Securities Code: 4506

Supplementary Financial Data for the First Quarter of the Year Ending March 31, 2017

July 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 Statement of Income

(Billions of yen)

	FY2015 1Q	FY2016 1Q	Change (%)	FY2016 Apr.-Sep. (Forecast)	Change (%)	FY2016 (Forecast)	Change (%)
Net sales	98.1	103.5	5.5	199.0	0.0	410.0	1.7
Cost of sales	26.4	23.9	(9.2)	49.0	(5.9)	99.5	(4.8)
SG&A expenses	67.3	65.0	(3.4)	134.0	3.1	270.5	3.3
SG&A expenses less R&D costs	47.2	45.7	(3.3)	93.5	4.1	186.0	3.5
R&D costs	20.1	19.3	(3.8)	40.5	0.7	84.5	3.0
Operating income	4.4	14.6	227.7	16.0	(5.0)	40.0	8.3
Ordinary income	4.7	12.7	168.4	16.0	(8.6)	40.0	13.6
Net income attributable to owners of the parent	5.9	8.4	40.8	8.0	(39.5)	25.0	1.2

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.
2: Change (%) represents ratio of changes from the corresponding period of the previous year.

EBITDA (Billions of yen)	9.7	17.4	26.0	61.0
Earnings per share (yen)	14.95	21.06	20.14	62.92
Return on equity (ROE)	1.3%	1.9%	-	5.5%

2. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2015 1Q	FY2016 1Q
Net cash provided by (used in) operating activities	5.4	(9.2)
Net cash provided by investing activities	25.8	5.3
Net cash used in financing activities	(6.4)	(3.5)
Cash and cash equivalents at the end of period	147.8	117.6

3. Foreign Exchange Rates

(Billions of yen)

	FY2015 Apr.-Jun.		FY2016 Apr.-Jun.		FY2016 Assumed rate	Forex sensitivity FY2016 (Impact of yen appreciation by 1yen/USD)	
	End of peiod rate	Average rate	End of peiod rate	Average rate			
Yen / USD	122.4	121.4	103.0	108.1	110.0	Net Sales	(2.0)
Yen / RMB	19.7	19.6	15.5	16.5	17.0	Operating Income	0.2

Note: Net sales and Operating income in FY2016 1Q decreased by 6.7 billion yen and 0.2 billion yen respectively, compared to FY2015 1Q due to exchange rate fluctuation.

4. Capital Expenditures

(Billions of yen)

	FY2015 1Q	FY2016 1Q	Change	FY2016 Forecast	FY2016 Change
Capital expenditures	1.0	1.3	0.3	10.0	2.6

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

Major capital expenditure project continuing in FY2016

Establishment of cell processing center in Regenerative & Cellular Medicine Center

Total expenditures ¥3.6billion, to be completed in FY2017

5. Depreciation and Amortization

(Billions of yen)

	FY2015 1Q	FY2016 1Q	Change	FY2016 Forecast	FY2016 Change
Property, plant and equipment	1.9	1.9	(0.1)	7.6	(0.2)
Intangible assets	1.0	1.2	0.2	5.1	0.3
Goodwill	1.5	1.3	(0.2)	6.1	0.1

II. Consolidated Statement of (Comprehensive) Income

1. Consolidated Statement of Income

(Billions of yen)

	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)
Net sales	98.1	103.5	5.4	5.5
Overseas sales	49.8	56.5	6.8	13.6
[% of net sales]	50.7%	54.6%		
Cost of sales	26.4	23.9	(2.4)	(9.2)
[% of net sales]	26.9%	23.1%		
Gross profit	71.8	79.6	7.8	10.9
SG&A expenses	67.3	65.0	(2.3)	(3.4)
Labor costs	19.6	19.0	(0.6)	(3.1)
Advertising and promotion costs	9.5	7.7	(1.9)	(19.4)
Sales promotion costs	2.9	2.9	0.0	0.7
Other costs	15.2	16.1	0.9	5.9
SG&A expenses less R&D costs	47.2	45.7	(1.6)	(3.3)
R&D costs	20.1	19.3	(0.8)	(3.8)
[% of net sales]	20.5%	18.7%		
Operating income	4.4	14.6	10.1	227.7
Non-operating income	0.9	1.0	0.1	
Non-operating expenses	0.6	2.9	2.3	
Ordinary income	4.7	12.7	8.0	168.4
Extraordinary income	6.0	—	(6.0)	
Gain on sales of investment securities	6.0	—	(6.0)	
Extraordinary loss	0.2	—	(0.2)	
Impairment loss	0.2	—	(0.2)	
Income before income taxes	10.6	12.7	2.1	19.9
Income taxes	4.6	4.3	(0.3)	
Net income	5.9	8.4	2.4	40.8
Net income attributable to owners of the parent	5.9	8.4	2.4	40.8

・Japan Segment (¥2.1B)
・North America Segment ¥5.0B
[incl. FX rate impact (¥5.8B)]
・China Segment ¥0.2B
[incl. FX rate impact (¥0.9B)]
・ Other regions ¥1.6B

・Segment mix
・FX rate impact related to unrealized profit of inventory

・FX rate impact (¥3.6B)

・Foreign exchange losses ¥2.4B

・FY2015 1Q:
Sale of listed stock (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 Statement of Comprehensive Income

(Billions of yen)

	FY2015 1Q	FY2016 1Q
Net income	5.9	8.4
Other comprehensive income	7.8	(25.6)
Unrealized gains (losses) on available-for-sale securities, net of tax	1.7	(0.2)
Deferred gains or losses on hedges	0.0	(0.1)
Foreign currency translation adjustments	5.9	(25.3)
Remeasurements of defined benefit plans	0.1	0.1
Comprehensive income	13.7	(17.3)

FX rate	16/ 3		16/ 6
USD	¥ 112.6	⇒	¥ 103.0
RMB	¥ 17.4	⇒	¥ 15.5

3. Segment Information (FY2016 1Q) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	36.0	47.3	4.8	4.3	92.4	11.1	103.5
Sales to customers	36.0	47.3	4.8	4.3	92.4	11.1	103.5
Intersegment	–	–	–	–	–	–	–
Cost of sales	10.7	1.8	0.6	2.0	15.1	8.9	23.9
Gross profit	25.3	45.5	4.2	2.3	77.4	2.2	79.6
SG&A expenses less R&D costs	14.2	27.4	1.8	0.7	44.1	1.6	45.7
*Amortization included in above*1*	–	*1.7*	–	–	*1.7*	–	*1.7*
Income (loss) of segment	11.1	18.1	2.5	1.6	33.3	0.6	33.9
R&D costs*3					19.1	0.2	19.3
Operating income					14.2	0.4	14.6

Segment Information (FY2015 1Q) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	38.2	42.3	4.6	2.8	87.8	10.3	98.1
Sales to customers	38.2	42.3	4.6	2.8	87.8	10.3	98.1
Intersegment	0.0	–	–	–	0.0	(0.0)	–
Cost of sales	11.4	3.9	1.0	1.8	18.1	8.3	26.4
Gross profit	26.8	38.4	3.6	1.0	69.7	2.0	71.8
SG&A expenses less R&D costs	14.2	28.9	1.9	0.7	45.7	1.6	47.2
*Amortization included in above*1*	–	*1.9*	–	–	*1.9*	–	*1.9*
Income (loss) of segment	12.6	9.5	1.6	0.3	24.1	0.5	24.6
R&D costs*3					19.9	0.2	20.1
Operating income					4.2	0.3	4.4

Segment Information (FY2016 Forecasts) (Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	137.6	200.7	16.0	11.8	366.1	43.9	410.0
Sales to customers	137.6	200.7	16.0	11.8	366.1	43.9	410.0
Intersegment	–	–	–	–	–	–	–
Cost of sales	45.4	11.0	2.8	5.0	64.2	35.3	99.5
Gross profit	92.2	189.7	13.2	6.8	301.9	8.6	310.5
SG&A expenses less R&D costs	57.8	110.0	8.1	3.5	179.4	6.6	186.0
*Amortization included in above*1*	–	*9.4*	–	–	*9.4*	–	*9.4*
Income (loss) of segment	34.4	79.7	5.1	3.3	122.5	2.0	124.5
R&D costs*3					83.5	1.0	84.5
Operating income					39.0	1.0	40.0

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

	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)	FY2016 Apr.-Sep. Forecasts	Progress vs. Apr.-Sep. forecasts (%)	FY2016 Forecasts
Japan	38.2	36.0	(2.1)	(5.6)	68.5	52.6	137.6
North America	42.3	47.3	5.0	11.7	94.2	50.2	200.7
China	4.6	4.8	0.2	5.2	8.3	57.9	16.0
Other Regions	2.8	4.3	1.6	56.7	6.9	62.6	11.8

5. Sales of Major Products

Japan (Strategic Products) (Gross sales basis, Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)	FY2016 Apr.-Sep. Forecasts	Progress vs. Apr.-Sep. forecasts (%)	FY2016 Forecasts
AIMIX® (irbesartan/amlodipine) Therapeutic agent for hypertension	3.5	4.2	0.7	19.6	7.9	52.9	16.1
LONASEN® (blonanserin) Atypical antipsychotic	3.1	3.5	0.4	12.0	6.9	50.1	13.8
TRERIEF® (zonisamide) Parkinson's disease drug	3.3	3.9	0.6	18.8	6.9	56.1	14.5

Japan (Other Products) (Gross sales basis, Billions of yen)

REPLAGAL® (agalsidase alfa) Anderson-Fabry disease drug	2.8	2.7	(0.1)	(4.1)	5.2	51.0	10.5
AmBisome® (amphotericin B) Therapeutic agent for systemic fungal infection	1.0	1.0	0.0	4.3	2.2	46.9	4.3
AVAPRO® (irbesartan) Therapeutic agent for hypertension	2.7	2.7	0.0	1.2	4.8	56.7	9.3
SUREPOST® (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	0.8	1.1	0.3	35.6	2.2	50.4	4.6
METGLUCO® (metformin) Biguanide oral hypoglycemic	4.9	2.9	(2.0)	(40.2)	5.0	58.4	9.8
AMLODIN® (amlodipine) Therapeutic agent for hypertension and angina pectoris	4.2	3.6	(0.6)	(15.0)	6.4	56.0	12.2
PRORENAL® (limaprost alfadex) Vasodilator	2.3	1.8	(0.5)	(20.8)	3.6	50.7	7.0
GASMOTIN® (mosapride citrate) Gastroprokinetic	2.2	1.7	(0.5)	(24.0)	3.2	52.8	6.0
MEROPEN® (meropenem) Carbapenem antibiotic	1.6	1.2	(0.5)	(29.7)	2.4	48.2	4.5

North America (Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)	FY2016 Apr.-Sep. Forecasts	Progress vs. Apr.-Sep. forecasts (%)	FY2016 Forecasts
LATUDA® (lurasidone) Atypical antipsychotic	26.5	31.5	5.0	18.8	61.4	51.2	126.7
APTIOM® (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	1.5	2.4	0.9	60.5	6.0	40.6	13.7
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	7.0	7.6	0.6	8.7	14.3	53.3	31.5
Ciclesonide * Inhaled corticosteroid / corticosteroid nasal spray	2.1	1.4	(0.7)	(34.0)	3.1	43.8	6.1
XOPENEX® (levalbuterol HCI) Short-acting beta-agonist	1.6	1.3	(0.3)	(18.5)	2.8	46.8	4.7
LUNESTA® (eszopiclone) Sedative hypnotic	1.3	0.9	(0.4)	(34.1)	1.5	57.2	2.9
Industrial property revenues	1.1	1.1	(0.0)	(0.2)	2.2	51.4	4.4

China (Billions of yen)

Brand name (Generic name)	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)	FY2016 Apr.-Sep. Forecasts	Progress vs. Apr.-Sep. forecasts (%)	FY2016 Forecasts
MEROPEN® (meropenem)	3.8	4.2	0.5	12.7	7.1	59.8	13.7

Other Regions (Billions of yen)

Brand name (Generic name)	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)	FY2016 Apr.-Sep. Forecasts	Progress vs. Apr.-Sep. forecasts (%)	FY2016 Forecasts
MEROPEN® (meropenem) (Export)	1.7	2.5	0.8	46.2	3.0	83.2	5.7
Industrial property revenues	0.0	0.2	0.2	1,118.7	3.0	6.7	4.0

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

Brand name (Generic name)	FY2015 1Q (A)	FY2016 1Q (B)	(B)-(A)	Change (%)	FY2016 Apr.-Sep. Forecasts	Progress vs. Apr.-Sep. forecasts (%)	FY2016 Forecasts
LATUDA® (lurasidone)	218	291	73	33.5	558	52.2	1,152
APTIOM® (eslicarbazepine acetate)	13	23	10	80.4	54	41.8	124
BROVANA® (arformoterol tartrate)	58	71	13	22.2	130	54.3	286
Ciclesonide *	17	13	(4)	(25.8)	28	44.8	55
XOPENEX® (levalbuterol HCI)	13	12	(1)	(8.5)	25	48.5	43
LUNESTA® (eszopiclone)	11	8	(3)	(26.0)	13	61.1	26
Industrial property revenues	9	10	1	12.1	20	52.3	40

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

III. Consolidated Balance Sheet

ASSETS

(Billions of yen)

	As of Mar. 31, 2016 (A)	As of Jun. 30, 2016 (B)	(B)-(A)
[Assets]	707.7	658.1	(49.6)
Current assets:	421.6	388.7	(32.9)
Cash and time deposits	54.9	76.9	22.0
Notes and accounts receivable	107.2	107.1	(0.1)
Marketable securities	81.0	40.9	(40.1)
Inventories	59.6	54.6	(4.9)
Deferred tax assets	64.0	64.1	0.2
Short-term loans receivable	48.4	36.0	(12.4)
Others	6.5	8.9	2.4
Allowance for doubtful receivables	(0.0)	(0.0)	(0.0)
Fixed assets:	286.1	269.4	(16.7)
Property, plant and equipment:	61.8	60.1	(1.7)
Buildings and structures	40.3	39.5	(0.8)
Machinery, equipment and carriers	7.8	7.6	(0.2)
Land	6.3	6.2	(0.0)
Construction in progress	1.5	1.2	(0.3)
Others	5.9	5.6	(0.3)
Intangible assets:	156.6	141.7	(14.9)
Goodwill	77.0	69.1	(7.8)
In-process research & development	60.1	55.0	(5.2)
Others	19.5	17.6	(1.9)
Investments and other assets:	67.7	67.6	(0.1)
Investment securities	60.4	60.2	(0.2)
Asset for retirement benefit	0.1	0.0	(0.0)
Deferred tax assets	2.3	2.4	0.1
Others	5.0	4.9	(0.0)
Allowance for doubtful receivables	(0.0)	(0.0)	0.0
Total assets	707.7	658.1	(49.6)

・Change of fund management method
・ Decrease due to FX rate impact

・Collection of a part of loan
・Decrease due to FX rate impact

Amortization (¥1.3B)
FX rate (¥6.5B)

FX rate (¥5.2B)

Accounts receivable turnover period (in months)	3.19	3.10

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2016 (A)	As of Jun. 30, 2016 (B)	(B)-(A)
[Liabilities]	261.2	232.3	(29.0)
Current liabilities:	179.7	155.0	(24.8)
Notes and accounts payable	12.2	14.4	2.2
Short-term loans payable	1.0	0.9	(0.1)
Current portion of bonds payable	10.0	10.0	—
Current portion of long-term loans payable	12.0	12.0	—
Income taxes payable	26.4	6.8	(19.5)
Reserve for bonuses	10.8	5.7	(5.1)
Reserve for sales returns	9.1	7.9	(1.2)
Reserve for sales rebates	49.2	47.5	(1.7)
Accounts payable-other	34.2	28.4	(5.8)
Others	14.9	21.3	6.5
Long-term liabilities:	81.5	77.3	(4.2)
Bonds payable	20.0	20.0	—
Long-term loans payable	8.0	8.0	—
Deferred tax liabilities	16.2	14.7	(1.5)
Liability for retirement benefit	16.2	16.1	(0.0)
Others	21.2	18.4	(2.7)
[Net assets]	446.5	425.8	(20.6)
Shareholders' equity:	379.0	384.2	5.2
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	—
Retained earnings	341.4	346.6	5.2
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	67.5	41.7	(25.8)
Unrealized gains on available-for-sale securities, net of tax	25.3	24.9	(0.4)
Deferred gains or losses on hedges	(0.0)	(0.1)	(0.1)
Foreign currency translation adjustments	48.0	22.7	(25.3)
Remeasurement of defined benefit plans	(5.8)	(5.8)	0.1
Total liabilities and net assets	707.7	658.1	(49.6)

Total interest-bearing debt
51.0→50.9 [FX rate impact]

・Decrease by payment

・Transfer to accrued bonus

FX rate	16/ 3		16/ 6
USD	¥ 112.6	⇒	¥ 103.0
RMB	¥ 17.4	⇒	¥ 15.5

IV. Quarterly Business Results

(Billions of yen)

	FY2015				FY2016
	1Q	2Q	3Q	4Q	1Q
Net sales	98.1	100.8	105.6	98.7	103.5
Cost of sales	26.4	25.7	27.0	25.4	23.9
SG&A expenses	67.3	62.7	64.4	67.4	65.0
SG&A expenses less R&D costs	47.2	42.6	45.6	44.3	45.7
R&D costs	20.1	20.1	18.8	23.1	19.3
Operating income (loss)	4.4	12.4	14.2	5.8	14.6
Non-operating income	0.9	1.6	0.6	0.2	1.0
Non-operating expenses	0.6	1.3	1.2	1.9	2.9
Ordinary income (loss)	4.7	12.8	13.6	4.1	12.7
Extraordinary income	6.0	0.1	(0.0)	0.0	—
Extraordinary loss	0.2	0.0	0.1	1.5	—
Income (Loss) before income taxes	10.6	12.8	13.5	2.6	12.7
Net income (loss) attributable to owners of the parent	5.9	7.3	10.1	1.4	8.4

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

V. Major Consolidated Subsidiaries (As of June 30, 2016)

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	170	109	57
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	1,633	100	654
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, 2015	As of Mar. 31, 2016	As of Jun. 30, 2016
consolidated		6,868	6,697	6,729
non-consolidated		4,126	4,000	3,987
MRs Japan	（excluding managers）	1,350	1,300	1,300
	（including managers）	1,530	1,460	1,460
MRs U.S.	（excluding managers）	700	710	700
	（including managers）	800	810	800
MRs China	（excluding managers）	370	300	320
	（including managers）	470	370	390

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

■ **Submitted**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Submitted	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 (1/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase III	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Japan	Approved in the U.S., Canada, Europe, Australia and Taiwan
			Bipolar I depression			Approved in the U.S. and Canada
			Bipolar maintenance			

■ **Phase III (2/2)**

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

■ **Phase II / III**

Stage	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	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	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	amcasertib	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.	Co-development with SanBio
	EPI-589 Oral	TBD	Parkinson disease	Edison Pharma-ceuticals	U.S.	Conducted by Edison Pharmaceuticals
			Amyotrophic lateral sclerosis (ALS)		U.S.	

■ **Phase I / II**

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	amcasertib	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
			Pediatric malignant glioma			
	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharma-ceutical	Japan	Independent development after April 2013

■ **Phase I (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., Japan	
	SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S., Japan	
	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.	

■ **Phase I (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase I	BBI503 Oral	amcasertib	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	In-house	Japan	
	BBI608+BBI503 Oral	-	Solid tumors (Combination therapy)	In-house	U.S.	
	DSP-7888 Injection	TBD	Solid tumors, Hematologic malignancies	In-house	U.S.	
	DSP-1200 Oral	TBD	Treatment-resistant depression	In-house	U.S.	

[Main revisions since the announcement of May 2016]

Napabucasin (Non-small cell lung cancer / Combination therapy) Newly added in Phase lll in the U.S.

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	Out-licensed to Daiichi Sankyo for rights or option rights for commercialization in four South American countries to commercialize in January 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. Daiichi Sankyo submitted an NDA in Brazil for schizophrenia and biplolar I depression in September 2015

[Main revisions since the announcement of May 2016]

None

VII. Profile of Major Products under Development (As of July 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, and in Taiwan in March 2016.

  For the treatment of bipolar I depression, LATUDA was approved as the first atypical antipsychotic indicated for the treatment of bipolar I depression both as a monotherapy and as an adjunctive therapy to lithium or valproate in the U.S. in June 2013. In addition, LATUDA was approved for the same indication in Canada in March 2014.
- Development stage:

Stage	Proposed indication	Country/ Area	Partners
Submitted	Schizophrenia	Thailand, Hong Kong, Singapore	DKSH
	Schizophrenia	Venezuela	Daiichi Sankyo
	Schizophrenia, Bipolar I depression	Brazil	
	Schizophrenia	Russia, Turkey	In-house
	Schizophrenia	China	
Phase III	Schizophrenia	Japan	
	Bipolar I depression, Bipolar maintenance	Japan	

napabucasin (BBI608) Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is an orally-administered small molecule 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 the challenges in cancer treatment 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 studies.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase III	Gastric and Gastro-esophageal junction adenocarcinoma (combination therapy)	U.S., Canada, Japan, etc.	paclitaxel	BRIGHTER (336)
	Colorectal cancer (combination therapy)	U.S.	FOLFIRI[*2], FOLFIRI[*2] + bevacizumab	CanStem303C (303CRC)
	Non-small cell lung cancer (combination therapy)	U.S.	paclitaxel	CanStem43L
Phase II	Colorectal cancer (combination therapy)	U.S., Canada	cetuximab, panitumumab, capecitabine	224

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase I / II	Solid tumors[*1] (combination therapy)	U.S., Canada	paclitaxel	201
	Malignant pleural mesothelioma (combination therapy)	Japan	cisplatin + 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, nivolumab	201CIT
Phase I	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX[*2], FOLFOX[*2] + bevacizumab, CAPOX[*2], FOLFIRI[*2], FOLFIRI[*2] + bevacizumab, regorafenib, irinotecan	246
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel, FOLFIRINOX[*2], FOLFIRI[*2], irinotecan liposome injection + fluorouracil + leucovorin	118
	Hematologic malignancies (monotherapy / combination therapy)	U.S.	dexamethasone, bortezomib, imatinib, ibrutinib	103HEME
	Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	D8808001
	Solid tumors (combination therapy)	U.S.	amcasertib	401-101
	Colorectal cancer (combination therapy)	Japan	FOLFIRI[*2] + bevacizumab	D8809001

*1 Phase II : Ovarian cancer, Brest cancer, Melanoma, etc.

*2 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
CAPOX: Combination therapy with capecitabine, oxaliplatin
FOLFIRI: Combination therapy with fluorouracil, leucovorin, irinotecan
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 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 by dosing at 24-hour intervals.
- 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.

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

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SUN-101 is a long-acting muscarinic antagonist (LAMA) bronchodilator delivered via the innovative, proprietary investigational eFlow nebulizer closed system. It is a portable, hand-held nebulizer system and is designed to deliver the medication in two to three minutes. A standard jet nebulizer typically takes up to 10 minutes. 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 at 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 expected to show efficacy by removing the oxidative stress which is generated excessively by decreased mitochondrial function. It is expected to be the world's first treatment for mitochondrial diseases, which there is no effective therapy, 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 cholangitis (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

amcasertib (BBI503)　　Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI503 is an orally administered small molecule agent designed to inhibit Nanog and other cancer stem cell pathways by targeting kinases. By inhibiting cancer stem cell pathways, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis.
- BBI503 has been shown to inhibit multiple kinases in pre-clinical studies.
- Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase II	Renal cell carcinoma, Urothelial carcinoma (monotherapy)	Canada	-	205a
	Hepatocellular carcinoma, Cholangiocarcinoma (monotherapy)	Canada	-	205b
	Gastrointestinal stromal tumor (monotherapy)	Canada	-	205c
	Ovarian cancer (monotherapy)	U.S.	-	205GYN-M
Phase I / II	Solid tumors* (monotherapy)	U.S., Canada	-	101
	Hepatocellular carcinoma (combination therapy)	U.S.	sorafenib	HCC-103
	Solid tumors (combination therapy)	U.S., Canada	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib	201

Stage	Proposed indication	Country/ Area	Combination products	Study number
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 co-developing 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 up 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 expected to show efficacy by removing the oxidative stress which is generated excessively by decreased mitochondrial function. 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 derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a vaccine containing peptides that induces WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become a treatment option for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific CTLs that attack WT1-expressing cancers cells. By adding a helper T cell-inducing peptide, stronger efficacy is expected than with 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.
  Pediatric malignant glioma: Phase I/II in Japan

WT4869 Cancer

- Developed in-house (Joint research with Chugai Pharmaceutical)
- WT4869 is a therapeutic cancer peptide vaccine 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 an agent 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 central nervous system or cardiovascular system 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., the U.S. and Japan

WT2725 Cancer

- Developed in-house (Joint research with Chugai Pharmaceutical)
- WT2725 is a therapeutic cancer peptide vaccine 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. In addition to having efficacy for positive symptoms, SEP-363856 has efficacy for negative symptoms in the pre-clinical model where existing antipsychotics don't show efficacy. Even in combination treatment with atypical antipsychotics, extrapyramidal side effects were not exacerbated. SEP-363856 is expected to have high efficacy in the treatment of schizophrenia, while improving the patients' QOL.
- Development stage: Phase I in the U.S. and Japan

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.

DSP-1200 Treatment-resistant depression

- Developed in-house
- DSP-1200 is a dopamine D_2, serotonin 5-HT_{2A} and adrenergic α2A receptors antagonist. DSP-1200 is expected to enhance acetylcholine, dopamine, and noradrenaline release in prefrontal cortex, which would provide improvement of depressive symptoms and cognitive function. DSP-1200 is expected to have fewer safety concerns compared with marketed antipsychotics, because it has low or negligible affinities for receptors associated with safety profile.
- Development stage: Phase I in the U.S.