

Second Quarter Financial Results for FY2012  
(Apr. 1 to Sep. 30, 2012)

November 1, 2012

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Dainippon Sumitomo Pharma Co., Ltd.

# Second Quarter Financial Results for FY2012

# FY2012 2Q Financial Results

Billions of yen

	FY2011 2Q	FY2012 2Q	Change			FY2012 2Q	
			Value		Percentage (%)	Forecast	Progress (%)
				Exchange Impact			
Net sales	178.0	<b>178.7</b>	0.7	- 1.6	0.4 %	179.0	99.9%
Cost of sales	49.8	<b>50.0</b>	0.3	- 0.2	0.5 %	50.3	99.5%
Gross profit	128.3	<b>128.7</b>	0.5	- 1.4	0.4 %	128.7	100.0%
SG&A expenses	113.5	<b>108.7</b>	- 4.8	- 1.6	- 4.2 %	111.5	97.5%
SG&A expenses less R&D costs	86.2	<b>80.9</b>	- 5.3	- 1.3	- 6.2 %	82.5	98.1%
R&D Costs	27.3	<b>27.8</b>	0.5	- 0.3	1.9 %	29.0	95.9%
Operating income	14.7	<b>20.0</b>	5.3	0.2	35.7 %	17.2	116.2%
Ordinary income	14.5	<b>19.9</b>	5.4		37.6 %	17.0	117.2%
Extraordinary income	1.2	—	- 1.2		—	—	—
Extraordinary loss	—	<b>1.5</b>	1.5		—	—	—
Net income	9.6	<b>11.0</b>	1.4		14.4 %	8.8	124.5%

Notes: 1. All values are rounded to the nearest 100 million yen.

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

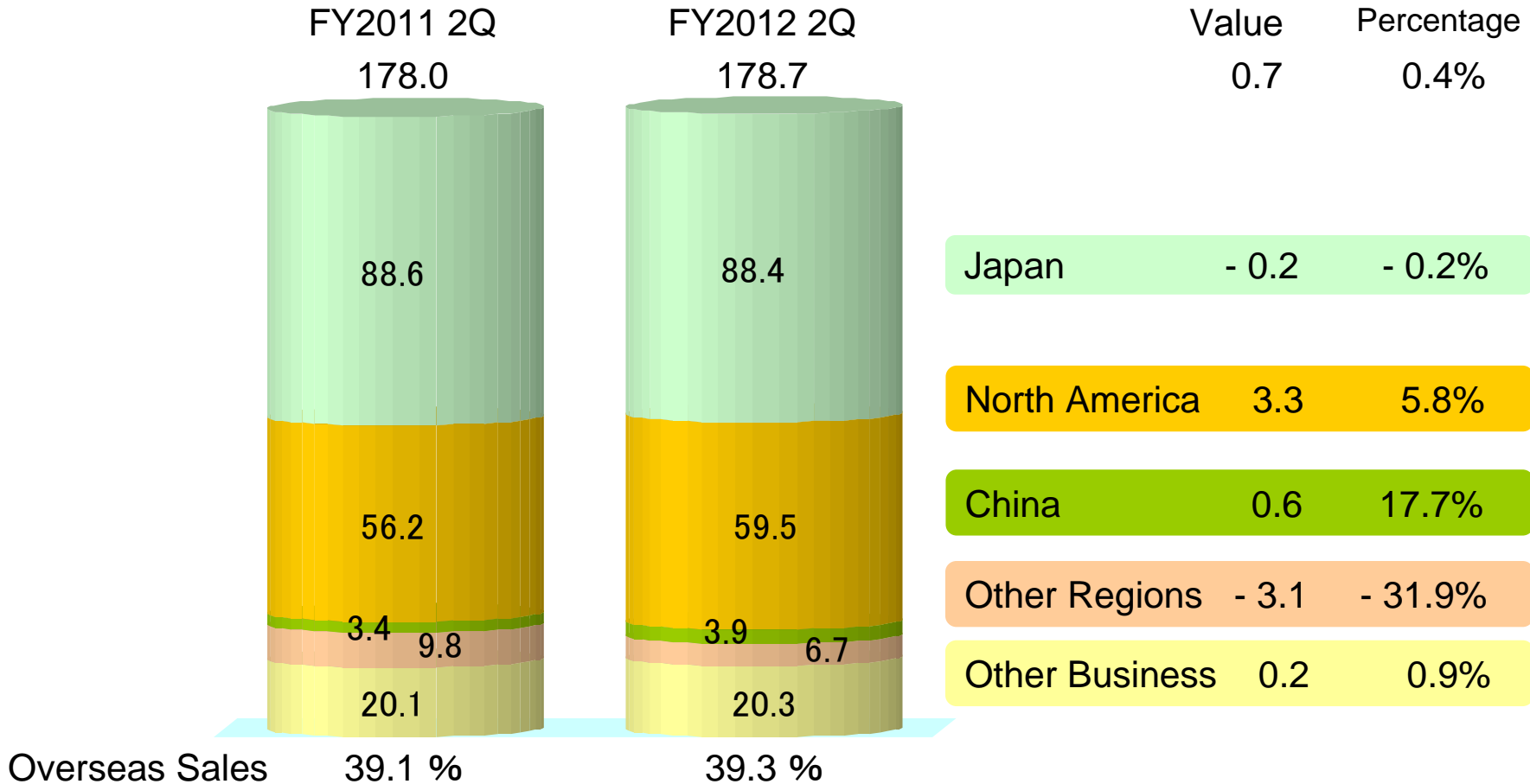
3. Forecasts are those announced on July 27, 2012.

4. Exchange Rate: FY2011 2Q: 1US\$ = ¥82.01, 1RMB = ¥12.56, FY2012 2Q: 1US\$ = ¥79.78, 1RMB=¥12.65

# Net Sales by Segment

Billions of yen

Change  
Value Percentage  
0.7 0.4%



**【Japan】** While there is impact from NHI price revisions, because of the growth of strategic and new products there is a slight decrease.

**【North America】** Increase due to LATUDA® growth and income from royalties.

**【Other Regions】** Decrease in Meropen® exports, etc.

# Sales in Japan

Billions of yen

	FY2011 2Q	FY2012 2Q	Change
AVAPRO®	4.9	5.8	17.7 %
LONASEN®	5.0	5.4	8.8 %
PRORENAL®	7.8	7.3	- 6.6 %
TRERIEF®	2.5	3.4	37.0 %
Strategic Products Total	20.2	21.9	8.5 %
MIRIPLA®	0.7	0.6	- 15.9 %
METGLUCO® (Including MELBIN®)	3.6	5.7	58.0 %
SUREPOST®	0.1	0.3	352.5 %
New Products Total	4.4	6.6	50.5 %
REPLAGAL®	4.3	5.1	16.9 %
AmBisome®	2.2	2.2	0.8 %
AMLODIN®	18.2	14.9	- 18.3 %
GASMOTIN®	10.4	10.1	- 2.7 %
MEROPEN®	6.2	5.2	- 15.3 %
Others	22.8	22.5	- 1.5 %
<b>Japan Total</b>	<b>88.6</b>	<b>88.4</b>	<b>- 0.2 %</b>

FY2012 2Q	
7/27 Forecast	Progress
6.7	86.6 %
6.1	88.6 %
8.0	90.8 %
3.3	103.2 %
24.1	90.8 %
0.6	94.8 %
5.3	108.2 %
0.8	32.7 %
6.7	98.0 %
4.9	103.6 %
2.4	92.6 %
14.8	100.4 %
9.4	107.4 %
4.7	110.8 %
20.3	110.8 %
87.3	101.3 %

FY2012 Forecast		
7/27 Forecast	10/31 Forecast	Change
14.3	12.1	- 2.2
13.0	11.3	- 1.7
15.2	14.7	- 0.5
7.0	7.2	0.2
49.5	45.3	- 4.2
1.3	1.3	—
11.9	12.5	0.6
2.2	1.0	- 1.2
15.4	14.8	- 0.6
10.0	10.2	0.2
4.8	4.8	—
28.7	28.7	—
18.5	20.0	1.5
10.2	10.2	—
41.4	42.7	1.3
178.5	176.7	- 1.8

Notes: Sales figures before reduction of rebates.  
Sales figures do not include intersegment transactions.

# Sales in North America & China

Billions of yen

	FY2011 2Q	FY2012 2Q	Change
LATUDA®	3.4	6.4	91.1 %
LUNESTA®	21.4	22.2	3.4 %
XOPENEX®	17.7	14.9	- 16.2 %
BROVANA®	5.1	6.1	20.1 %
Ciclesonide Products	4.2	1.8	- 57.0 %
Industrial property revenues	3.4	6.0	76.3 %
Others	0.9	2.0	131.6 %
<b>North America Total</b>	<b>56.2</b>	<b>59.5</b>	<b>5.8 %</b>
MEROPEN®	2.9	3.3	12.7 %
Others	0.5	0.7	48.4 %
<b>China Total</b>	<b>3.4</b>	<b>3.9</b>	<b>17.7 %</b>

FY2012 Forecast			
7/27 Forecast	10/31 Forecast	Change	Exchange Impact
15.2	16.0	0.8	- 0.1
43.6	43.6	—	- 0.3
22.9	23.6	0.7	- 0.1
12.8	12.8	—	- 0.1
5.2	5.8	0.6	—
7.9	7.9	—	—
3.2	3.2	—	—
<b>110.8</b>	<b>112.9</b>	<b>2.1</b>	<b>- 0.7</b>
5.8	6.2	0.4	—
1.3	1.4	0.1	—
<b>7.1</b>	<b>7.6</b>	<b>0.5</b>	<b>—</b>



【Exchange Rates】 FY2011: 1US\$ = ¥79.8  
 July 2012 Forecast: 1US\$ = ¥80.0  
 October 2012 Forecast: 1US\$ = ¥79.5

# Sales in North America Segment (U.S. Dollar Basis)

Millions of US\$

	FY2011 2Q	FY2012 2Q	Change
LATUDA®	41	80	96.4 %
LUNESTA®	261	278	6.3 %
XOPENEX®	216	186	- 13.9 %
BROVANA®	62	77	23.4 %
Ciclesonide Products	52	23	- 55.8 %
Industrial property revenues	42	76	81.2 %
Others	10	25	138.1 %
<b>North America Total</b>	<b>685</b>	<b>745</b>	<b>8.8 %</b>

FY2012 Forecast		
7/27 Forecast	10/31 Forecast	Change
190	201	11
545	548	3
286	296	10
160	161	1
65	73	8
99	100	1
40	40	—
<b>1,385</b>	<b>1,419</b>	<b>34</b>

# Segment Breakdown for North America

Billions of yen [M\$]

< Excluding amortization of patent rights and goodwill >

	FY2011 2Q		FY2012 2Q		Change	
Net sales	[ 685 ]	56.2	[ 745 ]	59.5	[ 60 ]	3.3
Cost of sales	[ 72 ]	5.9	[ 76 ]	6.1	[ 4 ]	0.2
Gross profit	[ 613 ]	50.2	[ 669 ]	53.4	[ 56 ]	3.1
SG&A expenses	[ 425 ]	34.9	[ 367 ]	29.2	[ - 58 ]	- 5.6
Income (loss) of Segment	[ 188 ]	15.4	[ 302 ]	24.1	[ 115 ]	8.7

Breakdown	
Exchange Impact	Others
- 1.6	4.8
- 0.2	0.3
- 1.4	4.5
- 0.8	- 4.8
- 0.6	9.3

< Amortization of patent rights and goodwill >

SG&A expenses	[ 174 ]	14.3	[ 200 ]	16.0	[ 26 ]	1.7
Income (loss) of Segment	[ - 174 ]	- 14.3	[ - 200 ]	- 16.0	[ - 26 ]	- 1.7

- 0.4	2.1
0.4	- 2.1



# Segment Information

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America*1	Amortization*2	China	Other Regions	Subtotal			
FY2012 2Q Results	Net sales (external)	88.4	59.5	—	3.9	6.7	158.5	20.3	178.7	
	Cost of sales	23.8	6.1	—	0.9	3.6	34.4	15.7	50.0	
	Gross profit	64.7	53.4	—	3.0	3.1	124.2	4.5	128.7	
	SG&A expenses	31.0	29.2	16.0	1.6	0.2	78.0	2.9	80.9	
	<b>Income (loss) of Segment</b>	<b>33.7</b>	<b>24.1</b>	<b>- 16.0</b>	<b>1.4</b>	<b>2.9</b>	<b>46.2</b>	<b>1.6</b>	<b>47.8</b>	
	R&D costs							27.4	0.4	27.8
	Operating income							18.8	1.2	20.0

FY2011 2Q Results	Net sales (external)	88.6	56.2	—	3.4	9.8	157.9	20.1	178.0	
	Cost of sales	22.3	5.9	—	0.9	5.1	34.3	15.5	49.8	
	Gross profit	66.4	50.2	—	2.4	4.6	123.7	4.5	128.3	
	SG&A expenses	32.5	34.9	14.3	1.5	0.2	83.4	2.9	86.2	
	<b>Income (loss) of Segment</b>	<b>33.9</b>	<b>15.4</b>	<b>- 14.3</b>	<b>0.9</b>	<b>4.5</b>	<b>40.4</b>	<b>1.6</b>	<b>42.0</b>	
	R&D costs							26.9	0.3	27.3
	Operating income							13.4	1.3	14.7

Change	Net sales (external)	- 0.2	3.3	—	0.6	- 3.1	0.5	0.2	0.7	
	<b>Income (loss) of Segment</b>	<b>- 0.2</b>	<b>8.7</b>	<b>- 1.7</b>	<b>0.5</b>	<b>- 1.6</b>	<b>5.8</b>	<b>- 0.0</b>	<b>5.8</b>	
	R&D costs							0.5	0.0	0.5
	Operating income							5.3	- 0.1	5.3

※ 1. Excluding amortization of patent rights and goodwill

※ 2. Amortization of patent rights and goodwill

# Ordinary income & Net income

Billions of yen

	FY2011 2Q	FY2012 2Q	Change	
			Value	Percentage
Operating Income	14.7	20.0	5.3	35.7 %
Non-operating income and expenses	- 0.2	- 0.1	0.2	
Finance income and expenses including dividend income	- 0.0	0.1	0.1	
Contributions	- 0.7	- 0.7	- 0.0	
Others	0.5	0.6	0.1	
Ordinary income	14.5	19.9	5.4	37.6 %
Extraordinary income	1.2	–	- 1.2	
Gain on sales of fixed assets	1.2	–	- 1.2	
Extraordinary loss	–	1.5	1.5	
Business structure improvement expenses	–	1.1	1.1	
Impairment loss	–	0.4	0.4	
Income taxes	6.1	7.5	1.3	
Net income	9.6	11.0	1.4	14.4 %

【Business structure improvement expenses】 Cost for U.S. subsidiary organization and operation reforms (workforce reduction)

【Impairment loss】 Impairment loss for a part of in-process R&D

# Valuations and accounting procedures following the acquisition of SRD

SRD (Formerly Elevation Pharmaceuticals Inc.) was acquired by Sunovion in September 2012.

Valuation of assets and the accounting procedures associated with acquisition are as follows:

The amount of the purchase price allocation is provisional at this time.

Billions of yen

	Before purchase price allocation	After purchase price allocation (provisional)	Valuation differences	Accounting procedures (Amortization)
In-process R&D (Intangible Assets)	—	18.4	18.4	Capitalize (Amortize after approval)
Deferred Tax Liabilities (of the above)	—	- 6.9	- 6.9	—
Present value of the contingent consideration	—	- 8.3	- 8.3	Recorded in the Liabilities
Other Assets & Liabilities (Net)	0.0	1.3	1.3	—
Goodwill	—	3.3	3.3	Amortization for 20 years
Total	0.0	7.9	7.9	

# Financial Position

Billions of yen

	as of Mar.31, 2012	as of Sep.30, 2012	Change
Assets	559.4	579.2	19.7
Current assets	334.3	321.5	- 12.7
Fixed assets	225.2	257.6	32.4
Liabilities	240.2	250.6	10.4
Current liabilities	106.0	100.8	- 5.2
Long-term liabilities	134.2	149.8	15.6
Net assets	319.2	328.6	9.4

(Shareholders' equity ratio)

57.1%

56.7%

## (Assets)

Increase in intangible assets ..... 34.6 billion yen

## (Liabilities)

Decrease in interest-bearing debt ..... 5.0 billion yen

Increase in long-term deferred tax liabilities ..... 11.0 billion yen

## (Net Assets)

Increase in retained earnings ..... 7.4 billion yen

# Cash Flows

Billions of yen

<b>I</b>	<b>Net cash provided by operating activities</b>	<b>+ 28.4</b>
	▪ Income before income taxes and minority interests	+ 18.4
	▪ Depreciation and amortization	+ 20.5
	▪ Income taxes paid	- 5.5
<b>II</b>	<b>Net cash used in investing activities</b>	<b>- 46.8</b>
	▪ Purchases of marketable securities	- 28.4
	▪ Proceeds from sale and redemption of marketable securities	+ 16.0
	▪ Purchases of investments in subsidiaries newly consolidated	- 23.9
<b>III</b>	<b>Net cash used in financing activities</b>	<b>- 8.6</b>
	▪ Decrease in long-term loans payable	- 5.0
	▪ Cash dividends paid	- 3.6

Cash and cash equivalents at the end of period: 65.8 billion yen  
 (compared with the beginning of period: - 26.4 billion yen)

# Financial Forecasts for FY2012

# FY2012 Revision of Financial Forecasts

## (Compared to previous Forecast)

Billions of yen

	Forecast (as of July 27)	Revision of Forecast (as of Oct. 31)	Comparison to Previous Forecast		
			Value	Exchange Impact	Percentage
Net Sales	348.0	<b>348.0</b>	—	- 0.7	—
Cost of Sales	100.2	<b>100.0</b>	- 0.2	- 0.1	- 0.2 %
Gross profit	247.8	<b>248.0</b>	0.2	- 0.6	0.1 %
SG&A expenses	222.8	<b>220.0</b>	- 2.8	- 0.5	- 1.3 %
SG&A expenses less R&D costs	163.1	<b>160.8</b>	- 2.3	- 0.4	- 1.4 %
R&D costs	59.7	<b>59.2</b>	- 0.5	- 0.1	- 0.8 %
Operating Income	25.0	<b>28.0</b>	3.0	0.1	12.0 %
Ordinary Income	24.0	<b>27.0</b>	3.0	\	12.5 %
Extraordinary income or loss	- 2.0	<b>- 3.0</b>	- 1.0		—
Net income	12.0	<b>13.5</b>	1.5		12.5 %
EBITDA	60.0	<b>63.0</b>	3.0		5.0 %

Notes:

1. All values are rounded to the nearest 100 million yen.
2. EBITDA: earnings before interest, taxes, depreciation and amortization

【Exchange Rates】

July 2012 Forecast: 1US\$ =¥80.0 1RMB =¥12.3  
 October 2012 Forecast : 1US\$ =¥79.5 1RMB =¥12.5

# FY2012 Revision of Financial Forecasts (Compared to FY2011 Results)

Billions of yen

	FY2011 Results	Revision of Forecast (as of Oct. 31)	Comparison to FY2011 Results		
			Value		Percentage
				Exchange Impact	
Net Sales	350.4	<b>348.0</b>	- 2.4	- 0.4	- 0.7 %
Cost of Sales	98.9	<b>100.0</b>	1.1	—	1.2 %
Gross profit	251.5	<b>248.0</b>	- 3.5	- 0.4	- 1.4 %
SG&A expenses	231.1	<b>220.0</b>	- 11.1	- 0.4	- 4.8 %
SG&A expenses less R&D costs	174.2	<b>160.8</b>	- 13.4	- 0.3	- 7.7 %
R&D costs	56.9	<b>59.2</b>	2.3	- 0.1	4.1 %
Operating Income	20.4	<b>28.0</b>	7.6	—	37.2 %
Ordinary Income	18.9	<b>27.0</b>	8.1	\	43.1 %
Extraordinary income or loss	- 2.5	<b>- 3.0</b>	- 0.5		—
Net income	8.6	<b>13.5</b>	4.9		56.4 %
EBITDA	59.9	<b>63.0</b>	3.1		5.2 %

Notes:

1. All values are rounded to the nearest 100 million yen.
2. EBITDA: earnings before interest, taxes, depreciation and amortization

**【Exchange Rates】**

FY2011 Results: 1US\$ =¥79.8 1RMB =¥12.4  
 FY2012 Forecast: 1US\$ =¥79.5 1RMB =¥12.5



# Revision of Financial Forecasts (FY2012) by Segment (Compared to previous Forecast)

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America*1	Amortization*2	China	Other Regions	Subtotal			
Revised Forecast FY2012	Net sales (external)	176.7	112.9	—	7.6	9.2	306.4	41.6	348.0	
	Cost of Sales	48.1	13.5	—	1.8	4.6	68.0	32.0	100.0	
	Gross Profit	128.8	99.4	—	5.8	4.6	238.6	9.4	248.0	
	SG&A expenses	63.0	62.0	25.5	3.8	0.4	154.7	6.1	160.8	
	Income (loss) of Segment	<b>65.8</b>	<b>37.4</b>	<b>-25.5</b>	<b>2.0</b>	<b>4.2</b>	<b>83.9</b>	<b>3.3</b>	<b>87.2</b>	
	R&D costs							58.4	0.8	59.2
	Operating income							25.5	2.5	28.0

Previous Forecast FY2012	Net sales (external)	178.5	110.8	—	7.1	9.2	305.6	42.4	348.0	
	Cost of Sales	48.7	12.6	—	1.8	4.7	67.8	32.4	100.2	
	Gross Profit	130.1	98.2	—	5.3	4.5	238.1	9.7	247.8	
	SG&A expenses	63.0	63.8	25.6	4.1	0.4	156.9	6.2	163.1	
	Income (loss) of Segment	<b>67.1</b>	<b>34.4</b>	<b>-25.6</b>	<b>1.2</b>	<b>4.1</b>	<b>81.2</b>	<b>3.5</b>	<b>84.7</b>	
	R&D costs							58.8	0.9	59.7
	Operating income							22.4	2.6	25.0

Change	Net sales (external)	-1.8	2.1	—	0.5	—	0.8	-0.8	—	
	Income (loss) of Segment	<b>-1.3</b>	<b>3.0</b>	<b>0.1</b>	<b>0.8</b>	<b>0.1</b>	<b>2.7</b>	<b>-0.2</b>	<b>2.5</b>	
	R&D costs							-0.4	-0.2	-0.5
	Operating income							3.1	-0.1	3.0



\*1 Excluding amortization of patent rights and goodwill

\*2 Amortization of patent rights and goodwill

# Revision of Financial Forecasts (FY2012 2H) by Segment (Compared to previous Forecast)

Billions of yen

		Pharmaceuticals Business						Other Business	Total	
		Japan	North America*1	Amortization*2	China	Other Regions	Subtotal			
Revised Forecast FY2012 2H	Net sales (external)	88.3	53.4	—	3.7	2.5	147.9	21.3	169.3	
	Cost of Sales	24.3	7.4	—	0.9	1.0	33.6	16.3	50.0	
	Gross Profit	64.1	46.0	—	2.8	1.5	114.4	4.9	119.3	
	SG&A expenses	32.0	32.8	9.5	2.2	0.2	76.7	3.2	79.9	
	Income (loss) of Segment	<b>32.1</b>	<b>13.3</b>	<b>-9.5</b>	<b>0.6</b>	<b>1.3</b>	<b>37.7</b>	<b>1.7</b>	<b>39.4</b>	
	R&D costs							31.0	0.4	31.4
	Operating income							6.7	1.3	8.0

Previous Forecast FY2012 2H	Net sales (external)	91.2	51.3	—	3.1	2.3	147.9	21.1	169.0	
	Cost of Sales	24.9	6.9	—	0.8	1.0	33.6	16.3	49.9	
	Gross Profit	66.4	44.4	—	2.3	1.3	114.4	4.7	119.1	
	SG&A expenses	31.6	33.6	9.6	2.5	0.2	77.5	3.1	80.6	
	Income (loss) of Segment	<b>34.8</b>	<b>10.8</b>	<b>-9.6</b>	<b>-0.2</b>	<b>1.1</b>	<b>36.9</b>	<b>1.6</b>	<b>38.5</b>	
	R&D costs							30.3	0.4	30.7
	Operating income							6.6	1.2	7.8

Change	Net sales (external)	-2.9	2.1	—	0.6	0.2	—	0.2	0.3	
	Income (loss) of Segment	<b>-2.7</b>	<b>2.5</b>	<b>0.1</b>	<b>0.8</b>	<b>0.2</b>	<b>0.8</b>	<b>0.1</b>	<b>0.9</b>	
	R&D costs							0.7	—	0.7
	Operating income							0.1	0.1	0.2



\*1 Excluding amortization of patent rights and goodwill

\*2 Amortization of patent rights and goodwill

# North America Segment Revised FY2012 Forecast

Millions of US\$

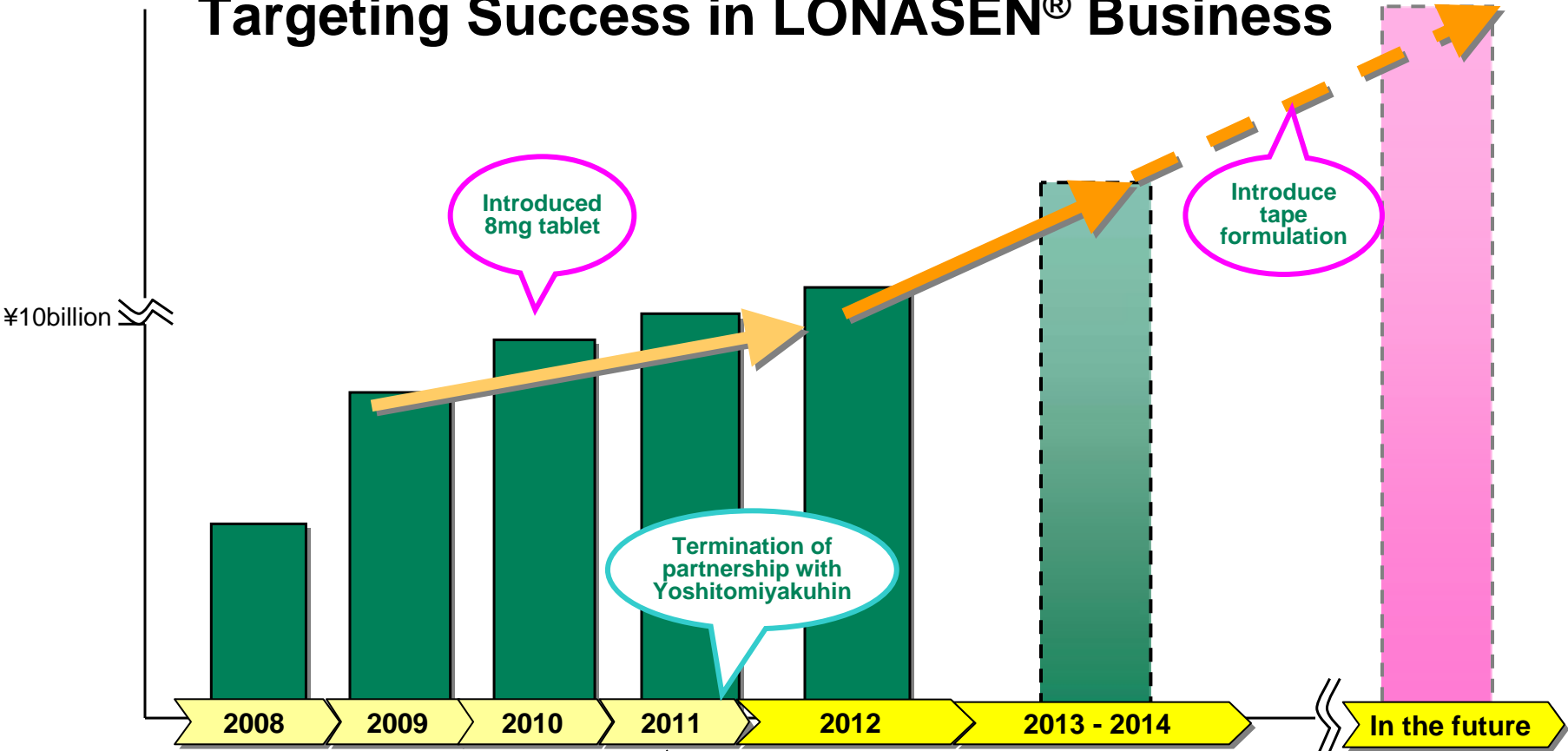
	FY2011 Results	FY2012 Previous Forecast (July 27)		FY2012 Forecast Revision		Value compared to previous forecast	
		2Q	FY2012	2Q	FY2012	2Q	FY2012
Net Sales	1,359	745	1,385	745	1,419	0	34
Cost of Sales	140	71	157	76	169	5	12
Gross Profit	1,218	674	1,228	669	1,250	- 5	22
SG&A expenses	875	379	797	367	779	- 12	- 18
<b>Income (loss) of Segment</b>	<b>343</b>	<b>295</b>	<b>431</b>	<b>302</b>	<b>471</b>	<b>7</b>	<b>40</b>

Billions of yen

	FY2011 Results	FY2012 Previous Forecast (July 27)		FY2012 Forecast Revision		Value compared to previous forecast			
		2Q	FY2012	2Q	FY2012	2Q		FY2012	
							Exchange Impact		Exchange Impact
Net Sales	108.4	59.5	110.8	59.5	112.9	—	—	2.1	- 0.7
Cost of Sales	11.2	5.7	12.6	6.1	13.5	0.4	—	0.9	- 0.1
Gross Profit	97.2	53.8	98.2	53.4	99.4	- 0.4	—	1.2	- 0.6
SG&A expenses	69.8	30.2	63.8	29.2	62.0	- 1.0	—	- 1.8	- 0.4
<b>Income (loss) of Segment</b>	<b>27.4</b>	<b>23.6</b>	<b>34.4</b>	<b>24.1</b>	<b>37.4</b>	<b>0.5</b>	<b>—</b>	<b>3.0</b>	<b>- 0.2</b>

# Key Business Challenges in FY2012

# Targeting Success in LONASEN® Business



**Quantitative strengthening**

- Increased number of CNS specialist MRs (Growth in no. of MRs, FY2008 - 2011)

88 → 144 → 196 → 230

**Qualitative strengthening**

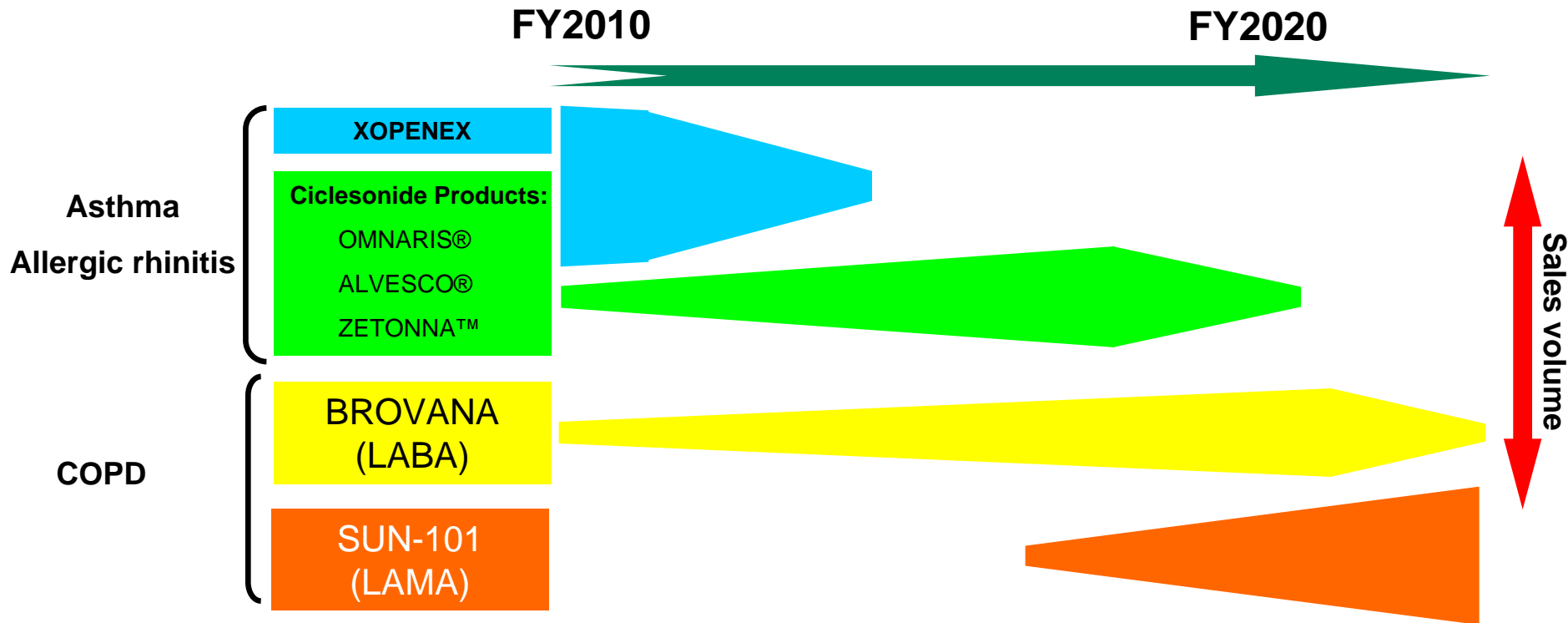
- Launch of e-promotion
- Establishment of CNS Sales and Marketing
- Establishment of Medical Science Liaison (MSL) academic promotion group

**Strengthening measures for FY2012**

- Strengthen and enhance academic support system through MSL
- Set up LONASEN® promotion group → promote impactful detailing
- Enhance and leverage evidence data

# Strengthened Respiratory Drug Pipeline in US with Acquisition of Elevation Pharmaceuticals

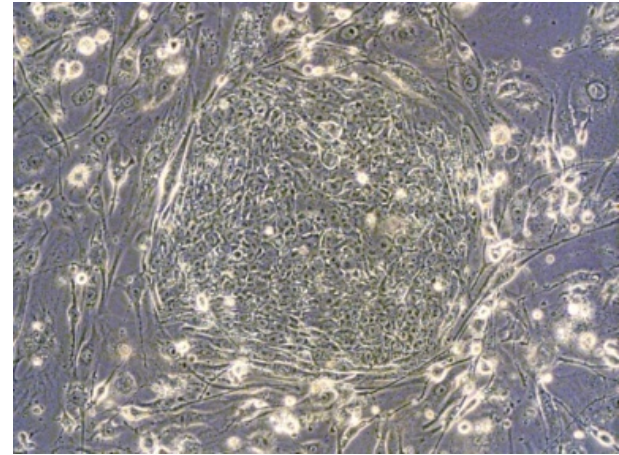
- Enhance respiratory franchise built by Sunovion
- SUN-101: Currently the only LAMA for COPD in nebulized form. High probability of success
- Plan to launch by 2016, synergy with Brovana expected



LABA: Long-Acting Beta Agonist  
LAMA: Long-Acting Muscarinic receptor Antagonist

# Strengthen Drug Discovery Through Application of Cutting-edge Science

- Approaches to regenerative medicine and drug discovery using the latest cell technology, including iPS
  - ✓ Promoting joint research with Kyoto University's Center for iPS Cell Research and Application (CiRA) with the goal of discovering treatments for rare intractable diseases
  - ✓ Began joint research with Johns Hopkins University and Keio University using iN cells and iPS cells from patients with bipolar disorder
  - ✓ Synergy with SanBio SB623 (mesenchymal stem cell derivative) expected
- Use of “K Computer” for drug discovery research
  - ✓ Reduce time taken to select candidate compounds (discovery and research period) by about 20%



# Acceleration of Oncology Business

## Promote development of BBI608, BBI503

### 1. BBI608

- ✓ Agreed on Special Protocol Assessment with the FDA. The Phase III trial is scheduled to begin in 2012 Q4
- ✓ Initiated investigation of the US commercialization framework
- ✓ Scheduled to launch in the US market in 2015

### 2. BBI503

- ✓ Currently undergoing a Phase I trial

## Establishment of global cancer R&D framework

- ✓ Japan: Creation of the DSP Cancer Institute (September 2012)
- ✓ North America: BBI to move to new site in Cambridge at the beginning of 2013
- ✓ Rapid decision-making led by Dr. Chiang Li as Head of Global Oncology



# Clinical Development Status

# Development Pipeline (1) (as of October 31, 2012)

## Central Nervous System Field

Domestic Overseas


Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
LATUDA (SM-13496)	lurasidone hydrochloride	Schizophrenia	Europe, etc.*				
		(New indication) Bipolar I Depression	U.S/Canada				
		Schizophrenia	Japan				
		(New indication) Bipolar Maintenance	US/Europe, etc.				
		(New indication) MDD with mixed features	US				
STEDESA™	eslicarbazepine acetate	Epilepsy-Adjunct	US				
		Epilepsy-Adult monotherapy	US				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New Formulation: Transdermal Tape) Schizophrenia	Japan				
SEP-225289	TBD	Attention-deficit hyperactivity disorder (ADHD)	US				
DSP-8658	TBD	Alzheimer's disease	US				
DSP-1053	TBD	Depression	US				
DSP-2230	TBD	Neuropathic Pain	UK				
SEP-363856	TBD	Schizophrenia	US				





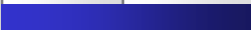












\*LATUDA(SM-13496) : Co-development with Takeda Pharmaceutical in Europe (Submitted: Schizophrenia, Phase III Study: Bipolar disorder)

Revisions since the previous announcement are in red.

# Development Pipeline (2) (as of October 31, 2012)




## Cancer Field

 Domestic  Overseas

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 (2nd/3rd line) (Monotherapy)	US/Canada				
		Colorectal Cancer (3rd/4th line) (Combination therapy)	US/Canada				
		Solid Cancer (2nd/3rd line) (Combination therapy with paclitaxel)	US/Canada		※		
WT4869	TBD	Myelodysplastic syndromes	Japan		※		
		Solid cancer	Japan				
WT2725	TBD	Advanced cancer	US				
BBI503	TBD	Solid cancer (monotherapy)	US/Canada				

## Respiratory Field

※on Phase I of Phase I/II study  Under Preparation








Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-3025	TBD	Asthma/Allergic Rhinitis	Japan				
SUN-101	TBD	Chronic obstructive pulmonary disease (COPD)	US/UK				

Revisions since the previous announcement are in red.








# Development Pipeline (3) (as of October 31, 2012)

## Cardiovascular/ Diabetes Field


Domestic Overseas

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
DSP-8153	amlodipine besilate/irbesartan	Hypertension/Combination agent	Japan				
SUREPOST®	repaglinide	(New indication) Type 2 diabetes (Combination therapy with thiazolidine or biguanide)	Japan				
		(New indication) Type 2 diabetes (All combination therapies including DPP4 inhibitors)	Japan				
METGLUCO®	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
DSP-8658	TBD	Type 2 diabetes	US				
DSP-9599	TBD	Hypertension	Japan				

## Other Fields

Brand name/ Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
MEROPEN®	meropenem hydrate	(Change of maximum dose) Purulent meningitis: 6g daily	Japan				
SMP-986	afacifenacin fumarate	Overactive bladder	Japan				
			US/Europe				
PRORENAL®	limaprost alfadex	(New Indication) Carpal-tunnel syndrome	Japan				
DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan				
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan				
DSP-5990	ceftaroline fosamil	MRSA Infection	Japan				

Revisions since the previous announcement are in red.

 Approved/Preparing for Launch <sup>27</sup>

# Development Pipeline State of Progress (Main changes after July 27, 2012)

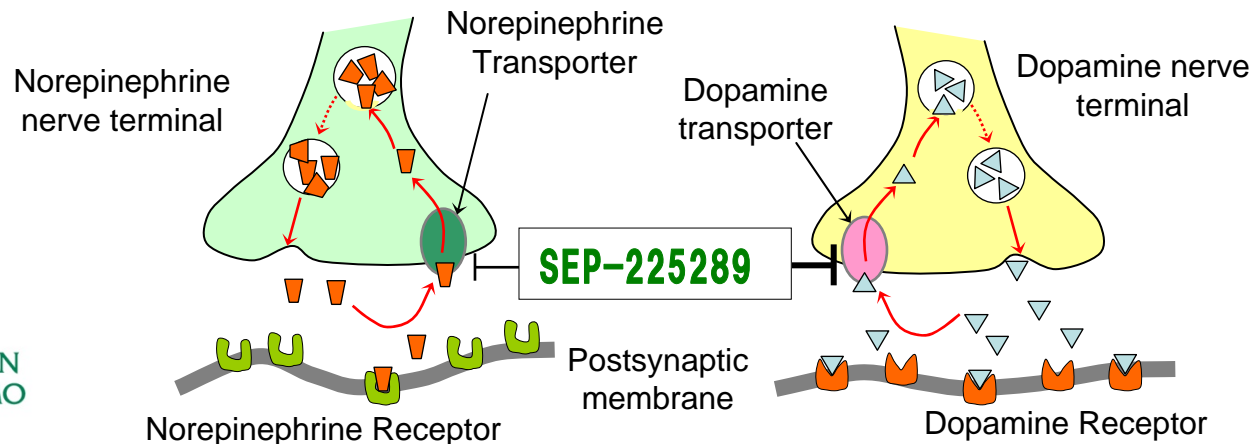
- **LATUDA<sup>®</sup>** (lurasidone hydrochloride)
  - Canada: Launched for adults with schizophrenia (September 2012)
  - U.S. and Canada: NDA submitted for bipolar I depression (August 2012)
- **AIMIX<sup>®</sup> (DSP-8153)**
  - Approved in Japan (September 2012)
- **DSP-1747**
  - Japan: Started Phase II for Nonalcoholic steatohepatitis (NASH)
- **STEDESA<sup>™</sup>** (eslicarbazepine acetate)
  - U.S.: Re-submitted NDA (August 2012)
- **Amrubicin hydrochloride**
  - China: Submitted imported drug registration application (August 2012)
- **New Additions**
  - SUN -101 (U.S. and U.K. Phase I)
  - SEP-225289 (U.S. Phase II)
  - SEP-363856 (U.S. Phase I)
- **Discontinued Compounds**
  - SEP-228432 (U.S. Phase I), DSP-0565 (U.S. Phase 1)

# Profile of SUN-101

- Target Indication: Chronic Obstructive Pulmonary Disease (COPD)
- Pharmacological Mechanism: Long-Acting Muscarinic Receptor Antagonism (LAMA)
- In-house/In-license: In-house (Sunovion / from the former Elevation Pharmaceuticals)
- Development stage: Phase II in the U.S. and U.K.
- Characteristics:
  - Long Acting Muscarinic Receptor Antagonism (LAMA) Bronchodilator, proprietary solution formulation of glycopyrrolate.
  - Delivered by a customized eFlow<sup>®</sup> Nebulizer System (originated by and licensed from PARI Pharma GmbH).
  - Including products on the market and in development in this therapeutic area, SUN-101 is currently the only LAMA in nebulized form.

# Profile of SEP-225289

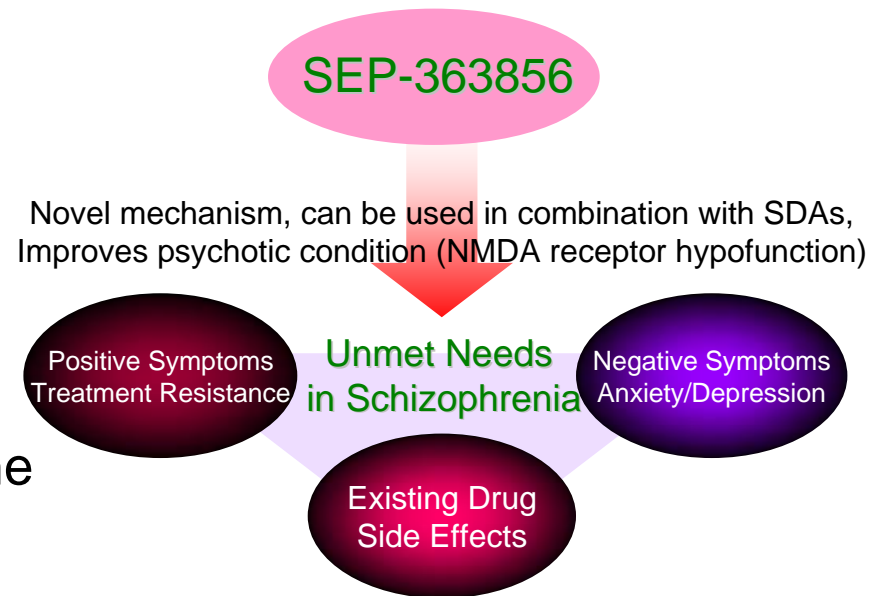
- Target Indication: Attention-deficit hyperactivity disorder (ADHD)
- Pharmacological Mechanism: Dopamine and Norepinephrine Reuptake Inhibitor (DNRI)
- In-house/In-license: In-house (Sunovion)
- Development stage: Phase II in the U.S.
- Characteristics:
  - Because of its ability to maintain a stable concentration in blood levels all day, it is expected to be effective over the course of the day.
  - Reduced risks of dependence and abuse observed in existing medications are expected.



# Profile of SEP-363856

- Target Indication: Schizophrenia
- Pharmacological Mechanism:  
An antipsychotic with a novel mechanism of action
- In-house/In-license: In-house (Sunovion)
- Development stage: Phase I in the U.S.
- Characteristics:

- Compared to existing antipsychotics that are effective for positive symptoms of schizophrenia, this also shows efficacy for the negative symptoms.
- Even in combination treatment with atypical antipsychotics, extrapyramidal side effects were not observed. High efficacy and improved QOL are expected for the treatment of schizophrenia.





# LATUDA® (Lurasidone) – Clinical development status (1)

## US (schizophrenia)

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### ■ Key Current LATUDA® Studies in Schizophrenia

- Schizophrenia Maintenance Study: initiated in 3Q 2011, in progress.
- Pediatric (6-17 yrs) PK Study: initiated in 2Q 2012, in progress.

### ■ Planned LATUDA® Studies in Schizophrenia

- Low-dose Schizophrenia Study with 20mg/day: to be initiated in 1Q 2013
- Pediatric (6-17 yrs) Efficacy Study: to be initiated in 3Q 2013

## U.S. (Bipolar disorder, others)

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### ■ Bipolar I depression Phase III studies (PREVAIL Studies)

- NDA submitted for bipolar I depression in the U.S. and Canada. (Submitted in August 2012)
- PREVAIL#3: Placebo controlled, lithium or valproate adjunctive study  
Initiated in December 2010

### ■ 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

# LATUDA® (Lurasidone) – Clinical development status (2)

## Outside the U.S.

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- Japan: Schizophrenia/ New Phase III study in progress (Initiated in April 2012)
- Canada: Schizophrenia/ Launched in Canada (September 2012)  
Bipolar I Depression/ NDA submitted in the U.S. and Canada (August 2012)
- China: Schizophrenia/ IND submitted (September 2011)
- Europe: **Schizophrenia/ MAA submitted by Takeda Switzerland (March, 2012)**  
**Europe: (September, 2012)**  
**Submitted by the centralized authorization procedure**  
Bipolar disorder/ Co-development with Takeda Pharmaceutical in Europe (Phase III).  
DSP plans to commercialize lurasidone independently in the UK

# 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.

Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.