



**Santen Pharmaceutical Co., Ltd.**

**Investor Meeting on 1st Half of FY2010 Results**

**Financial Results for the 1st Half of FY2010;  
Financial Forecast for the FY2010;**

**November 4, 2010**

**President & CEO**

**Akira Kurokawa**



# **Financial Results for the 1st Half FY2010**

# Performance Overview of 1st Half FY2010

(JPY billions)

	FY2009 1st Half Actual	FY2010 1st Half Actual	Var. %	FY2010 1st Half Forecast*	Achieve- ment %
<b>Net Sales</b>	59.12	53.91	- 8.8%	54.30	99.3%
<b>Operating Income</b>	19.03	14.11	- 25.9%	13.80	102.3%
<b>Ordinary Income</b>	18.87	14.49	- 23.2%	14.20	102.0%
<b>Net Income</b>	11.67	9.27	- 20.5%	9.40	98.6%

\*As of: May 11, FY2010

# Summary of FY2010 1st Half

## ■ Sales

- Down by 8.8% YOY mainly due to reduced one time income related to licensing contracts.
  - Sales results excluding the impact from the one-time income remained at the same level as same period last year despite the WHI price reduction.
  - Japan: Steady growth in glaucoma; e.g., Tapros/Cosopt
  - Overseas: Steady growth in China, and EU remained flat reflecting the currency impact

## ■ Operating Income

- Down by 25.9% but exceeded 1H guidance.



1st Half FY2010

# Net Sales: Variances (vs. 1st Half FY2009)

**FY2009**  
**1st Half**  
**Net Sales**  
**(Actual)**  
**¥59.12billion**

**-¥5.20billion**

**FY2010**  
**1st Half**  
**Net Sales**  
**(Actual)**

**¥53.91billion**

### Japan: -0.06billion

- + Prescription Ophthalmics +¥0.12billion
- + Anti-rheumatics -¥0.05billion
- + OTC Drugs -¥0.27billion
- + Medical Devices +¥0.23billion
- + Others -¥0.10billion

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

- + Anti-infective -¥0.07billion
- + Cornea (Dry Eye) -¥0.42billion
- + Glaucoma +¥1.18billion
- { Tapros: +¥1.30billion }
- { Cosopt: +¥1.00billion }
- + Anti-allergy -¥0.18billion
- + Others -¥0.35billion

### Outside Japan - ¥5.14billion

- + U.S. -¥5.37billion  
  (Forex loss impact -0.06billion)
- + Europe -¥0.01billion  
  (Forex loss impact -0.56billion)
- + Asia +¥0.23billion
  - China +¥0.24billion  
  (Forex loss impact: -¥0.07billion)
  - Korea +0.05billion  
  (Forex loss impact: +¥0.01billion)

### **Europe**

- + Prescription Ophthalmics +¥0.15billion
  - Western Europe +¥0.17billion  
  (Germany +¥0.13billion)
  - Eastern Europe -¥0.06billion
  - Northern Europe +¥0.06billion
  - Russia -¥0.01billion

#### <Currency Rates>

	<u>FY09 2Q</u>	<u>FY10 Q2</u>
US\$	JPY 95.48	JPY 88.88
Euro	JPY 132.14	JPY 115.85
CNY	JPY 14.00	JPY 13.40



1st Half FY2010

# Net Sales: Variances (vs. Forecast of FY2010)

**FY2010  
1st Half  
Net Sales  
(Forecast\*)  
¥54.30billion**

**-¥0.38billion**

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

### Japan: +¥0.40billion

- + Prescription Ophthalmics +¥0.76billion
- + Anti-rheumatics +¥0.27billion
- + OTC Drugs -¥0.29billion
- + Medical Devices -¥0.18billion
- + Others -¥0.14billion

### Outside Japan -¥0.79billion

- + U.S. -¥0.11billion  
(Forex loss impact -¥0.02billion)
- + Europe -¥0.53billion  
(Forex gain impact +0.31billion)
- + Asia -¥0.14billion
  - China -¥0.20billion
  - Korea +¥0.05billion

### Prescription Ophthalmics (Japan)

- + Anti-infective +¥0.39billion
- + Cornea (Dry Eye) +¥0.03billion
- + Glaucoma +¥0.56billion
  - [ Tapros -¥0.77billion
  - [ Cosopt +1.00billion ]
- + Anti-allergy -¥0.25billion
- + Others +¥0.03billion

### Europe

- + Prescription Ophthalmics -¥0.44billion
  - Western Europe -¥0.13billion  
(Germany -¥0.21billion)
  - Eastern Europe -¥0.22billion
  - Northern Europe +¥0.03billion
  - Russia -¥0.11billion

#### <Currency Rates>

	<u>FY09 2Q</u> Forecast	<u>FY10 Q2</u> Actual
US\$	JPY 90.00	JPY 88.88
Euro	JPY 125.00	JPY 115.85
CNY	JPY 13.30	JPY 13.40

\*As of: May 11, 2010



# Summary of Changes in Income Statement

(JPY billions)

	FY2009	FY2010														
	1st Half Actual	1st Half Actual	Var.	Major Changes												
Net Sales	59.12	53.91	-5.2	(Details in pervious slide.)												
Cost of Sales (% of net sales)	17.76 30.1%	17.43 32.3%	-0.33 2.3pt	Affected by improved product mix, NHI price revision and reduced one-time income realized in FY10.												
SGA Total (% of net sales)	22.31 37.7%	22.36 41.5%	0.04 3.8pt													
SGA excluding R&D (% of net sales)	15.39 26.0%	15.98 29.7%	0.59 3.6pt	Increase in SGA •Domestic (JPY +0.172bil) •Overseas (JPY +0.18bil) •Others (JPY +0.25bil)												
R&D Expenses (% of net sales)	6.92 11.7%	6.37 11.8%	-0.54 0.1pt													
Operating Profit (% of net sales)	19.03 32.2%	14.11 26.2%	-4.92 -6.0pt													
Non-operating Income	0.44	0.48	0.03													
Non-operating Expense	0.60	0.10	-0.50													
Ordinary Income	18.87	14.49	-4.38													
Extraordinary Gain	-	0.00	0.00													
Extraordinary Loss	0.20	0.11	-0.09													
Net Income before Tax	18.66	14.38	-4.28	<Currency Rates> <table border="1"> <thead> <tr> <th></th> <th>FY09 Q2</th> <th>FY10 Q2</th> </tr> </thead> <tbody> <tr> <td>US\$</td> <td>JPY 95.48</td> <td>JPY 88.88</td> </tr> <tr> <td>Euro</td> <td>JPY 132.14</td> <td>JPY 115.85</td> </tr> <tr> <td>CNY</td> <td>JPY 14.00</td> <td>JPY 13.40</td> </tr> </tbody> </table>		FY09 Q2	FY10 Q2	US\$	JPY 95.48	JPY 88.88	Euro	JPY 132.14	JPY 115.85	CNY	JPY 14.00	JPY 13.40
	FY09 Q2	FY10 Q2														
US\$	JPY 95.48	JPY 88.88														
Euro	JPY 132.14	JPY 115.85														
CNY	JPY 14.00	JPY 13.40														
Corporate Tax	6.99	5.11	-1.88													
Net Profit	11.67	9.27	-2.39													



# Summary of Change in Balance Sheet

(JPY billions)

	FY 2009		FY2010 1 <sup>st</sup> Half Actual		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	118.83	71.2%	118.92	71.1%	0.09
Fixed Asset	48.04	28.8%	48.45	28.9%	0.4
Deferred Asset	-	-	-	-	-
<b>Total Asset</b>	<b>166.87</b>	<b>100.0%</b>	<b>167.37</b>	<b>100.0%</b>	<b>0.5</b>
Current Liabilities	25.28	15.2%	21.58	12.9%	-3.69
Non-current Liabilities	3.98	2.4%	4.09	2.4%	0.10
<b>Total Liabilities</b>	<b>29.27</b>	<b>17.5%</b>	<b>25.68</b>	<b>15.3%</b>	<b>-3.58</b>
<b>Total Net Asset</b>	<b>137.6</b>	<b>82.5%</b>	<b>141.69</b>	<b>84.7%</b>	<b>4.09</b>
<b>Total Liabilities Net Assets</b>	<b>166.87</b>	<b>100.0%</b>	<b>167.37</b>	<b>100.0%</b>	<b>0.50</b>

## Major Changes

- **Current Asset:** Cash and deposits -1.2bil, Notes and accounts +1.9bil, Finished goods inventories -0.7bil
- **Fixed Asset :** Buildings and structures -0.6bil, Machinery, equipment and vehicles -0.2bil, Land -0.2bil  
Incensement securities +1.6bil
- **Current Liabilities :** Notes and accounts payable trade -0.4bil, Short term debt -0.2bil,  
other payables-0.4bil, income taxed payable -0.2bil
- **Net asset :** Retained earnings +5.8bil, Unrealized gains on securities, net of taxes -0.6bil,  
Foreign currency translation adjustments -1.2bil





# **Financial Forecast for the FY2010**

# Overall Outlook of FY2010

(JPY billions)

	FY2009 Actual	FY2010 Forecast	Var. vs. FY2009
<b>Net Sales</b>	110.59	108.50	-1.9%
<b>Operating Income</b>	29.64	26.30	-11.3%
<b>Ordinary Income</b>	29.86	27.00	-9.6%
<b>Net Income</b>	18.72	17.50	-6.5%
<b>ROE</b>	14.3%	12.3%	-2.0pt



## Highlights for FY2010 2nd Half

Strengthen Market Presence in Glaucoma

Accelerate Market Penetration  
with Tapros and Cosopt

Maintain Steady Growth in EU and China



# Sales/Income Outlook for FY2010

(JPY billions)

	FY2009 Actual	FY2010	
		Forecast	Var. vs. FY2009
<b>Net Sales</b>	<b>110.59</b>	<b>108.50</b>	<b>-2.09</b>
<b>Cost of Sales</b>	<b>34.71</b>	<b>35.00</b>	<b>0.29</b>
(% of net sales)	<b>31.4 %</b>	<b>32.3 %</b>	<b>0.9pt</b>
<b>SGA Total</b>	<b>46.24</b>	<b>47.20</b>	<b>0.96</b>
(% of net sales)	<b>41.8 %</b>	<b>43.5 %</b>	<b>1.7pt</b>
SGA excluding R&D	<b>32.12</b>	<b>33.10</b>	<b>0.98</b>
(% of net sales)	<b>29.0 %</b>	<b>30.5 %</b>	<b>1.5 pt</b>
R&D Expense	<b>14.12</b>	<b>14.10</b>	<b>-0.02</b>
(% of net sales)	<b>12.8 %</b>	<b>13.0 %</b>	<b>0.2 pt</b>
Operating Income	<b>29.64</b>	<b>26.30</b>	<b>-3.34</b>
(% of net sales)	<b>26.8 %</b>	<b>24.2%</b>	<b>-2.6pt</b>
No operating profit and loss	<b>0.22</b>	<b>0.70</b>	<b>0.48</b>
Ordinary Income	<b>29.86</b>	<b>27.0</b>	<b>-2.86</b>
Extraordinary loss	<b>-1.25</b>	<b>0.0</b>	<b>1.25</b>
Net Income before Tax	<b>28.61</b>	<b>27.00</b>	<b>-1.61</b>
Income Taxes	<b>9.88</b>	<b>9.50</b>	<b>-0.38</b>
Net Income	<b>18.72</b>	<b>17.50</b>	<b>-1.22</b>
<b>ROE</b>	<b>14.3%</b>	<b>12.3%</b>	<b>-2.0pt</b>



# References



**Reference:  
Financial Results for the  
1st Half FY2010**



# Net Sales by Business Segment

(JPY billions)

	Actual of 1st Half of FY2010					
	Japan		Overseas		Total	
	Sales	Var. (%)	Sales	Var. (%)	Sales	Var. (%)
<b>Pharmaceuticals</b>	<b>45.23</b>	<b>-0.7 %</b>	<b>7.72</b>	<b>-39.9 %</b>	<b>52.96</b>	<b>-9.3 %</b>
Prescription Pharmaceuticals	42.73	-0.1 %	7.72	-39.9 %	50.45	-9.2 %
Ophthalmic	37.42	0.3 %	7.46	4.0 %	44.88	0.9 %
Anti-RA	4.98	-1.0 %	0.05	-0.6 %	5.04	-1.0 %
Others	0.32	-24.0 %	0.20	-96.4 %	0.52	-91.3 %
OTC Pharmaceuticals	2.5	-9.9 %	0.00	-65.5 %	2.50	-10.2 %
<b>Others</b>	<b>0.67</b>	<b>52.2 %</b>	<b>0.27</b>	<b>-5.3 %</b>	<b>0.95</b>	<b>29.7 %</b>
Medical Devices	0.67	54.1 %	0.27	-5.3 %	0.94	30.6 %
Others	0.0	-38.8 %	—	—	0.00	-38.8 %
<b>Total</b>	<b>45.91</b>	<b>-0.1 %</b>	<b>7.99</b>	<b>-39.1 %</b>	<b>53.91</b>	<b>-8.8 %</b>



# Net Sales by Oversea Sales

(JPY billions)

	Actual of 1st Half of FY2009	Actual of 1st Half of FY2010		
		Actual	Var.	Var. %
Europe	4.08	4.07	-0.01	-0.3 %
U.S.	5.99	0.62	-5.37	-89.6%
Asia	3.06	3.30	0.23	7.8 %
Others	0.00	0.00	0.00	—
<b>Total</b>	<b>13.14</b>	<b>7.99</b>	<b>-5.14</b>	<b>-39.1%</b>





# Summary of Cash Flows

(JPY billions)

	FY2010 1st Half Actual
<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>-3.53</b>
Cash flows from operating activities	6.29
Cash flows from investing activities	-5.76
Cash flows from financial activities	-3.59
Effect of exchange rate changes on cash and cash equivalents	-0.46
<b>Cash and cash equivalents at the end of the year</b>	<b>60.81</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 1st Half Actual	FY2010 1st Half	
		Actual	Var.
Capital Expenditures	0.37	0.49	0.12
Depreciation and Amortization	1.58	1.37	-0.20
Lease Payments	0.33	0.12	-0.20



**Reference:  
Financial Forecasts for the  
FY2010**



# Net Sales by Business Segment

(JPY billions)

	FY2010					
	Japan		Overseas		Total	
	Sales	Var. (%)	Sales	Var. (%)	Sales	Var. (%)
<b>Pharmaceuticals</b>	<b>88.75</b>	<b>0.2 %</b>	<b>16.93</b>	<b>-17.2 %</b>	<b>105.69</b>	<b>-3.1 %</b>
Prescription Pharmaceuticals	83.40	0.0 %	16.92	-17.2 %	100.33	-3.3 %
Ophthalmic	72.59	-0.1 %	16.19	14.1 %	88.79	2.2 %
Anti-RA	9.63	-1.4 %	0.12	-7.1 %	9.76	-1.5 %
Others	1.16	25.3 %	0.60	-90.1 %	1.77	-74.8 %
OTC Pharmaceuticals	5.36	2.4 %	0.00	-55.8 %	5.36	2.2 %
<b>Others</b>	<b>1.99</b>	<b>103.4 %</b>	<b>0.81</b>	<b>45.5 %</b>	<b>2.80</b>	<b>82.4 %</b>
Medical Devices	1.95	102.6 %	0.81	45.5 %	2.76	81.7 %
Others	0.04	150.6 %	—	—	0.04	150.6 %
<b>Total</b>	<b>90.75</b>	<b>1.3 %</b>	<b>17.74</b>	<b>-15.5 %</b>	<b>108.50</b>	<b>-1.9 %</b>



# Net Sales by Oversea Sales

(JPY billions)

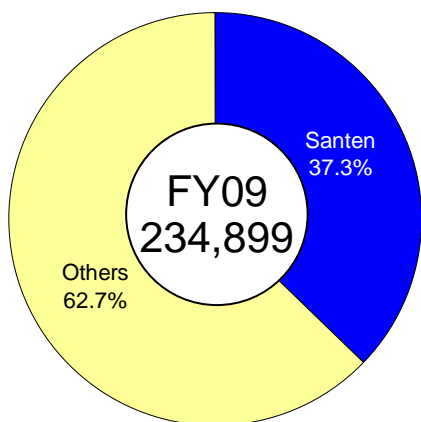
	FY2009 Actual	FY2010		
		Forecast	Var.	Var. %
Europe	8.71	9.32	6.00	7.0 %
U.S.	6.71	1.60	-5.11	-76.2%
Asia	5.57	6.81	1.23	-1.0 %
Others	0.00	0.01	0.01	17.73 %
<b>Total</b>	<b>21.00</b>	<b>17.74</b>	<b>-3.26</b>	<b>-15.5%</b>

# S Japan: Trend & Competition in Ophthalmics - 1

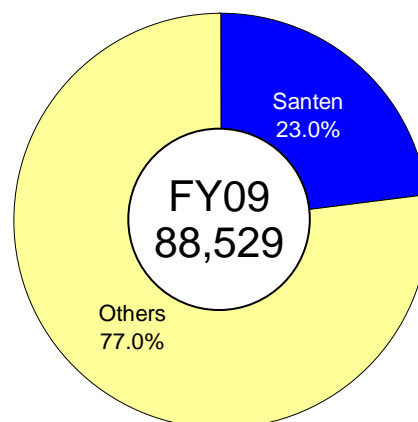
- **Ophthalmology Total:** Market grew by 2.1% in the period up to 2nd quarter FY10. Santen maintained market share at 37.0% under the situation of rapid growth in the retinal segment.
- **Glaucoma:** Santen outperformed the market with the contribution of the Tapros and Cosopt. Santen's share stands at 24.8%.
- **Corneal:** Market is slightly in declining trend by -2.0% in the period up to 2nd quarter FY10. Santen managed to maintain market share at 75.1%.

Market Size:  
millions of yen  
%: Value Share

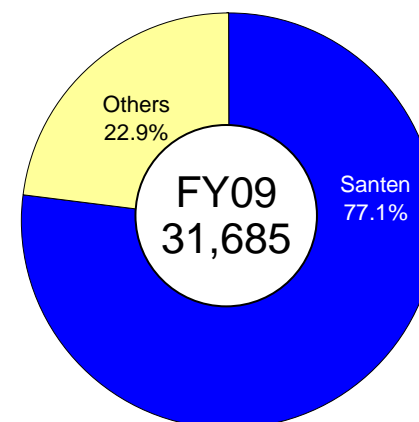
## Ophthalmology Total



## Anti-glaucoma



## Corneal: Dry Eye



		FY09	FY10 2QYTD
YoY change	Market	+3.5%	+2.1%
	Santen	+1.7%	-1.5%
Santen's Share		37.3%	37.0%

		FY09	FY10 2QYTD
YoY change		+4.1%	+3.1%
Santen		+18.4%	+11.6%
Santen's Share		23.0%	24.8%

		FY09	FY10 2QYTD
YoY change		+3.9%	-2.0%
Santen		+3.0%	-4.9%
Santen's Share		77.1%	75.1%

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

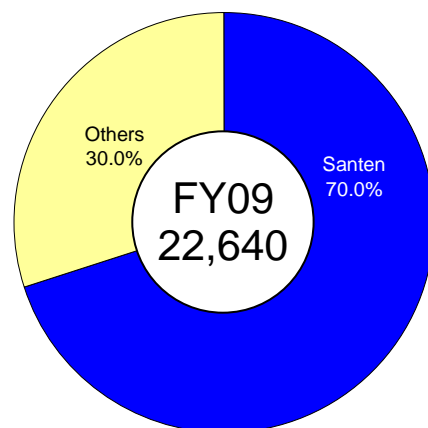
Source: ©2010 IMS Japan  
IMS-JPM 2008-10  
Santen analysis based on IMS data

# S Japan: Trend & Competition in Ophthalmics - 2

- **Anti-infection:** Market slightly declined by 0.9% in the period up to 2nd quarter FY10. Treatment days/head is in declining trend.
- **Anti-allergy:** Santen has been underperforming the market. Competitor's growth continues.

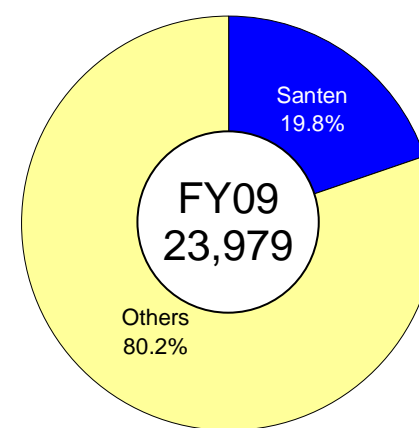
Market Size:  
millions of yen  
%: Value Share

## Anti-infection



		FY09	FY10 2QYTD
YoY change	Market	-4.4%	-0.9%
	Santen	-5.6%	-2.9%
Santen's Share		70.0%	68.7%

## Anti-allergy



		FY09	FY10 2QYTD
YoY change		-15.0%	-5.8%
Market		-19.7%	-19.4%
Santen's Share		+19.8%	18.7%

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

Source: ©2010 IMS Japan  
IMS-JPM 2008-10  
Santen analysis based on IMS data



# **FY2010 Second Quarter Status of Clinical Development**

**November 4, 2010**

**Member of the Board**

**Senior Corporate Officer**

**Head of Research and Development Division**

**Toshiaki Nishihata, Ph.D.**



# Major Clinical Pipeline List (Red Letters: Changes from FY10 1Q)

Global product

Japan (Asia)  
Product

Domain	Phase I	Phase II	Phase III	NDA filed	Approved
Glaucoma	<b>DE-111</b> Tafluprost/ Timolol maleate (combination drug)		China	<b>DE-085</b> Tafluprost	JP, HK, Korea, EU, Latin America (launched)
		<b>DE-090</b> Lomerizine HCl			
Corneal Disease (Dry Eye)		<b>DE-101</b> Rivoglitazone US Japan	China	<b>DE-089</b> Diquafosol sodium	JP (approved)
		<b>DE-105</b> Combination of peptides			
			<b>DE-110</b> SEGRA		
Retinal Disease		<b>DE-109</b> Sirolimus			
		<b>DE-102</b> Steroid DDS			
Others Infection, RA		<b>DE-098</b> Apoptosis inducer		<b>DE-108</b> Levofloxacin (Higher Concentration)	

# Status of Major Drug Candidate (DE-085)

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

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

Region	Development Stage		Remarks
	As of November 2, 2010	As of August 3, 2010 (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: 23 countries</b> <b>Approved: 28 countries</b> Partly out-licensed to Merck*	<b>Launched: 16 countries</b> <b>Approved: 27 countries</b> Partly out-licensed to Merck*	
Asia	<b>Launched: 2 countries</b> <b>Approved: 3 countries</b> <b>China: P3</b>	<b>Launched: 2 countries</b> <b>Approved: 2 countries</b> <b>China: P3</b>	
U.S./ Others	Out-licensed to Merck* <b>Launched: 4 countries</b> <b>Approved: 4 countries</b> (Latin America)	Out-licensed to Merck*	

**Launched: Total 30 countries worldwide** (newly added: 11 countries)

- Santen: Japan, 2 countries in Asia (Hong Kong, Korea), and 16 countries in Europe (12 countries including Germany, Finland, and Slovakia, Lithuania, Armenia, Kyrgyz)
- Merck\*: 7 countries in Europe (U.K., Spain, Netherlands, Italy, Portugal, Austria, Switzerland), and 4 countries in Latin America (Bahamas, etc.)

**Approved: Total 36 countries worldwide** (newly added: 6 countries including Singapore)

\*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 November 2, 2010	As of August 3, 2010 (Previous announcement)	
Japan	Approved	Approved	Generic name: <b>Diquafosol sodium</b>
Asia	China: P3	China: P3	



## Status of Major Pipeline - Glaucoma, Ocular hypertension -

- **DE-090**

Region	Development Stage		Remarks
	As of November 2, 2010	As of August 3, 2010 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

- **DE-111**

Region	Development Stage		Remarks
	As of November 2, 2010	As of August 3, 2010 (Previous announcement)	
Japan	P1 (PK test*)	-	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	Preparing P3	-	

\*PK test: Pharmacokinetics test, to clarify drug disposition

# 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 November 2, 2010	As of August 3, 2010 (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 November 2, 2010	As of August 3, 2010 (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 November 2, 2010	As of August 3, 2010 (Previous announcement)	
U.S.	P2	Preparing P2	A selective glucocorticoid receptor agonist (SEGRA)

# Status of Major Pipeline - Retinal Disease -

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

Region	Development Stage		Remarks
	As of November 2, 2010	As of August 3, 2010 (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 November 2, 2010	As of August 3, 2010 (Previous announcement)	
Japan	P1 / 2	P1 / 2	Generic name: Sirolimus

\*Santen acquired global development, manufacturing and marketing rights of sirolimus in June 2010.

# Status of Major Pipeline - Others -

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

Region	Development Stage		Remarks
	As of November 2, 2010	As of August 3, 2010 (Previous announcement)	
Japan	NDA Filed	NDA Filed	Levofloxacin (1.5%)

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

Region	Development Stage		Remarks
	As of November 2, 2010	As of August 3, 2010 (Previous announcement)	
Japan	P1 / 2	P1 / 2	Anti-APO-1 antibody
Europe	P1 / 2	P1 / 2	



## 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.