Securities Code: 4506

Supplementary Financial Data for the First Quarter of the Year Ending March 31, 2014

July 31, 2013

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)

	FY2012 1Q	FY2013 1Q	Change (%)	FY2013 2Q (Forecast)	Change (%)	FY2013 (Forecast)	Change (%)
Net sales	89.1	89.6	0.6	178.0	(0.4)	369.0	6.1
Cost of sales	25.2	25.3	0.2	52.0	3.9	106.0	4.2
SG&A expenses	53.0	55.3	4.4	116.0	6.7	237.0	7.2
SG&A expenses less R&D costs	38.9	40.6	4.4	86.0	6.3	170.0	5.5
R&D costs	14.1	14.7	4.5	30.0	7.9	67.0	12.0
Operating income	10.9	9.0	(17.1)	10.0	(49.9)	26.0	3.8
Ordinary income	11.5	9.5	(17.4)	10.0	(49.8)	25.0	2.0
Net income	5.7	4.8	(15.6)	5.0	(54.3)	13.0	29.4

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: Changed the period of FY2013 as Apr-Mar for Sunovion Pharmaceuticals Inc. and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (The period for the previous year was Jan-Dec 2012)

EBITDA (Billions of yen)	21.9	16.8	25.0	54.0
Earnings per share (yen)	14.34	12.10	12.58	32.72
Return on equity (ROE)	1.8%	1.3%	—	—

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2012 1Q	FY2013 1Q
Net cash provided by operating activities	17.6	7.3
Net cash used in investing activities	(20.9)	(1.6)
Net cash used in financing activities	(6.0)	(6.0)
Cash and cash equivalents at the end of period	84.5	74.2

←
・DSP 18.1
・U.S. Subsidiaries 48.1

3. Financial Results of U.S. Subsidiaries（Simple addition of Sunovion and BBI）

(1) Excluding mainly amortization of patent rights and goodwill

(Billions of yen)

	FY2012 1Q	FY2013 1Q
Net sales	30.3	32.8
Cost of sales	3.9	4.0
SG&A expenses	18.7	21.7
SG&A expenses less R&D costs	13.7	17.0
R&D costs	5.1	4.7
Operating income	7.6	7.1
Ordinary income	7.6	7.2
Extraordinary loss	1.1	1.0
Net income	4.1	3.6

(2) Mainly amortization of patent rights and goodwill

(Billions of yen)

	FY2012 1Q	FY2013 1Q
Net sales	—	—
Cost of sales	—	—
SG&A expenses	8.0	5.2
Operating income	(8.0)	(5.2)
Ordinary income	(8.0)	(5.2)
Extraordinary loss	0.4	—
Net income	(5.6)	(3.7)

4. Currency Exchange Rates (Billions of yen)

	2012 Jan-Mar Average rate	2013 Apr-Jun Average rate	2013 End of Jun	FY2013 assumued rate	Forex sensitivity FY2013 (Impact of yen strength by 1yen/$)	
Yen / USD	79.4	98.8	98.6	100.0	Net Sales	(1.4)
Yen / RMB	12.6	16.1	16.0	15.0	Operating Income	0.1

Note: Net sales in FY2013 1Q was increased by 6.2 billion yen and Operating income in FY2013 1Q was by 0.2 billion yen compared to FY2012 1Q due to exchange rate fluctuation.

5. Capital Expenditures and Depreciation (Billions of yen)

	FY2012 1Q	FY2013 1Q	Change	FY 2013	
				Forecast	Change
Capital expenditures (including intangible assets)	1.4	2.8	1.4	15.0	4.6
Depreciation and amortization (Note)	2.0	2.1	0.0	9.0	1.1

Note: Excluding the amortization associated with acquisition of the U.S. subsidiaries.

・Major capital expenditure projects completed in FY2013
Construction of the New Chemistry Research Building in Osaka research center:
(Total budget 6.4 billion yen,completed in Jun 2013)

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

	FY2012 1Q	FY2013 1Q	Change (%)	Group-to-parent ratio
Net sales	49.2	47.4	(3.7)	1.89
Cost of sales	14.8	14.1	(5.1)	
SG&A expenses	26.5	26.3	(0.8)	
SG&A expenses less R&D costs	15.2	15.5	2.1	
R&D costs	11.3	10.7	(4.6)	
Operating income	8.0	7.1	(10.9)	1.27
Ordinary income	9.0	8.6	(4.8)	1.10
Net income	5.9	6.1	4.0	0.79
Earnings per share (yen)	14.75	15.35		

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2012 1Q (A)	FY2013 1Q (B)	(B)-(A)	Change (%)
Net sales	89.1	89.6	0.5	0.6
Overseas sales	33.0	36.9	3.8	11.6
[% of net sales]	37.1	40.9		
Cost of sales	25.2	25.3	0.0	0.2
[% of net sales]	28.3	28.2		
Gross profit	63.9	64.4	0.5	0.8
SG&A expenses	53.0	55.3	2.4	4.4
Labor costs	16.5	16.2	(0.3)	(1.8)
Advertising and promotion costs	3.7	3.6	(0.1)	(2.1)
Sales promotion costs	2.0	3.1	1.1	53.4
Other costs	16.7	17.7	1.0	6.0
SG&A expenses less R&D costs	38.9	40.6	1.7	4.4
R&D costs	14.1	14.7	0.6	4.5
[% of net sales]	15.8	16.4		
Operating income	10.9	9.0	(1.9)	(17.1)
Non-operating income	1.1	0.9	(0.2)	
Non-operating expenses	0.5	0.5	(0.1)	
Ordinary income	11.5	9.5	(2.0)	(17.4)
Extraordinary loss	1.5	1.0	(0.5)	
Business structure improvement expenses	1.1	0.6	(0.5)	
Impairment loss	0.4	0.4	(0.0)	
Income before income taxes and minority interests	10.0	8.5	(1.5)	(15.0)
Income taxes	4.3	3.7	(0.6)	
Income before minority interests	5.7	4.8	(0.9)	(15.6)
Net income	5.7	4.8	(0.9)	(15.6)

・Japan Segment -2.2
・North America Segment +2.8

・Increase in overseas subsidiaries

・Restructuring costs in the U.S. subsidiary

・FY2012:Impairment loss for in-process R&D
・FY2013: Impairment loss for production facility in the U.S.

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)

	FY2012 1Q	FY2013 1Q
Income before minority interests	5.7	4.8
Other comprehensive income (loss)	9.9	11.0
Unrealized gains (losses) on available-for-sale securities, net of tax	(0.0)	0.6
Deferred gains or losses on hedges	(0.0)	—
Foreign currency translation adjustments	10.0	10.4
Comprehensive income	15.6	15.8

currency exchange rates:

12/2011	03/2012		03/2013	06/2013	
77.7	→ 82.1		94.0	→ 98.6	yen/$
	+4.4			+4.6	

3. Segment Information (FY2013 1Q)

(Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	42.5	31.9	—	2.4	2.5	79.3	10.4	89.6
Sales to customers	42.4	31.9	—	2.4	2.5	79.2	10.4	89.6
Intersegment	0.0	—	—	—	—	0.0	(0.0)	—
Cost of sales	11.4	3.9	—	0.6	1.3	17.2	8.0	25.3
Gross profit	31.0	28.0	—	1.8	1.2	62.0	2.3	64.4
SG&A expenses less R&D costs	15.2	17.2	5.2	1.4	0.2	39.2	1.5	40.6
Income (loss) of segment	15.9	10.8	(5.2)	0.4	1.0	22.9	0.9	23.7
R&D costs*3						14.5	0.2	14.7
Operating income						8.4	0.6	9.0

Segment Information (FY2012 1Q)

(Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	44.7	29.0	—	1.7	3.1	78.5	10.6	89.1
Sales to customers	44.6	29.0	—	1.7	3.1	78.5	10.6	89.1
Intersegment	0.0	—	—	—	—	0.0	(0.0)	—
Cost of sales	12.1	2.9	—	0.4	1.6	17.0	8.2	25.2
Gross profit	32.5	26.1	—	1.3	1.5	61.5	2.4	63.9
SG&A expenses less R&D costs	15.0	13.7	8.0	0.7	0.1	37.5	1.5	38.9
Income (loss) of segment	17.6	12.4	(8.0)	0.6	1.4	24.0	1.0	24.9
R&D costs*3						13.9	0.2	14.1
Operating income						10.1	0.8	10.9

Segment Information (FY2013 Forecast)

(Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	173.9	125.8	—	10.5	15.6	325.8	43.2	369.0
Sales to customers	173.7	125.8	—	10.5	15.6	325.6	43.4	369.0
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	51.1	15.0	—	2.1	3.8	72.0	34.0	106.0
Gross profit	122.8	110.8	—	8.4	11.8	253.8	9.2	263.0
SG&A expenses less R&D costs	63.1	74.7	18.8	5.8	1.1	163.5	6.5	170.0
Income (loss) of segment	59.7	36.1	(18.8)	2.6	10.7	90.3	2.7	93.0
R&D costs*3						66.0	1.0	67.0
Operating income						24.3	1.7	26.0

Notes *1: Excluding amortization of patent rights and goodwill, etc.

*2: Including the elimination of intersegment transaction.

*3: R&D costs are controlled globally and not allocated to each segment.

4. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

	FY2012 1Q(A)	FY2013 1Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 2Q Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
Japan	44.6	42.4	(2.2)	(4.9)	49.5	85.7	173.7
North America	29.0	31.9	2.8	9.7	52.5	60.7	125.8
China	1.7	2.4	0.7	43.4	43.5	5.5	10.5
Other Regions	3.1	2.5	(0.6)	(18.5)	55.0	4.6	15.6

5. Sales of Major Products

Japan(Strategic Products)

(Sales figures are before reduction of rebates, Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2012 1Q(A)	FY2013 1Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 2Q Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	—	0.8	0.8	—	45.8	1.8	5.5
AVAPRO® (irbesartan) Therapeutic agent for hypertension	2.9	3.0	0.1	4.5	49.5	6.1	12.1
LONASEN® (blonanserin) Atypical antipsychotic	2.7	3.0	0.2	8.5	49.7	6.0	13.0
TRERIEF® (zonisamide) Parkinson's disease drug	1.7	2.1	0.3	18.4	46.8	4.4	9.2
Japan（New Products）							
METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	2.9	3.5	0.7	23.7	47.8	7.4	15.2
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.1	0.3	0.2	209.2	36.6	0.9	2.5
Japan（Specialty Products）							
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	1.1	1.1	0.1	8.2	45.7	2.5	5.0
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma	0.3	0.3	0.0	2.3	49.9	0.6	1.3
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	2.6	2.6	(0.1)	(2.3)	50.2	5.1	10.5
Japan(Others)							
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	7.8	7.2	(0.6)	(7.5)	53.9	13.3	25.4
GASMOTIN® (mosapride citrate) Gastroprokinetic	5.2	4.0	(1.1)	(22.1)	46.3	8.7	16.3
PRORENAL® (limaprost alfadex) Vasodilator	3.7	3.5	(0.1)	(3.9)	51.8	6.8	13.3
MEROPEN® (meropenem) Carbapenem antibiotic	2.6	2.5	(0.2)	(6.7)	48.3	5.1	9.6
EBASTEL® (ebastine) Antiallergic	1.2	1.0	(0.2)	(20.3)	40.4	2.4	5.6
DOPS® (droxidopa) Noradrenergic neural function	0.8	0.8	(0.0)	(3.2)	53.5	1.5	3.0
EXCEGRAN® (zonisamide) Antiepileptic	0.9	0.8	(0.1)	(6.0)	50.1	1.6	3.2

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2012 1Q(A)	FY2013 1Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 2Q Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
LUNESTA® (eszopiclone) Sedative hypnotic	11.3	13.4	2.2	19.1	57.0	23.6	46.5
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	3.1	6.8	3.6	117.0	50.4	[13.4] 15.0	[30.3] 35.0
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	3.1	4.0	0.9	29.9	41.9	9.6	19.8
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	8.0	3.5	(4.5)	(55.9)	88.3	4.0	7.4
ALVESCO® (ciclesonide) Inhaled corticosteroid	0.7	1.1	0.4	55.2	42.6	2.6	5.3
OMNARIS® (ciclesonide) Corticosteroid nasal spray	0.0	0.6	0.6	4,444.7	36.7	[1.7] 1.1	[3.6] 2.2
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	—	0.5	0.5	—	23.4	[2.2] 1.2	[5.8] 2.5
Industrial property revenues	2.2	0.9	(1.3)	(57.3)	72.8	1.3	2.7

Note: Figures in parentheses [ ] are forecasts released in May, 2013.

China (Billions of yen)

Brand name (Generic name)	FY2012 1Q(A)	FY2013 1Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 2Q Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
MEROPEN® (meropenem)	1.3	1.8	0.5	41.9	41.7	4.4	8.4

Other Regions (Billions of yen)

Brand name (Generic name)	FY2012 1Q(A)	FY2013 1Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 2Q Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
MEROPEN® (meropenem) (Export)	2.3	1.7	(0.6)	(25.4)	65.9	2.6	4.4
EXCEGRAN® (zonisamide) (Export)	0.5	0.5	0.0	6.5	74.3	0.7	1.2
GASMOTIN® (mosapride citrate) (Export)	0.2	0.1	(0.1)	(57.1)	33.5	0.3	0.7
Industrial property revenues	0.0	0.0	0.0	223.4	0.3	0.6	8.8

(Reference) Sales of Products in the North America Segment (based on local currency) (Millions of dollars)

Brand name (Generic name) Therapeutic indication	FY2012 1Q(A)	FY2013 1Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2013 2Q Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
LUNESTA® (eszopiclone)	142	136	(6)	(4.3)	57.7	236	465
LATUDA® (lurasidone)	39	68	29	74.3	51.0	[134] 150	[303] 350
BROVANA® (arformoterol tartrate)	39	41	2	4.4	42.4	96	198
XOPENEX® (levalbuterol HCl)	101	36	(65)	(64.6)	89.4	40	74
ALVESCO® (ciclesonide)	9	11	2	24.7	43.1	26	53
OMNARIS® (ciclesonide)	0	6	6	3,550.9	37.2	[17] 11	[36] 22
ZETONNA® (ciclesonide)	—	5	5	—	23.7	[22] 12	[58] 25
Industrial property revenues	28	10	(18)	(65.7)	73.7	13	27

Note: Figures in parentheses [ ] are forecasts released in May, 2013.

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of Mar 31, 2013 (A)	As of Jun 30, 2013 (B)	(B)-(A)
[Assets]	607.2	634.0	26.8
Current assets:	333.4	338.6	5.2
Cash and time deposits	18.8	24.6	5.9
Notes and accounts receivable	97.2	98.6	1.5
Marketable securities	86.5	79.6	(6.9)
Inventories	62.7	63.1	0.4
Deferred tax assets	30.1	31.2	1.1
Short-term loans	34.4	34.9	0.5
Others	4.0	6.7	2.7
Allowance for doubtful receivables	(0.1)	(0.1)	0.0
Fixed assets:	273.8	295.4	21.7
Property, plant and equipment:	69.9	73.9	4.0
Buildings and structures	39.9	45.6	5.7
Machinery, equipment and carriers	9.4	10.1	0.7
Land	10.3	10.3	0.0
Construction in progress	5.8	1.9	(3.9)
Others	4.4	5.9	1.5
Intangible assets:	146.3	156.4	10.1
Goodwill	71.3	81.0	9.7
Patent rights	17.4	13.0	(4.4)
In-process Research & Development	50.7	55.5	4.9
Others	7.0	6.8	(0.1)
Investments and other assets:	57.6	65.2	7.6
Investment securities	40.8	42.4	1.5
Deferred tax assets	7.6	13.5	6.0
Others	9.2	9.3	0.1
Allowance for doubtful receivables	(0.0)	(0.0)	(0.0)
Total assets	607.2	634.0	26.8

New Chemistry Research Building in Osaka research center
Building +4.2
Other +1.1
Construction in progress -2.3

Increase +2.4
Amortization -2.4
Currency +9.7

Transfer +0.5
Amortization -7.1
Currency +2.2

Transfer -0.5
Currency +5.4

Accounts receivable turnover period (in months)	3.35	3.30

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar 31, 2013 (A)	As of Jun 30, 2013 (B)	(B)-(A)
[Liabilities]	258.0	259.3	1.3
Current liabilities:	124.8	126.4	1.6
Notes and accounts payable	14.3	12.7	(1.5)
Current portion of bonds payable	10.0	10.0	—
Current portion of long-term loans payable	10.0	10.0	—
Income taxes payable	2.1	3.6	1.5
Reserve for bonuses	7.6	3.8	(3.8)
Reserve for sales returns	5.7	6.9	1.3
Reserve for sales rebates	19.2	24.1	5.0
Accounts payable-other	34.8	27.0	(7.7)
Others	21.3	28.1	6.8
Long-term liabilities:	133.1	132.8	(0.3)
Bonds payable	60.0	60.0	—
Long-term loans payable	35.0	32.5	(2.5)
Deferred tax liabilities	14.5	15.2	0.7
Liability for retirement benefits	11.0	11.2	0.1
Others	12.6	14.0	1.4
[Net assets]	349.2	374.8	25.5
Shareholders' equity:	346.2	344.8	(1.4)
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	308.6	307.2	(1.4)
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	3.1	30.0	26.9
Unrealized gains on available-for-sale securities, net of tax	14.1	15.0	0.9
Foreign currency translation adjustment	(11.0)	15.0	26.0
Total liabilities and net assets	607.2	634.0	26.8

Total interest-bearing debt
115.0 → 112.5
- 2.5

Payment of the license value, etc.

・Quarterly net income +4.8
・Payment of the dividend - 3.6
・Influence of fiscal year change - 2.6
（U.S -2.9 China +0.3 ）

currency exchange rates:
12/2012 06/2013
86.6 → 98.6 yen/$

IV. Quarterly Business Results

(Billions of yen)

	FY2012				FY2013
	1Q	2Q	3Q	4Q	1Q
Net sales	89.1	89.7	90.5	78.5	89.6
Cost of sales	25.2	24.8	26.3	25.3	25.3
SG&A expenses	53.0	55.7	51.4	60.8	55.3
SG&A expenses less R&D costs	38.9	42.0	39.3	40.9	40.6
R&D costs	14.1	13.7	12.1	19.9	14.7
Operating income (loss)	10.9	9.1	12.7	(7.7)	9.0
Non-operating income	1.1	0.3	0.8	0.8	0.9
Non-operating expenses	0.5	1.0	0.7	1.4	0.5
Ordinary income (loss)	11.5	8.4	12.8	(8.2)	9.5
Extraordinary loss	1.5	—	2.9	2.0	1.0
Income (loss) before income taxes and minority interests	10.0	8.4	10.0	(10.2)	8.5
Net income (loss)	5.7	5.3	5.9	(6.8)	4.8

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

V. Major consolidated subsidiaries (as of Jun 30, 2013)

Domestic	DSP Gokyo Food & Chemical Co., Ltd.	DS Pharma Animal Health Co., Ltd.	DS Pharma Biomedical Co., Ltd.
Establishment	October 1947	July 2010	June 1998
Ownership	100%	100%	100%
Number of employees	148	99	64
Businesses	Manufacturing and sales of food ingredients, food additives, chemical product materials, etc.	Manufacturing, and sales of veterinary medicines, etc.	Manufacturing and sales of diagnostics, etc.

Overseas	Sunovion Pharmaceuticals Inc.	Boston Biomedical, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	December 2003
Ownership	100%	100%	100%
Number of employees	1,538	45	733
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

（Reference) Number of employees and MRs

	As of Mar 31, 2013	As of Jun 30, 2013
consolidated	7,218	7,129
non-consolidated	4,457	4,502
MRs Japan（excluding managers）	1,410	1,410
（including managers）	1,610	1,610
MRs U.S. （excluding managers）	830	690
（including managers）	940	780
MRs China（excluding managers）	350	390
（including managers）	470	510

VI. Development Pipeline (as of July 31, 2013)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Submitted	MEROPEN® Injection	meropenem hydrate	(Change of maximum dose) Purulent meningitis: 6g daily	In-house	Submitted in Jan. 2013 Approved maximum recommended dose: 3g daily for severe or refractory cases of infectious diseases
Phase III	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	
	SUREPOST® Oral	repaglinide	(New indication) Type 2 diabetes All combination therapies including DPP4 inhibitors	Novo Nordisk	Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes (Monotherapy, Combination with α-GI, BG and TZD)
	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Merck Santé	
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	
Phase II	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	
	LONASEN® Transdermal Patch	blonanserin	(New formulation – Transdermal patch) Schizophrenia	In-house	Co-development with Nitto Denko Approved dose: Oral

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharmaceutical	
Phase I	DSP-3025 Collunarium	TBD	Bronchial asthma, Allergic rhinitis	In-house	
	WT4869 Injection	TBD	Solid cancer	Joint research with Chugai Pharmaceutical	
	DSP-5990 Injection	ceftaroline fosamil	MRSA infection	Takeda Pharmaceutical	
	BBI608 Oral	TBD	Solid cancer (Monotherapy)	In-house (BBI)	

[Main revisions since the announcement of May 2013]

None

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
Submitted	SEP-0002093 Oral	eslicarbazepine acetate	Epilepsy (Adjunctive therapy)	BIAL	U.S.	NDA submitted in March 2009 Re-submitted in February 2013 (Formerly proposed trade name: STEDESA®)
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED®
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Australia	Submitted in March 2013 Approved in the U.S and Canada
	LATUDA® Oral	lurasidone hydrochloride	(New indication) Bipolar I depression	In-house	Canada	Submitted in August 2012 Approved for schizophrenia in Canada
Phase III	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house (BBI)	U.S., Canada	
	SEP-0002093 Oral	eslicarbazepine acetate	Epilepsy (Monotherapy)	BIAL	U.S.	(Formerly proposed trade name: STEDESA®)
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Brand name in Japan: LONASEN®
	LATUDA® Oral	lurasidone hydrochloride	(New indication) Bipolar maintenance	In-house	U.S., Europe, etc.	Approved for schizophrenia in the U.S. and Canada, Bipolar I depression in the U.S.
			(New indication) MDD with mixed features		U.S., Europe, etc.	
Phase II	BBI608 Oral	TBD	Colorectal cancer (Combination therapy)	In-house (BBI)	U.S., Canada	
	SUN-101 Inhalant	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	In-house (Sunovion)	U.S.	From the former Elevation Pharmaceuticals
	SEP-225289 Oral	TBD	Attention-deficit hyperactivity disorder (ADHD)	In-house (Sunovion)	U.S.	

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
Phase I/II	BBI608 Oral	TBD	Solid cancer Combination therapy with paclitaxel	In-house (BBI)	U.S., Canada	
Phase I	DSP-8658 Oral	TBD	Type 2 diabetes, Alzheimer's disease	In-house	U.S.	
	DSP-1053 Oral	TBD	Major depressive disorder (MDD)	In-house	U.S.	
	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K.	
	WT2725 Injection	TBD	Solid cancer, Hematologic cancer	Joint research with Chugai	U.S.	
	BBI503 Oral	TBD	Solid cancer (Monotherapy)	In-house (BBI)	U.S., Canada	
	SEP-363856 Oral	TBD	Schizophrenia	In-house (Sunovion)	U.S.	

[Main revisions since the announcement of May 2013]

LATUDA® (New Indication: Bipolar I depression)	Deleted "U.S." due to approval for bipolar depression in U.S. (June 2013).

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 completed 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. NDA submitted in the U.S. by Chelsea for neurogenic orthostatic hypotension in September 2011. Complete Response Letter received from FDA in March 2012. Chelsea resubmitted in July 2013. Phase II study of fibromyalgia in the U.K. and phase II study of intradialytic hypotension in the U.S. completed 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 as a collunarium was completed in Europe, while a Phase I study as an inhalant was started in the U.K. by AstraZeneca. (AstraZeneca's product code: AZD8848).
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 U.K. in March 2011. Both companies are currently developing lurasidone in Europe. Takeda submitted an MAA in Switzerland for schizophrenia in March 2012. Takeda submitted an MAA in Europe for schizophrenia by the centralised authorisation procedure in September 2012.
SMP-986	Nocturia	Entered into a license agreement with Nippon Shinyaku Co., Ltd. for exclusive rights in Japan to develop and commercialize in March 2013.

[Main revisions since the announcement of May 2013]

Droxidopa (DOPS®) Chelsea resubmitted in the U.S. in July 2013.

VII. Profile of Major Products under Development (as of July 31, 2013)

eslicarbazepine acetate (SEP-0002093) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- A novel voltage-gated sodium channel blocker. The compound has been studied in Phase III, multi-center, randomized, placebo-controlled studies, which involved patients from 23 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. The target indication for this drug is for adjunctive use in adult patients with partial onset seizures. This drug is expected to be safe and tolerable, have clear dose-response correlation and marked and sustained seizure reduction.
- Development stage:

  Epilepsy (adjunctive therapy): NDA submitted in March 2009 in the U.S.
  Resubmitted NDA in the U.S. in February 2013

  Epilepsy (monotherapy): Phase III in the U.S.

LATUDA® (lurasidone hydrochloride) Schizophrenia, Bipolar disorder

- Developed in-house
- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent which is believed to have 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. In the clinical trials supporting the U.S. FDA approval, the efficacy of LATUDA for the treatment of schizophrenia was established in four, short-term (6-week), placebo-controlled clinical studies in adult patients. In these studies, LATUDA demonstrated significantly greater improvement versus placebo. A total of five short-term placebo controlled clinical trials contributed to the understanding of the tolerability and safety profile of LATUDA. LATUDA was approved for the treatment of schizophrenia by the U.S. FDA in October 2010, and launched by Sunovion in February 2011 in the U.S. Launched in Canada for the treatment of schizophrenia in September 2012. LATUDA was approved as the first atypical antipsychotic indicated for the treatment of bipolar I depression as a monotherapy and as an adjunctive therapy to lithium or valproate by the U.S. FDA in June 2013.
- Development stage:

  Schizophrenia: Submitted MAA (Europe: Co-development with Takeda Pharmaceutical)
  Submitted in Australia
  Phase III in Japan
  In addition, Phase III study is ongoing in the U.S., Europe, etc. to test the hypothesis that LATUDA is effective in the long term maintenance treatment of schizophrenia.

  Bipolar I depression: Submitted in Canada.
  In addition, plans to submit an MAA in Europe through co-development with Takeda Pharmaceutical. (Phase III in Europe).

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

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

ranirestat (AS-3201)　　Diabetic neuropathy

- Developed in-house
- AS-3201 is expected to alleviate 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 in Japan

BBI608　　Colorectal cancer, Solid cancer

- Developed in-house (BBI)
- First-in class Molecular Targeted Drug (small molecular compound, oral agent). BBI608 is expected to have excellent efficacy in monotherapy and combination therapy with chemotherapy by inhibiting both growth of tumor cells and maintenance of cancer stem cells. Highly safe, easy-to-use with existing chemotherapy. No particular hematologic toxicity observed.
- Development stage:
  Colorectal cancer (monotherapy): Phase III in the U.S. and Canada
  Colorectal cancer (combination therapy): Phase II in the U.S. and Canada
  Solid cancer (combination therapy with paclitaxel): Phase I/II in the U.S. and Canada
  Solid cancer (monotherapy): Phase I in Japan

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

- In-licensed from Intercept Pharmaceuticals Inc. (Intercept's product code: INT-747)
- DSP-1747 is an agonist to farnesoid X receptor (FXR) whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. The compound is expected to be effective for hepatic dysfunction and hepatic fibrosis associated with an increase of bile acid in the liver.
- Development stage: Phase II in Japan for NASH. Phase II for PBC is under consideration.

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 II in Japan

glycopyrrolate bromide(SUN-101)　　Chronic obstructive pulmonary disease (COPD)

- Developed in-house (Sunovion)
- SUN-101 is a proprietary solution formulation of glycopyrrolate bromide, delivered by a customized eFlow® Nebulizer System (originated by and licensed from PARI Pharma GmbH), which was developed to optimize medication delivery and allow ease of use. Including products on the market and in development in this therapeutic area, SUN-101 is currently the only LAMA (long-acting muscarinic antagonist) in nebulized form.
- Development stage: Phase II in the U.S.

SEP-225289 Attention-deficit hyperactivity disorder (ADHD)

- Developed in-house
- SEP-225289 is a DNRI that inhibits the reuptake of dopamine and norepinephrine. SEP225289 is being developed as a once daily long-acting treatment that will be effective throughout the day. Because of its ability to maintain a stable concentration in blood levels all day, it is expected to be effective over the course of the day.
- Development stage: Phase II in the U.S.

WT4869 Myelodysplastic syndromes (MDS), Solid cancer

- Developed in house (Joint-research with Chugai Pharmaceutical)
- WT4869 is a therapeutic cancer vaccine candidate using a peptide derived from Wilms' tumor gene 1 (WT1) protein. WT4869 is expected to treat patients with various types of hematologic and solid cancers that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- 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
- DSP-3025 is 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 was 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 has completed a Phase II study in Europe as a collunarium and started a Phase I study in the U.K. as an inhalant. (AstraZeneca's code name: AZD8848)
- Development stage: Phase I (collunarium) in Japan

DSP-5990 MRSA infection

- In-licensed from Takeda Pharmaceutical (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.
- In October 2010, approved in the U.S. by Forest Laboratories. In August 2012, approved in Europe by AstraZeneca .
- Development stage: Phase I in Japan

DSP-8658 Diabetes, Alzheimer's disease

- Developed in-house
- DSP-8658 is a novel PPARα/γ modulator.
- 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.

- DSP-8658 may also have the potential as a treatment for Alzheimer's disease as the compound may improve symptomatic cognitive decline and show disease modification with mechanism of reduction in β amyloid by impacting a number of different mechanisms in marketed compounds.
- Development stage: Phase I in the U.S.

DSP-1053 Major depressive disorder (MDD)

- 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 has the potential to show early onset of action and efficacy for depression and anxiety.
- Development stage: Phase I in the U.S.

DSP-2230 Neuropathic pain

- Developed in-house
- DSP-2230 is a novel compound that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8 with higher potencies than those against the other sodium channel subtypes studied. In addition, DSP-2230 has demonstrated antiallodynic effects in animal models of neuropathic pain that have been shown to be predictive of efficacy in humans. Due to its novel mechanism, DSP-2230 is expected not to produce CV or CNS side effects, which are present with the current drugs, such as non-selective sodium channel blockers and anti-epilepsy medicines.
- Development stage: Phase I in the U.K.

WT2725 Solid cancer, Hematologic cancer

- Developed in-house (Joint-research with Chugai Pharmaceutical)
- WT2725 is a therapeutic cancer vaccine candidate using a peptide derived from Wilms' tumor gene 1 (WT1) protein. WT2725 is expected to treat patients with various types of hematologic and solid cancers that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- Development stage: Phase I in the U.S.

BBI503 Solid cancer

- Developed in-house (BBI)
- First-in class Molecular Targeted Drug (small molecular compound, oral agent). BBI503 is expected to have excellent efficacy in monotherapy and combination therapy with chemotherapy by inhibiting both growth of tumor cells and maintenance of cancer stem cells by a different mechanism to BBI608. Easy-to-use with existing chemotherapy, expected to be highly safe.
- Development stage: Phase I in the U.S. and Canada

SEP-363856 Schizophrenia

- Developed in-house (Sunovion)
- SEP-363856 is an antipsychotic with a novel mechanism of action. Compared to existing antipsychotics that are effective for positive symptoms of schizophrenia, this also shows efficacy for the negative symptoms. Even in combination treatment with atypical antipsychotics, extrapyramidal side effects were not observed. High efficacy and improved QOL are expected for the treatment for schizophrenia.
- Development stage: Phase I in the U.S.