Securities Code: 4506

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

July 30,2010

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)

	FY2009 1Q	FY2010 1Q	Change (%)	FY2010 2Q (Forecast)*3	Change (%)	FY2010 (Forecast)*3	Change (%)
Net sales	66.0	101.8	54.1	186.0	40.7	359.0	21.2
Cost of sales	25.4	32.6	28.4	56.5	10.1	108.0	(3.8)
SG&A expenses	29.4	54.4	84.9	115.0	85.6	242.5	63.4
SG&A expenses less R&D costs	17.5	39.9	127.4	83.5	121.3	175.0	80.4
R&D costs	11.9	14.5	22.1	31.5	29.9	67.5	31.4
Operating income	11.2	14.8	31.6	14.5	(23.4)	8.5	(76.1)
Ordinary income	11.8	14.8	25.4	13.5	(29.1)	6.0	(82.3)
Net income	7.8	9.3	18.7	8.1	(36.0)	3.0	(85.7)

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.
2: Change (%) represent ratio of changes from the corresponding period of the previous year.
3: Forecast released on May 10, 2010 are revised.

EBITDA (Billions of yen)	14.3	28.0	39.7	57.2
Earnings per share (yen)	19.68	23.35	20.39	7.55
Return on equity (ROE)	2.4%	2.7%	2.3%	0.9%

2. Financial Results of US Subsidiary

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

	FY2010 1Q	FY2010 2Q (Unaudited)	FY2010 (Forecast)
Net sales	34.0	63.0	119.3
Cost of sales	3.1	6.1	12.2
SG&A expenses	19.8	40.8	89.9
SG&A expenses less R&D costs	13.9	29.5	65.2
R&D costs	5.9	11.3	24.7
Operating income	11.1	16.1	17.2
Ordinary income	11.1	16.5	17.7
Net income	6.8	10.2	10.8

Note: Forecast released on May 10, 2010 are revised.

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

(Billions of yen)

	FY2010 1Q	FY2010 2Q (Unaudited)	FY2010 (Forecast)
Net sales	—	—	—
Cost of sales	1.6	2.6	3.4
SG&A expenses	8.2	16.6	33.0
SG&A expenses less R&D costs	8.2	16.6	33.0
R&D costs	—	—	—
Operating income	(9.8)	(19.2)	(36.4)
Ordinary income	(9.8)	(19.2)	(36.4)
Net income	(6.5)	(12.8)	(24.2)

4. Currency Exchange Rates

	FY2010 1Q average rate	FY2010 Forecast rate
Yen / USD	91	90
Yen / Yuan	13	13

5. Capital Expenditures and Depreciation

(Billions of yen)

	FY2009 1Q	FY2010 1Q	Change	FY2009	FY2010 (Forecast)	Change
Capital expenditures (including intangible assets)	1.2	1.6	0.4	6.5	15.0	8.5
Depreciation and amortization	2.5	2.8	0.3	11.0	14.0	3.0

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

II. Consolidated Statements of Income

1. Statements of Income (Billions of yen)

	FY2009 1Q (A)	FY2010 1Q (B)	(B)-(A)	Change (%)	Breakdown of (B)-(A)	
					US Subsidiary	Except US Subsidiary
Net sales	66.0	101.8	35.8	54.1	32.9	2.9
Overseas sales	6.1	40.5	34.3	558.2	32.9	1.4
[% of net sales]	[9.3%]	[39.8%]				
Cost of sales	25.4	32.6	7.2	28.4	4.7	2.5
Gross profit	40.7	69.2	28.5	70.2	28.2	0.4
SG&A expenses	29.4	54.4	25.0	84.9	26.9	(1.9)
Labor costs	8.3	16.2	7.9	95.8	7.6	0.3
Advertising and promotion costs	0.8	3.5	2.7	318.6	2.8	(0.1)
Sales promotion costs	2.3	2.7	0.3	13.6	0.4	(0.1)
Other costs	6.1	17.5	11.4	187.7	11.3	0.1
SG&A expenses less R&D costs	17.5	39.9	22.3	127.4	22.1	0.2
R&D costs	11.9	14.5	2.6	22.1	4.8	(2.2)
Operating income	11.2	14.8	3.6	31.6	1.2	2.3
Non-operating income	1.1	1.1	0.0		0.1	(0.1)
Non-operating expenses	0.5	1.1	0.6		0.1	0.5
Ordinary income	11.8	14.8	3.0	25.4	1.3	1.8
Income before income taxes and minority interests	11.8	14.8	3.0	25.4	1.3	1.8
Income taxes	4.0	5.6	1.5		0.9	0.6
Minority interests in net income	0.0	—	(0.0)		—	(0.0)
Net income	7.8	9.3	1.5	18.7	0.3	1.1

Note: Overseas sales includes the sales of export.

(Reference)

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

	FY2009 1Q (A)	FY2010 1Q (B)	Change (%)	Group-to-parent ratio
Net sales	62.2	64.0	2.9	1.59
Cost of sales	22.6	24.6	8.7	
SG&A expenses	28.6	26.6	(7.1)	
SG&A expenses less R&D costs	16.8	16.9	0.9	
R&D costs	11.9	9.7	(18.2)	
Operating income	11.0	12.8	17.0	1.15
Ordinary income	11.5	12.9	11.6	1.15
Net income	7.5	8.3	11.3	1.11

Earnings per share (yen)	18.88	21.01

2. Segment Information (1Q, FY2010) (Billions of yen)

	Pharmaceuticals Segment						Others	Total
	Japan	U.S.*1	Impact of purchase price allocation*2	China	Elimination	Total		
Net sales	53.4	34.0	—	1.5	(2.0)	86.8	15.0	101.8
Sales to customers	52.6	32.9	—	1.3	—	86.8	15.0	101.8
Intersegment	0.8	1.1	—	0.1	(2.0)	—	—	—
Cost of sales	15.6	3.1	1.6	0.5	(0.8)	20.0	12.6	32.6
Gross profit	37.9	30.8	(1.6)	1.0	(1.3)	66.8	2.4	69.2
SG&A expenses	25.5	19.8	8.2	0.4	(1.2)	52.7	1.7	54.4
SG&A expenses less R&D costs	16.0	13.9	8.2	0.4	(0.1)	38.3	1.5	39.9
R&D costs	9.5	5.9	—	—	(1.1)	14.3	0.2	14.5
Operating income	12.4	11.1	(9.8)	0.6	(0.0)	14.1	0.7	14.8

Note: *1: Excluding the impact of purchase price allocation by acquisition of Sepracor Inc.

*2: Mainly amortization of patent rights and goodwill

(Reference) Segment Information (1Q, FY2009) (Billions of yen)

	Pharmaceuticals Segment				Others	Total
	Japan	China	Elimination	Total		
Net sales	51.7	0.8	(0.5)	52.0	14.0	66.0
Cost of sales	13.6	0.3	(0.3)	13.6	11.8	25.4
Gross profit	38.1	0.6	(0.2)	38.4	2.2	40.7
SG&A expenses	27.6	0.3	(0.1)	27.8	1.6	29.4
Operating income	10.5	0.3	(0.1)	10.6	0.6	11.2

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

		FY2009 1Q (A)	**FY2010 1Q (B)**	(B)-(A)	Change (%)	FY2010 2Q(Forecast)		FY2010 (Forecast)	
Japan		51.3	**52.6**	1.3	2.5	[96.3]	98.6	[193.4]	194.2
	Domestic	45.9	**46.4**	0.5	1.2	[87.5]	88.1	[177.0]	176.5
	Export	5.4	**6.2**	0.8	14.1	[8.8]	10.5	[16.4]	17.7
U.S.		—	**32.9**	32.9	—	[58.8]	60.8	[111.0]	115.0
China		0.7	**1.3**	0.6	90.2	[2.4]	2.6	[5.6]	5.8
Overseas Sales Total									
Overseas sales (Pharmaceuticals)		6.1	**40.4**	34.3	561.8	[70.0]	73.9	[133.0]	138.5
[% of net sales (Pharmaceuticals)]		[11.7%]	**[46.5%]**				[45.6%]		[44.0%]

4. Sales of Major Products

Pharmaceuticals (Domestic) (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2009 1Q (A)	**FY2010 1Q (B)**	(B)-(A)	Change (%)	FY2010 2Q(Forecast)		FY2010 (Forecast)	
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	13.6	**10.9**	(2.8)	(20.3)	[20.0]	20.5	[38.5]	39.0
GASMOTIN® (mosapride citrate) Gastroprokinetic	5.2	**5.1**	(0.0)	(0.5)		10.1		20.4
PRORENAL® (limaprost alfadex) Vasodilator	3.9	**3.7**	(0.2)	(4.3)		7.8		16.0
MEROPEN® (meropenem) Carbapenem antibiotic	3.7	**3.3**	(0.4)	(11.0)	[5.5]	6.0	[10.2]	11.0
LONASEN® (blonanserin) Antipsychotic	1.4	**2.2**	0.8	57.7	[5.3]	4.5	[12.0]	10.5
AVAPRO® (irbesartan) Therapeutic agent for hypertension	0.2	**1.8**	1.5	646.7		3.6		8.0
EBASTEL® (ebastine) Antiallergic	2.0	**1.6**	(0.4)	(19.7)		2.8		7.3
SUMIFERON® (interferon-α NAMALWA) Natural alpha interferon	1.5	**1.4**	(0.2)	(11.9)		2.7		5.3
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	0.4	**1.1**	0.7	156.1		1.9		4.0
MELBIN® (metformin) Oral hypoglycemic	1.0	**1.1**	0.1	15.7		1.7		3.5
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	0.8	**1.1**	0.2	28.8		2.4		5.1
GROWJECT® (somatropin) Growth hormone	1.2	**1.1**	(0.1)	(12.1)		1.1		1.1
EXCEGRAN® (zonisamide) Antiepileptic	0.9	**0.9**	(0.0)	(2.0)		1.7		3.4
DOPS® (droxidopa) Neural function ameliorant	0.9	**0.9**	(0.1)	(6.4)		1.7		3.3
GLIMICRON® (gliclazide) Oral hypoglycemic	0.9	**0.8**	(0.1)	(11.9)		1.5		2.9
QVAR™ (beclomethasone dipropionate) Bronchial asthma	0.8	**0.7**	(0.1)	(11.0)		1.4		2.5
ALMARL® (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	0.8	**0.7**	(0.1)	(8.2)		1.3		2.5
LULLAN® (perospirone) Antipsychotic	0.7	**0.7**	(0.0)	(4.1)		1.2		2.4
SEDIEL® (tandospirone) Serotonin-agonist antianxiety drug	0.7	**0.6**	(0.1)	(7.6)		1.2		2.4

Note: Figures in parentheses [ ] are forecasts released on May 10, 2010.

Pharmaceuticals（Domestic, New Products）　　（Billions of yen）

Brand name (Generic name) Therapeutic indication	FY2009 1Q (A)	**FY2010 1Q (B)**	(B)-(A)	Change (%)	FY2010 2Q(Forecast)	FY2010 (Forecast)
TRERIEF® (zonisamide) Parkinson's disease drug (Launch: March, 2009)	0.2	**0.8**	0.6	337.3	1.3	2.8
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: December, 2009)	—	**0.4**	0.4	—	0.6	1.5
METGLUCO® (metformin) Oral hypoglycemic (Launch: May, 2010)	—	**0.0**	0.0	—	0.3	0.7

Pharmaceuticals（Export）

MEROPEN® (meropenem) Carbapenem antibiotic	4.8	**5.2**	0.4	8.2	[6.9]	8.1	[13.2]	13.6
GASMOTIN® (mosapride citrate) Gastroprokinetic	0.3	**0.4**	0.1	52.2	[0.6]	0.7	[1.0]	1.1
EXCEGRAN® (zonisamide) Antiepileptic	0.1	**0.5**	0.4	319.8	[0.5]	0.9	[0.8]	1.6
Industrial property revenues	0.1	**0.0**	(0.1)	(97.0)	[0.5]	0.7	[0.9]	1.1

Note: Sales to unaffiliated customers

U.S.

LUNESTA® (eszopiclone) Sedative hypnotic	—	**14.6**	14.6	—	[25.6]	28.5	[46.5]	50.4
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	—	**11.5**	11.5	—	[21.1]	19.0	[41.3]	39.4
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	—	**2.3**	2.3	—	[3.5]	4.5	[7.2]	8.7
OMNARIS® (ciclesonide) Corticosteroid nasal spray	—	**1.0**	1.0	—	[2.4]	2.6		4.8
Industrial property revenues	—	**2.2**	2.2	—	[3.8]	3.9		6.6

China

MEROPEN® (meropenem) Carbapenem antibiotic	0.7	**1.2**	0.6	82.4	[2.2]	2.3	[5.0]	5.2

Note: Figures in parentheses [ ] are forecasts released on May 10, 2010.

(Reference)
Quarterly Business Results of Sepracor Inc. (Millions of doller)

	Jan-Mar 2010	Apr-Jun 2010 (Unaudited)	Jan-Jun 2010 (Unaudited)
Net sales	363	315	677
Cost of sales	52	43	96
SG&A expenses	287	309	596
SG&A expenses less R&D costs (Excluding depreciation of patent rights)	149	163	313
R&D costs	58	66	124
Depreciation of patent rights*	80	80	159
Operating income	24	(38)	(14)

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

(Reference)
Sales of Products (Millions of dollar)

Brand name (Generic name) Therapeutic indication	Jan-Mar 2010	Apr-Jun 2010 (Unaudited)	Jan-Jun 2010 (Unaudited)
LUNESTA® (eszopiclone) Sedative hypnotic	161	151	312
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	127	81	207
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	25	24	49
OMNARIS® (ciclesonide) Corticosteroid nasal spray	11	17	28
Industrial property revenues	25	18	42
Others	14	24	38
Total	363	315	677

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 3/31/10 (A)	As of 6/30/10 (B)	(B)-(A)
[Assets]	626.7	624.8	(2.0)
Current assets:	287.6	303.1	15.6
Cash and time deposits	13.8	12.9	(0.9)
Notes and accounts receivable	94.0	101.3	7.4
Marketable securities	51.2	64.2	13.0
Inventories	65.2	60.7	(4.5)
Deferred tax assets	32.4	31.7	(0.7)
Short-term loans	25.0	25.0	—
Others	6.1	7.3	1.2
Allowance for doubtful receivables	(0.2)	(0.1)	0.1
Fixed assets:	339.2	321.6	(17.6)
Property, plant and equipment:	74.1	73.2	(0.9)
Buildings and structures	43.0	43.4	0.4
Machinery, equipment and carriers	12.8	12.8	0.0
Land	10.3	10.3	0.0
Construction in progress	2.7	1.5	(1.2)
Others	5.3	5.1	(0.2)
Intangible assets:	199.5	191.0	(8.5)
Goodwill	83.6	80.2	(3.4)
Patent rights	104.0	99.2	(4.8)
Others	11.9	11.6	(0.3)
Investments and other assets:	65.6	57.5	(8.2)
Investment securities	53.2	45.3	(7.8)
Deferred tax assets	2.4	2.4	0.0
Others	10.2	9.8	(0.4)
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)
Total assets	626.7	624.8	(2.0)

・Mainly increase in US subsidiary

・Transfer from investment securities
・Increase in negotiable certificates of deposit

・Decrease in inventories added according to accounting for business combinations

・Amortization according to accounting for business combinations

・Transfer to marketable securities
・Decrease by revaluation of investment securities

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 3/31/10 (A)	As of 6/30/10 (B)	(B)-(A)
[Liabilities]	283.3	275.7	(7.5)
Current liabilities:	265.0	258.4	(6.6)
Notes and accounts payable	16.9	15.3	(1.6)
Short-term loans payable	165.8	166.4	0.6
Income taxes payable	8.6	5.4	(3.2)
Reserve for bonuses	7.4	3.6	(3.8)
Reserve for sales returns	2.7	2.6	(0.1)
Reserve for sales rebates	15.7	15.3	(0.4)
Accounts payable-other	33.4	28.8	(4.6)
Others	14.5	21.0	6.5
Long-term liabili	18.3	17.3	(0.9)
Liability for retirement benefits	9.8	9.8	(0.0)
Liability for directors' retirement benefits	0.1	0.0	(0.0)
Others	8.4	7.6	(0.9)
[Net assets]	343.5	349.0	5.6
Shareholders' e	332.3	338.0	5.7
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	294.7	300.4	5.7
Treasury stock	(0.6)	(0.6)	(0.0)
Valuation, translation adjustments and others:	11.2	11.0	(0.1)
Unrealized gains on available-for-sale securities, net of tax	7.9	6.8	(1.2)
Deferred gains or losses on hedges	—	(0.0)	(0.0)
Foreign currency translation adjustment	3.2	4.3	1.1
Total liabilities and net assets	626.7	624.8	(2.0)

・Transfer from reserve to others (accrued expenses) due to settlement of bonus amounts

・Increase by net income
・Decrease by dividends payment

IV. Quarterly Business Results

(Billions of yen)

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

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

VII. Development Pipeline (as of July. 30, 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	TBD	Bronchial asthma, Allergic rhinitis	In-house	TLR7 agonist
	SMP-028 Oral	TBD	Bronchial asthma	In-house	

[Main revisions since the announcement of May 2010]

MEROPEN ® NDA field about change of the maximum daily dose ＜NDA field in May ,2010＞

SMP-508 Started “Phase III” for combination therapy with beguanide/thiazolidine

SMP-986 Changed from “Phase I” to “Phase II”

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 disease	In-house (Sepracor)	U.S.	
	SEP-228432 Oral	TBD	Attention-deficit hyperactivity disorder	In-house (Sepracor)	U.S.	

[Main revisions since the announcement of May. 2010]

None

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
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 May. 2010]

SMP-601 Removed from the chart, because Protez Pharmaceuticals has discontinued the development in the US.

VIII. Profile of Major Products under Development (as of June 30, 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 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 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 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.
- 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)
- SEP-227900 is an inhibitor of D-Serine Amino Acid Oxidase (DAAO). The compound is anticipated 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)
- SEP-228432 is a new triple reuptake inhibitor (TRI) that 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.