.0	152.0
Other income	3.0	0.8	8.3	1.1	0.8	0.2	25.8	(2.2)	4.5	6.5
Other expenses	2.0	0.5	3.5	0.5	0.9	0.2	46.8	(1.0)	—	—
Operating profit	5.3	1.5	40.0	5.4	31.4	8.4	598.3	26.2	51.0	50.0
Financial income	3.7	1.0	7.2	1.0	5.4	1.4	143.7	1.6	—	—
Financial costs	0.9	0.2	2.3	0.3	1.1	0.3	133.3	0.3	—	—
Profit before income taxes	8.1	2.3	45.0	6.0	35.7	9.5	438.4	27.5	57.5	52.0
Income taxes	(23.7)	(6.6)	(11.8)	(1.6)	11.5	3.1	—	35.2	—	—
Profit for the period	31.8	8.9	56.8	7.6	24.2	6.5	76.0	(7.6)	43.0	39.0
Profit for the period attributable to										
Owners of the parent	30.5	8.5	55.4	7.4	23.1	6.2	75.9	(7.3)	41.5	38.0
Non-controlling interests	1.3	0.4	1.4	0.2	1.0	0.3	77.9	(0.3)	—	—
Comprehensive income for the period	102.1	28.5	96.9	13.0	85.7	22.9	83.9	(16.4)		
Earnings per share (EPS, yen)	106.25		193.31		80.64				145.30	132.60
Dividend per share (DPS, yen)	80.0		160.0		80.0				160.0	160.0
Return on equity (ROE, %)	—		7.2		—				5.1	4.9
Dividends on equity ratio (DOE, %)	—		5.9		—				5.6	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	<ul style="list-style-type: none"> - 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 Lenvima: 151.4 billion yen (the same period in previous fiscal year: 128.2 billion yen) Dayvigo: 19.4 billion yen (the same period in previous fiscal year: 13.6 billion yen) - Decrease due to expiration of the co-promotion agreement in Japan for fully human anti-TNF-α monoclonal antibody Humira in June 2023: 13.4 billion yen (the same period in previous fiscal year: 24.7 billion yen) - Decrease due to the transfer of the commercial rights for antiepileptic agent Fycompa in the United States in January 2023: 13.6 billion yen (the same period in previous fiscal year: 20.1 billion yen)
Selling, general and administrative expenses	<ul style="list-style-type: none"> - Recording of expenses regarding shared profit of Lenvima paid to Merck & Co., Inc., Rahway, NJ, USA: 69.9 billion yen (the same period in previous fiscal year: 61.0 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: 5.5 billion yen), while selling expenses increased for AD treatment Leqembi in the United States - Reversal of Leqembi-related expenses received from Biogen: -10.1 billion yen (the same period in previous fiscal year: -3.5 billion yen)
Research and development expenses	<ul style="list-style-type: none"> - Control of expenses through the partnership model (partner's burden: 30.8 billion yen (the same period in previous fiscal year: 32.0 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 ADUHELM along with contract modification (the same period in previous fiscal year: 4.6 billion yen) - Recording of impairment losses of 2.2 billion yen related to the research facilities at the U.S. consolidated subsidiary
Income taxes	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Revenue: +8.13 billion yen, operating profit: +1.16 billion yen
Exchange rate sensitivity (annual effect of 1 yen depreciation in currency value)	<ul style="list-style-type: none"> - Revenue (U.S. dollars: +1.76 billion yen, Euro: +0.29 billion yen, U.K. pounds: +0.07 billion yen, Chinese renminbi: +6.25 billion yen) - Operating profit (U.S. dollars: -0.73 billion yen, Euro: +0.07 billion yen, U.K. pounds: -0.04 billion yen, Chinese renminbi: +3.36 billion yen)

2. Segment Information

1) Revenue

(billions of yen)

	FY 2022		FY 2023		CER YOY (%)
	Q2	Full year	Q2	YOY (%)	
Pharmaceutical Business Total	352.6	684.4	355.6	100.9	98.9
Japan pharmaceutical business	123.2	238.9	116.0	94.2	94.2
Americas pharmaceutical business	106.4	212.7	110.9	104.2	99.1
United States	104.7	209.0	108.6	103.7	98.5
China pharmaceutical business	63.3	110.8	63.3	100.0	100.5
EMEA pharmaceutical business	35.0	72.2	37.7	108.0	105.7
Asia and Latin America pharmaceutical business	24.8	49.8	27.8	112.0	107.4
Other business	6.1	60.0	17.9	295.8	277.3
Consolidated revenue	358.6	744.4	373.6	104.2	101.9

* CER=Constant Exchange Rates

* Indicates revenue from external customers.

2) Profit by Reporting Segment

(billions of yen)

	FY 2022		FY 2023		CER YOY (%)
	Q2	Full year	Q2	YOY (%)	
Pharmaceutical Business Total	173.0	325.6	185.1	107.0	104.7
Japan pharmaceutical business	40.9	72.9	39.6	96.7	96.7
Americas pharmaceutical business	64.4	133.4	72.3	112.2	106.9
China pharmaceutical business	35.3	55.6	38.2	108.2	108.6
EMEA pharmaceutical business	20.5	41.6	21.4	104.4	104.0
Asia and Latin America pharmaceutical business	11.8	22.1	13.5	114.7	108.9
Other business	1.3	48.5	13.4	1054.7	968.4
Research and development expenses	(81.5)	(173.0)	(82.8)	101.5	96.4
Group headquarters' management costs and other expenses	(87.5)	(161.0)	(84.2)	96.2	96.5
Consolidated operating profit	5.3	40.0	31.4	598.3	576.3

* 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	
	Q2	Full year	Q2	YOY (%)
Revenue	123.2	238.9	116.0	94.2
Japan pharmaceutical business	110.6	215.4	104.2	94.2
OTC and others	12.6	23.5	11.9	93.9
Segment profit	40.9	72.9	39.6	96.7
Japan prescription medicines - revenue from major products				
Insomnia treatment Dayvigo	11.1	24.2	16.7	150.6
Fully human anti-TNF- α monoclonal antibody Humira	24.7	47.2	13.4	54.3
Anticancer agent Lenvima	6.9	13.7	8.2	118.8
Janus kinase inhibitor Jyseleca	3.0	7.3	6.2	203.0
Peripheral neuropathy treatment Methycobal	5.3	10.3	4.9	92.1
Anticancer agent Halaven	4.3	8.5	4.1	96.8
Elemental diet Elental [#]	3.6	7.0	3.7	101.6
Antiepileptic agent Fycompa	3.0	6.1	3.5	116.1
Chronic constipation treatment Goofice [#]	3.3	6.5	3.5	106.8
Chronic constipation treatment MOVICOL [#]	2.8	5.8	3.2	111.9
Parkinson's disease treatment Eqfina	2.2	4.6	2.9	129.6
Proton pump inhibitor Pariet [#]	3.0	5.5	2.1	71.7
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	2.3	4.2	1.7	74.6
Japan OTC and others - revenue from major products				
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	7.7	14.1	8.0	103.2

[#] EA Pharma product

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

* 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	
	Q2	Full year	Q2	YOY (%)
Revenue	106.4	212.7	110.9	104.2 <99.1>
United States	104.7	209.0	108.6	103.7 <98.5>
Segment profit	64.4	133.4	72.3	112.2 <106.9>
Americas - revenue from major products				
Anticancer agent Lenvima	80.2	161.6	98.8	123.3 <117.2>
United States	79.6	160.5	98.2	123.4 <117.2>
	[Millions USD] [594]	[1,185]	[697]	
Anticancer agent Halaven	7.7	13.9	6.0	77.6 <73.8>
United States	7.5	13.5	5.8	77.5 <73.7>
	[Millions USD] [56]	[100]	[41]	
Insomnia Treatment Dayvigo	2.3	4.8	2.2	95.1 <92.0>
United States	1.8	3.5	1.2	66.1 <62.8>
	[Millions USD] [14]	[26]	[9]	
Antiepileptic agent Banzel	2.0	4.4	1.8	89.0 <84.9>
United States	1.8	4.1	1.6	85.6 <81.3>
	[Millions USD] [14]	[30]	[11]	
Alzheimer's disease Leqembi	—	0.0	0.4	—
United States	—	0.0	0.4	—
	[Millions USD] [—]	[0]	[3]	<—>

* 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	
	Q2	Full year	Q2	YOY (%)
Revenue	63.3	110.8	63.3	100.0 <100.5>
Segment profit	35.3	55.6	38.2	108.2 <108.6>
China - revenue from major products				
Anticancer agent Lenvima	20.7	32.2	18.4	88.7 <89.1>
Peripheral neuropathy treatment Methycobal	8.4	14.5	7.1	84.6 <85.1>
Vertigo and equilibrium disturbance treatment Merislon	5.1	9.9	7.0	137.5 <138.4>
Proton pump inhibitor Pariet	4.9	8.4	4.8	98.9 <99.4>
Liver disease / Allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets	4.5	7.9	3.6	81.4 <82.0>
Alzheimer's disease treatment Aricept	3.4	6.1	3.3	96.6 <97.1>
Antiepileptic agent Fycompa	1.3	2.4	2.6	207.5 <208.7>
Anticancer agent Halaven	1.1	2.0	1.1	96.1 <96.5>

* 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	
	Q2	Full year	Q2	YOY (%)
Revenue	35.0	72.2	37.7	108.0 <105.7>
Segment profit	20.5	41.6	21.4	104.4 <104.0>
EMEA - revenue from major products				
Anticancer agent Lenvima/Kispplx	15.0	30.9	19.2	127.9 <128.2>
Antiepileptic agent Fycompa	5.5	11.7	6.1	110.4 <104.0>
Anticancer agent Halaven	6.8	13.6	5.8	84.4 <83.4>
Antiepileptic agent Inovelon	1.5	3.1	1.6	106.4 <99.7>

* 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	
	Q2	Full year	Q2	YOY (%)
Revenue	24.8	49.8	27.8	112.0 <107.4>
Segment profit	11.8	22.1	13.5	114.7 <108.9>
Asia and Latin America - revenue from major products				
Anticancer agent Lenvima	5.4	11.1	6.9	126.1 <119.3>
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	6.7	13.0	6.7	99.5 <96.0>
Proton pump inhibitor Pariet	2.2	4.5	2.8	129.0 <123.8>
Peripheral neuropathy treatment Methycobal	1.8	3.9	2.1	113.1 <109.9>
Anticancer agent Halaven	1.5	3.3	1.8	123.6 <115.9>
Antiepileptic agent Fycompa	0.9	1.7	1.0	112.9 <109.7>

* 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	
	Q2	Full year	Q2	YOY (%)
Neurology Products Total	74.5	144.5	70.9	95.2 <93.9>
Dayvigo (Insomnia treatment)	13.6	29.4	19.4	142.6 <142.0>
Japan	11.1	24.2	16.7	150.6
Americas	2.3	4.8	2.2	95.1 <92.0>
Methycobal (Peripheral neuropathy treatment)	16.4	30.8	15.0	91.1 <91.0>
Japan	5.3	10.3	4.9	92.1
China	8.4	14.5	7.1	84.6 <85.1>
Asia and Latin America	1.8	3.9	2.1	113.1 <109.9>
Fycompa (Antiepileptic agent)	20.1	37.1	13.6	67.5 <65.6>
Japan	3.0	6.1	3.5	116.1
China	1.3	2.4	2.6	207.5 <208.7>
EMEA	5.5	11.7	6.1	110.4 <104.0>
Asia and Latin America	0.9	1.7	1.0	112.9 <109.7>
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	12.6	24.4	12.6	99.3 <97.0>
Japan	2.3	4.2	1.7	74.6
China	3.4	6.1	3.3	96.6 <97.1>
Asia and Latin America	6.7	13.0	6.7	99.5 <96.0>
Inovelon/Banzel (Antiepileptic agent)	3.8	8.2	3.7	97.6 <92.8>
Americas	2.0	4.4	1.8	89.0 <84.9>
EMEA	1.5	3.1	1.6	106.4 <99.7>
Leqembi (Alzheimer's disease)	—	0.0	0.4	— <—>
Americas	—	0.0	0.4	— <—>
Other	7.9	14.6	6.4	80.4 <80.1>

* 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	
	Q2	Full year	Q2	YOY (%)
Oncology Products Total	153.7	299.1	174.2	113.3 <109.6>
Lenvima/Kispix (Anticancer agent)	128.2	249.6	151.4	118.1 <114.1>
Japan	6.9	13.7	8.2	118.8
Americas	80.2	161.6	98.8	123.3 <117.2>
China	20.7	32.2	18.4	88.7 <89.1>
EMEA	15.0	30.9	19.2	127.9 <128.2>
Asia and Latin America	5.4	11.1	6.9	126.1 <119.3>
Halaven (Anticancer agent)	21.4	41.3	18.8	87.7 <85.6>
Japan	4.3	8.5	4.1	96.8
Americas	7.7	13.9	6.0	77.6 <73.8>
China	1.1	2.0	1.1	96.1 <96.5>
EMEA	6.8	13.6	5.8	84.4 <83.4>
Asia and Latin America	1.5	3.3	1.8	123.6 <115.9>
Other	4.2	8.2	4.1	97.9 <95.1>

* 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		
	Q2	Full year	Q2	Full year forecast	
				Revised	Previous
Japan	123.2	238.9	116.0	<u>224.5</u>	238.5
Prescription medicines	110.6	215.4	104.2	<u>201.0</u>	215.0
Insomnia treatment					
Dayvigo	11.1	24.2	16.7	35.0	35.0
Anticancer agent					
Lenvima	6.9	13.7	8.2	17.5	17.5
Janus kinase inhibitor					
Jyseleca	3.0	7.3	6.2	15.0	15.0
Fully human anti-TNF- α monoclonal antibody					
Humira	24.7	47.2	13.4	13.5	13.5
Peripheral neuropathy treatment					
Methycobal	5.3	10.3	4.9	10.0	10.0
Anticancer agent					
Halaven	4.3	8.5	4.1	8.5	8.5
Chronic constipation treatment					
Goofice [#]	3.3	6.5	3.5	<u>7.5</u>	8.0
Antiepileptic agent					
Fycompa	3.0	6.1	3.5	7.5	7.5
Parkinson's disease treatment					
Equfina	2.2	4.6	2.9	7.0	7.0
Chronic constipation treatment					
MOVICOL [#]	2.8	5.8	3.2	7.0	7.0
Elemental diet					
Elental [#]	3.6	7.0	3.7	<u>6.5</u>	7.0
OTC and others	12.6	23.5	11.9	23.5	23.5
Vitamin B2 preparation, "Chocola BB Plus," etc.					
Chocola BB Group	7.7	14.1	8.0	16.0	16.0
Americas	106.4	212.7	110.9	<u>229.0</u>	205.5
United States	104.7	209.0	108.6	<u>223.5</u>	201.0
China	63.3	110.8	63.3	<u>109.5</u>	104.5
EMEA	35.0	72.2	37.7	<u>74.0</u>	67.0
Asia and Latin America	24.8	49.8	27.8	<u>53.0</u>	49.5
Other	6.1	60.0	17.9	<u>51.0</u>	47.0
Consolidated revenue	358.6	744.4	373.6	<u>741.0</u>	712.0
Global revenue from major products					
Lenvima/Kisplyx	128.2	249.6	151.4	<u>293.0</u>	261.0
Japan	6.9	13.7	8.2	17.5	17.5
Americas	80.2	161.6	98.8	<u>198.5</u>	174.0
China	20.7	32.2	18.4	<u>28.0</u>	27.0
EMEA	15.0	30.9	19.2	<u>37.0</u>	32.0
Asia and Latin America	5.4	11.1	6.9	<u>12.0</u>	10.5
Dayvigo	13.6	29.4	19.4	42.5	42.5
Japan	11.1	24.2	16.7	35.0	35.0
Americas	2.3	4.8	2.2	<u>5.0</u>	6.5
Halaven	21.4	41.3	18.8	<u>37.0</u>	34.5
Japan	4.3	8.5	4.1	8.5	8.5
Americas	7.7	13.9	6.0	<u>11.0</u>	9.0
China	1.1	2.0	1.1	<u>2.0</u>	2.5
EMEA	6.8	13.6	5.8	<u>12.0</u>	11.5
Asia and Latin America	1.5	3.3	1.8	<u>3.5</u>	3.0
Fycompa	20.1	37.1	13.6	<u>25.5</u>	25.5
Japan	3.0	6.1	3.5	7.5	7.5
China	1.3	2.4	2.6	3.0	3.0
EMEA	5.5	11.7	6.1	12.5	12.5
Asia and Latin America	0.9	1.7	1.0	2.0	2.0

[#] EA Pharma product

* The development and marketing agreement for Humira in Japan with AbbVie GK 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		
	Q2	Full year	Q2	YOY (%)	Diff.
Profit for the period	31.8	56.8	24.2	76.0	(7.6)
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)	4.1	5.5	3.7	91.5	(0.3)
Remeasurements of defined benefit plans	—	1.1	—	—	—
Subtotal	4.1	6.6	3.7	91.5	(0.3)
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	66.2	33.4	57.9	87.5	(8.3)
Cash flow hedges	0.0	0.0	(0.1)	—	(0.2)
Subtotal	66.2	33.5	57.8	87.3	(8.4)
Total other comprehensive income (loss), net of tax	70.3	40.1	61.5	87.5	(8.8)
Comprehensive income (loss) for the period	102.1	96.9	85.7	83.9	(16.4)
Comprehensive income (loss) for the period attributable to					
Owners of the parent	100.7	95.5	84.6	84.0	(16.1)
Non-controlling interests	1.4	1.4	1.1	80.0	(0.3)

7. Consolidated Statement of Cash Flows

(billions of yen)

	FY 2022	FY 2023	
	Q2	Q2	Diff.
Operating activities			
Profit before income taxes	8.1	35.7	27.5
Depreciation and amortization	19.7	19.5	(0.2)
Impairment losses	0.3	2.3	2.1
(Increase) decrease in working capital	(26.6)	(20.9)	5.7
Interest and dividends received	1.3	4.3	3.0
Interest paid	(0.7)	(0.8)	(0.1)
Income taxes paid	(13.0)	(6.9)	6.1
Income taxes refund	—	3.0	3.0
Other	(8.0)	(7.0)	1.0
Net cash from (used in) operating activities	(18.8)	29.3	48.1
Investing activities			
Purchases of property, plant and equipment	(14.2)	(9.4)	4.8
Purchases of intangible assets	(6.5)	(2.5)	4.0
Proceeds from sale of property, plant and equipment and intangible assets	0.3	0.1	(0.3)
Purchases of financial assets	(1.9)	(4.7)	(2.8)
Proceeds from sale and redemption of financial assets	5.9	0.6	(5.3)
Subtotal <Capital expenditures (cash basis)>	(16.4)	(16.0)	0.4
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	(0.0)
Other	0.0	0.1	0.0
Net cash from (used in) investing activities	(16.4)	(15.9)	0.5
Financing activities			
Net increase (decrease) in short-term borrowings	—	17.1	17.1
Repayments of long-term borrowings	(0.0)	(10.0)	(10.0)
Repayments of lease liabilities	(4.9)	(4.7)	0.2
Dividends paid	(22.9)	(23.0)	(0.0)
Other	0.0	(0.5)	(0.5)
Net cash from (used in) financing activities	(27.8)	(21.0)	6.8
Effect of exchange rate change on cash and cash equivalents	17.9	21.8	3.8
Net increase (decrease) in cash and cash equivalents	(45.1)	14.1	59.2
Cash and cash equivalents at beginning of period	309.6	267.4	(42.3)
Cash and cash equivalents at end of period	264.5	281.5	16.9

Free cash flows	(35.3)	13.3	48.5
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* "Free cash flows" = "Net cash from (used in) operating activities" - "Capital expenditures (cash basis)"

Notes

<p>■ Net cash from (used in) operating activities Working capital increased mainly due to increase in inventories for Leqembi and decrease in accounts payable-other</p> <p>■ Net cash from (used in) investing activities Capital expenditures occurred following the expansion of research facilities and production facilities</p> <p>■ 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</p>
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8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2022		FY 2023		FY 2023
	Q2	Full year	Q2	Diff.	Full year forecast
Capital expenditures (cash basis)	20.7	34.6	11.9	(8.8)	35.5
Property, plant and equipment	14.2	22.6	9.4	(4.8)	13.5
Intangible assets	6.5	12.0	2.5	(4.0)	22.0
Depreciation and amortization	19.7	40.0	19.5	(0.2)	40.0
Property, plant and equipment	11.3	22.8	11.1	(0.2)	23.0
Intangible assets	8.4	17.2	8.4	(0.0)	17.0

9. Consolidated Statement of Financial Position

<Assets>

(billions of yen)

	FY 2022		September 30, 2023	FY 2023		Diff.
	March 31, 2023	Ratio (%)		Ratio (%)	% change	
Assets						
Non-current assets						
Property, plant and equipment	166.6	13.2	165.3	12.4	99.2	(1.3)
Goodwill	208.8	16.5	233.5	17.5	111.8	24.7
Intangible assets	89.2	7.1	86.0	6.4	96.4	(3.2)
Other financial assets	52.5	4.2	63.1	4.7	120.3	10.6
Other assets	21.4	1.7	20.9	1.6	97.7	(0.5)
Deferred tax assets	102.6	8.1	105.9	7.9	103.2	3.3
Total non-current assets	641.1	50.7	674.7	50.6	105.2	33.6
Current assets						
Inventories	140.4	11.1	160.0	12.0	113.9	19.6
Trade and other receivables	187.3	14.8	191.9	14.4	102.5	4.7
Other financial assets	0.5	0.0	0.5	0.0	92.9	(0.0)
Other assets	26.6	2.1	25.4	1.9	95.5	(1.2)
Cash and cash equivalents	267.4	21.2	281.5	21.1	105.3	14.1
Total current assets	622.2	49.3	659.3	49.4	106.0	37.1
Total assets	1,263.4	100.0	1,334.0	100.0	105.6	70.6

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 (%)	September 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	78.9	5.9	100.1	0.1
Treasury shares	(33.6)	(2.7)	(33.6)	(2.5)	99.9	0.0
Retained earnings	522.8	41.4	526.7	39.5	100.7	3.9
Other components of equity	187.0	14.8	244.8	18.3	130.9	57.7
Total equity attributable to owners of the parent	800.0	63.3	861.7	64.6	107.7	61.7
Non-controlling interests	22.6	1.8	23.2	1.7	102.5	0.6
Total equity	822.6	65.1	884.8	66.3	107.6	62.3
Liabilities						
Non-current liabilities						
Borrowings	84.9	6.7	84.9	6.4	100.0	0.0
Other financial liabilities	37.0	2.9	38.8	2.9	105.0	1.8
Provisions	1.3	0.1	1.3	0.1	103.1	0.0
Other liabilities	18.0	1.4	16.3	1.2	90.5	(1.7)
Deferred tax liabilities	0.7	0.1	0.5	0.0	72.2	(0.2)
Total non-current liabilities	141.8	11.2	141.8	10.6	100.0	0.0
Current liabilities						
Borrowings	41.2	3.3	48.3	3.6	117.2	7.1
Trade and other payables	86.8	6.9	61.1	4.6	70.4	(25.7)
Other financial liabilities	34.7	2.7	36.0	2.7	104.0	1.4
Income taxes payable	2.2	0.2	8.2	0.6	367.6	5.9
Provisions	23.0	1.8	28.4	2.1	123.4	5.4
Other liabilities	111.0	8.8	125.3	9.4	112.9	14.3
Total current liabilities	298.9	23.7	307.3	23.0	102.8	8.4
Total liabilities	440.8	34.9	449.1	33.7	101.9	8.4
Total equity and liabilities	1,263.4	100.0	1,334.0	100.0	105.6	70.6

Notes

<p>■ Equity (Other components of equity)</p>	Increase in exchange differences on translation of foreign operations following the depreciation of the Japanese yen
<p>■ Liabilities (Borrowings - current)</p>	Increase in short-term borrowings, decrease in long-term borrowings (current portion)
(Trade and other payables)	Decrease mainly in accounts payable-other
(Other liabilities - current)	Increase mainly in shared profit of Lenvima paid to Merck & Co., Inc., Rahway, NJ, USA

10. Changes in Quarterly Results

1) Income Statement

(billions of yen)

	FY 2022				FY2023	
	Q1	Q2	Q3	Q4	Q1	Q2
Revenue	184.3	174.4	187.6	198.2	196.9	176.6
Cost of sales	47.4	45.1	46.7	38.6	43.9	36.4
Gross profit	136.9	129.2	140.8	159.6	153.0	140.2
Selling, general and administrative expenses	92.3	88.1	92.6	85.3	86.1	92.8
Selling expenses	50.2	45.3	48.9	44.5	45.0	50.0
Personnel expenses	24.0	24.7	25.7	25.8	26.0	28.7
Administrative and other expenses	18.1	18.1	17.9	14.9	15.1	14.1
Research and development expenses	38.5	43.0	39.9	51.6	41.1	41.6
Other income	2.5	0.6	0.4	4.9	0.6	0.1
Other expenses	1.1	0.9	0.2	1.4	0.4	0.5
Operating profit	7.4	(2.2)	8.6	26.2	26.0	5.4
Financial income	2.7	1.0	1.5	2.0	2.8	2.6
Financial costs	0.4	0.4	0.6	0.8	0.5	0.6
Profit before income taxes	9.7	(1.6)	9.5	27.4	28.3	7.4
Income taxes	(18.2)	(5.4)	0.3	11.5	7.4	4.1
Profit for the period	28.0	3.8	9.1	15.9	20.9	3.3
Profit for the period attributable to						
Owners of the parent	26.9	3.6	8.6	16.3	20.3	2.8
Non-controlling interests	1.1	0.3	0.5	(0.4)	0.6	0.5
Comprehensive income for the period	79.7	22.4	(30.7)	25.5	68.4	17.2
Earnings per share (EPS, yen)	93.81	12.44	30.14	56.92	70.92	9.73

* 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	Q2
Net cash from (used in) operating activities	3.9	(22.8)	(6.9)	24.0	12.6	16.6
Net cash from (used in) investing activities	(16.8)	0.4	(3.8)	(2.5)	(11.6)	(4.3)
Net cash from (used in) financing activities	(25.2)	(2.6)	29.7	(26.4)	(15.5)	(5.5)
Cash and cash equivalents at end of period	287.8	264.5	268.0	267.4	269.3	281.5
Free cash flow	(12.6)	(22.7)	(10.7)	21.6	1.0	12.3

* "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	Q2
Capital expenditures (cash basis)	15.9	4.8	7.1	6.7	8.6	3.4
Property, plant and equipment	11.6	2.6	5.4	3.0	7.0	2.4
Intangible assets	4.3	2.3	1.7	3.7	1.6	0.9
Depreciation and amortization	9.8	9.9	10.2	10.1	9.8	9.8
Property, plant and equipment	5.6	5.6	5.9	5.7	5.5	5.6
Intangible assets	4.2	4.2	4.3	4.5	4.2	4.2

4) Financial Positions

(billions of yen)

	Jun. 30, 2022	Sept. 30, 2022	Dec. 31, 2022	Mar. 31, 2023	Jun. 30, 2023	Sept. 30, 2023
Total assets	1,272.9	1,261.3	1,251.1	1,263.4	1,305.1	1,334.0
Equity	828.3	850.7	797.1	822.6	867.7	884.8
Attributable to owners of the parent	804.5	828.1	774.0	800.0	844.9	861.7
Liabilities	444.5	410.6	454.0	440.8	437.4	449.1
Borrowings	94.9	94.9	150.1	126.1	136.2	133.2
Ratio of equity attributable to owners of the parent (%)	63.2	65.7	61.9	63.3	64.7	64.6
Net debt equity ratio (times)	(0.28)	(0.24)	(0.18)	(0.21)	(0.19)	(0.20)

* "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	Q2
Neurology Total	37.1	37.4	39.7	30.3	36.7	34.2
Dayvigo (Insomnia treatment)	6.5	7.1	8.4	7.4	9.4	10.0
Japan	5.3	5.8	7.0	6.1	8.1	8.6
Americas	1.1	1.2	1.2	1.2	1.0	1.2
Methycobal (Peripheral neuropathy treatment)	8.2	8.2	8.2	6.2	7.8	7.2
Japan	2.7	2.6	2.8	2.2	2.5	2.4
China	4.4	4.0	3.6	2.5	3.8	3.3
Asia and Latin America	0.8	1.1	1.2	0.9	1.0	1.1
Fycompa (Antiepileptic agent)	9.9	10.2	10.4	6.6	8.1	5.5
Japan	1.6	1.5	1.7	1.3	1.8	1.7
China	0.6	0.7	0.6	0.5	2.6	0.1
EMEA	2.8	2.7	3.0	3.2	3.1	3.0
Asia and Latin America	0.4	0.4	0.5	0.4	0.5	0.5
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	6.3	6.4	6.4	5.3	6.2	6.4
Japan	1.2	1.1	1.1	0.8	0.9	0.8
China	1.6	1.8	1.8	0.9	1.6	1.7
Asia and Latin America	3.3	3.4	3.3	3.0	3.2	3.4
Inovelon/Banzel (Antiepileptic agent)	1.8	2.0	2.7	1.7	2.0	1.8
Americas	0.9	1.1	1.7	0.8	1.0	0.8
EMEA	0.7	0.8	0.8	0.8	0.8	0.8
Leqembi (Alzheimer's disease)	—	—	—	0.0	0.1	0.3
Americas	—	—	—	0.0	0.1	0.3
Other	4.5	3.4	3.7	3.0	3.3	3.1

* 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				FY2023	
	Q1	Q2	Q3	Q4	Q1	Q2
Oncology Total	79.7	74.0	75.7	69.7	82.4	91.8
Lenvima/Kispplx (Anticancer agent)	66.3	61.8	63.1	58.3	70.8	80.6
Japan	3.6	3.3	3.7	3.1	4.1	4.1
Americas	38.5	41.7	43.0	38.4	48.1	50.7
China	13.9	6.9	6.7	4.8	6.9	11.5
EMEA	8.1	6.9	7.0	8.9	9.0	10.1
Asia and Latin America	2.3	3.1	2.7	3.0	2.6	4.3
Halaven (Anticancer agent)	11.1	10.3	10.4	9.6	9.5	9.3
Japan	2.2	2.1	2.2	2.0	2.1	2.0
Americas	4.1	3.6	3.3	2.9	2.9	3.1
China	0.6	0.6	0.5	0.3	0.6	0.5
EMEA	3.5	3.3	3.4	3.4	3.0	2.8
Asia and Latin America	0.8	0.7	0.9	1.0	0.8	1.0
Other	2.2	1.9	2.2	1.8	2.2	1.9

11. Stock Information

1) Number of Shares Issued and Shareholders

As of September 30, 2023

Total Number of Authorized Shares	Number of Shares Issued and Outstanding	Number of Shares Held as Treasury Stock	Number of Shareholders	Average Number of Shares per Shareholder
1,100,000,000	296,566,949	9,530,211	88,506	3,351

* Number of shares issued and outstanding includes treasury stock.

2) Principal Shareholders

As of September 30, 2023

Shareholders	Shares (1,000 shares)	Percentage of shares held (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	54,142	18.86
Custody Bank of Japan, Ltd. (Trust Account)	34,363	11.97
State Street Bank and Trust Company 505001	20,447	7.12
JP Morgan Chase Bank 385632	6,644	2.31
Nippon Life Insurance Company	6,500	2.26
Saitama Resona Bank, Limited	4,800	1.67
State Street Bank West Client - Treaty 505234	4,780	1.67
The Naito Foundation	4,212	1.47
Goldman, Sachs & Co. Reg	3,858	1.34
JP Morgan Chase Bank 385781	3,598	1.25

* Number of shares has been rounded down to the nearest thousand.

* The percentage of shares held is calculated in proportion to the number of shares issued and outstanding (excluding treasury stock).

* Treasury stock (9,530 thousand shares, the percentage of treasury stock calculated in proportion to the number of shares issued and outstanding: 3.21%) has been excluded from the table as it has no voting rights.

* While the large shareholding reports (amendment reports) received up until September 30, 2023 are listed below, in cases where large shareholdings cannot be confirmed by the shareholder registry as of September 30, 2023 or where the number of shares held does not account among the top 10 shareholders, such shareholders are not listed in the above table. Furthermore, the percentage of shares held (rounded down) given inside the brackets is calculated in proportion to the number of shares issued and outstanding including treasury stock.

(1) As of August 15, 2017, eleven companies including BlackRock Japan Co., Ltd. jointly hold 18,308 thousand shares (6.17%).

(Amendment report dated August 21, 2017)

(2) As of July 15, 2020, three companies including Nomura Securities Co., Ltd. jointly hold 18,380 thousand shares (6.20%).

(Amendment report dated July 21, 2020)

(3) As of September 15, 2020, Bank's Shareholdings Purchase Corporation holds 14,945 thousand shares (5.04%).

(Large shareholding report dated September 23, 2020)

(4) As of August 31, 2022, the Wellington Management Company, LLP holds 20,752 thousand shares (7.00%).

(Amendment report dated September 5, 2022)

(5) As of September 29, 2023, Sumitomo Mitsui Trust Asset Management Co., Ltd. and Nikko Asset Management Co., Ltd. jointly hold 16,353 thousand shares (5.51%).

(Amendment report dated October 5, 2023)

3) Number of Shares Held by Category

(1,000 shares)

	March 31, 2023	Ratio (%)	September 30, 2023	Ratio (%)	Diff.
Financial institutions	119,634	40.3	111,100	37.5	(8,533)
Financial instruments traders (securities companies)	9,730	3.3	9,386	3.2	(344)
Other companies	17,388	5.9	15,578	5.3	(1,810)
Foreign entities, etc.	98,821	33.3	108,661	36.6	9,840
Individuals, other	41,323	13.9	42,308	14.3	985
Treasury stock	9,667	3.3	9,530	3.2	(137)
Total	296,566	100.0	296,566	100.0	-

* Number of shares has been rounded down to the nearest thousand.

12. Number of Employees

1) Number of Employees on Consolidated Basis

(employees)

	March 31, 2021	March 31, 2022	March 31, 2023	September 30, 2023
Total employees	11,237	11,322	11,076	11,102
Japan	4,613	4,591	4,490	4,416
Americas (North America)	1,820	1,982	1,755	1,862
China	2,060	2,044	2,002	1,985
EMEA (Europe, the Middle East, Africa, Russia and Oceania)	1,166	1,200	1,234	1,253
Asia and Latin America	1,578	1,505	1,595	1,586

2) Number of Employees on Non-Consolidated Basis

(employees)

	March 31, 2021	March 31, 2022	March 31, 2023	September 30, 2023
Total employees (Eisai Co., Ltd.)	3,005	3,034	3,043	3,042
Production	375	389	395	405
Research and development	857	859	909	911
Sales, marketing and administration	1,773	1,786	1,739	1,726

* The number of total employees shown above includes staff dispatched to Eisai Co., Ltd. from other group companies, and excludes the employees of Eisai Co., Ltd. dispatched to other group companies.

13. 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-A β protofibril antibody				Injection
Description: An IgG1 antibody that targets amyloid beta (A β) 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 A β 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. In September 2023, the agent was approved in Japan as a treatment for slowing progression of mild cognitive impairment and mild dementia due to AD. Applications have been submitted for use in the treatment of early AD in Europe, China, Canada, Great Britain, Australia, Switzerland, South Korea, Israel, Taiwan, Singapore, Brazil and Hong Kong. The applications have been designated for priority review in 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 A β 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 (Clarity AD)	US JP EU CH Asia (SK)	⊙ ⊙ ○	Traditional approval (July 2023) Approval (September 2023) Submission (accepted: January 2023) Submission (December 2022) Submission (June 2023)
Preclinical AD	Study 303 (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 (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 Alzheimer's disease dementia (Additional Indication)	Study 202	JP/US		PII

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

⊙ : Development progress from July 2023 onwards ○ : Development progress from April 2023 onwards

Development Code: E2023 Generic Name: lorcaserin				In-license (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

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 Study103	JP/US/EU US/EU		PII/III 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 (Development conducted by EA Pharma)	—	JP	PI

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◎ : Development progress from July 2023 onwards ○ : 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 (PDGFR α), 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 (first-line) 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 (following prior systemic therapy) 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
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
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 LEAP-003 for melanoma / First-line in the United States, Europe and China, has been discontinued and therefore was removed from this list.
- The Phase III clinical study LEAP-017 for colorectal cancer / Third-line in the United States and Europe, didn't meet its primary endpoint and therefore was removed from this list.
- ⊙ The Phase III clinical study LEAP-010 for head and neck cancer / First-line in Japan, the United States, Europe and China, has been discontinued and therefore was removed from this list.
- ⊙ Both the Phase III clinical study LEAP-006 for non-small cell lung cancer / First-line in Japan, the United States, Europe and China, and the Phase III clinical study LEAP-008 for non-small cell lung cancer / Second-line in Japan, the United States and Europe, didn't meet their primary endpoints and therefore were removed from this list.

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⊙ : Development progress from July 2023 onwards ○ : 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 <i>Halichondria okadae</i> . 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 / ER α inhibitor				Oral
Description: An orally administered selective estrogen receptor (ER) α covalent antagonist that inhibits ER α wild type / ER α 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 <i>FGFR2</i> gene fusion is ongoing. It has been granted the orphan drug designation with a prospective indication for unresectable biliary tract cancer with <i>FGFR2</i> 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 eribulin (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 July 2023 onwards ○ : 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. A Phase IIb/III clinical study was conducted in Sudan by DNDi and the Mycetoma Research Center of the University of Khartoum, Sudan. Currently, discussions regarding registration with the regulatory authorities (National Medicines and Poisons Board) in Sudan are underway. 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 July 2023 onwards ○ : 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, hyperuricemia	—	Asia (Philippines)	Submission (September 2023)
	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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