



**Santen Pharmaceutical Co., Ltd.
Investor Meeting on FY2011 Results**

**Financial Results for the FY2011
Financial Forecast for the FY2012**

May 9th, 2012
Akira Kurokawa
President & CEO



Consolidated Results FY2011

Med-term Policies FY2011-2013

To become a specialized pharmaceutical company with 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 FY2011

(JPY billions)	FY2010 Actual	FY2011 Actual	Var. %	FY2011 Forecast*	Achievement %
Net Sales	110.81	114.41	+3.3%	116.00	98.6%
Operating Income	30.73	26.73	-13.0%	30.00	89.1%
Ordinary Income	31.48	27.78	-11.8%	30.50	91.1%
Net Income	21.33	17.16	-19.6%	20.50	83.7%

*As of Nov. 1, 2011

FY2011 Highlights

Sales

■ Japan domestic sales :

- In the prescription pharmaceutical segment, got larger market share by the increase of the sales from FY2010 both in the glaucoma and dry-eye segments
- The newly launched drugs these few years such as 'Tapros', 'Diquas' and 'Cosopt' drove the growth

■ Overseas sales :

- Europe/China : marked solid growth
 - Europe: The growth engine 'Tafluprost' retained the momentum of consistent sales expansion
 - China: The larger number of sales, the wider coverage of the market. The adjustment of inventories due to the change of our distribution policy decreased the sales in 1Q, from 2Q on outpaced market growth

FY2011 Highlights

Operating Profit

- COGS: Controlled within the targeted range
- SG&A: Increase the costs to reinforce overseas sales platform and the amortization of Novagali-related goodwill
- R&D: Increase the costs related to the progress of P3, the Novagali P/L consolidation and the accounting policy change in overseas contracted R&D expenses

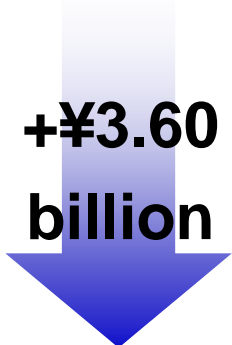


FY2011

Net Sales: Variances (vs. FY2010 Results)

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

**+¥3.60
billion**



**FY2011
Net Sales
(Actual)
¥114.41billion**

Japan: + ¥ 2.82billion

- + Prescription Ophthalmics +¥2.16bil
- + Anti-rheumatics +¥0.15bil
- + OTC Drugs -¥0.12bil
- + Medical Devices +¥0.42bil
- + Others +¥0.20bil

Overseas + ¥0.78billion

- + U.S. +¥0.38bil
(Currency impact -¥0.08bil)
- + Europe +¥0.36bil
(Currency impact -¥0.25bil)
- + Asia +¥0.03bil
 - China +¥0.20bil
 - (Currency impact: -¥0.18bil)
 - Korea -¥0.23bil
 - (Currency impact: -¥0.02bil)

Prescription Ophthalmics (Japan)

- + Anti-infective -¥0.96bil -6.8%
- + Cornea (Dry Eye) +¥2.75bil +13.3%
 - Diquas +¥2.10bil +282%
- + Glaucoma +¥2.56bil +13.0%
 - Tapros: +¥0.60bil +9.1%
 - Cosopt: +¥3.33bil +114%
- + Anti-allergy -¥0.59bil -13.8%
- + Others -¥1.58bil -9.5%

Europe

- + Prescription Ophthalmics +¥0.74bil +9.3%
 - (-Western Europe +¥0.13bil +6.5%)
 - Eastern Europe +¥0.32bil +23.8%
 - Northern Europe +¥0.18bil +6.1%
 - Russia +¥0.10bil +6.6%

<Currency Rates>

	FY10 actual	FY11 actual
US\$	JPY 85.57	JPY 79.03
Euro	JPY 113.45	JPY 110.27
CNY	JPY 12.94	JPY 12.34



FY2011

Net Sales: Variances (vs. FY2011 Forecast)

FY2011
Net Sales
(Forecast*)
¥116.00
billion

- ¥1.58
billion



FY2011
Net Sales
(Actual)
¥114.41
billion

Japan - ¥0.89 billion

- Prescription Ophthalmics - ¥ 0.81billion
- RA drugs - ¥ 0.02billion
- OTC drugs - ¥ 0.05billion
- Medical Device - ¥ 0.06billion
- Others + ¥ 0.06billion

Overseas - ¥0.68 billion

- U.S. - ¥0.17 billion
(Currency impact: - ¥0.06 billion)
- Europe - ¥ 0.17billion
(Currency impact: - ¥ 0.21billion)
- Asia - ¥ 0.32billion
 - China - ¥ 0.04billion
(Currency impact: - ¥ 0.04billion)
 - Korea - ¥ 0.27billion
(Currency impact: - ¥ 0.02billion)

Prescription Ophthalmics (Japan)

+ Anti-infective	-¥0.60bil	95.6%
+ Cornea (Dry Eye)	-¥0.33bil	98.6%
Diquas	-¥0.45bil	86.3%
+ Glaucoma	+¥0.35bil	101.6%
Tapros:	-¥1.11bil	86.5%
Cosopt:	+¥0.75bil	113.6%
+ Anti-allergy	+¥0.24bil	106.8%
+ Others	-¥0.47bil	97.0%

Europe

+ Prescription Ophthalmics	-¥0.19bil	97.8%
- Western Europe	-¥0.25bil	89.9%
- Eastern Europe	-¥0.24bil	87.5%
- Northern Europe	+¥0.21bil	107.1%
- Russia	+¥0.08bil	105.6%

<Currency rates>

	FY2011 forecast	FY2011 actual
US\$	¥ 82.00	¥79.03
Euro	¥ 113.00	¥110.27
RMB	¥ 12.50	¥12.34

*As of Nov. 1, 2011



Changes in Income Statement

(JPY billions)	FY2010	FY2011		Major Changes												
	Actual	Actual	Variance													
Net Sales	110.81	114.41	+3.60													
Cost of Sales (% of net sales)	34.43 31.1%	35.38 30.9%	+0.94 -0.2pt	<ul style="list-style-type: none"> • Change in model mix : -0.1pt • Income from license-out : -0.1pt 												
SGA excluding R&D (% of net sales)	32.41 29.3%	35.07 30.7%	+2.65 +1.4pt	<ul style="list-style-type: none"> • EU/U.S. : +1.02 • Novagali : +0.64 (consolidated Novagali P/L+0.47, Amortization of Goodwill+0.16) • Asia : +1.27 (China +0.40, Korea +0.58, Others +0.28) • Japan : -0.75 												
R&D Expenses (% of net sales)	13.22 11.9%	17.22 15.1%	+4.00 +3.1pt	Japan : +1.47 (incl. accounting policy change in overseas contracted R&D expenditure +0.50, FY2010 overseas contracted R&D adjustment +0.38, other adjustment +0.02) EU/U.S. : +2.07, Novagali : +0.38												
Operating Profit (% of net sales)	30.73 27.7%	26.73 23.4%	-4.00 -4.4pt													
Non-operating Income	1.01	1.11	+0.10													
Non-operating Expense	0.26	0.07	-0.19													
Ordinary Income	31.48	27.78	-3.70	<div style="border: 1px solid black; padding: 5px;"> <Currency Rates> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">FY10 actual</th> <th style="text-align: center;">FY11 actual</th> </tr> </thead> <tbody> <tr> <td>US\$</td> <td style="text-align: center;">JPY 85.57</td> <td style="text-align: center;">JPY 79.03</td> </tr> <tr> <td>Euro</td> <td style="text-align: center;">JPY 113.45</td> <td style="text-align: center;">JPY 110.27</td> </tr> <tr> <td>CNY</td> <td style="text-align: center;">JPY 12.94</td> <td style="text-align: center;">JPY 12.34</td> </tr> </tbody> </table> </div>		FY10 actual	FY11 actual	US\$	JPY 85.57	JPY 79.03	Euro	JPY 113.45	JPY 110.27	CNY	JPY 12.94	JPY 12.34
	FY10 actual	FY11 actual														
US\$	JPY 85.57	JPY 79.03														
Euro	JPY 113.45	JPY 110.27														
CNY	JPY 12.94	JPY 12.34														
Extraordinary Gain	0.01	0.06	+0.04													
Extraordinary Loss	0.42	0.05	-0.37													
Net Income before Tax	31.07	27.79	-3.28													
Corporate Tax	9.74	10.63	+0.88													
Net Profit	21.33	17.16	-4.17													



Financial Forecast for FY2012



Financial Forecast for FY2012

(JPY billions)	FY2011 Actual	FY2012 Forecast	Var. %
Net Sales	114.41	114.50	+0.1%
Operating Income	26.73	23.50	-12.1%
Ordinary Income	27.78	24.00	-13.6%
Net Income	17.16	16.00	-6.8%

ROE	10.7%	9.6%	-1.1pt
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Highlights for FY2012

Solid growth driven by the new drugs,
Tapros and Diquas

Continually outpaced market growth
in Asia & Europe

Intensively focus on P3 development in R&D
for the growth from FY14 onwards



FY2012

Net Sales Forecast: Variances (vs. FY2011 Result)

FY2011
Net Sales
(Actual)
¥114.41 billion

+ ¥0.08
billion



FY2012
Net Sales
(Forecast)
¥114.50 billion

Japan +¥0.80billion

- Prescription Ophthalmics -¥1.04billion
- RA Drugs -¥0.42billion
- OTC Drugs +¥1.52billion
- Medical Device +¥0.96billion
- Others -¥0.21billion

Outside Japan -0.72billion

- U.S. -2.53billion
(Currency impact: -0.00billion)
- Europe +0.37billion
(Currency impact: -0.54billion)
- Asia +1.42billion
 - China +1.28billion
(Currency impact: +0.06billion)
 - Korea -0.06billion
(Currency impact: -0.01billion)

Prescription Ophthalmics (Japan)

- Anti-infective -¥1.37billion
- Corneal Disease -¥0.49billion
(Diquas +¥2.45billion)
- Anti-glaucoma +¥1.56billion
(Tapros +¥0.58billion)
(Cosopt +¥2.39billion)
- Anti-allergy +¥0.05billion
- Others -¥0.79billion

Europe

- Prescription Ophthalmics +¥0.41billion
 - West Europe +¥0.30billion
 - East Europe +¥0.45billion
 - North Europe -¥0.33billion
 - Russia -¥0.01billion

<Currency rate>

	FY2011 actual	FY2012 forecast
US\$	JPY79.03	JPY79.00
Euro	JPY110.27	JPY104.00
CNY	JPY12.34	JPY12.50



Sales/Income Outlook for the FY2012

(JPY billions)	FY2011 Actual	FY2012	
		Forecast	Var.
Net Sales	114.41	114.50	+0.08
Cost of Sales	35.38	38.00	+2.61
(% of net sales)	30.9%	33.2%	+2.3pt
SG&A excluding R&D	35.07	35.50	+0.42
(% of net sales)	30.7%	31.0%	+0.4pt
R&D Expense	17.22	17.50	+0.27
(% of net sales)	15.1%	15.3%	+0.2pt
Operating Income	26.73	23.50	-3.23
(% of net sales)	23.4%	20.5%	-2.8pt
Non-operating Income/Loss	1.04	0.50	-0.54
Ordinary Income	27.78	24.00	-3.78
Extraordinary Income/Loss	0.01	0.00	-0.01
Net Income before Tax	27.79	24.00	-3.79
Income Taxes	10.63	8.00	-2.63
Net Income	17.16	16.00	-1.16

<Currency rate>	
	<u>FY2011 actual</u>
US\$	JPY 79.03
Euro	JPY 110.27
CNY	JPY 12.34
	<u>FY2012 forecast</u>
US\$	JPY 79.00
Euro	JPY104.00
CNY	JPY 12.50



Dividend Forecast for 2nd Half FY2011 and FY2012



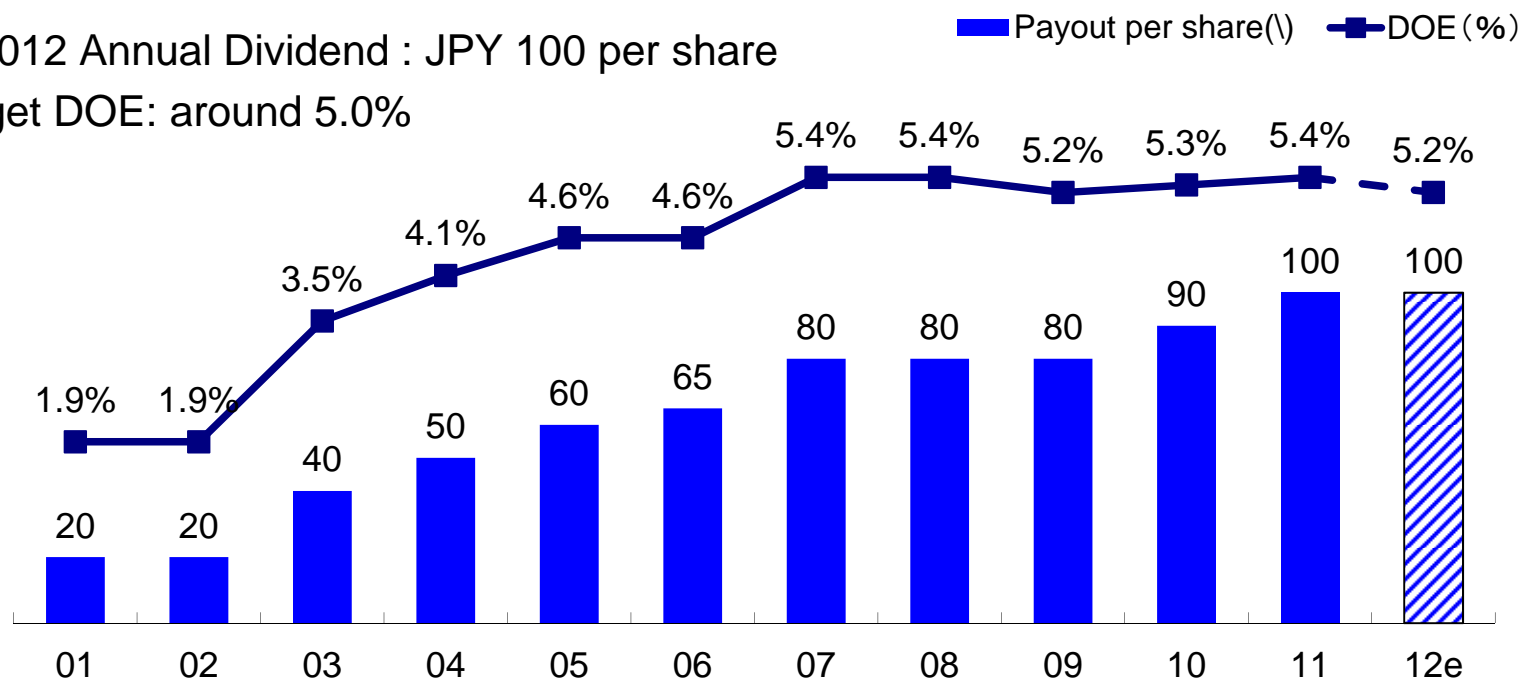
Dividend Forecast for 2nd Half FY2011 and FY2012

■ FY2011

- FY2011 2nd Half Dividend : JPY 50 per share
- FY2011 Annual Dividend : JPY 100 per share
- DOE: 5.4%

■ FY2012

- FY2012 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	36.3	36.0	50.8	54.5
Share Buy-back (¥ billion)	3.2	3.2	0	2.6	0	0	4.8	0	0	0	0	-
Total Return (%)	96.4	59.5	55.8	63.3	39.9	42.9	85.8	67.2	36.4	36.7	50.8	-



**Reference:
Consolidated Results
FY2011**



Net Sales by Business Segment

(JPY billions)	FY2011 Actual					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
Pharmaceuticals	93.44	+2.6%	18.39	+5.0%	111.84	+3.0%
Prescription Pharmaceuticals	88.86	+2.9%	18.38	+4.9%	107.24	+3.3%
Ophthalmic	77.75	+2.9%	15.86	+4.3%	93.62	+3.1%
Anti-RA	9.88	+1.6%	0.10	-3.1%	9.98	+1.6%
Others	1.22	+20.0%	2.41	+9.8%	3.64	+13.0%
OTC Pharmaceuticals	4.58	-2.7%	0.01	+24.3%	4.59	-2.7%
Others	1.92	+28.1%	0.64	-12.1%	2.57	+14.9%
Medical Devices	1.91	+28.3%	0.64	-12.1%	2.55	+15.0%
Others	0.01	+2.1%	-	-	0.01	+2.1%
Total	95.37	+3.1%	19.04	+4.3%	114.41	+3.3%



Oversea Sales

(JPY billions)	FY2010 Actual	FY2011		
		Actual	Var.	Var. %
U.S.	3.06	3.45	+0.38	+12.4%
Europe	8.51	8.88	+0.36	+4.3%
Asia	6.66	6.70	+0.03	+0.6%
Others	0.00	0.00	-0.00	-
Total	18.26	19.04	+0.78	+4.3%



Summary of Change in Balance Sheet

(JPY billions)	As of March 31, 2011		As of March 31, 2012		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	137.66	74.5%	140.28	70.6%	2.62
Fixed Asset	47.13	25.5%	58.51	29.4%	11.38
Total Asset	184.80	100.0%	198.80	100.0%	14.00
Current Liabilities	24.10	13.0%	27.42	13.8%	3.32
Non-current Liabilities	4.29	2.3%	6.51	3.3%	2.22
Total Liabilities	28.39	15.4%	33.94	17.1%	5.54
Total Net Asset	156.40	84.6%	164.86	82.9%	8.45
Total Liabilities Net Assets	184.80	100.0%	198.80	100.0%	14.00

Major Changes

- **Current Asset:** Cash and deposits +¥0.67bil, Merchandise and finished products -¥1.05bil, Marketable securities -¥0.59bil, Inventories +¥2.89bil, Materials +¥0.20bil
- **Fixed Asset :** Buildings and structures -¥0.64bil, Construction in progress +¥1.17bil, Goodwill +¥5.80bil, R&D in Progress +5.94bil, investment securities -¥0.27bil, LT deferred tax assets -¥1.03bil, Other intangible assets -¥0.30bil,
- **Current Liabilities:** Trade accounts payable +¥2.04bil, Other payables +¥0.56bil, Income tax payable +¥0.65bil, Provision for bonus +¥0.23bil
- **Fixed Liabilities :** Provisions for directors' retirement fund -¥0.23bil, LT deferred tax liability +¥1.97bil
- **Net asset :** Retained earnings +¥8.45bil, Foreign currency translation adjustments -¥0.68bil
Other securities evaluation adjustments +¥0.49



Summary of Cash Flows

(JPY billions)	FY2011 Actual
Cash and cash equivalents at the beginning of the year	72.48
Net increase/decrease in cash and cash equivalents	2.55
Cash flows from operating activities	21.48
Cash flows from investing activities	-10.27
Cash flows from financial activities	-8.55
Effect of exchange rate changes on cash and cash equivalents	-0.09
Cash and cash equivalents at the end of the year	75.03

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	
	Actual	Actual	Var.
Capital Expenditures	1.70	3.49	+1.78
Depreciation and Amortization	2.80	2.71	-0.09
Lease Payments	0.15	0.02	-0.13



**Reference:
FY2012 Financial Forecasts**



Mid-term Consolidated Income Comparison

(JPY billions)	FY2008 Actual	FY2009 Actual	FY2010 Actual	FY2011 Actual	FY2012 Forecast
Net Sales	101.61	110.59	110.81	114.41	114.50
Operating Income	15.49	29.64	30.73	26.73	23.50
Ordinary Income	15.93	29.86	31.48	27.78	24.00
Net Income	10.12	18.72	21.33	17.16	16.00
ROE	8.0%	14.3%	14.5%	10.7%	9.6%



Sales Forecast by Business Segment / Overseas Sales

(JPY billions)	FY2012 Forecast					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var.	Sales	Var.
Pharmaceuticals	93.28	-0.2%	18.31	-0.5%	111.59	-0.2%
Prescription Pharmaceuticals	87.17	-1.9%	18.26	-0.7%	105.43	-1.7%
Ophthalmic	76.71	-1.3%	17.57	+10.8%	94.28	+0.7%
Anti-RA	9.45	-4.3%	0.09	-13.1%	9.54	-4.4%
Others	1.00	-17.8%	0.59	-75.2%	1.60	-55.4%
OTC Pharmaceuticals	6.11	+33.3%	0.04	+377%	6.16	+34.1%
Others	2.89	+50.2%	0.01	-98.4%	2.90	+12.9%
Medical Devices	2.88	+50.6%	0.01	-98.4%	2.89	+13.0%
Others	0.01	-11.9%	-	-	0.01	-11.9%
Total	96.17	+0.8%	18.32	-3.8%	114.50	+0.1%



Overseas Sales

(JPY billions)	FY2011 Actual	FY2012 Forecast		
		Forecast	Var.	Var. %
U.S.	3.45	0.91	-2.53	-73.5%
Europe	8.88	9.25	+0.37	+4.2%
Asia	6.70	8.12	+1.42	+21.2%
Others	0.00	0.02	+0.01	330%
Total	19.04	18.32	-0.72	-3.8%



Capital Expenditures / Depreciation & Amortization / Lease Expenses

(JPY billions)	FY2011 Actual	FY2012	
		Forecast	Var.
Capital Expenditures	3.49	6.43	+2.93
Depreciation and Amortization	2.71	2.84	+0.12
Lease Payments	0.02	0.02	+0.00



**Reference:
Financial Results in Novagali**



Income statement in Novagali

(EUR' mil)	FY2011	FY2012	
	Actual	Forecast	Var.
Sales	0.4	2.1	+1.7
COGS	0.2	1.4	+1.2
SGA(excl.R&D)	6.0	10.5	+4.5
(in SGA) Amortization of Goodwill	1.5	6.2	+4.7
R&D	3.7	14.6	+10.9
Operating Profit	▲9.6	▲24.4	▲14.8

Note: the above figures in FY2011 show full year results, of which only FY2011 4Q was consolidated.



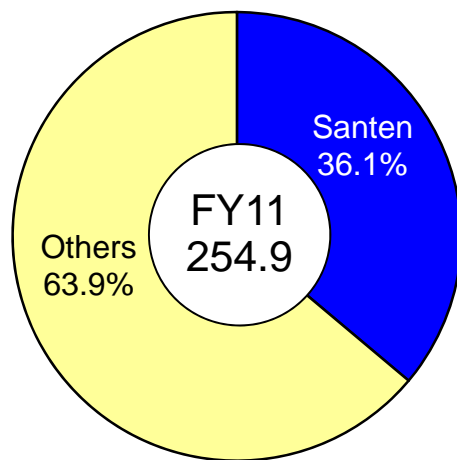
**Reference:
Market Overview of
Prescription Ophthalmic in Japan**

S Japan: Trend & Competition in Ophthalmics (1)

- **Ophthalmology Total:** Market grew by 3.1% Y to Y in FY11. The growth of retinal segment and corneal segment continued. Santen's market share was 36.1%.
- **Glaucoma:** Market grew by 2.3% Y to Y in FY11. Santen's sales grew by 13.1%. Santen held 28.4% share of the glaucoma market by the contribution of Tapros and Cosopt.
- **Corneal:** Market grew by 11.3% Y to Y in FY11. Santen's sales grew by 13.7% and Santen's market share increased to 77.5% with growth of Hyalein and Diquas.

Market Size:
billions of yen
%: Value Share

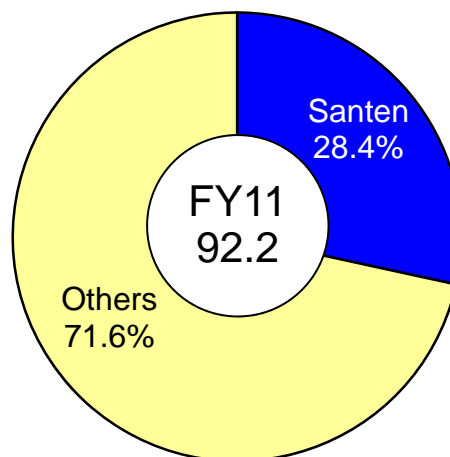
Ophthalmology Total



FY10 FY11

YoY change	Market	+5.3%	+3.1%
	Santen	+1.0%	+4.1%
Santen's Share		35.8%	36.1%

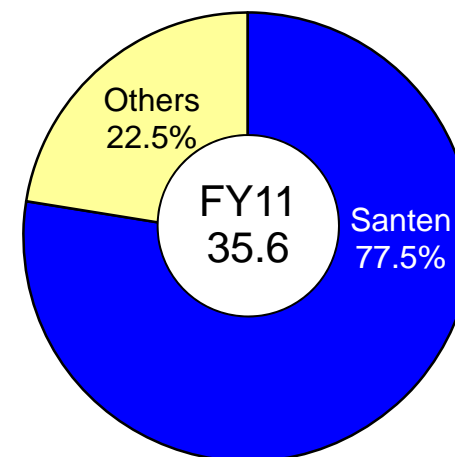
Anti-glaucoma



FY10 FY11

Market	+1.8%	+2.3%
Santen	+13.5%	+13.1%
Santen's Share		25.7%
		28.4%

Corneal: Dry Eye



FY10 FY11

Market	+1.0%	+11.3%
Santen	-0.5%	+13.7%
Santen's Share		76.0%
		77.5%

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

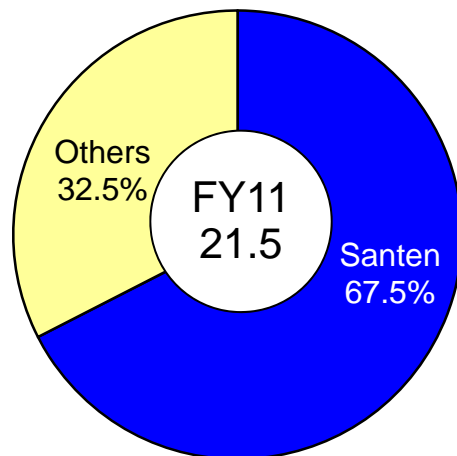
Source: ©2012 IMS Japan
IMS-JPM 2009-12
Santen analysis based on IMS data
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S Japan: Trend & Competition in Ophthalmics (2)

- **Anti-infection:** Market declined by 4.2% Y to Y in FY11. Santen maintained 67.5% of market share with primary contribution by Cravit.
- **Anti-allergy:** Market declined by 9.9% Y to Yin FY11. Santen's share was 17.6%.

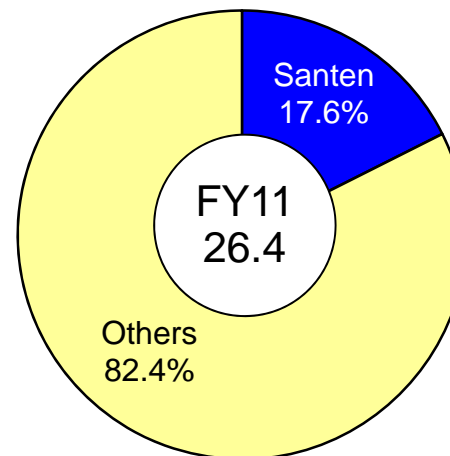
Market Size:
billions of yen
%: Value Share

Anti-infection



		FY10	FY11
YoY change	Market	-1.0%	-4.2%
	Santen	-3.3%	-5.5%
Santen's Share		68.4%	67.5%

Anti-allergy



		FY10	FY11
YoY change		+22.3%	-9.9%
Santen's Share		16.7%	17.6%

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

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 IMS-JPM 2009-12
 Santen analysis based on IMS data
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Status of Clinical Development FY2011

May 9, 2012

Toshiaki Nishihata, Ph.D.

Director,

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 Q3 FY11 Presentation)

Global Product

Japan (Asia)
Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved/ Launched
Glaucoma			DE-111 Tafluprost/Timolol	China	<u>DE-085</u> Tafluprost JP·Asia EU·Latin America Australia· <u>US</u>
		DE-090 Lomerizine HCl	EU JP	DE-118 Tafluprost	
Corneal/ Conjunctival Disease		DE-101 Rivoglitazone			<u>DE-089</u> China Diquafosol Sodium Korea JP
		DE-105 Peptide Combination	US JP		
		<u>DE-110</u> SEGRA			
		Cyclokat Ciclosporin	US EU		
Retinal/ Uveal Disease			DE-109 Sirolimus		
			DE-102 Betamethasone		
Other Infection, Allergy, RA		<u>DE-098</u> Anti APO-1 Antibody			DE-108 Korea Levofloxacin 1.5% Japan
			DE-114 Epinastine HCl		
			<u>Vekacia</u> Ciclosporin		

*The other Novagali products(Catioprost and Cortiject) are under project evaluation.

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

(Red underlined: Change from Q3 FY11 Presentation)

Global Product

Japan (Asia)
Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved - Launched
Japan			DE-102 Betamethasone	DE-118 Tafluprost	DE-085 Tafluprost
		DE-090 Lomerizine HCl	DE-111 Tafluprost/ Timolol		DE-089 Diquafosol Sodium
		DE-105 Peptide Combination	DE-114 Epinastine HCl		DE-108 Levofloxacin 1.5%
		DE-098 Anti APO-1 Antibody	DE-109 Sirolimus		
North America (Including Latin America)	DE-105 Peptide Combination	DE-110 <u>SEGRA</u>	DE-109 Sirolimus		DE-085 <u>Tafluprost</u> US, Latin America
		DE-101 Rivoglitazone			
		Cyclokat Ciclosporin			
Asia (including Oceania)				China DE-085 Tafluprost Korea, Australia	
				<u>China</u> DE-089 Diquafosol Sodium Korea	
				DE-108 Levofloxacin 1.5% Korea	
EU			DE-111 Tafluprost/ Timolol		DE-085 Tafluprost
			Cyclokat Ciclosporin		
			Vekacia <u>Ciclosporin</u>		

*The other Novagali products(Catioprost and Cortiject) are under project evaluation.

Major Clinical Projects Update (DE-085)

- DE-085 (Glaucoma, Ocular hypertension)
TAPROS, TAFLOTAN, SAFLUTAN, ZIOPTAN

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	Launched	Launched	Generic name: Tafulprost Launched in: Japan (Dec. 2008) Europe (Jun. 2008) Asia (Mar. 2010) United States (Mar. 2012) Latin America (Aug. 2010) Out-licensed to: Merck & Co. (Apr. 2009)
Europe**	Launched: 27 countries Approved: 39 countries Partly out-licensed to Merck*	Launched: 27 countries Approved: 39 countries Partly out-licensed to Merck*	
Asia**	Launched: 4 countries Approved: 7 countries NDA filed: China	Launched: 4 countries Approved: 7 countries NDA filed: China	
Americas**	Out-licensed to Merck* Launched: 5 countries Approved: 11 countries Launched: U.S.	Out-licensed to Merck* Launched: 4 countries Approved: 10 countries NDA filed: U.S.	

Launched: Total of 37 countries worldwide

- Santen: Japan, 4 countries in Asia, 20 countries in
- Merck*: 7 countries in Europe, US, 4 countries in Latin America

Approved: Total of 58 countries worldwide

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

**EU: Including CIS, Asia: Including Oceania, Americas: US, Latin America



Major Clinical Projects Update

- **DE-118** (Glaucoma, ocular hypertension)

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	NDA filed	NDA filed	Generic name: Tafluprost (preservative-free, unit dose)

- **DE-089** (Dry eye)

Product Name: *DIQUAS* in Japan

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	Launched	Launched	Generic name: Diquafosol Sodium
Asia	China: NDA filed Korea: Approved	China: Preparing NDA Korea: Approved	



Major Clinical Projects Update - Glaucoma, Ocular hypertension -

- DE-090

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

- DE-111

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	P3	P3	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	P3	P3	

- DE-112

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
U.S.	Discontinued	P1/2a	Adenosine A _{2A} 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 May 9, 2012	As of February 7, 2012 (Previous announcement)	
U.S.	P2	P2	Generic Name: Rivoglitazone

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

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (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 May 9, 2012	As of February 7, 2012 (Previous announcement)	
U.S.	P2 Completed	P2	Selective glucocorticoid receptor agonist (SEGRA)



Major Clinical Projects Update - Retinal / Uveitis Disease -

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

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	P2/3	P2/3	Generic name: Betamethasone

- **DE-109** (Uveitis)

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
US	P3	P3	Generic name: Sirolimus
Japan	P3	P3	



Major Clinical Projects Update – Infection, Allergy, Arthritis -

- **DE-108** (Extraocular infection)

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	Launched	Launched	Generic name: Levofloxacin 1.5%
Korea	NDA Filed	NDA Filed	

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

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	P3	P3	Generic name: Epinastine HCl

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

Region	Development Stage		Remarks
	As of May 9, 2012	As of February 7, 2012 (Previous announcement)	
Japan	P2 Completed	P2	Anti-APO-1 antibody

Major Clinical Projects Update – Novagali -

- **Cyclokot** (Severe Dry Eye)

Region	Development Stage		Remarks
	5/9/2012	2/7 (Previous)	
EU	P3	P3	Generic Name: Ciclosporin
US	P2 Completed	P2 Completed	

- **Vekacia** (Vernal Conjunctivitis)

Region	Development Stage		Remarks
	As of May 9, 2012		
EU	P3		Generic Name: Ciclosporin

*The following products are under project evaluation.

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.