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FY 2017 (Ending March 31, 2018)  
First Quarter Financial Results

# Reference Data

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## **Forward-Looking Statements and Risk Factors**

Materials and information provided in this financial disclosure may contain “forward-looking statements” based on current expectations, forecasts, estimates, business goals and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations.

Risks that may cause significant fluctuations in the consolidated results of the Eisai Group or have a material effect on investment decisions are described below. These are risk factors that have been identified and assessed as of the disclosure date of the Financial Report.

Risk factors associated with our business include, but are not limited to, risks related to product safety and quality, possible occurrence of side effects, lawsuits, changes in laws and regulations, intellectual property, uncertainties in new drug development, impact of medical cost containment measures, generic products, challenges arising in overseas operations, alliances with other companies, acquisitions of companies and product lines, outsourcing, IT security and information management, internal control systems for financial reporting, financial market conditions and currency movement, plant closure or shutdown, environmental issues, and disasters.

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.

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## Currency Exchange Rates

		US (USD/JPY)	EU (EUR/JPY)	UK (GBP/JPY)	China (RMB/JPY)
FY 2016 Q1	Quarterly Average Rate	108.14	122.01	155.10	16.52
	Quarter End Rate	102.91	114.39	138.41	15.46
FY 2016	Yearly Average Rate	108.38	118.78	141.59	16.10
	Year End Rate	112.19	119.79	140.08	16.29
FY 2017 Q1	Quarterly Average Rate	111.09	122.19	142.00	16.21
	Quarter End Rate	112.00	127.97	145.79	16.49
FY 2017	Forecast Rate	113.00	120.00	141.00	16.30

\* Eisai Co., Ltd. ("the Company") discloses its consolidated financial statements according to 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 five reporting segments in this report: Japan (primarily Prescription Medicines, Generics, and OTC), Americas (North, Central and South America), China, EMEA (Europe, the Middle East, Africa, and Oceania) and Asia (mainly South Korea, Taiwan, Hong Kong, India, and ASEAN).

\* All amounts are rounded to the nearest specified unit.

# 1. Consolidated Statement of Income

(billions of yen)

	FY 2016				FY 2017				FY 2017	
	Q1	Ratio (%)	Full year	Ratio (%)	Q1	Ratio (%)	YOY (%)	Diff.	Full year (forecasts)	Ratio (%)
Revenue	136.9	100.0	539.1	100.0	141.9	100.0	103.6	4.9	575.5	100.0
Cost of sales	49.8	36.4	195.9	36.3	49.4	34.8	99.2	(0.4)	206.0	35.8
Gross profit	87.1	63.6	343.2	63.7	92.5	65.2	106.1	5.3	369.5	64.2
Selling, general and administrative expenses	42.6	31.1	174.9	32.5	44.3	31.2	104.1	1.7	177.5	30.8
Selling expenses	12.5	9.1	55.9	10.4	13.2	9.3	105.8	0.7	—	—
Personnel expenses	19.0	13.9	75.2	14.0	20.0	14.1	105.5	1.0	—	—
Administrative and other expenses	11.1	8.1	43.9	8.1	11.0	7.8	99.8	(0.0)	—	—
Research and development expenses	27.3	19.9	117.2	21.7	33.2	23.4	121.6	5.9	134.0	23.3
Other income	10.3	7.5	13.6	2.5	0.6	0.4	6.0	(9.7)	2.0	0.3
Other expenses	1.7	1.3	5.6	1.0	0.4	0.3	25.8	(1.3)	—	—
Operating profit	25.8	18.9	59.1	11.0	15.1	10.7	58.6	(10.7)	60.0	10.4
Financial income	0.7	0.5	1.8	0.3	0.7	0.5	104.2	0.0	—	—
Financial costs	0.7	0.5	3.2	0.6	0.7	0.5	102.9	0.0	—	—
Profit before income taxes	25.8	18.8	57.7	10.7	15.1	10.7	58.6	(10.7)	58.3	10.1
Income taxes	4.9	3.6	15.4	2.9	4.5	3.2	93.1	(0.3)	—	—
Profit for the period	20.9	15.3	42.2	7.8	10.6	7.5	50.6	(10.3)	41.3	7.2
Attributable to										
Owners of the parent	19.7	14.4	39.4	7.3	9.8	6.9	49.7	(9.9)	39.8	6.9
Non-controlling interests	1.2	0.9	2.9	0.5	0.8	0.5	65.6	(0.4)	—	—
Comprehensive income for the period	(23.0)	(16.8)	36.8	6.8	15.2	10.7	—	38.2		

Earnings per share (EPS, yen)	69.0	137.6	34.3	139.2
Dividends per share (DPS, yen)	—	150.0	—	150.0
Return on equity (ROE, %)	—	6.8	—	6.8
Dividend on equity ratio (DOE, %)	—	7.4	—	7.4
Overseas revenue ratio (%)	43.2	45.2	44.3	

\* The influence of risks relating to the patent infringement litigation for antiemetic agent Aloxi in the United States announced on May 3, 2017 has not been included in the consolidated forecasts.

\* Full year estimation for other income has had other expenses deducted from it.

\* From this period, the Group has clarified the definition of research and development expenses in order to more accurately reflect the condition of the business, and this has resulted in a portion of expenses relating to medical affairs activities, such as creation and provision of scientific evidence for health care providers, being apportioned to research and development expenses. Accordingly, an amount which was included in selling, general and administrative expenses during the previous period has been reclassified as research and development expenses.

## Notes

Revenue	Increase due to growth of Halaven, Lenvima, Humira, and Fycompa (Revenue from the Japan pharmaceutical business increased and China, EMEA, and Asia pharmaceutical businesses each achieved double-digit growth)
Research and development expenses	Aggressive R&D investment in Alzheimer disease projects, such as beta secretase cleaving enzyme (BACE) inhibitor E2609, and oncology projects.
Other income	One-off income (gain from a bargain purchase) of 9.3 billion recorded due to acquisition of a subsidiary in the same period of the previous fiscal year
Exchange rate effects	Revenue: +990 million yen, operating profit: +50 million yen
Exchange rate sensitivity (annual effect of a 1 yen appreciation in currency value)	Revenue (U.S. dollars: -1.04 billion yen, Euro: -260 million yen, U.K. pounds: -40 million yen, Chinese renminbi: -3.23 billion yen) Operating profit (U.S. dollars: +380 million yen, Euro: -200 million yen, U.K. pounds: +90 million yen, Chinese renminbi: -1.44 billion yen)

## 2. Segment Information

### 1) Revenue by Reporting Segment

(billions of yen)

	FY 2016		FY 2017		
	Q1	Full year	Q1	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	135.1	530.1	139.8	103.5	102.8
Japan Pharmaceutical Business	77.1	291.1	78.0	101.1	101.1
Americas Pharmaceutical Business	29.2	117.2	28.8	98.8	96.2
United States	28.8	115.7	28.4	98.4	95.8
China Pharmaceutical Business	11.2	49.3	13.1	117.2	119.4
EMEA Pharmaceutical Business	9.0	37.8	10.1	111.2	112.1
Asia Pharmaceutical Business	8.6	34.7	9.9	115.3	108.8
Other Business	1.9	9.0	2.0	108.9	109.4
Consolidated revenue	136.9	539.1	141.9	103.6	102.9

\* Indicates revenue from external customers

\* CER=Constant Exchange Rates

### 2) Profit by Reporting Segment

(billions of yen)

	FY 2016		FY 2017		
	Q1	Full year	Q1	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	47.7	177.4	50.8	106.5	105.4
Japan Pharmaceutical Business	29.0	102.7	30.5	105.1	105.1
Americas Pharmaceutical Business	8.6	36.9	9.8	113.8	110.8
China Pharmaceutical Business	3.6	13.8	4.0	109.3	112.4
EMEA Pharmaceutical Business	3.8	14.6	3.6	93.3	87.7
Asia Pharmaceutical Business	2.6	9.3	2.9	114.0	107.3
Other Business	0.4	2.1	0.6	157.7	170.8
R&D Expenses	(27.3)	(117.2)	(33.2)	121.6	120.0
Group headquarters' management costs and other expenses	(4.3)	(12.6)	(3.1)	71.3	71.4
Gain from a bargain purchase	9.3	9.3	—	—	—
Gain on sale of subsidiaries	0.1	0.1	—	—	—
Consolidated operating profit	25.8	59.1	15.1	58.6	58.4

\* CER=Constant Exchange Rates

\* From this period, the Group has clarified the definition of research and development expenses in order to more accurately reflect the condition of the business, and this has resulted in a portion of expenses relating to medical affairs activities, such as creation and provision of scientific evidence for health care providers, being apportioned to research and development expenses. Accordingly, an amount which was included in selling, general and administrative expenses during the previous period has been reclassified as research and development expenses.

### 3. Financial Results by Reporting Segment

#### 1) Japan Pharmaceutical Business

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
Revenue	77.1	291.1	78.0	101.1
Prescription Medicines	65.3	244.0	65.2	99.9
Generics	7.1	28.0	7.1	101.0
Consumer Healthcare Business	4.7	19.0	5.6	118.3
Segment profit	29.0	102.7	30.5	105.1
<b>Japan prescription medicines - revenue from major products</b>				
Fully human anti-TNF- $\alpha$ monoclonal antibody Humira	9.4	37.7	11.2	119.0
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	8.9	29.5	7.0	78.3
Pain treatment (neuropathic pain, fibromyalgia) Lyrica	6.1	24.3	6.7	110.4
Proton pump inhibitor Pariet**	6.0	21.2	4.9	81.9
Peripheral neuropathy treatment Methycobal	5.0	18.2	4.6	92.2
Insomnia treatment Lunesta	1.9	8.0	2.5	131.5
Anticancer agent Halaven	2.0	7.8	2.3	117.4
Elemental diet Elental**	1.6	6.6	1.7	103.9
Anticancer agent Treakisym	1.1	4.2	1.7	160.4
Oral anticoagulant Warfarin	1.9	6.8	1.7	86.0
Branched-chain amino acid preparation Livact**	1.9	6.7	1.6	85.3
Anticancer agent Lenvima	0.7	2.7	0.8	108.4
Antiepileptic agent Fycompa	0.1	0.5	0.3	281.4
<b>Consumer Healthcare Business—Japan - revenue from major products</b>				
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	3.2	12.4	3.7	116.8

\* 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, Central and South America)

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
Revenue	29.2	117.2	28.8	98.8 <96.2>
United States	28.8	115.7	28.4	98.4 <95.8>
Segment profit	8.6	36.9	9.8	113.8 <110.8>
<b>Americas - revenue from major products</b>				
Antiemetic agent Aloxi	12.0	48.1	10.6	88.4
United States	12.0	48.1	10.6	88.4
[Millions USD]	[111]	[444]	[95]	<86.0>
Anticancer agent Lenvima	3.2	15.1	4.9	152.4
United States	3.2	15.0	4.8	151.0
[Millions USD]	[30]	[138]	[43]	<147.0>
Anticancer agent Halaven	4.2	16.6	4.2	99.9
United States	4.0	15.8	3.9	98.9
[Millions USD]	[37]	[146]	[35]	<96.3>
Antiepileptic agent Banzel	3.1	13.8	4.1	131.9
United States	3.0	13.7	4.0	132.2
[Millions USD]	[28]	[126]	[36]	<128.7>
Antiepileptic agent Fycompa	1.2	5.3	1.6	132.3
United States	1.1	5.0	1.5	132.3
[Millions USD]	[11]	[46]	[14]	<128.8>
Proton pump inhibitor AcipHex	1.8	7.2	1.6	85.2
[Millions USD]	[17]	[66]	[14]	<82.9>
Antiobesity agent BELVIQ	1.0	3.7	1.0	98.6
[Millions USD]	[9]	[34]	[9]	<96.0>

\* Year-on-year percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.

\* The U.S. is the only country in the Americas where the Eisai directly markets AcipHex and BELVIQ.

### 3) China Pharmaceutical Business

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
Revenue	11.2	49.3	13.1	117.2 <119.4>
Segment profit	3.6	13.8	4.0	109.3 <112.4>
<b>China - revenue from major products</b>				
Peripheral neuropathy treatment Methycobal	4.0 [Millions RMB]	18.0 [1,116]	4.9 [303]	124.1 <126.5>
Liver disease / Allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets	2.1 [Millions RMB]	8.4 [523]	2.2 [137]	107.1 <109.1>
Alzheimer's disease treatment Aricept	1.4 [Millions RMB]	6.2 [383]	1.6 [101]	118.7 <121.0>
Proton pump inhibitor Pariet	0.9 [Millions RMB]	3.9 [244]	1.3 [80]	142.7 <145.4>

\* Year-on-year percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.

### 4) EMEA Pharmaceutical Business (Europe, the Middle East, Africa and Oceania)

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
Revenue	9.0	37.8	10.1	111.2 <112.1>
Segment profit	3.8	14.6	3.6	93.3 <87.7>
<b>EMEA - revenue from major products</b>				
Anticancer agent Halaven	2.7	10.9	2.8	103.1 <103.5>
Anticancer agent Lenvima / Kispplx	0.4	3.3	1.3	292.9 <293.7>
Antiepileptic agent Fycompa	1.1	4.2	1.2	109.4 <110.0>
Antiepileptic agent Zonegran	1.5	5.2	1.1	72.2 <72.9>
Antiepileptic agent Zebinix	0.7	3.6	1.0	146.6 <147.8>
Antiepileptic agent Inovelon	0.5	1.9	0.5	114.6 <116.7>

\* Year-on-year percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.

## 5) Asia Pharmaceutical Business (mainly South Korea, Taiwan, Hong Kong, India and ASEAN)

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
Revenue	8.6	34.7	9.9	115.3 <108.8>
Segment profit	2.6	9.3	2.9	114.0 <107.3>

### Asia - revenue from major products

Fully human anti-TNF- $\alpha$ monoclonal antibody Humira	2.4	9.6	2.9	120.0 <111.5>
Alzheimer's disease treatment Aricept	2.4	9.8	2.7	113.6 <107.0>
Proton pump inhibitor Pariet	0.9	3.6	1.0	111.5 <106.3>
Peripheral neuropathy treatment Methycobal	0.7	2.9	0.7	103.2 <98.3>
Anticancer agent Halaven	0.5	2.0	0.4	81.5 <76.6>
Anticancer agent Lenvima	0.0	0.3	0.3	1580.8 <1550.7>
Antiepileptic agent Fycompa	0.1	0.4	0.1	203.0 <190.4>

\* Year-on-year percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.



## 4. Revenue from Major Products

### 1) Neurology Products

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
<b>Neurology Products Total</b>	40.6	161.9	42.8	105.4 <104.8>
<b>Aricept (Alzheimer's disease / dementia with Lewy bodies treatment)</b>	13.2	49.2	11.8	89.2 <88.2>
Japan	8.9	29.5	7.0	78.3
China	1.4	6.2	1.6	118.7 <121.0>
Asia	2.4	9.8	2.7	113.6 <107.0>
<b>Methycobal (Peripheral neuropathy treatment)</b>	9.8	40.0	10.4	106.5 <107.1>
Japan	5.0	18.2	4.6	92.2
China	4.0	18.0	4.9	124.1 <126.5>
Asia	0.7	2.9	0.7	103.2 <98.3>
<b>Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan</b>	6.1	24.3	6.7	110.4
<b>Inovelon/Banzel (Antiepileptic agent)</b>	3.7	16.2	4.7	128.9 <126.2>
Americas	3.1	13.8	4.1	131.9 <128.5>
EMEA	0.5	1.9	0.5	114.6 <116.7>
<b>Fycompa (Antiepileptic agent)</b>	2.5	10.3	3.2	131.1 <129.5>
Japan	0.1	0.5	0.3	281.4
Americas	1.2	5.3	1.6	132.3 <129.1>
EMEA	1.1	4.2	1.2	109.4 <110.0>
Asia	0.1	0.4	0.1	203.0 <190.4>
<b>Lunesta (Insomnia treatment) - Japan</b>	1.9	8.0	2.5	131.5
<b>Zonegran (Antiepileptic agent)</b>	1.6	5.6	1.2	75.6 <75.7>
EMEA	1.5	5.2	1.1	72.2 <72.9>
<b>Zebinix (Antiepileptic agent) - EMEA</b>	0.7	3.6	1.0	146.6 <147.8>
<b>BELVIQ (Antiobesity agent) - United States</b>	1.0	3.7	1.0	98.6 <96.0>
<b>Other</b>	0.3	1.0	0.3	100.8 <100.8>

\* Year-on-year 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 and the Philippines.

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

## 2) Oncology Products

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	YOY (%)
<b>Oncology Products Total</b>	28.5	118.3	31.1	109.1 <107.3>
<b>Aloxi (Antiemetic agent) - Americas</b>	12.0	48.1	10.6	88.4 <86.0>
<b>Halaven (Anticancer agent)</b>	9.4	37.3	9.7	103.6 <102.2>
Japan	2.0	7.8	2.3	117.4
Americas	4.2	16.6	4.2	99.9 <97.1>
EMEA	2.7	10.9	2.8	103.1 <103.5>
Asia	0.5	2.0	0.4	81.5 <76.6>
<b>Lenvima / Kisplyx (Anticancer agent)</b>	4.4	21.5	7.3	165.9 <162.9>
Japan	0.7	2.7	0.8	108.4
Americas	3.2	15.1	4.9	152.4 <148.3>
EMEA	0.4	3.3	1.3	292.9 <293.7>
Asia	0.0	0.3	0.3	1580.8 <1550.7>
<b>Treakisym/Symbenda (Anticancer agent)</b>	1.1	4.5	1.8	155.9 <155.7>
<b>Other</b>	1.6	7.0	1.7	109.2 <109.5>

\* Year-on-year percentage: figures shown in angle brackets "< >" exclude the effects of foreign currency fluctuations.

## 5. Revenue Forecasts by Reporting Segment (FY 2017)

(billions of yen)

	FY 2016		FY 2017	
	Q1	Full year	Q1	Full year (forecasts)
<b>Japan</b>	77.1	291.1	78.0	293.0
<b>Prescription Medicines</b>	65.3	244.0	65.2	243.0
Fully human anti-TNF- $\alpha$ monoclonal antibody				
<b>Humira</b>	9.4	37.7	11.2	43.5
Alzheimer's disease / Dementia with Lewy bodies treatment				
<b>Aricept</b>	8.9	29.5	7.0	22.0
Proton pump inhibitor				
<b>Pariet**</b>	6.0	21.2	4.9	18.5
Peripheral neuropathy treatment				
<b>Methycobal</b>	5.0	18.2	4.6	17.0
Insomnia treatment				
<b>Lunesta</b>	1.9	8.0	2.5	10.5
Anticancer agent				
<b>Halaven</b>	2.0	7.8	2.3	8.5
Elemental diet				
<b>Eletal**</b>	1.6	6.6	1.7	6.5
Anticancer agent				
<b>Treakisym</b>	1.1	4.2	1.7	6.5
Oral anticoagulant				
<b>Warfarin</b>	1.9	6.8	1.7	6.0
Branched-chain amino acid preparation				
<b>Livact**</b>	1.9	6.7	1.6	6.0
<b>Generics</b>	7.1	28.0	7.1	30.0
<b>Consumer Healthcare Business</b>	4.7	19.0	5.6	19.5
Vitamin B2 preparation, "Chocola BB Plus," etc.				
<b>Chocola BB Group</b>	3.2	12.4	3.7	12.5
<b>Americas</b>	29.2	117.2	28.8	132.0
<b>United States</b>	28.8	115.7	28.4	130.0
<b>China</b>	11.2	49.3	13.1	54.0
<b>EMEA</b>	9.0	37.8	10.1	44.5
<b>Asia</b>	8.6	34.7	9.9	38.0
<b>Other</b>	1.9	9.0	2.0	14.0
<b>Consolidated revenue</b>	<b>136.9</b>	<b>539.1</b>	<b>141.9</b>	<b>575.5</b>
<b>Global revenue from major products</b>				
<b>Halaven</b>	9.4	37.3	9.7	43.0
Japan	2.0	7.8	2.3	8.5
Americas	4.2	16.6	4.2	18.5
EMEA	2.7	10.9	2.8	13.5
Asia	0.5	2.0	0.4	2.5
<b>Lenvima / Kisplyx</b>	4.4	21.5	7.3	33.0
Japan	0.7	2.7	0.8	3.0
Americas	3.2	15.1	4.9	23.5
EMEA	0.4	3.3	1.3	6.0
Asia	0.0	0.3	0.3	0.5
<b>Fycompa</b>	2.5	10.3	3.2	20.5
Japan	0.1	0.5	0.3	4.0
Americas	1.2	5.3	1.6	9.5
EMEA	1.1	4.2	1.2	6.5
Asia	0.1	0.4	0.1	0.5
<b>BELVIQ</b>	1.0	3.7	1.0	5.0
Americas				
<b>Aricept</b>	13.2	49.2	11.8	41.5
<b>Pariet/AcipHex</b>	9.7	36.4	8.8	32.0

\* The influence of risks relating to the patent infringement litigation for antiemetic agent Aloxi in the United States announced on May 3, 2017 has not been included in the consolidated forecasts.

\* 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

## 6. Consolidated Statement of Comprehensive Income

(billions of yen)

	FY 2016		FY 2017		
	Q1	Full year	Q1	YOY (%)	Diff.
Profit for the period	20.9	42.2	10.6	50.6	(10.3)
Other comprehensive income					
Items that will not be reclassified to profit or loss					
Financial assets measured at fair value through other comprehensive income	(2.2)	(0.6)	2.1	—	4.3
Remeasurements of defined benefit plans	—	4.0	—	—	—
Subtotal	(2.2)	3.4	2.1	—	4.3
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	(41.4)	(9.3)	2.5	—	43.9
Cash flow hedges	(0.3)	0.5	0.0	—	0.3
Subtotal	(41.7)	(8.8)	2.6	—	44.2
Total other comprehensive income, net of tax	(43.9)	(5.4)	4.6	—	48.6
Comprehensive income for the period	(23.0)	36.8	15.2	—	38.2
Attributable to					
Owners of the parent	(24.1)	34.0	14.5	—	38.6
Non-controlling interests	1.2	2.9	0.8	66.4	(0.4)

## 7. Consolidated Statement of Cash Flows

(billions of yen)

	FY 2016	FY 2017	
	Q1	Q1	Diff.
Operating activities			
Profit before income taxes	25.8	15.1	(10.7)
Depreciation and amortization	8.0	6.4	(1.5)
(Increase) decrease in working capital	(23.9)	(18.0)	5.9
Interest and dividends received	0.7	0.7	0.0
Interest paid	(0.7)	(0.7)	(0.0)
Income taxes paid	(5.2)	(5.0)	0.2
Income taxes refund	0.3	0.2	(0.2)
Other	(9.8)	(2.5)	7.4
Net cash from operating activities	(4.8)	(3.7)	1.1
Investing activities			
Purchases of property, plant and equipment (1)	(1.4)	(3.4)	(2.0)
Proceeds from sales of property, plant and equipment (2)	0.2	0.0	(0.2)
Purchases of intangible assets (3)	(1.2)	(6.2)	(5.0)
Net cash inflow on acquisition of subsidiaries (4)	19.3	—	(19.3)
Net cash inflow on sale of subsidiaries (5)	6.5	—	(6.5)
<Capital expenditures (cash basis)> (1)+(2)+(3)+(4)+(5)	23.4	(9.6)	(33.0)
Purchases of financial assets	(2.7)	(3.6)	(1.0)
Proceeds from sales and redemption of financial assets	2.4	3.2	0.7
Payments of time deposits exceeding 3 months	(1.8)	(1.3)	0.4
Proceeds from redemption of time deposits exceeding 3 months	1.9	0.9	(1.0)
Other	0.1	0.0	(0.0)
Net cash from (used in) investing activities	23.4	(10.4)	(33.8)
Financing activities			
Net increase (decrease) in short-term borrowings	—	11.4	11.4
Proceeds from long-term borrowings	10.0	—	(10.0)
Dividends paid	(22.9)	(22.9)	(0.0)
Other	(1.8)	(0.1)	1.7
Net cash from (used in) financing activities	(14.7)	(11.7)	3.1
Effect of exchange rate change on cash and cash equivalents	(10.4)	1.2	11.6
Net increase (decrease) in cash and cash equivalents	(6.6)	(24.6)	(18.0)
Cash and cash equivalents at beginning of year	179.3	186.8	7.4
Cash and cash equivalents at end of year	172.7	162.2	(10.6)

Free cash flow	18.7	(13.3)	(31.9)
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\* "Free cash flow" = "Net cash from operating activities" - "Capital expenditures (cash basis)"

### Notes

#### Cash flow from investing activities:

Net cash inflow on acquisition of subsidiaries and net cash inflow on sale of subsidiaries in the same period of the previous fiscal year

#### Cash flow from financing activities:

Proceeds from short-term borrowings

## 8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2016		FY 2017		
	Q1	Full year	Q1	Diff.	Full year (forecasts)
Capital expenditures (cash basis)	2.6	20.0	9.6	7.0	22.0
Property, plant and equipment	1.4	7.8	3.4	2.0	12.0
Intangible assets	1.2	12.2	6.2	5.0	10.0
Depreciation and amortization	8.0	26.5	6.4	(1.5)	26.0
Property, plant and equipment	2.9	11.0	2.7	(0.1)	11.0
Intangible assets	5.1	15.5	3.7	(1.4)	15.0

\*Capital expenditures are shown on an accrual basis

## 9. Consolidated Statement of Financial Position

### <Assets>

(billions of yen)

	FY 2016		FY 2017			
	March 31, 2016	Ratio (%)	June 30, 2017	Ratio (%)	% change	Diff.
Assets						
Non-current assets						
Property, plant and equipment	103.6	10.0	103.8	10.2	100.3	0.3
Goodwill	174.0	16.9	173.7	17.0	99.9	(0.3)
Intangible assets	112.5	10.9	113.3	11.1	100.7	0.8
Other financial assets	54.5	5.3	56.9	5.6	104.4	2.4
Other assets	13.8	1.3	14.4	1.4	104.7	0.6
Deferred tax assets	88.3	8.6	85.9	8.4	97.2	(2.4)
Total non-current assets	546.6	53.0	548.0	53.7	100.3	1.4
Current assets						
Inventories	82.9	8.0	84.4	8.3	101.9	1.6
Trade and other receivables	154.5	15.0	163.7	16.0	106.0	9.2
Other financial assets	42.9	4.2	44.2	4.3	103.2	1.4
Other assets	17.1	1.7	17.8	1.7	104.0	0.7
Cash and cash equivalents	186.8	18.1	162.2	15.9	86.8	(24.6)
Total current assets	484.2	47.0	472.4	46.3	97.6	(11.8)
Total assets	1,030.8	100.0	1,020.4	100.0	99.0	(10.3)

### Notes

#### Assets

Decrease in cash and cash equivalents due to payment of dividends and acquisition of marketing rights

**<Equity and Liabilities >**

(billions of yen)

	FY 2016		FY 2017			
	March 31, 2016	Ratio (%)	June 30, 2017	Ratio (%)	% change	Diff.
Equity						
Equity attributable to owners of the parent						
Share capital	45.0	4.4	45.0	4.4	100.0	—
Capital surplus	77.7	7.5	77.5	7.6	99.8	(0.1)
Treasury shares	(35.9)	(3.5)	(35.8)	(3.5)	99.8	0.1
Retained earnings	395.0	38.3	384.1	37.6	97.3	(10.8)
Other components of equity	102.9	10.0	105.5	10.3	102.5	2.6
Total equity attributable to owners of the parent	584.6	56.7	576.3	56.5	98.6	(8.3)
Non-controlling interests	18.0	1.7	18.7	1.8	104.2	0.8
Total equity	602.6	58.5	595.0	58.3	98.7	(7.6)
Liabilities						
Non-current liabilities						
Borrowings	163.5	15.9	163.4	16.0	100.0	(0.0)
Other financial liabilities	2.5	0.2	2.7	0.3	108.5	0.2
Retirement benefit liabilities	13.8	1.3	13.5	1.3	97.8	(0.3)
Provisions	1.2	0.1	1.2	0.1	101.3	0.0
Other liabilities	23.0	2.2	21.6	2.1	93.6	(1.5)
Deferred tax liabilities	0.4	0.0	0.4	0.0	85.0	(0.1)
Total non-current liabilities	204.5	19.8	202.8	19.9	99.2	(1.7)
Current liabilities						
Bonds and borrowings	50.0	4.9	61.4	6.0	122.8	11.4
Trade and other payables	70.7	6.9	55.6	5.4	78.6	(15.1)
Other financial liabilities	4.0	0.4	4.9	0.5	122.1	0.9
Income tax payables	5.9	0.6	4.4	0.4	74.1	(1.5)
Provisions	14.6	1.4	16.6	1.6	113.4	2.0
Other liabilities	78.4	7.6	79.8	7.8	101.7	1.4
Total current liabilities	223.7	21.7	222.6	21.8	99.5	(1.1)
Total liabilities	428.2	41.5	425.4	41.7	99.4	(2.7)
Total equity and liabilities	1,030.8	100.0	1,020.4	100.0	99.0	(10.3)

## Notes

**Equity**

Decrease in retained earnings mainly due to payment of dividends

**Liabilities**

Decrease in trade and other payables mainly due to payment of expenditures

Increase in short-term borrowings

## 10. Changes in Quarterly Results

### 1) Income Statement

(billions of yen)

	FY 2016				FY 2017
	Q1	Q2	Q3	Q4	Q1
Revenue	136.9	133.0	139.3	129.9	141.9
Cost of sales	49.8	48.4	49.7	48.0	49.4
Gross profit	87.1	84.6	89.7	81.8	92.5
Selling, general and administrative expenses	42.6	42.3	44.7	45.4	44.3
Research and development expenses	27.3	29.8	25.8	34.3	33.2
Other income	10.3	0.8	1.2	1.2	0.6
Other expenses	1.7	0.6	1.4	1.9	0.4
Operating profit	25.8	12.8	19.0	1.4	15.1
Financial income	0.7	0.2	0.6	0.3	0.7
Financial costs	0.7	0.7	0.7	1.1	0.7
Profit before income taxes	25.8	12.3	18.9	0.6	15.1
Income taxes	4.9	3.6	7.6	(0.7)	4.5
Profit for the period	20.9	8.7	11.4	1.3	10.6
Attributable to					
Owners of the parent	19.7	8.2	10.5	0.9	9.8
Non-controlling interests	1.2	0.5	0.8	0.4	0.8
Comprehensive income for the period	(23.0)	2.0	66.7	(8.9)	15.2
Earnings per share (EPS, yen)	69.0	28.6	36.7	3.3	34.3

\* From this period, the Group has clarified the definition of research and development expenses in order to more accurately reflect the condition of the business, and this has resulted in a portion of expenses relating to medical affairs activities, such as creation and provision of scientific evidence for health care providers, being apportioned to research and development expenses. Accordingly, an amount which was included in selling, general and administrative expenses during the previous period has been reclassified as research and development expenses.

### 2) Cash Flows

(billions of yen)

	FY 2016				FY 2017
	Q1	Q2	Q3	Q4	Q1
Cash flow from operating activities	(4.8)	31.6	15.8	33.3	(3.7)
Cash flow from investing activities	23.4	(10.3)	(24.5)	(17.1)	(10.4)
Cash flow from financing activities	(14.7)	(0.1)	(20.7)	0.1	(11.7)
Cash and cash equivalents at the end of period	172.7	190.8	172.4	186.8	162.2
Free cash flow	18.7	28.6	12.1	22.6	(13.3)

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



### 3) Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2016				FY 2017
	Q1	Q2	Q3	Q4	Q1
Capital expenditures (cash basis)	2.6	3.0	3.7	10.7	9.6
Property, plant and equipment	1.4	1.1	1.6	3.7	3.4
Intangible assets	1.2	1.9	2.1	7.0	6.2
Depreciation and amortization	8.0	5.9	6.1	6.5	6.4
Property, plant and equipment	2.9	2.7	2.7	2.8	2.7
Intangible assets	5.1	3.2	3.5	3.7	3.7

### 4) Financial Positions

(billions of yen)

	June 30, 2016	September 30, 2016	December 31, 2016	March 31, 2017	June 30, 2017
Total assets	963.1	965.2	1,040.4	1,030.8	1,020.4
Equity	562.7	564.9	611.1	602.6	595.0
Attributable to owners of the parent	545.9	547.7	593.5	584.6	576.3
Liabilities	400.4	400.3	429.3	428.2	425.4
Borrowings	210.7	210.1	214.8	213.5	224.8
Ratio of equity attributable to owners of the parent (%)	56.7	56.7	57.0	56.7	5.65
Liabilities ratio (Net DER / times)	0.04	(0.01)	(0.01)	(0.05)	0.01

\* "Liabilities ratio (Net DER)" = ("Interest-bearing debt" ("Bonds and borrowings") - "Cash and cash equivalents" - "Time deposits exceeding three months, etc.") / "Equity attributable to owners of the parent"

## 5) Changes in Quarterly Revenue from Major Products

### (1) Neurology Products

(billions of yen)

	FY 2016				FY 2017
	Q1	Q2	Q3	Q4	Q1
<b>Neurology Total</b>	40.6	39.4	42.3	39.6	42.8
<b>Aricept (Alzheimer's disease / dementia with Lewy bodies treatment)</b>	13.2	11.9	12.2	11.9	11.8
Japan	8.9	7.5	7.7	5.4	7.0
China	1.4	1.5	1.6	1.7	1.6
Asia	2.4	2.4	2.5	2.5	2.7
<b>Methycobal (Peripheral neuropathy treatment)</b>	9.8	10.3	10.8	9.0	10.4
Japan	5.0	4.6	4.8	3.8	4.6
China	4.0	4.8	5.0	4.2	4.9
Asia	0.7	0.7	0.8	0.7	0.7
<b>Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan</b>	6.1	5.8	6.5	5.9	6.7
<b>Inovelon/Banzel (Antiepileptic agent)</b>	3.7	3.8	4.1	4.6	4.7
Americas	3.1	3.3	3.5	4.0	4.1
EMEA	0.5	0.5	0.5	0.5	0.5
<b>Fycompa (Antiepileptic agent)</b>	2.5	2.3	2.7	2.9	3.2
Japan	0.1	0.1	0.1	0.1	0.3
Americas	1.2	1.1	1.4	1.6	1.6
EMEA	1.1	1.0	1.0	1.1	1.2
Asia	0.1	0.1	0.1	0.1	0.1
<b>Lunesta (Insomnia treatment) - Japan</b>	1.9	1.9	2.3	2.0	2.5
<b>Zonegran (Antiepileptic agent)</b>	1.6	1.4	1.3	1.3	1.2
EMEA	1.5	1.3	1.2	1.2	1.1
<b>Zebinix (Antiepileptic agent) - EMEA</b>	0.7	1.0	0.9	1.0	1.0
<b>BELVIQ (Antiobesity agent) - United States</b>	1.0	0.7	1.1	0.9	1.0
<b>Other</b>	0.3	0.3	0.3	0.2	0.3

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

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

### (2) Oncology Products

(billions of yen)

	FY 2016				FY 2017
	Q1	Q2	Q3	Q4	Q1
<b>Oncology Total</b>	28.5	29.4	29.5	30.9	31.1
<b>Aloxi (Antiemetic agent) - Americas</b>	12.0	12.1	11.4	12.6	10.6
<b>Halaven (Anticancer agent)</b>	9.4	9.3	9.7	9.0	9.7
Japan	2.0	2.0	2.0	1.8	2.3
Americas	4.2	4.1	4.2	4.1	4.2
EMEA	2.7	2.6	3.1	2.5	2.8
Asia	0.5	0.5	0.5	0.5	0.4
<b>Lenvima / Kisplyx (Anticancer agent)</b>	4.4	5.2	5.5	6.4	7.3
Japan	0.7	0.7	0.7	0.6	0.8
Americas	3.2	3.7	3.8	4.4	4.9
EMEA	0.4	0.8	0.9	1.2	1.3
Asia	0.0	0.1	0.1	0.1	0.3
<b>Treakisym / Symbenda (Anticancer agent)</b>	1.1	1.1	1.1	1.2	1.8
<b>Other</b>	1.6	1.8	1.8	1.8	1.7

# 11. Major R&D Pipeline

## In-House R&D Pipeline List

Product Name / Development Code	Additional Indication, etc.**	Development Stage***	Therapeutic Area****
<b>New Approval</b>			
⊙ Fycompa (Monotherapy for partial-onset seizures)	AI	(US) approved	Neurology
<b>Submitted / Preparing for Submission</b>			
Aricept (Severe Alzheimer's disease)	AI	(CN) submitted	Neurology
AJG511 (Ulcerative colitis)*		(JP) submitted	GI
Pariet (Maintenance therapy for proton pump inhibitor (PPI)-resistant reflux esophagitis)	ADA	(JP) submitted	GI
AJG533 (Chronic constipation)*		(JP) submitted	GI
⊙ Lenvima (Hepatocellular carcinoma)	AI	(JP/US/EU)submitted, (CN/AS) preparing for submission	Oncology
⊙ Halaven (Breast cancer)		(CN) preparing for re-submission	Oncology
<b>Clinical Trial Stage</b>			
E2006 (Insomnia disorder)		(JP/US/EU) PIII	Neurology
E2609 (Early Alzheimer's disease)		(JP/US/EU) PIII	Neurology
Lenvima (Thyroid cancer)		(CN) PIII	Oncology
AJM300 (Ulcerative colitis)*		(JP) PIII	GI
AJG555 (Chronic constipation)*		(JP) PIII	GI
Livact (Hypoalbuminemia)		(CN) PIII	GI
Fycompa (Lennox-Gastaut syndrome)	AI	(JP/US/EU) PIII	Neurology
Fycompa (Pediatric epilepsy)	AI	(JP/US/EU) PIII	Neurology
⊙ Fycompa (Monotherapy for partial-onset seizures)	AI	(JP) PIII	Neurology
Lenvima (Renal cell carcinoma, first-line)	AI	(US/EU) PIII	Oncology
ME2125 (Parkinson's disease)		(JP) PII/ III	Neurology
BAN2401 (Alzheimer's disease)		(JP/US/EU) PII	Neurology
E2006 (Irregular sleep-wake rhythm disorder associated with Alzheimer's disease)		(JP/US) PII	Neurology
MORAb-003 (Platinum-sensitive ovarian cancer)		(JP/US/EU) PII	Oncology
MORAb-004 (Melanoma)		(US/EU) PII	Oncology
MORAb-009 (Mesothelioma)		(US/EU) PII	Oncology
E7777 (Peripheral T-cell lymphoma, cutaneous T-cell lymphoma)		(JP) PII	Oncology
Halaven (Combination therapy with anti-PD1 antibody pembrolizumab in breast cancer)		(US) PI/II	Oncology
Lenvima (Combination therapy with anti-PD1 antibody pembrolizumab in select solid tumors)		(US) PI/II (JP) PI	Oncology
E6007 (Ulcerative colitis)*		(JP) PII	GI
E6011 (Rheumatoid arthritis)		(JP) PII	Other
E6011 (Primary biliary cholangitis)*		(JP) PII	Other
Aricept (Regression symptoms in people with Down syndrome)	AI	(JP) PII	Neurology
Halaven (Bladder cancer)	AI	(US/EU) PI/II	Oncology
Lenvima (Non-small cell lung cancer, RET translocations)	AI	(JP/US/EU/AS) PII	Oncology
Lenvima (Biliary tract cancer)	AI	(JP) PII	Oncology
Halaven (Combination therapy with PEGPH20 in breast cancer)		(US) PI/II	Oncology
E6011 (Crohn's disease)*		(JP) PI/II	Other
BELVIQ (Obesity)		(JP) PI	Neurology
E2027 (Alzheimer's disease)		(US) PI	Neurology
E2730(Epilepsy)		(US) PI	Neurology
E7090 (Solid tumors)		(JP) PI	Oncology
MORAb-066 (Solid tumors)		(US) PI	Oncology
E7046 (Solid tumors)		(US/EU) PI	Oncology
H3B-6527 (Hepatocellular carcinoma)		(US) PI	Oncology
H3B-8800 (Blood cancer)		(US/EU) PI	Oncology
E7438 (Non-Hodgkin B-cell lymphoma)		(JP) PI	Oncology
⊙ E7386 (Solid tumors)		(EU) PI	Oncology
E6130 (Inflammatory bowel disease)*		(JP) PI	GI
MORAb-022 (Rheumatoid arthritis)		(US) PI	Other
E6071 (Autoimmune disease)		(EU) PI	Other
⊙ E6742 (Autoimmune disease)		(US) PI	Other
Lenvima (Renal cell carcinoma, second-line)	AI	(JP) PI	Oncology
Halaven (Liposome formulation)	AF	(JP/EU) PI	Oncology

\* EA Pharma pipeline product \*\* AI: Additional Indication, ADA: Additional Dosage and Administration AF: Additional Formulation \*\*\* P: Clinical Phase; JP: Japan, US: United States, EU: Europe, CN: China, AS: Asia (excluding Japan and China) \*\*\*\*GI: Gastrointestinal Disorders

- ME2125 has been added to this list.

⊙: Development progress from April 2017 onwards

## (1) Neurology

Development Code: **E2020** Generic Name: **donepezil** Product Name: **Aricept**

Indications / Drug class: Treatment for Alzheimer's disease / dementia with Lewy bodies			In-house
Description: Increases levels of the neurotransmitter acetylcholine in the brain by inhibiting the enzyme acetylcholinesterase from breaking down acetylcholine, thereby slowing the overall progression of symptoms associated with Alzheimer's disease (AD). Currently approved in more than 100 countries around the world for the treatment of mild to moderate AD. Also approved as a treatment for patients with severe AD in numerous countries including the United States, Japan, Canada, and several other Asian and Latin American countries. Approved in Japan and the Philippines for dementia with Lewy bodies.			
Severe Alzheimer's disease (Additional Indication)	Study 339	CN: submitted (February 2015)	Oral
Regression symptoms in people with Down syndrome (Additional Indication)	345	JP: PII	Oral

Development Code: **E2007** Generic Name: **perampanel** Product Name: **Fycompa**

Indications / Drug class: Antiepileptic agent / AMPA receptor antagonist			In-house
Description: A selective antagonist against the AMPA receptor (a glutamate receptor subtype). Approved as an adjunctive therapy for partial-onset seizures in over 55 countries including Japan, the United States, in Europe and in Asia. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 45 countries including Japan, the United States, in Europe and in Asia. In the United States, an oral suspension formulation has been approved and is being marketed.			
Monotherapy for partial-onset seizures (Additional Indication)	Study 342	© US: approved (July 2017) © JP: PIII	Oral
Lennox-Gastaut syndrome (Additional Indication)	338	JP/US/EU: PIII	Oral
Pediatric epilepsy (Additional Indication)	311	JP/US/EU: PIII	Oral

Development Code: **E2006** Generic Name: **lemborexant**

Indications / Drug class: Orexin receptor antagonist			In-house
Description: By antagonizing the orexin receptors that are involved in the regulation of sleep and wakefulness, it is expected to alleviate wakefulness, thereby facilitating the initiation and maintenance of natural sleep.			
Insomnia disorder	Study 303/304	JP/US/EU: PIII	Joint development with Purdue Pharma L.P. Oral
Irregular sleep-wake rhythm disorder associated with Alzheimer's disease	202	JP/US: PII	Joint development with Purdue Pharma L.P. Oral

Development Code: **E2609**

Indications / Drug class: Anti-Alzheimer's agent / beta secretase cleaving enzyme (BACE) inhibitor			In-house
Description: By inhibiting beta-site amyloid precursor protein cleaving enzymes (BACE), the agent reduces the amount of amyloid beta in the brain, potentially slowing the progression of Alzheimer's disease.			
Early Alzheimer's disease	Study 301/302 (MISSION AD1/2)	JP/US/EU: PIII	Joint development with Biogen Inc. Oral

Development Code: **BAN2401**

Indications / Drug class: Anti-Alzheimer's agent / anti-A $\beta$ protofibril monoclonal antibody			In-license (BioArctic Neuroscience)
Description: An IgG1 monoclonal antibody that targets amyloid beta (A $\beta$ ) protofibrils. Expected to be effective in the treatment of Alzheimer's disease by halting disease progression through the elimination of neurotoxic A $\beta$ protofibrils.			
Alzheimer's disease	Study 201	JP/US/EU: PII	Joint development with Biogen Inc. Inj.

© Development progress from April 2017 onwards

Development Code: **ME2125** Generic Name: **safinamide**

Indications / Drug class: Anti-Parkinson's disease agent / MAO-B inhibitor		In-license (Meiji Seika Pharma)
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. Additionally, it blocks sodium ion channels and inhibits glutamate release, and as such, has potential as a new Parkinson's disease treatment which possesses both dopaminergic and non-dopaminergic mechanisms.		
Parkinson's disease	JP: PII/III	Oral

- ME2125 has been added to this list.

Development Code: **APD356** Generic Name: **lorcaserin** Product Name: **BELVIQ**

Indications / Drug class: Anti-obesity agent / serotonin 2C receptor agonist		In-license (Arena Pharmaceuticals)
Description: Anti-obesity agent with novel mechanism of action. By selectively activating serotonin 2C receptors in the brain, it is believed to decrease food consumption and promote satiety. Approved in the United States by the U.S. Food and Drug Administration in June 2012 as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m <sup>2</sup> or greater (obese) or 27 kg/m <sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition. Launched in the United States in June 2013 after receiving a final scheduling designation from the U.S. Drug Enforcement Administration (DEA). Approved in Mexico in July 2016 and Brazil in December 2016. Additionally, in the United States, a once-daily formulation has been approved and is being marketed.		
Obesity	JP: PI	Oral

Development Code: **E2027**

Alzheimer's disease	US: PI	In-house	Oral
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Development Code: **E2730**

Epilepsy	US: PI	In-house	Oral
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## (2) Oncology

Development Code: **E7389** Generic Name: **eribulin** Product Name: **Halaven**

Indications / Drug class: Anticancer agent / microtubule dynamics inhibitor			In-house
Description: A synthetic analog of halichondrin B derived from the marine sponge, <i>Halichondria okadae</i> . Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved in over 60 countries including Japan, the United States, in Europe and in Asia for use in chemotherapy for breast cancer. Approved in over 40 countries including Japan, the United States, in Europe and in Asia for use in the treatment of soft tissue sarcoma.			
© Breast cancer	Study304	CN: preparing for re-submission	Inj.
Bladder cancer (Additional Indication)	702	US/EU: PI/II	Inj.
Triple negative breast cancer (in combination with anti-PD1 antibody pembrolizumab)	218	US: PI/II	Co-development with Merck & Co., Inc., Kenilworth, N.J., U.S.A. Inj.
HER2-negative breast cancer (in combination with PEGPH20)	219	US: PI/II	Co-development with Halozyme Therapeutics, Inc. Inj.
Liposome formulation (Additional Formulation)	—	JP/EU: PI	Inj.

Development Code: **E7080** Generic Name: **lenvatinib** Product Name: **Lenvima/Kisplyx**

Indications / Drug class: Anticancer agent / molecular targeted drug			In-house
Description: Discovered and developed in-house, the agent is 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. Confirmed through X-ray crystal structural analysis to be the first compound to demonstrate a new binding mode (Type V) to VEGFR2, exhibiting rapid and potent inhibition of kinase activity, according to kinetic analysis. Approved as a treatment for refractory thyroid cancer in over 50 countries including Japan, the United States, in Europe and in Asia. Also approved as a second-line treatment for renal cell carcinoma in over 35 countries including the United States and in Europe. The agent is marketed under the product name Kisplyx only for this indication in Europe.			
Thyroid cancer	Study 308	CN: PIII	Oral
Renal cell carcinoma/First-line (Additional Indication)	307	US/EU: PIII	Oral
Hepatocellular carcinoma (Additional Indication)	304	© JP: submitted (June 2017) © US/EU: submitted (July 2017) CN/AS: preparing for submission	Oral
Non-small cell lung cancer (RET translocations) (Additional Indication)	209	JP/US/EU/AS: PII	Oral
Biliary tract cancer (Additional Indication)	215	JP: PII	Oral
Select solid tumors (Endometrial cancer, Renal cell carcinoma, head and neck cancer, urothelial cancer, non-small cell lung cancer, melanoma) Select solid tumors (Hepatocellular carcinoma, Endometrial cancer etc.) (in combination with anti-PD1 antibody pembrolizumab)	111 —	US: PI/II JP: PI	Co-development with Merck & Co., Inc., Kenilworth, N.J., U.S.A. Oral /Inj.
Renal cell carcinoma/Second-line (Additional Indication)	—	JP: PI	Oral

Development Code: **MORAb-003** Generic Name: **farletuzumab**

Indications / Drug class: Anticancer agent / humanized anti-FRA monoclonal antibody			In-house
Description: A humanized IgG1 monoclonal antibody that targets folate receptor alpha (FRA). Expected to show an antitumor effect against cancers that over-express FRA.			
Platinum-sensitive ovarian cancer	Study 011	JP/US/EU: PII	Inj.

© Development progress from April 2017 onwards

Development Code: **MORAb-004**

Indications / Drug class: Anticancer agent / humanized anti-endosialin monoclonal antibody		In-house	
Description: A humanized IgG1 monoclonal antibody that targets Tumor Endothelial Marker 1 (TEM-1) / endosialin. Expected to show an antitumor effect against cancers that express endosialin.			
Melanoma	Study 201	US/EU: PII	Inj.

Development Code: **MORAb-009** Generic Name: **amatuximab**

Indications / Drug class: Anticancer agent / chimeric anti-mesothelin monoclonal antibody		In-house	
Description: A chimeric IgG1 monoclonal antibody that targets mesothelin. Expected to show an antitumor effect against cancers that express mesothelin.			
Mesothelioma	Study 003/201	US/EU: PII	Inj.

Development Code: **E7777**

Indications / Drug class: Anticancer agent / interleukin-2 diphtheria toxin fusion protein		In-house	
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, causing diphtheria toxins that have entered cells to inhibit protein synthesis.			
Peripheral T-cell lymphoma and cutaneous T-cell lymphoma	Study 205	JP: PII	Inj.

Development Code: **E7090**

Solid tumors	JP: PI	In-house	Oral
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Development Code: **MORAb-066**

Solid tumors	US: PI	In-license (Janssen Biotech)	Inj.
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Development Code: **E7046**

Solid tumors	US/EU: PI	In-house	Oral
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Development Code: **H3B-6527**

Hepatocellular carcinoma	US: PI	In-house	Oral
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Development Code: **H3B-8800**

Blood cancer	US/EU: PI	In-house	Oral
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Development Code: **E7438**

Non-Hodgkin B-cell lymphoma	JP: PI	In-license (Epizyme, Inc.)	Oral
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Development Code: **E7386**

© Solid tumors	EU: PI	Collaboration (PRISM Pharma)	Oral
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### (3) Gastrointestinal Disorders

Development Code: **E3810** Generic Name: **rabeprazole** Product Name: **Pariet/AcipHex**

Indications / Drug class: Proton pump inhibitor		In-house	
Description: A proton pump inhibitor approved for the treatment of gastric and duodenal ulcers, reflux esophagitis, eradication of <i>Helicobacter pylori</i> infections and triple formulation packs (combination packs) for <i>H. pylori</i> eradication that include rabeprazole. Approved for the prevention of recurrent gastric or duodenal ulcer caused by low-dose aspirin therapy as well as 5 mg tablet formulation in December 2014.			
Maintenance therapy for proton pump inhibitor (PPI)-resistant reflux esophagitis 10 mg twice daily (Additional Dosage and Administration)	Study 311	JP: submitted (October 2016) Joint development with EA Pharma	Oral

Development Code: **AJG511** Generic Name: **budesonide**

Indications / Drug class: Ulcerative colitis treatment / locally-active steroid		In-license (Dr. Falk Pharma)	
Description: The first rectal foam product in Japan containing budesonide as active ingredient. Budesonide is a locally-active steroid and, thus, is expected to reduce systemic side effects. In addition, AJG511 is a foam type product that can reach the inflamed sites of rectum and sigmoid colon by rectal administration, and has a characteristic feature of preventing leakage after administration. Budesonide rectal foam is already available on the market in Europe.			
Ulcerative colitis	Study CT1	JP: submitted (October 2016) Joint development by EA Pharma and Kissei Pharmaceutical	Foam

Development Code: **AJG533** Generic Name: **elobixibat**

Indications / Drug class: Chronic constipation treatment / bile acid transporter inhibitor		In-license (Albireo)	
Description: An orally available constipation treatment having a novel action mechanism. AJG533 inhibits the bile acid transporter that regulates reabsorption of bile acids and thereby increases spontaneous colonic motility			
Chronic constipation	Study CT1	JP: submitted (February 2017) Joint development by EA Pharma and Mochida Pharmaceutical	Oral

Development Code: **AJM300** Generic Name: **carotegrast methyl**

Indications / Drug class: Ulcerative colitis treatment / $\alpha$ 4 integrin antagonist		In-house	
Description: $\alpha$ 4 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 $\alpha$ 4 integrin antagonist in the world to be effective in ulcerative colitis.			
Ulcerative colitis	JP: PIII	Joint development by EA Pharma and Kissei Pharmaceutical	Oral

Development Code: **AJG555**

Indications / Drug class: Chronic constipation treatment / polyethylene glycol preparation		In-license (Norgine)	
Description: An orally available constipation treatment consisting of a polyethylene glycol preparation which facilitates bowel movement by suppressing osmotic pressure in the intestines.			
Chronic constipation	Study CT1/CT2	JP: PIII Development conducted by EA Pharma	Oral

Generic Name: **isoleucine, leucine and valine granules** Product Name: **Livact Granules**

Indications / Drug class: Branched-chain amino acid formula		In-house	
Description: A branched-chain amino acid formula developed by Ajinomoto that increases serum albumin levels in patients with decompensated hepatic cirrhosis. Approved in Japan for "improvement of hypoalbuminemia in patients with decompensated hepatic cirrhosis that have hypoalbuminemia despite adequate dietary intake", and marketed by EA Pharma.			
Hypoalbuminemia	CN: PIII	Submission Target: FY2017 Joint development with EA Pharma	Oral



Development Code: **E6007**

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

Development Code: **E6130**

Inflammatory bowel disease		JP: PI	In-house (development conducted by EA Pharma)	Oral
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**(4) Other**Development Code: **E6011**

Indications / Drug class: Anti-Fractalkine antibody			In-house	
Description: The world's first humanized anti-fractalkine monoclonal antibody discovered by Eisai Group subsidiary KAN Research Institute Inc. Believed 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 rheumatoid arthritis and inflammatory bowel disease.				
Rheumatoid arthritis	Study 201/202	JP: PII		Inj.
Primary biliary cholangitis		ET1 JP: PII	Development conducted by EA Pharma	Inj.
Crohn's disease	101	JP: PI/II	Development conducted by EA Pharma	Inj.

Development Code: **MORAb-022**

Rheumatoid arthritis (antibody)		US: PI	In-house	Inj.
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Development Code: **E6071(GSK3050002)**

Autoimmune disorder (antibody)		EU: PI	In-house (joint development with GlaxoSmithKline)	Inj.
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Development Code: **E6742**

© Autoimmune disorder		US: PI	In-house	Oral
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