Securities Code: 4506

Supplementary Financial Data for the Year Ended March 31, 2014

May 8, 2014

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	FY2013	Change (%)	FY2014 Apr.-Sep. (Forecast)	Change (%)	FY2014 (Forecast)	Change (%)
Net sales	347.7	387.7	11.5	178.0	(1.9)	352.0	(9.2)
Cost of sales	101.7	104.1	2.4	51.5	2.1	102.5	(1.5)
SG&A expenses	221.0	241.5	9.3	114.5	0.9	229.5	(4.9)
SG&A expenses less R&D costs	161.2	171.6	6.5	82.0	0.0	159.5	(7.1)
R&D costs	59.8	69.8	16.6	32.5	3.2	70.0	0.3
Operating income	25.0	42.1	68.3	12.0	(31.2)	20.0	(52.5)
Ordinary income	24.5	40.6	65.8	11.5	(33.9)	19.0	(53.2)
Net income	10.0	20.1	99.7	6.3	(27.6)	12.0	(40.2)

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.

EBITDA (Billions of yen)	60.3	68.1	21.0	38.0
Earnings per share (yen)	25.28	50.49	15.86	30.20
Return on equity (ROE)	3.0%	5.4%	—	—
Payout ratio	71.2%	35.7%	56.7%	59.6%

2. Consolidated Statements of Cash Flows (Billions of yen)

	FY2012	FY2013
Net cash provided by operating activities	49.9	49.9
Net cash used in investing activities	(55.0)	(26.2)
Net cash used in financing activities	(20.2)	(27.2)
Cash and cash equivalents at the end of period	71.4	73.9

3. Currency Exchange Rates (Billions of yen)

	FY2013		FY2014 Assumed rate	Forex sensitivity FY2014 (Impact of yen strength by 1yen/$)	
	Fiscal year end rate	Average rate			
Yen / USD	102.9	100.2	100.0	Net Sales	(1.3)
Yen / RMB	16.6	16.4	16.0	Operating Income	0.1

Note: Net sales and Operating income in FY2013 increased by 32.2 billion yen and 1.1 billion yen respectively, compared to the previous year due to exchange rate fluctuation.

4. Capital Expenditures and Depreciation (Billions of yen)

	FY2012	FY2013	Change	FY2014	
				Forecast	Change
Capital expenditures	10.4	13.5	3.1	12.0	(1.5)
Depreciation and amortization	7.9	8.8	0.9	9.5	0.7

Note: The amount of capital expenditures, depreciation and amortization for tangible fixed assets and software.

・Major capital expenditure projects completed in FY2013
The New Chemistry Research Building in Osaka Research Center:
(Total expenditures 5.8billion yen,completed in Jun. 2013)

(Reference)

Financial Results for DSP (Billions of yen)

	FY2012	FY2013	Change (%)	Group-to-parent ratio
Net sales	190.0	200.7	5.7	1.93
Cost of sales	59.0	59.5	0.8	
SG&A expenses	112.4	117.3	4.4	
SG&A expenses less R&D costs	64.9	63.5	(2.1)	
R&D costs	47.5	53.8	13.3	
Operating income	18.6	23.9	28.8	1.76
Ordinary income	18.5	23.4	26.5	1.74
Extraordinary income	—	2.8		
Extraordinary loss	1.8	5.0		
Net income	11.4	15.2	33.9	1.31

Financial Results for Sunovion (Millions of dollars)

	FY2012	FY2013	Change (%)
Net sales	1,502	1,499	(0.3)
Cost of sales	218	166	(24.2)
SG&A expenses	1,302	1,132	(13.1)
SG&A expenses less R&D costs	1,082	952	(12.0)
[amortization of patent rights and goodwill, etc]	(324)	(179)	(44.6)
R&D costs	220	180	(18.3)
Operating income	(18)	201	—
Ordinary income	(16)	203	—
Extraordinary income	—	13	
Extraordinary loss	60	50	
Net income	(69)	82	—

Note: Total of Sunovion's result and amortization of goodwill.

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2012 (A)	FY2013 (B)	(B)-(A)	Change (%)
Net sales	347.7	387.7	40.0	11.5
Overseas sales	133.1	174.3	41.2	30.9
[% of net sales]	38.3%	45.0%		
Cost of sales	101.7	104.1	2.4	2.4
[% of net sales]	29.2%	26.9%		
Gross profit	246.0	283.6	37.6	15.3
SG&A expenses	221.0	241.5	20.5	9.3
Labor costs	66.0	65.4	(0.5)	(0.8)
Advertising and promotion costs	16.4	22.2	5.8	35.5
Sales promotion costs	11.8	13.7	1.9	16.1
Other costs	67.0	70.3	3.3	4.9
SG&A expenses less R&D costs	161.2	171.6	10.5	6.5
R&D costs	59.8	69.8	10.0	16.6
[% of net sales]	17.2%	18.0%		
Operating income	25.0	42.1	17.1	68.3
Non-operating income	3.1	2.1	(1.0)	
Non-operating expenses	3.6	3.6	0.0	
Ordinary income	24.5	40.6	16.1	65.8
Extraordinary income	–	4.1	4.1	
Gain on sales of investment securities	–	2.8	2.8	
Fair value adjustment of contingent consideration	–	1.3	1.3	
Extraordinary loss	6.3	10.0	3.6	
Impairment loss	0.4	7.6	7.2	
Business structure improvement expenses	4.8	2.3	(2.5)	
Loss on litigation	1.1	–	(1.1)	
Income before income taxes and minority interests	18.2	34.7	16.6	91.2
Income taxes	8.1	14.6	6.5	
Income before minority interests	10.0	20.1	10.0	99.7
Net income	10.0	20.1	10.0	99.7

- Net sales: ・Japan Segment -2.6 ・North America Segment +29.4 (FX rate impact +29.5) ・Other Regions Segment +7.4
- Advertising and promotion costs: ・Increase by lower yen ・Increase in North America
- Sales promotion costs: ・Increase by lower yen ・Decrease in Japan / Increase in North America and China
- R&D costs: ・Increase by lower yen ・Increase in Japan and North America (Boston Biomedical, Inc.)
- Impairment loss: FY2012: ・Impairment loss for in-process R&D in North America; FY2013: ・Impairment loss for production facility / in-process R&D in North America ・Impairment loss for idle assets in Japan
- Business structure improvement expenses: FY2012: ・Restructuring costs in North America ・Transfer of assigned employees to related companies in Japan; FY2013: ・Restructuring costs in North America ・Retirement payments in Japan

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.
2: Overseas sales includes exports of non-Pharmaceutical products.

2. Consolidated Statements of Comprehensive Income

(Billions of yen)

	FY2012	FY2013
Income before minority interests	10.0	20.1
Other comprehensive income	27.1	25.1
Unrealized gains (losses) on available-for-sale securities, net of tax	6.1	2.9
Deferred gains or losses on hedges	–	(0.0)
Foreign currency translation adjustments	21.0	22.3
Comprehensive income	37.2	45.2

Currency exchange rates : yen/$

12/2011	12/2012	03/2013	03/2014
77.7	→ 86.6	94.0	→ 102.9
	+8.9		+8.9

3. Segment Information (FY2013) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	172.1	145.3	—	11.9	16.7	346.0	41.7	387.7
Sales to customers	171.9	145.3	—	11.9	16.7	345.8	41.9	387.7
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	49.3	15.0	—	2.6	4.4	71.3	32.8	104.1
Gross profit	122.7	130.3	—	9.3	12.3	274.6	8.9	283.6
SG&A expenses less R&D costs	61.9	78.3	18.2	6.1	0.9	165.4	6.2	171.6
Income (loss) of segment	60.8	52.0	(18.2)	3.2	11.4	109.2	2.7	111.9
R&D costs*3						68.9	0.9	69.8
Operating income						40.4	1.8	42.1

Segment Information (FY2014 Forecast) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	169.1	119.0	—	13.2	7.8	309.1	42.9	352.0
Sales to customers	169.0	119.0	—	13.2	7.8	309.0	43.0	352.0
Intersegment	0.1	—	—	—	—	0.1	(0.1)	—
Cost of sales	50.7	11.6	—	2.4	4.4	69.1	33.4	102.5
Gross profit	118.4	107.4	—	10.8	3.4	240.0	9.5	249.5
SG&A expenses less R&D costs	60.1	75.8	8.6	6.5	2.0	153.0	6.5	159.5
Income (loss) of segment	58.3	31.6	(8.6)	4.3	1.4	87.0	3.0	90.0
R&D costs*3						69.0	1.0	70.0
Operating income						18.0	2.0	20.0

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 (A)	FY2013 (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	FY2014 (Forecast)
Japan	174.5	171.9	(2.6)	(1.5)	84.6	169.0
North America	115.8	145.3	29.4	25.4	60.9	119.0
China	7.6	11.9	4.3	56.1	6.9	13.2
Other Regions	9.3	16.7	7.4	80.3	4.1	7.8

5. Sales of Major Products

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

Brand name (Generic name) Therapeutic indication	FY2012 (A)	FY2013 (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	FY2014 (Forecast)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	2.0	6.9	4.9	243.1	5.5	12.8
AVAPRO® (irbesartan) Therapeutic agent for hypertension	11.7	12.1	0.4	3.6	5.5	11.6
LONASEN® (blonanserin) Atypical antipsychotic	10.7	12.6	1.9	17.2	6.7	13.5
TRERIEF® (zonisamide) Parkinson's disease drug	7.0	9.5	2.5	35.1	5.5	11.7
Japan(New Products)						
METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	12.0	15.8	3.8	31.3	7.9	16.1
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.7	1.7	1.0	149.3	1.5	3.2
Japan(Specialty Products)						
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	4.6	4.8	0.2	4.3	2.6	5.4
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma	1.1	1.2	0.0	2.8	0.5	1.0
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	9.9	9.8	(0.1)	(1.2)	5.4	10.8
Japan(Others)						
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	29.2	27.0	(2.2)	(7.5)	11.5	22.4
GASMOTIN® (mosapride citrate) Gastroprokinetic	19.5	15.0	(4.4)	(22.8)	5.9	11.4
PRORENAL® (limaprost alfadex) Vasodilator	14.2	13.5	(0.7)	(4.9)	5.9	11.6
MEROPEN® (meropenem) Carbapenem antibiotic	10.3	9.8	(0.5)	(4.8)	4.2	8.1
EBASTEL® (ebastine) Antiallergic	5.8	4.4	(1.3)	(23.3)	1.8	4.6
EXCEGRAN® (zonisamide) Antiepileptic	3.1	3.0	(0.1)	(3.6)	1.6	2.8
DOPS® (droxidopa) Noradrenergic neural function	3.1	3.0	(0.1)	(3.9)	1.5	2.9

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2012 (A)	FY2013 (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	FY2014 (Forecast)
LUNESTA® (eszopiclone) Sedative hypnotic	44.8	58.0	13.2	29.5	6.1	8.5
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	16.1	42.2	26.1	161.6	29.5	61.0
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	12.7	16.8	4.1	32.0	9.7	20.8
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	25.3	12.1	(13.3)	(52.3)	5.9	9.2
ALVESCO® (ciclesonide) Inhaled corticosteroid	3.1	4.2	1.1	36.3	2.2	4.3
OMNARIS® (ciclesonide) Corticosteroid nasal spray	1.9	2.1	0.2	9.8	1.4	2.9
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	0.4	1.9	1.5	369.6	1.1	2.1
APTIOM® (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	—	—	—	—	1.2	3.5
Industrial property revenues	7.8	4.1	(3.7)	(47.8)	1.7	3.3

China (Billions of yen)

Brand name (Generic name)	FY2012 (A)	FY2013 (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	FY2014 (Forecast)
MEROPEN® (meropenem)	6.3	9.8	3.5	56.5	5.6	10.6

Other Regions (Billions of yen)

Brand name (Generic name)	FY2012 (A)	FY2013 (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	FY2014 (Forecast)
MEROPEN® (meropenem) (Export)	6.2	5.6	(0.6)	(9.2)	1.8	3.7
EXCEGRAN® (zonisamide) (Export)	1.8	1.3	(0.5)	(28.7)	1.0	1.3
GASMOTIN® (mosapride citrate) (Export)	0.8	0.3	(0.4)	(55.4)	0.3	0.5
Industrial property revenues	0.3	9.1	8.8	—	0.2	0.7

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

Brand name (Generic name) Therapeutic indication	FY2012 (A)	FY2013 (B)	(B)-(A)	Change (%)	FY2014 Apr.-Sep. (Forecast)	FY2014 (Forecast)
LUNESTA® (eszopiclone)	561	579	18	3.2	61	85
LATUDA® (lurasidone)	202	421	219	108.4	295	610
BROVANA® (arformoterol tartrate)	160	168	8	5.1	97	208
XOPENEX® (levalbuterol HCl)	317	121	(197)	(62.0)	59	92
ALVESCO® (ciclesonide)	38	42	3	8.6	22	43
OMNARIS® (ciclesonide)	24	21	(3)	(12.5)	14	29
ZETONNA® (ciclesonide)	5	19	14	274.1	11	21
APTIOM® (eslicarbazepine acetate)	—	—	—	—	12	35
Industrial property revenues	98	41	(57)	(58.4)	17	33

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of Mar. 31, 2013 (A)	As of Mar. 31, 2014 (B)	(B)-(A)
[Assets]	607.2	659.0	51.8
Current assets:	333.4	359.6	26.2
Cash and time deposits	18.8	22.7	4.0
Notes and accounts receivable	97.2	111.7	14.5
Marketable securities	86.5	82.0	(4.5)
Inventories	62.7	59.1	(3.5)
Deferred tax assets	30.1	37.3	7.2
Short-term loans receivable	34.4	41.7	7.3
Others	4.0	5.2	1.3
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)
Fixed assets:	273.8	299.4	25.6
Property, plant and equipment:	69.9	72.7	2.8
Buildings and structures	39.9	44.4	4.5
Machinery, equipment and carriers	9.4	9.6	0.2
Land	10.3	8.4	(1.9)
Construction in progress	5.8	3.1	(2.7)
Others	4.4	7.2	2.7
Intangible assets:	146.3	156.8	10.5
Goodwill	71.3	80.7	9.4
In-process research & development	50.7	56.1	5.4
Others	24.4	20.1	(4.3)
Investments and other assets:	57.6	69.9	12.3
Investment securities	40.8	50.8	10.0
Asset for retirement benefit	—	4.7	4.7
Deferred tax assets	7.6	8.6	1.0
Others	9.2	5.9	(3.4)
Allowance for doubtful receivables	(0.0)	(0.0)	0.0
Total assets	607.2	659.0	51.8

Milestone revenue
Impact of FX rate

New Chemistry Research Building in Osaka Research Center(excluding depreciation)
Buildings +4.5
Construction in progress -2.3
Others +1.3

Increase +2.4
Amortization -6.2
Currency +13.1

Transfer -0.6
Impairment -4.3
Currency +10.2

Patent rights, Sales rights, etc.

Including aquisition of securities of Edison

Accounts receivable turnover period (in months)	3.35	3.46

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2013 (A)	As of Mar. 31, 2014 (B)	(B)-(A)
[Liabilities]	258.0	260.5	2.5
Current liabilities:	124.8	131.2	6.4
Notes and accounts payable	14.3	11.7	(2.5)
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	10.5	8.4
Reserve for bonuses	7.6	7.8	0.2
Reserve for sales returns	5.7	9.9	4.2
Reserve for sales rebates	19.2	26.4	7.3
Accounts payable-other	34.8	35.9	1.2
Others	21.3	18.9	(2.3)
Long-term liabilities:	133.1	129.3	(3.9)
Bonds payable	60.0	60.0	—
Long-term loans payable	35.0	25.0	(10.0)
Deferred tax liabilities	14.5	15.7	1.2
Reserve for retirement benefit	11.0	—	(11.0)
Liability for retirement benefit	—	13.9	13.9
Others	12.6	14.7	2.1
[Net assets]	349.2	398.5	49.3
Shareholders' equity:	346.2	356.5	10.3
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	308.6	318.9	10.3
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	3.1	42.1	39.0
Unrealized gains on available-for-sale securities, net of tax	14.1	17.2	3.1
Deferred gains or losses on hedges	—	(0.0)	(0.0)
Foreign currency translation adjustments	(11.0)	26.8	37.8
Remeasurement of defined benefit plans	—	(2.0)	(2.0)
Total liabilities and net assets	607.2	659.0	51.8

Total interest-bearing debt
115.0→95.0 (-20.0)

Net income +20.1
Payment of the dividend -7.2
Influence of fiscal year change -2.6
(North America -2.9, China +0.3)

Currency exchange rates: yen/$
12/2012 03/2014
86.6 → 102.9

IV. Quarterly Business Results

(Billions of yen)

	FY2012				FY2013			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Net sales	89.1	89.7	90.5	78.5	89.6	91.8	103.1	103.2
Cost of sales	25.2	24.8	26.3	25.3	25.3	25.2	27.7	26.0
SG&A expenses	53.0	55.7	51.4	60.8	55.3	58.2	58.2	69.7
SG&A expenses less R&D costs	38.9	42.0	39.3	40.9	40.6	41.4	40.7	48.9
R&D costs	14.1	13.7	12.1	19.9	14.7	16.8	17.5	20.8
Operating income (loss)	10.9	9.1	12.7	(7.7)	9.0	8.4	17.2	7.5
Non-operating income	1.1	0.3	0.8	0.8	0.9	0.3	0.5	0.4
Non-operating expenses	0.5	1.0	0.7	1.4	0.5	0.8	0.8	1.6
Ordinary income (loss)	11.5	8.4	12.8	(8.2)	9.5	7.9	16.9	6.3
Extraordinary income	—	—	—	—	—	3.8	0.0	0.2
Extraordinary loss	1.5	—	2.9	2.0	1.0	5.3	0.1	3.6
Income (Loss) before income taxes and minority interests	10.0	8.4	10.0	(10.2)	8.5	6.5	16.8	2.9
Net income (loss)	5.7	5.3	5.9	(6.8)	4.8	3.9	10.5	0.9

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

V. Major consolidated subsidiaries (As of March 31, 2014)

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	103	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	1,565	57	743
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 Mar. 31, 2014
consolidated		7,218	7,015
non-consolidated		4,457	4,331
MRs Japan	(excluding managers)	1,410	1,400
	(including managers)	1,610	1,600
MRs U.S.	(excluding managers)	830	710
	(including managers)	940	810
MRs China	(excluding managers)	350	390
	(including managers)	470	480

VI. Shareholder Positioning (As of March 31, 2014)

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

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 593,962)

3. Number of shareholders: 25,672

4. Major shareholders:

Shareholders	Status of ownership	
	Number of shares held (Thousand shares)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	199,434	50.20
Inabata & Co., Ltd.	27,282	6.87
The Master Trust Bank of Japan, Ltd. (Trust account)	15,574	3.92
Japan Trustee Services Bank, Ltd. (Trust account)	11,793	2.97
Nippon Life Insurance Company	8,529	2.15
Japan Trustee Services Bank, Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12
Dainippon Sumitomo Pharma Employee shareholders' association	4,116	1.04
BNP Paribas Securities (Japan) Limited	3,334	0.84

Notes: *1: Percentage of shareholding is calculated excluding treasury stock (593,962 stocks).
*2: The numbers of shares held are rounded down to the nearest thousand shares.

VII. Development Pipeline (As of May 8, 2014)

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Submitted	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Merck Santé	Submitted in October 2013
	SUREPOST® Oral	repaglinide	(New indication) Type 2 diabetes All combination therapies including DPP-4 inhibitors	Novo Nordisk	Submitted in December 2013 Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes (Monotherapy, Combination with α-GI, BG and TZD)
Phase III	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Approved in the U.S., Canada, Europe and Australia
			Bipolar I depression		Approved in the U.S. and Canada
			Bipolar maintenance		
	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house	Global clinical trial
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	
Phase II/III	EPI-743 Oral	TBD	Leigh syndrome	Edison Pharmaceuticals	

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
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
	TRERIEF® Oral	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	In-house	
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharmaceutical	Independent development after April 2013
Phase I	DSP-3025 Collunarium	TBD	Bronchial asthma, Allergic rhinitis	In-house	
	WT4869 Injection	TBD	Solid cancer	Joint research with Chugai Pharmaceutical	Independent development after April 2013
	WT2725 Injection	TBD	Solid cancer	Joint research with Chugai	Independent development after April 2013
	BBI608 Oral	TBD	Gastric cancer (Combination therapy)	In-house	

[Main revisions since the 3Q announcement of January 2014]

DSP-5990 (ceftaroline fosamil) Deleted due to discontinued development

Major Products under Development in Foreign Markets

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
Approved /preparing for Launch	LATUDA® Oral	lurasidone hydrochloride	Schizophrenia	In-house	Australia	Approved in March 2014
Submitted	APTIOM® Oral	eslicarbazepine acetate	Epilepsy (Adjunctive therapy)	BIAL	Canada	Submitted in June 2013 Approved in the U.S.
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Submitted in August 2013 Brand name in Japan: CALSED®
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Submitted in September 2013 Brand name in Japan: LONASEN®
Phase III	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house	U.S., Canada, etc.	Global clinical trial
			Gastric cancer (Combination therapy)		U.S.	Global clinical trial
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Approved in the U.S., Canada, Europe and Australia
	LATUDA® Oral		(New indication) Bipolar maintenance		U.S., Europe, etc.	
			(New indication) MDD with mixed features			
	APTIOM® Oral	eslicarbazepine acetate	(New indication) Epilepsy (Monotherapy)	BIAL	U.S.	Approved indication: Epilepsy (Adjunctive therapy)

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
Phase II	BBI608 Oral	TBD	Colorectal cancer (Combination therapy)	In-house	U.S., Canada	
	SUN-101 Inhalant	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	In-house	U.S.	From the former Elevation Pharmaceuticals
	SEP-225289 Oral	TBD	Attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	
Phase I/II	BBI608 Oral	TBD	Solid cancer (Combination therapy)	In-house	U.S., Canada	
Phase I	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S.	
	WT2725 Injection	TBD	Solid cancer, Hematologic cancer	Joint research with Chugai	U.S.	Independent development after April 2013
	BBI503 Oral	TBD	Solid cancer (Monotherapy)	In-house	U.S., Canada	
	SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S.	
	BBI608 Oral	TBD	Gastrointestinal cancer (Combination therapy)	In-house	U.S., Canada	

* Phase I study of EPI-589 which was in-licensed from Edison Pharmaceuticals (in-licensed territories: Japan and North America) is ongoing in Europe by Edison Pharmaceuticals.

[Main revisions since the 3Q announcement of January 2014]

APTIOM® (eslicarbazepine acetate)	Deleted due to launch in the U.S. (Launched in April 2014)
LATUDA® (lurasidone hydrochloride)	Deleted due to approval for bipolar I depression in Canada (Approved in March 2014) Approved and preparing for launch in Australia (Approved in March 2014)
BBI608 (Gastric cancer / Combination therapy)	Newly added in Phase III in the U.S.
DSP-1053	Deleted due to discontinued development

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 to FDA in July 2013 and obtained the approval in February 2014.. Phase II study of fibromyalgia and phase II study of intradialytic hypotension 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. Takeda submitted an MAA in Switzerland for schizophrenia in March 2012. Takeda submitted an MAA in Europe for schizophrenia in September 2012. Takeda obtained the approval for schizophrenia in Switzerland in August 2013. Out-licensed to Standard Chem. & Pharm. for Taiwan in August 2013, and submitted for schizophrenia in Taiwan in October 2013. Takeda obtained the approval in Europe for schizophrenia in March 2014.
SMP-986	Nocturia	Out-licensed to Nippon Shinyaku Co., Ltd. for rights in Japan to develop and commercialize in March 2013. Phase II study ongoing in Japan by Nippon Shinyaku.(Nippon Shinyaku's product code: NS-986).

[Main revisions since the 3Q announcement of January 2014]

Droxidopa (DOPS®)	Chelsea obtained the approval for neurogenic orthostatic hypotension in the U.S. in February 2014.
Lurasidone hydrochloride (SM-13496)	Takeda Pharmaceutical obtained the approval for schizophrenia in Europe in March 2014.

VIII. Profile of Major Products under Development (As of May 8, 2014)

APTIOM® (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- A novel voltage-gated sodium channel inhibitor. Sunovion obtained the approval of APTIOM® for use as adjunctive treatment of partial-onset seizures in the U.S. in November 2013 and launched in the U.S. in April 2014. The approval is based on three global studies which were jointly performed with BIAL. These were randomized, double-blind, placebo-controlled studies, which included more than 1,400 people living with partial-onset seizures inadequately controlled by one to three concomitant AEDs. This drug is expected to be an important new treatment option for people living with epilepsy.
- Development stage:
  Epilepsy (adjunctive therapy): Submitted in Canada
  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 studies 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 studies 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 the U.S. in February 2011. For the treatment of schizophrenia, LATUDA was launched in Canada in September 2012 and launched in Switzerland in September 2013 through a local subsidiary of Takeda Pharmaceutical, DSP's partner in Europe. Takeda obtained the approval in Europe from European Commission in March 2014. In addition, LATUDA was approved in Australia in March 2014.
  For the treatment of bipolar I depression, 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. In addition, LATUDA was approved in Canada in March 2014.
- Development stage:

Schizophrenia:	Approved in March 2014 and preparing for launch in Europe and Australia
	Submitted in Taiwan by Standard Chem. & Pharm.
	Phase III in Japan and China
Bipolar I depression:	Phase III in Japan
	In addition, plans to submit an MAA in Europe by Takeda Pharmaceutical. (Phase III in Europe)
Bipolar maintenance:	Phase III in the U.S., Europe and Japan, etc.
MDD with mixed features:	Phase III in the U.S. and 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 **Solid cancer**

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is a small-molecule compound with a novel mechanism that blocks cancer stem cell (cancer cell with stem cell-like properties) self-renewal and induces cell death in CSC as well as other heterogeneous cancer cells. By targeting cancer stem cells in addition to heterogeneous cancer cells, efficacy is expected in the current challenges in therapy against cancer, such as treatment resistance, metastasis and recurrence.
- Development stage:
  Colorectal cancer (monotherapy): Phase III in the U.S., Canada and Japan, etc.
  Gastric cancer (combination therapy with paclitaxel): Phase III in the U.S.
  Colorectal cancer (combination therapy with cetuximab, panitumumab or capecitabine): Phase II in the U.S. and Canada
  Solid cancer (combination therapy with paclitaxel): Phase I/II in the U.S. and Canada
  Gastric cancer (combination therapy with paclitaxel): Phase I in Japan
  Gastrointestinal cancer (combination therapy with FOLFOX[*1], FOLFOX[*1] and bevacizumab, CAPOX[*2], FOLFIRI[*3], FOLFIRI[*3] and bevacizumab, or regorafenib): Phase I in the U.S. and Canada
  *1 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
  *2 CAPOX: Combination therapy with capecitabine, oxaliplatin
  *3 FOLFIRI: Combination therapy with fluorouracil, leucovorin,irinotecan

EPI-743 **Leigh syndrome**

- In-licensed from Edison Pharmaceuticals
- EPI-743 is to synchronize energy generation in the mitochondria with the counterbalancing of redox stress. It is expected to be a world first treatment for mitochondrial diseases beginning with Leigh syndrome.
- Development stage: Phase II/III in Japan

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

- 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 Pharmaceuticals Inc.)
- 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 (Sunovion Pharmaceuticals Inc.)
- SEP-225289 is a DNRI that inhibits the reuptake of dopamine and norepinephrine. SEP-225289 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 in Japan

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. and the U.S.

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:
  Hematologic and Solid cancers: Phase I in the U.S.
  Solid cancer: Phase I in Japan

BBI503 Solid cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI503 is a small-molecule compound with a novel and a different mechanism to BBI608 that blocks cancer stem cell (cancer cell with stem cell-like properties) self-renewal and induces cell death in CSC as well as other heterogeneous cancer cells. By targeting cancer stem cells in addition to heterogeneous cancer cells, efficacy is expected in the current challenges in therapy against cancer, such as treatment resistance, metastasis and recurrence.
- Development stage: Phase I in the U.S. and Canada

SEP-363856 Schizophrenia

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- 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.

EPI-589 Neurodegenerative diseases

- In-licensed from Edison Pharmaceuticals
- EPI-589 is a generation 2 redox cofactor modeled after EPI-743. It is expected to be developed for neurodegenerative indications arising through redox stress based on defects in mitochondrial function.
- Development stage: Phase I in Europe by Edison Pharmaceuticals.