

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

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October 28, 2015

Sumitomo Dainippon Pharma Co., Ltd.

- Forecasts provided in this document are based on the management's assumptions and beliefs, made in light of information available up to the day of announcement. Actual financial results may differ materially from those presented in this document, being dependent upon a number of factors.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

## I. Consolidated Financial Highlights

### 1. Consolidated Statements of Income

(Billions of yen)

1. Consolidated Statements of Income				(Billions of Yen)			
	FY2014 Apr.-Sep.	FY2015 Apr.-Sep.	Change (%)	FY2014	Change (%)	FY2015 (Forecast)	Change (%)
Net sales	178.3	198.9	11.6	371.4	(4.2)	401.0	8.0
Cost of sales	48.5	52.1	7.5	101.2	(2.8)	103.5	2.2
SG&A expenses	117.9	130.0	10.3	246.9	2.2	[270.5] 268.5	8.8
SG&A expenses less R&D costs	84.7	89.8	6.0	175.6	2.3	[181.0] 179.0	2.0
R&D costs	33.2	40.2	21.2	71.3	2.1	89.5	25.5
Operating income	11.9	16.8	41.0	23.3	(44.8)	[27.0] 29.0	24.6
Ordinary income	12.7	17.5	37.7	23.3	(42.6)	[26.5] 28.5	22.2
Net income attributable to owners of the parent	11.8	13.2	12.4	15.4	(23.0)	[18.0] 20.0	29.5

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

2: Change (%) represent ratio of changes from the corresponding period of the previous year.

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)	22.7	27.7	43.1	49.3
Earnings per share (yen)	29.60	33.26	38.88	50.34
Return on equity (ROE)	2.9%	2.9%	3.6%	4.4%
Payout ratio	30.4%	27.1%	46.3%	35.8%

### 2. Consolidated Statements of Cash Flows (Billions of yen)

	FY2014 Apr.-Sep.	FY2015 Apr.-Sep.
Net cash provided by operating activities	21.6	14.3
Net cash provided by investing activities	15.2	28.2
Net cash used in financing activities	(8.3)	(8.3)
Cash and cash equivalents at the end of period	106.3	154.5

### 3. Currency Exchange Rates

(Billions of yen)

	2014 Apr.-Sep. Average rate	2015 Apr.-Sep. Average rate	2015 End of Sep.	FY2015 Assumed rate	Forex sensitivity FY2015 (Impact of yen weakness by 1yen/USD)
Yen / USD	103.0	121.9	119.9	120.0	Net Sales 1.7
Yen / RMB	16.6	19.5	19.0	19.0	Operating Income 0.2

Note: Net sales and Operating income in FY2015 Apr.-Sep. increased by 15.4 billion yen and 1.0 billion yen respectively, compared to FY2014 Apr.-Sep. due to exchange rate fluctuation.

### 4. Capital Expenditures

(Billions of yen)

	FY2014 Apr.-Sep.	FY2015 Apr.-Sep.	Change	FY2015 Forecast	Change
Capital expenditures	4.2	3.2	(1.0)	10.0	0.3

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

Major continuing capital expenditure projects for FY2015

Earthquake resistant renewal of research building No.2 in Osaka research center: ¥1.6billion  
(Total budget ¥1.6billion, plan to be completed in November 2015)

### 5. Depreciation and Amortization

(Billions of yen)

	FY2014 Apr.-Sep.	FY2015 Apr.-Sep.	Change	FY2015 Forecast	Change
Property, plant and equipment	3.8	3.9	0.1	7.4	(0.4)
Intangible assets	2.3	2.2	(0.1)	5.2	1.1
Goodwill	2.5	3.0	0.5	6.0	0.6

## II. Consolidated Statements of (Comprehensive) Income

### 1. Consolidated Statements of Income

(Billions of yen)

	FY2014 Apr.- Sep. (A)	FY2015 Apr.- Sep. (B)	(B)-(A)	Change (%)	
Net sales	178.3	198.9	20.6	11.6	<ul style="list-style-type: none"> <li>• Japan Segment (¥4.2B)</li> <li>• North America Segment ¥22.7B [ FX rate impact ¥14.0B ]</li> <li>• China Segment ¥1.2B [ FX rate impact ¥1.4B ]</li> </ul>
Overseas sales	80.6	104.6	24.0	29.8	
[ % of net sales ]	45.2%	52.6%			
Cost of sales	48.5	52.1	3.6	7.5	
[ % of net sales ]	27.2%	26.2%			
Gross profit	129.8	146.8	17.0	13.1	
SG&A expenses	117.9	130.0	12.1	10.3	
Labor costs	34.6	38.9	4.3	12.4	<ul style="list-style-type: none"> <li>• Due to increase in North America and weak yen</li> </ul>
Advertising and promotion costs	12.6	16.0	3.3	26.3	
Sales promotion costs	6.3	6.1	(0.1)	(2.2)	<ul style="list-style-type: none"> <li>• Due to cost reversal from fair value adjustment of contingent consideration liabilities</li> </ul>
Other costs	31.2	28.7	(2.4)	(7.7)	
SG&A expenses less R&D costs	84.7	89.8	5.1	6.0	
R&D costs	33.2	40.2	7.0	21.2	<ul style="list-style-type: none"> <li>• Due to increase in clinical development expense in North America and weak yen</li> </ul>
[ % of net sales ]	18.6%	20.2%			
Operating income	11.9	16.8	4.9	41.0	
Non-operating income	2.4	2.5	0.1		
Non-operating expenses	1.6	1.8	0.2		
Ordinary income	12.7	17.5	4.8	37.7	
Extraordinary income	10.0	6.1	(3.9)		
Gain on sales of investment securities	—	6.1	6.1		<ul style="list-style-type: none"> <li>• Sale of listed stock (North America)</li> </ul>
Gain on sales of property, plant and equipment	8.3	—	(8.3)		
Compensation income for damage	1.7	—	(1.7)		
Extraordinary loss	0.6	0.2	(0.5)		
Impairment loss	—	0.2	0.2		<ul style="list-style-type: none"> <li>• Impairment of intangible asset (North America)</li> </ul>
Business structure improvement expenses	0.6	—	(0.6)		
Income before income taxes	22.1	23.4	1.4	6.2	
Income taxes	10.3	10.2	(0.1)		
Net income	11.8	13.2	1.5	12.4	
Net income attributable to owners of the parent	11.8	13.2	1.5	12.4	

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.- Sep.	FY2015 Apr.- Sep.
Net income	11.8	13.2
Other comprehensive income	13.6	(2.1)
Unrealized gains (losses) on available-for-sale securities, net of tax	0.1	(1.2)
Deferred gains or losses on hedges	0.0	(0.0)
Foreign currency translation adjustments	13.3	(1.2)
Remeasurements of defined benefit plans	0.2	0.3
Comprehensive income	25.4	11.1

Currency exchange rates : yen/\$

3/2014	9/2014	3/2015	9/2015
102.9	→ 109.5	120.2	→ 119.9
	+6.6		(0.2)

## 3. Segment Information (FY2015 Apr.-Sep.)

(Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	74.0	90.2	9.6	4.7	178.4	20.5	198.9
Sales to customers	74.0	90.2	9.6	4.7	178.4	20.5	198.9
Intersegment	0.0	—	—	—	0.0	(0.0)	—
Cost of sales	22.7	8.6	1.7	2.6	35.6	16.5	52.1
Gross profit	51.3	81.6	7.8	2.1	142.8	4.0	146.8
SG&A expenses less R&D costs	29.3	52.0	4.0	1.3	86.6	3.1	89.8
Amortization included in above*1	—	0.8	—	—	0.8	—	0.8
Income (loss) of segment	22.1	29.5	3.8	0.8	56.2	0.9	57.0
R&D costs*3	39.8					0.4	40.2
Operating income	16.4					0.4	16.8

## Segment Information (FY2014 Apr.-Sep.)

(Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America*1	China	Other Regions	Subtotal		
Net sales	78.2	67.4	8.4	4.5	158.4	19.9	178.3
Sales to customers	78.2	67.4	8.4	4.5	158.4	19.9	178.3
Intersegment	—	—	—	—	—	—	—
Cost of sales	22.8	5.7	1.4	2.8	32.7	15.8	48.5
Gross profit	55.3	61.7	7.0	1.7	125.7	4.1	129.8
SG&A expenses less R&D costs	29.1	48.1	3.3	1.1	81.6	3.1	84.7
Amortization included in above*1	—	4.9	—	—	4.9	—	4.9
Income (loss) of segment	26.2	13.7	3.7	0.6	44.1	1.0	45.1
R&D costs*3	32.7					0.4	33.2
Operating income	11.4					0.6	11.9

## 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	9.4	359.3	41.7	401.0
Sales to customers	149.4	182.6	17.8	9.4	359.2	41.8	401.0
Intersegment	0.1	—	—	—	0.1	(0.1)	—
Cost of sales	46.5	15.5	2.6	5.4	70.0	33.5	103.5
Gross profit	103.0	167.1	15.2	4.0	289.3	8.2	297.5
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	44.5	64.1	6.7	1.5	116.8	1.7	118.5
R&D costs*3	88.5					1.0	89.5
Operating income	28.3					0.7	29.0

Notes \*1: Amortization of goodwill and patent rights, fair value change of contingent consideration liability

\*2: Including elimination of intersegment transaction.

\*3: R&amp;D costs are controlled globally and not allocated to each segment.

\*4: FY2015 forecasts have been revised.

#### 4. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

	FY2014 Apr.-Sep. (A)	FY2015 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2014		FY2015 (Forecasts)	
					2nd Half	Full Year	2nd Half	Full Year
Japan	78.2	74.0	(4.2)	(5.3)	78.4	156.6	75.4	[156.7] 149.4
North America	67.4	90.2	22.7	33.7	80.8	148.2	92.4	[174.8] 182.6
China	8.4	9.6	1.2	14.5	8.7	17.1	8.2	[19.7] 17.8
Other Regions	4.5	4.7	0.2	4.1	4.3	8.8	4.7	[7.4] 9.4

#### 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.-Sep. (A)	FY2015 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2014		FY2015 (Forecasts)	
					2nd Half	Full Year	2nd Half	Full Year
AIMIX <sup>®</sup> (irbesartan/amlodipine) Therapeutic agent for hypertension (Launch: Dec. 2012)	5.4	7.0	1.6	30.8	6.6	12.0	8.2	[17.5] 15.2
AVAPRO <sup>®</sup> (irbesartan) Therapeutic agent for hypertension	5.6	5.4	(0.2)	(3.0)	5.8	11.4	5.4	[11.5] 10.8
LONASEN <sup>®</sup> (blonanserin) Atypical antipsychotic	5.4	6.3	0.9	17.2	6.1	11.5	6.7	13.0
TRERIEF <sup>®</sup> (zonisamide) Parkinson's disease drug	5.3	6.5	1.2	23.1	6.3	11.6	7.5	[15.2] 14.0

##### Japan (Other Products)

SUREPOST <sup>®</sup> (repaglinide) Rapid-acting insulin secretagogue (Launch: May 2011)	1.0	1.7	0.6	63.0	1.4	2.4	2.0	3.7
AmBisome <sup>®</sup> (amphotericin B) Therapeutic agent for systemic fungal infection	2.1	2.1	0.0	1.5	2.2	4.3	2.2	[4.9] 4.3
REPLAGAL <sup>®</sup> (agalsidase alfa) Anderson-Fabry disease drug	4.8	5.2	0.4	8.0	4.9	9.7	5.3	[11.0] 10.5
METGLUCO <sup>®</sup> (metformin) Biguanide oral hypoglycemic	7.9	8.4	0.5	6.1	9.2	17.1	5.6	14.0
AMLODIN <sup>®</sup> (amlodipine) Therapeutic agent for hypertension and angina pectoris	9.9	8.4	(1.5)	(15.1)	9.7	19.6	7.7	[17.0] 16.1
GASMOTIN <sup>®</sup> (mosapride citrate) Gastroprokinetic	5.3	4.4	(1.0)	(18.1)	5.2	10.5	3.9	8.3
PRORENAL <sup>®</sup> (limaprost alfadex) Vasodilator	5.3	4.6	(0.8)	(14.5)	5.3	10.6	4.5	9.1
MEROPEN <sup>®</sup> (meropenem) Carbapenem antibiotic	4.1	3.3	(0.7)	(18.1)	3.8	7.9	3.2	[6.8] 6.5
EBASTEL <sup>®</sup> (ebastine) Antiallergic	1.6	1.2	(0.4)	(23.0)	2.3	3.9	2.0	3.2

Note: The forecasts of some products have been revised. Figures in parentheses [ ] are previously disclosed forecasts.

## North America

(Billions of yen)

Brand name (Generic name) Therapeutic indication	FY2014 Apr.-Sep. (A)	FY2015 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2014		FY2015 (Forecasts)	
					2nd Half	Full Year	2nd Half	Full Year
LATUDA® (lurasidone) Atypical antipsychotic (Launch: Feb. 2011)	36.5	57.6	21.1	57.8	46.0	82.5	62.4	[120.4] 120.0
APTOM® (eslicarbazepine acetate) Antiepileptic (Launch: Apr. 2014)	0.9	3.3	2.4	261.1	1.6	2.5	4.4	[7.0] 7.7
BROVANA® (arformoterol tartrate) Long-acting beta-agonist	9.6	14.6	5.0	52.6	12.6	22.2	14.7	[26.2] 29.3
Ciclesonide * Inhaled corticosteroid / corticosteroid nasal spray	3.4	3.7	0.4	11.0	3.3	6.7	3.2	[6.3] 6.9
XOPENEX® (levalbuterol HCl) Short-acting beta-agonist	5.1	3.5	(1.6)	(31.3)	3.4	8.5	3.0	[2.6] 6.5
LUNESTA® (eszopiclone) Sedative hypnotic	7.1	2.7	(4.4)	(61.9)	4.4	11.5	1.5	[3.9] 4.2
Industrial property revenues	2.6	2.4	(0.2)	(8.3)	7.3	9.9	2.2	4.6

## China

(Billions of yen)

Brand name (Generic name)	FY2014 Apr.-Sep. (A)	FY2015 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2014		FY2015 (Forecasts)	
					2nd Half	Full Year	2nd Half	Full Year
MEROPEN® (meropenem)	6.9	8.1	1.2	17.0	7.4	14.3	6.8	[16.1] 14.9

## Other Regions

(Billions of yen)

Brand name (Generic name)	FY2014 Apr.-Sep. (A)	FY2015 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2014		FY2015 (Forecasts)	
					2nd Half	Full Year	2nd Half	Full Year
MEROPEN® (meropenem) (Export)	2.0	2.4	0.4	19.5	2.6	4.6	2.8	[4.3] 5.2
Industrial property revenues	0.2	0.3	0.1	52.2	0.1	0.3	0.7	1.0

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

(Millions of dollars)

Brand name (Generic name)	FY2014 Apr.-Sep. (A)	FY2015 Apr.-Sep. (B)	(B)-(A)	Change (%)	FY2014		FY2015 (Forecasts)	
					2nd Half	Full Year	2nd Half	Full Year
LATUDA® (lurasidone)	354	472	118	33.4	398	752	528	1,000
APTOM® (eslicarbazepine acetate)	9	27	18	205.2	14	23	37	[58] 64
BROVANA® (arformoterol tartrate)	93	120	27	29.0	109	202	124	[218] 244
Ciclesonide *	33	31	(2)	(6.2)	28	61	26	[52] 57
XOPENEX® (levalbuterol HCl)	50	29	(21)	(41.9)	28	78	25	[22] 54
LUNESTA® (eszopiclone)	69	22	(47)	(67.8)	36	105	13	[32] 35
Industrial property revenues	25	20	(6)	(22.5)	65	90	18	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.

### III. Consolidated Balance Sheets

#### ASSETS

(Billions of yen)

	As of Mar. 31, 2015 (A)	As of Sep. 30, 2015 (B)	(B)-(A)
[ Assets ]	711.6	726.0	14.4
Current assets:	401.7	425.1	23.4
Cash and time deposits	30.6	42.1	11.5
Notes and accounts receivable	103.1	106.2	3.1
Marketable securities	111.3	113.6	2.3
Inventories	62.4	62.8	0.4
Deferred tax assets	38.9	50.9	12.1
Short-term loans receivable	49.1	42.0	(7.1)
Others	6.6	7.5	0.9
Allowance for doubtful receivables	(0.1)	(0.0)	0.1
Fixed assets:	309.9	301.0	(8.9)
Property, plant and equipment:	65.2	63.4	(1.7)
Buildings and structures	41.4	40.4	(1.0)
Machinery, equipment and carriers	9.1	8.5	(0.5)
Land	6.3	6.3	(0.0)
Construction in progress	1.2	1.6	0.4
Others	7.2	6.6	(0.6)
Intangible assets:	173.9	171.2	(2.6)
Goodwill	88.1	84.9	(3.2)
In-process research & development	64.5	64.0	(0.4)
Others	21.3	22.3	1.0
Investments and other assets:	70.9	66.3	(4.6)
Investment securities	58.2	56.2	(2.0)
Asset for retirement benefit	1.9	2.1	0.1
Deferred tax assets	4.8	2.7	(2.0)
Others	6.0	5.4	(0.6)
Allowance for doubtful receivables	(0.0)	(0.0)	0.0
Total assets	711.6	726.0	14.4

← Increase in elimination of  
inventory unrealized profit

← Amortization (¥3.0B)  
Exchange rate (¥0.1B)

← Exchange rate (¥0.3B)  
Impairment (¥0.2B)

Accounts receivable turnover period  
(in months)

3.33

3.20

# LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2015 (A)	As of Sep. 30, 2015 (B)	(B)-(A)
[ Liabilities ]	260.6	270.4	9.9
Current liabilities:	156.8	190.8	33.9
Notes and accounts payable	12.5	13.0	0.5
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	12.8	6.2
Income taxes payable	3.3	16.3	13.0
Reserve for bonuses	9.4	10.1	0.7
Reserve for sales returns	8.6	8.9	0.3
Reserve for sales rebates	36.4	44.4	8.1
Accounts payable-other	35.3	32.3	(3.0)
Others	14.9	12.0	(3.0)
Long-term liabilities:	103.7	79.7	(24.0)
Bonds payable	30.0	20.0	(10.0)
Long-term loans payable	20.0	8.0	(12.0)
Deferred tax liabilities	17.4	17.2	(0.2)
Liability for retirement benefit	15.3	15.5	0.2
Others	21.1	19.1	(2.0)
[ Net assets ]	451.0	455.6	4.5
Shareholders' equity:	364.3	371.1	6.8
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	326.7	333.5	6.8
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	86.7	84.5	(2.3)
Unrealized gains on available-for-sale securities, net of tax	23.1	21.9	(1.2)
Deferred gains or losses on hedges	0.0	(0.0)	(0.0)
Foreign currency translation adjustments	68.2	66.9	(1.3)
Remeasurement of defined benefit plans	(4.5)	(4.3)	0.3
Total liabilities and net assets	711.6	726.0	14.4

Total interest-bearing debt  
86.5→81.9

Increase in LATUDA® sales

Currency exchange rates: yen/\$  
03/2015 09/2015  
120.2 → 119.9



#### IV. Quarterly Business Results

(Billions of yen)

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

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

#### V. Major Consolidated Subsidiaries (As of Sep. 30, 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	164	104	65
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	1,627	95	712
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 Sep. 30, 2015
consolidated		7,015	6,868	6,891
non-consolidated		4,331	4,126	4,107
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	710
	(including managers)	810	800	810
MRs China	(excluding managers)	390	370	350
	(including managers)	480	470	450

## VI. Shareholder Positioning (As of September 30, 2015)

1. Total number of authorized shares: 1,500,000,000
2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 597,471)
3. Number of shareholders by category:

	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	53	76,106	19.13
Securities companies	59	5,389	1.35
Other Japanese corporations	353	238,578	59.96
Corporations outside Japan, etc.	432	43,243	10.87
Individuals and others (Including treasury stock)	29,440	34,583	8.69
Total	30,337	397,900	100

Note: The numbers of shares are rounded down to the nearest thousand shares.

### 4. Major shareholders:

Shareholders	Status of ownership	
	Number of shares held (Thousands)	Percentage of shareholding(%)
Sumitomo Chemical Co., Ltd.	199,434	50.20
Inabata & Co., Ltd.	27,282	6.87
The Master Trust Bank of Japan, Ltd. (Trust account)	14,185	3.57
Japan Trustee Services Bank, Ltd. (Trust account)	8,673	2.18
Nippon Life Insurance Company	7,581	1.91
Japan Trustee Services Bank, Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Aioi Nissay Dowa Insurance Co., Ltd.	4,435	1.12
Sumitomo Dainippon Pharma Employee shareholders' association	4,191	1.05
NORTHERN TRUST CO. (AVFC) RE U.S. TAX EXEMPTED PENSION FUNDS	3,476	0.88

Notes: \*1: Percentage of shareholding is calculated excluding treasury stock (597,471 stocks).

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

## VII. Development Pipeline (As of October 28, 2015)

### ■ Submitted stage

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Submitted	Amrubicin hydrochloride Injection	amrubicin hydrochloride	Small cell lung cancer	In-house	China	Submitted in August 2012 Brand name in Japan: CALSED®
	Blonanserin Oral	blonanserin	Schizophrenia	In-house	China	Submitted in September 2013 Brand name in Japan: LONASEN®
	APTOM® 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)

### ■ Phase III stage (1/2)

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

■ Phase III stage (2/2)

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase III	BBI608 Oral	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
	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)			

■ 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	
	WT4869 Injection	TBD	Myelodysplastic syndromes	Joint research with Chugai Pharma- ceutical	Japan	Independent development after April 2013
	DSP-7888 Injection	TBD	Myelodysplastic syndromes	In-house	Japan	

■ Phase I stage (1/2)

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase I	WT4869 Injection	TBD	Solid tumors	Joint research with Chugai 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	
	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 July 2015]

APTiom® (New indication: Epilepsy (Monotherapy)) Deleted "U.S." due to approval for Epilepsy (Monotherapy) in the U.S. (August 2015)



### Major Products under Development by Licensees

Generic / Product code (Brand name in JPN)	Proposed indications	Status of development
vosaroxin AG-7352	Cancer	Out-licensed to Sunesis Pharmaceuticals Inc. for the worldwide territory in October 2003. Multinational Phase III study completed by Sunesis (Sunesis' product code: SNS-595) in October 2014.
amrubicin hydrochloride (CALSED®)	Small cell lung cancer	Out-licensed to Celgene (former Pharmion) for the U.S. and European territories in June 2005. Phase III study completed in the U.S. and Europe by Celgene.
droxidopa (DOPS®)	Neurogenic orthostatic hypotension, Intradialytic hypotension, Fibromyalgia	Out-licensed to Lundbeck (former Chelsea Therapeutics) for the worldwide territory, excluding Japan, China, Korea and Taiwan in May 2006. Lundbeck obtained the approval for neurogenic orthostatic hypotension in the U.S. in February 2014, and launched in the U.S. in September 2014 (Lundbeck's brand name: NORTHERA™). Phase II study of fibromyalgia and phase II study of intradialytic hypotension completed by Lundbeck.
lurasidone hydrochloride SM-13496	Schizophrenia Bipolar disorder	Entered into a license agreement with Takeda Pharmaceutical for co-development and exclusive commercialization for the European territory, excluding the U.K. in March 2011. Takeda submitted an MAA in Europe for schizophrenia in September 2012. Takeda obtained the approval for schizophrenia in Switzerland in August 2013. Out-licensed to Standard Chem. & Pharm. for Taiwan in August 2013, and submitted for schizophrenia in Taiwan in October 2013. Out-licensed to Daiichi Sankyo for rights or option rights in four South American countries to commercialize in January 2014. Takeda obtained the approval in Europe for schizophrenia in March 2014. Takeda submitted 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 bipolar 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 July 2015]

Lurasidone hydrochloride (SM-13496)

Daiichi Sankyo submitted in Brazil for schizophrenia and bipolar I depression in September 2015

## VIII. Profile of Major Products under Development (As of October 28, 2015)

### **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<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 studies supporting the U.S. FDA approval, the efficacy of LATUDA for the treatment of schizophrenia was established in four, short-term (6-week), placebo-controlled clinical studies in adult patients. In these studies, LATUDA demonstrated significantly greater improvement versus placebo. A total of five short-term placebo-controlled clinical studies contributed to the understanding of the tolerability and safety profile of LATUDA. LATUDA was approved for the treatment of schizophrenia by the U.S. FDA in October 2010, and launched by Sunovion in the U.S. in February 2011. For the treatment of schizophrenia, LATUDA was approved in Canada in June 2012, in Switzerland in August 2013, in Europe and Australia in March 2014.

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

- Development stage:

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

\*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 A Phase III study completed, development strategy under consideration

### **ranirestat (AS-3201) Diabetic neuropathy**

- Developed in-house
- AS-3201 is expected to alleviate diabetic neuropathy, a complication of diabetes, by inhibiting aldose reductase and thereby inhibiting the accumulation of intracellular sorbitol that causes diabetic neuropathy. This compound has a stronger inhibitory effect and is longer-acting compared to other drugs in this therapeutic area. Clinical studies have shown AS-3201 to have good penetration into nerve tissues, resulting in dose-dependent inhibition of intraneural accumulation of sorbitol and fructose. Based on the results of clinical studies, AS-3201 is expected to show improvement of neuronal function and symptoms related to diabetic neuropathy.
- Development stage: Phase III in Japan

**napabucasin (BBI608)****Anticancer drug**

- 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  $\beta$ -catenin pathways in the pre-clinical study.
- Development stage:

Stage	Proposed indication	Country, Area	Combination products	Study number
Phase III	Colorectal cancer (monotherapy) <sup>*1</sup>	U.S., Canada, Japan, etc.	-	CO.23
	Gastric and Gastro-esophageal junction adenocarcinoma (combination therapy)	U.S., Canada, Japan, etc.	paclitaxel	336 (BRIGHTER)
Phase II	Colorectal cancer (combination therapy)	U.S., Canada	cetuximab, panitumumab or capecitabine	224
Phase I / II	Solid tumors <sup>*2</sup> (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 <sup>*3</sup> , FOLFOX <sup>*3</sup> and bevacizumab, CAPOX <sup>*3</sup> , FOLFIRI <sup>*3</sup> , FOLFIRI <sup>*3</sup> and bevacizumab, or regorafenib	246
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine and nab-paclitaxel, or FOLFIRINOX <sup>*4</sup>	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

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

\*2 Phase II : Ovarian cancer, Breast 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 DNRI that inhibits the reuptake of dopamine and norepinephrine. SEP-225289 is being developed as a once daily long-acting treatment. Due to its ability to maintain a stable concentration in blood levels all day, it is expected to be effective over the course of the day.
- Development stage:  
Adult attention-deficit hyperactivity disorder (ADHD): Phase III in the U.S.  
Pediatric attention-deficit hyperactivity disorder (ADHD): Phase II/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<sup>®</sup> 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                      Anticancer drug**

- 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
	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.	BBI608	401-101

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

**SB623                      Stroke**

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

**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

**WT4869                      Anticancer drug**

- Developed in-house (Joint research with Chugai Pharmaceutical)
- WT4869 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. WT4869 is expected to treat various types of hematologic malignancies and solid tumors that express WT1, by 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-7888                      Anticancer drug**

- Developed in-house
- DSP-7888 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a novel peptide vaccine candidate containing peptides 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.

**DSP-2230                      Neuropathic pain**

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

**WT2725                      Anticancer drug**

- Developed in-house (Joint research with Chugai Pharmaceutical)
- WT2725 is a therapeutic cancer peptide vaccine candidate derived from Wilms' tumor gene 1 (WT1) protein. WT2725 is expected to treat various types of hematologic malignancies and solid tumors that express WT1, by 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  $\alpha 7$ -type nicotinic acetylcholine receptor ( $\alpha 7$ nAChR). DSP-3748 is expected to treat patients with cognitive impairment associated with schizophrenia (CIAS) by enhancing the ACh transmission via  $\alpha 7$ nAChR. DSP-3748 is expected to cause less desensitization compared with a conventional agonist.
- Development stage: Phase I in the U.S.