# FY2018 Results and FY2019 Forecasts



### Kazuo Koshiji

Senior Corporate Officer Corporate Administration Chief Financial Officer Head of Finance and Administration Division

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## FY2018 Financial Results ended March 31, 2019



## **FY2018 Financial Highlights**

Achieved higher revenue with steady growth overseas and key products in Japan more than offsetting negative impact from NHI price cuts in Japan; Strong OP growth on higher revenue and cost optimization

(JPY billions)	FY2017		FY2018						
Core basis	Full Year actual	Full Year actual	YoY	Full year forecast	vs FY forecast				
Revenue	224.9	234.0	4.0%	237.0	98.7%				
COGS	-86.4	-90.8	5.1%	-91.0	99.7%				
<b>Gross profit</b>	138.6	143.3	3.4%	146.0	98.1%				
SGA	-68.8	-71.3	3.6%	-73.0	97.6%				
R&D expenses	-24.4	-23.8	-2.6%	-25.0	95.0%				
OP	45.4	48.2	6.3%	48.0	100.5%				
Net profit	33.5	36.1	7.9%	35.3	102.2%				
IFRS									
OP	38.7	45.1	16.6%	40.7	110.8%				
Net profit	35.3	31.9	-9.4%	30.4	105.1%				
Actual tax ratio	10.2%	25.9%							
ROE	13.0%	11.1%	-1.9pt						
USD	JPY 110.94	JPY 110.82	+0.1%	JPY 110.00	-0.7%				
EUR	JPY 129.92	JPY 128.38	+1.2%	JPY 130.00	+1.2%				
CNY	JPY 16.84	JPY 16.52	+1.9%	JPY 17.00	+2.8%				
			+: JPY appre	ciation: JPY	depreciation				

### Revenue

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

Overseas: Continued strong growth, particularly in Asia

Consolidated total growth: 9.1 bil JPY (+4.0%)

### **Operating profit**

### **Core basis**

**Increased 2.9 bil JPY (+6.3%)** with continued overseas growth and group-wide cost optimization offsetting negative impact from NHI price cuts

### **IFRS**

Business growth on core basis and gain on sale of former HQ/Osaka plant site, **increased by 6.4 bil JPY (+16.6%)** 

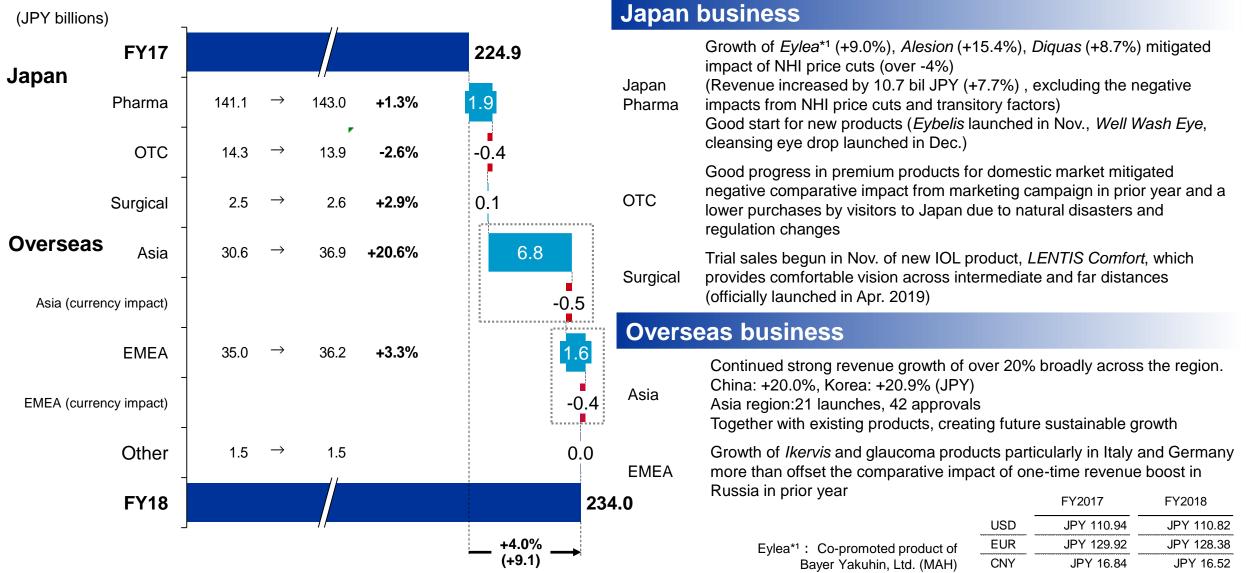
### **IFRS Net profit**

With one-time benefit of reduced corporate tax rate in U.S. in prior year and impact of accounting treatment of InnFocus acquisition costs, **decreased by 3.3 bil JPY (-9.4%)** 



## FY2018 Revenue

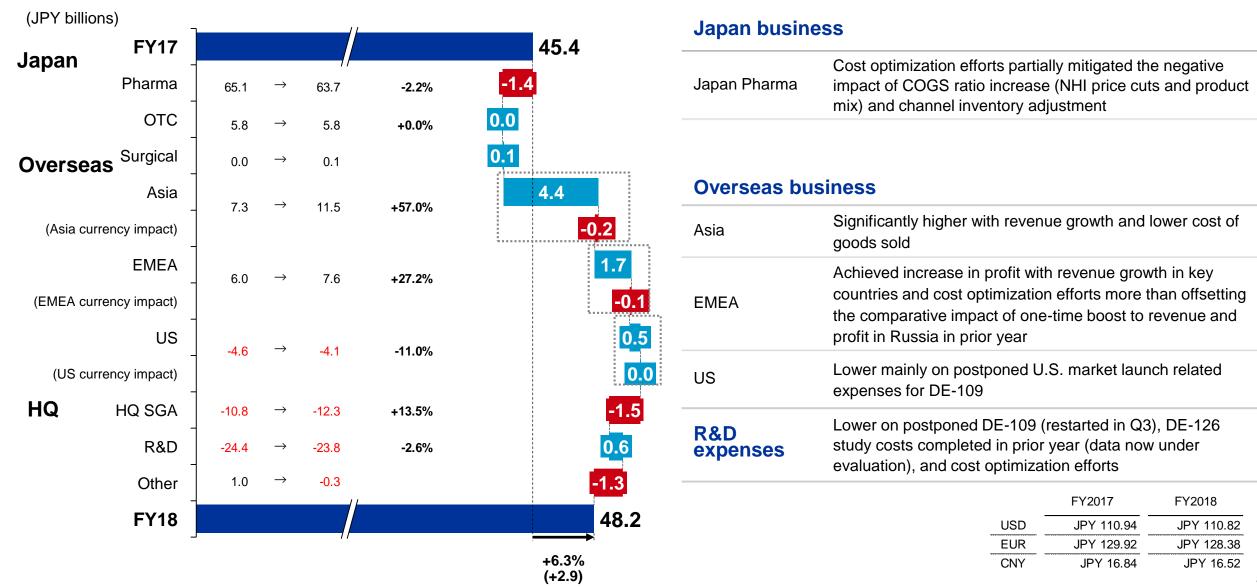
### Japan: steady growth of key products; Overseas: strong growth, particularly in Asia





## **FY2018 Core Operating Profit**

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



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## FY2019 Forecast ended March 31, 2020



## **FY2019 Forecast Overview**

As middle year of MTP2020, targeting to raise both revenue growth and operating efficiency

(JPY billions)	FY2018	FY2	019
Core basis	Actual	Forecast	YoY
Revenue	234.0	248.0	6.0%
COGS	-90.8	-95.0	4.7%
Gross profit	143.3	153.0	6.8%
SGA	-71.3	-74.0	3.8%
R&D expenses	-23.8	-28.0	17.9%
Operating profit	48.2	51.0	5.7%
Net profit	36.1	37.7	4.5%
Actual tax ratio	25.2%	26.1%	
ROE	12.5%	12.8%	0.3pt
IFRS			
Operating profit	45.1	34.5	-23.5%
Net profit	31.9	23.2	-27.4%
Actual tax ratio	25.9%	32.4%	
ROE	11.1%	7.9%	-3.2pt
USD	110.82	110.00	+0.7%
EUR	128.38	130.00	-1.2%
CNY	16.52	16.00	+3.3%
		oppropiotion : II	DV depression

+: JPY appreciation, -: JPY depreciation

#### Revenue

#### Japan:

To grow with increased revenue from key products (including *Eybelis*, Highdose *Alesion* and *LENTIS Comfort*) covering the negative impact from NHI price cuts

#### **Overseas:**

Maximize revenue both in Asia and EMEA Consolidated total revenue 248 bil JPY (+6.0%)

### **Core basis**

### **Continuous profit improvement from core business**

• SGA: 74 bil JPY (+3.8%)

Accelerate cost optimization under new management framework

• R&D expenses: 28 bil JPY (+17.9%)

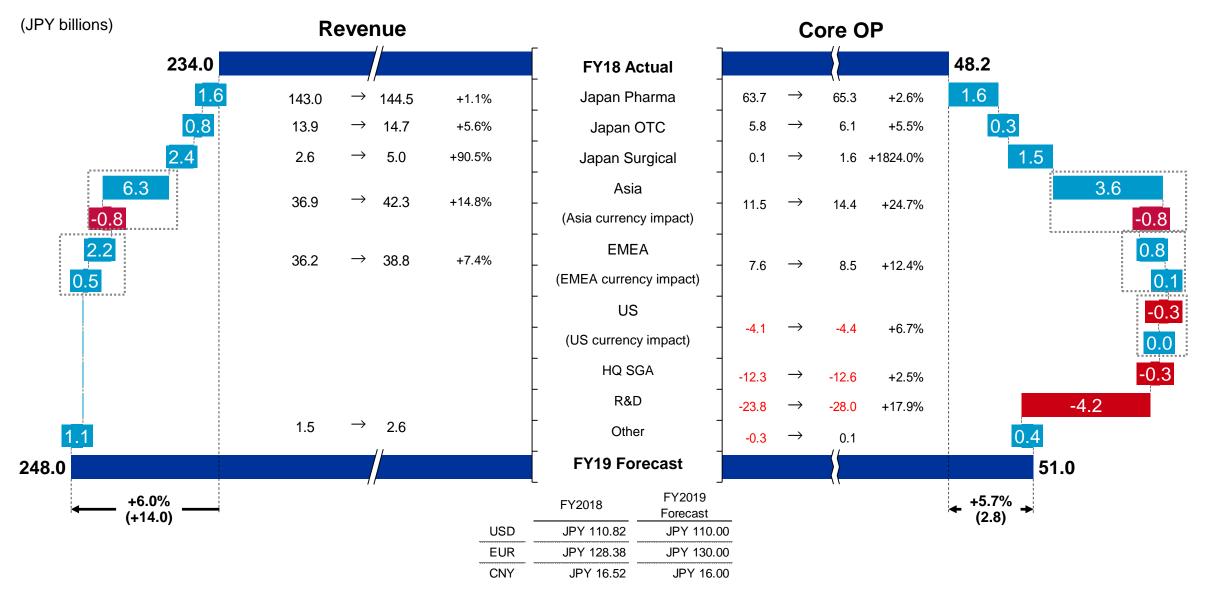
Continue strategic investment to lead growth to 2020 and beyond Operating profit: 51 bil JPY (+5.7%)

### IFRS

Other expenses increase mainly from raised assumptions regarding DE-128 milestone payment probability based on development progress; Operating profit and net profit lower YoY

## **FY2019 Forecast**

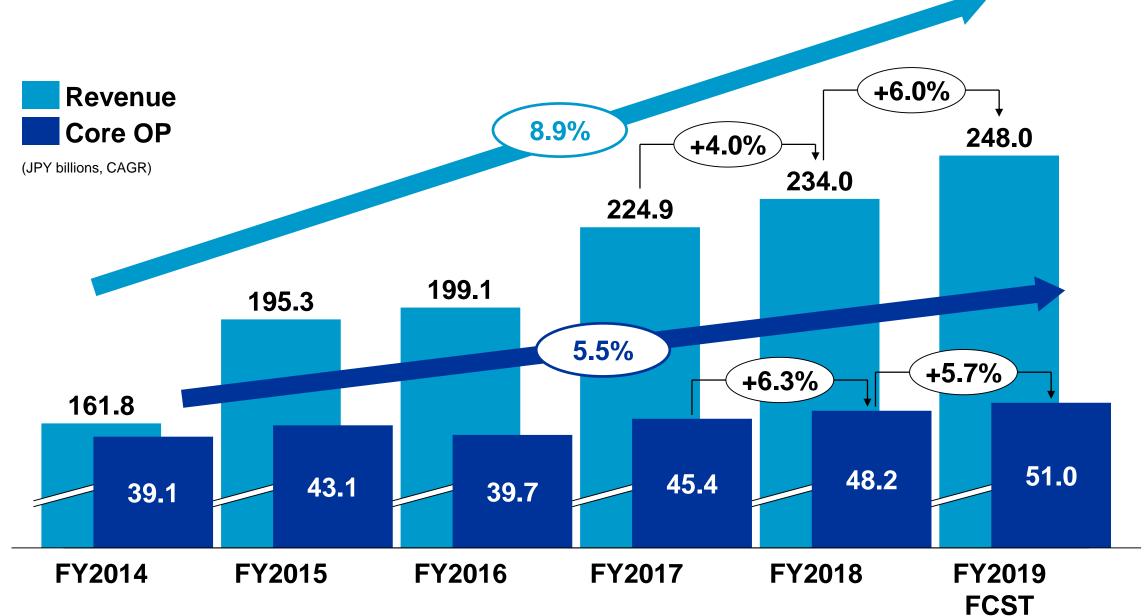
Growth in Japan and overseas businesses and further optimization of costs in order to realize strategic investment and higher profit



Santen

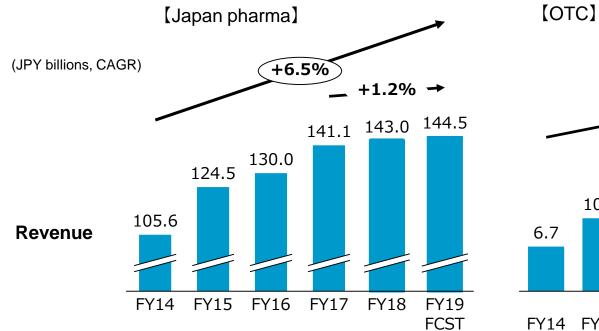


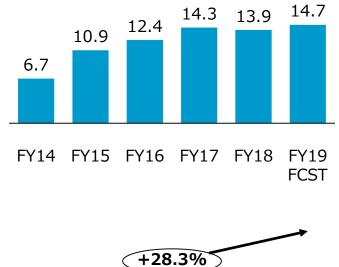
### **Consolidated Performance**





## Performance by Business (Japan)





+17.2%

+1.4% +



6.1

5.8

5.8

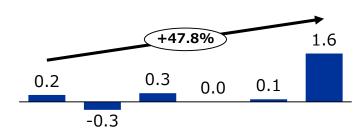
4.7

4.0

1.8

[Surgical]

2.3



+16.3%

2.5

2.5

2.4

+40.0%

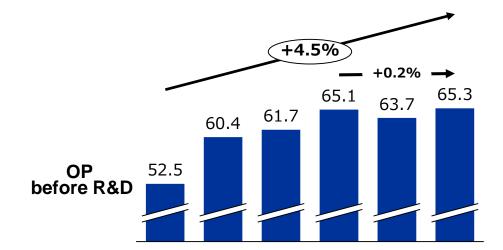
2.6

FY18

5.0

FY19

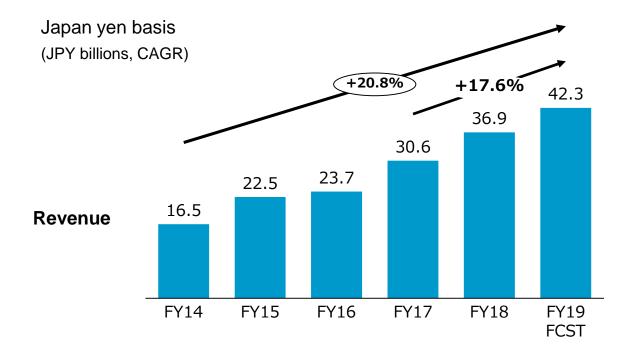
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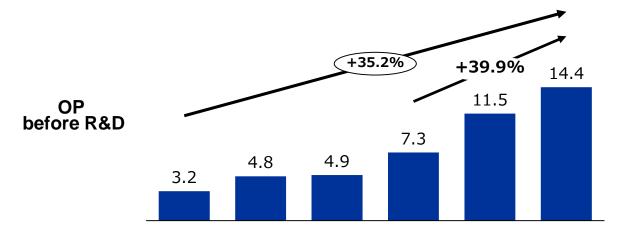


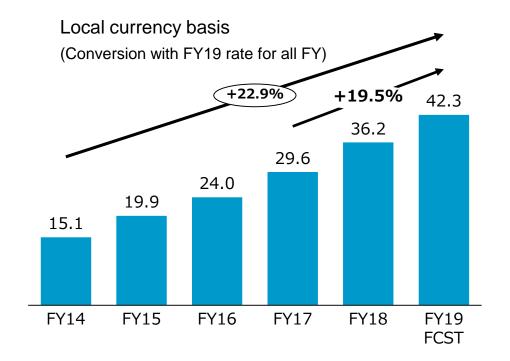
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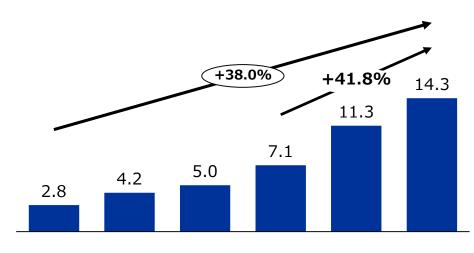


## **Performance by Business (Asia)**



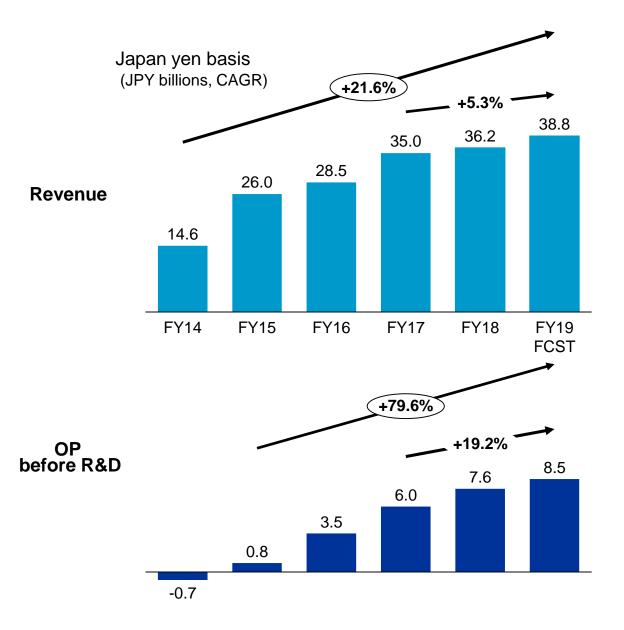


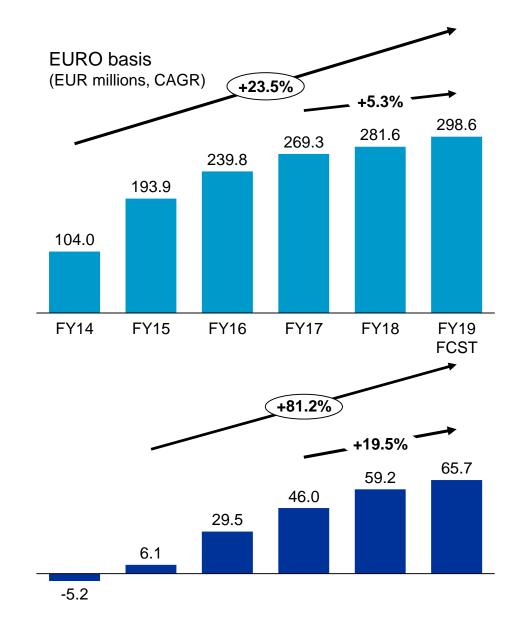






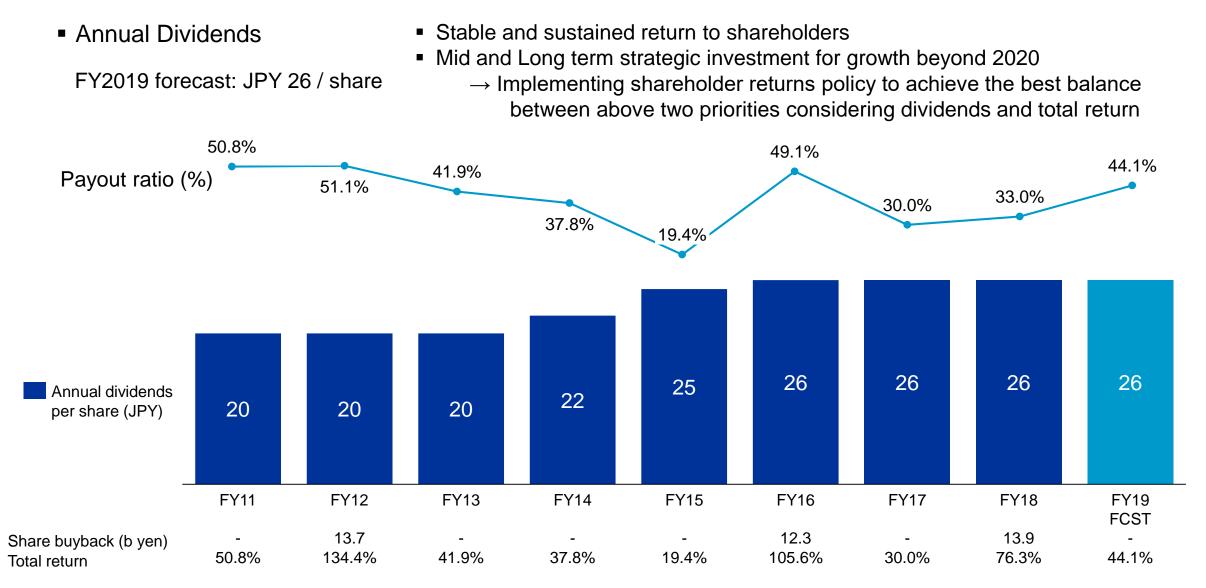
## **Performance by Business (EMEA)**







## **FY2019 Dividend Forecast**



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 May 9, 2019 Updated information is underlined

	Indication	Region	Status					
<b>DE-111</b> <i>TAPCOM / TAPTIQOM</i> Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 Plan: 1 <sup>st</sup> half FY2020 P3 completion					
		US	P3 Plan: Jan~Jun 2020 P3 completion					
DE-117 EYBELIS	Glaucoma / ocular hypertension	Japan	Launched					
EP2 receptor agonist		Asia	<u>Filed (Apr 2019, including Korea)</u> Plan: <u>1<sup>st</sup> half of FY2020 approval</u>					
DE-126	Glaucoma /	US	P2b					
FP/EP3 receptors dual agonist	ocular hypertension	Japan	ΓZD					
DE-128 PRESERFLO MicroShunt	Glaucoma	US	P2/3 Plan: calendar 2019 PMA rolling submission completion, calendar 2020 launch					
		Europe	CE mark received					
DE-130A	Glaucoma /	Europe	P3 started (Apr 2019)					
Catioprost latanoprost	ocular hypertension	Asia	Plan: <u>calendar 2021 P3 completion</u>					

## **Pipeline / Product Development Status (2)**

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As of May 9, 2019 Updated information is underlined

	Indication	Region	Status	opuated information is underlined					
		US	P3 Plan: Jan~Jun 2021 P3 completion						
DE-109	Uveitis	Japan	P3						
IVT sirolimus		Europe	P3						
		Asia	Asia Filed						
<b>DE-122</b> Anti-endoglin antibody	Wet age-related macular degeneration	US	P2a Plan: 2nd half of FY2019 P2a completion						
DE-089 Diquas	Dry eye	China	Launched						
DE-076C		Europe	Launched						
Vekacia / Verkazia	Vernal kerato-conjunctivits	Asia*	Filed, Plan: Jul~Dec 2019 approval	*Product name IKERVIS					
ciclosporin		Others	Approved, Plan: calendar 2019 launch						
<b>DE-114A</b> epinastine HCI (high dose)	Allergic conjunctivitis	Japan	Filed Plan: Jul~Dec 2019 approval						
DE 407		Japan	Plan: <u>1<sup>st</sup> half of FY2019 P2/3 start</u>						
<b>DE-127</b> atropine sulfate	Муоріа	Asia	P2 Plan: 2 <sup>nd</sup> half of FY2019 P2 completion						
MD-16 Intraocular lens	Cataract	Japan	P3 completion (Mar 2019) Plan: <u>1<sup>st</sup> half of FY2019 submission</u>						



## Appendix



## **FY2018 Profit and Loss Statement**

	FY20	)17	FY20		
(JPY billions)	Actual	vs Revenue	Actual	vs Revenue	YoY
Revenue	224.9		234.0		4.0%
COGS	-86.4	-38.4%	-90.8	-38.8%	5.1%
Gross profit	138.6	61.6%	143.3	61.2%	3.4%
SGA expenses	-68.8	-30.6%	-71.3	-30.5%	3.6%
R&D expenses	-24.4	-10.8%	-23.8	-10.2%	-2.6%
Amortization on intangible assets assosiated with products	-6.7	-3.0%	-7.0	-3.0%	3.7%
Other income	0.4	0.2%	4.0	1.7%	865.3%
Other expenses	-0.4	-0.2%	-0.2	-0.1%	-52.7%
Operating profit (IFRS)	38.7	17.2%	45.1	19.3%	16.6%
Finance income	1.0	0.4%	0.9	0.4%	-10.3%
Finance expenses	-0.4	-0.2%	-2.9	-1.2%	563.5%
Profit before tax	39.3	17.5%	43.1	18.4%	9.8%
Income tax expenses	-4.0	-1.8%	-11.2	-4.8%	179.4%
Actual tax ratio	10.2%		25.9%		15.7pt
Net profit (IFRS)	35.3	15.7%	31.9	13.6%	-9.4%
Core operating profit	45.4	20.2%	48.2	20.6%	6.3%
Core net profit	33.5	14.9%	36.1	15.4%	7.9%

Gain on sale of former HQ / Osaka plant site

Due to the yearly re-evaluation of non-current liability from the acquisition of InnFocus

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.



## **FY2019 Profit and Loss Statement Forecast**

	FY2	018	FY2019			
(JPY billions)	Actual	vs Revenue	Forecast	vs Revenue	YoY	
Revenue	234.0		248.0		6.0%	
COGS	-90.8	-38.8%	-95.0	-38.3%	4.7%	
Gross profit	143.3	61.2%	153.0	61.7%	6.8%	
SGA expenses	-71.3	-30.5%	-74.0	-29.8%	3.8%	
R&D expenses	-23.8	-10.2%	-28.0	-11.3%	17.9%	
Amortization on intangible assets assosiated with products	-7.0	-3.0%	-9.9	-4.0%	41.1%	
Other income	4.0	1.7%	0.9	0.4%	-77.3% —	
Other expenses	-0.2	-0.1%	-7.6	-3.0%	4287.5%	
Operating profit (IFRS)	45.1	19.3%	34.5	13.9%	-23.5%	
Finance income	0.9	0.4%	0.8	0.3%	-6.8%	
Finance expenses	-2.9	-1.2%	-1.0	-0.4%	-63.9%	
Profit before tax	43.1	18.4%	34.3	13.8%	-20.4%	
Income tax expenses	-11.2	-4.8%	-11.1	-4.5%	-0.7%	
Actual tax ratio	25.9%		32.4%		6.4pt	
Net profit (IFRS)	31.9	13.6%	23.2	9.4%	-27.4%	
Core operating profit	48.2	20.6%	51.0	20.6%	5.7%	
Core net profit	36.1	15.4%	37.7	15.2%	4.5%	

## Starting amortization of intangible assets on PRESERFLO MicroShunt

Due to the increase of the fair value of contingent payment on InnFocus acquisition (milestone would be paid on the progress of DE-128 status during FY2019)

Tax effect cannot be recognized on the expense from the change in the fair value of contingent payment (described above), income tax expense would not be reduced, resulting in an increase in actual tax ratio

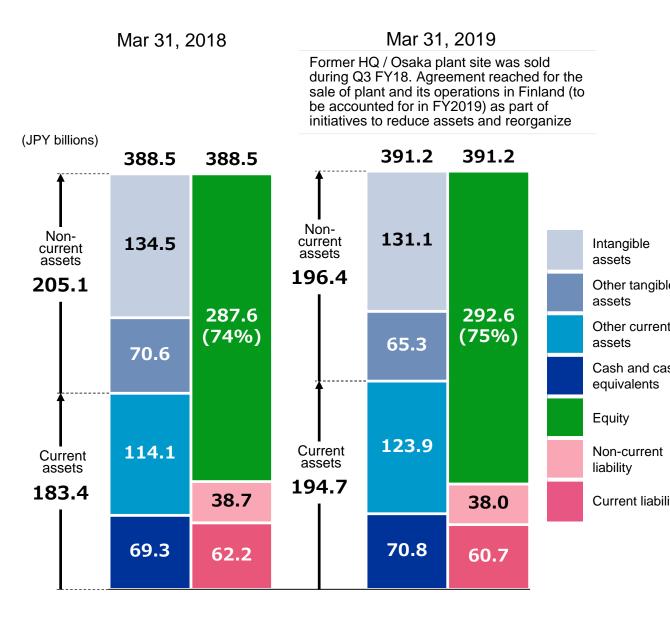


### FY2017, FY2018, FY2019 (Forecast) Profit and Loss Statement

_	FY20	017		FY2018		FY2019			
(JPY billions)	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast	vs Revenue	YoY	
Revenue	224.9		234.0		4.0%	248.0		6.0%	
COGS	-86.4	-38.4%	-90.8	-38.8%	5.1%	-95.0	-38.3%	4.7%	
Gross profit	138.6	61.6%	143.3	61.2%	3.4%	153.0	61.7%	6.8%	
SGA expenses	-68.8	-30.6%	-71.3	-30.5%	3.6%	-74.0	-29.8%	3.8%	
R&D expenses	-24.4	-10.8%	-23.8	-10.2%	-2.6%	-28.0	-11.3%	17.9%	
Amortization on intangible assets assosiated with products	-6.7	-3.0%	-7.0	-3.0%	3.7%	-9.9	-4.0%	41.1%	
Other income	0.4	0.2%	4.0	1.7%	865.3%	0.9	0.4%	-77.3%	
Other expenses	-0.4	-0.2%	-0.2	-0.1%	-52.7%	-7.6	-3.0%	4287.5%	
Operating profit (IFRS)	38.7	17.2%	45.1	19.3%	16.6%	34.5	13.9%	-23.5%	
Finance income	1.0	0.4%	0.9	0.4%	-10.3%	0.8	0.3%	-6.8%	
Finance expenses	-0.4	-0.2%	-2.9	-1.2%	563.5%	-1.0	-0.4%	-63.9%	
Profit before tax	39.3	17.5%	43.1	18.4%	9.8%	34.3	13.8%	-20.4%	
Income tax expenses	-4.0	-1.8%	-11.2	-4.8%	179.4%	-11.1	-4.5%	-0.7%	
Actual tax ratio	10.2%		25.9%		15.7pt	32.4%		6.4pt	
Net profit (IFRS)	35.3	15.7%	31.9	13.6%	-9.4%	23.2	9.4%	-27.4%	
Core operating profit	45.4	20.2%	48.2	20.6%	6.3%	51.0	20.6%	5.7%	
Core net profit	33.5	14.9%	36.1	15.4%	7.9%	37.7	15.2%	4.5%	



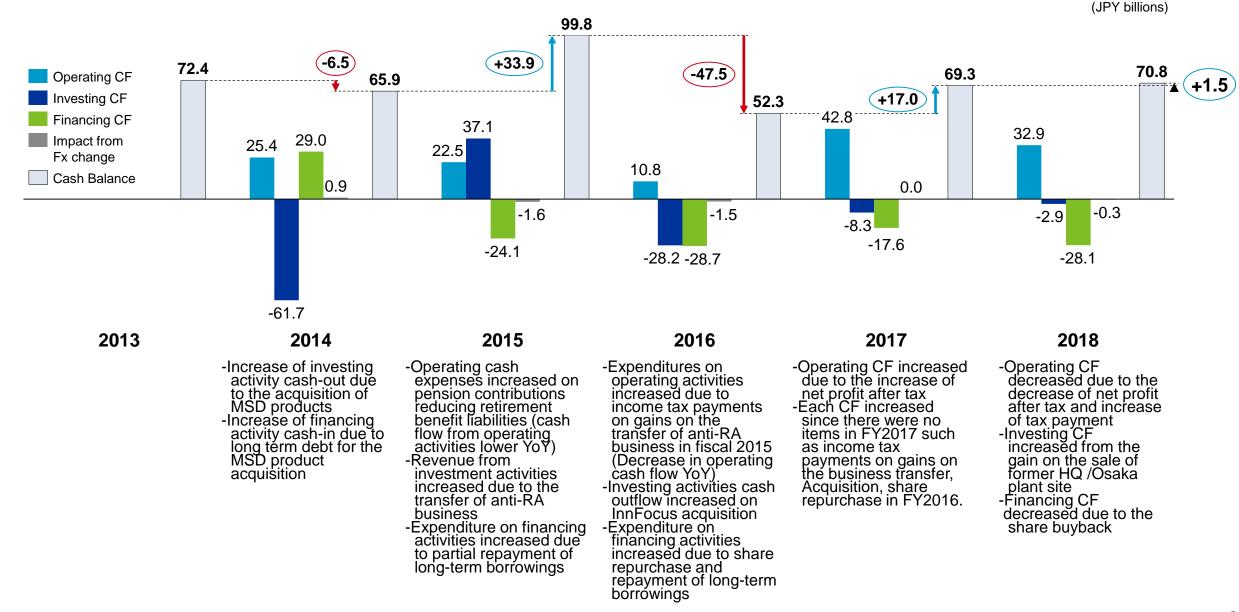
## **FY2018 Financial Position**



		March 31, 2018	Mar 31, 2019	Change
	Non-current assets	205.1	196.4	-8.7
	Property, plant and equipment	29.7	31.7	2.0
	Intangible assets	134.5	131.1	-3.4
	Financial assets	35.8	30.0	-5.7
	Deferred tax assets	2.3	1.8	-0.5
	Other	2.9	1.8	-1.0
	Current assets	183.4	194.7	11.4
	Inventories	30.6	35.2	4.6
	Trade and other receivables	78.7	84.6	6.0
	Cash and cash equivalents	69.3	70.8	1.5
ole	Other	4.8	4.1	-0.7
nt ash	Equity	287.6	292.6	5.0
	Non-current liabilities	38.7	38.0	-0.8
	Financial liabilities	3.5	3.6	0.1
	Deferred tax liabilities	12.9	9.4	-3.5
	Other	22.3	25.0	2.7
ility	Current liabilities	62.2	60.7	-1.5
,	Trade and other liabilities	29.7	32.1	2.3
	Other financial liabilities	14.4	12.1	-2.3
	Income tax payable	7.7	7.2	-0.5
	Other	10.4	9.3	-1.1



### **Cash Flow Changes**





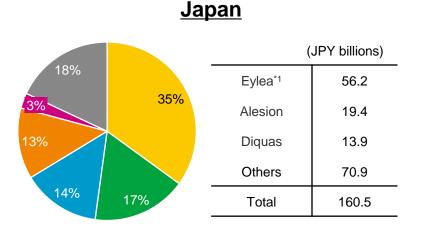
## FY2018 Segment Revenue

						Segment	Revenue	•				
		Jap	ban		Overseas				Total			
(JPY billions)	FY2017 Actual	FY2018 Actual	YoY	FY2019 Forecast	FY2017 Actual	FY2018 Actual	YoY	FY2019 Forecast	FY2017 Actual	FY2018 Actual	YoY	FY2019 Forecast
Pharamaceuticals	158.7	160.5	1.1%	166.1	66.3	73.6	11.0%	81.9	224.9	234.0	4.0%	248.0
Prescription	141.1	143.0	1.3%	144.5	65.9	73.1	10.9%	80.9	207.0	216.0	4.4%	225.4
Ophthalmic	140.4	142.6	1.5%	144.1	65.5	72.7	11.1%	80.7	205.9	215.3	4.6%	224.8
Others	0.7	0.4	-43.6%	0.4	0.4	0.4	-19.4%	0.2	1.1	0.7	-33.8%	0.6
OTC	14.3	13.9	-2.6%	14.7	0.3	0.3	-0.1%	0.4	14.6	14.2	-2.5%	15.1
Medical devices	2.5	2.6	2.9%	5.0	0.1	0.1	95.7%	0.5	2.6	2.7	4.9%	5.4
Others	0.8	1.0	28.9%	1.9	0.0	0.1	121.0%	0.1	0.8	1.1	33.5%	2.0
Sales ratio	70.5%	68.6%		67.0%	29.5%	31.4%		33.0%				

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## **Revenue by Business (Graph) / FY2018**



 12%
 (JPY billions)

 4%1%
 Cosopt
 9.4

 7apros
 6.4

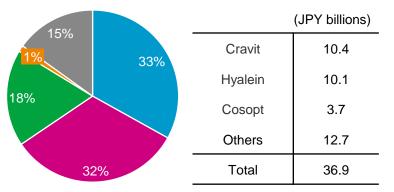
 Ikervis
 2.9

 Others
 17.5

 Total
 36.2

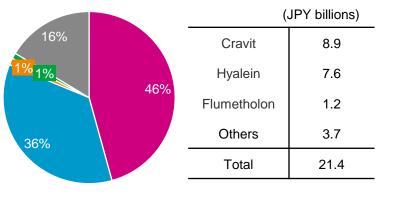
**EMEA** 

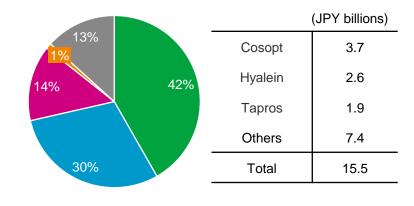




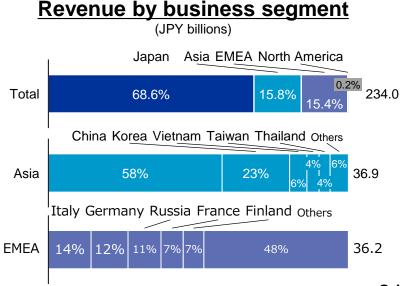
Eylea\*: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

<u>China</u>





Asia (Ex. China)





## **Capital Expenditures / Depreciation & Amortization**

	FY201	7	FY2	018	FY2019	
(JPY billions)	Actual	YoY	Actual	YoY	Forecast	YoY
Capital expenditures	5.4	4.4%	7.2	32.6%	10.0	38.5%
Depreciation and amortization*	4.2	19.7%	4.0	-4.2%	4.8	19.6%
Amortization on intangible assets associated with products	6.7	5.1%	7.0	3.7%	9.9	41.7%
Intangible assets -Merck products	5.6	4.4%	5.8	3.9%	5.8	0.0%
Intangible assets -PRESERFLO MicroShunt	-	-	-	-	2.8	-
Intangible assets -lkervis	0.7	9.2%	0.7	-1.2%	0.7	1.8%

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



## **Prescription Ophthalmic Market in Japan**

	FY2017							FY2018						
	San	ten*	Mark	ket	Oraclas			en*	Market		Orantaa			
JPY billions	Value	Change (YoY)	Value	Change (YoY)	Santen – market share* –	Value	Change (YoY)	Value	Change (YoY)	Santen market share*				
Total	167.9	6.7%	363.3	5.1%	46.2%	No.1	172.6	2.8%	365.2	0.5%	47.3%	No.1		
Glaucoma	35.9	-2.4%	114.9	0.5%	31.2%	No.1	33.1	-7.8%	109.8	-4.4%	30.1%	No.1		
Anti-VEGF	61.2	13.5%	85.3	14.5%	71.8%	No.1	67.5	10.3%	93.6	9.8%	72.1%	No.1		
Corneal/dry eye	29.0	1.7%	46.6	2.5%	62.2%	No.1	28.1	-3.2%	45.7	-2.1%	61.5%	No.1		
Allergy	20.5	26.7%	42.9	13.5%	47.9%	No.1	24.7	20.3%	47.3	10.3%	52.2%	No.1		
Anti-infection	5.6	-13.4%	13.9	-4.7%	40.0%	No.1	4.4	-20.4%	12.6	-9.4%	35.1%	No.1		

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

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## Agreement with Glaukos for Exclusive Distribution of PRESERFLO MicroShunt (DE-128) in U.S.

Santen U.S. market entry strategy



- Maximize the value of each differentiated product
- through tailored strategy
- Achieve profit at earliest timing

### **GLAUK** S°

- High surgical glaucoma expertise
- Strong presence in US

### **PRESERFLO MicroShunt**



 Aiming for leading efficacy and greater safety compared to existing surgical methods

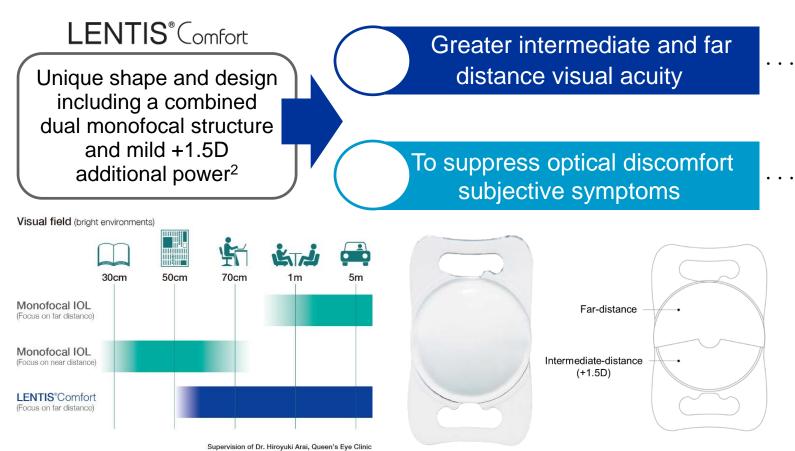
- Upon approval, provide PRESERFLO MicroShunt to more patients in the most timely way possible
- Shorten the start-up period / minimize U.S. entry costs
- Agreement with Glaukos for exclusive distribution is solely for the U.S.
- Santen to gain a foothold in U.S. market and build experience in areas including marketing, manufacture, quality and safety controls, regulatory activities and post-approval marketing requirements for PRESERFLO MicroShunt. Such experience can be leveraged in future with other pipeline projects.

## Launched LENTIS®Comfort in Japan

\*Pipeline: MD-16 (toric lens)

A low-add segmental intraocular lens and 1<sup>st</sup> covered by the Japanese national health insurance system **To provide patients with more comfortable visual acuity compared to** <u>monofocal lenses</u>

(90% of intraocular lens market in Japan (unit base), excluding toric lens<sup>1</sup>)



1) Santen internal data 2) an added power in diopter to focus on near objects (equivalent to the difference between an diopter for near distance and far distance 3) Clinical trial summary reports version 2.1 of MD-15 intraocular lens Phase 3, open label study for aphakic eyes after cataract surgery

 Existing monofocal lens
 Limited focus range → good vision is limited to near or far distance

- LENTIS Comfort
- Expected greater intermediate and far distance visual acuity with a wide focus range<sup>3</sup>

Halo / glare temporal changes

98.3% of the patients 52 weeks after the surgery scored halos / glare subjective symptoms as "No subjective symptoms" or "Sometimes noticing subjective symptoms, however no impact on daily life" <sup>3</sup>

#### Halo / glare

Unwanted visual images surrounding light sources in low-light situations that interferes with vision



Above images are simulations



## **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.
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