



**Santen Pharmaceutical Co., Ltd.  
Investor Meeting on FY2010 Results**

**Financial Results for the FY2010  
Financial Forecast for the FY2011**

**May 11th, 2011  
Akira Kurokawa  
President & CEO**



# **Consolidated Results FY2010**



# Financial Highlights for FY2010

(JPY billions)	FY2009 Actual	FY2010 Actual	Var. %	FY2010 Forecast*	Achievement %
<b>Net Sales</b>	<b>110.59</b>	110.81	+0.2%	108.50	102.1%
<b>Operating Income</b>	<b>29.64</b>	30.73	+3.7%	26.30	116.9%
<b>Ordinary Income</b>	<b>29.86</b>	31.48	+5.4%	27.00	116.6%
<b>Net Income</b>	<b>18.72</b>	21.33	+13.9%	17.50	121.9%

\*FY2010 Forecast as of: November 4, 2010

## Net Sales

- Japan: Continued growth in Glaucoma and Dry-Eye segments.
  - Glaucoma: Steady market penetration by Tapros and Cosopt.
  - Dry-Eye: Steady growth with Hyalein and Dquas.
- Overseas: Growth in Europe and China
  - Europe: Steady growth with Tafluprost.
  - China: Outpaced market growth through direct marketing.
  - Others: One-time contribution from licensing contract revenues.

## Operating Income

- COGS : Improvement in net gross margin excluding one time income.
- SG&A: Decreased spending through adequate cost control.
- R&D Expense: Underspent due to delay in projects.



FY2010

# Net Sales: Variances (vs. FY2009)

**FY2009**  
Net Sales  
(Actual)  
¥110.59  
billion

**+¥0.21**  
billion

**FY2010**  
Net Sales  
(Actual)  
¥110.81  
billion

## Japan: +2.96billion

- + Prescription Ophthalmics +¥2.91billion
- + Anti-rheumatics -¥0.04billion
- + OTC Drugs -¥0.51billion
- + Medical Devices +¥0.52billion
- + Others +¥0.08billion

## Overseas - ¥2.74billion

- + U.S. -¥3.64billion  
(Forex impact -¥0.16billion)
- + Europe -¥0.19billion  
(Forex impact -¥1.31billion)
- + Asia +¥1.09billion
  - China +¥0.87billion  
(Forex impact: -¥0.21billion)
  - Korea +¥0.26billion  
(Forex impact: -¥0.00billion)

## Prescription Ophthalmics (Japan)

- + Anti-infective -¥0.04billion
- + Cornea (Dry Eye) +¥0.40billion
  - Diquas +¥0.74billion
- Glaucoma +¥2.53billion
  - Tapros: +¥1.89billion
  - Cosopt: +¥2.93billion
- Anti-allergy +¥0.63billion
- Others -¥0.61billion

## Europe

- + Prescription Ophthalmics +¥0.08billion
  - Western Europe +¥0.08billion
  - Eastern Europe -¥0.00billion
  - Northern Europe +¥0.13billion
  - Russia -¥0.12billion

<Currency Rates>		
	FY09 actual	FY10 actual
US\$	JPY 92.79	JPY 85.57
Euro	JPY 131.12	JPY 113.45
CNY	JPY 13.70	JPY 12.94



# Net Sales: Variances (vs. FY2010 Forecast)

**FY2010  
Net Sales  
(Forecast\*)  
¥108.50  
billion**

**+ ¥2.31  
billion**



**FY2010  
Net Sales  
(Actual)  
¥110.81  
billion**

### Japan + ¥1.79 billion

- Prescription Ophthalmics + ¥2.98 billion
- RA drugs + ¥0.09 billion
- OTC drugs - ¥0.64 billion
- Medical Device - ¥0.46 billion
- Others - ¥0.17 billion

### Overseas + ¥0.51 billion

- U.S. + ¥1.46 billion
  - Forex impact: - ¥0.10 billion
- Europe - ¥0.80 billion
  - (Forex impact: - ¥0.85 billion)
- Asia - ¥0.14 billion
  - China - ¥0.36 billion
    - (Forex impact: - ¥0.10 billion)
  - Korea + ¥0.21 billion
    - (Forex impact: - ¥0.04 billion)

### Prescription Ophthalmics (Japan)

- Anti-infective + ¥0.48 billion
- Corneal Disease + ¥0.85 billion
  - Diquas + ¥0.17 billion
- Anti-glaucoma + ¥0.05 billion
  - Tapros: - ¥0.95 billion
  - Cosopt: + ¥0.79 billion
- Anti-allergy + ¥0.98 billion
- Others + ¥0.60 billion

### Europe

- Prescription Ophthalmics - ¥0.84 billion
  - West Europe - ¥0.50 billion
  - East Europe - ¥0.37 billion
  - North Europe + ¥0.15 billion
  - Russia - ¥ 0.12 billion

<Currency rate>

	<u>FY2010 forecast</u>	<u>FY2010 actual</u>
US\$	¥90.00	¥85.57
Euro	¥125.00	¥113.45
RMB	¥13.30	¥12.94

\*As of Nov. 4, 2010



# Changes in Income Statement

(JPY billions)	FY2009	FY2010		
	Actual	Actual	Variance	Major Changes
<b>Net Sales</b>	<b>110.59</b>	<b>110.81</b>	<b>+0.21</b>	
<b>Cost of Sales</b> (% of net sales)	<b>34.71</b> 31.4%	<b>34.43</b> 31.1%	<b>-0.27</b> -0.3pt	
<b>SGA excluding R&amp;D</b> (% of net sales)	<b>32.12</b> 29.0%	<b>32.41</b> 29.3%	<b>+0.29</b> +0.2pt	<ul style="list-style-type: none"> <li>•Domestic JPY +0.00bil</li> <li>•Europe JPY -0.11bil</li> <li>•Asia JPY +0.20bil</li> </ul>
<b>R&amp;D Expenses</b> (% of net sales)	<b>14.12</b> 12.8%	<b>13.22</b> 11.9%	<b>-0.90</b> -0.8pt	Forex impact : JPY -0.36 bil
<b>Operating Profit</b> (% of net sales)	<b>29.64</b> 26.8%	<b>30.73</b> 27.7%	<b>+1.09</b> +0.9pt	
<b>Non-operating Income</b>	0.84	1.01	+0.16	•Dividend received JPY +0.08bil
<b>Non-operating Expense</b>	0.62	0.26	-0.35	•Forex impact JPY -0.26bil
<b>Ordinary Income</b>	<b>29.86</b>	<b>31.48</b>	<b>+1.62</b>	
<b>Extraordinary Gain</b>	0.07	0.01	-0.05	
<b>Extraordinary Loss</b>	1.32	0.42	-0.90	
<b>Net Income before Tax</b>	<b>28.61</b>	<b>31.07</b>	<b>+2.46</b>	
<b>Corporate Tax</b>	9.88	9.74	-0.14	
<b>Net Profit</b>	<b>18.72</b>	<b>21.33</b>	<b>+2.61</b>	

<Currency Rates>

	FY09 actual	FY10 actual
US\$	JPY 92.79	JPY 85.57
Euro	JPY 131.12	JPY 113.45
CNY	JPY 13.70	JPY 12.94



# **Financial Forecast for FY2011**





# Financial Forecast for FY2011

(JPY billions)	FY2010 Actual	FY2011 Forecast	Var. %
<b>Net Sales</b>	110.81	116.00	4.7%
<b>Operating Income</b>	30.73	30.00	-2.4%
<b>Ordinary Income</b>	31.48	30.50	-3.1%
<b>Net Income</b>	21.33	20.50	-3.9%

<b>ROE</b>	14.5%	12.6%	-1.9pt
------------	-------	-------	--------

Growth by Tapros and Diquas

Contribution from Asian & European Businesses

Thorough Investment in R&D



# Net Sales Forecast: Variances (vs. FY2010)

**FY2010**  
**Net Sales**  
**(Actual)**  
**¥110.81 billion**

**+ ¥5.18**  
**billion**



**FY2011**  
**Net Sales**  
**(Forecast)**  
**¥116.00 billion**

**Japan + ¥3.72 billion**

- Prescription Ophthalmics + ¥2.97 billion
- RA Drugs + ¥0.18 billion
- OTC Drugs - ¥0.06 billion
- Medical Device + ¥0.48 billion

**Outside Japan + ¥1.46 billion**

- U.S. + ¥0.55 billion
  - Forex impact: - ¥0.04 billion
- Europe + ¥0.53 billion
  - Forex impact: - ¥0.03 billion
- Asia + ¥0.36 billion
  - China + ¥0.24 billion
  - Forex impact: - ¥0.13 billion
  - Korea + ¥0.04 billion
  - Forex impact: - ¥0.00 billion

**Prescription Ophthalmics (Japan)**

- Anti-infective - ¥0.36 billion
- Corneal Disease + ¥3.08 billion
  - (Diquas + ¥2.55 billion)
- Anti-glaucoma + ¥2.20 billion
  - (Tapros + ¥1.72 billion)
  - (Cosopt + ¥2.58 billion)
- Anti-allergy - ¥0.83 billion

**Europe**

- Prescription Ophthalmics + ¥0.94 billion
  - West Europe + ¥0.39 billion
  - East Europe + ¥0.56 billion
  - North Europe - ¥0.02 billion
  - Russia + ¥0.01 billion

<Currency rate>

	FY2010 actual	FY2011 forecast
US\$	¥85.57	¥82.00
Euro	¥113.45	¥113.00
RMB	¥12.94	¥12.50



# Sales/Income Outlook for the FY2011

(JPY billions)	FY2010 Actual	FY2011	
		Forecast	Var.
<b>Net Sales</b>	<b>110.81</b>	<b>116.00</b>	<b>5.18</b>
<b>Cost of Sales</b>	<b>34.43</b>	<b>36.00</b>	<b>1.56</b>
(% of net sales)	31.1%	31.0 %	-0.0 pt
<b>SG&amp;A excluding R&amp;D</b>	<b>32.41</b>	<b>34.00</b>	<b>1.58</b>
(% of net sales)	29.3 %	29.3 %	0.1 pt
<b>R&amp;D Expense</b>	<b>13.22</b>	<b>16.00</b>	<b>2.77</b>
(% of net sales)	11.9 %	13.8 %	1.9 pt
<b>Operating Income</b>	<b>30.73</b>	<b>30.00</b>	<b>-0.73</b>
(% of net sales)	27.7 %	25.9%	- 1.9 pt
<b>Non-operating Income or Loss</b>	0.74	0.50	-0.24
<b>Ordinary Income</b>	<b>31.48</b>	<b>30.50</b>	<b>- 0.98</b>
<b>Extraordinary Income or Loss</b>	- 0.40	0.00	0.40
<b>Net Income before Tax</b>	<b>31.07</b>	<b>30.50</b>	<b>- 0.57</b>
<b>Income Taxes</b>	9.74	10.00	0.25
<b>Net Income</b>	<b>21.33</b>	<b>20.50</b>	<b>- 0.83</b>

<b>ROE</b>	<b>14.5 %</b>	<b>12.6%</b>	<b>- 1.9 pt</b>
------------	---------------	--------------	-----------------

<Currency rate>	
	FY2010 actual
US\$	¥85.57
Euro	¥113.45
RMB	¥12.94
FY2011 forecast	
US\$	¥82.00
Euro	¥113.00
RMB	¥12.50



# **Dividend Forecast for 2<sup>nd</sup> Half FY2010 and FY2011**



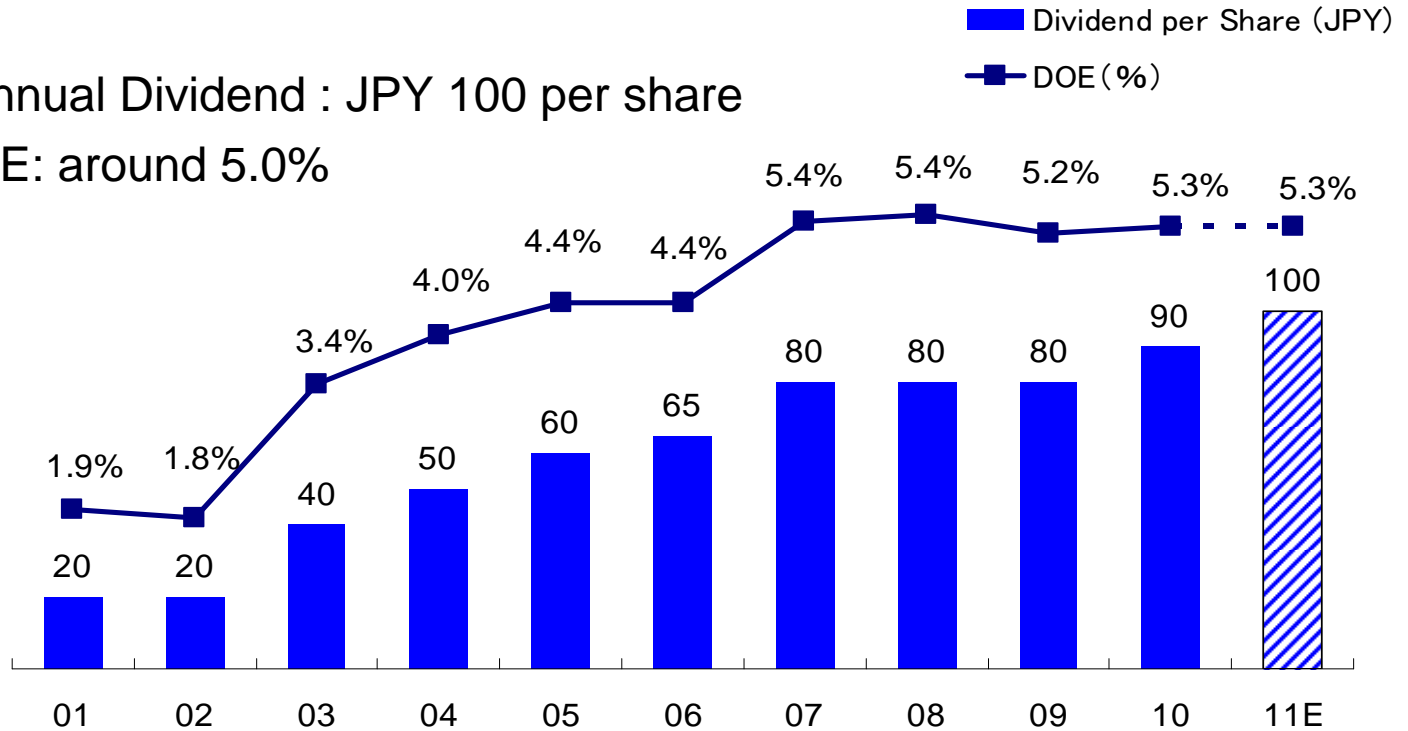
# Dividend Forecast for 2<sup>nd</sup> Half FY2010 and FY2011

## ■ FY2010

- 2<sup>nd</sup> Half FY2010 : Increased to JPY 50 per share
- FY2010 Annual Dividend : JPY 90 per share
- DOE : 5.3%

## ■ FY2011

- FY2011 Annual Dividend : JPY 100 per share
- Target DOE: around 5.0%



Pay-out Ratio (%)	34.9	21.4	55.8	39.7	39.9	42.9	54.7	67.2	36.4	36.7	41.7
Share Buy-back (¥ billion)	32	32	0	26	0	0	48	0	0	0	-
Total Return Ratio (%)	96.4	59.5	55.8	63.3	39.9	42.9	85.8	67.2	36.4	36.7	-



**Reference:  
Consolidated Results FY2010**



# Comparison of Income

## Excluding One-time Income

(JPY billions)	<b>FY2009 Actual</b>	<b>FY2010 Actual</b>	<b>Variance</b>
<b>Net sales</b> (excluding one-time income*)	<b>104.75</b>	<b>108.37</b>	<b>+3.5%</b>
<b>COGS/Sales (%)</b>	<b>33.1%</b>	<b>31.8%</b>	<b>-1.4pt</b>
<b>Operating income</b> (% of net sales)	<b>23.80</b> <b>22.7%</b>	<b>28.30</b> <b>26.1%</b>	<b>18.9%</b> <b>+3.4pt</b>

\*One time income related to licensing contracts (i.e., upfront fee and milestone payment)





# Net Sales by Business Segment

(JPY billions)	FY2010 Actual					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
<b>Pharmaceuticals</b>	<b>91.04</b>	<b>2.8 %</b>	<b>17.52</b>	<b>-14.3 %</b>	<b>108.57</b>	<b>- 0.4 %</b>
Prescription Pharmaceuticals	86.33	3.6 %	17.51	- 14.3 %	103.85	0.0 %
Ophthalmic	75.58	4.0 %	15.21	7.1 %	90.79	4.5 %
Anti-RA	9.72	- 0.5 %	0.10	- 21.1 %	9.83	- 0.7 %
Others	1.02	9.3 %	2.20	- 63.9 %	3.22	- 54.2 %
OTC Pharmaceuticals	4.71	- 9.9 %	0.00	- 55.9 %	4.72	- 10.1 %
<b>Others</b>	<b>1.50</b>	<b>53.2 %</b>	<b>0.73</b>	<b>31.9 %</b>	<b>2.23</b>	<b>45.5 %</b>
Medical Devices	1.49	54.6 %	0.73	31.9 %	2.22	46.3 %
Others	0.01	- 30.8 %	—	—	0.01	- 30.8 %
<b>Total</b>	<b>92.54</b>	<b>3.3 %</b>	<b>18.26</b>	<b>- 13.1 %</b>	<b>110.81</b>	<b>0.2 %</b>

 **Overseas Sales**

(JPY billions)	FY2009	FY2010 Actual		
	Actual	Actual	Var.	Var. %
<b>U.S.</b>	<b>6.71</b>	<b>3.06</b>	<b>-3.64</b>	<b>-54.3%</b>
<b>Europe</b>	<b>8.71</b>	<b>8.51</b>	<b>-0.19</b>	<b>-2.3%</b>
<b>Asia</b>	<b>5.57</b>	<b>6.66</b>	<b>1.09</b>	<b>19.6%</b>
<b>Others</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>110.3%</b>
<b>Total</b>	<b>21.00</b>	<b>18.26</b>	<b>-2.74</b>	<b>-13.1%</b>



# Summary of Change in Balance Sheet

(JPY billions)	As of March 31, 2010		As of March 31, 2010		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	118.83	71.2%	137.66	74.5%	18.83
Fixed Asset	48.04	28.8%	47.13	25.5%	-0.91
Deferred Asset	-	-	-	-	-
<b>Total Asset</b>	<b>166.87</b>	<b>100.0%</b>	<b>184.80</b>	<b>100.0%</b>	<b>17.92</b>
Current Liabilities	25.28	15.2%	24.10	13.0%	-1.18
Non-current Liabilities	3.98	2.4%	4.29	2.3%	0.30
<b>Total Liabilities</b>	<b>29.27</b>	<b>17.5%</b>	<b>28.39</b>	<b>15.4%</b>	<b>-0.87</b>
<b>Total Net Asset</b>	<b>137.60</b>	<b>82.5%</b>	<b>156.40</b>	<b>84.6%</b>	<b>18.80</b>
<b>Total Liabilities Net Assets</b>	<b>166.87</b>	<b>100.0%</b>	<b>184.80</b>	<b>100.0%</b>	<b>17.92</b>

## Major Changes

- **Current Asset:** Cash and deposits +8.8bil, Accounts receivable +3.7bil, Marketable securities +4.3bil, Merchandise and finished goods +0.5bil, Deferred tax assets -0.1bil
- **Fixed Asset :** Buildings and structures -1.1bil, Machinery, equipment and vehicles -0.3bil, Land -0.2bil, Software -0.2bil
- **Current Liabilities:** Notes and payable trade +0.4bil, Short term debt -0.5bil, Other payable +0.5bil, Income tax payable -1.9bil
- **Net asset :** Retained earnings +14.5bil, Unrealized gains on securities, net of taxes -0.5bil, Foreign currency translation adjustments -0.9bil



# Summary of Cash Flows

(JPY billions)		<b>FY2010 Actual</b>
<b>Cash and cash equivalents at the beginning of the year</b>		<b>64.34</b>
<b>Net increase/decrease in cash and cash equivalents</b>		<b>8.13</b>
	Cash flows from operating activities	17.76
	Cash flows from investing activities	-7.67
	Cash flows from financial activities	-1.57
	Effect of exchange rate changes on cash and cash equivalents	-0.38
<b>Cash and cash equivalents at the end of the year</b>		<b>72.48</b>

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



## Capital Expenditures / Depreciation & Amortization / Lease Expenses

(JPY billions)	FY2009 Actual	FY2010	
		Actual	Var.
Capital Expenditures	1.22	1.70	0.48
Depreciation and Amortization	3.20	2.80	-0.39
Lease Payments	0.52	0.15	-0.37



**Reference:  
FY2011 Financial Forecasts**



# Mid-term Consolidated Income Comparison

(JPY billions)	FY2007 Actual	FY2008 Actual	FY2009 Actual	FY2010 Actual	FY2011 Forecast
<b>Net Sales</b>	103.39	101.61	110.59	<b>110.81</b>	<b>116.00</b>
<b>Operating Income</b>	20.37	15.49	29.64	<b>30.73</b>	<b>30.00</b>
<b>Ordinary Income</b>	20.70	15.93	29.86	<b>31.48</b>	<b>30.50</b>
<b>Net Income</b>	12.65	10.12	18.72	<b>21.33</b>	<b>20.50</b>

ROE	9.9%	8.0%	14.3%	<b>14.5%</b>	<b>12.6%</b>
-----	------	------	-------	--------------	--------------



# Sales Forecast by Business Segment / Overseas Sales

(JPY billions)	FY2011 Forecast					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
<b>Pharmaceuticals</b>	94.28	3.6 %	19.07	8.8 %	113.35	4.4 %
Prescription Pharmaceuticals	89.64	3.8 %	19.05	8.8 %	108.69	4.7 %
Ophthalmic	78.56	3.9 %	16.31	7.3 %	94.88	4.5 %
Anti-RA	9.91	1.9 %	0.10	- 3.5 %	10.01	1.8 %
Others	1.16	13.9 %	2.63	19.9%	3.80	18.0 %
OTC Pharmaceuticals	4.64	- 1.5 %	0.01	36.0 %	4.65	- 1.4 %
<b>Others</b>	1.98	32.3 %	0.65	- 10.7 %	2.64	18.2 %
Medical Devices	1.97	32.6 %	0.65	- 10.7 %	2.63	18.3 %
Others	0.01	- 6.5 %	—	—	0.01	- 6.5 %
<b>Total</b>	96.27	4.0%	19.72	8.0 %	116.00	4.7 %



(JPY billions)	FY2010 Actual	FY2011 Forecast		
		Forecast	Var.	Var. %
<b>U.S.</b>	3.06	3.62	0.55	18.2%
<b>Europe</b>	8.51	9.05	0.53	6.3%
<b>Asia</b>	6.66	7.02	0.36	5.4%
<b>Others</b>	0.00	0.01	0.00	60.0%
<b>Total</b>	18.26	19.72	1.46	8.0%



## Capital Expenditures / Depreciation & Amortization / Lease Expenses

(JPY billions)	FY2010 Actual	FY2011	
		Forecast	Var.
<b>Capital Expenditures</b>	1.70	6.21	4.50
<b>Depreciation and Amortization</b>	2.80	2.95	0.14
<b>Lease Payments</b>	0.15	0.16	0.00



**Reference:  
Market Overview of  
Prescription Ophthalmics in Japan**

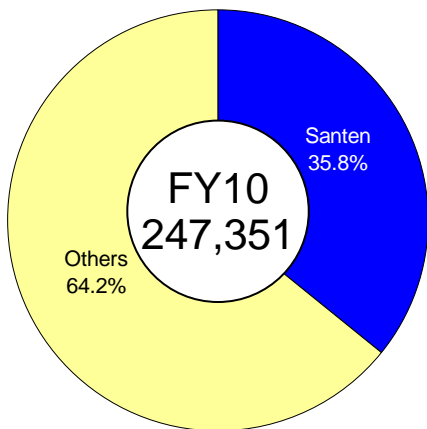


# Japan: Trend & Competition in Ophthalmics - 1

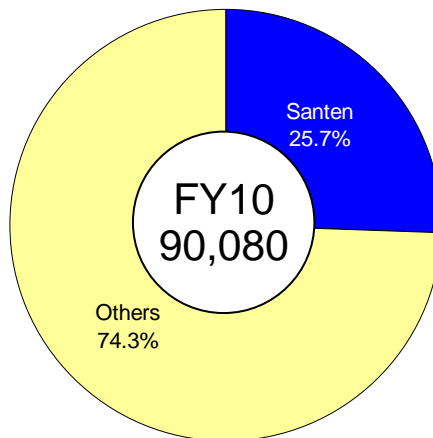
- Ophthalmology Total:** Market grew by 5.3% Y to Y in FY10. Santen's market share was 35.8% under the situation of growth in the retinal segment and anti-allergy segment.
- Glaucoma:** Market slightly grew by 1.8% Y to Y in FY10. Santen's sales grew by 13.5%. Santen held 25.7% of the share by the contribution of Tapros and Cosopt.
- Corneal:** Market slightly grew by 1.0% Y to Y in FY10. Santen maintained market share at 76.0% with the contribution Hyalein and Diquaus.

Market Size:  
millions of yen  
%: Value Share

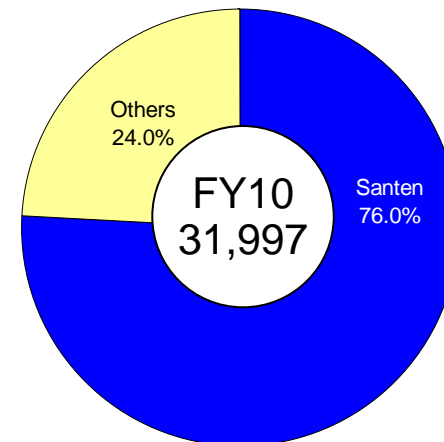
Ophthalmology Total



Anti-glaucoma



Corneal: Dry Eye



		FY09	FY10
YoY change	Market	+3.5%	+5.3%
	Santen	+1.7%	+1.0%
Santen's Share		37.3%	35.8%

		FY09	FY10
YoY change		+4.1%	+1.8%
Santen		+18.4%	+13.5%
Santen's Share		23.0%	25.7%

		FY09	FY10
YoY change		+3.9%	+1.0%
Santen		+3.0%	-0.5%
Santen's Share		77.1%	76.0%

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

Source: ©2011 IMS Japan  
IMS-JPM 2008-11  
Santen analysis based on IMS data

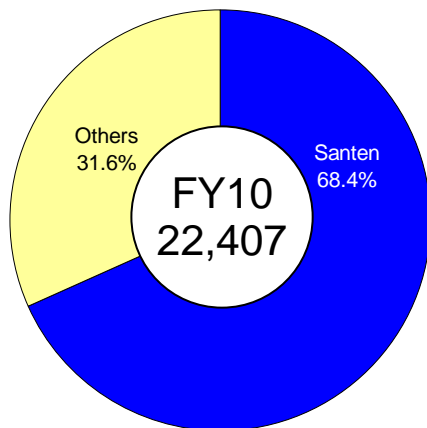


# Japan: Trend & Competition in Ophthalmics - 2

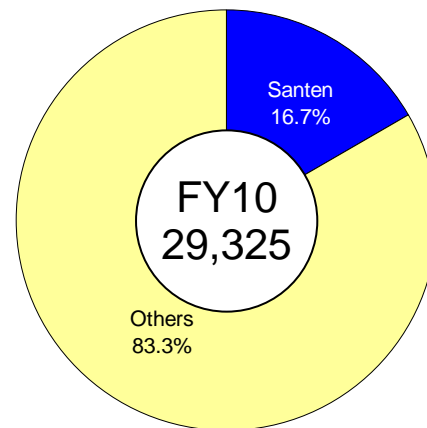
- **Anti-infection:** Market declined by 1.0%. Santen maintained 68.4% of market share with contribution of Cravit.
- **Anti-allergy:** Market grew by 22.3% Y to Y in 10FY. Santen's share was 16.7% in the situation of competitor's growth continues.

Market Size:  
millions of yen  
%: Value Share

## Anti-infection



## Anti-allergy



		FY09	FY10
YOY change	Market	-4.4%	-1.0%
	Santen	-5.6%	-3.3%
Santen's Share		70.0%	68.4%

		FY09	FY10
Market		-15.0%	+22.3%
Santen		-19.7%	+2.9%
Santen's Share		19.8%	16.7%

- Santen:
  - Anti-infection: Cravit, Tarivid, etc.
  - Anti-allergy: Livostin, Alegysal



# Status of Clinical Development FY2010

Member of the Board  
Executive Corporate Officer  
Head of Research and Development Division  
Toshiaki Nishihata, Ph.D.



# Major Clinical Pipeline List (Red Letters: Changes from FY10 3Q)

Global product

Japan (Asia) Product

Domain	Phase I	Phase II	Phase III	NDA filed	Approved
Glaucoma		<b>DE-112</b> Adenosine A <sub>2A</sub> Agonist			<b>DE-085</b> Tafluprost (Launch) JP, Asia EU, Latin America
		<b>DE-090</b> Lomerizine HCl	<b>DE-111</b> Tafluprost/ Timolol maleate (combination drug) Europe, <u>Japan</u>	China <u>U.S.</u>	
Corneal Disease (Dry Eye)		<b>DE-101</b> US Rivoglitazone JP		<b>DE-089</b> Diquafosol sodium	
		<b>DE-105</b> Combination of peptides	China	<u>Korea</u>	(Launch) Japan
		<b>DE-110</b> SEGRA			
Retinal Disease		<b>DE-102</b> Steroid DDS	<b>DE-109</b> Sirolimus		
Others Infection, RA, Allergy		<b>DE-098</b> Apoptosis inducer	<b>DE-114</b> Epinastine		<b>DE-108</b> Levofloxacin (Higher Concentration)

# Status of Major Drug Candidate (DE-085)

- **DE-085 (Glaucoma, Ocular hypertension)**

*TAPROS, TAFLOTAN* in Santen areas, *SAFLUTAN* in Merck\* areas

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	Launched	Launched	<b>Generic name: Tafulprost</b>  Launched in: Japan (Dec. 2008) Europe (Jun. 2008) Asia (Mar. 2010) Latin America (Aug. 2010)  Out-licensed to: Merck & Co., (Apr. 2009)
Europe**	<b>Launched: 27 countries</b> <b>Approved: 30 countries</b> Partly out-licensed to Merck*	<b>Launched: 25 countries</b> <b>Approved: 29 countries</b> Partly out-licensed to Merck*	
Asia	<b>Launched: 2 countries</b> <b>Approved: 4 countries</b> <b>China: NDA filed</b>	<b>Launched: 2 countries</b> <b>Approved: 4 countries</b> <b>China: NDA filed</b>	
U.S./ Others	Out-licensed to Merck* <b>Launched: 4 countries</b> <b>Approved: 6 countries</b> <b>NDA filed: U.S.</b>	Out-licensed to Merck* <b>Launched: 4 countries</b> <b>Approved: 4 countries</b>	

**Launched:** Total 34 countries worldwide (newly added: 2 countries)

- Santen: Japan, 2 countries in Asia (Hong Kong, Korea), and 20 countries in Europe (18 countries including Germany, Finland, Kazakhstan, Turkmenistan)
- Merck\*: 7 countries in Europe (U.K., Spain, Netherlands, Italy, Portugal, Austria, Switzerland), and 4 countries in Latin America (Bahamas, etc.)

**Approved:** Total 41 countries worldwide (newly added: 3 countries; Guatemala, Colombia, Turkmenistan)

\*Merck areas (since April 2009): Western Europe except Germany, North America, South America, and Africa

\*\*Including CIS





# Status of Major Drug Candidate (DE-089)

- **DE-089 (Dry eye)**  
*DIQUAS* in Japan

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	Launched	Launched (December, 2010)	Generic name: <b>Diquafosol sodium</b>
Asia	China: P3 Korea: NDA filed	China: P3	



# Status of Major Pipeline - Glaucoma, Ocular hypertension -

- DE-090

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

- DE-111

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	P3	Preparing P3	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	P3	P3	

- DE-112

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
U.S.	P1/2a	P1/2a	Adenosine A <sub>2A</sub> agonist



# Status of Major Pipeline - Corneal and conjunctival disease -

- **DE-101** (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
U.S.	P1 / 2*	P1 / 2*	Generic name: Rivoglitazone
Japan	P2b	P2b	

\*Pilot P2b trial using higher concentration formula.

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

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
U.S.	Preparing P2	Preparing P2	Combination of peptides
Japan	P2	P2	

- **DE-110** (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
U.S.	P2	P2	A selective glucocorticoid receptor agonist (SEGRA)



# Status of Major Pipeline - Retinal Disease -

- **DE-102** (Diabetic macular edema)

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	P1 / 2	P1 / 2	Steroid DDS

- **DE-109\*** (Wet age related macular degeneration, diabetic macular edema)

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	Completed P1 / 2	P1 / 2	Generic name: Sirolimus
U.S.	P3	–	

\*Target disease

Japan: Wet age related macular degeneration (wet AMD) / Diabetic macular edema (DME)

U.S: Uveitis

# Status of Major Pipeline - Others -

- **DE-108** (Bacterial conjunctivitis)

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	Approved	Approved	Levofloxacin (1.5%)

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

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	P3	–	Epinastine

- **DE-098** (Rheumatoid arthritis)

Region	Development Stage		Remarks
	As of May 10, 2011	As of February 8, 2011 (Previous announcement)	
Japan	P2	P2	Anti-APO-1 antibody



## 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.