

Santen Investor Meeting

FY2015 First Half Results

A Clear Vision For Life™ 

Akira Kurokawa

President & CEO

November 5, 2015

Santen's Corporate Values

天機に参与する

Tenki ni sanyo suru

By focusing our efforts on ophthalmology and related areas, Santen develops scientific knowledge and organizational capabilities which are unique and original to Santen. We use our unique capabilities to contribute to patients and their loved ones, and consequently to society.

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

2013

- Strengthen the Japan business
- Prepare for business expansion in Asia/Europe

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

2017

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

2020
Santen

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
Active investment in sustainable growth

Business expansion

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

Organization and talent

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

FY2015 First Half Results

Period ended September 30, 2015

Financial Highlights for 1H FY2015

(JPY billions) <i>IFRS basis</i>	1H FY2014 Actual	1H FY2015	
		Actual	Var. (YoY)
Revenue	71.9	97.9	+36.1%
Operating profit	14.2	65.4	+359.3%
Profit before tax	14.5	65.3	+349.4%
Net profit for the period	9.8	43.7	+347.3%

Core basis

Revenue	71.9	97.9	+36.1%
Core operating profit*	15.3	24.5	+60.4%
Core net profit for the period	10.1	16.4	+61.7%

* Core operating profit = operating profit + amortization associated with products – other revenue + other expenses

Reconciliation of IFRS to Core OP

(JPY billions)	1H FY2014 (actual)	1H FY2015 (actual)	FY2015 (forecast)
IFRS operating profit	14.2	65.4	78.0
Non-core deduction items	+1.1	-40.8	-37.7
Amortization associated with products	+1.3	+3.0	+6.1
Other income	-0.3	-44.7	-45.0
Other expenses	+0.1	+0.9	+1.2
Core operating profit	15.3	24.5	40.3

Financial Highlights for 1H FY2015

- **Japan business maintains positive momentum**
 - Increased revenue contributions from new products such as *EYLEA*, *Diquas* and *Alesion*
 - Domestic share in prescription ophthalmic pharmaceuticals grew to 43.4% (1H FY15)
- **Overseas business continues strong growth**
 - Asia: Continued growth of product revenue in key countries, particularly China
 - Europe: Revenue growth resulting from the acquisition of products from Merck
- **Transfer of anti-rheumatic pharmaceutical business completed**
 - Resulted in 45 billion yen recorded as other income

Changes in Income Statement

(JPY billions)	1H FY14 Actual	1H FY15		Major Changes
		Actual	Var.	
Revenue	71.9	97.9	+36.1%	
Cost of sales (% of revenue)	-26.6 37.0%	-36.5 37.3%	+37.3% +0.3pt	• Product mix change +1.8pt • NPM* -1.1pt • Other -0.4pt
SGA excluding R&D (% of revenue)	-21.9 30.4%	-27.6 28.2%	+26.2% -2.2pt	• Japan -0.4 • Asia -1.8 (FX-0.5) • US/EU -3.4 (FX-0.0)
R&D expenses (% of revenue)	-8.2 11.4%	-9.2 9.4%	+13.1% -1.9pt	• Japan -0.3 • Overseas -1.0 (FX-0.3)
Amortization associated with products (% of revenue)	-1.3 1.8%	-3.0 3.1%	+131.2% +1.3pt	• Amortization of Merck asset -1.4
Other income	0.3	44.7	-	• Transfer of anti-rheumatic business +43.9
Other expenses	-0.1	-0.9	-	
Operating profit (% of revenue)	14.2 19.8%	65.4 66.8%	+359.3% +47.0pt	
Finance income	0.5	0.4	-2.0%	Currency rates
Finance expenses	-0.2	-0.5	+224.8%	1H FY2014 <u>Actual</u>
Profit before tax	14.5	65.3	+349.4%	1H FY2015 <u>Actual</u>
Income tax expenses	-4.8	-21.7	+353.5%	US \$ JPY 103.12 JPY 121.82
Net profit for the period	9.8	43.7	+347.3%	Euro JPY 138.98 JPY 134.95
				CYN JPY 16.71 JPY 19.67
Core operating profit	15.3	24.5	+60.4%	
Core net profit for the period	10.1	16.4	+61.7%	

* Net Profit Margin(NPM): Profit generated from US Merck ophthalmic products which Santen has acquired and has consigned them to Merck until the completion of transfer of the underlying marketing rights.

Revenue by Business Segment

(JPY billions)	1H FY15 Actual					
	Japan		Overseas		Total	
	Sales	Var. %	Sales	Var. %	Sales	Var. %
Pharmaceuticals	69.1	+23.3%	27.4	+87.9%	96.5	+36.6%
Prescription Pharmaceuticals	64.2	+21.6%	27.4	+88.1%	91.6	+35.9%
Ophthalmic	60.4	+26.5%	24.1	+72.2%	84.5	+36.9%
Anti-RA	3.5	-26.9%	-	-100.0%	3.5	-27.3%
Others	0.3	+7.6%	3.2	+535.3%	3.6	+330.2%
OTC Pharmaceuticals	4.9	+51.5%	0.0	+13.7%	4.9	+51.0%
Others	1.3	+3.4%	0.0	+196.8%	1.3	+5.1%
Medical Devices	1.1	+0.3%	0.0	+196.8%	1.2	+2.2%
Others	0.2	+34.9%	-	-	0.2	+34.9%
Total	70.4	+22.8%	27.5	+88.0%	97.9	+36.1%

Overseas Revenue and Core Operating Profit

(JPY billions)	1H FY2014	1H FY2015		
	Actual	Actual		Operating profit**
	Revenue	Revenue	Var. %	
U.S.	0.5	3.3*	+529.4%	-1.1
Europe	6.2	11.6	+86.5%	2.3
Asia	7.9	12.6	+59.7%	4.3
China	5.5	7.8	+40.3%	
Total	14.6	27.5	+88.0%	5.6

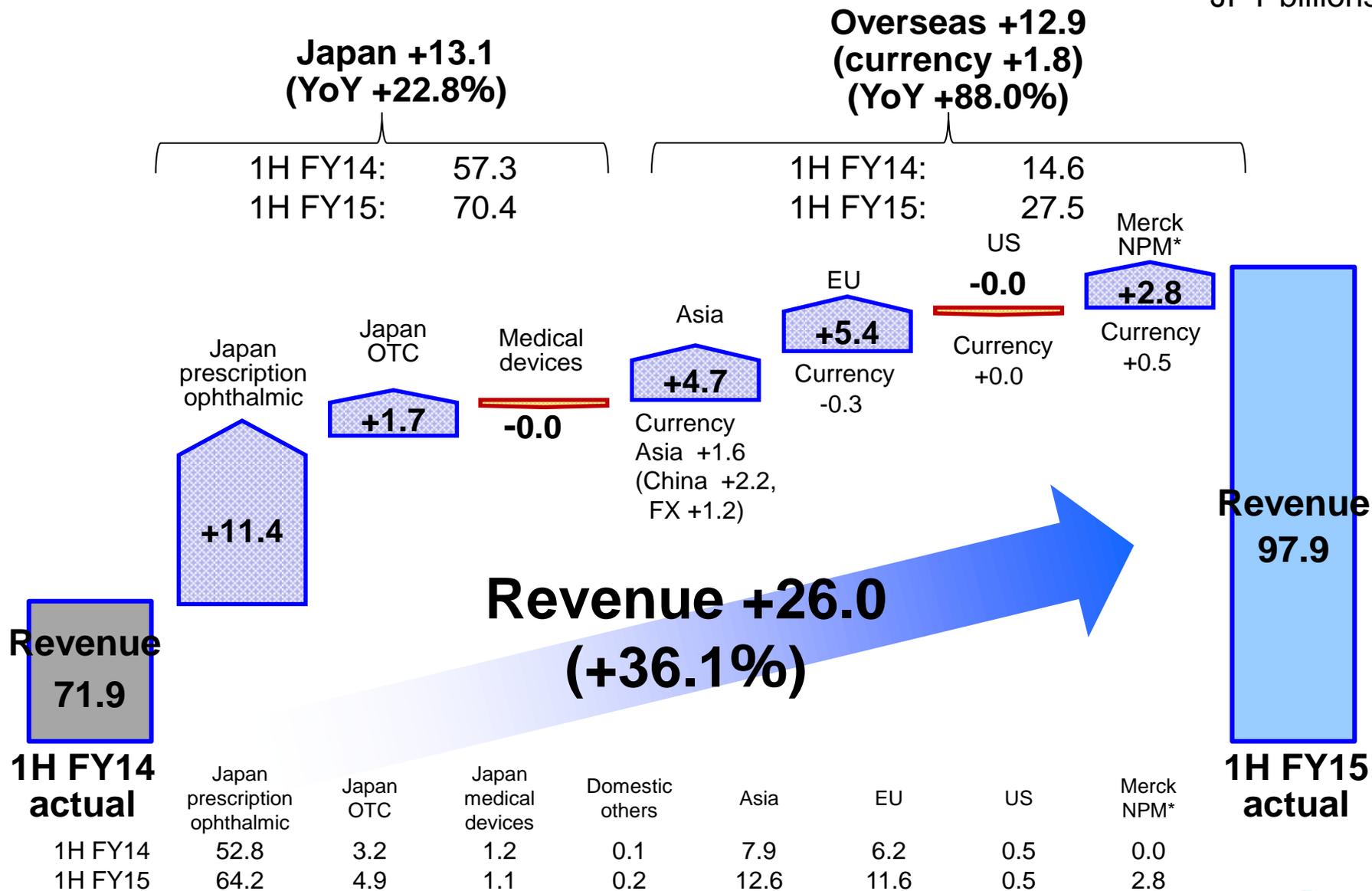
Overseas sales / sales	20.3%	28.1%	+7.8pt	-
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* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

** Company policy on accounting for profit excludes certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from Merck to Santen.

1H FY15 Revenue Change

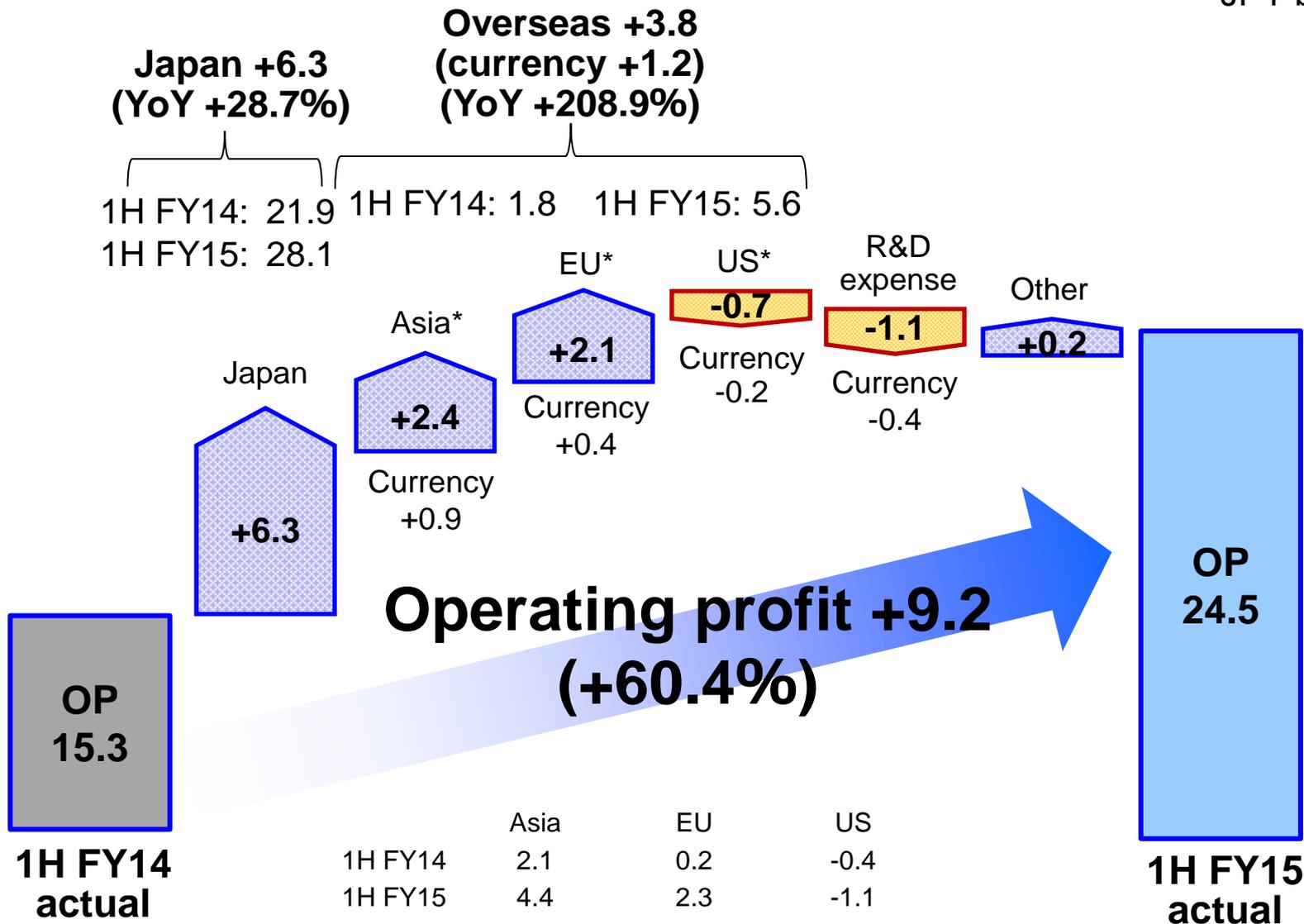
JPY billions



* Net Profit Margin(NPM): Profit generated from US Merck ophthalmic products which Santen has acquired and has consigned them to Merck until the completion of transfer of the underlying marketing rights.

1H FY15 Core Operating Profit Change

JPY billions



* Company policy on accounting for profit excludes certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from Merck to Santen.

Merck Project Results

(JPY billions)	1H FY15 Actual		FY2015 Forecast	
	Merck	Total	Merck	Total
Revenue	10.8	97.9	21.5	186.5
NPM*	2.8	2.8	4.1	4.1
Santen sales (marketing rights transferred)	8.0	95.1	17.4	182.4

By March 2015

- Marketing authorization transferred from Merck to Santen in 11 regions (Finland, Germany, Sweden, etc.)

April to September 2015

- Santen sales begun in 12 additional regions, most recently, Ireland, U.K., Portugal, etc.

* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

Completion of the Transfer of Anti-Rheumatic Pharmaceutical Business

Completion of the Transfer of Anti-Rheumatic Pharmaceutical Business

- On August 3, 2015, Santen completed the simplified company split relating to the transfer of its anti-rheumatic pharmaceutical business to AYUMI Pharmaceutical Corporation* originally announced on May 12, 2015
- Upon the official completion of the company split, Santen received 45 billion yen on August 3, 2015 in consideration for the transfer of all rights and obligations of the business

* AYUMI Pharmaceutical Corporation changed its name from Hyperion Pharma Co., Ltd. on June 2, 2015.

FY2015 Consolidated Forecasts

Year ending March 31, 2016

FY2015 Consolidated Forecasts

(JPY billions)	FY2014 Actual		FY2015 Forecast	
	Full year	Var.%	Full year	Var.%
Revenue	161.8	+10.6%	186.5	+15.2%
Cost of sales (% of revenue)	-56.4 34.8%	-1.7% -4.4pt	-66.4 35.6%	+17.8% +0.8pt
SGA excluding R&D (% of revenue)	-48.9 30.2%	+17.4% +1.7pt	-56.9 30.5%	+16.4% +0.3pt
R&D expenses (% of revenue)	-17.5 10.8%	+3.7% -0.7pt	-22.9 12.3%	+31.0% +1.5pt
Amortization associated with products (% of revenue)	-4.0 2.5%	- +2.3pt	-6.1 3.3%	+53.3% +0.8pt
Other income	0.7	+6.3%	45.0	-
Other expenses	-0.5	-54.9%	-1.2	+162.0%
Operating profit (% of revenue)	35.4 21.9%	+18.4% +1.4pt	78.0 41.8%	+120.5% +20.0pt
Core operating profit (% of revenue)	39.1 24.2%	+28.6%	40.3 21.6%	+3.1%

Foreign exchange	FY14 actual	FY15 forecast
US \$	JPY 110.14	JPY 125.00
Euro	JPY 139.01	JPY 135.00
CNY	JPY 17.84	JPY 20.00

FY2015 Dividend Forecast

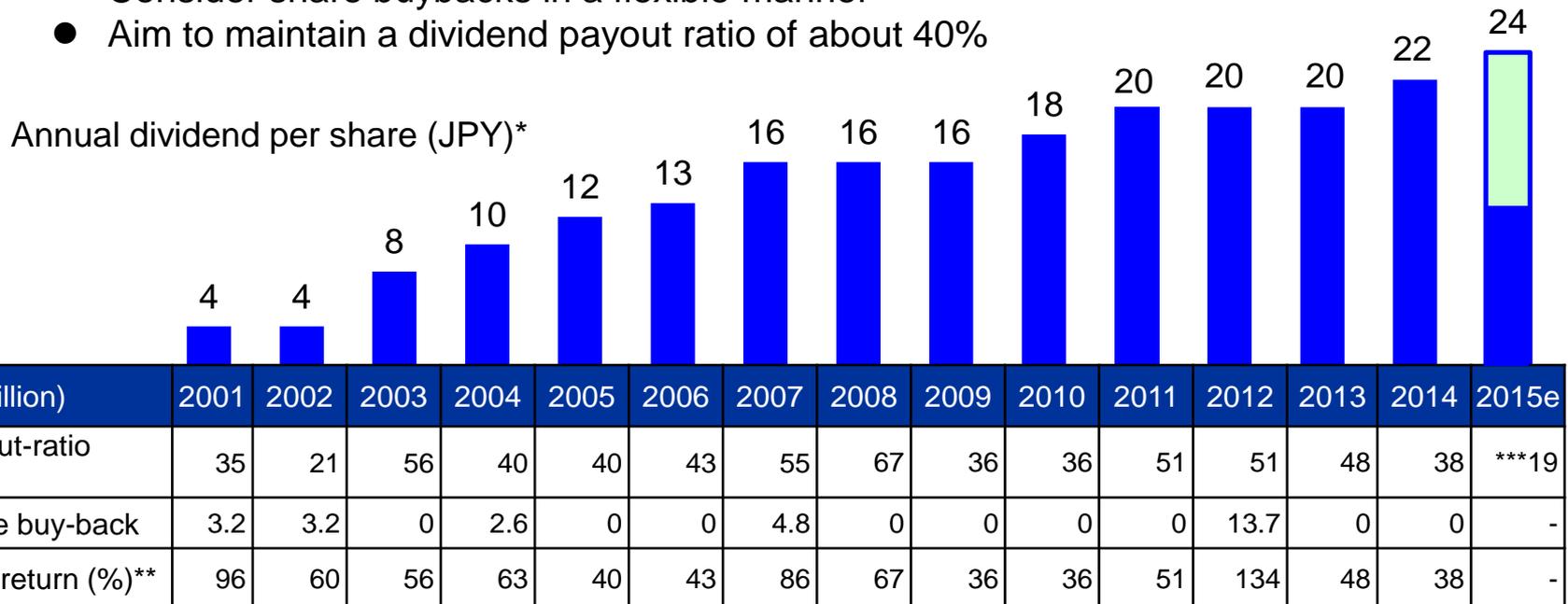
Dividends for FY2014 Actual and FY2015 Forecast

■ FY2015

- 1H Dividend: JPY 12 per share
- Annual dividend (forecast): JPY 24 per share

■ FY2014-FY2017 Shareholder return policy

- Stable and sustained return to shareholders
- Maintain a sound and flexible financial position to enable product acquisitions and M&A for future growth
- Consider share buybacks in a flexible manner
- Aim to maintain a dividend payout ratio of about 40%



* The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of annual dividends per share have been adjusted in all periods for comparison purposes.

** J-GAAP standards used until 2013, IFRS applied from 2014.

***Removing the impact of a gain related to the succession of the company's anti-rheumatic pharmaceutical business in FY15, payout ratio is forecast to be 39%.

Reference: 1H FY2015 Consolidated Results

Summary of Financial Position

(JPY billions)	As of March 31, 2015		As of September 30, 2015		
	Actual	% of Total	Actual	% of Total	Var.
Non-current assets	153.5	50.5%	152.9	43.4%	-0.6
Current assets	150.7	49.5%	199.2	56.6%	+48.5
Total assets	304.2	100.0%	352.1	100.0%	+47.9
Total equity	211.8	69.6%	250.9	71.3%	+39.1
Non-current liabilities	36.1	11.9%	30.4	8.6%	-5.6
Current liabilities	56.3	18.5%	70.7	20.1%	+14.4
Total liabilities	92.4	30.4%	101.2	28.7%	+8.8
Total equity and liabilities	304.2	100.0%	352.1	100.0%	+47.9

Shares issued*: End of March 2015: 413,266 thousand → End of September 2015: 413,836 thousand

Major Changes

- Non-current assets: Right of approval for manufacture and sales +¥8.0bil, In-process R&D -¥7.6bil
- Current assets: Cash and deposits +¥42.1bil
- Equity: Retained earnings +¥39.1bil
- Non-current liabilities: Long term borrowing -¥5.9bil
- Current liabilities: Income taxes payable +¥16.0bil

*The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of the number of shares issued have been adjusted in all periods for comparison purposes.

Summary of Cash Flows

(JPY billions)		1H FY14	1H FY15	Var.
	Cash flows from operating activities	3.5	12.4	+8.9
	Cash flows from investing activities	-56.0	40.5	+96.5
	Cash flows from financial activities	30.9	-10.5	-41.5
Net increase (decrease) in cash and cash equivalents		-21.5	42.4	+63.9
Cash and cash equivalents at the beginning of period		72.4	65.9	-6.5
Effect of exchange rate changes on cash and cash equivalents		0.6	-0.3	-0.9
Cash and cash equivalents at the end of period		51.5	108.0	+56.6

Capital Expenditures / Depreciation & Amortization

(JPY billions)	1H FY14 Actual	1H FY2015	
		Actual	Var.
Capital expenditures	1.4	1.8	+0.4
Depreciation and amortization	2.7	4.5*	+1.8

*Includes JPY2.6 billion amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products

Reference: FY2015 Consolidated Forecast

Revenue Forecast by Business Segment / Overseas Revenue

(JPY billions)	FY2015 Forecast					
	Japan		Overseas		Total	
	Sales	Var.	Sales	Var. %	Sales	Var. %
Pharmaceuticals	129.4	5.8%	53.9	+45.8%	183.3	+13.3%
Prescription Pharmaceuticals	123.0	6.3%	53.8	+45.9%	176.8	+11.0%
Ophthalmic	118.5	+12.5%	49.1	+59.9%	167.6	+23.2%
Anti-RA	3.6	-62.2%	0	-	3.6	-62.4%
Others	0.9	+14.4%	4.7	-23.0%	5.6	-18.9%
OTC Pharmaceuticals	6.4	-3.2%	0.1	-0.6%	6.5	-3.2%
Others	2.8	+11.3%	0.4	+831.0%	3.2	+25.2%
Medical devices	2.5	+9.5%	0.1	+19.1%	2.6	+9.7%
Others	0.3	+28.5%	0.4	-	0.7	+174.3%
Total	132.2	+5.9%	54.3	+46.8%	186.5	+15.2%

Overseas Revenue and Core Operating Profit Forecast

(JPY billions)	FY2014 Actual	FY2015 Forecast		
	Revenue	Revenue	Var. %	Operating profit**
U.S.	6.2	4.9*	-20.0%	-2.5
Europe	14.2	25.4	+79.5%	3.8
Asia	16.7	23.9	+43.4%	5.8
China	10.7	13.5	+26.5%	-
Total	37.0	54.3	+46.8%	7.1

Overseas sales / sales	22.9%	29.1%	+6.3pt	-
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* Net profit margin (NPM) relating to the Merck product acquisition is treated as revenue in the U.S.

** Company policy on accounting for profit excludes certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from Merck to Santen.

Forecast of Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY14 Actual	FY2015	
		Forecast	Var.
Capital expenditures	5.4	7.7	+2.3
Depreciation and amortization*	7.0	9.3	+2.4

*Amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products was recorded of 3.7 billion yen in FY14 and forecast to be 5.1 billion yen in FY15.

IFRS and Core Comparisons

IFRS	Core
Revenue	Revenue
Cost of sales	Cost of sales
Gross profit	Gross profit
SG&A	SG&A
R&D	R&D
Amortization associated with products	Excluded from core
Other income	Excluded from core
Other expenses	Excluded from core
Operating profit	Core operating profit
Finance income (interest, dividends, forex gains)	Excluded from core
Finance expenses (interest, forex losses)	Excluded from core
Profit before tax	Core profit before tax
Income tax expense	Income tax expense
Net profit	Core net profit

Use of Core Basis Indicators

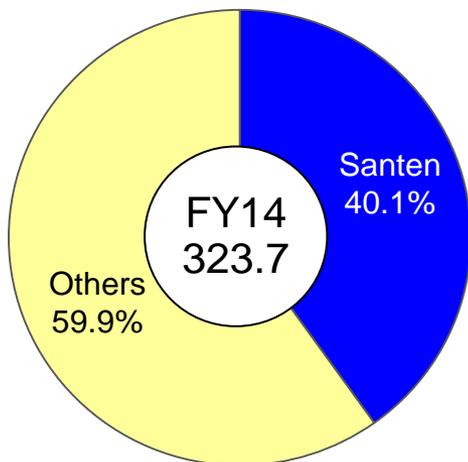
- Core results are now used as financial indicators to better express underlying business performance by removing certain gains and expenses from IFRS results
- Items excluded from IFRS to calculate core results: Amortization associated with products, other income and expenses, and finance income and expenses

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

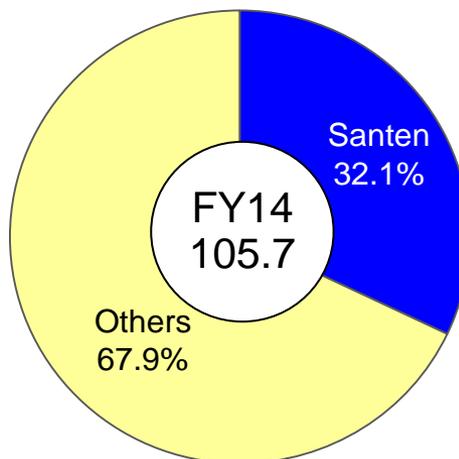
Japan: Trend & Competition in Ophthalmics (1)

Market Size:
billions of yen
%: Value Share

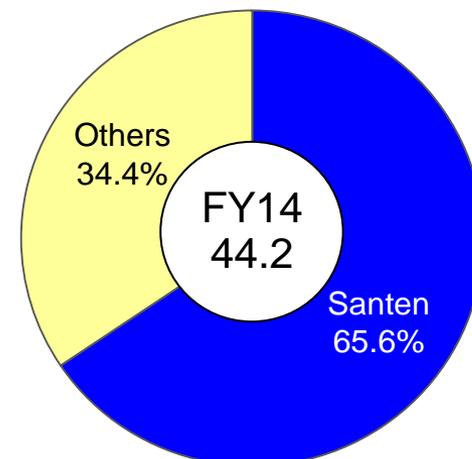
Ophthalmology Total



Glaucoma



Cornea / Dry Eye



		FY14	1H FY15
YoY change	Market	+7.4%	+10.2%
	Santen	+9.3%	+21.5%
Santen's Share		40.1%	43.4%

		FY14	1H FY15
YoY change		+0.9%	+9.0%
Santen		+6.1%	+15.5%
Santen's Share		32.1%	32.8%

		FY14	1H FY15
YoY change		-0.0%	+6.3%
Santen		-7.0%	+2.1%
Santen's Share		65.6%	63.9%

-Santen:

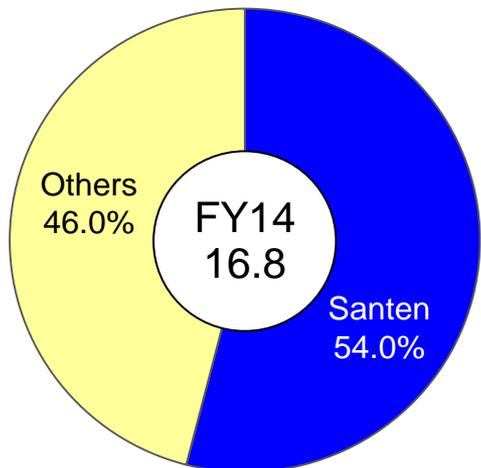
- Anti-Glaucoma : Tapros, Cosopt, Timoptol/XE, Trusopt, Rescula, Detantol, Tapcom
- Cornea / Dry Eye : Hyalein, Diquas

Source: ©2015 IMS Health
IMS-JPM 2013-15
Santen analysis based on IMS data
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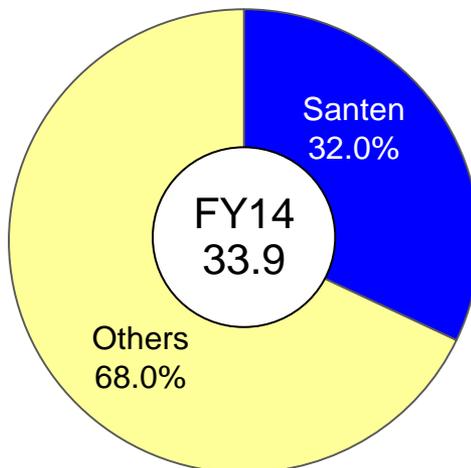
Japan: Trend & Competition in Ophthalmics (2)

Market Size:
billions of yen
%: Value Share

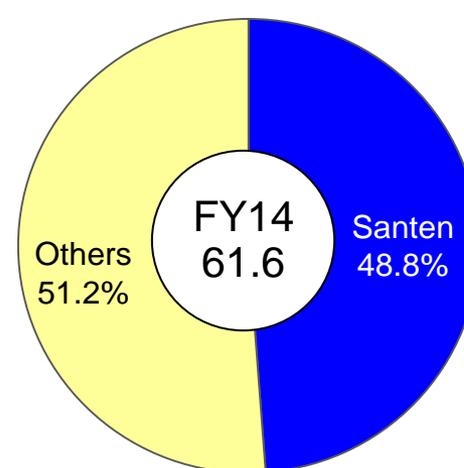
Anti-infection



Anti-allergy



Anti-VEGF



		FY14	1H FY15
YoY change	Market	-8.2%	-2.0%
	Santen	-15.3%	-10.0%
Santen's Share		54.0%	50.7%

		FY14	1H FY15
		+21.4%	+8.6%
		+83.3%	+29.4%
Santen's Share		32.0%	36.2%

		FY14	1H FY15
		+42.6%	+30.0%
		+43.0%	+75.4%
Santen's Share		48.8%	61.7%

-Santen:

- Anti-infection: Cravit, Tarivid
- Anti-allergy: Alesion, Livostin, Alegysal
- Anti-VEGF: Eylea

Source: ©2015 IMS Health
IMS-JPM 2013-15
Santen analysis based on IMS data
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Status of Clinical Development 1H FY2015

A Clear Vision For Life™ 

Naveed Shams, M.D., Ph.D.

Senior Corporate Officer

Chief Scientific Officer (CSO)

Head of Global Research & Development

Status of main projects in clinical development (1)

Global

JP (Asia)

Disease Area	PJ	Compound/ MOA	Region	Development Stage					Changes from 1QFY15
				P1	P2	P3	Reg.	APV/ Launch	
Glaucoma/ ocular hypertension	DE-111	Tafluprost/ Timolol (FDC*)	JP						
			EU						
			KR						
			Asia						
	DE-118	Tafluprost UD	JP						
			Asia						
	DE-085	Tafluprost	CN					★	Approved
	DE-117	EP2 agonist	US						
DE-090	Lomerizine	JP							
Kerato- conjunctival disease	Cyclokat/ Ikervis	Ciclosporin	EU						
			US						
	DE-089	Diquafosol	CN						
			Asia						

*Fixed dose combination

Status of main projects in clinical development (2)

Global

JP (Asia)

Disease Area	PJ	Compound/ MOA	Region	Development Stage					Changes from 1QFY15
				P1	P2	P3	Reg.	APV/ Launch	
Retinal/ Uveal disease	DE-109	Sirolimus	EU						
			JP						
			US						
			Asia						
	DE-120	VEGF/PDGF inhibitor	US						
DE-122	Anti-endoglin antibody	US	★					Started Phase1/2	
Allergy	Vekacia	Ciclosporin	EU						

Major Clinical Projects Update

-Glaucoma /
Ocular hypertension-

■ DE-085 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
China	Approved	NDA Filed	Generic name: Tafluprost

■ DE-090 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

■ DE-111 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
Japan	Launched	Launched	Generic name: Tafluprost/ Timolol maleate (FDC)
Europe	Launched	Launched	
Korea	Approved	Approved	
Asia	NDA Filed	NDA Filed	

Major Clinical Projects Update -Glaucoma / Ocular hypertension-

■ DE-117 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
U.S.	P2b completed	P2b completed	EP2 receptor agonist

■ DE-118 (Glaucoma / Ocular hypertension)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
Asia	Approved	Approved (Hong Kong)	Generic name: Tafluprost

Major Clinical Projects Update -Corneal disease-

■ DE-089 (Dry eye)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
Asia	Approved	Approved (Thai)	Generic name: Diquafosol Sodium

■ Cyclokot / Ikervis (Severe keratitis in adult patients with dry eye)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
EU	Launched	Launched (Germany)	Generic Name: Ciclosporin
U.S.	P2 completed	P2 completed	

■ Vekacia (Vernal Keratoconjunctivitis)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
EU	P3	P3	Generic Name: Ciclosporin

Major Clinical Projects Update -Retinal Disease- -Uveitis-

■ DE-109 (Uveitis)

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
U.S.	P3	P3	Generic name: Sirolimus
Japan	P3	P3	
EU	NDA filed	NDA filed	
Asia	NDA filed	NDA filed	

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

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
U.S.	P2a	P2a	VEGF/PDGF dual inhib.

■ DE-122 (Wet Age-related Macular Degeneration (w-AMD))

Region	Development Stage		Remarks
	As of November 4, 2015	As of August 4, 2015 (Previous announcement)	
U.S.	P1/2	IND filed	Anti-endoglin 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.

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