

# Q1 FY2018 Earnings Conference Call



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August 2, 2018

Santen Pharmaceutical Co., Ltd

# Santen's Values and Mission Statement

Values

天機に参与する

*Tenki ni sanyo suru*<sup>1</sup>

- 1 **“Exploring the secrets and mechanisms of nature in order to contribute to people’s health”**

Santen’s original interpretation of a passage from chapter 22 of *Zhongyong (The Doctrine of the Mean)* by Confucius.

**We think carefully about what is essential, decide clearly what we should do, and act quickly.**

Mission Statement

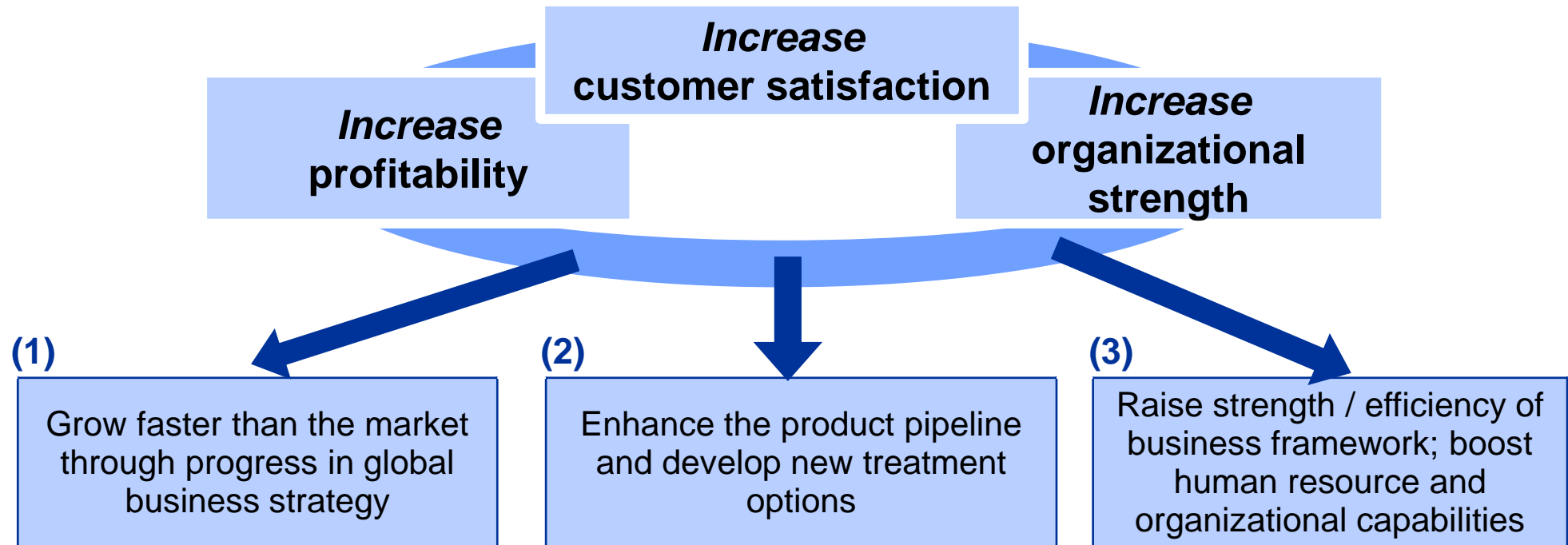
**By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.**

# MTP2020 Fundamental Policy and Strategic Goals

## Fundamental policy

- To become a “Specialized Pharmaceutical Company with a Global Presence”
- Construct a path for sustainable growth beyond FY2020

## Strategic goals



**Responding to the needs of patients and medical professionals worldwide, Santen will achieve reliable growth while sustainably contributing to ophthalmic treatment worldwide**

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# **Q1 FY2018 Financial Results ended June 30, 2018**

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# Q1 FY2018 Financial Overview

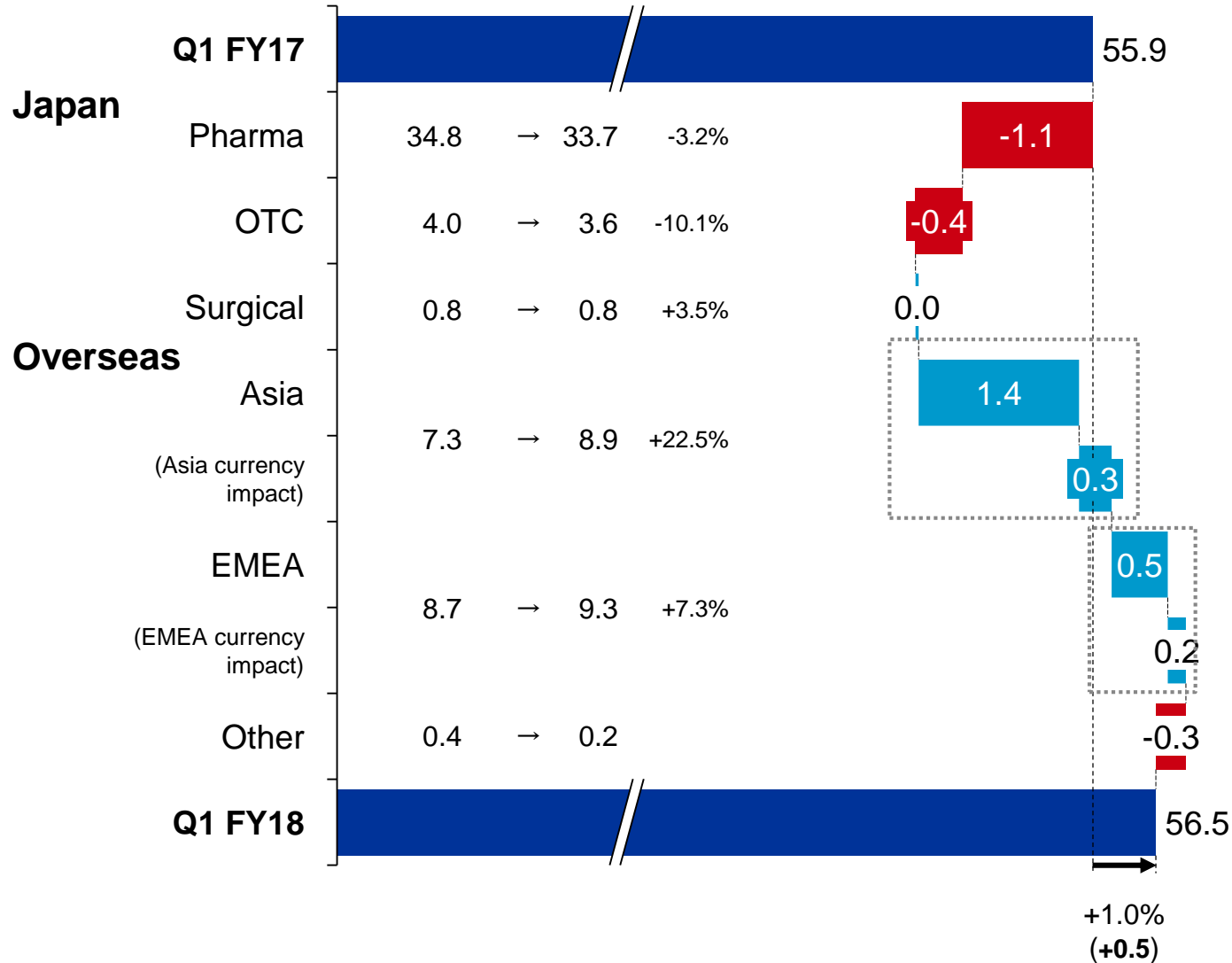
***Achieved revenue growth despite Japan NHI price cuts; profit lower YoY; Results in-line with annual forecast***

<b>Revenue</b>	Higher revenue as overseas business growth offset negative impact from NHI price cuts	
	<b><u>56.5 bil yen</u></b> YoY: <b>+1.0%</b>	
<b>Operating profit</b>	NHI price cuts and transitory positive factor in Q1 of prior year caused lower profit YoY; cost optimization activities implemented to control SGA expenses across businesses; results in-line with annual forecast	
	Core basis <b><u>11.7 bil yen</u></b> YoY: -14.8%	IFRS basis <b><u>10.0 bil yen</u></b> YoY: -16.9%
	<b>SGA</b> 16.2 bil yen	YoY: +7.4%
	<b>R&amp;D</b> 5.6 bil yen	YoY: +0.1%

# Q1 FY2018 Revenue

## Overseas business continued strong growth

(JPY billions)



### Japan business

Japan pharma	Negative impact of NHI price cuts (total impact exceeded -4%) mitigated by revenue growth of <i>Eylea</i> *1 (+6.6%), <i>Diquas</i> (+5.2%)
OTC	Inbound and domestic demand trends stable, though revenue lower by comparison due to sales campaign for <i>Sante FX</i> in Q1 of prior year
Surgical	Promoting sales activities in cooperation with Japan pharma business

### Overseas business

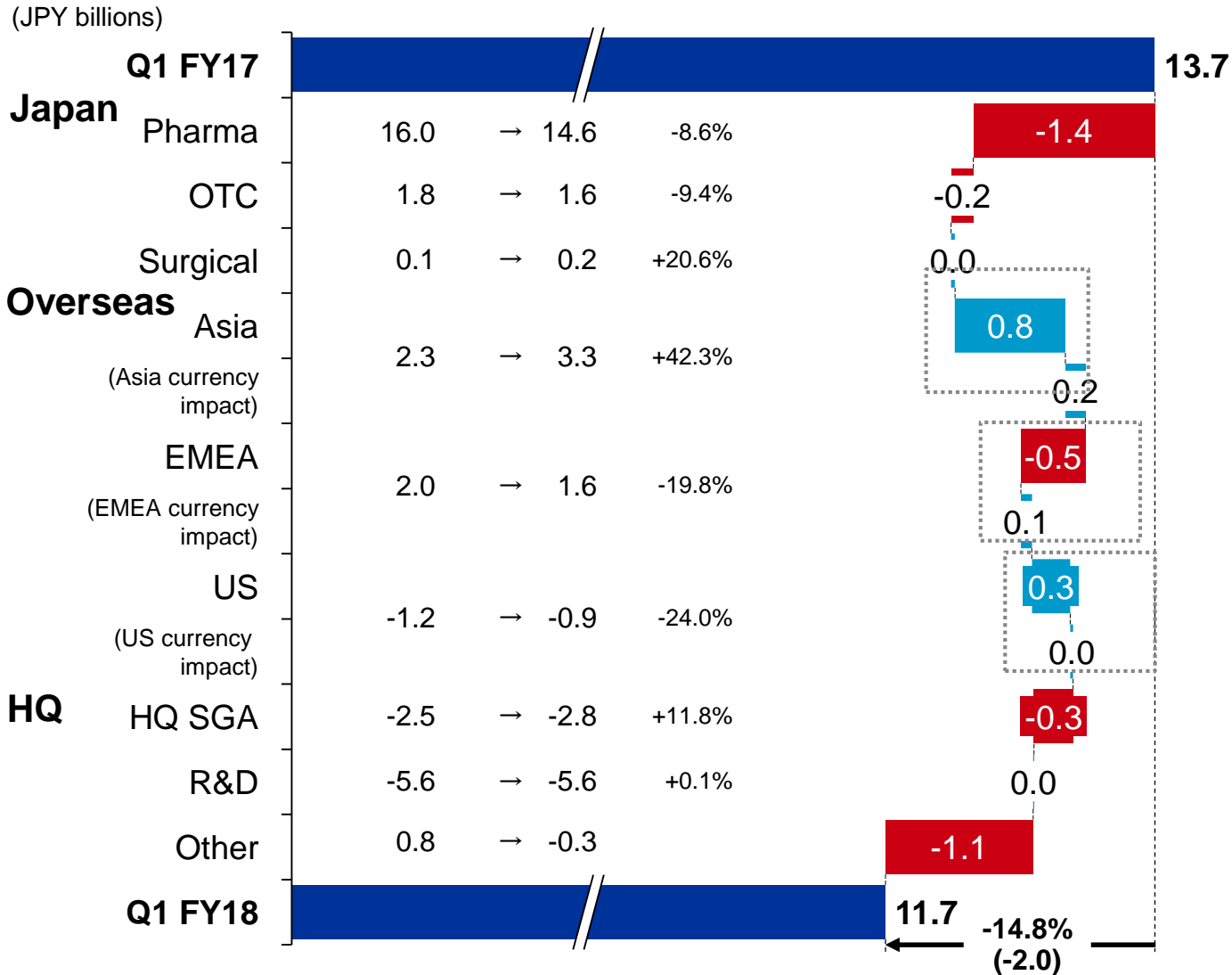
Asia	Continued strong growth especially in China and Korea; China: +32.0%, Korea: +25.2% (JPY)
EMEA	Continued strong growth especially in Italy and Germany with <i>Cosopt</i> , <i>Tapros</i> and <i>Ikervis</i> , though Russia decreased due to transitory factor in prior year Italy: +17.2%, Germany: +8.4%

	Q1 FY17	Q1 FY18
USD	JPY 111.33	JPY 108.87
EUR	JPY 122.95	JPY 129.57
CNY	JPY 16.22	JPY 17.01

*Eylea*\*1: co-promoted product of Bayer Yakuhin, Ltd. (MAH)

# Q1 FY2018 Core Operating Profit

**Cost optimization efforts reduced the negative impact from NHI price cuts; results in-line with annual forecast**



## Japan business

Japan pharma	YoY impact from transitory revenue boost in Q1 of prior year, COGS ratio increase due to NHI price cut and product mix; SGA expenses lower with cost control efforts
OTC	YoY impact with sales campaign boost in Q1 of prior year; SGA expenses lower with cost control efforts

## Overseas business

Asia	Higher with revenue growth and expense management
EMEA	Though good profit recorded in the various countries, profit was temporarily lower, impacted by Russia which experienced demand boost in 1H of prior year
US	Lower mainly with suspension of DE-109 U.S. market launch related expenses

## R&D expenses

Nearly flat on completion of DE-117 clinical trials in Japan, the suspension of DE-109 and cost optimization efforts

	Q1 FY17	Q1 FY18
USD	JPY 111.33	JPY 108.87
EUR	JPY 122.95	JPY 129.57
CNY	JPY 16.22	JPY 17.01

# Performance by Business (Japan)

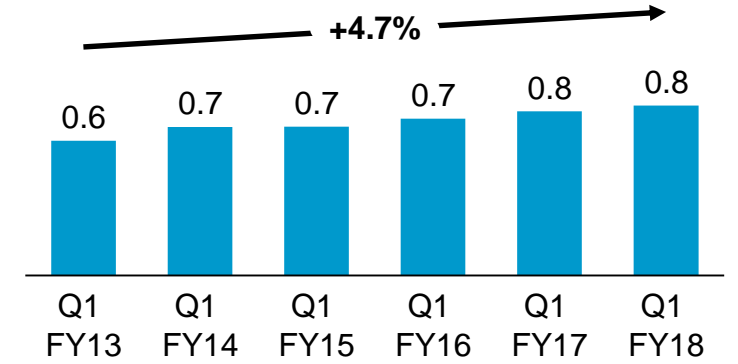
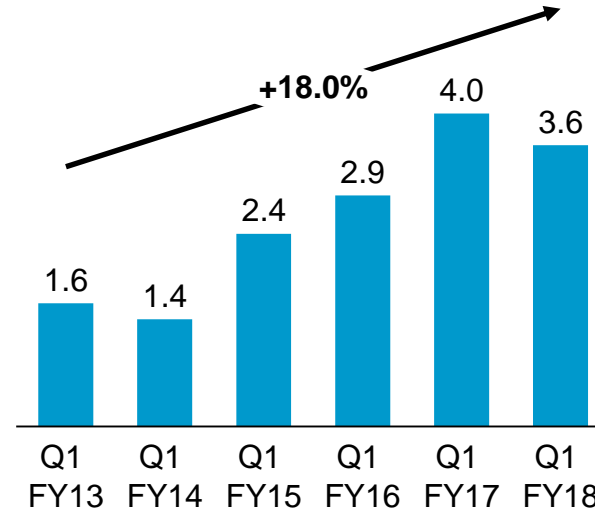
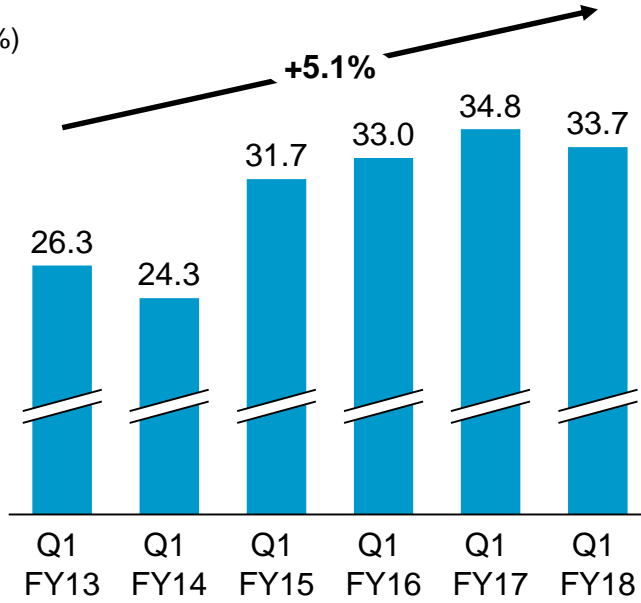
【Japan pharma】

【OTC】

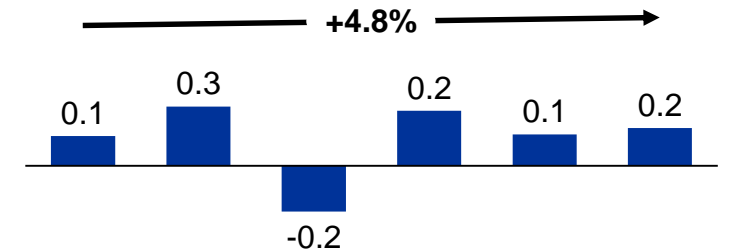
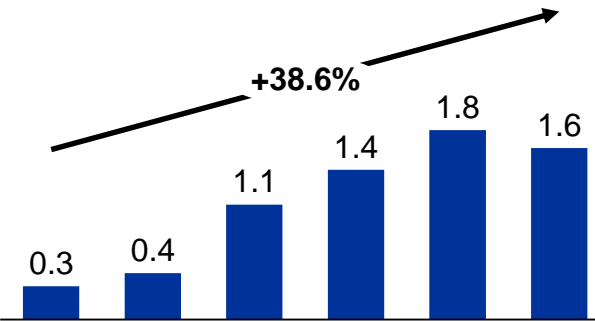
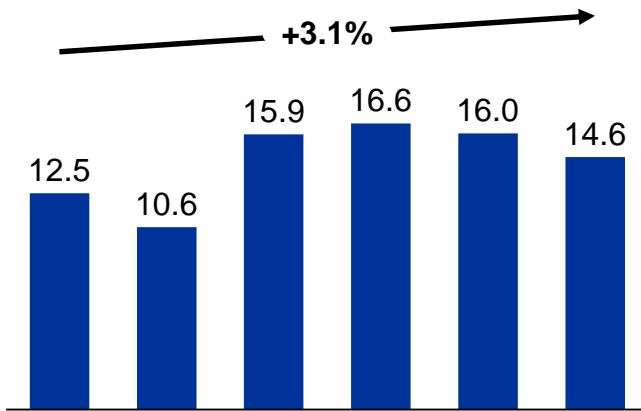
【Surgical】

(JPY billions, CAGR%)

Revenue



OP before R&D

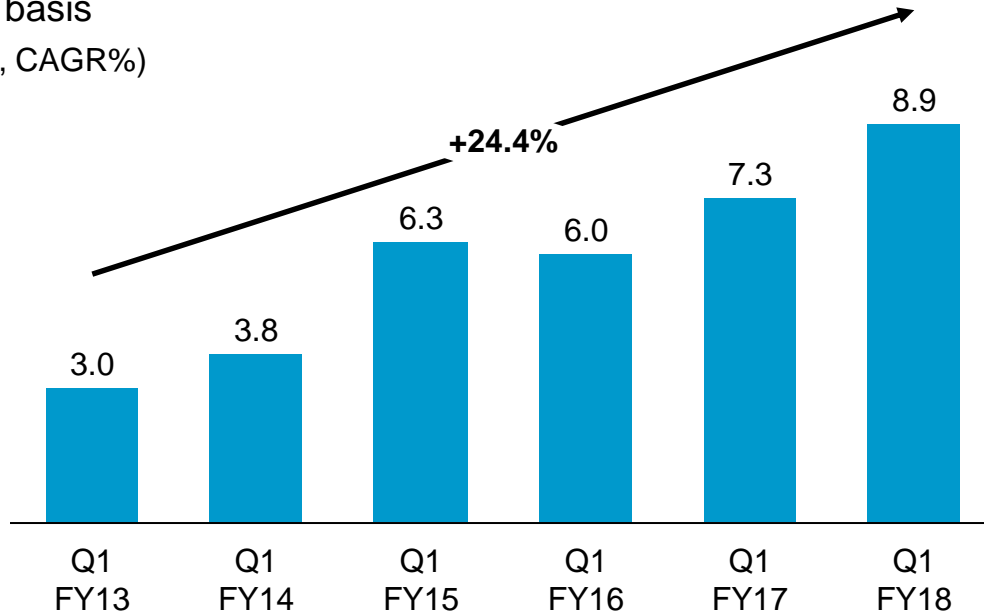




# Performance by Business (Asia)

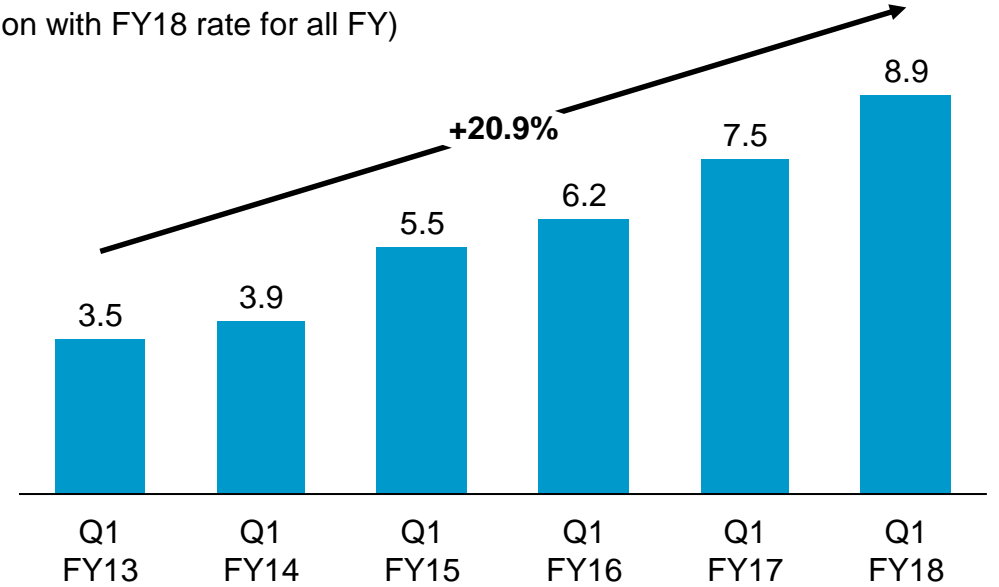
Japan yen basis  
(JPY billions, CAGR%)

Revenue

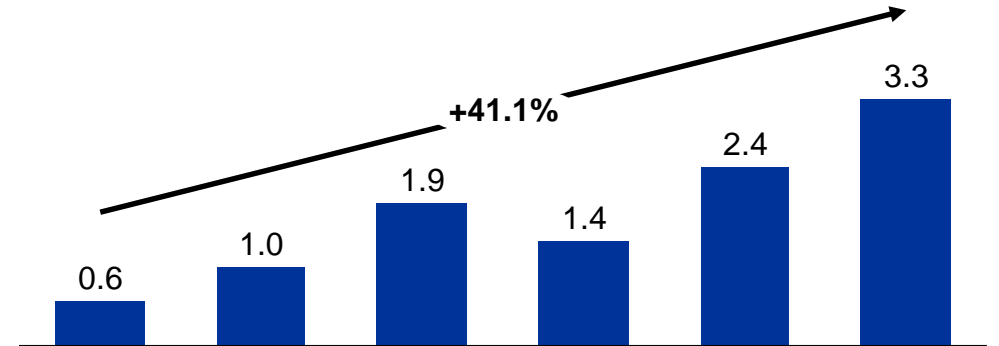
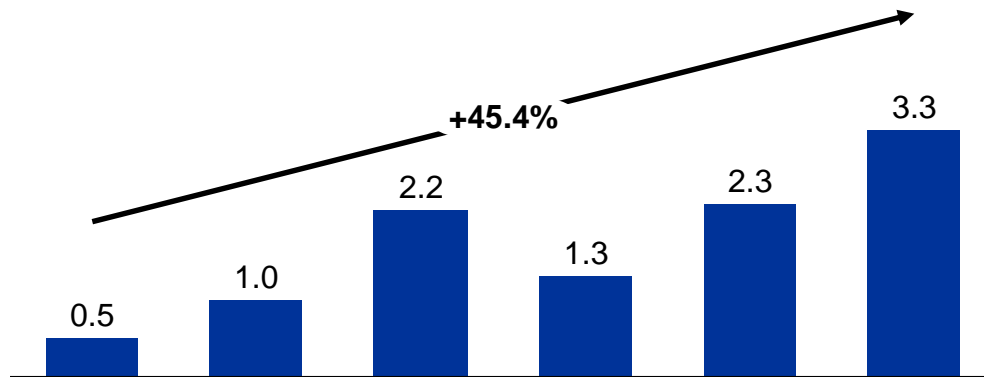


Local currency basis

(Conversion with FY18 rate for all FY)

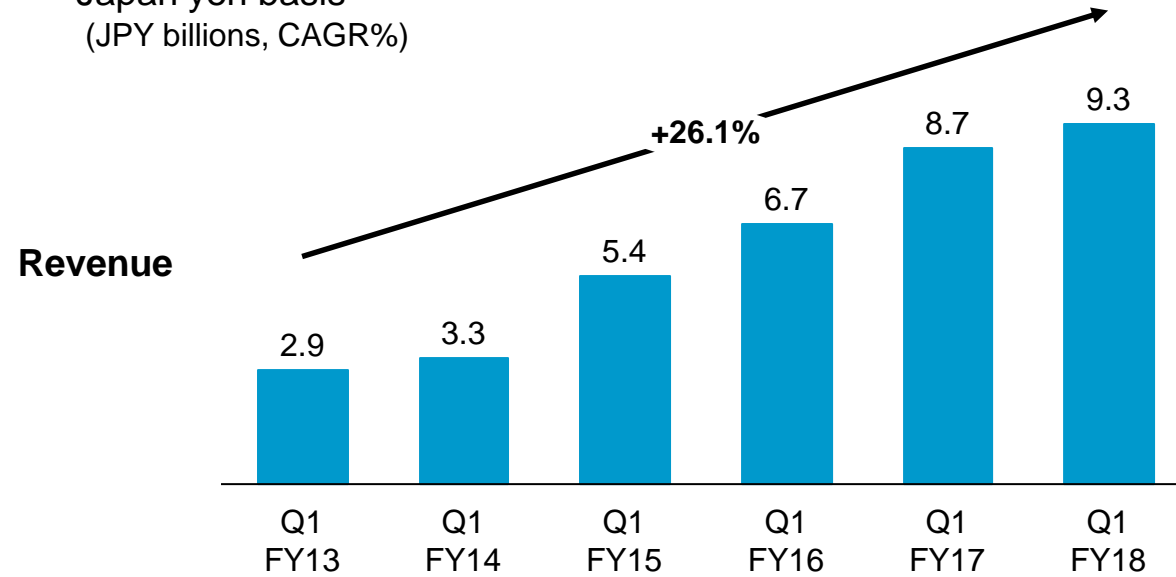


OP  
before R&D

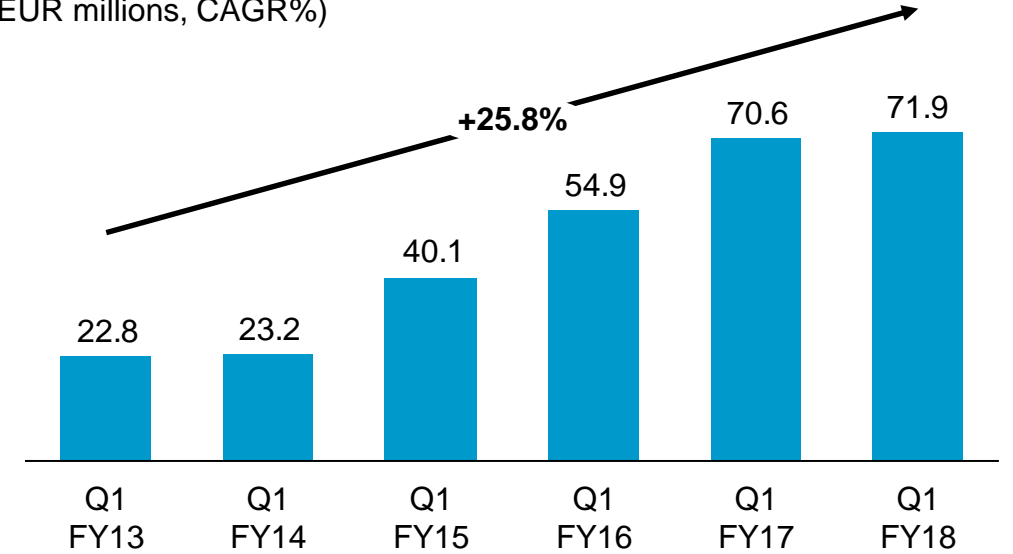


# Performance by Business (EMEA)

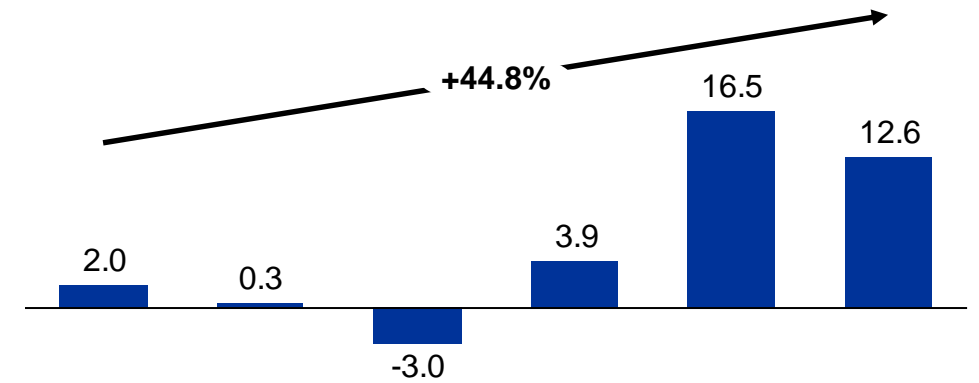
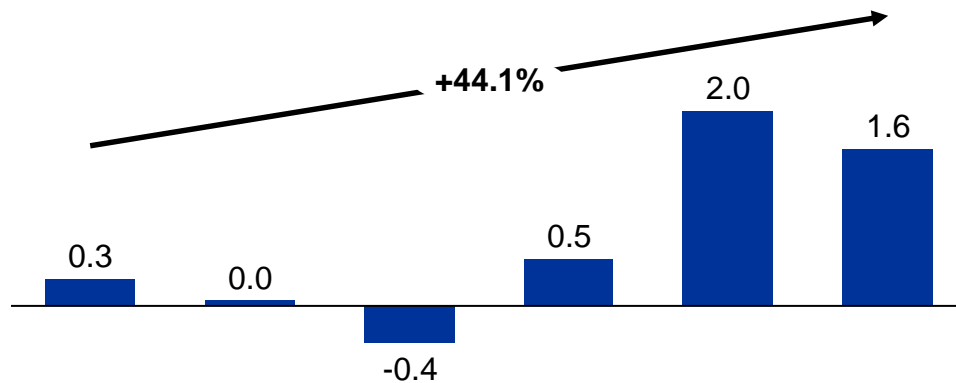
Japan yen basis  
(JPY billions, CAGR%)



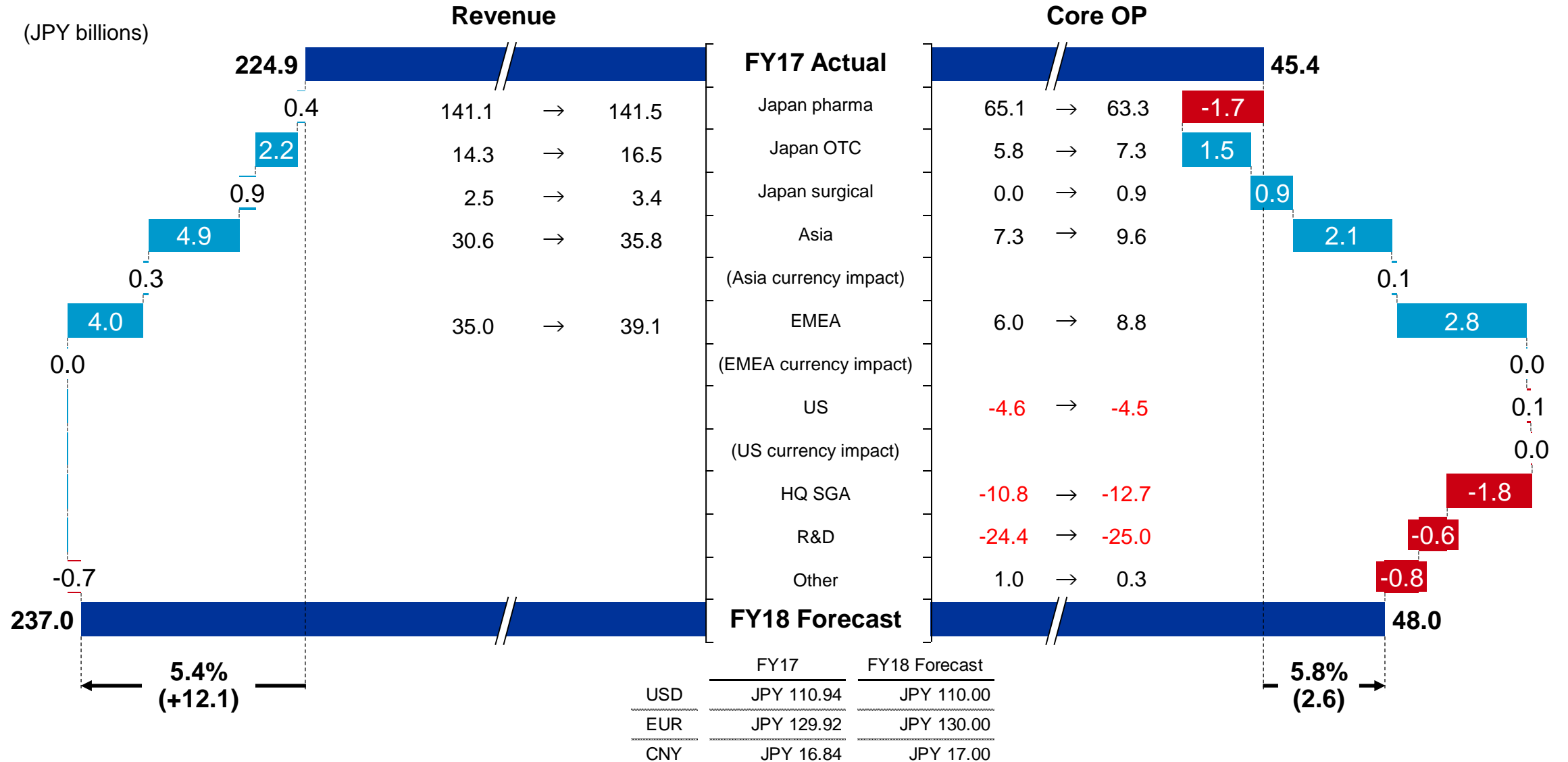
EURO basis  
(EUR millions, CAGR%)



**OP  
before R&D**



# FY2018 Forecast (No change from May 9)



# Dividend Forecast for FY2018 (No change from May 9)

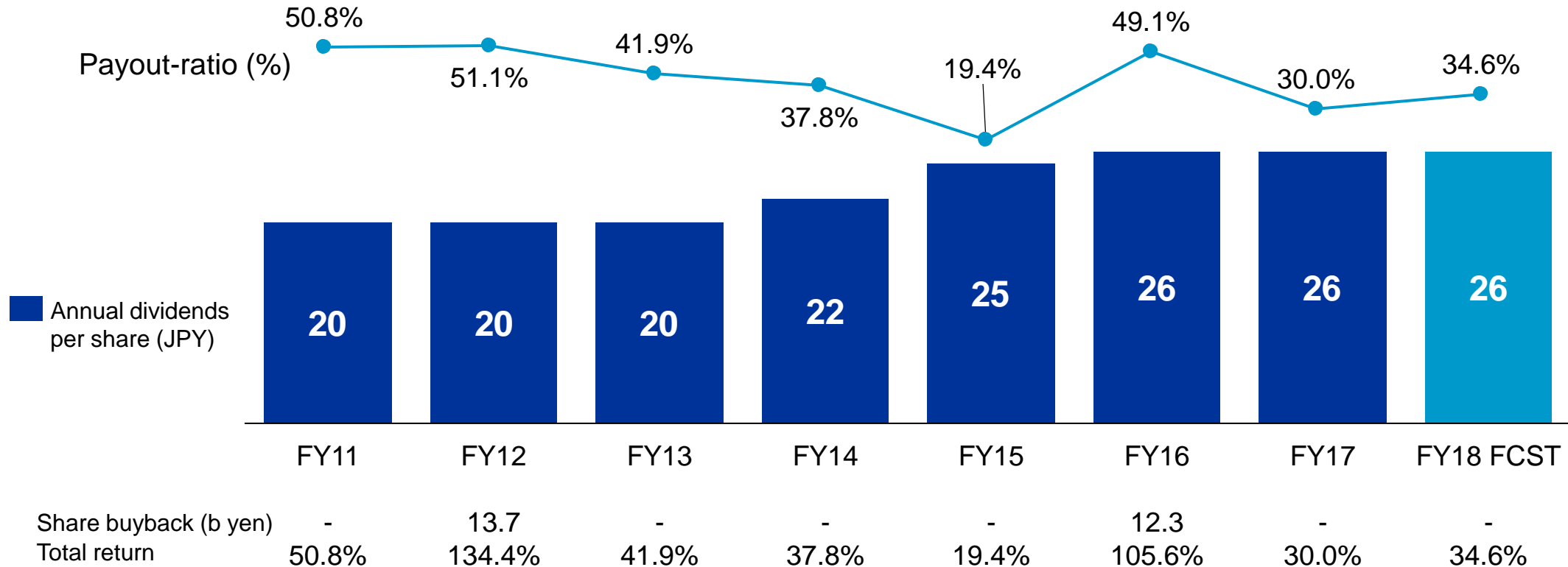
- Annual Dividends

FY2018 forecast: JPY 26 / share

- Stable and sustained return to shareholders

- Mid and Long term strategic investment for the growth beyond 2020

>>>Implementing shareholder returns policy to achieve the best balance between above two priorities considering dividends and total return



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.

# Status of Research & Development

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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 August 1, 2018

	Indication	Region	Status
<b>DE-117</b> EP2 receptor agonist	Glaucoma / ocular hypertension	US	P2 <i>Plan: 2<sup>nd</sup> half FY2018 P3 start</i>
		Japan	Filed <i>Plan: 2<sup>nd</sup> half FY2018 approval</i>
		Asia	P3 <i>Plan: 2<sup>nd</sup> half FY2018 P3 completion</i>
<b>DE-126</b> FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b
		Japan	
<b>DE-128</b> <i>InnFocus MicroShunt</i>	Glaucoma	US	P2/3 <i>Plan: Calendar 2018~2019 P2/3 completion, Calendar 2020~2021 launch</i>
		Europe	CE mark granted
<b>DE-109</b> IVT sirolimus	Uveitis	US	P3 <i>Plan: 2<sup>nd</sup> half FY2018 an additional clinical trial start</i>
		Japan	P3
		Europe	P3
		Asia	Filed
<b>DE-122</b> Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a <i>Plan: Jan~Jun 2019 P2a completion</i>

# Pipeline / Product Development Status (2)

	Indication	Region	Status
<b>DE-089</b> <i>Diquas</i>	Dry eye	China	Approved <i>Plan: FY2018 launch</i>
<b>DE-076B</b> <i>Cyclokat / Ikervis</i> ciclosporin	Severe keratitis in patients with dry eye	Asia	Launched
		US	P2
<b>DE-076C</b> <i>Vekacia / Verkazia</i> ciclosporin	Vernal kerato-conjunctivitis	Europe	<u>Approved</u>
<b>DE-114A</b> epinastine HCl (high dose)	Allergic conjunctivitis	Japan	<u>P3 completion</u> <i>Plan: 2<sup>nd</sup> half of FY2018 filing</i>
<b>DE-127</b> atropine sulfate	Myopia	Asia	P2 <i>Plan: 2<sup>nd</sup> half of FY2019 P2 completion</i>

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# Appendix

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# Q1 FY2018 Profit and Loss Statement

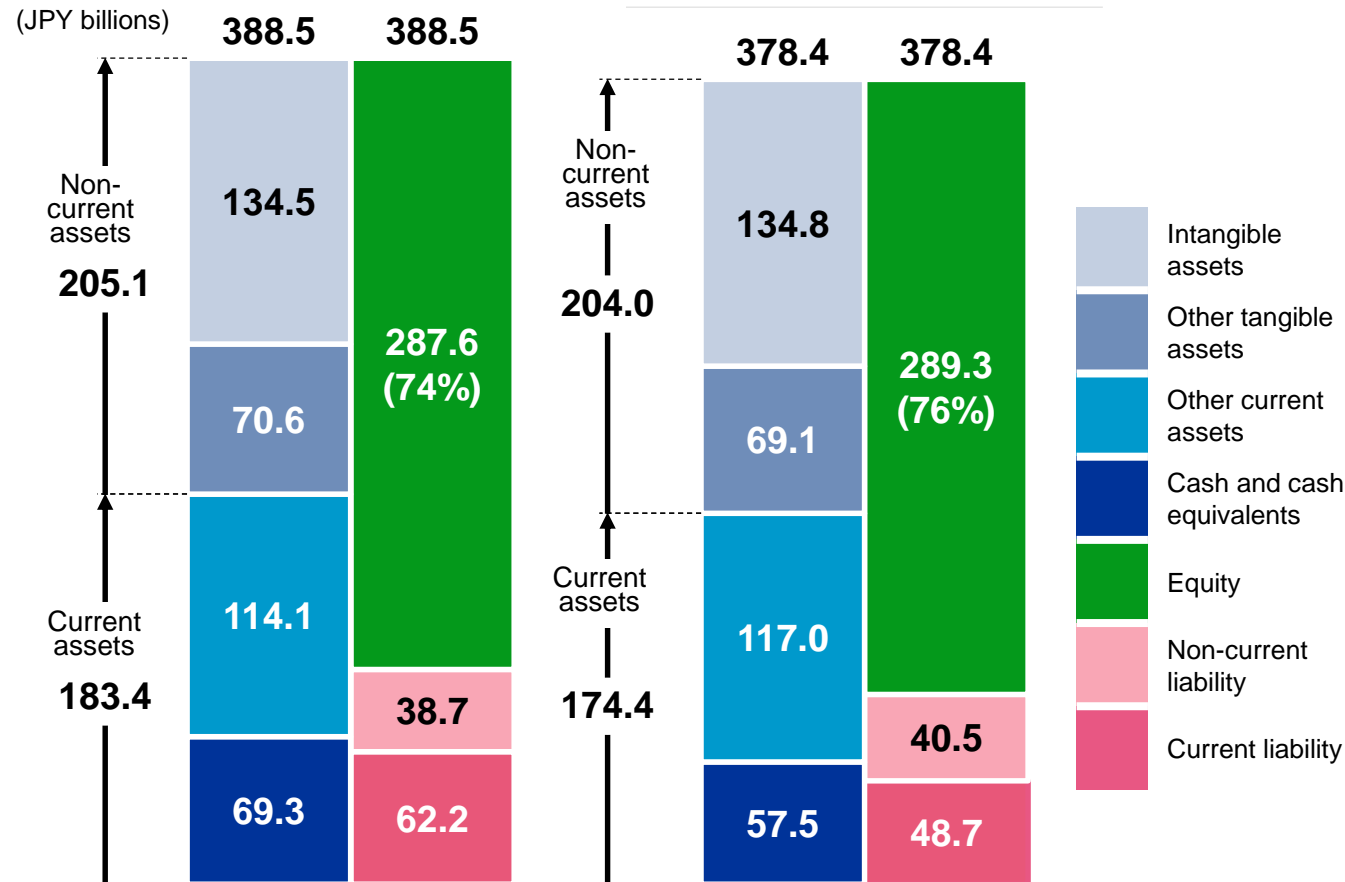
(JPY billions)	Q1 FY17		Q1 FY18		YoY
	Actual	vs Revenue	Actual	vs Revenue	
Revenue	55.9		56.5		1.0%
COGS	-21.6	-38.6%	-23.0	-40.8%	6.7%
SGA expenses	-15.1	-26.9%	-16.2	-28.6%	7.4%
R&D expenses	-5.6	-10.0%	-5.6	-9.9%	0.1%
Amortization on intangible assets associated with products	-1.7	-3.0%	-1.7	-3.1%	5.0%
Other income	0.1	0.1%	0.1	0.2%	42.9%
Other expenses	-0.1	-0.1%	-0.0	-0.1%	-52.4%
Operating profit (IFRS)	12.1	21.5%	10.0	17.7%	-16.9%
Finance income	0.5	0.8%	0.5	0.9%	10.8%
Finance expenses	-0.4	-0.8%	-1.1	-1.9%	149.6%
Profit before tax	12.1	21.6%	9.5	16.7%	-21.7%
Income tax expenses	-3.1	-5.5%	-2.6	-4.6%	-15.2%
<i>Actual tax ratio</i>	<i>25.4%</i>		<i>27.5%</i>		<i>2.1pt</i>
Net profit (IFRS)	9.0	16.1%	6.9	12.1%	-24.0%
Core operating profit	13.7	24.5%	11.7	20.7%	-14.8%
Core net profit	10.2	18.2%	8.6	15.3%	-15.1%

# Q1 FY2018 Financial Position

March 31, 2018

Jun 30, 2018

Decreased Cash and cash equivalents and current liabilities mainly due to the payment of Income tax, dividends and bonuses



	March 31, 2018	June 30, 2018	Change
<b>Non-current assets</b>	<b>205.1</b>	<b>204.0</b>	<b>-1.1</b>
Property, plant and equipment	29.7	30.6	0.9
Intangible assets	134.5	134.8	0.3
Financial assets	35.8	34.1	-1.7
Other	5.1	4.4	-0.7
<b>Current assets</b>	<b>183.4</b>	<b>174.4</b>	<b>-8.9</b>
Inventories	30.6	31.8	1.2
Trade and other receivables	78.7	80.6	1.9
Cash and cash equivalents	69.3	57.5	-11.8
Other	4.8	4.6	-0.2
<b>Equity</b>	<b>287.6</b>	<b>289.3</b>	<b>1.7</b>
<b>Non-current liabilities</b>	<b>38.7</b>	<b>40.5</b>	<b>1.8</b>
Financial liabilities	3.5	3.5	-
Long-term liabilities	17.7	18.6	0.9
Deferred tax liabilities	12.9	13.6	0.7
Other	4.6	4.9	0.2
<b>Current liabilities</b>	<b>62.2</b>	<b>48.7</b>	<b>-13.6</b>
Trade and other liabilities	29.7	27.1	-2.6
Other financial liabilities	14.4	11.5	-2.9
Income tax payable	7.7	2.3	-5.4
Other	10.4	7.8	-2.6

# Q1 FY2018 Segment Revenue

Segment Revenue									
(JPY billions)	Japan			Overseas			Total		
	Q1 FY2017	Q1 FY2018	YoY	Q1 FY2017	Q1 FY2018	YoY	Q1 FY2017	Q1 FY2018	YoY
Pharmaceuticals	39.7	38.0	-4.1%	16.3	18.4	13.3%	55.9	56.5	1.0%
Prescription	35.0	33.7	-3.8%	16.2	18.3	13.1%	51.2	52.0	1.6%
Ophthalmic	34.9	33.6	-3.6%	16.1	18.2	13.5%	50.9	51.9	1.8%
Others	0.2	0.1	-52.3%	0.1	0.1	-32.4%	0.3	0.2	-43.0%
OTC	3.9	3.5	-11.8%	0.1	0.1	-2.2%	4.0	3.5	-11.7%
Medical devices	0.6	0.6	5.6%	0.0	0.0	340.4%	0.6	0.7	8.3%
Others	0.1	0.2	107.1%	0.0	0.0	626.3%	0.1	0.3	126.6%
<b>Sales ratio</b>	<b>70.9%</b>	<b>67.4%</b>		<b>29.1%</b>	<b>32.6%</b>				

# Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY2017		FY2018		
	Q1	Full year	Q1		Full year
	Actual	Actual	Actual	YoY	Forecast
Capital expenditures	1.0	5.4	1.3	31.4%	7.5
Depreciation and amortization*	1.0	4.2	1.0	-0.2%	4.3
Amortization on intangible assets associated with products	1.7	6.7	1.7	5.0%	6.9
Intangible assets -Merck products	1.4	5.6	1.5	5.2%	5.8
Intangible assets -Ikervis	0.2	0.7	0.2	5.2%	0.7

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

# Prescription Ophthalmic Market in Japan

(JPY billions)	Q1 FY2017						Q1 FY2018					
	Santen*		Market		Santen market share*		Santen*		Market		Santen market share*	
	Value	Change (YoY)	Value	Change (YoY)	Value	Rank	Value	Change (YoY)	Value	Change (YoY)	Value	Rank
Total	41.4	6.5%	90.4	4.3%	45.8%	#1	42.9	3.6%	91.7	1.5%	46.8%	#1
Glaucoma	9.2	-2.2%	29.3	0.5%	31.4%	#1	8.9	-3.6%	28.7	-1.9%	30.9%	#1
Anti-VEGF	15.1	14.6%	21.1	14.1%	71.5%	#1	16.8	11.1%	23.3	10.2%	72.1%	#1
Corneal/dry eye	7.3	3.0%	11.7	3.5%	62.5%	#1	7.0	-4.3%	11.4	-3.2%	61.7%	#1
Allergy	4.1	20.9%	8.9	8.8%	46.4%	#1	5.1	22.9%	10.0	13.1%	50.4%	#1
Anti-infection	1.5	-13.0%	3.7	-4.2%	41.3%	#1	1.3	-18.3%	3.4	-7.1%	36.4%	#1

## Jul 1, 2017 - Jun 30, 2018

	Santen*		Market		Santen market share*	
	Value	Change (YoY)	Value	Change (YoY)	Value	Rank
Total	169.4	6.0%	364.6	4.4%	46.5%	#1
Glaucoma	35.6	-2.8%	114.4	-0.1%	31.1%	#1
Anti-VEGF	62.9	12.6%	87.4	13.4%	72.0%	#1
Corneal/dry eye	28.7	-0.1%	46.3	0.8%	62.0%	#1
Allergy	21.5	26.9%	44.0	14.4%	48.7%	#1
Anti-infection	5.3	-14.7%	13.6	-5.4%	38.8%	#1

\*Including co-promoted product (Anti-VEGF *Eylea*) of Bayer Yakuhin, Ltd.(MAH)

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# 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 large, stylized letter 'S' on the left. The 'S' is composed of two overlapping shapes: a light blue one on top and a darker blue one on the bottom, creating a sense of depth and movement. To the right of the 'S', the word 'Santen' is written in a bold, dark blue, sans-serif typeface.

*A Clear Vision For Life™*