Securities Code: 4506

Supplementary Financial Data for the Third Quarter of the Year Ending March 31, 2016

January 27, 2016

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)

	FY2014 Apr.-Dec.	FY2015 Apr.-Dec.	Change (%)	FY2014	Change (%)	FY2015 (Forecast)		Change (%)
Net sales	279.1	304.5	9.1	371.4	(4.2)	[401.0]	403.0	8.5
Cost of sales	75.1	79.1	5.3	101.2	(2.8)	[103.5]	104.5	3.2
SG&A expenses	181.2	194.4	7.3	246.9	2.2	[268.5]	265.5	7.5
SG&A expenses less R&D costs	130.0	135.4	4.1	175.6	2.3		179.0	2.0
R&D costs	51.2	59.0	15.2	71.3	2.1	[89.5]	86.5	21.3
Operating income	22.8	31.1	36.2	23.3	(44.8)	[29.0]	33.0	41.8
Ordinary income	22.5	31.1	38.3	23.3	(42.6)	[28.5]	32.5	39.3
Net income attributable to owners of the parent	19.0	23.3	22.9	15.4	(23.0)	[20.0]	23.0	48.9

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 have been revised. Figures in parentheses [ ] are previously disclosed forecasts. Change (%) represents ratio of changes to the revised forecasts.

EBITDA (Billions of yen)	37.3	46.6	43.1	53.3
Earnings per share (yen)	47.81	58.76	38.88	57.89
Return on equity (ROE)	4.5%	5.1%	3.6%	5.0%

2. Consolidated Statements of Cash Flows

(Billions of yen)

	FY2014 Apr.-Dec.	FY2015 Apr.-Dec.
Net cash provided by operating activities	26.9	32.5
Net cash provided by investing activities	26.7	26.8
Net cash used in financing activities	(12.9)	(12.2)
Cash and cash equivalents at the end of period	125.4	167.7

3. Currency Exchange Rates

(Billions of yen)

	2014 Apr.-Dec. Average rate	2015 Apr.-Dec. Average rate	2015 End of Mar.	2015 End of Dec.	FY2015 Assumed rate	Forex sensitivity FY2015 (Impact of yen weakness by 1yen/USD)	
Yen / USD	106.7	121.8	120.2	120.5	120.0	Net Sales	1.7
Yen / RMB	17.3	19.3	19.4	18.3	19.0	Operating Income	0.2

Note: Net sales and Operating income in FY2015 Apr.-Dec. increased by 18.5 billion yen and 1.6 billion yen respectively, compared to FY2014 Apr.-Dec. due to exchange rate fluctuation.

4. Capital Expenditures

(Billions of yen)

	FY2014 Apr.-Dec.	FY2015 Apr.-Dec.	Change	FY2015 Forecast	FY2015 Change
Capital expenditures	8.5	5.5	(2.9)	10.0	0.3

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

Major capital expenditure projects completed in FY2015
Earthquake resistant renewal of research building No.2 in Osaka research center: ¥1.6billion
(Total expenditures ¥1.6billion, completed in December 2015)

5. Depreciation and Amortization

(Billions of yen)

	FY2014 Apr.-Dec.	FY2015 Apr.-Dec.	Change	FY2015 Forecast	FY2015 Change
Property, plant and equipment	5.8	5.8	0.1	7.4	(0.4)
Intangible assets	3.2	3.5	0.3	5.2	1.1
Goodwill	4.0	4.5	0.6	6.0	0.6

II. Consolidated Statements of (Comprehensive) Income

1. Consolidated Statements of Income

(Billions of yen)

	FY2014 Apr.- Dec. (A)	FY2015 Apr.- Dec. (B)	(B)-(A)	Change (%)
Net sales	279.1	304.5	25.4	9.1
Overseas sales	128.8	158.9	30.1	23.4
[% of net sales]	46.1%	52.2%		
Cost of sales	75.1	79.1	4.0	5.3
[% of net sales]	26.9%	26.0%		
Gross profit	204.0	225.5	21.4	10.5
SG&A expenses	181.2	194.4	13.2	7.3
Labor costs	52.4	57.6	5.2	10.0
Advertising and promotion costs	20.8	22.6	1.8	8.8
Sales promotion costs	9.6	10.4	0.7	7.5
Other costs	47.2	44.8	(2.4)	(5.0)
SG&A expenses less R&D costs	130.0	135.4	5.4	4.1
R&D costs	51.2	59.0	7.8	15.2
[% of net sales]	18.3%	19.4%		
Operating income	22.8	31.1	8.3	36.2
Non-operating income	2.8	3.1	0.2	
Non-operating expenses	3.1	3.0	(0.1)	
Ordinary income	22.5	31.1	8.6	38.3
Extraordinary income	17.7	6.1	(11.6)	
Gain on sales of investment securities	—	6.1	6.1	
Gain on sales of property, plant and equipment	16.0	—	(16.0)	
Compensation income for damage	1.7	—	(1.7)	
Extraordinary loss	5.9	0.3	(5.7)	
Impairment loss	5.1	0.3	(4.9)	
Business structure improvement expenses	0.8	—	(0.8)	
Income before income taxes	34.3	36.9	2.7	7.8
Income taxes	15.3	13.6	(1.7)	
Net income	19.0	23.3	4.4	22.9
Net income attributable to owners of the parent	19.0	23.3	4.4	22.9

・Japan Segment (¥6.1B)
・North America Segment ¥27.6B
[FX rate impact ¥16.9B]
・China Segment ¥2.1B
[FX rate impact ¥1.5B]

・Due to increase in North America and weak yen

・Due to cost reversal from fair value adjustment of contingent consideration liabilities

・Due to increase in clinical development expense in North America and weak yen

・Sale of listed stock (North America)

・Impairment of intangble asset (North America)

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)

	FY2014 Apr.- Dec.	FY2015 Apr.- Dec.
Net income	19.0	23.3
Other comprehensive income	42.2	3.8
Unrealized gains (losses) on available-for-sale securities, net of tax	2.3	3.5
Deferred gains or losses on hedges	0.0	(0.0)
Foreign currency translation adjustments	39.6	(0.1)
Remeasurements of defined benefit plans	0.2	0.4
Comprehensive income	61.2	27.2

3. Segment Information (FY2015 Apr.-Dec.) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	114.5	137.3	14.5	6.7	273.1	31.5	304.5
Sales to customers	114.5	137.3	14.5	6.7	273.0	31.5	304.5
Intersegment	0.0	—	—	—	0.0	(0.0)	—
Cost of sales	35.0	12.3	2.6	3.8	53.7	25.3	79.1
Gross profit	79.5	125.0	11.8	3.0	219.3	6.1	225.5
SG&A expenses less R&D costs	44.1	78.6	6.2	1.9	130.7	4.7	135.4
*Amortization included in above*1*	—	*2.7*	—	—	*2.7*	—	*2.7*
Income (loss) of segment	35.4	46.4	5.7	1.1	88.6	1.4	90.0
R&D costs*3					58.3	0.6	59.0
Operating income					30.3	0.8	31.1

Segment Information (FY2014 Apr.-Dec.) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America*1	China	Other Regions	Subtotal		
Net sales	120.8	109.7	12.3	6.2	249.0	30.1	279.1
Sales to customers	120.6	109.7	12.3	6.2	248.9	30.3	279.1
Intersegment	0.1	—	—	—	0.1	(0.1)	—
Cost of sales	36.3	9.1	2.1	3.7	51.2	23.9	75.1
Gross profit	84.5	100.6	10.2	2.5	197.8	6.2	204.0
SG&A expenses less R&D costs	43.7	74.2	5.7	1.8	125.4	4.6	130.0
*Amortization included in above*1*	—	*7.1*	—	—	*7.1*	—	*7.1*
Income (loss) of segment	40.8	26.4	4.5	0.7	72.4	1.7	74.0
R&D costs*3					50.6	0.6	51.2
Operating income					21.8	1.0	22.8

Segment Information (FY2015 Forecasts)*4 (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America*1	China	Other Regions	Subtotal		
Net sales	149.5	182.6	17.8	11.4	361.3	41.7	403.0
Sales to customers	149.4	182.6	17.8	11.4	361.2	41.8	403.0
Intersegment	0.1	—	—	—	0.1	(0.1)	—
Cost of sales	46.3	15.5	2.9	6.4	71.1	33.4	104.5
Gross profit	103.2	167.1	14.9	5.0	290.2	8.3	298.5
SG&A expenses less R&D costs	58.5	103.0	8.5	2.5	172.5	6.5	179.0
*Amortization included in above*1*	—	*5.7*	—	—	*5.7*	—	*5.7*
Income (loss) of segment	44.7	64.1	6.4	2.5	117.7	1.8	119.5
R&D costs*3					85.5	1.0	86.5
Operating income					32.2	0.8	33.0

Notes *1: Amortization of goodwill and patent rights, fair value change of contingent consideration liability
*2: Including elimination of intersegment transaction.
*3: R&D costs are controlled globally and not allocated to each segment.
*4: FY2015 forecasts of some segments have been revised.

4. Sales of Pharmaceuticals Business (Sales to customers) （Billions of yen）

	FY2014 Apr.-Dec. (A)	FY2015 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2015 Forecasts(%)	FY2014	FY2015 (Forecasts)
Japan	120.6	114.5	(6.1)	(5.1)	76.6	156.6	149.4
North America	109.7	137.3	27.6	25.2	75.2	148.2	182.6
China	12.3	14.5	2.1	17.4	81.2	17.1	17.8
Other Regions	6.2	6.7	0.5	8.6	71.6	8.8	[9.4] 11.4

5. Sales of Major Products

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

Brand name (Generic name) Therapeutic indication	FY2014 Apr.-Dec. (A)	FY2015 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2015 Forecasts(%)	FY2014	FY2015 (Forecasts)
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	9.1	11.9	2.8	30.6	78.4	12.0	15.2
AVAPRO® (irbesartan) Therapeutic agent for hypertension	8.7	8.4	(0.2)	(2.6)	78.2	11.4	10.8
LONASEN® (blonanserin) Atypical antipsychotic	8.5	9.8	1.3	14.7	75.3	11.5	13.0
TRERIEF® (zonisamide) Parkinson's disease drug	8.5	10.1	1.6	19.1	72.4	11.6	14.0

Japan（Other Products)

SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	1.7	2.7	1.0	57.3	72.1	2.4	3.7
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	3.4	3.3	(0.1)	(2.0)	76.9	4.3	4.3
REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	7.5	7.9	0.3	4.3	74.8	9.7	10.5
METGLUCO® (metformin) Biguanide oral hypoglycemic	12.7	12.0	(0.7)	(5.7)	85.8	17.1	14.0
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	15.0	12.9	(2.1)	(13.9)	80.3	19.6	16.1
GASMOTIN® (mosapride citrate) Gastroprokinetic	8.1	6.7	(1.4)	(17.3)	80.5	10.5	8.3
PRORENAL® (limaprost alfadex) Vasodilator	8.2	6.9	(1.2)	(14.8)	76.3	10.6	9.1
MEROPEN® (meropenem) Carbapenem antibiotic	6.2	5.0	(1.2)	(19.1)	76.8	7.9	6.5
EBASTEL® (ebastine) Antiallergic	2.6	2.1	(0.5)	(20.1)	64.3	3.9	3.2

Note: The forecasts of some products have been revised. Figures in parentheses [ ] are previously disclosed forecasts. Progress rate is against previous forecast.

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2014 Apr.-Dec. (A)	FY2015 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2014 Forecasts(%)	FY2014	FY2015 (Forecasts)
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	59.3	88.8	29.5	49.8	74.0	82.5	120.0
APTIOM® (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	1.6	5.4	3.8	241.6	70.1	2.5	7.7
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	15.6	22.2	6.5	41.8	75.6	22.2	29.3
Ciclesonide * Inhaled corticosteroid / corticosteroid nasal spray	5.4	5.6	0.2	3.2	80.9	6.7	6.9
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	6.8	5.1	(1.7)	(24.5)	79.2	8.5	6.5
LUNESTA® (eszopiclone) Sedative hypnotic	9.6	3.6	(6.0)	(62.2)	86.1	11.5	4.2
Industrial property revenues	8.4	3.7	(4.7)	(56.3)	79.3	9.9	4.6

China (Billions of yen)

Brand name (Generic name)	FY2014 Apr.-Dec. (A)	FY2015 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2014 Forecasts(%)	FY2014	FY2015 (Forecasts)
MEROPEN® (meropenem)	10.2	12.2	2.0	19.4	81.7	14.3	14.9

Other Regions (Billions of yen)

Brand name (Generic name)	FY2014 Apr.-Dec. (A)	FY2015 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2014 Forecasts(%)	FY2014	FY2015 (Forecasts)
MEROPEN® (meropenem) (Export)	2.9	3.7	0.8	27.5	72.0	4.6	[5.2] 6.3
Industrial property revenues	0.2	0.3	0.1	47.9	33.1	0.3	1.0

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

Brand name (Generic name)	FY2014 Apr.-Dec. (A)	FY2015 Apr.-Dec. (B)	(B)-(A)	Change (%)	Progress Rate vs. FY2014 Forecasts(%)	FY2014	FY2015 (Forecasts)
LATUDA® (lurasidone)	555	729	174	31.3	72.9	752	1,000
APTIOM® (eslicarbazepine acetate)	15	44	30	199.5	69.2	23	64
BROVANA® (arformoterol tartrate)	146	182	36	24.3	74.6	202	244
Ciclesonide *	51	46	(5)	(9.5)	80.5	61	57
XOPENEX® (levalbuterol HCl)	64	42	(22)	(33.8)	78.3	78	54
LUNESTA® (eszopiclone)	90	30	(60)	(66.9)	84.9	105	35
Industrial property revenues	78	30	(48)	(61.7)	78.9	90	38

* Total of 3 ciclesonide products (ALVESCO®, OMNARIS®, ZETONNA®)

Note: The forecasts of some products have been revised. Figures in parentheses [ ] are previously disclosed forecasts. Progress rate is against previous forecast.

III. Consolidated Balance Sheets

ASSETS

(Billions of yen)

	As of Mar. 31, 2015 (A)	As of Dec. 31, 2015 (B)	(B)-(A)
[Assets]	711.6	756.6	45.0
Current assets:	401.7	450.7	49.0
Cash and time deposits	30.6	57.2	26.7
Notes and accounts receivable	103.1	112.2	9.2
Marketable securities	111.3	110.9	(0.4)
Inventories	62.4	65.2	2.8
Deferred tax assets	38.9	57.1	18.3
Short-term loans receivable	49.1	42.2	(6.9)
Others	6.6	5.9	(0.7)
Allowance for doubtful receivables	(0.1)	(0.0)	0.1
Fixed assets:	309.9	305.9	(4.0)
Property, plant and equipment:	65.2	63.3	(1.9)
Buildings and structures	41.4	41.4	(0.0)
Machinery, equipment and carriers	9.1	8.3	(0.8)
Land	6.3	6.3	0.0
Construction in progress	1.2	1.2	(0.1)
Others	7.2	6.2	(1.0)
Intangible assets:	173.9	169.6	(4.3)
Goodwill	88.1	83.8	(4.3)
In-process research & development	64.5	64.4	(0.1)
Others	21.3	21.4	0.1
Investments and other assets:	70.9	73.1	2.2
Investment securities	58.2	63.3	5.1
Asset for retirement benefit	1.9	2.2	0.2
Deferred tax assets	4.8	2.7	(2.1)
Others	6.0	5.0	(1.0)
Allowance for doubtful receivables	(0.0)	(0.0)	0.0
Total assets	711.6	756.6	45.0

Amortization (¥4.5B)
Exchange rate ¥0.3B

Exchange rate ¥0.2B
Impairment (¥0.2B)

Accounts receivable turnover period (in months)	3.33	3.32

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2015 (A)	As of Dec. 31, 2015 (B)	(B)-(A)
[Liabilities]	260.6	288.5	28.0
Current liabilities:	156.8	205.8	49.0
Notes and accounts payable	12.5	15.9	3.4
Short-term loans payable	—	1.1	1.1
Current portion of bonds payable	30.0	40.0	10.0
Current portion of long-term loans payable	6.5	12.4	5.9
Income taxes payable	3.3	20.1	16.9
Reserve for bonuses	9.4	7.1	(2.4)
Reserve for sales returns	8.6	9.8	1.2
Reserve for sales rebates	36.4	51.9	15.5
Accounts payable-other	35.3	31.7	(3.5)
Others	14.9	15.9	1.0
Long-term liabilities:	103.7	82.7	(21.0)
Bonds payable	30.0	20.0	(10.0)
Long-term loans payable	20.0	8.0	(12.0)
Deferred tax liabilities	17.4	19.5	2.1
Liability for retirement benefit	15.3	15.5	0.2
Others	21.1	19.8	(1.3)
[Net assets]	451.0	468.1	17.0
Shareholders' equity:	364.3	377.6	13.4
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	326.7	340.1	13.4
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	86.7	90.4	3.7
Unrealized gains on available-for-sale securities, net of tax	23.1	26.6	3.5
Deferred gains or losses on hedges	0.0	(0.0)	(0.0)
Foreign currency translation adjustments	68.2	67.9	(0.2)
Remeasurement of defined benefit plans	(4.5)	(4.1)	0.4
Total liabilities and net assets	711.6	756.6	45.0

Total interest-bearing debt
86.5→81.5

Increase in LATUDA® sales

IV. Quarterly Business Results

(Billions of yen)

	FY2014				FY2015		
	1Q	2Q	3Q	4Q	1Q	2Q	3Q
Net sales	89.7	88.5	100.8	92.2	98.1	100.8	105.6
Cost of sales	24.1	24.4	26.6	26.1	26.4	25.7	27.0
SG&A expenses	57.0	60.9	63.3	65.6	67.3	62.7	64.4
SG&A expenses less R&D costs	41.8	43.0	45.3	45.5	47.2	42.6	45.6
R&D costs	15.2	18.0	18.0	20.1	20.1	20.1	18.8
Operating income (loss)	8.7	3.3	10.9	0.5	4.4	12.4	14.2
Non-operating income	1.3	1.0	0.5	1.4	0.9	1.6	0.6
Non-operating expenses	0.5	1.1	1.6	1.0	0.6	1.3	1.2
Ordinary income (loss)	9.6	3.2	9.8	0.8	4.7	12.8	13.6
Extraordinary income	1.7	8.3	7.7	0.0	6.0	0.1	(0.0)
Extraordinary loss	0.1	0.5	5.3	1.4	0.2	0.0	0.1
Income (Loss) before income taxes	11.1	10.9	12.2	(0.5)	10.6	12.8	13.5
Net income (loss) attributable to owners of the parent	5.8	6.0	7.2	(3.5)	5.9	7.3	10.1

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

V. Major Consolidated Subsidiaries (As of Dec. 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	163	105	63
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	1,607	92	684
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, 2014	As of Mar. 31, 2015	As of Dec. 31, 2015
consolidated		7,015	6,868	6,791
non-consolidated		4,331	4,126	4,062
MRs Japan	（excluding managers）	1,400	1,350	1,350
	（including managers）	1,600	1,530	1,530
MRs U.S.	（excluding managers）	710	700	700
	（including managers）	810	800	800
MRs China	（excluding managers）	390	370	340
	（including managers）	480	470	420

VI. Development Pipeline (As of January 27, 2016)

■ **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	Canada	Submitted in October 2014 Approved indication in the U.S.: Epilepsy (Adjunctive therapy / Monotherapy) Approved indication in Canada: Epilepsy (Adjunctive therapy)
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Submitted in December 2015 Approved in the U.S., Canada, Europe and Australia

■ **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
			Bipolar I depression			Approved in the U.S. and Canada
			Bipolar maintenance			

■ **Phase III stage (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase III	BBI608 Oral	napabucasin	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
			Colorectal cancer (Combination therapy)		U.S.	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			Joint 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	vatiquinone	Leigh syndrome	Edison Pharma-ceuticals	Japan	A Phase II / III study completed, development strategy under consideration
	SEP-225289 Oral	dasotraline	Pediatric attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	
			Binge eating disorder (BED)			

■ **Phase II stage**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase II	BBI608 Oral	napabucasin	Colorectal cancer (Combination therapy)	In-house	U.S., Canada	
	DSP-1747 Oral	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Intercept Pharma-ceuticals	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
	EPI-589 Oral	TBD	Parkinson disease	Edison Pharma-ceuticals	U.S.	Conducting by Edison Pharmaceuticals
			Amyotrophic lateral sclerosis (ALS)		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	napabucasin	Solid tumors (Combination therapy)	In-house	U.S., Canada	Phase II : Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.
			Malignant pleural mesothelioma (Combination therapy)		Japan	Phase II
			Hepatocellular carcinoma (Combination therapy)		U.S.	
			Glioblastoma (Combination therapy)		Canada	
			Solid tumors (Combination therapy)		U.S.	
	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.	
			Solid tumors (Combination therapy)		U.S., Canada	
	DSP-7888 Injection	TBD	Myelodysplastic syndromes	In-house	Japan	Phase II
	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharma-ceutical	Japan	Independent development after April 2013

■ **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 Pharma-ceutical	Japan	Independent development after April 2013
	WT2725 Injection	TBD	Solid tumors, Hematologic malignancies	Joint research with Chugai Pharma-ceutical	U.S.	Independent development after April 2013
			Solid tumors		Japan	
	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S.	
	SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S.	
	BBI608 Oral	napabucasin	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	
			Colorectal cancer (Combination therapy)			
	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	

■ **Phase I stage (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase I	BBI608+BBI503 Oral	-	Solid tumors (Combination therapy)	In-house	U.S.	
	DSP-7888 Injection	TBD	Solid tumors, Hematologic malignancies	In-house	U.S.	

[Main revisions since the announcement of October 2015]

LATUDA® (Schizophrenia)	Changed from Phase III to submitted in China (Submitted in December 2015)
Napabucasin (Colorectal cancer / Combination therapy)	Newly added in Phase III in the U.S. Newly added in Phase I in Japan
DSP-7888 (Myelodysplastic syndromes)	Started Phase II of Phase I / II in Japan
LATUDA® (Bipolar maintenance)	Deleted due to completion of Phase III study in the U.S. and Europe, etc. (sNDA will not be submitted)

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. Sunesis submitted an MAA in Europe for Acute Myeloid Leukemia (AML) in December 2015.
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.
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 an NDA in Russia and Turkey for schizophrenia in December 2014. Daiichi Sankyo submitted an NDA 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 an NDA 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. Daiichi Sankyo submitted an NDA in Brazil for schizophrenia and biplolar I depression in September 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 October 2015]

Vosaroxin	Sunesis submitted an MAA in Europe for AML in December 2015
Droxidopa (DOPS®)	Deleted due to completion of Phase II studies of fibromyalgia and intradialytic hypotension in the U.S. (sNDA will not be submitted)

VII. Profile of Major Products under Development (As of January 27, 2016)

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.
- For the treatment of schizophrenia, LATUDA was approved in the U.S. in October 2010, 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 in the U.S. 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
	Schizophrenia, Bipolar I depression	Brazil	
	Schizophrenia	China	In-house
Phase III	Schizophrenia	Japan*2,	
	Bipolar I depression, Bipolar maintenance	Japan	
	Bipolar I depression	Europe	Takeda Pharmaceutical*1

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

*2 Preparing for the new Phase lll study

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

napabucasin (BBI608) Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is an orally administered small molecule investigational agent that targets Stat3, leading to inhibition of the critical genes for maintaining cancer stemness. By targeting cancer stem cell pathways, 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)
	Colorectal cancer (combination therapy)	U.S.	FOLFIRI *3, or FOLFIRI *3 and bevacizumab	303CRC
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
	Malignant pleural mesothelioma (combination therapy)	Japan	cisplatin and pemetrexed	D8807005
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
	Glioblastoma (combination therapy)	Canada	temozolomide	251
	Solid tumors (combination therapy)	U.S.	ipilimumab, pembrolizumab or nivolumab	201CIT
Phase I	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX*3, FOLFOX*3 and bevacizumab, CAPOX*3, FOLFIRI*3, FOLFIRI*3 and bevacizumab, regorafenib, or irinotecan	246
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine and nab-paclitaxel, or FOLFIRINOX*4	118
	Hematologic malignancies (monotherapy / combination therapy)	U.S.	dexamethasone, bortezomib, imatinib or ibrutinib	103HEME
	Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	D8808001
	Solid tumors (combination therapy)	U.S.	BBI503	401-101
	Colorectal cancer (combination therapy)	U.S.	FOLFIRI*3 and bevacizumab	D8809001

*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

*4 FOLFIRINOX: Combination therapy with fluorouracil, leucovorin, irinotecan, oxaliplatin

dasotraline (SEP-225289) Attention-deficit hyperactivity disorder (ADHD), Binge eating disorder (BED)

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SEP-225289 is a new chemical entity that is a dopamine and norepinephrine reuptake inhibitor (DNRI). SEP-225289 has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval at steady state.
- Development stage:
  Adult attention-deficit hyperactivity disorder (ADHD): Phase III in the U.S.
  Pediatric attention-deficit hyperactivity disorder (ADHD): Phase II/III in the U.S.
  Binge eating disorder (BED): Phase II/III 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 is portable and able to deliver medication in approximately two minutes utilizing a vibrating membrane. Currently, there are no LAMAs delivered via nebulizer that are approved by the U.S. Food and Drug Administration (FDA). SUN-101 is a nebulizer delivered LAMA for COPD that the most advanced development stage.
- Development stage: Phase III in the U.S.

vatiquinone (EPI-743)　　Mitochondrial disease

- In-licensed from Edison Pharmaceuticals
- EPI-743 is for synchronizing energy generation in the mitochondria with the counterbalancing of redox stress. It is expected to be the world's first treatment for mitochondrial diseases beginning with Leigh syndrome.
- Development stage:
  A Phase II/III study for Leigh syndrome in Japan completed, development strategy under consideration

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 for 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　　Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI503 is an orally administered small-molecule investigational agent designed to inhibit Nanog and other cancer stem cell pathways by targeting kinases. By targeting cancer stem cell pathways, 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

Stage	Proposed indication	Country, Area	Combination products	Study number
Phase II	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
	Solid tumors (combination therapy)	U.S., Canada	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel or sunitinib	201
Phase I	Solid tumors (monotherapy), Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	DA101003
	Solid tumors (combination therapy)	U.S.	napabucasin	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.
- Development stage: Phase II in the U.S.

EPI-589 Neurodegenerative diseases

- In-licensed from Edison Pharmaceuticals
- EPI-589 is for synchronizing energy generation in the mitochondria with the counterbalancing of redox stress. It is expected to be developed for neurodegenerative indications arising through redox stress.
- Development stage:
  Parkinson disease: Phase II in the U.S. by Edison Pharmaceuticals
  Amyotrophic lateral sclerosis (ALS): Phase II in the U.S. by Edison Pharmaceuticals

DSP-7888 Cancer

- 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 that 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 that attack WT1-expressing cancers cells. By adding a helper T cell-inducing peptide, stronger efficacy is expected than for a CTL-inducing peptide alone. DSP-7888 is expected to be an option for a wide range of patients.
- Development stage:
  Myelodysplastic syndromes (MDS): Phase I/II in Japan
  Solid tumors, Hematologic malignancies : Phase I in the U.S.

WT4869 Cancer

- 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 inducing WT1-specific cytotoxic T-lymphocytes that attack WT1-expressing cancerous cells.
- Development stage:
  Myelodysplastic syndromes (MDS): Phase I/II in Japan
  Solid tumors: Phase I in Japan

DSP-2230 Neuropathic pain

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

WT2725 Cancer

- 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 inducing WT1-specific cytotoxic T-lymphocytes that 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.

DSP-3748 Cognitive impairment associated with schizophrenia (CIAS)

- Developed in-house
- DSP-3748 is a 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 compared with a conventional agonist.
- Development stage: Phase I in the U.S.