



**Santen Pharmaceutical Co., Ltd.  
Investor Meeting**

**Financial Results for the 1st Half of FY2011;  
Financial Forecast for the FY2011;**

**November 2, 2011  
Akira Kurokawa  
President & CEO**



# **Financial Results for the 1st Half FY2011**



# Financial Highlights for 1st Half FY2011

	FY2010 1st Half Actual	FY2011 1st Half Actual	Var. %	FY2011 1st Half Forecast*	Achieve- ment %
<b>Net Sales</b>	53.91	56.78	+5.3%	57.30	99.1%
<b>Operating Income</b>	14.11	14.57	+3.2%	14.50	100.5%
<b>Ordinary Income</b>	14.49	15.05	+3.9%	14.80	101.7%
<b>Net Income</b>	9.27	9.90	+6.8%	10.00	99.1%

\*Forecast as of: May 10, 2011

# Summary of 1st Half FY2011

## ■ Sales

- Steady growth of 5.3% from the same period last year.
  - Japan sales was driven mainly by steady growth in glaucoma and dry-eye segments.
  - Overseas sales maintained steady growth, both in Asia and Europe.

## ■ Operating Income

- Operating expense excluding R&D costs increased due to increased HR costs related to strengthening of overseas sales platforms.
- Maintained thorough R&D related investments.
- Despite the increased spending, total operating expense level was controlled within the budget.



**FY2010  
1st Half  
Net Sales  
(Actual)  
¥53.91billion**

**+¥2.87  
billion**

**FY2011  
1st Half  
Net Sales  
(Actual)  
¥56.78billion**

### Japan: +1.78billion

- + Prescription Ophthalmics +¥1.26billion
- + Anti-rheumatics +¥0.08billion
- + OTC Drugs -¥0.06billion
- + Medical Devices +¥0.24billion
- + Others +¥0.25billion

### Overseas + ¥1.08billion

- + U.S. +¥0.30billion  
(Forex impact -¥0.08billion)
- + Europe +¥0.40billion  
(Forex impact +¥0.00billion)
- + Asia +¥0.38billion
  - China +¥0.09billion  
(Forex impact: -¥0.13billion)
  - Korea +¥0.25billion  
(Forex impact: -¥0.01billion)

### **Prescription Ophthalmics (Japan)**

- + Anti-infective -¥0.41billion
- + Cornea (Dry Eye) +¥1.38billion
- Diquas +¥1.12billion
- + Glaucoma +¥1.23billion
- Tapros: +¥0.26billion
- Cosopt: +¥1.82billion
- + Anti-allergy +¥0.06billion
- + Others -¥1.00billion

### **Europe**

- + Prescription Ophthalmics +¥0.52billion
- Western Europe +¥0.06billion
- Eastern Europe +¥0.21billion
- Northern Europe +¥0.13billion
- Russia +¥0.10billion

<Currency Rates>		
	FY10.Q2 actual	FY11.Q2 actual
US\$	JPY 88.88	JPY 79.74
Euro	JPY 115.85	JPY 116.08
CNY	JPY 13.40	JPY 12.51



# Net Sales: Variances (vs. 1st Half FY2011 Forecast)

**FY2011  
1st Half  
Net Sales  
(Forecast\*)  
¥57.30billion**

**-¥0.51billion**

**FY2011  
1st Half  
Net Sales  
(Actual)  
¥56.78billion**

### Japan: -¥0.63billion

- + Prescription Ophthalmics -¥0.67billion
- + Anti-rheumatics -¥0.01billion
- + OTC Drugs +¥0.00billion
- + Medical Devices +¥0.01billion
- + Others +¥0.04billion

### Overseas: + ¥0.12billion

- + U.S. -¥0.08billion  
(Forex impact -¥0.01billion)
- + Europe +¥0.08billion  
(Forex impact +¥0.11billion)
- + Asia +¥0.12billion
  - China -¥0.03billion  
(Forex impact: -¥0.00billion)
  - Korea +¥0.14billion  
(Forex impact: -¥0.00billion)

### Prescription Ophthalmics (Japan)

- + Anti-infective -¥0.14billion
- + Cornea (Dry Eye) -¥0.35billion
- Diquas -¥0.23billion
- + Glaucoma +¥0.22billion
- Tapros: -¥0.38billion
- Cosopt: +¥0.29billion
- + Anti-allergy -¥0.24billion
- + Others -¥0.15billion

### Europe

- + Prescription Ophthalmics +¥0.07billion
- Western Europe -¥0.01billion
- Eastern Europe -¥0.08billion
- Northern Europe +¥0.13billion
- Russia +¥0.03billion

<Currency Rates>		
	FY11 Forecast	FY11.Q2 Actual
US\$	JPY 82.00	JPY 79.74
Euro	JPY 113.00	JPY 116.08
CNY	JPY 12.50	JPY 12.51

\*Forecast as of: May 10, 2011



# Changes in Income Statement

(JPY billions)	FY2010 1st Half Actual	FY2011 1st Half		
		Actual	Variance	Major Changes
<b>Net Sales</b>	<b>53.91</b>	<b>56.78</b>	+2.87	
<b>Cost of Sales</b> (% of net sales)	<b>17.43</b> 32.3%	<b>17.76</b> 31.3%	+0.33 <b>-1.0pt</b>	Decrease in fixed cost <b>-0.1pt</b> , change in product mix <b>-0.5pt</b> , decrease in license related income <b>-0.2pt</b> , others <b>-0.2pt</b>
<b>SGA excluding R&amp;D</b> (% of net sales)	<b>15.98</b> 29.7%	<b>16.84</b> 29.7%	+0.86 +0.0pt	<ul style="list-style-type: none"> <li>•Japanese sales expense : <b>-¥0.29bil</b></li> <li>•Overseas expenses : Europe +¥0.62bil, Asia +¥0.40bil (Forex impact <b>-¥0.10bil</b>)</li> </ul>
<b>R&amp;D Expenses</b> (% of net sales)	<b>6.37</b> 11.8%	<b>7.60</b> 13.4%	+1.22 +1.5pt	
<b>Operating Profit</b> (% of net sales)	<b>14.11</b> 26.2%	<b>14.57</b> 25.7%	+0.45 <b>-0.5pt</b>	
<b>Non-operating Income</b>	0.48	0.50	+0.02	
<b>Non-operating Expense</b>	0.10	0.02	<b>-0.08</b>	
<b>Ordinary Income</b>	<b>14.49</b>	<b>15.05</b>	+0.55	
<b>Extraordinary Gain</b>	0.00	0.06	+0.05	
<b>Extraordinary Loss</b>	0.11	0.02	<b>-0.09</b>	
<b>Net Income before Tax</b>	<b>14.38</b>	<b>15.08</b>	+0.70	
<b>Corporate Tax</b>	5.11	5.18	+0.07	
<b>Net Profit</b>	<b>9.27</b>	<b>9.90</b>	+0.63	

<Currency Rates>

	FY10.Q2 actual	FY11.Q2 actual
US\$	JPY 88.88	JPY 79.74
Euro	JPY 115.85	JPY 116.08
CNY	JPY 13.40	JPY 12.51

# Summery of Change in Balance Sheet

(JPY billions)	FY 2010		FY2011 1 <sup>st</sup> Half		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	137.66	74.5%	142.28	75.5%	+4.61
Fixed Asset	47.13	25.5%	46.17	24.5%	-0.95
Deferred Asset	-	-	-	-	-
<b>Total Asset</b>	<b>184.80</b>	<b>100.0%</b>	<b>188.45</b>	<b>100.0%</b>	<b>+3.65</b>
Current Liabilities	24.10	13.0%	22.29	11.8%	-1.81
Non-current Liabilities	4.29	2.3%	4.00	2.1%	-0.28
<b>Total Liabilities</b>	<b>28.39</b>	<b>15.4%</b>	<b>26.30</b>	<b>14.0%</b>	<b>-2.09</b>
<b>Total Net Asset</b>	<b>156.40</b>	<b>84.6%</b>	<b>162.15</b>	<b>86.0%</b>	<b>+5.75</b>
<b>Total Liabilities Net Assets</b>	<b>184.80</b>	<b>100.0%</b>	<b>188.45</b>	<b>100.0%</b>	<b>+3.65</b>

## Major Changes

- **Current Asset:** Cash and deposits +¥4.43bil, Merchandise and finished products +¥1.01bil, Raw materials -¥0.31bil
- **Fixed Asset :** Buildings and structures -¥0.49bil, Construction in progress +¥0.41bil, Software -¥0.21bil, Investment securities -¥0.35bil, LT deferred tax assets -¥0.45bil
- **Current Liabilities:** Accounts payable -¥0.71bil, Unpaid billings -¥0.79bil, Income tax payable +¥0.57bil, Provision for bonus -¥0.11bil
- **Fixed Liabilities :** Provisions for employees' retirement fund +¥0.12bil, Provisions for directors' retirement fund -¥0.26bil
- **Net asset :** Retained earnings +5.55bil, Other securities revaluation profit +¥0.35bil, Foreign currency translation adjustments -¥0.31bil





# **Financial Forecast for the 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
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\*Forecast as of: May 10, 2011



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

\*Forecast as of: May 10, 2011



# References



**Reference:  
Financial Results for the  
1st Half FY2011**



# Net Sales by Business Segment

(JPY billions)	FY2011 1 <sup>st</sup> Half Actual					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
Pharmaceuticals	46.77	+3.4%	8.44	+9.3%	<b>55.22</b>	<b>+4.3%</b>
Prescription Pharmaceuticals	44.33	+3.8%	8.44	+9.3%	<b>52.77</b>	<b>+4.6%</b>
Ophthalmic	38.68	+3.4%	8.24	+10.5%	<b>46.93</b>	<b>+4.6%</b>
Anti-RA	5.07	+1.7%	0.08	+45.5%	<b>5.15</b>	<b>+2.2%</b>
Others	0.57	+78.6%	0.10	-46.7%	<b>0.68</b>	<b>+30.4%</b>
OTC Pharmaceuticals	2.44	-2.4%	0.00	-11.2%	<b>2.44</b>	<b>-2.4%</b>
Others	0.92	+35.9%	0.64	+136.5%	<b>1.56</b>	<b>+64.6%</b>
Medical Devices	0.91	+36.2%	0.64	+136.5%	<b>1.55</b>	<b>+65.0%</b>
Others	0.00	+6.1%	-	-	<b>0.00</b>	<b>+6.1%</b>
<b>Total</b>	<b>47.70</b>	<b>+3.9%</b>	<b>9.08</b>	<b>+13.6%</b>	<b>56.78</b>	<b>+5.3%</b>



# Overseas Sales

(JPY billions)	FY2010 1 <sup>st</sup> Half Actual	FY2011 1 <sup>st</sup> Half		
		Actual	Var.	Var. %
<b>U.S.</b>	0.62	<b>0.92</b>	+0.30	+49.0%
<b>Europe</b>	4.07	<b>4.47</b>	+0.40	+9.9%
<b>Asia</b>	3.30	<b>3.68</b>	+0.38	+11.7%
<b>Others</b>	0.00	<b>0.00</b>	-0.00	—
<b>Total</b>	7.99	<b>9.08</b>	+1.08	+13.6%



# Summary of Cash Flows

(JPY billions)		<b>FY2011 1<sup>st</sup> Half Actual</b>
<b>Cash and cash equivalents at the beginning of the year</b>		<b>72.48</b>
<b>Net increase/decrease in cash and cash equivalents</b>		<b>6.23</b>
	Cash flows from operating activities	9.32
	Cash flows from investing activities	1.41
	Cash flows from financial activities	-4.24
	Effect of exchange rate changes on cash and cash equivalents	-0.26
<b>Cash and cash equivalents at the end of the year</b>		<b>78.71</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)	FY2010		FY2011	
	1st Half Actual	Full Year Actual	1st Half Actual	Full Year Forecast
<b>Capital Expenditures</b>	0.49	1.70	<b>1.26</b>	<b>6.21</b>
<b>Depreciation and Amortization</b>	1.37	2.80	<b>1.31</b>	<b>2.95</b>
<b>Lease Payments</b>	0.12	0.15	<b>0.01</b>	<b>0.04</b>

\*Forecast as of: May 10, 2011



**Reference:  
FY2011 Financial Forecasts**



# 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 %

\*Forecast as of: May 10, 2011

(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%



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

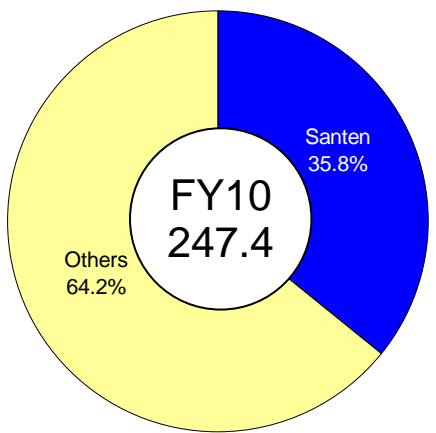


# Japan: Trend & Competition in Ophthalmics (1)

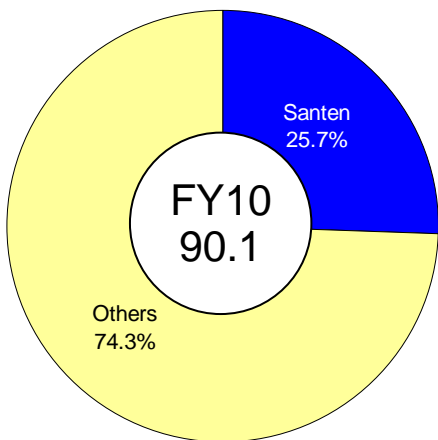
- Ophthalmology Total:** Market grew by 6.1% in the first half of FY11. Retinal segment and anti-allergy segment continued to lead the market growth. Santen's market share was 36.7%
- Glaucoma:** Market grew by 1.8% in the first half of FY11. Santen's sales grew by 15.0%. Santen held 28.0% share of the glaucoma market by the contribution of Tapros and Cosopt.
- Corneal:** Market grew by 11.0% in the first half of FY11. Santen's sales grew by 14.7%, and Santen's market share increased to 77.6% with the contribution of Hyalein and Diquas.

Market Size:  
billions of yen  
%: Value Share

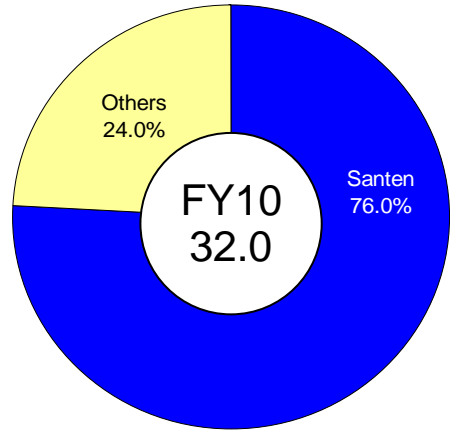
**Ophthalmology Total**



**Anti-glaucoma**



**Corneal: Dry Eye**



		FY10	Q2YTD FY11
YoY change	Market	+5.3%	+6.1%
	Santen	+1.0%	+5.5%
Santen's Share		35.8%	36.7%

		FY10	Q2YTD FY11
YoY change		+1.8%	+1.8%
Sales change		+13.5%	+15.0%
Santen's Share		25.7%	28.0%

		FY10	Q2YTD FY11
YoY change		+1.0%	+11.0%
Sales change		-0.5%	+14.7%
Santen's Share		76.0%	77.6%

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

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 IMS-JPM 2009-11  
 Santen analysis based on IMS data  
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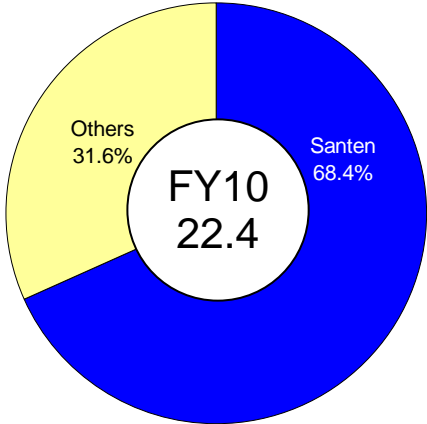


# Japan: Trend & Competition in Ophthalmics (2)

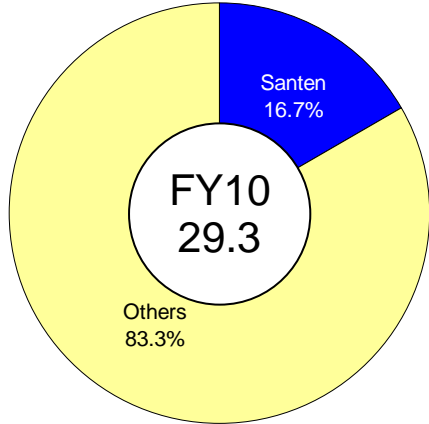
- **Anti-infection:** Market in the period in the first half of FY11 shrunk by 3.6%. Santen maintained 68.3% of market share with primary contribution from Cravit.
- **Anti-allergy:** Market grew by 17.9% in the first half of FY11 Santen's share was 19.1%.

Market Size:  
billions of yen  
%: Value Share

## Anti-infection



## Anti-allergy



		FY10	Q2YTD FY11
YOY change	Market	-1.0%	-3.6%
	Santen	-3.3%	-4.1%
Santen's Share		68.4%	68.3%

		FY10	Q2YTD FY11
YOY change		+22.3%	+17.9%
Market		+2.9%	+20.3%
Santen's Share		16.7%	19.1%

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

Source: ©2011 IMS Japan  
IMS-JPM 2009-11  
Santen analysis based on IMS data  
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# **FY2011 Second Quarter Status of Clinical Development**

**Toshiaki Nishihata, Ph.D.**

Member of the Board

Executive Corporate Officer, U.S. and Europe Business,  
Head of Research and Development Division





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

(Red underlined: Change from Q1 FY11 Presentation)

Global Product

Japan (Asia) Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved/ Launched
Glaucoma		<b>DE-112</b> Adenosine A <sub>2A</sub>		<b>DE-111</b> Tafluprost/Timolol  EU JP	<b><u>DE-085</u></b> Tafluprost  China US JP-Asia <u>EU-Latin America</u>
		<b>DE-090</b> Lomerizine HCl			
Corneal/ conjunctival disease (Dry eye)		<b><u>DE-101</u></b> Rivoglitazone	<b><u>DE-089</u></b> Diquafosol Sodium  China Korea Japan		
	US	<b>DE-105</b> Peptide combo	JP		
		<b>DE-110</b> SEGRA			
Retinal/ Uveal disease			<b>DE-109</b> Sirolimus		
			<b>DE-102</b> Betamethasone		
Other Infection, Allergy, RA		<b>DE-098</b> Anti APO-1 Antibody	<b>DE-114</b> Epinastine HCl		<b>DE-108</b> Levofloxacin 1.5%



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

(Red underlined: Change from Q1 FY11 Presentation)

Global product

Japan (Asia)  
Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved/ Launched
Japan			<b>DE-102</b> Betamethasone		<b>DE-085</b> Tafluprost
		<b>DE-090</b> Lomerizine HCl	<b>DE-111</b> Tafluprost/Timolol		<b>DE-089</b> Diquafosol Sodium
		<b>DE-105</b> Peptide Combo	<b>DE-114</b> Epinastine HCl		<b>DE-108</b> Levofloxacin 1.5%
		<b>DE-098</b> Anti APO-1 Antibody			
North America (Including Latin America)	<b>DE-105</b> Peptide combo	<b>DE-110</b> SEGRA	<b>DE-109</b> Sirolimus	US	<u><b>DE-085</b></u> Tafluprost <u>Latin America</u>
		<u><b>DE-101</b></u> Rivoglitazone			
	<b>DE-112</b> Adenosine A <sub>2A</sub>				
Asia				China	<u><b>DE-085</b></u> Tafluprost <u>Korea, etc</u>
				<u>China</u> <b>DE-089</b> <u>Korea</u> Diquafosol Sodium	
Europe			<b>DE-111</b> Tafluprost/Timolol		<u><b>DE-085</b></u> Tafluprost

# Major Clinical Projects (DE-085)

- DE-085 (Glaucoma, Ocular hypertension)

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011	
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: 39 countries</b> Partly out-licensed to Merck*	<b>Launched: 27 countries</b> <b>Approved: 37 countries</b> Partly out-licensed to Merck*	
Asia	<b>Launched: 4 countries</b> <b>Approved: 6 countries</b> <b>NDA filed: China</b>	<b>Launched: 4 countries</b> <b>Approved: 5 countries</b> <b>NDA filed: China</b>	
U.S./ Others	Out-licensed to Merck* <b>Launched: 4 countries</b> <b>Approved: 10 countries</b> <b>NDA filed: U.S.</b>	Out-licensed to Merck* <b>Launched: 4 countries</b> <b>Approved: 9 countries</b> <b>NDA filed: U.S.</b>	

**Launched: Total of 36 countries worldwide**

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

**Approved: Total of 56 countries worldwide**  
(newly added: 4 countries; Thailand, Hungary, Azerbaijan, Panama)

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

\*\*Including CIS



## Major Clinical Projects Update (DE-089)

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	Launched	Launched	Generic name: Diquafosol sodium
Asia	China: Preparing NDA Korea: NDA filed	China: P3 Korea: NDA filed	



## Major Clinical Projects Update - Glaucoma, Ocular hypertension -

- DE-090

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

- DE-111

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	P3	P3	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	P3	P3	

- DE-112

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
U.S.	P1/2a	P1/2a	Adenosine A <sub>2A</sub> receptor agonist

# Major Clinical Projects Update – Corneal disease -

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
U.S.	P2	Preparing P2	Generic name: Rivoglitazone
Japan	P2b completed	P2b completed	

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	P2	P2	Combination of peptides
U.S.	Preparing P2	Preparing P2	

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
U.S.	P2	P2	Selective glucocorticoid receptor agonist (SEGRA)



## Major Clinical Projects Update - Retinal / Uveitis Disease -

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	P2/3	P2/3	Generic name: Betamethasone

- **DE-109** (Uveitis)

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
U.S.	P3	P3	Generic name: Sirolimus



## Major Clinical Projects Update - Others -

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	Launched (June 2011)	Launched (June 2011)	Generic name: Levofloxacin (1.5%)

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 2011 (Previous announcement)	
Japan	P3	P3	Generic name: Epinastine HCl

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

Region	Development Stage		Remarks
	As of November 1, 2011	As of August 2, 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.