Q3 FY2020 Results

Presentation / Q&A

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Q&A

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February 4, 2021

Santen
Imagine Your Happiness

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 the Zhongyong (The Doctrine of the Mean) by Confucius.

Santen 2030 Toward 2030 and beyond

Santen's VISION

Become A Social Innovator

Orchestrate and mobilize key technologies and players around the world, to deliver happiness through vision.

GOAL

Aim to reduce the loss of social and economic opportunities for people around the world due to eye conditions.

STRATEGY

A **Ophthalmology**
Innovation in Ophthalmology and Acceleration of Ecosystem Development

B **Wellness**
Awareness and Proactive Care toward Better Eye Condition

C **Inclusion**
Building Society that is Inclusive regardless of Visual Impairment

Q3 FY2020 Progress

Steady progress in each region despite the impact of COVID-19 and the Japan NHI drug price revision, and increased net profit for the period.

- Strong performance in Japan's Rx and Asia
- Smooth launch of Eyevance products as a first step to enter the U.S.
- China in line with expectations; long-term growth potential remains unchanged, we maintain to develop business actively

(JPY billions)	Q3 FY2019	Q3 FY2020	YoY
Revenue	182.3	181.8	-0%
Core OP	38.0	36.4	-4%
Net profit for the period	20.3	20.9	+3%

China Short-term Business Impact and Direction

Despite a short-term impact from VBP*, we continue to aggressively expand our business to steadily adapt to the changing market environment, and to achieve medium- to long-term growth.

1. Cravit VBP* short-term impact

- Focus on retail and private hospital market; achieved healthy growth
- In Q3 (3 months) , maintain about 70% (value) of the Q3 FY2019 level

2. Hyalein 0.1 and Hyalein Mini 0.3 targeted for VBP*

- Bidding was held on February 3rd; local manufacturers won
- Limited impact expected on financial results in FY2021 and beyond

3. Steady progress for the mid-to-long term growth

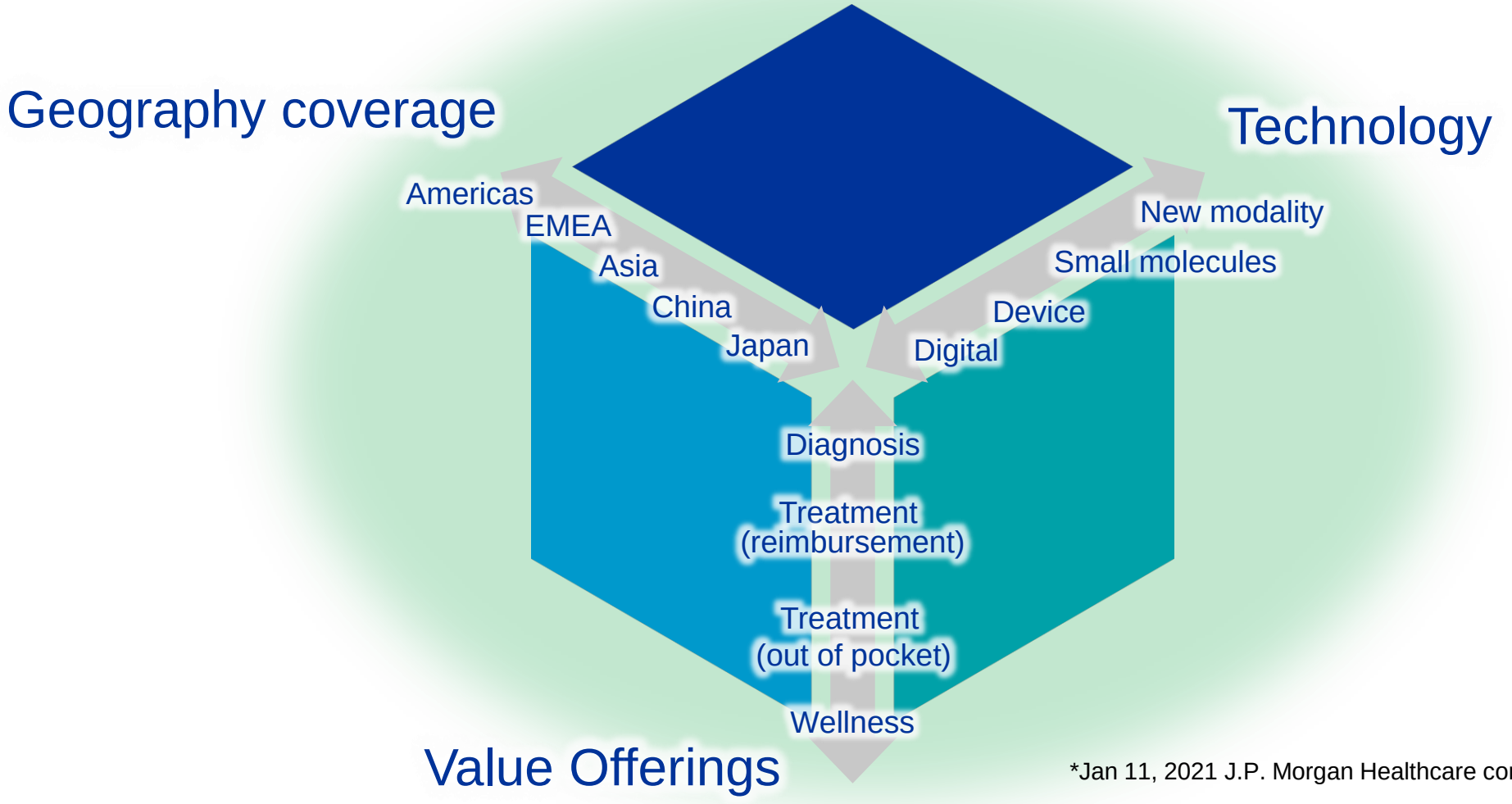
- Development of measures exploiting growth opportunity

*VBP: Value-Based Purchasing

At 16:00 (JST) on February 5, we will present details of mid-long term China business strategy in the teleconference

Challenge of Diversification in Ophthalmology

Expanding business scope for further growth as a specialized company



*Jan 11, 2021 J.P. Morgan Healthcare conference presentation material

Expanding Solutions in Ophthalmology

Enter new modality, device and digital domains while also enhancing core expertise.
Expansion of portfolio for sustainable growth

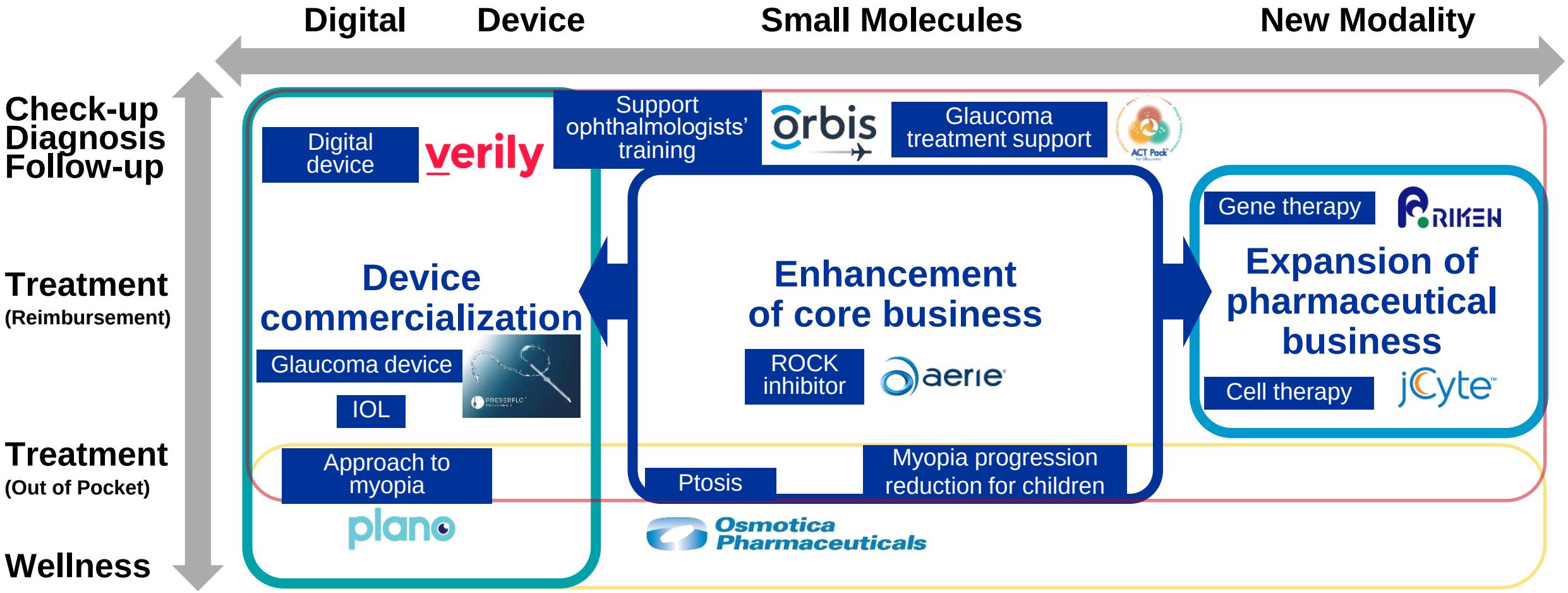


*Chart: Jan 11, 2021 J.P. Morgan Healthcare conference presentation material

Strategy Toward Sustainable Growth

Accelerate global growth by advancing steady pipeline progress and building infrastructure to support future growth

1. Building growth drivers to advance global growth

- Expansion of product pipelines
- Accelerate global expansion (US, China)
- Progress toward realizing growth opportunities in new business domains

2. Expansion of business platform

- Enhancement of global management structure
- Strengthening the strategy promotion framework
- Building a product supply system to support medium- to long-term growth

Q3 FY2020 Financial Results Ended December 31, 2020

Q3 FY2020 Results

Sales and net profit for the period maintained year-on-year despite impact of COVID-19

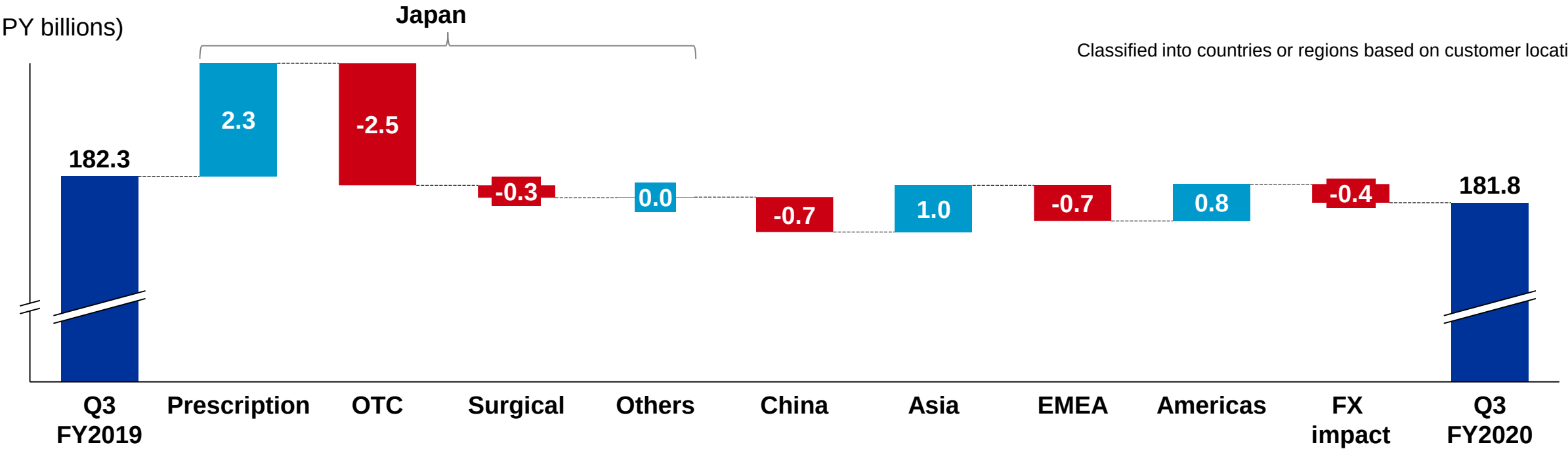
(JPY billions)	FY2019 Q3 Actual	vs Revenue	FY2020 Q3 Actual	vs Revenue	YoY
Revenue	**182.3**		**181.8**		**-0.3%**
Cost of sales	74.4	41%	75.9	42%	+2.1%
Gross margin	108.0	59%	105.9	58%	-1.9%
SG&A expenses	52.8	29%	51.8	28%	-1.9%
R&D expenses	17.2	9%	17.7	10%	+2.9%
Core operating profit	**38.0**	**21%**	**36.4**	**20%**	**-4.1%**
Non core SG&A expense	--	--	1.0	1%	--
Amortization on intangible assets associated with products	7.4	4%	7.4	4%	-0.4%
Other income	0.3	0%	0.5	0%	+81.1%
Other expenses	1.9	1%	1.3	1%	-32.7%
Operating profit (IFRS)	28.9	16%	27.3	15%	-5.8%
Finance income	0.9	0%	1.0	1%	+16.3%
Finance expenses	0.9	0%	1.1	1%	+34.5%
Share of loss of Investments accounted for using equity method	--	--	0.2	0%	--
Profit before tax	29.0	16%	27.0	15%	-6.9%
Income tax expenses	8.7	5%	6.0	3%	-30.7%
Actual tax ratio	*30.0%*		*22.3%*		
Net profit for the period (IFRS)	**20.3**	**11%**	**20.9**	**12%**	**+3.3%**
Core net profit	27.2	15%	28.3	16%	+4.2%
USD (JPY)	108.87		105.96		
EUR (JPY)	121.06		122.34		
CNY (JPY)	15.66		15.38		

- **Revenue:**
  Maintain flat year-on-year level in spite of the COVID-19 impact and the Japan NHI drug price revision
- **Core OP**
  Decreased year-on-year due to COGS increase (product mix changes)
- **Net profit for the period (IFRS):**
  Increased profit due to the decrease of other expenses and tax burden rate

Q3 FY2020 Revenue (YoY)

Japan Rx led the sales increase despite the impact of COVID-19

(JPY billions)



Japan

- Prescription pharmaceuticals: Sales 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 exceeded expectations, despite sales decline due to the negative impact of Cravit VBP and COVID-19 (-4% excluding FX impact)
- Asia: Korea and Taiwan, which are recovering from the COVID-19 outbreak, led the increase in sales (+8% excluding FX impact)
- EMEA: Solid sales led by glaucoma products despite the negative impact of COVID-19. (-3% excluding FX impact)
- Americas: Increase sales on contribution from Eyevance products (+126% excluding FX impact)

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

FY2020 Forecast (Unchanged from May 8th)

Aim to achieve earnings forecast by expense control despite some factors for uncertainty

(JPY billions)	FY2019 Actual	FY2019 vs Revenue	FY2020 Forecast	FY2020 vs Revenue	YoY
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%
Actual tax ratio	*32.3%*		*32.4%*		
Net profit (IFRS)	**21.7**	**9%**	**23.0**	**10%**	**+6%**
Core net profit	35.9	15%	38.7	16%	+8%
Core ROE	12.1%		12.6%		--
ROE	8.0%		7.5%		--
USD (JPY)	108.81		110.00		
EUR (JPY)	120.80		120.00		
CNY (JPY)	15.64		15.00		

Status of Research & Development

STN1011700 / DE-117: Acceptance of NDA Submission in US

Aim to provide a new option for glaucoma patients in US

- Submitted NDA with the data of a total of 12 clinical studies including four P3 studies (3 being US pivotal)
- One US and one Asian pivotal study met their primary endpoints, while one additional US study did not.
- P3 study data in US and Asia planned to be disclosed in H1 FY2021
- PDUFA date: November 19, 2021

List of STN1011700 clinical studies for NDA submission in US

	Region		Purpose
Spectrum-4	US	P3	**Pivotal** (non-inferiority v.s. timolol maleate)
Spectrum-3	US	P3	**Pivotal** (non-inferiority v.s. timolol maleate) & Long-term safety
PEONY	Asia	P3	**Pivotal** (non-inferiority v.s. latanoprost)
AYAME	Japan	P2	Dose finding
		P3	Pivotal for Japan (non-inferiority v.s. latanoprost)

	Region		Purpose
PK	Japan	P1	Human pharmacokinetics
	US	P1/2	Dose finding
	US	P2	Dose finding
	US	P2b	Dose finding
Spectrum-6	US	P2	Dose frequency finding
RENGE	Japan	P3	Long-term Safety
FUJI	Japan	P3b	Study in latanoprost low/non-responder patients
Spectrum-5	US	P3b	Study in latanoprost low/non-responder patients

Topics in China Clinical Development

Promote the clinical development of STN2000100 and STN1007603

STN2000100 / DE-128

Glaucoma implant device

PRESERFLO MicroShunt

- Initiate unapproved medical device use program at Boao Super Hospital in the Hainan Boao Lecheng International Medical Toursim Pilot Zone
- **Successful first surgeries** operated on January 9, 2021

STN1007603 / DE-076C

Vernal keratoconjunctivitis

Verkazia

- **Listed** in the third batch of **urgent unmet clinical needs list**
- Confirmed **clinical trial waiver** in China
  (post-marketing clinical study required)

Current Status of Research and Development

Pipeline / product development (1)

As of January, 2021
Updated information is underlined

	Dev. code	Indication	Region	Status
Omidenepag isopropyl *EYBELIS*	**STN1011700** DE-117	Glaucoma / ocular hypertension	US	Filed in November 2020 *Plan: FY2021 approval*
			Japan	Launched
			Asia	Approved *Plan: launch in February 2021 in Korea*
Sepetaprost	**STN1012600** DE-126	Glaucoma / ocular hypertension	US	Started additional P2 in December 2020 *Plan: FY2022 additional P2 completion*
			Japan	P2b (dose finding study completed)
Glaucoma implant device *PRESERFLO MicroShunt*	**STN2000100** DE-128	Glaucoma	US	Completed PMA rolling submission *Plan: ~H1 FY2021 approval*
			Europe	Launched
			Asia	Filed *Plan: FY2020 approval*
			Others	Filed in October 2020 in Canada *Plan: FY2021 approval*
Netarsudil dimesylate *Rhopressa*	**STN1013900** AR-13324	Glaucoma / ocular hypertension	Japan	Started P3 in November 2020 *Plan: FY2023 P3 completion*

Current Status of Research and Development

Pipeline / product development (2)

As of January, 2021
Updated information is underlined

	Dev. code	Indication	Region	Status
Atropine sulfate	**STN1012700** DE-127	Myopia	Japan	P2/3 *Plan: FY2023 P2/3 completion*
			China	*Plan: FY2021 P1 start*
			Asia	P2 (met primary endpoint)
Diquafosol sodium (long-lasting) *Diquas*	**STN1008903** DE-089C	Dry eye	Japan	P3 *Plan: FY2021 P3 completion*
Sirolimus (intravitreous injection)	**STN1010900** DE-109	Uveitis	US	P3 *Plan: FY2022 P3 completion*
			Japan	P3
			Europe	P3
			Asia	Filed

Current Status of Research and Development

Pipeline / product development (3)

As of January, 2021
Updated information is underlined

	Dev. code	Indication	Region	Status
Tafluprost / timolol maleate (combination) *TAPCOM / TAPTIQOM*	**STN1011101** DE-111A	Glaucoma / ocular hypertension	China	P3 *Plan: FY2023 P3 completion*
Latanoprost	**STN1013001** DE-130A Catioprost	Glaucoma / ocular hypertension	Europe	P3 *Plan: FY2021 P3 completion*
			Asia	
Intraocular lens *Lentis Comfort*	**MD-16**	Cataract	Japan	Launched in November 2020

- STN1013800 (RVL-1201); The company is planning to start clinical trials for blepharoptosis in FY2021 in Japan and also considering the filing in Asia with data used for US approval.
  Licensing region / Japan, China, Asia and Europe

- STN6000100 (jCell); The company is planning to start clinical trials for retinitis pigmentosa in FY2021.
  Licensing region / Japan, China, Asia and Europe

Appendix

Commencement of Preparation for Transition to a Holding Company Structure through Sole-Share Transfer

1. Background

Establishing and enhancing a management and organizational system to enable efficient management of diversified businesses or divisions, and to swiftly reflect Santen's vision by executing global strategies over the mid-to-long term

2. Purpose

- Enhance global corporate headquarter functions
- Facilitate swift decision-making and enhance organic collaboration among regions and business units
- Reinforce the governance system and facilitate a full understanding of the overall corporate strategy throughout the Group

3. Scheduled date of the Transition

April 2022*1

*1: Will require approval from shareholders at the extraordinary annual general meeting of shareholders to be held in December, 2021, and from related government offices

Change in Fiscal Year

1. Purpose

Promote global business operations by changing the fiscal year to January to December

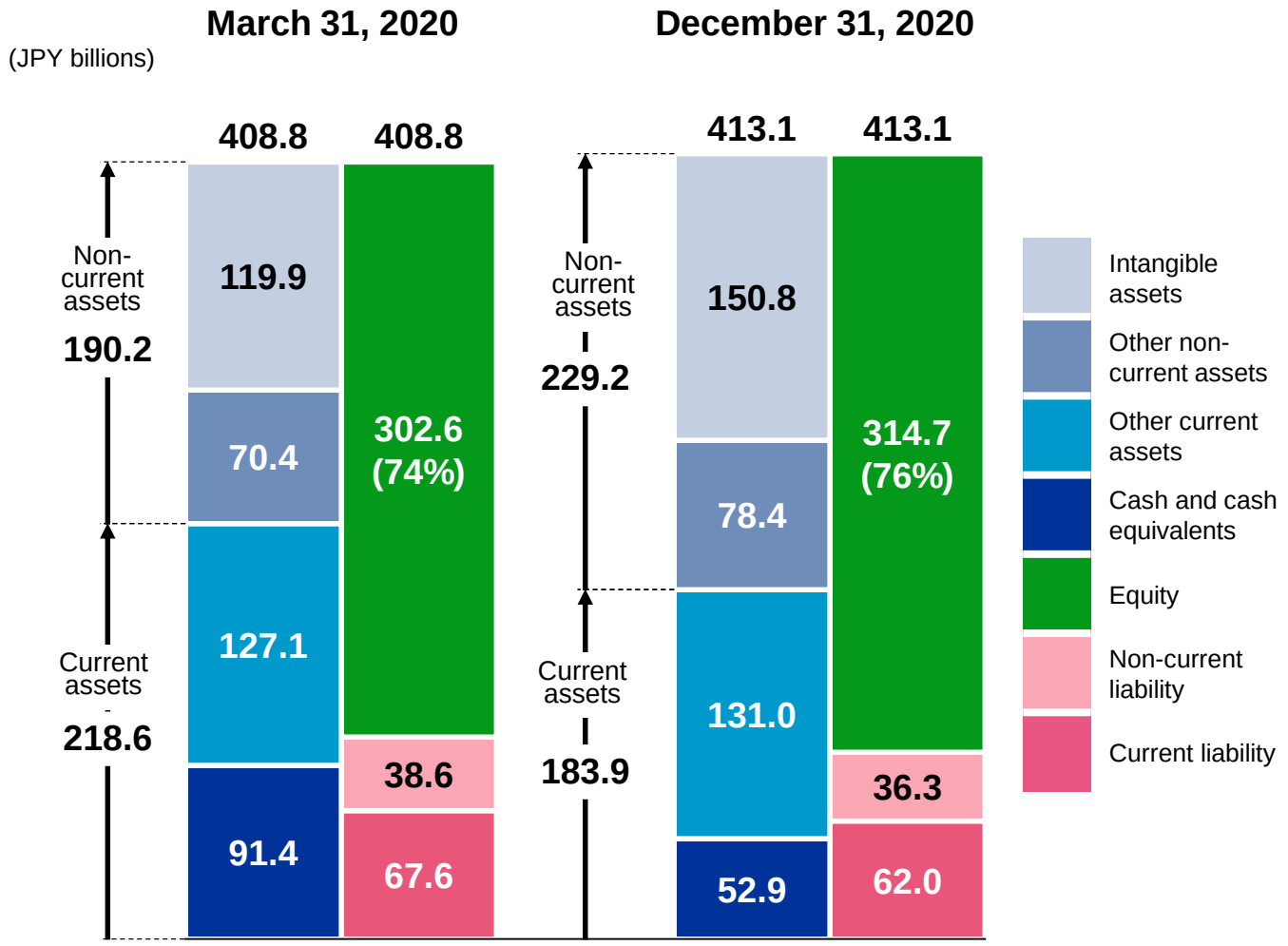
2. Fiscal year change

Current fiscal year end: 31 March
New fiscal year end: 31 December

FY2021 (110th) : 1 April, 2021 to 31 December, 2021 (9 months)
FY2022 (111th) : 1 January, 2022 to 31 December, 2022

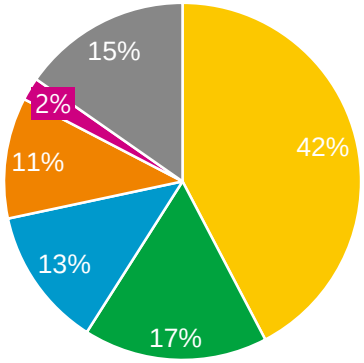
*1: Will require approval of partial amendments to the articles of incorporation at the 109th annual general meeting of shareholders to be held in June 25, 2021. Board of Directors to vote on resolution at board meeting to be held in May 2021; amendments to be disclosed in a timely manner following board approval

Q3 FY2020 Financial Position



Q3 FY2020 Revenue by Region

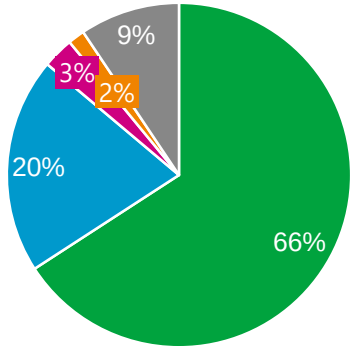
Japan



	(JPY billions)
EYLEA*	51.0
Alesion (Incl. Alesion LX)	12.7
Diquas	9.6
Others	47.1
Total	120.4

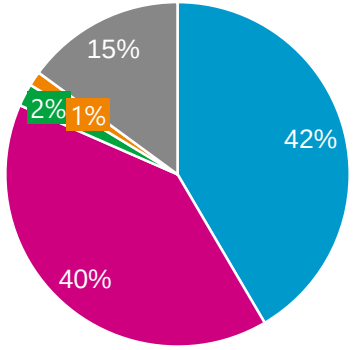
EYLEA*: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

EMEA



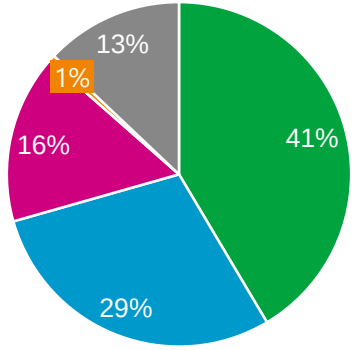
	(JPY billions)
Cosopt	7.2
Tapros	5.1
Ikervis	2.7
Others	13.4
Total	28.4

China



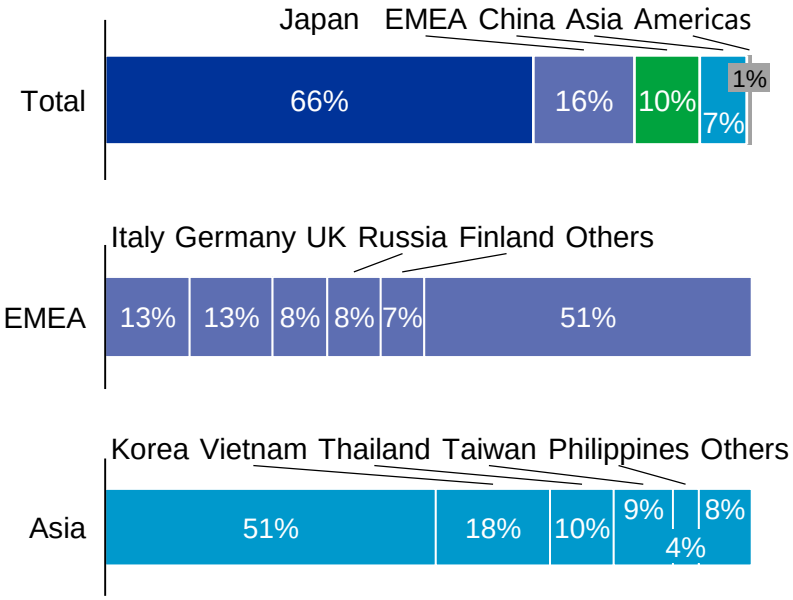
	(JPY billions)
Hyalein	7.2
Cravit	6.6
Flumetholon	1.1
Others	3.4
Total	18.3

Asia



	(JPY billions)
Cosopt	3.3
Hyalein	2.0
Tapros	1.4
Others	6.7
Total	13.3

Revenue in each region



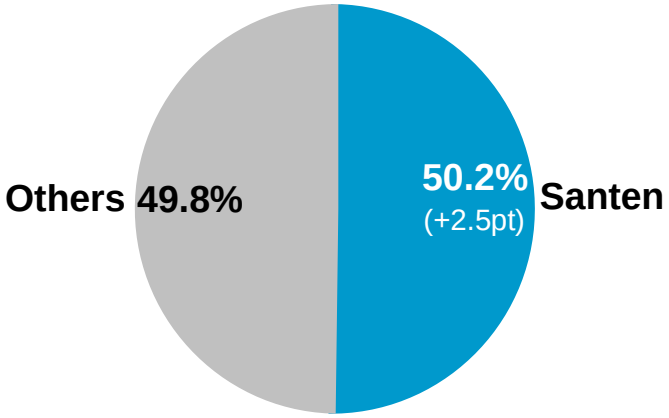
Intravitreal VEGF inhibitor | Glaucoma/Device | Dry eye | Allergy | Bacterial conjunctivitis | Others

Prescription Ophthalmic Market in Japan (Jan. 2020 - Dec. 2020)

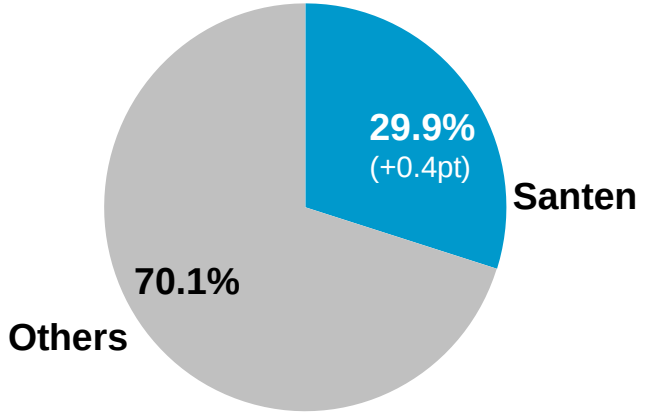
Remain No.1 for overall market and all segments

Segment: Market size
Graph: Market share (change from last year)

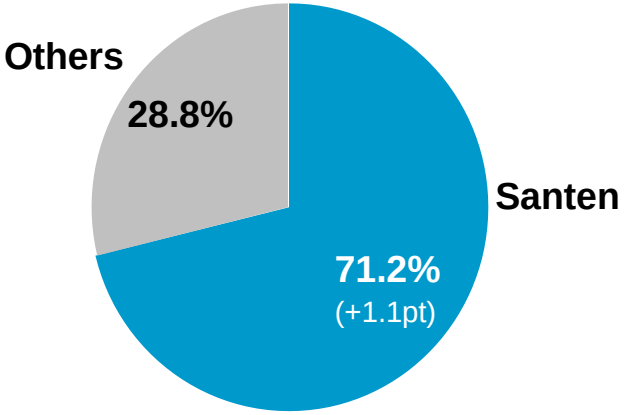
Total: JPY371.1bil



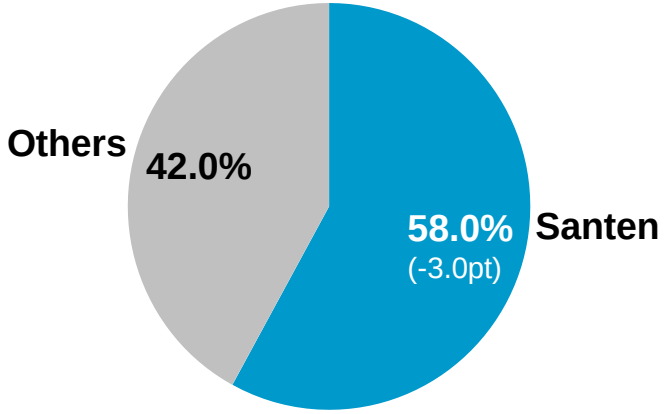
Glaucoma: JPY105.6bil



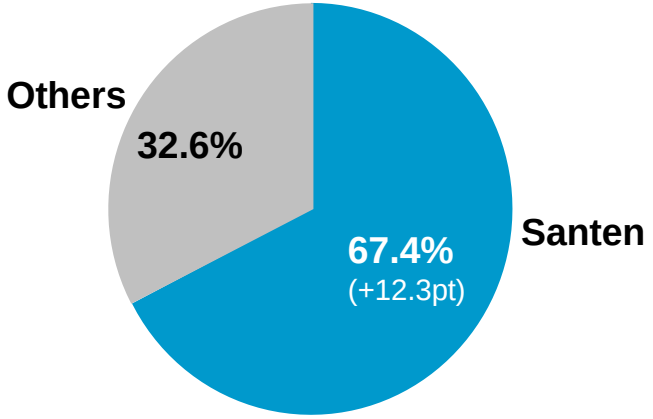
Retinal disorders*: JPY108.6bil



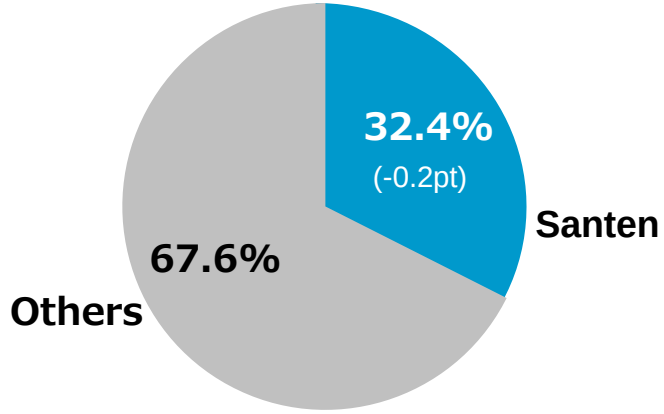
Corneal / dry eye: JPY42.9bil



Allergy: JPY52.4bil



Anti-infection: JPY9.2bil



*Including co-promoted product (Anti-VEGF *EYLEA*) of Bayer Yakuhin, Ltd. (MAH)
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IR Event Schedule after Q3FY2020 Disclosure

Date	Scheduled Time	Means	Contents
Feb. 5 (Fri.)	16:00-17:00 (*15:00 disclosure)	CC	Q3 FY2020 disclosure Follow-up meeting (China business)
Mar. 10 (Wed.)	15:30-17:00 (*15:00 disclosure)	WebEx	Strategy presentation ahead of the next mid-term plan
Apr. 7 (Wed.)	TBD	TBD	FY2021-2025 Mid-term plan presentation

Schedule subject to change
Details will be announced separately