

Financial Results for the Nine Month
Period Ended December 31, 2014
(Apr. 1 to Dec. 31, 2014)

January 29, 2015
Sumitomo Dainippon Pharma Co., Ltd.

Financial Results for FY2014 Apr.-Dec.

Billions of yen

	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change			FY2014	
			Value		Percentage (%)	Previous forecasts *	Progress (%)
				Exchange Impact			
Net sales	284.5	279.1	(5.4)	7.9	(1.9)	366.0	76.3
Cost of sales	78.1	75.1	(3.0)	0.7	(3.9)	100.5	74.7
Gross profit	206.4	204.0	(2.4)	7.2	(1.1)	265.5	76.9
SG&A expenses	171.7	181.2	9.5	7.0	5.5	245.5	73.8
SG&A expenses less R&D costs	122.8	130.0	7.3	5.4	5.9	173.5	74.9
R&D Costs	49.0	51.2	2.2	1.6	4.5	72.0	71.1
Operating income	34.7	22.8	(11.8)	0.1	(34.2)	20.0	114.1
Ordinary income	34.3	22.5	(11.8)		(34.4)	19.5	115.4
Net income	19.2	19.0	(0.2)		(0.9)	14.0	135.7
E B I T D A	55.2	37.3				39.0	

* The forecasts for FY2014 have been revised.

Exchange Rate:

FY2013 3Q

: 1US\$ = ¥ 99.4, 1RMB = ¥16.2

FY2014 3Q

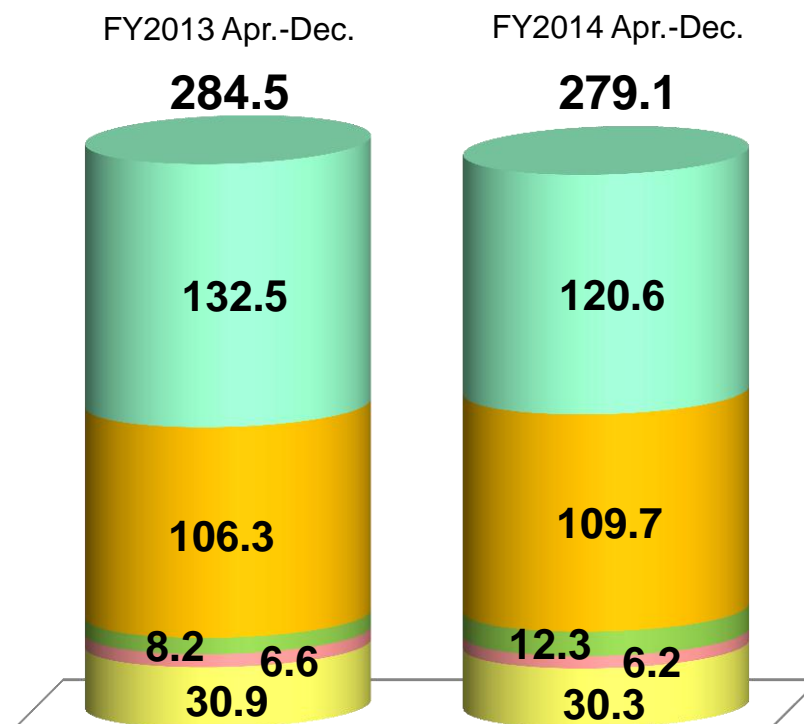
: 1US\$ = ¥106.7, 1RMB = ¥17.3

3Q Net Sales by Segment

Billions of yen

Change

	Value	Percentage
	(5.4)	(1.9)%



Japan	(11.9)	(9.0)%
North America	3.4	3.2%
China	4.2	50.9%
Other Regions	(0.4)	(5.8)%
Other Business	(0.7)	(2.2)%

Overseas Sales **42.6 %** **46.1 %**

【 Japan 】 Effect from NHI price revision and decrease in long-listed products
【 North America 】 Growth of LATUDA[®] and weak yen offset drop in LUNESTA[®]
【 China 】 Strong sales of MEROPEN[®]

3Q Sales in Japan

Billions of yen

	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change		FY2014	
			Value	Percentage (%)	Previous forecasts *	Progress (%)
AIMIX®	4.9	9.1	4.2	86.5	12.8	71.3
AVAPRO®	9.4	8.7	(0.7)	(7.6)	11.6	74.7
LONASEN®	9.3	8.5	(0.8)	(8.5)	12.3	69.4
TRERIEF®	6.8	8.5	1.7	24.6	12.1	70.3
Strategic Products Total	30.4	34.8	4.4	14.5	48.8	71.4
METGLUCO®	11.7	12.7	1.1	9.1	17.1	74.4
SUREPOST®	1.2	1.7	0.5	43.1	2.5	67.8
AmBisome®	3.8	3.4	(0.5)	(12.4)	4.9	68.8
MIRIPLA®	0.9	0.7	(0.2)	(22.8)	1.0	71.0
REPLAGAL®	7.7	7.5	(0.2)	(2.6)	10.0	75.3
New / Specialty Products Total	25.3	26.0	0.7	2.7	35.5	73.3
AMLODIN®	21.2	15.0	(6.2)	(29.3)	19.7	76.2
GASMOTIN®	11.9	8.1	(3.8)	(32.1)	10.5	77.0
PRORENAL®	10.7	8.2	(2.6)	(24.0)	10.5	77.6
MEROPEN®	7.8	6.2	(1.6)	(21.0)	8.1	76.2
Others	25.1	22.4	(2.7)	(10.8)	26.9	83.1
Japan Total	132.5	120.6	(11.9)	(9.0)	160.0	75.4

Note: Sales figures are before reduction of rebates

* Forecasts of some products have been revised.

3Q Sales in North America & China

	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	
						Value	Exchange Rate Impact
North America	(Million \$)			(Billion yen)			
LATUDA®	289	555	266	28.7	59.3	30.6	4.1
BROVANA®	124	146	23	12.3	15.6	3.4	1.1
LUNESTA®	432	90	(343)	42.9	9.6	(33.4)	0.7
XOPENEX®	95	64	(31)	9.4	6.8	(2.6)	0.5
Ciclesonide	65	51	(14)	6.5	5.4	(1.1)	0.4
APTiom®	—	15	15	—	1.6	1.6	—
Industrial property revenues	32	78	47	3.1	8.4	5.2	0.3
Others	33	29	(4)	3.3	3.1	(0.2)	0.2
Total	1,070	1,028	(42)	106.3	109.7	3.4	7.2
China	(Million RMB)			(Billion yen)			
MEROPEN®	409	591	182	6.6	10.2	3.6	0.6
Others	93	122	30	1.5	2.1	0.6	0.1
Total	502	713	212	8.2	12.3	4.2	0.7

FY2014		
Previous forecasts *		Yen-based Progress
(Million \$)	(Billion yen)	(%)
749	78.7	75.3
207	21.8	71.7
88	9.3	103.0
62	6.6	103.3
54	5.6	96.6
35	3.6	43.9
87	9.1	91.8
41	4.3	71.7
1,324	139.0	78.9
(Million RMB)	(Billion yen)	(%)
823	14.0	72.8
159	2.7	78.2
982	16.7	73.7

Exchange Rate:

FY2013 3Q

: 1US\$ = ¥ 99.4, 1RMB = ¥16.2

FY2014 3Q

: 1US\$ = ¥106.7, 1RMB = ¥17.3

* Forecasts of some products have been revised.

3Q Segment Breakdown for North America

< Excluding amortization of patent rights and goodwill, etc. >

	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
Net sales	1,070	1,028	(42)	106.3	109.7	3.4	7.2
Cost of sales	114	85	(28)	11.3	9.1	(2.2)	0.6
Gross profit	956	943	(14)	95.0	100.6	5.6	6.6
SG&A expenses	533	629	96	52.9	67.1	14.1	4.5
Income (loss) of Segment	424	314	(110)	42.1	33.5	(8.6)	2.0

< Amortization of patent rights and goodwill, etc. >

	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	Exchange Rate Impact
	(Million \$)			(Billion yen)			
SG&A expenses	140	67	(73)	14.0	7.1	(6.8)	0.5
Income (loss) of Segment	(140)	(67)	73	(14.0)	(7.1)	6.8	(0.5)

Exchange Rate:

FY2013 3Q : 1US\$ = ¥ 99.4

FY2014 3Q : 1US\$ = ¥106.7

Segment Information

Billions of yen

		Pharmaceuticals Business						Other Business	Total
		Japan	North America※1	Amortization※2	China	Other Regions	Subtotal		
FY2014 3Q Results	Net sales (Sales to customers)	120.6	109.7	—	12.3	6.2	248.9	30.3	279.1
	Cost of sales	36.3	9.1	—	2.1	3.7	51.2	23.9	75.1
	Gross profit	84.5	100.6	—	10.2	2.5	197.8	6.2	204.0
	SG&A expenses less R&D costs	43.7	67.1	7.1	5.7	1.8	125.4	4.6	130.0
	Income (loss) of Segment	40.8	33.5	(7.1)	4.5	0.7	72.4	1.7	74.0
	R&D costs							50.6	0.6
	Operating income							21.8	1.0
FY2013 3Q Results	Net sales (Sales to customers)	132.5	106.3	—	8.2	6.6	253.6	30.9	284.5
	Cost of sales	37.3	11.3	—	1.9	3.4	53.8	24.3	78.1
	Gross profit	95.3	95.0	—	6.3	3.2	199.8	6.6	206.4
	SG&A expenses less R&D costs	46.1	52.9	14.0	4.6	0.7	118.3	4.5	122.8
	Income (loss) of Segment	49.3	42.1	(14.0)	1.7	2.5	81.6	2.1	83.6
	R&D costs							48.3	0.6
	Operating income							33.2	1.4
Change	Net sales (Sales to customers)	(11.9)	3.4	—	4.2	(0.4)	(4.7)	(0.7)	(5.4)
	SG&A expenses less R&D costs	(2.3)	14.1	(6.8)	1.1	1.1	7.2	0.1	7.3
	Income (loss) of Segment	(8.5)	(8.6)	6.8	2.8	(1.8)	(9.2)	(0.4)	(9.6)
	R&D costs							2.2	0.0
	Operating income							(11.4)	(0.4)

※ 1. Excluding amortization of patent rights and goodwill, etc.

※ 2. Amortization of patent rights and goodwill, etc.

Exchange Rate:

FY2013 3Q : 1US\$ = ¥ 99.4, 1RMB = ¥16.2

FY2014 3Q : 1US\$ = ¥106.7, 1RMB = ¥17.3

3Q Ordinary income & Net income

Billions of yen

	FY2013 Apr.-Dec.	FY2014 Apr.-Dec.	Change	
			Value	Percentage(%)
Operating Income	34.7	22.8	(11.8)	(34.2)
Non-operating income and expenses	(0.3)	(0.3)	0.0	
Ordinary income	34.3	22.5	(11.8)	(34.4)
Extraordinary income	3.8	17.7	13.8	
Gain on sales of property, plant and equipment	—	16.0		
Compensation income for damage	—	1.7		
Gain on sales of investment securities	2.8	—		
Fair value adjustment of contingent consideration	1.1	—		
Extraordinary loss	6.4	5.9	(0.5)	
Impairment loss	4.6	5.1		
Business structure improvement expenses	1.8	0.8		
Income taxes	12.6	15.3	2.7	
Net income	19.2	19.0	(0.2)	(0.9)

Revised Financial Forecasts for FY2014

Billions of yen

	FY2013 (a)	FY2014 Previous Forecasts (b)	FY2014 Revised Forecasts (c)	Change (c)-(b)	
				Value	Exchange Rate Impact
Net sales	387.7	366.0	371.0	5.0	5.7
Cost of sales	104.1	100.5	101.5	1.0	0.6
Gross profit	283.6	265.5	269.5	4.0	5.1
SG&A expenses	241.5	245.5	249.5	4.0	5.0
SG&A expenses less R&D costs	171.6	173.5	176.0	2.5	3.7
R&D costs	69.8	72.0	73.5	1.5	1.3
Operating income	42.1	20.0	20.0	—	0.1
Ordinary income	40.6	19.5	20.0	0.5	
Net income	20.1	14.0	12.5	(1.5)	
EBITDA	68.1	39.0	39.5	0.5	

Exchange Rate:

FY2013 : 1US\$ = ¥100.2, 1RMB= ¥16.4

FY2014 Previous forecast : 1US\$ = ¥105.0, 1RMB = ¥17.0

FY2014 Revised forecast : 1US\$ = ¥108.8, 1RMB = ¥17.6

Outline of Revised Forecast for FY2014

■ Net Sales: Revised up ¥5 B (Consolidated)

- Japan segment: Revised down ¥1.5 B ¥160B⇒¥158.5B

Product	Previous forecast	Revised forecast	Variance
LONASEN®	¥12.3B	11.6B	-0.7B
AmBisome®	4.9B	4.5B	-0.4B

- North America segment: Revised up ¥7 B ¥139B⇒¥146B

Product	Previous forecast	Revised forecast	Variance
LATUDA®	¥78.7B	82.7B	4.0B
XOPENEX®	6.6B	8.5B	1.9B
LUNESTA®	9.3B	10.9B	1.6B
APTiom®	3.6B	2.3B	-1.3B

- China: Unchanged ¥16.7B
- Other: Revised down ¥1B ¥42B⇒¥41B

■ Expenses: SG & A expenses Up ¥4 B Operating income is unchanged.

✓ Increase of expenses due to weaker yen

■ Net Income: Revised down ¥1.5B ¥14.0B ⇒ ¥12.5B

- ✓ Reversal of deferred tax assets due to anticipated reduction of the corporate tax rate

Sales by Product in Japan Segment

Billions of yen

	FY2013	FY2014 Previous Forecasts	FY2014 Revised Forecasts	Change
AIMIX®	6.9	12.8	12.8	—
AVAPRO®	12.1	11.6	11.6	—
LONASEN®	12.6	12.3	11.6	(0.7)
TRERIEF®	9.5	12.1	12.1	—
Strategic products total	41.1	48.8	48.1	(0.7)
METGLUCO®	15.8	17.1	17.1	—
SUREPOST®	1.7	2.5	2.5	—
AmBisome®	4.8	4.9	4.5	(0.4)
MIRIPLA®	1.2	1.0	1.0	—
REPLAGAL®	9.8	10.0	10.0	—
New / Specialty products total	33.2	35.5	35.1	(0.4)
AMLODIN®	27.0	19.7	19.7	—
GASMOTIN®	15.0	10.5	10.5	—
PRORENAL®	13.5	10.5	10.5	—
MEROPEN®	9.8	8.1	8.1	—
Others	32.2	26.9	26.5	(0.4)
Japan total	171.9	160.0	158.5	(1.5)

Note: Sales figures are before reduction of rebates.

Sales by Product in North America and China Segments

	FY2013	FY2014 Previous Forecasts	FY2014 Revised Forecasts	Change	FY2013	FY2014 Previous Forecasts	FY2014 Revised Forecasts	Change
North America	(Million \$)				(Billion yen)			
LATUDA®	421	749	760	11	42.2	78.7	82.7	4.0
BROVANA®	168	207	198	(9)	16.8	21.8	21.5	(0.3)
LUNESTA®	579	88	100	12	58.0	9.3	10.9	1.6
XOPENEX®	121	62	78	16	12.1	6.6	8.5	1.9
Ciclesonide	81	54	61	7	8.2	5.6	6.6	1.0
APTIOM®	—	35	21	(14)	—	3.6	2.3	(1.3)
Industrial property revenues	41	87	87	—	4.1	9.1	9.5	0.4
Others	40	41	38	(3)	4.0	4.3	4.0	(0.3)
Total	1,450	1,324	1,343	19	145.3	139.0	146.0	7.0
China	(Million RMB)				(Billion yen)			
MEROPEN®	597	823	794	(29)	9.8	14.0	14.0	—
Others	131	159	153	(6)	2.1	2.7	2.7	—
Total	727	982	947	(35)	11.9	16.7	16.7	—

Exchange Rate:

FY2014 Previous forecast : 1US\$ = ¥105.0, 1RMB = ¥17.0

FY2014 Revised forecast : 1US\$ = ¥108.8, 1RMB = ¥17.6

Revised Forecasts for FY2014 (by Segment)

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America※1	Amortization※2	China	Other Regions	Subtotal			
Revised Forecasts	FY2014	Net sales (Sales to customers)	158.5	146.0		16.7	8.8	330.0	41.0	371.0
		Cost of sales	48.0	12.4		3.3	5.5	69.2	32.3	101.5
		Gross profit	110.6	133.6		13.4	3.3	260.9	8.6	269.5
		SG&A expenses less R&D costs	59.5	91.0	9.4	7.4	2.4	169.7	6.3	176.0
		Income (loss) of Segment	51.1	42.6	(9.4)	6.0	0.9	91.2	2.3	93.5
		R&D costs	72.5						1.0	73.5
		Operating income	18.7						1.3	20.0
Previous Forecasts	FY2014	Net sales (Sales to customers)	160.0	139.0	—	16.7	8.3	324.0	42.0	366.0
		Cost of sales	48.1	11.0	—	3.3	5.1	67.5	33.0	100.5
		Gross profit	112.0	128.0	—	13.4	3.2	256.6	8.9	265.5
		SG&A expenses less R&D costs	59.5	89.0	9.4	6.8	2.4	167.1	6.4	173.5
		Income (loss) of Segment	52.5	39.0	(9.4)	6.6	0.8	89.5	2.5	92.0
		R&D costs	71.0						1.0	72.0
		Operating income	18.5						1.5	20.0
Change		Net sales (Sales to customers)	(1.5)	7.0	—	—	0.5	6.0	(1.0)	5.0
		SG&A expenses less R&D costs	—	2.0	—	0.6	—	2.6	(0.1)	2.5
		Income (loss) of Segment	(1.4)	3.6	—	(0.6)	0.1	1.7	(0.2)	1.5
		R&D costs	1.5						—	1.5
		Operating income	0.2						(0.2)	—

※ 1. Excluding amortization of patent rights and goodwill, etc.

※ 2. Amortization of patent rights and goodwill, etc.

Exchange Rate:

FY2014 Previous forecast : 1US\$ = ¥105.0, 1RMB = ¥17.0

FY2014 Revised forecast : 1US\$ = ¥108.8, 1RMB = ¥17.6 12

Development Pipeline (1) (as of January 29, 2015)

Psychiatry & Neurology Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
APTiom® (SEP-0002093)	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	U.S. / Canada				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
LATUDA® (SM-13496)	lurasidone hydrochloride	Schizophrenia	Japan / China				
		Bipolar I depression, Bipolar maintenance	Japan				
		(New indication) Bipolar maintenance	U.S. / Europe, etc.				
		(New indication) MDD with mixed features	U.S. / Europe, etc.				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	TBD	Leigh syndrome	Japan				※1
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
SB623	TBD	Chronic stroke	U.S.				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				

※1 Phase II/III study

Development Pipeline (2) (as of January 29, 2015)

Oncology Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
BBI608	TBD	Colorectal cancer (Monotherapy) (Global clinical trial)	U.S. / Canada / Japan, etc.	Accrual of new patients has been stopped			
		Gastric cancer, Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy)	U.S. / Canada			※1	
		Hepatocellular carcinoma (Combination therapy)	U.S.		※2		
		Glioblastoma (Combination therapy)	Canada		※2		
		Malignant pleural mesothelioma (Combination therapy)	Japan		※2		
		Gastrointestinal cancer (Combination therapy)	U.S. / Canada				
		Pancreatic cancer (Combination therapy)	U.S.				
		Hematologic malignancies (Monotherapy / Combination therapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy)	Japan				
BBI503	TBD	Solid tumors (Monotherapy)	U.S. / Canada			※1	
		Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stromal tumor (Monotherapy)	Canada				
		Hepatocellular carcinoma (Combination therapy)	U.S.		※2		
		Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan				
WT4869	TBD	Myelodysplastic syndromes	Japan		※2		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				

※1 Phase II of Phase I/II study

※2 Phase I of Phase I/II study

Revisions since the previous announcement are in red.

Development Pipeline (3) (as of January 29, 2015)

Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUN-101	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				

Cardiovascular / Diabetes Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (Combination therapies including DPP-4 inhibitors)	Japan				

Other Areas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

 Approved

Revisions since the previous announcement are in red.

BBI608 - Clinical development progress (1)

Development status

Development stage	Development location	Proposed indication	Combination products	Study number	Initiation of study
Phase III	U.S. / Canada / Japan, etc.	Gastric cancer, Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical trial)	paclitaxel	BBI608-336 (BRIGHTER)	1Q 2014
Phase II	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, or capecitabine	BBI608-224	1Q 2012
Phase II	U.S. / Canada	Solid tumors* ¹ (Combination therapy)	paclitaxel	BBI608-201	2Q 2011
Phase I	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX* ² , FOLFOX* ² and bevacizumab, CAPOX* ² , FOLFIRI* ² , FOLFIRI* ² and bevacizumab, or regorafenib	BBI608-246	4Q 2013
Phase I	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	3Q 2014
Phase I	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine and nab-paclitaxel	BBI608-118	3Q 2014
Phase I	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	4Q 2014
Phase I	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin and pemetrexed	D8807005	4Q 2014
Phase I	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone	BBI608-103HEME	4Q 2014
Phase I	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	4Q 2014

*1 : Ovarian cancer, Breast cancer, Non-small cell lung cancer, Melanoma, etc.

*2 : FOLFOX (Combination with fluorouracil, leucovorin, oxaliplatin)

CAPOX (Combination with capecitabine, oxaliplatin)

FOLFIRI (Combination with fluorouracil, leucovorin, irinotecan)

Submission plan

North America and Japan : Target submission date FY2017
(Proposed indication : Gastric cancer, Gastro-esophageal junction adenocarcinoma)

Revisions since the previous announcement are in red.

BBI608 - Clinical development progress (2)

◆ Data analysis progress of Phase III global clinical trial for advanced colorectal cancer (CO.23 study)

- The second interim analysis including secondary efficacy parameters such as Disease Control Rate (DCR) has been conducted by NCIC-CTG with 217 patients enrolled by March 28, 2014.
- Final results including Overall Survival (OS) and Biomarker will be made available in 1H 2015. NCIC-CTG retains publication right.



Further development plan for colorectal cancer will be determined based on the final results of CO.23 as well as other Phase II studies.

◆ Publication of pre-clinical data on BBI608

- An article entitled “Suppression of Cancer Relapse and Metastasis by Inhibiting Cancer Stemness” was published in early edition of Proceedings of National Academy of Sciences of the United States of America (PNAS) in January 2015.
- Key points:
 - ✓ BBI608 inhibited gene transcription driven by Stat3 and blocked cancer stemness properties.
 - ✓ BBI608 effectively blocked cancer relapse and metastasis in xenografted human cancers.
 - ✓ These data demonstrate targeting cancer stemness as a novel approach to develop the next generation of cancer therapeutics to suppress cancer relapse and metastasis.

*For details of the article, please refer to the web page of PNAS.

(<http://www.pnas.org/content/early/2015/01/15/1424171112.abstract>)

BBI503 - Clinical development progress

Development status

Development stage	Development location	Proposed indication	Combination products	Study number	Initiation of study
Phase II	U.S. / Canada	Solid tumors*1 (Monotherapy)	—	BBI503-101	1Q 2012
Phase II	Canada	Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stromal tumor (Monotherapy)	—	BBI503-205a, 205b, 205c	2Q 2014
Phase I	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	3Q 2014
Phase I	Japan	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	sorafenib	DA101003	1Q 2015

*1 Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.

Submission plan

North America and Japan : Target submission date FY2017
(Cancer type: TBD)

Revisions since the previous announcement are in red.

LATUDA®(Lurasidone) – Clinical development progress

U.S. (Schizophrenia)

Key Current (or Ongoing) Studies in Schizophrenia

- Low-dose Schizophrenia Study with 20mg/day: initiated in 2Q 2013, in progress
- Pediatric (6-17 yrs) Efficacy Study: initiated in 3Q 2013, in progress

Outside the U.S.

U.S. (Bipolar disorder, others)

- **Bipolar maintenance**
 - Phase III study initiated in 2Q 2011
- **MDD with mixed features**
 - Phase III study initiated in 2Q 2011
- **IM depot formulation**
 - Pre-clinical stage

Development location	Indication, Proposed indication	Development status	Partners
Japan	Schizophrenia Bipolar I depression , Bipolar maintenance	Phase III Phase III	In-house
China	Schizophrenia	Phase III	In-house
Europe	Bipolar disorder	Phase III	Takeda Pharmaceutical
Russia	Schizophrenia	Submitted in 4Q 2014	Takeda Pharmaceutical
Turkey	Schizophrenia	Submitted in 4Q 2014	Takeda Pharmaceutical
Taiwan	Schizophrenia	Submitted in 4Q 2013	Standard Chem. & Pharm
Thailand	Schizophrenia	Submitted in 4Q 2014	DKSH
Hong Kong	Schizophrenia	Submitted in 4Q 2014	DKSH
Venezuela	Schizophrenia	Submitted in 4Q 2014	Daiichi Sankyo

Approved countries / areas

- **Schizophrenia:** U.S., Canada, Europe and Australia
- **Bipolar I depression:** U.S. and Canada

Disclaimer Regarding Forward-looking Statements

The statements made in this presentation material are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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