

Investor Meeting on Q2 FY2018 Results



Shigeo Taniuchi

President & COO

November 7, 2018

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

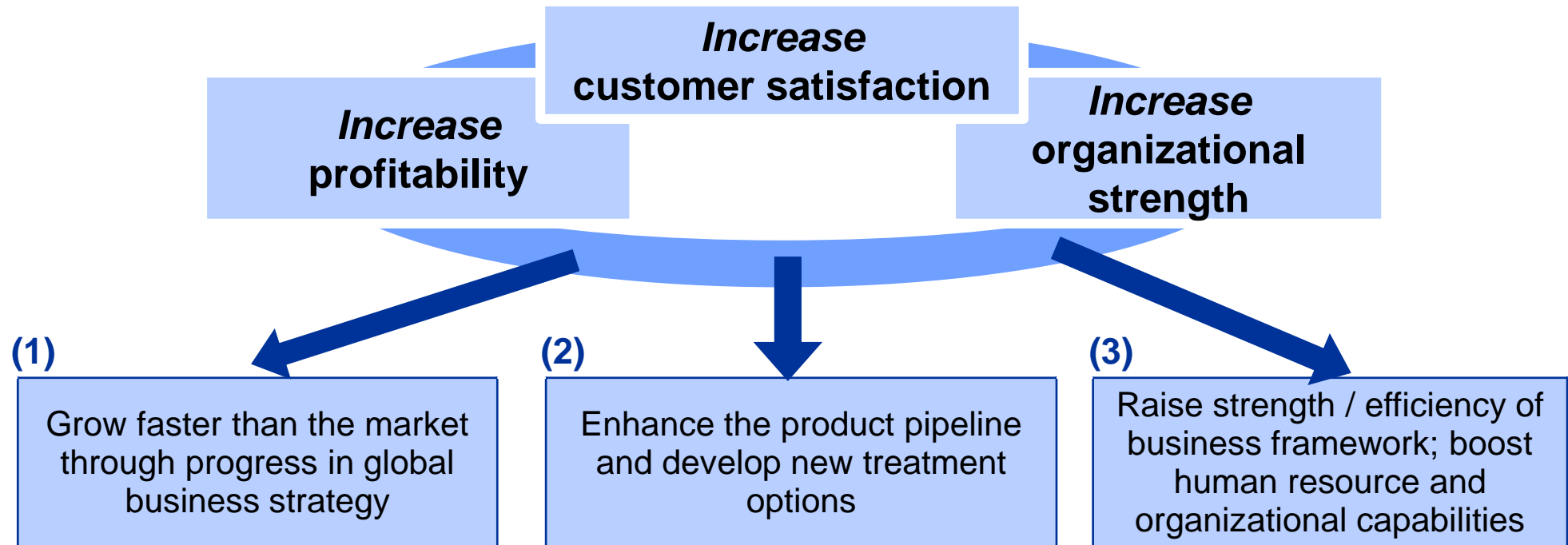
By focusing on ophthalmology, Santen develops unique scientific knowledge and organizational capabilities that contribute to the well-being of patients, their loved ones and consequently to society.

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

Q2 FY2018 Financial Results ended September 30, 2018

Q2* FY2018 Financial Overview (year-on-year comparisons)

Higher consolidated revenue as strong growth from overseas business more than offset certain negative factors in Japan

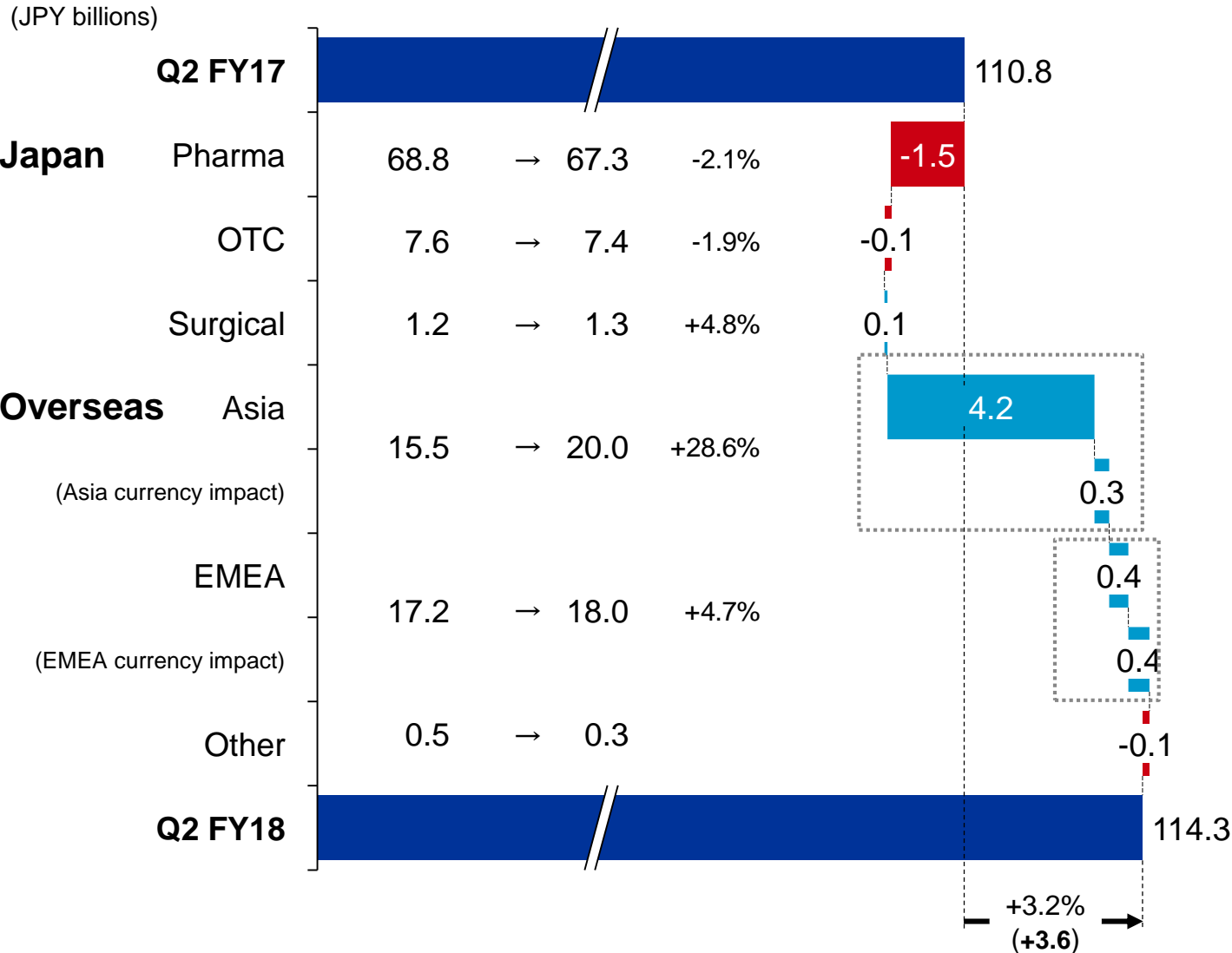
OP made steady progress toward annual forecast, while the amount was relatively unchanged YoY

Revenue	In Japan, revenue growth of key products was achieved, though nearly flat overall due to transitory factors. Continued strong growth was generated from overseas businesses, particularly Asia, leading to overall consolidated revenue growth.	
	<u>114.3 bil yen</u> YoY: +3.2%	
Operating Profit (OP)	Strong growth from overseas business offset by Japan transitory positive factors in prior period and negative impacts in current period, resulting in relatively flat OP YoY. Steady progress toward annual forecast both in core basis and IFRS OP supported by cost control efforts.	
	Core basis <u>24.1 bil yen</u> YoY: -1.0%	IFRS basis <u>20.8 bil yen</u> YoY: -1.0%
	SGA 33.5 bil yen YoY: +5.7%	
	R&D 11.0 bil yen YoY: -6.6%	

Notes: *Santen results herein describe Q2 results cumulatively as the six month period ended September 30, 2018. A summary profit and loss statement can be found in the Appendix.

Q2 FY2018 Revenue

Japan business generally in-line with projection; Overseas business above Q2 FY17 and projection



Japan business

Japan pharma Negative impact of NHI price cuts (total impact exceeded -4%) and transitory factors mitigated by revenue growth of *Eylea** (+7.6%), *Diquas* (+8.0%)

OTC Good progress in premium products for domestic market offset by impacts from marketing campaign in prior year and a decrease of foreign visitors to Japan due to natural disasters in Q2 FY18

Surgical Promoting sales activities in cooperation with Japan pharma business

Overseas business

Asia Continued strong revenue growth of approx 30% broadly across the region.
China: +31.2%, Korea: +21.4% (JPY)

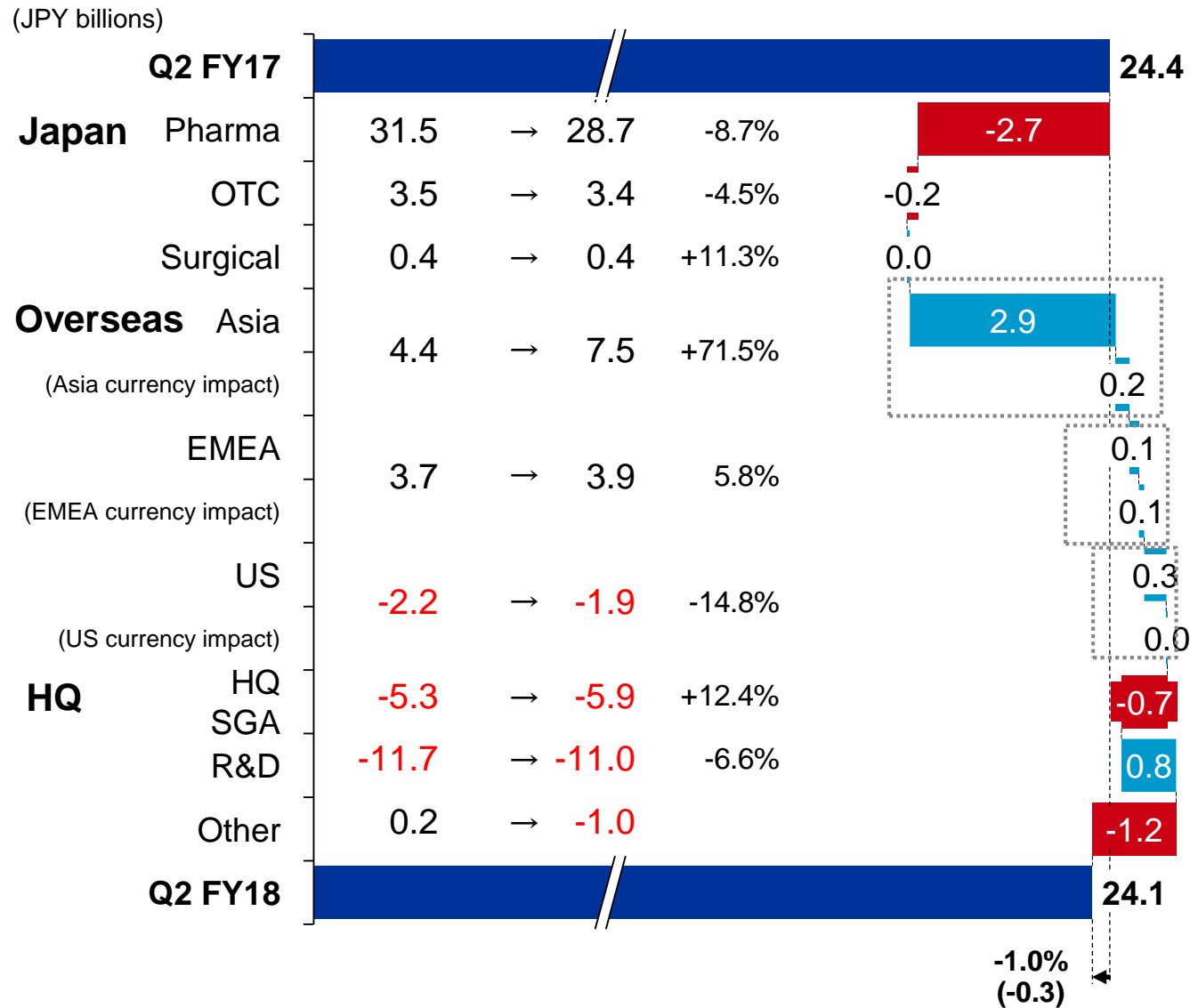
EMEA Continued growth in major countries such as Italy and Germany with *Ikervis* and glaucoma products, though Russia decreased due to transitory factor in prior year

	Q2 FY17	Q2 FY18
USD	JPY 111.18	JPY 110.21
EUR	JPY 126.76	JPY 129.81
CNY	JPY 16.43	JPY 16.70

*Eylea**: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

Q2 FY2018 Core Operating Profit

Steady progress toward annual forecast, offsetting negative YoY impacts



Japan business

Japan pharma	In addition to the negative impact from channel inventory adjustment, COGS ratio increase due to NHI price cuts and product mix; SGA expenses lower with cost control efforts
OTC	Nearly flat due to the cost control efforts in line with the revenue transition

Overseas business

Asia	Significantly higher with revenue growth and expense management in COGS and SGA
EMEA	Profit was nearly flat with good progress made in profit in many countries offset by impact of Russia which had a demand boost in Q2 of prior year
US	Lower mainly with suspension of DE-109 U.S. market launch related expenses

R&D expenses

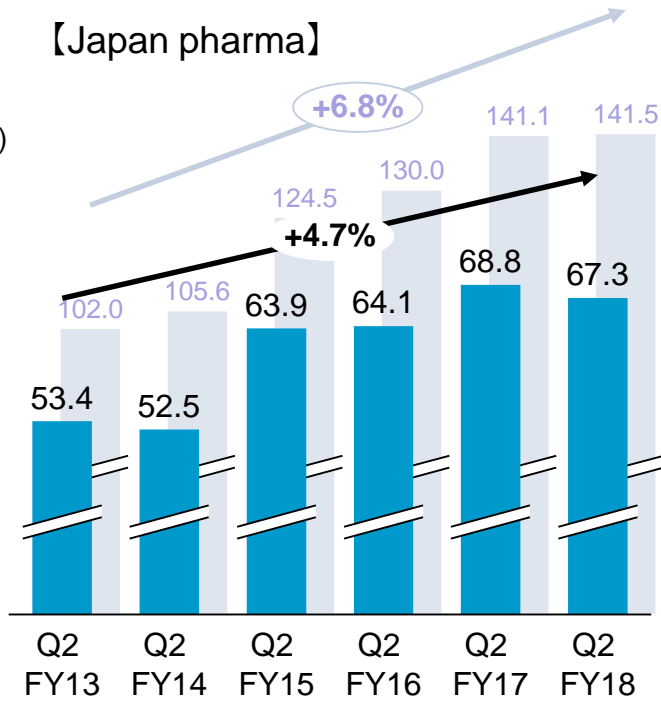
Lower on completion of DE-117 clinical trials in Japan, the suspension of DE-109, and cost optimization efforts

	Q2 FY17	Q2 FY18
USD	JPY 111.18	JPY 110.21
EUR	JPY 126.76	JPY 129.81
CNY	JPY 16.43	JPY 16.70

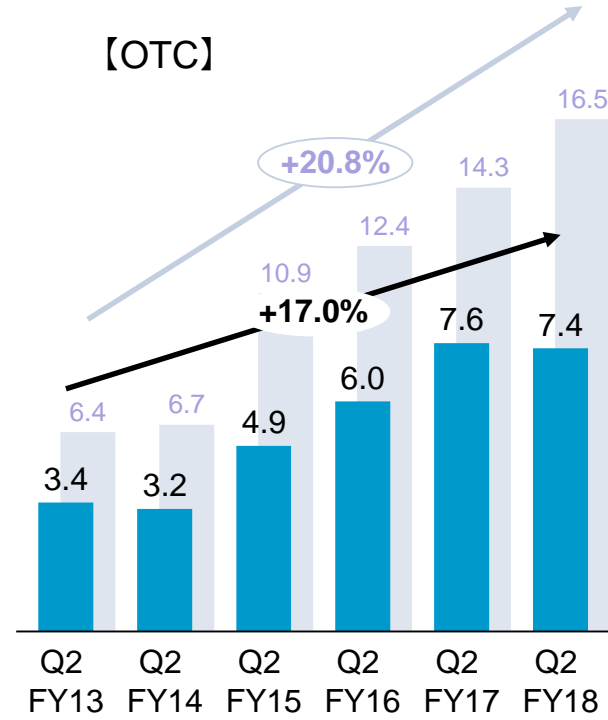
Performance by Business (Japan)

■ Full Year
(JPY billions, CAGR)

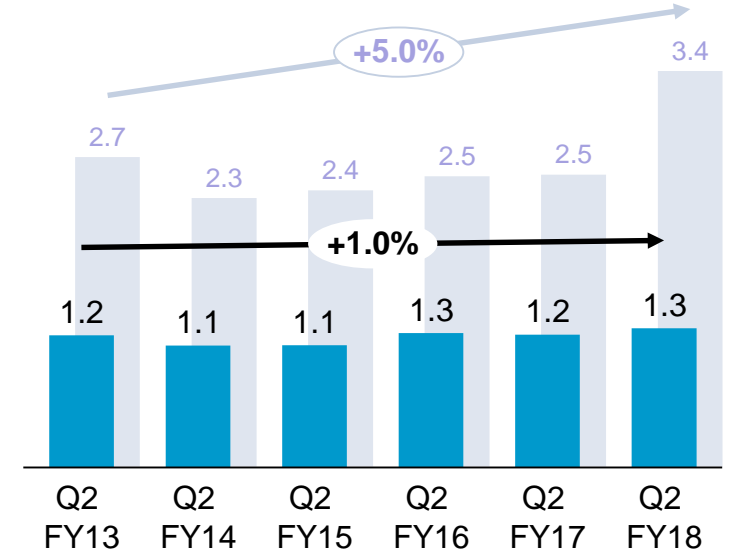
【Japan pharma】



【OTC】



【Surgical】



Revenue

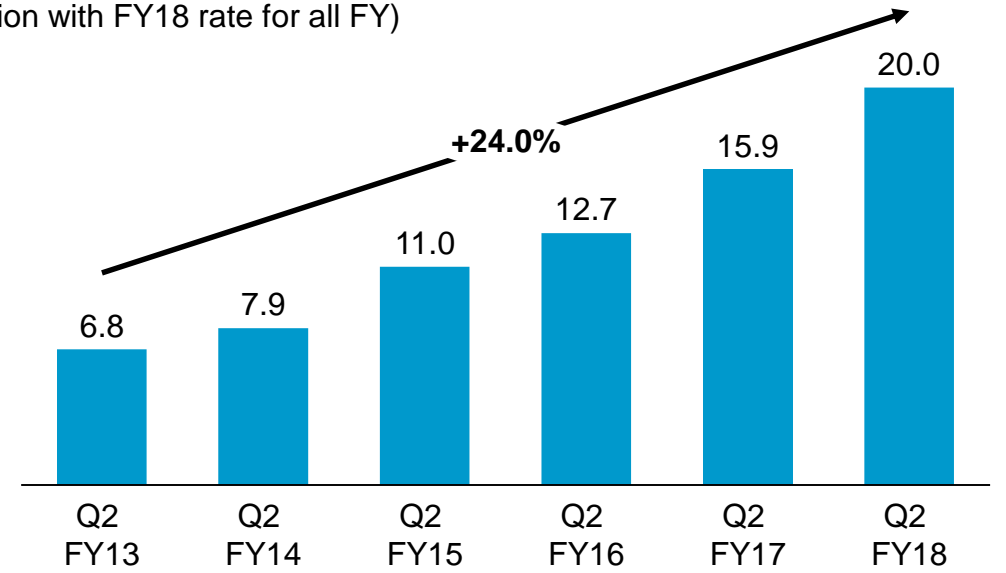
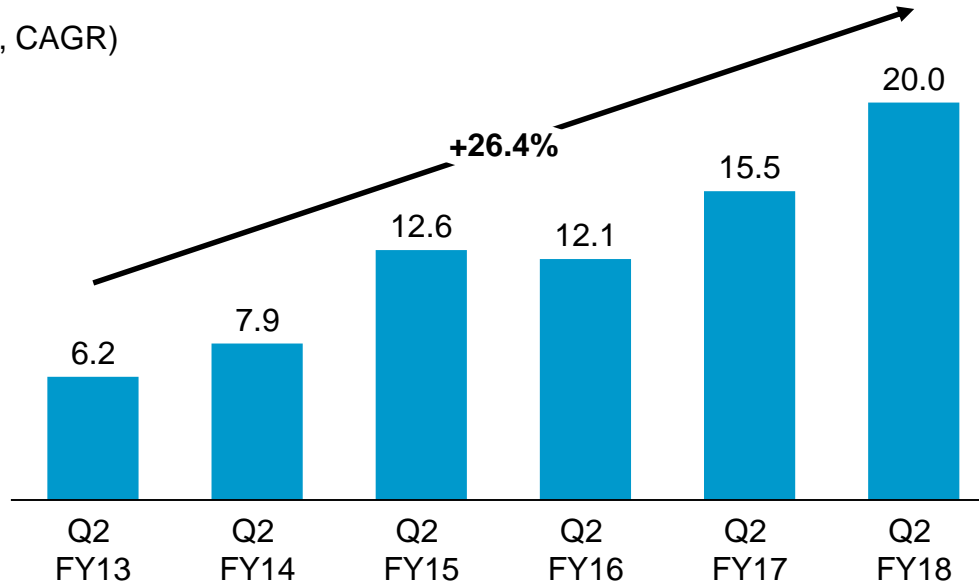
OP before R&D

Performance by Business (Asia)

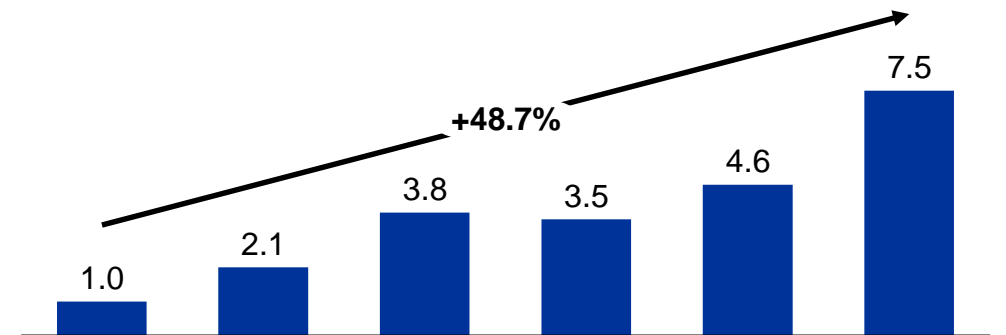
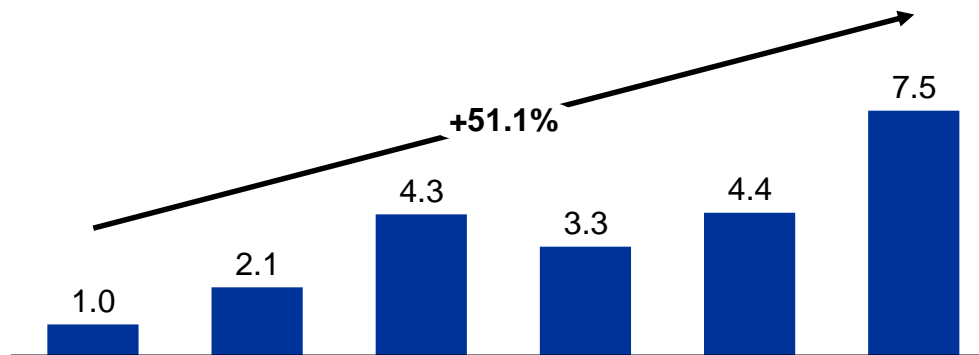
Japan yen basis
(JPY billions, CAGR)

Local currency basis
(Conversion with FY18 rate for all FY)

Revenue

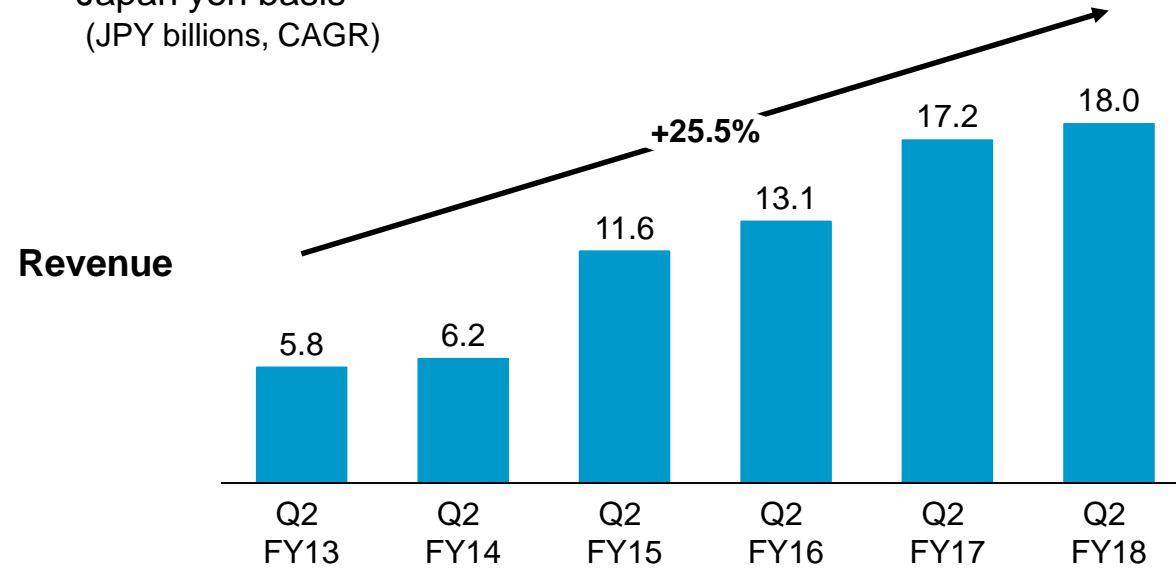


OP
before R&D

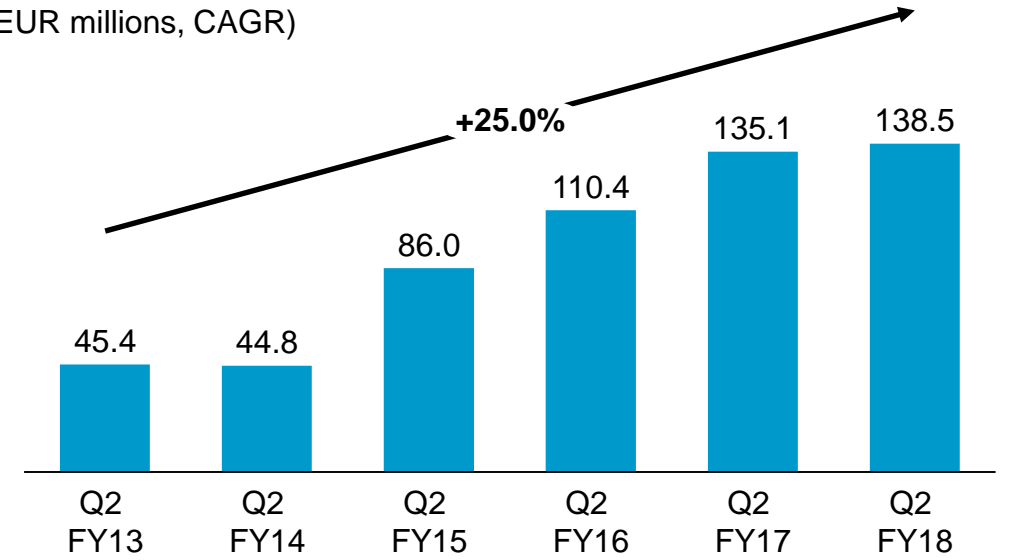


Performance by Business (EMEA)

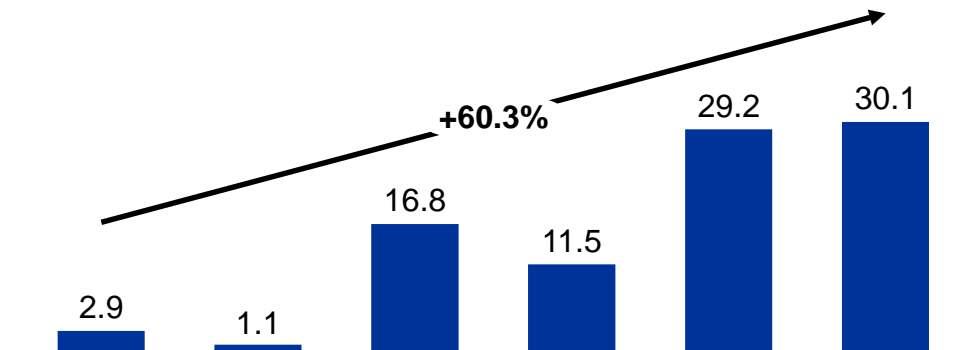
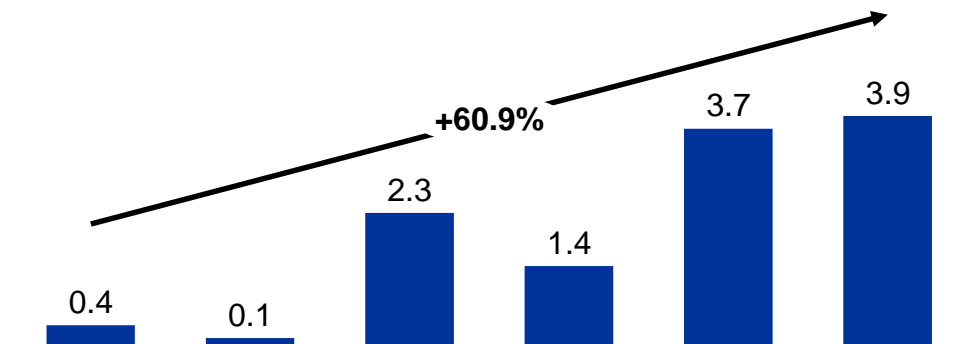
Japan yen basis
(JPY billions, CAGR)



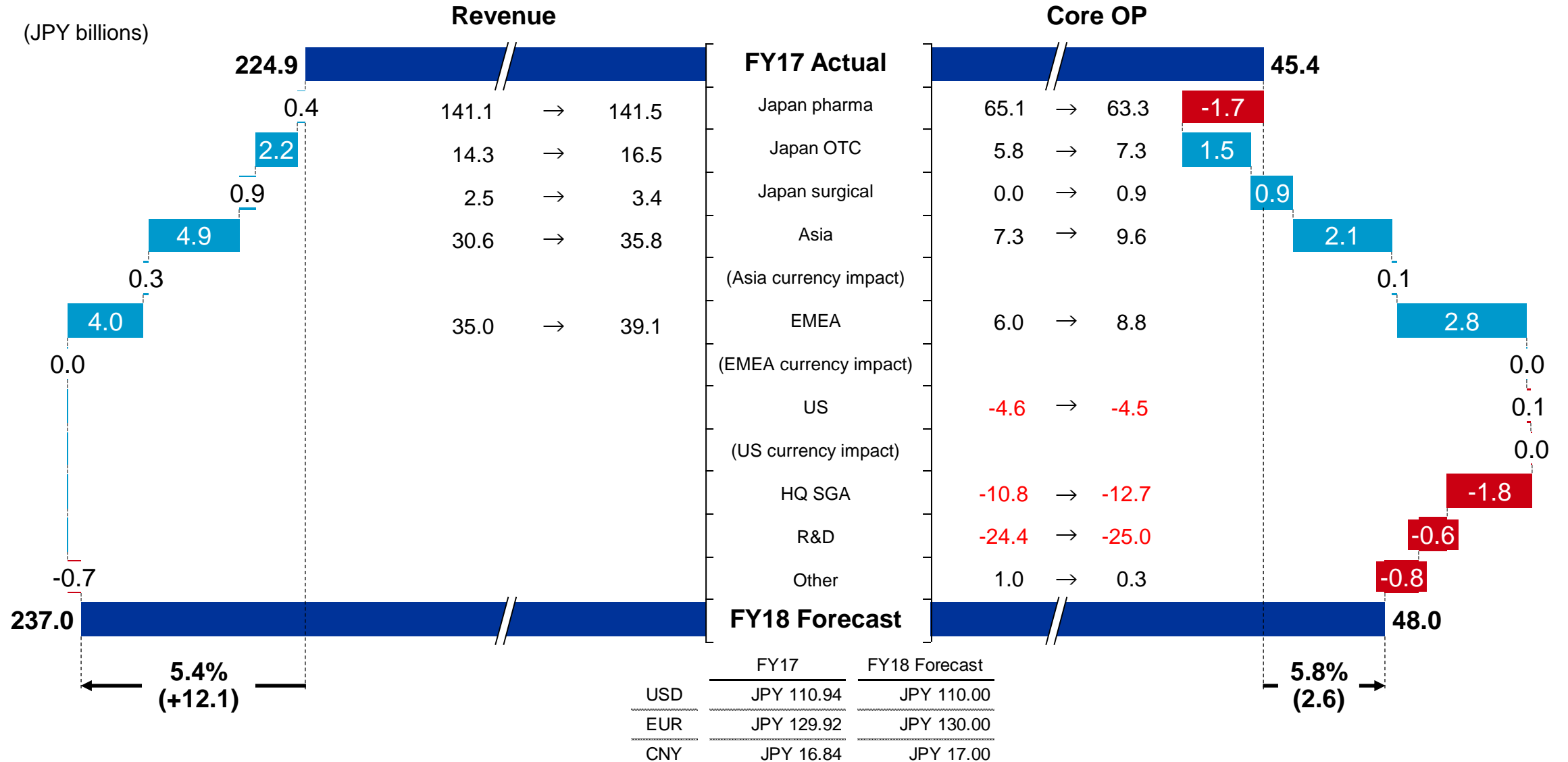
EURO basis
(EUR millions, CAGR)



**OP
before R&D**



FY2018 Forecast (No change from May 9)

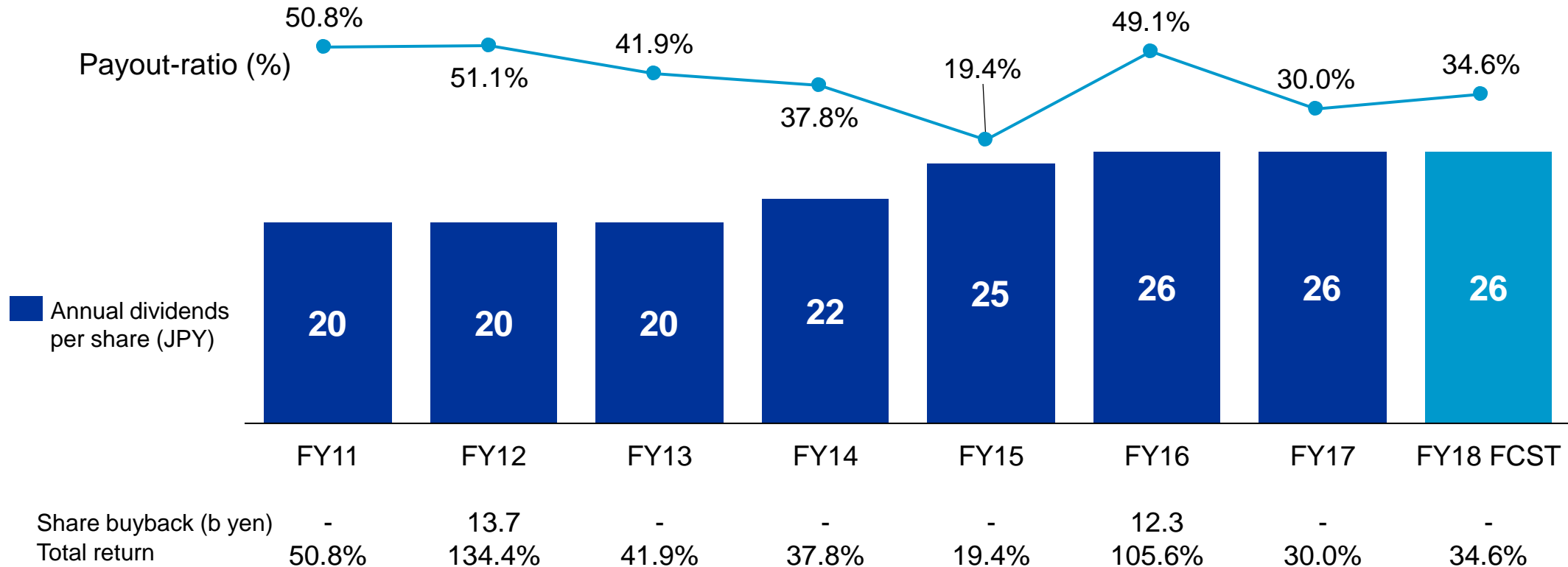


Dividend Forecast for FY2018 (No change from May 9)

- 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



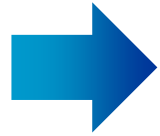
The company implemented a 5-for-1 stock split on April 1, 2015. Accordingly, the calculations of annual dividend per share have been adjusted in all periods for comparison purposes. J-GAAP standards used until FY13, IFRS applied from FY14.

EYBELIS Ophthalmic Solution 0.002% Approval in Japan, World's First Selective EP2 Receptor Agonist for Glaucoma

Increasing number of new patients suffering visual impairment from glaucoma in Japan¹⁾



Demand for new treatment options



EYBELIS :

New MOA in glaucoma treatment

→ **First new mechanism of action for 1st-line medicine approved in Japan in nearly 20 years***

➤ **Significant IOP lowering effect²⁾**

Demonstrated non-inferiority to latanoprost in a clinical trial where primary endpoint was IOP lowering

➤ **Stable maintenance of IOP lowering for 52 weeks³⁾**

Demonstrated that *EYBELIS* stably maintains efficacy and the combination therapy with timolol enhances efficacy for 52 weeks in a clinical trial

➤ **IOP lowering for non/low-responders to other mechanism of action⁴⁾**

Demonstrated significant effect in non-/low-responders to other mechanism of action after switching to *EYBELIS*

*Since latanoprost launch in 1999. In Japan, prostaglandin analogues and β -blockers are used 1st-line drugs in glaucoma treatment. Latanoprost and timolol are respectively classified prostaglandin analogue and β -blocker.⁵⁾

1) Morizane Y, et al: *Jpn J Ophthalmol*. 2018 Sep 25

2) A Phase II/III Study of *EYBELIS* Ophthalmic Solution in Subjects With Primary Open Angle Glaucoma or Ocular Hypertension, Santen Pharmaceutical Co., Ltd. internal document (that assessed for approval in Japan)

3) A Long-term Open-label Phase III Study of *EYBELIS* Ophthalmic Solution Monotherapy and Concomitant Use of *EYBELIS* Ophthalmic Solution With Timolol Ophthalmic Solution in Patients With Open-angle Glaucoma or Ocular Hypertension, Santen Pharmaceutical Co., Ltd. internal document (that assessed for approval in Japan)

4) A Phase III Study of DE-117 Ophthalmic Solution in Subjects With Primary Open-angle Glaucoma or Ocular Hypertension Who Are Non-/Low-responders to Latanoprost Ophthalmic Solution, Santen Pharmaceutical Co., Ltd. internal document (that assessed for approval in Japan)

5) The Japan Glaucoma Society Guidelines for Glaucoma (4th Edition) : *Nippon Ganka Gakkai Zasshi*. 122(1): 5-53, 2018

Status of Research & Development



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 November 7, 2018

	Indication	Region	Status
DE-117 <u>EYBELIS</u> EP2 receptor agonist	Glaucoma / ocular hypertension	US	<u>Started P3 in Sep 2018</u> <u>Plan: Jan~Jun 2020 P3 completion</u>
		Japan	<u>Approved in Sep 2018</u> <u>Plan: Nov 2018 NHI price listing and launch soon after</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>MicroShunt</u>	Glaucoma	US	P2/3 <u>Plan: Calendar 2018~2019 P2/3 completion, Calendar 2020~2021 launch</u>
		Europe	CE mark granted
DE-109 IVT sirolimus	Uveitis	US	P3 <u>Plan: Nov 2018 additional clinical trial start</u>
		Japan	P3
		Europe	P3
		Asia	Filed
DE-122 Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a <u>Plan: Jan~Jun 2019 P2a completion</u>

Pipeline / Product Development Status (2)

As of November 7, 2018

	Indication	Region	Status
DE-089 <i>Diquas</i>	Dry eye	China	<u>Launched in Sep 2018</u>
DE-076B Cyclokat / <i>Ikervis</i> ciclosporin	Severe keratitis in patients with dry eye	Asia	Launched
		US	P2
DE-076C Vekacia / <i>Verkazia</i> ciclosporin	Vernal kerato-conjunctivitis	Europe	<u>Launched in Oct 2018</u>
DE-114A epinastine HCl (high dose)	Allergic conjunctivitis	Japan	<u>Filed in Sep 2018</u> <u>Plan: Jul~Dec 2019 approval</u>
DE-127 atropine sulfate	Myopia	Asia	P2 <u>Plan: 2nd half of FY2019 P2 completion</u>

Appendix

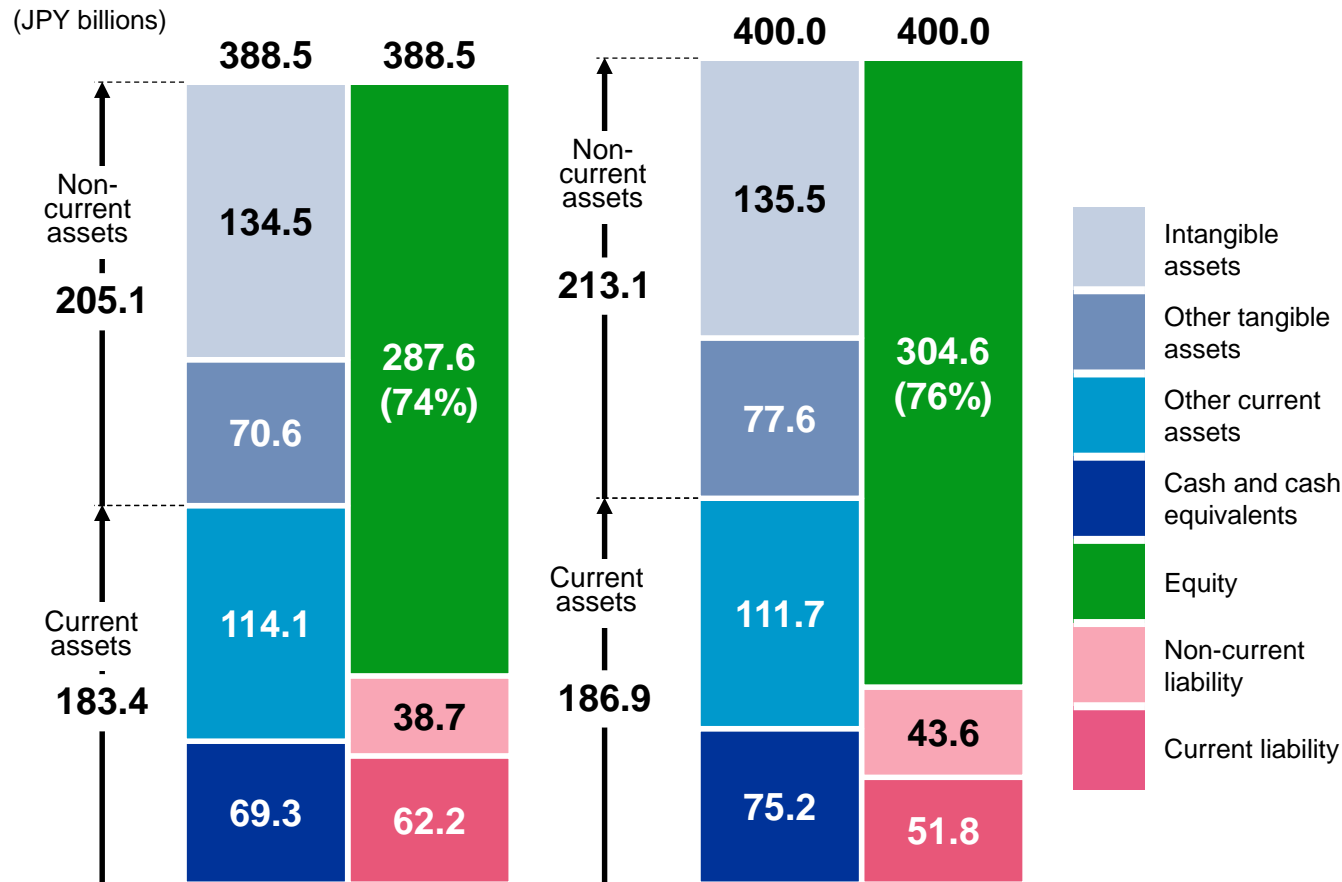
Q2 FY2018 Profit and Loss Statement

(JPY billions)	Q2 FY17		Q2 FY18		YoY
	Actual	vs Revenue	Actual	vs Revenue	
Revenue	110.8		114.3		3.2%
COGS	-43.0	-38.8%	-45.8	-40.0%	6.5%
	67.8	61.2%	68.6	60.0%	1.1%
SGA expenses	-31.7	-28.6%	-33.5	-29.3%	5.7%
R&D expenses	-11.7	-10.6%	-11.0	-9.6%	-6.6%
Amortization on intangible assets associated with products	-3.3	-3.0%	-3.5	-3.0%	4.5%
Other income	0.2	0.2%	0.3	0.2%	29.4%
Other expenses	-0.2	-0.2%	-0.1	-0.1%	-56.8%
Operating profit (IFRS)	21.0	19.0%	20.8	18.2%	-1.0%
Finance income	0.5	0.4%	0.5	0.5%	10.0%
Finance expenses	-0.9	-0.8%	-1.6	-1.4%	85.8%
Profit before tax	20.7	18.7%	19.8	17.3%	-4.3%
Income tax expenses	-5.4	-4.9%	-5.4	-4.7%	-0.5%
<i>Actual tax ratio</i>	<i>26.3%</i>		<i>27.4%</i>		<i>1.1pt</i>
Net profit (IFRS)	15.2	13.8%	14.4	12.6%	-5.7%
Core operating profit	24.4	22.0%	24.1	21.1%	-1.0%
Core net profit	17.9	16.2%	17.8	15.6%	-0.6%

Q2 FY2018 Financial Position

March 31, 2018

Sep 30, 2018



	31-Mar-18	30-Sep-18	Change
Non-current assets	205.1	213.1	8.0
Property, plant and equipment	29.7	31.5	1.8
Intangible assets	134.5	135.5	1.0
Financial assets	35.8	41.8	6.0
Other	5.1	4.3	-0.8
Current assets	183.4	186.9	3.6
Inventories	30.6	31.8	1.2
Trade and other receivables	78.7	76.2	-2.4
Cash and cash equivalents	69.3	75.2	6.0
Other	4.8	3.6	-1.2
Equity	287.6	304.6	17.0
Non-current liabilities	38.7	43.6	4.9
Financial liabilities	3.5	3.7	0.2
Long-term liabilities	17.7	19.2	1.6
Deferred tax liabilities	12.9	15.2	2.3
Other	4.6	5.4	0.8
Current liabilities	62.2	51.8	-10.4
Trade and other liabilities	29.7	28.4	-1.3
Other financial liabilities	14.4	9.6	-4.8
Income tax payable	7.7	5.2	-2.5
Other	10.4	8.6	-1.8

Q2 FY2018 Segment Revenue

(JPY billions)	Segment Revenue								
	Japan			Overseas			Total		
	Q2 FY2017	Q2 FY2018	YoY	Q2 FY2017	Q2 FY2018	YoY	Q2 FY2017	Q2 FY2018	YoY
Pharmaceuticals	78.0	76.2	-2.2%	32.8	38.1	16.2%	110.8	114.3	3.2%
Prescription	68.9	67.0	-2.8%	32.6	37.9	16.2%	101.5	104.9	3.3%
Ophthalmic	68.5	66.8	-2.5%	32.4	37.7	16.3%	101.0	104.6	3.5%
Others	0.4	0.2	-55.5%	0.2	0.2	1.0%	0.6	0.4	-35.8%
OTC	7.6	7.4	-1.9%	0.2	0.1	-3.4%	7.7	7.6	-1.9%
Medical devices	1.2	1.3	4.8%	0.0	0.0	69.1%	1.3	1.3	5.7%
Others	0.2	0.5	100.7%	0.0	0.1	154.9%	0.3	0.5	104.9%
Sales ratio	70.4%	66.7%		29.6%	33.3%				

Capital Expenditures / Depreciation & Amortization

(JPY billions)	FY2017		FY2018		
	Q2	Full year	Q2	Full year	
	Actual	Actual	Actual	YoY	Forecast
Capital expenditures	2.7	5.4	3.2	18.4%	9.0
Depreciation and amortization*	2.1	4.2	2.0	-1.1%	4.3
Amortization on intangible assets associated with products	3.3	6.7	3.5	4.5%	6.9
Intangible assets					
- Merck products	2.8	5.6	2.9	5.2%	5.8
Intangible assets					
- Ikervis	0.4	0.7	0.4	2.4%	0.7

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

Prescription Ophthalmic Market in Japan

JPY billions	Q2FY2017 (6 months)					Q2FY2018 (6 months)						
	Santen*		Market		Santen market share*		Santen*		Market		Santen market share*	
	Value	Change (YoY)	Value	Change (YoY)			Value	Change (YoY)	Value	Change (YoY)		
Total	81.8	6.4%	177.5	4.9%	46.1%	No.1	82.7	1.2%	176.2	-0.7%	47.0%	No.1
Glaucoma	18.3	-1.9%	58.3	1.0%	31.4%	No.1	16.9	-7.5%	55.8	-4.3%	30.3%	No.1
Anti-VEGF	30.4	15.0%	42.3	15.8%	71.8%	No.1	33.5	10.1%	46.2	9.1%	72.4%	No.1
Corneal/dry eye	14.7	3.0%	23.5	3.5%	62.5%	No.1	14.0	-4.3%	22.7	-3.4%	61.9%	No.1
Allergy	7.4	18.8%	15.6	7.9%	47.3%	No.1	8.4	14.2%	16.4	5.5%	51.1%	No.1
Anti-infection	3.0	-12.8%	7.4	-4.4%	41.0%	No.1	2.4	-20.5%	6.7	-9.5%	36.0%	No.1

	Oct 1, 2017 - Sep 30, 2018 (12 months)					
	Santen*		Market		Santen market share*	
Value	Change (YoY)	Value	Change (YoY)			
Total	168.9	4.1%	361.9	2.3%	46.7%	No.1
Glaucoma	34.5	-5.2%	112.5	-2.1%	30.7%	No.1
Anti-VEGF	64.3	11.1%	89.1	11.1%	72.2%	No.1
Corneal/dry eye	28.4	-2.0%	45.8	-1.0%	61.9%	No.1
Allergy	21.6	24.2%	43.7	12.4%	49.3%	No.1
Anti-infection	4.9	-17.3%	13.2	-7.4%	37.4%	No.1

*Including co-promoted product (Anti-VEGF *Eylea*) of Bayer Yakuhin, Ltd. (MAH)
 Source: Copyright © 2018 IQVIA. IMS-JPM 2016.4-2018.9; Santen analysis based on IQVIA data. Reprinted with permission.

DE-117 Started P3 studies in US and plan to complete in Jan~Jun 2020

DE-109 Plan to start an additional clinical trial in US in Nov 2018

	DE-117			DE-109
Trial No.	NCT03691649 (Spectrum 3)	NCT03691662 (Spectrum 4)	NCT03697811 (Spectrum 5)	NCT03711929 (LUMINA)
Indication	Glaucoma / ocular hypertension	Glaucoma / ocular hypertension	Glaucoma / ocular hypertension and latanoprost low/non-responder	Non-Infectious uveitis of the posterior segment
Study arms	<ul style="list-style-type: none"> 0.002% DE-117 once daily and vehicle once daily* 0.5% Timolol maleate twice daily 	<ul style="list-style-type: none"> 0.002% DE-117 once daily and vehicle once daily 0.5% Timolol maleate twice daily 	<ul style="list-style-type: none"> 0.002% DE-117 once daily 	<ul style="list-style-type: none"> DE-109 440µg intravitreal injection Sham procedure Dummy (DE-109, undisclosed, fixed dose) Administration at Day1, Month2 and 4
Primary endpoint	Change in IOP ¹⁾ for 3 months	Change in IOP for 3 months	Change in IOP for 3 months	VH ²⁾ of zero response at Month 3
Estimated enrollment	430 (including 30 pediatric subjects)	430 (including 30 pediatric subjects)	150	200
Reference	https://clinicaltrials.gov/ct2/show/NCT03691649?term=DE-117&rank=2	https://clinicaltrials.gov/ct2/show/NCT03691662?term=DE-117&rank=3	https://clinicaltrials.gov/ct2/show/NCT03697811?term=DE-117&rank=1	https://clinicaltrials.gov/ct2/show/record/NCT03711929?term=DE-109&rank=2
	*Followed by DE-117 once daily for additional 9 months for adult subjects only for long-safety data			

1) Intraocular pressure, 2) Vitreous haze

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 'anten' in a bold, dark blue sans-serif font. The 'S' is composed of two overlapping shapes, one light blue and one dark blue, creating a sense of depth and movement.

Santen

A Clear Vision For Life™