

Conference Call on Q3 FY2018 Results



Shigeo Taniuchi

President and Chief Operating Officer

February 5, 2019

Santen's Values and Mission Statement

Values

天機に参与する

*Tenki ni sanyo suru*¹

- 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

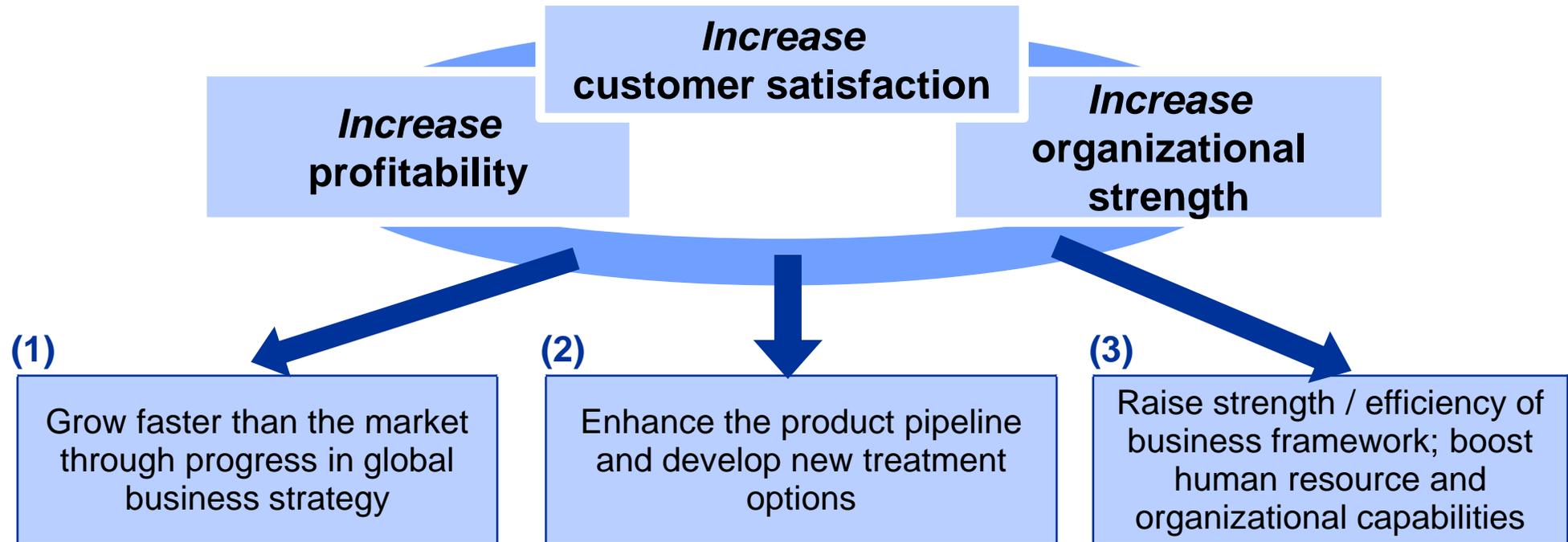
By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.

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

Q3 FY2018 Financial Results ended December 31, 2018

Q3* FY2018 Financial Overview (year-on-year comparisons)

Achieved higher revenue with strong overseas growth more than offsetting negative impact from NHI price cut in Japan

(JPY billions)	FY2017	FY2018	
	Q3 actual	Q3 actual	YoY
Core basis			
Revenue	168.6	173.2	2.7%
COGS	-66.1	-69.8	5.5%
Gross margin	102.4	103.4	0.9%
SGA	-49.5	-51.2	3.5%
R&D expenses	-17.9	-17.1	-4.5%
OP	35.0	35.1	0.1%
IFRS			
OP	30.1	33.7	11.9%
Net profit	27.3	23.4	-14.6%
	USD JPY 111.75	JPY 111.15	
	EUR JPY 128.90	JPY 129.51	
	CNY JPY 16.64	JPY 16.57	

■ Revenue

Japan: Growth of key products absorbed the negative impact from NHI price cut

Overseas: Continued strong growth, particularly Asia
Consolidated total growth: 4.6 bil JPY (+2.7%)

■ Operating profit (Core basis)

Maintained prior year level with continued overseas growth and group-wide cost optimization offsetting negative impact from NHI price cut

(IFRS basis)

With achievement of asset reduction / business reorganization including gain on sale of former HQ / Osaka plant site, **increased by 3.6 bil JPY (+11.9%)** (Agreed sale of plant and its operations in Finland in Q4 to be accounted for in FY2019)

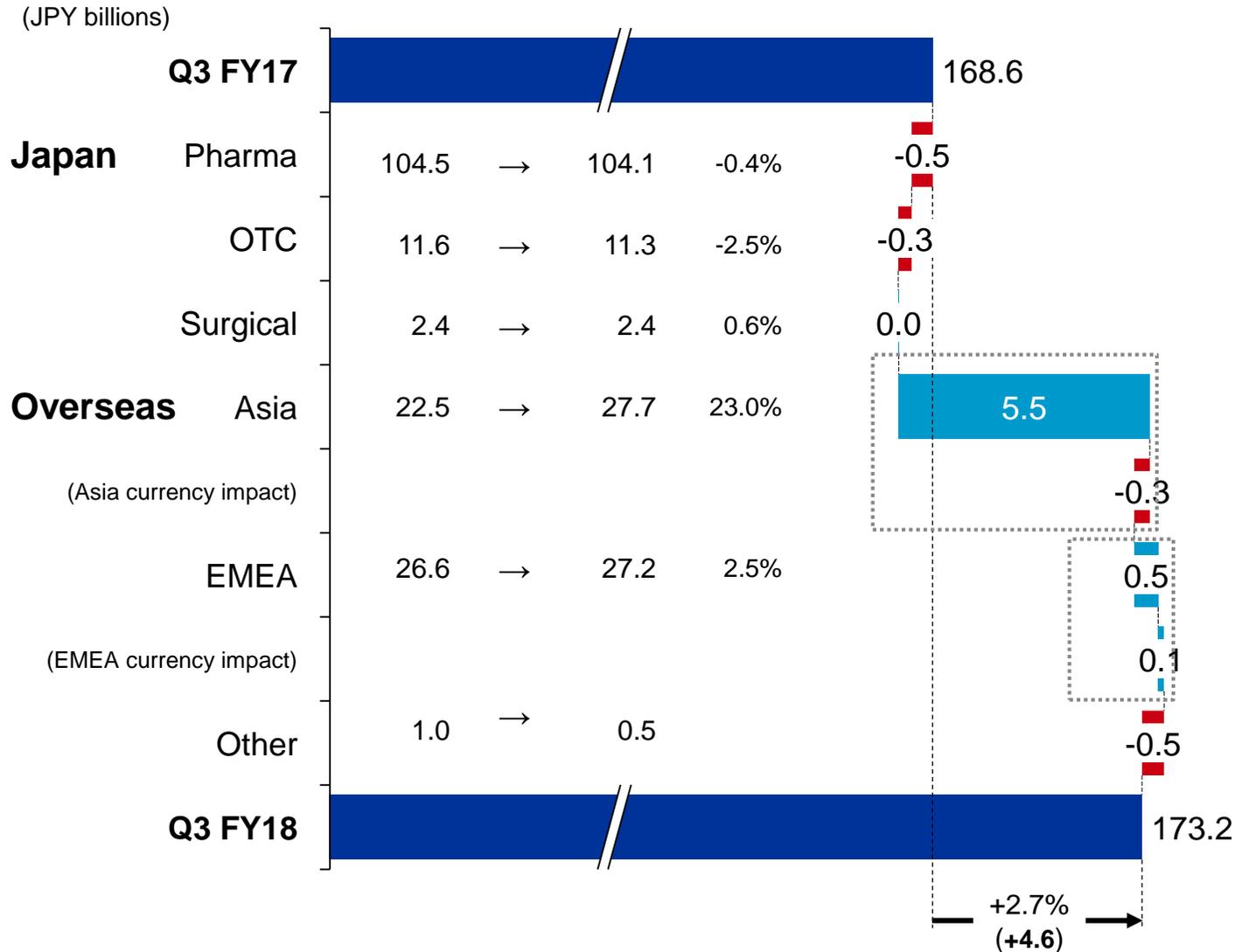
■ Net profit

Mainly due to one-time benefit of reduced corporate tax rate in U.S. in prior year, **decreased by 4.0 bil JPY (14.6%)**

Notes: *Santen results herein describe Q3 results cumulatively as the nine month period ended December 31, 2018.

Q3 FY2018 Revenue

With contributions from key products, Japan business makes progress in line with plans;
Overseas business above Q3 FY17 and forecast



Japan business

Japan
pharma

Growth of *Eylea** (+9.4%), *Diquas* (+8.5%) mitigated impact of NHI price cuts (over -4%)
Revenue increased by 5.6 bil JPY(+5.4%), excluding the negative impact from NHI price cuts and transitory factors
Good start for *Eybelis* since Nov launch (institution adoption already about 50%)
Well Wash Eye, cleansing eye drop launched in December

OTC

Good progress in premium products for domestic market mitigated negative comparative impact from marketing campaign in prior year and a decrease of foreign visitors to Japan due to natural disasters in current FY

Surgical

In November, began trial sales of new IOL product, *LENTIS Comfort*, which provides comfortable vision across medium and long distances

Overseas business

Asia

Continued strong revenue growth of over 20% broadly across the region. China: +23.4%, Korea: +18.4% (JPY)
Asia region: 18 launches, 22 approvals
Together with existing products, creating future sustainable growth

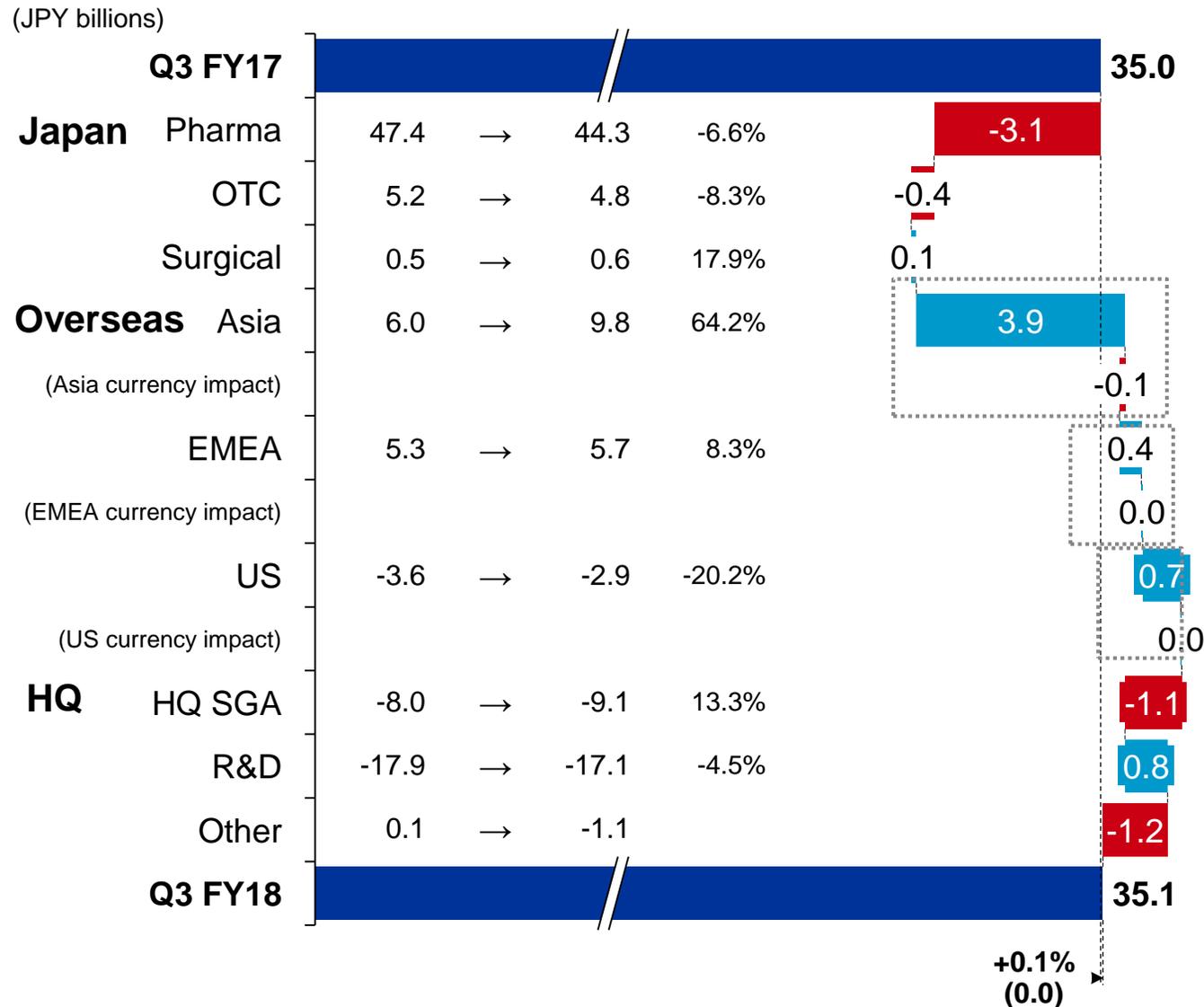
EMEA

Growth of *Ikervis* and glaucoma products particularly in Italy and Germany more than offset the comparative impact of one-time boost to revenue in Russia in prior year

		Q3 FY17	Q3 FY18
<i>Eylea</i> *: Co-promoted product of Bayer Yakuin, Ltd. (MAH)	USD	JPY 111.75	JPY 111.15
	EUR	JPY 128.90	JPY 129.51
	CNY	JPY 16.64	JPY 16.57

Q3 FY2018 Core Operating Profit

Strong growth in overseas business and group-wide cost optimization offset NHI price cut impacts



Japan business

Japan pharma Cost optimization efforts partially mitigated the negative impact of COGS ratio increase (NHI price cuts and product mix) and channel inventory adjustment

Overseas business

Asia Significantly higher with revenue growth and COGS expense management

EMEA Achieved increase in profit with revenue growth in key countries and cost optimization efforts more than offsetting the comparative impact of one-time boost to revenue and profit in Russia in prior year

US Lower mainly with suspension of DE-109 U.S. market launch related expenses

R&D expenses

Lower on suspension of DE-109 (restarted in Q3), DE-126 study costs completed in prior year (data now under evaluation), and cost optimization efforts

	Q3 FY17	Q3 FY18
USD	JPY 111.75	JPY 111.15
EUR	JPY 128.90	JPY 129.51
CNY	JPY 16.64	JPY 16.57

Performance by Business (Japan)

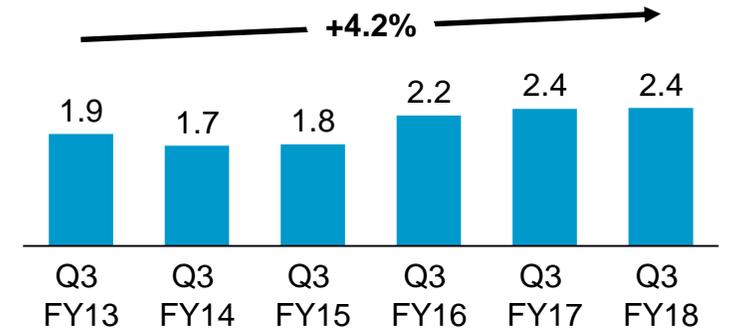
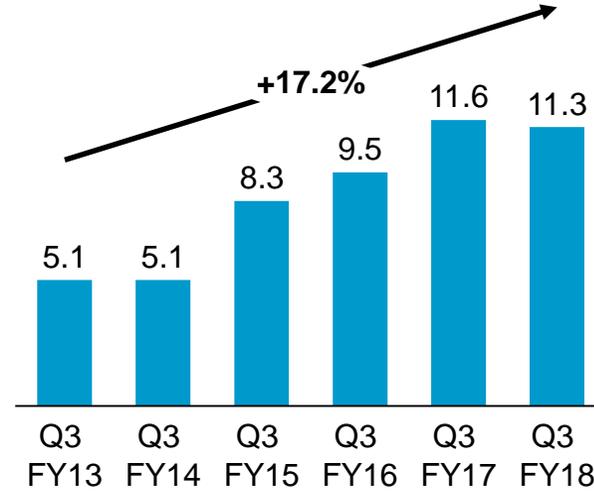
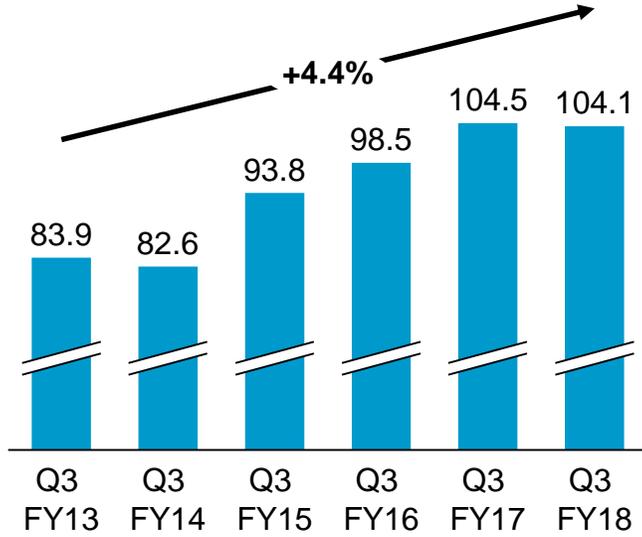
【Japan pharma】

【OTC】

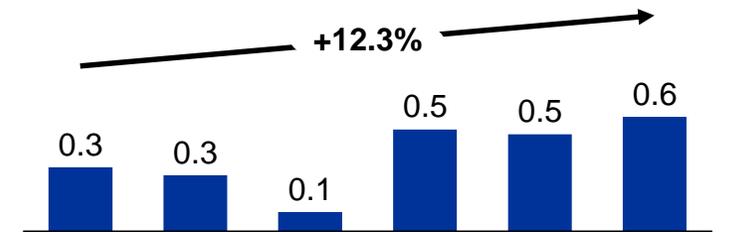
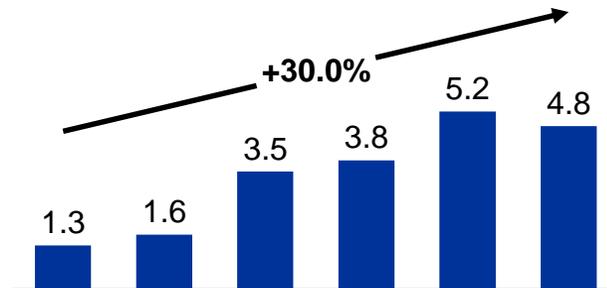
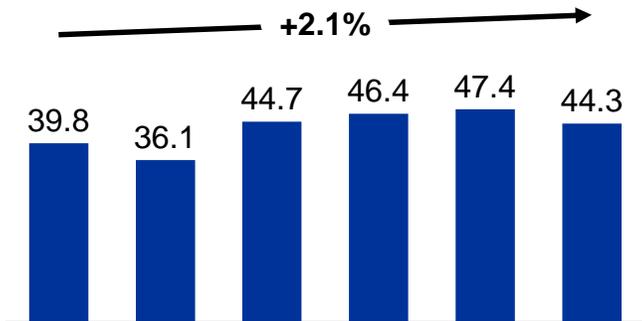
【Surgical】

(JPY billions, CAGR)

Revenue



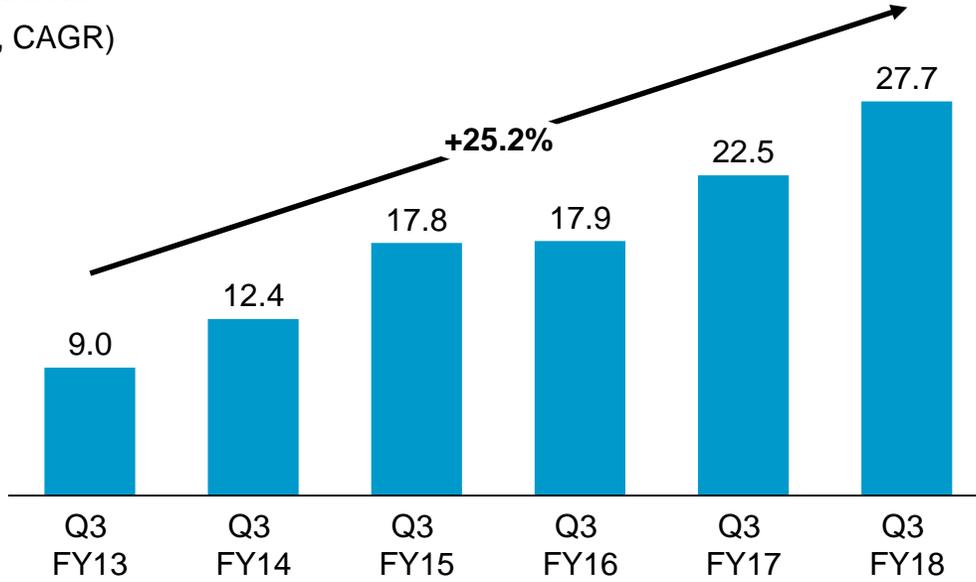
OP before R&D



Performance by Business (Asia)

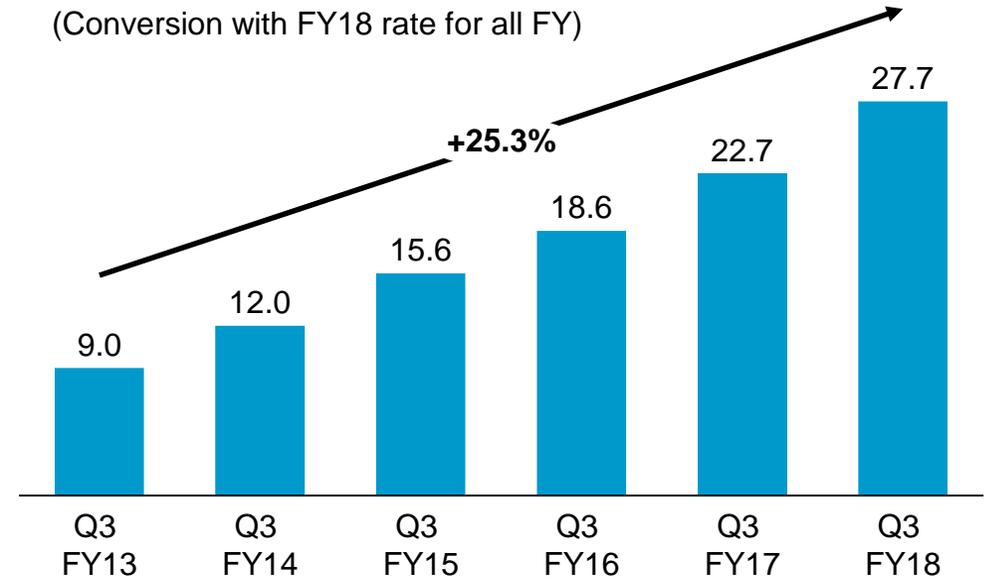
Japan yen basis
(JPY billions, CAGR)

Revenue

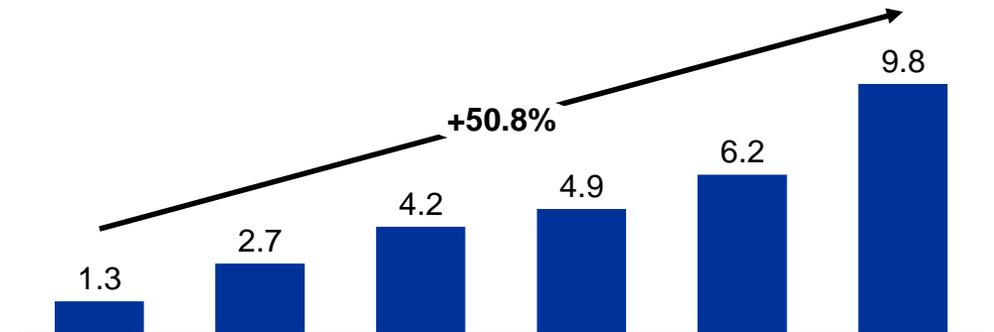
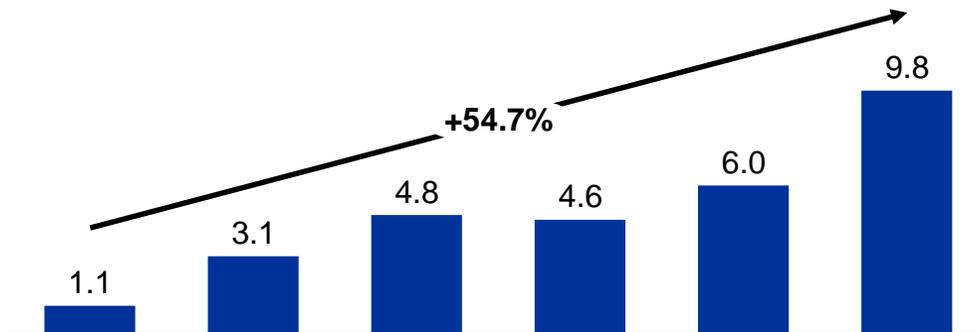


Local currency basis

(Conversion with FY18 rate for all FY)

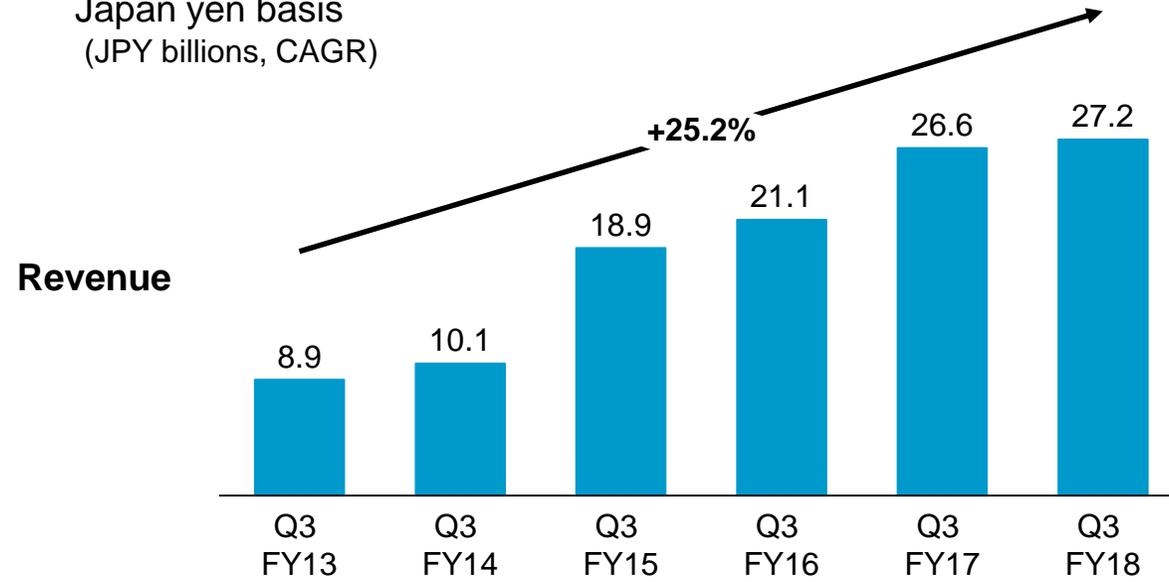


OP
before R&D

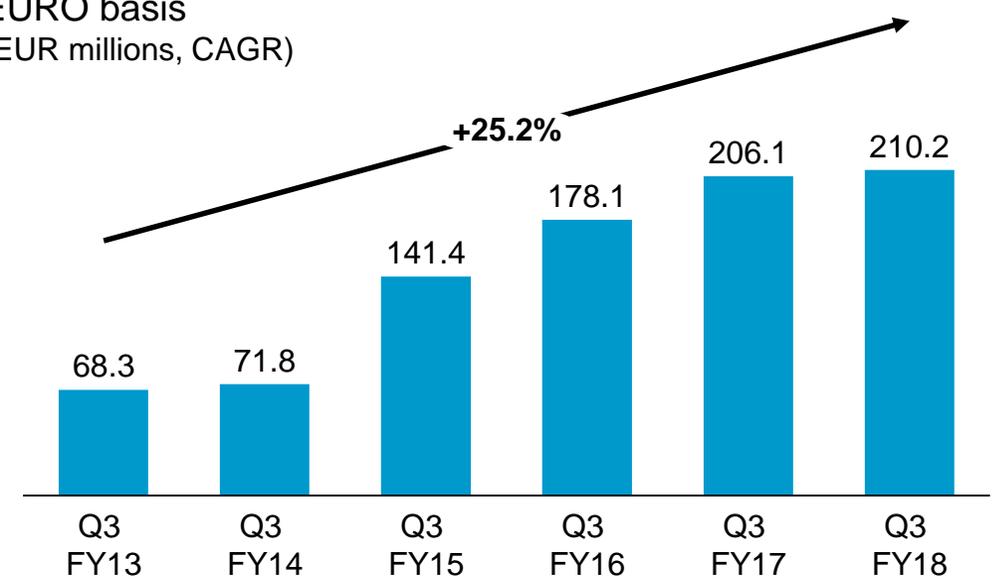


Performance by Business (EMEA)

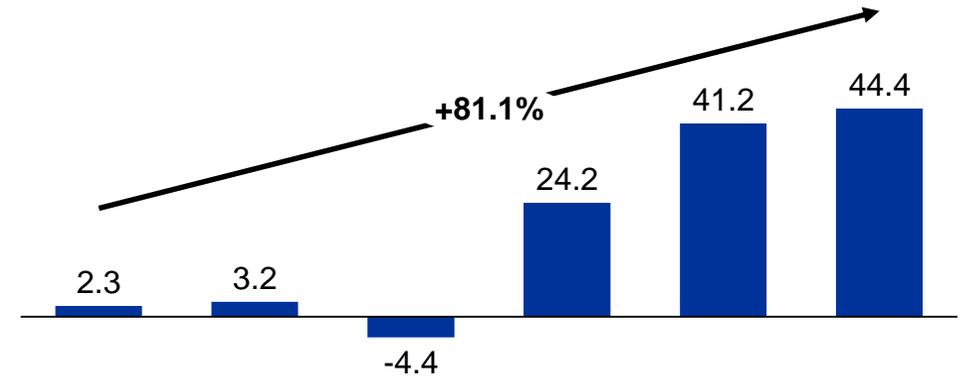
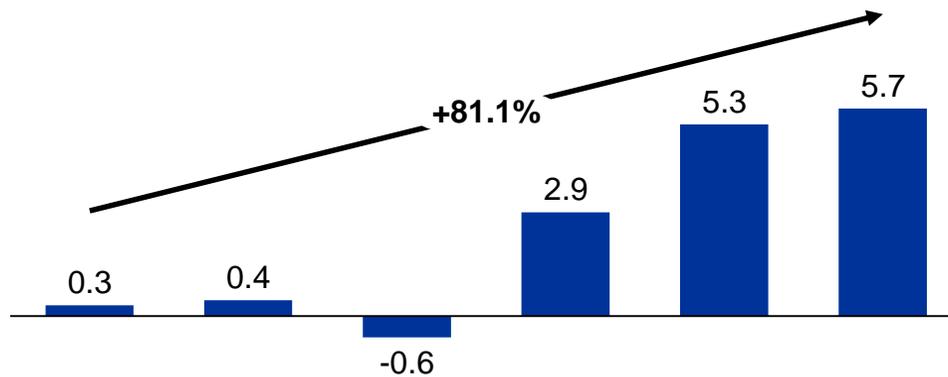
Japan yen basis
(JPY billions, CAGR)



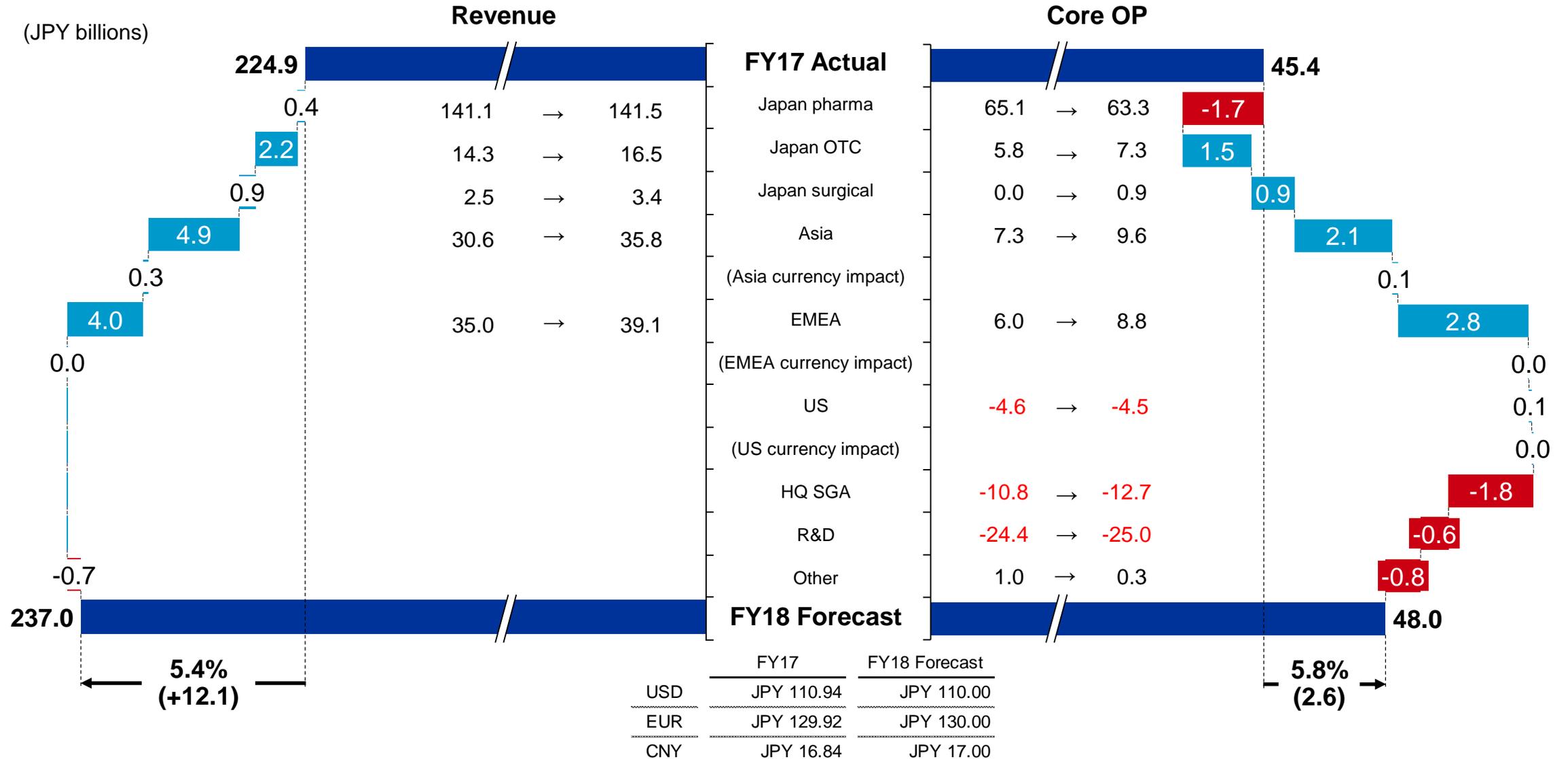
EURO basis
(EUR millions, CAGR)



OP before R&D



FY2018 Forecast (No change from May 9)

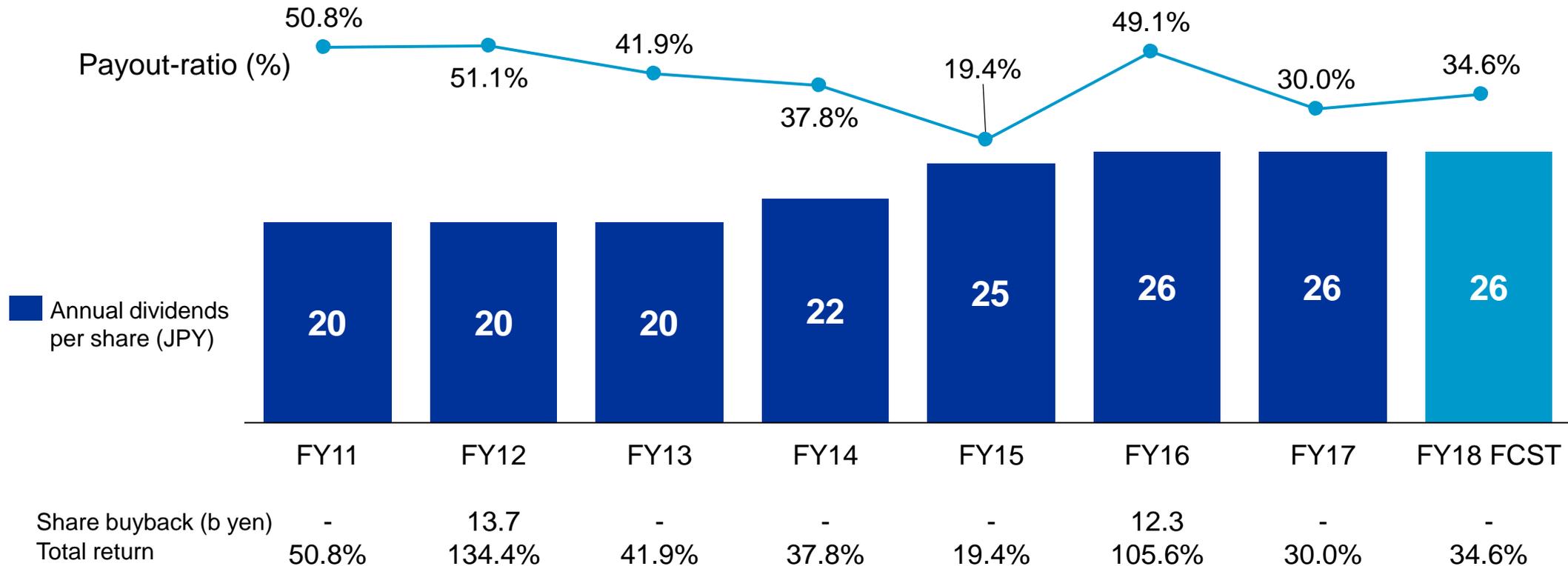


Dividend Forecast for FY2018 (No change from May 9)

- Annual Dividends

FY2018 forecast: JPY 26 / share

- Stable and sustained return to shareholders
- Mid and Long term strategic investment for 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



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

Senior Corporate Officer

Chief Scientific Officer

Head of Global Research & Development

Pipeline / Product Development Status (1)

As of February 5, 2019
Updated information is underlined

	Indication	Region	Status
DE-111 <i>TAPCOM / TAPTIQOM</i> Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	<u>Started P3 in Jan 2019</u> <u>Plan: 1st half FY2020 P3 completion</u>
DE-117 <i>EYBELIS</i> EP2 receptor agonist		US	P3 <u>Plan: Jan~Jun 2020 P3 completion</u>
	Japan	<u>Launched in Nov 2018</u>	
	Asia	P3 <u>Plan: 2nd half FY2018 P3 completion</u>	
DE-126 FP/EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b
		Japan	
DE-128 <u>PreserFlo¹</u>	Glaucoma	US	P2/3 <u>Plan: calendar 2019 PMA rolling submission completion, calendar 2020 launch</u>
		Europe	CE mark granted

¹PreserFlo is the new name of the pipeline project which has been known by the development code DE-128 and/or trade name *InnFocus MicroShunt* in Europe.

Pipeline / Product Development Status (2)

As of February 5, 2019
Updated information is underlined

	Indication	Region	Status
DE-109 IVT sirolimus	Uveitis	US	P3 (<u>LUMINA trial started in Dec 2018</u>) <i>Plan: <u>Jan~Jun 2021 P3 completion</u></i>
		Japan	P3
		Europe	P3
		Asia	Filed
DE-122 Anti-endothelin antibody	Wet age-related macular degeneration	US	P2a <i>Plan: <u>2nd half of FY2019 P2a completion</u></i>
DE-089 <i>Diquas</i>	Dry eye	China	Launched
DE-076B Cyclokat / <i>Ikervis</i> ciclosporin	Severe keratitis in patients with dry eye	Asia	Launched
		US	P2
DE-076C <i>Vekacia / Verkazia</i> ciclosporin	Vernal kerato-conjunctivitis	Europe	Launched
		Asia*	<u>Filed in Nov 2018, Plan: <u>Jul~Dec 2019 approval</u></u> *Product name is <i>Ikervis</i> .
		Others	<u>Approved in Dec 2018 in Canada, Plan: <u>calendar 2019 launch</u></u>
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	Filed <i>Plan: <u>Jul~Dec 2019 approval</u></i>
DE-127 atropine sulfate	Myopia	Asia	P2 <i>Plan: <u>2nd half of FY2019 P2 completion</u></i>

Appendix

Q3 FY2018 Profit and Loss Statement

(JPY billions)	Q3 FY17		Q3 FY18		YoY
	Actual	vs Revenue	Actual	vs Revenue	
Revenue	168.6		173.2		2.7%
COGS	-66.1	-39.2%	-69.8	-40.3%	5.5%
Gross profit	102.4	60.8%	103.4	59.7%	0.9%
SGA expenses	-49.5	-29.4%	-51.2	-29.6%	3.5%
R&D expenses	-17.9	-10.6%	-17.1	-9.9%	-4.5%
Amortization on intangible assets associated with products	-5.0	-3.0%	-5.2	-3.0%	4.7%
Other income	0.4	0.2%	3.9	2.3%	968.2%
Other expenses	-0.3	-0.2%	-0.1	-0.1%	-62.9%
Operating profit (IFRS)	30.1	17.8%	33.7	19.4%	11.9%
Finance income	0.8	0.5%	0.9	0.5%	6.7%
Finance expenses	-1.4	-0.8%	-2.1	-1.2%	55.9%
Profit before tax	29.5	17.5%	32.4	18.7%	9.7%
Income tax expenses	-2.2	-1.3%	-9.0	-5.2%	312.3%
<i>Actual tax ratio</i>	<i>7.4%</i>		<i>27.9%</i>		<i>20.5pt</i>
Net profit (IFRS)	27.3	16.2%	23.4	13.5%	-14.6%
Core operating profit	35.0	20.8%	35.1	20.3%	0.1%
Core net profit	26.2	15.6%	25.7	14.8%	-2.2%



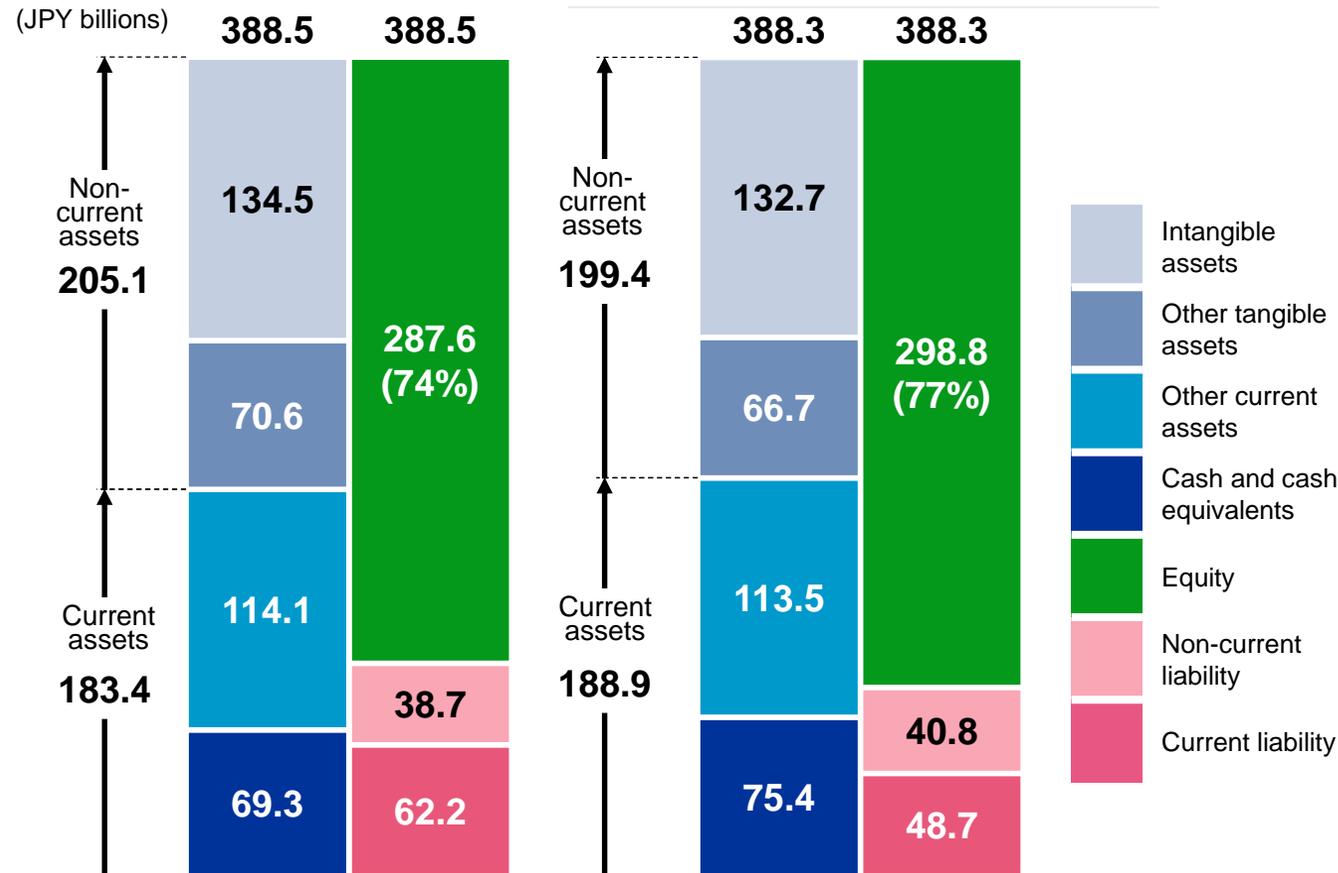
Changes in the corporate income tax expense rate were due to a significant reduction in income tax expense for the previous fiscal year associated with a reduction in the US corporate tax rate at the end of 2017 and the deferred tax liabilities recognized as a result of the acquisition of InnFocus, Inc.

Q3 FY2018 Financial Position

March 31, 2018

Dec 31, 2018

Former HQ / Osaka plant site was sold during Q3 FY18. Agreement reached for the sale of plant and its operations in Finland (to be accounted for in FY2019) as part of initiatives to reduce assets and reorganize.



	March 31, 2018	Dec 31, 2018	Change
Non-current assets	205.1	199.4	-5.7
Property, plant and equipment	29.7	31.0	1.3
Intangible assets	134.5	132.7	-1.8
Financial assets	35.8	31.7	-4.0
Other	5.1	3.9	-1.2
Current assets	183.4	188.9	5.5
Inventories	30.6	31.1	0.4
Trade and other receivables	78.7	78.7	0.1
Cash and cash equivalents	69.3	75.4	6.1
Other	4.8	3.7	-1.1
Equity	287.6	298.8	11.2
Non-current liabilities	38.7	40.8	2.1
Financial liabilities	3.5	4.1	0.6
Deferred tax liabilities	12.9	12.3	-0.6
Other	22.3	24.5	2.2
Current liabilities	62.2	48.7	-13.5
Trade and other liabilities	29.7	28.0	-1.8
Other financial liabilities	14.4	9.1	-5.3
Income tax payable	7.7	3.6	-4.1
Other	10.4	8.0	-2.4

Q3 FY2018 Segment Revenue

Segment Revenue									
	Japan			Overseas			Total		
(JPY billions)	Q3 FY2017	Q3 FY2018	YoY	Q3 FY2017	Q3 FY2018	YoY	Q3 FY2017	Q3 FY2018	YoY
Pharmaceuticals	118.8	117.7	-0.9%	49.8	55.5	11.4%	168.6	173.2	2.7%
Prescription	104.9	104.0	-0.9%	49.6	55.2	11.3%	154.5	159.2	3.0%
Ophthalmic	104.5	103.8	-0.7%	49.3	54.9	11.3%	153.8	158.7	3.2%
Others	0.5	0.3	-41.9%	0.3	0.3	4.0%	0.7	0.6	-24.9%
OTC	11.4	11.0	-3.5%	0.2	0.2	4.7%	11.6	11.2	-3.3%
Medical devices	1.9	1.9	2.6%	0.0	0.1	147.7%	1.9	2.0	4.4%
Others	0.5	0.7	38.2%	0.0	0.1	142.8%	0.6	0.8	43.3%
Sales ratio	70.4%	68.0%		29.6%	32.0%				

Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY2017		FY2018		
	Q3	Full year	Q3	Full year	
	Actual	Actual	Actual	YoY	Forecast
Capital expenditures	4.5	5.4	5.1	13.7%	9.0
Depreciation and amortization*	3.1	4.2	3.0	-3.4%	4.3
Amortization on intangible assets associated with products	5.0	6.7	5.2	4.7%	6.9
Intangible assets					
-Merck products	4.1	5.6	4.4	5.2%	5.8
Intangible assets					
-Ikervis	0.5	0.7	0.6	0.5%	0.7

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

Prescription Ophthalmic Market in Japan

Q3 FY2017 (9 months)

Q3 FY2018 (9 months)

JPY billions	Santen*		Market		Santen market share*		Santen*		Market		Santen market share*	
	Value	Change (YoY)	Value	Change (YoY)			Value	Change (YoY)	Value	Change (YoY)		
Total	123.4	6.4%	268.1	5.3%	46.0%	No.1	124.7	1.0%	266.0	-0.8%	46.9%	No.1
Glaucoma	27.8	-1.4%	88.7	1.6%	31.4%	No.1	25.5	-8.2%	84.8	-4.5%	30.1%	No.1
Anti-VEGF	46.3	15.1%	64.8	16.2%	71.5%	No.1	51.0	10.3%	70.7	9.2%	72.2%	No.1
Corneal/dry eye	22.3	2.8%	35.9	3.6%	62.3%	No.1	21.5	-3.8%	34.8	-2.8%	61.6%	No.1
Allergy	10.5	15.8%	22.1	6.3%	47.3%	No.1	11.9	13.4%	23.1	4.7%	51.3%	No.1
Anti-infection	4.4	-12.5%	11.0	-4.0%	40.5%	No.1	3.5	-20.8%	9.9	-9.6%	35.5%	No.1

Jan 1, 2018 - Dec 31, 2018 (12 months)

	Santen*		Market		Santen market share*	
	Value	Change (YoY)	Value	Change (YoY)		
Total	169.2	2.7%	361.2	0.6%	46.8%	No.1
Glaucoma	33.6	-7.7%	111.0	-4.1%	30.3%	No.1
Anti-VEGF	66.0	10.0%	91.2	9.2%	72.3%	No.1
Corneal/dry eye	28.1	-3.4%	45.6	-2.4%	61.7%	No.1
Allergy	21.9	24.4%	43.9	12.4%	49.9%	No.1
Anti-infection	4.6	-19.8%	12.8	-9.1%	36.1%	No.1

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

Source: Copyright © 2019 IQVIA. IMS-JPM 2016.4-2018.12; Santen analysis based on IQVIA data. Reprinted with permission.

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' in a light blue color, followed by the word 'Santen' in a bold, dark blue sans-serif font.

A Clear Vision For Life™