Securities Code: 4506

Supplementary Financial Data for the First Quarter of the Year Ending March 31, 2015

July 30, 2014

Sumitomo Dainippon Pharma Co., Ltd.

- Forecasts provided in this document are based on the management's assumptions and beliefs, made in light of information available up to the day of announcement. Actual financial results may differ materially from those presented in this document, being dependent upon a number of factors.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

I. Consolidated Financial Highlights

1. Consolidated Statements of Income

(Billions of yen)

	FY2013 1Q	FY2014 1Q	Change (%)	FY2014 Apr.-Sep. Forecast (Note 3)	Change (%)	FY2014 Forecast (Note 3)	Change (%)
Net sales	89.6	89.7	0.1	178.0	(1.9)	352.0	(9.2)
Cost of sales	25.3	24.1	(4.7)	[51.5] 51.0	1.1	[102.5] 100.0	(3.9)
SG&A expenses	55.3	57.0	2.9	[114.5]115.0	1.3	[229.5] 232.0	(3.9)
SG&A expenses less R&D costs	40.6	41.8	2.7	[82.0] 82.5	0.6	[159.5] 162.0	(5.6)
R&D costs	14.7	15.2	3.6	32.5	3.2	70.0	0.3
Operating income	9.0	8.7	(3.7)	12.0	(31.2)	20.0	(52.5)
Ordinary income	9.5	9.6	0.6	11.5	(33.9)	19.0	(53.2)
Net income	4.8	5.8	19.7	[6.3] 11.0	26.5	12.0	(40.2)

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.
2: Change (%) represent ratio of changes from the corresponding period of the previous year.
3: The forecasts have been revised. Figures in parentheses [ ] are previously disclosed forecasts. Change (%) represents ratio of changes to the revised forecasts.

EBITDA (Billions of yen)	16.8	14.9	21.0	38.0
Earnings per share (yen)	12.10	14.49	27.69	30.20
Return on equity (ROE)	1.3%	1.4%	—	—

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2013 1Q	FY2014 1Q
Net cash provided by operating activities	7.3	8.8
Net cash provided (used) in investing activities	(1.6)	8.6
Net cash used in financing activities	(6.0)	(5.7)
Cash and cash equivalents at the end of period	74.2	85.0

3. Currency Exchange Rates

(Billions of yen)

	2013 Apr.-Jun. Average rate	2014 Apr.-Jun. Average rate	2014 End of Jun.	FY2014 Assumed rate	Forex sensitivity FY2014 (Impact of yen strength by 1yen/$)	
Yen / USD	98.8	102.2	101.4	100.6	Net Sales	(1.4)
Yen / RMB	16.1	16.4	16.3	16.1	Operating Income	0.1

Note: Net sales and Operating income in FY2014 1Q increased by 1.2 billion yen and 0.0 billion yen respectively, compared to FY2013 1Q due to exchange rate fluctuation.

4. Capital Expenditures

(Billions of yen)

	FY2013 1Q	FY2014 1Q	Change	FY2014 Forecast	FY2014 Change
Capital expenditures	2.8	1.9	(0.9)	12.0	(1.5)

Note: The amount of capital expenditures for tangible fixed assets and software.

5. Depreciation and Amortization

(Billions of yen)

	FY2013 1Q	FY2014 1Q	Change	FY2014 Forecast	FY2014 Change
Property, plant and equipment	1.6	1.9	0.3	7.3	0.1
Intangible assets	4.0	1.5	(2.4)	4.5	(8.9)
Goodwill	1.3	1.3	(0.0)	5.3	0.2

（Reference）

Financial Results for DSP (Billions of yen)

	FY2013 1Q	FY2014 1Q	Change (%)	Group-to-parent ratio
Net sales	47.4	44.2	(6.7)	2.03
Cost of sales	14.1	14.5	3.3	
SG&A expenses	26.3	26.2	(0.3)	
SG&A expenses less R&D costs	15.5	15.1	(2.4)	
R&D costs	10.7	11.0	2.8	
Operating income	7.1	3.5	(50.4)	2.47
Ordinary income	8.6	5.5	(36.3)	1.74
Extraordinary income	—	1.7		
Extraordinary loss	—	0.1		
Net income	6.1	5.0	(17.4)	1.14

Financial Results for Sunovion (Millions of dollars)

	FY2013 1Q	FY2014 1Q	Change (%)
Net sales	332	359	8.2
Cost of sales	41	35	(12.9)
SG&A expenses	267	265	(0.8)
SG&A expenses less R&D costs	225	228	1.7
[amortization of patent rights and goodwill, etc]	52	25	(50.9)
R&D costs	43	37	(13.9)
Operating income	24	59	143.7
Ordinary income	25	60	136.6
Extraordinary loss	10	—	
Net income	4	28	571.5

Note: Total of Sunovion's result and amortization of goodwill.

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)
Net sales	89.6	89.7	0.1	0.1
Overseas sales	36.9	42.5	5.6	15.3
[% of net sales]	40.9%	46.3%		
Cost of sales	25.3	24.1	(1.2)	(4.7)
[% of net sales]	28.2%	26.8%		
Gross profit	64.4	65.7	1.3	2.0
SG&A expenses	55.3	57.0	1.6	2.9
Labor costs	16.2	17.1	0.9	5.4
Advertising and promotion costs	3.6	6.9	3.3	90.5
Sales promotion costs	3.1	2.9	(0.2)	(7.7)
Depreciation and amortization	4.2	1.8	(2.4)	(57.6)
Other costs	13.5	13.1	(0.4)	(2.8)
SG&A expenses less R&D costs	40.6	41.8	1.1	2.7
R&D costs	14.7	15.2	0.5	3.6
[% of net sales]	16.4%	17.0%		
Operating income	9.0	8.7	(0.3)	(3.7)
Non-operating income	0.9	1.3	0.4	42.9
Non-operating expenses	0.5	0.5	0.0	0.6
Ordinary income	9.5	9.6	0.1	0.6
Extraordinary income	—	1.7	1.7	
Compensation income for damage	—	1.7	1.7	
Extraordinary loss	1.0	0.1	(0.9)	
Business structure improvement expenses	0.6	0.1	(0.5)	
Impairment loss	0.4	—	(0.4)	
Income before income taxes and minority interests	8.5	11.1	2.6	31.1
Income taxes	3.7	5.4	1.7	
Income before minority interests	4.8	5.8	0.9	19.7
Net income	4.8	5.8	0.9	19.7

・Japan Segment -5.0
・North America Segment +3.8
(FX rate impact +1.2)
・China Segment +1.8

Cost of sales %
・Decrease in North America and China
(product mix, sales increase)
・Increase in Japan
(NHI price revision)

・Increase in North America

・Completed amortization of a patent right

FY2013:
・Restructuring costs in North America
FY2014:
・Retirement payments in Japan

FY2013:
・Impairment loss for production facility in North America

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.
2: Overseas sales includes exports of non-Pharmaceutical products.

2. Consolidated Statements of Comprehensive Income

(Billions of yen)

	FY2013 1Q	FY2014 1Q
Income before minority interests	4.8	5.8
Other comprehensive income	11.0	(4.2)
Unrealized gains (losses) on available-for-sale securities, net of tax	0.6	(0.5)
Deferred gains or losses on hedges	—	(0.0)
Foreign currency translation adjustments	10.4	(3.8)
Remeasurements of defined benefit plans	—	0.1
Comprehensive income	15.8	1.5

Currency exchange rates : yen/$

3/2013	6/2013	3/2014	6/2014
94.0	→ 98.6	102.9	→ 101.4
	+4.6		(1.5)

3. Segment Information (FY2014 1Q) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	37.5	35.6	—	4.2	2.5	79.8	9.9	89.7
Sales to customers	37.5	35.6	—	4.2	2.5	79.8	9.9	89.7
Intersegment	—	—	—	—	—	—	—	—
Cost of sales	11.2	3.0	—	0.6	1.4	16.2	7.8	24.1
Gross profit	26.3	32.6	—	3.6	1.0	63.6	2.1	65.7
SG&A expenses less R&D costs	14.4	21.1	2.6	1.6	0.5	40.2	1.5	41.8
Income (loss) of segment	11.9	11.5	(2.6)	2.0	0.5	23.3	0.6	23.9
R&D costs*3						15.0	0.2	15.2
Operating income						8.3	0.4	8.7

Segment Information (FY2013 1Q) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	42.5	31.9	—	2.4	2.5	79.3	10.4	89.6
Sales to customers	42.4	31.9	—	2.4	2.5	79.2	10.4	89.6
Intersegment	0.0	—	—	—	—	0.0	(0.0)	—
Cost of sales	11.4	3.9	—	0.6	1.3	17.2	8.0	25.3
Gross profit	31.0	28.0	—	1.8	1.2	62.0	2.3	64.4
SG&A expenses less R&D costs	15.2	17.2	5.2	1.4	0.2	39.2	1.5	40.6
Income (loss) of segment	15.9	10.8	(5.2)	0.4	1.0	22.9	0.9	23.7
R&D costs*3						14.5	0.2	14.7
Operating income						8.4	0.6	9.0

Segment Information (FY2014 Forecast) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	163.1	124.0	—	15.5	7.8	310.4	41.6	352.0
Sales to customers	163.0	124.0	—	15.5	7.8	310.3	41.7	352.0
Intersegment	0.1	—	—	—	—	0.1	(0.1)	—
Cost of sales	49.2	11.2	—	3.1	4.4	67.9	32.1	100.0
Gross profit	113.9	112.8	—	12.4	3.4	242.5	9.5	252.0
SG&A expenses less R&D costs	59.9	78.8	8.3	6.5	2.0	155.5	6.5	162.0
Income (loss) of segment	54.0	34.0	(8.3)	5.9	1.4	87.0	3.0	90.0
R&D costs*3						69.0	1.0	70.0
Operating income						18.0	2.0	20.0

Notes *1: Excluding amortization of patent rights and goodwill, etc.
*2: Including the elimination of intersegment transaction.
*3: R&D costs are controlled globally and not allocated to each segment.
4: FY2014 forecasts of each segment have been revised.
Total net sales, income of segment, operating income are unchanged.

4. Sales of Pharmaceuticals Business (Sales to customers) (Billions of yen)

	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	Progress Rate vs. Apr.-Sep. Forecast(%)	FY2014 (Forecast)
Japan	42.4	37.5	(5.0)	(11.7)	[84.6] 80.5	44.3	[169.0]163.0
North America	31.9	35.6	3.8	11.9	[60.9] 64.0	58.5	[119.0]124.0
China	2.4	4.2	1.8	76.4	[6.9] 8.0	61.2	[13.2] 15.5
Other Regions	2.5	2.5	(0.1)	(3.2)	4.1	59.8	7.8

5. Sales of Major Products

Japan(Strategic Products) (Sales figures before reduction of rebates, Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	Progress Rate vs. Apr.-Sep. Forecast(%)	FY2014 (Forecast)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	0.8	2.6	1.7	212.1	5.5	46.8	12.8
AVAPRO® (irbesartan) Therapeutic agent for hypertension	3.0	2.8	(0.2)	(8.1)	5.5	50.4	11.6
LONASEN® (blonanserin) Atypical antipsychotic	3.0	2.3	(0.6)	(21.7)	[6.7] 6.3	34.8	13.5
TRERIEF® (zonisamide) Parkinson's disease drug	2.1	2.4	0.4	17.1	5.5	43.8	11.7

Japan（New Products)

METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	3.5	3.6	0.1	3.0	7.9	46.2	16.1
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.3	0.5	0.1	41.6	1.5	31.1	3.2

Japan（Specialty Products)

AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	1.1	0.9	(0.2)	(20.4)	[2.6] 2.3	34.9	5.4
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma	0.3	0.2	(0.1)	(30.4)	0.5	41.7	1.0
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	2.6	2.4	(0.2)	(6.3)	5.4	44.4	10.8

Japan(Others)

AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	7.2	5.1	(2.1)	(28.9)	[11.5] 10.0	44.4	[22.4] 20.0
GASMOTIN® (mosapride citrate) Gastroprokinetic	4.0	2.7	(1.3)	(32.6)	[5.9] 5.5	46.0	[11.4] 10.5
PRORENAL® (limaprost alfadex) Vasodilator	3.5	2.7	(0.9)	(24.3)	[5.9] 5.5	45.3	[11.6] 10.5
MEROPEN® (meropenem) Carbapenem antibiotic	2.5	2.0	(0.4)	(17.5)	4.2	48.3	8.1
EBASTEL® (ebastine) Antiallergic	1.0	0.9	(0.1)	(6.3)	[1.8] 1.5	50.5	[4.6] 3.9

Note: The forcasts of some products have been revised. Figures in parentheses [ ] are previously disclosed forecasts.
Progress rate is against previous forecast.

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	Progress Rate vs. Apr.-Sep. Forecast(%)	FY2014 (Forecast)
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	6.8	18.4	11.6	172.2	[29.5] 35.0	62.3	[61.0] 72.0
LUNESTA® (eszopiclone) Sedative hypnotic	13.4	4.7	(8.7)	(64.7)	6.1	77.9	8.5
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	4.0	4.7	0.7	18.0	9.7	48.9	20.8
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	3.5	2.4	(1.1)	(31.2)	[5.9] 4.1	41.2	[9.2] 6.8
ALVESCO® (ciclesonide) Inhaled corticosteroid	1.1	0.9	(0.2)	(16.4)	[2.2] 1.8	42.1	[4.3] 3.7
APTIOM® (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	—	0.9	0.9	—	1.2	70.9	3.5
OMNARIS® (ciclesonide) Corticosteroid nasal spray	0.6	0.4	(0.2)	(30.3)	[1.4] 0.8	31.1	[2.9] 1.3
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	0.5	0.2	(0.3)	(53.8)	[1.1] 0.5	21.6	[2.1] 0.9
Industrial property revenues	0.9	1.3	0.3	34.3	[1.7] 2.2	74.7	3.3

China (Billions of yen)

Brand name (Generic name)	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	Progress Rate vs. Apr.-Sep. Forecast(%)	FY2014 (Forecast)
MEROPEN® (meropenem)	1.8	3.5	1.7	90.4	[5.6] 6.8	62.4	[10.6]13.0

Other Regions (Billions of yen)

Brand name (Generic name)	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	Progress Rate vs. Apr.-Sep. Forecast(%)	FY2014 (Forecast)
MEROPEN® (meropenem) (Export)	1.7	1.0	(0.7)	(43.5)	1.8	53.8	3.7
EXCEGRAN® (zonisamide) (Export)	0.5	0.6	0.1	9.6	1.0	57.0	1.3
Industrial property revenues	0.0	0.1	0.1	—	0.2	54.2	0.7

(Reference) Sales of Products in North America Segment (based on local currency (Millions of dollars)

Brand name (Generic name) Therapeutic indication	FY2013 1Q (A)	FY2014 1Q (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	Progress Rate vs. Apr.-Sep. Forecast(%)	FY2014 (Forecast)
LATUDA® (lurasidone)	68	180	112	163.2	[295] 346	61.0	[610] 716
LUNESTA® (eszopiclone)	136	46	(90)	(65.8)	[61] 60	76.2	85
BROVANA® (arformoterol tartrate)	41	46	6	14.1	[97] 96	47.8	[208] 207
XOPENEX® (levalbuterol HCl)	36	24	(12)	(33.5)	[59] 41	40.3	[92] 68
ALVESCO® (ciclesonide)	11	9	(2)	(19.2)	[22] 18	41.2	[43] 37
APTIOM® (eslicarbazepine acetate)	—	8	8	—	12	69.4	35
OMNARIS® (ciclesonide)	6	4	(2)	(32.6)	[14] 8	30.4	[29] 13
ZETONNA® (ciclesonide)	5	2	(3)	(55.3)	[11] 5	21.2	[21] 9
Industrial property revenues	10	12	3	29.8	[17] 22	73.2	33

Note: The forcasts of some products have been revised. Figures in parentheses [ ] are previously disclosed
Progress rate is against previous forecast.

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of Mar. 31, 2014 (A)	As of Jun. 30, 2014 (B)	(B)-(A)	
[Assets]	659.0	638.4	(20.6)	
Current assets:	359.6	343.5	(16.2)	
Cash and time deposits	22.7	26.3	3.6	
Notes and accounts receivable	111.7	97.6	(14.1)	← Receipt of Milestone Revenue
Marketable securities	82.0	81.7	(0.2)	
Inventories	59.1	61.0	1.9	
Deferred tax assets	37.3	35.0	(2.2)	
Short-term loans receivable	41.7	35.5	(6.2)	
Others	5.2	6.4	1.2	
Allowance for doubtful receivables	(0.1)	(0.1)	0.0	
Fixed assets:	299.4	294.9	(4.5)	
Property, plant and equipment:	72.7	71.8	(0.9)	
Buildings and structures	44.4	44.1	(0.3)	
Machinery, equipment and carriers	9.6	9.4	(0.3)	
Land	8.4	8.4	(0.0)	
Construction in progress	3.1	2.7	(0.3)	
Others	7.2	7.2	(0.0)	
Intangible assets:	156.8	152.0	(4.8)	Amortization -1.3 Currency -1.2
Goodwill	80.7	78.2	(2.5)	←
In-process research & development	56.1	54.9	(1.1)	← Currency -1.1
Others	20.1	18.9	(1.2)	
Investments and other assets:	69.9	71.1	1.2	
Investment securities	50.8	51.3	0.4	
Asset for retirement benefit	4.7	4.8	0.1	
Deferred tax assets	8.6	7.2	(1.4)	
Others	5.9	7.9	2.0	
Allowance for doubtful receivables	(0.0)	(0.0)	0.0	
Total assets	659.0	638.4	(20.6)	

Accounts receivable turnover period (in months)	3.46	3.26

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2014 (B)	As of Jun. 30, 2014 (B)	(B)-(A)
[Liabilities]	260.5	242.2	(18.3)
Current liabilities:	131.2	115.6	(15.6)
Notes and accounts payable	11.7	12.8	1.1
Current portion of long-term loans payable	10.0	10.1	0.1
Income taxes payable	10.5	3.2	(7.3)
Reserve for bonuses	7.8	4.4	(3.4)
Reserve for sales returns	9.9	8.2	(1.7)
Reserve for sales rebates	26.4	25.0	(1.4)
Accounts payable-other	35.9	27.7	(8.2)
Others	18.9	24.1	5.2
Long-term liabilities:	129.3	126.6	(2.7)
Bonds payable	60.0	60.0	—
Long-term loans payable	25.0	22.7	(2.3)
Deferred tax liabilities	15.7	14.8	(0.9)
Liability for retirement benefit	13.9	14.3	0.4
Others	14.7	14.9	0.2
[Net assets]	398.5	396.1	(2.4)
Shareholders' equity:	356.5	358.3	1.9
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	318.9	320.7	1.9
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	42.1	37.8	(4.2)
Unrealized gains on available-for-sale securities, net of tax	17.2	16.8	(0.5)
Deferred gains or losses on hedges	(0.0)	(0.0)	(0.0)
Foreign currency translation adjustments	26.8	22.9	(3.8)
Remeasurement of defined benefit plans	(2.0)	(1.9)	0.1
Total liabilities and net assets	659.0	638.4	(20.6)

Payment of expense (advertisement, etc.)

Total interest-bearing debt
95.0→92.8(-2.2)
(scheduled payment -2.5)

Net income +5.8
Payment of dividend -3.6

Currency exchange rates: yen/$
03/2014 06/2014
102.9 → 101.4

IV. Quarterly Business Results

(Billions of yen)

	FY2013				FY2014
	1Q	2Q	3Q	4Q	1Q
Net sales	89.6	91.8	103.1	103.2	89.7
Cost of sales	25.3	25.2	27.7	26.0	24.1
SG&A expenses	55.3	58.2	58.2	69.7	57.0
SG&A expenses less R&D costs	40.6	41.4	40.7	48.9	41.8
R&D costs	14.7	16.8	17.5	20.8	15.2
Operating income (loss)	9.0	8.4	17.2	7.5	8.7
Non-operating income	0.9	0.3	0.5	0.4	1.3
Non-operating expenses	0.5	0.8	0.8	1.6	0.5
Ordinary income (loss)	9.5	7.9	16.9	6.3	9.6
Extraordinary income	―	3.8	0.0	0.2	1.7
Extraordinary loss	1.0	5.3	0.1	3.6	0.1
Income (Loss) before income taxes and minority interests	8.5	6.5	16.8	2.9	11.1
Net income (loss)	4.8	3.9	10.5	0.9	5.8

Note: Cost of sales includes provision for (reversal of) reserve for sales returns.

V. Major consolidated subsidiaries (As of June 30, 2014)

Domestic	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Biomedical Co., Ltd.
Establishment	October 1947	July 2010	June 1998
Ownership	100%	100%	100%
Number of employees	160	102	65
Businesses	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.	Manufacturing, and sales of veterinary medicines, etc.	Manufacturing and sales of diagnostics, etc.

Overseas	Sunovion Pharmaceuticals Inc.	Boston Biomedical, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	December 2003
Ownership	100%	100%	100%
Number of employees	1,573	64	742
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

(Reference) Number of employees and MRs

		As of Mar. 31, 2014	As of Jun. 30, 2014
consolidated		7,015	7,009
non-consolidated		4,331	4,291
MRs Japan	(excluding managers)	1,400	1,360
	(including managers)	1,600	1,540
MRs U.S.	(excluding managers)	710	700
	(including managers)	810	790
MRs China	(excluding managers)	390	380
	(including managers)	480	480

VI. Development Pipeline (As of July 30, 2014)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Remarks
Submitted	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Merck Santé	Submitted in October 2013
	SUREPOST® Oral	repaglinide	(New indication) Type 2 diabetes All combination therapies including DPP-4 inhibitors	Novo Nordisk	Submitted in December 2013 Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes (Monotherapy, Combination with α-GI, BG and TZD)
Phase III	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Approved in the U.S., Canada, Europe and Australia
			Bipolar I depression		Approved in the U.S. and Canada
			Bipolar maintenance		
	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house	Global clinical trial Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	
Phase II/III	EPI-743 Oral	TBD	Leigh syndrome	Edison Pharmaceuticals	

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Remarks
Phase II	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	
	LONASEN® Transdermal Patch	blonanserin	(New formulation – Transdermal patch) Schizophrenia	In-house	Co-development with Nitto Denko Approved formulation: Oral
	TRERIEF® Oral	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	In-house	
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharmaceutical	Independent development after April 2013
Phase I	DSP-3025 Collunarium	TBD	Bronchial asthma, Allergic rhinitis	In-house	
	WT4869 Injection	TBD	Solid tumors	Joint research with Chugai Pharmaceutical	Independent development after April 2013
	WT2725 Injection	TBD	Solid tumors	Joint research with Chugai Pharmaceutical	Independent development after April 2013
	BBI608 Oral	TBD	Gastric cancer (Combination therapy)	In-house	

[Main revisions since the announcement of May 2014]

BBI608 (Colorectal cancer / Monotherapy) Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Approved /Preparing for launch	LATUDA® Oral	lurasidone hydrochloride	Schizophrenia	In-house	Australia	Approved in March 2014
	APTIOM™ Oral	eslicarbazepine acetate	Epilepsy (Adjunctive therapy)	BIAL	Canada	Approved in July 2014
Submitted	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Submitted in August 2013 Brand name in Japan: CALSED®
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Submitted in September 2013 Brand name in Japan: LONASEN®
Phase III	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house	U.S., Canada, etc.	Global clinical trial Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014
			Gastric cancer, Gastro-esophageal junction adenocarcinoma (Combination therapy)		U.S., Canada	Global clinical trial
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Approved in the U.S., Canada, Europe and Australia
	LATUDA® Oral		(New indication) Bipolar maintenance		U.S., Europe, etc.	
			(New indication) MDD with mixed features			
	APTIOM® Oral	eslicarbazepine acetate	(New indication) Epilepsy (Monotherapy)	BIAL	U.S.	Approved indication: Epilepsy (Adjunctive therapy)
Phase II	BBI608 Oral	TBD	Colorectal cancer (Combination therapy)	In-house	U.S., Canada	
	SUN-101 Inhalant	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	In-house	U.S.	From the former Elevation Pharmaceuticals

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase II	SEP-225289 Oral	dasotraline	Attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	
	BBI503 Oral	TBD	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	In-house	Canada	
			Hepatocellular carcinoma, Cholangio carcinoma (Monotherapy)			
			Gastrointestinal stromal tumor (Monotherapy)			
Phase I/II	BBI608 Oral	TBD	Solid tumors (Combination therapy)	In-house	U.S., Canada	Phase II : Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.
	BBI503 Oral	TBD	Solid tumors (Monotherapy)	In-house	U.S., Canada	Phase II : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.
Phase I	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S.	
	WT2725 Injection	TBD	Solid tumors, Hematologic cancers	Joint research with Chugai Pharmaceutical	U.S.	Independent development after April 2013
	SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S.	
	BBI608 Oral	TBD	Gastrointestinal cancer (Combination therapy)	In-house	U.S., Canada	

* Phase I study of EPI-589 which was in-licensed from Edison Pharmaceuticals (in-licensed territories: Japan and North America) is ongoing in Europe by Edison Pharmaceuticals.

[Main revisions since the announcement of May 2014]

APTIOM™ (eslicarbazepine acetate)	Approved and preparing for launch in Canada (Epilepsy / Adjuctive therapy: Approved in July 2014)
BBI608 (Colorectal cancer / Monotherapy)	Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014.
BBI503 (Renal cell carcinoma, Urothelial carcinoma / Monotherapy)	Newly added in Phase II in Canada
BBI503 (Hepatocellular carcinoma, Cholangiocarcinoma / Monotherapy)	Newly added in Phase II in Canada
BBI503 (Gastrointestinal stromal tumor / Monotherapy)	Newly added in Phase II in Canada
BBI503 (Solid tumors / Monotherapy)	Changed from Phase I to Phase I / II in the U.S. and Canada

Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Proposed indications	Status of development
vosaroxin AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003. Phase III study ongoing in North America by Sunesis (Sunesis' product code: SNS-595).
amrubicin hydrochloride (CALSED®)	Small cell lung cancer	Out-licensed to Celgene (former Pharmion) for the U.S. and European territories in June 2005. Phase III study completed in the U.S. and Europe by Celgene.
droxidopa (DOPS®)	Neurogenic orthostatic hypotension, Intradialytic hypotension, Fibromyalgia	Out-licensed to Chelsea Therapeutics for the worldwide territory, excluding Japan, China, Korea and Taiwan in May 2006. Chelsea obtained the approval for neurogenic orthostatic hypotension in the U.S. in February 2014 (Chelsea's brand name: NORTHERA™). Phase II study of fibromyalgia and phase II study of intradialytic hypotension completed by Chelsea.
DSP-3025	Bronchial asthma, Allergic rhinitis	Entered into a development and marketing agreement in March 2005. AstraZeneca has the right for the worldwide territory, excluding Japan, China, Korea and Taiwan. Phase II study as a collunarium was completed in Europe, while a Phase I study as an inhalant was started in the U.K. by AstraZeneca (AstraZeneca's product code: AZD8848).
lurasidone hydrochloride SM-13496	Schizophrenia Bipolar disorder	Entered into a license agreement with Takeda Pharmaceutical for co-development and exclusive commercialization for the European territory, excluding the U.K. in March 2011. Takeda submitted an MAA in Europe for schizophrenia in September 2012. Takeda obtained the approval for schizophrenia in Switzerland in August 2013. Out-licensed to Standard Chem. & Pharm. for Taiwan in August 2013, and submitted for schizophrenia in Taiwan in October 2013. Takeda obtained the approval in Europe for schizophrenia in March 2014.
SMP-986	Nocturia	Out-licensed to Nippon Shinyaku Co., Ltd. for rights in Japan to develop and commercialize in March 2013. Phase II study ongoing in Japan by Nippon Shinyaku.(Nippon Shinyaku's product code: NS-986).

[Main revisions since the announcement of May 2014]

ranirestat (AS-3201)	Deleted from the list because Eisai, the licensee for overseas, discontinued the overseas development.

VII. Profile of Major Products under Development (As of July 30, 2014)

APTIOM® (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- A novel voltage-gated sodium channel blocker, is taken once daily and can be taken whole or crushed, with or without food. APTIOM® is not classified as a controlled substance by the FDA.
- Sunovion obtained the approval of APTIOM® for use as adjunctive treatment of partial-onset seizures in the U.S. in November 2013 and launched in the U.S. in April 2014. The approval is based on three global studies which were jointly performed with BIAL. These were randomized, double-blind, placebo-controlled studies, which included more than 1,400 people living with partial-onset seizures inadequately controlled by one to three concomitant AEDs.
- Development stage:
  Epilepsy (adjunctive therapy): Approved in July 2014 and preparing for launch in Canada
  Epilepsy (monotherapy): Phase III in the U.S.

LATUDA® (lurasidone hydrochloride) Schizophrenia, Bipolar disorder

- Developed in-house
- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine or muscarinic receptors.
- In the clinical studies supporting the U.S. FDA approval, the efficacy of LATUDA for the treatment of schizophrenia was established in four, short-term (6-week), placebo-controlled clinical studies in adult patients. In these studies, LATUDA demonstrated significantly greater improvement versus placebo. A total of five short-term placebo-controlled clinical studies contributed to the understanding of the tolerability and safety profile of LATUDA. LATUDA was approved for the treatment of schizophrenia by the U.S. FDA in October 2010, and launched by Sunovion in the U.S. in February 2011. For the treatment of schizophrenia, LATUDA was launched in Canada in September 2012 and launched in Switzerland in September 2013 through a local subsidiary of Takeda Pharmaceutical, Sumitomo Dainippon Pharma's partner in Europe. Takeda obtained the approval in Europe from the European Commission in March 2014. In addition, LATUDA was approved in Australia in March 2014.
  For the treatment of bipolar I depression, LATUDA was approved as the first atypical antipsychotic indicated for the treatment of bipolar I depression as a monotherapy and as an adjunctive therapy to lithium or valproate by the U.S. FDA in June 2013. In addition, LATUDA was approved in Canada in March 2014.
- Development stage:

Schizophrenia:	Approved in March 2014 and preparing for launch in Europe and Australia
	Submitted in Taiwan by Standard Chem. & Pharm.
	Phase III in Japan and China
Bipolar I depression:	Phase III in Japan
	In addition, plans to submit an MAA in Europe by Takeda Pharmaceutical. (Phase III in Europe)
Bipolar maintenance:	Phase III in the U.S., Europe and Japan, etc.
MDD with mixed features:	Phase III in the U.S. and Europe, etc.

ranirestat (AS-3201)　　Diabetic neuropathy

- Developed in-house
- AS-3201 is expected to alleviate diabetic neuropathy, a complication of diabetes, by inhibiting aldose reductase and thereby inhibiting the accumulation of intracellular sorbitol that causes diabetic neuropathy. This compound has a stronger inhibitory effect and is longer-acting compared to other drugs in this therapeutic area. Clinical studies have shown AS-3201 to have good penetration into nerve tissues, resulting in dose-dependent inhibition of intraneural accumulation of sorbitol and fructose. Based on the results of clinical studies, AS-3201 is expected to show improvement of neuronal function and symptoms related to diabetic neuropathy.
- Development stage: Phase III in Japan

BBI608　　Solid tumors

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is a small-molecule compound with a novel mechanism that blocks cancer stem cells (cancer cells with stem cell-like properties) self-renewal and induces cell death in cancer stem cells as well as other heterogeneous cancer cells. By targeting cancer stem cells in addition to heterogeneous (non-stem) cancer cells, it may provide a new therapeutic option against cancer challenges such as treatment resistance, recurrence and metastasis.
- BBI608 has been shown to inhibit the Stat3 pathways, Nanog pathways and β-catenin pathways in the pre-clinical study.
- Development stage:
  Colorectal cancer (monotherapy): Phase III in the U.S., Canada and Japan, etc.
  *Further enrollment of new patients was stopped and all study drug was discontinued in patients in May 2014.
  Gastric cancer, Gastro-esophageal junction adenocarcinoma (combination therapy with paclitaxel): Phase III in the U.S. and Canada
  Colorectal cancer (combination therapy with cetuximab, panitumumab or capecitabine): Phase II in the U.S. and Canada
  Solid tumors (combination therapy with paclitaxel): Phase I/II in the U.S. and Canada
  * Phase II : Ovarin cancer, Brest cancer, Non-small cell lung cancer, Melanoma, etc.
  Gastric cancer (combination therapy with paclitaxel): Phase I in Japan
  Gastrointestinal cancer (combination therapy with FOLFOX[*1], FOLFOX[*1] and bevacizumab, CAPOX[*2], FOLFIRI[*3], FOLFIRI[*3] and bevacizumab, or regorafenib): Phase I in the U.S. and Canada
  *1 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
  *2 CAPOX: Combination therapy with capecitabine, oxaliplatin
  *3 FOLFIRI: Combination therapy with fluorouracil, leucovorin,irinotecan

EPI-743　　Mitochondrial disease

- In-licensed from Edison Pharmaceuticals
- EPI-743 is to synchronize energy generation in the mitochondria with the counterbalancing of redox stress. It is expected to be a world's first treatment for mitochondrial diseases beginning with Leigh syndrome.
- Development stage: Phase II/III in Japan for Leigh syndrome

DSP-1747 Nonalcoholic steatohepatitis (NASH), Primary biliary cirrhosis (PBC)

- In-licensed from Intercept Pharmaceuticals Inc. (Intercept's product code: INT-747)
- DSP-1747 is an agonist to farnesoid X receptor (FXR) whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. The compound is expected to be effective for hepatic dysfunction and hepatic fibrosis associated with an increase of bile acid in the liver.
- Development stage: Phase II in Japan for NASH. Phase II for PBC is under consideration.

DSP-6952 IBS with constipation, Chronic idiopathic constipation

- Developed in-house
- DSP-6952 is a high affinity serotonin-4 receptor partial agonist with enterokinetic effect. DSP-6952 is expected to be effective for IBS with constipation and chronic idiopathic constipation by increasing complete spontaneous bowel movement.
- Development stage: Phase II in Japan

glycopyrrolate bromide (SUN-101) Chronic obstructive pulmonary disease (COPD)

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SUN-101 is a proprietary solution formulation of glycopyrrolate bromide, delivered by a customized eFlow® Nebulizer System (originated by and licensed from PARI Pharma GmbH), which was developed to optimize medication delivery and allow ease of use. Including products on the market and in development in this therapeutic area, SUN-101 is currently the only LAMA (long-acting muscarinic antagonist) in nebulized form.
- Development stage: Phase II in the U.S.

dasotraline (SEP-225289) Attention-deficit hyperactivity disorder (ADHD)

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SEP-225289 is a DNRI that inhibits the reuptake of dopamine and norepinephrine. SEP-225289 is being developed as a once daily long-acting treatment that will be effective throughout the day. Because of its ability to maintain a stable concentration in blood levels all day, it is expected to be effective over the course of the day.
- Development stage: Phase II in the U.S.

BBI503 Solid tumors

- Developed in-house (Boston Biomedical, Inc.)
- BBI503 is a small-molecule compound with a novel and a mechanism different to that of BBI608 that blocks cancer stem cell (cancer cell with stem cell-like properties) self-renewal and induces cell death in CSC as well as other heterogeneous cancer cells. By targeting cancer stem cells in addition to heterogeneous (non-stem) cancer cells, it may provide a new therapeutic option against cancer challenges such as treatment resistance, recurrence and metastasis.
- BBI503 has been shown to inhibit multi-kinase in pre-clinical study.
- Development stage:
  Renal cell carcinoma, Urothelial carcinoma (monotherapy): Phase II in Canada
  Hepatocelluar carcinoma, Cholangiocarcinoma (monotherapy): Phase II in Canada
  Gastrointestinal stromal tumor (monotherapy): Phase II in Canada
  Solid tumors (monotherapy): Phase I / II in the U.S. and Canada
  * Phase II : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

WT4869 Myelodysplastic syndromes (MDS), Solid tumors

- Developed in house (Joint research with Chugai Pharmaceutical)
- WT4869 is a therapeutic cancer vaccine candidate using a peptide derived from Wilms' tumor gene 1 (WT1) protein. WT4869 is expected to treat patients with various types of hematologic cancers and solid tumors that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- Development stage:

Myelodysplastic syndromes (MDS):	Phase I/II in Japan
Solid tumors:	Phase I in Japan

DSP-3025 Bronchial asthma, Allergic rhinitis

- Developed in-house
- DSP-3025 is an immune response modifier with agonistic activity against Toll-like receptor 7 (TLR7). It is expected to become a therapeutic agent providing long-term disease remission in bronchial asthma and allergic rhinitis.
- A series of promising compounds was identified from drug discovery research for a therapeutic agent with a novel mechanism of action against allergic disorders. With this as a turning point, we started research collaboration with AstraZeneca in 2004 and discovered a drug candidate as an outcome based on this research collaboration.
- We entered into a development and marketing agreement with AstraZeneca in March 2005. Under the agreement, we will retain development and commercialization rights in Japan, China, Korea and Taiwan and AstraZeneca will retain development and commercialization rights worldwide excluding the three countries and one territory. AstraZeneca has completed a Phase II study in Europe as a collunarium and started a Phase I study in the U.K. as an inhalant. (AstraZeneca's code name: AZD8848)
- Development stage: Phase I in Japan

DSP-2230 Neuropathic pain

- Developed in-house
- DSP-2230 is a novel compound that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8 with higher potencies than those against the other sodium channel subtypes studied. In addition, DSP-2230 has demonstrated antiallodynic effects in animal models of neuropathic pain that have been shown to be predictive of efficacy in humans. Due to its novel mechanism, DSP-2230 is expected not to produce CV or CNS side effects, which are present with the current drugs, such as non-selective sodium channel blockers and anti-epilepsy medicines.
- Development stage: Phase I in the U.K. and the U.S.

WT2725 Solid tumors, Hematologic cancers

- Developed in-house (Joint research with Chugai Pharmaceutical)
- WT2725 is a therapeutic cancer vaccine candidate using a peptide derived from Wilms' tumor gene 1 (WT1) protein. WT2725 is expected to treat patients with various types of hematologic cancers and solid tumors that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- Development stage:

Solid tumors, Hematologic cancers:	Phase I in the U.S.
Solid tumors:	Phase I in Japan

SEP-363856 Schizophrenia

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SEP-363856 is an antipsychotic with a novel mechanism of action. Compared to existing antipsychotics that are effective for positive symptoms of schizophrenia, this also shows efficacy for the negative symptoms. Even in combination treatment with atypical antipsychotics, extrapyramidal side effects were not observed. High efficacy and improved QOL are expected for the treatment for schizophrenia.
- Development stage: Phase I in the U.S.

EPI-589 Neurodegenerative diseases

- In-licensed from Edison Pharmaceuticals
- EPI-589 is a generation 2 redox cofactor modeled after EPI-743. It is expected to be developed for neurodegenerative indications arising through redox stress based on defects in mitochondrial function.
- Development stage: Phase I in Europe by Edison Pharmaceuticals.