Securities Code: 4506

Supplementary Financial Data for the Third Quarter of the Year Ending March 31, 2013

January 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)

	FY2011 3Q	FY2012 3Q	Change (%)	FY2011	Change (%)	FY2012 (Forecast)*3	Change (%)
Net sales	265.2	269.2	1.5	350.4	(7.7)	348.0	(0.7)
Cost of sales	74.0	76.4	3.2	98.9	(10.2)	100.0	1.2
SG&A expenses	168.9	160.2	(5.2)	231.1	(3.1)	220.0	(4.8)
SG&A expenses less R&D costs	128.2	120.2	(6.2)	174.2	2.3	160.8	(7.7)
R&D costs	40.7	39.9	(1.9)	56.9	(16.5)	59.2	4.1
Operating income	22.3	32.7	46.5	20.4	(34.1)	28.0	37.2
Ordinary income	22.0	32.7	49.0	18.9	(34.0)	27.0	43.1
Net income	10.3	16.9	64.2	8.6	(48.6)	13.5	56.4

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: The forecasts released on October 31, 2012 have not been revised.

EBITDA (Billions of yen)	52.8	61.8	59.9	63.0
Earnings per share (yen)	25.86	42.45	21.72	33.98
Return on equity (ROE)	3.2%	5.2%	2.7%	—
Payout ratio	52.2%	31.8%	82.9%	53.0%

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2011 3Q	FY2012 3Q
Net cash provided by operating activities	35.4	41.1
Net cash used in investing activities	(2.3)	(46.9)
Net cash used in financing activities	(30.4)	(14.7)
Cash and cash equivalents at the end of period	83.4	71.1

DSP 30.7
U.S. Subsidiaries 33.4

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

(1) Excluding mainly amortization of patent rights and goodwill

(Billions of yen)

	FY2011 3Q	FY2012 3Q
Net sales	83.2	93.7
Cost of sales	10.1	13.1
SG&A expenses	65.3	57.2
SG&A expenses less R&D costs	50.9	43.8
R&D costs	14.4	13.5
Operating income	7.9	23.4
Ordinary income	8.1	23.4
Extraordinary loss	1.2	2.4
Net income	4.4	13.2

(2) Mainly amortization of patent rights and goodwill

(Billions of yen)

	FY2011 3Q	FY2012 3Q
Net sales	—	—
Cost of sales	—	—
SG&A expenses	21.0	21.6
Operating income	(21.0)	(21.6)
Ordinary income	(21.0)	(21.6)
Extraordinary loss	2.4	0.4
Net income	(15.7)	(14.8)

Note: BBI results are included in the above.

4. Currency Exchange Rates

(Billions of yen)

	FY2011 Jan - Sep Average rate	FY2011 Average rate	FY2012 Jan - Sep Average rate	FY2012 Forecast rate	Forex sensitivity (2012 Jan-Dec) (Impact of yen strength by 1yen/$)	
Yen / USD	80.6	79.8	79.4	79.5	Net Sales	(1.4)
Yen / RMB	12.4	12.4	12.6	12.5	Operating Income	0.1

5. Capital Expenditures and Depreciation

(Billions of yen)

	FY2011 3Q	FY2012 3Q	Change	FY2011	FY2012 Forecast	Change
Capital expenditures (including intangible assets)	5.1	7.0	1.9	8.7	12.0	3.3
Depreciation and amortization	8.5	6.1	(2.4)	11.5	9.0	(2.5)

Notes 1:Excluding the amortization associated with acquisition of the U.S. Subsidiaries.

2:From FY2012 the method of depreciation for tangible fixed assets has been changed to the straight-line method.

Major capital expenditure projects for FY2012

(Continuing) Construction operation of new research building in Osaka Research Center: ¥3.5billion

(Total budget ¥8.7billion, plan to be completed in June 2013)

(New) Construction for the transfer of BBI: $21million

(Total budget $21million, completed in January 2013)

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

	FY2011 3Q	FY2012 3Q	Change (%)	Group-to-parent ratio
Net sales	157.5	148.6	(5.6)	1.81
Cost of sales	44.2	44.5	0.7	
SG&A expenses	79.0	79.6	0.7	
SG&A expenses less R&D costs	49.8	48.0	(3.5)	
R&D costs	29.3	31.6	7.9	
Operating income	34.2	24.5	(28.3)	1.33
Ordinary income	34.2	25.1	(26.5)	1.30
Net income	21.2	15.2	(28.5)	1.11
Earnings per share (yen)	53.39	38.19		

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2011 3Q (A)	FY2012 3Q (B)	(B)-(A)	Change (%)
Net sales	265.2	269.2	4.0	1.5
Overseas sales	96.4	101.7	5.4	5.6
[% of net sales]	36.3	37.8		
Cost of sales	74.0	76.4	2.4	3.2
Gross profit	191.2	192.9	1.6	0.9
SG&A expenses	168.9	160.2	(8.7)	(5.2)
Labor costs	52.9	49.7	(3.1)	(6.0)
Advertising and promotion costs	12.4	10.9	(1.4)	(11.6)
Sales promotion costs	9.7	7.6	(2.0)	(21.2)
Other costs	53.3	51.9	(1.3)	(2.5)
SG&A expenses less R&D costs	128.2	120.2	(8.0)	(6.2)
R&D costs	40.7	39.9	(0.8)	(1.9)
Operating income	22.3	32.7	10.4	46.5
Non-operating income	2.0	2.3	0.2	
Non-operating expenses	2.4	2.2	(0.2)	
Ordinary income	22.0	32.7	10.8	49.0
Extraordinary income	1.2	—	(1.2)	
Gain on sales of property, plant and equipment	1.2	—	(1.2)	
Extraordinary loss	3.6	4.4	0.8	
Business structure improvement expenses	1.2	3.9	2.7	
Impairment loss	2.4	0.4	(1.9)	
Income before income taxes and minority interests	19.6	28.4	8.8	44.7
Income taxes	9.3	11.5	2.2	
Income before minority interests	10.3	16.9	6.6	64.2
Net income	10.3	16.9	6.6	64.2

- Net sales: North America Segment +8.3 (Including Impact of appreciation of the yen -1.3); Decrease in export of Meropen -3.3
- SG&A expenses: Workforce reduction, etc. in U.S.
- Advertising and promotion costs: Decrease in U.S.
- Sales promotion costs: Decrease in sales commissions due to contract termination
- Gain on sales of property, plant and equipment: FY2011:Sale of Tokyo Northern Office
- Business structure improvement expenses: FY2011: Restructuring costs in U.S. subsidiary; FY2012: Restructuring costs in U.S. subsidiary +2.4; Transfer of assigned employees to related companies in Japan +1.5
- Impairment loss: FY2011: Impairment loss from patent rights; FY2012: Impairment loss from in-process R&D

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)

	FY2011 3Q	FY2012 3Q
Income before minority interests	10.3	16.9
Other comprehensive income (loss)	(11.1)	(1.2)
Unrealized gains (losses) on available-for-sale securities, net of tax	0.3	0.0
Foreign currency translation adjustment	(11.4)	(1.2)
Comprehensive income	(0.8)	15.7

3. Segment Information (FY2012 3Q)

(Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	137.2	88.1	—	5.9	7.6	238.7	30.6	269.2
Sales to customers	137.0	88.1	—	5.9	7.6	238.5	30.8	269.2
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	37.7	9.7	—	1.4	3.8	52.6	23.7	76.4
Gross profit	99.5	78.3	—	4.5	3.7	186.0	6.8	192.9
SG&A expenses less R&D costs	47.2	44.1	21.6	2.6	0.3	115.8	4.4	120.2
Income (Loss) of segment	52.2	34.2	(21.6)	1.9	3.4	70.3	2.4	72.7
R&D costs*3						39.4	0.6	39.9
Operating income						30.9	1.8	32.7

Segment Information (FY2011 3Q)

(Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	139.3	79.8	—	4.8	11.3	235.1	30.1	265.2
Sales to customers	139.1	79.8	—	4.8	11.3	234.9	30.3	265.2
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	35.5	8.0	—	1.5	5.7	50.7	23.3	74.0
Gross profit	103.8	71.7	—	3.3	5.5	184.4	6.8	191.2
SG&A expenses less R&D costs	49.3	50.9	21.0	2.4	0.2	123.9	4.3	128.2
Income (Loss) of segment	54.5	20.8	(21.0)	0.9	5.3	60.5	2.5	63.0
R&D costs*3						40.2	0.5	40.7
Operating income						20.3	2.0	22.3

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

*2: Includes the elimination of intersegment transaction.

*3: In order to manage R&D costs globally, they are not included in each segment.

Segment Information (FY2012 Forecast)

(Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	176.9	115.7	—	7.6	9.2	309.4	38.6	348.0
Sales to customers	176.7	115.7	—	7.6	9.2	309.2	38.8	348.0
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	48.1	13.8	—	1.8	4.6	68.3	31.7	100.0
Gross profit	128.8	101.9	—	5.8	4.6	241.1	6.9	248.0
SG&A expenses less R&D costs	63.0	61.1	25.7	3.8	0.4	154.0	6.8	160.8
Income (Loss) of segment	65.8	40.8	(25.7)	2.0	4.2	87.1	0.1	87.2
R&D costs*3						58.4	0.8	59.2
Operating income						28.7	(0.7)	28.0

Note: The segment forecasts released on October 31, 2012 have been revised

Segment Information (FY2011)

(Billions of yen)

	Pharmaceuticals Business						Other Business*2	Total
	Japan	North America*1	Amortization	China	Other Regions	Subtotal		
Net sales	180.1	108.4	—	6.5	15.2	310.3	40.1	350.4
Sales to customers	179.9	108.4	—	6.5	15.2	310.1	40.3	350.4
Intersegment	0.2	—	—	—	—	0.2	(0.2)	—
Cost of sales	46.8	11.2	—	1.9	7.9	67.8	31.0	98.9
Gross profit	133.3	97.2	—	4.6	7.3	242.4	9.1	251.5
SG&A expenses less R&D costs	66.8	69.8	27.7	3.6	0.3	168.3	5.9	174.2
Income (Loss) of segment	66.4	27.4	(27.7)	1.0	7.0	74.1	3.2	77.3
R&D costs*3						56.2	0.7	56.9
Operating income						17.9	2.5	20.4

Notes *1: Excluding amortization of patent rights and goodwill.
*2: Includes the elimination of intersegment transaction.
*3: In order to manage R&D costs globally, they are not included in each segment.

4. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

	FY2011 3Q (A)	FY2012 3Q (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2012 Forecast(%)	FY2011	FY2012 (Forecast)
Japan	139.1	137.0	(2.2)	(1.6)	77.5	179.9	176.7
North America	79.8	88.1	8.3	10.4	78.0	108.4	[112.9] 115.7
China	4.8	5.9	1.1	23.1	77.3	6.5	7.6
Other Regions	11.3	7.6	(3.7)	(32.9)	82.4	15.2	9.2

Note: Figures in parentheses [ ] are forecasts released on October 31, 2012.

5. Sales of Major Products

Japan

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

Brand name (Generic name) Therapeutic indication	FY2011 3Q(A)	FY2012 3Q(B)	(B)-(A)	Change (%)	Progress Rate vs. FY2012 Forecast(%)	FY2011	FY2012 (Forecast)
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	28.2	22.8	(5.4)	(19.0)	79.6	36.0	28.7
GASMOTIN® (mosapride citrate) Gastroprokinetic	16.3	15.7	(0.6)	(3.7)	78.5	21.2	20.0
PRORENAL® (limaprost alfadex) Vasodilator	12.1	11.2	(0.9)	(7.5)	76.2	15.5	14.7
AVAPRO® (irbesartan) Therapeutic agent for hypertension	8.6	9.0	0.5	5.3	74.6	10.7	12.1
LONASEN® (blonanserin) Atypical antipsychotic	7.8	8.4	0.6	8.0	74.1	9.8	11.3
MEROPEN® (meropenem) Carbapenem antibiotic	9.6	8.2	(1.4)	(14.4)	80.2	12.2	10.2
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	7.0	7.8	0.8	11.9	76.4	9.1	10.2
TRERIEF® (zonisamide) Parkinson's disease drug	4.0	5.4	1.4	33.8	75.0	5.3	7.2
EBASTEL® (ebastine) Antiallergic	4.3	3.7	(0.6)	(14.7)	64.5	6.6	5.7
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	3.5	3.6	0.1	3.0	74.8	4.5	4.8
EXCEGRAN® (zonisamide) Antiepileptic	2.6	2.5	(0.1)	(4.8)	77.3	3.3	3.2
DOPS® (droxidopa) Noradrenergic neural function	2.5	2.5	(0.1)	(3.8)	79.2	3.2	3.1
SUMIFERON® (interferon-α NAMALWA) Natural alpha interferon	3.0	2.1	(0.9)	(31.1)	78.8	3.6	2.6
(Reference)							
MELBIN® (metformin) Biguanide oral hypoglycemic	0.8	—	(0.8)	—	—	0.8	—
Japan (New Products)							
METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	5.4	9.1	3.7	68.9	72.9	7.8	12.5
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	—	2.6	2.6	—	91.4	—	2.8
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: Jan. 2010)	1.0	0.9	(0.1)	(12.2)	68.4	1.3	1.3
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.1	0.5	0.4	641.3	47.7	0.1	1.0

North America

(Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2011 3Q (A)	FY2012 3Q (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2012 Forecast(%)	FY2011	FY2012 (Unaudited)
LUNESTA® (eszopiclone) Sedative hypnotic	32.6	33.2	0.7	2.1	76.2	42.1	[43.6] 44.8
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	24.3	20.9	(3.4)	(14.1)	88.6	33.4	[23.6] 25.3
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	3.9	11.1	7.3	187.0	69.7	6.9	[16.0] 16.1
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	7.4	9.3	1.9	25.1	72.5	10.2	[12.8] 12.7
ALVESCO® (ciclesonide) Inhaled corticosteroid	2.0	2.2	0.2	11.6	72.5	2.8	[3.1] 3.1
OMNARIS® (ciclesonide) Corticosteroid nasal spray	3.9	1.1	(2.8)	(71.0)	59.2	5.1	[1.9] 1.9
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	—	0.4	0.4	—	45.3	—	[0.8] 0.4
Industrial property revenues	4.5	6.8	2.3	51.4	85.7	5.8	[7.9] 7.8

China

(Billions of yen)

Brand name (Generic name)	FY2011 3Q (A)	FY2012 3Q (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2012 Forecast(%)	FY2011	FY2012 (Unaudited)
MEROPEN® (meropenem)	4.0	4.8	0.8	20.5	78.0	5.5	[6.2] 6.3

Other Regions

(Billions of yen)

Brand name (Generic name)	FY2011 3Q (A)	FY2012 3Q (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2012 Forecast(%)	FY2011	FY2012 (Forecast)
MEROPEN® (meropenem) (Export)	8.7	5.3	(3.4)	(38.9)	82.3	11.9	6.5
EXCEGRAN® (zonisamide) (Export)	0.9	1.3	0.4	39.4	88.0	1.2	1.5
GASMOTIN® (mosapride citrate) (Export)	0.7	0.6	(0.1)	(12.6)	83.1	0.8	0.7
Industrial property revenues	0.3	0.2	(0.2)	(52.1)	51.7	0.5	0.3

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

(Millions of dollars)

Brand name (Generic name)	FY2011 Jan-Sep(A)	FY2012 Jan-Sep(B)	(B)-(A)	Change (%)	FY2012 Oct-Dec (Unaudited)	FY2011 Jan-Dec	FY2012 Jan-Dec (Unaudited)
LUNESTA® (eszopiclone)	404	419	15	3.6	143	528	[548] 561
XOPENEX® (levalbuterol HCl)	302	263	(39)	(12.9)	54	419	[296] 317
LATUDA® (lurasidone)	48	140	92	191.3	62	86	[201] 202
BROVANA® (arformoterol tartrate)	92	117	25	26.9	43	127	[161] 160
ALVESCO® (ciclesonide)	25	28	3	13.2	10	35	[39] 38
OMNARIS® (ciclesonide)	48	14	(34)	(70.5)	10	64	[23] 24
ZETONNA® (ciclesonide)	—	5	5	—	0	—	[10] 5
Industrial property revenues	56	85	30	53.6	13	72	[100] 98
Others	15	38	23	158.1	6	27	[40] 44
Total	990	1,109	119	12.0	340	1,359	[1,419] 1,449

Note: Figures in parentheses [ ] are forecasts released on October 31, 2012.

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of 2012/03/31 (A)	As of 2012/12/31 (B)	(B)-(A)
[Assets]	559.4	573.8	14.4
Current assets:	334.3	325.3	(9.0)
Cash and time deposits	13.0	19.5	6.5
Notes and accounts receivable	102.0	98.8	(3.2)
Marketable securities	99.1	85.5	(13.6)
Inventories	58.1	62.8	4.7
Deferred tax assets	31.8	29.4	(2.4)
Short-term loans	25.0	25.0	—
Others	5.4	4.5	(1.0)
Allowance for doubtful receivables	(0.1)	(0.1)	0.0
Fixed assets:	225.2	248.6	23.4
Property, plant and equipment:	66.7	67.9	1.2
Buildings and structures	40.4	39.6	(0.7)
Machinery, equipment and carriers	9.9	9.3	(0.5)
Land	10.2	10.2	(0.0)
Construction in progress	2.1	4.6	2.5
Others	4.1	4.1	(0.0)
Intangible assets:	107.7	133.7	26.0
Goodwill	64.3	64.9	0.6
Patent rights	32.5	18.7	(13.8)
In-process Research & Development	5.7	45.4	39.7
Others	5.2	4.7	(0.5)
Investments and other assets:	50.8	47.0	(3.8)
Investment securities	29.9	30.4	0.6
Deferred tax assets	11.6	7.4	(4.2)
Others	9.3	9.2	(0.1)
Allowance for doubtful receivables	(0.1)	(0.1)	0.0
Total assets	559.4	573.8	14.4

New research building in Osaka Research Center

BBI +0.3
SRD +3.3
Amortization -2.8
Currency -0.2

Amortization -18.8
Transfer +4.7
Currency +0.3

BBI +28.5
SRD +18.4
Transfer -4.7
Currency -2.1
Impairment -0.4

Accounts receivable turnover period (in months)	3.49	3.30

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of 2012/03/31 (A)	As of 2012/12/31 (B)	(B)-(A)
[Liabilities]	240.2	246.1	5.9
Current liabilities:	106.0	99.1	(6.8)
Notes and accounts payable	16.9	15.3	(1.5)
Current portion of long-term loans payable	10.0	10.0	—
Income taxes payable	5.4	5.8	0.4
Reserve for bonuses	7.6	3.9	(3.7)
Reserve for sales returns	3.7	5.0	1.4
Reserve for sales rebates	18.5	18.5	(0.0)
Accounts payable-other	30.0	21.8	(8.2)
Others	13.9	18.8	4.9
Long-term liabilities:	134.2	146.9	12.7
Bonds payable	70.0	70.0	—
Long-term loans payable	48.0	40.5	(7.5)
Deferred tax liabilities	0.3	11.1	10.8
Liability for retirement benefits	10.8	11.2	0.4
Others	5.1	14.2	9.1
[Net assets]	319.2	327.8	8.5
Shareholders' equity:	343.3	353.0	9.7
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	305.7	315.4	9.7
Treasury stock	(0.6)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	(24.0)	(25.2)	(1.2)
Unrealized gains on available-for-sale securities, net of tax	8.0	8.0	0.0
Foreign currency translation adjustment	(32.1)	(33.3)	(1.2)
Total liabilities and net assets	559.4	573.8	14.4

Total interest-bearing debt -7.5
(128.0→120.5)

Deferred tax liabilities for in-process R&D from the acquisition of BBI

The contingent consideration recognized as liabilities in accordance with the acquisition of SRD

Exchange Rates ($)
77.7 → 77.6

IV. Quarterly Business Results

(Billions of yen)

	FY2011				FY2012		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Net sales	94.8	83.2	87.2	85.2	89.1	89.7	90.5
Cost of sales	25.8	24.0	24.2	24.9	25.2	24.8	26.3
SG&A expenses	56.2	57.3	55.4	62.2	53.0	55.7	51.4
SG&A expenses less R&D costs	42.6	43.7	42.0	46.1	38.9	42.0	39.3
R&D costs	13.6	13.7	13.4	16.2	14.1	13.7	12.1
Operating income (loss)	12.8	1.9	7.6	(1.9)	10.9	9.1	12.7
Non-operating income	1.0	0.5	0.6	0.1	1.1	0.3	0.8
Non-operating expenses	0.6	1.1	0.7	1.2	0.5	1.0	0.7
Ordinary income (loss)	13.2	1.3	7.5	(3.1)	11.5	8.4	12.8
Extraordinary income	—	1.2	0.0	—	—	—	—
Extraordinary loss	—	—	3.6	0.2	1.5	—	2.9
Income (Loss) before income taxes and minority interests	13.2	2.6	3.9	(3.3)	10.0	8.4	10.0
Net income (loss)	8.1	1.5	0.7	(1.6)	5.7	5.3	5.9

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

V. Major consolidated subsidiaries (as of 2012/12/31)

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
Fiscal year	March 31	March 31	March 31
Ownership	100%	100%	100%
Number of employees	150	96	62
Businesses	Manufacturing and sales of food ingredients, food additives, and chemical product materials	Manufacturing and sales of veterinary medicines, feedstuff, feed additives	Manufacturing and sales of diagnostics and research materials

Overseas	Sunovion Pharmaceuticals Inc.	Boston Biomedical, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	December 2003
Fiscal year	December 31	December 31	December 31
Ownership	100%	100%	100%
Number of employees	1,997	31	670
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

Number of employees (as of 2012/12/31):

7,504 (consolidated)

4,498 (non-consolidated)

Number of MRs (as of 2012/12/31):

Japan	1,410 (excluding managers)	1,610 (including managers)
U.S.	1,080 (excluding managers)	1,200 (including managers)
China	350 (excluding managers)	450 (including managers)

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

Major Products under Development in Japan

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Submitted	SUREPOST® Oral	Repaglinide	(New Indication) Type 2 diabetes Combination therapy with biguanide	Novo Nordisk	Submitted in April 2012 Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes Monotherapy Combination with α-GI
			(New Indication) Type 2 diabetes Combination therapy with thiazolidine		
	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
	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes Pediatric usage	Merck Santé	
	LONASEN® Oral	Blonanserin	(Addition of pediatric usage) Schizophrenia	In-house	
Phase II	SMP-986 Oral	afacifenacin fumarate	Overactive bladder	In-house	
	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	
	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Phase II	LONASEN® Transdermal Patch	Blonanserin	(New Formulation – Transdermal Patch) Schizophrenia	In-house	Co-development with Nitto Denko
Phase I/II	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharmaceutical	Co-development 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	Co-development with Chugai Pharmaceutical
	DSP-5990 Injection	ceftaroline fosamil	MRSA Infection	Takeda Pharmaceutical	

[Main revisions since the 2Q announcement of October 2012]

AIMIX® (DSP-8153)	Deleted due to launch in Japan (Launched in December 2012)
MEROPEN® (Change of maximum dose)	Change from Phase III to Submitted (Submitted in January 2013)
DSP-6952	Change from Phase I to Phase II
PRORENAL® (New indication)	Deleted due to discontinued development.
DSP-9599	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
Submitted	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy Adjunctive therapy	BIAL	U.S.	NDA submitted in March 2009. Re-submitted in August 2012
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED®
	LATUDA® Oral	lurasidone hydrochloride	(New Indication) Bipolar I Depression	In-house	U.S. and Canada	Submitted in August 2012. Approved for schizophrenia in the U.S and Canada
Phase III	BBI608 Oral	TBD	Colorectal cancer (2nd/3rd line) Monotherapy	In-house (BBI)	U.S., Canada	
	STEDESA™ Oral	eslicarbazepine acetate	Epilepsy Monotherapy	BIAL	U.S.	
	Blonanserin Oral	Blonanserin	Schizophrenia	In-house	China	Brand name in Japan: LONASEN®
	LATUDA® Oral	lurasidone hydrochloride	(New Indication) Bipolar Maintenance	In-house	U.S. and Europe, etc.	Approved for schizophrenia in the U.S. and Canada
			MDD with mixed features		U.S.	
Phase II	SMP-986 Oral	afacifenacin fumarate	Overactive bladder	In-house	U.S. and Europe	
	BBI608 Oral	TBD	Colorectal cancer (3rd/4th line) 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 (2nd/3rd line) 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	Advanced cancer	Joint research with Chugai	U.S.	Co-development with Chugai Pharmaceutical
	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 2Q announcement of October 2012]

BBI608 (Colorectal Cancer, 2nd/3rd line, monotherapy) Changed from Phase III under preparation to Phase III (U.S. and Canada)

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. Phase III study for orthostatic hypotension in Europe and Phase II study of fibromyalgia in the UK are ongoing by Chelsea. Phase II study of intradialytic hypotension completed in the U.S. by Chelsea.
DSP-3025 Collunarium, Inhalant	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: AZD-8848).
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.

[Main revisions since the 2Q announcement of October 2012]

DSP-3025	Astrazeneca completed a Phase II study as a collunarium in Europe and started a Phase I study in the U.K. as an inhalant.

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

STEDESA™ (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C[a], S.A
- STEDESA, the proposed trade name for eslicarbazepine acetate, is a novel voltage-gated sodium channel blocker. STEDESA has been studied in Phase III, multi-center, randomized, placebo-controlled studies, which involved patients from 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 STEDESA is for adjunctive use in adult patients with partial onset seizures. STEDESA 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.
  Complete Response Letter received April 2010. Resubmitted NDA in August 2012.

  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 who met DSM-IV criteria for schizophrenia. In these studies, LATUDA demonstrated significantly greater improvement versus placebo on the primary efficacy measures [the Positive and Negative Syndrome Scale (PANSS) total score and the Brief Psychiatric Rating Scale-derived from PANSS (BPRSd)] at study endpoint. A total of five 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. Food and Drug Administration (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.
- Development stage:

  Schizophrenia: Submitted MAA (Europe: Co-development with Takeda Pharmaceutical)
  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 the U.S. and 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. and Europe, etc.

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

AS-3201 (ranirestat)　　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 (2nd/3rd line, monotherapy): Phase III in the U.S. and Canada
  Colorectal Cancer (3rd/4th line, combination therapy): Phase II in the U.S. and Canada
  Solid Cancer (2nd/3rd line combination therapy with paclitaxel): Phase I/II in the U.S. and Canada

SMP-986 (afacifenacin fumarate)　　Overactive bladder

- Developed in-house
- SMP-986 possesses the dual pharmacological actions of muscarinic receptor antagonism (non-selective) and inhibition of the bladder afferent pathway through Na^+-channel blockade. This compound is being evaluated for its ability to ease urinary urgency and reduce the frequency of both urination and incontinence. The compound has also exhibited the potential to have lower incidence of side effects related to muscarinic receptor antagonism, such as dry mouth.
- Development stage: Phase II in the U.S. and Europe. Phase II in Japan

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

- In-licensed from Intercept Pharmaceuticals Inc. (Intercept's product code: INT-747)
- DSP-1747 is a 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 I in Japan

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

- Developed in-house (Sunovion)
- SUN-101 is a proprietary solution formulation of glycopyrrolate, 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**

- Co-development 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 were identified from drug discovery research for a therapeutic agent with a novel mechanism of action against allergic disorders. With this as a turning point, we started a research collaboration with AstraZeneca in 2004 and discovered a drug candidate as an outcome based on this research collaboration.
- We entered into a development and marketing agreement with AstraZeneca in March 2005. Under the agreement, we will retain development and commercialization rights in Japan, China, Korea and Taiwan and AstraZeneca will retain development and commercialization rights worldwide excluding the four countries. AstraZeneca 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: AZD-8848)
- Development stage: Phase I (collunarium) in Japan

DSP-5990 **MRSA Infection**

- In-licensed from Takeda Pharmaceutical Company Limited (Takeda's product code: TAK-599)
- DSP-5990 is a cephem antibiotic, and has strong activities against gram-positive bacteria including MRSA and multiply-resistant *Streptococcus pneumonia* and also gram-negative bacteria.
- 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 on 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 Advanced cancer

- Co-development 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: Solid Cancer (monotherapy) 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.