Securities Code: 4506

Supplementary Financial Data for the Year Ended March 31, 2012

May 10, 2012

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)

	FY2010	FY2011	Change (%)	FY2012 2Q (Forecast)	Change (%)	FY2012 (Forecast)	Change (%)
Net sales	379.5	350.4	(7.7)	176.0	(1.1)	348.0	(0.7)
Cost of sales	110.0	98.9	(10.2)	50.0	0.5	101.0	2.2
SG&A expenses	238.5	231.1	(3.1)	115.0	1.3	225.0	(2.7)
SG&A expenses less R&D costs	170.4	174.2	2.3	86.0	(0.3)	163.0	(6.5)
R&D costs	68.2	56.9	(16.5)	29.0	6.3	62.0	9.0
Operating income	31.0	20.4	(34.1)	11.0	(25.3)	22.0	7.8
Ordinary income	28.6	18.9	(34.0)	10.5	(27.5)	21.0	11.3
Net income	16.8	8.6	(48.6)	5.0	(47.8)	10.5	21.7

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.

EBITDA (Billions of yen)	78.0	59.9	32.5	58.5
Earnings per share (yen)	42.27	21.72	12.58	26.43
Return on equity (ROE)	5.0%	2.7%	—	—
Payout ratio	42.6%	82.9%	71.5%	68.1%

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2010	FY2011
Net cash provided by operating activities	55.0	48.4
Net cash used in investing activities	(6.6)	(4.4)
Net cash used in financing activities	(20.3)	(32.9)
Cash and cash equivalents at the end of period	82.9	92.2

DSP 48.1
US Subsidiary 37.1

3. Financial Results of U.S. Subsidiary（Before Elimination）

(1) Excluding mainly amortization of patent rights and goodwill.

(Billions of yen)

	FY2010	FY2011
Net sales	121.9	112.8
Cost of sales	12.5	14.3
SG&A expenses	86.4	89.3
SG&A expenses less R&D costs	63.5	69.7
R&D costs	22.9	19.5
Operating income	23.0	9.2
Ordinary income	23.3	9.3
Extraordinary loss	0.2	1.2
Net income	15.3	5.5

(2) Mainly amortization of patent rights and goodwill.

(Billions of yen)

	FY2010	FY2011
Net sales	—	—
Cost of sales	3.3	—
SG&A expenses	31.4	27.7
Operating income	(34.7)	(27.7)
Ordinary income	(34.7)	(27.7)
Extraordinary loss	2.2	2.3
Net income	(24.6)	(20.2)

4. Currency Exchange Rates (Billions of yen)

	FY2011		FY2012	Forex sensitivity (2012 Jan-Dec) (Impact of yen strength by 1yen/dollar)	
	Fiscal Year end rate	Average rate	(Forecast rate)		
Yen / USD	77.7	79.8	83.0	Net Sales	(1.3)
Yen / RMB	12.3	12.4	12.0	Operating Income	0.3

5. Capital Expenditures and Depreciation (Billions of yen)

	FY2010	FY2011	Change	FY 2012 Forecast	Change
Capital expenditures (including intangible assets)	8.7	8.7	0.1	12.0	3.3
Depreciation and amortization	12.3	11.5	(0.8)	9.0	(2.5)

Note: Excluding the amortization associated with acquisition of U.S subsidiary

・Major continuing capital expenditure projects for FY2012
Construction operation of new research building in Osaka research center¥3.5billion
(Total budget ¥8.7billion, plan to be completed in March 2013)

(Reference) Statements of Income (Non-Consolidated)
(Billions of yen)

	FY2010	FY2011	Change (%)	FY2011 Group-to-parent ratio
Net sales	229.8	203.5	(11.4)	1.72
Cost of sales	69.4	58.7	(15.4)	
SG&A expenses	116.9	108.5	(7.2)	
SG&A expenses less R&D costs	67.9	67.5	(0.6)	
R&D costs	49.1	41.0	(16.4)	
Operating income	43.5	36.3	(16.4)	0.56
Ordinary income	41.2	35.2	(14.5)	0.54
Net income	26.8	22.1	(17.6)	0.39
Earnings per share (yen)	67.34	55.52		

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Incoı

(Billions of yen)

	FY2010 (A)	FY2011 (B)	(B)-(A)	Change (%)
Net sales	379.5	350.4	(29.1)	(7.7)
Overseas sales	152.2	130.2	(22.0)	(14.4)
〔% of net sales〕	[40.1]	[37.2]		
Cost of sales	110.0	98.9	(11.2)	(10.2)
Gross profit	269.5	251.5	(17.9)	(6.7)
SG&A expenses	238.5	231.1	(7.4)	(3.1)
Labor costs	67.5	69.8	2.3	3.4
Advertising and promotion costs	17.2	18.9	1.8	10.4
Sales promotion costs	14.0	14.1	0.0	0.3
Depreciation and amortiz	35.2	31.3	(3.8)	(10.9)
Other costs	36.6	40.1	3.6	9.8
SG&A expenses less R&D costs	170.4	174.2	3.9	2.3
R&D costs	68.2	56.9	(11.3)	(16.5)
Operating income	31.0	20.4	(10.5)	(34.1)
Non-operating income	3.3	2.1	(1.2)	
Non-operating expenses	5.6	3.6	(2.0)	
Ordinary income	28.6	18.9	(9.7)	(34.0)
Extraordinary income	—	1.2	1.2	
Gain on sales of property, plant and	—	1.2	1.2	
Extraordinary loss	3.6	3.8	0.2	
Impairment loss	3.2	2.3	(0.9)	
Business structure improvement	—	1.2	1.2	
Loss on valuation of investment securities	0.3	0.2	(0.1)	
Income before income taxes and minority interests	25.0	16.3	(8.7)	(34.8)
Income taxes	8.3	7.7	(0.6)	
Income before minority interests	16.8	8.6	(8.2)	(48.6)
Net income	16.8	8.6	(8.2)	(48.6)

・Effect of yen appreciation (10.2)
・Decrease due to the FY2010 lump-sum income for the out-licensing of lurasidone (10.0)
・Influence of changing method of summing up sales for Pet Food (4.7)

・Decreased amortization of patent rights and goodwill (3.6)

・Increased costs related to LATUDA® launch
・Effect of yen appreciation (9.8)

・Decrease of industrial property lump-sum
・Effect of yen appreciation (2.3)

・Sale of Tokyo Northern Office

・Loss from impairment of patent rights

・Restructuring charges in U.S subsidiary

・Increase due to revision of the Corporation Tax Act of Japan

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

2. Consolidated Statements of Comprehensive Income (I

(Billions of yen)

	FY2010	FY2011
Income before minority interests	16.8	8.6
Other comprehensive incom	(28.9)	(6.2)
Unrealized gains (losses) on available-for-sale securities, net of tax	(2.5)	2.6
Foreign currency translation adjustment	(26.3)	(8.8)
Comprehensive income (loss)	(12.1)	2.4

3. Segment Information（FY2011） (Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	180.1	108.4	—	6.5	15.2	310.3	40.1	350.4
Sales to customers	179.9	108.4	—	6.5	15.2	310.1	40.3	350.4
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	46.8	11.2	—	1.9	7.9	67.8	31.0	98.9
Gross profit	133.3	97.2	—	4.6	7.3	242.4	9.1	251.5
SG&A expenses less R&D costs	66.8	69.8	27.7	3.6	0.3	168.3	5.9	174.2
Income (loss) of segment	66.4	27.4	(27.7)	1.0	7.0	74.1	3.2	77.3
R&D costs						56.2	0.7	56.9
Operating income						17.9	2.5	20.4

Notes *1: Excluding amortization of patent rights and goodwill.
*2: Includes the elimination of intersegment transaction.
*3: Pharmaceuticals segmentation has been changed since FY2011.
In order to manage R&D costs globally, they are not included in each segment.

Segment Information（FY2012 Forecast） (Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	180.0	109.1	—	7.1	9.7	305.9	42.1	348.0
Sales to customers	179.7	109.1	—	7.1	9.7	305.6	42.4	348.0
Intersegment	0.3	—	—	—	—	0.3	(0.3)	—
Cost of sales	49.8	11.8	—	1.8	5.2	68.6	32.4	101.0
Gross profit	130.2	97.3	—	5.3	4.5	237.3	9.7	247.0
SG&A expenses less R&D costs	63.4	61.7	27.2	4.1	0.4	156.8	6.2	163.0
Income (loss) of segment	66.8	35.6	(27.2)	1.2	4.1	80.5	3.5	84.0
R&D costs						61.1	0.9	62.0
Operating income						19.4	2.6	22.0

Notes *1: Excluding amortization of patent rights and goodwill.
*2: Includes the elimination of intersegment transaction.

(Reference) Segment Information（FY2010） (Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	183.0	117.6	—	5.7	28.4	334.8	44.7	379.5
Sales to customers	182.9	117.6	—	5.7	28.4	334.6	44.9	379.5
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	49.2	12.5	3.3	1.2	8.0	74.2	35.9	110.0
Gross profit	133.9	105.2	(3.3)	4.5	20.4	260.6	8.9	269.5
SG&A expenses less R&D costs	65.7	63.6	31.4	3.3	0.3	164.3	6.1	170.4
Income (loss) of segment	68.2	41.6	(34.7)	1.2	20.1	96.3	2.8	99.1
R&D costs						67.4	0.8	68.2
Operating income						29.0	2.0	31.0

Notes *1: Excluding mainly amortization of patent rights and goodwill.
*2: Includes the elimination of intersegment transaction.
*3: According to change of segmentation from FY2011, results from FY2010 are recalculated by new segmentation.

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

	FY2010 (A)	FY2011 (B)	(B)-(A)	Change (%)	FY2012 2Q (Forecast)	FY2012 (Forecast)
Japan	182.9	179.9	(3.0)	(1.6)	87.3	179.7
North America	117.6	108.4	(9.2)	(7.8)	57.9	109.1
China	5.7	6.5	0.9	15.0	3.3	7.1
Other Regions	28.4	15.2	(13.2)	(46.4)	6.2	9.7

5. Sales of Major Products

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

Brand name (Generic name) Therapeutic indication	FY2010(A)	FY2011(B)	(B)-(A)	Change (%)	FY2012 2Q (Forecast)	FY2012 (Forecast)
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	41.4	36.0	(5.4)	(13.0)	14.8	28.7
GASMOTIN® (mosapride citrate) Gastroprokinetic	21.0	21.2	0.2	0.9	9.4	18.5
PRORENAL® (limaprost alfadex) Vasodilator	14.9	15.5	0.6	3.8	8.0	15.8
MEROPEN® (meropenem) Carbapenem antibiotic	12.6	12.2	(0.5)	(3.6)	4.7	10.2
AVAPRO® (irbesartan) Therapeutic agent for hypertension	8.3	10.7	2.4	28.5	6.7	14.3
LONASEN® (blonanserin) Atypical antipsychotic	9.0	9.8	0.9	9.8	6.1	13.0
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	6.2	9.1	3.0	48.1	4.9	10.0
EBASTEL® (ebastine) Antiallergic	8.6	6.6	(2.0)	(23.2)	2.6	5.9
TRERIEF® (zonisamide) Parkinson's disease drug	3.7	5.3	1.6	44.0	3.3	7.0
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	4.6	4.5	(0.1)	(1.7)	2.4	4.8
SUMIFERON® (interferon-αNAMALWA) Natural alpha interferon	5.1	3.6	(1.4)	(28.3)	1.6	2.8
EXCEGRAN® (zonisamide) Antiepileptic	3.5	3.3	(0.2)	(5.0)	1.6	3.3
DOPS® (droxidopa) Noradrenergic neural function	3.3	3.2	(0.1)	(3.6)	1.6	3.1

(Reference)

MELBIN® (metformin) Biguanide oral hypoglycemic	4.4	0.8	(3.6)	(82.9)	—	—

Japan (New products)

METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	0.3	7.8	7.5	2,855.8	5.3	11.9
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular carcinoma (Launch: Jan. 2010)	1.5	1.3	(0.2)	(16.0)	0.6	1.3
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	—	0.1	0.1	—	0.8	2.2

North America

(Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2010 (A)	FY2011 (B)	(B)-(A)	Change (%)	FY2012 2Q (Forecast)	FY2012 (Forecast)
LUNESTA® (eszopiclone) Sedative hypnotic	53.9	42.1	(11.8)	(21.9)	22.2	42.6
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	38.4	33.4	(5.0)	(12.9)	13.0	21.4
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	9.3	10.2	0.9	9.9	6.1	13.2
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb, 2011)	—	6.9	6.9	—	7.0	15.8
OMNARIS® (ciclesonide) Corticosteroid nasal spray	4.8	5.1	0.4	7.9	—	0.3
ALVESCO® (ciclesonide) Inhaled corticosteroid	2.5	2.8	0.3	11.1	1.8	3.8
Industrial property revenues	6.6	5.8	(0.9)	(13.2)	6.1	7.7

China

(Billions of yen)

Brand name (Generic name)	FY2010 (A)	FY2011 (B)	(B)-(A)	Change (%)	FY2012 2Q (Forecast)	FY2012 (Forecast)
MEROPEN® (meropenem)	5.0	5.5	0.6	11.1	2.7	5.8

Other Regions (Sales to customers)

(Billions of yen)

Brand name (Generic name)	FY2010 (A)	FY2011 (B)	(B)-(A)	Change (%)	FY2012 2Q (Forecast)	FY2012 (Forecast)
MEROPEN® (meropenem) (Export)	14.5	11.9	(2.6)	(17.6)	4.6	6.4
EXCEGRAN® (zonisamide) (Export)	1.5	1.2	(0.3)	(19.6)	0.6	1.2
GASMOTIN® (mosapride citrate) (Export)	1.0	0.8	(0.2)	(20.8)	0.3	0.6
Industrial property revenues	11.2	0.5	(10.7)	(95.5)	0.4	0.7

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

(Millions of dollars)

Brand name (Generic name)	Jan-Mar 2011(A)	Jan-Mar 2012(B) (Unaudited)	(B)-(A)	Change (%)	Jan-Jun 2012 (Forecast)	Jan-Dec	
						FY2011	FY2012 (forecast)
LUNESTA® (eszopiclone)	124	142	19	15.1	267	528	513
XOPENEX® (levalbuterol HCl)	137	101	(36)	(26.1)	157	419	257
BROVANA® (arformoterol tartrate)	33	39	6	16.6	74	127	158
LATUDA® (lurasidone)	35	39	4	13.0	84	86	190
OMNARIS® (ciclesonide)	16	0	(16)	(98.9)	—	64	3
ALVESCO® (ciclesonide)	9	9	0	4.4	22	35	46
Industrial property revenues	23	28	5	20.1	73	72	93
Others	7	7	0	9.5	21	27	55
Total	383	366	(17)	(4.5)	698	1,359	1,315

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 2011/03/31 (A)	As of 2012/03/31 (B)	(B)-(A)
[Assets]	589.9	559.4	(30.5)
Current assets:	333.0	334.3	1.3
Cash and time deposits	14.9	13.0	(2.0)
Notes and accounts receivable	107.8	102.0	(5.8)
Marketable securities	90.9	99.1	8.2
Inventories	56.0	58.1	2.1
Deferred tax assets	33.5	31.8	(1.7)
Short-term loans	25.0	25.0	—
Others	5.0	5.4	0.4
Allowance for doubtful receivables	(0.1)	(0.1)	0.0
Fixed assets:	256.9	225.2	(31.7)
Property, plant and equipment:	69.8	66.7	(3.1)
Buildings and structures	41.7	40.4	(1.4)
Machinery, equipment and carriers	12.1	9.9	(2.2)
Land	10.3	10.2	(0.0)
Construction in progress	0.9	2.1	1.2
Others	4.8	4.1	(0.7)
Intangible assets:	143.3	107.7	(35.6)
Goodwill	70.4	64.3	(6.1)
Patent rights	61.0	32.5	(28.5)
Others	11.9	10.9	(1.0)
Investments and other assets:	43.8	50.8	6.9
Investment securities	27.9	29.9	1.9
Deferred tax assets	7.0	11.6	4.6
Others	9.0	9.3	0.4
Allowance for doubtful receivables	(0.1)	(0.1)	0.0
Total assets	589.9	559.4	(30.5)

・The lump-sum for out-licensing of lurasidone was stated as account receivable.

・Amortization (24.0)
・Currency translation (2.2)
・Loss from impairment of patent rights (2.3)

Accounts receivable turnover period (in months)	3.41	3.49

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 2011/03/31 (A)	As of 2012/03/31 (B)	(B)-(A)
[Liabilities]	265.9	240.2	(25.7)
Current liabilities:	157.2	106.0	(51.2)
Notes and accounts payable	15.6	16.9	1.2
Short-term loans payable	50.0	—	(50.0)
Current portion of long-term loans payable	10.6	10.0	(0.6)
Income taxes payable	7.7	5.4	(2.2)
Reserve for bonuses	7.4	7.6	0.2
Reserve for sales returns	2.3	3.7	1.4
Reserve for sales rebates	15.9	18.5	2.7
Accounts payable-other	33.8	30.0	(3.8)
Others	13.8	13.9	0.0
Long-term liabilities:	108.7	134.2	25.5
Bonds payable	50.0	70.0	20.0
Long-term loans payable	43.0	48.0	5.0
Liability for retirement benefits	10.3	10.8	0.5
Others	5.4	5.4	0.0
[Net assets]	324.0	319.2	(4.8)
Shareholders' equity:	341.8	343.3	1.5
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	304.2	305.7	1.5
Treasury stock	(0.6)	(0.6)	(0.0)
Accumulated other comprehensive income (loss):	(17.8)	(24.0)	(6.2)
Unrealized gains on available-for-sale securities, net of tax	5.4	8.0	2.6
Foreign currency translation adjustment	(23.2)	(32.1)	(8.8)
Total liabilities and net assets	589.9	559.4	(30.5)

・Total interest-bearing debt
153.6→128.0 (25.6)

・Exchange Rates($)
81.5→77.7

IV. Quarterly Business Results

(Billions of yen)

	FY2010				FY2011			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Net sales	101.8	86.8	92.2	98.7	94.8	83.2	87.2	85.2
Cost of sales	32.6	25.2	25.9	26.3	25.8	24.0	24.2	24.9
SG&A expenses	54.4	61.4	54.2	68.5	56.2	57.3	55.4	62.2
SG&A expenses less R&D costs	39.9	43.1	40.7	46.7	42.6	43.7	42.0	46.1
R&D costs	14.5	18.3	13.5	21.8	13.6	13.7	13.4	16.2
Operating income	14.8	0.1	12.1	3.9	12.8	1.9	7.6	(1.9)
Non-operating income	1.1	0.8	0.7	0.7	1.0	0.5	0.6	0.1
Non-operating expenses	1.1	1.4	1.0	2.2	0.6	1.1	0.7	1.2
Ordinary income (loss)	14.8	(0.5)	11.8	2.4	13.2	1.3	7.5	(3.1)
Extraordinary income	—	—	—	—	—	1.2	0.0	—
Extraordinary loss	—	—	2.2	1.3	—	—	3.6	0.2
Income (loss) before income taxes and minority interests	14.8	(0.5)	9.6	1.1	13.2	2.6	3.9	(3.3)
Net income (loss)	9.3	(0.6)	6.1	2.0	8.1	1.5	0.7	(1.6)

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

V. Major consolidated subsidiaries (as of 2012/3/31)

	Domestic			Overseas	
	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Biomedical Co., Ltd.	Sunovion Pharmaceuticals Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	October 1947	July 2010	June 1998	January 1984	December 2003
Fiscal year	March 31	March 31	March 31	December 31	December 31
Ownership	100%	100%	100%	100%	100%
Sales (Billions of yen)	26.6	11.0	2.8	112.8	6.7
Number of employees	145	102	63	2,216	626
Businesses	Manufacturing and sales of food ingredients, food additives, and chemical product materials	Manufacturing, and sales of veterinary medicines, feedstuff, feed additives	Manufacturing and sales of diagnostics and research materials	Manufacturing and sales of pharmaceuticals	Manufacturing and sales of pharmaceuticals

Number of employees (as of 2012/03/31):

7,601 (consolidated)

4,449 (non-consolidated)

Number of MRs (as of 2012/3/31):

Japan 1,410 (excluding mana 1,620 (including managers)

U.S. 1,190 (excluding mana 1,320 (including managers)

China 330 (excluding mana 420 (including managers)

VI. Shareholder Positioning (As of March 31, 2012)

1. Total number of authorized shares: 1,500,000,000

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 588,699)

3. Number of shareholders: 18,350

4. Major shareholders:

Shareholders	Status of ownership	
	Number of shares held (Thousand shares)	Percentage of shareholding (%)
Sumitomo Chemical Co., Ltd.	199,434	50.20
Inabata & Co., Ltd.	27,282	6.87
The Master Trust Bank of Japan, Ltd. (Trust account)	14,829	3.73
Nippon Life Insurance Company	10,530	2.65
Japan Trustee Services Bank, Ltd. (Trust account)	8,724	2.20
Japan Trustee Services Bank, Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,928	1.24
Dainippon Sumitomo Pharma Employee shareholders' association	4,327	1.09
JP Morgan Securities Japan Co., Ltd.	2,850	0.72

Notes: *1: Percentage of shareholding is calculated excluding treasury stock (588,699 stocks).

*2: The numbers of shares held are rounded down to the nearest thousand shares.

VII. Development Pipeline (as of May 10, 2012)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Submitted	DSP-8153 Oral	amlodipine besilate / irbesartan	Hypertension	In-house	Submitted in Nov. 2011 Combination product
	SUREPOST® Oral	repaglinide	(New Indication) Type 2 diabetes Combination therapy with biguanide	Novo Nordisk	Submitted in Aug. 2012 Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes Monotherapy Combination with α-GI
			(New Indication) Type 2 diabetes Combination therapy with thiazolidine		
Phase III	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	
	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes Pediatric usage	Merck Santé	
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	
	MEROPEN® Injection	meropenem hydrate	(Change of maximum dose) Purulent meningitis: 6g daily	In house	Approved maximum recommended dose: 3g daily for severe or refractory cases of infectious diseases
	SUREPOST® Oral	repaglinide	(New Indication) Type 2 diabetes All combination therapies including DPP4 inhibitors	Novo Nordisk	Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes Monotherapy Combination with α-GI
Phase II	SMP-986 Oral	afacifenacin fumarate	Overactive bladder	In-house	
	PRORENAL® Oral	limaprost alfadex	(New Indication Carpal-tunnel syndrome	Joint research with Ono Pharmaceutical	Co-development with Ono Pharmaceutical. Approved indication: lumbar spinal canal stenosis, etc.

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharmaceutical	Co-development with Chugai Pharmaceutical
Phase I	DSP-3025 Collunarium	TBD	Bronchial asthma, Allergic rhinitis	In-house	
	WT4869 Injection	TBD	Solid cancer	Joint research with Chugai Pharmaceutical	Co-development with Chugai Pharmaceutical
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	
	DSP-1747 Oral	obeticholic acid	Primary biliary cirrhosis (PBC) , Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	
	DSP-5990 Injection	ceftaroline fosamil	MRSA Infection	Takeda Pharmaceutical	
	DSP-9599 Oral	TBD	Hypertension	In-house	

[Main revisions since the announcement of February 2012]

SUREPOST® (New indication)	Changed from Phase III to "Submitted" for Type 2 diabetes combination therapy with thiazolidine/biguanide (Submitted in April 2012) Newly added in Phase III for Type 2 diabetes, all combination therapies including DPP4 inhibitors
Lurasidone hydrochloride	Started New Phase III study
MEROPEN® (Change of maximum dose)	Newly added in Phase III
DSP-9599	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	Ciclesonide Nasal Aerosol Collunarium	ciclesonide	(HFA - New Formulation) Allergic rhinitis	Nycomed	U.S.	Approved in Jan. 2012. Brand name: ZETONNA™
Submitted	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy Adjunctive therapy	BIAL	U.S.	NDA submitted in March 2009.
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Canada	Submitted in June 2011. Approved in the U.S
Phase III	LATUDA® Oral	lurasidone hydrochloride	(New Indication) Bipolar I Depression	In-house	U.S. and Europe, etc.	Approved indication in the U.S.: Schizophrenia
			(New Indication) Bipolar Maintenance		U.S. and Europe, etc.	
			(New Indication) MDD with mixed features		U.S.	
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED®
	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy Monotherapy	BIAL	U.S.	
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Brand name in Japan: LONASEN®
Phase III under preparation	BBI608 Oral	TBD	Colorectal cancer (2^{nd}/3^{rd} line) Monotherapy	In-house (BBI)	U.S., Canada	
Phase II	SMP-986 Oral	afacifenacin fumarate	Overactive bladder	In-house	U.S. and Europe	
	BBI608 Oral	TBD	Colorectal cancer (2^{nd}/3^{rd} line) Combination therapy	In-house (BBI)	U.S., Canada	

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
Phase I/II	BBI608 Oral	TBD	Solid cancer (2^{nd}/3^{rd} line) Combination therapy with paclitaxel	In-house (BBI)	U.S., Canada	
Phase I	DSP-8658 Oral	TBD	Type 2 diabetes, Alzheimer's disease	In-house	U.S.	
	SEP-228432 Oral	TBD	Neuropathic pain, Major Depressive Disorder (MDD)	In-house (Sunovion)	U.S.	
	DSP-1053 Oral	TBD	Major Depressive Disorder (MDD)	In-house	U.S.	
	DSP-0565 Oral	TBD	Epilepsy	In-house	U.S.	
	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K	
	WT2725 Injection	TBD	Solid cancer	Joint research with Chugai	U.S.	Co-development with Chugai Pharmaceutical
	BBI503 Oral	TBD	Solid cancer monotherapy	In-house (BBI)	U.S., Canada	

[Main revisions since the announcement of February 2012]

LATUDA® (lurasidone hydrochloride)	Deleted due to approval for expansion of dose (new maximum recommended dose: 160 mg/day, U.S. approved in April 2012)
BBI608	Newly added in Phase III under preparation (Colorectal cancer monotherapy), Phase II (Colorectal cancer combination therapy), Phase I/II (Solid cancer)
DSP-2230	Newly added in Phase I (U.K)
WT2725	Newly added in Phase I (U.S)
BBI503	Newly added in Phase I

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. Phase III study for orthostatic hypotension in Europe and Phase II study of fibromyalgia in the UK are ongoing by Chelsea. Phase II study of intradialytic hypotension completed in the U.S. 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 is ongoing in Europe by AstraZeneca (AstraZeneca's product code: AZD-8848).
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. Both companies are currently developing lurasidone in Europe (Phase III study stage).

[Main revisions since the announcement of February 2012]

droxidopa	Chelsea received a Complete Response Letter from the FDA (March 2012)
eszopiclone	Deleted due to launch in Japan by Eisai (April 2012)

VIII. Profile of Major Products under Development (as of May 10, 2012)

DSP-8153 Hypertension

- Developed in-house
- DSP-8153 is a combination product of irbesartan (angiotensin II receptor blocker) with evidence for renoprotective effects and amlodipine besilate (calcium channel blocker) with evidence for cerebroprotective and cardioprotective effects. In clinical trials in Japan, DSP-8153 was effective for patients with essential hypertension uncontrolled by irbesartan or amlodipine besilate alone. Moreover, two doses are included in the application for this combination product, irbesartan 100mg/ amlodipine 5mg and irbesartan 100mg/ amlodipine 10mg. If approved, this will be the first combination product in Japan including 10mg of amlodipine.
- Development stage: NDA submitted in Japan

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 who met DSM-IV criteria for schizophrenia. In these studies, LATUDA demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. 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. Food and Drug Administration (FDA) in October 2010, and launched by Sunovion in February 2011 in the U.S.
- Development stage:

  Schizophrenia: NDS submitted in Canada
  Phase III in Japan
  Phase III (Co-development with Takeda Pharmaceutical in Europe)
  In addition, Phase III study is ongoing in the U.S., Europe, etc. to test the hypothesis that LATUDA is effective in the long term maintenance treatment of schizophrenia.

  Bipolar disorder: Bipolar I Depression: Phase III in the U.S. and Europe, etc.
  Bipolar Maintenance: Phase III in the U.S. and Europe, etc.

  MDD with mixed features: Phase III in the U.S.

STEDESA™ (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- STEDESA, the proposed trade name for eslicarbazepine acetate, is a novel voltage-gated sodium channel blocker. STEDESA has been studied in Phase III, multi-center, randomized, placebo-controlled studies, which involved patients from 23 countries. Patients involved in the studies were required to have at least four partial-onset seizures per month despite treatment with one to three concomitant antiepileptic drugs. After a two-week titration period, patients were assessed over a 12-week maintenance period with continued follow-up over a one-year, open-label period. The target indication for STEDESA is for adjunctive use in adult patients with partial onset seizures. STEDESA is expected to be safe and

tolerable, have clear dose-response correlation and marked and sustained seizure reduction.

- Development stage:
  Epilepsy (adjunctive therapy): NDA submitted in March 2009 in the U.S.
  Complete Response Letter received April 2010. Sunovion plans to resubmit the NDA in 3Q 2012 with new Phase III results.
  Epilepsy (monotherapy): Phase III in the U.S.

AS-3201 (ranirestat) 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 Colorectal cancer, 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 (2nd/3rd line, monotherapy): Phase III under preparation in the U.S. and Canada
  Colorectal Cancer (2nd/3rd line, combination therapy): Phase II in the U.S. and Canada
  Solid Cancer (2nd/3rd line combination therapy with paclitaxel): Phase I/II in the U.S. and Canada

SMP-986 Overactive bladder

- Developed in-house
- SMP-986 possesses the dual pharmacological actions of muscarinic receptor antagonism (non-selective) and inhibition of the bladder afferent pathway through Na^+-channel blockade. This compound is being evaluated for its ability to ease urinary urgency and reduce the frequency of both urination and incontinence. The compound has also exhibited the potential to have lower incidence of side effects related to muscarinic receptor antagonism, such as dry mouth.
- Development stage: Phase II in the U.S. and Europe. Phase II in Japan

WT4869 Myelodysplastic syndromes (MDS), Solid cancer

- Co-development 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 were 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 is conducting Phase II study in Europe. (AstraZeneca's code name: AZD-8848)
- Development stage: Phase I in Japan

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 I in Japan

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

- In-licensed from Intercept Pharmaceuticals Inc. (Intercept's product code: INT-747)
- DSP-1747 is a 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 I in Japan

DSP-5990 MRSA Infection

- In-licensed from Takeda Pharmaceutical Company Limited (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.
- Development stage: Phase I in Japan

DSP-8658 Diabetes, Alzheimer's disease

- Developed in-house
- DSP-8658 is a novel PPARα/γ modulator.
- Non-clinical studies suggest that DSP-8658 may offer advantages over marketed PPARγ agonists, particularly with respect to improvements in lipid metabolism and incidence of fluid retention or body weight gain in the treatment of diabetes.
- DSP-8658 may also have the potential as a treatment for Alzheimer's disease as the compound may improve symptomatic cognitive decline and show disease modification with mechanism of reduction in β amyloid by impacting a number of different mechanisms in marketed compounds.
- Development stage: Phase I in the U.S.

SEP-228432 Neuropathic pain, Major Depressive Disorder (MDD)

- Developed in-house (Sunovion)
- SEP-228432 is a new triple unbalanced reuptake inhibitor (TRI) that inhibits reuptake of serotonin, norepinephrine and dopamine. The compound is under development for neuropathic pain and MDD.
- Development stage: Phase I in the U.S.

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 on-set of action and higher antidepressant efficacy.
- Development stage: Phase I in the U.S.

DSP-0565 Epilepsy

- Developed in-house
- DSP-0565 is a new antiepileptic drug candidate which possesses new mechanisms in addition to blocking actions for sodium and calcium channel. This drug shows potent and broad antiepileptic efficacies in various animal models in which existing drugs do not have effect, DSP-0565 is expected to be a useful therapeutic option for treatment-resistant epilepsy or various types of seizures. Furthermore, since this drug has anti-depressant like action and weaker CNS side effects, DSP-0565 is expected to improve quality of life in epileptic patients.
- Development stage: Phase I in the U.S.

DSP-9599 Hypertension

- Developed in-house
- DSP-9599 is an oral direct renin inhibitor for treatment of hypertension. Unlike the ACE inhibitors and ARBs, DSP-9599 decreases plasma renin activity and inhibits the production of angiotensin I, and all downstream angiotensin peptides in the RAS (rennin-angiotensin system) such as angiotensin II. DSP-9599 is expected to reduce blood pressure and protect organs at least as effectively as ACE inhibitors or ARBs.
- Development stage: Phase I in Japan.

DSP-2230 Neurophathic 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.

WT2725 Solid cancer

- Co-development 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: Phase I in the U.S.

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: Solid Cancer (monotherapy) Phase I in the U.S. and Canada