

Supplementary Financial Data
for the Second Quarter of the Year Ending March 31, 2011

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October 29, 2010

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

I. Highlights of the Statements of Income

(Billions of yen)

	Six months ended 9/30/09	Six months ended 9/30/10	Change (%)	Year ended	Change (%)	Year ending	Change (%)
				3/31/10		3/31/11 (Forecast) ³	
Net sales	132.2	188.6	42.6	296.3	12.2	365.0	23.2
Cost of sales	51.3	57.8	12.7	112.3	8.2	108.5	(3.4)
SG&A expenses	62.0	115.8	86.9	148.4	14.9	238.5	60.7
SG&A expenses less R&D costs	37.7	83.0	120.0	97.0	27.1	171.5	76.8
R&D costs	24.2	32.8	35.3	51.4	(2.7)	67.0	30.4
Operating income	18.9	14.9	(21.0)	35.6	14.3	18.0	(49.5)
Ordinary income	19.1	14.4	(24.5)	33.8	7.8	15.5	(54.2)
Net income	12.7	8.7	(31.6)	21.0	4.9	9.0	(57.1)

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: Forecast released on July 30, 2010 are revised.

EBITDA (Billions of yen)	24.2	40.4	56.4	66.8
Earnings per share (yen)	31.85	21.77	52.75	22.65
Return on equity (ROE)	3.8%	2.5%	6.3%	2.7%
Payout ratio	28.3%	41.3%	34.1%	79.5%

2. Financial Results of US Subsidiary

(Excluding Impact of Valuations and Accounting Procedures) (Billions of yen)

	Six months ended 6/30/10	Nine months ended 9/30/10	Year ending
			12/31/10 (Forecast)
Net sales	63.0	91.9	121.5
Cost of sales	6.1	9.4	12.6
SG&A expenses	40.9	60.4	85.9
SG&A expenses less R&D costs	29.4	43.9	63.1
R&D costs	11.5	16.4	22.8
Operating income	16.0	22.1	23.0
Ordinary income	16.4	22.5	23.2
Net income	10.2	14.1	14.3

Note: Forecast released on July 30, 2010 are revised.

3. Impact of Accounting for Business Combinations Associated with Acquisition of Sunovion Pharmaceuticals Inc.

(Billions of yen)

	Six months ended 6/30/10	Nine months ended 9/30/10	Year ending
			12/31/10 (Forecast)
Net sales	—	—	—
Cost of sales	2.6	3.4	3.4
SG&A expenses	16.6	24.4	32.1
SG&A expenses less R&D costs	16.6	24.4	32.1
R&D costs	—	—	—
Operating income	(19.2)	(27.7)	(35.5)
Ordinary income	(19.2)	(27.7)	(35.5)
Net income	(12.8)	(18.5)	(23.7)

4. Currency Exchange Rates

	FY2010 1st half average rate	FY2010 2nd half Forecast rate
Yen / USD	91	85
Yen / Yuan	13	13

5. Capital Expenditures and Depreciation

(Billions of yen)

	Six months ended 9/30/09	Six months ended 9/30/10	Change	Year ended	Year ending	Change
				3/31/10	3/31/11 (Forecast)	
Capital expenditures (including intangible assets)	2.6	4.1	1.5	6.5	13.5	7.0
Depreciation and amortization	5.1	5.7	0.6	11.0	13.5	2.5

Note: Excluding the depreciation associated with acquisition of Sunovion Pharmaceuticals Inc.

II. Consolidated Statements of Income

1. Statements of Income

(Billions of yen)

	Six months ended 9/30/09 (A)	Six months ended 9/30/10 (B)	Breakdown of (B)-(A)	
			(B)-(A)	Change (%)
			US Subsidiaries	Except US Subsidiaries
Net sales	132.2	188.6	56.4	42.6
Overseas sales [% of net sales]	12.4 [9.4%]	74.0 [39.2%]	61.5	494.9
Cost of sales	51.3	57.8	6.5	12.7
Gross profit	80.9	130.7	49.9	61.6
SG&A expenses	62.0	115.8	53.8	86.9
Labor costs	16.8	34.1	17.3	103.3
Advertising and promotion costs	2.1	7.2	5.1	243.8
Sales promotion costs	5.4	6.3	0.8	15.0
Other costs	13.4	35.5	22.0	164.0
SG&A expenses less R&D costs	37.7	83.0	45.3	120.0
R&D costs	24.2	32.8	8.6	35.3
Operating income	18.9	14.9	(4.0)	(21.0)
Non-operating income	1.4	1.9	0.5	
Non-operating expenses	1.3	2.4	1.1	
Ordinary income	19.1	14.4	(4.7)	(24.5)
Income before income taxes and minority interests	19.1	14.4	(4.7)	(24.5)
Income taxes	6.4	5.7	(0.7)	
Minority interests in net income	0.0	—	(0.0)	
Net income	12.7	8.7	(4.0)	(31.6)

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.

2: Overseas sales includes the sales of export.

(Reference)

Statements of Income (Non-Consolidated)

(Billions of yen)

	Six months ended 9/30/09 (A)	Six months ended 9/30/10 (B)	Change (%)	Group-to-parent ratio
Cost of sales	45.6	38.6	(15.3)	
SG&A expenses	60.1	57.7	(4.0)	
SG&A expenses less R&D costs	35.9	34.3	(4.4)	
R&D costs	24.2	23.4	(3.5)	
Operating income	18.2	16.7	(8.1)	0.90
Ordinary income	18.3	15.7	(14.1)	0.91
Net income	11.9	10.2	(14.4)	0.85

Earnings per share (yen)

30.00

25.69

2. Segment Information (Six months ended 9/30/10)

(Billions of yen)

	Pharmaceuticals Segment						Others	Total
	Japan	U.S.*1	Impact of purchase price allocation*2	China	Elimination	Total		
Net sales	102.0	63.0	—	2.9	(3.8)	164.0	24.5	188.6
Sales to customers	100.8	60.8	—	2.5	—	164.0	24.5	188.6
Intersegment	1.2	2.2	—	0.4	(3.8)	0.0	(0.0)	—
Cost of sales	29.2	6.1	2.6	1.0	(1.1)	37.8	20.0	57.8
Gross profit	72.8	56.9	(2.6)	1.9	(2.7)	126.2	4.5	130.7
SG&A expenses	56.5	40.9	16.6	1.0	(2.6)	112.4	3.4	115.8
SG&A expenses less R&D costs	33.3	29.4	16.6	1.0	(0.4)	80.0	3.0	83.0
R&D costs	23.2	11.5	—	—	(2.2)	32.4	0.4	32.8
Operating income	16.3	16.0	(19.2)	0.8	(0.1)	13.8	1.1	14.9

Notes: *1: Excluding the impact of purchase price allocation by acquisition of Sunovion Pharmaceuticals Inc.

*2: Mainly amortization of patent rights and goodwill

(Reference) Segment Information (Six months ended 9/30/09)

(Billions of yen)

	Pharmaceuticals Segment				Others	Total
	Japan	China	Elimination	Total		
Net sales	102.7	2.0	(1.2)	103.5	28.7	132.2
Cost of sales	27.4	0.6	(0.7)	27.3	24.0	51.3
Gross profit	75.4	1.4	(0.5)	76.2	4.6	80.9
SG&A expenses	58.0	0.8	(0.2)	58.6	3.4	62.0
Operating income	17.4	0.6	(0.3)	17.7	1.2	18.9

3. Sales of Pharmaceuticals Segment (Sales to unaffiliated customers)

(Billions of yen)

	Six months ended 9/30/09(A)	Six months ended 9/30/10 (B)	(B)-(A)	Change (%)	FY2009		FY2010 (Forecast)	
					2nd half	Full Year	2nd half	Full Year
Japan	101.8	100.8	(1.0)	(1.0)	102.3	204.0	96.5	[194.2] 197.3
Domestic	91.4	90.2	(1.2)	(1.3)	92.8	184.2	89.2	[176.5] 179.4
Export	10.3	10.5	0.2	2.2	9.5	19.8	7.4	[17.7] 17.9
U.S.	—	60.8	60.8	—	28.6	28.6	56.2	[115.0] 117.0
China	1.8	2.5	0.7	39.6	2.3	4.1	3.2	[5.8] 5.7

Overseas Sales Total

Overseas sales (Pharmaceuticals)	12.1	73.8	61.7	509.5	40.4	52.6	66.8	[138.5] 140.6
[% of net sales (Pharmaceuticals)]	11.7%	45.0%			30.4%	22.2%	42.7%	43.9%

4. Sales of Major Products

Pharmaceuticals (Domestic)

(Billions of yen)

Brand name (Generic name) Therapeutic indication	Six months ended 9/30/09(A)	Six months ended 9/30/10(B)	(B)-(A)	Change (%)	FY2009		FY2010 (Forecast)	
					2nd half	Full Year	2nd half	Full Year
AMLODIN [®] (amlodipine) Therapeutic agent for hypertension and angina pectoris	26.9	21.0	(5.9)	(21.9)	25.2	52.0	18.5	[39.0] 39.5
GASMOTIN [®] (mosapride citrate) Gastroprokinetic	10.4	10.2	(0.1)	(1.3)	10.4	20.7	10.2	20.4
PRORENAL [®] (limaprost alfadex) Vasodilator	7.8	7.4	(0.4)	(5.3)	7.5	15.4	8.1	[16.0] 15.5
MEROPEN [®] (meropenem) Carbapenem antibiotic	7.6	6.6	(1.1)	(13.8)	7.1	14.7	5.0	[11.0] 11.6
LONASEN [®] (blonanserin) Antipsychotic	3.0	4.3	1.3	45.1	3.3	6.3	6.2	10.5
AVAPRO [®] (irbesartan) Therapeutic agent for hypertension	1.0	3.7	2.7	258.7	2.7	3.7	4.3	8.0
EBASTE [®] (ebastine) Antiallergic	4.0	2.9	(1.1)	(27.0)	5.2	9.2	4.4	7.3
SUMIFERON [®] (interferon- α NAMALWA) Natural alpha interferon	3.0	2.6	(0.4)	(12.6)	2.7	5.8	2.7	5.3
REPLAGAL [®] (agalsidase alfa) Anderson-Fabry disease drug	0.9	2.5	1.6	171.4	1.6	2.5	2.5	[4.0] 5.0
AmBisome [®] (amphotericin B) Therapeutic agent for systemic fungal infection	1.9	2.3	0.4	22.4	2.1	4.0	2.6	[5.1] 4.9
MELBIN [®] (metformin) Oral hypoglycemic	1.9	2.2	0.3	13.3	2.0	3.9	2.0	[3.5] 4.2
EXCEGRAN [®] (zonisamide) Antiepileptic	1.8	1.8	(0.1)	(4.3)	1.7	3.6	1.6	3.4
DOPS [®] (droxidopa) Neural function ameliorant	1.9	1.7	(0.2)	(8.9)	1.7	3.6	1.6	3.3
GLIMICRON [®] (gliclazide) Oral hypoglycemic	1.7	1.4	(0.3)	(15.1)	1.5	3.2	1.5	2.9
QVAR [™] (beclomethasone dipropionate) Bronchial asthma	1.4	1.4	(0.0)	(0.1)	1.6	3.0	1.1	2.5
ALMARL [®] (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	1.5	1.3	(0.1)	(9.4)	1.3	2.8	1.2	2.5
LULLAN [®] (perospirone) Antipsychotic	1.3	1.3	(0.1)	(6.3)	1.2	2.6	1.3	[2.4] 2.6
SEDIEL [®] (tandospirone) Serotonin-agonist antianxiety drug	1.3	1.2	(0.1)	(10.1)	1.2	2.5	1.2	2.4

Note: Figures in parentheses [] are forecasts released on July 30, 2010.

Pharmaceuticals (Domestic, New Products)

(Billions of yen)

Brand name (Generic name) Therapeutic indication	Six months ended 9/30/09(A)	Six months ended 9/30/10(B)	(B)-(A)	Change (%)	FY2009		FY2010 (Forecast)	
					2nd half	Full Year	2nd half	Full Year
TRERIEF [®] (zonisamide) Parkinson's disease drug (Launch: March, 2009)	0.4	1.6	1.2	329.2	0.4	0.8	1.8	[2.8] 3.4
MIRIPLA [®] (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: January, 2010)	—	0.7	0.7	—	0.2	0.2	0.8	1.5
METGLUCO [®] (metformin) Oral hypoglycemic (Launch: May, 2010)	—	0.1	0.1	—	—	—	0.2	[0.7] 0.3

Pharmaceuticals (Export)

MEROPEN [®] (meropenem) Carbapenem antibiotic	8.2	8.1	(0.1)	(1.6)	7.5	15.7	5.5	13.6
GASMOTIN [®] (mosapride citrate) Gastroprokinetic	0.5	0.7	0.3	62.5	0.6	1.1	0.4	1.1
EXCEGRAN [®] (zonisamide) Antiepileptic	0.2	0.8	0.6	280.3	0.4	0.6	0.8	1.6
Industrial property revenues	1.4	0.8	(0.6)	(40.2)	0.8	2.2	0.5	[1.1] 1.3

Note: Sales to unaffiliated customers

U.S.

LUNESTA [®] (eszopiclone) Sedative hypnotic	—	28.5	28.5	—	10.5	10.5	24.3	[50.4] 52.8
XOPENEX [®] (levalbuterol HCl) Short-acting beta-agonist	—	19.0	19.0	—	13.6	13.6	19.4	[39.4] 38.4
BROVANA [®] (arformoterol tartrate) Long-acting beta-agonist	—	4.5	4.5	—	1.7	1.7	4.8	[8.7] 9.3
OMNARIS [®] (ciclesonide) Corticosteroid nasal spray	—	2.6	2.6	—	0.6	0.6	2.3	[4.8] 4.9
Industrial property revenues	—	3.9	3.9	—	1.5	1.5	2.9	[6.6] 6.8

China

MEROPEN [®] (meropenem) Carbapenem antibiotic	1.7	2.3	0.6	38.8	2.1	3.8	2.9	5.2
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Note: Figures in parentheses [] are forecasts released on July 30, 2010.

(Reference)

Quarterly Business Results of Sunovion Pharmaceuticals Inc.

(Millions of dollar)

	Jan-Mar 2010	Apr-Jun 2010	Jan-Jun 2010	Jul-Sep 2010 (Unaudited)
Net sales	363	315	677	337
Cost of sales	52	43	96	47
SG&A expenses	287	309	596	306
SG&A expenses less R&D costs (Excluding depreciation of patent rights)	149	164	312	163
R&D costs	58	66	124	63
Depreciation of patent rights*	80	80	159	80
Operating income	24	(38)	(14)	(16)

*Amortization according to valuations and accounting procedures by acquisition of Sunovion Pharmaceuticals Inc.

(Reference)

Sales of Products

(Millions of dollar)

Brand name (Generic name) Therapeutic indication	Jan-Mar 2010	Apr-Jun 2010	Jan-Jun 2010	Jul-Sep 2010 (Unaudited)
LUNESTA [®] (eszopiclone) Sedative hypnotic	161	151	312	154
XOPENEX [®] (levalbuterol HCl) Short-acting beta-agonist	127	81	207	99
BROVANA [®] (arformoterol tartrate) Long-acting beta-agonist	25	24	49	28
OMNARIS [®] (ciclesonide) Corticosteroid nasal spray	11	17	28	12
Industrial property revenues	25	18	43	16
Others	14	24	38	28
Total	363	315	677	337

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 3/31/10 (A)	As of 9/30/10 (B)	(B)-(A)	
[Assets]	626.7	601.9	(24.8)	
Current assets:	287.6	303.5	15.9	
Cash and time deposits	13.8	14.7	0.9	
Notes and accounts receivable	94.0	90.3	(3.7)	
Marketable securities	51.2	76.6	25.4	• Transfer from investment securities • Increase in short-term operating funds
Inventories	65.2	58.6	(6.6)	• Decrease in inventories added according to accounting for business combinations
Deferred tax assets	32.4	31.7	(0.8)	
Short-term loans	25.0	25.0	—	
Others	6.1	6.7	0.6	
Allowance for doubtful receivables	(0.2)	(0.1)	0.1	
Fixed assets:	339.2	298.4	(40.8)	
Property, plant and equipment:	74.1	71.9	(2.2)	
Buildings and structures	43.0	42.8	(0.2)	
Machinery, equipment and carriers	12.8	12.1	(0.7)	
Land	10.3	10.3	(0.0)	
Construction in progress	2.7	1.6	(1.1)	
Others	5.3	5.2	(0.1)	
Intangible assets:	199.5	173.8	(25.7)	
Goodwill	83.6	76.5	(7.1)	• Decrease by amortization • Decrease in yen amounts by yen strength
Patent rights	104.0	86.1	(17.9)	
Others	11.9	11.2	(0.7)	
Investments and other assets:	65.6	52.7	(12.9)	
Investment securities	53.2	39.5	(13.7)	• Transfer to marketable securities • Decrease by revaluation of investment securities
Deferred tax assets	2.4	3.5	1.1	
Others	10.2	9.8	(0.4)	
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)	
Total assets	626.7	601.9	(24.8)	

Accounts receivable turnover period (in months)	Year ended 3/31/10	Six months ended 9/30/10
	3.81	2.87

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 3/31/10 (A)	As of 9/30/10 (B)	(B)-(A)
[Liabilities]	283.3	264.7	(18.6)
Current liabilities:	265.0	247.3	(17.7)
Notes and accounts payable	16.9	13.5	(3.4)
Short-term loans payable	165.8	160.9	(4.9)
Income taxes payable	8.6	6.6	(2.0)
Reserve for bonuses	7.4	7.2	(0.2)
Reserve for sales returns	2.7	2.7	(0.0)
Reserve for sales rebates	15.7	15.3	(0.4)
Accounts payable-other	33.4	28.0	(5.4)
Others	14.5	13.0	(1.5)
Long-term liabilities:	18.3	17.4	(0.9)
Liability for retirement benefits	9.8	10.0	0.2
Liability for directors' retirement benefits	0.1	0.0	(0.0)
Others	8.4	7.3	(1.1)
[Net assets]	343.5	337.3	(6.2)
Shareholders' equity:	332.3	337.4	5.1
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	294.7	299.8	5.1
Treasury stock	(0.6)	(0.6)	(0.0)
Valuation, translation adjustments and others:	11.2	(0.1)	(11.3)
Unrealized gains on available-for-sale securities, net of tax	7.9	5.9	(2.1)
Foreign currency translation adjustment	3.2	(6.0)	(9.3)
Total liabilities and net assets	626.7	601.9	(24.8)

•Repayment of bridge loan △
5.0

•Impact of yen strength

IV. Major consolidated subsidiaries (as of 9/30/10)

	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%
Number of employees	135	93	65	2,189	502
Businesses	Manufacture, processing, sale/purchase, and import/export of food materials, raw materials for cosmetics, pharmaceutical additives, chemicals for electronic materials, coating materials, and others	Manufacture, processing, sale/purchase, and import/export of veterinary medicines, veterinary reagents, medical devices for animals, feedstuff, and feed additives	Research, development, manufacture, sale, import and export of diagnostic reagents, medical devices and physicochemistry-measuring instruments for medical use	Manufacturing, sales of ethical pharmaceuticals	Manufacturing, sales of ethical pharmaceuticals

3. Number of employees (as of 9/30/10):

7,513 (consolidated)

4,529 (non-consolidated)

4. Number of MRs (as of 9/30/10):

Japan 1,370 (excluding managers) 1,560 (including managers)

U.S. 1,180 (excluding managers) 1,330 (including managers)

China 260 (excluding managers) 320 (including managers)

V. Quarterly Business Results

(Billions of yen)

	FY2009				FY2010	
	1Q	2Q	3Q	4Q	1Q	2Q
Net sales	66.0	66.2	71.5	92.5	101.8	86.8
Cost of sales	25.4	25.9	27.8	33.2	32.6	25.2
SG&A expenses	29.4	32.6	30.7	55.7	54.4	61.4
SG&A expenses less R&D costs	17.5	20.2	19.3	40.0	39.9	43.1
R&D costs	11.9	12.4	11.4	15.7	14.5	18.3
Operating income	11.2	7.7	13.1	3.6	14.8	0.1
Non-operating income	1.1	0.3	0.5	0.4	1.1	0.8
Non-operating expenses	0.5	0.8	0.8	2.0	1.1	1.4
Ordinary income	11.8	7.2	12.8	2.0	14.8	(0.5)
Extraordinary income	—	—	—	—	—	—
Extraordinary loss	—	—	—	2.4	—	—
Income before income taxes and minority interests	11.8	7.2	12.8	(0.4)	14.8	(0.5)
Net income	7.8	4.8	8.5	(0.2)	9.3	(0.6)

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

VI.Shareholder Positioning (As of September 30, 2010)

1. Total number of authorized shares: 1,500,000,000
2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 585,475)
3. Number of shareholders: 21,742

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)	14,981	3.77
Japan Trustee Services Bank, Ltd. (Trust account)	11,055	2.78
Nippon Life Insurance Company	10,530	2.65
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	3,572	0.90
The Bank of Tokyo-Mitsubishi UFJ, Ltd.	3,144	0.79

Note: Percentage of shareholding is calculated excluding treasury stock (585,475 stocks).

VII. Development Pipeline (as of October. 29, 2010)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
NDA filed	SMP-508 Oral	repaglinide	Diabetes	Novo Nordisk	Rapid insulin secretagogue NDA filed in Sep. 2009
	MEROPEN® Injection	meropenem hydrate	Change of the maximum daily dose from 2g to 3g	In-house	Approved maximum daily dose:2g for patients with severe/refractory infection

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Phase III	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Pan-Asia study (Japan, Korea and Taiwan)
	SMP-508 Oral	repaglinide	Diabetes Combination therapy with biguanide	Novo Nordisk	Rapid insulin secretagogue
			Diabetes Combination therapy with thiazolidine		

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Phase II	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	Co-developed with Kyorin Pharmaceutical
	DSP-8153 Oral	amlodipine besilate / irbesartan	Hypertension	In-house	Combination product
	SMP-986 Oral	TBD	Overactive bladder	In-house	

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Phase I	DSP-3235 Oral	TBD	Diabetes	Kissei Pharmaceutical	SGLT1 inhibitor
	DSP-3025 Intranasal	TBD	Bronchial asthma, Allergic rhinitis	In-house	TLR7 agonist
	SMP-028 Oral	TBD	Bronchial asthma	In-house	

[Main revisions since the announcement of July 2010]

None

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Approved	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	U.S.	Approved in Oct.2010 Brand name in U.S.: LATUDA®
NDA filed	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy-Adjunct	BIAL	U.S.	NDA submitted in Mar.2009

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Phase III	SM-13496 Oral	lurasidone hydrochloride	Bipolar disorder	In-house	U.S. and Europe, etc.	
	amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED®
	CiclesonideHF A Nasal Aerosol Collunarium	ciclesonide	(New Formulation) Allergic rhinitis	Nycomed	U.S.	approved formulation: OMNARIS® Nasal Spray, an aqueous solution nasal spray
	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy-Adult monotherapy	BIAL	U.S.	

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Phase II	SMP-986 Oral	TBD	Overactive bladder	In-house	U.S. and Europe	
	ALVESCO® HFA Inhaler	ciclesonide	(New Indication) Asthma-Pediatric (Age range: TBD)	Nycomed	U.S.	approved indication: asthma (12 years of age and older)

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Phase I	SMP-028 Oral	TBD	Bronchial asthma	In-house	U.S. and Europe	
	DSP-7238 Oral	TBD	Diabetes	In-house	Europe	DPPIV inhibitor
	DSP-8658 Oral	TBD	Diabetes	In-house	U.S.	PPAR α / γ modulator
	SEP-228432 Oral	TBD	Neuropathic Pain, Major Depressive Disorder (MDD)	In-house (Sunovion)	U.S.	

[Main revisions since the announcement of July 2010]

lurasidone hydrochloride
SEP-227900
SEP-228432

Changed from "NDA filed" to "Approved" for Schizophrenia in U.S.

Deleted because of discontinuation

Therapeutic indication changed from "Attention-deficit hyperactivity disorder" to
"Neuropathic Pain, Major Depressive Disorder"

Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Therapeutic indications	Status of development
AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003 Phase II 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 ongoing 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. Phase III study of neurogenic orthostatic hypotension in the U.S. and 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 concluded 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' product code: AZD-8848)
eszopiclone	Insomnia	Out-licensed by Sunovion to Eisai for the Japanese territory in July, 2007. (Brand name in U.S.: LUNESTA [®])

[Main revisions since the announcement of July 2010]

None

VIII. Profile of Major Products under Development (as of October 29, 2010)

SMP-508 (repaglinide) Diabetes

- In-licensed from Novo Nordisk
- Repaglinide is a rapid-acting insulin secretagogue and approved/marketed in more than 90 countries including the world's major countries.
- Repaglinide is expected to suppress the postprandial elevation of blood glucose levels, resulting in lower HbA_{1C} and fasting blood glucose levels, therefore repaglinide is expected to be a medicine that is superior to existing rapid insulin secretagogue.
- Diabetes: Development stage: NDA filed in Japan
Diabetes: (Combination therapy with beguanide) : Phase III in Japan
Diabetes: (Combination therapy with thiazolidine) : Phase III in Japan

SM-13496 (lurasidone hydrochloride) Schizophrenia, Bipolar disorder

- Developed in-house
- Lurasidone is an atypical antipsychotic agent with a unique chemical structure. Lurasidone has high affinity for dopamine D₂, serotonin 5-HT_{2A} and serotonin 5-HT₇ receptors where it has antagonist effects. In addition, lurasidone is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine or muscarinic receptors. In four double-blind clinical studies in schizophrenia patients, lurasidone demonstrated significantly greater improvement versus placebo in the Positive and Negative Syndrome Scale total score at study endpoint. Also, lurasidone was well-tolerated and the impact of lurasidone on weight gain, changes in movement disorder parameters and prolactin levels was limited. SM-13496 is also being studied as a potential treatment of Bipolar disorder.
- Development stage:
Schizophrenia: Approved in the U.S., Phase III as Pan-Asia study (Japan, Korea and Taiwan)
Planning to develop in other countries including Europe by using global Phase III data
Bipolar disorder: Phase III as Global study

STEDESTM (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL
- STEDES is a novel voltage-gated sodium channel blocker. STEDES 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. STEDES is expected to have clear dose-response correlation and marked and sustained seizure reduction with favorable tolerability and safety profiles.
- NDA filed in the U.S.

AS-3201 (ranirestat) Diabetic neuropathy

- Developed in-house
- AS-3201 alleviates 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 study in the U.S., Canada and Europe.

- Development stage: Phase IIb in Japan (co-developed with Kyorin Pharmaceutical)

DSP-8153 Hypertension

- Developed in-house
- Combination product of amlodipine besilate (AMLODIN[®]; calcium channel blocker) and irbesartan (AVAPRO[®]; angiotensin II receptor blocker). DSP-8153 is expected to have an antihypertensive activity for the patients with essential hypertension who do not have sufficient antihypertensive effect by irbesartan or amlodipine treatment. In addition, the product is expected to have cerebroprotective, cardioprotective and renoprotective effect for patients with essential hypertension, because irbesartan has renoprotective effect and amlodipine has cerebroprotective and cardioprotective effects.
- Development stage: Phase II in Japan

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 expected to ease urinary urgency and reduce the frequency of both urination and incontinence. The compound is also expected 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

DSP-3235 Diabetes

- In-licensed from Kissei Pharmaceutical
- DSP-3235 is a selective inhibitor for an isoform of sodium-dependent glucose cotransporters (SGLT1). It is expected to improve postprandial hyperglycemia by suppressing glucose absorption from the intestine with a novel mechanism of action different from that of conventional alpha-glucosidase inhibitors.
- Development stage: Phase I in Japan

DSP-3025 Bronchial asthma, Allergic rhinitis

- Developed in-house
- 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' product code: AZD-8848)
- Development stage: Phase I in Japan

SMP-028 Bronchial asthma

- Developed in-house
- SMP-028 shows a variety of effects on a wide range of inflammatory cells involved in the pathology of bronchial asthma. It suppresses inflammatory mediator release/production and *in vivo* studies have shown effectiveness of SMP-028 in animal models of asthma. It is expected to become a new treatment for asthma as a potent anti-inflammatory agent with a novel mechanism of action. Allergen challenge clinical pharmacology studies are ongoing in the UK.
- Development stage: Phase I in the U.S. , Europe and Japan

DSP-7238 Diabetes

- Developed in-house
- DSP-7238 is a dipeptidyl peptidase IV (DPP IV) inhibitor and improves hyperglycemia through the GLP-1-induced acceleration of insulin secretion. Since DSP-7238 has a selective and strong inhibitory activity for the GLP-1-degrading enzyme DPP IV, it may be a promising DPP IV inhibitor that achieves better glycemic control.
- Development stage: Phase I in Europe

DSP-8658 Diabetes

- Developed in-house
- DSP-8658 is a novel PPAR α / γ modulator that exhibits potent antihyperglycemic and lipid lowering activity in several animal models.
- Non-clinical studies suggest that DSP-8658 may offer advantages over marketed PPAR γ agonists, particularly with respect to improvements in lipid metabolism and incidence of fluid retention or body weight gain.
- 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 reuptake inhibitor (TRI) that inhibits reuptake of serotonin, norepinephrine and dopamine. The compound is under development for neuropathic pain and MDD in central nervous disorders (CNS) area.
- Development stage: Phase I in the U.S.