

# Investor Meeting on FY2016 First Quarter Results and FY2016 Forecasts



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## Kazuo Koshiji

Senior Corporate Officer  
Chief Financial Officer (CFO)  
Head of Finance Division

August 2, 2016

**SANTEN PHARMACEUTICAL CO., LTD.**

# Santen's Corporate Values

天機に参与する

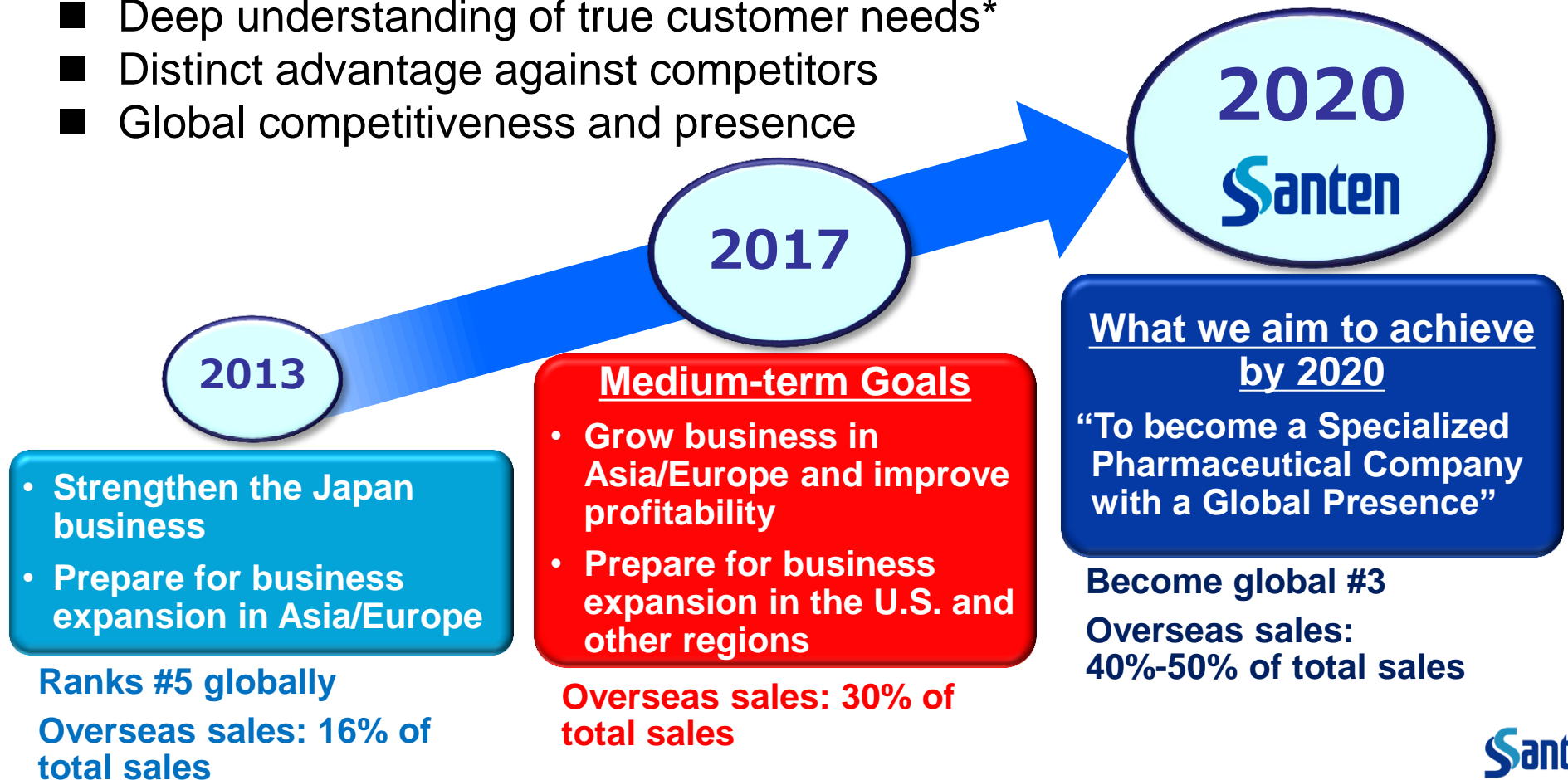
*Tenki ni sanyo suru*

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 and Growth Targets

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

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# **1Q FY2016 Financial Results ended June 30, 2016**

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# 1Q FY2016 Consolidated Highlights

- Revenue and core operating profit increased year-on-year
- Japan business
  - Prescription pharmaceuticals business rose 4% despite impact from NHI price revisions and exit from anti-rheumatic pharmaceutical business
  - Strong growth of revenue from new products and higher-than-expected revenue from long-listed drugs
  - Double digit growth in OTC revenue though some slowing in growth rate from purchases by visitors to Japan
- Overseas business
  - Asia: Decreased 5% due to the yen's appreciation
  - China: Continued strength as local currency revenue grew 18%
  - Europe: Local currency revenue increased 37% on contribution from *Ikervis* and products acquired from US-based Merck

# 1Q FY2016 Financial Highlights

## ***Core basis***

(JPY billions)	1Q FY15 Actual	1Q FY16	
		Actual	Var. (YoY)
Revenue	48.0	50.0	+4.2%
Core operating profit*	12.2	12.4	+1.2%
Core net profit for the period	8.2	8.8	+6.8%

## ***IFRS basis***

Operating profit	10.8	10.8	+0.1%
Net profit for the period	7.5	7.3	-2.9%

\* Core operating profit = operating profit + amortization associated with products – other revenue + other expenses (see page 24)

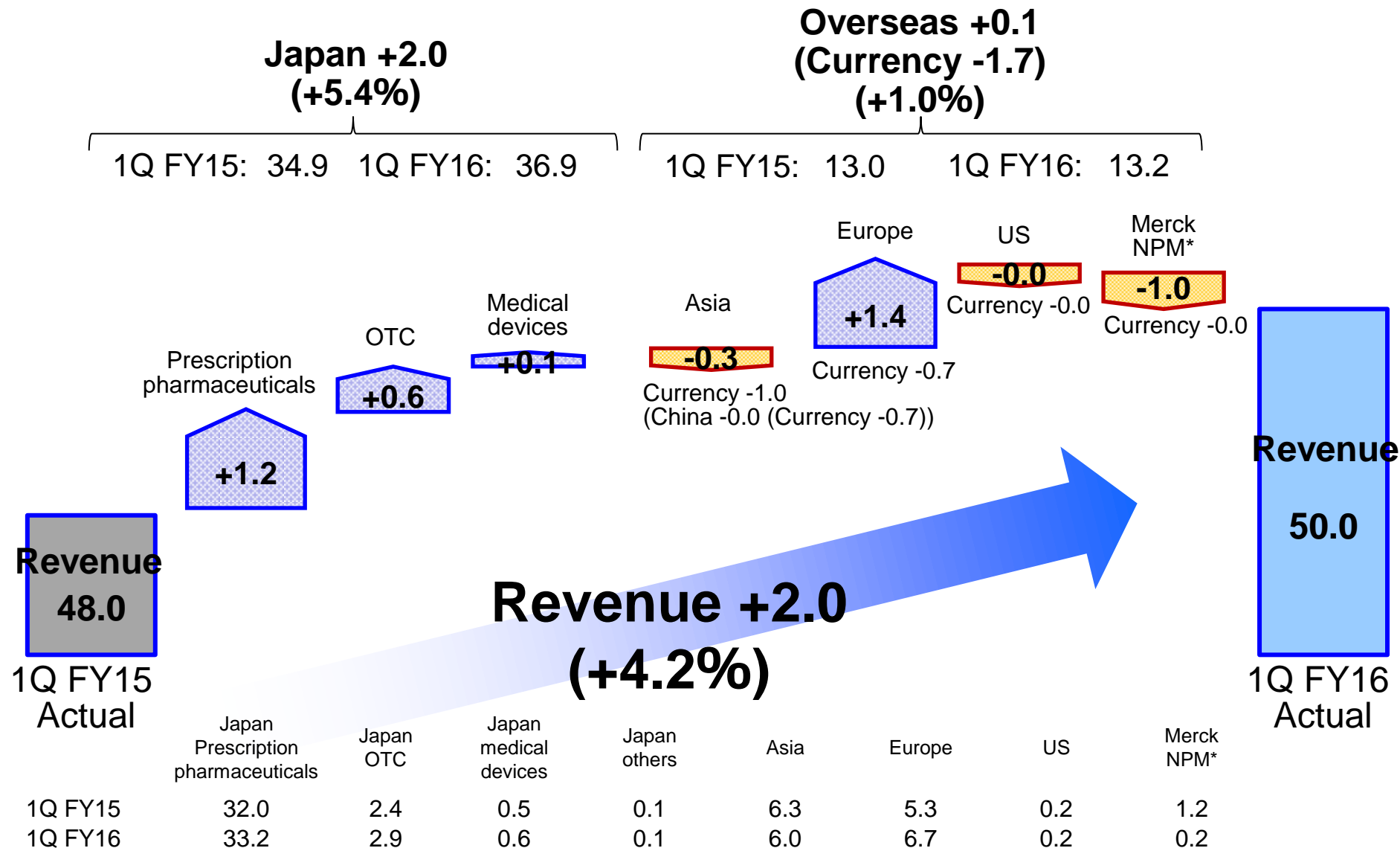
# Changes in P&L Statement

(JPY billions)	1Q FY15 Actual	1Q FY16		Major Changes
		Actual	Var. (YoY)	
<b>Revenue</b>	<b>48.0</b>	<b>50.0</b>	<b>+4.2%</b>	
Cost of sales (% of revenue)	-17.9 37.2%	-18.4 36.8%	+2.9% -0.5pt	Product mix change •Japan -1.5pt •Overseas +1.0pt
SG&A expenses (% of revenue)	-13.3 27.8%	-14.1 28.2%	+5.9% +0.4pt	•Japan -0.6 •Asia -0.5 •US/Europe +0.1
R&D expenses (% of revenue)	-4.6 9.6%	-5.2 10.3%	+12.5% +0.8pt	•Japan -0.1 •Overseas -0.4
<b>Core operating profit</b> (% of revenue)	<b>12.2</b> <b>25.4%</b>	<b>12.4</b> <b>24.7%</b>	<b>+1.2%</b> <b>-0.7pt</b>	
Amortization on intangible assets associated with products (% of revenue)	-1.4 3.0%	-1.6 3.2%	+10.8% +0.2pt	
Other revenue	0.1	0.1	-	
Other expenses	-0.1	-0.1	-11.4%	
<b>Operating profit</b> (% of revenue)	<b>10.8</b> <b>22.5%</b>	<b>10.8</b> <b>21.6%</b>	<b>+0.1%</b> <b>-0.9pt</b>	
<b>Core net profit for the period</b>	<b>8.2</b>	<b>8.8</b>	<b>+6.8%</b>	
<b>Net profit for the period</b>	<b>7.5</b>	<b>7.3</b>	<b>-2.9%</b>	

Currency rates	1Q FY15 Actual	1Q FY16 Actual
US \$	JPY 121.51	JPY 108.83
Euro	JPY 134.01	JPY 122.53
CNY	JPY 19.81	JPY 16.63

# 1Q FY2016 Revenue Change

JPY billions

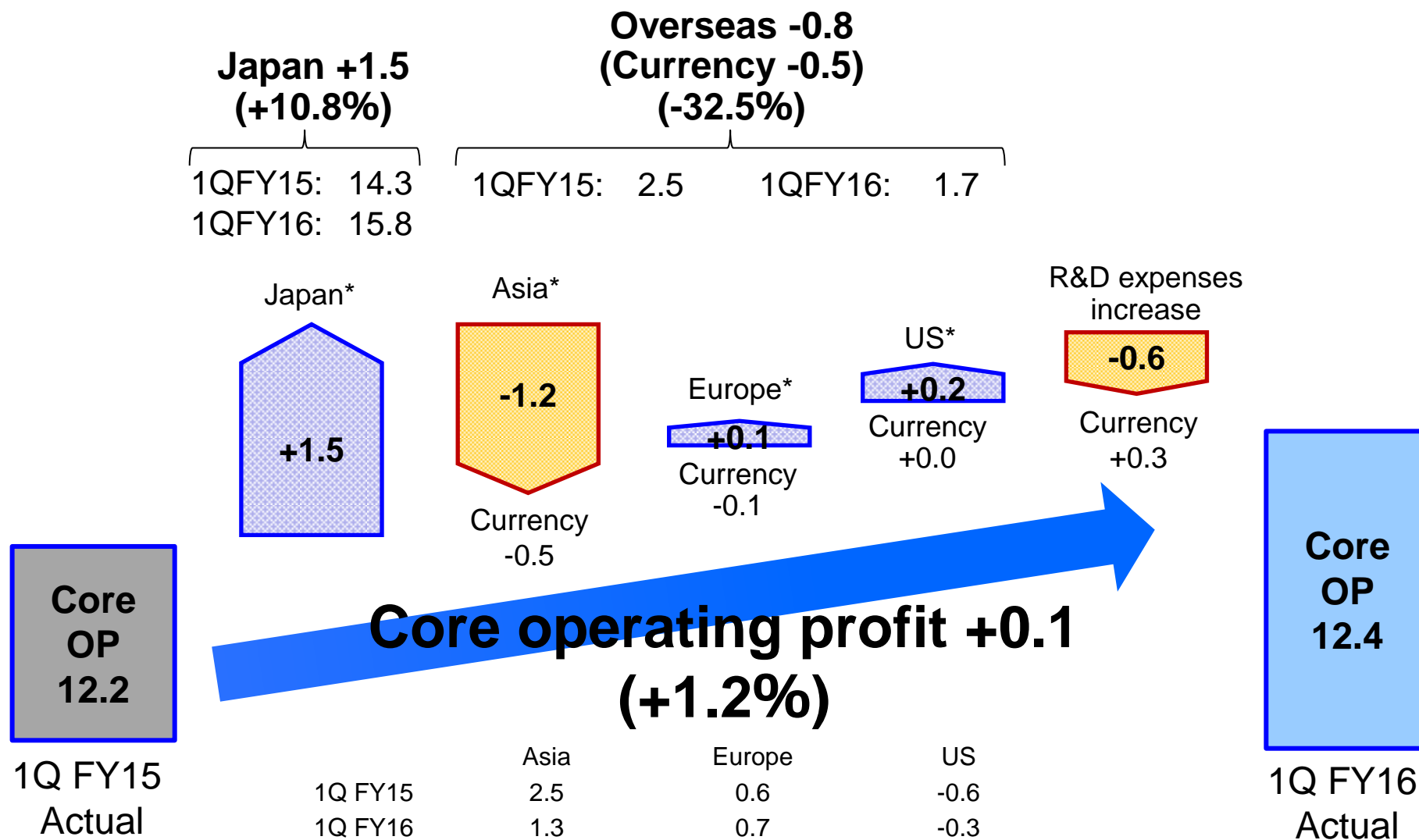


\* NPM (Net Profit Margin): Profit generated from US-based Merck ophthalmic products which Santen has acquired and has consigned them to US-based Merck until the completion of transfer of the underlying marketing rights.



# 1Q FY2016 Core Operating Profit Change

JPY billions



\* Company policy on accounting for profit does not allocate certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from US-based Merck to Santen.

# Overseas Revenue and Operating Profit

(JPY billions)		1Q FY15	1Q FY16		
		Actual	Actual		
		Revenue	Revenue	Var. (YoY)	Operating profit***
U.S.		1.4*	0.4*	-70.7%	-0.3
Europe		5.3	6.7	+26.7%**	0.7
Asia		6.3	6.0	-4.8%	1.3
	China	3.6	3.6	-1.1%**	
Total		13.0	13.2	+1.0%	1.7

<b>Overseas revenue / Total revenue</b>	<b>27.2%</b>	<b>26.3%</b>	<b>-0.9pt</b>	
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\* Net profit margin (NPM) relating to the US-based Merck product acquisition is treated as revenue in the U.S.

\*\*Year-on-year change on a local currency basis: Europe +37.0%, China +17.7%

\*\*\*Company policy on accounting for profit does not allocate certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from US-based Merck to Santen.

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# **FY2016 Consolidated Forecast ending March 31, 2017 (Revised)**

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# FY2016 Consolidated Forecast (Revised)

- **Forecasts are revised to account for the appreciation of the Japanese yen and the acquisition of InnFocus, Inc. (U.S.) announced in July 2016**
- **Revenue forecast change -4.0 billion yen**
  - Currency translation impact causes forecasts to be adjusted from 204b yen to 200b yen
- **Core operating profit change -1.9 billion yen**
  - No net impact on core OP from change in foreign exchange rate assumptions
  - Increased cost of 1.9b yen from SG&A, R&D, etc. resulting from the consolidation of InnFocus

Note: Forecasts are based on current accounting treatment and assumptions about the acquisition. Santen discloses promptly when significant differences arise.

# FY2016 P&L Statement Forecast (Revised)

(JPY billions)	FY15 Actual	FY16				
		Forecast (Previous)	Impact of fluctuations in currency	Impact of Acquisition of InnFocus	Forecast (Revised)	Var. (YoY)
<b>Revenue</b>	<b>195.3</b>	<b>204.0</b>	<b>-4.0</b>	<b>-</b>	<b>200.0</b>	<b>+2.4%</b>
Cost of sales (% of revenue)	-72.8 37.3%	-78.0 38.2%	+1.5	-	-76.5 38.3%	+5.0% +1.0pt
SG&A expenses (% of revenue)	-59.4 30.4%	-59.5 29.2%	+1.5	-1.0	-59.0 29.5%	-0.7% -0.9pt
R&D expenses (% of revenue)	-20.0 10.2%	-20.5 10.0%	+1.0	-0.9	-20.4 10.2%	+2.1% -0.0pt
<b>Core operating profit</b> (% of revenue)	<b>43.1</b> <b>22.1%</b>	<b>46.0</b> <b>22.5%</b>	<b>0.0</b>	<b>-1.9</b>	<b>44.1</b> <b>22.1%</b>	<b>+2.3%</b> <b>-0.0pt</b>
Non-recurring SG&A expenses	-	-	-	-0.6	-0.6	-
Amortization on intangible assets associated with products (% of revenue)	-6.2 3.2%	-7.1 3.5%	+0.1	-	-7.0 3.5%	+12.8% +0.3pt
Other revenue	45.0	-	-	-	-	-
Other expenses	-1.7	-0.2	-	-	-0.2	-88.1%
<b>Operating profit</b> (% of revenue)	<b>80.2</b> <b>41.1%</b>	<b>38.7</b> <b>19.0%</b>	<b>+0.1</b>	<b>-2.5</b>	<b>36.3</b> <b>18.1%</b>	<b>-54.7%</b> <b>-22.9pt</b>
<b>Core net profit for the year</b>	<b>29.2</b>	<b>31.8</b>	<b>+0.2</b>	<b>-1.8</b>	<b>30.2</b>	<b>+3.5%</b>
<b>Core ROE</b>	<b>12.4%</b>	<b>12.0%</b>	<b>-</b>	<b>-</b>	<b>11.4%</b>	<b>-1.0pt</b>
<b>Net profit for the year</b>	<b>53.4</b>	<b>26.9</b>	<b>+0.1</b>	<b>-1.8</b>	<b>25.3</b>	<b>-52.6%</b>
<b>ROE</b>	<b>22.6%</b>	<b>10.0%</b>	<b>-</b>	<b>-</b>	<b>9.5%</b>	<b>-13.1pt</b>

Currency rates	FY15 Actual	FY16 Forecast (Previous)	FY16 Forecast (Revised)
US \$	JPY 120.45	JPY 115.00	JPY 105.00
Euro	JPY 132.46	JPY 125.00	JPY 115.00
CNY	JPY 19.05	JPY 17.50	JPY 15.00

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# **FY2016 Dividend Forecast**

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# Dividend for FY2015 and FY2016 Forecast

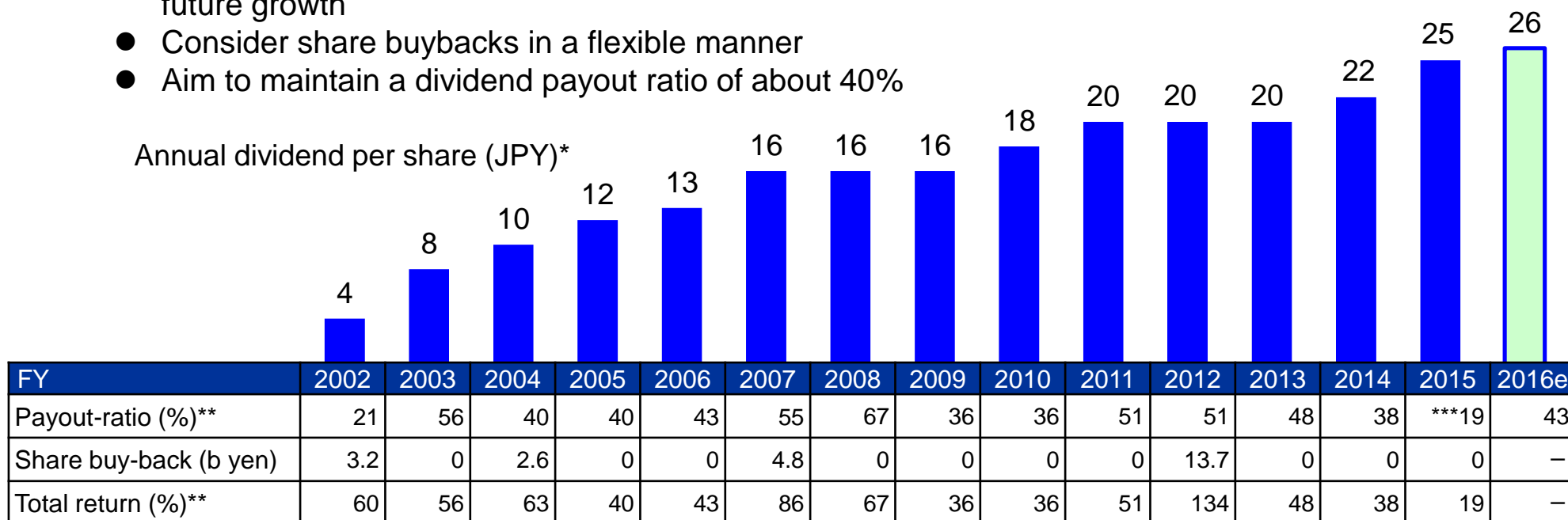
## ■ Annual dividend

- 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
- Consider share buybacks in a flexible manner
- Aim to maintain a dividend payout ratio of about 40%

Annual dividend per share (JPY)\*



\* 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 35.5% in FY15.

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**Reference:**  
**1Q FY2016 Consolidated Results**

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# Revenue by Business Segment

(JPY billions)	1Q FY16 Actual					
	Japan		Overseas		Total	
	Revenue	Var. (YoY)	Revenue	Var. (YoY)	Revenue	Var. (YoY)
<b>Pharmaceuticals</b>	<b>36.1</b>	<b>+5.2%</b>	<b>13.1</b>	<b>+0.8%</b>	<b>49.3</b>	<b>+4.0%</b>
Prescription Pharmaceuticals	33.2	+3.8%	13.1	+0.7%	46.3	+2.9%
Ophthalmic	33.1	+13.1%	12.7	+9.2%	45.7	+12.0%
Others	0.1	+12.2%	0.4	-69.8%	0.6	-62.9%
OTC Pharmaceuticals	2.9	+24.3%	0.0	+37.0%	3.0	+24.4%
<b>Others</b>	<b>0.7</b>	<b>+16.8%</b>	<b>0.0</b>	<b>+220.9%</b>	<b>0.7</b>	<b>+20.9%</b>
Medical devices	0.6	+15.5%	0.0	-54.1%	0.6	+13.9%
Others	0.1	+26.5%	0.0	-	0.1	+72.3%
<b>Total</b>	<b>36.9</b>	<b>+5.4%</b>	<b>13.2</b>	<b>+1.0%</b>	<b>50.0</b>	<b>+4.2%</b>

\* Anti-RA business was transferred to AYUMI Pharmaceutical Corporation in August 2015.

# Summary of Financial Position

(JPY billions)	As of March 31, 2016		As of June 30, 2016		
	Actual	% of Total	Actual	% of Total	Var. (YoY)
Non-current assets	160.7	45.2%	155.7	47.3%	-5.0
Current assets	194.7	54.8%	173.1	52.7%	-21.6
Cash and cash equivalent	99.8	28.1%	74.5	22.7%	-25.3
<b>Total assets</b>	<b>355.4</b>	<b>100.0%</b>	<b>328.8</b>	<b>100.0%</b>	<b>-26.6</b>
<b>Total equity</b>	<b>260.0</b>	<b>73.2%</b>	<b>256.3</b>	<b>77.9%</b>	<b>-3.8</b>
Non-current liabilities	22.2	6.2%	23.5	7.1%	+1.3
Current liabilities	73.2	20.6%	49.0	14.9%	-24.2
<b>Total liabilities</b>	<b>95.4</b>	<b>26.8%</b>	<b>72.5</b>	<b>22.1%</b>	<b>-22.9</b>
<b>Total equity and liabilities</b>	<b>355.4</b>	<b>100.0%</b>	<b>328.8</b>	<b>100.0%</b>	<b>-26.6</b>

Shares issued : End of March 2016: 414,192 thousand → End of June 2016: 414,227 thousand

## Major Changes

- Current assets: Cash and cash equivalent -25.3 billion yen (Income tax paid)
- Equity: Foreign currency translation adjustment -4.6 billion yen
- Current liabilities: Income tax payable -19.0 billion yen, Financial liabilities -4.6 billion yen

# Summary of Cash Flows

(JPY billions)		1Q FY15 Actual	1Q FY16	
			Actual	Var. (YoY)
	Cash flows from operating activities	-0.3	-14.3	-13.9
	Cash flows from investing activities	-2.6	-4.1	-1.6
	Cash flows from financial activities	-7.6	-4.7	+2.9
	<b>Net increase (decrease) in cash and cash equivalents</b>	<b>-10.5</b>	<b>-23.0</b>	<b>-12.6</b>
	<b>Cash and cash equivalents at the beginning of period</b>	<b>65.9</b>	<b>99.8</b>	<b>+33.9</b>
	Effect of exchange rate changes on cash and cash equivalents	+0.6	-2.2	-2.8
	<b>Cash and cash equivalents at the end of period</b>	<b>56.1</b>	<b>74.5</b>	<b>+18.5</b>

# Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY15		FY16	
	1Q Actual	Full Year Actual	1Q Actual	Full Year Forecast (Revised)
Capital expenditures	0.8	4.5	1.6	7.1
Depreciation and amortization*	0.7	3.1	0.8	3.5
Amortization on intangible assets associated with products	1.4	6.2	1.6	7.1
Amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products	1.3	5.2	1.3	5.3
Amortization of intangible assets related to Ikervis	0.1	0.6	0.2	0.7

\* Excludes amortization on intangible assets associated with products and long-term advance expense

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**Reference:  
FY2016 Consolidated Forecast  
(Revised)**

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# FY2016 Forecast: Business Segment / Overseas Revenue (Revised)

(JPY billions)	FY16 Forecast (Revised)					
	Japan		Overseas		Total	
	Revenue	Var. (YoY)	Revenue	Var. (YoY)	Revenue	Var. (YoY)
<b>Pharmaceuticals</b>	<b>145.7</b>	<b>+4.7%</b>	<b>51.1</b>	<b>-4.3%</b>	<b>196.8</b>	<b>+2.2%</b>
Prescription Pharmaceuticals	132.0	+2.9%	51.0	-4.3%	182.9	+0.8%
Ophthalmic	131.3	+5.8%	49.6	+2.4%	180.9	+4.8%
Others	0.6	+4.6%	1.4	-71.5%	2.0	-63.0%
OTC Pharmaceuticals	13.8	+26.0%	0.1	+7.9%	13.8	+25.9%
<b>Others</b>	<b>3.0</b>	<b>+12.1%</b>	<b>0.3</b>	<b>+198.4%</b>	<b>3.2</b>	<b>+17.8%</b>
Medical devices	2.6	+10.9%	0.1	-6.2%	2.6	+10.4%
Others	0.4	+21.2%	0.2	-	0.6	+70.1%
<b>Total</b>	<b>148.7</b>	<b>+4.8%</b>	<b>51.3</b>	<b>-4.0%</b>	<b>200.0</b>	<b>+2.4%</b>

# FY2016 Forecast: Overseas Revenue and Operating Profit (Revised)

(JPY billions)		FY15 Actual	FY16 Forecast (Revised)		
		Revenue	Revenue*	Var. (YoY)	Operating profit**
U.S.		5.3	1.7	-68.1%	-3.9
Europe		25.6	28.1	+9.8%	4.6
Asia		22.6	21.4	-5.2%	4.0
	China	13.5	11.4	-15.6%	
Total		53.4	51.3	-4.0%	4.7
<b>Overseas revenue / Total revenue</b>		<b>27.4%</b>	<b>25.7%</b>	<b>-1.7pt</b>	

\* 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 does not allocate certain SG&A and R&D expenses. NPM is distributed by region after operationally transferred from US-based Merck to Santen.

# Reconciliation of IFRS to Core OP

(JPY billions)	FY15 Actual	FY16 Forecast (Revised)
<b>IFRS operating profit</b>	<b>80.2</b>	<b>36.3</b>
Non-core deduction items	-37.1	+7.8
Non-recurring SG&A expenses	-	+0.6
Amortization on intangible assets associated with products	+6.2	+7.0
Other revenue	-45.0	-
Other expenses	+1.7	+0.2
<b>Core operating profit</b>	<b>43.1</b>	<b>44.1</b>



# IFRS and Core Comparisons

IFRS		Core
<b>Revenue</b>		<b>Revenue</b>
Cost of sales		Cost of sales
<b>Gross profit</b>		<b>Gross profit</b>
SG&A		SG&A
R&D		R&D
Amortization on intangible assets associated with products	----->	Excluded from core
Other income	----->	Excluded from core
Other expenses	----->	Excluded from core
<b>Operating profit</b>		<b>Core operating profit</b>
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 expenses		Income tax expenses
<b>Net profit</b>		<b>Core net profit</b>

## 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
- Non-recurring items excluded from IFRS to calculate core results: amortization associated with products, other income and expenses, finance income and expenses, etc.

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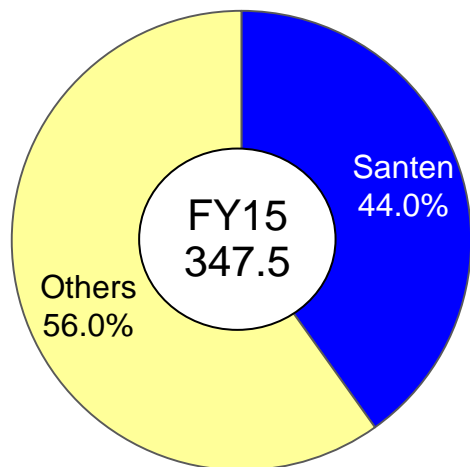
**Reference:**  
**Market Overview of**  
**Prescription Ophthalmic in Japan**

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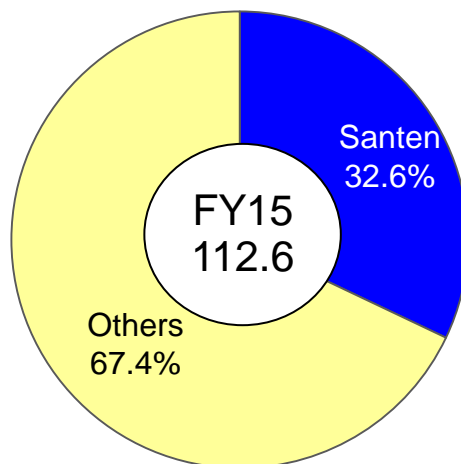
# Japan: Trends & Competition in Ophthalmics (1)

Market Size:  
JPY billions  
%: Value Share

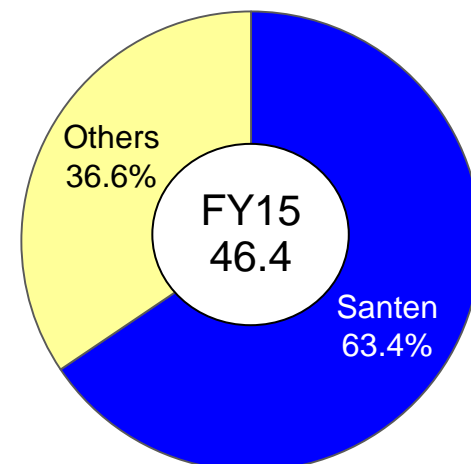
## Ophthalmology Total



## Anti-glaucoma



## Cornea / Dry Eye



		FY2015	1Q FY2016
YoY	Market	+7.3%	+1.2%
	Santen	+17.6%	+6.7%
Santen's Share		44.0%	44.9%

		FY2015	1Q FY2016
YoY		+6.5%	+4.0%
Santen		+8.4%	+2.6%
Santen's Share		32.6%	32.3%

		FY2015	1Q FY2016
YoY		+4.9%	-0.8%
Santen		+1.4%	-2.6%
Santen's Share		63.4%	62.8%

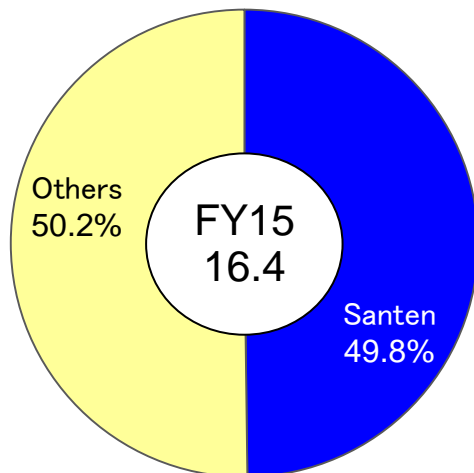
- Santen:
  - Anti-Glaucoma : Cosopt, Tapros, Timoptol/XE, Trusopt, Rescula, Tapcom, Detantol
  - Cornea / Dry Eye : Hyalein, Diquas

Source: ©2016 IMS Health  
IMS-JPM 2014-16  
Santen analysis based on IMS data  
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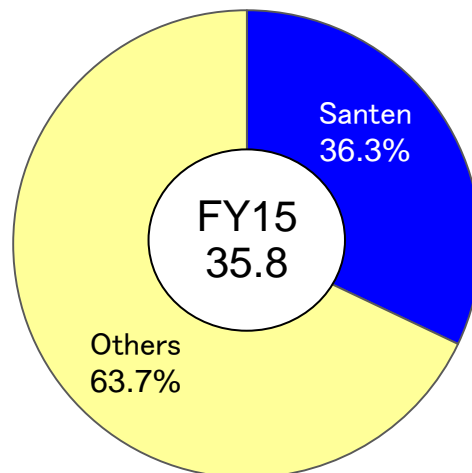
# Japan: Trends & Competition in Ophthalmics (2)

Market Size:  
JPY billions  
%: Value Share

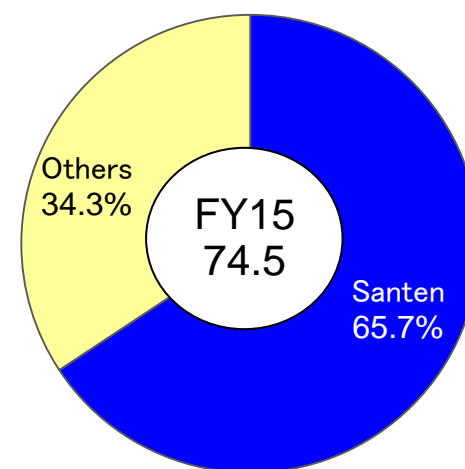
## Anti-infection



## Anti-allergy



## Anti-VEGF



		FY2015	1Q FY2016
YoY	Market	-2.5%	-9.6%
	Santen	-10.1%	-19.4%
Santen's Share		49.8%	45.5%

		FY2015	1Q FY2016
Market		+5.7%	+14.5%
Santen		+19.5%	+26.6%
Santen's Share		36.3%	41.8%

		FY2015	1Q FY2016
Market		+20.9%	-1.3%
Santen		+62.7%	+22.4%
Santen's Share		65.7%	71.2%

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

Source: ©2016 IMS Health  
IMS-JPM 2014-16  
Santen analysis based on IMS data  
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# Status of Clinical Development 1Q FY2016



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**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)

As of August 2, 2016

Disease Area	Project	Mechanism of Action	Compound /Product	Region	Development Stage					Changes from Previous Announcement
					P1	P2	P3	Filed	APV/ Launch	
Glaucoma/ Ocular hypertension	DE-111	Prostaglandin F <sub>2α</sub> derivative/ Beta-adrenergic receptor blocker	Tafluprost and Timolol maleate	KR					★	Launched
				Asia						
	DE-118	Prostaglandin F <sub>2α</sub> derivative	Tafluprost (single-use type)	Asia						
	DE-085	Prostaglandin F <sub>2α</sub> derivative	Tafluprost	CN						
	DE-117	EP2 receptor agonist	Undetermined	US						
				JP			P2b/3			
	DE-090	Calcium antagonist	Lomerizine HCl	JP						
	DE-126	FP/EP3 receptors dual agonist	Sepetaprost	US						

# Status of Main Projects in Clinical Development (2)

As of August 2, 2016

Global

JP (Asia)

Disease Area	Project	Mechanism of Action	Compound /Product	Region	Development Stage					Changes from Previous Announcement
					P1	P2	P3	Filed	APV/ Launch	
Kerato-conjunctival disease	Cyclokat	Immuno suppression /Cationic emulsion	Ciclosporin/ <i>Ikervis</i>	EU						
				US						
				KR						
				Asia						
	DE-089	P2Y <sub>2</sub> receptor agonist	Diquafosol sodium	CN						
				Asia					★	Launched in VN and TH
Retinal/ Uveal disease	DE-109	mTOR inhibitor	Sirolimus	EU			★			Withdrew, plan to resubmit
				JP						
				US						
				Asia						
	DE-120	VEGF/PDGF inhibitor	Undetermined	US						
	DE-122	Anti-endoglin antibody	Undetermined	US		P1/2				
Allergy	Vekacia	Immuno suppression /Cationic emulsion	Ciclosporin	EU						

# 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 an event were to adversely affect supply capabilities for related final products.



The logo for Santen features a stylized 'S' on the left, composed of two overlapping curved shapes in light blue and dark blue. To the right of the 'S' is the word 'Santen' in a bold, dark blue, sans-serif typeface.

**Santen**

*A Clear Vision For Life*