

# Investor Meeting on Q3 FY2016 Results



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## Kazuo Koshiji

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

February 7, 2017

**SANTEN PHARMACEUTICAL CO., LTD.**

# Santen's Values

天機に参与する

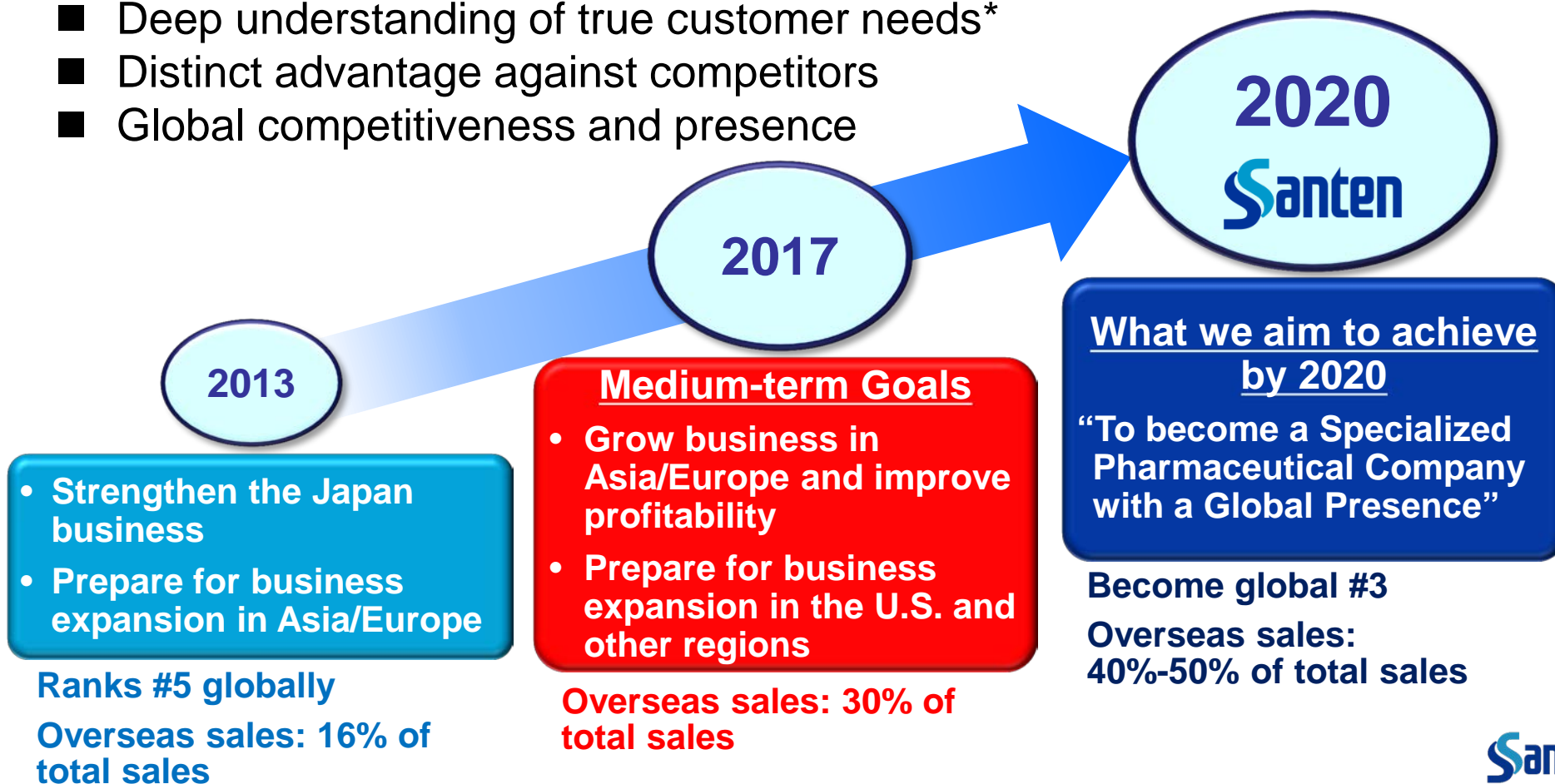
*Tenki ni sanyo suru*

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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# **Q3 FY2016 Financial Results ended December 31, 2016**

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# Q3 FY2016<sup>(1)</sup> Financial Highlights

## Core basis

(JPY billions)	Q3 FY15 Actual	Q3FY16	
		Actual	Var. (YoY)
Revenue	(3) 149.2	150.7	+1.0%
Excluding anti-RA business and forex impacts			+7.7%
Core operating profit <sup>(2)</sup>	(3) 35.1	33.1	-5.9%
Excluding anti-RA business and forex impacts			-0.7%
Core net profit for the period	23.6	24.4	+3.2%

## IFRS basis<sup>(4)</sup>

Operating profit	74.4	27.5	-63.1%
Net profit for the period	49.9	19.8	-60.3%

(1) Santen results herein describe Q3 results cumulatively as the nine month period ended December 31, 2016

(2) Core operating profit = operating profit + amortization associated with products – other revenue + other expenses (see slide 17)

(3) Including revenue of anti-RA business, 3.5 bil and core operating profit, 2.0 bil yen

(4) Including gain on transfer of anti-RA business of 45.0 bil yen

# Q3 FY2016 Consolidated Highlights

**Q3 core basis results were above company forecasts with solid revenue growth and profit maintained, excl. anti-rheumatoid business transfer and forex impacts**

- **Revenue:** +1% YoY (+8% revenue growth excl. RA and forex<sup>(1)</sup> impacts)
  - **Japan business:** Revenue +2% YoY (revenue grew +5% excl. RA impact)
    - Growth of new products overcomes NHI price cuts and RA business transfer
    - New product ratio increased to 70%; Market share grew to 46%
  - **Overseas business:** Revenue -2% YoY (revenue grew +8% excl. forex impact)
    - Asia: Revenue +1% in Japanese yen terms, China +17% in CNY
    - EMEA<sup>(2)</sup>: Acquired MSD products contributed to +26% growth in EURO
- **Core operating profit:** -6% YoY (-1% excl. RA and forex impacts)
  - With increased R&D investment, core OP was lower YoY and in-line with prior year Q3 excl. RA and forex impacts
- **Core net profit:** +3% YoY
  - Higher on factors including increased tax deductions for R&D expenses in Japan
- **Q3 results above internal plans, FY16 forecasts maintained**
- **Conducted repurchase of own shares (Sep-Nov 2016) followed by cancellation of treasury shares (2% of outstanding)**

(1) Forex: foreign exchange

(2) EMEA: Europe, the Middle East and Africa

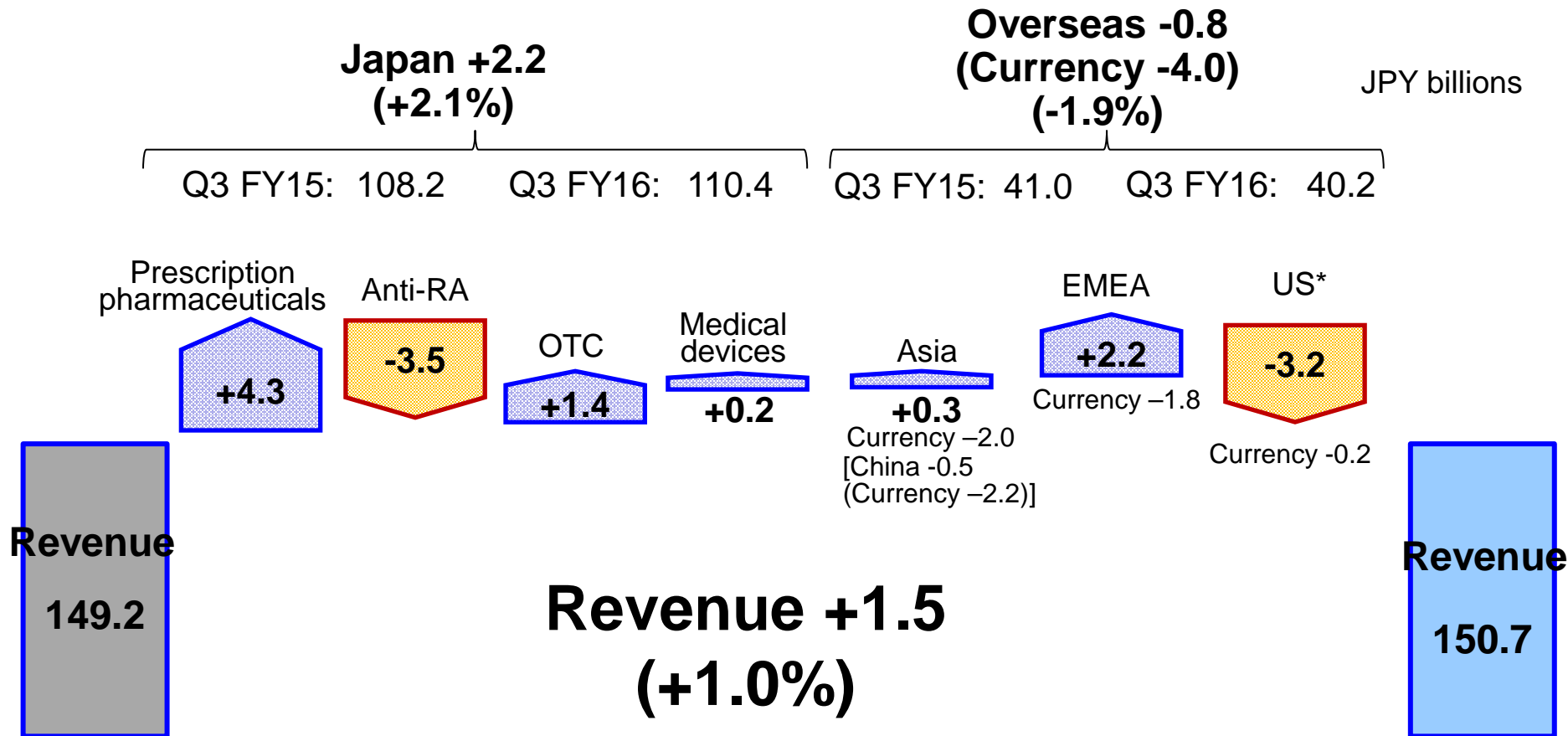
# Changes in P&L Statement

(JPY billions)	Q3 FY15	Q3 FY16		Major Changes
	Actual	Actual	Var. (YoY)	
<b>Revenue</b>	<b>149.2</b>	<b>150.7</b>	<b>+1.0%</b>	
Cost of sales (% of revenue)	-56.7 38.0%	-57.6 38.3%	+1.6% +0.2pt	Product mix change •Japan 0.5pt •Overseas -0.2pt
SG&A expenses (% of revenue)	-43.1 28.9%	-44.0 29.2%	+2.3% +0.4pt	•Japan +1.6 •Asia +0.2 •US/EMEA -1.1
R&D expenses (% of revenue)	-14.3 9.6%	-15.9 10.6%	+11.5% +1.0pt	•Japan +1.0 •Overseas +0.2
<b>Core operating profit</b> (% of revenue)	<b>35.1</b> <b>23.5%</b>	<b>33.1</b> <b>21.9%</b>	<b>-5.9%</b> <b>-1.6pt</b>	
Non-recurring SG&A expenses*	-	-0.5	-	
Amortization on intangible assets associated with products (% of revenue)	-4.6 3.1%	-4.8 3.2%	+3.8% +0.1pt	
Other revenue	44.8	0.3	-	
Other expenses	-0.9	-0.6	-40.3%	
<b>Operating profit</b> (% of revenue)	<b>74.4</b> <b>49.9%</b>	<b>27.5</b> <b>18.2%</b>	<b>-63.1%</b> <b>-31.6pt</b>	
<b>Core net profit for the period</b>	<b>23.6</b>	<b>24.4</b>	<b>+3.2%</b>	
<b>Net profit for the period</b>	<b>49.9</b>	<b>19.8</b>	<b>-60.3%</b>	

Currency rates	Q3 FY15 Actual	Q3FY16 Actual
US \$	JPY 121.65	JPY 106.93
Euro	JPY 133.93	JPY 118.36
CNY	JPY 19.45	JPY 16.02

\* Payment of consulting fees relating to the acquisition of InnFocus

# Q3 FY2016 Revenue Change



JPY billions

Q3 FY15 Actual

Q3 FY16 Actual

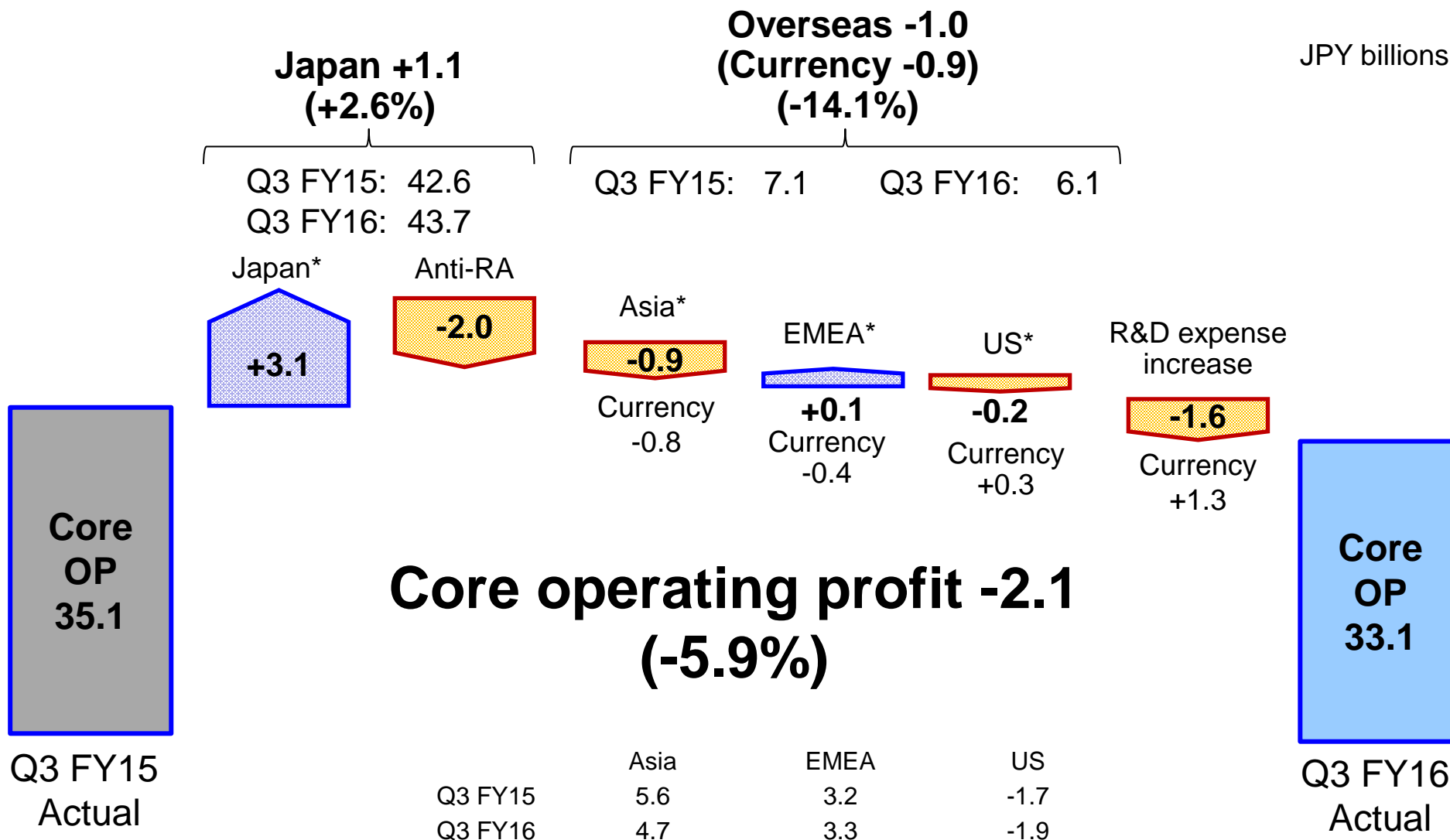
	Japan prescription pharmaceuticals	Japan OTC	Japan medical devices	Asia	EMEA	US*
Q3 FY15	94.3	8.1	1.7	17.8	18.7	4.5
Q3 FY16	98.5	9.5	1.9	18.1	20.9	1.2

\* US includes Net profit margin (NPM) relating to the US-based Merck product acquisition.



# Q3 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)		Q3 FY15	Q3 FY16		
		Actual	Actual		
		Revenue	Revenue	Var. (YoY)	Operating profit <sup>(3)</sup>
U.S.		4.5 <sup>(1)</sup>	1.2 <sup>(1)</sup>	-72.5%	-1.9
EMEA		18.7	20.9	+11.6% <sup>(2)</sup>	3.3
Asia		17.8	18.1	+1.5%	4.7
	China	10.9	10.5	-4.1% <sup>(2)</sup>	
Total		41.0	40.2	-1.9%	6.1

<b>Overseas revenue / Total revenue</b>	<b>27.5%</b>	<b>26.7%</b>	<b>-0.8pt</b>	
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(1) Net profit margin (NPM) relating to the US-based Merck product acquisition is treated as revenue in the U.S.

(2) Year-on-year change on a local currency basis: Euro +26.0%, CNY +16.8%

(3) 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.

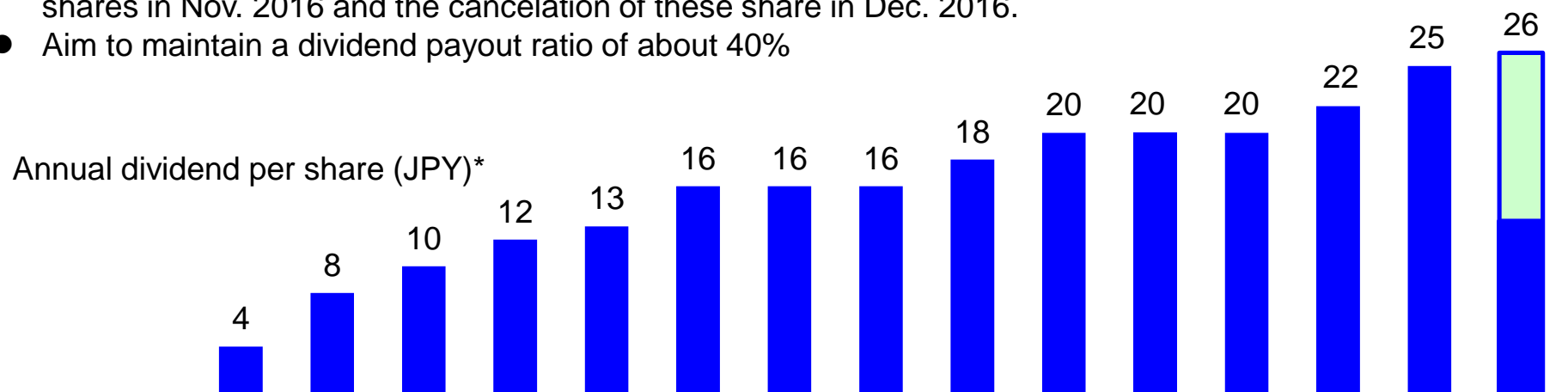
# Historical Dividends and FY2016 Forecast

## ■ Annual dividend

- FY2015: JPY 25 per share
- FY2016 (forecast): JPY 26 per share (as of September 30, 2016: JPY 13)

## ■ 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, included the share buyback about 2% of outstanding shares in Nov. 2016 and the cancelation of these share in Dec. 2016.
- Aim to maintain a dividend payout ratio of about 40%



FY	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016e
Payout-ratio (%)**	21	56	40	40	43	55	67	36	36	51	51	48	38	***19	42
Share buybacks (b yen)	3.2	0	2.6	0	0	4.8	0	0	0	0	13.7	0	0	0	12.3
Total return (%)**	60	56	63	40	43	86	67	36	36	51	134	48	38	19	91

\* 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:**  
**Q3 FY2016 Consolidated Results**  
**Market Overview of Prescription Ophthalmic**  
**in Japan**

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# Revenue by Business Segment

(JPY billions)	Q3 FY16 Actual					
	Japan		Overseas		Total	
	Revenue	Var. (YoY)	Revenue	Var. (YoY)	Revenue	Var. (YoY)
<b>Pharmaceuticals</b>	<b>108.3</b>	<b>+1.9%</b>	<b>40.1</b>	<b>-2.1%</b>	<b>148.4</b>	<b>+0.8%</b>
Prescription Pharmaceuticals	98.8	+0.7%	40.0	-2.2%	138.8	-0.2%
Ophthalmic	98.5	+4.5%	38.9	+6.5%	137.5	+5.1%
Others	0.3	-32.2%	1.1	-75.0%	1.4	-71.5%
OTC Pharmaceuticals	9.5	+17.1%	0.1	+52.8%	9.6	+17.4%
<b>Others</b>	<b>2.2</b>	<b>+11.1%</b>	<b>0.1</b>	<b>+105.8%</b>	<b>2.3</b>	<b>+14.5%</b>
Medical devices	1.9	+9.3%	0.0	-70.6%	1.9	+6.5%
Others	0.3	+23.4%	0.1	-	0.4	+69.1%
<b>Total</b>	<b>110.4</b>	<b>+2.1%</b>	<b>40.2</b>	<b>-1.9%</b>	<b>150.7</b>	<b>+1.0%</b>

# Summary of Financial Position

(JPY billions)	As of March 31, 2016		As of December 31, 2016		
	Actual	% of Total	Actual	% of Total	Var. (YoY)
Non-current assets	160.7	45.2%	170.1	53.0%	+9.5
Current assets	194.7	54.8%	151.1	47.0%	-43.6
Cash and cash equivalent	99.8	28.1%	48.1	15.0%	-51.7
<b>Total assets</b>	<b>355.4</b>	<b>100.0%</b>	<b>321.2</b>	<b>100.0%</b>	<b>-34.2</b>
<b>Total equity</b>	<b>260.0</b>	<b>73.2%</b>	<b>254.0</b>	<b>79.1%</b>	<b>-6.0</b>
Non-current liabilities	22.2	6.2%	16.6	5.2%	-5.6
Current liabilities	73.2	20.6%	50.7	15.8%	-22.6
<b>Total liabilities</b>	<b>95.4</b>	<b>26.8%</b>	<b>67.3</b>	<b>20.9%</b>	<b>-28.1</b>
<b>Total equity and liabilities</b>	<b>355.4</b>	<b>100.0%</b>	<b>321.2</b>	<b>100.0%</b>	<b>-34.2</b>

Shares issued : End of March 2016: 414,192 thousand → End of December 2016: 406,005 thousand

## Major Changes

- Non-current assets: Goodwill +24.5 bil yen, Investment securities -12.9 bil yen
- Current assets: Account Receivable +7.0 bil yen, Cash and cash equivalents -51.7 bil yen (Income tax paid, payment of InnFocus acquisition, Repurchase of own shares)
- Equity: Valuation difference on available for sale securities -7.6 bil yen,
- Current liabilities: Income tax payable -11.6 bil yen

# Summary of Cash Flows

(JPY billions)		Q3 FY15 Actual	Q3 FY16	
			Actual	Var. (YoY)
	Cash flows from operating activities	18.0	0.3	-17.7
	Cash flows from investing activities	38.8	-24.8	-63.6
	Cash flows from financing activities	-18.3	-26.4	-8.0
	<b>Net increase (decrease) in cash and cash equivalents</b>	<b>38.5</b>	<b>-50.8</b>	<b>-89.3</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	-0.3	-0.9	-0.5
	<b>Cash and cash equivalents at the end of period</b>	<b>104.1</b>	<b>48.1</b>	<b>-56.0</b>

# Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY15 Q3 Actual	FY16 Q3 Actual
Capital expenditures	3.1	4.1
Depreciation and amortization*	2.3	2.6
Amortization on intangible assets associated with products	4.6	4.8
Amortization of intangible assets related to Santen's acquisition of US-based Merck ophthalmic products	3.9	4.0
Amortization of intangible assets related to <i>Ikervis</i>	0.4	0.5

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



# FY2016 P&L Statement Forecast

(JPY billions)	FY15 Actual	FY16	
		Forecast	Var. (YoY)
<b>Revenue</b>	<b>195.3</b>	<b>200.0</b>	<b>+2.4%</b>
Cost of sales (% of revenue)	-72.8 37.3%	-76.5 38.3%	+5.0% +1.0pt
SG&A expenses (% of revenue)	-59.4 30.4%	-59.0 29.5%	-0.7% -0.9pt
R&D expenses (% of revenue)	-20.0 10.2%	-20.4 10.2%	+2.1% -0.0pt
<b>Core operating profit</b> (% of revenue)	<b>43.1</b> <b>22.1%</b>	<b>44.1</b> <b>22.1%</b>	<b>+2.3%</b> <b>-0.0pt</b>
Non-recurring SG&A expenses	-	-0.6	-
Amortization on intangible assets associated with products (% of revenue)	-6.2 3.2%	-7.0 3.5%	+12.8% +0.3pt
Other revenue	45.0	-	-
Other expenses	-1.7	-0.2	-88.1%
<b>Operating profit</b> (% of revenue)	<b>80.2</b> <b>41.1%</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>30.2</b>	<b>+3.5%</b>
<b>Core ROE</b>	<b>12.4%</b>	<b>11.4%</b>	<b>-1.0pt</b>
<b>Net profit for the year</b>	<b>53.4</b>	<b>25.3</b>	<b>-52.6%</b>
<b>ROE</b>	<b>22.6%</b>	<b>9.5%</b>	<b>-13.1pt</b>

Currency rates	FY15 Actual	FY16 Forecast
US \$	JPY 120.45	JPY 105.00
Euro	JPY 132.46	JPY 115.00
CNY	JPY 19.05	JPY 15.00

# 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.

# Japan: Trends & Competition in Ophthalmics

		Var. (YoY)*		Santen Share*	Santen Major Products
		Market	Santen		
Ophthalmology Total	FY2015	+7.3%	+17.6%	44.0%	-
	Q3 FY2016	-0.9%	+2.8%	45.5%	
Anti-glaucoma	FY2015	+6.5%	+8.4%	32.6%	<i>Cosopt, Tapros, Timoptol/XE, Trusopt, Rescula, Tapcom, Detantol</i>
	Q3 FY2016	+1.4%	+0.2%	32.3%	
Cornea / Dry Eye	FY2015	+4.9%	+1.4%	63.4%	<i>Hyalein, Diquas</i>
	Q3 FY2016	-1.9%	-3.2%	62.7%	
Anti-infection	FY2015	-2.5%	-10.1%	49.8%	<i>Cravit, Tarivid</i>
	Q3 FY2016	-11.4%	-21.6%	44.5%	
Anti-allergy	FY2015	+5.7%	+19.5%	36.3%	<i>Alesion, Livostin, Alegysal</i>
	Q3 FY2016	+8.5%	+28.9%	43.4%	
Anti-VEGF	FY2015	+20.9%	+62.7%	65.7%	<i>Eylea</i>
	Q3 FY2016	-1.0%	+11.6%	72.2%	

\*Value-based

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IMS-JPM 2014-16  
Santen analysis based on IMS data  
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# Status of Research & Development Q3 FY2016



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

Senior Corporate Officer

Chief Scientific Officer (CSO)

Head of Global Research & Development

# Pipeline / Product Development Status (1)

As of February 7, 2017

Global

JP (Asia)

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						
				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	omidenepag isopropyl	US						
				JP			P2b/3			
	DE-090	Calcium antagonist	lomerizine HCl	JP						
	DE-126	FP/EP3 receptors dual agonist	sepetaprost	US						
	DE-128	MIGS* device	<i>InnFocus MicroShunt</i>	US						
Euro										

\*MIGS: Micro-invasive glaucoma surgery

# Pipeline / Product Development Status (2)

As of February 7, 2017

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>	Euro						
				US						
				KR						
				Asia					★	Approved in Thailand
	DE-089	P2Y <sub>2</sub> receptor agonist	diquafosol sodium	CN						
				Asia						
Retinal/ uveal disease	DE-109	mTOR inhibitor	sirolimus injection	Euro						Preparing to file
				JP						
				US						Preparing to file
				Asia						
	DE-120	VEGF/PDGF inhibitor	TBD	US						
DE-122	Anti-endoglin antibody	carotuximab	US		P1/2					
Allergy	Vekacia	Immuno suppression /cationic emulsion	ciclosporin	Euro				★		Filed

★ Changes from previous announcement

# Future Development and Regulatory Milestones

As of February 7, 2017

<b>DE-117</b>	Q2/Q3 FY17 Filing in Japan	
<b>DE-126</b>	Q1/Q2 FY17 P2b start	
<b>DE-128 (MicroShunt)</b>	Calendar 2018-2019 P2/3 Completion	Calendar 2020-2021 Launch in US
<b>DE-109</b>	~Mar 2017 Filing in US	Jan~Jun 2018 Launch in US
	2 <sup>nd</sup> half of FY17 Re-filing in EU (After filing in US)	
<b>DE-120</b>	FY2016 P2a Completion	
<b>DE-122</b>	FY2017 P1/2 Completion	

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# **Reference: Topline Results of SAKURA Program**

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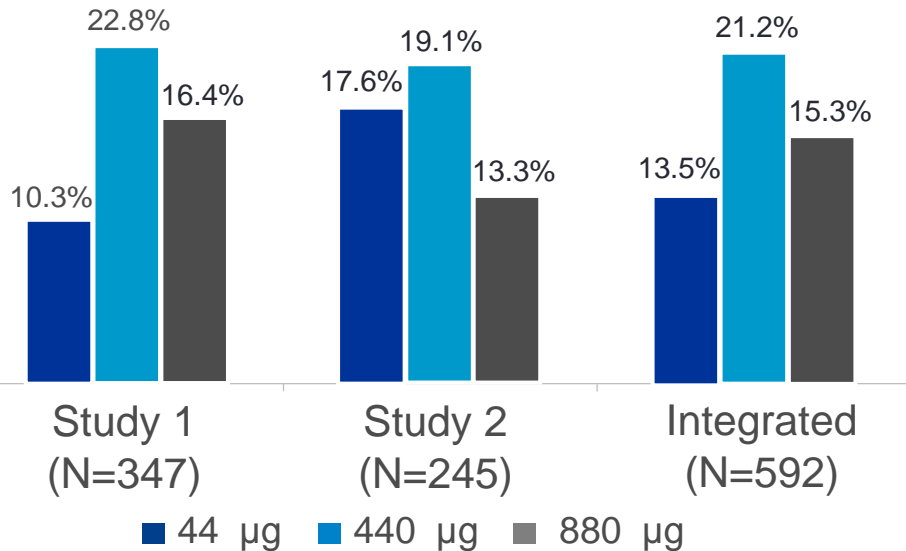
# DE-109: Candidate for Unmet Medical Need of Uveitis

**SAKURA Program Supports Benefit-Risk Profile of Sirolimus Injection, with 440 µg as Optimal Dose for Treatment of Non-Infectious Uveitis of Posterior Segment**

## Reduction or Elimination of Corticosteroids (≤5 mg/day)

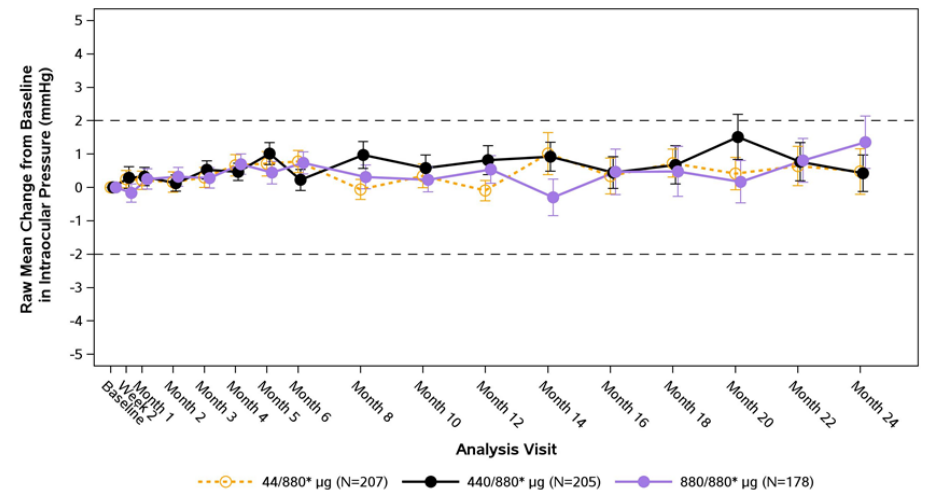
**VH 0 Response, Intent to Treat (ITT) Population P-value (440 µg vs. 44 µg)**

**P = 0.010      P = 0.783      P = 0.038**



Tapering of Corticosteroid for Intent-to-Taper Patients	44 µg N=32	440 µg N=46	880 µg N=32
Baseline mean dose, mg/day	24.2	<b>26.2</b>	20.74
Tapering success (n)	(22) 68.8%	<b>(32) 69.6%</b>	(22) 68.8%
Tapering success and VH 0/0.5+ (n)	(9) 40.9%	<b>(20) 62.5%</b>	(10) 45.5%

## Minimal Impact on IOP post Sirolimus Intravitreal Injection



\*Patients received 44, 440 or 880 µg double-masked dose for the first six months, and then all patients received 880 µg open-labeled dose.

# 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.

**Santen**

*A Clear Vision For Life*