Securities Code: 4506

Supplementary Financial Data for the First Quarter of the Year Ending March 31, 2012

July 29, 2011

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. Consolidated Statements of Income

(Billions of yen)

	FY2010 1Q	FY2011 1Q	Change (%)	FY2011 2Q (Forecast)	Change (%)	FY2011 (Forecast)	Change (%)
Net sales	101.8	94.8	(6.9)	179.7	(4.7)	362.0	(4.6)
Cost of sales	32.6	25.8	(20.9)	50.1	(13.4)	103.8	(5.7)
SG&A expenses	54.4	56.2	3.4	120.7	4.2	241.2	1.1
SG&A expenses less R&D costs	39.9	42.6	6.8	90.1	8.6	179.2	5.2
R&D costs	14.5	13.6	(6.0)	30.6	(6.7)	62.0	(9.0)
Operating income	14.8	12.8	(13.5)	8.9	(40.4)	17.0	(45.1)
Ordinary income	14.8	13.2	(11.3)	8.4	(41.6)	15.5	(45.8)
Net income	9.3	8.1	(12.8)	4.8	(44.5)	8.5	(49.4)

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: Forecasts are unchanged from those announced in May 2011.

EBITDA (Billions of yen)	28.0	23.5	30.1	59.5
Earnings per share (yen)	23.35	20.35	12.08	21.39
Return on equity (ROE)	2.7%	2.5%	—	—

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2010 1Q	FY2011 1Q	Change
Net cash provided by operating activities	10.9	12.6	1.7
Net cash used in investing activities	(0.6)	(0.2)	0.4
Net cash used in financing activities	(3.5)	(13.6)	(10.1)
Cash and cash equivalents at the end of period	65.2	82.4	17.2

3. Financial Results of U.S. Subsidiary（Before Elimination）

(1) Excluding Impact of Purchase Price Allocation

(Billions of yen)

	FY2010 1Q	FY2011 1Q
Net sales	34.0	32.6
Cost of sales	3.1	4.2
SG&A expenses	19.8	22.7
SG&A expenses less R&D costs	13.9	17.7
R&D costs	5.9	5.0
Operating income	11.1	5.7
Ordinary income	11.1	5.8
Net income	6.8	3.7

(2) Impact of Purchase Price Allocation

(Billions of yen)

	FY2010 1Q	FY2011 1Q
Net sales	—	—
Cost of sales	1.6	—
SG&A expenses	8.2	7.1
Operating income	(9.8)	(7.1)
Net income	(6.5)	(4.8)

4. Currency Exchange Rates (Billions of yen)

	FY2010 1Q Average rate	FY2011 1Q Average rate	FY2011 Forecast rate	Forex sensitivity (2011 Jan-Dec) (Impact of yen strength by 1yen/$)	
Yen / USD	90.7	82.3	85.0	Net Sales	(1.4)
Yen / RMB	13.3	12.5	13.0	Operating Income	0.3

5. Capital Expenditures and Depreciation (Billions of yen)

	FY2010 1Q	FY2011 1Q	Change	FY 2011 Forecast	Change
Capital expenditures (including intangible assets)	1.6	2.4	0.8	13.5	4.8
Depreciation and amortization	2.8	2.7	(0.0)	12.5	0.2

Note: Excluding the amortization associated with acquisition of Sunovion Pharmaceuticals Inc.

・Major continuing capital expenditure projects for FY2011

Relocation of Tokyo office:

Total budget: ¥0.7 billion, completed in June 2011

Construction operation of new research building in Osaka research center:

Total budget ¥8.7billion, plan to be completed in March 2013

(Reference) Statements of Income (Non-Consolidated)

(Billions of yen)

	FY2010 1Q	FY2011 1Q	Change (%)	Group-to-parent ratio
Net sales	64.0	51.8	(19.2)	1.83
Cost of sales	24.6	15.2	(38.2)	
SG&A expenses	26.6	25.3	(4.8)	
SG&A expenses less R&D costs	16.9	15.8	(6.4)	
R&D costs	9.7	9.5	(1.9)	
Operating income	12.8	11.2	(12.6)	1.14
Ordinary income	12.9	11.9	(7.2)	1.10
Net income	8.3	7.7	(7.3)	1.05
Earnings per share (yen)	21.01	19.47		

II. Consolidated Statements (Comprehensive) of Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2010 1Q (A)	FY2011 1Q (B)	(B)-(A)	Change (%)
Net sales	101.8	94.8	(7.0)	(6.9)
Overseas sales	40.5	40.0	(0.5)	(1.2)
[% of net sales]	〔39.8〕	〔42.2〕		
Cost of sales	32.6	25.8	(6.8)	(20.9)
Gross profit	69.2	69.0	(0.2)	(0.2)
SG&A expenses	54.4	56.2	1.8	3.4
Labor costs	16.2	17.7	1.5	9.6
Advertising and promotion costs	3.5	4.5	1.0	28.6
Sales promotion costs	2.7	2.8	0.2	6.0
Depreciation and amortization	9.1	8.0	(1.1)	(11.8)
Other costs	8.5	9.5	1.0	12.3
SG&A expenses less R&D costs	39.9	42.6	2.7	6.8
R&D costs	14.5	13.6	(0.9)	(6.0)
Operating income	14.8	12.8	(2.0)	(13.5)
Non-operating income	1.1	1.0	(0.1)	
Non-operating expenses	1.1	0.6	(0.5)	
Ordinary income	14.8	13.2	(1.7)	(11.3)
Income before income taxes and minority interests	14.8	13.2	(1.7)	(11.3)
Income taxes	5.6	5.1	(0.5)	
Income before minority interests	9.3	8.1	(1.2)	(12.8)
Net income	9.3	8.1	(1.2)	(12.8)

・Influence of changing method of summing up sales for Pet Food.

・Decreased amortization of patent rights and goodwill.

・Increased costs related to LATUDA® launch.

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.

2: Overseas sales includes the sales of exports of non-Pharmaceutical products.

2. Consolidated Statements of Comprehensive Income (Loss)

(Billions of yen)

	FY2010 1Q	FY2011 1Q
Income before minority interests	9.3	8.1
Other comprehensive income (loss)	(0.1)	3.7
Unrealized gains (losses) on available-for-sale securities, net of tax	(1.2)	(0.4)
Deferred gains or losses on hedges	(0.0)	—
Foreign currency translation adjustment	1.1	4.1
Comprehensive income	9.1	11.8

3. Segment Information (1Q, FY2011)

(Billions of yen)

	Pharmaceuticals Business						Other Business	Elimination	Total
	Japan	North America*1	Impact of purchase price allocation*2	China	Other Regions	Subtotal			
Net sales	44.6	31.5	—	1.9	6.4	84.4	10.5	(0.1)	94.8
Sales to customers	44.6	31.5	—	1.9	6.4	84.4	10.4	—	94.8
Intersegment	0.1	—	—	—	—	0.1	0.0	(0.1)	—
Cost of sales	10.9	3.0	—	0.4	3.5	17.8	8.1	(0.1)	25.8
Gross profit	33.7	28.5	—	1.4	2.9	66.6	2.4	(0.0)	69.0
SG&A expenses less R&D	15.6	17.7	7.1	0.6	0.1	41.2	1.4	(0.0)	42.6
Income (loss) of segment	18.1	10.8	(7.1)	0.8	2.8	25.5	1.0	0.0	26.4
R&D costs									13.6
Operating income									12.8

Notes *1: Excluding the impact of purchase price allocation by acquisition of Sunovion Pharmaceuticals Inc.

*2: Amortization of patent rights and goodwill.

*3: Pharmaceuticals Segmentation is changed from FY2011.

(Reference) Segment Information (1Q, FY2010)

(Billions of yen)

	Pharmaceuticals Business						Other Business	Elimination	Total
	Japan	North America*1	Impact of purchase price allocation*2	China	Other Regions	Subtotal			
Net sales	46.4	32.9	—	1.5	6.0	86.8	15.0	—	101.8
Sales to customers	46.4	32.9	—	1.5	6.0	86.8	15.0	—	101.8
Intersegment	—	—	—	—	—	—	—	—	—
Cost of sales	12.0	3.1	1.6	0.2	3.0	20.0	12.6	—	32.6
Gross profit	34.4	29.7	(1.6)	1.3	3.0	66.8	2.4	—	69.2
SG&A expenses less R&D	15.6	13.9	8.2	0.5	0.1	38.3	1.5	—	39.9
Income (loss) of segment	18.8	15.8	(9.8)	0.8	2.9	28.5	0.8	—	29.3
R&D costs									14.5
Operating income									14.8

Notes *1: Excluding the impact of purchase price allocation by acquisition of Sunovion Pharmaceuticals Inc.

*2: Mainly amortization of patent rights and goodwill

*3: According to change of segmentation, from FY2011 results from 1Q, FY2010 are recalculated by new segmentation.

4. Sales of Pharmaceuticals Business (Sales to customers) (Billions of yen)

	FY2010 1Q (A)	FY2011 1Q (B)	(B)-(A)	Change (%)	FY2011 2Q (Forecast)	FY2011 (Forecast)
Japan	46.4	44.6	(1.9)	(4.1)	88.4	179.9
North America	32.9	31.5	(1.4)	(4.2)	57.7	115.5
China	1.5	1.9	0.4	24.7	3.6	7.0
Other Regions	6.0	6.4	0.4	6.9	9.6	18.1

Overseas Sales Total

Overseas sales (Pharmaceuticals)	40.4	39.9	(0.5)	(1.2)	70.9	140.6
% of net sales (Pharmaceuticals)	46.5%	47.3%			44.5%	43.9%

5. Sales of Major Products

Pharmaceuticals (Japan) (Sales figures before reduction of rebates, Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2010 1Q(A)	FY2011 1Q(B)	(B)-(A)	Change (%)	FY2011 2Q (Forecast)	FY2011 (Forecast)
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	10.9	9.2	(1.7)	(15.4)	16.3	31.0
GASMOTIN® (mosapride citrate) Gastroprokinetic	5.1	5.2	0.0	0.7	10.3	21.0
PRORENAL® (limaprost alfadex) Vasodilator	3.7	3.9	0.1	3.5	8.3	17.0
MEROPEN® (meropenem) Carbapenem antibiotic	3.3	3.0	(0.3)	(9.3)	5.4	10.0
LONASEN® (blonanserin) Atypical antipsychotic	2.2	2.4	0.2	8.3	6.1	13.0
AVAPRO® (irbesartan) Therapeutic agent for hypertension	1.8	2.3	0.6	31.5	5.5	12.0
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	1.1	2.1	1.0	89.3	3.6	7.5
EBASTEL® (ebastine) Antiallergic	1.6	1.5	(0.1)	(8.8)	2.6	6.7
SUMIFERON® (interferon-α NAMALWA) Natural alpha interferon	1.4	1.1	(0.3)	(22.1)	2.5	5.0
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	1.1	1.0	(0.1)	(4.6)	2.4	5.0
EXCEGRAN® (zonisamide) Antiepileptic	0.9	0.9	(0.1)	(6.9)	1.7	3.4
DOPS® (droxidopa) Neural function ameliorant	0.9	0.8	(0.1)	(10.6)	1.7	3.2
MELBIN® (metformin) Biguanide oral hypoglycemic	1.1	0.7	(0.4)	(38.2)	1.0	1.0
QVAR™ (beclomethasone dipropionate) Bronchial asthma	0.7	0.6	(0.1)	(12.2)	1.4	2.4
ALMARL® (arotinolol) Therapeutic agent for hypertension, angina pectoris and arrhythmia	0.7	0.6	(0.1)	(11.3)	1.3	2.5
GLIMICRON® (gliclazide) Sulfonylurea oral hypoglycemic	0.8	0.6	(0.2)	(21.9)	1.3	2.6
LULLAN® (perospirone) Atypical antipsychotic	0.7	0.6	(0.1)	(12.1)	1.4	2.7
SEDIEL® (tandospirone) Serotonin-agonist antianxiety drug	0.6	0.6	(0.1)	(10.5)	1.3	2.6

Japan (New Products) (Sales figures before reduction of rebates, Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2010 1Q (A)	FY2011 1Q (B)	(B)-(A)	Change (%)	FY2011 2Q (Forecast)	FY2011 (Forecast)
TRERIEF® (zonisamide) Parkinson's disease drug (Launch: Mar, 2009)	0.8	1.2	0.4	58.6	2.2	4.6
METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May, 2010)	0.0	0.9	0.9	2,640.1	1.5	5.0
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: Jan, 2010)	0.4	0.3	(0.0)	(7.0)	0.8	1.7
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May, 2011)	—	0.1	0.1	—	0.1	0.2

North America (Billions of yen)

XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	11.5	11.3	(0.3)	(2.2)	16.5	33.0
LUNESTA® (eszopiclone) Sedative hypnotic	14.6	10.2	(4.4)	(30.2)	23.8	45.5
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb, 2011)	—	2.9	2.9	—	4.0	10.2
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	2.3	2.8	0.5	19.6	5.2	10.8
OMNARIS® (ciclesonide) Corticosteroid nasal spray	1.0	1.3	0.3	26.9	3.2	6.4
ALVESCO® (ciclesonide) Inhaled corticosteroid	0.7	0.7	0.0	4.7	1.9	4.1
Industrial property revenues	2.2	2.1	(0.1)	(6.3)	2.3	3.9

China (Billions of yen)

MEROPEN® (meropenem) Carbapenem antibiotic	1.2	1.6	0.4	33.4	3.0	5.9

Other Regions (Sales to customers) (Billions of yen)

MEROPEN® (meropenem) (Export) Carbapenem antibiotic	5.2	5.2	(0.0)	(0.8)	7.6	14.0
EXCEGRAN® (zonisamide) (Export) Antiepileptic	0.5	0.6	0.1	22.1	0.8	1.4
GASMOTIN® (mosapride citrate) (Export)	0.4	0.3	(0.1)	(34.3)	0.3	0.6
Industrial property revenues	0.0	0.0	(0.0)	(99.1)	0.4	1.0

(Reference) Sales of Products in U.S. Subsidiaries (based on local currency)

(Millions of dollars)

Brand name (Generic name)	Jan-Mar 2010(A)	Jan-Mar 2011(B)	(B)-(A)	Change (%)	Jan-Jun 2011 (Unaudited)	Jan-Dec 2011 (Forecast)
XOPENEX® (levalbuterol HCl)	127	137	10	7.7	216	388
LUNESTA® (eszopiclone)	161	124	(37)	(23.1)	261	535
LATUDA® (lurasidone)	—	35	35	—	41	120
BROVANA® (arformoterol tartrate)	25	33	8	31.8	62	127
OMNARIS® (ciclesonide)	11	16	5	39.8	34	75
ALVESCO® (ciclesonide)	7	9	1	15.4	17	48
Industrial property revenues	25	25	1	3.3	42	46
Others	6	7	0	6.3	14	20
Total	363	385	22	6.2	688	1,359

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 2011/03/31 (A)	As of 2011/06/30 (B)	(B)-(A)
[Assets]	589.9	581.7	(8.1)
Current assets:	333.0	329.0	(4.0)
Cash and time deposits	14.9	16.5	1.5
Notes and accounts receivable	107.8	105.9	(1.9)
Marketable securities	90.9	86.3	(4.6)
Inventories	56.0	54.5	(1.4)
Deferred tax assets	33.5	32.9	(0.6)
Short-term loans	25.0	25.0	—
Others	5.0	8.0	3.0
Allowance for doubtful receivables	(0.1)	(0.1)	0.0
Fixed assets:	256.9	252.8	(4.1)
Property, plant and equipment:	69.8	69.7	(0.1)
Buildings and structures	41.7	42.1	0.3
Machinery, equipment and carriers	12.1	11.5	(0.6)
Land	10.3	10.3	(0.0)
Construction in progress	0.9	1.0	0.1
Others	4.8	4.8	0.1
Intangible assets:	143.3	138.8	(4.5)
Goodwill	70.4	70.8	0.5
Patent rights	61.0	56.0	(5.0)
Others	11.9	12.0	0.0
Investments and other assets:	43.8	44.4	0.6
Investment securities	27.9	27.4	(0.5)
Deferred tax assets	7.0	7.9	0.9
Others	9.0	9.2	0.2
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)
Total assets	589.9	581.7	(8.1)

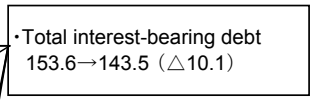
・Goodwill
Amortization (0.9), Currency+1.4
・Patent rights
Amortization (6.2), Currency+1.2

Accounts receivable turnover period (in months)	3.41	3.35

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 2011/03/31 (A)	As of 2011/06/30 (B)	(B)-(A)
[Liabilities]	265.9	249.5	(16.4)
Current liabilities:	157.2	143.2	(14.0)
Notes and accounts payable	15.6	16.4	0.7
Short-term loans payable	50.0	43.0	(7.0)
Current portion of long-term loans payable	10.6	10.0	(0.6)
Income taxes payable	7.7	4.9	(2.7)
Reserve for bonuses	7.4	3.8	(3.6)
Reserve for sales returns	2.3	2.7	0.4
Reserve for sales rebates	15.9	18.9	3.0
Accounts payable-other	33.8	24.9	(9.0)
Others	13.8	18.7	4.8
Long-term liabilities:	108.7	106.3	(2.4)
Bonds payable	50.0	50.0	—
Long-term loans payable	43.0	40.5	(2.5)
Liability for retirement benefits	10.3	10.4	0.1
Others	5.4	5.4	(0.0)
[Net assets]	324.0	332.2	8.2
Shareholders' equity:	341.8	346.3	4.5
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	304.2	308.7	4.5
Treasury stock	(0.6)	(0.6)	(0.0)
Accumulated other comprehensive income (loss):	(17.8)	(14.1)	3.7
Unrealized gains on available-for-sale securities, net of tax	5.4	5.0	(0.4)
Foreign currency translation adjustment	(23.2)	(19.1)	4.1
Total liabilities and net assets	589.9	581.7	(8.1)



IV. Quarterly Business Results

(Billions of yen)

	FY2010				FY2011
	1Q	2Q	3Q	4Q	1Q
Net sales	101.8	86.8	92.2	98.7	94.8
Cost of sales	32.6	25.2	25.9	26.3	25.8
SG&A expenses	54.4	61.4	54.2	68.5	56.2
SG&A expenses less R&D costs	39.9	43.1	40.7	46.7	42.6
R&D costs	14.5	18.3	13.5	21.8	13.6
Operating income	14.8	0.1	12.1	3.9	12.8
Non-operating income	1.1	0.8	0.7	0.7	1.0
Non-operating expenses	1.1	1.4	1.0	2.2	0.6
Ordinary income (loss)	14.8	(0.5)	11.8	2.4	13.2
Extraordinary loss	—	—	2.2	1.3	—
Income (loss) before income taxes and minority interests	14.8	(0.5)	9.6	1.1	13.2
Net income (loss)	9.3	(0.6)	6.1	2.0	8.1

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

V. Major consolidated subsidiaries (as of 2011/06/30)

	Domestic			Overseas	
	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Biomedical Co., Ltd.	Sunovion Pharmaceuticals Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	October 1947	July 2010	June 1998	January 1984	December 2003
Fiscal year	March 31	March 31	March 31	December 31	December 31
Ownership	100%	100%	100%	100%	100%
Number of employees	143	102	64	2,421	580
Businesses	Manufacturing and sales of food ingredients, food additives, and chemical product materials	Manufacturing, and sales of veterinary medicines, feedstuff, and feed additives	Manufacturing and sales of diagnostics and research materials	Manufacturing and sales of pharmaceuticals	Manufacturing and sales of pharmaceuticals

Number of employees (as of 2011/06/30):

7,857 (consolidated)

4,547 (non-consolidated)

Number of MRs (as of 2011/06/30):

Japan	1,380 (excluding managers)	1,580 (including managers)
U.S.	1,500 (excluding managers)	1,660 (including managers)
China	310 (excluding managers)	390 (including managers)

VI. Development Pipeline (as of July 29, 2011)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Phase III	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	New Phase III study under preparation
	SUREPOST® Oral	repaglinide	(New Indication) Type 2 diabetes Combination therapy with biguanide	Novo Nordisk	Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes Monotherapy Combination with α-GI
			(New Indication) Type 2 diabetes Combination therapy with thiazolidine		
	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes Pediatric usage	Merck Santé	
Phase III Under preparation	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	
Phase II	DSP-8153 Oral	amlodipine besilate / irbesartan	Hypertension	In-house	Combination product
	SMP-986 Oral	afacifenacin	Overactive bladder	In-house	
	PRORENAL® Oral	limaprost alfadex	(New Indication Carpal-tunnel syndrome	In-house (with Ono Pharmaceutical)	Co-development with Ono Pharmaceutical. Approved indication: lumbar spinal canal stenosis, etc.
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	In-house (with Chugai Pharmaceutical)	Co-development with Chugai Pharmaceutical

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Phase I	DSP-3025 Collunarium	TBD	Bronchial asthma, Allergic rhinitis	In-house	
	WT4869 Injection	TBD	Solid cancer	In-house (with Chugai Pharmaceutical)	Co-development with Chugai Pharmaceutical
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	
Phase I Under preparation	DSP-1747 Oral	obeticholic acid	Primary biliary cirrhosis (PBC) , Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	
	DSP-5990 Injection	ceftaroline fosamil	MRSA Infection	Takeda Pharmaceutical	

[Main revisions since the announcement of May 2011]

SUREPOST® (repaglinide)	Launched (May 2011)
lurasidone hydrochloride (SM-13496)	Japan/Korea/Taiwan Co-study completed. New Phase III study under preparation.
ranirestat (AS-3201)	Change from Phase II to Phase III under preparation. Co-development agreement with Kyorin Pharmaceutical canceled
PRORENAL®	Newly added in Phase II (new indication)
DSP-3235	Deleted because of discontinuation
WT4869	Newly added in Phase I for Solid Cancer
DSP-6952	Newly added in Phase I
DSP-1747	Newly added in Phase I under preparation
DSP-5990	Newly added in Phase I under preparation

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/Area	Remarks
Application submitted	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy-adjunct	BIAL	U.S.	NDA submitted in Mar.2009
	ciclesonide Nasal Aerosol (HFA) Collunarium	ciclesonide	(HFA - New Formulation) Allergic rhinitis	Nycomed	U.S.	NDA submitted in Mar. 2011. Approved formulation: OMNARIS® Nasal Spray
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Canada	NDS submitted in June 2011. Approved countries: U.S
	LATUDA® Oral	lurasidone hydrochloride	(Change of maximum dose) Schizophrenia: 160mg daily	In-house	U.S.	sNDA submitted in June 2011. Approved maximum recommended dose: 80mg daily
Phase III	LATUDA® Oral	lurasidone hydrochloride	(New Indication) Bipolar disorder	In-house	U.S. and Europe, etc.	Approved indication: Schizophrenia :U.S
			(New Indication) MDD with mixed features		U.S.	
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED®
	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy-adult monotherapy	BIAL	U.S.	
Phase II	SMP-986 Oral	afacifenacin	Overactive bladder	In-house	U.S. and Europe	
Phase I	DSP-8658 Oral	TBD	Type 2 diabetes, Alzheimer's disease	In-house	U.S.	
	SEP-228432 Oral	TBD	Neuropathic pain, Depressive disorder	In-house (Sunovion)	U.S.	
	DSP-1053 Oral	TBD	Depressive disorder	In-house	U.S.	

[Main revisions since the announcement of May 2011]

LATUDA® (lurasidone hydrochloride)	NDS submitted in Canada. sNDA submitted for change of maximum dose in the U.S. Newly added for MDD with mixed features in Phase III (new indication)
DSP-7238	Deleted because of discontinuation

Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Proposed Indication	Status of development
AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003 Phase III 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 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 (AstraZeneca's product code: AZD-8848)
eszopiclone	Insomnia	Out-licensed by Sunovion to Eisai for the Japanese territory in July, 2007. (Brand name in U.S.: LUNESTA®) NDA filed in Japan by Eisai
lurasidone hydrochloride (SM-13496)	Schizophrenia Bipolar disorder	Entered into a license agreement with Takeda Pharmaceutical for Co-development and exclusive commercialization for the European territory, excluding the United Kingdom in March 2011. Both companies are currently developing lurasidone in Europe (Phase III study stage)

[Main revisions since the announcement of May 2011]

lurasidone hydrochloride (SM-13496) Newly added license agreement in Europe

VII. Profile of Major Products under Development (as of July 29, 2011)

LATUDA® (lurasidone hydrochloride) Schizophrenia, Bipolar disorder

- Developed in-house
- LATUDA® (lurasidone hydrochloride) tablets was approved for the treatment of schizophrenia by the U.S. Food and Drug Administration (FDA) in October 2010, and launched by Sunovion in February 2011 in the U.S. LATUDA is an atypical antipsychotic agent with an affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine or muscarinic receptors. The efficacy of LATUDA for the treatment of schizophrenia has been established in four, short-term (6-week), placebo-controlled clinical studies in adult patients who met DSM-IV criteria for schizophrenia. In these studies, LATUDA demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. A total of five clinical trials contributed to the understanding of the tolerability and safety profile of LATUDA.
- Development stage:

  Schizophrenia: NDS submitted in Canada
  sNDA submitted for change of maximum dose in the U.S.
  Phase III under preparation in Japan
  Phase III (Co-development with Takeda Pharmaceutical in Europe)

  Bipolar disorder: Phase III in the U.S. and Europe, etc.

  MDD with mixed features : Phase III in the U.S.

STEDESA™ (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- 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 over 20 countries. Patients involved in the studies were required to have 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 be safe and tolerable, have clear dose-response correlation and marked and sustained seizure reduction.
- NDA submitted in March 2009 in the U.S.
- NDA Complete Response received April 2010.
- Sunovion is committed to seeking FDA approval of STEDESA as a once-daily, adjunctive therapy in the treatment of partial-onset seizures in adults with epilepsy 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 studies in the U.S., Canada and Europe.

- Development stage: Phase III under preparation in Japan

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 effects 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

WT4869 Myelodysplastic syndromes (MDS), Solid cancer

- Co-development with Chugai Pharmaceutical
- WT4869 is being developed as a therapeutic cancer vaccine targeting various types of cancer. It is expected that administration of WT4869 will show efficacy in the treatment of leukemia and other types of cancers that express Wilms' tumor gene 1 (WT1), by inducing WT1-specific cytotoxic T-lymphocytes that have the potential to attack tumor cells.
- Development stage:

Myelodysplastic syndromes (MDS):	Phase I/II in Japan
Solid cancer:	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.
  (AstraZeneca's product code: AZD-8848)
- Development stage: Phase I in Japan

DSP-6952 IBS with constipation, Chronic idiopathic constipation

- Developed in-house
- DSP-6952 is a high affinity serotonin-4 receptor partial agonist with enterokinetic effect. DSP-6952 is expected to be effective for IBS with constipation and chronic idiopathic constipation by increasing complete spontaneous bowel movement.
- Development stage: Phase I in Japan

DSP-8658 Diabetes, Alzheimer's disease

- 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 in the treatment of diabetes.
- Also it is expected that DSP-8658 may improve symptomatic cognitive decline and show disease modification with mechanism of reduction in β amyloid by impacting a number of different mechanism in marketed compounds.
- Development stage: Phase I in the U.S.

SEP-228432 Neuropathic pain, Depressive disorder

- Developed in-house (Sunovion)
- SEP-228432 is a new triple unbalanced reuptake inhibitor (TRI) that inhibits reuptake of serotonin, norepinephrine and dopamine. The compound is under development for neuropathic pain and MDD in central nervous disorders (CNS) area.
- Development stage: Phase I in the U.S.

DSP-1053 Depressive disorder

- Developed in-house
- DSP-1053 is a new antidepressant drug candidate that shows an inhibitory effect on serotonin transporter and modulatory effects on monoamine receptors. By these mechanisms, DSP-1053 is expected to show early on-set of action and higher efficacies in patients.
- Development stage: Phase I in the U.S.

DSP-1747 Primary biliary cirrhosis (PBC), Nonalcoholic steatohepatitis (NASH)

- In-licensed from Intercept Pharmaceuticals Inc. (Intercept's product code: INT-747)
- DSP-1747 is a potent, first-in-class farnesoid X receptor (FXR) agonist derived from the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist.
- Development stage: Phase I under preparation in Japan

DSP-5990 MRSA Infection

- In-licensed from Takeda Pharmaceutical Company Limited (Takeda's product code: TAK-599)
- DSP-5990 is a cephem antibiotic, and has strong activities against gram-positive bacteria including MRSA and multiply-resistant *Streptococcus pneumonia* and also gram-negative bacteria.
- Development stage: Phase I under preparation in Japan