Securities Code: 4523

FY 2020 (Ended March 31, 2021)
Full Year Financial Results

Reference Data

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Forward-Looking Statements and Risk Factors

The materials and information provided in this announcement include current forecasts, targets, evaluations, estimates, assumptions that are accompanied by risks, and other matters that are based on uncertain factors. Accordingly, it is possible that actual results will deviate significantly from forecasts, etc., due to changes to a variety of factors. These risks and uncertainties include general industry and market conditions, fluctuation of interest rates and currency exchange rates, and other aspects of economic conditions in Japan and internationally.
Risks and uncertainties that could cause significant fluctuations in the results of the Group or have a material effect on investment decisions are as follows. However, these do not cover all of the risks and uncertainties faced by the Group, and it is possible that they will be affected in the future by other factors that cannot be foreseen, or are not deemed to be important, at this point in time.
These are judgments as of the time of the announcement, and statements in the text regarding the future are not guarantees that they will occur or be achieved.
Risks factors include risks related to management based on the Corporate Philosophy, risks related to establishment of AD franchise, risks related to maximization of the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to uncertainties in new drug development, risks related to occurrences of side effects, risks related to product quality and stable supply, risks related to intellectual property, risks related to litigations, risks related to data reliability, risks related to medical cost containment measures, risks related to succession, risks related to information security, risks related to COVID-19, risks related to climate change, risks related to impairment of goodwill and intangible assets.
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 2018	Yearly Average Rate	110.90	128.40	145.67	16.53
	Year End Rate	110.99	124.56	144.98	16.47
FY 2019	Yearly Average Rate	108.73	120.81	138.24	15.60
	Year End Rate	108.83	119.55	133.32	15.31
FY 2020	Yearly Average Rate	106.06	123.70	138.68	15.67
	Year End Rate	110.71	129.80	152.23	16.84
FY 2021	Forecast Rate	104.50	123.50	136.50	15.50

* Eisai Co., Ltd. ("the Company") discloses its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRS).
* The 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, Hong Kong, India, ASEAN, Central and South America), and OTC and others (Japan).
* All amounts are rounded to the nearest specified unit.

1. Consolidated Statement of Income

(billions of yen)

	FY 2019		FY 2020				FY 2021	
	Full year	Ratio (%)	Full year	Ratio (%)	YOY (%)	Diff.	Full year (est.)	Ratio (%)
Revenue	695.6	100.0	645.9	100.0	92.9	(49.7)	681.0	100.0
Cost of sales	175.7	25.3	161.3	25.0	91.8	(14.4)	158.0	23.2
Gross profit	519.9	74.7	484.6	75.0	93.2	(35.3)	523.0	76.8
Selling, general and administrative expenses	256.3	36.8	281.4	43.6	109.8	25.1	321.0	47.1
Selling expenses	107.2	15.4	116.6	18.1	108.8	9.4	—	—
Personnel expenses	88.1	12.7	90.6	14.0	102.8	2.5	—	—
Administrative and other expenses	61.0	8.8	74.2	11.5	121.7	13.2	—	—
Research and development expenses	140.1	20.1	150.3	23.3	107.3	10.2	160.0	23.5
Other income	6.4	0.9	1.5	0.2	22.7	(4.9)	16.0	2.3
Other expenses	4.4	0.6	2.6	0.4	59.5	(1.8)	—	—
Operating profit	125.5	18.0	51.8	8.0	41.2	(73.7)	58.0	8.5
Financial income	4.0	0.6	2.1	0.3	53.3	(1.9)	—	—
Financial costs	1.5	0.2	1.4	0.2	93.0	(0.1)	—	—
Profit before income taxes	128.1	18.4	52.6	8.1	41.0	(75.5)	58.5	8.6
Income taxes	5.6	0.8	10.1	1.6	179.9	4.5	—	—
Profit for the year	122.5	17.6	42.5	6.6	34.7	(80.0)	45.0	6.6
Profit for the year attributable to								
Owners of the parent	121.8	17.5	42.1	6.5	34.6	(79.6)	44.5	6.5
Non-controlling interests	0.7	0.1	0.4	0.1	52.0	(0.3)	—	—
Comprehensive income for the year	96.2	13.8	71.0	11.0	73.9	(25.2)		

Earnings per share (EPS, yen)	425.01	146.95	158.00
Dividend per share (DPS, yen)	160.0	160.0	160.0
Return on equity (ROE, %)	18.6	6.1	6.7
Dividends on equity ratio (DOE, %)	7.0	6.6	6.7
Overseas revenue ratio (%)	59.8	59.2	

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

Notes

Revenue	Continuous growth of the anticancer agent Lenvima: 133.9 billion yen (previous fiscal year: 111.9 billion yen) Recording of one-time payments for certain option rights from Merck & Co., Inc., Kenilworth, N.J., U.S.A.: 12.9 billion yen (previous fiscal year: 21.6 billion yen) Recording of sales milestone payment revenue from Merck & Co., Inc., Kenilworth, N.J., U.S.A.: 20.7 billion yen (achieved 1.2 billion U.S. dollars for CY2020) (previous fiscal year: 54.6 billion yen) Transfer rights regarding the anticancer agent tazemetostat to Royalty Pharma (U.S.): 11.5 billion yen (previous fiscal year: 24.0 billion yen)
Selling, general and administrative expenses	Shared profit of Lenvima paid to Merck & Co., Inc., Kenilworth, N.J., U.S.A.: 60.2 billion yen (previous fiscal year: 49.4 billion yen)
Research and development expenses	Increase due to aggressive resource investment in projects, mainly anti amyloid-beta protofibril antibody lecanemab, anti amyloid-beta antibody aducanumab, and Lenvima Control of the expenses using the partnership model (partners' burden): 58.1 billion yen (previous fiscal year: 63.5 billion yen)
Other income	Recording of gain on transfer of Elmed Eisai Co., Ltd. in the previous fiscal year: 4.4 billion yen
Income Taxes	Reflecting a reversal of provisions in accounting on income taxes in the U.S. and a decrease in income taxes at the Company following a repayment of paid-in capital from a U.S. subsidiary to the Company in the previous fiscal year
Exchange rate effects	Revenue: -5.36 billion yen, operating profit: +1.09 billion yen
Exchange rate sensitivity (annual effect of 1 yen appreciation in currency value)	Revenue (U.S. dollars: -1.83 billion yen, Euro: -310 million yen, U.K. pounds: -60 million yen, Chinese renminbi: -5.43 billion yen) Operating profit (U.S. dollars: +460 million yen, Euro: -180 million yen, U.K. pounds: +90 million yen, Chinese renminbi: -2.35 billion yen)

2. Segment Information

1) Revenue by Reporting Segment

(billions of yen)

	FY 2019	FY 2020		
	Full year	Full year	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	577.3	586.1	101.5	102.1
Japan pharmaceutical business	247.1	231.9	93.8	93.8
Americas pharmaceutical business	127.9	142.8	111.6	114.4
United States	126.5	140.9	111.4	114.2
China pharmaceutical business	77.0	85.1	110.5	110.0
EMEA pharmaceutical business	53.7	55.2	103.0	102.3
Asia and Latin America pharmaceutical business	46.6	45.9	98.4	99.3
OTC and others	24.9	25.2	101.0	101.0
Other business	118.4	59.9	50.6	52.4
Consolidated revenue	695.6	645.9	92.9	93.6

* Indicates revenue from external customers.
* CER=Constant Exchange Rates

2) Profit by Reporting Segment

(billions of yen)

	FY 2019	FY 2020		
	Full year	Full year	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	230.4	238.4	103.4	104.0
Japan pharmaceutical business	94.2	83.9	89.0	89.0
Americas pharmaceutical business	60.0	64.7	107.9	110.7
China pharmaceutical business	32.8	40.4	123.3	122.8
EMEA pharmaceutical business	23.0	25.7	111.8	111.3
Asia and Latin America pharmaceutical business	16.0	18.6	116.8	115.6
OTC and others	4.5	5.1	111.6	111.6
Other business	108.5	51.5	47.4	49.2
Research and development expenses	(140.1)	(150.3)	107.3	109.2
Group headquarters' management costs and other expenses[#]	(77.7)	(87.8)	112.9	114.9
Gain on sale of subsidiaries	4.4	–	–	–
Consolidated operating profit	125.5	51.8	41.2	40.4

[#] Includes the amount of profits and expenses shared under strategic collaborations with partners.

3. Financial Results by Reporting Segment

1) Japan pharmaceutical business

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Revenue	247.1	231.9	93.8
Segment profit	94.2	83.9	89.0
Japan prescription medicines - revenue from major products			
Fully human anti-TNF-α monoclonal antibody Humira	51.9	52.0	100.2
Pain treatment (neuropathic pain, fibromyalgia) Lyrica	28.6	21.5	75.2
Insomnia treatment Lunesta	12.6	13.9	110.3
Peripheral neuropathy treatment Methycobal	13.9	12.4	89.0
Anticancer agent Lenvima	13.1	12.2	92.9
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	13.3	9.3	69.9
Anticancer agent Halaven	9.2	8.5	91.6
Proton pump inhibitor Pariet[#]	10.6	7.9	75.0
Antirheumatic agent Careram	6.4	7.8	120.2
Elemental diet Elental[#]	6.4	6.6	102.4
Anticancer agent Treakisym	7.7	5.2	67.3
Antiepileptic agent Fycompa	3.9	5.1	129.4
Chronic constipation treatment Goofice[#]	3.6	5.0	139.0

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

* Co-promotion income has been booked as revenue for Lyrica.

[#] EA Pharma product

2) Americas pharmaceutical business (North America)

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Revenue	127.9	142.8	111.6 <114.4>
United States	126.5	140.9	111.4 <114.2>
Segment profit	60.0	64.7	107.9 <110.7>
Americas - revenue from major products			
Anticancer agent Lenvima	68.0	81.0	119.0 <122.0>
United States [Millions USD]	67.6 [622]	80.1 [756]	118.5 <121.5>
Antiepileptic agent Banzel	22.4	18.9	84.6 <86.7>
United States [Millions USD]	22.1 [204]	18.7 [176]	84.4 <86.6>
Anticancer agent Halaven	14.7	12.6	86.0 <88.2>
United States [Millions USD]	14.3 [132]	12.3 [116]	86.2 <88.3>
Antiepileptic agent Fycompa	13.0	12.2	94.0 <96.3>
United States [Millions USD]	12.5 [115]	11.8 [111]	93.7 <96.1>
Proton pump inhibitor AcipHex [Millions USD]	4.0 [37]	2.8 [27]	71.2 <73.0>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.

* All the above revenue of AcipHex is in the United States.

3) China pharmaceutical business

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Revenue	77.0	85.1	110.5 <110.0>
Segment profit	32.8	40.4	123.3 <122.8>
China - revenue from major products			
Anticancer agent Lenvima [Millions RMB]	13.3 [850]	18.5 [1,178]	139.2 <138.5>
Peripheral neuropathy treatment Methycobal [Millions RMB]	20.1 [1,290]	17.5 [1,116]	86.9 <86.5>
Liver disease / Allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets [Millions RMB]	10.3 [660]	10.1 [643]	97.9 <97.5>
Proton pump inhibitor Pariet [Millions RMB]	5.0 [323]	6.7 [430]	133.4 <132.8>
Alzheimer's disease treatment Aricept [Millions RMB]	9.7 [623]	5.8 [367]	59.2 <58.9>
Anticancer agent Halaven [Millions RMB]	0.4 [25]	1.6 [100]	401.3 <399.6>
Antiepileptic agent Fycompa [Millions RMB]	0.1 [4]	0.5 [30]	668.1 <665.2>

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

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

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Revenue	53.7	55.2	103.0 <102.3>
Segment profit	23.0	25.7	111.8 <111.3>
EMEA - revenue from major products			
Anticancer agent Lenvima/Kisplyx	12.7	15.8	124.6 <124.5>
Anticancer agent Halaven	13.8	12.4	89.6 <90.5>
Antiepileptic agent Fycompa	7.1	7.6	106.8 <105.3>
Antiepileptic agent Zebinix	6.5	5.8	89.8 <87.9>
Antiepileptic agent Zonegran	3.9	3.9	99.3 <98.1>
Antiepileptic agent Inovelon	2.4	2.5	102.1 <100.6>

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

5) Asia and Latin America pharmaceutical business

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Revenue	46.6	45.9	98.4 <99.3>
Segment profit	16.0	18.6	116.8 <115.6>
Asia and Latin America - revenue from major products			
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	10.8	10.9	100.3 <100.6>
Fully human anti-TNF-α monoclonal antibody Humira	9.6	8.5	88.6 <89.1>
Anticancer agent Lenvima	4.8	6.5	135.2 <136.0>
Proton pump inhibitor Pariet	4.2	4.0	96.8 <98.4>
Peripheral neuropathy treatment Methycobal	3.0	3.0	102.8 <104.8>
Anticancer agent Halaven	2.1	2.6	122.6 <124.3>
Antiepileptic agent Fycompa	1.1	1.3	120.4 <120.7>

* YOY percentage: figures shown in angle brackets “< >” exclude the effects of foreign currency 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 2019	FY 2020	
	Full year	Full year	YOY (%)
Revenue	24.9	25.2	101.0
Segment profit	4.5	5.1	111.6
OTC and others, revenue from major products			
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	15.5	13.4	86.7

4. Revenue from Major Products

1) Neurology Products

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Neurology Products Total	183.3	161.4	88.1 <88.3>
Methycobal (Peripheral neuropathy treatment)	38.0	34.2	90.0 <89.9>
Japan	13.9	12.4	89.0
China	20.1	17.5	86.9 <86.5>
Asia and Latin America	3.0	3.0	102.8 <104.8>
Fycompa (Antiepileptic agent)	25.3	26.7	105.8 <106.6>
Japan	3.9	5.1	129.4
Americas	13.0	12.2	94.0 <96.3>
China	0.1	0.5	668.1 <665.2>
EMEA	7.1	7.6	106.8 <105.3>
Asia and Latin America	1.1	1.3	120.4 <120.7>
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	34.9	26.3	75.4 <75.5>
Japan	13.3	9.3	69.9
China	9.7	5.8	59.2 <58.9>
Asia and Latin America	10.8	10.9	100.3 <100.6>
Inovelon/Banzel (Antiepileptic agent)	25.4	22.0	86.6 <88.3>
Americas	22.4	18.9	84.6 <86.7>
EMEA	2.4	2.5	102.1 <100.6>
Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan	28.6	21.5	75.2
Lunesta (Insomnia treatment) - Japan	12.6	13.9	110.3
Zebinix (Antiepileptic agent) - EMEA	6.5	5.8	89.8 <87.9>
Zonegran (Antiepileptic agent)	4.5	4.4	97.3 <96.4>
EMEA	3.9	3.9	99.3 <98.1>
Other	7.6	6.5	86.5 <87.1>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.

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

* Co-promotion income has been booked as revenue for Lyrica.

2) Oncology Products

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	YOY (%)
Oncology Products Total	165.9	183.3	110.5 <111.9>
Lenvima/Kisplyx (Anticancer agent)	111.9	133.9	119.7 <121.4>
Japan	13.1	12.2	92.9
Americas	68.0	81.0	119.0 <122.0>
China	13.3	18.5	139.2 <138.5>
EMEA	12.7	15.8	124.6 <124.5>
Asia and Latin America	4.8	6.5	135.2 <136.0>
Halaven (Anticancer agent)	40.2	37.6	93.5 <94.7>
Japan	9.2	8.5	91.6
Americas	14.7	12.6	86.0 <88.2>
China	0.4	1.6	401.3 <399.6>
EMEA	13.8	12.4	89.6 <90.5>
Asia and Latin America	2.1	2.6	122.6 <124.3>
Treakisym/Symbenda (Anticancer agent)	8.0	5.4	68.2 <68.2>
Other	5.8	6.3	108.4 <107.8>

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

5. Revenue Forecasts by Reporting Segment (FY 2021)

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year (forecasts)	YOY (%)
Japan (Prescription Medicines)	231.9	207.0	89.3
Fully human anti-TNF-α monoclonal antibody Humira	52.0	46.0	88.5
Anticancer agent Lenvima	12.2	12.5	102.6
Peripheral neuropathy treatment Methycobal	12.4	10.5	84.8
Anticancer agent Halaven	8.5	7.5	88.6
Antirheumatic agent Careram	7.8	7.5	96.8
Chronic constipation treatment Goofice[#]	5.0	7.0	141.1
Antiepilepsy agent Fycompa	5.1	6.5	127.2
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	9.3	6.5	70.1
Elemental diet Elental[#]	6.6	6.5	98.5
Insomnia treatment Lunesta	13.9	6.0	43.1
Americas	142.8	154.5	108.2
United States	140.9	152.0	107.9
China	85.1	91.0	107.0
EMEA	55.2	55.5	100.5
Asia and Latin America	45.9	47.5	103.5
OTC and others	25.2	26.0	103.4
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	13.4	13.0	96.9
Other	59.9	99.5	166.2
Consolidated revenue	**645.9**	**681.0**	**105.4**
Global revenue from major products			
Lenvima/Kisplyx	133.9	172.0	128.4
Japan	12.2	12.5	102.6
Americas	81.0	104.5	129.1
China	18.5	26.5	143.6
EMEA	15.8	20.5	129.7
Asia and Latin America	6.5	8.0	123.3
Halaven	37.6	35.0	93.1
Japan	8.5	7.5	88.6
Americas	12.6	9.5	75.3
China	1.6	2.5	159.5
EMEA	12.4	12.5	101.0
Asia and Latin America	2.6	3.0	116.0
Fycompa	26.7	32.0	119.7
Japan	5.1	6.5	127.2
Americas	12.2	14.5	118.5
China	0.5	1.0	213.6
EMEA	7.6	8.5	111.6
Asia and Latin America	1.3	1.5	115.4

[#] EA Pharma product

6. Consolidated Statement of Comprehensive Income

(billions of yen)

	FY 2019	FY 2020		
	Full year	Full year	YOY (%)	Diff.
Profit for the year	122.5	42.5	34.7	(80.0)
Other comprehensive income (loss)				
Items that will not be reclassified to profit or loss				
Financial assets measured at fair value through other comprehensive income	(6.2)	3.2	―	9.4
Remeasurements of defined benefit plans	(2.9)	3.2	―	6.1
Subtotal	(9.1)	6.4	―	15.5
Items that may be reclassified subsequently to profit or loss				
Exchange differences on translation of foreign operations	(17.4)	22.0	―	39.5
Cash flow hedges	0.2	0.1	54.7	(0.1)
Subtotal	(17.2)	22.2	―	39.4
Total other comprehensive income (loss), net of tax	(26.3)	28.6	―	54.8
Comprehensive income (loss) for the year	96.2	71.0	73.9	(25.2)
Comprehensive income (loss) for the year attributable to				
Owners of the parent	95.5	70.6	73.9	(24.9)
Non-controlling interests	0.7	0.4	61.1	(0.3)

7. Consolidated Statement of Cash Flows

(billions of yen)

	FY 2019	FY 2020	
	Full year	Full year	Diff.
Operating activities			
Profit before income taxes	128.1	52.6	(75.5)
Depreciation and amortization	33.7	36.3	2.6
Impairment losses	12.3	0.2	(12.1)
(Increase) decrease in working capital	(43.9)	0.3	44.2
Interest and dividends received	4.0	1.9	(2.2)
Interest paid	(1.1)	(1.0)	0.1
Income taxes paid	(20.0)	(17.9)	2.1
Income taxes refund	0.6	1.1	0.4
Other	(11.0)	0.5	11.5
Net cash from (used in) operating activities	102.8	73.9	(28.9)
Investing activities			
Purchases of property, plant and equipment	(15.3)	(19.1)	(3.9)
Proceeds from sale of property, plant and equipment	5.8	0.0	(5.7)
Purchases of intangible assets	(35.0)	(19.0)	16.0
Proceeds from sale of subsidiaries	5.8	―	(5.8)
Payments on investments in joint ventures	―	(0.2)	(0.2)
Purchases of financial assets	(1.9)	(2.6)	(0.7)
Proceeds from sale and redemption of financial assets	6.0	3.5	(2.5)
Subtotal <Capital expenditures (cash basis)>	(34.6)	(37.4)	(2.9)
Payments of time deposits exceeding three months	(0.2)	(0.0)	0.2
Proceeds from redemption of time deposits exceeding three months	7.0	0.2	(6.8)
Other	0.1	0.4	0.2
Net cash from (used in) investing activities	(27.6)	(36.9)	(9.2)
Financing activities			
Net increase (decrease) in short-term borrowings	(9.0)	―	9.0
Proceeds from long-term borrowings	―	34.9	34.9
Repayments of long-term borrowings	(40.0)	(35.0)	5.0
Repayments of lease liabilities	(8.9)	(10.0)	(1.0)
Dividends paid	(45.8)	(45.9)	(0.0)
Other	0.3	0.0	(0.3)
Net cash from (used in) financing activities	(103.5)	(55.9)	47.6
Effect of exchange rate change on cash and cash equivalents	(9.3)	13.4	22.7
Net increase (decrease) in cash and cash equivalents	(37.7)	(5.5)	32.2
Cash and cash equivalents at beginning of year	291.9	254.2	(37.7)
Cash and cash equivalents at end of year	254.2	248.7	(5.5)

Free cash flows	68.2	36.4	(31.8)

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

Notes

■Net cash from (used in) operating activities
While collection of trade receivables proceeded, profit before income taxes decreased

■Net cash from (used in) investing activities
Mainly additional investment in research facilities and manufacturing facilities

■Net cash from (used in) financing activities
Refinancing of long-term borrowings

8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2019	FY 2020		FY 2021
	Full year	Full year	Diff.	Full year (est.)
Capital expenditures (cash basis)	50.2	38.1	(12.1)	56.0
Property, plant and equipment	15.3	19.1	3.9	23.5
Intangible assets	35.0	19.0	(16.0)	32.5
Depreciation and amortization	33.7	36.3	2.6	36.5
Property, plant and equipment	17.8	19.3	1.5	20.5
Intangible assets	15.9	17.0	1.1	16.0

9. Consolidated Statement of Financial Position

<Assets>

(billions of yen)

	FY 2019		FY 2020			
	March 31, 2020	Ratio (%)	March 31, 2021	Ratio (%)	% change	Diff.
Assets						
Non-current assets						
Property, plant and equipment	144.6	13.6	160.9	14.8	111.3	16.3
Goodwill	168.7	15.9	171.8	15.8	101.8	3.1
Intangible assets	106.1	10.0	108.6	10.0	102.4	2.5
Other financial assets	39.8	3.7	43.8	4.0	110.2	4.0
Other assets	15.1	1.4	19.6	1.8	129.5	4.5
Deferred tax assets	66.4	6.3	66.9	6.1	100.7	0.5
Total non-current assets	540.7	50.9	571.7	52.4	105.7	30.9
Current assets						
Inventories	65.7	6.2	85.1	7.8	129.5	19.4
Trade and other receivables	180.0	16.9	160.3	14.7	89.1	(19.7)
Other financial assets	1.6	0.1	0.3	0.0	17.2	(1.3)
Other assets	19.8	1.9	23.9	2.2	120.5	4.1
Cash and cash equivalents	254.2	23.9	248.7	22.8	97.8	(5.5)
Total current assets	521.4	49.1	518.3	47.6	99.4	(3.1)
Total assets	1,062.1	100.0	1,090.0	100.0	102.6	27.9

Notes

■ Assets

(Property, plant and equipment)	Increase mainly due to additional investment in research facilities and manufacturing facilities
(Inventories)	Increase mainly due to stockpiling for stable supply
(Trade and other receivables)	Decrease due to collecting of sales milestone payments

<Equity and Liabilities>

(billions of yen)

	FY 2019		FY 2020			
	March 31, 2020	Ratio (%)	March 31, 2021	Ratio (%)	% change	Diff.
Equity						
Equity attributable to owners of the parent						
Share capital	45.0	4.2	45.0	4.1	100.0	—
Capital surplus	77.6	7.3	77.6	7.1	100.0	0.0
Treasury shares	(34.3)	(3.2)	(34.0)	(3.1)	99.2	0.3
Retained earnings	505.4	47.6	508.0	46.6	100.5	2.6
Other components of equity	84.5	8.0	106.6	9.8	126.2	22.1
Total equity attributable to owners of the parent	678.1	63.8	703.2	64.5	103.7	25.1
Non-controlling interests	24.5	2.3	24.8	2.3	101.0	0.3
Total equity	702.6	66.2	727.9	66.8	103.6	25.3
Liabilities						
Non-current liabilities						
Borrowings	54.9	5.2	49.9	4.6	90.8	(5.0)
Other financial liabilities	36.6	3.4	39.8	3.7	108.9	3.3
Provisions	1.3	0.1	1.4	0.1	103.0	0.0
Other liabilities	14.1	1.3	14.4	1.3	102.2	0.3
Deferred tax liabilities	0.6	0.1	0.5	0.0	89.9	(0.1)
Total non-current liabilities	107.5	10.1	106.1	9.7	98.6	(1.5)
Current liabilities						
Borrowings	35.0	3.3	40.0	3.7	114.3	5.0
Trade and other payables	76.9	7.2	94.5	8.7	123.0	17.7
Other financial liabilities	25.5	2.4	17.0	1.6	66.6	(8.5)
Income taxes payable	5.4	0.5	2.5	0.2	47.1	(2.8)
Provisions	18.7	1.8	17.9	1.6	95.3	(0.9)
Other liabilities	90.5	8.5	84.1	7.7	93.0	(6.4)
Total current liabilities	252.0	23.7	256.0	23.5	101.6	4.1
Total liabilities	359.5	33.8	362.1	33.2	100.7	2.6
Total equity and liabilities	1,062.1	100.0	1,090.0	100.0	102.6	27.9

Notes

■ Equity

(Other components of equity) Increase in exchange differences on translation of foreign operations due to depreciation of yen

■ Liabilities

(Trade and other payables) Increase mainly in accounts payable-other (launch preparation expense assuming approval of aducanumab)

(Other financial liabilities - current) Decrease mainly in deposits received (reimbursement for research and development payment from Merck & Co., Inc., Kenilworth, N.J., U.S.A.)

10. Changes in Quarterly Results

1) Income Statement

(billions of yen)

	FY 2019				FY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	154.0	145.3	186.8	209.6	165.6	151.5	181.3	147.6
Cost of sales	42.9	40.3	44.0	48.5	38.3	41.4	40.4	41.1
Gross profit	111.1	105.0	142.8	161.0	127.3	110.0	140.8	106.5
Selling, general and administrative expenses	60.0	60.5	68.0	67.9	64.9	69.0	77.5	70.0
Selling expenses	24.7	25.8	29.4	27.4	28.2	28.4	31.8	28.3
Personnel expenses	21.1	20.8	24.2	22.0	22.0	22.6	24.1	21.9
Administrative and other expenses	14.2	13.9	14.4	18.5	14.7	18.0	21.5	19.9
Research and development expenses	29.4	38.6	35.0	37.1	30.5	37.0	40.6	42.1
Other income	4.8	0.6	1.0	0.0	0.7	(0.1)	0.1	0.7
Other expenses	0.7	0.2	(0.5)	4.0	0.4	2.0	(0.7)	1.0
Operating profit	25.8	6.2	41.3	52.2	32.1	2.0	23.6	(5.9)
Financial income	1.4	0.9	1.1	0.6	0.7	0.3	0.6	0.6
Financial costs	0.3	0.3	0.3	0.6	0.3	0.3	0.3	0.4
Profit before income taxes	27.0	6.8	42.1	52.3	32.4	2.0	23.9	(5.8)
Income taxes	4.9	1.5	(4.5)	3.7	7.7	0.6	4.2	(2.4)
Profit for the period	22.1	5.3	46.5	48.6	24.8	1.4	19.7	(3.4)
Profit for the period attributable to								
Owners of the parent	21.7	5.3	46.3	48.5	24.4	1.4	19.4	(3.0)
Non-controlling interests	0.4	(0.1)	0.3	0.1	0.3	(0.0)	0.4	(0.3)
Comprehensive income for the period	3.1	1.6	58.1	33.4	23.7	(0.6)	17.3	30.6
Earnings per share (EPS, yen)	75.64	18.58	161.46	169.31	85.23	4.79	67.58	(10.63)

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

2) Cash Flows

(billions of yen)

	FY 2019				FY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Net cash from (used in) operating activities	(4.1)	12.5	20.8	73.6	10.0	8.6	3.5	51.7
Net cash from (used in) investing activities	(20.1)	(3.5)	(2.9)	(1.2)	(12.5)	(4.9)	(13.7)	(5.8)
Net cash from (used in) financing activities	(34.2)	(16.3)	(27.1)	(26.0)	(25.4)	(2.9)	(25.4)	(2.3)
Cash and cash equivalents at the end of period	225.5	215.4	212.5	254.2	226.3	228.0	193.8	248.7
Free cash flow	(24.5)	8.6	13.8	70.4	(2.6)	3.7	(10.4)	45.7

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

3) Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2019				FY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Capital expenditures (cash basis)	26.5	4.5	6.8	12.4	12.1	4.6	14.2	7.3
Property, plant and equipment	4.5	2.6	2.6	5.6	8.8	4.0	1.6	4.7
Intangible assets	22.0	1.9	4.2	6.9	3.2	0.6	12.6	2.6
Depreciation and amortization	8.3	8.2	8.6	8.6	8.7	9.0	9.2	9.5
Property, plant and equipment	4.4	4.3	4.5	4.6	4.7	4.7	4.8	5.1
Intangible assets	3.9	3.9	4.1	4.0	4.0	4.3	4.4	4.3

4) Financial Positions

(billions of yen)

	Jun. 30, 2019	Sept. 30, 2019	Dec. 31, 2019	Mar. 31, 2020	Jun. 30, 2020	Sept. 30, 2020	Dec. 31, 2020	Mar. 31, 2021
Assets	1,026.2	1,010.2	1,051.4	1,062.1	1,040.3	1,046.6	1,028.6	1,090.0
Equity	632.1	633.8	669.0	702.6	703.3	702.8	697.2	727.9
Attributable to owners of the parent	607.8	609.7	644.6	678.1	678.6	678.2	672.2	703.2
Liabilities	394.1	376.3	382.4	359.5	337.0	343.8	331.4	362.1
Borrowings	129.9	115.4	113.9	89.9	89.9	89.9	89.9	89.9
Ratio of equity attributable to owners of the parent (%)	59.2	60.4	61.3	63.8	65.2	64.8	65.4	64.5
Net debt equity ratio (times)	(0.24)	(0.24)	(0.22)	(0.29)	(0.25)	(0.25)	(0.20)	(0.27)

* "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 2019				FY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Neurology Total	50.3	45.7	48.8	38.5	43.8	43.1	40.4	34.0
Methycobal (Peripheral neuropathy treatment)	11.1	10.6	10.0	6.3	10.9	9.4	6.3	7.6
Japan	3.8	3.5	3.7	2.8	3.3	3.0	3.0	3.1
China	6.4	6.1	5.4	2.3	6.9	5.1	2.1	3.4
Asia and Latin America	0.7	0.8	0.8	0.7	0.6	0.9	0.7	0.8
Fycompa (Antiepileptic agent)	6.0	5.9	6.9	6.5	6.4	6.7	7.0	6.7
Japan	1.0	1.0	1.1	0.9	1.2	1.4	1.3	1.3
Americas	3.0	3.0	3.8	3.3	3.0	3.1	3.2	2.9
China	—	—	0.0	0.1	0.1	0.1	0.2	0.0
EMEA	1.7	1.6	1.8	2.0	1.7	1.8	2.0	2.1
Asia and Latin America	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.4
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	10.0	9.2	9.2	6.6	7.8	6.3	6.2	6.0
Japan	4.1	3.3	3.5	2.3	2.9	2.3	2.2	1.9
China	2.8	3.1	2.7	1.1	2.2	1.2	1.1	1.3
Asia and Latin America	2.9	2.6	2.7	2.6	2.6	2.7	2.8	2.7
Inovelon/Banzel (Antiepileptic agent)	7.6	5.4	6.3	6.1	5.9	5.9	5.5	4.7
Americas	6.8	4.7	5.5	5.4	5.1	5.1	4.7	4.0
EMEA	0.6	0.6	0.6	0.6	0.6	0.6	0.7	0.6
Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan	7.1	6.8	8.2	6.5	6.1	7.2	7.1	1.1
Lunesta (Insomnia treatment) - Japan	3.3	3.1	3.5	2.8	3.6	3.3	3.5	3.5
Zebinix (Antiepileptic agent) - EMEA	1.6	1.5	1.6	1.8	1.6	1.7	1.5	1.0
Zonegran (Antiepileptic agent)	1.2	1.1	1.0	1.2	1.0	1.1	1.3	1.1
EMEA	1.0	1.0	0.9	1.0	0.8	1.0	1.1	0.9
Other	2.5	2.1	2.2	0.7	0.6	1.4	2.0	2.5

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

* Co-promotion income has been booked as revenue for Lyrica.

(2) Oncology Products

(billions of yen)

	FY 2019				FY 2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Oncology Total	39.6	39.0	43.4	43.9	47.7	46.4	48.2	40.9
Lenvima/Kisplyx (Anticancer agent)	24.8	25.8	30.0	31.4	34.7	33.8	35.3	30.2
Japan	3.4	3.5	3.3	2.9	3.7	3.3	2.8	2.4
Americas	13.8	14.5	18.8	20.9	21.5	20.4	20.2	18.8
China	3.5	3.6	3.6	2.6	4.2	4.9	6.0	3.3
EMEA	3.0	2.8	3.2	3.7	3.9	3.5	4.3	4.0
Asia and Latin America	1.0	1.3	1.2	1.3	1.4	1.7	1.9	1.5
Halaven (Anticancer agent)	10.9	9.7	9.9	9.7	9.4	9.2	9.5	9.5
Japan	2.6	2.5	2.3	1.9	2.2	2.1	2.0	2.2
Americas	3.7	3.9	3.7	3.5	3.2	3.1	3.2	3.1
China	—	—	0.1	0.3	0.1	0.5	0.6	0.4
EMEA	3.9	3.2	3.3	3.4	3.2	2.9	3.1	3.2
Asia and Latin America	0.8	0.2	0.5	0.6	0.7	0.6	0.7	0.6
Treakisym/Symbenda (Anticancer agent)	2.1	2.2	2.1	1.6	2.0	1.8	1.8	(0.1)
Other	1.8	1.3	1.4	1.3	1.7	1.6	1.6	1.4

11. Trends in Financial Results

(billions of yen)

	FY 2013 Full year	FY 2014 Full year	FY 2015 Full year	FY 2016 Full year	FY 2017 Full year	FY 2018 Full year	FY 2019 Full year	FY 2020 Full year
<Income statement data>								
Revenue	599.5	548.5	547.9	539.1	600.1	642.8	695.6	645.9
Cost of sales	194.7	193.6	194.5	195.9	201.3	184.5	175.7	161.3
Selling, general and administrative expenses	203.3	194.5	192.8	174.9	183.9	228.2	256.3	281.4
Research and development expenses	136.3	131.9	122.3	117.2	139.6	144.8	140.1	150.3
Other income	4.1	1.0	17.7	13.6	3.0	2.6	6.4	1.5
Other expenses	2.8	1.1	4.1	5.6	1.1	1.7	4.4	2.6
Operating profit	66.4	28.3	51.9	59.1	77.2	86.2	125.5	51.8
Profit for the year	38.5	43.5	55.0	42.2	54.4	66.5	122.5	42.5
Comprehensive income for the year	84.5	114.2	16.5	36.8	53.8	79.5	96.2	71.0
<Cash flows>								
Net cash from (used in) operating activities	91.3	76.0	95.6	75.9	149.6	103.7	102.8	73.9
Net cash from (used in) investing activities	20.9	(18.8)	(6.7)	(28.6)	17.0	(7.9)	(27.6)	(36.9)
Net cash from (used in) financing activities	(115.1)	(59.7)	(72.9)	(35.4)	(81.9)	(79.2)	(103.5)	(55.9)
Free cash flows	87.3	61.3	81.2	81.7	136.7	85.1	68.2	36.4
<Financial positions>								
Assets	973.8	1,053.8	974.0	1,030.8	1,049.0	1,071.5	1,062.1	1,090.0
Equity	529.4	602.1	576.8	602.6	614.1	652.0	702.6	727.9
Share capital	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0
Attributable to owners of the parent	526.3	598.7	573.7	584.6	593.6	628.1	678.1	703.2
<Capital expenditures, Depreciation and Amortization>								
Capital expenditures (cash basis)	27.4	18.4	40.1	20.0	24.7	27.6	50.2	38.1
Depreciation and amortization	39.9	38.9	34.1	26.5	26.2	26.8	33.7	36.3
<Managerial indices>								
Dividend payment (billions of yen)	42.8	42.8	42.9	42.9	42.9	43.0	45.9	45.9
Dividends on equity (DOE, %)	8.5	7.6	7.3	7.4	7.3	7.0	7.0	6.6
Dividend payout ratio (DPR, %)	111.8	99.0	78.0	109.0	82.8	67.8	37.6	108.9
Return on sales ratio (%)	6.4	7.9	10.0	7.8	9.1	10.3	17.6	6.6
Return on equity (ROE, %)	7.6	7.7	9.4	6.8	8.8	10.4	18.6	6.1
Return on assets (ROA, %)	3.9	4.3	5.4	4.2	5.2	6.3	11.3	3.9
Total capital turnover ratio (number of times)	0.6	0.5	0.5	0.5	0.6	0.6	0.6	0.6
Ratio of equity attributable to owners of the parent (%)	54.0	56.8	58.9	56.7	56.6	58.6	63.8	64.5
Net debt equity ratio (times)	0.08	0.00	(0.06)	(0.11)	(0.27)	(0.32)	(0.29)	(0.27)
Leverage (times)	1.9	1.8	1.7	1.8	1.8	1.7	1.6	1.6
Earnings per share (EPS, yen)	134.1	151.6	192.2	137.6	181.2	221.3	425.0	147.0
Diluted EPS (yen)	134.0	151.4	191.8	137.4	181.0	221.1	424.8	146.9
Dividend per share (DPS, yen)	150.0	150.0	150.0	150.0	150.0	150.0	160.0	160.0
Price-book value ratio (PBR, times)	2.2	4.1	3.4	2.8	3.3	2.8	3.4	3.0
Number of consolidated subsidiaries	47	48	46	45	44	44	45	46

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

* "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"

* "Leverage" = "Total assets" / "Equity attributable to owners of the parent"

12. Stock Information

1) Number of Shares Issued and Shareholders

As of March 31, 2021

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	9,839,021	61,040	4,859

* Number of shares issued and outstanding includes treasury stock.

2) Principal Shareholders

As of March 31, 2021

Shareholders	Shares (1,000 shares)	Percentage of shares held (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	36,843	12.85
Custody Bank of Japan, Ltd. (Trust Account)	33,119	11.55
State Street Bank and Trust Company 505001	18,974	6.62
Nippon Life Insurance Company	11,781	4.11
Custody Bank of Japan, Ltd. (Trust Account 7)	6,913	2.41
Saitama Resona Bank, Limited	6,300	2.20
Custody Bank of Japan, Ltd. as trustee for Mizuho Bank, Ltd. Retirement Benefit Trust Account re-entrusted by Mizuho Trust and Banking Co., Ltd.	4,437	1.55
State Street Bank West Client - Treaty 505234	4,259	1.49
The Naito Foundation	4,207	1.47
Government of Norway	3,980	1.39

* 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 (9,839 thousand shares, the percentage of treasury stock calculated in proportion to the number of shares issued and outstanding: 3.32%) has been excluded from the table as it has no voting rights.

* While the large shareholding reports (amendment reports) received up until March 31, 2021 are listed below, in cases where large shareholdings cannot be confirmed by the shareholder registry as of March 31, 2021 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 July 31, 2015, two companies including the Wellington Management Company, LLP jointly hold 27,087 thousand shares (9.13%).
(Amendment report dated August 7, 2015)

(3) 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)

(4) As of December 14, 2018, three companies including Sumitomo Mitsui Trust Bank, Ltd. jointly hold 15,967 thousand shares (5.38%).
(Amendment report dated December 21, 2018)

(5) As of January 15, 2020, two companies including Mizuho Bank, Ltd. jointly hold 15,777 thousand shares (5.32%).
(Amendment report dated January 22, 2020)

(6) 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)

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

3) Number of Shares Held by Category

(1,000 shares)

	March 31, 2020	Ratio (%)	March 31, 2021	Ratio (%)	Diff.
Financial institutions	133,094	44.9	129,991	43.8	(3,103)
Financial instruments traders (securities companies)	4,629	1.6	8,872	3.0	4,242
Other companies	20,559	6.9	19,381	6.5	(1,177)
Foreign entities, etc.	91,152	30.7	89,495	30.2	(1,656)
Individuals, other	37,228	12.6	38,986	13.1	1,758
Treasury stock	9,903	3.3	9,839	3.3	(64)
Total	296,566	100.0	296,566	100.0	—

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

13. Number of Employees

1) Number of Employees on Consolidated Basis

(employees)

	March 31, 2018	March 31, 2019	March 31, 2020	March 31, 2021
Total employees	10,456	10,683	10,998	11,237
Japan	4,914	4,888	4,593	4,613
Americas (North America)	1,240	1,261	1,682	1,820
China	1,906	2,069	2,087	2,060
EMEA (Europe, the Middle East, Africa, Russia and Oceania)	1,022	1,046	1,113	1,166
Asia and Latin America	1,374	1,419	1,523	1,578

2) Number of Employees on Non-Consolidated Basis

(employees)

	March 31, 2018	March 31, 2019	March 31, 2020	March 31, 2021
Total employees (Eisai Co., Ltd.)	3,172	3,140	2,953	3,005
Production	415	408	367	375
Research and development	883	868	839	857
Sales, marketing and administration	1,874	1,864	1,747	1,773

* 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.

14. 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: A selective antagonist against the AMPA receptor (a glutamate receptor subtype). Approved as an adjunctive therapy for partial-onset seizures in over 70 countries including Japan, the United States, China and other 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 and the United States. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 70 countries including Japan, the United States, and other countries in Europe and in Asia. In the United States and other countries in Europe, an oral suspension formulation has been approved. A fine granule formulation has been approved in Japan.					
	Pediatric epilepsy (Additional Dosage and Administration)	Study 311	EU CH	○ ○	Approved (November, 2020) Submitted (accepted: October, 2020)
○	Monotherapy for partial-onset seizures (Additional Indication)	Study 335	CH		Submitted (accepted: October, 2020)
	Lennox-Gastaut syndrome (Additional Indication)	Study 338	JP/US/EU		PIII

Development Code: **ME2125** Generic Name: **safinamide** Product Name: **Equfina**					In-license (Meiji Seika Pharma)
Indications / Drug class: Anti-Parkinson's disease agent / MAO-B inhibitor					Oral
Description: A selective monoamine oxidase B (MAO-B) inhibitor, which reduces the degradation of secreted dopamine, helping to maintain the density of dopamine in the brain. Eisai took over by transfer the manufacturing and marketing approval of safinamide from Meiji Seika Pharma in Japan , and has the exclusive rights to develop and market safinamide in Asia.					
	Improvement of wearing-off phenomenon in patients with Parkinson's disease	—	South Korea	○	Approved (June, 2020)

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 onset and maintenance of sleep. It has been approved for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults in the United States. It has been approved for the treatment of insomnia in Japan. In addition, development for Irregular sleep-wake rhythm disorder and Alzheimer's disease dementia is ongoing.					
	Irregular sleep-wake rhythm disorder and Alzheimer's disease dementia (Additional Indication)	Study 202	JP/US		PII

Development Code: **BIIB037** Generic Name: **aducanumab**					Co-development (Biogen Inc.)
Indications / Drug class: Treatment for Alzheimer's disease / anti-Aβ monoclonal antibody					Injection
Description: A human recombinant monoclonal antibody (mAb) that is derived from a de-identified library of B cells collected from healthy elderly subjects with no signs of cognitive impairment or cognitively impaired elderly subjects with unusually slow cognitive decline using Neurimmune's technology platform, Reverse Translational Medicine (RTM). Biogen Inc. licensed aducanumab from Neurimmune. Aducanumab is thought to target aggregated forms of amyloid beta (Aβ) including soluble oligomers and insoluble fibrils, which can form into amyloid plaque in Alzheimer's disease patients. The United States Food and Drug Administration (FDA) accepted Biologics License Application (BLA) with Priority Review in August 2020. Marketing Authorization Application (MAA) was accepted by the European Medicines Agency (EMA) in October 2020, and in Japan, New Drug Application (NDA) was submitted in December 2020. It was disclosed in April 2021 that submission of MAA has been conducted in Brazil, Canada, Australia and Switzerland. In Canada, Australia and Switzerland, the validation of whether the applications are accepted is underway. Joint development with Biogen Inc.					
	Alzheimer's disease	ENGAGE/ EMERGE Studies	US EU JP	○ ○ ○	Submitted (accepted: August, 2020) Submitted (accepted: October, 2020) Submitted (December, 2020)

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 onwards

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 halting disease progression through the elimination of neurotoxic Aβ protofibrils. Joint development with Biogen Inc. The Phase III clinical study Clarity AD in patients with mild cognitive impairment due to AD or mild AD (collectively known as early AD) is underway. The Phase III clinical study AHEAD 3-45 for preclinical (asymptomatic) AD has been initiated and is underway in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC).					
	Early AD	Study 301 (Clarity AD)	JP/US/ EU/CH		PIII
○	Preclinical AD	Study 303 (AHEAD 3-45)	JP/US/EU		PIII

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 has been initiated and is underway for this indication. The 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 / PDE 9 inhibitor					Oral
Description: A selective phosphodiesterase (PDE) 9 inhibitor that reduces the degradation of cyclic GMP, which is critical to signal transmission 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	Study 201 (DELPHIA)	JP/US/EU		PII/III
◎	Dementia with Lewy bodies, Parkinson's disease dementia	Study 203	US		PII

Development Code: **E2730**					In-house
Indications / Drug class: Antiepileptic agent, treatment for neurological diseases / synapse function modulator					Oral
Description: A compound with a novel mechanism of action that selectively regulates the function of activated synapses. Expected to be a new treatment for neurological diseases such as epilepsy, including orphan epilepsy and epileptogenesis.					
	Epilepsy	Study 201	US		PII

Development Code: **E2814**			Collaboration (University College London)		Injection
	Alzheimer's disease	—	US		PI

Development Code: **E2511**			In-house		Oral
○	Alzheimer's disease	—	US		PI

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

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 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 administered multiple receptor tyrosine kinase (RTK) inhibitor that selectively inhibits the kinase activities of vascular endothelial growth factor receptors (VEGFR) and fibroblast growth factor receptors (FGFR) in addition to other proangiogenic and oncogenic pathway related RTKs (including the platelet-derived growth factor receptor (PDGFR), KIT and RET) involved in angiogenesis and tumor proliferation. Discovered and developed in-house. Approved for use in the treatment of thyroid cancer in over 70 countries including Japan, the United States, China and other countries in Europe and in Asia. Also approved in combination with everolimus for use in the treatment of renal cell carcinoma (second-line) in over 60 countries including the United States and other countries in Europe. The agent is marketed under the product name Kisplyx only for this indication in Europe. Approved for use in the treatment of hepatocellular carcinoma (first-line) in over 70 countries including in Japan, the United States, China and other countries in Europe and in Asia. Approved for use in the treatment of endometrial cancer in combination with pembrolizumab in over 10 countries, including the United States, Canada and Australia. Joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate.					
Monotherapy, joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate (Additional Indication)					
	Thyroid cancer	Study 303/308	CH	○	Approved (November, 2020)
	Thymic cancer	NCCH1508	JP	◎	Approved (March, 2021)
In combination with anti-PD-1 antibody pembrolizumab, joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate (Additional Indication)					
	Renal cell carcinoma/First-line	Study 307	EU JP US	◎ ◎ ◎	Submitted (accepted: March, 2021) Submitted (March, 2021) Submitted (accepted: April, 2021)
	Endometrial cancer/Second-line	Study 309	EU JP US	◎ ◎ ◎	Submitted (accepted: March, 2021) Submitted (April, 2021) Submitted (accepted: April, 2021)
	Hepatocellular carcinoma/First-line	LEAP-002	JP/US/EU/CH		PIII
	Melanoma/First-line	LEAP-003	US/EU/CH		PIII
	Nonsquamous non-small cell lung cancer/First-line	LEAP-006	JP/US/EU/CH		PIII
	Non-small cell lung cancer, PD-L1 positive/First-line	LEAP-007	JP/US/EU/CH		PIII
	Endometrial carcinoma/First-line	LEAP-001	JP/US/EU/CH		PIII
	Non-small cell lung cancer/Second-line	LEAP-008	JP/US/EU		PIII
	Bladder cancer, cisplatin-ineligible/First-line	LEAP-011	JP/US/EU/CH		PIII
	Head and neck cancer/First-line	LEAP-010	JP/US/EU/CH		PIII
○	Gastric cancer/First-line	LEAP-015	JP/US/EU/CH		PIII
◎	Colorectal cancer/Third-line	LEAP-017	US/EU		PIII
	Selected solid tumors (Endometrial cancer, renal cell carcinoma, head and neck cancer, urothelial cancer, non-small cell lung cancer and melanoma)	Study 111 —	US/EU JP		PI/II PI
	Melanoma/Second-line	LEAP-004	US/EU		PII
	Selected solid tumors (Triple negative breast cancer, ovarian cancer, gastric cancer, colorectal cancer, glioblastoma, biliary tract cancers and pancreatic cancer)	LEAP-005	US/EU		PII

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 onwards

○	Head and neck cancer/Second-line	LEAP-009	US/EU		PII
In combination with anti-PD-1 antibody pembrolizumab and transcatheter arterial chemoembolization, joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate (Additional Indication)					
○	Hepatocellular carcinoma/First-line	LEAP-012	JP/US/EU/ CH		PIII
In combination with anticancer agent everolimus, joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., 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

○In July 2020, regarding applications seeking accelerated approval of the combination therapy with pembrolizumab for the first-line treatment of patients with unresectable hepatocellular carcinoma in the United States based on the Study 116 results, a Complete Response Letter (CRL) was received from the FDA and therefore were removed from this list.

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 75 countries including Japan, the United States, China and other countries in Europe and in Asia for use in the treatment of breast cancer. Approved in over 75 countries including Japan, the United States and other countries in Europe and in Asia for use in the treatment of liposarcoma (soft tissue sarcoma in Japan).					
Monotherapy (Additional Formulation)					
	Liposome formulation	—	JP/EU		PI
In combination with anti-PD-1 antibody nivolumab, Joint development with Ono Pharmaceutical (Additional Formulation)					
	Liposome formulation	Study 120	JP		PI/II

○The development of the agent in combination with PEGPH20 by Halozyme Therapeutics, Inc. for HER2-negative breast cancer which was in Phase I/II stage in the United States has been finished.

○The development of the agent in combination with anti-PD-1 antibody pembrolizumab for triple negative breast cancer which was in Phase I/II stage in the United States has been finished.

Development Code: **E7777** Generic Name: **denileukin diftitox (genetic recombinant)** Product Name: **Remitoro**					In-house
Indications / Drug class: Anticancer agent / a fusion protein that combines the interleukin-2 receptor binding domain with diphtheria toxins					Injection
Description: A fusion protein that combines the interleukin-2 (IL-2) receptor-binding domain with diphtheria toxins. Specifically binds to IL-2 receptors on the cell surface of tumoral lymphocyte, causing diphtheria toxins that have entered cells to inhibit protein synthesis and induce cell death.					
	Peripheral T-cell lymphoma and cutaneous T-cell lymphoma	Study 205	JP	◎	Approved (March, 2021)

Development Code: **E7438** Generic Name: **tazemetostat**					In-license (Epizyme, Inc.)
Indications / Drug class: Anticancer agent / EZH2 inhibitor					Oral
Description: Believed to have an important role in carcinogenesis, the epigenetic enzyme EZH2 is one of the proteins that constitute the histone methyltransferases. Discovered by Epizyme, Inc. through its proprietary product platform, E7438 is a first-in-class, orally administered small molecule inhibitor, and is expected to exhibit antitumor effects via inhibition of the epigenetic enzyme EZH2. Eisai holds development and commercialization rights within Japan.					
	Non-Hodgkin B-cell lymphoma	Study 206	JP	○	Submitted (June, 2020)

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 onwards

Development Code: **MORAb-009** Generic Name: **amatuximab**					In-house
Indications / Drug class: Anticancer agent / chimeric anti-mesothelin monoclonal antibody					Injection
Description: A chimeric IgG1 antibody that targets mesothelin. Expected to show an antitumor effect against cancers that express mesothelin.					
	Mesothelioma	Study 003/201	US/EU		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**					In-house
Indications / Drug class: Anticancer agent / FGFR1,2,3 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 ongoing. It has been granted the SAKIGAKE designation by Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of unresectable biliary tract cancer with FGFR2 gene fusion, and it has received orphan drug designation with a prospective indication for unresectable biliary tract cancer with FGFR2 gene fusion by the MHLW.					
	Cholangiocarcinoma	Study 201	JP/CH		PII
○	Breast cancer	—	JP		PI

Development Code: **H3B-6527**					In-house	Oral
	Hepatocellular carcinoma	—	US/EU		PI	

Development Code: **H3B-8800**					In-house	Oral
	Blood cancer	—	US/EU		PI	

Development Code: **E7386**					Collaboration (PRISM BioLab)	Oral
	Solid tumors	—	JP/EU		PI	
	Solid tumors (in combination with lenvatinib)	—	JP		PI	

Development Code: **MORAb-202**					In-house	Injection
	Solid tumors	—	JP		PI	
○	Solid tumors	—	US		PI/II	

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

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

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 onwards

(3) Gastrointestinal Disorders

Development Code: **EAM007** Product Name: **Eleview**					In-license (Cosmo Technologies)
Indications / Drug class: Submucosal injectable composition/ medical device					Submucosal injectable composition
Description: A submucosal injectable composition that provides a submucosal cushion of optimal height and duration, achieving an easier and safer resection procedure in endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) in the esophagus, the stomach, the intestine and the rectum. This is the EA Pharma's first medical device to be approved marketing authorization. Development conducted by EA Pharma.					
○	Submucosal injectable composition for endoscopic mucosal resection and submucosal dissection	—	JP		Approved (November, 2020)

Development Code: **AJM300** Generic Name: **carotegrast methyl**					In-house
Indications / Drug class: Ulcerative colitis treatment / α4 integrin antagonist					Oral
Description: α4 integrin antagonist with a novel mechanism of action believed to suppress adhesion and infiltration of lymphocytes. Aiming to be marketed as the first orally-available α4 integrin antagonist in the world to be effective in ulcerative colitis. In January 2021, EA Pharma and Kissei Pharmaceutical disclosed that the Phase III clincal study in Japan met the primary endpoint. Joint development by EA Pharma and Kissei Pharmaceutical.					
	Ulcerative colitis	—	JP	◎	Preparation of submission

Development Code: **E6007** Generic Name: **milategrast**					In-house
Indications / Drug class: Ulcerative colitis treatment / integrin activation inhibitor					Oral
Description: A compound with a novel mechanism of action that is believed to suppress the adhesion and infiltration of multiple leukocyte types by inhibiting integrin activation. EA Pharma aims for commercialization jointly with the University of Tsukuba as an industry-academia practical application project under the Japan Science and Technology Agency. Development conducted by EA Pharma.					
	Ulcerative colitis	Study 201	JP		PII

Development Code: **E6011** Generic Name: **quetmolimab**					In-house
Indications / Drug class: Crohn's disease / Anti-humanized monoclonal fractalkine antibody					Injection
Description: The world's first humanized anti-fractalkine monoclonal antibody discovered by the Eisai Group subsidiary KAN Research Institute Inc. Expected to exert an anti-inflammatory effect by neutralizing fractalkine. Fractalkine is found in vascular endothelial cells and induces an inflammatory response associated with diseases such as inflammatory bowel disease. Development conducted by EA Pharma.					
	Crohn's disease	Study ET2	JP/EU		PII

Development Code: **EA4000**			In-license (Norgine)		Oral
○	Bowel cleansing agent (Development conducted by EA Pharma)	—	JP		PI/II

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

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 onwards

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

Development Code: **EA3355**			In-license (Dr. Falk Pharma)		Oral
○	Liver disease (Development conducted by EA Pharma)	—	JP		PI

(4) Other

Development Code: **E5564** Generic Name: **eritoran**			In-house		
Indications / Drug class: Suppression for increasing of severity of COVID-19/ TLR4 antagonist			Injection		
Description: Eritoran is a TLR (Toll-Like Receptor) 4 antagonist created with natural product organic synthesis technology. It is a structural analogue of Lipid A which is an activator of endotoxins of bacteria. It is expected to suppress inflammation and increasing in severity caused by COVID-19 by inhibiting the activation of TLR4, which is found in the most upstream position of various cytokine gene expression signaling that causes the cytokine-storm. Development is in collaboration with GCAR (Global Coalition for Adaptive Research).					
○	Suppression for increasing of severity of COVID-19	REMAP-COVID	US		PIII

Development Code: **E6742**			In-house		Oral
	Autoimmune disease	—	JP/US		PI

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

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

○：Development progress from April 2020 onwards, ◎：Development progress from January 2021 onwards