Securities Code: 4506

Supplementary Financial Data for the Year Ended March 31, 2015

May 11, 2015

Sumitomo Dainippon 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)

	FY2013	FY2014	Change (%)	FY2015 Apr.-Sep. (Forecast)	Change (%)	FY2015 (Forecast)	Change (%)
Net sales	387.7	371.4	(4.2)	193.0	8.3	392.0	5.6
Cost of sales	104.1	101.2	(2.8)	51.0	5.2	102.0	0.8
SG&A expenses	241.5	246.9	2.2	131.0	11.1	263.0	6.5
SG&A expenses less R&D costs	171.6	175.6	2.3	89.5	5.7	176.0	0.2
R&D costs	69.8	71.3	2.1	41.5	25.1	87.0	22.0
Operating income	42.1	23.3	(44.8)	11.0	(7.9)	27.0	16.0
Ordinary income	40.6	23.3	(42.6)	11.0	(13.5)	26.5	13.6
Net income	20.1	15.4	(23.0)	8.0	(32.0)	18.0	16.5

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)	68.1	43.1	21.5	47.5
Earnings per share (yen)	50.49	38.88	20.14	45.31
Return on equity (ROE)	5.4%	3.6%	1.8%	4.0%
Payout ratio	35.7%	46.3%	44.7%	39.7%

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2013	FY2014
Net cash provided by operating activities	49.9	30.3
Net cash provided by (used in) investing activities	(26.2)	23.4
Net cash used in financing activities	(27.2)	(15.7)
Cash and cash equivalents at the end of period	73.9	122.8

3. Currency Exchange Rates

(Billions of yen)

	FY2013		FY2014		FY2015 Assumed rate	Forex sensitivity FY2015 (Impact of yen weakness by 1yen/USD)	
	Fiscal year end rate	Average rate	Fiscal year end rate	Average rate			
Yen / USD	102.9	100.2	120.2	109.8	115.0	Net Sales	1.6
Yen / RMB	16.6	16.4	19.4	17.7	18.5	Operating Income	0.1

Note: Net sales and Operating income in FY2014 increased by 13.6billion yen and 0.0billion yen respectively, compared to FY2013 due to exchange rate fluctuation.

4. Capital Expenditures

(Billions of yen)

	FY2013	FY2014	Change	FY2015	
				Forecast	Change
Capital expenditures	13.5	9.7	(3.8)	11.5	1.8

Note: The amount of capital expenditures are for tangible fixed assets and software.

Major continuing capital expenditure projects for FY2015
Earthquake resistant renewal of research building No.2 in Osaka research center: ¥1.6billion
(Total budget ¥1.6billion, plan to be completed in November 2015)

5. Depreciation and Amortization

(Billions of yen)

	FY2013	FY2014	Change	FY2015	
				Forecast	Change
Property, plant and equipment	7.2	7.8	0.6	7.4	(0.4)
Intangible assets	13.4	4.1	(9.3)	5.1	1.0
Goodwill	5.1	5.4	0.4	6.2	0.8

（Reference）

Financial Results for DSP (Billions of yen)

	FY2013	FY2014	Change (%)	Group-to-parent ratio
Net sales	200.7	183.1	(8.8)	2.03
Cost of sales	59.5	60.2	1.3	
SG&A expenses	117.3	108.5	(7.5)	
SG&A expenses less R&D costs	63.5	61.7	(2.9)	
R&D costs	53.8	46.8	(12.9)	
Operating income	23.9	14.3	(40.1)	1.62
Ordinary income	23.4	15.1	(35.3)	1.54
Extraordinary income	2.8	17.6		
Extraordinary loss	5.0	7.2		
Net income	15.2	17.0	11.6	0.91

Financial Results for Sunovion (Millions of dollars)

	FY2013	FY2014	Change (%)
Net sales	149.9	141.0	(5.9)
Cost of sales	16.6	13.2	(20.0)
SG&A expenses	113.2	112.7	(0.4)
SG&A expenses less R&D costs	95.2	91.9	(3.4)
[amortization of patent rights and goodwill, etc]	[17.9]	[8.5]	[(52.6)]
R&D costs	18.0	20.8	15.5
Operating income	20.1	15.0	(25.5)
Ordinary income	20.3	15.3	(24.3)
Extraordinary income	1.3	—	
Extraordinary loss	5.0	—	
Net income	8.2	5.9	(28.2)

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

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)
Net sales	387.7	371.4	(16.3)	(4.2)
Overseas sales	174.3	174.9	0.6	0.4
[% of net sales]	45.0%	47.1%		
Cost of sales	104.1	101.2	(2.9)	(2.8)
[% of net sales]	26.9%	27.3%		
Gross profit	283.6	270.1	(13.4)	(4.7)
SG&A expenses	241.5	246.9	5.4	2.2
Labor costs	65.4	70.6	5.1	7.8
Advertising and promotion costs	22.2	28.8	6.6	29.7
Sales promotion costs	13.7	13.0	(0.7)	(4.9)
Depreciation and amortization	14.4	5.1	(9.2)	(64.3)
Other costs	55.9	58.0	2.1	3.7
SG&A expenses less R&D costs	171.6	175.6	3.9	2.3
R&D costs	69.8	71.3	1.5	2.1
[% of net sales]	18.0%	19.2%		
Operating income	42.1	23.3	(18.9)	(44.8)
Non-operating income	2.1	4.2	2.1	
Non-operating expenses	3.6	4.1	0.5	
Ordinary income	40.6	23.3	(17.3)	(42.6)
Extraordinary income	4.1	17.7	13.6	
Gain on sales of property, plant and equipment	—	16.0	16.0	
Compensation income for damage	—	1.7	1.7	
Gain on sales of investment securities	2.8	—	(2.8)	
Fair value adjustment of contingent consideration	1.3	—	(1.3)	
Extraordinary loss	10.0	7.3	(2.7)	
Impairment loss	7.6	5.3	(2.3)	
Business structure improvement expenses	2.3	2.0	(0.4)	
Income before income taxes and minority interests	34.7	33.8	(1.0)	(2.7)
Income taxes	14.6	18.3	3.7	
Income before minority interests	20.1	15.4	(4.6)	(23.0)
Net income	20.1	15.4	(4.6)	(23.0)

・Japan Segment -15.3
・North America Segment +2.9
(FX rate impact +12.3)
・China Segment +5.2
(FX rate impact +1.3)
・Other Regions Segment -7.9

Cost of sales %
・Increase in Japan
(NHI price revision)
・Decrease in North America and China
(product mix, sales increase)

・Increase in North America

・Completed amortization of a part of patent rights

・Increase in Pharma fee

・Increase in gain on investments to partnership

・Sale of idle real estate

FY2013:
・In-process R&D in North America
・Idle real estate in Japan
FY2014:
・Fixed assets related to reoraganization of production sites

FY2013:
・Restructuring costs in North America
・Retirement payments in Japan
FY2014:
・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)

	FY2013	FY2014
Income before minority interests	20.1	15.4
Other comprehensive income	25.1	44.7
Unrealized gains (losses) on available-for-sale securities, net of tax	2.9	5.9
Deferred gains or losses on hedges	(0.0)	0.0
Foreign currency translation adjustments	22.3	41.4
Remeasurements of defined benefit plans	—	(2.6)
Comprehensive income	45.2	60.1

Currency exchange rates : yen/$
3/2013 3/2014 3/2015
94.0 → 102.9 → 120.2
+8.9 +17.3

3. Segment Information (FY2014) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	156.7	148.2	—	17.1	8.8	330.8	40.6	371.4
Sales to customers	156.6	148.2	—	17.1	8.8	330.7	40.7	371.4
Intersegment	0.1	—	—	—	—	0.1	(0.1)	—
Cost of sales	47.6	12.4	—	3.6	5.5	69.1	32.2	101.2
Gross profit	109.1	135.8	—	13.6	3.3	261.8	8.4	270.1
SG&A expenses less R&D costs	58.5	91.6	9.4	7.3	2.4	169.4	6.2	175.6
Income (loss) of segment	50.6	44.2	(9.4)	6.2	0.8	92.4	2.2	94.6
R&D costs*3						70.4	0.9	71.3
Operating income						22.0	1.3	23.3

Segment Information (FY2015 Forecast) (Billions of yen)

	Pharmaceuticals Business						Other Business *2	Total
	Japan	North America*1	Amortization etc.	China	Other Regions	Subtotal		
Net sales	156.8	166.8	—	18.7	7.4	349.7	42.3	392.0
Sales to customers	156.7	166.8	—	18.7	7.4	349.6	42.4	392.0
Intersegment	0.1	—	—	—	—	0.1	(0.1)	—
Cost of sales	48.0	12.7	—	3.6	4.3	68.6	33.4	102.0
Gross profit	108.8	154.1	—	15.1	3.1	281.1	8.9	290.0
SG&A expenses less R&D costs	58.1	93.0	7.5	8.3	2.5	169.4	6.6	176.0
Income (loss) of segment	50.7	61.1	(7.5)	6.8	0.6	111.7	2.3	114.0
R&D costs*3						86.0	1.0	87.0
Operating income						25.7	1.3	27.0

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)

	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)	FY2015 Apr.-Sep. (Forecast)	FY2015 (Forecast)
Japan	171.9	156.6	(15.3)	(8.9)	78.7	156.7
North America	145.3	148.2	2.9	2.0	80.0	166.8
China	11.9	17.1	5.2	43.7	9.6	18.7
Other Regions	16.7	8.8	(7.9)	(47.4)	3.6	7.4

5. Sales of Major Products

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

Brand name (Generic name) Therapeutic indication	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)	FY2015 Apr.-Sep. (Forecast)	FY2015 (Forecast)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	6.9	12.0	5.0	72.7	7.8	17.5
AVAPRO® (irbesartan) Therapeutic agent for hypertension	12.1	11.4	(0.7)	(5.8)	5.8	11.5
LONASEN® (blonanserin) Atypical antipsychotic	12.6	11.5	(1.1)	(9.0)	6.4	13.0
TRERIEF® (zonisamide) Parkinson's disease drug	9.5	11.6	2.1	22.4	7.0	15.2

Japan（New Products / Specialty Products)

METGLUCO® (metformin) Biguanide oral hypoglycemic	15.8	17.1	1.3	8.4	8.0	14.0
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	1.7	2.4	0.7	42.3	1.7	3.7
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	4.8	4.3	(0.5)	(9.7)	2.4	4.9
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma	1.2	0.9	(0.3)	(22.8)	0.5	1.0
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	9.8	9.7	(0.1)	(1.2)	5.4	11.0

Japan(Others)

AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	27.0	19.6	(7.4)	(27.3)	8.9	17.0
GASMOTIN® (mosapride citrate) Gastroprokinetic	15.0	10.5	(4.6)	(30.5)	4.4	8.3
PRORENAL® (limaprost alfadex) Vasodilator	13.5	10.6	(3.0)	(21.8)	4.7	9.1
MEROPEN® (meropenem) Carbapenem antibiotic	9.8	7.9	(1.9)	(19.8)	3.6	6.8
EBASTEL® (ebastine) Antiallergic	4.4	3.9	(0.5)	(11.8)	1.4	3.2

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)	FY2015 Apr.-Sep. (Forecast)	FY2015 (Forecast)
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	42.2	82.5	40.3	95.6	53.9	115.0
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	16.8	22.2	5.3	31.8	11.8	25.1
LUNESTA® (eszopiclone) Sedative hypnotic	58.0	11.5	(46.5)	(80.1)	2.1	3.7
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	12.1	8.5	(3.6)	(29.5)	2.1	2.5
ALVESCO® (ciclesonide) Inhaled corticosteroid	4.2	4.2	0.0	0.5	2.0	3.9
APTIOM® (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	—	2.5	2.5	—	2.2	6.2
OMNARIS® (ciclesonide) Corticosteroid nasal spray	2.1	1.4	(0.7)	(33.4)	0.6	1.2
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	1.9	1.1	(0.8)	(40.3)	0.5	0.9
Industrial property revenues	4.1	9.9	5.8	142.6	2.2	4.4

China (Billions of yen)

Brand name (Generic name)	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)	FY2015 Apr.-Sep. (Forecast)	FY2015 (Forecast)
MEROPEN® (meropenem)	9.8	14.3	4.5	45.7	7.9	15.3

Other Regions (Billions of yen)

Brand name (Generic name)	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)	FY2015 Apr.-Sep. (Forecast)	FY2015 (Forecast)
MEROPEN® (meropenem) (Export)	5.6	4.6	(0.9)	(16.7)	2.0	4.3
EXCEGRAN® (zonisamide) (Export)	1.3	1.4	0.1	6.8	0.9	1.2
Industrial property revenues	9.1	0.3	(8.8)	(96.3)	0.3	1.0

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

Brand name (Generic name) Therapeutic indication	FY2013 (A)	FY2014 (B)	(B)-(A)	Change (%)	FY2015 Apr.-Sep. (Forecast)	FY2015 (Forecast)
LATUDA® (lurasidone)	421	752	331	78.5	469	1,000
BROVANA® (arformoterol tartrate)	168	202	34	20.3	103	218
LUNESTA® (eszopiclone)	579	105	(474)	(81.9)	18	32
XOPENEX® (levalbuterol HCl)	121	78	(43)	(35.7)	18	22
ALVESCO® (ciclesonide)	42	38	(3)	(8.3)	17	34
APTIOM® (eslicarbazepine acetate)	—	23	23	—	19	54
OMNARIS® (ciclesonide)	21	13	(8)	(39.2)	5	10
ZETONNA® (ciclesonide)	19	10	(9)	(45.5)	4	8
Industrial property revenues	41	90	49	121.4	19	38

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of Mar. 31, 2014 (A)	As of Mar. 31, 2015 (B)	(B)-(A)	
[Assets]	659.0	711.6	52.6	
Current assets:	359.6	401.7	42.1	
Cash and time deposits	22.7	30.6	7.8	
Notes and accounts receivable	111.7	103.1	(8.6)	
Marketable securities	82.0	111.3	29.3	← Increase in certificate of deposit
Inventories	59.1	62.4	3.2	
Deferred tax assets	37.3	38.9	1.6	
Short-term loans receivable	41.7	49.1	7.3	
Others	5.2	6.6	1.4	
Allowance for doubtful receivables	(0.1)	(0.1)	(0.0)	
Fixed assets:	299.4	309.9	10.5	
Property, plant and equipment:	72.7	65.2	(7.5)	
Buildings and structures	44.4	41.4	(3.0)	
Machinery, equipment and carriers	9.6	9.1	(0.6)	
Land	8.4	6.3	(2.1)	← Sale of idle real estate
Construction in progress	3.1	1.2	(1.8)	
Others	7.2	7.2	0.0	
Intangible assets:	156.8	173.9	17.1	Amortization -5.4 Exchange rate +12.9
Goodwill	80.7	88.1	7.4	
In-process research & development	56.1	64.5	8.4	← Exchange rate +8.5
Others	20.1	21.3	1.3	
Investments and other assets:	69.9	70.9	0.9	
Investment securities	50.8	58.2	7.4	
Asset for retirement benefit	4.7	1.9	(2.8)	
Deferred tax assets	8.6	4.8	(3.8)	
Others	5.9	6.0	0.1	
Allowance for doubtful receivables	(0.0)	(0.0)	(0.0)	
Total assets	659.0	711.6	52.6	

Accounts receivable turnover period (in months)	3.46	3.33

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2014 (A)	As of Mar. 31, 2015 (B)	(B)-(A)
[Liabilities]	260.5	260.6	0.1
Current liabilities:	131.2	156.8	25.6
Notes and accounts payable	11.7	12.5	0.8
Current portion of bonds payable	—	30.0	30.0
Current portion of long-term loans payable	10.0	6.5	(3.5)
Income taxes payable	10.5	3.3	(7.2)
Reserve for bonuses	7.8	9.4	1.6
Reserve for sales returns	9.9	8.6	(1.3)
Reserve for sales rebates	26.4	36.4	9.9
Accounts payable-other	35.9	35.3	(0.7)
Others	18.9	14.9	(4.0)
Long-term liabilities:	129.3	103.7	(25.6)
Bonds payable	60.0	30.0	(30.0)
Long-term loans payable	25.0	20.0	(5.0)
Deferred tax liabilities	15.7	17.4	1.7
Liability for retirement benefit	13.9	15.3	1.4
Others	14.7	21.1	6.4
[Net assets]	398.5	451.0	52.5
Shareholders' equity:	356.5	364.3	7.8
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	318.9	326.7	7.8
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	42.1	86.7	44.7
Unrealized gains on available-for-sale securities, net of tax	17.2	23.1	5.9
Deferred gains or losses on hedges	(0.0)	0.0	0.0
Foreign currency translation adjustments	26.8	68.2	41.4
Remeasurement of defined benefit plans	(2.0)	(4.5)	(2.6)
Total liabilities and net assets	659.0	711.6	52.6

Maturity date in March 2016

Impact of weak yen and Latuda sales increase

Total interest-bearing debt
95.0→86.5

Net income +15.4
Payment of dividend -7.2

Currency exchange rates: yen/$
03/2014 03/2015
102.9 → 120.2

IV. Quarterly Business Results

(Billions of yen)

	FY2013				FY2014			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Net sales	89.6	91.8	103.1	103.2	89.7	88.5	100.8	92.2
Cost of sales	25.3	25.2	27.7	26.0	24.1	24.4	26.6	26.1
SG&A expenses	55.3	58.2	58.2	69.7	57.0	60.9	63.3	65.6
SG&A expenses less R&D costs	40.6	41.4	40.7	48.9	41.8	43.0	45.3	45.5
R&D costs	14.7	16.8	17.5	20.8	15.2	18.0	18.0	20.1
Operating income (loss)	9.0	8.4	17.2	7.5	8.7	3.3	10.9	0.5
Non-operating income	0.9	0.3	0.5	0.4	1.3	1.0	0.5	1.4
Non-operating expenses	0.5	0.8	0.8	1.6	0.5	1.1	1.6	1.0
Ordinary income (loss)	9.5	7.9	16.9	6.3	9.6	3.2	9.8	0.8
Extraordinary income	—	3.8	0.0	0.2	1.7	8.3	7.7	0.0
Extraordinary loss	1.0	5.3	0.1	3.6	0.1	0.5	5.3	1.4
Income (Loss) before income taxes and minority interests	8.5	6.5	16.8	2.9	11.1	10.9	12.2	(0.5)
Net income (loss)	4.8	3.9	10.5	0.9	5.8	6.0	7.2	(3.5)

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

V. Major Consolidated Subsidiaries (As of March 31, 2015)

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	155	104	62
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	1,610	79	723
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	As of Mar. 31, 2015
consolidated		7,218	7,015	6,868
non-consolidated		4,457	4,331	4,126
MRs Japan	(excluding managers)	1,410	1,400	1,350
	(including managers)	1,610	1,600	1,530
MRs U.S.	(excluding managers)	830	710	700
	(including managers)	940	810	800
MRs China	(excluding managers)	350	390	370
	(including managers)	470	480	470

VI. Shareholder Positioning (As of March 31, 2015)

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

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 596,335)

3. Number of shareholders: 28,558

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)	13,241	3.33
Japan Trustee Services Bank, Ltd. (Trust account)	10,615	2.67
Nippon Life Insurance Company	7,581	1.91
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
Sumitomo Dainippon Pharma Employee shareholders' association	4,127	1.04
Japan Trustee Services Bank, Ltd. (Trust account 9)	2,482	0.62

Notes: *1: Percentage of shareholding is calculated excluding treasury stock (596,335 stocks).
*2: The numbers of shares held are rounded down to the nearest thousand shares.

VII. Development Pipeline (As of May 11, 2015)

■ **Submitted stage**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Submitted	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Submitted in August 2012 Brand name in Japan: CALSED®
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Submitted in September 2013 Brand name in Japan: LONASEN®
	APTIOM® Oral	eslicarbazepine acetate	(New indication) Epilepsy (Monotherapy)	BIAL	U.S. , Canada	Submitted in October 2014 Approved indication: Epilepsy (Adjunctive therapy)

■ **Phase III stage (1/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase III	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	Japan	
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Japan	Approved in the U.S., Canada, Europe and Australia (A Phase III study completed, development policy under consideration)
			Bipolar I depression			Approved in the U.S. and Canada
			Bipolar maintenance			
			Schizophrenia		China	Approved in the U.S., Canada, Europe and Australia
	LATUDA® Oral		(New indication) Bipolar maintenance		U.S., Europe, etc.	

■ **Phase III stage (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase III	BBI608 Oral	TBD	Colorectal cancer (Monotherapy)	In-house	U.S., Canada, Japan, etc.	Global clinical trial Further enrollment of new patients was stopped and all patients discontinued study therapy in May 2014
			Gastric and Gastro-esopha geal junction adenocarcinoma (Combination therapy)		U.S., Canada, Japan, etc.	Global clinical trial
	SEP-225289 Oral	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	
	SUN-101 Inhalant	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	In-house	U.S.	From the former Elevation Pharmaceuticals
	LONASEN® Oral	blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	Japan	
	LONASEN® Transdermal Patch		(New formulation – Transdermal patch) Schizophrenia			Co-development with Nitto Denko Approved formulation: Oral
	TRERIEF® Oral	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	In-house	Japan	

■ **Phase II / III stage**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase II/III	EPI-743 Oral	TBD	Leigh syndrome	Edison Pharma-ceuticals	Japan	

■ **Phase II stage**

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	
	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceu-ticals	Japan	
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	Japan	
	BBI503 Oral	TBD	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	In-house	Canada	
			Hepatocellular carcinoma, Cholangio carcinoma (Monotherapy)			
			Gastrointestinal stromal tumor (Monotherapy)			
			Ovarian cancer (Monotherapy)		U.S.	
	SB623 Injection	TBD	Chronic Stroke	SanBio	U.S.	Joint development with SanBio
	SEP-225289 Oral	dasotraline	Pediatric attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	

■ **Phase I / II stage**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase I/II	BBI608 Oral	TBD	Solid tumors (Combination therapy)	In-house	U.S., Canada	Phase II : Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.
			Hepatocellular carcinoma (Combination therapy)		U.S.	
			Glioblastoma (Combination therapy)		Canada	
			Malignant pleural mesothelioma (Combination therapy)		Japan	
	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharmace-utical	Japan	Independent development after April 2013
	BBI503 Oral	TBD	Solid tumors (Monotherapy)	In-house	U.S., Canada	Phase II : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.
			Hepatocellular carcinoma (Combination therapy)		U.S.	
	DSP-7888 Injection	TBD	Myelodysplastic syndromes	In-house	Japan	

■ **Phase I stage (1/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase I	WT4869 Injection	TBD	Solid tumors	Joint research with Chugai Pharmace-utical	Japan	Independent development after April 2013
	WT2725 Injection	TBD	Solid tumors, Hematologic malignancies	Joint research with Chugai Pharmace-utical	U.S.	Independent development after April 2013
			Solid tumors		Japan	

■ **Phase I stage (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase I	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S.	
	SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S.	
	BBI608 Oral	TBD	Gastrointestinal cancer (Combination therapy)	In-house	U.S., Canada	
			Pancreatic cancer (Combination therapy)		U.S.	
			Hematologic malignancies (Monotherapy / Combination therapy)			
			Hepatocellular carcinoma (Combination therapy)		Japan	
	DSP-3748 Oral	TBD	Cognitive impairment associated with schizophrenia	In-house	U.S.	
	BBI503 Oral	TBD	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	In-house	Japan	
	BBI608+BBI503 Oral	-	Solid tumors (Combination therapy)	In-house	U.S.	

* 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 announcement of January 2015]

TRERIEF® (New indication : Parkinsonism in DLB)	Changed from Phase II to Phase III in Japan
SEP-225289 (Pediatric attention-deficit hyperactivity disorder)	Changed from Phase I to Phase II in the U.S.
BBI503 (Ovarian cancer / Monotherapy)	Newly added in Phase II in the U.S.
DSP-7888 (Myelodysplastic syndromes)	Newly added in Phase I /II in Japan
BBI608+BBI503 (Solid tumors / Combination therapy)	Newly added in Phase I in U.S.
LATUDA® (MDD with mixed features)	Deleted due to completion of Phase III in U.S. and Europe, etc. (FDA submission planned for label change (No new indication))

Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Proposed indications	Status of development
vosaroxin AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003. Multinational Phase III study completed by Sunesis (Sunesis' product code: SNS-595) in October 2014.
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.
droxidopa (DOPS®)	Neurogenic orthostatic hypotension, Intradialytic hypotension, Fibromyalgia	Out-licensed to Lundbeck (former Chelsea Therapeutics) for the worldwide territory, excluding Japan, China, Korea and Taiwan in May 2006. Lundbeck obtained the approval for neurogenic orthostatic hypotension in the U.S. in February 2014, and launched in the U.S. in September 2014 (Lundbeck's brand name: NORTHERA™). Phase II study of fibromyalgia and phase II study of intradialytic hypotension completed by Lundbeck.
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 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. Out-licensed to Daiichi Sankyo for rights or option rights in four South American countries to commercialize in January 2014. Takeda obtained the approval in Europe for schizophrenia in March 2014. Takeda submitted in Russia and Turkey for schizophrenia in December 2014. Daiichi Sankyo submitted in Venezuela for schizophrenia in December 2014. Entered into a distribution, marketing and sales agreement with DKSH Thailand for Thailand, Hong Kong and Singapore in January 2015. DKSH submitted for schizophrenia in Thailand in November 2014, in Hong Kong in December 2014, in Singapore in April 2015. The license agreement with Takeda for the joint development and exclusive commercialization in Europe will be terminated, and discussions for establishing a transition plan for the transfer of the rights and activities was started in May 2015.
SMP-986	Nocturia	Out-licensed to Nippon Shinyaku for rights in Japan to develop and commercialize in March 2013. Phase II study completed in Japan by Nippon Shinyaku. (Nippon Shinyaku's product code: NS-986).

[Main revisions since the announcement of January 2015]

Lurasidone hydrochloride (SM-13496)	DKSH submitted for schizophrenia in Singapore in April 2015. The license agreement with Takeda for the joint development and exclusive commercialization in Europe will be terminated, and discussions for establishing a transition plan for the transfer of the rights and activities was started in May 2015.

VIII. Profile of Major Products under Development (As of May 11, 2015)

APTIOM® (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A.
- A novel voltage-gated sodium channel blocker, is taken once daily and can be taken whole or crushed, with or without food. APTIOM® is not classified as a controlled substance by the FDA.
- 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. APTIOM™ was approved for use as adjunctive treatment of partial-onset seizures in Canada in July 2014.
- Development stage: Epilepsy (monotherapy): Submitted in the U.S. and Canada in October 2014.

LATUDA® (lurasidone hydrochloride) Atypical antipsychotic

- Developed in-house
- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that 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 approved in Canada in June 2012, in Switzerland in August 2013, in Europe and 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:

Stage	Proposed indication	Country, Area	Partners
Submitted	Schizophrenia	Russia, Turkey	Takeda Pharmaceutical*1
	Schizophrenia	Taiwan	Standard Chem. & Pharm.
	Schizophrenia	Thailand, Hong Kong, Singapore	DKSH
	Schizophrenia	Venezuela	Daiichi Sankyo
Phase III	Schizophrenia	Japan*2, China	In-house
	Bipolar I depression	Japan	In-house
	Bipolar I depression	Europe	Takeda Pharmaceutical*1
	Bipolar maintenance	U.S., Europe, Japan, etc.	In-house

*1 The license agreement with Takeda for the joint development and exclusive commercialization in Europe will be terminated, and discussions for establishing a transition plan for the transfer of the rights and activities was started in May 2015.

*2 A Phase lll study completed, development policy under consideration

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.
- Development stage: Phase III in Japan

BBI608　　Anticancer drug

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is a small-molecule compound with a novel mechanism that blocks cancer stem cells (cancer cells with stem cell-like properties) self-renewal and induces cell death in cancer stem cells as well as other heterogeneous cancer cells. By targeting cancer stem cells in addition to heterogeneous (non-stem) cancer cells, it may provide a new therapeutic option against cancer challenges such as treatment resistance, recurrence and metastasis.
- BBI608 has been shown to inhibit the Stat3 pathways, Nanog pathways and β-catenin pathways in the pre-clinical study.
- Development stage:

Stage	Proposed indication	Country, Area	Combination products	Study number
Phase III	Colorectal cancer (monotherapy) *1	U.S., Canada, Japan, etc.	-	CO.23
	Gastric and Gastro-esophageal junction adenocarcinoma (combination therapy)	U.S., Canada, Japan, etc.	paclitaxel	336 (BRIGHTER)
Phase II	Colorectal cancer (combination therapy)	U.S., Canada	cetuximab, panitumumab or capecitabine	224
Phase I / II	Solid tumors *2 (combination therapy)	U.S., Canada	paclitaxel	201
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
	Glioblastoma (combination therapy)	Canada	temozolomide	251
	Malignant pleural mesothelioma (combination therapy)	Japan	cisplatin and pemetrexed	D8807005
Phase I	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX*3, FOLFOX*3 and bevacizumab, CAPOX*3, FOLFIRI*3, FOLFIRI*3 and bevacizumab, or regorafenib	246
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine and nab-paclitaxel	118
	Hematologic malignancies (monotherapy / combination therapy)	U.S.	dexamethasone	103HEME
	Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	D8808001
	Solid tumors (combination therapy)	U.S.	BBI503	401-101

*1 Further enrollment of new patients was stopped and all patients discontinued study therapy in May 2014.

*2 Phase II : Ovarian cancer, Brest cancer, Non-small cell lung cancer, Melanoma, etc.
*3 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
CAPOX: Combination therapy with capecitabine, oxaliplatin
FOLFIRI: Combination therapy with fluorouracil, leucovorin, irinotecan

dasotraline (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:
  Adult attention-deficit hyperactivity disorder (ADHD): Phase III in the U.S.
  Pediatric attention-deficit hyperactivity disorder (ADHD): Phase II in the U.S.

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

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SUN-101 is an inhalation solution of a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the Pari eFlow® nebulizer system, which portable and able to deliver medication in approximately two minutes utilizing a vibrating membrane. Currently, there are no LAMAs delivered via nebulizer are not currently that are approved by the U.S. Food and Drug Administration (FDA). SUN-101 is the most advanced development stage LAMA for COPD delivered via nebulizer.
- Development stage: Phase III in the U.S.

EPI-743　　Mitochondrial disease

- 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's first treatment for mitochondrial diseases beginning with Leigh syndrome.
- Development stage: Phase II/III in Japan for Leigh syndrome

obeticholic acid (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

BBI503 Anticancer drug

- Developed in-house (Boston Biomedical, Inc.)
- BBI503 is a small-molecule compound with a novel and a mechanism different to that of 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 (non-stem) cancer cells, it may provide a new therapeutic option against cancer challenges such as treatment resistance, recurrence and metastasis.
- BBI503 has been shown to inhibit multi-kinase in pre-clinical study.
- Development stage:

Stage	Proposed indication	Country, Area	Combination products	Study number
Phase II	Renal cell carcinoma, Urothelial carcinoma (monotherapy)	Canada	-	205a
	Hepatocellular carcinoma, Cholangiocarcinoma (monotherapy)	Canada	-	205b
	Gastrointestinal stromal tumor (monotherapy)	Canada	-	205c
	Ovarian cancer (monotherapy)	U.S.	-	205GYN-M
Phase I / II	Solid tumors* (monotherapy)	U.S., Canada	-	101
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
Phase I	Solid tumors (monotherapy), Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	DA101003
	Solid tumors (combination therapy)	U.S.	BBI608	401-101

* Phase II : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

SB623 Stroke

- In-licensed from SanBio and joint development with SanBio
- SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. Unlike autologous cell therapy, which requires individualized cell preparation at the health care institution, SB623 production can be scaled from a single donor's cells, enabling delivery of uniform quality products to a large number of stroke patients. In preclinical and clinical studies to date, SB623 has shown beneficial results for stroke disability with no serious adverse events which are associated with SB623.
- Development stage: Phase II in the U.S.

WT4869 Anticancer drug

- Developed in house (Joint research with Chugai Pharmaceutical)
- WT4869 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. WT4869 is expected to treat various types of hematologic malignancies and solid tumors that express WT1, by the inducing WT1-specific cytotoxic T-lymphocytes which attack WT1-expressing cancerous cells.
- Development stage:

  Myelodysplastic syndromes (MDS): Phase I/II in Japan
  Solid tumors: Phase I in Japan

DSP-7888 Anticancer drug

- Developed in-house
- DSP-7888 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a novel peptide vaccine candidate containing peptides which induce WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become treatment options for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing of WT1-specific CTLs which attack WT1-expressing cancers cells. By adding a helper T cell-inducing peptide, stronger efficacy is expected than a CTL-inducing peptide alone. DSP-7888 is expected to be options for wide range of patients.
- Development stage:
  Myelodysplastic syndromes (MDS): Phase I/II 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 Anticancer drug

- Developed in-house (Joint research with Chugai Pharmaceutical)
- WT2725 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. WT2725 is expected to treat various types of hematologic malignancies and solid tumors that express WT1, by the inducing of WT1-specific cytotoxic T-lymphocytes which attack WT1-expressing cancerous cells.
- Development stage:
  Solid tumors, Hematologic malignancies: Phase I in the U.S.
  Solid tumors: Phase I in Japan

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, the preclinical model 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

DSP-3748 Cognitive impairment associated with schizophrenia (CIAS)

- Developed in-house
- DSP-3748 is positive allosteric modulator (PAM) of α7 type nicotinic acetylcholine receptor (α7nAChR). DSP-3748 is expected to treat patients with cognitive impairment associated with schizophrenia (CIAS) by enhancing the ACh transmission via α7nAChR. DSP-3748 is expected to cause less desensitization in comparison with a conventional agonist.
- Development stage: Phase I in the U.S.