



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

**Financial Results for the 1st Half of FY2014
Financial Forecast for the FY2014**

November 6, 2014

Akira Kurokawa

President & CEO



**Long-term Strategic Vision,
Medium-term Management Plan for
FY2014-2017**

Long-term Strategic Vision

To become a Specialized Pharmaceutical Company with a Global Presence

- Deep Understanding of True Customer Needs*
- Distinct Advantage Against Competitors
- Global Competitiveness and Presence

*True customer needs: Unmet medical needs of patients, consumers, doctors and healthcare professionals.

Long-term Growth Targets



- Strengthen the domestic business
- Preparations for business expansion in Asia/Europe

Ranks #5 globally
Overseas sales: 16%
of total sales

Medium-term Goal

- Grow business in Asia/Europe and improve profitability
- Prepare for business expansion in the U.S. and other regions

Overseas sales: 30%
of total sales

What we aim to achieve by 2020

“To become a Specialized Pharmaceutical Company with a Global Presence”

Become global #3

Overseas sales:
40%-50% of total
sales

Basic Policy of Medium-term Management Plan for FY2014-2017

Product development

Transform product development to realize enhanced productivity and achieve sustained growth

Business expansion

Grow business in Asia/Europe and strengthen market presence by entering into new markets

Organization and talents

Develop talents and organization to realize sustained growth and strengthen the global management system



Financial Results for the 1st Half of FY2014

Financial Highlights for 1H FY2014

(JPY billions)	1H FY13 Actual	1H FY14 Actual	Var. %
Net Sales	69.26	71.92	+3.8%
Cost of Sales (% of net sales)	27.16 39.2%	26.59 37.0%	-2.1% -2.2pt
SGA excluding R&D (% of net sales)	19.56 28.2%	23.64 32.9%	+20.9% +4.6pt
R&D Cost (% of net sales)	8.07 11.7%	8.48 11.8%	+5.1% +0.1pt
Operating Profit (% of net sales)	14.45 20.9%	13.19 18.3%	-8.7% -2.5pt
Ordinary Income	14.86	13.60	-8.5%
Net Income	8.99	9.09	+1.2%
Operating profit before amortization	16.12	16.31	+1.2%

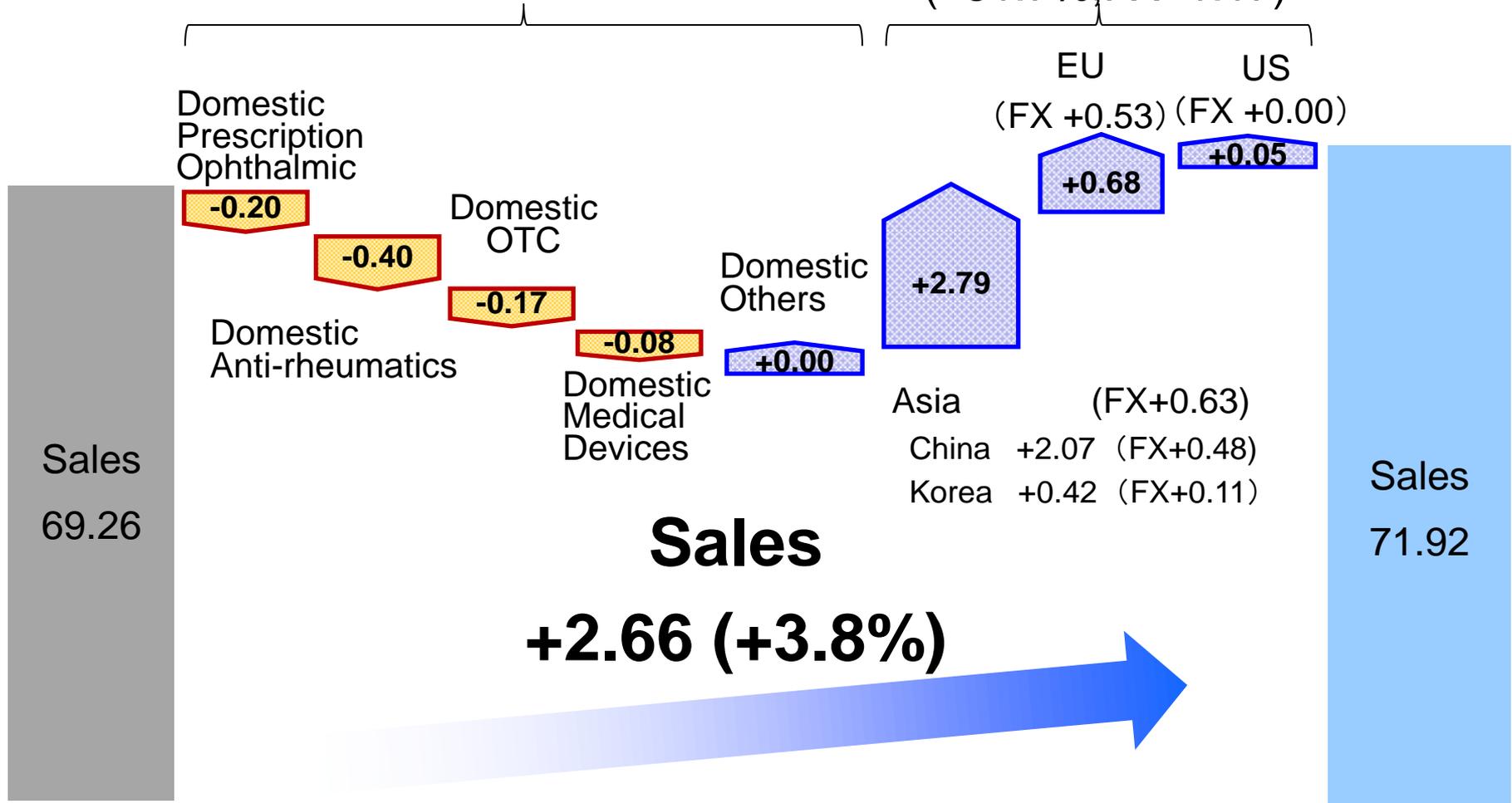
Foreign Exchange	1H FY13 actual	1H FY14 actual
US \$	JPY 98.31	JPY 103.12
Euro	JPY 127.47	JPY 138.98
CNY	JPY 15.25	JPY 16.71

Sales Increase/Decrease

JPY billions

Domestic -0.85 (-1.5%)

Overseas +3.51
(+31.7%, FX+1.17)



Sales
69.26

Sales

+2.66 (+3.8%)

Sales
71.92

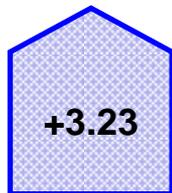
1H FY13 Actual

1H FY14 Actual

Operating Profit Change

SG&A (excl. R&D cost) +4.08 (+20.9%)

Gross profit



Domestic



Asia



(FX+0.22)

US/EU



(FX+0.37)

Merck related



Other



R&D cost
(FX+0.21)



JPY billions

Operating Profit

-1.26 (-8.7%)

OP
14.45

1H FY13 Actual

OP
13.19

1H FY14 Actual

FX=Currency impact



Merck Project

Current status progress

Merck Project -Current status progress-

■ As of July, 2014

- 1st Closing: Santen announces closing of asset purchase agreement
- Project area: Asia including Japan, South Korea and Europe excluding some countries.

■ As of October, 2014

- 2nd Closing: Santen announces closing of asset purchase agreement
- Project area: Italy and France

With the completion of the 2nd Closing, all the underlying assets under the agreement have been closed.

■ As of October, 2014

- Established a wholly owned subsidiary in Italy, and the United Kingdom (UK).
- Will plan to launch commercial teams in Switzerland and Spain accordingly.



Consolidated Forecast of FY2014

FY2014 Financial Forecast

(JPY :billions)	FY2013 Actual (Japanese Standard) *	FY2014 Forecast (Japanese Standard)	Var. %
Net Sales	148.66	156.00	+4.9%
Cost of Sales (% of net sales)	58.10 39.1%	52.00 33.3%	-10.5% -5.8pt
SGA excluding R&D (% of net sales)	44.10 29.7%	54.70 35.1%	+24.0% +5.4pt
R&D Cost (% of net sales)	19.04 12.8%	19.30 12.4%	+1.4% -0.4pt
Operating profit (% of net sales)	27.41 18.4%	30.00 19.2%	+9.4% +0.8pt
Ordinary Income	27.92	30.00	+7.4%
Net Income	17.10	19.50	+14.0%
Operating profit before amortization	31.20	37.70	+20.8%
Cash ROE (JPY)	-	14.6%	-
ROE	9.9%	10.5%	+0.6pt

FY2014 Financial Forecast

(JPY billions)	FY2014 Forecast			
	Existing business	Merck*	Total	Var. %
Net Sales	151.00	5.00	156.00	+4.9%
Cost of Sales (% of net sales)	57.50 38.1%	-5.50 -	52.00 33.3%	-10.5% -5.8pt
SGA excluding R&D (% of net sales)	46.50 30.8%	8.20 -	54.70 35.1%	+24.0% +5.4pt
R&D Cost (% of net sales)	19.00 12.6%	0.30 -	19.30 12.4%	+1.4% -0.4pt
Operating Profit (% of net sales)	28.00 18.5%	2.00 40.0%	30.00 19.2%	+9.4% +0.8pt
Ordinary Income	28.50	1.50	30.00	+7.4%
Net Income	18.60	0.90	19.50	+14.0%
Operating profit before amortization	32.00	5.70	37.70	+20.8%

*Merck project is indicated the contribution from acquisition of Merck's ophthalmology asset which Santen contracted as of May 8th, 2014.

Dividend for 1H FY2014 Actual and FY2014 Forecast

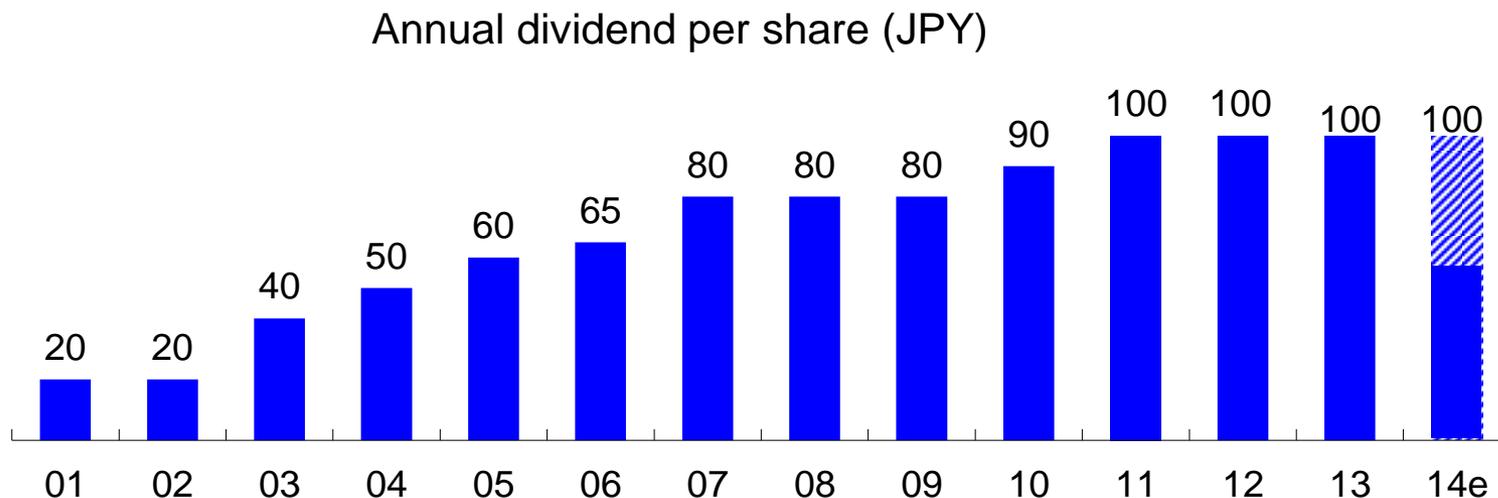
Dividend for 1H FY2014 Actual and FY2014 Forecast

- **FY2014 1st Half**

- FY2014 First Half Dividend : JPY 50 per share

- **FY2014**

- FY2014 Annual Dividend : JPY 100 per share
 - Target dividend payout ratio: 40.0%



(¥ billion)	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014e
Payout-ratio (%)	34.9	21.4	55.8	39.7	39.9	42.9	54.7	67.2	36.3	36.0	50.8	51.1	48.2	42.3
Share Buy-back	3.2	3.2	0	2.6	0	0	4.8	0	0	0	0	13.7	0	-
Total Return (%)	96.4	59.5	55.8	63.3	39.9	42.9	85.8	67.2	36.3	36.0	50.8	134.4	48.2	-



**Reference:
Consolidated Results
1st Half of FY2014**

Net Sales by Business Segment

(JPY billions)	1H FY14 Actual					
	Japan		Overseas		Total	
	Sales	Var. %	Sales	Var. %	Sales	Var. %
Pharmaceuticals	56.04	-1.3%	14.60	+31.9%	70.64	+4.1%
Prescription Pharmaceuticals	52.83	-1.1%	14.56	+31.8%	67.39	+4.5%
Ophthalmic	47.70	-0.4%	14.02	+30.8%	61.73	+5.3%
Anti-RA	4.80	-7.7%	0.03	-38.6%	4.83	-8.0%
Others	0.32	+6.5%	0.51	+83.3%	0.83	+43.4%
OTC Pharmaceuticals	3.20	-5.1%	0.03	+91.4%	3.24	-4.5%
Others	1.26	-7.0%	0.01	-47.3%	1.27	-7.7%
Medical Devices	1.15	-6.9%	0.01	-47.3%	1.16	-7.6%
Others	0.11	-8.4%	-	-	0.11	-8.4%
Total	57.31	-1.5%	+14.61	+31.7%	71.92	+3.8%

Overseas Sales

(JPY billions)	1H FY13 Actual	1H FY14		
		Actual	Var.	Var. %
U.S.	0.47	0.52	+0.05	+11.0%
Europe	5.53	6.21	+0.68	+12.3%
Asia	5.07	7.86	+2.79	+55.1%
China	3.45	5.52	+2.07	+60.2%
Korea	1.08	1.51	+0.42	+38.6%
Others	0.01	0.00	-0.00	-78.9%
Total	11.09	14.61	+3.51	+31.7%

Overseas sale/sales	16.0%	20.3%	+4.3pt	-
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Summary of Balance Sheet

(JPY billions)	As of March 31, 2014		As of September 30, 2014		
	Actual	% of Total	Actual	% of Total	Var.
Current Asset	156.00	67.5%	130.32	49.8%	-25.68
Fixed Asset	75.09	32.5%	131.31	50.2%	+56.21
Total Asset	231.10	100.0%	261.63	100.0%	+30.52
Current Liabilities	39.09	16.9%	62.53	23.9%	+23.43
Non-current Liabilities	10.80	4.7%	10.89	4.2%	+0.09
Total Liabilities	49.89*	21.6%	73.43*	28.1%	+23.53
Total Net Asset	181.20	78.4%	188.20	71.9%	+6.99
Total Liabilities Net Assets	231.10	100.0%	261.63	100.0%	+30.52

*Capital adequacy ratio: End of March, 2014: 78.2% → End of September, 2014: 71.7%,
 Issued shares: End of March, 2014: 82,582 thousands → End of September, 2014: 82,611 thousands

Major Changes

- **Current Asset:** Cash and deposits -¥16.43bil, Securities -¥6.60bil, Products -¥1.42bil
- **Fixed Asset:** Right of approval for manufacture and sales +¥55.39bil, Investment securities +¥1.99bil, Deferred tax assets -¥0.54bil
- **Current Liabilities:** Notes and accounts payable -¥6.84bil, Short term borrowing +¥35.00bil, Account payable -¥0.96bil, Income tax payable -¥3.45bil
- **Net asset:** Earned surpluses +¥4.97bil, Valuation difference on available for sale securities +¥1.22bil, Foreign currency translation adjustments +¥0.46bil

Changes in Income Statement

(JPY billions)	1HFY13 Actual	1HFY14		Major Changes
		Actual	Var. %	
Net Sales	69.26	71.92	+3.8%	
Cost of Sales (% of net sales)	27.16 39.2%	26.59 37.0%	-2.1% -2.2pt	<ul style="list-style-type: none"> ▪ Merck -2.9pt ▪ Decrease of cost of sales overseas -0.5pt ▪ Impact of product mix change +1.5pt ▪ Effect from NHI price revision +0.4pt
SGA excluding R&D (% of net sales)	19.56 28.2%	23.64 32.9%	+20.9% +4.6pt	<ul style="list-style-type: none"> ▪ Domestic +0.14 ▪ Asia +0.83 (FX+0.22) ▪ US/EU +0.88 (FX+0.37) ▪ Merck related +1.87
R&D Expenses (% of net sales)	8.07 11.7%	8.48 11.8%	+5.1% +0.1pt	<ul style="list-style-type: none"> ▪ Domestic +0.11 ▪ Overseas +0.28 (FX+0.21)
Operating Profit (% of net sales)	14.45 20.9%	13.19 18.3%	-8.7% -2.5pt	
Non-operating Income	0.56	0.58	+4.2%	
Non-operating Expense	0.15	0.17	+12.6%	
Ordinary Income	14.86	13.60	-8.5%	
Extraordinary Gain	-	0.05	-	
Extraordinary Loss	0.87	-	-	
Net Income before Tax	13.98	13.66	-2.3%	
Corporate Tax	4.98	4.56	-8.6%	
Net Profit	8.99	9.09	+1.2%	

<Currency Rates>		
	1H FY13 actual	1H FY14 actual
US\$	JPY 98.31	JPY 103.12
Euro	JPY 127.47	JPY 138.98
CNY	JPY 15.25	JPY 16.71

Summary of Cash Flows

(JPY billions)	1H FY14 Actual
Cash and cash equivalents at the beginning of 1H FY14	72.39
Net increase/decrease in cash and cash equivalents	-20.94
Cash flows from operating activities	+3.25
Cash flows from investing activities	-55.74
Cash flows from financial activities	+30.93
Effect of exchange rate changes on cash and cash equivalents	+0.60
Cash and cash equivalents at the end of 1H FY14	51.45

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

Capital Expenditures / Depreciation & Amortization

(JPY billions)	1H FY13	1H FY14	
	Actual	Actual	Var.
Capital Expenditures	1.84	1.35	-0.49
Depreciation and Amortization	1.17	2.61	+1.44



**Reference:
Consolidated Forecast of FY2014**

FY2014 Financial Forecast

(JPY : billions)	FY2013 Actual (Japanese Standard)	FY2014 forecast (Japanese Standard)	Var. %	FY2014 Forecast (IFRS)*
Net Sales	148.66	156.00	+4.9%	156.00
Cost of Sales (% of net sales)	58.10 39.1%	52.00 33.3%	-10.5% -5.8pt	52.00 33.3%
SGA excluding R&D (% of net sales)	44.10 29.7%	54.70 35.1%	+24.0% +5.4pt	53.80** 34.5%
R&D Cost (% of net sales)	19.04 12.8%	19.30 12.4%	+1.4% -0.4pt	19.10 12.2%
Operating profit (% of net sales)	27.41 18.4%	30.00 19.2%	+9.4% +0.8pt	31.10 19.9%
Ordinary Income	27.92	30.00	+7.4%	31.10
Net Income	17.10	19.50	+14.0%	20.50
Operating profit before amortization	31.20	37.70	+20.8%	-
Cash ROE (JPY)	-	14.6%	-	-
ROE	9.9%	10.5%	+0.6pt	10.6%

* 【Difference between Japanese Standard forecast and IFRS】

- Including the depreciation of intangible asset
- Reported asset of license in payment

** Including Merck depreciate of intangible asset, ¥3.7bil

< Foreign exchange >

US\$
Euro
CNY

FY13 Actual

JPY 100.04
JPY 132.98
JPY 15.93

FY14 Forecast

JPY 103.00
JPY 141.00
JPY 16.90

Sales Forecast by Business Segment / Overseas Sales (Japanese Standard)

(JPY billions)	FY2014 Forecast					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var. %	Sales	Var. %
Pharmaceuticals	121.10	+1.6%	31.56	+19.1%	152.66	+4.8%
Prescription Pharmaceuticals	114.79	+1.8%	31.54	+19.2%	146.33	+5.1%
Ophthalmic	103.77	+2.0%	28.35	+10.7%	132.12	+3.7%
Anti-RA	9.95	-2.0%	0.03	-61.4%	9.99	-2.5%
Others	1.06	+23.9%	3.15	+318.1%	4.21	+161.7%
OTC Pharmaceuticals	6.30	-1.7%	0.02	-36.6%	6.33	-1.9%
Others	3.28	+13.3%	0.04	-6.7%	3.33	+12.9%
Medical Devices	2.90	+10.5%	0.04	-20.7%	2.94	+9.8%
Others	0.38	+40.7%	0.00	-	0.39	+43.4%
Total	124.38	+1.9%	31.61	+19.1%	156.00	+4.9%

Overseas Sales Revised Forecast (Japanese Standard)

(JPY billions)	FY2013 Actual (Unification of Accounting Period)	FY2014 Forecast		
		Forecast	Var.	Var. %
U.S.	1.07	3.10	+2.03	+189.1%
Europe	12.29	13.64	+1.34	+11.0%
Asia	13.17	14.85	+1.68	+12.8%
<i>China</i>	<i>9.79</i>	<i>10.06</i>	<i>+0.26</i>	<i>+2.7%</i>
<i>Korea</i>	<i>2.10</i>	<i>2.75</i>	<i>+0.65</i>	<i>+31.1%</i>
Others	0.00	0.01	+0.00	+71.9%
Total	26.55	31.61	+5.06	+19.1%
Overseas sale/sales	17.9%	20.3%	+2.4pt	-

Capital Expenditures / Depreciation & Amortization (Japanese Standard)

(JPY billions)	FY2013 Actual (Unification of Accounting Period)	FY2014	
		Forecast	Var.
Capital Expenditures	3.15	4.50*	+1.34
Depreciation and Amortization	2.61	6.70	+4.08

* Capital expenditures is revised: previous forecast JPY 6.69bil



Reference:

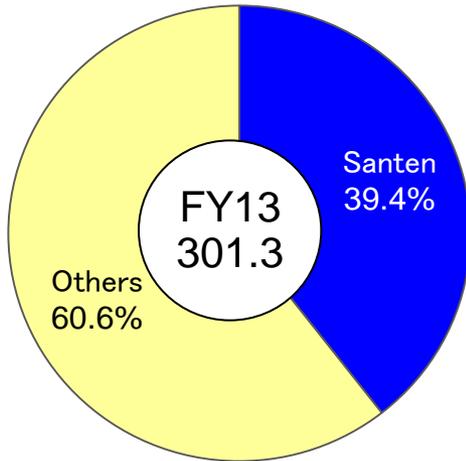
**Market Overview of
Prescription Ophthalmic in Japan**

Japan: Trend & Competition in Ophthalmics (1)

- **Ophthalmology Total:** Market grew by +8.4% Y on Y in 1H FY14. The growth is driven by retina and anti allergy market. Santen's market share was 39.4%.
- **Anti-Glaucoma:** Market grew by +0.9% Y on Y in 1H FY14. Santen's sales increased by +1.7% due to the addition of anti-glaucoma products from Merck/MSD. Santen's market share was 30.9%.
- **Corneal:** Market grew by +0.4% Y on Y in 1H FY14. Santen's sales dropped -7.1% due to influence of use of generic drug promotion. Santen's market share was 66.5%.

Market Size:
billions of yen
%: Value Share

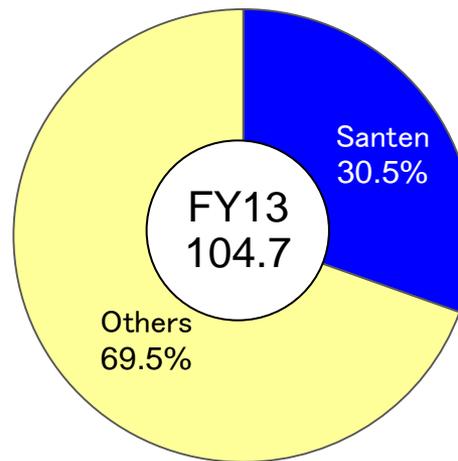
Ophthalmology Total



FY13 1H FY14

YoY change	Market	+10.2%	+8.4%
	Santen	+23.1%	+6.0%
Santen's Share		39.4%	39.4%

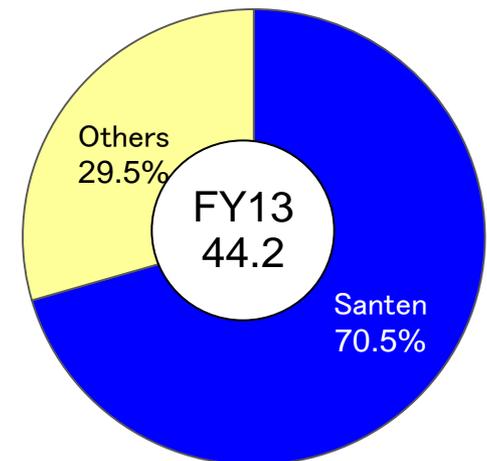
Anti-glaucoma



FY13 1H FY14

YoY change	Market	+10.5%	+0.9%
	Santen	+10.7%	+1.7%
Santen's Share		30.5%	30.9%

Corneal: Dry Eye



FY13 1H FY14

YoY change	Market	+11.5%	+0.4%
	Santen	+5.4%	-7.1%
Santen's Share		70.5%	66.5%

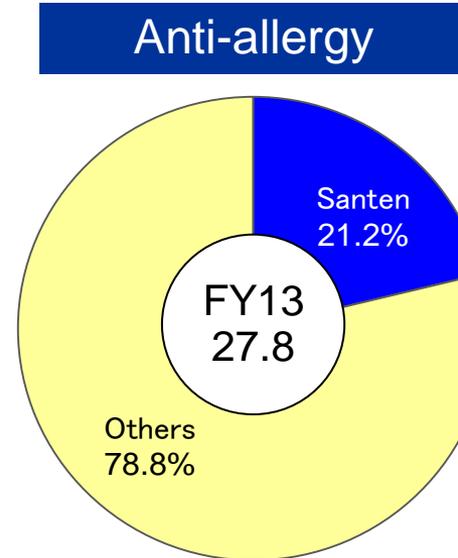
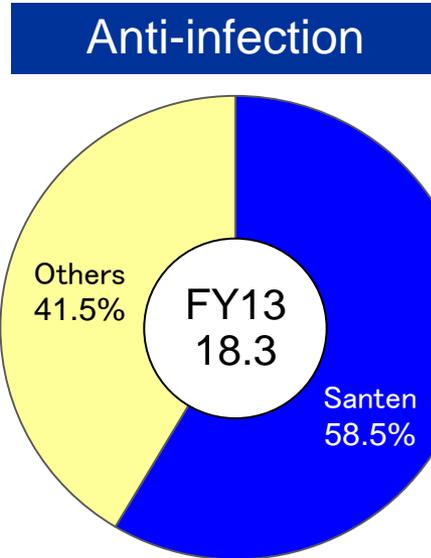
- Santen:
 - Anti-Glaucoma : Tapros, Cosopt, Timoptol/XE, Trusopt, Rescula, Detantol
 - Cornea / Dry Eye : Hyalein, Diquas

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 IMS-JPM 2012-14
 Santen analysis based on IMS data
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Japan: Trend & Competition in Ophthalmics (2)

- **Anti-infection:** Market declined by -8.0% Y on Y in 1H FY14. Santen maintained 55.2% of market share with primary contribution by Cravit.
- **Anti-allergy:** Market increased by +20.4% Y on Y in 1H FY14. Santen's share was 30.4%.
The launch of Alesion in Nov, 2013 generated the increase of Santen market share.

Market Size:
billions of yen
%: Value Share



		FY13	1H FY14
change YoY	Market	-3.0%	-8.0%
	Santen	-7.8%	-15.1%
Santen's Share		58.5%	55.2%

		FY13	1H FY14
Market		-9.7%	+20.4%
Santen		+19.7%	+99.6%
Santen's Share		21.2%	30.4%

- Santen:
- Anti-infection: Cravit, Tarivid
 - Anti-allergy: Alesion, Livostin, Alegysal

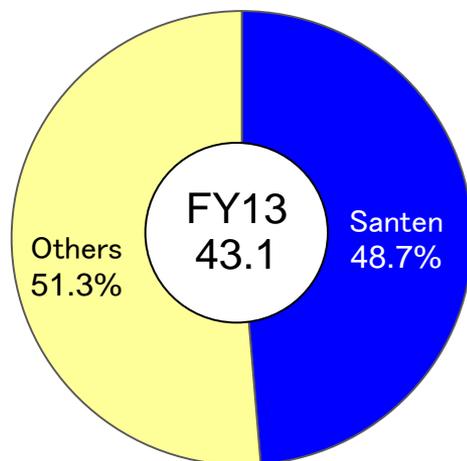
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IMS-JPM 2012-14
Santen analysis based on IMS data
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Japan: Trend & Competition in Ophthalmics (3)

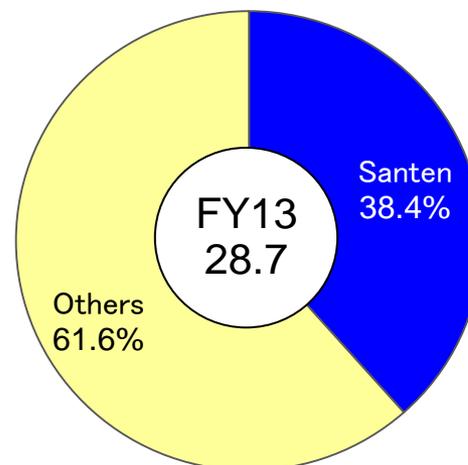
- **Anti-VEGF:** Market increased by +59.6% Y on Y in 1H FY14. Eylea has continued the strong growth. Santen's share was 45.7%.
- **Anti-RA(DMARDs):** Market slightly decreased by -0.8% in 1H FY14. Santen maintained 37.1% of market share.

Market Size:
billions of yen
%: Value Share

Anti-VEGF



Anti-RA(DMARDs)



		FY13	1H FY14
YoY change	Market	+52.6%	+59.6%
	Santen	-	+41.9%
Santen's Share		48.7%	45.7%

		FY13	1H FY14
YoY change		+5.5%	-0.8%
Santen's Share		38.4%	37.1%

-Santen:
- Anti-VEGF: Eylea
- Anti-RA(DMARDs): Rimatil, Azulfidine, Metolate

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IMS-JPM 2012-14
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Status of Clinical Development 1st Half of FY2014

Naveed Shams, M.D. Ph.D.

Senior Corporate Officer

Chief Scientific Officer (CSO)

Head of Global Research & Development

Major Clinical Pipeline List (1) [by Disease]

Global Product

Japan (Asia)Product

Disease	Phase 1	Phase 2	Phase 3	NDA	Approved-Launch
Glaucoma/ Ocular Hypertension		DE-117 ^{P2b} EP2 Receptor Agonist		China DE-085 Tafluprost	
		DE-090 Lomerizine HCl		EU DE-111 Tafluprost/Timolol	JP
				Asia DE-118 Tafluprost UD	JP
Corneal/ Conjunctival Disease				China DE-089 Diquafosol Sodium	Korea
		U.S. Cyclokat Ciclosporin		Cyclokat EU Ciclosporin	
Retina/ Uveitis	U.S. DE-120 VEGF/PDGF inhibitor		DE-109 Sirolimus		
Other Infection, Allergy, RA			Vekacia Ciclosporin		

Major Clinical Pipeline List (2) [by Region]

Global Product

Japan (Asia)Product

Region	Phase 1	Phase 2	Phase 3	NDA	Approved-Launch
Japan		DE-090 Lomerizine HCl	DE-109 Sirolimus		DE-111 Tafluprost/Timolol
					DE-118 Tafluprost UD
North America (Including Latin America)		DE-117 P2b EP2 Receptor Agonist	DE-109 Sirolimus		
	DE-120 VEGF/PDGF inhibitor				
		Cyclokot Ciclosporin			
Asia (including Oceania)				DE-085 China Tafluprost	
				DE-089 China Diquafosol Sodium Korea	
				DE-118 Tafluprost UD	
EU			DE-109 Sirolimus	DE-111 Tafluprost/Timolol	
			Vekacia Ciclosporin	Cyclokot Ciclosporin	

Major Clinical Projects Update -Glaucoma / Ocular hypertension-

■ DE-085 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
China	NDA Filed	NDA Filed	Generic name: Tafluprost

■ DE-090 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

■ DE-111 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
Japan	Approved	Approved	Generic name: Tafluprost/ Timolol maleate (Combination drug)
Europe	NDA Filed	NDA Filed	

Major Clinical Projects Update

-Glaucoma /
Ocular hypertension-
-Corneal disease-

■ DE-117 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
U.S.	P2b	P2b	EP2 receptor agonist

■ DE-089 (Dry eye)

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
Asia	China: NDA filed Korea: Launched	China: NDA filed Korea: Launched	Generic name: Diquafosol Sodium

Major Clinical Projects Update

-Retinal Disease-
-Uveitis-

■ **DE-120** (Wet Age-related Macular Degeneration (w-AMD))

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
U.S.	P1/2a	P1/2a	VEGF/PDGF dual inhibitor

■ **DE-109** (Uveitis)

Region	Development Stage		Remarks
	As of November 5, 2014	As of August 5, 2014 (Previous announcement)	
U.S.	P3	P3	Generic name: Sirolimus
Japan	P3	P3	
EU	P3	P3	

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■ **Cyclokot** (Severe Dry Eye)

Region	Development Stage		Remarks
	As of November 5, 2014	August 5, 2014 (Previous)	
EU	NDA filed	NDA filed	Generic Name: Ciclosporin
U.S.	P2 Completed	P2 Completed	

■ **Vekacia** (Vernal Keratoconjunctivitis)

Region	Development Stage		Remarks
	As of November 5, 2014	August 5, 2014 (Previous)	
EU	P3	P3	Generic Name: Ciclosporin

***Project evaluations are ongoing for the products below.**

Development Name	Indication	Region	Stage	Remarks
Catioprost	Glaucoma/ Ocular hypertension	EU	P2	Generic Name: Latanoprost
Cortiject	Diabetic macular edema	U.S.	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.

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