Securities Code: 4523

FY 2022 (Ending March 31, 2023)
Second Quarter Financial Results

Reference Data

November 7, 2022

Eisai Co., Ltd.

For Inquiries:
Public Relations: TEL +81-(0)3-3817-5120
Investor Relations: TEL +81-(0)70-8688-9685
https://www.eisai.com/

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 maximizing the value of next-generation Alzheimer's Disease treatments, risks related to maximizing the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to uncertainties in new drug development, risks related to 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 2021 Q2	Quarterly Average Rate	109.80	130.89	152.50	16.99
	Quarter End Rate	111.92	129.86	150.43	17.30
FY 2021	Yearly Average Rate	112.37	130.56	153.55	17.51
	Year End Rate	122.39	136.70	160.89	19.26
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	Q3-Q4 Forecast Rate	143.00	142.00	162.00	20.40

* The full year financial forecasts for FY 2022 (April 1, 2022 – March 31, 2023) 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 six reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia, and Oceania), Asia and Latin America (primarily South Korea, Taiwan, India, ASEAN, Central and South America), and OTC and others (Japan).
  Effective from April 1, 2022, Hong Kong has been changed from Asia and Latin America pharmaceutical business to China pharmaceutical business. This change has been reflected in the segment information for FY 2021.

* As described on page 19 of Conslidated Financial Report, Supplemental Materials, the figures for FY2021 have been revised for retroactive application due to changes in accounting policies.

* All amounts are rounded to the nearest specified unit.

1. Consolidated Statement of Income

(billions of yen)

	FY 2021				FY 2022				FY 2022 Full year forecast	
	Q2	Ratio (%)	Full year	Ratio (%)	Q2	Ratio (%)	YOY (%)	Diff.	Revised	Previous
Revenue	362.4	100.0	756.2	100.0	358.6	100.0	99.0	(3.7)	760.0	700.0
Cost of sales	79.9	22.0	174.8	23.1	92.5	25.8	115.9	12.7	184.0	160.5
Gross profit	282.5	78.0	581.4	76.9	266.1	74.2	94.2	(16.4)	576.0	539.5
Selling, general and administrative expenses	154.7	42.7	366.4	48.5	180.4	50.3	116.6	25.7	361.5	339.0
Selling expenses	72.7	20.1	190.4	25.2	95.5	26.6	131.3	22.8	—	—
Personnel expenses	45.6	12.6	101.3	13.4	48.7	13.6	106.7	3.1	—	—
Administrative and other expenses	36.3	10.0	74.8	9.9	36.2	10.1	99.6	(0.1)	—	—
Research and development expenses	79.9	22.1	171.7	22.7	81.5	22.7	102.0	1.6	166.5	159.0
Other income	13.7	3.8	14.6	1.9	3.0	0.8	22.2	(10.6)	7.0	13.5
Other expenses	0.8	0.2	4.1	0.5	2.0	0.5	236.4	1.1	—	—
Operating profit	60.7	16.8	53.7	7.1	5.3	1.5	8.7	(55.5)	55.0	55.0
Financial income	1.2	0.3	2.4	0.3	3.7	1.0	306.4	2.5	—	—
Financial costs	0.8	0.2	1.7	0.2	0.9	0.2	109.9	0.1	—	—
Profit before income taxes	61.2	16.9	54.5	7.2	8.1	2.3	13.3	(53.0)	56.5	56.5
Income taxes	14.8	4.1	8.7	1.2	(23.7)	(6.6)	—	(38.4)	—	—
Profit for the period	46.4	12.8	45.7	6.0	31.8	8.9	68.5	(14.6)	58.0	58.0
Profit for the period attributable to										
Owners of the parent	46.0	12.7	48.0	6.3	30.5	8.5	66.2	(15.6)	57.0	57.0
Non-controlling interests	0.4	0.1	(2.2)	(0.3)	1.3	0.4	375.0	1.0	—	—
Comprehensive income for the period	50.2	13.9	90.8	12.0	102.1	28.5	203.2	51.8		
Earnings per share (EPS, yen)	160.61		167.27		106.25				197.80	197.80
Dividend per share (DPS, yen)	80.0		160.0		80.0				160.0	160.0
Return on equity (ROE, %)	—		6.6		—				7.2	7.5
Dividends on equity ratio (DOE, %)	—		6.3		—				5.8	6.1

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

Notes

Revenue	Significant growth of the anticancer agent Lenvima: 128.2 billion yen (the same period in previous fiscal year: 91.8 billion yen) Recording of an upfront payment from Bristol Myers Squibb under strategic collaboration for antibody drug conjugate MORAb-202: 49.6 billion yen in the same period of the previous fiscal year
Selling, general and administrative expenses	Recording of expenses regarding shared profit of Lenvima paid to Merck & Co., Inc., Rahway, NJ, USA: 61.0 billion yen (the same period in previous fiscal year: 41.4 billion yen)
Research and development expenses	Receipt of regulatory milestone payments from Merck & Co., Inc., Rahway, NJ, USA regarding Lenvima: 3.2 billion yen due to obtaining additional indication for renal cell carcinoma and health insurance reimbursement in Europe (the same period in previous fiscal year: 8.3 billion yen due to obtaining additional indication for renal cell carcinoma in the U.S.) Control of the expenses through the partnership model (partner's burden: 32.0 billion yen (the same period in previous fiscal year: 35.2 billion yen))
Income taxes	Recording of a credit of income taxes due to recognition of losses on transferring of investments in subsidiaries for tax purposes following a repayment of paid-in capital from a U.S. subsidiary to the Company as part of the Group's capital policy to optimize the global allocation of cash
Exchange rate effects	Revenue: +34.99 billion yen, operating profit: -9.07 billion yen
Exchange rate sensitivity (annual effect of 1 yen depreciation in currency value)	Revenue (U.S. dollars: +1.62 billion yen, Euro: +0.29 billion yen, U.K. pounds: +0.09 billion yen, Chinese renminbi: +6.23 billion yen) Operating profit (U.S. dollars: -1.20 billion yen, Euro: +0.16 billion yen, U.K. pounds: -0.03 billion yen, Chinese renminbi: +2.98 billion yen)

* Of 110 million USD (for April 2022 - December 2022), which is the remaining amount of Eisai's share of Alzheimer's disease treatment ADUHELM related expenses capped at 335 million USD by the amendment of the collaboration agreements with Biogen Inc. in March 2022, 72 million USD is recorded in selling, general and administrative expenses, and research and development expenses in this period.

2. Segment Information

1) Revenue by Reporting Segment

(billions of yen)

	FY 2021		FY 2022		
	Q2	Full year	Q2	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	299.4	617.3	352.6	117.8	106.3
Japan pharmaceutical business	104.0	214.0	110.6	106.3	106.3
Americas pharmaceutical business	75.4	167.6	106.4	141.2	115.8
United States	74.2	165.1	104.7	141.1	124.3
China pharmaceutical business	55.3	103.8	63.3	114.5	97.8
EMEA pharmaceutical business	28.0	59.3	35.0	124.7	112.6
Asia and Latin America pharmaceutical business	24.6	48.6	24.8	100.6	89.7
OTC and others	12.1	23.8	12.6	103.9	103.9
Other business	62.9	139.0	6.1	9.6	8.8
Consolidated revenue	362.4	756.2	358.6	99.0	89.3

* CER=Constant Exchange Rates

* Indicates revenue from external customers.

* Upfront payments and other factors received as consideration for license grants have been included in "Other business". As a result, these changes for the FY 2021 have been reflected in Segment Information.

2) Profit by Reporting Segment

(billions of yen)

	FY 2021		FY 2022		
	Q2	Full year	Q2	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	134.7	259.9	173.0	128.4	115.4
Japan pharmaceutical business	32.7	61.0	37.7	115.2	115.2
Americas pharmaceutical business	41.8	91.2	64.4	154.1	134.0
China pharmaceutical business	31.3	52.4	35.3	112.9	98.4
EMEA pharmaceutical business	15.3	30.1	20.5	134.2	113.6
Asia and Latin America pharmaceutical business	10.8	20.4	11.8	109.6	96.4
OTC and others	2.9	4.7	3.3	113.1	113.1
Other business	59.0	130.7	1.3	2.1	1.4
Research and development expenses	(79.9)	(171.7)	(81.5)	102.0	84.2
Group headquarters' management costs and other expenses	(53.1)	(165.0)	(87.5)	164.9	140.7
Consolidated operating profit	60.7	53.7	5.3	8.7	23.6

* CER=Constant Exchange Rates

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

* As the co-development and co-promotion agreements for ADUHELM with Biogen Inc. were changed in March 2022, all relevant expenses (selling, general and administrative expenses) that the Company should share have been included in the “Group headquarters’ management costs and other expenses” since April 1, 2022. In addition, gains and losses on sale of non-current assets have been included in the “Group headquarters’ management costs and other expenses”. As a result, these changes for the FY 2021 have been reflected in Segment Information.

3. Financial Results by Reporting Segment

1) Japan pharmaceutical business

(billions of yen)

	FY 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Revenue	104.0	214.0	110.6	106.3
Segment profit	32.7	61.0	37.7	115.2
Japan prescription medicines - revenue from major products				
Fully human anti-TNF-α monoclonal antibody Humira	24.8	50.6	24.7	99.4
Insomnia treatment Dayvigo	4.7	12.7	11.1	235.5
Anticancer agent Lenvima	5.1	10.3	6.9	134.3
Peripheral neuropathy treatment Methycobal	5.3	10.8	5.3	100.7
Anticancer agent Halaven	4.1	8.3	4.3	104.3
Elemental diet Elental[#]	3.4	6.8	3.6	106.6
Chronic constipation treatment Goofice[#]	2.9	6.1	3.3	113.7
Antiepileptic agent Fycompa	2.6	5.4	3.0	117.6
Janus kinase inhibitor Jyseleca	0.3	1.5	3.0	895.1
Proton pump inhibitor Pariet[#]	3.3	7.1	3.0	90.3
Chronic constipation treatment Movicol[#]	2.3	4.9	2.8	124.8
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	3.6	6.9	2.3	63.6

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

[#] EA Pharma product

2) Americas pharmaceutical business (North America)

(billions of yen)

	FY 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Revenue	75.4	167.6	106.4	141.2 <115.8>
United States	74.2	165.1	104.7	141.1 <124.3>
Segment profit	41.8	91.2	64.4	154.1 <134.0>
Americas - revenue from major products				
Anticancer agent Lenvima	51.3	116.5	80.2	156.3 <128.1>
United States	50.8	115.5	79.6	156.7
[Millions USD]	[463]	[1,028]	[594]	<128.4>
Antiepileptic agent Fycompa	7.0	14.6	9.4	135.1 <110.9>
United States	6.7	14.1	9.1	135.2
[Millions USD]	[61]	[125]	[68]	<110.8>
Anticancer agent Halaven	6.9	14.3	7.7	112.0 <91.9>
United States	6.7	14.0	7.5	111.9
[Millions USD]	[61]	[125]	[56]	<91.7>
Insomnia Treatment Dayvigo	1.6	3.7	2.3	145.4 <120.1>
United States	1.5	3.2	1.8	126.2
[Millions USD]	[13]	[29]	[14]	<103.4>
Antiepileptic agent Banzel	4.7	7.0	2.0	42.8 <35.2>
United States	4.5	6.7	1.8	40.3
[Millions USD]	[41]	[60]	[14]	<33.0>

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

3) China pharmaceutical business

(billions of yen)

	FY 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Revenue	55.3	103.8	63.3	114.5 <97.8>
Segment profit	31.3	52.4	35.3	112.9 <98.4>
China - revenue from major products				
Anticancer agent Lenvima	21.3	35.8	20.7	97.4 <83.1>
Peripheral neuropathy treatment Methycobal	6.6	12.7	8.4	127.2 <108.6>
Proton pump inhibitor Pariet	4.6	9.1	4.9	106.1 <90.6>
Liver disease / Allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets	5.3	9.5	4.5	84.2 <72.0>
Alzheimer's disease treatment Aricept	2.6	5.3	3.4	129.8 <110.9>
Antiepileptic agent Fycompa	0.5	1.2	1.3	248.9 <212.5>
Anticancer agent Halaven	1.3	1.6	1.1	88.6 <75.6>

* 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 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Revenue	28.0	59.3	35.0	124.7 <112.6>
Segment profit	15.3	30.1	20.5	134.2 <113.6>
EMEA - revenue from major products				
Anticancer agent Lenvima/Kisplyx	10.0	21.8	15.0	150.1 <133.5>
Anticancer agent Halaven	6.5	12.8	6.8	105.4 <93.5>
Antiepileptic agent Fycompa	4.3	9.2	5.5	126.9 <116.2>
Antiepileptic agent Inovelon	1.3	2.7	1.5	111.7 <103.4>

* 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 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Revenue	24.6	48.6	24.8	100.6 <89.7>
Segment profit	10.8	20.4	11.8	109.6 <96.4>
Asia and Latin America - revenue from major products				
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	5.9	11.8	6.7	112.7 <103.3>
Anticancer agent Lenvima	4.1	7.9	5.4	131.1 <114.4>
Proton pump inhibitor Pariet	2.1	4.0	2.2	102.5 <91.5>
Peripheral neuropathy treatment Methycobal	1.7	3.5	1.8	106.7 <93.5>
Anticancer agent Halaven	1.2	2.3	1.5	123.7 <107.8>
Antiepileptic agent Fycompa	0.7	1.5	0.9	118.2 <106.1>

* 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.

6) OTC and Others (Japan)

(billions of yen)

	FY 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Revenue	12.1	23.8	12.6	103.9
Segment profit	2.9	4.7	3.3	113.1
OTC and others, revenue from major products				
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	7.3	14.3	7.7	106.2

4. Revenue from Major Products

1) Neurology Products

(billions of yen)

	FY 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Neurology Products Total	67.4	135.6	74.5	110.6 <101.5>
Fycompa (Antiepileptic agent)	15.2	31.9	20.1	132.8 <116.7>
Japan	2.6	5.4	3.0	117.6
Americas	7.0	14.6	9.4	135.1 <110.9>
China	0.5	1.2	1.3	248.9 <212.5>
EMEA	4.3	9.2	5.5	126.9 <116.2>
Asia and Latin America	0.7	1.5	0.9	118.2 <106.1>
Methycobal (Peripheral neuropathy treatment)	14.1	28.1	16.4	116.6 <106.2>
Japan	5.3	10.8	5.3	100.7
China	6.6	12.7	8.4	127.2 <108.6>
Asia and Latin America	1.7	3.5	1.8	106.7 <93.5>
Dayvigo (Insomnia treatment)	6.3	16.4	13.6	214.4 <207.7>
Japan	4.7	12.7	11.1	235.5
Americas	1.6	3.7	2.3	145.4 <120.1>
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	12.5	24.4	12.6	101.5 <92.8>
Japan	3.6	6.9	2.3	63.6
China	2.6	5.3	3.4	129.8 <110.9>
Asia and Latin America	5.9	11.8	6.7	112.7 <103.3>
Inovelon/Banzel (Antiepileptic agent)	6.3	10.3	3.8	60.7 <53.1>
Americas	4.7	7.0	2.0	42.8 <35.2>
EMEA	1.3	2.7	1.5	111.7 <103.4>
Other	13.0	24.5	7.9	60.7 <58.9>

* 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.

2) Oncology Products

(billions of yen)

	FY 2021		FY 2022	
	Q2	Full year	Q2	YOY (%)
Oncology Products Total	115.2	238.5	153.7	133.4 <113.7>
Lenvima/Kisplyx (Anticancer agent)	91.8	192.3	128.2	139.6 <118.0>
Japan	5.1	10.3	6.9	134.3
Americas	51.3	116.5	80.2	156.3 <128.1>
China	21.3	35.8	20.7	97.4 <83.1>
EMEA	10.0	21.8	15.0	150.1 <133.5>
Asia and Latin America	4.1	7.9	5.4	131.1 <114.4>
Halaven (Anticancer agent)	19.9	39.4	21.4	107.5 <94.8>
Japan	4.1	8.3	4.3	104.3
Americas	6.9	14.3	7.7	112.0 <91.9>
China	1.3	1.6	1.1	88.6 <75.6>
EMEA	6.5	12.8	6.8	105.4 <93.5>
Asia and Latin America	1.2	2.3	1.5	123.7 <107.8>
Other	3.5	6.8	4.2	119.5 <107.4>

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

5. Revenue Forecast by Reporting Segment (FY 2022)

(billions of yen)

	FY 2021		FY 2022		
				Full year forecast	
	Q2	Full year	Q2	Revised	Previous
Japan (Prescription Medicines)	104.0	214.0	110.6	217.5	201.0
Fully human anti-TNF-α monoclonal antibody Humira	24.8	50.6	24.7	46.5	41.5
Insomnia treatment Dayvigo	4.7	12.7	11.1	25.0	18.0
Anticancer agent Lenvima	5.1	10.3	6.9	14.5	13.5
Peripheral neuropathy treatment Methycobal	5.3	10.8	5.3	10.0	9.0
Anticancer agent Halaven	4.1	8.3	4.3	8.5	8.5
Chronic constipation treatment Goofice#	2.9	6.1	3.3	7.0	7.0
Antiepilepsy agent Fycompa	2.6	5.4	3.0	6.5	6.5
Elemental diet Elental#	3.4	6.8	3.6	6.5	6.5
Proton pump inhibitor Pariet#	3.3	7.1	3.0	6.0	6.0
Chronic constipation treatment Movicol#	2.3	4.9	2.8	5.5	5.5
Americas	75.4	167.6	106.4	229.5	198.5
United States	74.2	165.1	104.7	225.0	195.5
China	55.3	103.8	63.3	117.0	97.5
EMEA	28.0	59.3	35.0	69.5	59.5
Asia and Latin America	24.6	48.6	24.8	49.0	45.5
OTC and others (Japan)	12.1	23.8	12.6	24.5	24.5
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	7.3	14.3	7.7	14.5	14.5
Other	62.9	139.0	6.1	53.0	73.5
Consolidated revenue	**362.4**	**756.2**	**358.6**	**760.0**	**700.0**
Global revenue from major products					
Lenvima/Kisplyx	91.8	192.3	128.2	262.0	218.0
Japan	5.1	10.3	6.9	14.5	13.5
Americas	51.3	116.5	80.2	174.0	145.5
China	21.3	35.8	20.7	33.0	23.5
EMEA	10.0	21.8	15.0	30.0	26.5
Asia and Latin America	4.1	7.9	5.4	10.5	9.0
Halaven	19.9	39.4	21.4	43.0	38.0
Japan	4.1	8.3	4.3	8.5	8.5
Americas	6.9	14.3	7.7	14.5	11.5
China	1.3	1.6	1.1	2.5	2.0
EMEA	6.5	12.8	6.8	14.5	13.0
Asia and Latin America	1.2	2.3	1.5	3.0	3.0
Fycompa	15.2	31.9	20.1	42.0	37.5
Japan	2.6	5.4	3.0	6.5	6.5
Americas	7.0	14.6	9.4	19.5	17.5
China	0.5	1.2	1.3	2.5	2.0
EMEA	4.3	9.2	5.5	11.5	10.0
Asia and Latin America	0.7	1.5	0.9	2.0	1.5
Dayvigo	6.3	16.4	13.6	31.0	27.0
Japan	4.7	12.7	11.1	25.0	18.0
Americas	1.6	3.7	2.3	6.0	9.0

EA Pharma product

6. Consolidated Statement of Comprehensive Income

(billions of yen)

	FY 2021		FY 2022		
	Q2	Full year	Q2	YOY (%)	Diff.
Profit for the period	46.4	45.7	31.8	68.5	(14.6)
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)	(0.0)	(0.8)	4.1	–	4.1
Remeasurements of defined benefit plans	–	(1.1)	–	–	–
Subtotal	(0.0)	(1.9)	4.1	–	4.1
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	3.8	46.9	66.2	1743.3	62.4
Cash flow hedges	0.0	0.1	0.0	75.7	(0.0)
Subtotal	3.8	47.0	66.2	1726.4	62.4
Total other comprehensive income (loss), net of tax	3.8	45.1	70.3	1840.4	66.4
Comprehensive income (loss) for the period	50.2	90.8	102.1	203.2	51.8
Comprehensive income (loss) for the period attributable to					
Owners of the parent	49.9	93.0	100.7	201.9	50.8
Non-controlling interests	0.3	(2.2)	1.4	396.5	1.0

7. Consolidated Statement of Cash Flows

(billions of yen)

	FY 2021	FY 2022	
	Q2	Q2	Diff.
Operating activities			
Profit before income taxes	61.2	8.1	(53.0)
Depreciation and amortization	19.0	19.7	0.7
Impairment losses	0.2	0.3	0.0
(Increase) decrease in working capital	4.0	(26.6)	(30.6)
Interest and dividends received	1.0	1.3	0.3
Interest paid	(0.6)	(0.7)	(0.1)
Income taxes paid	(4.8)	(13.0)	(8.2)
Income taxes refund	2.6	—	(2.6)
Other	(14.7)	(8.0)	6.7
Net cash from (used in) operating activities	67.9	(18.8)	(86.8)
Investing activities			
Purchases of property, plant and equipment	(18.3)	(14.2)	4.1
Purchases of intangible assets	(3.2)	(6.5)	(3.4)
Proceeds from sale of property, plant and equipment and intangible assets	13.3	0.3	(12.9)
Purchases of financial assets	(1.5)	(1.9)	(0.4)
Proceeds from sale and redemption of financial assets	2.3	5.9	3.6
Subtotal <Capital expenditures (cash basis)>	(7.4)	(16.4)	(9.0)
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)	0.0	0.1
Net cash from (used in) investing activities	(7.5)	(16.4)	(9.0)
Financing activities			
Repayments of long-term borrowings	—	(0.0)	(0.0)
Repayments of lease liabilities	(5.2)	(4.9)	0.3
Dividends paid	(22.9)	(22.9)	(0.0)
Other	0.2	0.0	(0.2)
Net cash from (used in) financing activities	(27.9)	(27.8)	0.1
Effect of exchange rate change on cash and cash equivalents	1.7	17.9	16.2
Net increase (decrease) in cash and cash equivalents	34.3	(45.1)	(79.4)
Cash and cash equivalents at beginning of period	248.7	309.6	60.9
Cash and cash equivalents at end of period	283.0	264.5	(18.5)

Free cash flows	60.5	(35.3)	(95.8)

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

Notes

■Net cash from (used in) operating activities

While accounts receivable-trades were collected, working capital increased mainly due to payment of accounts payable-other to partners

■Net cash from (used in) investing activities

Capital expenditures occurred due to additional investment in research facilities and production facilities, and the purchase of intangible assets

■Net cash from (used in) financing activities

Dividends were paid

8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2021		FY 2022		FY 2022
	Q2	Full year	Q2	Diff.	Full year forecast
Capital expenditures (cash basis)	21.4	40.5	20.7	(0.7)	50.0
Property, plant and equipment	18.3	29.0	14.2	(4.1)	28.5
Intangible assets	3.2	11.4	6.5	3.4	21.5
Depreciation and amortization	19.0	38.4	19.7	0.7	39.5
Property, plant and equipment	10.8	21.8	11.3	0.5	22.0
Intangible assets	8.2	16.6	8.4	0.2	17.5

9. Consolidated Statement of Financial Position

<Assets>

(billions of yen)

	FY 2021		FY 2022			
	March 31, 2022	Ratio (%)	September 30, 2022	Ratio (%)	% change	Diff.
Assets						
Non-current assets						
Property, plant and equipment	169.9	13.7	175.7	13.9	103.4	5.8
Goodwill	191.8	15.5	226.2	17.9	118.0	34.4
Intangible assets	95.5	7.7	93.8	7.4	98.2	(1.7)
Other financial assets	44.0	3.6	48.2	3.8	109.5	4.2
Other assets	20.9	1.7	20.5	1.6	98.2	(0.4)
Deferred tax assets	76.6	6.2	111.5	8.8	145.5	34.9
Total non-current assets	598.7	48.3	675.9	53.6	112.9	77.2
Current assets						
Inventories	99.0	8.0	114.4	9.1	115.6	15.4
Trade and other receivables	207.9	16.8	178.1	14.1	85.6	(29.9)
Other financial assets	0.4	0.0	1.0	0.1	231.5	0.6
Other assets	23.6	1.9	27.4	2.2	116.0	3.8
Cash and cash equivalents	309.6	25.0	264.5	21.0	85.4	(45.1)
Total current assets	640.6	51.7	585.4	46.4	91.4	(55.2)
Total assets	1,239.3	100.0	1,261.3	100.0	101.8	22.0

Notes

■ Assets	
(Deferred tax assets)	Increase due to recognition of losses on transferring of investments in subsidiaries for tax purposes following a repayment of paid-in capital from a U.S. subsidiary to the Company as part of the Group's capital policy to optimize the global allocation of cash
(Cash and cash equivalents)	Decrease mainly due to payments to partners and payment of dividends

<Equity and Liabilities>

(billions of yen)

	FY 2021		FY 2022			
	March 31, 2022	Ratio (%)	September 30, 2022	Ratio (%)	% change	Diff.
Equity						
Equity attributable to owners of the parent						
Share capital	45.0	3.6	45.0	3.6	100.0	—
Capital surplus	77.6	6.3	78.8	6.2	101.6	1.2
Treasury shares	(33.9)	(2.7)	(33.6)	(2.7)	99.1	0.3
Retained earnings	506.6	40.9	518.2	41.1	102.3	11.6
Other components of equity	153.6	12.4	219.8	17.4	143.1	66.2
Total equity attributable to owners of the parent	748.8	60.4	828.1	65.7	110.6	79.3
Non-controlling interests	22.7	1.8	22.6	1.8	99.4	(0.1)
Total equity	771.5	62.3	850.7	67.4	110.3	79.2
Liabilities						
Non-current liabilities						
Borrowings	94.9	7.7	84.9	6.7	89.5	(10.0)
Other financial liabilities	39.2	3.2	39.1	3.1	99.7	(0.1)
Provisions	1.5	0.1	1.5	0.1	103.9	0.1
Other liabilities	18.4	1.5	17.5	1.4	95.1	(0.9)
Deferred tax liabilities	0.5	0.0	1.0	0.1	208.0	0.5
Total non-current liabilities	154.4	12.5	144.0	11.4	93.3	(10.4)
Current liabilities						
Borrowings	—	—	10.0	0.8	—	10.0
Trade and other payables	108.1	8.7	76.8	6.1	71.1	(31.2)
Other financial liabilities	40.9	3.3	40.6	3.2	99.3	(0.3)
Income taxes payable	6.9	0.6	5.5	0.4	79.4	(1.4)
Provisions	17.9	1.4	25.4	2.0	141.2	7.4
Other liabilities	139.6	11.3	108.3	8.6	77.6	(31.3)
Total current liabilities	313.3	25.3	266.5	21.1	85.1	(46.8)
Total liabilities	467.8	37.7	410.6	32.6	87.8	(57.2)
Total equity and liabilities	1,239.3	100.0	1,261.3	100.0	101.8	22.0

Notes

■ Equity	
(Other components of equity)	Increase in exchange differences on translation of foreign operations due to depreciation of yen
■ Liabilities	
(Borrowings - current / non-current)	Reclassification of non-current liabilities to current liabilities
(Trade and other payables)	Decrease mainly in accounts payable - others to partners
(Other financial liabilities - current)	Decrease mainly in accrued expenses

10. Changes in Quarterly Results

1) Income Statement

(billions of yen)

	FY 2021				FY 2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Revenue	198.9	163.5	203.0	190.9	184.3	174.4
Cost of sales	39.2	40.6	44.2	50.7	47.4	45.1
Gross profit	159.6	122.8	158.8	140.2	136.9	129.2
Selling, general and administrative expenses	74.8	79.9	101.5	110.3	92.3	88.1
Selling expenses	32.4	40.3	53.7	64.0	50.2	45.3
Personnel expenses	22.7	22.9	28.3	27.4	24.0	24.7
Administrative and other expenses	19.7	16.6	19.5	18.9	18.1	18.1
Research and development expenses	41.8	38.1	43.4	48.5	38.5	43.0
Other income	13.4	0.2	0.4	0.5	2.5	0.6
Other expenses	1.1	(0.3)	0.7	2.6	1.1	0.9
Operating profit	55.3	5.4	13.6	(20.6)	7.4	(2.2)
Financial income	0.7	0.5	0.6	0.5	2.7	1.0
Financial costs	0.4	0.4	0.4	0.5	0.4	0.4
Profit before income taxes	55.7	5.4	13.9	(20.6)	9.7	(1.6)
Income taxes	13.5	1.3	0.8	(6.9)	(18.2)	(5.4)
Profit for the period	42.3	4.1	13.0	(13.7)	28.0	3.8
Profit for the period attributable to						
Owners of the parent	42.1	3.9	14.2	(12.2)	26.9	3.6
Non-controlling interests	0.1	0.2	(1.1)	(1.5)	1.1	0.3
Comprehensive income for the period	42.4	7.9	26.2	14.3	79.7	22.4
Earnings per share (EPS, yen)	146.89	13.72	49.39	(42.72)	93.81	12.44

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

2) Cash Flows

(billions of yen)

	FY 2021				FY 2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Net cash from (used in) operating activities	(14.5)	82.4	4.6	45.1	3.9	(22.8)
Net cash from (used in) investing activities	0.3	(7.8)	(10.5)	(10.9)	(16.8)	0.4
Net cash from (used in) financing activities	(22.5)	(5.4)	(25.5)	4.5	(25.2)	(2.6)
Cash and cash equivalents at end of period	213.1	283.0	258.4	309.6	287.8	264.5
Free cash flow	(14.1)	74.6	(5.9)	34.1	(12.6)	(22.7)

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

3) Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2021				FY 2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Capital expenditures (cash basis)	14.7	6.8	10.4	8.6	15.9	4.8
Property, plant and equipment	12.1	6.1	3.8	7.0	11.6	2.6
Intangible assets	2.5	0.7	6.6	1.6	4.3	2.3
Depreciation and amortization	9.3	9.7	9.7	9.7	9.8	9.9
Property, plant and equipment	5.3	5.5	5.5	5.5	5.6	5.6
Intangible assets	4.0	4.2	4.2	4.2	4.2	4.2

4) Financial Positions

(billions of yen)

	Jun. 30, 2021	Sept. 30, 2021	Dec. 31, 2021	Mar. 31, 2022	Jun. 30, 2022	Sept. 30, 2022
Total assets	1,127.7	1,138.4	1,165.6	1,239.3	1,272.9	1,261.3
Equity	745.7	753.6	756.9	771.5	828.3	850.7
Attributable to owners of the parent	720.9	728.6	733.0	748.8	804.5	828.1
Liabilities	382.0	384.8	408.7	467.8	444.5	410.6
Borrowings	92.7	89.9	89.9	94.9	94.9	94.9
Ratio of equity attributable to owners of the parent (%)	63.9	64.0	62.9	60.4	63.2	65.7
Net debt equity ratio (times)	(0.20)	(0.30)	(0.26)	(0.32)	(0.28)	(0.24)

* "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 2021				FY 2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Neurology Total	34.1	33.3	36.1	32.2	37.1	37.4
Fycompa (Antiepileptic agent)	7.4	7.7	8.4	8.3	9.9	10.2
Japan	1.2	1.4	1.5	1.3	1.6	1.5
Americas	3.4	3.5	3.8	3.8	4.6	4.9
China	0.2	0.3	0.3	0.4	0.6	0.7
EMEA	2.2	2.2	2.4	2.5	2.8	2.7
Asia and Latin America	0.3	0.4	0.4	0.4	0.4	0.4
Methycobal (Peripheral neuropathy treatment)	6.8	7.3	7.7	6.4	8.2	8.2
Japan	2.4	2.8	2.9	2.5	2.7	2.6
China	3.3	3.3	3.3	2.7	4.4	4.0
Asia and Latin America	0.8	0.9	0.9	0.8	0.8	1.1
Dayvigo (Insomnia treatment)	2.6	3.7	5.0	5.1	6.5	7.1
Japan	1.9	2.9	3.9	4.1	5.3	5.8
Americas	0.8	0.8	1.1	1.0	1.1	1.2
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	6.3	6.1	6.5	5.5	6.3	6.4
Japan	1.8	1.9	1.9	1.3	1.2	1.1
China	1.4	1.2	1.5	1.1	1.6	1.8
Asia and Latin America	3.0	2.9	3.0	2.9	3.3	3.4
Inovelon/Banzel (Antiepileptic agent)	3.7	2.6	2.4	1.6	1.8	2.0
Americas	2.8	1.8	1.5	0.8	0.9	1.1
EMEA	0.7	0.7	0.7	0.7	0.7	0.8
Other	7.3	5.8	6.1	5.3	4.5	3.4

* 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 2021				FY 2022	
	Q1	Q2	Q3	Q4	Q1	Q2
Oncology Total	56.1	59.1	60.8	62.5	79.7	74.0
Lenvima/Kisplyx (Anticancer agent)	44.2	47.6	49.3	51.2	66.3	61.8
Japan	2.5	2.6	2.6	2.6	3.6	3.3
Americas	24.4	26.9	31.3	33.8	38.5	41.7
China	10.8	10.5	7.1	7.4	13.9	6.9
EMEA	4.8	5.1	6.3	5.5	8.1	6.9
Asia and Latin America	1.7	2.4	2.0	1.8	2.3	3.1
Halaven (Anticancer agent)	10.2	9.8	9.8	9.7	11.1	10.3
Japan	2.0	2.1	2.2	2.0	2.2	2.1
Americas	3.3	3.6	3.6	3.9	4.1	3.6
China	0.9	0.3	0.0	0.3	0.6	0.6
EMEA	3.4	3.0	3.4	3.0	3.5	3.3
Asia and Latin America	0.6	0.6	0.5	0.6	0.8	0.7
Other	1.7	1.8	1.7	1.6	2.2	1.9

11. Stock Information

1) Number of Shares Issued and Shareholders

As of September 30, 2022

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	9,666,103	77,250	3,839

* Number of shares issued and outstanding includes treasury stock.

2) Principal Shareholders

As of September 30, 2022

Shareholders	Shares (1,000 shares)	Percentage of shares held (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	56,038	19.53
Custody Bank of Japan, Ltd. (Trust Account)	35,688	12.44
State Street Bank and Trust Company 505001	20,647	7.20
Nippon Life Insurance Company	9,030	3.15
Saitama Resona Bank, Limited	5,800	2.02
State Street Bank West Client - Treaty 505234	4,320	1.51
The Naito Foundation	4,212	1.47
JP Morgan Securities Japan Co., Ltd.	3,770	1.31
JP Morgan Chase Bank 385781	3,546	1.24
SSBTC Client Omnibus Account	2,860	1.00

* 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 (9,666 thousand shares, the percentage of treasury stock calculated in proportion to the number of shares issued and outstanding: 3.26%) has been excluded from the table as it has no voting rights.

* While the large shareholding reports (amendment reports) received up until September 30, 2022 are listed below, in cases where large shareholdings cannot be confirmed by the shareholder registry as of September 30, 2022 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 July 13, 2015, four companies including Mitsubishi UFJ Financial Group jointly hold 16,113 thousand shares (5.43%).
(Amendment report dated July 21, 2015)

(2) 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)

(3) As of July 15, 2020, three companies including Nomura Securities Co., Ltd. hold 18,380 thousand shares (6.20%).
(Amendment report dated July 21, 2020)

(4) As of September 15, 2020, Bank's Shareholdings Purchase Corporation holds 14,945 thousand shares (5.04%).
(Large shareholding report dated September 23, 2020)

(5) As of October 29, 2021, three companies including Sumitomo Mitsui Trust Bank, Ltd. jointly hold 19,442 thousand shares (6.56%).
(Amendment report dated November 5, 2021)

(6) As of August 31, 2022, the Wellington Management Company, LLP holds 20,752 thousand shares (7.00%).
(Amendment report dated September 5, 2022)

3) Number of Shares Held by Category

(1,000 shares)

	March 31, 2022	Ratio (%)	September 30, 2022	Ratio (%)	Diff.
Financial institutions	126,539	42.7	121,282	40.9	(5,256)
Financial instruments traders (securities companies)	10,987	3.7	12,496	4.2	1,509
Other companies	17,770	6.0	19,845	6.7	2,074
Foreign entities, etc.	89,937	30.3	92,174	31.1	2,236
Individuals, other	41,529	14.0	41,100	13.9	(429)
Treasury stock	9,801	3.3	9,666	3.3	(135)
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, 2020	March 31, 2021	March 31, 2022	September 30, 2022
Total employees	10,998	11,237	11,322	11,092
Japan	4,593	4,613	4,591	4,569
Americas (North America)	1,682	1,820	1,982	1,706
China	2,087	2,060	2,044	2,064
EMEA (Europe, the Middle East, Africa, Russia and Oceania)	1,113	1,166	1,200	1,202
Asia and Latin America	1,523	1,578	1,505	1,551

2) Number of Employees on Non-Consolidated Basis

(employees)

	March 31, 2020	March 31, 2021	March 31, 2022	September 30, 2022
Total employees (Eisai Co., Ltd.)	2,953	3,005	3,034	3,077
Production	367	375	389	400
Research and development	839	857	859	891
Sales, marketing and administration	1,747	1,773	1,786	1,786

* 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: **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 70 countries including Japan, the United States, China and countries in Europe and in Asia. Approved for monotherapy and adjunctive use in the treatment of partial onset seizures (with or without secondarily generalized seizures) in patients 4 years of age and older in Japan, the United States and China. Approved for adjunctive use in the treatment of partial onset seizures (with or without secondarily generalized seizures) in patients 4 years of age and older in Europe. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 70 countries including Japan, the United States, and countries in Europe and in Asia. Approved for an adjunctive therapy for primary generalized tonic-clonic seizures in patients 7 years of age and older in Europe, and 12 years of age and older in Japan and United States. An oral suspension formulation has been approved in the United States and Europe. A fine granule formulation has been approved in Japan.

◎	Injection formulation (Additional Formulation)	—	JP		Submission (August 2022)
	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 10 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

Development Code: **BAN2401** Generic Name: **lecanemab**	In-license (BioArctic AB)
Indications / Drug class: Disease modifying treatment for Alzheimer's disease / anti-Aβ protofibril antibody	Injection

Description: An lgG1 antibody that targets amyloid beta (Aβ) protofibrils. Expected to be effective in the treatment of Alzheimer's disease (AD) by slowing disease progression through the elimination of neurotoxic Aβ protofibrils. The United States Food and Drug Administration (FDA) granted Breakthrough Therapy designation and Fast Track designation. In July 2022, the Biological License Application was accepted by the FDA, under the accelerated approval pathway. In September 2022, the Phase III clinical study Clarity AD in patients with mild cognitive impairment due to AD or mild AD (collectively known as early AD) met the primary endpoint and all key secondary endpoints with highly statistically significant results. The incidence profile of amyloid-related imaging abnormalities (ARIA), an adverse event associated with anti-amyloid antibodies, was within expectations. Submission to the Pharmaceuticals and Medical Devices Agency (PMDA) of application data under the prior assessment consultation system has been initiated in Japan with the aim of obtaining early approval. Studies to determine new dosing regimen after removal of brain Aβ is also underway. In addition, developing subcutaneous injection formulation is underway in order to enhance benefit. 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 201	US	◎	Submission for accelerated approval (accepted: July 2022)
		Study 301 (Clarity AD)	US	◎	Preparation for submission of traditional approval
			JP/EU	◎	Preparation for submission
			CH		PIII
	Preclinical AD	Study 303 (AHEAD 3-45)	JP/US/EU		PIII

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

◎：Development progress from July 2022 onwards ○：Development progress from April 2022 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 seizure 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 have been initiated.					
	AD	Tau NexGen study Study103	US 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: **EA4017**					In-house	Oral
	Chemotherapy-induced peripheral neuropathy (Development conducted by EA Pharma)	—	JP		PI	

◎ Development of E2730 for the epilepsy at the Phase II stage in the U.S. has been finished and therefore was removed from this list.

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

◎：Development progress from July 2022 onwards ○：Development progress from April 2022 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 40 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 45 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 antibody 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 / First-line	LEAP-002	JP/US/EU/CH		PIII
	Melanoma / First-line	LEAP-003	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
	Selected solid tumors (Endometrial carcinoma, renal cell carcinoma, head and neck cancer, bladder cancer, non-small cell lung cancer and melanoma)	Study 111 —	US/EU JP		PI/II PI
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

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

◎：Development progress from July 2022 onwards ○：Development progress from April 2022 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 80 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**					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.					
	Solid tumors	—	US		PI/II
	Solid tumors	—	JP		PI

Development Code: **E7386**					Collaboration (PRISM BioLab)
Indications / Drug class: Anticancer agent / CBP/β-catenin 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/EU		PI
	Solid tumors (in combination with lenvatinib)	—	JP		PI

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

◎：Development progress from July 2022 onwards ○：Development progress from April 2022 onwards

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

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

◎ Phase I study of H3B-6527 for hepatocellular carcinoma in the U.S. and Europe has been finished and therefore was removed from this list.

(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 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.	

(4) Gastrointestinal Disorders

Development Code: **E3112**		In-house		Injection
Liver disease (Development conducted by EA Pharma)	—	JP		PI

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) grand program.				
Systemic lupus erythematosus	Study 101	JP		PI/II

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

○ Phase III REMAP-COVID study of eritoran for suppression for increasing of severity of COVID-19 in Japan and the U.S. was discontinued, therefore has been removed from this list.

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

◎：Development progress from July 2022 onwards ○：Development progress from April 2022 onwards