

Conference Call on Q1 FY2020 Results

Shigeo Taniuchi

President & Chief Executive Officer

Kazuo Koshiji

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

Kenji Morishima

Corporate Officer, China R&D Supervisor

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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 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 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.

CORE PRINCIPLE and WORLD VISION

CORE PRINCIPLE

天機に参与する

Tenki ni sanyo suru

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

WORLD VISION

Happiness with Vision

The Happiest Life for every individual, through the Best Vision Experience

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

Q1 FY2020 Highlights

1. Revenue: JPY 57.6bil, Core OP: JPY 11.7bil

Q1 results were in line with expectations

2. Entering the US market: Steady progress

Completed FDA rolling submission for DE-128 to provide new value to patients

3. New measures in line with our long-term vision

Addressing unmet needs through alliances with jCyte, Plano and Osmotica



Supporting COVID-19 Measures as a Specialized Ophthalmology Company

Donating breath shields to medical institutions



Providing eye care information

Santen
20,677 followers
4週間前 · 編集済み

As we all continue to adapt to a world with COVID-19, it's important for us to consider our eye health, particularly in this time of increased dependence on technology and greater exposure to LCD screens. Check out our tips below!

#ophthalmology #coronavirus #eyehealth

The impact of the pandemic means that many more of us are working on computers from home...

Santen

Webinar for medical professionals

Santen
A Clear Vision For Life®



WEBINAR
Treating Glaucoma Patients During
COVID-19

A case-based webinar to provide up-to-date guidance in the management of glaucoma patients during COVID-19

Developing New Working Styles for the New Normal

Developing work style not limited by time and place



Leveraging technology



Future offices



Q1 FY2020 Financial Results ended June 30, 2020

Q1 FY2020 Results

In line with expectations despite it was the impact of COVID-19

(JPY billions)	FY2019		FY2020		YoY
	Q1 Actual	vs Revenue	Q1 Actual	vs Revenue	
Revenue	59.1		57.6		-3%
Cost of sales	24.1	41%	24.7	43%	+3%
Gross margin	35.0	59%	32.8	57%	-6%
SG&A expenses	16.0	27%	15.6	27%	-3%
R&D expenses	6.2	10%	5.6	10%	-9%
Core operating profit	12.8	22%	11.7	20%	-9%
Amortization on intangible assets associated with products	2.5	4%	2.4	4%	-1%
Other income	0.1	0%	0.2	0%	+75%
Other expenses	1.2	2%	1.4	2%	+17%
Operating profit (IFRS)	9.2	16%	8.0	14%	-13%
Finance income	0.4	1%	0.5	1%	+20%
Finance expenses	0.7	1%	0.2	0%	-73%
Profit before tax	9.0	15%	8.4	15%	-7%
Income tax expenses	2.6	4%	2.2	4%	-14%
<i>Actual tax ratio</i>	<i>29.0%</i>		<i>26.7%</i>		
Net profit (IFRS)	6.4	11%	6.1	11%	-4%
Core net profit	9.7	16%	8.8	15%	-9%
USD (JPY)	109.86		107.46		
EUR (JPY)	123.06		118.69		
CNY (JPY)	16.14		15.13		

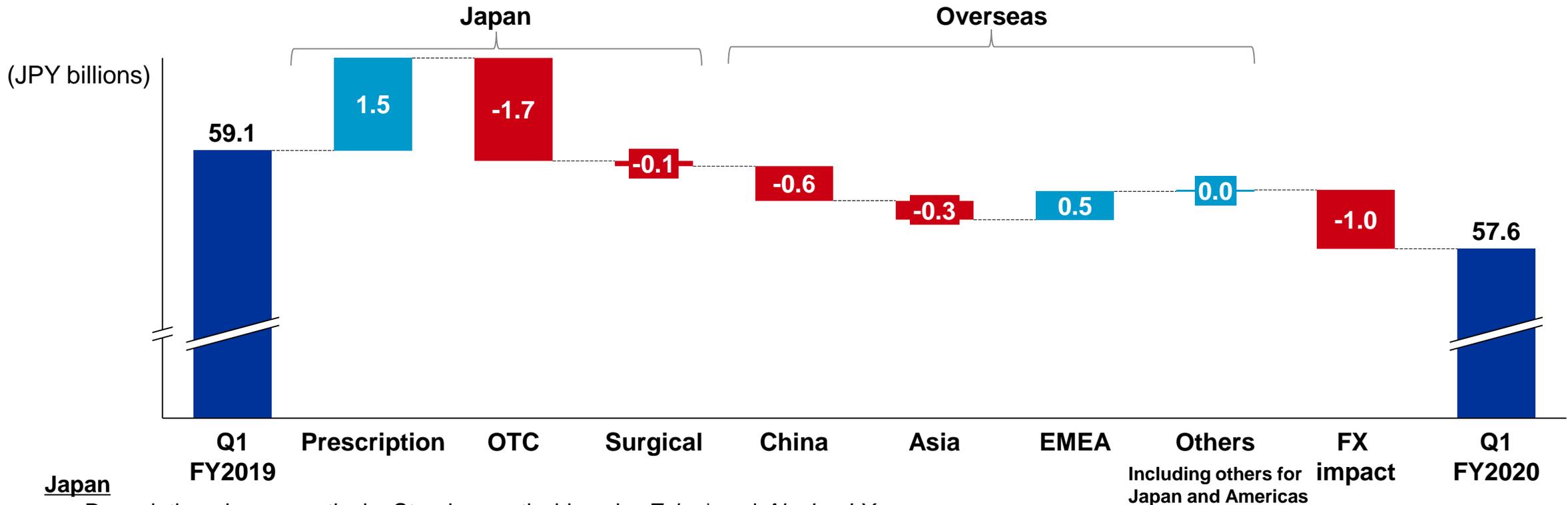
Core Basis

- **Revenue:**
In line with expectations
- **Core Operating Profit:**
Maintained 20% profit rate by controlling activity cost

Decrease in tax burden rate due to changes in the profit composition ratio of corporation in Santen Group

Q1 FY2020 Revenue (YoY)

Each region was in line with expectation and trends to recovery.



Japan

- Prescription pharmaceuticals: Steady growth driven by *Eylea** and *Alesion LX*.
- OTC: Decreased due to the impact of COVID-19, including sluggish demand from overseas tourists.

Overseas

- China: Sales decreased due to the negative impact of COVID-19 (local currency basis -8%). The recovery is higher than expected.
- Asia: Same as above (-7% excluding FX impact). Currently, Korea, Taiwan, and Thailand are recovering to almost normal times.
- EMEA: Increased +5% without FX impact led by solid sales of *Cosopt* and *Tapros*.

FY2020 Forecast (Unchanged from May 8th)

Aim to increase profits through efficient cost management

(JPY billions)	FY2019		FY2020		YoY
	Actual	vs Revenue	Forecast	vs Revenue	
Revenue	241.6		235.0		-3%
Cost of sales	94.8	39%	90.0	38%	-5%
Gross margin	146.7	61%	145.0	62%	-1%
SG&A expenses	73.4	30%	70.0	30%	-5%
R&D expenses	23.3	10%	23.0	10%	-1%
Core operating profit	50.0	21%	52.0	22%	+4%
Amortization on intangible assets associated with products	9.9	4%	9.7	4%	-2%
Other income	0.4	0%	0.9	0%	+131%
Other expenses	7.0	3%	8.2	3%	+17%
Operating profit (IFRS)	33.5	14%	35.0	15%	+4%
Finance income	1.0	0%	0.8	0%	-16%
Finance expenses	2.4	1%	1.0	0%	-58%
Investment loss by equity method	--	--	0.8	0%	--
Profit before tax	32.1	13%	34.0	14%	+6%
Income tax expenses	10.4	4%	11.0	5%	+6%
<i>Actual tax ratio</i>	<i>32.3%</i>		<i>32.4%</i>		
Net profit (IFRS)	21.7	9%	23.0	10%	+6%
Core net profit	35.9	15%	38.7	16%	+8%
USD (JPY)	108.81		110.00		
EUR (JPY)	120.80		120.00		
CNY (JPY)	15.64		15.00		

Core Basis

- Revenue: Expect COVID-19 impact
- Operating Profit: Expect growth due to lower activity levels resulting from COVID-19 restrictions, and cost optimization

Status of Research & Development

Osmotica Partnership: Acquired Blepharoptosis

Typically caused by aging, and current treatment is limited to surgery

Abnormal low-lying upper eyelid margin
with the eye in primary gaze



Loss of peripheral vision
Shoulder stiffness, headache, fatigue, etc.

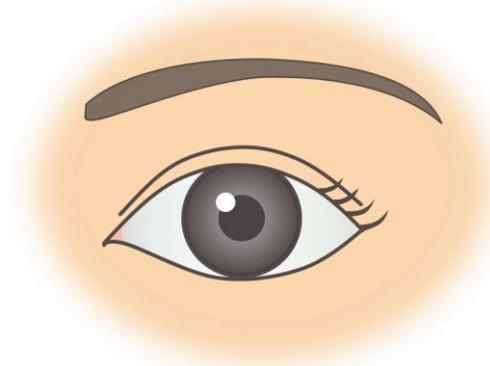
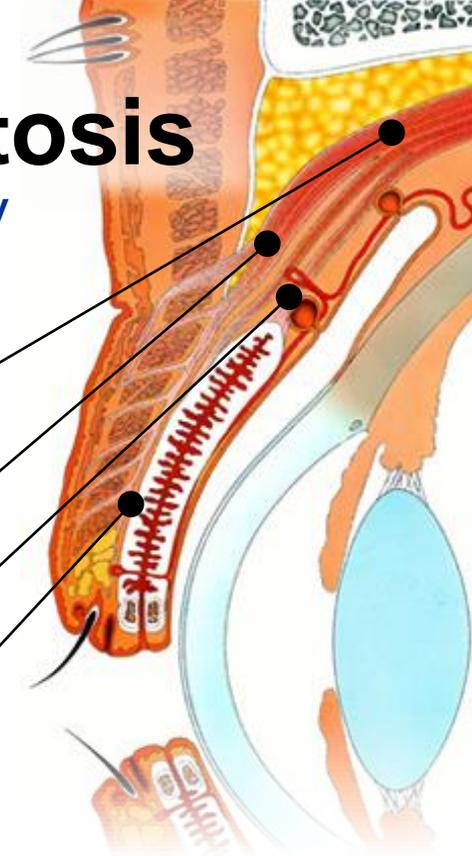
- ◆ Acquired ptosis is most commonly **age-related**
- ◆ Approx. **10%** of people aged 50 years and older are affected by acquired ptosis¹
- ◆ Current treatment is **surgery**

Levator palpebrae superioris

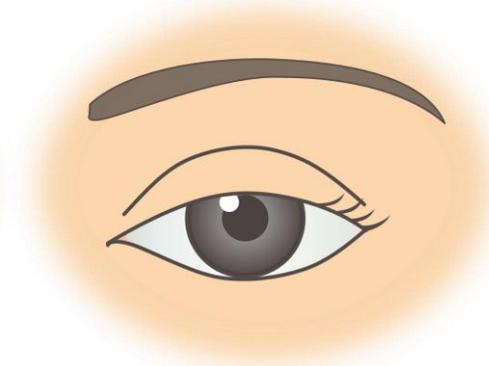
Levator aponeurosis

Müller's muscle

Upper eyelid



Normal



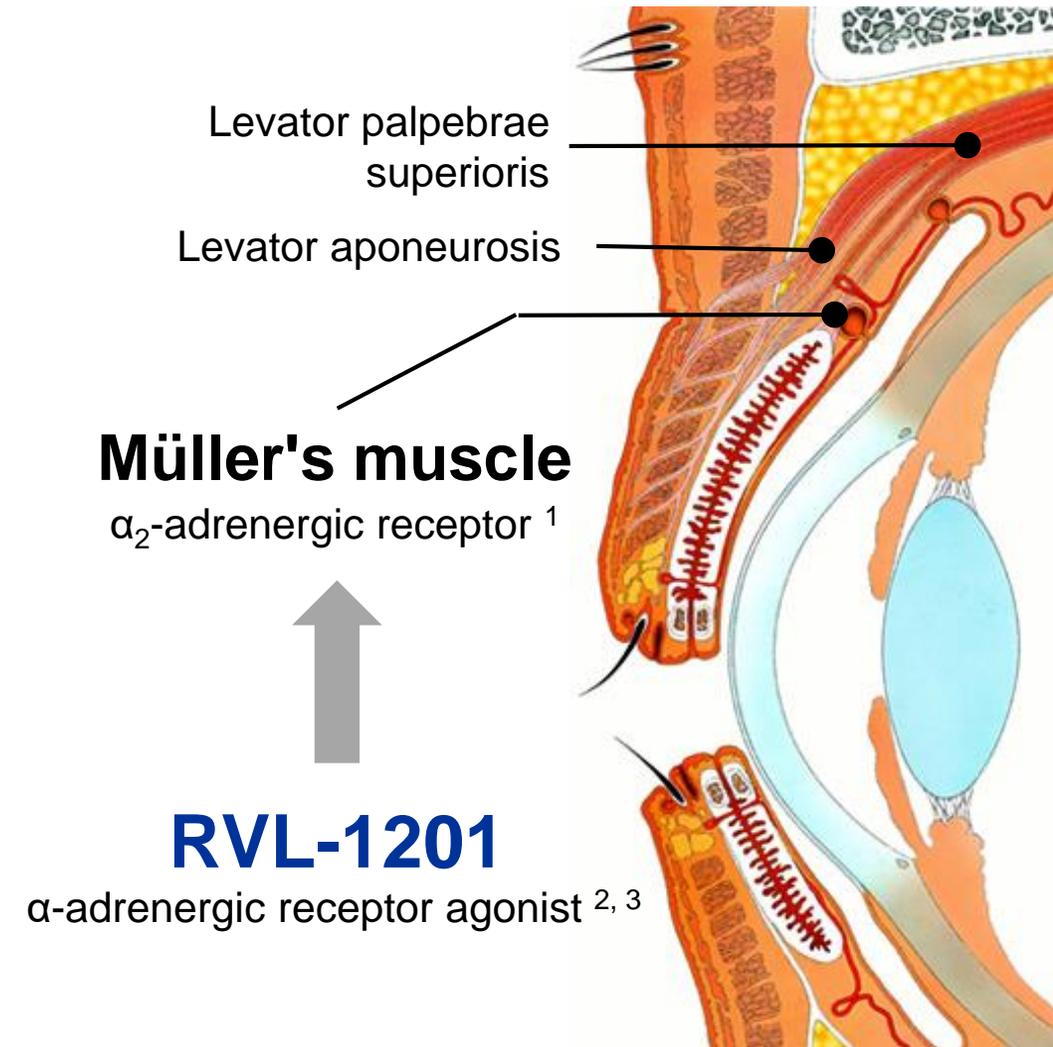
Blepharoptosis

Osmotica Partnership: RVL-1201

Planning to develop in Japan, China, Asia, and Europe

July 2020: Osmotica received approval from FDA as a treatment for acquired blepharoptosis in adults

- 0.1% oxymetazoline hydrochloride ophthalmic solution
- Instilled once a day
- Preservative-free eye drop
- Demonstrated improvement of superior visual field and MRD-1* in P3 in US



*MRD (Marginal Reflex Distance): distance between the margin of upper eyelid and center of pupil

1. *Ophthalmic Plast Reconstr Surg.* 1999 Mar;15(2):92-9.

2. *Fundam Clin Pharmacol.* 2010 Dec;24(6):729-39.

3. *Br J Pharmacol.* 1996 Jul;118(5):1246-52.

Current Status of Research and Development

Pipeline / product development (1)

As of July, 2020

Updated information is underlined

	Indication	Region	Status
DE-111 STN10111 <i>TAPCOM / TAPTIQOM</i> Combination of tafluprost and timolol maleate	Glaucoma / ocular hypertension	China	P3 <i>Plan: <u>FY2022 P3 completion</u></i>
DE-117 STN10117 <i>EYBELIS</i> EP2 receptor agonist		US	P3 <i>Plan: <u>FY2020 filing</u></i>
	Japan	Launched	
	Asia	Approved <i>Plan: <u>FY2020 launch</u></i>	
DE-126 STN10126 FP / EP3 receptors dual agonist	Glaucoma / ocular hypertension	US	P2b (dose finding study completed) <i>Plan: <u>FY2020 additional P2 start</u></i>
		Japan	
DE-128 <i>PRESERFLO MicroShunt</i>	Glaucoma	US	<u>Completed PMA rolling submission in June 2020</u> <i>Plan: <u>FY2020 approval, FY2020 launch</u></i>
		Europe	Launched
		Asia	Filed <i>Plan: <u>FY2020 approval</u></i>

Current Status of Research and Development

Pipeline / product development (2)

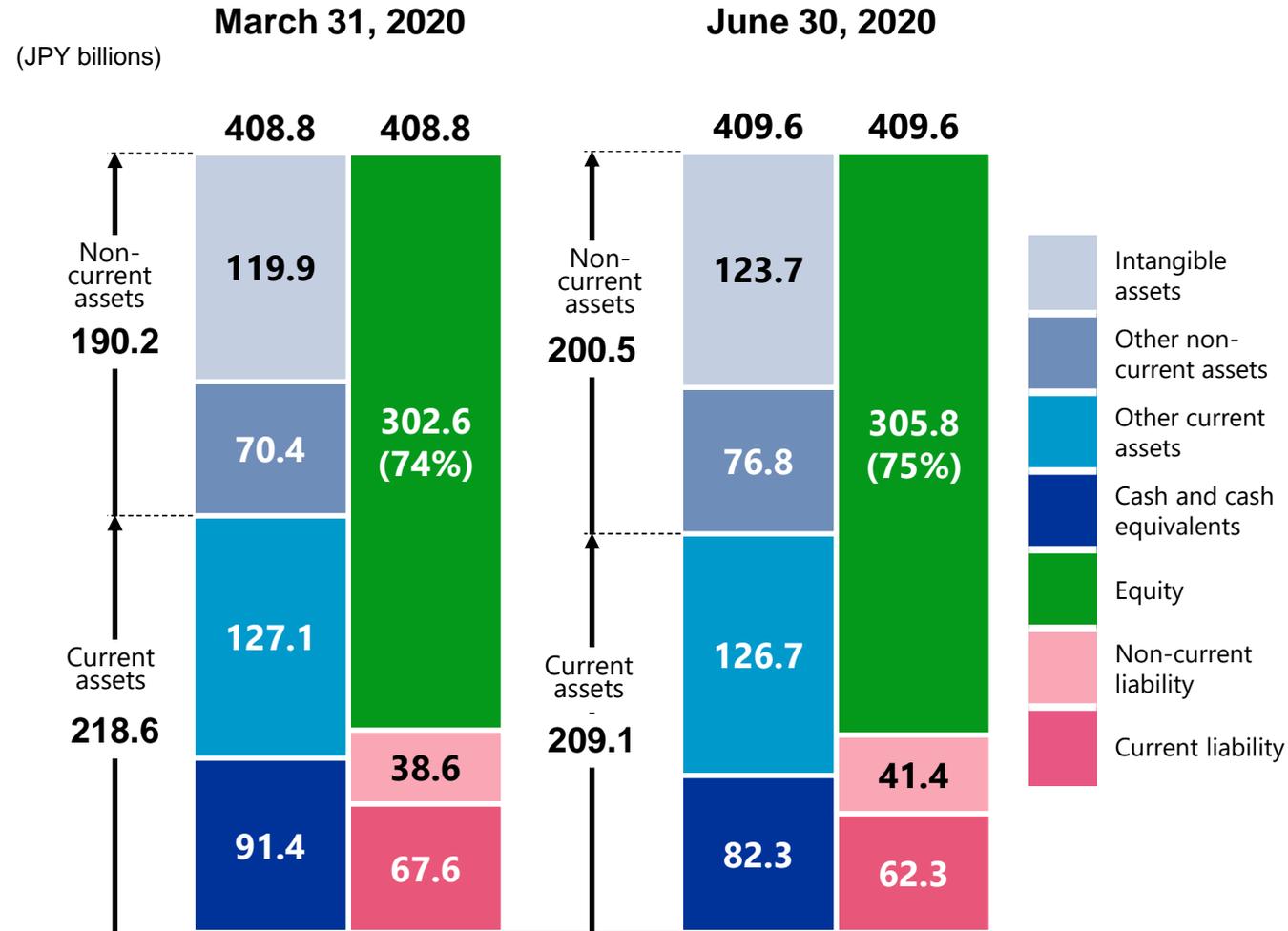
As of July, 2020

Updated information is underlined

	Indication	Region	Status
DE-130A STN10130 Catioprost latanoprost	Glaucoma / ocular hypertension	Europe	P3 <i>Plan: FY2021 P3 completion</i>
		Asia	
DE-109 STN10109 IVT sirolimus	Uveitis	US	P3 <i>Plan: FY2022 P3 completion</i>
		Japan	P3
		Europe	P3
		Asia	Filed
DE-127 STN10127 atropine sulfate	Myopia	Japan	P2/3 <i>Plan: FY2023 P2/3 completion</i>
		Asia	P2 (met primary endpoint)
MD-16 Intraocular lens	Cataract	Japan	Approved <i>Plan: FY2020 launch</i>

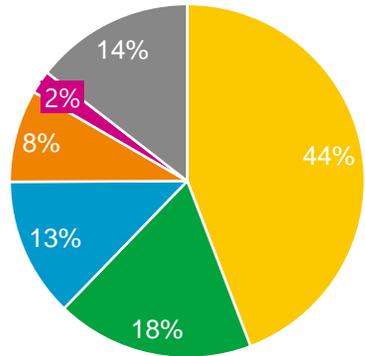
Appendix

Q1 FY2020 Financial Position



Q1 FY2020 Revenue by Region

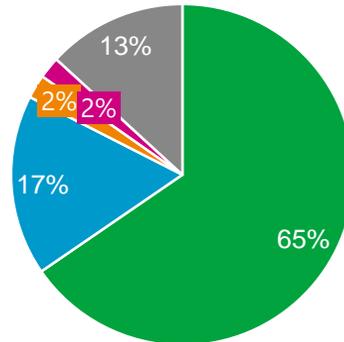
Japan



	(JPY billions)
Eylea*	16.8
Alesion (Incl. Alesion LX)	3.0
Diquas	3.0
Others	15.2
Total	38.0

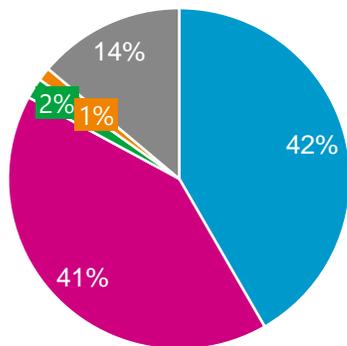
Eylea*: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

EMEA



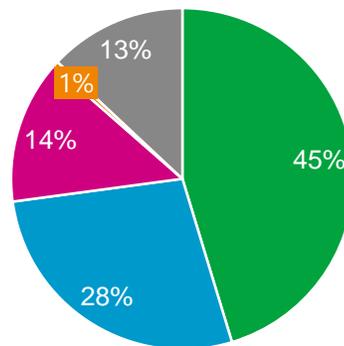
	(JPY billions)
Cosopt	2.5
Tapros	1.7
Oftan Catachrom	0.9
Others	4.5
Total	9.6

China



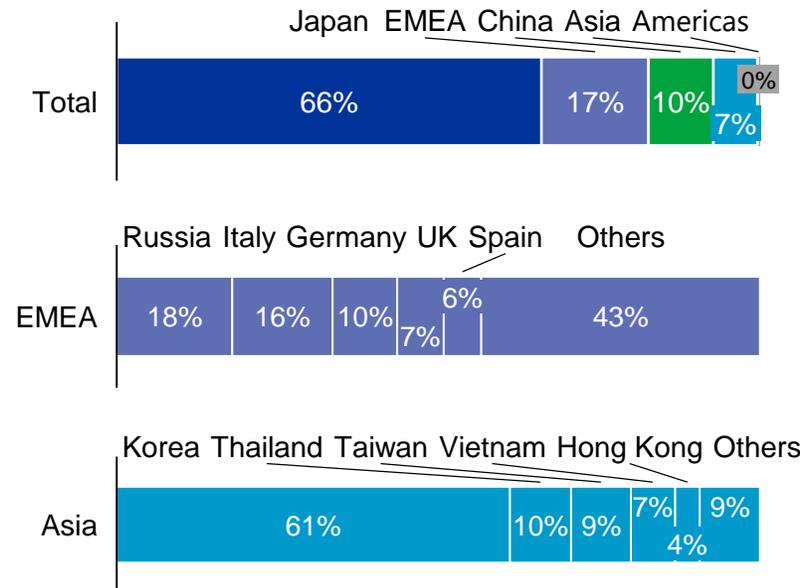
	(JPY billions)
Hyalein	2.3
Cravit	2.2
Flumetholon	0.3
Others	0.9
Total	5.8

Asia



	(JPY billions)
Cosopt	1.0
Diquas	0.5
Tapros	0.5
Others	2.0
Total	4.0

Revenue in each region



■ Intravitreal VEGF inhibitor
 ■ Glaucoma/Device
 ■ Dry eye
 ■ Allergy
 ■ Bacterial conjunctivitis
 ■ Others

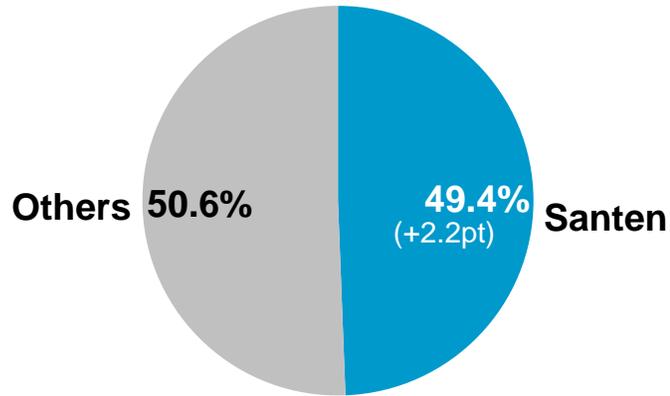
Prescription Ophthalmic Market in Japan (Jul. 2019 - Jun. 2020)

Remain No.1 for overall market and all segments

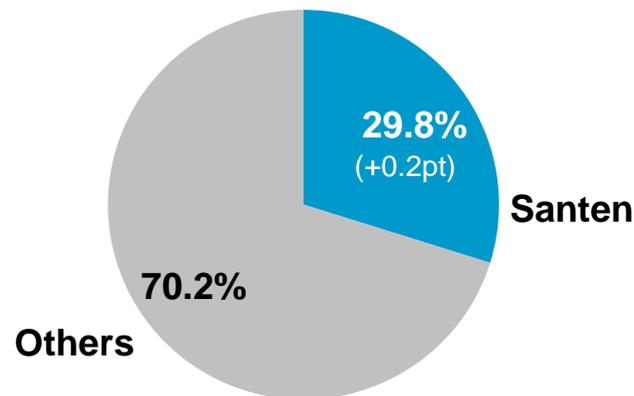
Segment: Market size

Graph: Market share (change from last year)

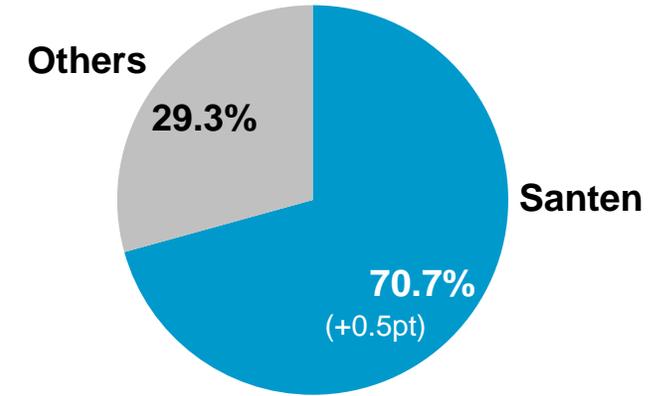
Total: JPY371.8bil



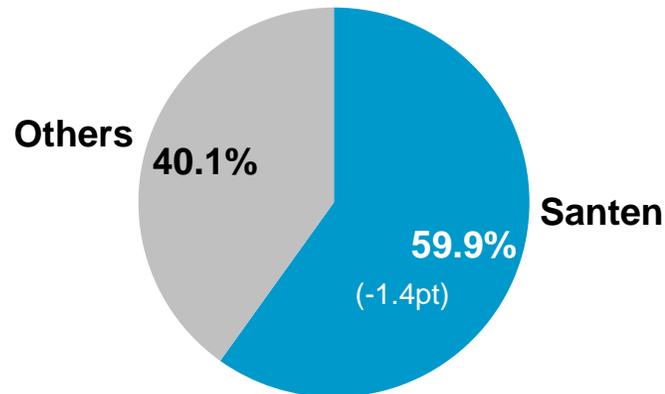
Glaucoma: JPY106.9bil



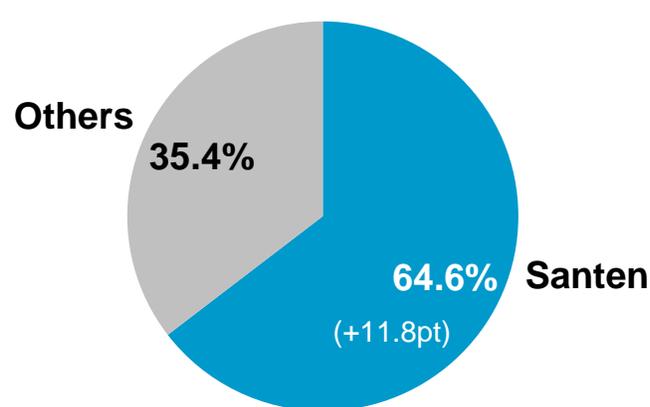
Retinal disorders*: JPY106.1bil



Corneal/dry eye: JPY44.8bil



Allergy: JPY49.2bil



Anti-Infection: JPY10.6bil

