# Supplementary Financial Data for the Year Ended March 31, 2013

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# May 9, 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)

				FY2013		FY2013	
	FY2011	FY2012	Change (%)	2Q (Forecast)	Change (%)		Change (%)
Net sales	350.4	347.7	(8.0)	178.0	(0.4)	369.0	6.1
Cost of sales	98.9	101.7	2.9	52.0	3.9	106.0	4.2
SG&A expenses	231.1	221.0	(4.4)	116.0	6.7	237.0	7.2
SG&A expenses less R&D costs	174.2	161.2	(7.5)	86.0	6.3	170.0	5.5
R&D costs	56.9	59.8	5.2	30.0	7.9	67.0	12.0
Operating income	20.4	25.0	22.8	10.0	(49.9)	26.0	3.8
Ordinary income	18.9	24.5	29.8	10.0	(49.8)	25.0	2.0
Net income	8.6	10.0	16.4	5.0	(54.3)	13.0	29.4

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

<sup>\*2:</sup> Change (%) represent ratio of changes from the corresponding period of the previous year.

EBITDA (Billions of yen)	59.9	60.3	25.0	54.0
Earnings per share (yen)	21.72	25.28	12.58	32.72
Return on equity (ROE)	2.7%	3.0%	_	_
Payout ratio	82.9%	71.2%	71.5%	55.0%

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2011	FY2012
Net cash provided by operating activities	48.4	49.9
Net cash used in investing activities	(4.4)	(55.0)
Net cash used in financing activities	(32.9)	(20.2)
Cash and cash equivalents at the end of period	92.2	71.4

DSP 25.5 U.S. Subsidiaries 38.0

- 3. Financial Results of U.S. Subsidiaries (Before Elimination)
- (1) Excluding impact of acquired intangible assets

(Billions of yen)

	١	
	FY2011	FY2012
Net sales	112.8	122.5
Cost of sales	14.3	17.4
SG&A expenses	89.3	78.8
SG&A expenses less R&D costs	69.7	60.6
R&D costs	19.5	18.3
Operating income	9.2	26.2
Ordinary income	9.3	26.4
Extraordinary loss	1.2	4.4
Net income	5.5	13.3

# (2) Impact of acquired intangible assets

(Billions of yen)

	FY2011	FY2012
Net sales	_	_
Cost of sales	_	_
SG&A expenses	27.7	25.9
Operating income	(27.7)	(25.9)
Ordinary income	(27.7)	(25.9)
Extraordinary loss	2.3	0.4
Net income	(20.2)	(17.9)

Note: BBI results are included in the above.

4. Valuations and accounting procedures by acquisition of BBI (April 2012) (Billions of yen)

	Before purchase price allocation	After purchase price allocation	Valuation differences	Accounting procedures (Amortization)
In-process R&D (Intangible Assets)	_	28.5	28.5	Capitalize (Amortize after approval)
Deferred tax liabilities (of the above)	_	(11.6)	(11.6)	_
Other assets & liabilities (Net)	0.2	0.2	ı	_
Goodwill		0.1	0.1	Amortization for 20 years
Total	0.2	17.3	17.0	

Note: The above amounts of purchase price allocation are provisionary for the present.

5. Valuations and accounting procedures by acquisition of SRD (September 2012) (Billions of yen)

	Before purchase price allocation	After purchase price allocation (provisional)	Valuation differences	Accounting procedures (Amortization)
In-process R&D (Intangible Assets)		18.4	18.4	Capitalize (Amortize after approval)
Deferred tax liabilities (of the above)	l	(6.9)	(6.9)	_
Contingent consideration (discounted present value)	l	(8.3)	(8.3)	Recorded in the liabilities
Other assets & liabilities (Net)	0.0	1.3	1.3	_
Goodwill		3.3	3.3	Amortization for 20 years
Total	0.0	7.9	7.9	

Note: The above amounts of purchase price allocation are provisionary for the present.

6. Currency Exchange Rates

(Billions of yen)

e. Garrency Exchange rates		(Dillio	ilis of yell)		
	FY2012 FY2013 Forecast II (F		Forex se (FY20	013)	
	Fiscal Year end rate	Average rate	rate	(Impact of yen strength by 1yen/\$)	
Yen / USD	86.6	79.8	100.0	Net Sales	(1.4)
Yen / RMB	13.9	12.7	15.0	Operating Income	0.1

7. Capital Expenditures and Depreciation

(Billions of yen)

	FY2011	FY2012	Change	FY2013 Forecast	Change
Capital expenditures (including intangible assets)	8.7	10.4	1.6	15.0	4.6
Depreciation and amortization (Note1)	11.5	7.9	(3.6)	9.0	1.1

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

Major continuing capital expenditure projects for FY2013

(Continuing) Construction operation of new research building in Osaka Research Center:  $\pm 4.1$  billion (Total budget  $\pm 6.4$ billion, plan to be completed in June 2013)

<sup>\*2:</sup> From FY2012 the method of depreciation for tangible fixed assets was changed to the straight-line method.

#### (Reference)

1.Statements of Income	lions of yen)			
	FY2011	FY2012	Change (%)	FY2012 Group-to-parent ratio
Net sales	203.5	190.0	(6.6)	1.83
Cost of sales SG&A expenses	58.7 108.5	59.0 112.4	0.5 3.6	
SG&A expenses less R&D co	ets 67.5	64.9	(3.8)	
R&D costs	41.0	47.5	15.8	
Operating income	36.3	18.6	(48.9)	1.35
Ordinary income	35.2	18.5	(47.4)	1.32
Net income	22.1	11.4	(48.5)	0.88

Earnings per share (yen) 55.52 28.58

### 2. Fisical year of consolidated subsidiaries

We have used the consolidated financial statements of Sunovion Pharmaceuticals Inc. and Sumitomo Pharmaceuticals (suzhou)Co., Ltd., as of December 31, to prepare the consolidated financial statements, but from FY2013, we use their financial statements as of March 31. While their results from January to March 2013 are not included in the consolidated income statements, their net income and loss after adjustments for significant transactions are posted in retained earnings. For reference, please find Sunovion's results from January to March 2013 below.(unaudited)

### Sunovion Results

(Millions of dollars)

(IVIIIIVI)	<u>is di dollars)</u>
	Jan - Mar 2013
Net sales	289
Cost of sales	37
SG&A expenses	331
SG&A expenses less R&D costs	222
Amortization, etc.	52
R&D costs	58
Operating income	(80)
Ordinary income	(79)
Net income	(31)

# Sunovion Net Sales for each product

(Millions of dollars)

(1011110)	13 of dollars
Brand Name	Jan - Mar 2013
LUNESTA®	125
LATUDA <sup>®</sup>	50
BROVANA <sup>®</sup>	40
XOPENEX <sup>®</sup>	32
ALVESCO®	8
OMNARIS <sup>®</sup>	5
Industrial property revenues	4
Others	11
Total	275

# II. Consolidated Statements of (Comprehensive) Income

### 1. Consolidated Statements of Income

1. Consolidated Statements of Incon	iie			(Billio	ns of yen)	-	
		FY2011 (A)	FY2012 (B)	(B)-(A)	Change (%)		
Net sales		350.4	347.7	(2.7)	(0.8)	•	Japan Segment -5.4
Overseas sales		130.2	133.1	2.9	2.2		North America Segment +7.4  Decrease in export of
[% of net sales]		37.2	38.3				MEROPEN® -5.8
Cost of sales		98.9	101.7	2.8	2.9		
Gross profit		251.5	246.0	(5.5)	(2.2)		
SG&A expenses		231.1	221.0	(10.1)	(4.4)		
Labor costs		69.8	66.0	(3.8)	(5.5)	lacksquare	Workforce reduction, etc. in U.S.
Advertising and promotion	on costs	18.9	16.4	(2.5)	(13.5)	$\leftarrow$	Decrease in U.S.
Sales promotion costs	6	14.1	11.8	(2.3)	(16.3)		
Other costs		71.4	67.0	(4.4)	(6.2)		Decrease in sales commissions due to
SG&A expenses less R&D costs		174.2	161.2	(13.1)	(7.5)		contract termination ,etc.
R&D costs		56.9	59.8	3.0	5.2		
Operating income		20.4	25.0	4.6	22.8		
Non-operating income		2.1	3.1	1.0			
Non-operating expenses		3.6	3.6	(0.0)			
Ordinary income		18.9	24.5	5.6	29.8		
Extraordinary income		1.2	_	(1.2)			FY2011:Sale of Tokyo Northern Office
Gain on sales of property, plant and ec	luipment	1.2	_	(1.2)			FY2011: Restructuring costs in U.S. subsidiary
Extraordinary loss		3.8	6.3	2.6			FY2012: Restructuring costs in U.S. subsidiary +3.3
Business structure impro expenses	ovement	1.2	4.8	3.6		•	Transfer of assigned employees to related companies in Japan +1
Loss on litigation		_	1.1	1.1		lacksquare	FY2012:Loss on litigation in U.S.
Impairment loss		2.3	0.4	(1.9)		L I	FY2011: Impairment loss from patent rights
Loss on valuation of inv securities	estment	0.2	_	(0.2)			FY2012: Impairment loss from in–process R8
Income before income taxes and minori	ty interests	16.3	18.2	1.8	11.2		
Income taxes		7.7	8.1	0.4			
Income before minority interests		8.6	10.0	1.4	16.4		
Net income		8.6	10.0	1.4	16.4		

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

# 2. Consolidated Statements of Comprehensive Income (Loss)

	(Billio	ns of yen)	
	FY2011	FY2012	
Income before minority interests	8.6	10.0	
Other comprehensive income (loss)	(6.2)	27.1	l
Unrealized gains (losses) on available-for-sale securities, net of tax	2.6	6.1	
Foreign currency translation adjustment	(8.8)	21.0	lacksquare
Comprehensive income	2.4	37.2	

currency exchange rates: 12/2010 12/2011 12/2012 81.5 → 77.7 → 86.6yen/\$ -3.8 +8.8

<sup>2:</sup> Overseas sales includes the sales of exports of non-Pharmaceutical products.

# 3. Segment Information (FY2012)

(Billions of yen)

Pharmaceuticals Business									
		Japan	North America*1	Amortization	China	Other Regions	Subtotal	Other Business*2	Total
Net s	ales	174.7	115.8	_	7.6	9.3	307.5	40.3	347.7
	Sales to customers	174.5	115.8	_	7.6	9.3	307.2	40.5	347.7
	Intersegment	0.3	_	_			0.3	(0.3)	_
(	Cost of sales	50.3	13.8	_	1.8	4.5	70.5	31.2	101.7
Gross	s profit	124.4	102.0	_	5.8	4.7	237.0	9.0	246.0
	SG&A expenses less R&D costs	63.8	61.1	25.9	4.0	0.4	155.1	6.0	161.2
Incor	Income (Loss) of segment		40.9	(25.9)	1.8	4.3	81.9	3.0	84.9
	R&D costs*3		•				59.1	0.8	59.8
Opera	ating income						22.8	2.3	25.0

# Segment Information (FY2013 Forecast)

(Billions of yen)

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

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

<sup>\*2:</sup> Includes the elimination of intersegment transaction.

 $<sup>^{\</sup>star}3$ : 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)

11 04100 011 11411114004110410 240111000 (00	100 10 00010	111010)				(Dillid	nio di ycii/
	FY2011 (A)	FY2012 (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2012 Forecast(%)	FY2013 2Q (Forecast)	FY2013 (Forecast)
Japan	179.9	174.5	(5.4)	(3.0)	98.7	85.7	173.7
North America	108.4	115.8	7.4	6.8	100.1	60.7	125.8
China	6.5	7.6	1.1	16.8	100.6	5.5	10.5
Other Regions	15.2	9.3	(5.9)	(39.1)	100.7	4.6	15.6
5. Sales of Major Products Japan(Strategic Products)	T		ales figures		eduction of r	ebates, Billio	
Brand name (Generic name) Therapeutic indication	FY2011 (A)	FY2012 (B)	(B)-(A)	Change (%)	vs. FY2012 Forecast(%)	2Q (Forecast)	FY2013 (Forecast)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	_	2.0	2.0	_	_	1.8	5.5
AVAPRO <sup>®</sup> (irbesartan) Therapeutic agent for hypertension	10.7	11.7	1.0	8.9	96.3	6.1	12.1
LONASEN® (blonanserin) Atypical antipsychotic	9.8	10.7	0.9	9.2	95.1	6.0	13.0
TRERIEF <sup>®</sup> (zonisamide) Parkinson's disease drug	5.3	7.0	1.7	31.8	97.6	4.4	9.2
Japan (New Products)							
METGLUCO® (metformin) Biguanide oral hypoglycemic (Launch: May 2010)	7.8	12.0	4.2	54.4	96.0	7.4	15.2
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.1	0.7	0.6	781.9	67.7	0.9	2.5
Japan(Specialty Products)	•	-	•	•	•	•	
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	4.5	4.6	0.1	2.3	95.4	2.5	5.0
MIRIPLA® (miriplatin hydrate) Therapeutic agent for hepatocellular Carcinoma (Launch: Jan. 2010)	1.3	1.1	(0.2)	(12.1)	86.0	0.6	1.3
REPLAGAL <sup>®</sup> (agalsidase alfa) Anderson-Fabry disease drug	9.1	9.9	0.8	8.7	97.4	5.1	10.5
Japan(Others)			_				
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	36.0	29.2	(6.8)	(18.9)	101.8	13.3	25.4
GASMOTIN <sup>®</sup> (mosapride citrate) Gastroprokinetic	21.2	19.5	(1.7)	(8.0)	97.4	8.7	16.3
PRORENAL® (limaprost alfadex) Vasodilator	15.5	14.2	(1.3)	(8.1)	96.9	6.8	13.3
MEROPEN <sup>®</sup> (meropenem) Carbapenem antibiotic	12.2	10.3	(1.9)	(15.6)	100.8	5.1	9.6
EBASTEL <sup>®</sup> (ebastine) Antiallergic	6.6	5.8	(0.9)	(13.1)	101.2	2.4	5.6
EXCEGRAN® (zonisamide) Antiepileptic	3.3	3.1	(0.2)	(4.7)	98.4	1.6	3.2
DOBS® (drovidopa)	1		1	1	1		

3.2

3.6

DOPS® (droxidopa) Noradrenergic neural function

SUMIFERON<sup>®</sup> (interferon-α NAMALWA) Natural alpha interferon

3.1

2.6

(0.1)

(1.1)

(3.7)

(29.3)

100.2

98.6

1.5

1.1

3.0

2.1

North America (Billions of yen)

Brand name (Generic name)  Therapeutic indication	FY2011 (A)	FY2012 (B)	(B)-(A)	Change (%)
LUNESTA® (eszopiclone) Sedative hypnotic	42.1	44.8	2.7	6.4
XOPENEX® (levalbuterol HCI) Short-acting beta-agonist	33.4	25.3	(8.1)	(24.2)
LATUDA <sup>®</sup> (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	6.9	16.1	9.2	134.5
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	10.2	12.7	2.6	25.3
ALVESCO® (ciclesonide) Inhaled corticosteroid	2.8	3.1	0.3	9.9
OMNARIS® (ciclesonide) Corticosteroid nasal spray	5.1	1.9	(3.2)	(63.1)
ZETONNA® (ciclesonide) Corticosteroid nasal spray (Launch: Jul. 2012)	_	0.4	0.4	_
Industrial property revenues	5.8	7.8	2.0	35.4

(Billions of yen						
FY2013 2Q (Forecast)	FY2013 (Forecast)					
23.6	46.5					
4.0	7.4					
13.4	30.3					
9.6	19.8					
2.6	5.3					
1.7	3.6					
2.2	5.8					
1.3	2.7					

China (Billions of yen)

Brand name (Generic name)	FY2011 (A)	FY2012 (B)	(B)-(A)	Change (%)	FY2013 2Q (Forecast)
MEROPEN® (meropenem)	5.5	6.3	0.7	13.3	4.4

Other Regions (Billions of yen)

Brand name (Generic name)	FY2011 (A)	FY2012 (B)	(B)-(A)	Change (%)
MEROPEN® (meropenem) (Export)	11.9	6.2	(5.8)	(48.5)
EXCEGRAN® (zonisamide) (Export)	1.2	1.8	0.6	49.3
GASMOTIN® (mosapride citrate) (Export)	0.8	0.8	(0.0)	(4.9)
Industrial property revenues	0.5	0.3	(0.2)	(46.6)

(Billions of yen						
FY2013 2Q (Forecast)	FY2013 (Forecast)					
2.6	4.4					
0.7	1.2					
0.3	0.7					
0.6	8.8					

FY2013 (Forecast)

8.4

#### III. Consolidated Balance Sheets

#### **ASSETS**

(Billions of yen) As of As of 2012/03/31 2013/03/31 (B)-(A) (A) (B) 607.2 47.8 **Assets** 559.4 334.3 333.4 (8.0)Current assets: 5.8 Cash and time deposits 13.0 18.8 Notes and accounts receivable 102.0 97.2 (4.8)Decrease in negotiable deposit Marketable securities 99.1 86.5 (12.7)associated with the acquisitions Inventories 58.1 62.7 4.6 Deferred tax assets 31.8 30.1 (1.7)Short-term loans 25.0 34.4 9.4 Others 5.4 4.0 (1.5)Allowance for doubtful receivables (0.1)0.0 (0.1)Fixed assets: 225.2 273.8 48.6 3.2 Property, plant and equipment: 66.7 69.9 Buildings and structures 40.4 39.9 (0.4)Machinery, equipment and carriers 9.9 9.4 (0.4)New research building in Osaka Land 10.2 10.3 0.0 Research Center Construction in progress 3.7 2.1 5.8 BBI +0.1 Others 4.1 4.4 0.3 SRD +3.3 107.7 Amortization -3.8 146.3 38.6 Intangible assets: Currency +7.3 Goodwill 64.3 7.0 71.3 Patent rights 32.5 17.4 (15.1)Amortization -22.1 Transfer +4.7 In-process research & development 5.7 50.7 45.0 Currency +2.2 5.2 Others 7.0 1.8 BBI +28.5 Investments and other assets: 50.8 57.6 6.9 SRD +18.4 Transfer -4.7 Investment securities 11.0 29.9 40.8 Currency +3.2 Impairment −0.4 Deferred tax assets 11.6 7.6 (4.1)(0.1)Others 9.3 9.2 Allowance for doubtful receivables (0.1)(0.0)0.0 Total assets 559.4 607.2 47.8

Accounts receivable turnover period (in months)

3.49

3.35

(Billions of yen)

		(	ilonis or you	
	As of 2012/03/31 (A)	As of 2013/03/31 (B)	(B)-(A)	
[ Liabilities ]	240.2	258.0	17.8	
Current liabilities:	106.0	124.8	18.9	
Notes and accounts payable	16.9	14.3	(2.6)	
Current portion of bonds payable	_	10.0	10.0	Total interest-bearing debt -13.0
Current portion of long-term loans payable	10.0	10.0	_	(128.0→115.0)
Income taxes payable	5.4	2.1	(3.3)	
Reserve for bonuses	7.6	7.6	0.0	
Reserve for sales returns	3.7	5.7	2.0	
Reserve for sales rebates	18.5	19.2	0.6	
Accounts payable-other	30.0	34.8	4.8	
Others	13.9	21.3	7.4	
Long-term liabilities:	134.2	133.1	(1.1)	]\
Bonds payable	70.0	60.0	(10.0)	
Long-term loans payable	48.0	35.0	(13.0)	
Deferred tax liabilities	0.3	14.5	14.2	Deferred tax liabilities for in-process R&D from the acquisition of BBI
Liability for retirement benefits	10.8	11.0	0.2	
Others	5.1	12.6	7.5	The contingent consideration recognized as liabilities in accordance
[ Net assets ]	319.2	349.2	30.0	with the acquisition of SRD
Shareholders' equity:	343.3	346.2	2.9	
Common stock	22.4	22.4	_	
Capital surplus	15.9	15.9	_	
Retained earnings	305.7	308.6	2.9	
Treasury stock	(0.6)	(0.7)	(0.0)	
Accumulated other comprehensive income (loss):	(24.0)	3.1	27.1	
Unrealized gains on available-for- sale securities, net of tax	8.0	14.1	6.1	
Foreign currency translation adjustment	(32.1)	(11.0)	21.0	Exchange Rates: 77.7yen/\$—86.6yen/\$
Total liabilities and net assets	559.4	607.2	47.8	

# IV. Quarterly Business Results

(Billions of yen)

	FY2011			FY2012				
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Net sales	94.8	83.2	87.2	85.2	89.1	89.7	90.5	78.5
Cost of sales	25.8	24.0	24.2	24.9	25.2	24.8	26.3	25.3
SG&A expenses	56.2	57.3	55.4	62.2	53.0	55.7	51.4	60.8
SG&A expenses less R&D costs	42.6	43.7	42.0	46.1	38.9	42.0	39.3	40.9
R&D costs	13.6	13.7	13.4	16.2	14.1	13.7	12.1	19.9
Operating income (loss)	12.8	1.9	7.6	(1.9)	10.9	9.1	12.7	(7.7)
Non-operating income	1.0	0.5	0.6	0.1	1.1	0.3	0.8	0.8
Non-operating expenses	0.6	1.1	0.7	1.2	0.5	1.0	0.7	1.4
Ordinary income (loss)	13.2	1.3	7.5	(3.1)	11.5	8.4	12.8	(8.2)
Extraordinary income	_	1.2	0.0	_	_	_	_	_
Extraordinary loss	_	_	3.6	0.2	1.5	_	2.9	2.0
Income (Loss) before income taxes and minority interests	13.2	2.6	3.9	(3.3)	10.0	8.4	10.0	(10.2)
Net income (loss)	8.1	1.5	0.7	(1.6)	5.7	5.3	5.9	(6.8)

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

# V. Major consolidated subsidiaries (as of 2013/03/31)

Businesses

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	148	96	61
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	March 31	December 31	December 31
Ownership	100%	100%	100%
Number of employees	1,739	31	686
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	Manufacturing and sales of pharmaceuticals

Number of employees (as of 2013/03/31): Number of MRs (as of 2013/03/31):

> 7,218 (consolidated) Japan 1,410 (excluding managers) 1,610 (including managers) (non-consolidated) U.S. 830 (excluding managers) 4,457 940 (including managers) China 350(excluding managers) 470 (including managers)

VI. Shareholder Positioning (as of March 31, 2013)

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

2. Total number of shares outstanding: 397,900,154

(Including number of treasury stock 590,246)

3. Number of shareholders: 27,479

4. Major shareholders:

	Status of ownership			
Shareholders	Number of shares held	Percentage of		
	(Thousand shares)	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)	15,265	3.84		
Nippon Life Insurance Company	9,477	2.39		
Japan Trustee Services Bank, Ltd. (Trust account)	8,982	2.26		
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		
Dainippon Sumitomo Pharma Employee shareholders' association	4,441	1.12		
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12		
BNY GCM CLIENT ACCOUNT JPRD AC ISG (FE-AC)	3,920	0.99		

Notes: \*1: Percentage of shareholding is calculated excluding treasury stock (590,246 stocks).

<sup>\*2:</sup> The numbers of shares held are rounded down to the nearest thousand shares.

# VII. Development Pipeline (as of May 9, 2013)

# **Major Products under Development in Japan**

Stage in JPN	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Remarks
Submitted	MEROPEN <sup>®</sup> 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
	AS-3201 Oral	ranirestat	Diabetic neuropathy	In-house	
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	
Phase III	SUREPOST <sup>®</sup> Oral	repaglinide	(New Indication) Type 2 diabetes All combination therapies including DPP4 inhibitors	Novo Nordisk	Approved indication: The reduction of postprandial blood glucose in patients with type 2 diabetes (Monotherapy, Combination with α-GI, BG and TZD)
	METGLUCO® Oral	metformin hydrochloride	(Addition of pediatric usage ) Type 2 diabetes Pediatric usage	Merck Santé	
	LONASEN <sup>®</sup> Oral	blonanserin	(Addition of pediatric usage ) Schizophrenia	In-house	
	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharmaceuticals	
Phase II	DSP-6952 Oral	TBD	IBS with constipation, Chronic idiopathic constipation	In-house	
	LONASEN <sup>®</sup> Transdermal Patch	blonanserin	(New Formulation  - Transdermal Patch) Schizophrenia	In-house	Co-development with Nitto Denko Approved dose: Oral

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

[Main revisions since the 3Q announcement of January 2013]

SUREPOST® (New indication)	Deleted due to approval for Type 2 diabetes combination
	therapy with biguanides and thiazolidinediones (February

WT4869 Remarks deleted due to termination of joint development

with Chugai Pharmaceutical Co., Ltd.

BBI608 Newly added in Phase 1 (Phase 1 started in Japan in

March 2013)

SMP-986 Deleted due to out-licensing rights to develop and

manufacture in Japan to Nippon Shinyaku Co., Ltd.

# **Major Products under Development in Foreign Markets**

Stage	Brand name/ Product code Formulation	Generic name	Proposed Indication	Origin	Country/ Area	Remarks
	STEDESA <sup>®</sup> Oral	eslicarbazepine acetate	Epilepsy Adjunctive therapy	BIAL	U.S.	NDA submitted in March 2009. Re-submitted in February 2013
	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Brand name in Japan: CALSED®
Submitted	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Australia	Submitted in March 2013. Approved in the U.S and Canada
	LATUDA <sup>®</sup> 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
	BBI608 Oral	TBD	Colorectal cancer (2nd/3rd line) Monotherapy	In-house (BBI)	U.S., Canada	
	STEDESA <sup>®</sup> Oral	eslicarbazepine acetate	Epilepsy Monotherapy	BIAL	U.S.	
Phase III	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Brand name in Japan: LONASEN®
	LATUDA <sup>®</sup>	lurasidone	(New Indication) Bipolar Maintenance	In-house	U.S. and Europe, etc.	Approved for schizophrenia in the U.S. and Canada
	Oral	hydrochloride	MDD with mixed features		U.S. and Europe, etc.	
	BBI608 Oral	TBD	Colorectal cancer (3rd/4th line) Combination therapy	In-house (BBI)	U.S., Canada	
Phase II	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	
	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	
Phase I	WT2725 Injection	TBD	Solid cancer, Hematologic cancer	Joint research with Chugai	U.S.	
	BBI503 Oral	TBD	Solid cancer monotherapy	In-house (BBI)	U.S., Canada	
	SEP-363856 Oral	TBD	Schizophrenia	In-house (Sunovion)	U.S.	

[Main revisions since the 3Q announcement of January 2013]

STEDESA® Lurasidone hydrochloride (SM13496) WT2725

SMP-986

Resubmitted in the US (February 2013) Submitted in Australia (March 2013) Remarks deleted due to termination of joint development with Chugai Pharmaceutical Co. Ltd. Deleted due to consideration of out-licensing overseas rights

# **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 <sup>®</sup> )	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 <sup>®</sup> )	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 plans to resubmit the NDA by the end of June 2013.  Phase II study of fibromyalgia in the UK and phase II study of intradialytic hypotension in the U.S. completed by Chelsea.
DSP-3025	Bronchial asthma, Allergic rhinitis	Entered into a development and marketing agreement in March 2005. AstraZeneca has the right for the worldwide territory, excluding Japan, China, Korea and Taiwan. Phase II study as a collunarium was completed in Europe, while a Phase I study as an inhalant was started in the U.K. by AstraZeneca. (AstraZeneca's product code: AZD8848).
lurasidone hydrochloride (SM-13496)	Schizophrenia Bipolar disorder	Entered into a license agreement with Takeda Pharmaceutical for co-development and exclusive commercialization for the European territory, excluding the U.K. in March 2011.  Both companies are currently developing lurasidone in Europe.  Takeda submitted an MAA in Switzerland for schizophrenia in March 2012.  Takeda submitted an MAA in Europe for schizophrenia by the centralised authorisation procedure in September 2012.
SMP-986	Nocturia	Entered into a license agreement with Nippon Shinyaku Co., Ltd. for exclusive rights in Japan to develop and commercialize in March 2013.

[Main revisions since the 3Q announcement of January 2013] SMP-986 Newly added

#### VIII. Profile of Major Products under Development (as of May 9, 2013)

# STEDESA<sup>®</sup> (eslicarbazepine acetate) Epilepsy

- In-licensed from BIAL Portela & C<sup>a</sup>, 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.

Resubmitted NDA in the US in February 2013

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

# LATUDA® (lurasidone hydrochloride) Schizophrenia, Bipolar disorder

Developed in-house

- LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent which is believed to have an affinity for dopamine D<sub>2</sub>, serotonin 5-HT<sub>2A</sub> and serotonin 5-HT<sub>7</sub> receptors where it has antagonist effects. In addition, LATUDA is a partial agonist at the serotonin 5-HT<sub>1A</sub> 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)
Submitted in Australia
Phase III in Japan

In addition, Phase III study is ongoing in the U.S., Europe, etc. to test the hypothesis that LATUDA is effective in the long term maintenance

treatment of schizophrenia.

Bipolar I Depression: Submitted in 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. and Europe, etc.

### 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 Solid Cancer (monotherapy): Phase I in Japan

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

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

#### DSP-6952 IBS with constipation, Chronic idiopathic constipation

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

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

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

### SEP-225289 Attention-deficit hyperactivity disorder (ADHD)

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

### WT4869 Myelodysplastic syndromes (MDS), Solid cancer

- Developed in house (Joint-research with Chugai Pharmaceutical)
- WT4869 is a therapeutic cancer vaccine candidate using a peptide derived from Wilms' tumor gene 1
  (WT1) protein. WT4869 is expected to treat patients with various types of hematologic and solid
  cancers that overexpress WT1, by the induction of WT1-specific cytotoxic T-lymphocytes.
- Development stage:

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

### DSP-3025 Bronchial asthma, Allergic rhinitis

- Developed in-house
- DSP-3025 is an immune response modifier with agonistic activity against Toll-like receptor 7 (TLR7).
   It is expected to become a therapeutic agent providing long-term disease remission in bronchial asthma and allergic rhinitis.
- A series of promising compounds 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: AZD8848)
- 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 Solid cancer, Hematologic cancer

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

### BBI503 Solid cancer

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

### SEP-363856 Schizophrenia

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