

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

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February 3, 2010

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 include figures of the subsidiaries in America.
- 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)

	Nine months ended 12/31/08	Nine months ended 12/31/09		Year ended 3/31/09	Year ending 3/31/10 (Forecasts)	
			Change (%)			Change (%)
Net sales	201.9	203.8	0.9	264.0	295.0	11.7
Cost of sales	78.9	79.1	0.3	103.7	113.5	9.4
SG&A expenses	95.5	92.7	(2.9)	129.1	150.5	16.5
SG&A expenses less R&D costs	57.2	57.0	(0.3)	76.3	97.0	27.1
R&D costs	38.3	35.7	(6.9)	52.8	53.5	1.3
Operating income	27.5	32.0	16.1	31.2	31.0	(0.5)
Ordinary income	28.4	31.8	11.8	31.4	29.0	(7.6)
Net income	17.1	21.2	23.8	20.0	19.0	(4.9)

Notes1: Cost of sales includes provision for (reversal of) reserve for sales returns.

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

3: The results of the subsidiaries in America (Dainippon Sumitomo Pharma America Holdings, Inc. / Dainippon Sumitomo Pharma America, Inc. / Sepracor Inc.) are to be included in consolidated results for Q4.

(No impact on profit for Q3)

Earnings per share (yen)	43.00	53.24	50.30	47.82
Return on equity (ROE)	5.3%	6.4%	6.2%	5.8%

2 . Valuations and accounting procedures by acquisition of Sepracor

(Millions of dollar)

	Before purchase price allocation	After purchase price allocation	Valuation differences	Accounting procedures (Amortization)	Impact on pretax income (Forecasts for FY2009)
Patent rights	—	1,208	1,208	Amortization years by products	69
In-process R&D (Intangible Assets)	—	57	57	Capitalize (Amortize after approval)	—
Inventories	67	146	79	Charge to cost of sales	40
Deferred tax liabilities (of the above)	—	(489)	(489)	—	—
Other assets & liabilities (Net)	661	721	6	—	—
Goodwill	26	864	838	Amortization for 20 years	9
Total	754	2,506	1,753		118

Notes: The above amounts of purchase price allocation are provisional for the present.

Patent rights include sales rights.

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

	As of 3/31/09 (A)	As of 12/31/09 (B)	(B) - (A)
Total assets	391.3	667.1	275.9
Net assets	324.5	338.6	14.1
Shareholders' equity	324.4	338.6	14.0
Shareholders' equity ratio	82.9%	50.8%	

4. Capital Expenditures and Depreciation (Billions of Yen)

	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)	(B) - (A)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts)	Change
Capital expenditures (including intangible assets)	8.7	3.9	(4.7)	10.6	11.0	0.4
Depreciation and amortization	7.9	7.8	(0.1)	10.7	12.0	1.3

Note: The above amounts don't include impact by asset valuation associated with acquisition of Sepracor.

- 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 April 2010)

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

	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)	(B)-(A)
Net cash provided by operating activities	12.6	20.4	7.8
Net cash used in investing activities	(23.9)	(173.9)	(149.9)
Net cash used in financing activities	(11.8)	169.8	181.6
Increase related to change in scope of consolidation	—	1.5	1.5
Cash and cash equivalents at the end of period	33.2	67.2	34.0

II. Consolidated Statements of Income

1. Statements of Income

(Billions of Yen)

	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)		
			(B)-(A)	Change (%)
Net sales	201.9	203.8	1.8	0.9
Overseas sales	14.7	16.1	1.4	9.2
Cost of sales	78.9	79.1	0.2	0.3
Gross profit	123.0	124.7	1.6	1.3
SG&A expenses	95.5	92.7	(2.8)	(2.9)
Labor costs	24.5	25.5	1.1	4.3
Advertising and promotion costs	3.8	3.0	(0.8)	(21.2)
Sales promotion costs	8.0	8.1	0.0	0.4
Other costs	21.0	20.5	(0.5)	(2.2)
SG&A expenses less R&D costs	57.2	57.0	(0.2)	(0.3)
R&D costs	38.3	35.7	(2.6)	(6.9)
Operating income	27.5	32.0	4.4	16.1
Non-operating income	2.6	1.9	(0.7)	
Non-operating expenses	1.7	2.1	0.4	
Ordinary income	28.4	31.8	3.4	11.8
Income before income taxes and minority interests	28.4	31.8	3.4	11.8
Income taxes	11.3	10.6	(0.7)	
Minority interests in net income	0.0	0.0	(0.0)	
Net income	17.1	21.2	4.1	23.8

(Positives)
 • Sales growth of LONASEN®、AVAPRO®、AmBisome®
 • Increased sales of DS Pharma Biomedical Co., Ltd.
 (Negatives)
 • Decreased sales of AMLODIN® due to the influence of generics

• Contribution of Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.

• Cost of sales ratio 39.1%⇒38.8%
 (Decrease in the influence of the application of "Accounting Standard for Measurement of Inventories")

• Efficient spending of R&D costs
 • Review of overseas development examination contents(lurasidone), influence of Yen's appreciation

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

2. Segment Information

(Billions of Yen)

	Nine months ended 12/31/08			Nine months ended 12/31/09			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	158.2	43.7	201.9	158.7	45.1	203.8	206.8	57.2	264.0	236.0	59.0	295.0
Operating income	26.4	1.2	27.5	29.8	2.2	32.0	29.8	1.3	31.2			

3. Sales of Major Products

(C): Figures in parentheses [] are forecasts released on October 29, 2009.

Pharmaceuticals (Domestic)

(Billions of Yen)

Brand name (Generic name) Therapeutic indication	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (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	46.1	41.6	(9.7)	82.4	57.9	[49.5] 50.5
GASMOTIN [®] (mosapride citrate) Gastroprokinetic	15.5	16.2	4.2	77.0	20.2	21.0
PRORENAL [®] (limaprost alfadex) Vasodilator	11.4	12.1	6.0	78.2	14.8	15.5
MEROPEN [®] (meropenem) Carbapenem antibiotic	11.5	11.6	0.9	83.7	14.8	13.9
EBASTEL [®] (ebastine) Long-acting Antiallergic	6.5	6.4	(1.1)	70.6	10.6	9.1
LONASEN [®] (blonanserin) Antipsychotic agent	2.4	4.7	93.6	72.7	3.4	6.5
SUMIFERON [®] (interferon- α NAMALWA)) Natural alpha interferon	4.7	4.5	(2.9)	75.8	6.0	6.0
GROWJECT [®] (somatropin) Growth hormone	3.3	3.6	6.7	77.6	4.3	4.6
AmBisome [®] (amphotericin B) Therapeutic agent for systemic fungal infection	2.3	3.1	31.4	71.3	3.1	4.3
MELBIN [®] (metformin) Oral hypoglycemic	2.5	3.0	17.5	76.8	3.4	3.9
DOPS [®] (droxidopa) Noradrenaline-activating neural function ameliorant	3.0	2.8	(4.0)	79.1	3.8	3.6
EXCEGRAN [®] (zonisamide) Antiepileptic	2.8	2.8	1.0	74.4	3.6	3.8
GLIMICRON [®] (gliclazide) Oral hypoglycemic	2.8	2.6	(8.0)	76.0	3.6	3.4
AVAPRO [®] (irbesartan) Therapeutic agent for hypertension	1.4	2.4	76.9	61.0	1.5	4.0
QVAR [™] (beclomethasone dipropionate) Inhaled steroid antiasthmatic	2.8	2.3	(17.7)	76.1	3.6	3.0
ALMARL [®] (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	2.4	2.2	(5.9)	77.0	3.0	2.9
LULLAN [®] (perospirone) Antipsychotic	2.2	2.0	(9.4)	75.1	2.8	2.7
SEDIEL [®] (tandospirone) Serotonin-agonist antianxiety drug	2.2	2.0	(6.0)	77.9	2.7	2.6
TAGAMET [®] (cimetidine) H ₂ -receptor antagonist	2.2	1.9	(12.6)	78.6	2.7	2.4
TRERIEF [®] (zonisamide) Therapeutic agent for Parkinson's disease	—	0.6	—	54.0	—	1.1

Pharmaceuticals (Overseas)

(Billions of Yen)

Generic name Therapeutic indication	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
meropenem trihydrate Carbapenem antibiotic	10.7	12.8	18.8	69.0	16.2	[16.5] 18.5
mosapride citrate Gastroprokinetic	0.8	0.8	(2.1)	67.7	1.0	1.2
Zonisamide Antiepileptic	1.0	0.4	(65.1)	90.1	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)

	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
Industrial property revenues	1.6	1.4	(16.4)	59.8	3.2	[2.5] 2.3

(Overseas Sales)

(Billions of Yen)

	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)	Change (%)	(B)/(C) (%)	Year ended 3/31/09	Year ending 3/31/10 (Forecasts) (C)
Overseas sales	14.7	16.1	9.2	30.9	22.1	[21.8] 52.1
Industrial property revenues	1.6	1.4	(16.4)	59.7	3.2	[2.5] 2.3
[% of net sales]	[7.3%]	[7.9%]			[8.4%]	[17.7%]

III. Consolidated Balance Sheets

ASSETS

(Billions of Yen)

	As of 3/31/09 (A)	As of 12/31/09 (B)	(B) - (A)	Impact of subsidiaries in US included in (B)-(A)
[Assets]	391.3	667.1	275.9	86.8
Current assets:	263.5	324.8	61.2	93.0
Cash and time deposits	22.0	14.2	(7.8)	3.3
Notes and accounts receivable	79.8	104.5	24.8	16.1
Marketable securities	34.5	64.5	30.0	33.5
Inventories	54.5	67.7	13.2	13.1
Deferred tax assets	17.1	26.8	9.6	9.2
Short-term loans	50.0	25.0	(25.0)	—
Others	6.0	22.2	16.1	17.8
Allowance for doubtful receivables	(0.4)	(0.2)	0.2	—
Fixed assets:	127.8	342.4	214.6	(6.3)
Property, plant and equipment:	69.1	74.1	5.0	8.0
Buildings and structures	39.5	42.7	3.2	4.5
Machinery, equipment and carriers	11.0	13.5	2.4	1.3
Land	10.0	10.3	0.4	0.4
Construction in progress	4.0	1.9	(2.2)	0.0
Others	4.6	5.7	1.2	1.9
Intangible assets	6.4	198.0	191.6	192.3
Goodwill	0.0	77.5	77.5	77.5
Patent rights	0.0	108.4	108.4	108.4
Others	6.4	12.0	5.6	6.4
Investments and other assets:	52.2	70.3	18.0	(206.6)
Investment securities	34.0	53.4	19.4	(210.8)
Deferred tax assets	3.7	4.2	0.4	1.2
Others	14.6	12.8	(1.8)	3.0
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)	—
Total assets	391.3	667.1	275.9	86.8

※ Eliminating DSP's investment account for the subsidiaries and the subsidiaries' capital account because of consolidation of subsidiaries in America.

LIABILITIES AND NET ASSETS

(Billions of Yen)

	As of 3/31/09 (A)	As of 12/31/09 (B)	(B) - (A)	Impact of subsidiaries in US included in (B) - (A)	
[Liabilities]	66.8	328.5	261.7	86.5	
Current liabilities:	53.3	307.3	254.0	79.3	
Notes and accounts payable	18.5	19.2	0.7	0.2	
Short-term loans payable	0.6	177.5	176.9	—	• Loans payable for acquisition of Sepracor
Current portion of bonds	—	25.9	25.9	25.9	
Current portion of long-term loans payable	—	0.3	0.3	—	
Income taxes payable	6.3	5.7	(0.6)	—	
Reserve for bonuses	8.1	4.0	(4.1)	—	
Reserve for sales returns	0.1	2.5	2.4	2.4	
Reserve for sales rebates	0.4	17.6	17.2	17.0	
Others	19.3	54.7	35.4	33.7	• Accounts payable-other, Accrued expenses
Long-term liabilities:	13.4	21.2	7.8	7.2	
Long-term debt	—	0.6	0.6	—	
Liability for retirement benefits	9.3	9.7	0.4	—	
Liability for directors' retirement benefits	0.0	0.0	0.0	—	
Others	4.2	10.9	6.7	7.2	
[Net assets]	324.5	338.6	14.1	0.2	
Shareholders' equity:	319.2	332.5	13.3	0.3	
Common stock	22.4	22.4	—	—	
Capital surplus	15.9	15.9	—	—	
Retained earnings	281.6	294.9	13.3	0.3	
Treasury stock	(0.6)	(0.6)	(0.0)	—	
Valuation, translation adjustments and others:	5.2	6.1	0.9	(0.1)	
Unrealized gains on available-for- sale securities, net of tax	5.2	6.3	1.1	—	
Deferred gains or losses on hedges	—	0.0	0.0	—	
Foreign currency translation adjustment	—	(0.2)	(0.2)	(0.1)	
Minority interests	0.1	—	(0.1)	—	
Total liabilities and net assets	391.3	667.1	275.9	86.8	

IV. Consolidated Statements of Cash Flows

(Billions of Yen)

	Nine months ended 12/31/08 (A)	Nine months ended 12/31/09 (B)	
Income before income taxes and minority interests	28.4	31.8	
Depreciation and amortization	8.4	8.4	
Decrease (increase) in notes and accounts receivable	(1.4)	(8.6)	
Decrease (increase) in inventories	(2.8)	0.3	
Increase (decrease) in notes and accounts payable	2.8	0.7	
Other – net	(5.7)	(1.8)	
Subtotal	29.8	30.8	
Interest and dividends received less paid	1.3	1.3	
Income taxes paid	(18.6)	(11.6)	
Net cash provided by operating activities	12.6	20.4	
Decrease (increase) in time deposits	2.0	5.0	
Purchases of property, plant and equipment / intangible assets	(15.0)	(4.6)	
Purchase of investments in subsidiaries resulting in change in scope of consolidation	—	(200.6)	• Net amount [Total purchase price of Sepracor] – [Cash equivalents of Sepracor]
Decrease (increase) in short-term loans receivable	(7.0)	25.0	
Other – net	(4.0)	1.4	
Net cash used in investing activities	(23.9)	(173.9)	
Net increase in short-term loans payable	—	176.9	• Loans for acquisition of Sepracor
Dividends paid	(7.1)	(7.1)	
Other – net	(4.7)	(0.0)	
Net cash used in financing activities	(11.8)	169.8	
Effect of exchange rate changes on cash and cash equivalents	0.0	(0.1)	
Net increase (decrease) in cash and cash equivalents	(23.1)	16.3	
Cash and cash equivalents at the beginning of period	56.3	49.5	• Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. • Dainippon Sumitomo Pharma America, Inc.
Increase in cash and cash equivalents related to change in scope of consolidation	—	1.5	
Cash and cash equivalents at the end of period	33.2	67.2	

V. 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	3rd quarter
Net sales	70.1	64.2	67.6	62.1	66.0	66.2	71.5
Cost of sales	27.8	25.0	26.0	24.9	25.4	25.9	27.8
SG&A expenses	32.1	31.2	32.2	33.6	29.4	32.6	30.7
SG&A expenses less R&D costs	19.5	19.1	18.6	19.1	17.5	20.2	19.3
R&D costs	12.7	12.1	13.5	14.5	11.9	12.4	11.4
Operating income	10.2	8.0	9.4	3.6	11.2	7.7	13.1
Non-operating income	1.0	0.4	1.2	0.4	1.1	0.3	0.5
Non-operating expenses	0.4	1.0	0.3	1.0	0.5	0.8	0.8
Ordinary income	10.8	7.4	10.2	2.9	11.8	7.2	12.8
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	12.8
Net income	6.4	4.4	6.2	2.9	7.8	4.8	8.5

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

VI. Development Pipeline (as of Feb. 3, 2010)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Remarks
Approved (awaiting NHI pricing)	METGLUCO® SMP-862 Oral	metformin hydrochloride	Diabetes	Merck Santé	Improvement of insulin resistance and reduction in hepatic glyconeogenesis (Approved in Jan. 2010)
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
Phase III	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 Oct. 2009]

MIRIPLA® (miriplatin hydrate)

Deleted because of “Launched” <Launched in Jan. 2010>

METGLUCO® (metformin hydrochloride)

Changed from “NDA filed” to “Approved (awaiting NHI pricing)” <Approved in Jan. 2010>

MEROPEN® (meropenem hydrate) for new indication

Deleted because of “Approved” <Approved in Jan. 2010>

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	Schizophrenia	In-house	U.S.	NDA submitted in Dec.2009
	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy-Adjunct	BIAL	U.S.	*NDA filed in Mar.2009

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Phase III	SM-13496 Oral	lurasidone	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.	*
	LUNESTA®	eszopiclone	(New Indication) Insomnia (Pediatrics)	In-house (Sepracor)	U.S.	*approved indication: Insomnia (adult)

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	
	SEP-227018 Oral	eszopiclone	(New Formulation) Insomnia	In-house (Sepracor)	U.S.	*
	ALVESCO® HFA Inhaler	ciclesonide	(New Indication) Asthma-Pediatric (age range TBD)	Nycomed	U.S.	*approved indication: asthma (12 years of age and older)
	SEP-225289 Oral	TBD	TBD	In-house (Sepracor)	U.S.	*
	SEP-227162 Oral	TBD	Major depressive disorder	In-house (Sepracor)	U.S.	*

Stage	Brand name/ Product code Formulation	Generic name	Therapeutic indications	Origin	Country/Area	Remarks
Phase I	SMP-028 Oral	TBD	Bronchial asthma	In-house	U.S. and Europe	
	DSP-7238 Oral	TBD	Diabetes	In-house	Europe	DPPIV inhibitor
	DSP-8658 Oral	TBD	Diabetes	In-house	U.S.	PPAR α/γ modulator
	SEP-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 Oct. 2009]

Lurasidone (SM-13496) Changed from "Phase III" to "NDA submitted" for schizophrenia in the U.S.
<NDA submitted in Dec. 2009>

* Pipeline candidates in Sepracor have been added.

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: 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 hypotension	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 is ongoing in Europe by AstraZeneca
eszopiclone	Insomnia	Out-licensed by Sepracor to Eisai for the Japanese territory in July, 2007. (Brand name in U.S.: LUNESTA®)

[Main revisions since the announcement of Oct. 2009]

eszopiclone

Newly added

VII. Profile of Major Products under Development (as of Feb. 3, 2010)

METGLUCO[®] (metformin hydrochloride) Diabetes

- In-licensed from Merck Santé
- METGLUCO[®] (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: Approved (awaiting NHI pricing) in Japan

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) 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- α 2c 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:
Schizophrenia: NDA submitted in the U.S., Phase III as Pan-Asia study (Japan, Korea and Taiwan)
Bipolar disorder: Phase III as Global study

STEDESAS[™] Antiepileptic

- In-licensed from BIAL
- STEDESAS, a new chemical entity, is a novel voltage-gated sodium channel blocker. STEDESAS has been studied in three Phase III, multi-center, randomized, placebo-controlled trials, which involved patients from 23 countries. Patients involved in the trials had a history of at least four partial-onset seizures per month despite treatment with one to three concomitant antiepileptic drugs. During the trials, patients were randomized to eslicarbazepine acetate or placebo, and after a two-week titration period, were assessed over a 12-week maintenance period with continued follow-up over a one-year, open-label period. Target profile: a clear dose-dependency, marked and sustained seizure reduction with favorable tolerability and safety profile.
- Development stage: 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

SEP-225289 Indication: to be determined

- Developed in-house (Sepracor)
- SEP-225289 is a new triple reuptake inhibitor (TRI) which inhibits reuptake of serotonin, norepinephrine and dopamine.
- Development stage: Phase II in the U.S.

SEP-227162 Major depressive disorder

- Developed in-house (Sepracor)
- SEP-227162 is a SNRI which inhibits reuptake of serotonin and norepinephrine. The compound is expected to show a better tolerability compared to existing medication..
- Development stage: Phase II in the U.S.

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. and Europe

DSP-7238 Diabetes

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

DSP-8658 Diabetes

- Developed in-house
- DSP-8658 is a novel PPAR α / γ modulator that exhibits potent antihyperglycemic and lipid lowering activity in several animal models.
- Non-clinical studies suggest that DSP-8658 may offer advantages over marketed PPAR γ agonists, particularly with respect to improvements in lipid metabolism and incidence of fluid retention or body weight gain.
- Development stage: Phase I in the U.S.

SEP-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 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)
- 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.