Securities Code: 4506

Supplementary Financial Data for the Year Ended March 31, 2017

May 11, 2017

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	FY2016	Change (%)	FY2017 Apr.-Sep. (Forecast)	Change (%)	FY2017 (Forecast)	Change (%)
Net sales	403.2	411.6	2.1	220.0	11.1	450.0	9.3
Cost of sales	104.5	100.1	(4.2)	57.5	20.1	116.0	15.9
SG&A expenses	261.8	258.8	(1.1)	136.0	10.1	279.0	7.8
SG&A expenses less R&D costs	179.8	178.0	(1.0)	95.5	11.4	194.0	9.0
R&D costs	82.0	80.8	(1.5)	40.5	7.3	85.0	5.2
Operating income	36.9	52.8	42.9	26.5	(0.9)	55.0	4.2
Ordinary income	35.2	54.3	54.3	26.5	11.0	55.0	1.2
Net income attributable to owners of the parent	24.7	29.0	17.4	18.0	64.8	36.0	24.2

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)	55.8	72.8	36.0	75.0
Earnings per share (yen)	62.16	72.97	45.31	90.61
Return on equity (ROE)	5.5%	6.4%	-	7.6%
Payout ratio	29.0%	27.4%	-	22.1%

2. Consolidated Statement of Cash Flows

(Billions of yen)

	FY2015	FY2016
Net cash provided by operating activities	49.4	21.6
Net cash provided by (used in) investing activities	15.9	(59.7)
Net cash provided by (used in) financing activities	(42.6)	9.9
Cash and cash equivalents at the end of period	135.6	105.6

3. Foreign Exchange Rates

(Billions of yen)

	FY2015		FY2016		FY2017 Assumed rate	Forex sensitivity FY2017 (Impact of yen appreciation by 1 yen)	
	Fiscal year end rate	Average rate	Fiscal year end rate	Average rate		Net Sales	Operating Income
Yen / USD	112.6	120.2	112.2	108.4	110.0	(2.2)	0.3
Yen / RMB	17.4	18.9	16.3	16.1	16.5	(1.1)	(0.1)

Note: Net sales and operating income in FY2016 decreased by 24.6 billion yen and increased by 1.1 billion yen, respectively, compared to FY2015 due to exchange rate fluctuation.

4. Capital Expenditures

(Billions of yen)

	FY2015	FY2016	Change	FY2017 Forecast	FY2017 Change
Capital expenditures	7.4	6.7	(0.7)	10.0	3.3

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

Major capital expenditure project continuing in FY2016

Establishment of a cell processing center in Central Research Labolatories (Suita city in Osaka)

Total expenditures ¥3.6billion, to start operation in FY2017

5. Depreciation and Amortization

(Billions of yen)

	FY2015	FY2016	Change	FY2017 Forecast	FY2017 Change
Property, plant and equipment	7.8	7.5	(0.4)	6.7	(0.8)
Intangible assets	4.8	4.9	0.1	6.4	1.5
Goodwill	6.0	5.6	(0.4)	6.4	0.8

6. Valuations and Accounting Procedures Following the Acquisition of Tolero (January 2017)

(Millions of dollar)

	Before purchase price allocation	After purchase price allocation	Valuation differences	Accounting procedures (Amortization)
In-process R&D (Intangible Assets)	—	526	526	Capitalize (Amortize after launch)
Deferred tax liabiliies (of the above)	—	(195)	(195)	
Contingent consideration (Fair value)	—	(310)	(310)	
Other assets & liabilities (Net)	(5)	10	16	
Goodwill	—	163	163	Amortization for 20 years
Total	(5)	195	200	

II. Consolidated Statement of (Comprehensive) Income

1. Consolidated Statement of Income

(Billions of yen)

	FY2015 (A)	FY2016 (B)	(B)-(A)	Change (%)
Net sales	403.2	411.6	8.4	2.1
Overseas sales	215.1	227.5	12.4	5.8
[% of net sales]	53.3%	55.3%		
Cost of sales	104.5	100.1	(4.4)	(4.2)
[% of net sales]	25.9%	24.3%		
Gross profit	298.7	311.6	12.8	4.3
SG&A expenses	261.8	258.8	(3.0)	(1.1)
Labor costs	77.3	74.9	(2.4)	(3.0)
Advertising and promotion costs	27.0	24.1	(2.9)	(10.7)
Sales promotion costs	14.1	13.0	(1.1)	(7.9)
Amortization of goodwill, etc. *3	5.8	7.2	1.4	24.2
Other costs	55.7	58.8	3.2	5.7
SG&A expenses less R&D costs	179.8	178.0	(1.8)	(1.0)
R&D costs	82.0	80.8	(1.2)	(1.5)
[% of net sales]	20.3%	19.6%		
Operating income	36.9	52.8	15.8	42.9
Non-operating income	3.2	3.5	0.3	
Non-operating expenses	4.9	1.9	(3.0)	
Ordinary income	35.2	54.3	19.1	54.3
Extraordinary income	6.1	5.8	(0.4)	
Gain on sales of investment securities	6.1	5.8	(0.4)	
Extraordinary loss	1.8	12.9	11.1	
Business structure improvement expenses	0.6	10.9	10.3	
Loss on discontinuation of R&D programs	—	2.0	2.0	
Loss on disposal of fixed assets	0.6	—	(0.6)	
Impairment loss	0.6	—	(0.6)	
Income before income taxes	39.6	47.2	7.7	19.4
Income taxes	14.9	18.2	3.4	
Net income	24.7	29.0	4.3	17.4
Net income attributable to owners of the parent	24.7	29.0	4.3	17.4

・Japan Segment (¥5.6B)
・North America Segment ¥13.0B
[incl. FX rate impact (¥21.5B)]
・China Segment (¥0.7B)
[incl. FX rate impact (¥3.0B)]

・Segment mix in sales
・Cost of sales decreased due to a downward impact from the unrealized profit of inventory on FY2015 FX rate realized in FY2016 with stronger yen.

・Decrease due to early retirement in Japan and FX rate impact

・Decrease in Japan and North America

・Increase due to M&A-related cost and others

・FY2015 : Sale of listed stocks (North America)
・FY2016 : Sale of listed stocks (Japan)

・Additional retirement payments related to offering the early retirement program (Japan)

・Cancelation fee related to collaborative research agreement and others

Notes 1: Cost of sales includes provision for (reversal of) reserve for sales returns.
2: Overseas sales includes exports of non-Pharmaceutical products.
*3: Amortization of goodwill and patent rights, fair value change of contingent consideration liability

2. Consolidated Statement of Comprehensive Income

(Billions of yen)

	FY2015	FY2016
Net income	24.7	29.0
Other comprehensive income	(19.1)	(7.8)
Unrealized gains (losses) on available-for-sale securities, net of tax	2.2	(6.7)
Deferred gains or losses on hedges	(0.0)	(0.0)
Foreign currency translation adjustments	(20.0)	(2.3)
Remeasurements of defined benefit plans	(1.3)	1.1
Comprehensive income	5.6	21.1

FX rate	16/ 3		17/3
USD	¥ 112.6	⇒	¥ 112.2
RMB	¥ 17.4	⇒	¥ 16.3

3. Segment Information (FY2016 Results)　　(Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	140.9	197.9	17.6	11.6	368.0	43.7	411.6
Sales to customers	140.8	197.9	17.6	11.6	367.9	43.7	411.6
Intersegment	0.1	—	—	—	0.1	(0.1)	—
Cost of sales	46.7	9.6	3.4	5.6	65.3	34.8	100.1
Gross profit	94.1	188.3	14.3	5.9	302.7	8.9	311.6
SG&A expenses less R&D costs	55.8	105.0	7.5	3.1	171.5	6.5	178.0
*Amortization included in above*1*	—	*7.2*	—	—	*7.2*	—	*7.2*
Income (loss) of segment	38.3	83.3	6.7	2.8	131.1	2.4	133.6
R&D costs*3					79.9	1.0	80.8
Operating income					51.3	1.5	52.8

Segment Information (FY2017 Forecasts)　　(Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	139.2	231.6	18.3	15.9	405.0	45.0	450.0
Sales to customers	139.2	231.6	18.3	15.9	405.0	45.0	450.0
Intersegment	—	—	—	—	—	—	—
Cost of sales	48.4	21.5	3.8	6.4	80.1	35.9	116.0
Gross profit	90.8	210.1	14.5	9.5	324.9	9.1	334.0
SG&A expenses less R&D costs	53.0	122.7	7.8	3.7	187.2	6.8	194.0
*Amortization included in above*1*	—	*13.2*	—	—	*13.2*	—	*13.2*
Income (loss) of segment	37.8	87.4	6.7	5.8	137.7	2.3	140.0
R&D costs*3					84.0	1.0	85.0
Operating income					53.7	1.3	55.0

[Reference]　Segment Information (FY2015 Results)　　(Billions of yen)

	Pharmaceuticals Business					Other Business *2	Total
	Japan	North America	China	Other Regions	Subtotal		
Net sales	146.6	184.9	18.4	11.2	361.1	42.1	403.2
Sales to customers	146.5	184.9	18.4	11.2	360.9	42.3	403.2
Intersegment	0.1	—	—	—	0.1	(0.1)	—
Cost of sales	45.8	16.0	2.8	6.1	70.6	33.8	104.5
Gross profit	100.8	168.9	15.6	5.1	290.4	8.3	298.7
SG&A expenses less R&D costs	59.3	103.8	7.6	2.6	173.3	6.5	179.8
*Amortization included in above*1*	—	*5.8*	—	—	*5.8*	—	*5.8*
Income (loss) of segment	41.5	65.2	8.0	2.4	117.1	1.8	119.0
R&D costs*3					81.1	0.9	82.0
Operating income					36.0	0.9	36.9

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 (A)	FY2016 (B)	(B)-(A)	Change (%)	FY2017 Apr.-Sep. (Forecasts)	FY2017 (Forecasts)
Japan	146.5	140.8	(5.6)	(3.9)	70.6	139.2
North America	184.9	197.9	13.0	7.0	111.1	231.6
China	18.4	17.6	(0.7)	(4.1)	9.7	18.3
Other Regions	11.2	11.6	0.4	3.4	6.6	15.9

5. Sales of Major Products

Japan (Strategic Products) (Invoice price basis, Billions of yen)

Brand name Therapeutic indication	FY2015 (A)	FY2016 (B)	(B)-(A)	Change (%)	FY2017 Apr.-Sep. (Forecasts)	FY2017 (Forecasts)
AIMIX® Therapeutic agent for hypertension	14.9	17.1	2.2	14.5	8.6	17.5
LONASEN® Atypical antipsychotic	12.6	12.8	0.2	1.6	6.7	13.2
TRERIEF® Therapeutic agent for Parkinson's disease	13.1	15.1	2.0	15.3	8.1	16.0

Japan (Other Products) (Invoice price sales basis, Billions of yen)

REPLAGAL® Anderson-Fabry disease	10.2	10.7	0.5	4.7	5.6	11.3
AmBisome® Therapeutic agent for systemic fungal infection	4.3	4.4	0.0	0.8	2.2	4.5
AVAPRO® Therapeutic agent for hypertension	10.8	10.3	(0.5)	(4.6)	4.7	8.0
SUREPOST® Rapid-acting insulin secretagogue	3.6	4.3	0.8	21.8	2.5	5.3
METGLUCO® Biguanide oral hypoglycemic	14.7	11.2	(3.5)	(23.9)	5.6	11.3
AMLODIN® Therapeutic agent for hypertension and angina pectoris	16.4	13.0	(3.4)	(20.8)	5.6	10.6
PRORENAL® Vasodilator	8.7	6.5	(2.2)	(24.9)	2.8	5.1
GASMOTIN® Gastroprokinetic	8.4	6.0	(2.4)	(28.2)	2.6	5.0
MEROPEN® Carbapenem antibiotic	6.2	4.3	(1.9)	(31.4)	2.2	4.1

(NHI price basis, Billions of yen)

Trulicity® GLP-1 receptor agonist (Launch:Sep. 2015)	0.7	6.8	6.0	812.3	5.0	11.0

North America (Billions of yen)

Brand name Therapeutic indication	FY2015 (A)	FY2016 (B)	(B)-(A)	Change (%)	FY2017 Apr.-Sep. (Forecasts)	FY2017 (Forecasts)
LATUDA® Atypical antipsychotic	120.4	135.9	15.5	12.9	77.9	158.4
APTIOM® Antiepileptic (Launch: Apr. 2014)	7.6	11.6	3.9	51.3	7.4	16.7
BROVANA® Long-acting beta-agonist	29.9	33.1	3.2	10.6	17.2	34.4
New products for COPD *	—	0.0	0.0	—	0.5	4.1
Ciclesonide Inhaled corticosteroid / corticosteroid nasal spray	7.0	5.1	(1.9)	(27.0)	2.4	4.6
XOPENEX® Short-acting beta-agonist	6.7	5.1	(1.6)	(23.5)	2.3	4.5
LUNESTA® Sedative hypnotic	4.6	(0.5)	(5.1)	—	1.2	2.4
Industrial property revenues	4.8	4.1	(0.8)	(15.9)	0.4	0.9

China (Billions of yen)

Brand name	FY2015 (A)	FY2016 (B)	(B)-(A)	Change (%)	FY2017 Apr.-Sep. (Forecasts)	FY2017 (Forecasts)
MEROPEN®	15.6	15.4	(0.2)	(1.4)	8.5	15.8

Other Regions (Billions of yen)

Brand name	FY2015 (A)	FY2016 (B)	(B)-(A)	Change (%)	FY2017 Apr.-Sep. (Forecasts)	FY2017 (Forecasts)
MEROPEN® (Export)	6.3	6.8	0.4	6.6	4.5	9.2
Industrial property revenues	1.1	1.3	0.2	19.2	0.2	2.5

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

Brand name	FY2015 (A)	FY2016 (B)	(B)-(A)	Change (%)	FY2017 Apr.-Sep. (Forecasts)	FY2017 (Forecasts)
LATUDA®	1,002	1,254	252	25.2	708	1,440
APTIOM®	64	107	43	67.8	68	152
BROVANA®	249	305	56	22.6	156	313
New products for COPD *	—	0	0	—	4	37
Ciclesonide	58	47	(11)	(19.1)	22	42
XOPENEX®	56	47	(8)	(15.2)	21	41
LUNESTA®	38	(5)	(43)	—	11	22
Industrial property revenues	40	37	(3)	(6.7)	4	8

* New products for COPD include UTIBRON™, SEEBRI™, ARCAPTA®, glycopyrronium bromide(SUN-101) which is under review by FDA.

III. Consolidated Balance Sheet

ASSETS

(Billions of yen)

	As of Mar. 31, 2016 (A)	As of Mar. 31, 2017 (B)	(B)-(A)	
[Assets]	707.7	794.0	86.2	
Current assets:	421.6	376.5	(45.1)	
Cash and time deposits	54.9	71.4	16.5	・Change of fund management method ・Cash out for purchase consideration and others
Notes and accounts receivable	107.2	110.9	3.8	
Marketable securities	81.0	34.2	(46.8)	
Inventories	59.6	68.8	9.2	
Deferred tax assets	64.0	61.0	(3.0)	
Short-term loans receivable	48.4	16.7	(31.7)	・Collection of a part of loans
Others	6.5	13.4	7.0	
Allowance for doubtful receivables	(0.0)	(0.0)	(0.0)	
Fixed assets:	286.1	417.5	131.4	
Property, plant and equipment:	61.8	59.3	(2.6)	
Buildings and structures	40.3	38.6	(1.8)	
Machinery, equipment and carriers	7.8	6.8	(1.0)	
Land	6.3	6.3	(0.0)	
Construction in progress	1.5	3.1	1.6	
Others	5.9	4.6	(1.4)	
Intangible assets:	156.6	304.3	147.7	Acquisition of Cynapsus ¥1.3B, Tolero ¥18.6B Amortization (¥5.6B) FX rate (¥0.6B)
Goodwill	77.0	90.6	13.6	
In-process research & development	60.1	194.0	133.8	Acquisition of Cynapsus ¥69.7B, Tolero ¥59.8B FX rate ¥4.3B
Others	19.5	19.8	0.3	
Investments and other assets:	67.7	53.9	(13.8)	
Investment securities	60.4	48.0	(12.4)	Sale of listed stocks, etc. (Japan)
Asset for retirement benefit	0.1	0.6	0.6	
Deferred tax assets	2.3	0.7	(1.6)	
Others	5.0	4.6	(0.4)	
Allowance for doubtful receivables	(0.0)	(0.0)	0.0	
Total assets	707.7	794.0	86.2	

Accounts receivable turnover period (in months)	3.19	3.23

LIABILITIES AND NET ASSETS

(Billions of yen)

	As of Mar. 31, 2016 (A)	As of Mar. 31, 2017 (B)	(B)-(A)
[Liabilities]	261.2	333.3	72.1
Current liabilities:	179.7	228.4	48.7
Notes and accounts payable	12.2	14.5	2.4
Short-term loans payable	1.0	40.0	39.0
Current portion of bonds payable	10.0	10.0	—
Current portion of long-term loans payable	12.0	8.0	(4.0)
Income taxes payable	26.4	8.8	(17.5)
Reserve for bonuses	10.8	11.0	0.2
Reserve for sales returns	9.1	11.3	2.2
Reserve for sales rebates	49.2	65.7	16.4
Accounts payable-other	34.2	37.0	2.8
Others	14.9	22.2	7.3
Long-term liabilities:	81.5	104.8	23.3
Bonds payable	20.0	10.0	(10.0)
Long-term loans payable	8.0	—	(8.0)
Deferred tax liabilities	16.2	32.6	16.4
Liability for retirement benefit	16.2	13.5	(2.7)
Others	21.2	48.8	27.6
[Net assets]	446.5	460.7	14.2
Shareholders' equity:	379.0	401.2	22.2
Common stock	22.4	22.4	—
Capital surplus	15.9	15.9	0.0
Retained earnings	341.4	363.6	22.2
Treasury stock	(0.7)	(0.7)	(0.0)
Accumulated other comprehensive income (loss):	67.5	59.4	(8.0)
Unrealized gains on available-for-sale securities, net of tax	25.3	18.4	(6.9)
Deferred gains or losses on hedges	(0.0)	(0.0)	(0.0)
Foreign currency translation adjustments	48.0	45.7	(2.3)
Remeasurement of defined benefit plans	(5.8)	(4.7)	1.1
Total liabilities and net assets	707.7	794.0	86.2

Total interest-bearing debt
51.0→68.0
[Short term loan +40.0]

・Decrease by payment

・Increase in Latuda sales

・Increase by acquired intangible assets related to Tolero acquisition

・Increase by recorded fair value of contingent consideration liability

FX rate	16/ 3		17/3
USD	¥ 112.6	⇒	¥ 112.2
RMB	¥ 17.4	⇒	¥ 16.3

IV. Quarterly Business Results

(Billions of yen)

	FY2015				FY2016			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Net sales	98.1	100.8	105.6	98.7	103.5	94.6	107.4	106.1
Cost of sales	26.4	25.7	27.0	25.4	23.9	24.0	26.5	25.7
SG&A expenses	67.3	62.7	64.4	67.4	65.0	58.5	63.4	71.9
SG&A expenses less R&D costs	47.2	42.6	45.6	44.3	45.7	40.1	44.0	48.2
R&D costs	20.1	20.1	18.8	23.1	19.3	18.4	19.4	23.7
Operating income (loss)	4.4	12.4	14.2	5.8	14.6	12.2	17.5	8.5
Non-operating income	0.9	1.6	0.6	0.2	1.0	0.4	5.5	(3.3)
Non-operating expenses	0.6	1.3	1.2	1.9	2.9	1.3	(3.0)	0.7
Ordinary income (loss)	4.7	12.8	13.6	4.1	12.7	11.2	26.0	4.5
Extraordinary income	6.0	0.1	(0.0)	0.0	―	3.8	1.0	0.9
Extraordinary loss	0.2	0.0	0.1	1.5	―	10.0	―	2.9
Income (Loss) before income taxes	10.6	12.8	13.5	2.6	12.7	5.0	27.0	2.5
Net income (loss) attributable to owners of the parent	5.9	7.3	10.1	1.4	8.4	2.6	18.6	(0.6)

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

V. Major Consolidated Subsidiaries (As of Mar. 31, 2017)

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	102	47
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.	Tolero Pharmaceuticals, Inc.	Sumitomo Pharmaceuticals (Suzhou) Co., Ltd.
Establishment	January 1984	November 2006	June 2011	December 2003
Ownership	100%	100%	100%	100%
Number of employees	1,723	123	18	676
Businesses	Manufacturing and sales of pharmaceuticals	R&D in the oncology area	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 Mar. 31, 2017
consolidated		6,868	6,697	6,492
non-consolidated		4,126	4,000	3,572
MRs Japan	(excluding managers)	1,350	1,300	1,130
	(including managers)	1,530	1,460	1,260
MRs U.S.	(excluding managers)	700	710	870
	(including managers)	800	810	990
MRs China	(excluding managers)	370	300	340
	(including managers)	470	370	410

Number of contracted MRs is included in MRs.

VI. Shareholder Positioning (As of March 31, 2017)

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

2. Total number of shares outstanding: 397,900,154 (Including number of treasury stock 600,484)

3. Number of shareholders by category:

	Number of shareholders	Number of shares (Thousands)	Percentage of total (%)
Financial institutions	52	81,068	20.38
Securities companies	42	4,465	1.12
Other Japanese corporations	292	235,606	59.21
Corporations outside Japan, etc.	512	52,135	13.10
Individuals and others (Including treasury stock)	20,486	24,623	6.19
Total	21,384	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.	201,134	50.63
Inabata & Co., Ltd.	25,582	6.44
The Master Trust Bank of Japan, Ltd. (Trust account)	17,153	4.32
Japan Trustee Services Bank, Ltd. (Trust account)	10,089	2.54
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	3,687	0.93
Trust & Custody Services Bank, Ltd. (Security investment trust account)	3,477	0.88

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (600,484 stocks).
2: The numbers of shares held are rounded down to the nearest thousand shares.

VII. Development Pipeline (As of May 11, 2017)

■ **Submitted**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Submitted	APTIOM® Oral	eslicarbazepine acetate	(New indication) Epilepsy (Monotherapy)	BIAL	Canada	Submitted in October 2014 Approved indication in Canada: Epilepsy (Adjunctive therapy)
			(New usage :pediatric) Epilepsy (Monotherapy/ Adjunctive therapy)		U.S.	Submitted in March 2017
	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	China	Submitted in December 2015 Approved in the U.S., Canada, Europe, etc.
	SUN-101 Inhalant	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	In-house	U.S.	Submitted in July 2016 From the former Elevation Pharmaceuticals

■ **Phase 3 (1/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 3	SM-13496 Oral	lurasidone hydrochloride	Schizophrenia	In-house	Japan	Approved in the U.S., Canada, Europe, etc.
			Bipolar I depression			Approved in the U.S. and Canada
			Bipolar maintenance			

■ **Phase 3 (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 3	BBI608 Oral	napabucasin	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy)	In-house	U.S., Canada, Japan, etc.	Global clinical study
			Colorectal cancer (Combination therapy)			
			Pancreatic cancer (Combination therapy)		U.S.	
			Non-small cell lung cancer (Combination therapy)			
	SEP-225289 Oral	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	In-house	U.S.	
			Pediatric attention-deficit hyperactivity disorder (ADHD)			
			Binge eating disorder (BED)			
	APL-130277 Sublingunal film	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	In-house	U.S.	From the former Cynapsus Therapeutics
	LONASEN® Oral	blonanserin	(New usage :pediatric) 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 2 / 3**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 2 / 3	EPI-743 Oral	vatiquinone	Leigh syndrome	BioElectron (former Edison Pharma-ceuticals)	Japan	Phase 2 / 3 study completed, development strategy under consideration

■ **Phase 2**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 2	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's disease	BioElectron (former Edison Pharma-ceuticals)	U.S.	Conducted by BioElectron
			Amyotrophic lateral sclerosis (ALS)			
	SEP-363856 Oral	TBD	Schizophrenia	In-house	U.S.	
			Parkinson's disease psychosis			
	alvocidib Injection	alvocidib	Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven)	Sanofi	U.S.	
	DSP-7888 Injection	TBD	Glioblastoma (Combination therapy)	In-house	U.S.	

■ **Phase 1 / 2**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 1 / 2	BBI608 Oral	napabucasin	Solid tumors (Combination therapy)	In-house	U.S., Canada	Phase 2 : Ovarian cancer, Breast cancer, Melanoma, etc.
			Malignant pleural mesothelioma (Combination therapy)		Japan	Phase 2
			Glioblastoma (Combination therapy)		Canada	
			Hepatocellular carcinoma (Combination therapy)		U.S.	
			Solid tumors (Combination therapy)			
			Gastrointestinal cancer (Combination therapy		U.S., Canada	
	BBI503 Oral	amcasertib	Solid tumors (Monotherapy)	In-house	U.S., Canada	Phase 2 : 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 (Monotherapy)	In-house	Japan	Phase 2
			Pediatric malignant gliomas (Monotherapy)			
	WT4869 Injection	TBD	Myelodysplastic syndromes (Monotherapy)	Joint research with Chugai Pharma-ceutical	Japan	Independent development after April 2013

■ **Phase 1 (1/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 1	WT4869 Injection	TBD	Solid tumors (Monotherapy)	Joint research with Chugai Pharma-ceutical	Japan	Independent development after April 2013
	WT2725 Injection	TBD	Solid tumors, Hematologic malignancies (Monotherapy)	Joint research with Chugai Pharma-ceutical	U.S.	Independent development after April 2013
			Solid tumors (Monotherapy)		Japan	
	DSP-2230 Oral	TBD	Neuropathic pain	In-house	U.K., U.S., Japan	
	SEP-363856 Oral	TBD	Schizophrenia	In-house	Japan	
	BBI608 Oral	napabucasin	Pancreatic cancer (Combination therapy)	In-house	U.S.	
			Hematologic malignancies (Monotherapy / Combination therapy)			
			Hepatocellular carcinoma (Combination therapy)		Japan	
	BBI503 Oral	amcasertib	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	In-house	Japan	

■ **Phase 1 (2/2)**

Stage	Brand name/ Product code Formulation	Generic name	Proposed indication	Origin	Country/ Area	Remarks
Phase 1	BBI608+BBI503 Oral	napabucasin amcasertib	Solid tumors (Combination therapy)	In-house	U.S.	
	DSP-7888 Injection	TBD	Solid tumors, Hematologic malignancies (Monotherapy)	In-house	U.S., Canada	
	DSP-1200 Oral	TBD	Treatment-resistant depression	In-house	U.S.	
	DSP-1958 Injection	thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT) (Monotherapy)	In-house	Japan	Development for the use of unapproved and off-labelled drugs
	DSP-6745 Oral	TBD	Parkinson's disease psychosis	In-house	U.S.	
	TP-0903 Oral	TBD	Solid tumors (Monotherapy)	In-house	U.S.	

[Main revisions since the announcement of January 2017]

Blonanserin (Schizophrenia)	Deleted due to approval in China (February 2017)
APTIOM® (Addition of pediatric usage / Epilepsy)	Newly added in Submitted in the U.S. (March 2017)
Dasotraline (Pediatric attention-deficit hyperactivity disorder)	Changed from Phase 2/3 to Phase 3 in the U.S.
Dasotraline (Binge eating disorder)	Changed from Phase 2/3 to Phase 3 in the U.S.
DSP-7888 (Glioblastoma / Combination therapy)	Newly added in Phase 2 in the U.S.
DSP-3748 (Cognitive Impairment Associated with Schizophrenia)	Deleted due to discontinued development 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 3 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 3 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 in January 2014. Daiichi Sankyo submitted an NDA in Venezuela for schizophrenia in December 2014 and in Brazil for schizophrenia and biplolar I depression in September 2015.

[Main revisions since the announcement of January 2017]

None

VIII. Profile of Major Products under Development (As of May 11, 2017)

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 H_1 or muscarinic M_1 receptors.
- Approved country and area:
  Schizophrenia 2010: U.S., 2012: Canada, 2013: Switzerland, 2014: Europe and Australia, 2016: Taiwan, Russia, Singapore, Thailand and Hong Kong
  Bipolar I depression 2013: U.S., 2014: Canada
- Development stage:

Stage	Proposed indication	Country/ Area	Partners
Submitted	Schizophrenia	Venezuela	Daiichi Sankyo
	Schizophrenia, Bipolar I depression	Brazil	
	Schizophrenia	Turkey	In-house
	Schizophrenia	China	
	Bipolar I depression,	Taiwan	Standard Chem. & Pharm.
Phase 3	Schizophrenia	Japan	In-house
	Bipolar I depression, Bipolar maintenance	Japan	

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

- Developed in-house (Sunovion Pharmaceuticals Inc., From the former Elevation Pharmaceuticals)
- 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 approximately 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: NDA submitted in the U.S. in July 2016

napabucasin (BBI608) Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI608 is an orally-administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways by targeting STAT3. By inhibiting pathways involved in the maintenance of cancer stemness, 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 STAT3 pathways, Nanog pathways and β-catenin pathways in pre-clinical studies.

・ Development stage:

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 3	Gastric and Gastro-esophageal junction adenocarcinoma (combination therapy)	U.S., Canada, Japan, etc.	paclitaxel	BRIGHTER
	Colorectal cancer (combination therapy)	U.S., Canada, Japan, etc.	FOLFIRI[*2], FOLFIRI[*2] + bevacizumab	CanStem303C
	Pancreatic cancer (combination therapy)	U.S.	gemcitabine + nab-paclitaxel	CanStem111P
	Non-small cell lung cancer (combination therapy)	U.S.	paclitaxel	CanStem43L
Phase 2	Colorectal cancer (combination therapy)	U.S., Canada	cetuximab, panitumumab, capecitabine	224
Phase 1 / 2	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
	Gastrointestinal cancer (combination therapy)	U.S., Canada	FOLFOX[*2], FOLFOX[*2] + bevacizumab, CAPOX[*2], FOLFIRI[*2], FOLFIRI[*2] + bevacizumab, regorafenib, irinotecan	246
Phase 1	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

*1 Phase 2 : 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 3 in the U.S.
Pediatric attention-deficit hyperactivity disorder (ADHD): Phase 3 in the U.S.
Binge eating disorder (BED): Phase 3 in the U.S.

apomorphine hydrochloride (APL-130277)　Parkinson's disease

- Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics)
- APL-130277 is a sublingual film formulation including apomorphine, a dopamine agonist, which is the only molecule approved in the U.S. for acute intermittent treatment of OFF episodes associated with Parkinson's disease. It is designed to rapidly, safely and reliably convert a Parkinson's disease patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine.
- Development stage:　Phase 3 in the U.S.

vatiquinone (EPI-743)　Mitochondrial disease

- In-licensed from BioElectron Technology Corporation (former Edison Pharmaceuticals, Inc.)
- 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 2 / 3 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 2 in Japan for NASH, Phase 2 for PBC is under consideration.

DSP-6952　IBS with constipation, Chronic idiopathic constipation

- Developed in-house
- DSP-6952 is an enterokinetic agent with a high affinity for serotonin 5-HT_4 receptor where it has partial agonist effects. DSP-6952 is expected to be effective for IBS with constipation and chronic idiopathic constipation by increasing complete spontaneous bowel movement.
- Development stage:　Phase 2 in Japan

amcasertib (BBI503)　Cancer

- Developed in-house (Boston Biomedical, Inc.)
- BBI503 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways, including Nanog, by targeting stemness kinases.　By inhibiting pathways involved in the maintenance of cancer stemness, 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 2	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

Stage	Proposed indication	Country/ Area	Combination products	Study number
Phase 1 / 2	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
Phase 1	Solid tumors (monotherapy), Hepatocellular carcinoma (combination therapy)	Japan	sorafenib	DA101003
	Solid tumors (combination therapy)	U.S.	napabucasin	401-101

* Phase 2 : Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

SB623 Stroke

- In-licensed from and co-developed with SanBio, Inc.
- SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. SB623 is expected to be effective for chronic stroke that has no effective treatments available, by promoting regeneration of central nerve cells. Unlike autologous cell therapies that require individualized cell preparation at the clinical site, 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 2 in the U.S.

EPI-589 Neurodegenerative diseases

- In-licensed from BioElectron Technology Corporation (former Edison Pharmaceuticals, Inc.)
- 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's disease: Phase 2 in the U.S. by BioElectron Technology Corporation
  Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S. by BioElectron Technology Corporation

SEP-363856 Schizophrenia, Parkinson's disease psychosis

- Developed in-house (Sunovion Pharmaceuticals Inc.)
- SEP-363856 is a psychotropic agent with a novel mechanism of action, and doesn't show affinity to dopamine D_2 receptors. The molecular target(s) responsible for the profile of effects is unknown, but may include agonist effects at serotonin 5-HT_{1A} and TAAR1 (trace amine-associated receptor 1) receptors. Results obtained with the preclinical models suggest that SEP-363856 may be able to treat the positive and negative symptoms of schizophrenia as well as Parkinson's disease psychosis. SEP-363856 is expected to have high efficacy in the treatment of schizophrenia and Parkinson's disease psychosis, while improving patients' QOL.
- Development stage:
  Schizophrenia: Phase 2 in the U.S.
  Parkinson's disease psychosis: Phase 2 in the U.S.
  Schizophrenia: Phase 1 in Japan

alvocidib Cancer

- In-licensed from Sanofi S.A.
- Alvocidib targets cyclin-dependent kinase (CDK) 9, a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.
- Development stage:
  Acute myeloid leukemia (AML) (Combination therapy / Biomarker-driven): Phase 2 in the U.S.

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, improved efficacy over that observed with a CTL-inducing peptide alone may be achieved. DSP-7888 is expected to be an option for a wide range of patients.
- Development stage:
  Glioblastoma (combination therapy): Phase 2 in the U.S.
  Myelodysplastic syndromes (MDS) (monotherapy): Phase 2 of Phase 1 / 2 in Japan
  Pediatric malignant gliomas (monotherapy): Phase 2 of Phase 1 / 2 in Japan
  Solid tumors, Hematologic malignancies (monotherapy) : Phase 1 in the U.S. and Canada

WT4869 Cancer

- Developed in-house (Joint research with Chugai Pharmaceutical Co.,Ltd.)
- 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 cancer cells.
- Development stage:
  Myelodysplastic syndromes (MDS) (monotherapy): Phase 1 / 2 in Japan
  Solid tumors (monotherapy): Phase 1 in Japan

WT2725 Cancer

- Developed in-house (Joint research with Chugai Pharmaceutical Co.,Ltd.)
- 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 cancer cells.
- Development stage:
  Solid tumors, Hematologic malignancies (monotherapy): Phase 1 in the U.S.
  Solid tumors (monotherapy): Phase 1 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 1 in the U.K., the U.S. and Japan

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 stronger improvement of depressive symptoms and cognitive function, compared with the existing SDAs (serotonin-dopamine antagonists). 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 1 in the U.S.

DSP-6745 Parkinson's disease psychosis

- Developed in-house
- DSP-6745 is a serotonin 5-HT_{2A} and serotonin 5-HT_{2C} receptors dual antagonist, which is expected to be effective for Parkinson's disease psychosis and one or more Parkinson's disease non-motor symptoms (depression, anxiety, or cognitive impairment). In addition, DSP-6745 has negligible affinity for dopamine D_2 receptors.
- Development stage: Phase 1 in the U.S.

TP-0903 Cancer

- Developed in-house (Tolero Pharmaceuticals, Inc.)
- TP-0903 is AXL receptor tyrosine kinase inhibitor. AXL is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 is expected to be an anti-cancer agent for a variety of cancer types.
- Development stage:
  Solid tumors (monotherapy): Phase 1 in the U.S.