Securities Code: 4506

Supplementary Financial Data for the Year Ended－ March 31, 2009

May 11, 2009

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)

	Year ended 3/31/08	Year ended 3/31/09	Change (%)	Six months ending 9/30/09 (Forecast)	Change (%)	Year ending 3/31/10 (Forecast)	Change (%)
Net sales	264.0	264.0	0.0	130.6	(2.8)	264.0	—
Cost of sales	99.4	103.7	4.4	52.2	(1.2)	106.5	2.7
SG&A expenses	124.8	129.1	3.5	65.6	3.6	132.5	2.6
SG&A expenses less R&D costs	77.5	76.3	(1.6)	38.9	0.9	78.0	2.2
R&D costs	47.3	52.8	11.7	26.7	7.7	54.5	3.2
Operating income	39.8	31.2	(21.7)	12.8	(29.6)	25.0	(19.8)
Ordinary income	37.7	31.4	(16.6)	12.4	(31.9)	24.0	(23.6)
Net income	25.6	20.0	(21.9)	7.8	(28.2)	15.0	(25.0)

Notes: Cost of sales includes provision for (reversal of) reserve for sales returns.
"Change(%)" represent ratio of changes from the corresponding period of the previous year.

Earnings per share (yen)	64.39	50.30	37.75
Return on equity (ROE)	8.2%	6.2%	4.6%
Payout ratio	28.0%	35.8%	47.7%

2. Highlights of the Balance Sheets (Billions of Yen)

	As of 3/31/08 (A)	As of 3/31/09 (B)	(B) - (A)
Total assets	399.8	391.3	(8.5)
Net assets	318.3	324.5	6.2
Shareholders' equity	318.2	324.4	6.2
Shareholders' equity ratio	79.6%	82.9%	

3. Capital Expenditures and Depreciation (Billions of Yen)

	Year ended 3/31/08	Year ended 3/31/09	Change	Year ending 3/31/10 (Forecast)	Change
Capital expenditures (including intangible assets)	15.5	10.6	(4.9)	13.0	2.4
Depreciation and amortization	11.1	10.7	(0.4)	12.0	1.3

- Major capital expenditure projects for the year ending March 31, 2010

Integration of product formulations development functions in Technology Research & Development Division :
¥0.90 billion (total budget: ¥0.90 billion, to be completed in January 2010)

4. Highlights of the Statements of Cash Flows (Billions of Yen)

	Year ended 3/31/08 (A)	Year ended 3/31/09 (B)	(B)-(A)
Net cash provided by operating activities	32.5	26.3	(6.2)
Net cash used in investing activities	(51.0)	(21.3)	29.7
Net cash used in financing activities	(6.9)	(11.8)	(4.9)
Cash and cash equivalents at the end of period	56.3	49.5	(6.8)

・(A): Short-term loans to the parent company (40 billion yen)
・(B): Purchase of property, plant and equipment (13.6 billion yen)
(new solid dosage form building at Suzuka Plant,etc.)
Increased short-term loans to the parent company (10 billion yen)

・(B):Repayment of long-term debt (4.6 billion yen)

II. Consolidated Statements of Income

1. Statements of Income (Billions of Yen)

	Year ended 3/31/08 (A)	Year ended 3/31/09 (B)	(B)-(A)	Change (%)
Net sales	264.0	264.0	0.0	0.0
Overseas sales	24.5	22.1	(2.5)	(10.1)
Cost of sales	99.4	103.7	4.4	4.4
Gross profit	164.6	160.3	(4.3)	(2.6)
SG&A expenses	124.8	129.1	4.3	3.5
Labor costs	32.3	32.9	0.6	1.7
Advertising and promotion costs	5.9	5.3	(0.6)	(10.1)
Sales promotion costs	9.4	10.8	1.4	14.6
Other costs	29.9	27.3	(2.6)	(8.6)
SG&A expenses less R&D costs	77.5	76.3	(1.2)	(1.6)
R&D costs	47.3	52.8	5.6	11.7
Operating income	39.8	31.2	(8.6)	(21.7)
Non-operating income	3.1	3.0	(0.1)	
Non-operating expenses	5.2	2.7	(2.5)	
Ordinary income	37.7	31.4	(6.3)	(16.6)
Extraordinary income	3.8	1.1	(2.7)	
Reversal of reserve for loss on litigation	—	1.1	1.1	
Gain on sales of investment securities	3.8	—	(3.8)	
Extraordinary loss	—	0.3	0.3	
Loss on valuation of investment securities	—	0.3	0.3	
Income before income taxes and minority interests	41.5	32.2	(9.3)	(22.4)
Income taxes	15.8	12.2	(3.6)	
Minority interests in net income	0.1	0.0	(0.1)	
Net income	25.6	20.0	(5.6)	(21.9)

(Positives)
・Sales of new products (LONASEN®／AVAPRO®)
・Start of new contract manufacturing
(Negatives)
・NHI price revision
・Decreased sales of AMLODIN®

・Rise in cost of sales ratio (37.6%→39.3%) due to NHI price revision and the application of "Accounting Standard for Measurement of Inventories"

・Increase due to launch of new products (LONASEN®／AVAPRO®)

・Overseas clinical trials of lurasidone in progress

・Loss on disposal／valuation of inventories included in Cost of sales from current period

・Reversal of reserve based on the appeal court's decision

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

2. Segment Information (Billions of Yen)

	Year ended 3/31/08			Year ended 3/31/09		
	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total
Net sales	208.7	55.3	264.0	206.8	57.2	264.0
Operating income	38.7	1.1	39.8	29.8	1.3	31.2

	Six months ending 9/30/09 (Forecast)			Year ending 3/31/10 (Forecast)		
	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total
Net sales	101.6	29.0	130.6	204.2	59.8	264.0

3. Sales of Major Products

Pharmaceuticals (Domestic) (Billions of Yen)

Brand name (Generic name) Therapeutic indication	Year ended 3/31/08 (A)	**Year ended 3/31/09 (B)**	(B)-(A)	Change (%)	Six months ending 9/30/09 (Forecast)	Year ending 3/31/10 (Forecast)
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	63.6	**57.9**	(5.7)	(9.0%)	25.3	48.0
GASMOTIN® (mosapride citrate) Gastroprokinetic	19.5	**20.2**	0.7	3.4%	10.4	21.0
PRORENAL® (limaprost alfadex) Vasodilator	14.5	**14.8**	0.3	2.1%	7.7	15.5
MEROPEN® (meropenem) Carbapenem antibiotic	14.8	**14.8**	0.0	0.1%	6.6	12.9
EBASTEL® (ebastine) Antiallergic	11.1	**10.6**	(0.5)	(4.1%)	3.3	8.6
SUMIFERON® (interferon-α NAMALWA)) Natural alpha interferon	6.0	**6.0**	(0.0)	(0.7%)	3.0	6.0
GROWJECT® (somatropin) Growth hormone	4.3	**4.3**	0.0	0.4%	2.3	4.6
DOPS® (droxidopa) Norepinephrine-activating neural function ameliorant	4.1	**3.8**	(0.3)	(7.7%)	1.8	3.6
EXCEGRAN® (zonisamide) Antiepileptic	3.5	**3.6**	0.0	0.9%	1.9	3.8
QVAR™ (beclomethasone dipropionate) Bronchial asthma	4.3	**3.6**	(0.7)	(16.7%)	1.4	3.0
GLIMICRON® (gliclazide) Oral hypoglycemic	3.9	**3.6**	(0.3)	(8.4%)	1.7	3.4
LONASEN® (blonanserin) Antipsychotic	—	**3.4**	3.4	—	2.8	6.5
MELBIN® (metformin) Oral hypoglycemic	2.8	**3.4**	0.5	17.7%	1.9	3.9
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	2.5	**3.1**	0.5	20.0%	1.9	4.3
ALMARL® (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	3.2	**3.0**	(0.2)	(5.1%)	1.5	2.9
LULLAN® (perospirone) Antipsychotic	3.0	**2.8**	(0.2)	(5.4%)	1.4	2.7
TAGAMET® (cimetidine) H_2-receptor antagonist	3.3	**2.7**	(0.5)	(16.1%)	1.2	2.4
SEDIEL® (tandospirone) Serotonin-agonist antianxiety drug	3.0	**2.7**	(0.2)	(8.3%)	1.3	2.6
AVAPRO® (irbesartan) Therapeutic agent for hypertension	—	**1.5**	1.5	—	2.1	6.0

New Products

TRERIEF® (zonisamide) Parkinson's disease drug	—	**0.1**	0.1	—	0.4	1.1

Pharmaceuticals (Overseas) (Billions of Yen)

Generic name Therapeutic indication	Year ended 3/31/08 (A)	**Year ended 3/31/09 (B)**	(B)-(A)	Change (%)	Six months ending 9/30/09 (Forecast)	Year ending 3/31/10 (Forecast)
meropenem trihydrate Carbapenem antibiotic	18.1	**16.2**	(1.8)	(10.0%)	9.2	15.8
zonisamide Antiepileptic	0.3	**1.0**	0.7	246.3%	0.2	0.4
mosapride citrate Gastroprokinetic	1.7	**1.0**	(0.7)	(40.3%)	0.6	1.2

Note: Forecasts shown above include sales arising in China because Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., a Chinese subsidiary, is newly added as a consolidated subsidiary from the year ending March 31, 2010.

Industrial Property Revenues (Billions of Yen)

	Year ended 3/31/08 (A)	**Year ended 3/31/09 (B)**	(B)-(A)	Change (%)	Six months ending 9/30/09 (Forecast)	Year ending 3/31/10 (Forecast)
Industrial property revenues	3.5	**3.2**	(0.3)	(9.0%)	1.8	3.1

(Overseas Sales) (Billions of Yen)

	Year ended 3/31/08 (A)	**Year ended 3/31/09 (B)**	(B)-(A)	Change (%)	Six months ending 9/30/09 (Forecast)	Year ending 3/31/10 (Forecast)
Overseas sales	24.5	**22.1**	(2.5)	(10.1%)	12.6	21.7
Industrial property revenues	3.5	**3.2**	(0.3)	(9.0%)	1.8	3.1
[% of net sales]	[9.3%]	**[8.4%]**			[9.6%]	[8.2%]

III. Consolidated Balance Sheets

ASSETS

(Billions of Yen)

	As of 3/31/08 (A)	As of 3/31/09 (B)	(B) - (A)
[Assets]	399.8	391.3	(8.5)
Current assets:	251.1	263.5	12.5
Cash and time deposits	28.2	22.0	(6.2)
Notes and accounts receivable	86.4	79.8	(6.6)
Marketable securities	30.1	34.5	4.4
Inventories	48.5	54.5	6.0
Short-term loans	40.0	50.0	10.0
Deferred tax assets	13.4	17.1	3.8
Others	4.9	6.0	1.2
Allowance for doubtful receivables	(0.3)	(0.4)	(0.1)
Fixed assets:	148.7	127.8	(21.0)
Property, plant and equipment:	70.3	69.1	(1.2)
Buildings and structures	39.8	39.5	(0.3)
Machinery, equipment and carriers	10.1	11.0	1.0
Land	10.0	10.0	—
Construction in progress	6.2	4.0	(2.1)
Others	4.3	4.6	0.3
Intangible assets	5.8	6.4	0.6
Investments and other assets:	72.6	52.2	(20.4)
Investment securities	44.3	34.0	(10.4)
Deferred tax assets	1.6	3.7	2.1
Others	26.9	14.6	(12.3)
Allowance for doubtful receivables	(0.3)	(0.1)	0.2
Total assets	399.8	391.3	(8.5)

・Decrease in time deposits and increase in negotiable certificates of deposit

・Increased short-term loans to the parent company

・Decrease by valuation of investment securities

・Withdrawal of long-term time deposits

	Year ended 3/31/08	Year ended 3/31/09
Accounts receivable turnover period (in months)	3.93	3.62

LIABILITIES AND NET ASSETS

(Billions of Yen)

	As of 3/31/08 (A)	As of 3/31/09 (B)	(B) - (A)
［Liabilities］	81.5	66.8	(14.7)
Current liabilities:	67.9	53.3	(14.6)
Notes and accounts payable	16.5	18.5	2.0
Current portion of long-term debt	4.6	—	(4.6)
Income taxes payable	10.9	6.3	(4.6)
Reserve for bonuses	8.2	8.1	(0.1)
Reserve for sales returns	0.1	0.1	(0.0)
Reserve for sales rebates	0.5	0.4	(0.0)
Reserve for loss on litigation	1.1	—	(1.1)
Other accounts payable	22.8	16.9	(5.9)
Others	3.3	3.0	(0.3)
Long-term liabilities:	13.6	13.4	(0.1)
Liability for retirement benefits	8.8	9.3	0.5
Liability for directors' retirement benefits	0.0	0.0	0.0
Others	4.8	4.2	(0.6)
［Net assets］	318.3	324.5	6.2
Shareholders' equity:	306.5	319.2	12.7
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	268.8	281.6	12.8
Treasury stock	(0.6)	(0.6)	(0.1)
Valuation, translation adjustments and others	11.7	5.2	(6.5)
Unrealized gains on available-for-sale securities, net of tax	11.7	5.2	(6.5)
Minority interests	0.1	0.1	0.0
Total liabilities and net assets	399.8	391.3	(8.5)

・Repayment of long-term debt

・Payments for construction of new solid dosage form building at Suzuka plant

・Decrease by valuation of investment securities

IV. Group-to-Parent Ratios, Consolidated Subsidiaries, Numbers of Employees and MRs

1. Group-to-parent ratios for the year ended 3/31/09

(Billions of Yen)

	Consolidated	Non-consolidated	Variance	Group-to-parent ratio
Net sales	264.0	248.4	15.6	1.06
Operating income	31.2	30.6	0.6	1.02
Ordinary income	31.4	30.9	0.5	1.02
Net income	20.0	19.7	0.3	1.01

2. Consolidated subsidiaries (as of 3/31/09)

	Establishment	Paid-in capital	Ownership
Gokyo Trading Co., Ltd.	October 1947	¥100 million	96.3%
DS Pharma Biomedical Co., Ltd.	April 2001	¥480 million	100%

3. Number of employees (as of 3/31/09): 4,787 (consolidated); 4,646 (non-consolidated)

4. Number of MRs (as of 3/31/09): 1,420 (excluding managers); 1,620 (including managers)

V. Quarterly Business Results

(Billions of Yen)

	Year ended 3/31/08				Year ended 3/31/09			
	1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter	3rd quarter	4th quarter
Net sales	65.3	63.4	70.5	64.8	70.1	64.2	67.6	62.1
Cost of sales	25.4	22.8	25.9	25.3	27.8	25.0	26.0	24.9
SG&A expenses	27.8	30.5	33.7	32.8	32.1	31.2	32.2	33.6
SG&A expenses less R&D costs	18.5	20.1	19.6	19.3	19.5	19.1	18.6	19.1
R&D costs	9.3	10.4	14.1	13.5	12.7	12.1	13.5	14.5
Operating income	12.1	10.2	10.9	6.6	10.2	8.0	9.4	3.6
Non-operating income	1.1	0.4	1.0	0.6	1.0	0.4	1.2	0.4
Non-operating expenses	0.4	1.3	0.8	2.8	0.4	1.0	0.3	1.0
Ordinary income	12.8	9.4	11.1	4.4	10.8	7.4	10.2	2.9
Extraordinary income	—	—	—	3.8	—	—	—	1.1
Extraordinary loss	—	—	—	—	—	—	—	0.3
Income before income taxes and minority interests	12.8	9.4	11.1	8.2	10.8	7.4	10.2	3.7
Net income	7.8	6.0	6.9	4.9	6.4	4.4	6.2	2.9

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

VI. Non-Consolidated Financial Highlights

1. Highlights of the Statements of Income (Billions of Yen)

	Year ended 3/31/08	Year ended 3/31/09		Six months ending 9/30/09 (Forecast)		Year ending 3/31/10 (Forecast)	
			Change (%)		Change (%)		Change (%)
Net sales	247.8	248.4	0.3	121.6	(3.6)	245.0	(1.4)
Cost of sales	86.2	91.2	5.8	45.5	(1.2)	93.1	2.1
SG&A expenses	122.1	126.6	3.7	63.3	1.9	128.0	1.1
SG&A expenses less R&D costs	75.0	73.9	(1.4)	36.7	(1.7)	73.7	(0.3)
R&D costs	47.1	52.7	11.9	26.6	7.5	54.3	3.0
Operating income	39.5	30.6	(22.5)	12.8	(29.1)	23.9	(21.9)
Ordinary income	38.0	30.9	(18.7)	12.5	(31.0)	23.0	(25.5)
Net income	25.4	19.7	(22.4)	7.7	(29.5)	14.1	(28.5)

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

"Change(%)" represent ratio of changes from the corresponding period of the previous year.

Earnings per share (yen)	63.99	49.65		35.49

2. Highlights of the Balance Sheets (Billions of Yen)

	As of 3/31/08 (A)	As of 3/31/09 (B)	(B) - (A)
Total assets	394.8	387.0	(7.7)
Net assets	317.0	323.0	6.0
Shareholders' equity ratio	80.3%	83.5%	

VII. Shareholder Positioning (As of March 31, 2009)

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

2. Total number of shares outstanding: 397,900,154 (Number of treasury stock 580,814)

3. Number of shareholders: 16,912

4. Major shareholders:

Shareholders	Status of ownership	
	Number of shares held (Thousand shares)	Percentage of issued shares (%)
Sumitomo Chemical Co., Ltd.	199,434	50.12
Inabata & Co., Ltd.	27,282	6.86
The Master Trust Bank of Japan, Ltd. (Trust account)	16,587	4.17
Nippon Life Insurance Company	10,530	2.65
Japan Trustee Services Bank, Ltd. (Trust account)	10,195	2.56
Japan Trustee Services Bank, Ltd. (Trust account 4G)	7,179	1.80
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
The Dai-ichi Mutual Life Insurance Company	3,248	0.82

VIII. Development Pipeline (as of May 11, 2009)

Major Products under Development in Japan by DSP

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
NDA filed	SM-11355 Injection	miriplatin hydrate	Hepatocellular carcinoma	In-house	Suspending in vehicle before use
	SMP-862 Oral	metformin hydrochloride	Diabetes	Merck Santé	Improvement of insulin resistance and reduction in hepatic glyconeogenesis
NDA filed New Indication	AmBisome® Injection	amphotericin B	Fungal species	Gilead Sciences	Approved indications: deep-seated mycosis, febrile neutropenia with possible mycotic infection
	MEROPEN® Injection	meropenem hydrate	Febrile neutropenia	In-house	Approved indications: moderate to severe bacterial infections

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Phase III	SMP-508 Oral	repaglinide	Diabetes	Novo Nordisk	Rapid insulin secretagogue
	SM-13496 Oral	lurasidone	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	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	

[Main revisions since the announcement of February 2009]

TRERIEF® (zonisamide)	Deleated because of "Launched"
GASMOTIN® for new indication	Deleated because of "Approved"
DSP-8153	Newly added in Phase II
DSP-3025	Phase I study is ongoing
AC-3933	Deleted because of discontinuation

Major Products under Development in Foreign Markets by DSP

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Phase III	SM-13496 Oral	lurasidone	Schizophrenia Bipolar disorder	In-house	U.S. and Europe, etc.	
	amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell cancer	In-house	China	Domestic brand name: CALSED®

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	

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.	
	DSP-7238 Oral	TBD	Diabetes	In-house	Europe	DPPIV inhibitor
	DSP-8658 Oral	TBD	Diabetes	In-house	U.S.	PPARα/γ modulator

[Main revisions since the announcement of February 2009]

AC-3933 Deleted because of discontinuation

Major Products under Development in Foreign Markets 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 trials ongoing 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 ongoing in the U.S. by Protez Pharmaceuticals (Protez's product code: PZ-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 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. Under preparation for Phase III in the U.S. and Europe by Eisai
droxidopa (DOPS®)	Intradialytic hypotension, neurogenic orthostatic hypotention	Out-licensed to Chelsea for the worldwide territory, excluding Japan, China, Korea and Taiwan in May 2006. Phase II study of intradialytic hypotension ongoing in the U.S. by Chelsea. Phase III study of neurogenic orthostatic hypotension ongoing in the U.S. and Europe 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 I ongoing in Europe by AstraZeneca

[Main revisions since the announcement of February 2009]

None

IX. Profile of Major Products under Development (as of May 11, 2009)

SM-11355 (miriplatin hydrate) Hepatocellular carcinoma

- Developed in-house
- This drug is a lipid-soluble platinum complex that is suspended in ethyl esters of iodized fatty acids of poppy seed oil (EEIFA) and the suspension is injected via a hepatic artery into the liver. By having it suspended in EEIFA, the active substance of this drug is localized around the tumor and gradually released for a long time from EEIFA. This mechanism of action was confirmed in clinical studies on this drug, resulting in a high anti-tumor effect with reduced systemic and hepatic adverse reactions.
- Development stage: NDA filed in Japan

SMP-862 (metformin hydrochloride) Diabetes

- In-licensed from Merck Santé
- SMP-862 (metformin hydrochloride) is an anti-diabetic agent that lowers blood glucose levels by reducing hepatic glyconeogenesis and improving peripheral glucose uptake, without enhancing insulin secretion. An oral formulation of metformin hydrochloride was first developed and launched as Melbin® in Japan by our company in 1961. However, the indication and dosage for Japanese patients are different from those for overseas. Following the accumulated findings from the large-scale clinical trials on this drug conducted in the U.S. and Europe, we have conducted clinical studies to obtain approval for metformin hydrochloride with appropriate indication and dosage regimen for Japanese patients.
- Development stage: NDA filed in Japan

SMP-508 (repaglinide) Diabetes

- In-licensed from Novo Nordisk
- A rapid insulin secretagogue. This drug is expected to suppress the postprandial elevation of blood glucose levels, resulting in lower HbAlc and fasting blood glucose levels.
- Development stage: Phase III in Japan

SM-13496 (lurasidone) Schizophrenia, Bipolar disorder

- Developed in-house
- SM-13496 is a potent antagonist against dopamine-2, serotonin-2 and serotonin-7 receptors with a high affinity for serotonin-1A receptor. This drug is expected to have high antipsychotic efficacy with superior safety profile due to a reduced incidence of extrapyramidal reactions, cardiac reactions and weight gain.
- Development stage: Phase III as Global study and Pan-Asia study (Japan, Korea and Taiwan)

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 drug has a stronger inhibitory effect and is longer acting compared to other drugs in this therapeutic area. AS-3201 showed good penetration into the nerve tissue, resulting in dose-dependent inhibition of intraneural accumulation of sorbitol and fructose in a clinical study. Based on the results of clinical studies, this drug 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 planning Phase III study.

- 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). The drug is expected to have an antihypertensive activity for the patients with essential hypertension who don't have enough antihypertensive effect by irbesartan or amlodipine treatment. In addition, it is expected to have cerebroprotective, cardioprotective and renal protective effects for patients with essential hypertension, because irbesartan has evidences for the renal protective effects and amlodipine has a lot of 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. The drug is expected to ease urinary urgency and reduce the frequency of both urination and incontinence. This drug is 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 the drug discovery research for a therapeutic agent with a novel mechanism of action targeting for allergic disorders. With this as a turning point, we started research collaboration with AstraZeneca in 2004, and discovered a drug candidate as an outcome from the research collaboration.
- 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. Phase I studies ongoing in Europe by AstraZeneca.
- Development stage: Phase I in Japan

SMP-028 Bronchial asthma

- Developed in-house
- SMP-028 shows a variety of effects to 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.

- Development stage: Phase I in the U.S.

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.