Investor Meeting on FY2015 Results and FY2016 Forecast



Akira Kurokawa

President & CEO

May 12, 2016

SANTEN PHARMACEUTICAL CO., LTD.

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Santen's Corporate Values

天機に参与する Tenki ni sanyo suru

By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, 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.





Overseas sales: 16%

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 Financial Results ended March 31, 2016



FY2015 Consolidated Highlights

- Revenue and operating profit reached record highs
- Japan business maintained positive momentum
 - Increased revenue from new products such as EYLEA and Alesion
 - Domestic share in prescription ophthalmic pharmaceuticals grew to 44.0% (FY2015)
 - OTC revenue rose sharply due to increase of purchases from overseas visitors to Japan and regular domestic demand

Overseas business continues strong growth

- Asia: Continued strength, particularly in China
- Europe: Successful integration of products acquired from US-based Merck, *Ikervis* rolled out in more countries
- Entered agreement to in-license DE-126 glaucoma treatment in March 2016
- Transfer of anti-rheumatic pharmaceutical business completed in August 2015



FY2015 Financial Highlights

IFRS basis			
(JPY billions)	FY14 Actual	FY15	
		Actual	Var. (YoY)
Revenue	161.8	195.3	+20.7%
Operating profit	35.4	80.2	+126.7%
Profit before tax	35.9	79.5	+121.6%
Net profit for the year	24.0	53.4	+122.1%
ROE	12.0%	22.6%	+10.6pt

Core basis

Revenue	161.8	195.3	+20.7%
Core operating profit*	39.1	43.1	+10.2%
Core net profit for the year	25.9	29.2	+12.4%
Core ROE	13.0%	12.4%	-0.6pt

* Core operating profit = operating profit + amortization associated with products – other revenue + other expenses (see page 32)

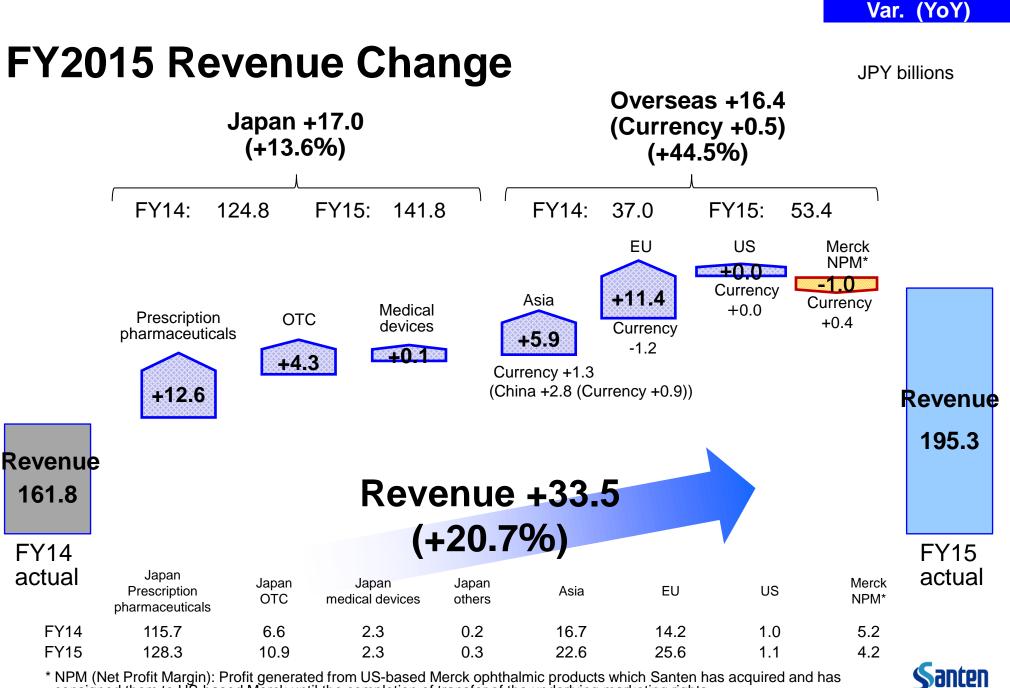


Changes in P&L Statement

			FY	15			
(JPY billions)		FY14 Actual	Actual	Var. (YoY)	Ν	lajor Changes	
Revenue		161.8	195.3	+20.7%			
Cost of sales		-56.4	-72.8	+29.2%	Product mix chang	e	
	(% of revenue)	34.8%	37.3%	+2.5pt	 Japan +1.9pt Overseas +0.3pt 		
SG&A excluding R&D		-48.9	-59.4	+21.5%	·Japan -1.4		
	(% of revenue)	30.2%	30.4%	+0.2pt	 Asia -3.2 (FX-0.4 US/EU -4.5 (FX+ 		
R&D expenses		-17.5	-20.0	+14.4%	•Japan -0.5		
	(% of revenue)	10.8%	10.2%	-0.6pt	•Overseas -1.9 ((FX-0.3)	
Amortization on intangible	assets	-4.0	-6.2	+56.0%	Amortization of US-based Merck asset -1.4		sset -1.4
associated with products	(% of revenue)	2.5%	3.2%	+0.7pt	Amortization of Ikervis -0.6		
Other revenue		0.7	45.0	-	 Transfer of anti-rh 	neumatic busines	s +44.3
Other expenses		-0.5	-1.7	+267.0%			
Operating profit		35.4	80.2	+126.7%			
	(% of revenue)	21.9%	41.1%	+19.2pt			
Financial revenue		0.8	0.8	+1.8%			
Financial expenses		-0.3	-1.5	+434.1%	Currency rates	FY14 Actual	FY15 Actual
Profit before tax		35.9	79.5	+121.6%	US \$	JPY 110.14	JPY 120.45
Income tax expenses		-11.8	-26.1	+120.6%	Euro	JPY 139.01	JPY 132.46
Net profit for the year		24.0	53.4	+122.1%	CNY	JPY 17.84	JPY 19.05
ROE		12.0%	22.6%	+10.6pt	L		

Core operating profit	39.1	43.1	+10.2%
Core net profit for the year	25.9	29.2	+12.4%
Core ROE	13.0%	12.4%	-0.6pt





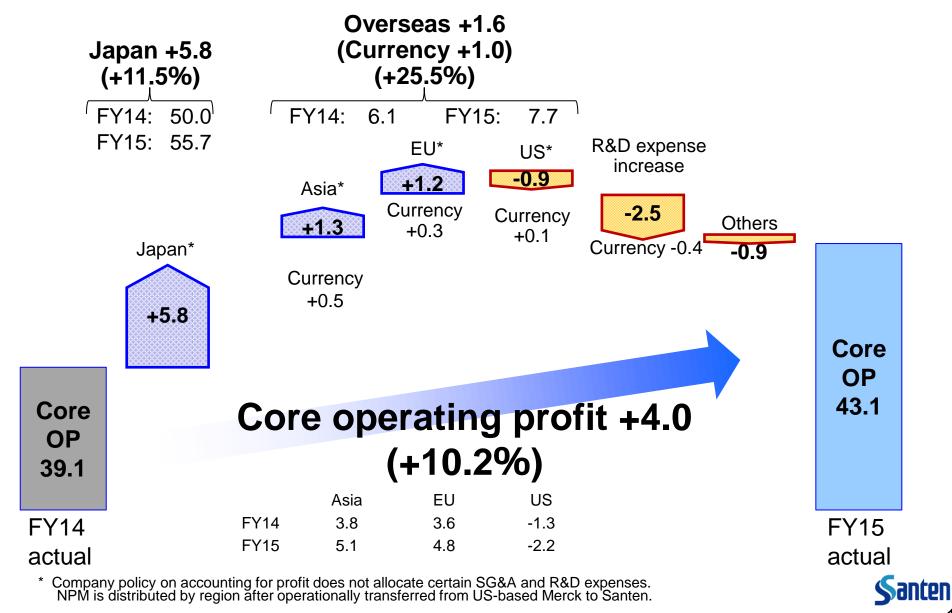
* NPM (Net Profit Margin): Profit generated from US-based Merck ophthalmic products which Santen has acquired and has consigned them to US-based Merck until the completion of transfer of the underlying marketing rights.

10

FY2015 Core Operating Profit Change

JPY billions

Var. (YoY)



Revenue by Business Segment

		FY15 Actual					
(JP	Y billions)	Jap	ban	Over	seas	То	tal
		Sales	Var. (YoY)	Sales	Var. (YoY)	Sales	Var. (YoY)
Pha	armaceuticals	139.2	+13.8%	53.4	+44.4%	192.6	+20.9%
	Prescription Pharmaceuticals	128.3	+10.9%	53.3	+44.4%	181.6	+19.0%
	Ophthalmic	124.2	+17.9%	48.4	+57.5%	172.5	+26.8%
	Anti-RA	3.5	-63.5%	-	-100.0%	3.5	-63.7%
	Others	0.6	-18.7%	4.9	-19.9%	5.5	-19.8%
	OTC Pharmaceuticals	10.9	+64.5%	0.1	+28.8%	11.0	+64.1%
Oth	ners	2.7	+5.1%	0.1	+92.4%	2.7	+6.5%
	Medical devices	2.3	+2.4%	0.1	+62.7%	2.4	+3.5%
	Others	0.3	+28.8%	0.0	-	0.3	+33.8%
Tot	al	141.8	+13.6%	53.4	+44.5%	195.3	+20.7%



Overseas Revenue and Operating Profit

(JPY billions)		FY14 Actual		FY15 Actual	
		Revenue	Revenue	Var. (YoY)	Operating profit**
U.S.		6.2	5.3*	-14.7%	-2.2
Europe		14.2	25.6	+80.6%	4.8
Asia		16.7	22.6	+35.6%	5.1
	China	10.7	13.5	+26.5%	
Total	•	37.0	53.4	+44.5%	7.7

Overseas sales / sales	22.9%	27.4%	+4.5pt	
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* Net profit margin (NPM) relating to the US-based 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 US-based Merck to Santen.

Merck Project Results

	(JPY billions)		FY16 Forecast		
		Merck	Total	Merck	Total
R	evenue	21.6	195.3	19.3	204.0
	NPM*	4.2	4.2	0.8	0.8
	Santen sales (marketing rights transferred)	17.4	191.1	18.5	203.2

As of March 31, 2016

- MA** transfers completed: 28 countries
- Further MA transfer plans: 15 countries
 - Includes all countries in which pre-marketing activities have begun
 - Includes 3 countries in which MSD label distribution has begun

** Marketing authorization



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

FY2016 Consolidated Forecast ending March 31, 2017



FY2016 Consolidated Forecast

Revenue and core operating profit expected to increase by 4.5% and 6.8%, respectively

• Operating profit (IFRS base) expected to be lower by 51.7% due to the 45 billion yen gain from the transfer of the anti-rheumatic business in August 2015

In Japan, steady performance expected

- Increased market penetration of new products and OTC revenue growth
- Some offset from impact of generics on long-listed products

■ In overseas markets, business growth to continue

- Asia: Continued expansion in growing markets
- Europe: Business growth supported by expanded sales platform

■ SG&A to increase just 0.2% year-over-year

 After key growth related investments (including new country launches) and efficient cost management

12.0% Core ROE targeted



FY2016 Consolidated Forecast

IFRS basis

(JPY billions)	FY15	FY16		
	Actual	Forecast	Var. (YoY)	
Revenue	195.3	204.0	+4.5%	
Operating profit	80.2	38.7	-51.7%	
Profit before tax	79.5	39.0	-50.9%	
Net profit for the year	53.4	26.9	-49.6%	
ROE	22.6%	10.0%	-12.6pt	

Core basis

Revenue	195.3	204.0	+4.5%
Core operating profit*	43.1	46.0	+6.8%
Core net profit for the year	29.2	31.8	+9.0%
Core ROE	12.4%	12.0%	-0.3pt

* Core operating profit = operating profit + amortization associated with products – other revenue + other expenses (see page 32)



FY2016 P&L Statement Forecast

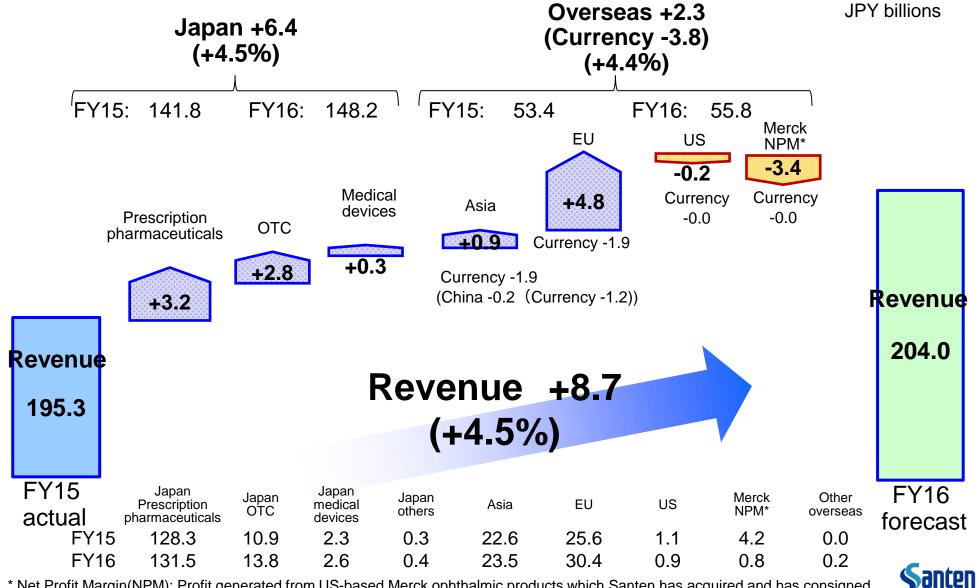
		FY	16
(JPY billions)	FY15 Actual	Forecast	Var. (YoY)
Revenue	195.3	204.0	+4.5%
Cost of sales	-72.8	-78.0	+7.1%
(% of revenue)	37.3%	38.2%	+0.9pt
SG&A excluding R&D	-59.4	-59.5	+0.2%
(% of revenue)	30.4%	29.2%	-1.3pt
R&D expenses	-20.0	-20.5	+2.6%
(% of revenue)	10.2%	10.0%	-0.2pt
Amortization on intangible assets associated with	-6.2	-7.1	+14.4%
products (% of revenue)	3.2%	3.5%	+0.3pt
Other revenue	45.0	-	-
Other expenses	-1.7	-0.2	-88.1%
Operating profit*	80.2	38.7	-51.7%
(% of revenue)	41.1%	19.0%	-22.1pt
Financial revenue	0.8	0.4	-48.8%
Financial expenses	-1.5	-0.1	-93.3%
Profit before tax	79.5	39.0	-50.9%
Income tax expenses	-26.1	-12.1	-53.6%
Net profit for the year	53.4	26.9	-49.6%
ROE	22.6%	10.0%	-12.6pt
Core operating profit	43.1	46.0	+6.8%
Core net profit for the year	29.2	31.8	+9.0%
Core ROE	12.4%	12.0%	-0.3pt

Currency rates	FY15 Actual	FY16 Forecast
US \$	JPY 120.45	JPY 115.00
Euro	JPY 132.46	JPY 125.00
CNY	JPY 19.05	JPY 17.50

*Calculation includes other revenue and other expenses

Santen

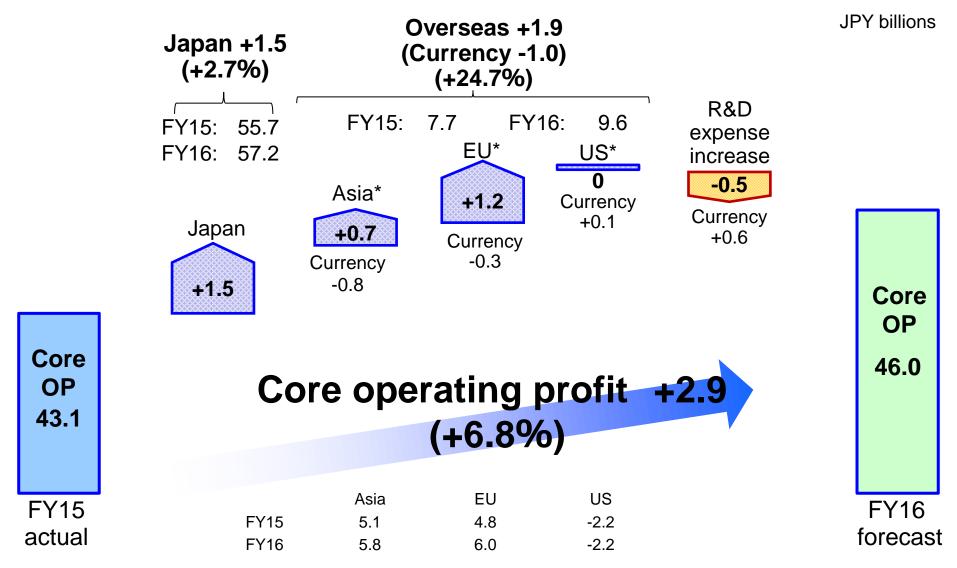
FY2016 Forecast: Revenue Change



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

Var. (YoY)

FY2016 Forecast: Core Operating Profit Change



* Certain SG&A and R&D expense allocations by region are adjusted based on company management accounting policies. NPM is distributed by region after operationally transferred from US-based Merck to Santen.

20

Santen

FY2016 Dividend Forecast



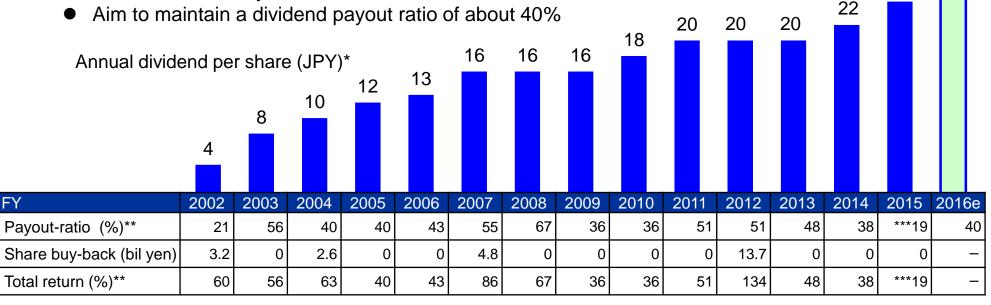
Dividend for FY2015 and FY2016 Forecast

Annual dividend

- FY2015: JPY 25 per share
- FY2016 (forecast): JPY 26 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 25
- Consider share buybacks in a flexible manner



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

** J-GAAP standards used until FY13, IFRS applied from FY14.

***Removing the related impact of the succession of the company's anti-rheumatic pharmaceutical business, the payout ratio is forecast will be 35% in FY15.

26

Reference: FY2015 Consolidated Results



Summary of Financial Position

(JPY billions)	As of Mar	As of March 31, 2015		As of March 31, 2016		
	Actual	% of Total	Actual	% of Total	Var. (YoY)	
Non-current assets	153.5	50.5%	160.7	45.2%	+7.1	
Current assets	150.7	49.5%	194.7	54.8%	+44.1	
Cash and cash equivalent	65.9	21.7%	99.8	28.1%	+33.9	
Total assets	304.2	100.0%	355.4	100.0%	+51.2	
Total equity	211.8	69.6%	260.0	73.2%	+48.2	
Non-current liabilities	36.1	11.9%	22.2	6.2%	-13.9	
Current liabilities	56.3	18.5%	73.2	20.6%	+16.9	
Total liabilities	92.4	30.4%	95.4	26.8%	+3.0	
Total equity and liabilities	304.2	100.0%	355.4	100.0%	+51.2	

Shares issued : End of March 2015: 413,266 thousand \rightarrow End of March 2016: 414,192 thousand

Major Changes

- Non-current assets: Investment securities +9.1billion yen
- Current assets: Cash and deposits +33.9 billion yen
- Equity: Retained earnings +43.1 billion yen, Valuation difference on available for sale securities +6.7 billion yen
- Non-current liabilities: Long term borrowing -12.4 billion yen
- Current liabilities: Income tax payable +13.7 billion yen



Summary of Cash Flows

	FY14	FY15	
(JPY billions)	Actual	Actual	Var. (YoY)
Cash flows from operating activities	25.4	22.5	-2.9
Cash flows from investing activities	-61.7	37.1	+98.8
Cash flows from financial activities	29.0	-24.1	-53.0
Net increase (decrease) in cash and cash equivalents	-7.4	+35.5	+42.9
Cash and cash equivalents at the beginning of year	72.4	65.9	-6.5
Effect of exchange rate changes on cash and cash equivalents	0.9	-1.6	-2.5
Cash and cash equivalents at the end of year	65.9	99.8	+33.9

25

Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY14	FY15		
	Actual	Actual	Var. (YoY)	
Capital expenditures	5.4	4.5	-0.9	
Depreciation and amortization*	3.0	3.1	+0.2	
Amortization on intangible assets associated with products**	4.0	6.2	+2.2	

- * Excludes amortization on intangible assets associated with products and long-term advance expense
- ** Includes amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products at 3.7 billion yen in FY14 and at 5.2 billion yen in FY15.

Reference: FY2016 Consolidated Forecast



FY2016 Forecast: Business Segment / Overseas Revenue

		FY16 Forecast					
(JP`	Y billions)	Jap	ban	Over	seas	То	tal
		Sales	Var. (YoY)	Sales	Var. (YoY)	Sales	Var. (YoY)
Pha	armaceuticals	145.2	+4.3%	55.5	+4.0%	200.8	+4.3%
	Prescription Pharmaceuticals	131.5	+2.5%	55.4	+4.0%	186.9	+2.9%
	Ophthalmic	130.8	+5.4%	54.0	+11.7%	184.9	+7.1%
	Others	0.6	+5.2%	1.4	-71.5%	2.0	-62.9%
	OTC Pharmaceuticals	13.8	+26.0%	0.1	+7.9%	13.8	+25.9%
Oth	ers	3.0	+12.1%	0.3	+223.6%	3.2	+18.6%
	Medical devices	2.6	+10.9%	0.1	+2.7%	2.6	+10.6%
	Others	0.4	+21.2%	0.2	-	0.6	+74.4%
Tota	al	148.2	+4.5%	55.8	4.4%	204.0	+4.5%



FY2016 Forecast: Overseas Revenue and Operating Profit

(JPY billions)		FY15 Actual	FY16 Forecast		
		Revenue	Revenue*	Var. (YoY)	Operating profit**
U.S.		5.3	1.7	-67.6%	-2.2
Europe		25.6	30.4	+18.9%	6.0
Asia		22.6	23.5	+4.2%	5.8
China		13.5	13.3	-1.5%	
Total		53.4	55.8	+4.4%	9.6
Overseas sales / sales		27.4%	27.3%	-0.0pt	

* Net profit margin (NPM) relating to the US-based Merck product acquisition is treated as revenue in the U.S.
 ** In line with company policy accounting for operating profit, NPM is distributed by region after operationally transferred from US-based Merck to Santen.

FY2016 Forecast: Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY15	FY16		
	Actual	Forecast	Var. (YoY)	
Capital expenditures	4.5	7.3	+2.9	
Depreciation and amortization*	3.1	3.6	+0.5	
Amortization on intangible assets associated with products**	6.2	7.1	+0.9	

- * Excludes amortization on intangible assets associated with products and long-term prepaid expenses
- ** Amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products was recorded as 5.2 billion yen in FY15 and forecast as 5.3 billion yen in FY16.

Reconciliation of IFRS to Core OP

(JPY billions)		FY15 Actual	FY16 Forecast
IFR	S operating profit	80.2	38.7
Non	-core deduction items	-37.1	+7.3
	Amortization on intangible assets associated with products	+6.2	+7.1
	Other revenue	-45.0	0.0
Other expenses		+1.7	+0.2
Cor	e operating profit	43.1	46.0



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 on intangible assets	> 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	> Excluded from core
Profit before tax	Core profit before tax
Income tax expenses	Income tax expenses
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

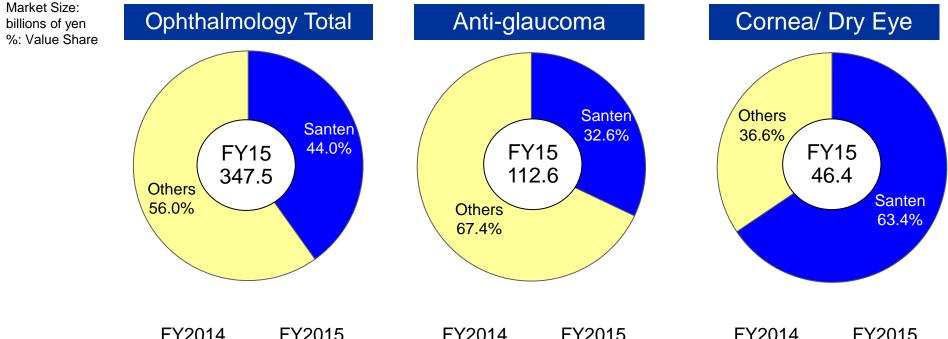
Items excluded from IFRS to calculate core results: Amortization associated with products, other income and expenses, and finance income and expenses



Reference: Market Overview of Prescription Ophthalmic in Japan



Japan: Trends & Competition in Ophthalmics (1)



		112014	112015
YoY	Market	+7.4%	+7.3%
	Santen	+9.3%	+17.6%
Sante	n's Share	40.1%	44.0%

FY2014	FY2015
+0.9%	+6.5%
+6.1%	+8.4%
32.1%	32.6%

FY2014	FY2015
-0.0%	+4.9%
-7.0%	+1.4%
65.6%	63.4%

-Santen:

- Anti-Glaucoma : Tapros, Cosopt, Timoptol/XE, Trusopt, Rescula, Detantol, Tapcom

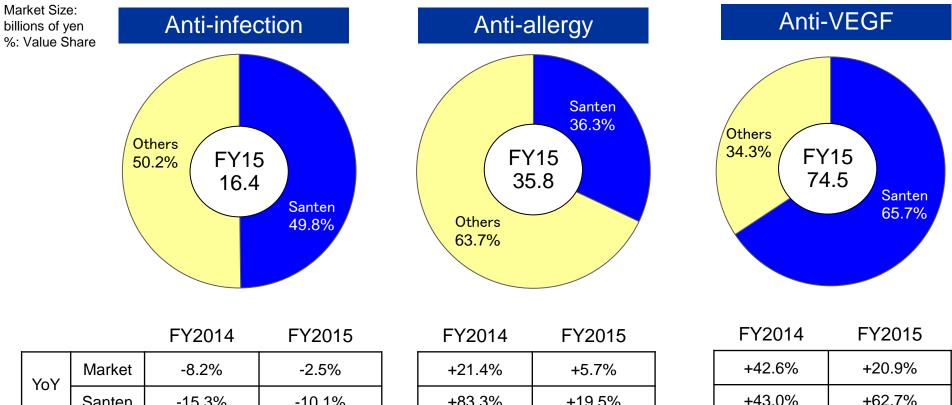
- Cornea / Dry Eye : Hyalein, Diquas

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34

Japan: Trends & Competition in Ophthalmics (2)



	Santen	-15.3%	-10.1%
Sante	n's Share	54.0%	49.8%

F12014	FIZUIS
+21.4%	+5.7%
+83.3%	+19.5%
32.0%	36.3%

FY2014	FY2015
+42.6%	+20.9%
+43.0%	+62.7%
48.8%	65.7%

-Santen:

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

- Anti-VEGF: Evlea

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Status of Clinical Development FY2015



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)
		Compound/			D	evel	opmer	nt Stage	;	Changes from
Disease Area	Project	MOA	Region	P1	F	2	P3	Filed	APV/ Launch	Changes from 3Q FY15
		Tafluprost/	EU							
	DE-111	Timolol (FDC*)	KR							
		(FDC)	Asia						*	Approved
	DE-118	Tafluprost UD	JP							
Glaucoma/			Asia						*	Launched
Ocular hypertension	DE-085	Tafluprost	CN						*	Launched
rigpentension	DE-117	DE-117 EP2 agonist	US							
		LI Z agomst	JP							
	DE-090	Lomerizine HCI	JP							
	DE-126	Sepetaprost	US							In-licensed



*Fixed dose combination

Status of Main Projects in Clinical Development (2)

									Global	JP (Asia)
		Compound/		Development Stage					Changes from	
Disease Area	Project	MOA	Region	P1	Р.	2	P3	Filed	APV/ Launch	3QFY15
			EU							
	Cyclokat/ Ikervis	Ciclosporin	US							
Kerato- conjunctival	Ikervis	Cloiosponn	KR							
disease			Asia							
	DE-089	Diquafosol sodium	CN							
	DE-009		Asia							
			EU							Plan to withdraw / resubmit
	DE-109	Sirolimus	JP							
			US							
Retinal/ Uveal disease			Asia							
	DE-120	VEGF/PDGF inhibitor	US							
	DE-122	Anti-endoglin antibody	US							
Allergy	Vekacia	Ciclosporin	EU				*			Completed Phase3



-Glaucoma / Ocular hypertension-

■ **DE-085** (Glaucoma / Ocular hypertension)

	Developm		
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
China	Launched	Approved	Generic name: Tafluprost

■ **DE-090** (Glaucoma / Ocular hypertension)

	Developm		
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
Japan	P2	P2	Generic name: Lomerizine HCI

DE-111 (Glaucoma / Ocular hypertension)

	Developr		
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
Europe	Launched	Launched	Generic name:
Korea	Approved	Approved	Tafluprost/
Acia	Approved		Timolol maleate
Asia	(Thailand)	NDA Filed	(FDC)



-Glaucoma / Ocular hypertension-

DE-117 (Glaucoma / Ocular hypertension)

	Developme		
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
U.S.	P2b completed	P2b completed	EP2 receptor agonist
Japan	P2b/3	P2b/3	EP2 receptor agonist

DE-118 (Glaucoma / Ocular hypertension)

	Developme		ent Stage	
R	Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
ļ	Asia	Launched (Singapore)	Approved	Generic name: Tafluprost

DE-126 (Glaucoma / Ocular hypertension)

Development Stage			
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
U.S.	P2 completed	-	Generic name: Sepetaprost



■ **DE-089** (Dry eye)

	Developr	ment Stage			
Region	Region As of May 11, 2016 As of February 2, 2016 (Previous announcement)		Remarks		
Asia	Approved	Approved	Generic name: Diquafosol sodium		
Cyclokat / Ikervis (Severe keratitis in adult patients with dry eye)					
	Develop	ment Stage			
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks		
EU	Launched	Launched			
U.S.	P2 completed	P2 completed	Generic Name:		
Korea	NDA Filed	NDA Filed	Ciclosporin		
Asia	NDA Filed	NDA Filed			
Veka	cia (Vernal Keratoconjunct	ivitis)			
	Developi				

	Developm	nent Stage	
Region	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
EU	P3 completed	P3	Generic Name: Ciclosporin



-Retinal Disease--Uveitis-

DE-109 (Uveitis)

Region	Development Stage		
	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
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		
	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
U.S.	P2a	P2a	VEGF/PDGF dual inhib.

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

Region	Development Stage		
	As of May 11, 2016	As of February 2, 2016 (Previous announcement)	Remarks
U.S.	P1/2	P1/2	Anti-endoglin antibody

* Santen plans to withdraw and later resubmit its Marketing Authorization Application to the European Medicines Agency

Santen

Forward-Looking Statements

- Information given in this presentation 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 and event were to adversely affect supply capabilities for related final products.



