Securities Code: 4506

Supplementary Financial Data for the Second Quarter of the Year Ending March 31, 2010

October 29, 2009

Dainippon Sumitomo Pharma Co., Ltd.

- This document contains forward-looking statements based on management's assumptions and beliefs in light of the information currently available, and involve risks and uncertainties. Actual financial results may differ materially depending on a number of factors, including economic conditions.
- Forecasts for the year ending March 31, 2010 do not include figures of Sepracor Inc..
- 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)

	Six months ended 9/30/08	SIx months ended 9/30/09		Year ended 3/31/09		Year ending 3/31/10 (Forecasts)	
			Change (%)		Change (%)		Change (%)
Net sales	134.4	132.2	(1.6)	264.0	0.0	264.0	—
Cost of sales	52.8	51.3	(2.9)	103.7	4.4	105.0	1.2
SG&A expenses	63.3	62.0	(2.2)	129.1	3.5	130.0	0.7
SG&A expenses less R&D costs	38.5	37.7	(2.1)	76.3	(1.6)	77.0	0.9
R&D costs	24.8	24.2	(2.2)	52.8	11.7	53.0	0.3
Operating income	18.2	18.9	4.1	31.2	(21.7)	29.0	(7.0)
Ordinary income	18.2	19.1	4.6	31.4	(16.6)	27.0	(14.0)
Net income	10.9	12.7	16.4	20.0	(21.9)	18.0	(9.9)

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.
Sumitomo Pharmaceuticals (Suzhou) Co.,Ltd. is newly added as a consolidated subsidiary from this fiscal year.

Earnings per share (yen)	27.35	31.85	50.30	45.30
Return on equity (ROE)	3.4%	3.8%	6.2%	5.5%
Payout ratio	32.9%	28.3%	35.8%	39.7%

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

	As of 3/31/09 (A)	As of 9/30/09 (B)	(B) - (A)
Total assets	391.3	394.2	2.9
Net assets	324.5	333.2	8.7
Shareholders' equity	324.4	333.1	8.7
Shareholders' equity ratio	82.9%	84.5%	

3. Capital Expenditures and Depreciation (Billions of Yen)

	Six months ended 9/30/08 (A)	Six months ended 9/30/09 (B)	(B) - (A)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts)	Change
Capital expenditures (including intangible assets)	6.9	2.6	(4.3)	10.6	11.0	0.4
Depreciation and amortization	5.1	5.1	(0.0)	10.7	11.5	0.8

- 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)

	Six months ended 9/30/08 (A)	Six months ended 9/30/09 (B)	(B)-(A)
Net cash provided by operating activities	10.4	13.0	2.6
Net cash used in investing activities	(13.0)	2.1	15.1
Net cash used in financing activities	(8.2)	(3.7)	4.6
Increase related to change in scope of consolidation	—	0.5	0.5
Cash and cash equivalents at the end of period	45.5	61.4	15.9

II. Consolidated Statements of Income

1. Statements of Income (Billions of Yen)

	Six months ended 9/30/08 (A)	Six months ended 9/30/09 (B)	(B)-(A)	Change (%)
Net sales	134.4	132.2	(2.1)	(1.6)
Overseas sales	12.6	12.4	(0.2)	(1.7)
Cost of sales	52.8	51.3	(1.5)	(2.9)
Gross profit	81.5	80.9	(0.6)	(0.8)
SG&A expenses	63.3	62.0	(1.4)	(2.2)
Labor costs	15.9	16.8	0.8	5.3
Advertising and promotion costs	2.8	2.1	(0.7)	(25.5)
Sales promotion costs	5.5	5.4	(0.1)	(1.5)
Other costs	14.3	13.4	(0.9)	(6.1)
SG&A expenses less R&D costs	38.5	37.7	(0.8)	(2.1)
R&D costs	24.8	24.2	(0.5)	(2.2)
Operating income	18.2	18.9	0.7	4.1
Non-operating income	1.4	1.4	(0.0)	
Non-operating expenses	1.4	1.3	(0.1)	
Ordinary income	18.2	19.1	0.8	4.6
Income before income taxes and minority interests	18.2	19.1	0.8	4.6
Income taxes	7.3	6.4	(0.9)	
Minority interests in net income	0.0	0.0	(0.0)	
Net income	10.9	12.7	1.8	16.4

(Positives)
・Increased sales of GASMOTIN®, PRORENAL®, MEROPEN®
・ Sales growth of LONASEN®, AmBisome®
(Negatives)
・Decreased sales of AMLODIN® due to the influence of generics

・Cost of sales ratio 39.3%→38.8%

・Decrease in costs related to new products (AVAPRO®／LONASEN®)
・Decrease in TV commercials, etc.

・Efficient spending of R&D costs
・Increase in overseas development cost of lurasidone

・Decrease by expansion of R&D tax reduction

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

2. Segment Information (Billions of Yen)

	Six months ended 9/30/08			Six months ended 9/30/09			Year ended 3/31/09			Year ending 3/31/10 (Forecasts)		
	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total	Pharmaceuticals	Other products	Total
Net sales	106.1	28.2	134.4	103.5	28.7	132.2	206.8	57.2	264.0	205.2	58.8	264.0
Operating income	17.5	0.7	18.2	17.7	1.2	18.9	29.8	1.3	31.2			

3. Sales of Major Products

Pharmaceuticals（Domestic） （Billions of Yen）

Brand name (Generic name) Therapeutic indication	Six months ended 9/30/08 (A)	**Six months ended 9/30 /09 (B)**	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	30.5	**26.9**	(12.0)	54.3	57.9	[48.0] 49.5
GASMOTIN® (mosapride citrate) Gastroprokinetic	9.9	**10.4**	4.9	49.4	20.2	21.0
PRORENAL® (limaprost alfadex) Vasodilator	7.3	**7.8**	7.0	50.6	14.8	15.5
MEROPEN® (meropenem) Carbapenem antibiotic	7.3	**7.6**	4.8	54.9	14.8	[12.9] 13.9
EBASTEL® (ebastine) Long-acting Antiallergic	3.9	**4.0**	2.6	44.2	10.6	[8.6] 9.1
SUMIFERON® (interferon-α NAMALWA)) Natural alpha interferon	3.0	**3.0**	(0.7)	50.2	6.0	6.0
LONASEN® (blonanserin) Antipsychotic agent	1.3	**3.0**	122.3	45.6	3.4	6.5
GROWJECT® (somatropin) Growth hormone	2.2	**2.4**	8.5	51.4	4.3	4.6
MELBIN® (metformin) Oral hypoglycemic	1.6	**1.9**	17.2	49.1	3.4	3.9
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	1.4	**1.9**	34.2	43.8	3.1	4.3
DOPS® (droxidopa) Noradrenaline-activating neural function ameliorant	1.9	**1.9**	(3.0)	51.7	3.8	3.6
EXCEGRAN® (zonisamide) Antiepileptic	1.8	**1.8**	1.2	48.3	3.6	3.8
GLIMICRON® (gliclazide) Oral hypoglycemic	1.8	**1.7**	(7.2)	50.2	3.6	3.4
ALMARL® (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	1.5	**1.5**	(5.6)	50.5	3.0	2.9
QVAR™ (beclomethasone dipropionate) Inhaled steroid antiasthmatic	1.8	**1.4**	(21.5)	46.4	3.6	3.0
LULLAN® (perospirone) Antipsychotic	1.5	**1.3**	(8.9)	49.8	2.8	2.7
SEDIEL® (tandospirone) Serotonin-agonist antianxiety drug	1.4	**1.3**	(6.1)	51.2	2.7	2.6
TAGAMET® (cimetidine) H_2-receptor antagonist	1.4	**1.2**	(12.0)	51.9	2.7	2.4
AVAPRO® (irbesartan) Therapeutic agent for hypertension	1.3	**1.0**	(22.2)	25.8	1.5	[6.0] 4.0
TRERIEF® (zonisamide) Therapeutic agent for Parkinson's disease	—	**0.4**	—	33.6	—	1.1

(C): Figures in parentheses [ ] are forecasts released on May 11, 2009.

Pharmaceuticals（Overseas） （Billions of Yen）

Generic name Therapeutic indication	Six months ended 9/30/08 (A)	**Six months ended 9/30/09 (B)**	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
meropenem trihydrate Carbapenem antibiotic	9.4	**9.8**	5.1	59.6	16.2	[15.8] 16.5
mosapride citrate Gastroprokinetic	0.6	**0.5**	(29.4)	37.7	1.0	1.2
Zonisamide Antiepileptic	0.7	**0.2**	(67.8)	54.8	1.0	0.4

Note: (B) and (C) include sales of Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., a Chinese subsidiary, which was newly added as a consolidated subsidiary from this fiscal year.

Industrial Property Revenues （Billions of Yen）

	Six months ended 9/30/08 (A)	**Six months ended 9/30/09 (B)**	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
Industrial property revenues	1.6	**1.4**	(16.1)	54.8	3.2	[3.1] 2.5

(Overseas Sales) （Billions of Yen）

	Six months ended 9/30/08 (A)	**Six months ended 9/30/09 (B)**	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
Overseas sales	12.6	**12.4**	(1.7)	57.0	22.1	[21.7] 21.8
Industrial property revenues	1.6	**1.4**	(16.1)	54.8	3.2	[3.1] 2.5
〔% of net sales〕	〔9.4%〕	〔9.4%〕			〔8.4%〕	〔8.3%〕

III. Consolidated Balance Sheets

ASSETS

(Billions of Yen)

	As of 3/31/09 (A)	As of 9/30/09 (B)	(B) - (A)
[Assets]	391.3	394.2	2.9
Current assets:	263.5	270.6	7.0
Cash and time deposits	22.0	22.4	0.4
Notes and accounts receivable	79.8	81.9	2.2
Marketable securities	34.5	42.5	8.0
Inventories	54.5	51.1	(3.4)
Short-term loans	50.0	50.0	—
Deferred tax assets	17.1	18.1	1.0
Others	6.0	4.8	(1.3)
Allowance for doubtful receivables	(0.4)	(0.2)	0.2
Fixed assets:	127.8	123.6	(4.1)
Property, plant and equipment:	69.1	67.3	(1.8)
Buildings and structures	39.5	38.7	(0.8)
Machinery, equipment and carriers	11.0	12.0	1.0
Land	10.0	10.0	—
Construction in progress	4.0	2.5	(1.6)
Others	4.6	4.2	(0.4)
Intangible assets	6.4	6.0	(0.4)
Investments and other assets:	52.2	50.3	(1.9)
Investment securities	34.0	38.1	4.1
Deferred tax assets	3.7	2.4	(1.3)
Others	14.6	9.9	(4.7)
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)
Total assets	391.3	394.2	2.9

・Increase in negotiable certificates of deposit

・Increase by revaluation of investment securities

・Withdrawal of long-term time deposits

	Year ended 3/31/09	Six months ended 9/30/09
Accounts receivable turnover period (in months)	3.62	3.72

LIABILITIES AND NET ASSETS

(Billions of Yen)

	As of 3/31/09 (A)	As of 9/30/09 (B)	(B) - (A)
［Liabilities］	66.8	61.0	(5.8)
Current liabilities:	53.3	46.9	(6.4)
Notes and accounts payable	18.5	12.4	(6.1)
Income taxes payable	6.3	6.9	0.6
Reserve for bonuses	8.1	7.0	(1.1)
Reserve for sales returns	0.1	0.1	(0.0)
Reserve for sales rebates	0.4	0.5	0.1
Others	19.9	20.0	0.1
Long-term liabilities:	13.4	14.1	0.6
Long-term debt	—	0.9	0.9
Liability for retirement benefits	9.3	9.5	0.2
Liability for directors' retirement benefits	0.0	0.0	0.0
Others	4.2	3.7	(0.5)
［Net assets］	324.5	333.2	8.7
Shareholders' equity:	319.2	327.3	8.1
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	281.6	289.7	8.1
Treasury stock	(0.6)	(0.6)	(0.0)
Valuation, translation adjustments and others:	5.2	5.8	0.6
Unrealized gains on available-for-sale securities, net of tax	5.2	7.1	2.0
Deferred gains or losses on hedges	—	(1.2)	(1.2)
Foreign currency translation adjustment	—	(0.1)	(0.1)
Minority interests	0.1	0.1	0.0
Total liabilities and net assets	391.3	394.2	2.9

・Loans payable of Sumitomo Pharmaceuticals (Suzhou)

・Increase by net income
・Decrease by dividends paid

・Valuation adjustments of foreign exchange contracts in preparation for the acquisition of Sepracor Inc.

IV. Consolidated Statements of Cash Flows

(Billions of Yen)

	Six months ended 9/30/08 (A)	Six months ended 9/30/09 (B)
Income before income taxes and minority interests	18.2	19.1
Depreciation and amortization	5.5	5.5
Interest and dividends income	(0.9)	(0.7)
Decrease (increase) in notes and accounts receivable	1.7	(2.1)
Decrease (increase) in inventories	1.5	3.9
Increase (decrease) in notes and accounts payable	(3.0)	(5.9)
Other－net	(3.5)	(1.7)
Subtotal	19.6	18.0
Interest and dividends received less paid	0.9	0.9
Income taxes paid	(10.1)	(5.9)
Net cash provided by operating activities	10.4	13.0
Decrease in time deposits	3.0	5.0
Proceeds from sales / redemption of marketable securities	1.0	2.0
Purchases of property, plant and equipment / intangible assets	(12.2)	(3.6)
Purchases of investment securities (including investments in subsidiaries)	(3.8)	(1.4)
Other－net	(0.9)	0.1
Net cash used in investing activities	(13.0)	2.1
Dividends paid	(3.6)	(3.6)
Other－net	(4.7)	(0.1)
Net cash used in financing activities	(8.2)	(3.7)
Effect of exchange rate changes on cash and cash equivalents	0.0	(0.0)
Net increase (decrease) in cash and cash equivalents	(10.8)	11.4
Cash and cash equivalents at the beginning of period	56.3	49.5
Increase in cash and cash equivalents related to change in scope of consolidation	—	0.5
Cash and cash equivalents at the end of period	45.5	61.4

・Withdrawal of long-term time deposits

(A) Purchase of property, plant and equipment (new solid dosage form building at Suzuka Plant,etc.)

(A) Repayment of long-term debt

・Increase by adding Sumitomo Pharmaceuticals (Suzhou) as a consolidated subsidiary

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

1. Group-to-parent ratios for the Six months ended 9/30/09 (Billions of Yen)

	Consolidated	Non-consolidated	Variance	Group-to-parent ratio
Net sales	132.2	123.8	8.4	1.07
Operating income	18.9	18.2	0.8	1.04
Ordinary income	19.1	18.3	0.7	1.04
Net income	12.7	11.9	0.7	1.06

2. Consolidated subsidiaries (as of 9/30/09)

	Establishment	Paid-in capital	Ownership
Gokyo Trading Co., Ltd.	October 1947	¥100 million	96.12%
DS Pharma Biomedical Co., Ltd.	April 2001	¥480 million	100%
Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.	December 2003	$14 million	100%

3. Number of employees (as of 9/30/09): 5,240 (consolidated); 4,740 (non-consolidated)

4. Number of MRs (as of 9/30/09): 1,480 (excluding managers); 1,680 (including managers)

VI.Quarterly Business Results

(Billions of Yen)

	Year ended 3/31/09				Year ending 3/31/10	
	1st quarter	2nd quarter	3rd quarter	4th quarter	1st quarter	2nd quarter
Net sales	70.1	64.2	67.6	62.1	66.0	66.2
Cost of sales	27.8	25.0	26.0	24.9	25.4	25.9
SG&A expenses	32.1	31.2	32.2	33.6	29.4	32.6
SG&A expenses less R&D costs	19.5	19.1	18.6	19.1	17.5	20.2
R&D costs	12.7	12.1	13.5	14.5	11.9	12.4
Operating income	10.2	8.0	9.4	3.6	11.2	7.7
Non-operating income	1.0	0.4	1.2	0.4	1.1	0.3
Non-operating expenses	0.4	1.0	0.3	1.0	0.5	0.8
Ordinary income	10.8	7.4	10.2	2.9	11.8	7.2
Extraordinary income	—	—	—	1.1	—	—
Extraordinary loss	—	—	—	0.3	—	—
Income before income taxes and minority interests	10.8	7.4	10.2	3.7	11.8	7.2
Net income	6.4	4.4	6.2	2.9	7.8	4.8

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

VII.Shareholder Positioning (As of September 30, 2009)

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

2. Total number of shares outstanding: 397,900,154 (Number of treasury stock 582,925)

3. Number of shareholders: 17,986

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)	13,213	3.32
Nippon Life Insurance Company	10,530	2.65
Japan Trustee Services Bank, Ltd. (Trust account)	10,109	2.54
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
Bank of Tokyo-Mitsubishi UFJ, Ltd.	3,144	0.79

VIII. Acquisition of Sepracor Inc.

1. Objectives of Acquisition
   - Potential to accelerate penetration and maximize sales of Lurasidone in the U.S.
     →Leverage Sepracor's strong sales and marketing network, Synergies with existing products in the CNS area, Minimize time and cost required to build an extensive sales network
   - Establish business platform in North America
   - Expand scale of pharmaceutical business
   - Reinforcement of product pipeline
     →Pipeline products in all phases, Synergies in research intensive areas

2. Acquisition Overview
   - September 3 , 2009 : Entered into a definitive agreement pursuant to which DSP will acquire Sepracor through a cash tender offer.
   - October 19 , 2009 : The Tender Offer was completed. Approximately 86.9% of Sepracor's outstanding shares were tendered in the tender offer.
   - October 20 , 2009 : By exercising an option to acquire additional shares directly from Sepracor, DSP caused Aptiom to complete a short-form merger with and into Sepracor, and then Sepracor became a wholly-owned subsidiary of U.S. Holding Company.
   - Acquisition Price : $23.00 per share
     Total acquisition value is approx. $2.6 billion（approx.¥230 billion）.
   - Source of Funds : Cash on hands： Approx. ¥50 billion
     Bridge Loans： Approx. ¥180 billion
     Consideration for permanent financing will be given from a wide range of alternatives.

3. Overview of Sepracor
   - Businesses : Sepracor is a fully integrated specialty pharmaceutical company that has capacity in research and development, manufacturing, marketing and sales of pharmaceutical products in the therapeutic areas of CNS and respiratory disorders. The company currently markets six products in the U.S., including LUNESTA® (eszopiclone) agent for insomnia, in the CNS area, and XOPENEX® (levalbuterol HCl), inhaled beta-agonist, in the respiratory area.
   - Established : January 1984
   - Head Office : Marlborough, Massachusetts, U.S.A.
   - Performance in Recent Fiscal Year: : Net Sales $1,292 million, Operating income $59 million (Fiscal year ended December 2008)
   - Number of Employees : Approximately 2,100 (including MRs: Approx.1,200, R&D: 256) (as of June 30, 2009)

4. Impact on Earnings
   - Goodwill and intangible assets related to in-process R&D, which are under evaluation at present, are expected to be recognized in the year ending March 2010. Details including the financial impact will be announced once determined.

IX. Development Pipeline (as of October 29, 2009)

Major Products under Development in Japan by DSP

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Approved (awaiting NHI pricing)	MIRIPLA® (SM-11355) Injection	miriplatin hydrate	Hepatocellular carcinoma	In-house	Suspend in vehicle before use
NDA filed	SMP-862 Oral	metformin hydrochloride	Diabetes	Merck Santé	Improvement of insulin resistance and reduction in hepatic glyconeogenesis
	MEROPEN® Injection	meropenem hydrate	Febrile neutropenia	In-house	Approved indications: moderate to severe bacterial infections
	SMP-508 Oral	repaglinide	Diabetes	Novo Nordisc	Rapid insulin secretagogue

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
PhaseⅢ	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 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

[Main revisions since the announcement of July 2009]

MIRIPLA ® (miriplatin hydrate) Changed from "NDA filed" to "Approved (awaiting NHI pricing)"

repaglinide (SMP-508) Changed from "PhaseⅢ" to "NDA filed"

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 lung cancer	In-house	China	Brand name in Japan: 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. and UK	
	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 July 2009]

None

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 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: 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 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®)	Intradialytic hypotension, neurogenic orthostatic hypotention	Out-licensed to Chelsea Therapeutics 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 II study started in Europe by AstraZeneca

[Main revisions since the announcement of July 2009]

DSP-3025 AstraZeneca has started Phase II study in Europe

X. Profile of Major Products under Development (as of October 29, 2009)

SM-11355 (miriplatin hydrate) Hepatocellular carcinoma

- Developed in-house
- SM-11355 is a lipid-soluble platinum complex that is suspended in the oily lymphographic agent (ethyl esters of iodized fatty acids of poppy seed oil) and the suspension is injected via a hepatic artery into the tumor. After the administration into the hepatic artery, the suspension will localize around the tumor and the active substance of this compound will be gradually released from EEIFA over a long period. This mechanism of action, which has been confirmed in clinical studies, results in high anti-tumor effect with reduced systemic and hepatic adverse reactions.
- Development stage: Approved (awaiting NHI pricing) 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 patients. Following accumulated findings from the large-scale clinical studies conducted in the U.S. and Europe, we have conducted clinical studies to obtain approval for metformin hydrochloride with appropriate indication and dose regimens for Japanese patients.
- Development stage: NDA filed in Japan

SMP-508 (repaglinide) Diabetes

- In-licensed from Novo Nordisk
- A rapid insulin secretagogue. SMP-508 is expected to suppress the postprandial elevation of blood glucose levels, resulting in lower HbAlc and fasting blood glucose levels.
- Development stage: NDA filed in Japan

SM-13496 (lurasidone) Schizophrenia, Bipolar disorder

- Developed in-house
- SM-13496 has a unique receptor-binding profile with a high affinity for dopamine-2, serotonin-2A, serotonin-7, serotonin-1A and noradrenalin-α2c receptors. It exhibits little or no affinity for histamine-1 or acetylcholine-M1 receptors. SM-13496 is expected to have high antipsychotic efficacy with superior safety profile due to a reduced incidence of extrapyramidal reactions, cardiac reactions and weight gain. Furthermore, SM-13496 is also expected to have potential for treating Bipolar disorders.
- 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 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. Phase II study started in Europe by AstraZeneca.
- 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 started in the UK.
- Development stage: Phase I in the U.S. and UK

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.