Securities Code: 4506

Supplementary Financial Data for the Third Quarter of the Year Ending March 31, 2014

January 31, 2014

Dainippon Sumitomo 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)

	FY2012 Apr.- Dec.	FY2013 Apr.- Dec.	Change (%)	FY2012	Change (%)	FY2013 (Forecasts)	Change (%)
Net sales	269.2	284.5	5.7	347.7	(0.8)	385.0	10.7
Cost of sales	76.4	78.1	2.3	101.7	2.9	104.4	2.7
SG&A expenses	160.2	171.7	7.2	221.0	(4.4)	245.6	11.1
SG&A expenses less R&D costs	120.2	122.8	2.1	161.2	(7.5)	172.6	7.1
R&D costs	39.9	49.0	22.6	59.8	5.2	73.0	22.0
Operating income	32.7	34.7	6.0	25.0	22.8	35.0	39.8
Ordinary income	32.7	34.3	4.9	24.5	29.8	34.0	38.7
Net income	16.9	19.2	13.6	10.0	16.4	17.0	69.3

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: Changed the period of FY2013 as Apr.-Mar. for Sunovion Pharmaceuticals Inc. and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (The period for the previous year was Jan.-Dec. 2012)
4:The forecasts released on Oct. 30, 2013 have been revised.

EBITDA (Billions of yen)	61.8	55.2	60.3	61.0
Earnings per share (yen)	42.45	48.22	25.28	42.79
Return on equity (ROE)	5.2%	5.1%	3.0%	—
Payout ratio	31.8%	28.0%	71.2%	42.1%

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2012 Apr.- Dec.	FY2013 Apr.- Dec.
Net cash provided by operating activities	41.1	35.4
Net cash used in investing activities	(46.9)	(14.8)
Net cash used in financing activities	(14.7)	(14.7)
Cash and cash equivalents at the end of period	71.1	85.1

3. Currency Exchange Rates

(Billions of yen)

	FY2012 Jan.- Sep. Average rate	FY2013 Apr.- Dec. Average rate	FY2013 End of Dec.	FY2013 Assumed rate	Forex sensitivity FY2013 (Impact of yen strength by 1yen/$)	
Yen / USD	79.4	99.4	105.4	99.5	Net Sales	(1.6)
Yen / RMB	12.6	16.2	17.3	15.9	Operating Income	(0.0)

Note: Net sales and Operating income in FY2013 Apr. - Dec. increased by 23.2 billion yen and 1.6 billion yen respectively, compared to the corresponding period of the previous year due to exchange rate fluctuation.

4. Capital Expenditures and Depreciation

(Billions of yen)

	FY2012 Apr.- Dec.	FY2013 Apr.- Dec.	Change	FY2013	
				Forecasts	Change
Capital expenditures	7.0	11.3	4.3	15.0	4.6
Depreciation and amortization	6.1	6.6	0.5	9.0	1.1

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

・Major capital expenditure projects completed in FY2013
Construction of the New Chemistry Research Building in Osaka Research Center:
(Total expenditures 5.8billion yen,completed in Jun. 2013)

（Reference）

Financial Results for DSP (Billions of yen)

	FY2012 Apr.- Dec.	FY2013 Apr.- Dec.	Change (%)	Group-to-parent ratio
Net sales	148.6	147.3	(0.9)	1.93
Cost of sales	44.5	44.6	0.3	
SG&A expenses	79.6	86.0	8.0	
SG&A expenses less R&D costs	48.0	47.3	(1.6)	
R&D costs	31.6	38.7	22.7	
Operating income	24.5	16.7	(32.0)	2.08
Ordinary income	25.1	17.2	(31.6)	2.00
Extraordinary income	—	2.8		
Extraordinary loss	1.5	1.4		
Net income	15.2	13.3	(12.1)	1.44

Earnings per share (yen)	38.19	33.59

Financial Results for Sunovion (Millions of dollars)

	FY2012 Apr.- Dec.	FY2013 Apr.- Dec.	Change (%)
Net sales	1,150	1,106	(3.9)
Cost of sales	165	125	(24.5)
SG&A expenses	985	792	(19.5)
SG&A expenses less R&D costs	822	667	(18.9)
[amortization of patent rights and goodwill, etc]	(272)	(139)	(48.9)
R&D costs	163	125	(22.9)
Operating income	(0)	188	—
Ordinary income	1	190	—
Extraordinary income	—	11	
Extraordinary loss	36	50	
Net income	(36)	80	—

Note: Including amortization of patent rights and goodwill.

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income (Billions of yen)

	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)
Net sales	269.2	284.5	15.3	5.7
Overseas sales	101.7	121.3	19.6	19.2
[% of net sales]	37.8%	42.6%		
Cost of sales	76.4	78.1	1.7	2.3
[% of net sales]	28.4%	27.5%		
Gross profit	192.9	206.4	13.5	7.0
SG&A expenses	160.2	171.7	11.6	7.2
Labor costs	49.7	48.3	(1.5)	(2.9)
Advertising and promotion costs	10.9	12.0	1.1	10.1
Sales promotion costs	7.6	10.2	2.6	33.8
Other costs	51.9	52.3	0.3	0.7
SG&A expenses less R&D costs	120.2	122.8	2.6	2.1
R&D costs	39.9	49.0	9.0	22.6
[% of net sales]	14.8%	17.2%		
Operating income	32.7	34.7	1.9	6.0
Non-operating income	2.3	1.7	(0.6)	(24.3)
Non-operating expenses	2.2	2.0	(0.2)	(9.1)
Ordinary income	32.7	34.3	1.6	4.9
Extraordinary income	—	3.8	3.8	
Gain on sales of investment securities	—	2.8	2.8	
Fair value adjustment of contingent consideration	—	1.1	1.1	
Extraordinary loss	4.4	6.4	2.0	
Impairment loss	0.4	4.6	4.2	
Business structure improvement expenses	3.9	1.8	(2.1)	
Income before income taxes and minority interests	28.4	31.8	3.4	12.0
Income taxes	11.5	12.6	1.1	
Income before minority interests	16.9	19.2	2.3	13.6
Net income	16.9	19.2	2.3	13.6

・Japan Segment -4.4
・North America Segment +18.3

・Increase in North America and China

・Increase in North America(BBI) and Japan

・FY2012:
Impairment loss for in-process R&D in North America
・FY2013:
Impairment loss for production facility in North America
Impairment loss for in-process R&D in North America

・FY2012:
Restructuring costs in North America
Transfer of assigned employees to related companies in Japan
FY2013:
Restructuring costs in North America
Retirement payments in Japan

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)

	FY2012 Apr.- Dec.	FY2013 Apr.- Dec.
Income before minority interests	16.9	19.2
Other comprehensive income	(1.2)	28.2
Unrealized gains (losses) on available-for-sale securities, net of tax	0.0	2.1
Foreign currency translation adjustments	(1.2)	26.1
Comprehensive income	15.7	47.4

Currency exchange rates : yen/$

12/2011	09/2012	03/2013	12/2013
77.7	→ 77.6	94.0	→ 105.4
	-0.1		+11.4

3. Segment Information (FY2013 Apr.- Dec.) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	132.6	106.3	—	8.2	6.6	253.6	30.9	284.5
Sales to customers	132.5	106.3	—	8.2	6.6	253.6	30.9	284.5
Intersegment	0.1	—	—	—	—	0.1	(0.1)	—
Cost of sales	37.3	11.3	—	1.9	3.4	53.8	24.3	78.1
Gross profit	95.3	95.0	—	6.3	3.2	199.8	6.6	206.4
SG&A expenses less R&D costs	46.1	52.9	14.0	4.6	0.7	118.3	4.5	122.8
Income (loss) of segment	49.3	42.1	(14.0)	1.7	2.5	81.6	2.1	83.6
R&D costs*3						48.3	0.6	49.0
Operating income						33.2	1.4	34.7

Segment Information (FY2012 Apr.- Dec.) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	137.2	88.1	—	5.9	7.6	238.7	30.6	269.2
Sales to customers	137.0	88.1	—	5.9	7.6	238.5	30.8	269.2
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	37.7	9.7	—	1.4	3.8	52.6	23.7	76.4
Gross profit	99.5	78.3	—	4.5	3.7	186.0	6.8	192.9
SG&A expenses less R&D costs	47.2	44.1	21.6	2.6	0.3	115.8	4.4	120.2
Income (loss) of segment	52.2	34.2	(21.6)	1.9	3.4	70.3	2.4	72.7
R&D costs*3						39.4	0.6	39.9
Operating income						30.9	1.8	32.7

Segment Information (FY2013 Forecasts)*4 (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	174.2	141.1	—	11.0	16.5	342.8	42.2	385.0
Sales to customers	174.0	141.1	—	11.0	16.5	342.6	42.4	385.0
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	49.7	15.1	—	2.5	4.2	71.5	32.9	104.4
Gross profit	124.5	126.0	—	8.5	12.3	271.3	9.3	280.6
SG&A expenses less R&D costs	62.9	78.0	18.0	6.0	1.1	166.0	6.6	172.6
Income (loss) of segment	61.6	48.0	(18.0)	2.5	11.2	105.3	2.7	108.0
R&D costs*3						72.0	1.0	73.0
Operating income						33.3	1.7	35.0

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: The forecasts released on Oct. 30, 2013 have been revised.

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

	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 Forecasts(%)	FY2012	FY2013 (Forecasts)
Japan	137.0	132.5	(4.4)	(3.2)	76.2	174.5	174.0
North America	88.1	106.3	18.3	20.7	75.3	115.8	[137.1] 141.1
China	5.9	8.2	2.3	38.8	74.1	7.6	11.0
Other Regions	7.6	6.6	(1.0)	(13.2)	39.9	9.3	16.5

5. Sales of Major Products

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

Brand name (Generic name) Therapeutic indication	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 Forecasts(%)	FY2012	FY2013 (Forecasts)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	1.9	4.9	3.0	160.6	80.2	2.0	6.1
AVAPRO® (irbesartan) Therapeutic agent for hypertension	9.0	9.4	0.4	3.9	77.5	11.7	12.1
LONASEN® (blonanserin) Atypical antipsychotic	8.4	9.3	1.0	11.4	71.8	10.7	13.0
TRERIEF® (zonisamide) Parkinson's disease drug	5.4	6.8	1.4	26.5	74.3	7.0	9.2

Japan（New Products)

METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	9.1	11.7	2.6	28.0	76.7	12.0	15.2
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.5	1.2	0.7	148.2	62.3	0.7	1.9

Japan（Specialty Products)

AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	3.6	3.8	0.3	7.1	77.0	4.6	5.0
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma	0.9	0.9	0.0	3.4	70.7	1.1	1.3
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	7.8	7.7	(0.1)	(0.7)	73.6	9.9	10.5

Japan(Others)

AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	22.8	21.2	(1.6)	(7.1)	78.9	29.2	26.9
GASMOTIN® (mosapride citrate) Gastroprokinetic	15.7	11.9	(3.8)	(24.2)	78.9	19.5	15.1
PRORENAL® (limaprost alfadex) Vasodilator	11.2	10.7	(0.5)	(4.2)	80.7	14.2	13.3
MEROPEN® (meropenem) Carbapenem antibiotic	8.2	7.8	(0.4)	(4.5)	81.4	10.3	9.6
EBASTEL® (ebastine) Antiallergic	3.7	2.9	(0.8)	(21.2)	51.7	5.8	5.6
EXCEGRAN® (zonisamide) Antiepileptic	2.5	2.4	(0.1)	(3.4)	74.7	3.1	3.2
DOPS® (droxidopa) Noradrenergic neural function	2.5	2.4	(0.1)	(2.4)	79.9	3.1	3.0

Note: Figures in parentheses [ ] are previously disclosed forecasts.

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 Forecasts(%)	FY2012	FY2013 (Forecasts)
LUNESTA® (eszopiclone) Sedative hypnotic	33.2	42.9	9.7	29.2	76.4	44.8	[55.2] 56.2
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	11.1	28.7	17.6	157.8	73.3	16.1	[36.2] 39.2
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	9.3	12.3	3.0	32.2	69.7	12.7	17.6
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	20.9	9.4	(11.5)	(54.9)	80.6	25.3	11.7
ALVESCO® (ciclesonide) Inhaled corticosteroid	2.2	3.3	1.1	47.4	80.8	3.1	4.1
OMNARIS® (ciclesonide) Corticosteroid nasal spray	1.1	1.6	0.5	45.9	65.7	1.9	2.5
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	0.4	1.5	1.2	317.2	68.8	0.4	2.2
Industrial property revenues	6.8	3.1	(3.6)	(53.5)	85.0	7.8	3.7

China (Billions of yen)

Brand name (Generic name)	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 Forecasts(%)	FY2012	FY2013 (Forecasts)
MEROPEN® (meropenem)	4.8	6.6	1.8	37.3	75.5	6.3	8.8

Other Regions (Billions of yen)

Brand name (Generic name)	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 Forecasts(%)	FY2012	FY2013 (Forecasts)
MEROPEN® (meropenem) (Export)	5.3	4.2	(1.1)	(20.6)	85.0	6.2	5.0
EXCEGRAN® (zonisamide) (Export)	1.3	1.1	(0.2)	(16.8)	84.5	1.8	1.3
GASMOTIN® (mosapride citrate) (Export)	0.6	0.3	(0.3)	(46.9)	44.1	0.8	0.7
Industrial property revenues	0.2	0.6	0.5	294.7	6.6	0.3	9.2

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

Brand name (Generic name) Therapeutic indication	FY2012 Apr.- Dec. (A)	FY2013 Apr.- Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 Forecasts(%)	FY2012	FY2013 (Forecasts)
LUNESTA® (eszopiclone)	419	432	14	3.3	76.5	561	[555] 565
LATUDA® (lurasidone)	140	289	149	106.0	73.4	202	[364] 394
BROVANA® (arformoterol tartrate)	117	124	7	5.7	69.8	160	177
XOPENEX® (levalbuterol HCl)	263	95	(168)	(63.9)	81.1	317	117
ALVESCO® (ciclesonide)	28	33	5	17.8	81.3	38	41
OMNARIS® (ciclesonide)	14	17	2	16.6	66.1	24	25
ZETONNA® (ciclesonide)	5	15	11	233.4	69.2	5	22
Industrial property revenues	85	32	(54)	(62.9)	85.5	98	37

Note: Figures in parentheses [ ] are previously disclosed forecasts.

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of Mar. 31, 2013 (A)	As of Dec. 31, 2013 (B)	(B)-(A)
[Assets]	607.2	658.2	51.0
Current assets:	333.4	355.2	21.7
Cash and time deposits	18.8	26.7	8.0
Notes and accounts receivable	97.2	106.6	9.4
Marketable securities	86.5	91.3	4.9
Inventories	62.7	62.4	(0.3)
Deferred tax assets	30.1	27.7	(2.4)
Short-term loans receivable	34.4	35.8	1.4
Others	4.0	4.8	0.8
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)
Fixed assets:	273.8	303.0	29.2
Property, plant and equipment:	69.9	74.6	4.7
Buildings and structures	39.9	45.7	5.8
Machinery, equipment and carriers	9.4	10.0	0.5
Land	10.3	10.3	0.1
Construction in progress	5.8	1.8	(4.0)
Others	4.4	6.8	2.3
Intangible assets:	146.3	160.2	13.9
Goodwill	71.3	83.8	12.5
Patent rights	17.4	7.9	(9.5)
In-process research & development	50.7	53.9	3.2
Others	7.0	14.6	7.7
Investments and other assets:	57.6	68.2	10.6
Investment securities	40.8	44.2	3.3
Deferred tax assets	7.6	14.4	6.9
Others	9.2	9.7	0.4
Allowance for doubtful receivables	(0.0)	(0.0)	0.0
Total assets	607.2	658.2	51.0

New Chemistry Research Building in Osaka Research Center(excluding depreciation)
Buildings +4.5
Construction in progress -2.3
Others +1.2

Increase +2.4
Amortization -4.9
Currency +15.0

Transfer +0.5
Amortization -12.7
Currency +2.8

Transfer -0.5
Impairment -4.2
Currency +8.0

Accounts receivable turnover period (in months)	3.35	3.37

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2013 (A)	As of Dec. 31, 2013 (B)	(B)-(A)
[Liabilities]	258.0	255.5	(2.5)
Current liabilities:	124.8	125.7	0.8
Notes and accounts payable	14.3	13.0	(1.3)
Current portion of bonds payable	10.0	10.0	—
Current portion of long-term loans payable	10.0	10.0	—
Income taxes payable	2.1	4.5	2.4
Reserve for bonuses	7.6	4.0	(3.6)
Reserve for sales returns	5.7	9.2	3.5
Reserve for sales rebates	19.2	26.7	7.5
Accounts payable-other	34.8	25.5	(9.2)
Others	21.3	22.8	1.5
Long-term liabilities:	133.1	129.8	(3.3)
Bonds payable	60.0	60.0	—
Long-term loans payable	35.0	27.5	(7.5)
Deferred tax liabilities	14.5	16.6	2.1
Liability for retirement benefits	11.0	11.2	0.1
Others	12.6	14.6	2.0
[Net assets]	349.2	402.7	53.5
Shareholders' equity:	346.2	355.6	9.4
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	308.6	318.0	9.4
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	3.1	47.1	44.1
Unrealized gains on available-for-sale securities, net of tax	14.1	16.5	2.4
Foreign currency translation adjustments	(11.0)	30.7	41.7
Total liabilities and net assets	607.2	658.2	51.0

Total interest-bearing debt
115.0→107.5(-7.5)

Payment of the license value, etc.

Net income +19.2
Payment of the dividend -7.2
Influence of fiscal year change -2.6
(North America -2.9, China +0.3)

Currency exchange rates: yen/$
12/2012 12/2013
86.6 → 105.4

IV. Quarterly Business Results

(Billions of yen)

	FY2012				FY2013		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Net sales	89.1	89.7	90.5	78.5	89.6	91.8	103.1
Cost of sales	25.2	24.8	26.3	25.3	25.3	25.2	27.7
SG&A expenses	53.0	55.7	51.4	60.8	55.3	58.2	58.2
SG&A expenses less R&D costs	38.9	42.0	39.3	40.9	40.6	41.4	40.7
R&D costs	14.1	13.7	12.1	19.9	14.7	16.8	17.5
Operating income (loss)	10.9	9.1	12.7	(7.7)	9.0	8.4	17.2
Non-operating income	1.1	0.3	0.8	0.8	0.9	0.3	0.5
Non-operating expenses	0.5	1.0	0.7	1.4	0.5	0.8	0.8
Ordinary income (loss)	11.5	8.4	12.8	(8.2)	9.5	7.9	16.9
Extraordinary income	—	—	—	—	—	3.8	0.0
Extraordinary loss	1.5	—	2.9	2.0	1.0	5.3	0.1
Income (Loss) before income taxes and minority interests	10.0	8.4	10.0	(10.2)	8.5	6.5	16.8
Net income (loss)	5.7	5.3	5.9	(6.8)	4.8	3.9	10.5

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

V. Major consolidated subsidiaries (As of December 31, 2013)

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	147	103	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	1,435	60	752
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, 2013	As of Dec. 31, 2013
consolidated		7,218	6,965
non-consolidated		4,457	4,403
MRs Japan	(excluding managers)	1,410	1,410
	(including managers)	1,610	1,610
MRs U.S.	(excluding managers)	830	600
	(including managers)	940	680
MRs China	(excluding managers)	350	400
	(including managers)	470	520

VI. Development Pipeline (As of January 31, 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 and Switzerland
			Bipolar I depression		Approved in the U.S.
			Bipolar maintenance		
	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house (BBI)	Global clinical trial
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	
Phase II/III	EPI-743 Oral	TBD	Leigh syndrome	Edison Pharmaceutical	

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 dose: 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 cancer	Joint research with Chugai Pharmaceutical	Independent development after April 2013
	DSP-5990 Injection	ceftaroline fosamil	MRSA infection	Takeda Pharmaceutical	
	WT2725 Injection	TBD	Solid cancer	Joint research with Chugai	Independent development after April 2013
	BBI608 Oral	TBD	Gastric cancer (Combination therapy)	In-house (BBI)	

[Main revisions since the 2Q announcement of October 2013]

MEROPEN® (Change of dose / bacterial meningitis)	Deleted due to approval (Approved in December 2013)
SUREPOST® (New indication)	Change from Phase III to Submitted (Submitted in December 2013)
BBI608 (Gastric cancer / Combination therapy)	Newly added in Phase I

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	APTIOM® Oral	eslicarbazepine acetate	Epilepsy (Adjunctive therapy)	BIAL	U.S.	Approved in November 2013
Submitted	APTIOM® Oral	eslicarbazepine acetate	Epilepsy (Adjunctive therapy)	BIAL	Canada	Submitted in June 2013 Approved in the U.S.
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Submitted in August 2013 Brand name in Japan: CALSED®
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Australia	Submitted in March 2013 Approved in the U.S. ,Canada and Switzerland
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Submitted in September 2013 Brand name in Japan: LONASEN®
	LATUDA® Oral	lurasidone hydrochloride	(New indication) Bipolar I depression	In-house	Canada	Submitted in August 2012 Approved in the U.S.
Phase III	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house (BBI)	U.S., Canada, etc.	Global clinical trial
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Approved in the U.S., Canada and Switzerland
	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)

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
Phase II	BBI608 Oral	TBD	Colorectal cancer (Combination therapy)	In-house (BBI)	U.S., Canada	
	SUN-101 Inhalant	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	In-house (Sunovion)	U.S.	From the former Elevation Pharmaceuticals
	SEP-225289 Oral	TBD	Attention-deficit hyperactivity disorder (ADHD)	In-house (Sunovion)	U.S.	
Phase I/II	BBI608 Oral	TBD	Solid cancer (Combination therapy)	In-house (BBI)	U.S., Canada	
Phase I	DSP-1053 Oral	TBD	Major depressive disorder (MDD)	In-house	U.S.	
	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S.	
	WT2725 Injection	TBD	Solid cancer, Hematologic cancer	Joint research with Chugai	U.S.	Independent development after April 2013
	BBI503 Oral	TBD	Solid cancer (Monotherapy)	In-house (BBI)	U.S., Canada	
	SEP-363856 Oral	TBD	Schizophrenia	In-house (Sunovion)	U.S.	
	BBI608 Oral	TBD	Gastrointestinal cancer (Combination therapy)	In-house (BBI)	U.S., Canada	

[Main revisions since the 2Q announcement of October 2013]

APTIOM® (Eslicarbazepine acetate)	Approved and preparing for launch in the U.S. (Epilepsy / Adjuctive therapy: Approved in November 2013)
BBI608 (Gastrointestinal cancer / Combination therapy)	Newly added in Phase I in the U.S. and Canada

Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Proposed Indication	Status of development
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.
ranirestat AS-3201	Diabetic neuropathy	Out-licensed to Eisai for the worldwide territory, excluding Japan, in September 2005. Phase II / III study ongoing in the U.S., Canada and Europe by Eisai.
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. NDA submitted in the U.S. by Chelsea for neurogenic orthostatic hypotension in September 2011. Complete Response Letter received from FDA in March 2012. Chelsea resubmitted to FDA in July 2013. FDA Advisory Committee recommended approval in January 2014. 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 Switzerland for schizophrenia in March 2012. Takeda submitted an MAA in Europe for schizophrenia by the centralised authorisation procedure 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. The Committee for Medicinal Products for Human Use (CHMP) of EMA recommended approval in January 2014.
SMP-986	Nocturia	Out-licensed to Nippon Shinyaku Co., Ltd. for rights in Japan to develop and commercialize in March 2013.

[Main revisions since the 2Q announcement of October 2013]

Droxidopa (DOPS®)	FDA Advisory Committee recommended approval in January 2014.
Lurasidone hydrochloride (SM-13496)	The Committee for Medicinal Products for Human Use (CHMP) of EMA recommended approval in January 2014.

VII. Profile of Major Products under Development (As of January 31, 2014)

APTIOM® (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- A novel voltage-gated sodium channel inhibitor. Sunovion obtained the approval of APTIOM® for use as adjunctive treatment of partial-onset seizures in the U.S. in November 2013. 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. This drug is expected to be an important new treatment option for people living with epilepsy.
- Development stage:

  Epilepsy (adjunctive therapy): Approved in November 2013 and preparing for launch in the U.S.
  Submitted in Canada in June 2013

  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 which 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 trials 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 trials 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 February 2011 in the U.S. Launched in Canada for the treatment of schizophrenia in September 2012. 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.
- Development stage:

Schizophrenia:	Submitted in Europe by Takeda Pharmaceutical and in Taiwan by Standard Chem. & Pharm. Submitted in Australia Phase III in Japan and China In addition, Phase III study in the U.S., Europe, etc. to test the hypothesis that LATUDA is effective in the long term maintenance treatment of schizophrenia completed and data analysis in progress.
Bipolar I depression:	Submitted in Canada 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.
- AS-3201 was out-licensed to Eisai for the overseas territory in September 2005. Eisai is conducting Phase II / III studies in the U.S., Canada and Europe.
- Development stage: Phase III in Japan

BBI608　　Solid cancer

- Developed in-house (BBI)
- First-in class Molecular Targeted Drug (small molecular compound, oral agent). BBI608 is expected to have excellent efficacy in monotherapy and combination therapy with chemotherapy by inhibiting both growth of tumor cells and maintenance of cancer stem cells. Highly safe, easy-to-use with existing chemotherapy. No particular hematologic toxicity observed.
- Development stage:
  Colorectal cancer (monotherapy): Phase III in the U.S., Canada and Japan, etc.
  Colorectal cancer (combination therapy with cetuximab, panitumumab or capecitabine): Phase II in the U.S. and Canada
  Solid cancer (combination therapy with paclitaxel): Phase I/II in the U.S. and Canada
  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

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

- 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)
- 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.

SEP-225289　　Attention-deficit hyperactivity disorder (ADHD)

- Developed in-house
- 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.

WT4869　　Myelodysplastic syndromes (MDS), Solid cancer

- 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 and solid cancers that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- Development stage:

Myelodysplastic syndromes (MDS):	Phase I/II in Japan
Solid cancer:	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 a 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 four countries. 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-5990 MRSA infection

- In-licensed from Takeda Pharmaceutical (Takeda's product code: TAK-599)
- DSP-5990 is a cephem antibiotic, and has strong activities against gram-positive bacteria including MRSA and multiply-resistant *Streptococcus pneumonia* and also gram-negative bacteria.
- In October 2010, approved in the U.S. by Forest Laboratories. In August 2012, approved in Europe by AstraZeneca .
- Development stage: Phase I in Japan

DSP-1053 Major depressive disorder (MDD)

- Developed in-house
- DSP-1053 is a new antidepressant drug candidate that shows an inhibitory effect on serotonin transporter and modulatory effects on monoamine receptors. By these mechanisms, DSP-1053 has the potential to show early onset of action and efficacy for depression and anxiety.
- Development stage: Phase I in the U.S.

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 cancer, Hematologic cancer

- 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 and solid cancers that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- Development stage:
  Hematologic and Solid cancers: Phase I in the U.S.
  Solid cancer: Phase I in Japan

BBI503 Solid cancer

- Developed in-house (BBI)
- First-in class Molecular Targeted Drug (small molecular compound, oral agent). BBI503 is expected to have excellent efficacy in monotherapy and combination therapy with chemotherapy by inhibiting both growth of tumor cells and maintenance of cancer stem cells by a different mechanism to BBI608. Easy-to-use with existing chemotherapy, expected to be highly safe.
- Development stage: Phase I in the U.S. and Canada

SEP-363856 Schizophrenia

- Developed in-house (Sunovion)
- 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-743 Leigh syndrome

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