Securities Code: 4506

Supplementary Financial Data for the Year Ended－ March 31, 2010

May 10, 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

1. Highlights of the Statements of Income

(Billions of yen)

	FY2008	FY2009		FY2010 2Q (Forecast)		FY2010 (Forecast)	
			Change (%)		Change (%)		Change (%)
Net sales	264.0	296.3	12.2	181.5	37.3	354.0	19.5
Cost of sales	103.7	112.3	8.2	57.0	11.1	108.0	(3.8)
SG&A expenses	129.1	148.4	14.9	121.0	95.2	242.5	63.4
SG&A expenses less R&D costs	76.3	97.0	27.1	87.4	131.7	175.0	80.4
R&D costs	52.8	51.4	(2.7)	33.6	38.6	67.5	31.4
Operating income	31.2	35.6	14.3	3.5	(81.5)	3.5	(90.2)
Ordinary income	31.4	33.8	7.8	2.0	(89.5)	1.0	(97.0)
Net income	20.0	21.0	4.9	0.7	(94.5)	0.0	(100.0)

Notes1: 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: Sumitomo Pharmaceuticals (Suzhou) Co.,Ltd. is newly added to the scope of consolidation from this fiscal year. FY2009 includes full-year（Jan.1 to Dec.31, 2009）figures of Sumitomo Pharmaceuticals (Suzhou) Co.,Ltd.

4: By acquisition of Sepracor inc. in Oct. 2009, US subsidiaries(including Sepracor inc.) are newly added to the scope of consolidation.
FY2009 includes 4Q（Oct.15 to Dec.31, 2009）figures of US subsidiaries.

EBITDA (Billions of yen)	42.0	56.4		52.0
Earnings per share (yen)	50.30	52.75		—
Return on equity (ROE)	6.2%	6.3%		—
Payout ratio	35.8%	34.1%		—

2. Financial Results of US Subsidiary
（Excluding Impact of Valuations and Accounting Procedures）

(Billions of yen)

	FY2009	FY2010 2Q (Forecast)	FY2010 (Forecast)
Net sales	28.6	58.8	111.0
Cost of sales	2.4	6.4	12.3
SG&A expenses	17.9	42.1	85.4
SG&A expenses less R&D costs	15.0	32.1	64.7
R&D costs	2.9	10.0	20.7
Operating income	8.3	10.3	13.3
Ordinary income	7.9	10.3	13.4
Net income	5.2	6.5	8.6

3．Valuations and Accounting Procedures by Acquisition of Sepracor Inc.

（Millions of dollar）

	Before purchase price allocation	After purchase price allocation	Valuation differences	Accounting procedures (Amortization)	Impact on pretax income	Impact on pretax income (Forecasts for FY2010)
Patent rights	—	1,197	1,197	Amortization years by products	67	319
In-process R&D (Intangible Assets)	—	59	59	Capitalize (Amortize after approval)	—	—
Inventories	67	144	78	Charge to cost of sales	40	38
Deferred tax liabilities (of the above)	—	(485)	(485)	—	—	—
Other assets & liabilities (Net)	633	678	45	—	—	—
Goodwill	26	914	888	Amortization for 20 years	10	46
Total	726	2,506	1,781		116	403

Note: Patent rights include sales rights.

4. Currency Exchange Rates

	FY2009 Fiscal year end rate	FY2010 Forecast rate
Yen / USD	92	90
Yen / Yuan	14	13

5. Capital Expenditures and Depreciation

(Billions of yen)

	FY2008	FY2009	Change	FY2010 (Forecast)	Change
Capital expenditures (including intangible assets)	10.6	6.5	4.1	15.0	8.5
Depreciation and amortization	10.7	11.0	0.3	14.0	3.0
Tangible fixed assets	8.4	8.9	0.5		
Intangible fixed assets	2.3	2.1	(0.2)		

Note: Excluding the depreciation associated with acquisition of Sepracor Inc.

- Major capital expenditure projects for FY2010
  Renewal of Press-through packaging line at Suzuka plant in Manufacturing Division
  ¥0.72 billion (total budget: ¥0.73 billion, plan to be completed in October 2010)

(Reference: Major capital expenditure projects in the future)
Construction operation of new research building in Osaka research center:
Total budget ¥8.70 billion, plan to be completed in FY2013
(Plan to be started in FY2010, plan to be booked after FY2011)

（Reference)

Highlights of the Statements of Income (Non-Consolidated) (Billions of yen)

	FY2008	FY2009		Group-to-parent ratio
			Change (%)	
Net sales	248.4	248.7	0.1	1.19
Cost of sales	91.2	93.6	2.6	
SG&A expenses	126.6	119.4	(5.7)	
SG&A expenses less R&D costs	73.9	71.1	(3.8)	
R&D costs	52.7	48.3	(8.3)	
Operating income	30.6	35.7	16.7	1.00
Ordinary income	30.9	34.4	11.4	0.98
Net income	19.7	20.9	6.1	1.00
Earnings per share (yen)	49.65	52.68		

II. Consolidated Statements of Income

1. Statements of Income

(Billions of yen)

	FY2008 (A)	FY2009 (B)	(B)-(A)	Change (%)	Breakdown of (B)-(A)	
					Except US Subsidiary	US Subsidiary
Net sales	264.0	296.3	32.2	12.2	3.6	28.6
Overseas sales	22.1	53.0	31.0	140.4	2.4	28.6
Cost of sales	103.7	112.3	8.5	8.2	2.5	6.0
Gross profit	160.3	184.0	23.7	14.8	1.1	22.6
SG&A expenses	129.1	148.4	19.2	14.9	(5.5)	24.8
Labor costs	32.9	39.5	6.6	20.0	1.2	5.3
Advertising and promotion costs	5.3	7.9	2.7	50.5	(1.0)	3.7
Sales promotion costs	10.8	12.1	1.2	11.5	0.3	0.9
Other costs	27.3	37.5	10.2	37.4	(1.7)	11.9
SG&A expenses less R&D costs	76.3	97.0	20.7	27.1	(1.2)	21.9
R&D costs	52.8	51.4	(1.4)	(2.7)	(4.4)	2.9
Operating income	31.2	35.6	4.5	14.3	6.6	(2.2)
Non-operating income	3.0	2.3	(0.7)		(0.8)	0.1
Non-operating expenses	2.7	4.0	1.3		0.8	0.5
Ordinary income	31.4	33.8	2.4	7.8	5.0	(2.5)
Extraordinary income	1.1	—	(1.1)		(1.1)	—
Reversal of reserve for loss on litigation	1.1	—	(1.1)		(1.1)	—
Extraordinary loss	0.3	2.4	2.1		2.1	—
Compensation for revision of personnel system	—	1.6	1.6		1.6	—
Loss on valuation of investment securities	0.3	0.8	0.6		0.6	—
Income before income taxes and minority interests	32.2	31.4	(0.7)	(2.3)	1.8	(2.5)
Income taxes	12.2	10.5	(1.7)		(0.9)	(0.9)
Minority interests in net income	0.0	0.0	(0.0)		(0.0)	—
Net income	20.0	21.0	1.0	4.9	2.6	(1.7)

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

2. Segment Information

(Billions of yen)

	FY2008			FY2009			FY2010 2Q (Forecast)			FY2010 (Forecast)		
	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total
Net sales	206.8	57.2	264.0	236.8	59.5	296.3	157.5	24.0	181.5	310.0	44.0	354.0
Operating income	29.8	1.3	31.2	33.0	2.6	35.6						

3. Sales of Major Products

Pharmaceuticals (Domestic) (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2008 (A)	**FY2009 (B)**	(B)-(A)	Change (%)	FY2010 2Q (Forecast)	FY2010 (Forecast)
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	57.9	**52.0**	(5.9)	(10.1)	20.0	38.5
GASMOTIN® (mosapride citrate) Gastroprokinetic	20.2	**20.7**	0.6	2.9	10.1	20.4
PRORENAL® (limaprost alfadex) Vasodilator	14.8	**15.4**	0.5	3.7	7.8	16.0
MEROPEN® (meropenem) Carbapenem antibiotic	14.8	**14.7**	(0.1)	(0.6)	5.5	10.2
EBASTEL® (ebastine) Antiallergic	10.6	**9.2**	(1.4)	(13.0)	2.8	7.3
LONASEN® (blonanserin) Antipsychotic	3.4	**6.3**	2.9	83.6	5.3	12.0
SUMIFERON® (interferon-α NAMALWA)) Natural alpha interferon	6.0	**5.8**	(0.2)	(3.8)	2.7	5.3
GROWJECT® (somatropin) Growth hormone	4.3	**4.6**	0.3	7.0	1.1	1.1
AMBISOME® (amphotericin B) Therapeutic agent for systemic fungal infection	3.1	**4.0**	1.0	31.4	2.4	5.1
MELBIN® (metformin) Oral hypoglycemic	3.4	**3.9**	0.6	16.7	1.7	3.5
AVAPRO® (irbesartan) Therapeutic agent for hypertension	1.5	**3.7**	2.3	154.7	3.6	8.0
EXCEGRAN® (zonisamide) Antiepileptic	3.6	**3.6**	(0.0)	(0.1)	1.7	3.4
DOPS® (droxidopa) Neural function ameliorant	3.8	**3.6**	(0.2)	(5.0)	1.7	3.3
GLIMICRON® (gliclazide) Oral hypoglycemic	3.6	**3.2**	(0.3)	(8.9)	1.5	2.9
QVAR™ (beclomethasone dipropionate) Bronchial asthma	3.6	**3.0**	(0.6)	(16.2)	1.4	2.5
ALMARL® (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	3.0	**2.8**	(0.2)	(7.1)	1.3	2.5
LULLAN® (perospirone) Antipsychotic	2.8	**2.6**	(0.3)	(9.0)	1.2	2.4
SEDIEL® (tandospirone) Serotonin-agonist antianxiety drug	2.7	**2.5**	(0.2)	(6.7)	1.2	2.4
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	1.1	**2.5**	1.4	131.4	1.9	4.0
New Products						
TRERIEF® (zonisamide) Parkinson's disease drug (Launch: March, 2009)	0.1	**0.8**	0.7	1,100.6	1.3	2.8
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: December, 2009)	—	**0.2**	0.2	—	0.6	1.5
METGLUCO® (metformin) Oral hypoglycemic (Launch: May, 2010)	—	—	—	—	0.3	0.7
Domestic total	185.0	**184.2**	(0.8)	(0.4)	87.5	177.0

Pharmaceuticals (Export) (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2008 (A)	**FY2009 (B)**	(B)-(A)	Change (%)	FY2010 2Q (Forecast)	FY2010 (Forecast)
MEROPEN® (meropenem) Carbapenem antibiotic	16.2	**15.7**	(0.5)	(3.2)	6.9	13.2
GASMOTIN® (mosapride citrate) Gastroprokinetic	1.0	**1.1**	0.1	9.3	0.6	1.0
EXCEGRAN® (zonisamide) Antiepileptic	1.0	**0.6**	(0.4)	(43.0)	0.5	0.8
Industrial property revenues	3.2	**2.2**	(1.0)	(31.4)	0.5	0.9
Others	0.4	**0.2**	(0.1)	(34.9)	0.3	0.5
Total	21.8	**19.8**	(2.0)	(9.1)	8.8	16.4

Note: Sales to unaffiliated customers

US Subsidiary (Billions of yen)

LUNESTA® (eszopiclone) Sedative hypnotic	—	**10.5**	10.5	—	25.6	46.5
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	—	**13.6**	13.6	—	21.1	41.3
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	—	**1.7**	1.7	—	3.5	7.2
OMNARIS® (ciclesonide) Corticosteroid nasal spray	—	**0.6**	0.6	—	2.4	4.8
Industrial property revenues	—	**1.5**	1.5	—	3.8	6.6
Others	—	**0.7**	0.7	—	2.4	4.6
Total	—	**28.6**	28.6	—	58.8	111.0

Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (Billions of yen)

MEROPEN® (meropenem) Carbapenem antibiotic	—	**3.8**	3.8	—	2.2	5.0
Others	—	**0.4**	0.4	—	0.2	0.6
Total	—	**4.1**	4.1	—	2.4	5.6

Overseas Sales Total (Billions of yen)

Overseas sales (Pharmaceuticals)	21.8	**52.6**	**30.7**	140.9	70.0	133.0
[% of net sales (Pharmaceuticals)]	[10.5%]	**[22.2%]**			[44.4%]	[42.9%]
Overseas sales (Pharmaceuticals and Others)	22.1	**53.0**	**31.0**	140.4	70.2	133.2
[% of net sales]	[8.4%]	**[17.9%]**			[38.7%]	[37.6%]

(Reference)
Financial results of Sepracor Inc.（Millions of dollar）

	Jan-Mar 2010 (Unaudited)
Net sales	363
Cost of sales	52
SG&A expenses	288
SG&A expenses less R&D costs (Excluding depreciation of patent rights)	150
R&D costs	58
Depreciation of patent rights*	80
Operating income	22

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

(Reference)
Sales by Item (Millions of dollar）

Brand name (Generic name) Therapeutic indication	Jan-Mar 2010 (Unaudited)
LUNESTA® (eszopiclone) Sedative hypnotic	161
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	127
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	25
OMNARIS® (ciclesonide) Corticosteroid nasal spray	11
Industrial property revenues	25
Others	14
Total	363

4. Major consolidated subsidiaries (as of 3/31/10)

	Domestic		Overseas	
	Gokyo Trading Co., Ltd.	DS Pharma Biomedical Co., Ltd.	Sepracor Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	October 1947	June 1998	January 1984	December 2003
Fiscal year	March 31	March 31	December 31	December 31
Ownership	100%	100%	100%	100%
Number of employees	73	67	2,068	413
Businesses	Sale, export and import of food additives, chemical products and chemicals	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 3/31/10): 7,407 (consolidated); 4,686 (non-consolidated)

4. Number of MRs (as of 3/31/10):

Japan 1,440 (excluding managers) 1,640 (including managers)
US 1,190 (excluding managers) 1,320 (including managers)
China 210 (excluding managers) 250 (including managers)

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 3/31/09 (A)	As of 3/31/10 (B)	(B) - (A)	Breakdown of (B)−(A)	
				Except US Subsidiary	US Subsidiary
[Assets]	391.3	626.7	235.4	185.1	50.4
Current assets:	263.5	287.6	24.0	(33.2)	57.2
Cash and time deposits	22.0	13.8	(8.2)	(10.0)	1.8
Notes and accounts receivable	79.8	94.0	14.2	2.1	12.1
Marketable securities	34.5	51.2	16.7	(4.5)	21.2
Inventories	54.5	65.2	10.7	1.2	9.5
Deferred tax assets	17.1	32.4	15.3	3.1	12.3
Short-term loans	50.0	25.0	(25.0)	(25.0)	—
Others	6.0	6.1	0.0	(0.3)	0.4
Allowance for doubtful receivables	(0.4)	(0.2)	0.2	0.2	—
Fixed assets:	127.8	339.2	211.4	218.2	(6.8)
Property, plant and equipment:	69.1	74.1	5.0	(3.0)	8.0
Buildings and structures	39.5	43.0	3.5	(1.1)	4.6
Machinery, equipment and carriers	11.0	12.8	1.7	0.2	1.5
Land	10.0	10.3	0.4	—	0.4
Construction in progress	4.0	2.7	(1.3)	(1.4)	0.0
Others	4.6	5.3	0.8	(0.7)	1.5
Intangible assets	6.4	199.5	193.1	(1.1)	194.2
Goodwill	0.0	83.6	83.6	(0.0)	83.6
Patent rights	0.0	104.0	104.0	(0.0)	104.0
Others	6.4	11.9	5.5	(1.1)	6.6
Investments and other assets:	52.2	65.6	13.4	222.4	(209.0)
Investment securities	34.0	53.2	19.2	229.7	(210.5)
Deferred tax assets	3.7	2.4	(1.4)	(2.6)	1.2
Others	14.6	10.2	(4.5)	(4.8)	0.3
Allowance for doubtful receivables	(0.1)	(0.1)	0.0	0.0	—
Total assets	391.3	626.7	235.4	185.1	50.4

	FY2008	FY2009
Accounts receivable turnover period (in months)	3.62	3.81

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 3/31/09 (A)	As of 3/31/10 (B)	(B) - (A)	Breakdown of (B)−(A)	
				Except US Subsidiary	US Subsidiary
[Liabilities]	66.8	283.3	216.5	168.0	48.5
Current liabilities:	53.3	265.0	211.6	167.3	44.4
Notes and accounts payable	18.5	16.9	(1.6)	(1.7)	0.1
Short-term loans payable	0.6	165.8	165.2	165.2	—
Income taxes payable	6.3	8.6	2.3	2.1	0.2
Reserve for bonuses	8.1	7.4	(0.7)	(0.7)	—
Reserve for sales returns	0.1	2.7	2.6	(0.0)	2.6
Reserve for sales rebates	0.4	15.7	15.3	0.0	15.3
Accounts payable-other	16.9	33.4	16.5	1.6	14.9
Others	2.4	14.5	12.2	0.9	11.3
Long-term liabilities:	13.4	18.3	4.8	0.7	4.1
Liability for retirement benefits	9.3	9.8	0.5	0.5	—
Liability for directors' retirement benefits	0.0	0.1	0.0	0.0	—
Others	4.2	8.4	4.3	0.1	4.1
[Net assets]	324.5	343.5	19.0	17.1	1.9
Shareholders' equity:	319.2	332.3	13.1	14.5	(1.4)
Common stock	22.4	22.4	—	—	—
Capital surplus	15.9	15.9	—	—	—
Retained earnings	281.6	294.7	13.1	14.5	(1.4)
Treasury stock	(0.6)	(0.6)	(0.0)	(0.0)	—
Valuation, translation adjustments and others	5.2	11.2	6.0	2.7	3.3
Unrealized gains on available-for-sale securities, net of tax	5.2	7.9	2.8	2.8	(0.1)
Foreign currency translation adjustment	—	3.2	3.2	(0.1)	3.3
Minority interests	0.1	—	(0.1)	(0.1)	—
Total liabilities and net assets	391.3	626.7	235.4	185.1	50.4

Shareholders' equity ratio	82.9%	54.8%

IV. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2008	FY2009	
Income before income taxes and minority interests	32.2	31.4	
Depreciation and amortization	11.5	18.6	・Increase in depreciation associated with consolidation of US subsidiary
Decrease (increase) in notes and accounts receivable	6.6	1.8	
Decrease (increase) in inventories	(6.0)	2.9	
Increase (decrease) in notes and accounts payable	2.0	(1.7)	
Other-net	(2.9)	(15.1)	・Decrease in accounts payable-other
Subtotal	43.3	37.9	
Interest and dividends received less paid	1.5	0.5	
Income taxes paid	(18.6)	(11.8)	
Net cash provided by operating activities	26.3	26.7	
Decrease (increase) in time deposits	11.0	5.0	
Purchases of property, plant and equipment / intangible assets	(16.8)	(6.1)	
Purchase of investments in subsidiaries resulting in change in scope of consolidation	—	(200.6)	・Net amount [Total purchase price of Sepracor Inc.] − [Cash equivalents of Sepracor Inc.]
Decrease (increase) in short-term loans receivable	(10.0)	25.0	
Other-net	(5.4)	24.9	
Net cash used in investing activities	(21.3)	(151.8)	
Net increase in short-term loans payable	—	164.9	・Loans for acquisition of Sepracor Inc.
Dividends paid	(7.2)	(7.2)	
Other-net	(4.7)	(25.8)	
Net cash used in financing activities	(11.8)	131.9	
Effect of exchange rate changes on cash and cash equivalents	0.0	0.4	
Net increase (decrease) in cash and cash equivalents	(6.8)	7.2	
Cash and cash equivalents at the beginning of period	56.3	49.5	・Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Increase in cash and cash equivalents related to change in scope of consolidation	—	1.5	・Dainippon Sumitomo Pharma America, Inc.
Cash and cash equivalents at the end of period	49.5	58.1	

V. Quarterly Business Results

(Billions of yen)

	FY2008				FY2009			
	1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter	3rd quarter	4th quarter
Net sales	70.1	64.2	67.6	62.1	66.0	66.2	71.5	92.5
Cost of sales	27.8	25.0	26.0	24.9	25.4	25.9	27.8	33.2
SG&A expenses	32.1	31.2	32.2	33.6	29.4	32.6	30.7	55.7
SG&A expenses less R&D costs	19.5	19.1	18.6	19.1	17.5	20.2	19.3	40.0
R&D costs	12.7	12.1	13.5	14.5	11.9	12.4	11.4	15.7
Operating income	10.2	8.0	9.4	3.6	11.2	7.7	13.1	3.6
Non-operating income	1.0	0.4	1.2	0.4	1.1	0.3	0.5	0.4
Non-operating expenses	0.4	1.0	0.3	1.0	0.5	0.8	0.8	2.0
Ordinary income	10.8	7.4	10.2	2.9	11.8	7.2	12.8	2.0
Extraordinary income	—	—	—	1.1	—	—	—	—
Extraordinary loss	—	—	—	0.3	—	—	—	2.4
Income before income taxes and minority interests	10.8	7.4	10.2	3.7	11.8	7.2	12.8	(0.4)
Net income	6.4	4.4	6.2	2.9	7.8	4.8	8.5	(0.2)

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

VI. Shareholder Positioning (As of March 31, 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 584,644)

3. Number of shareholders: 18,702

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)	13,552	3.41
Nippon Life Insurance Company	10,530	2.65
Japan Trustee Services Bank, Ltd. (Trust account)	8,867	2.23
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
Nissay Dowa General Insurance Co., Ltd.	4,928	1.24
Dainippon Sumitomo Pharma Employee shareholders' association	3,310	0.83
JP Morgan Securities Japan Co., Ltd.	3,277	0.82

Note: Percentage of shareholding is calculated excluding treasury stock (584,644 stocks).

VII. Development Pipeline (as of May. 10, 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

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
PhaseIII	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Pan-Asia study (Japan, Korea and Taiwan)

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

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Phase I	SMP-986 Oral	TBD	Overactive bladder	In-house	
	DSP-3235 Oral	TBD	Diabetes	Kissei Pharmaceutical	SGLT1 inhibitor
	DSP-3025	TBD	Bronchial asthma, Allergic rhinitis	In-house	TLR7 agonist
	SMP-028 Oral	TBD	Bronchial asthma	In-house	

[Main revisions since the announcement of Feb. 2010]

METGLUCO® (metformin hydrochloride) Deleted because of "Launched" <Launched in May 2010>

SMP-028 Changed from "Preparing for Phase I" to "Phase I"

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
NDA filed	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	U.S.	NDA submitted in Dec.2009
	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®
	OMNARIS® HFA Nasal MDI 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.	PPARα/γ modulator
	SEP-227900 Oral	TBD	Cognition, Pain Alzheimer's	In-house (Sepracor)	U.S.	
	SEP-228432 Oral	TBD	Attention-deficit hyperactivity disorder	In-house (Sepracor)	U.S.	

[Main revisions since the announcement of Feb. 2010]

Following a portfolio prioritization evaluation, we have discontinued the development of 3 compounds in the Phase 2 stage (SEP-227018, SEP-225289, SEP-227162). Accordingly, these development programs have been removed from the chart.

Studies conducted in response to a Written Request from the U.S. Food and Drug Administration (FDA) have been removed from the chart.
(relevant study: pediatric study of LUNESTA® in U.S.)

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)
SMP-601	Life-threatening infection	Out-licensed to Protez Pharmaceuticals for the U.S. and European territories in May 2005 Phase II study completed in the U.S. by Protez (Protez's product code: PTZ-601)
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
eszopiclone	Insomnia	Out-licensed by Sepracor Inc. to Eisai for the Japanese territory in July, 2007. (Brand name in U.S.: LUNESTA®)

[Main revisions since the announcement of Feb. 2010]

Droxidopa (DOPS®)	Initiated phase II study of fibromyalgia in the UK by Chelsea Completed phase II study of intradialytic hypotension in the U.S. by Chelsea

VIII. Profile of Major Products under Development (as of May 10, 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 major country.
- 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 as a medicine that is superior to an existing rapid insulin secretagogue.
- Development stage: NDA filed 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 D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 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 very limited.
  SM-13496 is also being studied as a potential treatment of Bipolar disorder.
- Development stage:
  Schizophrenia: NDA filed in the U.S., Phase III as Pan-Asia study (Japan, Korea and Taiwan)
  Bipolar disorder: Phase III as Global study

STEDESA™ (eslicarbazepine acetate)　Epilepsy

- In-licensed from BIAL
- STEDESA 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 had a history of 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. STEDESA 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 I 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.
- 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 PPARα/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 PPARγ 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-227900 Cognition, NP and Alzheimer's disease

- Developed in-house (Sepracor Inc.)
- SEP-227900 is an inhibitor of D-Serine Amino Acid Oxidase (DAAO). The compound is expected to enhance NMDA receptor activity which may result in improvement of neuropathic pain (NP), cognition and Alzheimer’s disease (AD).
- Development stage: Phase I in the U.S.

SEP-228432 Attention-deficit hyperactivity disorder

- Developed in-house (Sepracor Inc.)
- SEP-228432 is a new triple reuptake inhibitor (TRI) which inhibits reuptake of serotonin, norepinephrine and dopamine. The compound has the potential to show improved efficacy in ADHD.
- Development stage: Phase I in the U.S.