Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

Financial Results for 2Q FY2016
(April 1 to September 30, 2016)

October 28, 2016

Masayo Tada, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

Financial Results for 2Q FY2016

Financial Results for FY2016 Apr.-Sep.

Billions of yen

	FY2015 Apr.-Sep.	FY2016 Apr.-Sep.	Change			FY2016 2Q (Apr.-Sep.)		FY2016	
			Value	FX rate impact	%	Forecasts on May 11	Achievement %	Forecasts on May 11	Progress %
Net sales	198.9	198.1	(0.8)	(16.5)	(0.4)	199.0	99.5	410.0	48.3
Cost of sales	52.1	47.9	(4.2)	* (4.0)	(8.1)	49.0	97.7	99.5	48.1
Gross profit	146.8	150.2	3.4	(12.5)	2.3	150.0	100.1	310.5	48.4
SG&A expenses	130.0	123.5	(6.5)	(11.7)	(5.0)	134.0	92.1	270.5	45.6
SG&A expenses less R&D costs	89.8	85.7	(4.1)	(8.2)	(4.5)	93.5	91.7	186.0	46.1
R&D Costs	40.2	37.7	(2.5)	(3.5)	(6.1)	40.5	93.2	84.5	44.7
Operating income	16.8	26.7	9.9	(0.8)	58.7	16.0	167.1	40.0	66.8
Ordinary income	17.5	23.9	6.4		36.4	16.0	149.3	40.0	59.7
Extraordinary income (loss)	5.9	(6.2)	(12.1)			–		2.5	
Net income attributable to owners of the parent	13.2	10.9	(2.3)		(17.3)	8.0	136.5	25.0	43.7
E B I T D A	27.7	33.1	5.4		19.6	26.0		61.0	

＊ The number includes downward impact on cost of sales because unrealized profit of inventory on FY2015 FX rate realized in this period with stronger yen.

FX rates:
FY2015 2Q Results : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q Results : 1US$ = ¥ 105.2, 1RMB = ¥15.9
FY2016 Previous forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

Sales of Major Products in Japan

Billions of yen

	FY2015 Apr.-Sep.	FY2016 Apr.-Sep.	Change		2016 2Q (Apr.-Sep.)	
			Value	%	Forecasts on May 11	Achievement %
AIMIX®	7.0	8.3	1.3	18.9	7.9	105.4
LONASEN®	6.3	6.7	0.3	5.2	6.9	96.4
TRERIEF®	6.5	7.6	1.1	17.0	6.9	109.8
Strategic Products Total	19.8	22.6	2.8	13.9	21.7	103.9
REPLAGAL®	5.2	5.3	0.1	2.1	5.2	102.1
AmBisome®	2.1	2.2	0.1	3.4	2.2	100.7
AVAPRO®	5.4	5.3	(0.1)	(2.5)	4.8	109.9
SUREPOST®	1.7	2.2	0.5	29.4	2.2	98.1
METGLUCO®	8.4	5.7	(2.7)	(32.3)	5.0	113.9
AMLODIN®	8.4	6.7	(1.6)	(19.5)	6.4	105.3
PRORENAL®	4.6	3.5	(1.1)	(23.9)	3.6	96.4
GASMOTIN®	4.4	3.2	(1.2)	(26.7)	3.2	99.7
MEROPEN®	3.3	2.3	(1.0)	(31.3)	2.4	95.5
Others	10.8	11.6	0.9	8.2	11.8	98.7
Other Products Total	54.2	48.0	(6.2)	(11.5)	46.8	102.5
Japan Total	74.0	70.5	(3.5)	(4.7)	68.5	103.0

Note: Sales of each product above are shown by invoice price sales basis.

Sales of Major Products in North America & China

	FY2015 Apr.-Sep.	FY2016 Apr.-Sep.	Change	FY2015 Apr.-Sep.	FY2016 Apr.-Sep.	Change			FY2016 2Q (Apr.-Sep.)		
						Value	rate	FX rate impact	Forecasts on May 11		Yen-based Achievement
North America	Million $			Billion yen			%	Billion yen	Million $	Billion yen	%
LATUDA®	472	584	112	57.6	61.4	3.9	6.7	(9.7)	558	61.4	100.0
APTIOM®	27	47	20	3.3	5.0	1.7	50.8	(0.8)	54	6.0	82.9
BROVANA®	120	153	33	14.6	16.1	1.5	10.3	(2.5)	130	14.3	112.5
Ciclesonide	31	23	(8)	3.7	2.4	(1.3)	(36.1)	(0.4)	28	3.1	76.9
XOPENEX®	29	25	(4)	3.5	2.6	(0.9)	(25.9)	(0.4)	25	2.8	93.4
LUNESTA®	22	(5)	(27)	2.7	(0.5)	(3.2)	–	0.1	13	1.5	–
Others	39	42	3	4.8	4.4	(0.3)	(7.3)	(0.7)	46	5.1	86.5
Total	740	868	129	90.2	91.4	1.2	1.3	(14.5)	856	94.2	97.0
China	Million RMB			Billion yen			%	Billion yen	Million RMB	Billion yen	%
MEROPEN®	417	505	88	8.1	8.0	(0.1)	(0.8)	(1.8)	418	7.1	113.2
Others	76	71	(4)	1.5	1.1	(0.3)	(22.6)	(0.3)	71	1.2	94.8
Total	492	576	84	9.6	9.2	(0.4)	(4.1)	(2.0)	488	8.3	110.5

FX rates:
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FY2016 2Q Results : 1US$ = ¥ 105.2, 1RMB = ¥15.9
FY2016 Previous forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2016 2Q Results	Net sales (Sales to customers)	70.5	91.4	9.2	5.3	176.4	21.7	198.1
	Cost of sales	22.5	4.1	1.4	2.5	30.5	17.3	47.9
	Gross profit	48.1	87.2	7.8	2.7	145.8	4.4	150.2
	SG&A expenses less R&D costs	28.5	49.0	3.5	1.5	82.5	3.2	85.7
	Income (loss) of Segment	19.6	38.3	4.3	1.2	63.4	1.1	64.5
	R&D costs					37.3	0.5	37.7
	Operating income					26.1	0.6	26.7
FY2015 2Q Results	Net sales (Sales to customers)	74.0	90.2	9.6	4.7	178.4	20.5	198.9
	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
	Income (loss) of Segment	22.1	29.5	3.8	0.8	56.2	0.9	57.0
	R&D costs					39.8	0.4	40.2
	Operating income					16.4	0.4	16.8
Change	Net sales (Sales to customers)	(3.5)	1.2	(0.4)	0.6	(2.0)	1.2	(0.8)
	SG&A expenses less R&D costs	(0.8)	(3.1)	(0.5)	0.2	(4.1)	0.1	(4.1)
	Income (loss) of Segment	(2.5)	8.8	0.5	0.4	7.2	0.3	7.4
	R&D costs					(2.5)	0.0	(2.5)
	Operating income					9.7	0.2	9.9

FX rates:
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

Ordinary income & Net income attributable to owners of parent

Billions of yen

	FY2015 2Q Results	FY2016 2Q Results	Change	
			Value	%
Operating Income	16.8	26.7	9.9	58.7
Non-operating income and expenses	0.7	(2.8)	(3.5)	
Ordinary income	17.5	23.9	6.4	36.4
Extraordinary income	6.1	3.8	(2.3)	
Gain on sales of investment securities	6.1	3.8		
Extraordinary loss	0.2	10.0	9.8	
Business structure improvement expenses	–	10.0		
Impairment loss	0.2	–		
Income taxes	10.2	6.8	(3.4)	
Net income attributable to owners of the parent	13.2	10.9	(2.3)	(17.3)

FX rates:
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

Financial Forecasts for FY2016

Financial Forecasts for FY2016

Billions of yen

	FY2015 Result (a)	FY2016 Forecasts on May 11 (b)	FY2016 Revised Forecasts (c)	Change from forecasts on May 11 (c)-(b)		Change from FY2015 (c)-(a)		
				Value	FX rate impact	Value	FX rate impact	%
Net sales	403.2	410.0	398.0	(12.0)	(10.1)	(5.2)	(30.4)	(1.3)
Cost of sales	104.5	99.5	95.5	(4.0)	(4.1)	(9.0)	(11.8)	(8.6)
Gross profit	298.7	310.5	302.5	(8.0)	(6.0)	3.8	(18.6)	1.3
SG&A expenses	261.8	270.5	256.5	(14.0)	(7.1)	(5.3)	(22.0)	(2.0)
SG&A expenses less R&D costs	179.8	186.0	173.5	(12.5)	(5.1)	(6.3)	(15.3)	(3.5)
R&D Costs	82.0	84.5	83.0	(1.5)	(2.0)	1.0	(6.7)	1.2
Operating income	36.9	40.0	46.0	6.0	1.1	9.1	3.4	24.6
Ordinary income	35.2	40.0	44.0	4.0		8.8		24.9
Extraordinary income (loss)	4.3	2.5	(3.0)	(5.5)		(7.3)		
Net income attributable to owners of the parent	24.7	25.0	25.0	–		0.3		1.2
EBITDA	55.8	61.0	63.0	2.0		7.2		12.9

FX rates:
FY2015 Result : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Previous Forecast : 1US$ = ¥ 110.0, 1RMB = ¥17.0
FY2016 Revised Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0

Segment Information

Billions of yen

		Pharmaceuticals Business					Other Business	Total
		Japan	North America	China	Other Regions	Subtotal		
FY2016 Revised Forecasts	Net sales (Sales to customers)	139.0	188.0	16.8	10.8	354.6	43.4	398.0
	Cost of sales	46.0	6.5	3.1	5.1	60.7	34.8	95.5
	Gross profit	93.0	181.5	13.7	5.7	293.9	8.6	302.5
	SG&A expenses less R&D costs	57.5	98.6	7.7	3.1	166.9	6.6	173.5
	Income (loss) of Segment	35.5	82.9	6.0	2.6	127.0	2.0	129.0
	R&D costs					82.0	1.0	83.0
	Operating income					45.0	1.0	46.0
FY2016 Forecasts on May 11	Net sales (Sales to customers)	137.6	200.7	16.0	11.8	366.1	43.9	410.0
	Cost of sales	45.4	11.0	2.8	5.0	64.2	35.3	99.5
	Gross profit	92.2	189.7	13.2	6.8	301.9	8.6	310.5
	SG&A expenses less R&D costs	57.8	110.0	8.1	3.5	179.4	6.6	186.0
	Income (loss) of Segment	34.4	79.7	5.1	3.3	122.5	2.0	124.5
	R&D costs					83.5	1.0	84.5
	Operating income					39.0	1.0	40.0
Change	Net sales (Sales to customers)	1.4	(12.7)	0.8	(1.0)	(11.5)	(0.5)	(12.0)
	SG&A expenses less R&D costs	(0.3)	(11.4)	(0.4)	(0.4)	(12.5)	–	(12.5)
	Income (loss) of Segment	1.1	3.2	0.9	(0.7)	4.5	–	4.5
	R&D costs					(1.5)	–	(1.5)
	Operating income					6.0	–	6.0

FX rates:
FY2016 Previous Forecast : 1US$ = ¥ 110.0, 1RMB = ¥17.0
FY2016 Revised Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0

To strengthen robust revenue base

Strengthen robust revenue base in Japan

Maximize value of strategic products and new products

- Strengthen sales structure to enable response to local healthcare, and concentrate marketing resources on strategic products and new products to quickly maximize product value
- Dosing period limitation for Trulicity® lifted on September 1, 2016

Achieve optimal number of personnel; early retirement program offered from September to October 2016

- Number of applications received: 295

Schedule change for the production sites integration

- Integration of Ibaraki Plant functions into Suzuka Plant, schedule for which changed to be completed by the end of FY2018 (No change for Ehime Plant closure in FY2018)

Establish a subsidiary for promotion of Authorized Generics (AG) (Commence business in December 2016)

- Main Products: AG which it plans to deal in and METGLUCO®

  (Work together with Sumitomo Dainippon Pharma to promote proper usage of the products)
- Sales force: approx. 40

Strengthen robust revenue base in the U.S. (Psychiatry & Neurology Area)

Sunovion acquired Cynapsus in October 2016

Acquisition of APL-130277

- ✓ **High Unmet Needs : OFF episodes associated with Parkinson's disease**
- ✓ **Phase 3 Stage : Plan to submit NDA in 1H FY2017 in the U.S.**
  (Fast Track Designation granted)
- ✓ **Expected Peak Sales : About 50 billion yen**

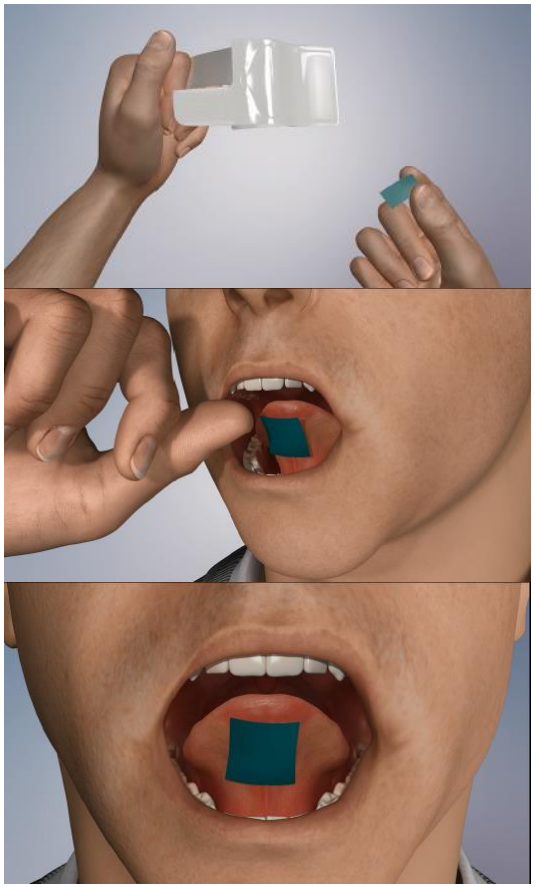
- **Outline of the acquisition**
  - ✓ Sunovion acquired all shares and warrants by cash in accordance with plan of arrangement under Canadian law

- **Financial Impact**
  - ✓ The total value for the acquisition is approximately US$ 635 million.
  - ✓ Valuations and accounting procedures outline will be disclosed at 3Q financial briefing

Outline of APL-130277

- **Profile of APL-130277**
  - ✓ Including apomorphine* as API

    *Apomorphine (dopamine agonist) is the only molecule approved for acute intermittent treatment of OFF episodes associated with Parkinson's disease, as a subcutaneous injection in the U.S.
  - ✓ Conveniently administered sublingual film
  - ✓ Rapid onset to effect
  - ✓ Bi-layer thin film (unique formulation technology)



- **Development stage: Phase 3 in the U.S.**
  - ✓ Cynapsus successfully completed a Phase 2 study
  - ✓ Phase 3 studies expected to complete in FY2016
  - ✓ NDA submission expected in 1H FY2017 in the U.S.

- **Sales structure**
  - ✓ Leverage Sunovion's sales infrastructure
  - ✓ Synergy with APTIOM® in the U.S.
  - ✓ Considering expansion in Europe and in Japan

Strengthen robust revenue base in the U.S. (Respiratory Area)

NDA Submission of SUN-101 in July 2016

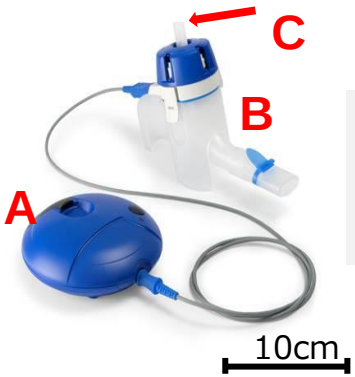
- **Indication:** Long-term, maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease (COPD)

- **Features:**
  - ✓ SUN-101 will be the first nebulizer delivered LAMA for COPD in the U.S.
  - ✓ This nebulizer system is portable and provides delivery of medication in approx. two to three minutes.
- **The expected action date by the FDA is May 29, 2017**

- **Sales structure:**
  - ✓ Leverage Sunovion's sales infrastruct
  - ✓ Synergy with BROVANA®

- **Expected Peak Sales:**
  About 50 billion yen

Investigational eFlow® nebulizer system portable, hand-held

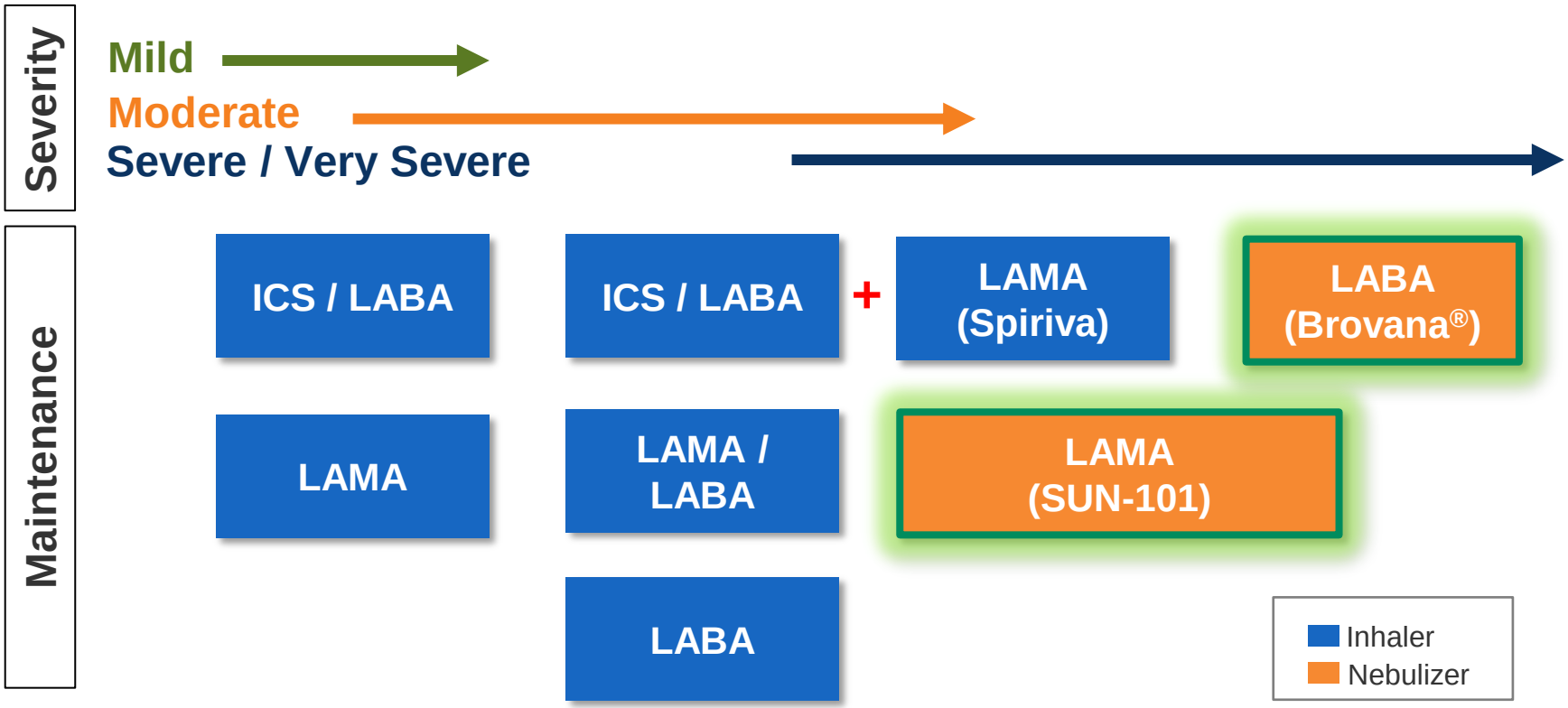


A: Controller
B: Handset (includes aerosol head)
C: Drug

To strengthen robust revenue base

Respiratory products portfolio in the U.S.

Treatment of moderate-to-very severe COPD



LAMA: Long-acting muscarinic antagonist
LABA: Long-acting beta-agonists
ICS: Inhaled corticosteroid

: Sunovion products and development products

* Patients with increasing severity are often treated with both a LAMA and a LABA

Brovana® & SUN-101 could be used as a combination therapy.

Clinical Development Status

Clinical Development Status (Major Changes since July 27, 2016)

Glycopyrronium (SUN-101)

- ✓ NDA filed in the U.S. in July 2016

Apomorphine (APL-130277)

- ✓ Newly added in Phase 3 through the acquisition of Cynapsus by Sunovion in October 2016

Napabucasin (BBI608)

- ✓ Started global Phase 3 study for Colorectal cancer (combination therapy with FOLFIRI, or FOLFIRI and bevacizumab) in Japan

SEP-363856

- ✓ Started Phase 2 study for Schizophrenia in the U.S.
- ✓ Started Phase 2 study for Parkinson's disease psychosis in the U.S.

DSP-7888

- ✓ Started Phase 2 of Phase 1 / 2 study for Pediatric malignant gliomas in Japan

Thiotepa (DSP-1958)

- ✓ Drug for which pharmaceutical companies were recruited to develop new use of unapproved or off-labeled drugs
- ✓ Started Phase 1 study for Conditioning treatment prior to hematopoietic cell transplantation (HPCT) in Japan

Dasotraline Pediatric ADHD Top Line Results

- **Study design**
  - ✓ Phase 2 / 3 study, six-week, randomized, double-blind, multi-center, placebo-controlled, parallel-group, children ages 6 to 12 years with ADHD
  - ✓ Enrolled patients: 342

    (dasotraline 2mg/day 111, dasotraline 4mg/day 115, Placebo 116)
  - ✓ Primary endpoint: Change from baseline at Week 6 in ADHD symptoms as measured by ADHD RS IV HV score

- **Study Results**
  - ✓ Efficacy: The 4mg/day dose arm demonstrated a statistically significant and clinically relevant difference compared to placebo.
  - ✓ Safety: Dasotraline was generally well tolerated.

- **Future Plan (Adult and Pediatric ADHD)**
  - ✓ Phase 3 studies to complete in FY2016
  - ✓ NDA submission is planned in FY2017

Napabucasin Clinical Development Status

- **Change of timeline for NDA submission**
  - ✓ Timeline for NDA submission changed from FY2017 to FY2018 in consideration of the enrollment progress of BRIGHTER study

- **Outline of CCTG's presentation for CO.23 study at ESMO 2016**

∗CO.23 study: A phase 3 study on CRC, closed to accrual and protocol treatment stopped in May, 2014

  - ✓ No significant difference in OS between napabucasin and placebo in the ITT analysis
  - ✓ Napabucasin significantly improved OS in patients with high p-STAT3 expression

Subset	Median OS (mos)		HR[95%CI], p value
	Placebo	Napabucasin	
ITT			
All Pts (n=282)	4.8	4.4	1.13 [0.88 – 1.46], p=0.34
p-STAT3 + (n=55)	3.0	5.1	0.24 [0.12 – 0.51], p=0.0002
p-STAT3 - (n=196)	4.9	4.0	1.44 [1.06 – 1.95], p=0.02
Pre-defined Minimum Effective Treatment			
All Pts (n=128)	5.8	6.6	0.88 [0.61 – 1.28], p=0.50
p-STAT3 + (n=25)	4.0	9.0	0.28 [0.11 – 0.69], p=0.0057
p-STAT3 - (n=88)	6.4	6.4	1.27 [0.80 – 2.01], p=0.32

Target submission date of key late-stage pipeline

(Updated October 2016)

Area	Development	Submission target			
		FY2016	FY2017	FY2018	FY2019 or later
Respiratory	**SUN-101 <glycopyrronium>** (Chronic obstructive pulmonary disease) U.S.	July 2016 Submitted			
Psychiatry & Neurology	**SEP-225289 <dasotraline>** (Adult , Pediatric ADHD) U.S.		●		
	APL-130277 <apomorphine > (Parkinson's disease) U.S.		●		
	TRERIEF® <zonisamide> (Parkinsonism in Dementia with Lewy Bodies) Japan		●		
	SEP-225289 <dasotraline> (BED) U.S.			●	
	LONASEN® <blonanserin> (Schizophrenia / Transdermal patch) Japan			●	
	SM-13496 <lurasidone > (Schizophrenia / Bipolar I depression / Bipolar maintenance) Japan				●
Oncology	**BBI608 <napabucasin>** (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan			●	
	BBI608 <napabucasin> (Colorectal cancer / Combination therapy) U.S./ Japan				●
	BBI608 <napabucasin> (NSCLC /Combination therapy) U.S.				●

New Chemical Entities | New Indication, etc.

Appendices

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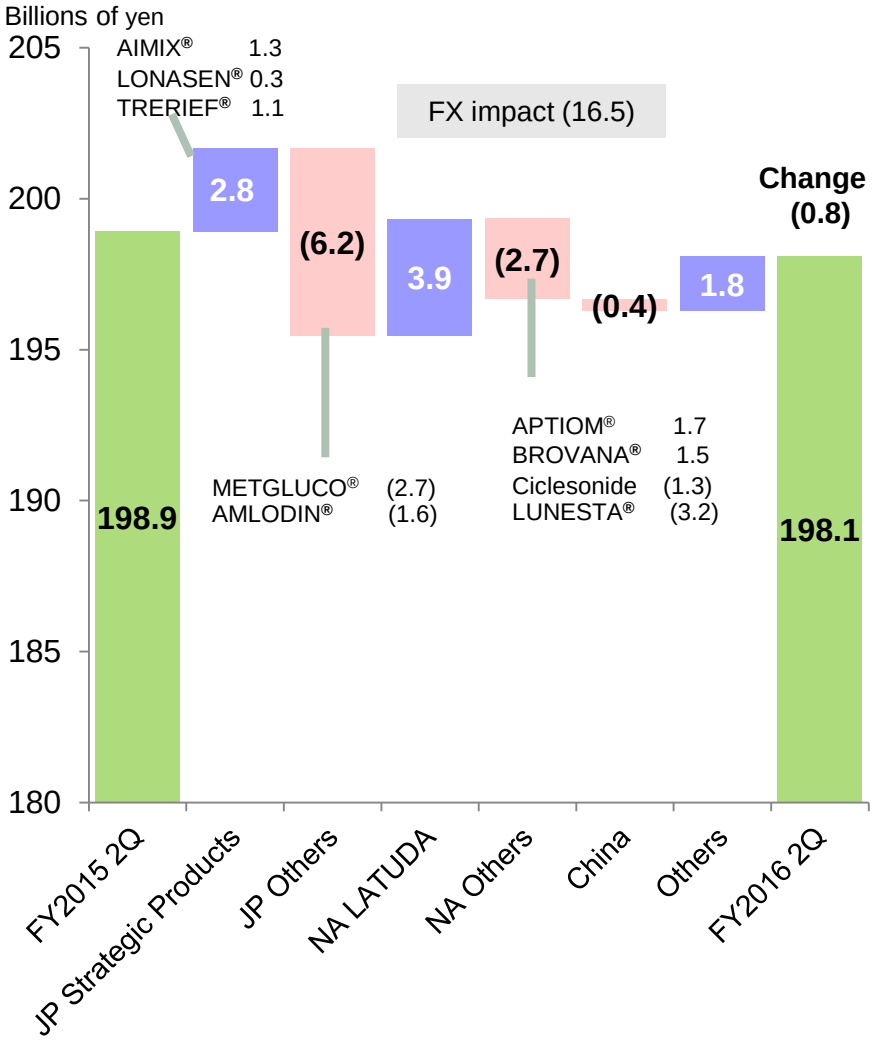
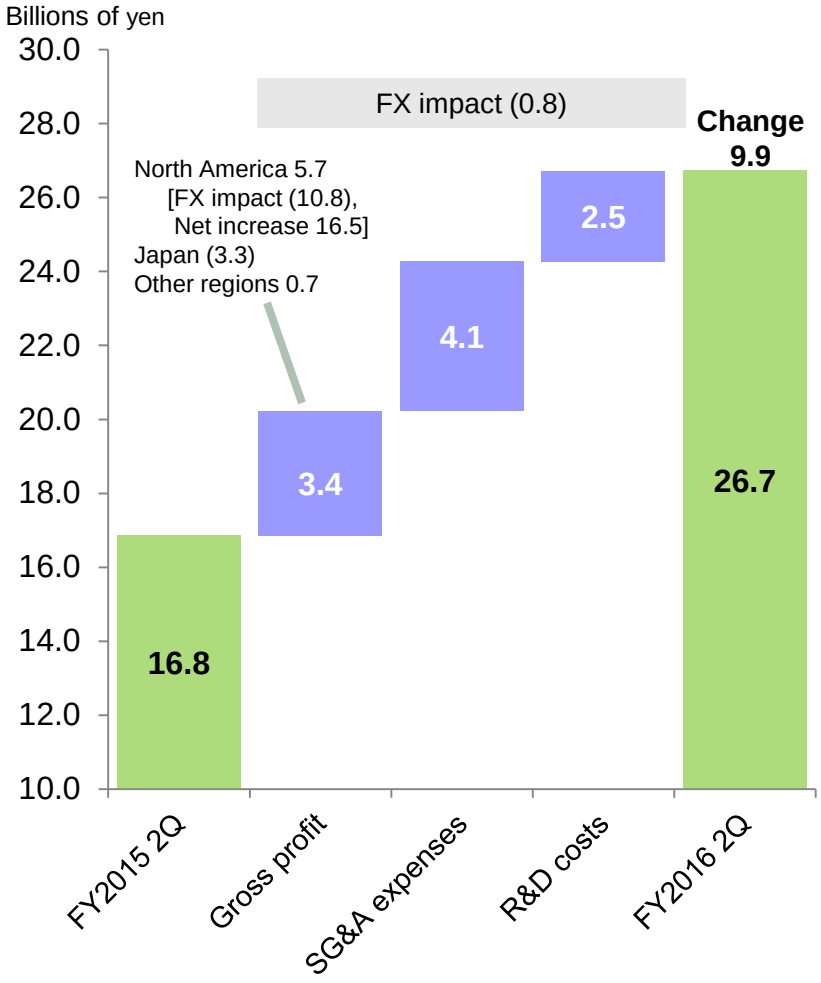
Changes from FY2015 2Q

Sales



Operating Income



FX rates:
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FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

Net Sales by Segment

Billions of yen

Changes (0.8) (0.4) %
Achievement 99.5 %

Japan ・Changes (3.5) (4.7) %
- NHI drug price revision Approx.(3.9)
  Decrease in long-listed products sales

・Achievement 103.0 %

North America
・Changes +1.2 +1.3 %
- Growth of LATUDA®, APTIOM® and BROVANA® offset impact of yen appreciation

・Achievement 97.0 %

China ・Changes (0.4) (4.1) %
- Slight decrease due to FX impact despite MEROPEN® increase

・Achievement 110.5 %

Other Regions
・Changes +0.6 +13.4 %
- Increase in MEROPEN® export

・Achievement 76.5 %

Other Business
・Changes +1.2 +5.8 %
・Achievement 103.0 %

FX rates:
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

Financial Position / Cash Flows

Billions of yen

B/S	As of March 31, 2016	As of Sep. 30, 2016	Change
Assets	707.7	641.2	(66.6)
Current assets	421.6	384.3	(37.2)
Fixed assets	286.1	256.8	(29.3)
Liabilities	261.2	222.3	(38.9)
Current liabilities	179.7	159.7	(20.0)
Long-term liabilities	81.5	62.6	(18.9)
Net assets	446.5	418.8	(27.6)
Shareholders' equity ratio	63.1%	65.3%	

【Assets】

Cash and time deposits	42.5
Marketable securities	(37.7)
Short-term loans receivable	(35.3)
Intangible assets	(19.5)

【Liabilities】

Income taxes payable	(15.6)
Total interest-bearing debt	(23.0)
Long-term ⇒Short-term	8.0
Balance	28.0

C/F	FY2015 2Q	FY2016 2Q	Change
Operating CF	14.3	13.5	(0.8)
Investment CF	28.2	31.6	3.4
Financial CF	(8.3)	(26.5)	(18.3)
Effect of exchange rate changes	(0.8)	(13.7)	(12.9)
Cash / Cash equivalents	154.5	140.4	(14.1)
Operating funds	197.6	153.9	(43.7)

(Reference)

Balance as of end of FY2015

Cash / CE	135.6
Operating funds	184.4

Sales of Major Products in Japan

Billions of yen

	FY2015	FY2016 Forecasts on May 11	FY2016 Revised Forecasts	Change from Forecasts on May 11
AIMIX®	14.9	16.1	16.1	–
LONASEN®	12.6	13.8	13.8	–
TRERIEF®	13.1	14.5	14.5	–
Strategic Products Total	40.7	44.4	44.4	–
REPLAGAL®	10.2	10.5	10.5	–
AmBisome®	4.3	4.3	4.3	–
AVAPRO®	10.8	9.3	10.0	0.7
SUREPOST®	3.6	4.6	4.6	–
METGLUCO®	14.7	9.8	10.8	1.0
AMLODIN®	16.4	12.2	12.2	–
PRORENAL®	8.7	7.0	7.0	–
GASMOTIN®	8.4	6.0	6.0	–
MEROPEN®	6.2	4.5	4.5	–
Others	22.4	25.0	24.7	(0.3)
Other Products Total	105.8	93.2	94.6	1.4
Japan Total	146.5	137.6	139.0	1.4

Note: Sales of each product above are shown by invoice price sales basis.

Sales of Major Products in North America & China

	FY2015	FY2016 Forecasts on May 11	FY2016 Revised Forecasts	Change from Forecasts on May 11	FY2015	FY2016 Forecasts on May 11	FY2016 Revised Forecasts	Change from Forecasts on May 11
North America	Million $				Billion yen			
LATUDA®	1,002	1,152	1,210	58	120.4	126.7	127.1	0.4
APTIOM®	64	124	117	(7)	7.6	13.7	12.3	(1.4)
BROVANA®	249	286	286	–	29.9	31.5	30.0	(1.5)
Ciclesonide	58	55	49	(6)	7.0	6.1	5.1	(1.0)
XOPENEX®	56	43	52	9	6.7	4.7	5.5	0.8
LUNESTA®	38	26	7	(19)	4.6	2.9	0.7	(2.2)
Others	72	139	69	(70)	8.7	15.1	7.3	(7.8)
Total	1,539	1,825	1,790	(35)	184.9	200.7	188.0	(12.7)
China	Million RMB				Billion yen			
MEROPEN®	826	805	902	97	15.6	13.7	14.4	0.7
Others	148	138	148	10	2.8	2.3	2.4	0.1
Total	974	943	1,050	107	18.4	16.0	16.8	0.8

FX rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Previous Forecast : 1US$ = ¥ 110.0, 1RMB = ¥17.0
FY2016 Revised Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0

Appendix (Clinical Development Status)

Development Pipeline (1) (Psychiatry & Neurology Area)

(as of October 27, 2016)

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
APTIOM®	eslicarbazepine acetate	(New indication) Epilepsy- Monotherapy	Canada				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
LATUDA® （SM-13496）	lurasidone hydrochloride	Schizophrenia	China				
		Schizophrenia	Japan				
		Bipolar I depression, Bipolar maintenance	Japan				
EPI-743	vatiquinone	Leigh syndrome	Japan				※1
SEP-225289	dasotraline	Adult attention-deficit hyperactivity disorder (ADHD)	U.S.				
		Pediatric attention-deficit hyperactivity disorder (ADHD)	U.S.				※2
		Binge eating disorder (BED)	U.S.				※2
APL-130277	apomorphine hydrochloride	OFF episodes associated with Parkinson's disease	U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
EPI-589	TBD	Parkinson's disease	U.S.				
		Amyotrophic lateral sclerosis (ALS)	U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
		Parkinson's disease psychosis	U.S.				
		Schizophrenia	Japan				
DSP-2230	TBD	Neuropathic pain	U.K. / U.S. / Japan				
DSP-3748	TBD	Cognitive Impairment Associated with Schizophrenia	U.S.				
DSP-1200	TBD	Treatment-resistant depression	U.S.				

※1／A Phase 2 / 3 study completed, development strategy under consideration ※2／Phase 2 / 3 study

Development Pipeline (2) (Oncology Area) (as of October 27, 2016)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
BBI608	napabucasin	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical study)	U.S. / Canada / Japan, etc.				
		Colorectal cancer (Combination therapy) (Global clinical study)	U.S. / Japan				
		Non-small cell lung cancer (Combination therapy) (Global clinical study)	U.S.				
		Colorectal cancer (Combination therapy)	U.S. / Canada			※1	
		Solid tumors (Ovarian cancer, Breast cancer, Melanoma, etc.) (Combination therapy)	U.S. / Canada				
		Malignant pleural mesothelioma (Combination therapy)	Japan			※1	
		Solid tumors (Combination therapy) ※3 Hematologic malignancies (Monotherapy / Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy) ※4	Japan				
BBI503	amcasertib	Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy)	U.S. / Canada			※1	
		Solid tumors (Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy)	Canada				
		Ovarian Cancer (Monotherapy)	U.S.				
		Hepatocellular carcinoma (Combination therapy)	U.S		※2		
		Solid tumors (Combination therapy)	U.S. / Canada				
		Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	Japan				
BBI608 + BBI503	napabucasin amcasertib	Solid tumors (Combination therapy)	U.S.				

※1／Phase 2 of Phase 1 / 2 study　※2／Phase 1 of Phase 1 / 2 study
※3／Multiple studies for different tumor types (Gastrointestinal cancer , Hepatocellular carcinoma, Glioblastoma, Pancreatic cancer)
※4／Multiple studies for different tumor types (Hepatocellular carcinoma)

Development Pipeline (3) (Oncology & Others Area)

(as of October 27, 2016)

Sumitomo Dainippon Pharma

Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the previous announcement are in red.

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-7888	TBD	Myelodysplastic syndromes	Japan			※1	
		Pediatric malignant gliomas	Japan			※1	
		Solid tumors, Hematologic malignancies	U.S.				
WT4869	TBD	Myelodysplastic syndromes	Japan		※2		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic malignancies	U.S.				
		Solid tumors	Japan				
DSP-1958 ※3	Thiotepa	Conditioning treatment prior to hematopoietic cell transplantation (HPCT)	Japan				

※1／Phase 2 of Phase 1 / 2 study　※2／Phase 1 of Phase 1 / 2 study　※3／Development for the use of unapproved or off-labeled drugs

Respiratory Area

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
SUN-101	glycopyrronium bromide	Chronic obstructive pulmonary disease (COPD)	U.S.				

Other Areas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase 1	Phase 2	Phase 3	Submitted
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				

Appendix (Clinical Development Status)

Napabucasin – Clinical development progress

(as of October 27, 2016)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 3	U.S. / Canada / Japan, etc.	Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy)	paclitaxel	BRIGHTER (BBI608-336)	Aug. 2014
	U.S. / Japan	Colorectal cancer (Combination therapy)	FOLFIRI, FOLFIRI + bevacizumab	CanStem303C (BB608-303CRC)	June 2016
	U.S.	Non-small cell lung cancer (Combination therapy)	paclitaxel	CanStem43L	Oct. 2016
Phase 2	U.S. / Canada	Colorectal cancer (Combination therapy)	cetuximab, panitumumab, capecitabine	BBI608-224	Mar. 2012
	U.S. / Canada	Solid tumors*1 (Combination therapy)	paclitaxel	BBI608-201	Apr. 2011
	Japan	Malignant pleural mesothelioma (Combination therapy)	cisplatin + pemetrexed	D8807005	Feb. 2015
Phase 1	U.S. / Canada	Gastrointestinal cancer (Combination therapy)	FOLFOX, FOLFOX + bevacizumab, CAPOX, FOLFIRI, FOLFIRI + bevacizumab, regorafenib, irinotecan	BBI608-246	Jan. 2014
	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
	U.S.	Pancreatic cancer (Combination therapy)	gemcitabine + nab-paclitaxel, FOLFIRINOX, irinotecan liposome injection + fluorouracil + leucovorin	BBI608-118	Aug. 2014
	Canada	Glioblastoma (Combination therapy)	temozolomide	BBI608-251	Mar. 2015
	U.S.	Hematologic Malignancies (Monotherapy / Combination therapy)	dexamethasone, bortezomib, imatinib, ibrutinib	BBI608-103HEME	May 2015
	Japan	Hepatocellular carcinoma (Combination therapy)	sorafenib	D8808001	Feb. 2015
	U.S.	Solid tumors (Combination therapy)	iplimumab, pembrolizumab, nivolumab	BBI608-201CIT	Aug. 2015

*1／Ovarian cancer, Breast cancer, Melanoma, etc.

Start date is based on Clinical Trials.gov (as of October 26, 2016)

Amcasertib, Napabucasin– Clinical development progress

(as of October 27, 2016)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 2	U.S. / Canada	Solid tumors*1 (Monotherapy)	–	BBI503-101	Feb. 2012
	Canada	Renal cell carcinoma, Urothelial carcinoma (Monotherapy)	–	BBI503-205a	Jan. 2017
	Canada	Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy)	–	BBI503-205b	Feb. 2015
	Canada	Gastrointestinal stromal tumor (Monotherapy)	–	BBI503-205c	Jan. 2017
	U.S.	Ovarian cancer (Monotherapy)	–	BBI503-205GYN-M	June 2015
Phase 1	U.S.	Hepatocellular carcinoma (Combination therapy)	sorafenib	BBIHCC-103	Dec. 2014
	Japan	Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy)	sorafenib	DA101003	Mar. 2015
	U.S. / Canada	Solid tumors (Combination therapy)	capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib	BBI503-201	Sep. 2015

*1／Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

Napabucasin + Amcasertib

Development stage	Development location	Proposed indication	Combination products	Study number	Start date
Phase 1	U.S.	Solid tumors (Combination therapy)	–	BBI401-101	Apr. 2015

Start date is based on Clinical Trials.gov (as of October 26, 2016)

LATUDA® (lurasidone) – Clinical development progress

Revisions since the previous announcement are in red.

Japan / China (In-house)

Indication, Proposed indication	Development location	Development status	Submission plan
Schizophrenia	China	Submitted	—
Schizophrenia	Japan	Phase 3	FY2019
Bipolar I depression , Bipolar maintenance		Phase 3	FY2019

Europe (In-house)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe was terminated on January 31st, 2016
- The Marketing Authorization (MA) for LATUDA® in EU and Switzerland was transferred to Sunovion Pharmaceuticals Europe Ltd. (SPE) in February 2016.
  - ✓ SPE started commercializing LATUDA® in May 2016 in the countries where the product has already been launched.
  - ✓ For other countries, we will continuously seek a licensing partner.

  (Reference)

  MA Submitted in: Turkey

  Approved in: Russia

  Launched in: UK, Switzerland, Denmark, Norway, the Netherlands, Finland, and Sweden

Asia, South America, etc. (Partnering)

- MA Submitted in: Thailand, Hong Kong, Singapore, Venezuela, Brazil
- Approved in: Singapore (DKSH is preparing for the launch.)
- Launched in: Australia (commercialization partnership with Servier Australia),
  Taiwan (commercialization partnership with Standard Chem. & Pharm.)

Product Launch Plan (Updated October 2016)

Sumitomo Dainippon Pharma

Area	FY2017	FY2018	FY2019	FY2020 - FY2022	
Japan		TRERIEF® (Parkinsonism in Dementia with Lewy Bodies)	LONASEN® (Schizophrenia / Transdermal patch)	lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance)	obeticholic acid (NASH)
		thiotepa (Conditioning treatment prior to HPCT)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	napabucasin (Colorectal cancer, etc.)	DSP-6952 (IBS with constipation, Chronic idiopathic constipation)
				amcasertib (Solid tumors)	iPS cell-derived RPE cells (Age-related macular degeneration)
				DSP-7888 (Solid tumors/ Hematologic cancer)	
U.S.	glycopyrronium (COPD)	dasotraline (ADHD)	dasotraline (BED)	SB623 (Chronic stroke)	napabucasin (Colorectal cancer, Pancreatic cancer, NSCLC)
		apomorphine (Parkinson's disease)	napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma)	DSP-2230 (Neuropathic pain)	amcasertib (Solid tumors)
				SEP-363856 (Schizophrenia)	DSP-7888 (Solid tumors/ Hematologic cancer)
China	LONASEN® (Schizophrenia)	lurasidone (Schizophrenia)			

／Psychiatry & Neurology ／Oncology ／Liver / Digestive ／Respiratory

New Chemical Entities | New Indication , etc.

Clinical Development Status

Regenerative Medicine / Cell Therapy Business Plan

(Updated July 2016)

Sumitomo Dainippon Pharma

	Partnering	Region (planned)	Cell type	Schedule for practical use (Calendar year) 2016	2017	2018	2019	2020
Chronic Stroke	**SanBio**	North America	Allo MSC	**Phase 2b**		**Phase 3**		**Approval Target**
AMD (age-related macular degeneration)	**Healios RIKEN**	Japan	Allo iPS cell	**Clinical research**	※ **Investigator or corporate initiated clinical study**			**Approval Target**
Parkinson's disease	**Kyoto Univ CiRA**	Global	Allo iPS cell	**Clinical research or clinical study**				
Retinitis pigmentosa	**RIKEN**	Global	Allo iPS cell			**Investigator initiated clinical study**		
Spinal Cord Injury	**Keio Univ Osaka National Hospital**	Global	Allo iPS cell			**Clinical research**		

※Start of clinical studies originally scheduled in 2017 may be delayed due to changes in non-clinical study plans.

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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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Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows