



# **FY 2014 First Quarter Results and Revised Consolidated Forecast**

**August 6th, 2014**

**Santen Pharmaceutical Co., Ltd**

Kazuo Koshiji

Chief Financial Officer (CFO),

Head of Finance and Administration Division



# **Consolidated Results FY2014 First Quarter**

# Financial Highlights for 1QFY2014

(JPY billions)	1QFY13 Actual	1QFY14 Actual	Var. %
<b>Net Sales</b>	<b>34.31</b>	<b>33.68</b>	<b>-1.8%</b>
Cost of Sales (% of net sales)	13.50 39.3%	13.58 40.3%	+0.6% +1.0pt
SGA excluding R&D (% of net sales)	9.15 26.7%	10.46 31.1%	+14.4% +4.4pt
R&D Cost (% of net sales)	3.84 11.2%	4.23 12.6%	+10.2% +1.4pt
<b>Operating Profit (% of net sales)</b>	<b>7.81 22.8%</b>	<b>5.39 16.0%</b>	<b>-31.0% -6.8pt</b>
Ordinary Income	8.21	5.49	-33.1%
Net Income	5.56	3.73	-32.9%

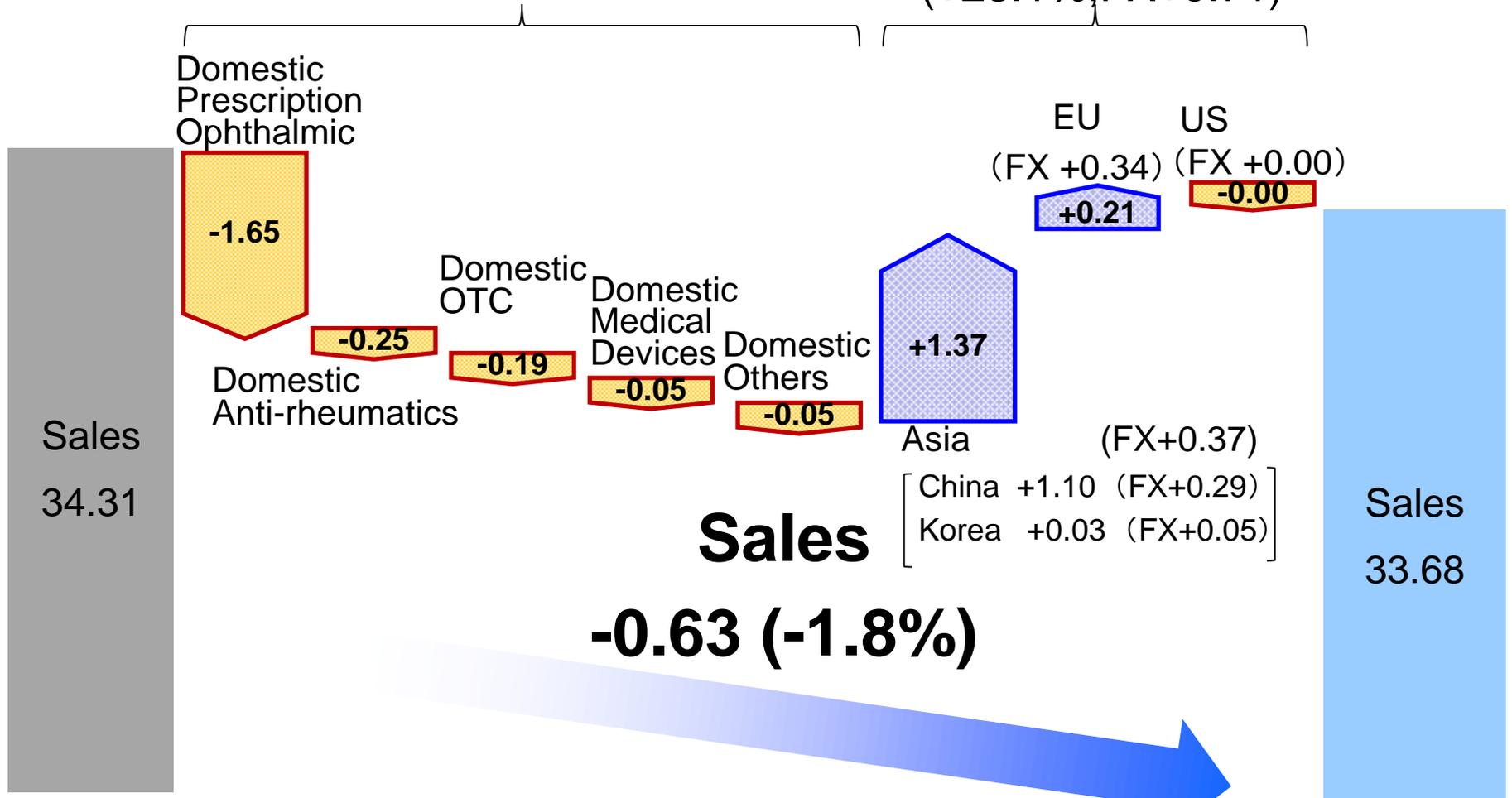
Foreign Exchange	<u>1QFY13 actual</u>	<u>1QFY14 actual</u>
US\$	JPY 98.28	JPY 102.17
Euro	JPY 125.11	JPY 140.18
CNY	JPY 14.62	JPY 16.54

# Sales Increase/Decrease

JPY billions

Domestic -2.21 (-7.7%)

Overseas +1.58  
(+28.1%, FX+0.71)



Sales  
34.31

**Sales**

**-0.63 (-1.8%)**

Sales  
33.68

1QFY13 Actual

1QFY14 Actual

# Operating Profit Change

SG&A (excl. R&D cost) +1.31 (+14.4%)

Gross profit

-0.71

Domestic

-0.07

Asia

(FX+0.12)

+0.42

US/EU (Incl. Santen S.A.S)

(FX+0.26)

+0.53

+0.43

Other

R&D cost

(FX+0.14)

+0.39

JPY billions

## Operating Profit

-2.42 (-31.0%)

OP  
7.81

1QFY13 Actual

OP  
5.39

1QFY14 Actual

FX=Currency impact



# **Revised Consolidated Forecast of FY2014**

# FY2014 Revised Financial Forecast

(JPY :billions)	FY2013 Actual (Japanese Standard)*	FY2014 Revised forecast (Japanese Standard)	Var. %	FY2014 Previous Forecast (Japanese Standard)
<b>Net Sales</b>	<b>148.66</b>	<b>156.00</b>	<b>+4.9%</b>	<b>151.00</b>
Cost of Sales (% of net sales)	58.10 39.1%	52.00 33.3%	-10.5% -5.8pt	57.50 38.1%
SGA excluding R&D (% of net sales)	44.10 29.7%	54.70 35.1%	+24.0% +5.4pt	46.50 30.8%
R&D Cost (% of net sales)	19.04 12.8%	19.30 12.4%	+1.4% -0.4pt	19.00 12.6%
<b>Operating profit (% of net sales)</b>	<b>27.41 18.4%</b>	<b>30.00 19.2%</b>	<b>+9.4% +0.8pt</b>	<b>28.00 18.5%</b>
Ordinary Income	27.92	30.00	+7.4%	28.50
Net Income	17.10	19.50	+14.0%	18.60
Operating profit before amortization	31.20	37.70	+21.0%	32.00
Cash ROE (JPY)	-	14.6%	-	-
ROE	9.9%	10.5%	+0.6pt	10.0%

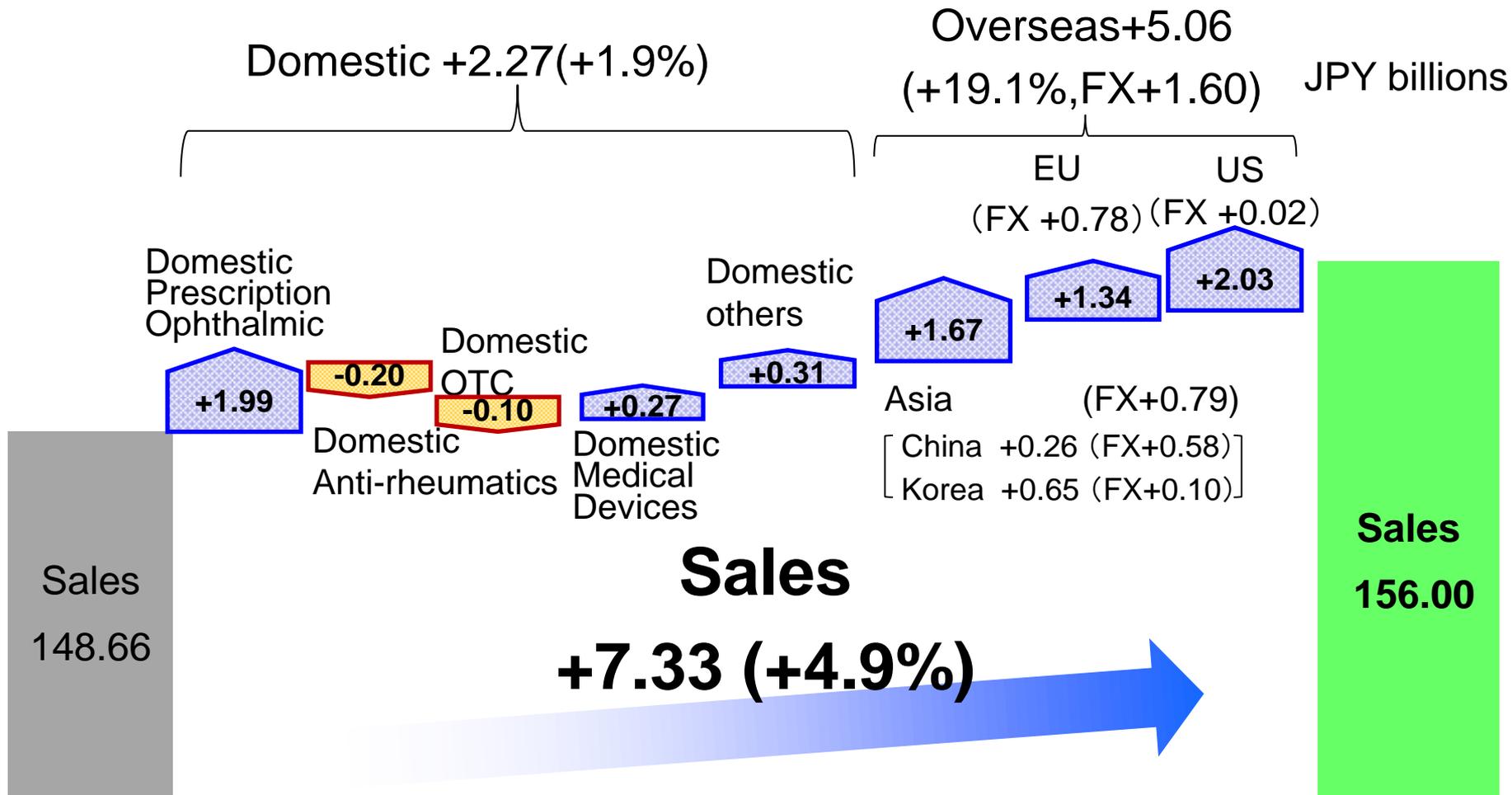
# FY2014 Revised Financial Forecast

(JPY billions)	FY2014 Revised Forecast			
	Existing business	Merck*	Total	Var. %
<b>Net Sales</b>	<b>151.00</b>	<b>5.00</b>	<b>156.00</b>	<b>+4.9%</b>
Cost of Sales (% of net sales)	57.50 38.1%	-5.50 -	52.00 33.3%	-10.5% -5.8pt
SGA excluding R&D (% of net sales)	46.50 30.8%	8.20 -	54.70 35.1%	+24.0% +5.4pt
R&D Cost (% of net sales)	19.00 12.6%	0.30 -	19.30 12.4%	+1.4% -0.4pt
<b>Operating Profit (% of net sales)</b>	<b>28.00 18.5%</b>	<b>2.00 40.0%</b>	<b>30.00 19.2%</b>	<b>+9.4% +0.8pt</b>
Ordinary Income	28.50	1.50	30.00	+7.4%
Net Income	18.60	0.90	19.50	+14.0%

Operating profit before amortization	32.00	5.70	37.70	+21.0%
--------------------------------------	-------	------	-------	--------

\*Merck project is indicated the contribution from acquisition of Merck's ophthalmology asset which Santen contracted as of May 8<sup>th</sup>, 2014.

# Sales Increase/Decrease



**FY13 Actual**  
(Unification of Accounting Period)

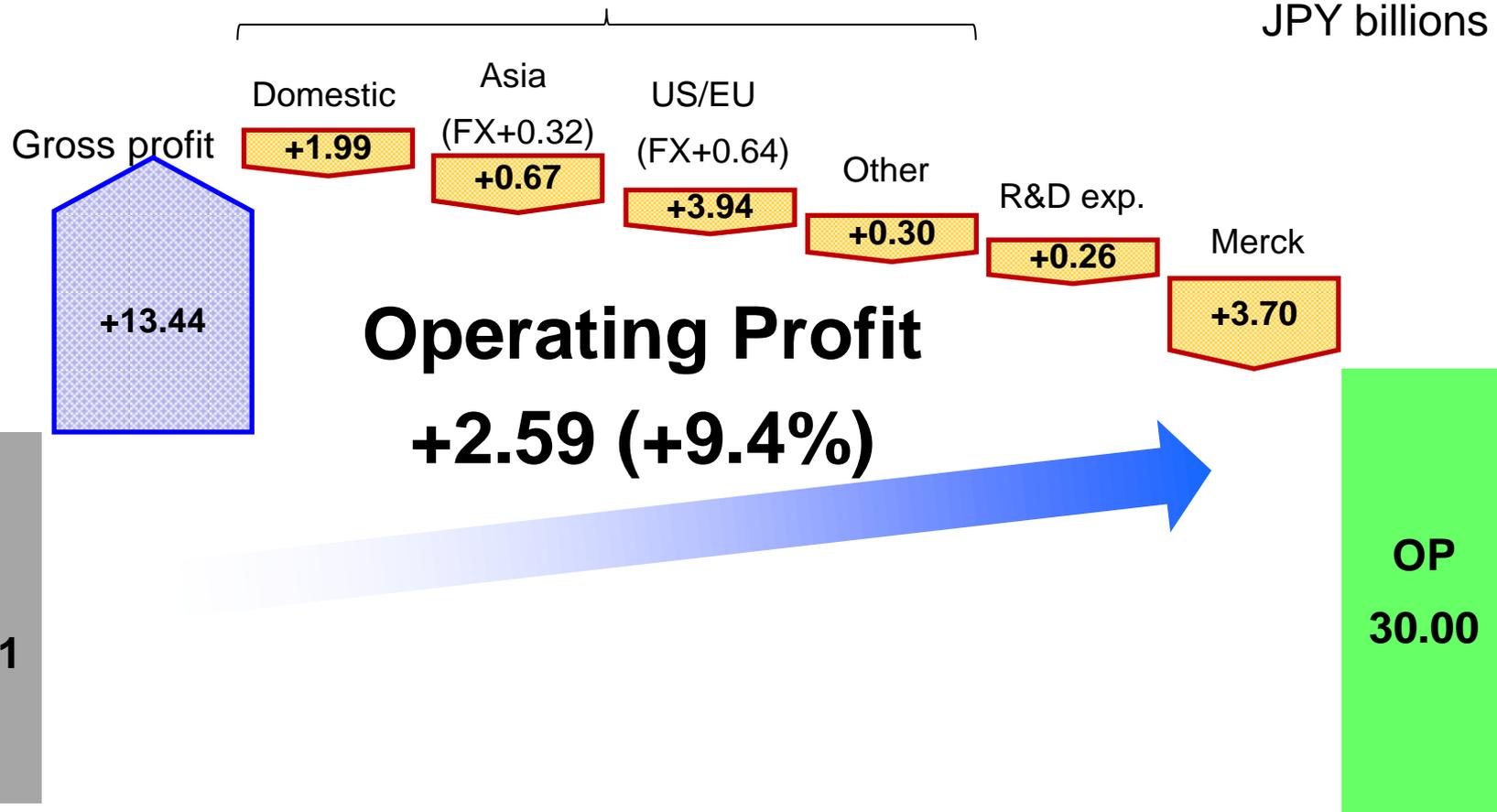
**FY14 Forecast**

Foreign Exchange	FY13 Actual	FY14 Revised Forecast
US \$	JPY 100.04	JPY 103.00
Euro	JPY 132.98	JPY 141.00
CNY	JPY 15.93	JPY 16.90

# Operating Profit Change

**SG&A (excl. R&D cost) +6.90 (+15.6%)**

JPY billions



**FY13 Actual**

(Unification of Accounting Period)

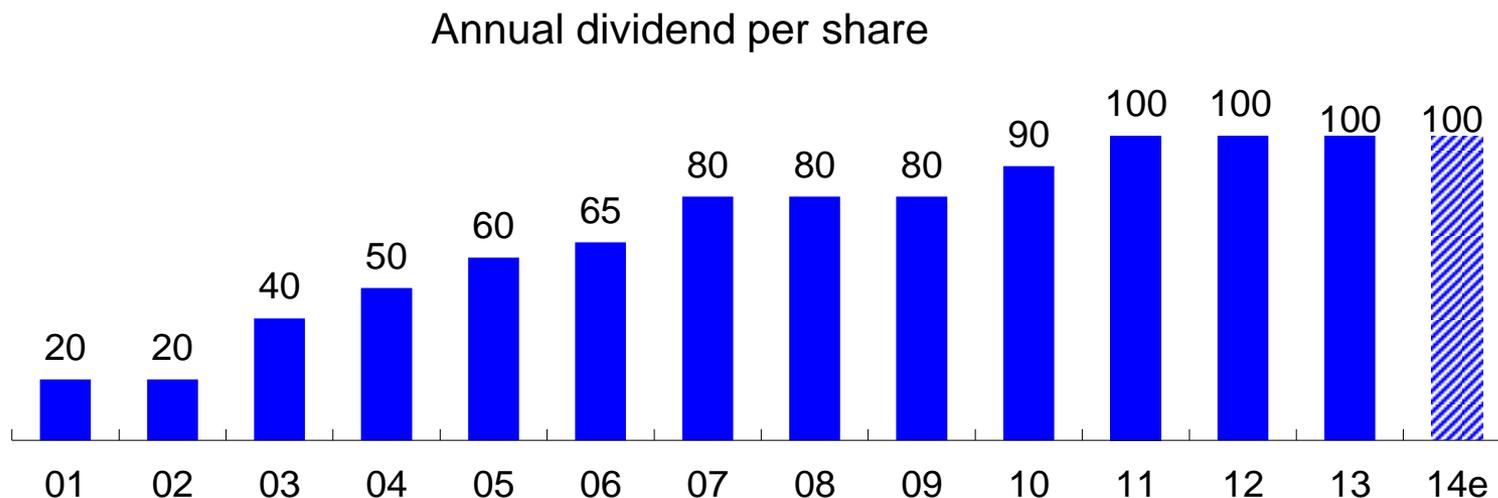


# **Dividend for FY2014 Forecast**

# Dividend for FY2014 Forecast

## ■ FY2014

- FY2014 Annual Dividend Forecast: JPY 100 per share
- Dividend payout ratio: 42.3%



(¥ billion)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014e
Payout-ratio (%)	34.9	21.4	55.8	39.7	39.9	42.9	54.7	67.2	36.3	36.0	50.8	51.1	48.2	42.3
Share Buy-back	3.2	3.2	0	2.6	0	0	4.8	0	0	0	0	13.7	0	-
Total Return (%)	96.4	59.5	55.8	63.3	39.9	42.9	85.8	67.2	36.3	36.0	50.8	134.4	48.2	-



**Reference:  
Consolidated Results  
FY2014 First Quarter**

# Net Sales by Business Segment

(JPY billions)	1QFY14 Actual					
	Japan		Overseas		Total	
	Sales	Var. %	Sales	Var. %	Sales	Var. %
<b>Pharmaceuticals</b>	<b>25.85</b>	<b>-7.7%</b>	<b>7.21</b>	<b>+28.3%</b>	<b>33.06</b>	<b>-1.7%</b>
Prescription Pharmaceuticals	24.54	-7.4%	7.20	+28.3%	31.75	-1.1%
Ophthalmic	22.01	-7.0%	6.92	+26.9%	28.94	-0.6%
Anti-RA	2.38	-9.7%	0.01	-44.2%	2.39	-10.1%
Others	0.15	-23.2%	0.25	+110.3%	0.40	+27.5%
OTC Pharmaceuticals	1.30	-13.0%	0.01	+29.2%	1.31	-12.8%
<b>Others</b>	<b>0.61</b>	<b>-9.4%</b>	<b>0.00</b>	<b>-94.5%</b>	<b>0.61</b>	<b>-10.7%</b>
Medical Devices	0.56	-9.2%	0.00	-94.5%	0.56	-10.6%
Others	0.05	-11.3%	-	-	0.05	-11.3%
<b>Total</b>	<b>26.46</b>	<b>-7.7%</b>	<b>7.21</b>	<b>+28.1%</b>	<b>33.68</b>	<b>-1.8%</b>

# Overseas Sales

(JPY billions)	1QFY13 Actual	1QFY14		
		Actual	Var.	Var. %
U.S.	0.25	0.25	-0.00	-0.1%
Europe	2.97	3.19	+0.21	+7.4%
Asia	2.38	3.75	+1.37	+57.5%
China	1.42	2.52	+1.10	+77.2%
Korea	0.69	0.73	+0.03	+4.9%
Others	0.00	0.00	-0.00	-74.8%
Total	5.62	7.21	+1.58	+28.1%

<b>Overseas sale/sales</b>	<b>16.4%</b>	<b>21.4%</b>	<b>+5.0pt</b>	<b>-</b>
----------------------------	--------------	--------------	---------------	----------

# Summary of Balance Sheet

(JPY billions)	As of March 31, 2014		As of June 30, 2014		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	156.00	67.5%	181.93	70.9%	+25.92
Fixed Asset	75.09	32.5%	74.56	29.1%	-0.52
Total Asset	231.10	100.0%	256.50	100.0%	+25.39
Current Liabilities	39.09	16.9%	64.92	25.3%	+25.82
Non-current Liabilities	10.80	4.7%	10.81	4.2%	+0.00
Total Liabilities	49.89	21.6%	75.73	29.5%	+25.83
Total Net Asset	181.20	78.4%	180.76	70.5%*	-0.44
Total Liabilities Net Assets	231.10	100.0%	256.50	100.0%	+25.39

\*Capital adequacy ratio: End of March, 2014: 78.2% → End of June, 2014: 70.3%,  
 Issued shares: End of March, 2014: 82,582 thousands → End of June, 2014: 82,587 thousands

## Major Changes

- **Current Asset:** Cash and deposits +¥29.20bil, Notes and account receivable -¥1.59bil, Securities -¥4.50bil, Products +¥4.11bil
- **Fixed Asset:** Goodwill -¥0.36bil, In-Process R&D -¥0.19bil, Investment securities +¥0.94bil, Deferred tax assets -¥0.49bil
- **Current Liabilities:** Notes and accounts payable +¥1.22bil, Short term borrowing +¥35.00bil, Account payable -¥1.73bil, Income tax payable -¥7.18bil, Reserve for bonus -¥1.91bil,
- **Net asset:** Retained earnings -¥0.39bil, Unrealized gains on securities +¥0.61bil, Foreign currency translation adjustments -¥0.70bil

# Changes in Income Statement

(JPY billions)	1QFY13	1QFY14		Major Changes
	Actual	Actual	Var. %	
<b>Net Sales</b>	<b>34.31</b>	<b>33.68</b>	<b>-1.8%</b>	
Cost of Sales (% of net sales)	13.50 39.3%	13.58 40.3%	+0.6% +1.0pt	<ul style="list-style-type: none"> <li>▪ Impact of product mix change +1.3pt</li> <li>▪ Effect from NHI price revision +0.5pt</li> <li>▪ Reduction of manufacturing cost -0.7pt</li> </ul>
SGA excluding R&D (% of net sales)	9.15 26.7%	10.46 31.1%	+14.4% +4.4pt	<ul style="list-style-type: none"> <li>▪ Domestic -0.07</li> <li>▪ Asia +0.42 (FX+0.12)</li> <li>▪ US/EU +0.53 (FX+0.21)</li> </ul>
R&D Expenses (% of net sales)	3.84 11.2%	4.23 12.6%	+10.2% +1.4pt	<ul style="list-style-type: none"> <li>▪ Domestic +0.25</li> <li>▪ Overseas +0.14 (FX+0.12)</li> </ul>
<b>Operating Profit</b> (% of net sales)	<b>7.81</b> 22.8%	<b>5.39</b> 16.0%	<b>-31.0%</b> -6.8pt	
Non-operating Income	0.45	0.47	+5.0%	
Non-operating Expense	0.05	0.36	-	
Ordinary Income	8.21	5.49	-33.1%	
Extraordinary Gain	-	-	-	
Extraordinary Loss	0.00	-	-	
Net Income before Tax	8.21	5.49	-33.1%	
Corporate Tax	2.65	1.76	-33.4%	
Net Profit	5.56	3.73	-32.9%	

<Currency Rates>		
	Q1 FY13 actual	Q1 FY14 actual
US\$	JPY 98.28	JPY 102.17
Euro	JPY 125.11	JPY 140.18
CNY	JPY 14.62	JPY 16.54

# Summary of Cash Flows

(JPY billions)	1QFY14 Actual
<b>Cash and cash equivalents at the beginning of 1QFY14</b>	<b>72.39</b>
<b>Net increase/decrease in cash and cash equivalents</b>	<b>+25.60</b>
Cash flows from operating activities	-5.21
Cash flows from investing activities	+0.39
Cash flows from financial activities	+30.96
Effect of exchange rate changes on cash and cash equivalents	-0.53
<b>Cash and cash equivalents at the end of 1QFY14</b>	<b>98.00</b>

Note: "Cash and cash equivalents" include cash equivalents thus differ from "cash and deposits" in the Balance Sheets.

# Capital Expenditures / Depreciation & Amortization

(JPY billions)	1QFY13	1QFY14	
	Actual	Actual	Var.
Capital Expenditures	1.02	0.38	-0.64
Depreciation and Amortization	0.56	0.69	+0.13



**Reference:  
Revised Consolidated Forecast of  
FY2014**

# FY2014 Revised Financial Forecast

(JPY billions)	FY2013 Actual (Unification of Accounting Period)	FY2014 Forecast (Japanese Standard)	FY2014 Forecast (IFRS)	FY2014 Revised forecast (Japanese standard)	Var. %	FY2014 Revised forecast (IFRS)*
<b>Net Sales</b>	<b>148.66</b>	<b>151.00</b>	<b>151.00</b>	<b>156.00</b>	<b>+4.9%</b>	<b>156.00</b>
Cost of sales (% of net sales)	58.10 39.1%	57.50 38.1%	57.50 38.1%	52.00 33.3%	-10.5% -5.8pt	52.00 33.3%
SGA excluding R&D (% of net sales)	44.10 29.7%	46.50 30.8%	45.60 30.1%	51.00 32.7%	+15.6% +3.0pt	53.80** 34.4%
R&D cost (% of net sales)	19.04 12.8%	19.00 12.6%	18.80 12.4%	19.30 12.4%	+1.4% -0.4pt	19.10 12.2%
<b>Operating profit (% of net sales)</b>	<b>27.41 18.4%</b>	<b>28.00 18.5%</b>	<b>29.10 19.2%</b>	<b>30.00 19.2%</b>	<b>+9.4% +0.8pt</b>	<b>31.10 19.9%</b>
Ordinary Income	27.92	28.50	29.60	30.00	+7.4%	31.10
Net Income	17.10	18.60	19.60	19.5	+14.0%	20.50
ROE	9.9%	10.0%	10.2%	10.5%	+0.6pt	10.6%

\* 【Difference between Japanese Standard forecast and IFRS】

• Including the depreciation of intangible asset

• Reported asset of license in payment

\*\* Including Merck depreciate of intangible asset, ¥3.7bil

< Foreign exchange >	FY13 Actual	FY14 Forecast
US \$	JPY 100.04	JPY 103.00
Euro	JPY 132.98	JPY 141.00
CNY	JPY 15.93	JPY 16.90

# FY2014 Revised Financial Forecast

## 1st Half · 2nd Half

(JPY billions)	FY2014 Revised Forecast (J-GAAP)					
	1 <sup>st</sup> Half	Var. %	2 <sup>nd</sup> Half	Var. %	Total	Var. %
<b>Net Sales</b>	<b>72.00</b>	<b>+4.0%</b>	<b>84.00</b>	<b>+5.8%</b>	<b>156.00</b>	<b>+4.9%</b>
Cost of Sales (% of net sales)	26.00 36.1%	-4.3%	26.00 31.0%	-16.0%	52.00 33.3%	-10.5%
SGA excluding R&D (% of net sales)	24.00 33.3%	+22.7%	30.70 36.5%	+25.1%	54.70 35.1%	+24.0%
R&D Cost (% of net sales)	9.00 12.5%	+11.4%	10.30 12.3%	-6.0%	19.30 12.4%	+1.4%
<b>Operating Profit</b> (% of net sales)	<b>13.00</b> <b>18.1%</b>	<b>-10.1%</b>	<b>17.00</b> <b>20.2%</b>	<b>+31.2%</b>	<b>30.00</b> <b>19.2%</b>	<b>+9.4%</b>

Operating profit before amortization (% of net sales)	16.00 22.2%	-0.0%	21.70 25.8%	+43.4%	37.70 24.1%	+21.0%
---	----------------	-------	----------------	--------	----------------	--------

# Revised Sales Forecast by Business Segment / Overseas Sales (Japanese Standard)

(JPY billions)	FY2014 Revised Forecast					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var. %	Sales	Var. %
<b>Pharmaceuticals</b>	<b>121.47</b>	<b>+1.9%</b>	<b>31.56</b>	<b>+19.1%</b>	<b>153.03</b>	<b>+5.0%</b>
Prescription Pharmaceuticals	115.16	+2.1%	31.54	+19.2%	146.70	+5.3%
Ophthalmic	103.77	+2.0%	28.35	+10.7%	132.12	+3.7%
Anti-RA	9.95	-2.0%	0.03	-61.4%	9.99	-2.5%
Others	1.43	+67.2%	3.15	+318.1%	4.58	+184.7%
OTC Pharmaceuticals	6.30	-1.7%	0.02	-36.6%	6.33	-1.9%
<b>Others</b>	<b>2.91</b>	<b>+0.5%</b>	<b>0.04</b>	<b>-6.7%</b>	<b>2.96</b>	<b>+0.4%</b>
Medical Devices	2.90	+10.5%	0.04	-20.7%	2.94	+9.8%
Others	0.01	-95.6%	0.00	-	0.01	-92.8%
<b>Total</b>	<b>124.38</b>	<b>+1.9%</b>	<b>31.61</b>	<b>+19.1%</b>	<b>156.00</b>	<b>+4.9%</b>

# Overseas Sales Revised Forecast (Japanese Standard)

(JPY billions)	FY2013 Actual (Unification of Accounting Period)	FY2014 Revised Forecast		
		Forecast	Var.	Var. %
U.S.	1.07	3.10	+2.03	+189.1%
Europe	12.29	13.64	+1.34	+11.0%
Asia	13.17	14.85	+1.68	+12.8%
<i>China</i>	<i>9.79</i>	<i>10.06</i>	<i>+0.26</i>	<i>+2.7%</i>
<i>Korea</i>	<i>2.10</i>	<i>2.75</i>	<i>+0.65</i>	<i>+31.1%</i>
Others	0.00	0.01	+0.00	+71.9%
Total	26.55	31.61	+5.06	+19.1%

<b>Overseas sale/sales</b>	<b>17.9%</b>	<b>20.3%</b>	<b>+2.4pt</b>	<b>-</b>
----------------------------	--------------	--------------	---------------	----------

# Capital Expenditures / Depreciation & Amortization (Japanese Standard)

(JPY billions)	FY2013 Actual (Unification of Accounting Period)	FY2014	
		Forecast	Var.
Capital Expenditures	3.15	6.69	+3.53
Depreciation and Amortization	2.61	6.70	+4.08

# Previous Sales Forecast by Business Segment / Overseas Sales (Japanese Standard)

(JPY billions)	FY2014 Forecast					
	Japan		Overseas		Total	
	Sales	Var. %	Sales	Var. %	Sales	Var. %
<b>Pharmaceuticals</b>	<b>118.75</b>	<b>-0.4%</b>	<b>29.27</b>	<b>+10.5%</b>	<b>148.03</b>	<b>+1.6%</b>
Prescription Pharmaceuticals	112.45	-0.3%	29.25	+10.6%	141.70	+1.8%
Ophthalmic	101.06	-0.7%	28.35	+10.7%	129.41	+1.6%
Anti-RA	9.95	-2.0%	0.03	-61.4%	9.99	-2.5%
Others	1.43	+67.2%	0.86	+15.0%	2.29	+42.8%
OTC Pharmaceuticals	6.30	-1.7%	0.02	-36.6%	6.33	-1.9%
<b>Others</b>	<b>2.91</b>	<b>+0.5%</b>	<b>0.04</b>	<b>-6.7%</b>	<b>2.96</b>	<b>+0.4%</b>
Medical Devices	2.90	+10.5%	0.04	-20.7%	2.94	+9.8%
Others	0.01	-95.6%	0.00	--	0.01	-92.8%
<b>Total</b>	<b>121.67</b>	<b>-0.4%</b>	<b>29.32</b>	<b>+10.5%</b>	<b>151.00</b>	<b>+1.6%</b>

# Previous Oversea Sales Forecast (Japanese Standard)

(JPY billions)	FY2013 Actual (Unification of Accounting Period)	FY2014 Revised Forecast		
		Forecast	Var.	Var. %
U.S.	1.07	0.81	-0.25	-23.8%
Europe	12.29	13.64	+1.34	+11.0%
Asia	13.17	14.85	+1.67	+12.8%
<i>China</i>	<i>9.79</i>	<i>10.06</i>	<i>+0.26</i>	<i>+2.7%</i>
<i>Korea</i>	<i>2.10</i>	<i>2.75</i>	<i>+0.65</i>	<i>+31.1%</i>
Others	0.00	0.01	+0.00	+71.9%
Total	26.55	29.32	+2.77	+10.5%

<b>Overseas sales/sales</b>	<b>17.9%</b>	<b>19.4%</b>	<b>+1.6pt</b>	<b>-</b>
-----------------------------	--------------	--------------	---------------	----------



**Reference:**

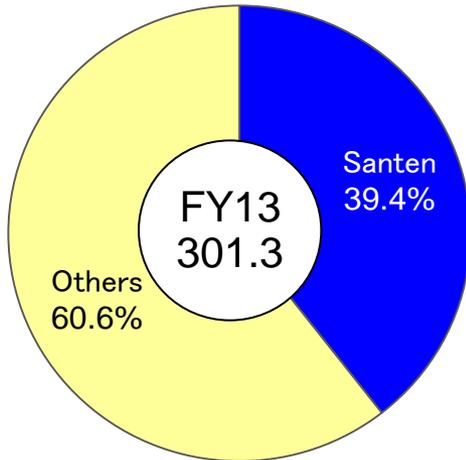
**Market Overview of  
Prescription Ophthalmic in Japan**

# Japan: Trend & Competition in Ophthalmics (1)

- **Ophthalmology Total:** Market grew by 6.5% Y on Y in 1QFY14. The growth is driven by retina and allergy market. Santen's market share was 38.5%.
- **Anti-Glaucoma:** Market shrunk by -1.1% Y on Y in 1QFY14. Santen's sales decreased by -4.8% due to influence of early demand before premium for new drug development. Santen's market share was 29.4%.
- **Corneal:** Market shrunk by -1.5% Y on Y in 1QFY14. Santen's sales dropped to -9.2% due to influence of early demand before premium for new drug development. Santen's market share was 66.6%.

Market Size:  
billions of yen  
%: Value Share

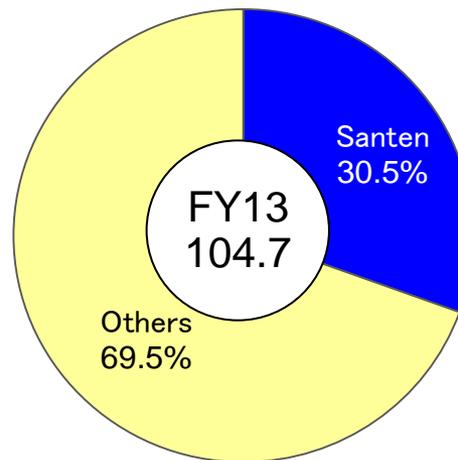
## Ophthalmology Total



FY13      1QFY14

YoY change	Market	+10.2%	+6.5%
	Santen	+23.1%	+2.8%
Santen's Share		39.4%	38.5%

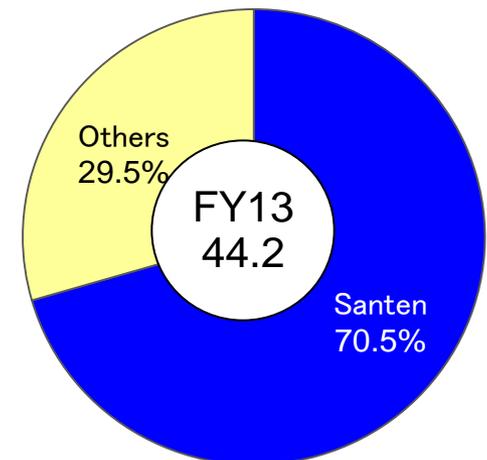
## Anti-glaucoma



FY13      1QFY14

YoY change	Market	+10.5%	-1.1%
	Santen	+10.7%	-4.8%
Santen's Share		30.5%	29.4%

## Corneal: Dry Eye



FY13      1QFY14

YoY change	Market	+11.5%	-1.5%
	Santen	+5.4%	-9.2%
Santen's Share		70.5%	66.6%

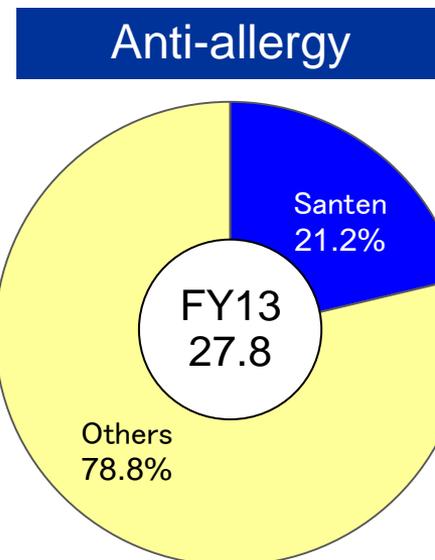
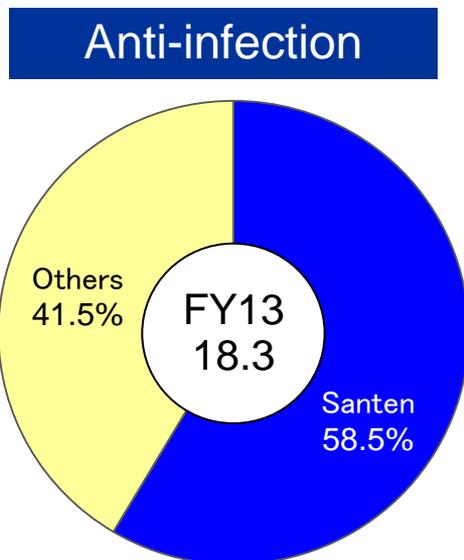
- Santen:  
 - Anti-Glaucoma : Tapros, Cosopt, Timoptol/XE, Rescula, Detantol  
 - Cornea / Dry Eye : Hyalein, Diquas

Source: ©2014 IMS Health  
 IMS-JPM 2012-14  
 Santen analysis based on IMS data  
 Reprinted with permission

# Japan: Trend & Competition in Ophthalmics (2)

- **Anti-infection:** Market declined by -9.2% Y on Y in 1QFY14. Santen maintained 56.4% of market share with primary contribution by Cravit.
- **Anti-allergy:** Market increased by 22.5% Y on Y in 1QFY14. Santen's share was 29.5%.  
The launch of Alesion in Nov,2013 generated the increase of Santen market share.

Market Size:  
billions of yen  
%: Value Share



		FY13	1QFY14
change YoY	Market	-3.0%	-9.2%
	Santen	-7.8%	-15.1%
Santen's Share		58.5%	56.4%

		FY13	1QFY14
Market		-9.7%	+22.5%
Santen		+19.7%	+100.1%
Santen's Share		21.2%	29.5%

- Santen:  
 - Anti-infection: Cravit, Tarivid  
 - Anti-allergy: Livostin, Alesion, Alegysal

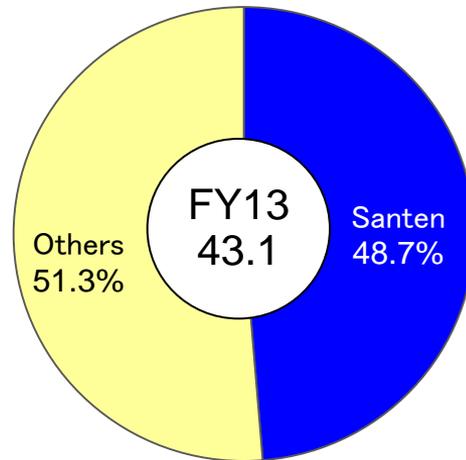
Source: ©2014 IMS Health  
 IMS-JPM 2012-14  
 Santen analysis based on IMS data  
 Reprinted with permission

# Japan: Trend & Competition in Ophthalmics (3)

- **Anti-VEGF:** Market increased by 52.8% Y on Y in 1QFY14. Eylea has continued the strong growth. Santen's share was 45.0%.
- **Anti-RA(DMARDs):** Market slightly decreased by -0.9% in 1QFY14. Santen maintained 37.6% of market share.

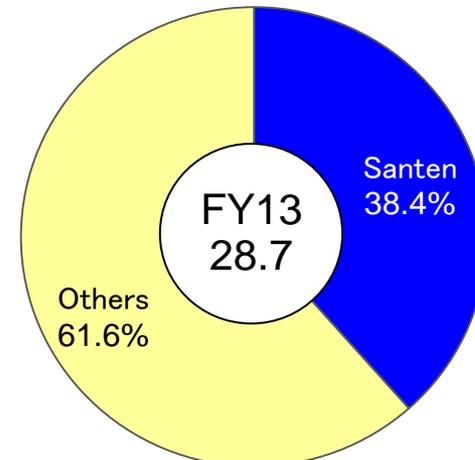
Market Size:  
billions of yen  
%: Value Share

## Anti-VEGF



		FY13	1QFY14
YoY change	Market	+52.6%	+52.8%
	Santen	-	+36.6%
Santen's Share		48.7%	45.0%

## Anti-RA(DMARDs)



		FY13	1QFY14
YoY change		+5.5%	-0.9%
Santen		+2.0%	-4.8%
Santen's Share		38.4%	37.6%

-Santen:  
- Anti-VEGF: Eylea  
- Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate

Source: ©2014 IMS Health  
IMS-JPM 2012-14  
Santen analysis based on IMS data  
Reprinted with permission



# **Status of Clinical Development FY2014 First Quarter**

Naveed Shams, Ph.D.

Senior Corporate Officer

Chief Scientific Officer (CSO)

Head of Global Research & Development

# Major Clinical Pipeline List (1) [by Disease]

(Red underlined: Change from 4Q FY13 Presentation)

Global Product

Japan (Asia)Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved - Launched
Glaucoma/ Ocular Hypertension		<u>DE-117</u> <sup>P2b</sup> EP2 Receptor Agonist		China <u>DE-085</u> Tafluprost	
		<u>DE-090</u> Lomerizine HCl		EU <u>DE-111</u> Tafluprost/Timolol	JP
				Asia <u>DE-118</u> Tafluprost UD	JP
Corneal/ Conjunctival Disease				China <u>DE-089</u> Diquafosol Sodium	Korea
		U.S. <u>Cyclokat</u> Ciclosporin		<u>Cyclokat</u> EU Ciclosporin	
Retina/ Uveitis	U.S. <u>DE-120</u> VEGF/PDGF inhibitor		<u>DE-109</u> Sirolimus		
Other Infection, Allergy, RA			<u>Vekacia</u> Ciclosporin		

# Major Clinical Pipeline List (2) [by Region]

(Red underlined: Change from 4Q FY13 Presentation)

Global Product

Japan (Asia)Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved-Launch
Japan		DE-090 Lomerizine HCl	DE-109 Sirolimus		DE-111 Tafuprost/Timolol
					DE-118 Tafuprost UD
North America (Including Latin America)		DE-117 <u>P2b</u> EP2 Receptor Agonist	DE-109 Sirolimus		
	DE-120 VEGF/PDGF inhibitor				
		Cyclokot Ciclosporin			
Asia (including Oceania)				China DE-085 Tafuprost	
				China DE-089 Diquafosol Sodium	Korea
				DE-118 Tafuprost UD	
EU			DE-109 Sirolimus	DE-111 Tafuprost/Timolol	
			Vekacia Ciclosporin	Cyclokot Ciclosporin	

# Major Clinical Projects Update -Glaucoma / Ocular hypertension-

## ■ DE-085 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
China	NDA Filed	NDA Filed	Generic name: Tafluprost

## ■ DE-090 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

## ■ DE-111 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
Japan	Approved	Approved	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	NDA Filed	NDA Filed	

# Major Clinical Projects Update

-Glaucoma /  
Ocular hypertension-  
-Corenal disease-

## ■ DE-117 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
U.S.	<b>P2b</b>	P2b preparation	EP2 receptor agonist

## ■ DE-089 (Dry eye)

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
Asia	China: NDA filed Korea: Launched	China: NDA filed Korea: Launched	Generic name: Diquafosol Sodium

# Major Clinical Projects Update

-Retinal Disease-  
-Uveitis-

■ **DE-120** (Wet Age-related Macular Degeneration (w-AMD))

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
U.S.	P1/2a	P1/2a	VEGF/PDGF dual inhibitor

■ **DE-109** (Uveitis)

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
U.S.	P3	P3	Generic name: <b>Sirolimus</b>
Japan	P3	P3	
EU	P3	P3	

# Major Clinical Projects Update -Santen S.A.S.-

## ■ Cyclokat (Severe Dry Eye)

Region	Development Stage		Remarks
	As of August 5, 2014	May 13, 2014 (Previous)	
EU	NDA filed	NDA filed	Generic Name: Ciclosporin
U.S.	P2 Completed	P2 Completed	

## ■ Vekacia (Vernal Keratoconjunctivitis)

Region	Development Stage		Remarks
	As of August 5, 2014	May 13, 2014 (Previous)	
EU	P3	P3	Generic Name: Ciclosporin

\*Project evaluations are ongoing for the products below.

Development Name	Indication	Region	Stage	Remarks
Catioprost	Glaucoma/ Ocular hypertension	EU	P2	Generic Name: Latanoprost
Cortiject	Diabetic macular edema	U.S.	P1/2	Generic Name: Dexamethasone Palmitate

# Major Clinical Projects Update

-Retinal Disease-  
-Uveitis-

- **DE-102** (Macular edema associated with diabetes or branch retinal vein occlusion (BRVO))

Region	Development Stage		Remarks
	As of August 5, 2014	As of May 13, 2014 (Previous announcement)	
Japan	<b>Discontinued</b>	<b>P2/3 Completed</b>	Generic name: <b>Betamethasone</b>

## Forward-Looking Statements

- Information given in this announcement and accompanying documentation contains certain forward-looking statements concerning forecasts, projections and plans whose realization is subject to risk and uncertainty from a variety of sources. Actual results may differ significantly from forecasts.
- Business performance and financial condition are subject to the effects of medical regulatory changes made by the governments of Japan and other nations concerning medical insurance, drug pricing and other systems, and to fluctuations in market variables such as interest rates and foreign exchange rates.
- The process of drug research and development from discovery to final approval and sales is long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Forecasts and projections concerning new products take into account assumptions concerning the development pipelines of other companies and any co-promotion agreements, existing or planned. The success or failure of such agreements could affect business performance and financial condition significantly.
- Business performance and financial conditions could be affected significantly by a substantial drop in sales of a major drug, either currently marketed or expected to be launched, due to termination of sales as a result of factors such as patent expiry and complications, product defects or unforeseen side effects. Santen Pharmaceutical also sells numerous products under sales and/or manufacturing license from other companies. Business performance could be affected significantly by changes in the terms and conditions of agreements and/or the non-renewal of agreements.
- Santen Pharmaceutical is reliant on specific companies for supplies of certain raw materials used in production. Business performance could be affected significantly by the suspension or termination of supplies of such raw materials if such an event were to adversely affect supply capabilities for related final products.

**Santen**