

Investor Meeting on Q1 FY2017 Results



Kazuo Koshiji

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

August 1, 2017

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.

To Become a Specialized Pharmaceutical Company with a Global Presence

~2013

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

- Strengthen Japan business
- Completed preparation for business expansion in Asia/EMEA

2014~2017

Overseas sales:
30% of total sales

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

2020

Become Global Top 3
Overseas sales:
40~50% of total sales

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

Current Mid-Term Plan (MTP)

Plan

Results

Product Development

- Transform product development to realize enhanced productivity and achieve sustained growth
- Active investment in sustainable growth

- Approval, Launch: *Tapcom, Ikervis*
- Development: progress of DE-109, 117, 122
- Licensing, Acquisition: DE-126, 128

Business Expansion

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

- Raised new products sales ratio in Japan: from 44% (FY13) to 71% (FY16)
- Growth in market share of OTC products in Japan
- Strengthened internal sales platform in Asian countries
- Grew the number EMEA countries with sales

Organization and Talent

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

- Introduced new HR appraisal system
- Held training aimed at nurturing the next generation of employees / managers

Q1 FY2017 Financial Results ended June 30, 2017

Q1 FY2017 Financial Highlights

Double-digit growth in revenue and profit

Higher revenue and profit as revenue growth both in Japan and overseas more than offset higher SG&A and R&D expenses

◆ Revenue: **55.9 bil yen, up 11.9% (YoY)**

- Japan pharma 34.8 bil yen (+5.4%), OTC 4.0 bil yen (+35.3%)
- Asia 7.3 bil yen (+21.4%), EMEA 8.7 bil yen (+29.1%)

◆ Operating profit: **Core basis 13.7 bil yen, up 10.9% (YoY); IFRS 12.1 bil yen, up 11.5% (YoY)**

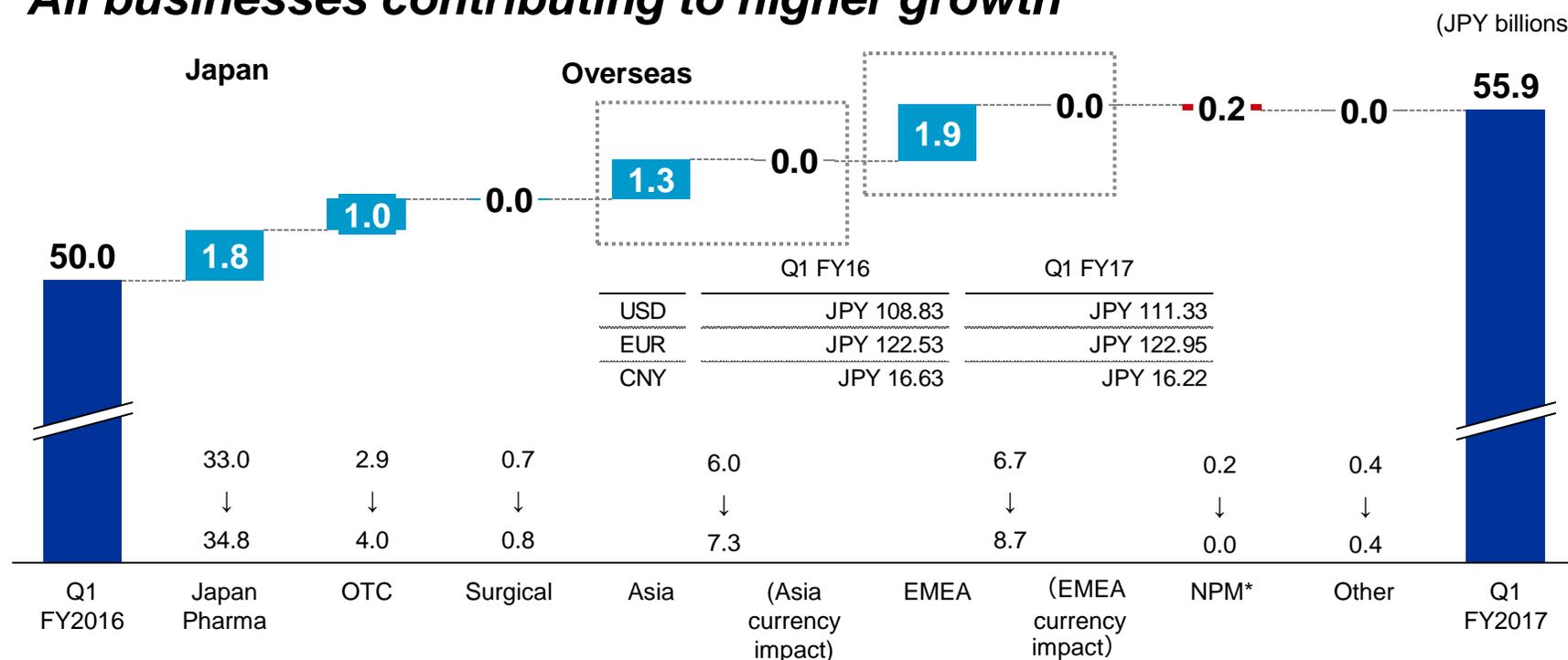
(JPY billions)	FY2016		FY2017		
	Q1 actual	Q1 actual	YoY	Full year forecast	vs FY forecast
Core basis					
Revenue	50.0	55.9	11.9%	218.0	25.7%
COGS	-18.4	-21.6	17.3%	-81.0	26.6%
Gross margin	31.6	34.4	8.7%	137.0	25.1%
SGA	-14.1	-15.1	6.8%	-68.0	22.1%
R&D expenses	-5.2	-5.6	8.8%	-25.0	22.5%
OP	12.4	13.7	10.9%	44.0	31.1%
Net profit	8.8	10.0	14.0%	31.2	32.0%
IFRS					
OP	10.8	12.1	11.5%	37.4	32.2%
Net profit	7.3	8.9	21.7%	26.8	33.3%
USD	108.83	111.33	-2.3%	110.00	-1.2%
EUR	122.53	122.95	-0.3%	120.00	-2.5%
CNY	16.63	16.22	2.5%	16.50	1.7%

+: JPY appreciation, -: JPY depreciation

Q1 FY2017 Revenue



All businesses contributing to higher growth



Japan business

Japan pharma	Revenue growth of new products, mainly <i>Eylea</i> , <i>Alesion</i> , <i>Diquas</i> , helped boost overall revenue +5.4%
OTC	In addition to inbound sales, good progress in new products and sales promotion for Japanese consumers added to +35.3% revenue growth
Surgical	+4.7% growth supported by sales collaborations with pharma business

Overseas business

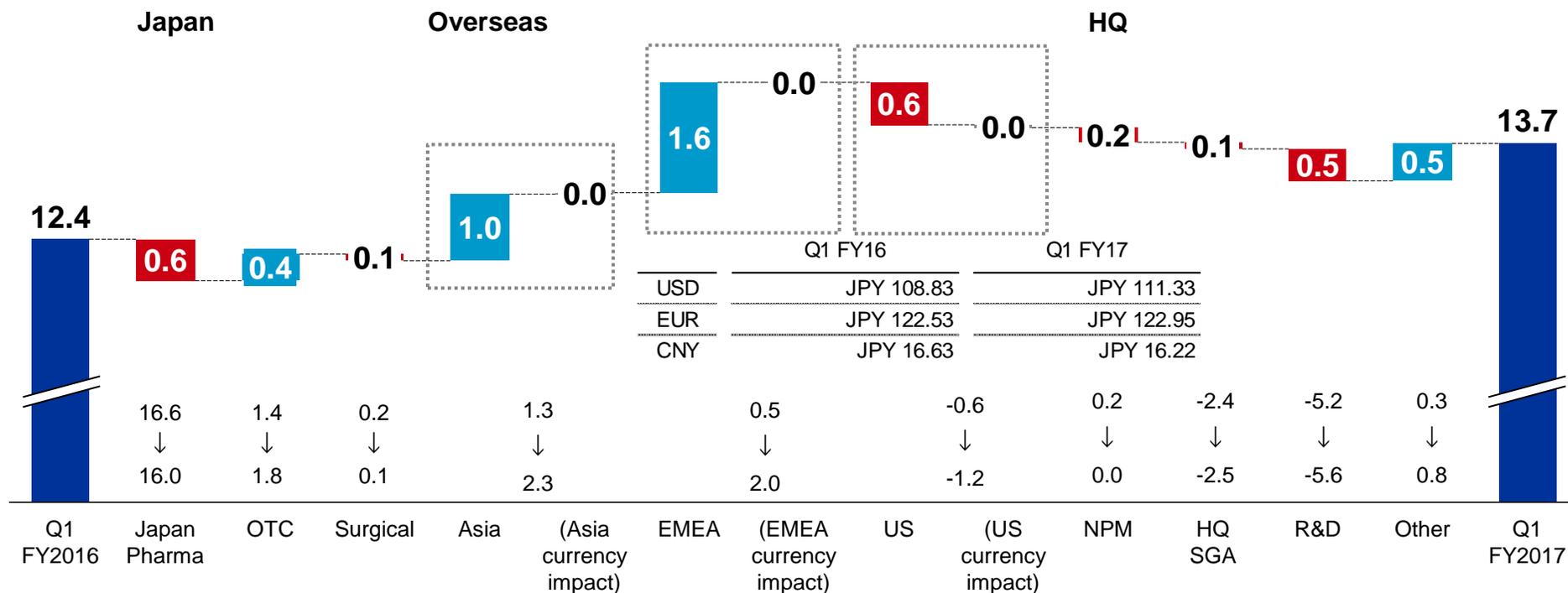
Asia	Overall growth of 21.4% (JPY base) due to continuous growth in China and S. Korea, and significant progress in ASEAN market (+75.9%, JPY base)
EMEA	Growth of acquired MSD products and <i>Ikervis</i> helped boost revenue +29.1% (JPY base)
NPM	No NPM from MSD with completion of MA transfers

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

Q1 FY2017 Core Operating Profit

High contributions from overseas operations

(JPY billions)



Japan business

Japan pharma Decline reflects transitory factor that lowered COGS in same period of prior year

OTC Overall higher with revenue growth

R&D expenses Higher expenses due to pipeline progress (DE-117, 122, 126, 128)

Overseas business

Asia Overall higher with revenue growth and expense management

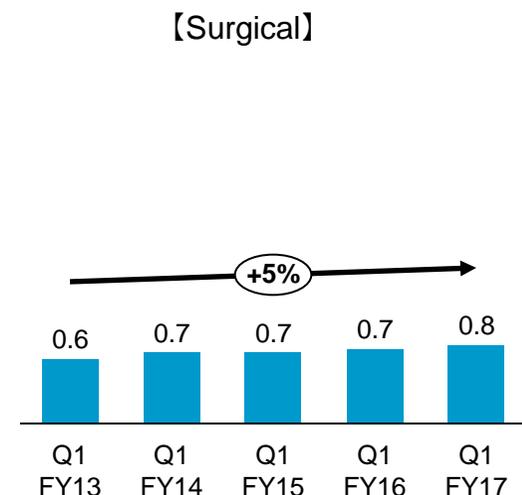
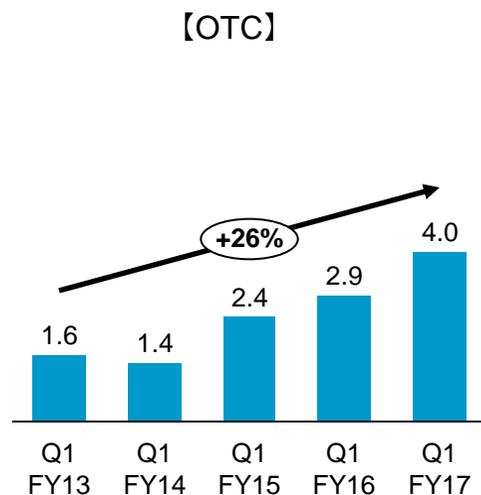
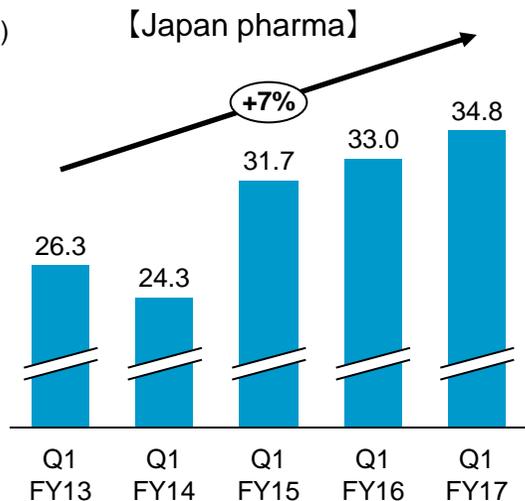
EMEA

US Preparation expenses for US entry increased

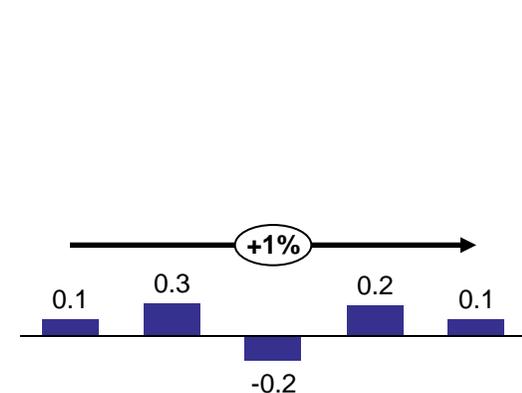
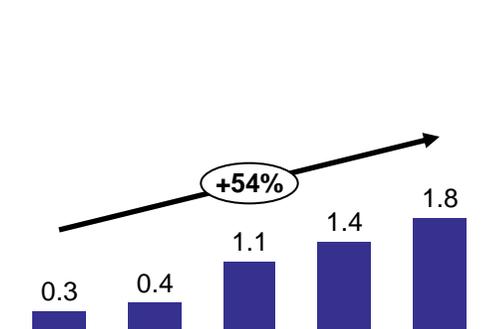
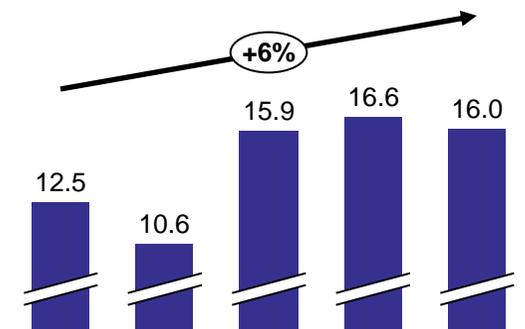
Performance by Business (Japan)

(JPY billions, CAGR%)

Sales



OP
before R&D



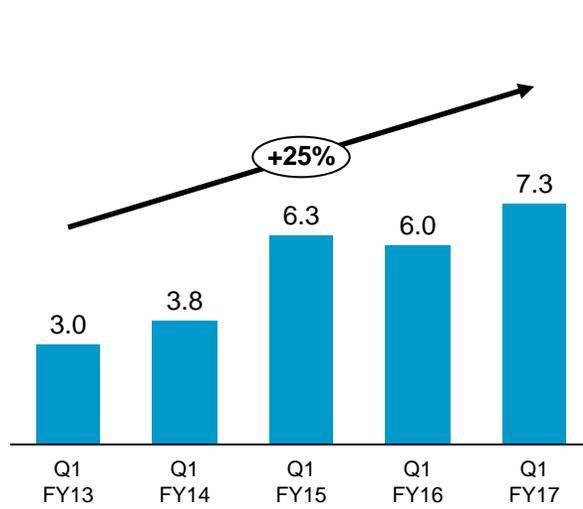
Increase in revenue on sales of new products, such as *Eylea*; Removing transitory factor in Q1 FY16, Q1 FY17 OP increased YoY; Going forward in FY17 efforts being made to increase profit through sales from higher margin products like *Alesion*

In addition to *FX* (inbound sales and domestic promotion), *Beauteye* (inbound sales), good progress in new products launched in prior autumn

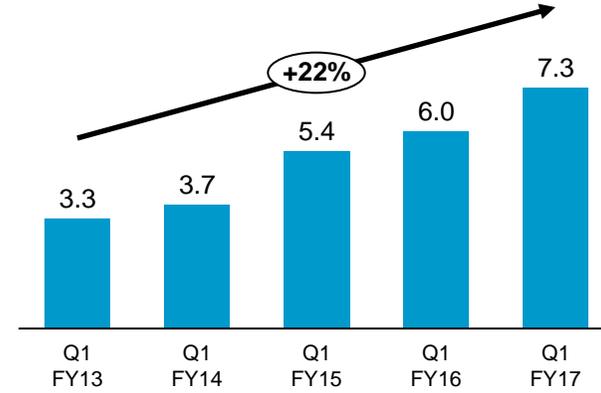
Performance by Business (Asia)

(JPY billions, CAGR%)

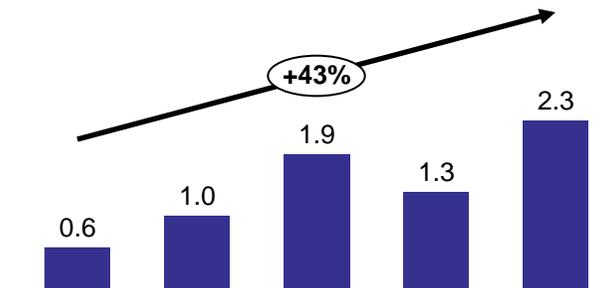
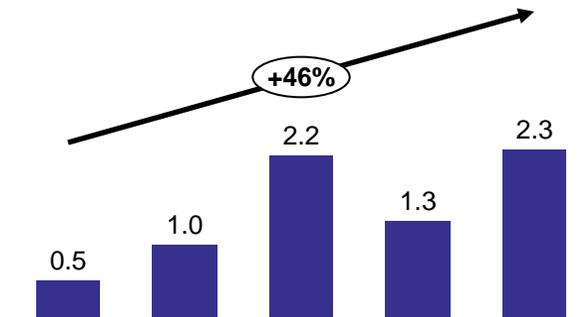
Sales



Local currency base
(Conversion with FY2017 forecast rate for all FY)



OP before R&D

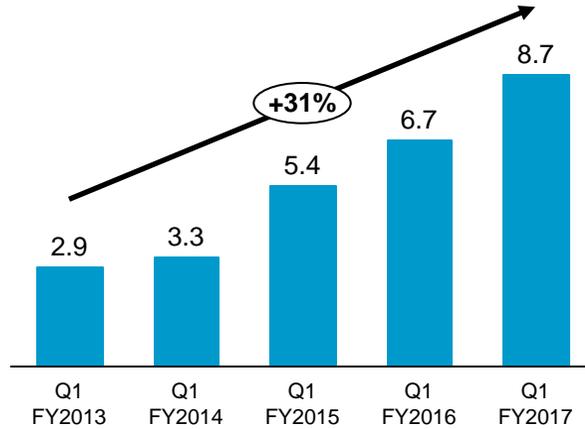


Good market penetration of Santen products particularly in China, S. Korea and Vietnam and other countries;
Business platform enhancements proceeding well – striving for continuous growth with gross margin improvement exceeding additional investments

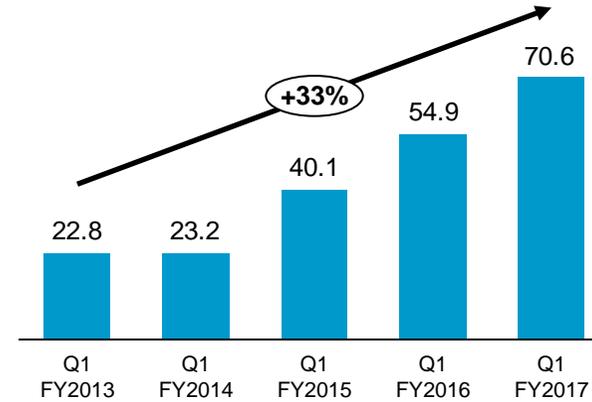
Performance by Business (EMEA)

(JPY billions, CAGR%)

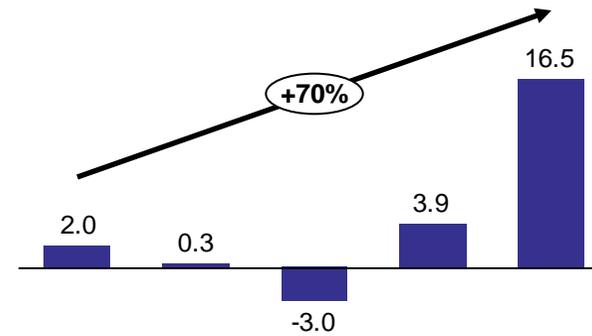
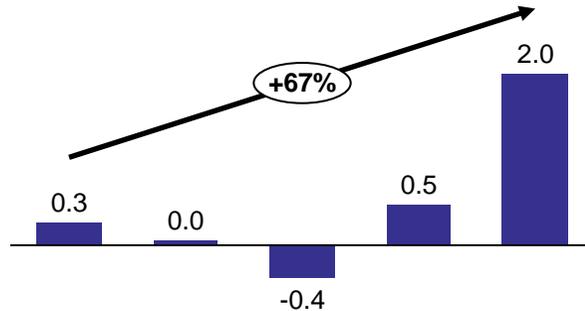
Sales



Local currency (EUR millions)



OP before R&D



Continuous good market penetration of both Santen and MSD products in glaucoma area (YoY: *Cosopt* +7.7%, *Tapros* +20.6%, *Trusopt* +12.4%);
Ikervis growth (YoY: +190.9%) above expectation at start of FY17

FY2017 P&L Forecast (No change from May 10)

Core basis **Revenue:** Growth forecast in all businesses, particularly overseas
Operating profit: Increased spending on future growth (listed below), while also strengthening cost control systems. OP is forecast to increase.

- Investments in pipeline progress and the maximization of product value
- Investments in US entry preparation

IFRS Amortization on intangible assets associated with products will change substantially; non-recurring items; revenue and core operating profit to grow in proportion

(JPY billions)	FY2016	FY2017	
	Actual	Forecast	YoY
Core basis			
Revenue	199.1	218.0	9.5%
COGS	-75.0	-81.0	8.1%
SGA	-61.7	-68.0	10.3%
R&D expenses	-22.8	-25.0	9.7%
Operating profit	39.7	44.0	10.9%
Net profit	28.7	31.2	8.8%
ROE	11.2%	12.3%	1.1pt
IFRS			
Operating profit	32.5	37.4	15.2%
Net profit	23.1	26.8	16.2%
ROE	9.0%	10.6%	1.6pt
USD	108.64	110.00	
EUR	118.96	120.00	
CNY	16.14	16.50	

FY2017 Dividends Forecast (No change from May 10)

Annual Dividends

FY2016:

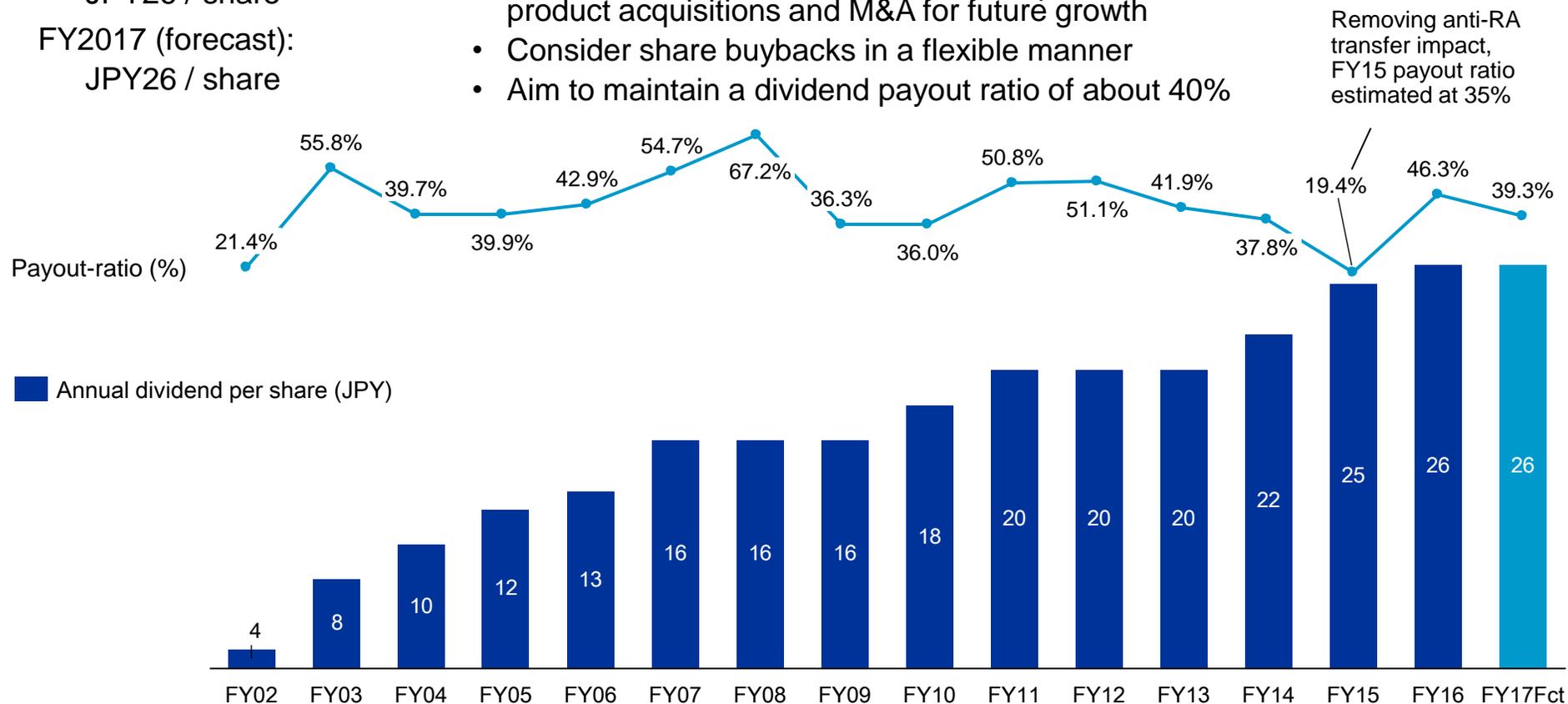
JPY26 / share

FY2017 (forecast):

JPY26 / 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%



Removing anti-RA transfer impact, FY15 payout ratio estimated at 35%

Share buyback (b yen)	3.2	-	2.6	-	-	4.8	-	-	-	-	13.7	-	-	-	12.3	-
Total return	59.1%	55.8%	62.8%	39.9%	42.9%	92.3%	67.2%	36.3%	36.0%	50.8%	134.4%	41.9%	37.8%	19.4%	100.2%	39.3%

* 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.

Reference

Q1 FY2017 Profit / Loss

(JPY billions)	Q1 FY16		Q1 FY17		YoY
	Actual	vs Revenue	Actual	vs Revenue	
Revenue	50.0		55.9		11.9%
COGS	-18.4	-36.8%	-21.6	-38.6%	17.3%
SGA expenses	-14.1	-28.2%	-15.1	-26.9%	6.8%
R&D expenses	-5.2	-10.3%	-5.6	-10.0%	8.8%
Amortization on intangible assets associated with products	-1.6	-3.2%	-1.7	-3.0%	4.4%
Other income	0.1	0.2%	0.1	0.1%	-24.8%
Other expenses	-0.1	-0.1%	-0.1	-0.1%	4.3%
Operating profit (IFRS)	10.8	21.6%	12.1	21.5%	11.5%
Finance income	0.4	0.9%	0.5	0.8%	5.6%
Finance expenses	-1.0	-2.0%	-0.3	-0.5%	-69.8%
Profit before tax	10.3	20.5%	12.2	21.8%	19.1%
Income tax expenses	-2.9	-5.9%	-3.3	-5.9%	12.4%
<i>Actual tax ratio</i>	28.6%		27.0%		-1.6pt
Net profit (IFRS)	7.3	14.6%	8.9	15.9%	21.7%
Core operating profit	12.4	24.7%	13.7	24.5%	10.9%
Core net profit	8.8	17.5%	10.0	17.9%	14.0%

- OTC +0.3 bil yen,
- Asia +0.3 bil yen, EMEA -0.1 bil yen, US +0.6 bil yen
- HQ admin +0.1 bil yen

- Decreased actual tax ratio due to increase of profit before tax and tax incentive on R&D expenses at HQ

	Q1 FY16	Q1 FY17
USD	JPY 108.83	JPY 111.33
EUR	JPY 122.53	JPY 122.95
CNY	JPY 16.63	JPY 16.22

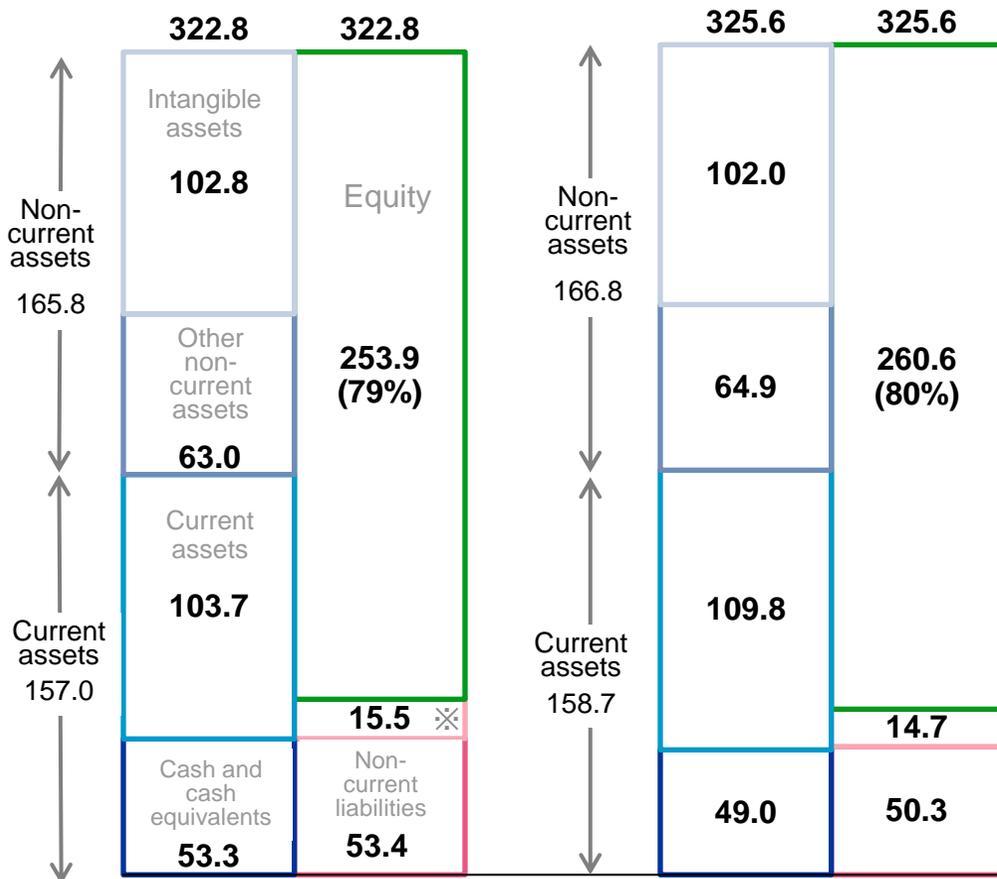
Q1 FY2017 Financial Position

March 31, 2017

June 30, 2017

(JPY billions)

Increase of trade receivables due to cash receipt timing, and decrease of cash due to tax and dividend payments



	March 31, 2017	June 30, 2017	Change
Non-current assets	165.8	166.8	1.1
Property, plant and equipment	28.6	28.6	0.1
Intangible assets	102.8	102.0	-0.8
Financial assets	29.9	31.8	1.9
Other	4.5	4.5	-0.1
Current assets	157.0	158.8	1.7
Inventories	28.5	27.0	-1.5
Trade and other receivables	71.0	77.1	6.1
Cash and cash equivalents	53.3	49.0	-4.3
Other	4.2	5.7	-1.4
Equity	253.9	260.6	6.8
Non-current liabilities	15.5	14.7	-0.8
Financial liabilities	7.6	6.1	-1.5
Deferred tax liabilities	2.6	3.6	1.0
Other	5.3	4.9	-0.3
Current liabilities	53.4	50.3	-3.1
Trade and other liabilities	23.9	23.7	-0.2
Other financial liabilities	17.6	14.7	-2.9
Income tax payable	3.3	3.2	0.0
Other	8.6	8.6	0.0

※ Current liability

Q1 FY2017 Segment Revenue

Q1 FY17 Segment Revenue

(JPY billions)	Japan		Overseas		Total	
	Revenue	YoY	Revenue	YoY	Revenue	YoY
Pharmaceuticals	39.0	7.8%	16.3	24.0%	55.2	12.1%
Prescription	35.0	5.5%	16.2	23.8%	51.2	10.7%
Ophthalmic	34.9	5.5%	16.1	26.8%	50.9	11.4%
Others	0.2	16.2%	0.1	-64.9%	0.3	-44.2%
OTC	3.9	33.1%	0.1	154.1%	4.0	34.1%
Others	0.7	1.5%	0.0	-76.3%	0.7	-2.7%
Medical devices	0.6	-1.7%	0.0	-13.4%	0.6	-1.8%
Others	0.1	22.1%	0.0	-86.8%	0.1	-6.8%
Total	39.7	7.7%	16.3	23.7%	55.9	11.9%
Sales ratio	70.9%		29.1%			

Capital Expenditures/Depreciation & Amortization



(JPY billions)	FY2016		FY2017		
	Q1	Full year	Q1		Full year
	Actual	Actual	Actual	YoY	Forecast
Capital expenditures	1.6	5.2	1.0	-37.6%	7.7
Depreciation and amortization*	0.8	3.5	1.0	24.8%	3.8
Amortization on intangible assets associated with products	1.6	6.4	1.7	4.4%	6.6
Intangible assets	1.3	5.4	1.4	4.7%	5.6
-Merck products					
Intangible assets	0.2	0.7	0.2	0.0%	0.7
-Ikervis					

* Excludes amortization on intangible assets associated with products and long-term prepaid expenses

Market Overview of Prescription Ophthalmic in Japan

JPY billions	Q1FY16						Q1FY17					
	Santen		Market		Santen share		Santen		Market		Santen share	
	Value	Change (YoY)	Value	Change (YoY)			Value	Change (YoY)	Value	Change (YoY)		
Total	38.9	6.7%	86.6	1.2%	44.9%	#1	41.4	6.5%	90.4	4.3%	45.8%	#1
Anti-glaucoma	9.4	2.6%	29.2	4.0%	32.3%	#1	9.2	-2.2%	29.3	0.5%	31.4%	#1
Anti-VEGF	13.2	22.4%	18.5	-1.3%	71.2%	#1	15.1	14.6%	21.1	14.1%	71.5%	#1
Corneal/dry eye	7.1	-2.6%	11.4	-0.8%	62.8%	#1	7.3	3.0%	11.8	3.5%	62.5%	#1
Anti-allergy	3.4	26.6%	8.2	14.5%	41.8%	#1	4.1	20.9%	8.9	8.8%	46.4%	#1
Anti-infection	1.8	-19.4%	3.9	-9.6%	45.5%	#1	1.5	-13.0%	3.7	-4.2%	41.3%	#1

Jul 1, 2016 - Jun 30, 2017

	Santen		Market		Santen share	
	Value	Change (YoY)	Value	Change (YoY)		
Total	159.8	3.0%	349.3	0.2%	45.8%	#1
Anti-glaucoma	36.6	-1.1%	114.5	0.6%	31.9%	#1
Anti-VEGF	55.9	8.8%	77.1	3.8%	72.5%	#1
Corneal/dry eye	28.7	-1.6%	45.9	-0.8%	62.6%	#1
Anti-allergy	16.9	23.5%	38.5	4.5%	44.0%	#1
Anti-infection	6.2	-20.2%	14.4	-9.9%	43.0%	#1

Status of Research & Development Q1 FY2017



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

Senior Corporate Officer

Chief Scientific Officer (CSO)

Head of Global Research & Development

Future Development and Regulatory Milestones

As of August 1, 2017

	Development status*	Indication	Development region: milestone*
DE-117	P2b/3	Glaucoma/ ocular hypertension	Japan: Q2/Q3 FY17 filing
DE-126	<u>P2b</u>	Glaucoma/ ocular hypertension	<u>US/Japan: Jan~Jun 2018 P2b completion</u>
DE-128 (<i>MicroShunt</i>)	P2/3	Glaucoma/ ocular hypertension	US: calendar 2018~2019 P2/3 completion, calendar 2020~2021 launch
DE-109 (IVT sirolimus)	Filing Accepted	Uveitis	US: Dec 24, 2017 PDUFA date; Jan~Jun 2018 launch
	P3		EU: 2 nd half of FY17 re-filing
DE-122	<u>P2a</u>	Wet AMD	US: <u>Jan~Jun 2019 P2a completion**</u> , FY17 P1/2 completion

Vekacia (*Verkazia*): In July 2017 EMA's CHMP adopted positive opinion recommending marketing authorization

*Updated information is underlined, **Conducting in the Philippines

Reference

Pipeline / Product Development Status (1)

As of August 1, 2017

Glaucoma/ ocular hypertension

		P1	P2	P3	Reg review	Launch	Current status or updated information
DE-117 EP2 receptor agonist	US	▶					
	JP	▶ P2b/3					P2b/3 on-going
	Asia	▶					P3 on-going
DE-126 FP/EP3 dual receptor agonist	US	▶ P2b					Started P2b in Jul 2017
	JP	▶ P2b					
DE-128 <i>InnFocus MicroShunt</i>	US	▶ P2/3					P2/3 on-going
	Europe	▶					

Pipeline / Product Development Status (2)

As of August 1, 2017

Kerato-conjunctival disease		P1	P2	P3	Reg review	Launch	Current status or <u>updated information</u>
DE-089 <i>Diquas</i>	CN	[Progress bar: P1 to Reg review]					Filed in Jan 2012
DE-114A Epinastine HCl (high dose)	JP	[Progress bar: P1 to P3]					<u>Started P3 in May 2017</u>
Cyclokat <i>Ikervis/ciclosporin</i>	US	[Progress bar: P1 to P2]					
	Asia	[Progress bar: P1 to Reg review]					Approved since Nov 2016
	Others	[Progress bar: P1 to Reg review]					Filed in Canada in Apr 2016
Vekacia <i>Verkazia/ciclosporin</i>	Europe	[Progress bar: P1 to Reg review]					Filed and granted Priority Review status in Dec 2016 and <u>received positive CHMP opinion in Jul 2017</u>

Retinal/ uveal disease		P1	P2	P3	Reg review	Launch	Current status or <u>updated information</u>
DE-109 IVT sirolimus	US	[Progress bar: P1 to Reg review]					Filed in Feb 2017
	JP	[Progress bar: P1 to P3]					
	Europe	[Progress bar: P1 to P3]					Preparing to re-file
	Asia	[Progress bar: P1 to Reg review]					Filed in Apr 2015
DE-122 Anti-endoglin antibody	US	[Progress bar: P1 to P2a]					<u>Started P2a in Jul 2017</u>

See Santen Consolidate Results for the 1st Quarter Fiscal 2017 for more details.
 "Asia" above excludes Japan and China.

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 'anten' in a bold, dark blue, sans-serif font. The 'S' and 'a' are connected, with the light blue part of the 'S' overlapping the 'a'.

Santen

A Clear Vision For Life