



2013.6

Forward-looking Statements and Risk Factors

Materials and information provided in this financial disclosure may contain “for

Contents

1. Consolidated Financial Highlights	-----	1
2. Consolidated Statement of Income	-----	3
3. Consolidated Statement of Cash Flows	-----	5
4. Financial Results by Reporting Segment	-----	6
5. Sales Forecasts by Reporting Segment	-----	12
6. Consolidated Balance Sheet	-----	13
7. Changes in Consolidated Quarterly Results	-----	15
8. Nonconsolidated Financial Highlights	-----	19
9. Major News Releases	-----	20
10. Major R&D Pipeline	-----	21

* All amounts are rounded to the nearest specified unit.

* The exchange rates used in the reference data are noted in the table below.

* All overseas profit and loss amounts have been converted into yen based on the average exchange rates for the periods shown in the table below.

Currency Exchange Rates

	US (JPY/USD)	EU (JPY/EUR)	UK (JPY/GBP)	China (JPY/RMB)
(Apr. 2012 - Jun. 2012) Three Months Average Rate	80.20	102.90	126.85	12.71
(Jun. 30, 2012) First Quarter End Rate	79.31	98.74	123.12	12.55
(Apr. 2012 - Mar. 2013) Fiscal Year Average Rate	83.10	107.14	131.13	13.25
(Mar. 31, 2013) Fiscal Year End Rate	94.05	120.73	143.16	15.16
(Apr. 2013 - Jun. 2013) Three Months Average Rate	98.75	128.94	151.59	16.05
(Jun. 30, 2013) First Quarter End Rate	98.59	128.53	150.30	16.05
Fiscal Year Ending March 31, 2014 Forecast Rate	95.00	125.00	145.00	15.00

About Indicators in This Reference Data

The Eisai Group believes that cash-generating ability is the most intrinsic element determining the true value of a company. Based upon this belief, in order to reflect our true earnings capacity, we focus on disclosing "cash income" and "cash EPS," which are affected by non-cash profit-and-loss items, such as depreciation of property, plant and equipment and intangible assets, amortization of goodwill produced by the acquisition of companies, loss on impairment of long-lived assets (including loss on devaluation of investment securities), and in-process R&D expenses.

*Cash income

Cash income is the total amount of cash available for investment in future growth, shareholder return, repayment of borrowings, and other expenditures. We consider cash income as an indicator to assess corporate growth potential and strategies.

Cash income = Net income + Depreciation of PP&E and amortization of intangible assets + In-process R&D expenses + Amortization of goodwill + Loss on impairment of long-lived assets (including loss on devaluation of investment securities)

*Cash income per share (Cash EPS)

Cash EPS = Cash income / Average number of outstanding shares for the period (after deduction of treasury stock)

Segment Information

The Eisai Group classifies its reporting segments into two business categories, namely, Pharmaceutical business and Other business. Furthermore, effective from the fiscal year ending March 31, 2014, the Group has defined the following segments as new reporting segments for its Pharmaceutical business: Japan (Prescription drugs, Generic drugs and Diagnostics), Americas (North, Central and South America), Asia (mainly China, Sout

1. Consolidated Financial Highlights

1) Income Statement Data

(billions of yen)

	<u>Three months ended June 30</u>			FY2012	FY2013 est.
	FY2012	FY2013	YOY %		
Net sales	146.9	154.2	105.0	573.7	578.0
Cost of sales	43.2	46.3	107.2	174.1	180.5
R&D expenses	28.4	39.6	139.7	120.4	127.5

4) Capital Expenditures and Depreciation/Amortization

(billions of yen)

	Three months ended June 30			Full year
	FY2012	FY2013	Diff.	FY2012
Capital expenditures	7.0	8.4	1.4	20.5
Property, plant and equipment	1.3	1.5	0.2	9.2
Intangible assets	5.6	6.9	1.3	11.3
Depreciation and amortization	10.2	10.2	(0.0)	43.3

* "Depreciation and amortization" includes amortization of "Intangible assets."

5) Financial Results by Business Segment

(1) Consolidated Net Sales by Reporting Segment

(billions of yen)

	Three months ended June 30			Full year
	FY2012	FY2013	YOY %	FY2012
Japan pharmaceutical business	81.3	81.0	99.6	307.8
Americas pharmaceutical business	38.6	41.3	106.9	153.3
U.S. pharmaceutical business	38.5	41.1	106.7	153.0
Asia pharmaceutical business	9.6	13.4	139.0	41.3
EMEA pharmaceutical business	6.9	7.9	114.5	25.8
Consumer Healthcare Business Japan (mainly OTC drugs)	4.1	4.7	112.7	21.1
Other	6.3	6.0	95.6	24.4
Consolidated net sales	146.9	154.2	105.0	573.7

* Net sales to external customers for each segment

(2) Consolidated Operating Income by Reporting Segment

(billions of yen)

	Three months ended June 30		
	FY2012	FY2013	YOY %
Japan pharmaceutical business	36.2	42.9	118.4
Americas pharmaceutical business	8.1	6.0	74.1
Asia pharmaceutical business	1.8	3.0	165.5
EMEA pharmaceutical business	0.4	0.7	163.6
Consumer Healthcare Business Japan (mainly OTC drugs)	0.3	0.5	163.7
Other	2.9	3.3	114.3
R&D expenses	28.4	39.6	139.7
Non-allocated SG&A expenses	2.3	2.6	115.4
Consolidated operating income	19.1	14.2	73.9

2. Consolidated Statement of Income

(billions of yen)

	FY2012	Sales %	FY2013	Sales %	YOY %	Diff.	FY2012	Sales %
Net sales	146.9	100.0	154.2	100.0	105.0	7.3	573.7	100.0
Cost of sales	43.2	29.4	46.3	30.0	107.2	3.1	174.1	30.3
Gross profit	103.7	70.6	108.0	70.0	104.1	4.2	399.6	69.7
R&D expenses	28.4	19.3	39.6	25.7	139.7	11.3	120.4	21.0
SG&A expenses	56.2	38.3	54.2	35.1	96.4	(2.0)	208.7	36.4
Personnel expenses	17.5	11.9	18.2	11.8	104.2	0.7	68.4	11.9
Selling expenses	27.1	18.4	22.3	14.5	82.4	(4.8)	92.7	16.2
Administrative and other expenses	11.7	7.9	13.7	8.9	117.0	2.0	47.7	8.3
Operating income	19.1	13.0	14.2	9.2	73.9	(5.0)	70.5	12.3
Nonoperating income	0.7	0.5	0.6	0.4		(0.1)	2.3	0.4
Nonoperating expenses	1.9	1.3	1.9	1.2		(0.0)	7.2	1.2
Ordinary income	17.9	12.2	12.9	8.3	71.7	(5.1)	65.6	11.4
Special gain	0.1	0.0	0.6	0.4		0.6	7.5	1.3
Special loss	0.3	0.2	0.0	0.0		(0.3)	1.7	0.3
Income before income taxes and minority interests	17.7	12.0	13.5	8.7	76.1	(4.2)	71.4	12.5
Income taxes current	6.3	4.3	7.3	4.7		1.0	30.6	5.3
Income taxes deferred	(0.5)	(0.4)	(3.3)	(2.1)		(2.8)	(7.7)	(1.3)
Income before minority interests	12.0	8.1	9.5	6.1		(2.5)	48.5	8.5

Consolidated Statement of Comprehensive Income

(billions of yen)

	Three months ended June 30			Diff.	Full year FY2012
	FY2012	FY2013	YOY %		
Income before minority interests	12.0	9.5	79.2	(2.5)	48.5
Other comprehensive income (loss)	(13.1)	16.6	-	29.7	46.6
Net unrealized gains/losses on available-for-sale securities	0.0	(0.1)		(0.1)	3.1
Deferred gain (loss) on derivatives under hedge accounting	(0.1)	0.2		0.2	0.1
Foreign currency translation adjustments	(13.1)	16.5		29.6	43.4
Comprehensive income (loss)	(1.1)	26.1	-	27.2	95.2
(Breakdown)					
Comprehensive income (loss) attributable to shareholders of the parent company	(1.1)	26.0	-	27.1	95.0
Comprehensive income (loss) attributable to minority interests	(0.1)	0.1	-	0.1	0.2

3. Consolidated Statement of Cash Flows

(billions of yen)

	<u>Three months ended June 30</u>		
	FY2012	FY2013	Diff.
Income before income taxes and minority interests	17.7	13.5	(4.2)
Depreciation and amortization / Amortization of goodwill	12.1	12.5	0.4
Decrease (increase) in notes and accounts receivable			

4. Financial Results by Reporting Segment

1) Japan Pharmaceutical Business

	(billions of yen)			
	FY2012	FY2013	YOY	<u>Full year</u>
			%	FY2012
Net sales	81.3	81.0	99.6	307.8
Segment profit	36.2	42.9	118.4	

Japan Net Sales Breakdown

Japan Prescription drug - major products (Eisan) 4236043 Tm Anti-Alzheimer's agent	73.8	97.7	282.2
Prescription drugs	97.9		
Diagnosis (IDIAi Co., Ltd.)			

2) Americas Pharmaceutical Business (North, Central and South America)

		Three months ended June 30			Full year
		FY2012	FY2013	YOY %	FY2012
Net sales	Billions JPY	38.6	41.3	106.9 <86.9>	153.3
Segment profit	Billions JPY	8.1	6.0	74.1	
Americas prescription drugs - major products					
Proton pump inhibitor Aciphex	Billions JPY [Millions USD]	13.2 [164]	15.5 [157]	117.7 <95.6>	51.4 [618]
Antiemetic agent Aloxi	Billions JPY	9.5	10.3	108.7 <88.3>	36.7
U.S. prescription drugs	Billions JPY [Millions USD]	9.5 [119]	10.3 [105]	108.7 <88.2>	36.7 [442]
DNA methylation inhibitor Dacogen	Billions JPY [Millions USD]	4.4 [55]	5.7 [58]	129.6 <105.3>	19.3 [232]
Anticancer agent Halaven	Billions JPY	3.1	3.3	104.7 <85.0>	11.6
U.S. prescription drugs	Billions JPY [Millions USD]	3.1 [39]	3.2 [32]	103.1 <83.8>	11.6 [139]
Injectable anticoagulant Fragmin	Billions JPY [Millions USD]	2.9 [36]	1.8 [18]	62.3 <50.6>	9.7 [116]
Anti-Alzheimer's agent Aricept	Billions JPY [Millions USD]	2.4 [30]	1.5 [16]	64.9 <52.7>	11.0 [133]

* Sales of Aricept 23 mg tablet out of total sales of Aricept for FY2013 (April 1, 2013 to June 30, 2013) totaled ¥1.1 billion (U.S.\$11 million).

* The U.S. is the only country where Eisai markets Dacogen and Fragmin; it is also the only country where Eisai books the sales of Aciphex and Aricept.

* Indices shown in parentheses "< >" compare data with the same period of the previous fiscal year on a constant currency basis.

4) EMEA Pharmaceutical Business

(Europe, the Middle East, Africa and Oceania)

		Three months ended June 30			Full year
		FY2012	FY2013	YOY %	FY2012
Net sales	Billions JPY	6.9	7.9	114.5 <92.2>	25.8
Segment profit	Billions JPY	0.4	0.7	163.6	
EMEA prescription drugs - major products					
Anticancer agent Halaven	Billions JPY	1.0	2.0	195.4 <157.0>	5.4
Antiepileptic agent Zonegran	Billions JPY	1.1	1.6	142.6 <114.5>	4.8
Antiepileptic drug Fycompa	Billions JPY		0.7	-	0.5
Anti-Alzheimer's agent Aricept	Billions JPY	1.2	0.4	37.6 <30.0>	2.7
Proton pump inhibitor Pariet	Billions JPY	1.2	0.2	14.3 <11.8>	2.7

* Indices shown in parentheses "< >" compare data with the same period of the previous fiscal year on a constant currency basis.

5) Consumer Healthcare Business Japan (mainly OTC drugs)

		Three months ended June 30			Full year
		FY2012	FY2013	YOY %	FY2012
Net sales	Billions JPY	4.1	4.7	112.7	21.1
Segment profit	Billions JPY	0.3	0.5	163.7	
Consumer Healthcare Business Japan (mainly OTC drugs)					
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group		2.4	2.9	119.3	11.2

6) Sales of Major Products
(1) Oncology-Related Products

		FY2012	FY2013	YOY %	<u>Full year</u> FY2012
Total	Billions JPY	25.2	27.1	107.7 <89.5>	100.4
Halaven (Anticancer agent)	Billions JPY	5.5	7.0	126.9 <108.3>	22.6
Japan	Billions JPY	1.3	1.6	122.7	5.5
Americas	Billions JPY	3.1	3.3	104.7 <85.0>	11.6
U.S. prescription drugs	Billions JPY [Millions USD]	3.1 [39]	3.2 [32]	103.1 <83.8>	11.6 [139]
Asia	Billions JPY	0.0	0.1	246.5 <195.5>	0.1
EMEA	Billions JPY	1.0	2.0	195.4 <157.0>	5.4
Aloxi (Antiemetic agent)	Billions JPY	9.5	10.3	108.7 <88.3>	36.7
U.S. prescription drugs	Billions JPY [Millions USD]	9.5 [119]	10.3 [105]	108.7 <88.2>	36.7 [442]

(3) Aricept (Anti-Alzheimer's agent)

		Three months ended June 30			Full year
		FY2012	FY2013	YOY %	FY2012
Total	Billions JPY	27.3	23.2	85.3 <81.7>	94.3
Japan	Billions JPY	21.7	18.3	84.3	72.4
Americas	Billions JPY [Millions USD]	2.4 [30]	1.5 [16]	64.9 <52.7>	11.0 [133]
Asia	Billions JPY	2.0	2.9	147.5 <117.0>	8.1
EMEA	Billions JPY	1.2	0.4	37.6 <30.0>	2.7

* Sales of Aricept 23 mg tablet out of total sales of Aricept for FY2013 (April 1, 2013 to June 30, 2013) totaled ¥1.1 billion (U.S.\$11 million).

* The U.S. is the only country in the Americas where Eisai books the sales of Aricept.

* Indices shown in parentheses "< >" compare data with the same period of the previous fiscal year on a constant currency basis.

(4) Humira (Fully human anti-TNF- monoclonal antibody)

		Three months ended June 30			Full year
		FY2012	FY2013	YOY %	FY2012
Total	Billions JPY	6.8	8.5	125.5 <120.8>	29.0
Japan	Billions JPY	5.8	6.9	120.5	24.1
Asia	Billions JPY	1.1	1.6	152.7 <122.8>	4.9

* Indices shown in parentheses "< >" compare data with the same period of the previous fiscal year on a constant currency basis.

7) Overseas Sales

(billions of yen)

	Three months ended June 30			Full year
	FY2012	FY2013	YOY %	FY2012
Overseas sales	58.5	64.9	110.9	231.6
Overseas sales (% of total sales)	39.8	42.1	-	40.4

* Net sales to external customers for each segment

5. Sales Forecasts by Reporting Segment (FY2013)

	(billions of yen)		
	Three months ended June 30 FY2013	FY2012	FY2013 est.
Japan	81.0	307.8	310.5
Prescription drugs	73.8	282.2	281.0
Anti-Alzheimer's agent Aricept	18.3	72.4	67.0
Proton pump inhibitor Pariet	12.8	50.1	45.0
Fully human anti-TNF- monoclonal antibody Humira	6.9	24.1	30.0
Peripheral neuropathy treatment Methycobal	6.7	26.1	24.5
Oral anticoagulant Warfarin	2.6	10.1	10.0
Anticancer agent Halaven	1.6	5.5	7.0
Generic drugs (Elmed Eisai Co., Ltd.)	5.8	19.6	23.5
Diagnostics (EIDIA Co., Ltd.)	1.4	6.0	6.0
Americas	41.3	153.3	138.5
U.S.	41.1	153.0	137.5
Asia	13.4	41.3	53.0
China	7.0	21.8	28.0
EMEA	7.9	25.8	32.5
Consumer Healthcare Business Japan (mainly OTC drugs)	4.7	21.1	22.5
Vitamin B ₂ preparation, "Chocola BB Plus," etc. Chocola BB Group	2.9	11.2	13.0
Other	6.0	24.4	21.0
Consolidated net sales	154.2	573.7	578.0
Global net sales of major products			
Pariet/Aciphex	29.9	108.4	84.5
Aricept	23.2	94.3	81.0
Halaven	7.0	22.6	34.0

* Sales amounts by new reporting segments for FY2012 are provided for reference purposes only.

6. Consolidated Balance Sheet

1) Consolidated Balance Sheet <Assets>

(billions of yen)

	March 31		June 30		% change	Diff.
	2013	%	2013	%		
Total current assets	530.7	53.6	470.7	50.1	88.7	(60.0)
Cash and deposits	88.7		40.1			(48.6)
Notes and accounts receivable trade	185.5		197.4			11.9
Short-term investments	98.8		76.7			(22.1)
Inventories	87.6		87.8			0.2
Deferred tax assets	47.1		46.6			(0.5)
Other	23.2		22.3			(0.8)
Allowance for doubtful receivables	(0.1)		(0.2)			(0.1)
Total noncurrent assets	459.5	46.4	469.1	49.9	102.1	9.6
Total property, plant and equipment	142.2	14.4	142.3	15.1	100.1	0.1
Buildings and structures	85.9		86.4			0.5
Other	56.3		55.9			(0.4)
Total intangible assets	236.0	23.8	244.3	26.0	103.5	8.3
Goodwill	127.3		131.2			3.8
Sales rights	51.4		55.1			3.6
Core technology	43.7		45.0			1.3
Other	13.5		13.1			(0.4)
Total investments and other assets	81.2	8.2	82.5	8.8	101.5	1.2
Investment securities	34.3		32.9			(1.3)
Deferred tax assets	40.7		42.8			2.1
Other	6.3		6.9			0.5
Allowance for doubtful receivables	(0.1)		(0.1)			(0.0)
Total assets	990.2	100.0	939.8	100.0	94.9	(50.4)

Notes

Total assets

Decrease in cash and deposits and short-term investments due to redemption of matured bond and debentures of ¥50.0 billion and repayment of long-term borrowings of US\$200 million

2) Consolidated Balance Sheet <Liabilities and Equity>

(billions of yen)

	March 31		June 30		% change	Diff.
	2013	%	2013	%		
Total current liabilities	215.7	21.8	172.5	18.4	80.0	(43.2)
Notes payable trade and accounts payable trade	26.1		26.2			0.1
Short-term borrowings	7.6		18.1			10.5
Long-term borrowings (current portion)	18.8		9.9			(9.0)
Bonds and debentures (current portion)	50.0		-			(50.0)
Accounts payable other / Accrued expenses	82.1		84.5			2.4
Income tax payable	7.4		7.4			(0.0)
Reserve for sales rebates	15.7		16.2			0.6
Other	8.1		10.3			2.2
Total noncurrent liabilities	300.2	30.3	289.6	30.8	96.5	(10.6)
Bonds and debentures	30.0		30.0			0.0
Long-term borrowings	207.6		199.6			(8.0)
Deferred tax liabilities	19.6		19.4			(0.3)
Liability for retirement benefits	13.8		13.7			(0.1)
Other	29.1		26.9			(2.3)
Total liabilities	515.9	52.1	462.1	49.2	89.6	(53.9)
Total shareholders' equity	532.5	53.8	519.3	55.3	97.5	(13.2)
Common stock	45.0		45.0			-
Capital surplus	56.9		57.0			0.1
Retained earnings	469.7		456.3			(13.4)
Treasury stock	(39.0)		(39.0)	39.)		
05 (13.4)						

7. Changes in Consolidated Quarterly Results

1) Income Statement Data

(billions of yen)

	1st	2nd	3rd	4th	<u>FY2013</u>
	Quarter	Quarter	Quarter	Quarter	1st
					Quarter

4) Capital Expenditures and Depreciation/Amortization

(billions of yen)

FY2013

1st Quarter	2nd Quarter	3rd Quarter
----------------	----------------	----------------

4th4thy7 83C62521s5Qua

5) Sales of Major Products

(1) Oncology-Related Products

		FY2012				FY2013
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter
Total	Billions JPY	25.2	23.3	25.3	26.6	27.1
Halaven	Billions JPY	5.5	5.3	5.6	6.2	7.0
Japan	Billions JPY	1.3	1.4	1.4	1.4	1.6
Americas	Billions JPY	3.1	2.7	2.7	3.1	3.3
U.S. prescription drugs	Billions JPY	3.1	2.7	2.7	3.1	3.2
	[Millions USD]	[39]	[34]	[34]	[33]	[32]
Asia	Billions JPY	0.0	0.0	0.0	0.1	0.1
EMEA	Billions JPY	1.0	1.2	1.4	1.7	2.0
Aloxi	Billions JPY	9.5	8.4	9.3	9.6	10.3
U.S. prescription drugs	Billions JPY	9.5	8.4	9.3	9.6	10.3
	[Millions USD]	[119]	[107]	[114]	[103]	[105]
Dacogen	Billions JPY	4.4	4.4	4.8	5.8	5.7
	[Millions USD]	[55]	[55]	[59]	[63]	[58]
Fragmin	Billions JPY	2.9	2.5	2.4	1.9	1.8
	[Millions USD]	[36]	[32]	[30]	[19]	[18]
Trekisym/Symbenda	Billions JPY	0.9	0.9	0.9	0.8	1.0
Other	Billions JPY	2.0	1.9	2.4	2.2	1.3

* The U.S. is the only country where Eisai markets Dacogen and Fragmin.

(2) Pariet/Aciphex

		FY2012				FY2012
		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter
Total	Billions JPY	28.5	24.8	28.8	26.4	29.9
Japan	Billions JPY	13.1	12.7	12.8	11.5	12.8
Americas	Billions JPY	13.2	10.2	14.4	13.6	15.5
	[Millions USD]	[164]	[131]	[178]	[146]	[157]
Asia	Billions JPY	1.1	1.1	1.1	1.1	1.4
EMEA	Billions JPY	1.2	0.8	0.5	0.2	0.2

* The U.S. is the only country in the Americas where Eisai books the sales of Aciphex.

(3) Aricept

		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	1st Quarter
Total	Billions JPY	27.3	26.2	20.1	20.7	23.2
Japan	Billions JPY	21.7	18.6	15.7	16.4	18.3
Americas	Billions JPY	2.4	5.1	1.9	1.7	1.5
	[Millions USD]	[30]	[64]	[23]	[16]	[16]

8. Nonconsolidated Financial Highlights

1) Nonconsolidated Financial Highlights

(1) Income Statement Data

	(billions of yen)			
	<u>Three months ended June 30</u>			<u>Full Year</u>
	FY2012	FY2013	YOY	FY2012
			%	
Net sales	90.6	88.4	97.5	348.0
Cost of sales	24.5	23.6	96.6	97.8
R&D expenses	26.4	37.0	139.8	111.0
SG&A expenses	28.1	19.6	69.7	100.5
Operating income	11.6	8.2	70.8	38.7
Ordinary income	10.7	7.2	66.8	34.9
Net income	7.3	6.1	83.5	27.6

* "Cost of sales" includes "Provision for (reversal of) sales returns net."

(2) Cash Flow Statement Data

	(billions of yen)			
	<u>Three months ended June 30</u>			<u>Full Year</u>
	FY2012	FY2013	Diff.	FY2012
Net cash provided by (used in) operating activities	18.3	11.8	(6.4)	40.6
Net cash provided by (used in) investing activities	6.7	35.4	28.7	28.6
Net cash provided by (used in) financing activities	(20.5)	(62.3)	(41.8)	(56.6)
Cash and cash equivalents at end of period	18.0	11.1	(6.9)	26.1
Free cash flow	13.6	9.5	(4.1)	28.9

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

(3) Balance Sheet Data

	(billions of yen)		
	<u>2013</u>		
	March 31	June 30	Diff.
Total assets	891.7	841.3	(50.5)
Liabilities	375.2	341.0	(34.2)
Borrowings	202.5	213.0	10.5

9. Major News Releases

Date	Description
April 2013	Eisai Establishes Pharma Sales Subsidiary in Moscow Ahead of Planned Direct Sales Launch in Russia <issued on April 5> Eisai Co-establishes the Global Health Innovative Technology Fund <issued on April 8> Eisai Announces Preclinical Research Findings Suggesting Novel Inhibitory Effect on Tumor Metastasis

10. Major R&D Pipeline

In-house R&D Pipeline List

Product Name / Research Code	Additional Indication, etc.*	Development Stage**	Therapeutic Area
New Approval			
DC Bead (Transcatheter arterial embolization (TAE) of hepatocellular carcinoma)		(JP) approved	Oncology and Supportive Care
Humira (Intestinal Behçet's disease)	AI	(JP) approved	Vascular and Immunological Reaction
Humira (Ulcerative colitis)	AI	(JP) approved	Vascular and Immunological Reaction
Submitted / Preparing for Submission			
clevudine (Chronic hepatitis B)		(CN) submitted	Gastrointestinal and Hepatic Disorders
cinitapride (Functional dyspepsia)		(CN) submitted	Gastrointestinal and Hepatic Disorders
Zonegran (Pediatric partial-onset seizures)	AI	(EU) submitted	Neurology
Halaven (Second-line treatment for breast cancer)	AI	(EU) submitted	Oncology and Supportive Care
Pariet (Triple formulation pack for <i>Helicobacter pylori</i> eradication)	AF	(JP) submitted	Gastrointestinal and Hepatic Disorders
Clinical			
Fycompa (Partial-onset seizures)		(JP/CN/AS) PIII	Neurology
E5501 (Idiopathic thrombocytopenic purpura (ITP))		(US/EU/AS) PIII	Vascular and Immunological Reaction
E5564 (Severe sepsis)		(JP/US/EU) PIII	Vascular and Immunological Reaction
E7080 (Thyroid cancer)		(JP/US/EU/AS) PIII	Oncology and Supportive Care
E7080 (Hepatocellular carcinoma)		(JP/US/EU/CN/AS) PIII	Oncology and Supportive Care
MORAb-003 (Platinum-sensitive ovarian cancer)		(JP/US/EU/AS) PIII	Oncology and Supportive Care
Fycompa (Generalized seizures)	AI	(JP/US/EU/AS) PIII	Neurology
Halaven (Second-line treatment for breast cancer)	AI	(US) PIII	Oncology and Supportive Care
Halaven (Non-small cell lung cancer)	AI	(JP/US/EU/AS) PIII	Oncology and Supportive Care

(1) Oncology and Supportive Care

Product Name: **Halaven** Research Code: **E7389** Generic Name: **eribulin** (Anticancer agent / microtubule dynamics inhibitor)

Description A synthetic analog of halichondrin B derived from the marine sponge, *Halichondria okadai*. Believed to exert an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Currently being investigated as a potential treatment for breast cancer and various other solid tumors. Approved in 48 countries including the United States, Singapore, European Union (EU) member states, Japan, and Switzerland.

Additional Indication: Second-line treatment for breast cancer	EU: submitted (April 2013), accepted (April 2013) US: PIII		Inj.
Additional Indication: Non-small cell lung cancer	JP/US/EU/AS: PIII	Submission Target FY2013	Inj.
Additional Indication: Sarcoma	US/EU/AS: PIII JP: PII	Submission Target FY2014	Inj.

Research Code: **MORAb-009** Generic Name: **amatuximab** (Anticancer agent / chimeric anti-mesothelin monoclonal antibody)

Description: A chimeric IgG1 monoclonal antibody that blocks the function of mesothelin. Expected to exhibit an antitumor effect against carcinomas that express mesothelin.

Mesothelioma

US/EU: PII

Inj.

Product Name: **Dacogen** Research Code: **E7373** Generic Name: **decitabine** (DNA methylation inhibitor)

Description: Induces cell differentiation by inhibiting DNA methylation. Currently approved in the United States for the treatment of myelodysplastic syndromes (MDS).

Additional Indication: Pediatric acute myeloid leukemia (AML) US: PII

Inj.

Product Name: **Ontak** Research Code: **E7272**

(2) Neurology

Product Name: **Aricept** Research Code: **E2020** Generic Name: **donepezil** (Anti-Alzheimer's agent)

Description: Increases levels of the neurotransmitter acetylcholine in the brain by inhibiting its breakdown by the enzyme acetylcholinesterase, thereby slowing the overall progression of symptoms associated with Alzheimer's disease (AD). Currently approved in more than 90 countries around the world for the treatment of mild to moderate AD. It is 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.

Additional Indication: Lewy body dementia	JP: PIII	Submission Target FY2013	Oral
Additional Indication: Severe Alzheimer's disease	CN: PIII		Oral
Additional Dosage & Administration, Formulation: Higher dose 23 mg tablet	JP: PIII	Submission Target FY2014	Oral
Additional Indication: Regression symptoms in people with Down syndrome	JP: PII		Oral

Research Code: **AS-3201** Generic Name: **ranirestat** (Treatment for diabetic complications / aldose reductase inhibitor)

Description: An aldose reductase inhibitor that is believed to reduce intracellular accumulation of sorbitol. Currently being investigated as a potential treatment for diabetic neuropathy, one of the most common diabetic complications.

Diabetic neuropathy	US/EU: PII/III	Oral
---------------------	----------------	------

Product Name: **Zonegran** Research Code: **E2090** Generic Name: **zonisamide** (Antiepileptic agent)

Description: Believed to exhibit a broad antiepileptic spectrum and is well-tolerated. Currently indicated as an adjunctive therapy and monotherapy for the treatment of partial-onset seizures in patients with epilepsy.

Additional Indication: Pediatric partial-onset seizures	EU: submitted (May 2012), accepted (June 2012)	Oral
--	--	------

(4) Gastrointestinal and Hepatic Disorders

Product Name: **Pariet/Aciphex** Research Code: **E3810** Generic Name: **rabeprazole** (Proton pump inhibitor)

Description: A proton pump inhibitor approved for the treatment of gastric and duodenal ulcers, reflux esophagitis and eradication of <i>Helicobacter pylori</i> infections, etc.		
Additional Formulation: Triple formulation pack for <i>Helicobacter pylori</i> eradication	JP: submitted (May 2012)	Oral
Additional Indication: Maintenance therapy for proton pump inhibitor (PPI)-resistant reflux esophagitis	JP: PIII	Oral
Additional Indication: Prevention of recurrence of gastric and duodenal ulcers during treatment with low-dosage aspirin	JP: PII/III	Submission Target FY2013 Oral
Additional Indication: Functional dyspepsia	JP: PII	Oral

Generic Name: **clevudine** (Anti-chronic hepatitis B agent)

Description: An antiviral drug that exerts an anti-HBV effect by inhibiting DNA polymerase.		
Chronic hepatitis B	CN: submitted (October 2010)	Oral

Generic Name: **cinitapride** (Gastroprokinetic agent)

Description: By stimulating 5-HT ₂ and 5-HT ₄ receptors found in the gastrointestinal tract, the agent increases acetylcholine release and improves upper gastrointestinal motility. Its antidopaminergic effects also help stimulate the release of acetylcholine by blocking dopamine receptors, thereby improving upper gastrointestinal function.		
Functional dyspepsia	CN: submitted (October 2011)	Oral