



# **FY 2013 First Quarter Results**

**August 6, 2013**

**Santen Pharmaceutical Co., Ltd**



# **Consolidated Results FY2013 First Quarter**

**Kazuo Koshiji**

Corporate Officer,

Head of Finance & Administration Division

# Med-term Policies FY2011-2013

**To become a specialized pharmaceutical company with a global presence**

1. Promote global oriented research and development operation.
2. Boost domestic business by maximizing new product value and implementation of sales/marketing strategies.
3. Accelerate growth in both Asia and Europe by reinforcing marketing platform.
4. Establish global product supply system with existing 4 plants which enables to meet the emerging market needs.
5. Develop talents and organizational capabilities to promote “Creation and Innovation” on a globally level.

# Financial Highlights for Q1 FY2013

(JPY billions)	Q1 FY2012 Actual	Q1 FY2013 Actual	Var. %
<b>Net Sales</b>	<b>27.95</b>	<b>34.31</b>	<b>+22.7%</b>
<b>Cost of Sales</b> (% of net sales)	9.44 33.8%	13.50 39.3%	+42.9% +5.6pt
<b>SGA excluding R&amp;D</b> (% of net sales)	8.38 30.0%	9.15 26.7%	+9.2% -3.3pt
<b>R&amp;D Cost</b> (% of net sales)	4.00 14.3%	3.84 11.2%	-4.0% -3.1pt
<b>Operating Profit</b> (% of net sales)	<b>6.12</b> 21.9%	<b>7.81</b> 22.8%	<b>+27.6%</b> +0.9pt
<b>Ordinary Income</b>	<b>6.54</b>	<b>8.21</b>	<b>+25.5%</b>
<b>Net Income</b>	<b>4.27</b>	<b>5.56</b>	<b>+30.0%</b>

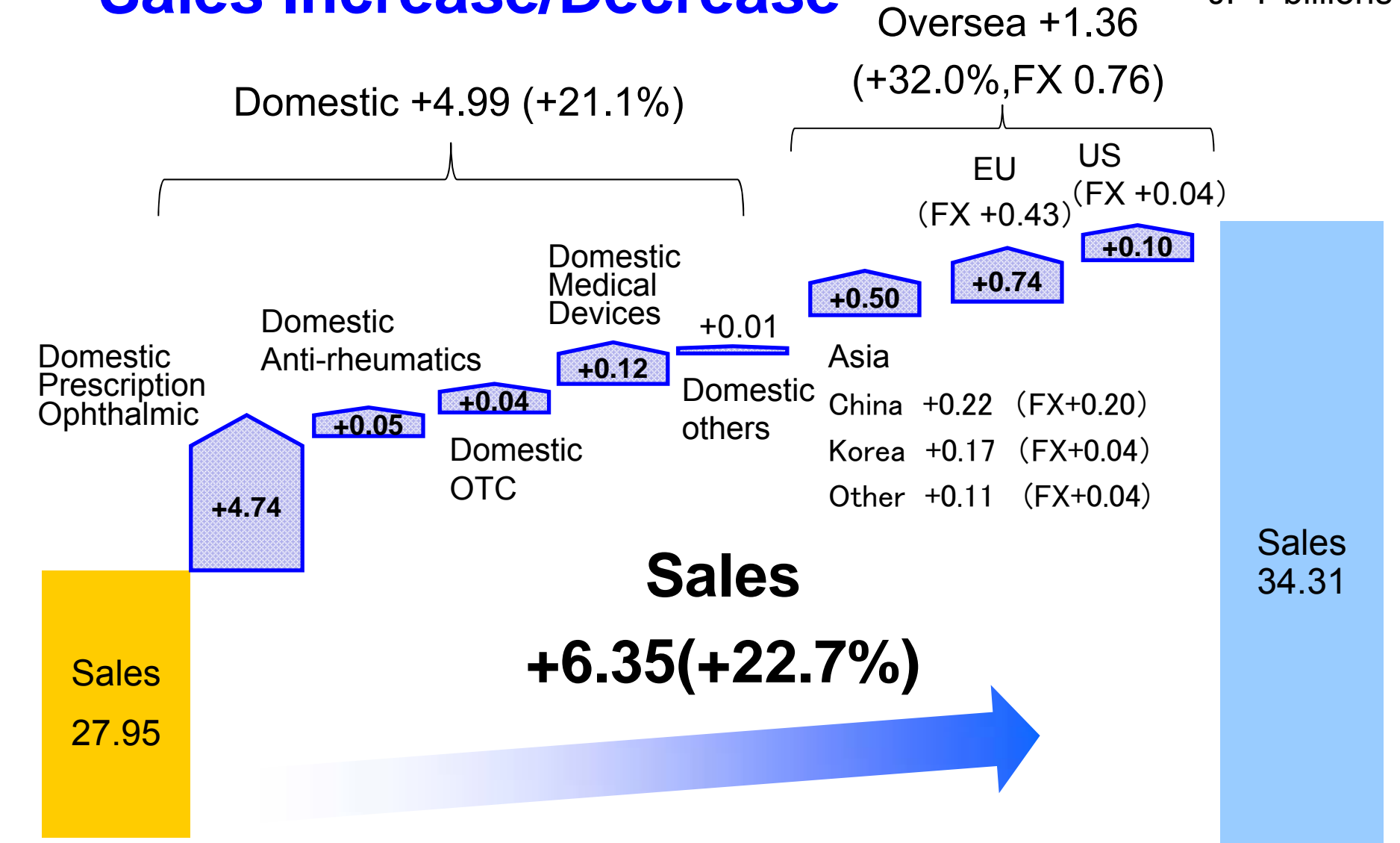
Foreign Exchange	Q1.FY12 actual	Q1.FY13 actual
US \$	JPY 80.20	JPY 98.28
Euro	JPY 106.60	JPY 125.11
RMB	JPY 12.51	JPY 14.62

Q1 FY2013

YoY %

# Sales Increase/Decrease

JPY billions



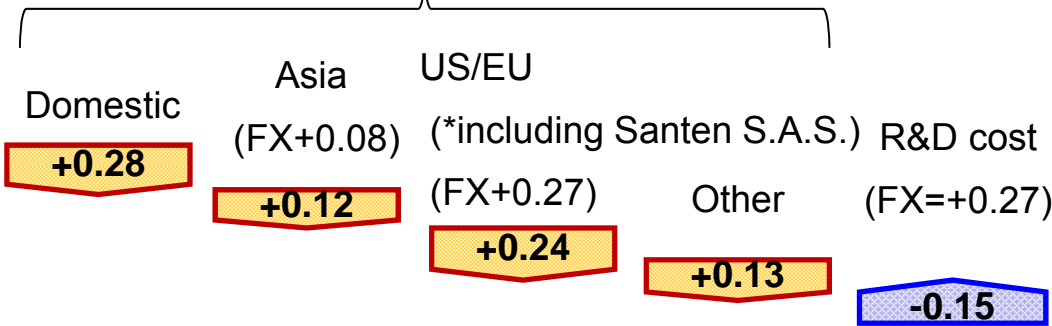
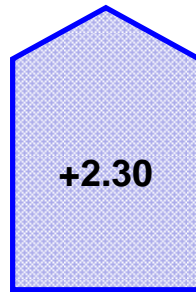
FX=Currency impact

# Operating Profit Change

JPY billions

SG&A (excl. R&D cost) +0.77 (+9.2%)

Gross profit



Operating Profit  
+1.69 (+27.6%)



Change in cost of sales (+5.6pt)

• Impact of product mix change	+5.7pt
• Increase of manufacturing cost due to the transfer of plant	+0.5pt
• Other decreasing of cost of sales	-0.5pt

R&D cost breakdown

• Domestic	-0.37
• US/EU	+0.17

12FY1Q actual

13FY1Q actual



**Reference:  
Consolidated Results  
FY2013 First Quarter**

# Net Sales by Business Segment

(JPY billions)	Q1 FY2013 Actual					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
<b>Pharmaceuticals</b>	<b>28.00</b>	<b>+20.7%</b>	<b>5.61</b>	<b>+32.2%</b>	<b>33.62</b>	<b>+22.5%</b>
Prescription Pharmaceuticals	26.50	+21.9%	5.61	+32.1%	32.11	+23.6%
Ophthalmic	23.66	+25.1%	5.46	+31.9%	29.12	+26.3%
Anti-RA	2.64	+2.3%	0.02	+70.6%	2.66	+2.7%
Others	0.19	-18.1%	0.12	+34.1%	0.32	-3.9%
OTC Pharmaceuticals	1.50	+3.4%	0.00	+160.4%	1.51	+3.8%
<b>Others</b>	<b>0.67</b>	<b>+36.0%</b>	<b>0.01</b>	<b>-17.6%</b>	<b>0.68</b>	<b>+34.7%</b>
Medical Devices	0.61	+25.0%	0.01	-17.6%	0.62	+24.0%
Others	0.05	--	--	--	0.05	--
<b>Total</b>	<b>28.68</b>	<b>+21.1%</b>	<b>5.62</b>	<b>+32.0%</b>	<b>34.31</b>	<b>+22.7%</b>



## Overseas Sales

(JPY billions)	Q1 FY2012 Actual	Q1 FY2013		
		Actual	Var.	Var. %
<b>U.S.</b>	<b>0.15</b>	0.25	+0.10	+70.9%
<b>Europe</b>	<b>2.23</b>	2.97	+0.74	+33.2%
<b>Asia</b>	<b>1.87</b>	2.38	+0.50	+27.0%
<b>Others</b>	-	0.00	+0.00	--
<b>Total</b>	<b>4.26</b>	5.62	+1.36	+32.0%

<b>Overseas sale/sales</b>	15.3%	16.4%	+1.2pt	--
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# Summery of Change in Balance Sheet

(JPY billions)	As of March 31, 2013		As of June 30, 2013		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	132.58	66.4%	130.93	64.3%	-1.64
Fixed Asset	67.05	33.6%	72.62	35.7%	+5.56
<b>Total Asset</b>	<b>199.64</b>	<b>100.0%</b>	<b>203.55</b>	<b>100.0%</b>	<b>+3.91</b>
Current Liabilities	27.01	13.5%	25.11	12.3%	-1.90
Non-current Liabilities	7.49	3.8%	9.94	4.9%	+2.44
<b>Total Liabilities</b>	<b>34.50</b>	<b>17.3%</b>	<b>35.05</b>	<b>17.2%</b>	<b>+0.54</b>
<b>Total Net Asset</b>	<b>165.13</b>	<b>82.7%</b>	<b>168.50</b>	<b>82.8%</b>	<b>+3.36</b>
<b>Total Liabilities Net Assets</b>	<b>199.64</b>	<b>100.0%</b>	<b>203.55</b>	<b>100.0%</b>	<b>+3.91</b>

## Major Changes

- **Current Asset:** Cash and deposits -¥5.52bil, Notes and account receivable +¥3.57bil, Goods and products -¥0.44bil,
- **Fixed Asset :** Buildings and structures +¥1.04bil, Construction in progress -¥0.82bil, Goodwill +¥0.12bil, In-Process R&D product +¥0.35bil, Investment securities +¥4.13bil
- **Current Liabilities:** Accounts payable +¥0.36bil, Other account payable -¥1.12bil, Income tax payable -¥0.82bil, Reserve for bonus -¥1.54bil, other current liabilities +¥1.22bil
- **Fixed Liabilities:** LT deferred tax debt +¥0.11bil, Liabilities relating to retirement benefits +¥2.41bil
- **Net asset :** Retained earnings +¥1.66bil, Unrealized gain on securities +¥1.37bil, Foreign currency translation adjustments +¥1.86bil, Cumulative adjustment to retirement benefits - ¥1.66bil

\*Issued shares: End of March, 2013: 82,469 thousand → end of June, 2013: 82,513 thousand

# Changes in Income Statement

(JPY billions)	Q1 FY2012	Q1 FY2013		Major Changes												
	Actual	Actual	YoY %													
<b>Net Sales</b>	<b>27.95</b>	<b>34.31</b>	+22.7%													
<b>Cost of Sales</b> (% of net sales)	9.44 33.8%	<b>13.50</b> 39.3%	+42.9% +5.6pt	<ul style="list-style-type: none"> <li>• Impact of product mix change +5.7pt</li> <li>• Increase of manufacturing cost due the transfer of plan +0.5pt</li> <li>• Other -0.5pt</li> </ul>												
<b>SGA excluding R&amp;D</b> (% of net sales)	8.38 30.0%	<b>9.15</b> 26.7%	+9.2% -3.3pt	<ul style="list-style-type: none"> <li>• Domestic +0.28</li> <li>• Asia +0.12</li> <li>• US/EU +0.24</li> </ul>												
<b>R&amp;D Expenses</b> (% of net sales)	4.00 14.3%	<b>3.84</b> 11.2%	-4.0% -3.1pt	<ul style="list-style-type: none"> <li>• Domestic -0.37</li> <li>• US/EU +0.17</li> </ul>												
<b>Operating Profit</b> (% of net sales)	<b>6.12</b> <b>21.9%</b>	<b>7.81</b> 22.8%	+27.6% +0.9pt													
<b>Non-operating Income</b>	0.46	0.45	-2.6%													
<b>Non-operating Expense</b>	0.04	0.05	+20.4%													
<b>Ordinary Income</b>	<b>6.54</b>	<b>8.21</b>	+25.5%													
<b>Extraordinary Gain</b>	0.01	-	-	<div style="border: 1px solid black; padding: 5px;"> <p>&lt;Currency Rates&gt;</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Q1 FY12 actual</th> <th>Q1 FY13 actual</th> </tr> </thead> <tbody> <tr> <td>US\$</td> <td>JPY 80.20</td> <td>JPY 98.28</td> </tr> <tr> <td>Euro</td> <td>JPY 106.60</td> <td>JPY 125.11</td> </tr> <tr> <td>CNY</td> <td>JPY 12.51</td> <td>JPY 14.62</td> </tr> </tbody> </table> </div>		Q1 FY12 actual	Q1 FY13 actual	US\$	JPY 80.20	JPY 98.28	Euro	JPY 106.60	JPY 125.11	CNY	JPY 12.51	JPY 14.62
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US\$	JPY 80.20	JPY 98.28														
Euro	JPY 106.60	JPY 125.11														
CNY	JPY 12.51	JPY 14.62														
<b>Extraordinary Loss</b>	-	0.00	-													
<b>Net Income before Tax</b>	6.56	8.21	+25.2%													
<b>Corporate Tax</b>	2.28	2.65	+16.1%													
<b>Net Profit</b>	<b>4.27</b>	5.56	30.0%													

# Summary of Cash Flows

(JPY billions)	<b>Q1 FY2013 Actual</b>
<b>Cash and cash equivalents at the beginning of the year</b>	<b>59.79</b>
<b>Net increase/decrease in cash and cash equivalents</b>	<b>-5.53</b>
Cash flows from operating activities	+1.65
Cash flows from investing activities	-3.81
Cash flows from financial activities	-3.89
Effect of exchange rate changes on cash and cash equivalents	+0.52
<b>Cash and cash equivalents at the end of the year</b>	<b>54.26</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)	1Q FY2012	Q1 FY2013	
	Actual	Actual	Var.
<b>Capital Expenditures</b>	0.45	<b>1.02</b>	+0.56
<b>Depreciation and Amortization</b>	0.58	<b>0.56</b>	-0.02



**Reference:  
FY2013 Financial Forecasts**

# Financial Forecast for FY2013

(JPY billions)	FY2012 Actual	FY2013 Forecast	Var. %
<b>Net Sales</b>	<b>119.06</b>	<b>134.5</b>	<b>+13.0%</b>
<b>Cost of Sales</b> (% of net sales)	41.50 34.9%	48.00 35.7%	+15.7% +0.8pt
<b>SGA excluding R&amp;D</b> (% of net sales)	36.16 30.4%	42.00 31.2%	+16.2% +0.9pt
<b>R&amp;D cost</b> (% of net sales)	16.71 14.0%	18.20 13.5%	+8.9% -0.5pt
<b>Operating Profit</b> (% of net sales)	<b>24.68</b> 20.7%	<b>26.30</b> 19.6%	<b>+6.6%</b> -1.2pt
<b>Ordinary Income</b>	<b>25.60</b>	<b>26.80</b>	<b>+4.7%</b>
<b>Net Income</b>	<b>16.52</b>	<b>18.20</b>	<b>+10.2%</b>
<b>ROE</b>	<b>10.0%</b>	<b>10.7%</b>	<b>+0.7pt</b>

Foreign Exchange	<u>FY12 actual</u>	<u>FY13 forecast</u>
US \$	JPY 82.91	JPY 94.00
Euro	JPY 106.01	JPY 124.00
RMB	JPY 12.64	JPY 15.10



**Reference:**

**Market Overview of  
Prescription Ophthalmic in Japan**

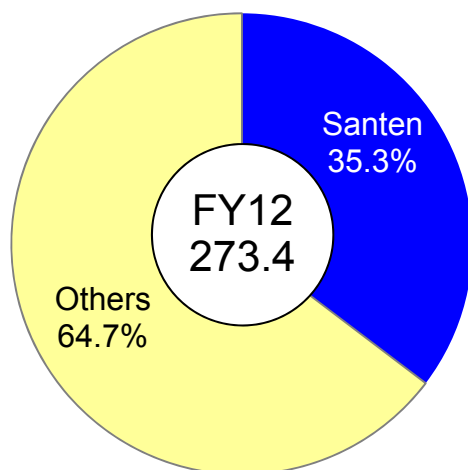


# Japan: Trend & Competition in Ophthalmics (1)

- **Ophthalmology Total:** Market grew by 8.1% Y to Y in 1Q FY13. The growth of retinal, anti-glaucoma and corneal segment continued. Santen's market share was 39.8%.
- **Anti-Glaucoma:** Market grew by 6.9% Y to Y in 1Q FY13. Santen's sales grew by 7.9%. Santen held 30.6% share of the anti-glaucoma market by the contribution of Tapros and Cosopt.
- **Corneal:** Market grew by 12.9% Y to Y in 1Q FY13. Santen's sales grew by 7.5% led by the sales increase of Diquas and Santen's market share was 72.3%.

Market Size:  
billions of yen  
%: Value Share

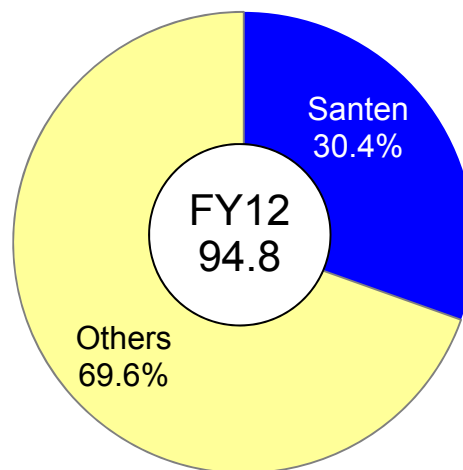
## Ophthalmology Total



FY12      1Q FY13

YoY change	Market	+7.3%	+8.1%
	Santen	+4.9%	+21.5%
Santen's Share		35.3%	39.8%

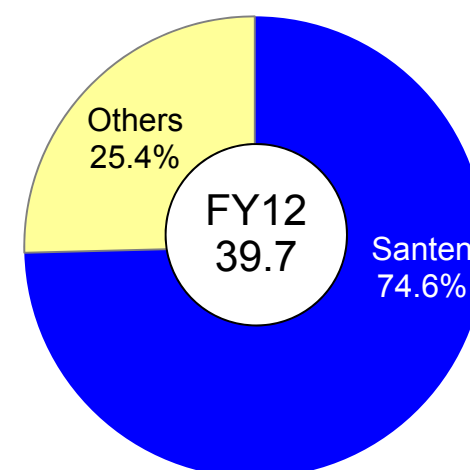
## Anti-glaucoma



FY12      1Q FY13

Market	+2.8%	+6.9%
Santen	+10.2%	+7.9%
Santen's Share		30.4%
		30.6%

## Corneal: Dry Eye



FY12      1Q FY13

Market	+11.3%	+12.9%
Santen	+7.1%	+7.5%
Santen's Share		74.6%
		72.3%



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

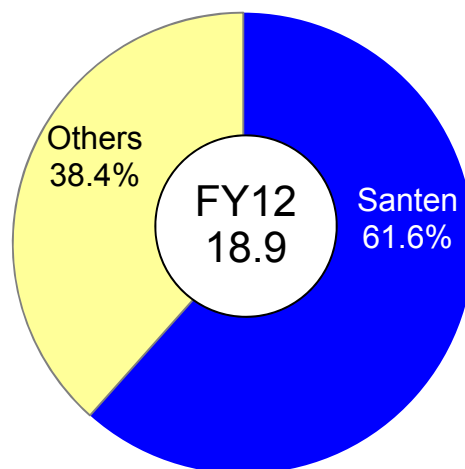
Source: ©2013 IMS Health  
IMS-JPM 2011-13  
Santen analysis based on IMS data  
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# Japan: Trend & Competition in Ophthalmics (2)

- **Anti-infection:** Market declined by 4.1% Y to Y in 1Q FY13. Santen maintained 60.3% of market share with primary contribution by Cravit.
- **Anti-allergy:** Market declined by 11.9% Y to Y in 1Q FY13. Santen's share was 18.1%.

Market Size:  
billions of yen  
%: Value Share

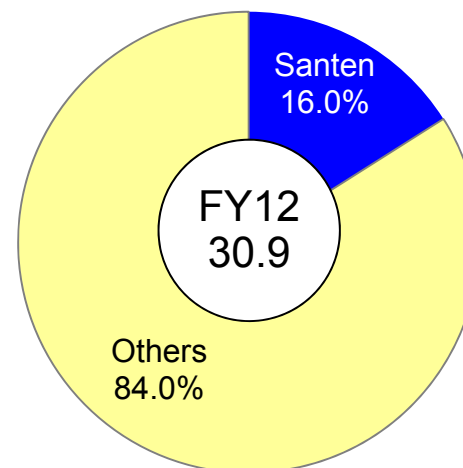
## Anti-infection



FY12      1Q FY13

YoY change	Market	-11.9%	-4.1%
	Santen	-19.6%	-6.8%
Santen's Share		61.6%	60.3%

## Anti-allergy



FY12      1Q FY13

Market		+16.8%	-11.9%
Santen		+6.4%	-12.8%
Santen's Share		16.0%	18.1%

- Santen:
- Anti-infection: Cravit, Tarivid, etc.
  - Anti-allergy: Livostin, Alegysal
  - Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate

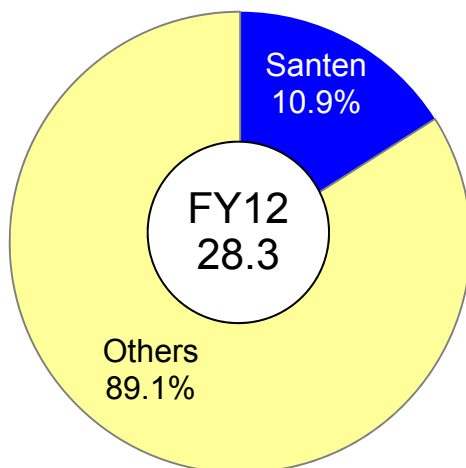


# Japan: Trend & Competition in Ophthalmics (3)

- **Anti-VEGF:** Market increased by 39.4% Y to Y in 1Q FY13. Santen maintained 50.3% of market share with strong sales growth of Eylea.
- **Anti-RA(DMARDs):** Market slightly increased by 1.8% in 1Q FY13. Santen's share was 39.2%.

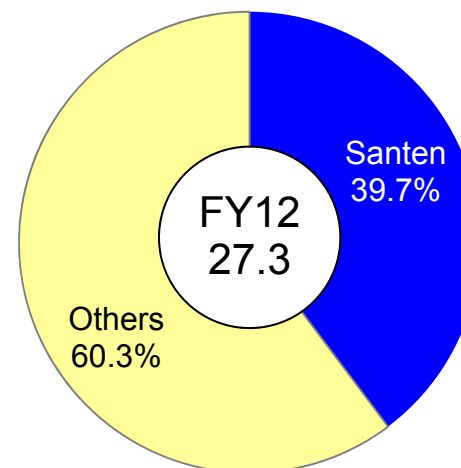
Market Size:  
billions of yen  
%: Value Share

## Anti-VEGF



		FY12	1Q FY13
YoY change	Market	+30.1%	+39.4%
	Santen	-	-
Santen's Share		10.9%	50.3%

## Anti-RA(DMARDs)



		FY12	1Q FY13
YoY change		+0.3%	+1.8%
Santen		-2.8%	-0.5%
Santen's Share		39.7%	39.2%



# **Status of Clinical Development FY2013 First Quarter**

Takashi Kaneko, M.D. Ph.D.  
Corporate Officer,  
Head of Research and Development Division

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

(Red underlined: Change from Q4 FY12 Presentation)

Global Product

Japan (Asia)Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved - Launched
Glaucoma	DE-117 EP2 Receptor Agonist			China DE-085 Tafluprost	
		DE-090 Lomerizine HCl		<u>DE-111</u> Tafluprost/Timolol	DE-118 Tafluprost
Corneal/ Conjunctival Disease	US DE-105 Peptide Combination	JP		China DE-089 Diquafosol Sodium	Korea JP
		US Cyclokat Ciclosporin	EU		
Retina Uveal Disease			DE-109 Sirolimus		
			DE-102 Betamethasone		
Other Infection, Allergy, RA		DE-098 Anti APO-1 Antibody		DE-114 Epinastine HCl	
			Vekacia Ciclosporin		

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

(Red underlined: Change from Q4 FY12 Presentation)

Global Product

Japan (Asia)Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved - Launched
Japan			DE-102 Betamethasone		DE-118 Tafluprost
		DE-090 Lomerizine HCl		DE-111 Tafluprost/Timolol	
		DE-105 Peptide Combination		DE-114 Epinastine HCl	
		DE-098 Anti APO-1 Antibody	DE-109 Sirolimus		
North America (Including Latin America)	DE-117 EP2 Receptor Agonist		DE-109 Sirolimus		
	DE-105 Peptide Combination	Cyclokat Ciclosporin			
Asia (including Oceania)				China DE-085 Tafluprost	
				China DE-089 Diquafosol Sodium	Korea
EU			DE-109 Sirolimus	DE-111 Tafluprost/Timolo	
			Cyclokat Ciclosporin		
			Vekacia Ciclosporin		

# Major Clinical Projects Update - Glaucoma, Ocular hypertension -

## ■ DE-090

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

## ■ DE-111

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	NDA Filed	NDA Filed	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	NDA Filed	P3	

## ■ DE-117

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
US	P1/2a	P1/2a	EP2 receptor agonist (Prostaglandin)

# Major Clinical Projects Update - Glaucoma, Corneal disease -

## ■ DE-118 (Glaucoma, ocular hypertension)

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	Approved	Approved	Generic name: <b>Tafluprost</b> (preservative-free, unit dose, single use)

## ■ DE-089 (Dry eye)

Product Name: *DIQUAS* in Japan

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	Launched	Launched	Generic name: <b>Diquafosol Sodium</b>
Asia	China: NDA filed Korea: Approved	China: NDA filed Korea: Approved	



# Major Clinical Projects Update - Corneal disease –

- Infection, Allergy –

■ **DE-105** (Persistent corneal epithelial defects)

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	P2 Completed	P2	Combination of peptides
US	Preparing P2	Preparing P2	

■ **DE-114** (Allergic conjunctivitis)

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	NDA filed	NDA filed	Generic name: Epinastine HCl

■ **DE-098** (Rheumatoid arthritis)

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	P2 Completed	P2 Completed	Anti-APO-1 Antibody

# Major Clinical Projects Update - Retinal / Uveitis Disease -

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

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
Japan	P2/3	P2/3	Generic name: Betamethasone

■ **DE-109** (Uveitis)

Region	Development Stage		Remarks
	As of August 6, 2013	As of May 8, 2013 (Previous announcement)	
US	P3	P3	Generic name: Sirolimus
Japan	P3	P3	
EU	P3	P3	

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

## ■ Cyclokat (Severe Dry Eye)

Region	Development Stage		Remarks
	As of Aug. 6, 2013	5/8 (Previous)	
EU	P3	P3	Generic Name: Ciclosporin
US	P2 Complete	P2 complete	

## ■ Vekacia (Vernal Conjunctivitis)

Region	Development Stage		Remarks
	As of Aug. 6, 2013	5/8 (Previous)	
EU	P3	P3	Generic Name: Ciclosporin

\*Project evaluations are ongoing for the products below.

Product Name	Indication	Region	Stage	Remarks
Catioprost	Glaucoma/ ocular hypertension	EU	P2	Generic Name: Latanoprost
Cortiject	Diabetic macular edema	US	P1/2	Generic Name: Dexamethasone Palmitate

## 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.