



Q1 FY2022 Financial Results

Presentation: August 4, 2022

Become A Social Innovator

Featuring



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Forward-looking statements

- Materials and information provided in this announcement include so-called "forward-looking statements". The earnings forecasts and other forward-looking statements herein are based on information currently available to the Company and certain assumptions that we believe to be reasonable. The realization of these forecasts is subject to various risks and uncertainties. Please be aware that actual results could differ materially from these forward-looking statements. We assume no obligation to update the contents of this document from time to time.
- Risk factors include, but are not limited to, the following:
External factors such as trends in pharmaceutical administration, social and economic conditions, changes in laws and regulations, and exchange rates. Changes in the competitive environment, such as the impact of generics. Reliance on certain products and business partners, such as dependence on mainstay products, reliance on licensed products, and reliance on certain business partners for the supply of bulk drugs. Uncertainty in the development of new drugs, the possibility that R&D investment will not produce sufficient results, the success or failure of alliances with other companies, and other R&D activities. Other factors include intellectual property rights, production slowdowns and delays caused by natural disasters, product supply issues such as discontinuations and product recalls, litigation, and risks related to global business development.
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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'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



Ophthalmology

Innovation in Ophthalmology and Acceleration of Ecosystem Development



Wellness

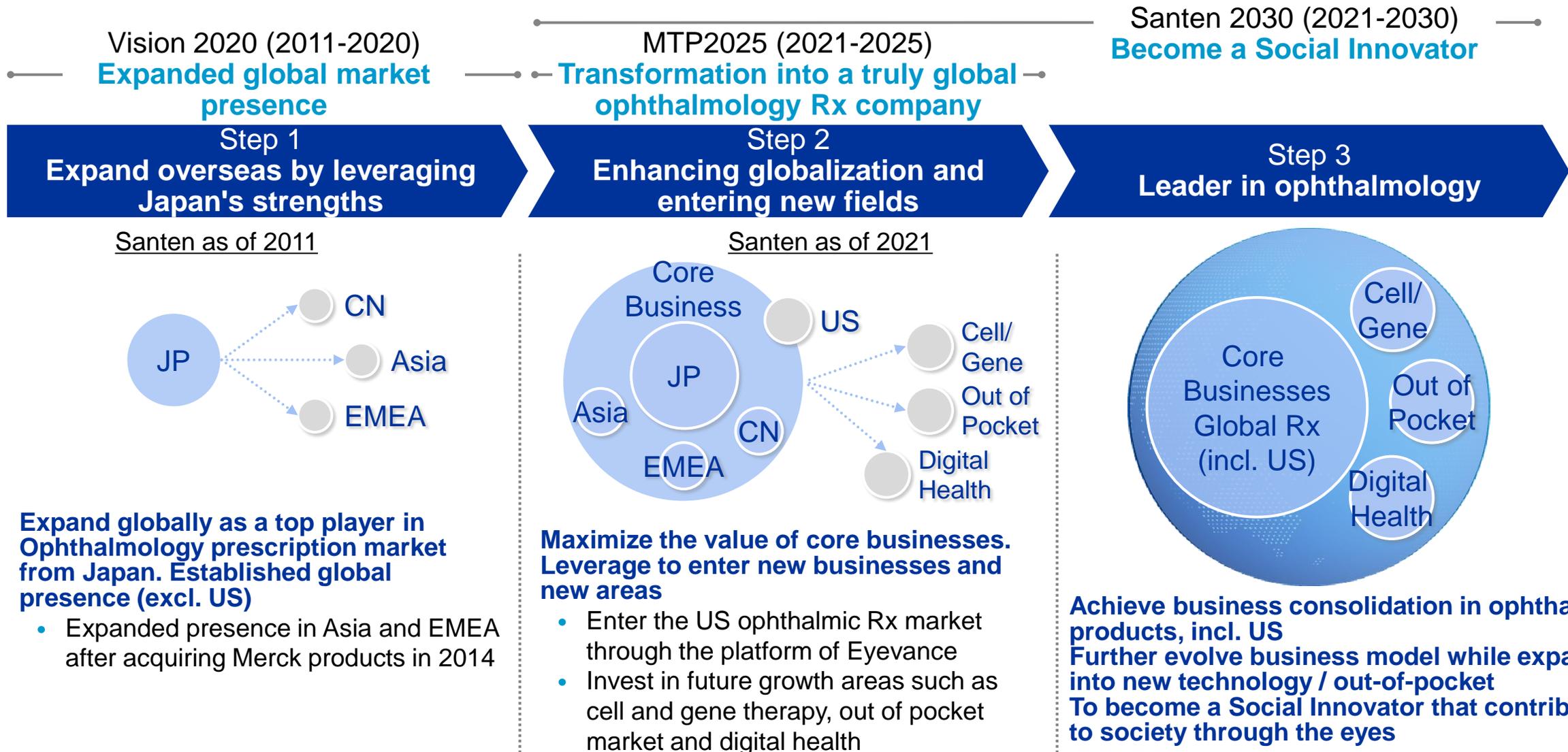
Awareness and Proactive Care toward Better Eye Condition



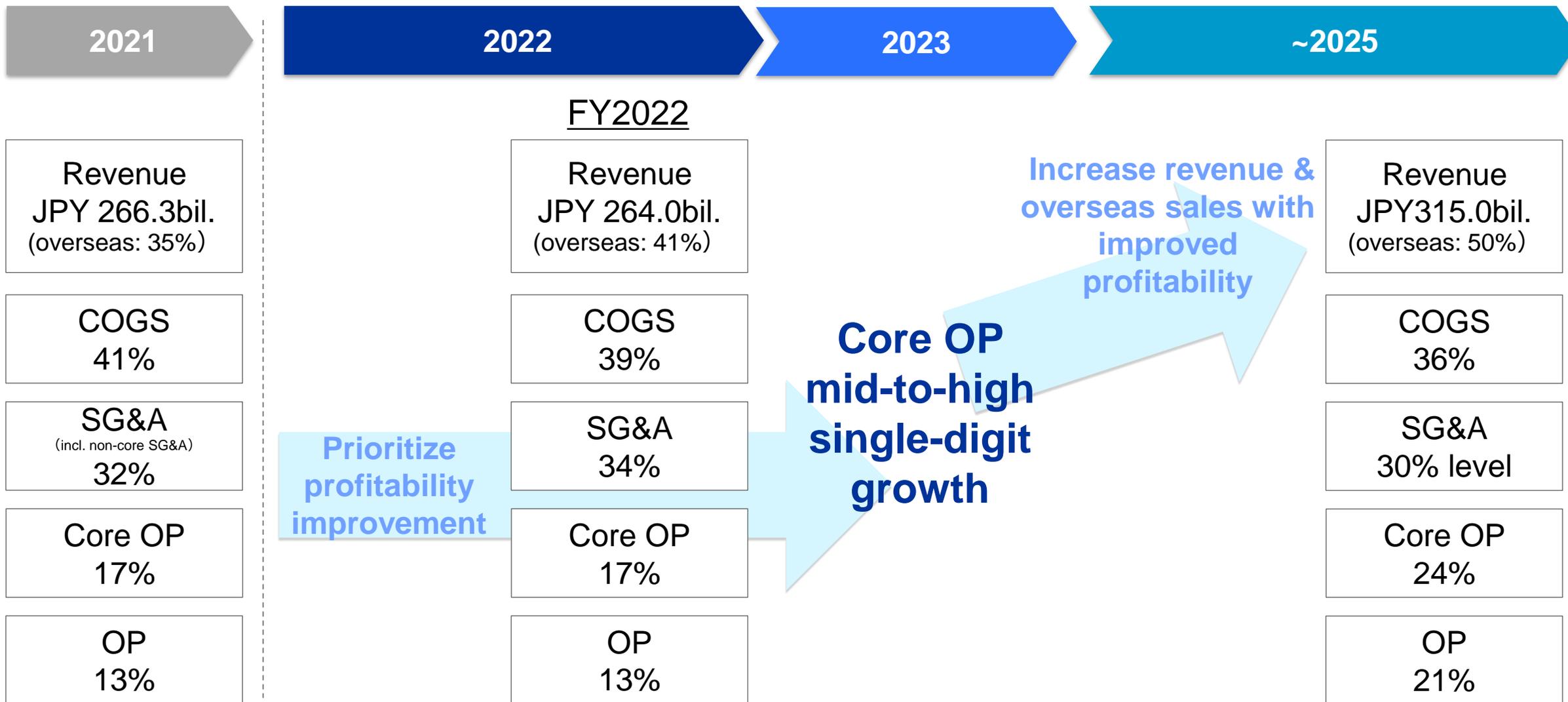
Inclusion

Building Society that is Inclusive regardless of Visual Impairment

Evolution from Vision 2020 to Santen 2030



FY2022-23: Transition to a resilient structure



Agenda

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R&D Update

Appendix

Revenue: Overall performance offsets significant shortfall in China

OP: Profits declined but rigorous cost controls in place

(JPY billions)	Q1 FY2021		Q1 FY2022			FY2022	
	Actual	vs Revenue	Actual	vs Revenue	YoY	Forecast	vs Revenue
Revenue	65.0	-	65.5	-	+0.8%	264.0	-
Cost of sales	26.9	41%	28.4	43%	+5.5%	103.0	39%
Gross margin	38.1	59%	37.1	57%	-2.5%	161.0	61%
SG&A expenses	20.2	31%	19.4	30%	-4.0%	88.5	34%
R&D expenses	6.1	9%	7.1	11%	+16.0%	27.0	10%
Core operating profit	11.7	18%	10.6	16%	-9.5%	45.5	17%
Non core SG&A expense	0.2	0%	-	-	-100.0%	-	-
Amortization on intangible assets associated with products	2.4	4%	2.6	4%	+5.5%	10.3	4%
Other income	0.1	0%	0.3	1%	+176.3%	0.5	0%
Other expenses	0.0	0%	0.0	0%	+17.5%	1.5	1%
Operating profit	9.2	14%	8.3	13%	-9.0%	34.2	13%
Finance income	0.6	1%	1.4	2%	+134.7%	0.9	0%
Finance expenses	0.3	0%	0.1	0%	-55.8%	0.6	0%
Share of loss of Investments accounted for using equity method	0.3	0%	0.5	1%	+75.4%	2.0	1%
Profit before tax	9.2	14%	9.1	14%	-1.1%	32.5	12%
Income tax expenses	1.8	3%	2.4	4%	+29.0%	8.1	3%
<i>Actual tax ratio</i>	20.1%	-	26.2%	-	+6.1pt	25.0%	-
Net profit	7.3	11%	6.7	10%	-8.6%	24.4	9%
Core net profit	9.0	14%	7.7	12%	-14.2%	34.1	13%

Gross margin

-2% YoY

- Revenue increase offset by YoY increase in COGS ratio from changes in regional / product mix.

Operating profit (Core basis)

-10% YoY

- Increase in R&D expenses as a result of pipeline progress, but rigorous cost controls in place.

Operating profit (IFRS)

-9% YoY

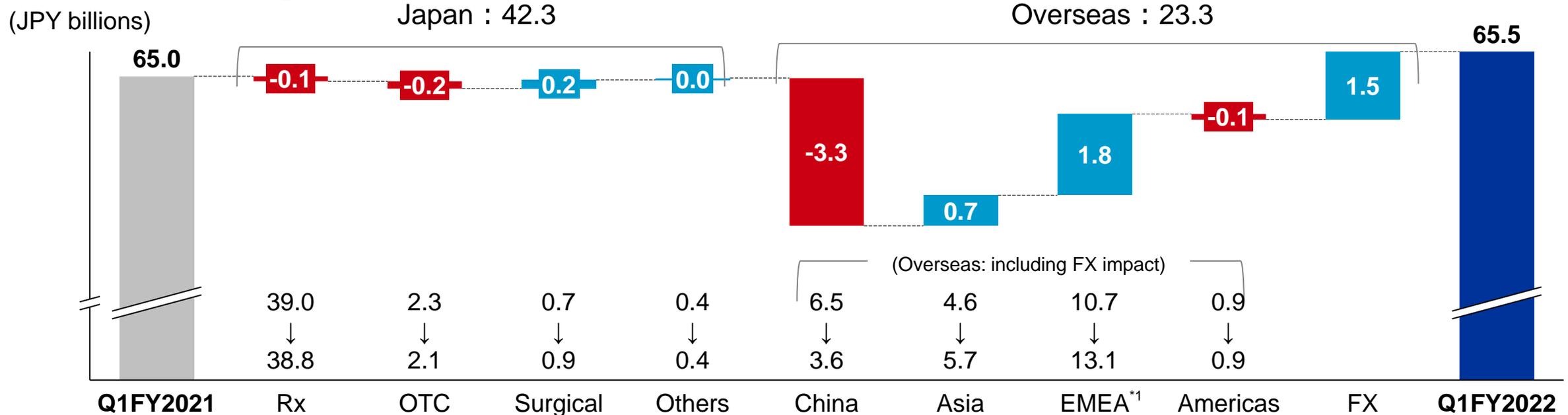
Net profit (IFRS)

-9% YoY

- Positive FX impact on finance income
- Increase in strategic invest. (equity-method investment loss)

Impact from China market contraction absorbed by other regions

	FY2021 Q1 ACT	FY2022 Q1 ACT	FY2022 FCST
USD (JPY)	109.81	129.16	125.00
EUR (JPY)	132.05	137.80	135.00
CNY (JPY)	17.03	19.58	19.00



Japan -0.1% YoY: Exceeded expectations. NHI price impact offset by market penetration in core products.

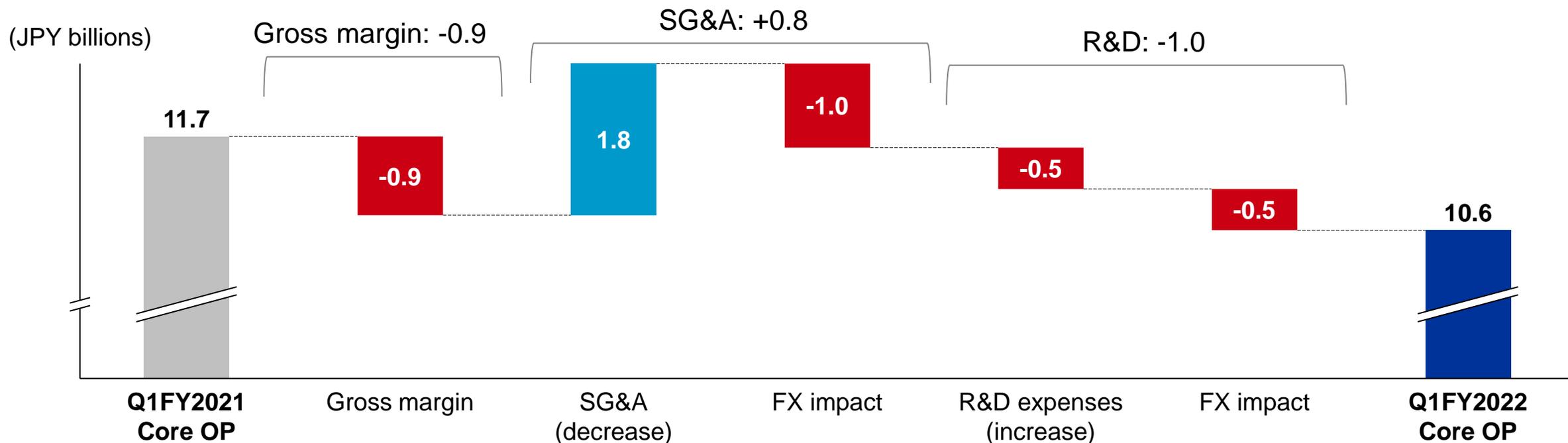
China -43.8% YoY (Ex. FX impact -51.1%): Sales materially impacted by macro environment.

Asia +23.5% YoY (Ex. FX impact +14.9%): Exceeded expectations. Growth led by glaucoma and dry eye in key markets.

EMEA +22.0% YoY (Ex. FX impact +16.9%): Steady, above-market growth trajectory confirmed, primarily driven by glaucoma products.

Americas -2.1% YoY (Ex. FX impact -13.9%): Eyevance sales declined from prolonged supply issues

Despite SG&A controls, Core OP down on lower gross margin and FX

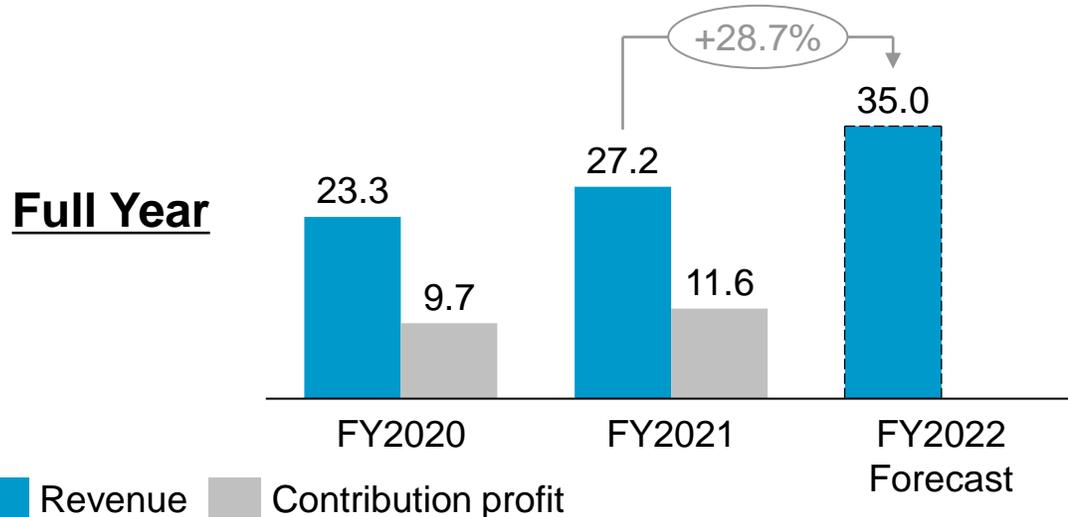
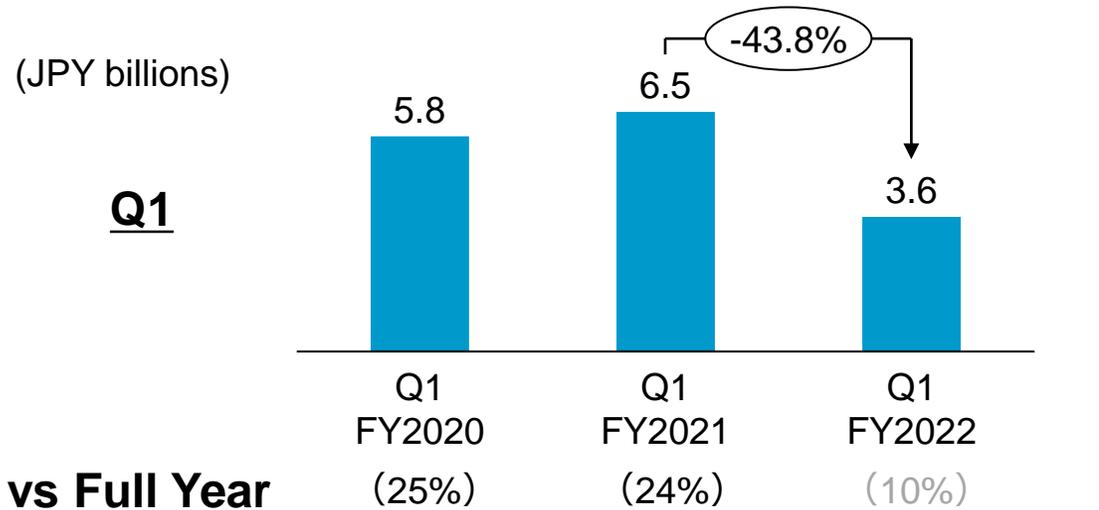


Gross margin Net -0.9bil YoY. Revenue increase (incl. FX) partially offset by region / product mix and FX impact on COGS ratio.

SG&A Net +0.8bil YoY. Despite cost controls, SG&A negatively impacted by FX.

R&D expenses Net -1.0bil YoY. Increase in expenses on the back of pipeline progress coupled with FX impact.

Sales materially impacted by macro environment



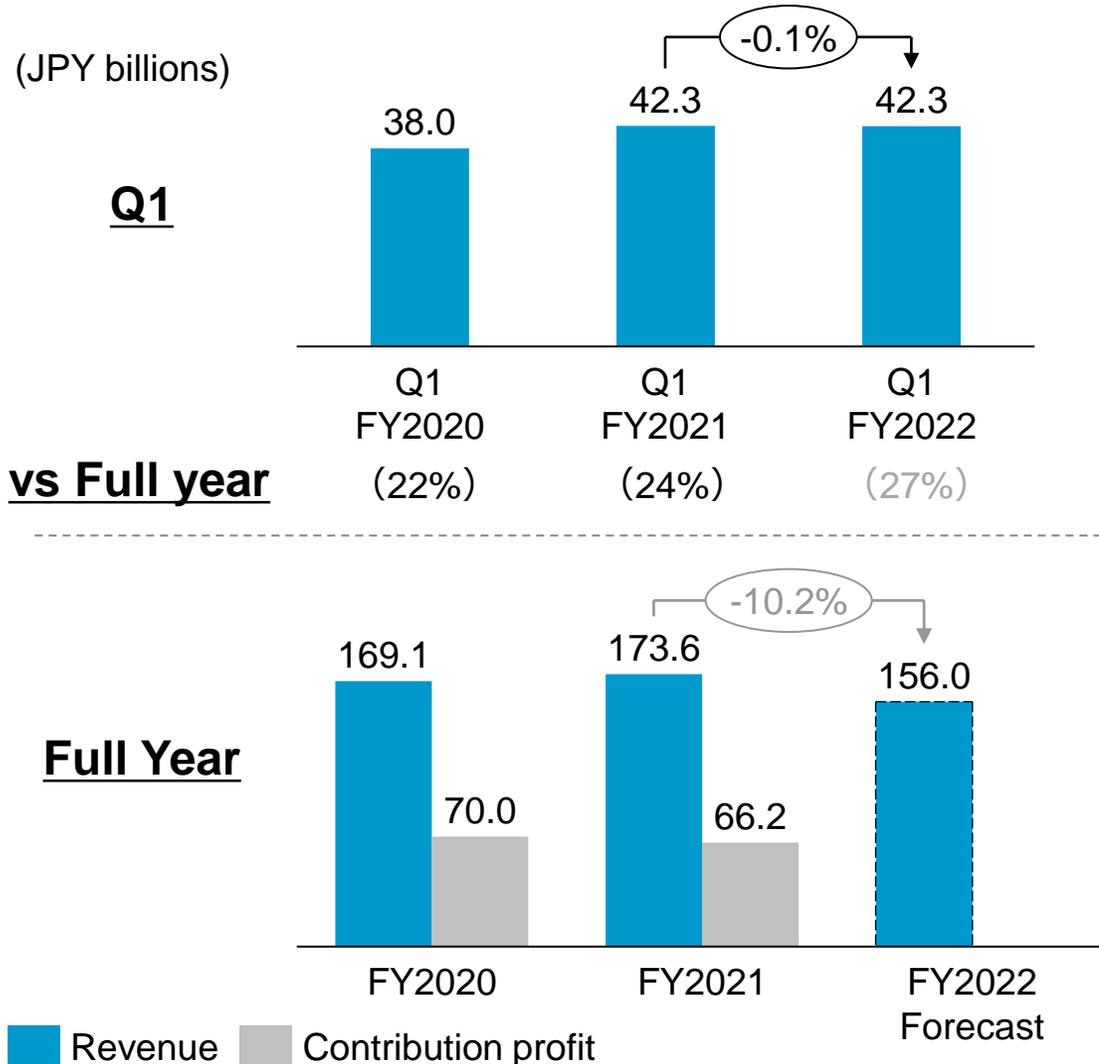
Highlights

- Significant impact from macro conditions as a result of high proportion of sales in dry eye and infection
- Continued focus on SG&A cost control but unable to fully mitigate impact of revenue decline.

FY2022 Outlook

- Macro environment impact including COVID-19 policy may exceed expectations in magnitude and duration for FY2022

Exceeded expectations. NHI price impact offset by market penetration of core products



Highlights

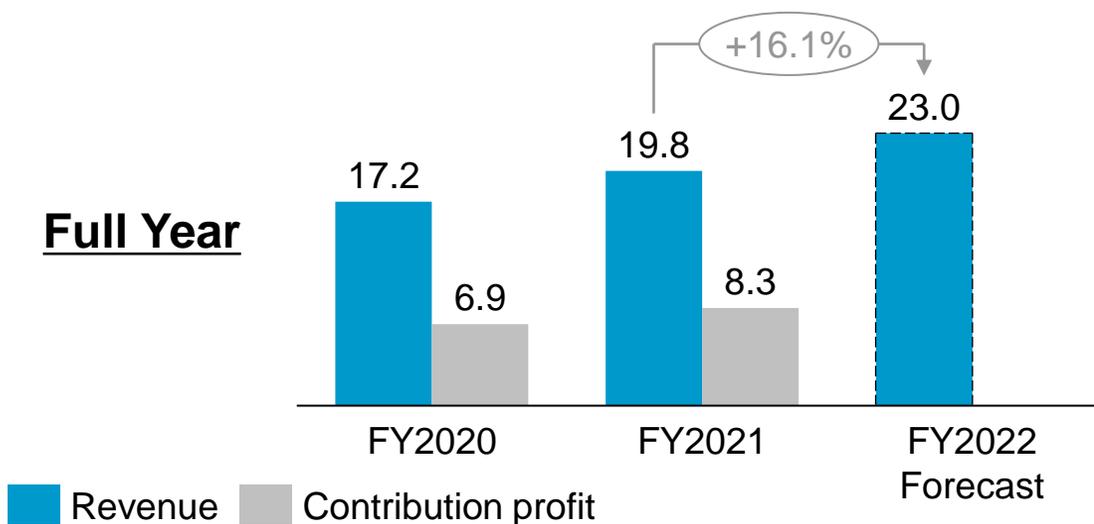
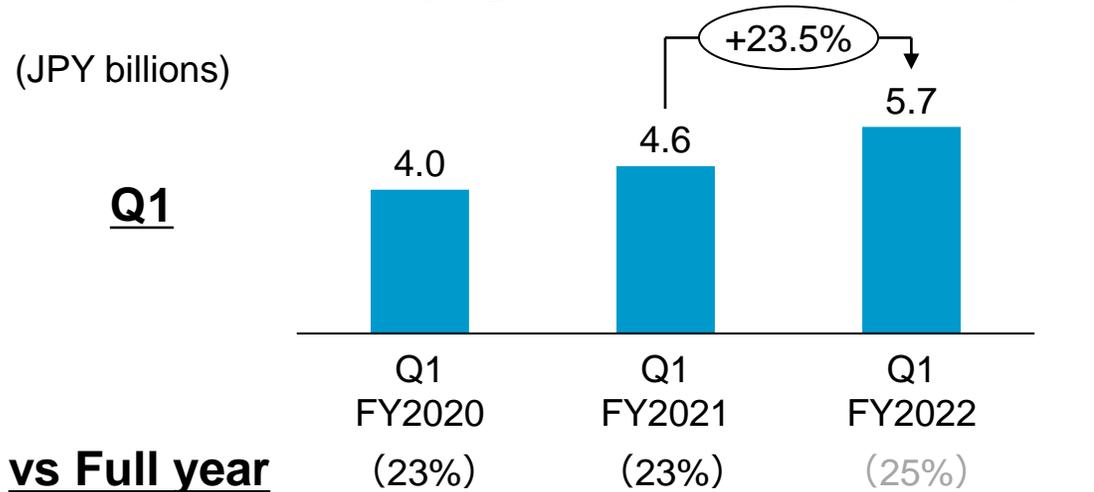
- Market penetration of core products mitigates NHI price reduction (mid -4% o/w -20% for *Alesion*). *Eybelis* +0.27bil, *Diquas* +0.47bil YoY.
- Absence of *Alesion LX* GE (not launched in June); Santen's competitiveness maintained in core product segment.
- Received approval for *Diquas LX*. Preparation for launch ongoing.

FY2022 Outlook

- Current trend and momentum expected to continue Q2 onward.
- Taking countermeasures to maintain competitiveness.

Exceeded expectations

Growth led by glaucoma and dry eye in key markets



Highlights

- Korea: JPY +0.58billion (+23% YoY)
Core products in glaucoma and dry eye led sales despite Omicron variant spread impact
- Double-digit growth in key markets (Taiwan: +0.14bil, Philippines:+0.11bil, Thailand: +0.11bil, Vietnam: +0.11bil.)

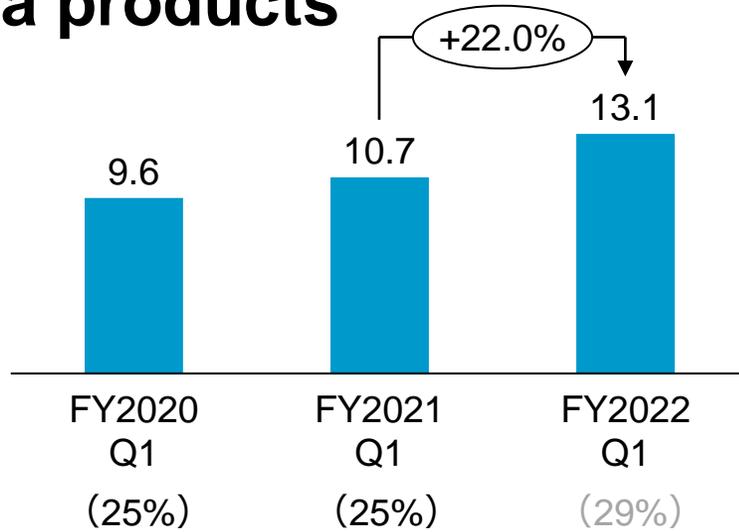
FY2022 Outlook

- Growth trend expected to continue subject to evolution of competitive landscape with GEs in key markets. Need to monitor changes in external environment.

Steady, above-market growth trajectory confirmed, primarily driven by glaucoma products

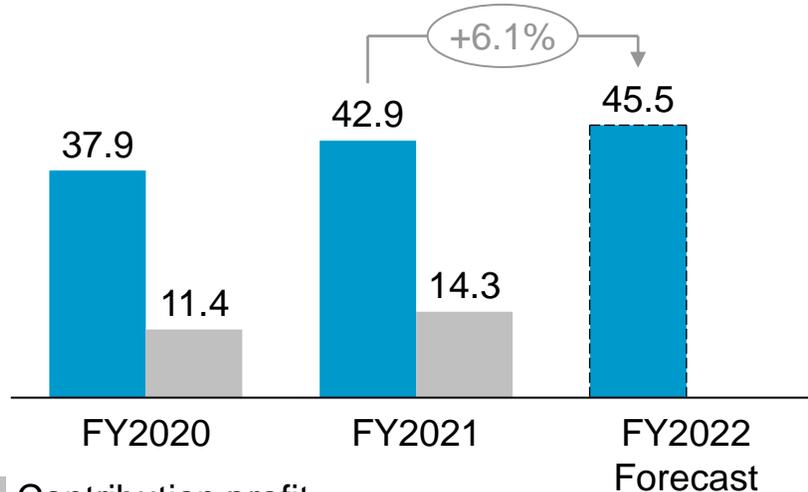
(JPY billions)

Q1



vs Full year

Full Year



■ Revenue ■ Contribution profit

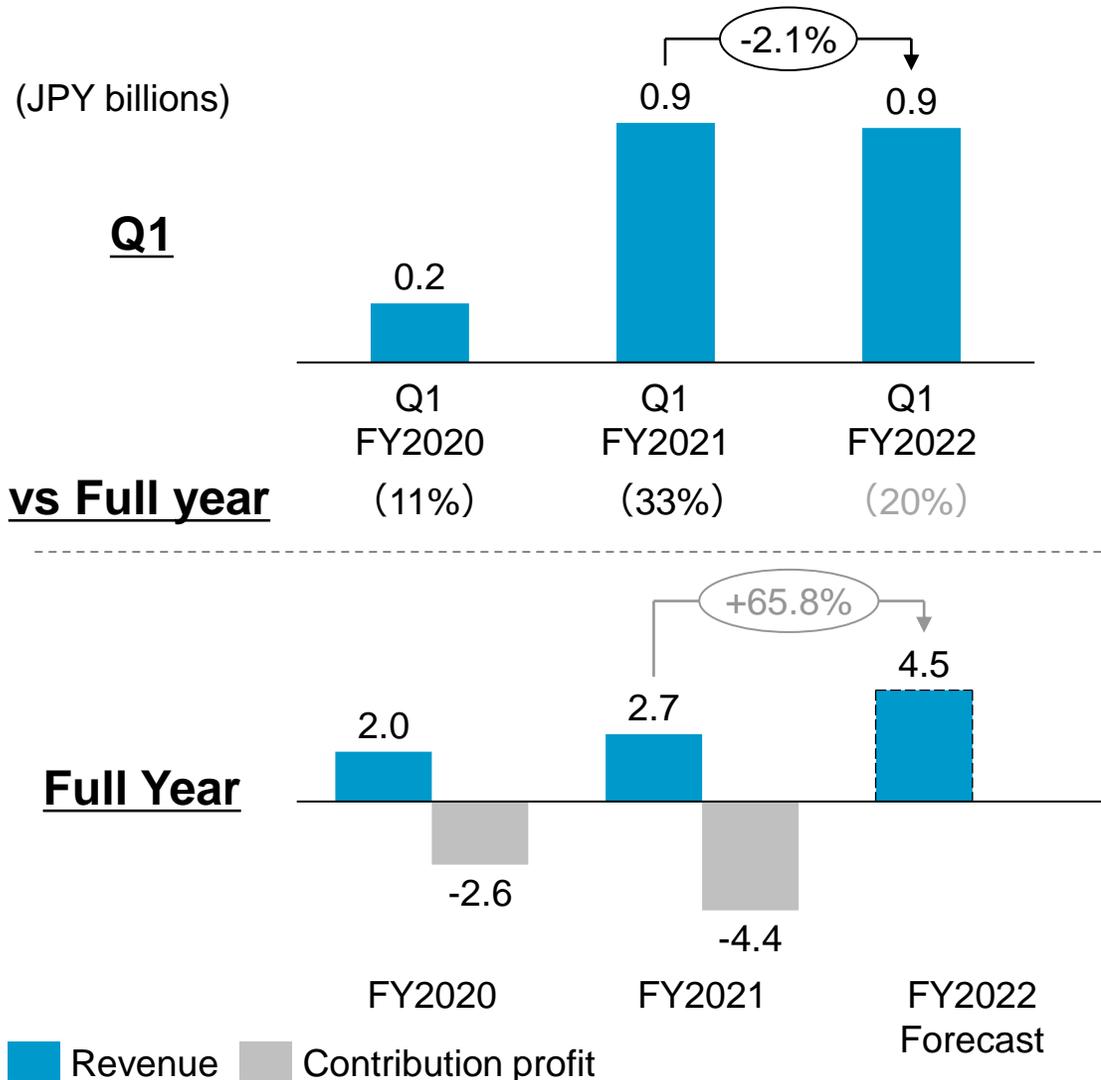
Highlights

- Steady growth in market penetration of glaucoma products. (*Cosopt* +0.52bil, *Tapros* +0.33bil, *Tapcom* +0.28bil and *PRESERFLO MicroShunt* +0.28bil YoY)
- New product growth: *Duressa* +0.11bil YoY

FY2022 Outlook

- Stable growth trajectory with necessary measures to be taken for *Tapros* LoE

Eyevance sales decline from prolonged supply issues



Highlights

- Expect recovery from back-orders impact on products Q2 onwards.
- Improved sales momentum in *Tobradex ST* and *Flarex* from commercial efforts.
- Positive impact from initial HCP feedback on *Verkazia* mitigated by launch post peak allergy season and Medicaid reimbursement procedure delay. Sales momentum expected post Q4 given seasonal trend.

FY2022 Outlook

- Aim to minimize loss. Revamping of U.S. strategy post STN1011700 PDUFA

Expect revenue -1% YoY on price revisions in Japan and flat OP margins

Firm-wide mitigation of region-specific volatilities in performance

(JPY billions)	FY2021		FY2022		
	Actual	vs Revenue	Forecast	vs Revenue	YoY
Revenue	266.3	-	264.0	-	-0.8%
Cost of sales	109.7	41%	103.0	39%	-6.1%
Gross margin	156.6	59%	161.0	61%	+2.8%
SG&A expenses	83.9	31%	88.5	34%	+5.5%
R&D expenses	26.4	10%	27.0	10%	+2.4%
Core operating profit	46.3	17%	45.5	17%	-1.8%
Non core SG&A expense	0.6	0%	-	-	-
Amortization on intangible assets associated with products	9.7	4%	10.3	4%	+5.8%
Other income	1.0	0%	0.5	0%	-52.0%
Other expenses	1.1	0%	1.5	1%	+32.4%
Operating profit	35.9	13%	34.2	13%	-4.7%
Finance income	2.5	1%	0.9	0%	-64.6%
Finance expenses	1.2	0%	0.6	0%	-50.4%
Share of loss of Investments accounted for using equity method	1.6	1%	2.0	1%	+24.7%
Profit before tax	35.6	13%	32.5	12%	-8.7%
Income tax expenses	8.4	3%	8.1	3%	-3.6%
<i>Actual tax ratio</i>	23.7%	-	25.0%	-	+1.3pt
Net profit	27.2	10%	24.4	9%	-10.3%
ROE	8.4%		7%		
Core net profit	35.2	13%	34.1	13%	-3.1%

Gross margin

+3% YoY

- Expect impact from change in product mix and measures to reduce manufacturing costs

Operating profit (Core basis)

-2% YoY

- Increasing allocation to R&D versus FY2021
- Reducing SG&A

Operating profit (IFRS)

-5% YoY

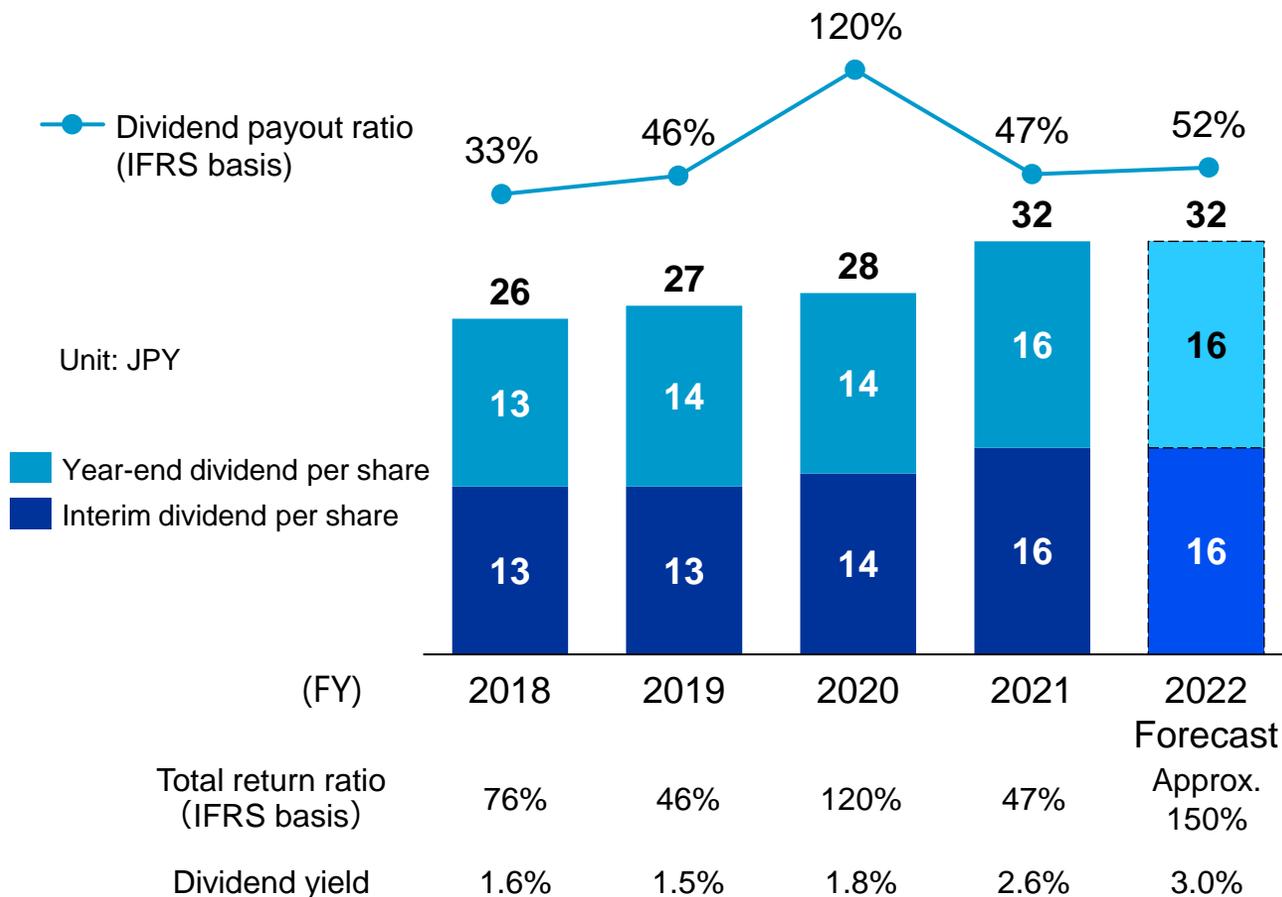
Net profit (IFRS)

-10% YoY

- Increase in strategic investments (equity-method investment loss)

Annual dividend of JPY32. FY2022 total payout ratio of approx. 150%

Current share buyback program until end of Q2



Current share buyback

1. Overview

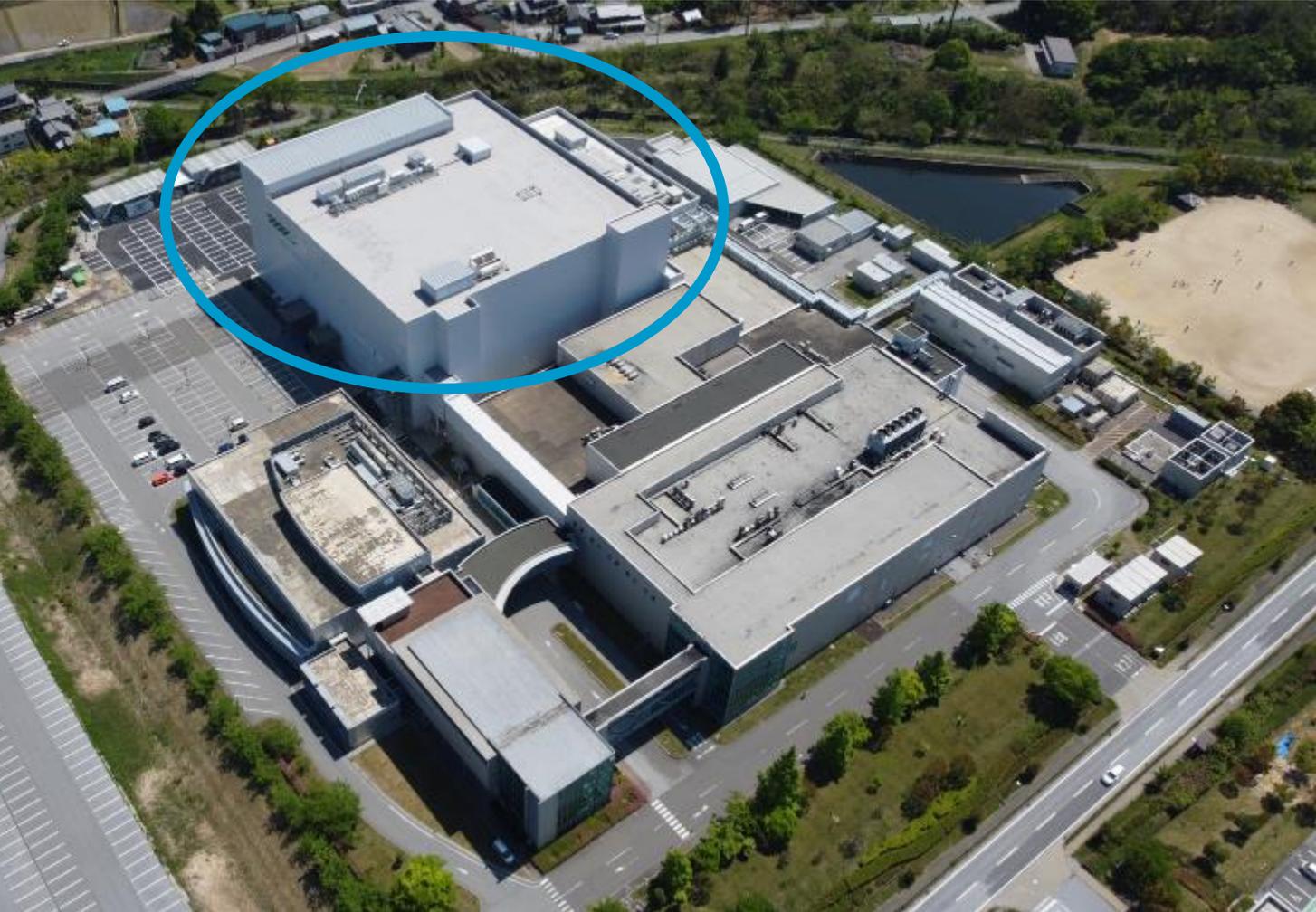
- Total number of shares to be repurchased: 12.5M shares (maximum)
- Total amount of repurchase: 15.0 billion yen (maximum)
- Period of repurchase: May11,2022 - Sep.30,2022

2. Status (end July)

- Total number of shares repurchased: 7,652,800 shares (progress: 61.22%)
- Total amount of repurchase: 7,793,548,859 yen (progress: 51.96%)

FY2022 return ratio forecast includes the share buy-back announced on May 10. Dividend payout ratio and total return ratio in FY2020 are adjusted due to the completion of the allocation of consideration for acquisition of Eyevance. Share buy-back: Representing 2.0% of the total number of shares outstanding (excluding treasury shares) in FY2018. Dividend yield calculated based on fiscal year-end share price (End-June share price for FY2022)

Completion of 3rd building in July On schedule for FY2023 start of operations



Higher productivity

- Automation and digitalization
- Labor-saving

Environmental-friendly

- Energy saving equipment
- Equipment layout

Capacity for global demand

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R&D Update

Appendix

Q1 progress in 12 pipeline products (9 in late phase)

Glaucoma	STN1011700 <i>EYBELIS</i>	Re-submission in US. PDUFA date; November 6, 2022
	STN2000100 <i>PRESEFLO MicroShunt</i>	Launched (soft launch) in Japan
	STN1013900 <i>Rhopressa®/Rhokiinsa®</i>	Met primary endpoint in P3 trial under concomitant use of latanoprost in Japan
	STN1014000 <i>Rocklatan®/Roclanda®</i>	Filed in Asia
Dry eye	STN1008903 <i>Diquas LX</i>	Received approval in Japan
Allergic conjunctivitis	STN1011402 Epinastine ophthalmic cream	Achieved LPI ^{*1} in P3 trials in Japan
VKC ^{*2}	STN1007603 <i>Verkazia</i>	Launched in US. Approved in China
Myopia	STN1012700 Atropine sulfate	Achieved FPI ^{*3} in P2/3 trial in China
	STN1013400 AFDX0250BS	Started preparations for P1 trial in China
Ptosis	STN1013800 Oxymetazoline hydrochloride	Started preparations for P3 trial in China
MGD ^{*4}	STN1010905 Sirolimus eye drop	Achieved LPO ^{*5} in P2a
FECD ^{*6}	STN1010904 ^{*7} Sirolimus eye drop	Achieved FPI in P2a

*1 LPI; Last Patient In. *2 VKC; Vernal keratoconjunctivitis *3 FPI; First Patient In. *4 MGD; Meibomian gland dysfunction. *5 LPO; Last Patient Out. *6 FECD; Fuchs endothelial corneal dystrophy. *7 Santen retains the option right for exclusive license of this program. Santen development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II clinical trial.

ROCK inhibitors for glaucoma – a global development

	STN1013900	STN1014000
	Netarsudil mesylate	Netarsudil mesylate / latanoprost (combination)
Contractual territory	Japan, Asia, Europe, China	
Development Status <small>*Only projects where the study protocols were approved in-house are shown,</small>	<p>Japan P3 <i>Plan: FY2023 P3 completion</i></p> <p>Europe Approved <i>Plan: FY2022 launch</i></p> <p>Asia Filed <i>Plan: FY2023 approval</i></p>	<p>Europe Approved <i>Plan: FY2022 launch</i></p> <p>Asia Filed <i>Plan: FY2023 approval</i></p>

Status on three Pivotal Phase 3 trials for Japan filing

Comparative study with ripasudil

- STN1013900 (QD) + vehicle (QD)
- Ripasudil (BID)

**Demonstrated superiority
to ripasudil**

Reported at Q2 FY2021 Financial Results Meeting
https://www.santen.com/en/assets/pdf/ir/document/202203/mtg2022_2q.pdf

Study of adjunctive use of STN1013900 with latanoprost

- STN1013900 (QD) + latanoprost (QD)
- Placebo (QD) + latanoprost (QD)

**Demonstrated adjunctive
effect of STN1013900**

Report on next page ▶▶▶

Long-term treatment study

- STN1013900 (QD) (for low-IOL patients)
- STN1013900 (QD)
- STN1013900 (QD) + latanoprost (QD)
- STN1013900 (QD) + timolol (BID)

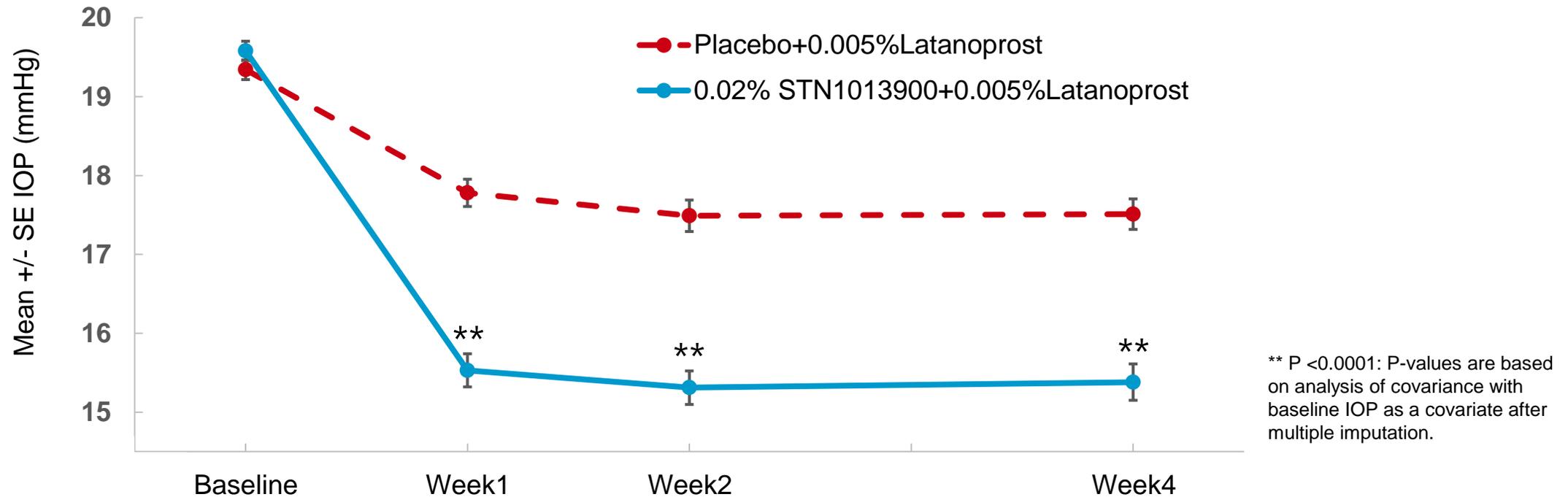
On-going

QD (quaque die); once a day. BID (bis in die); twice a day.

STN1013900 showed a significant adjunctive effect of lowering intraocular pressure in the latanoprost ophthalmic solution combination study



Mean +/- SE Study Eye Mean Diurnal Intraocular Pressure (mmHg) by Treatment Group and Visit



- STN1013900 met the study objective by demonstrating superiority to Placebo in Mean Diurnal IOP at Week 4 under concomitant use of latanoprost in Japanese subjects with POAG or OHT (Δ -2.36mmHg)
- The most frequent AE was conjunctival hyperaemia by 53.3% in STN1013900 group and 6.5% in Placebo group

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Foreign exchange rate assumptions and sensitivities

FX rate

(JPY)

	Q1 FY2021 Actual	Q1 FY2022 Actual	FY2022 Forecast
USD	109.81	129.16	125.00
EUR	132.05	137.80	135.00
CNY	17.03	19.58	19.00

Sensitivities

(JPY billions)

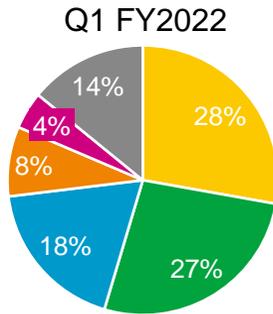
	USD	EUR	CNY
Revenue	+0.05	+0.45	+0.35
Core OP	-0.16	+0.05	+0.11

*Impact of a 1% depreciation of the yen on revenue and core operating profit
(vs FY2022 forecast rate)

Q1 FY2022 revenue by region (YTD)

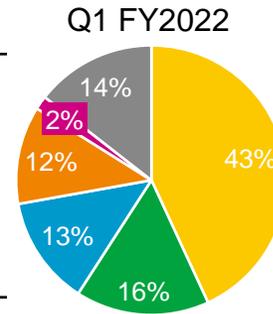
Consolidated

(JPY billions)	Q1 FY2021 (Ref.)	Q1 FY2022
EYLEA*1	18.7	18.2
Cosopt	5.4	6.0
Diquas	4.5	5.1
Other	36.3	36.2
Total	65.0	65.5



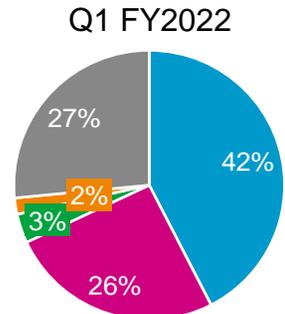
Japan

(JPY billions)	Q1 FY2021 (Ref.)	Q1 FY2022
EYLEA*1	18.7	18.2
Alesion*2 (Incl. Alesion LX)	5.0	4.8
Diquas	3.4	3.9
Other	15.2	15.4
Total	42.3	42.3



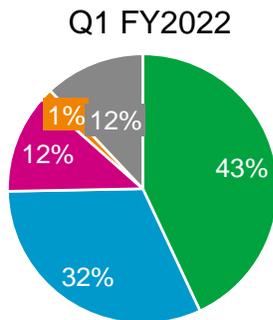
China

(JPY billions)	Q1 FY2021 (Ref.)	Q1 FY2022
Hyalein	2.1	0.9
Cravit	1.8	0.7
Diquas	0.7	0.7
Other	1.9	1.4
Total	6.5	3.6



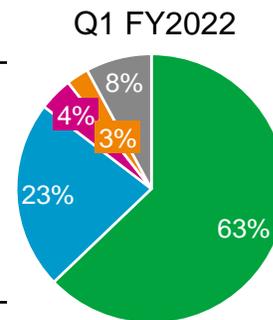
Asia

(JPY billions)	Q1 FY2021 (Ref.)	Q1 FY2022
Cosopt	1.2	1.5
Hyalein	0.4	0.8
Diquas	0.4	0.5
Other	2.5	2.9
Total	4.6	5.7

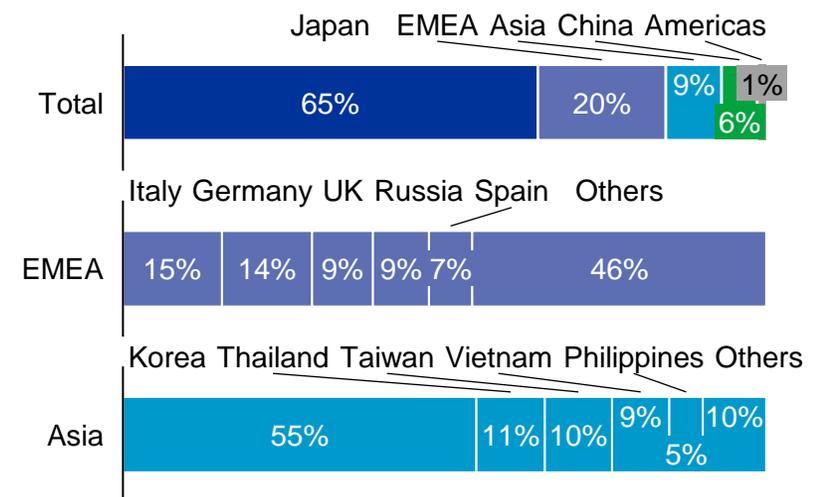


EMEA

(JPY billions)	Q1 FY2021 (Ref.)	Q1 FY2022
Cosopt	2.6	3.1
Tapros	1.6	2.0
Ikervis	1.4	1.5
Other	5.0	6.5
Total	10.7	13.1



Revenue in each region (Q1 FY2022)



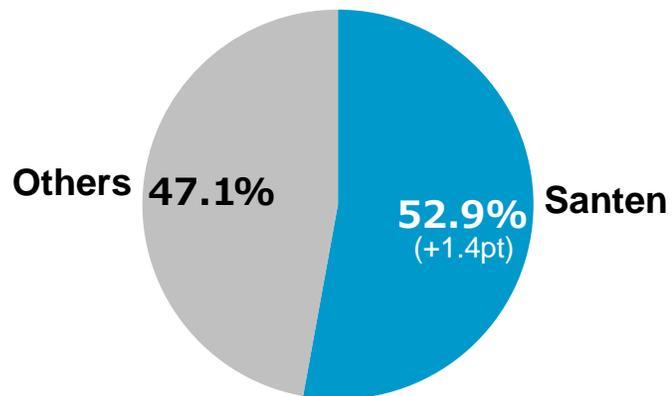
*1EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

*2 Alesion: Trademark of alliance partner, Nippon Boehringer Ingelheim

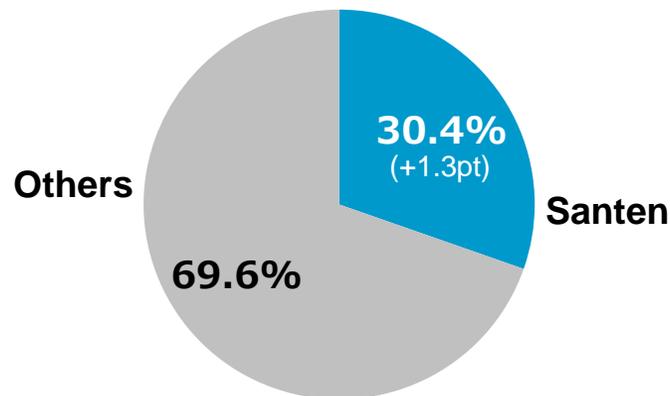
Remain No.1 for overall market and all segments

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

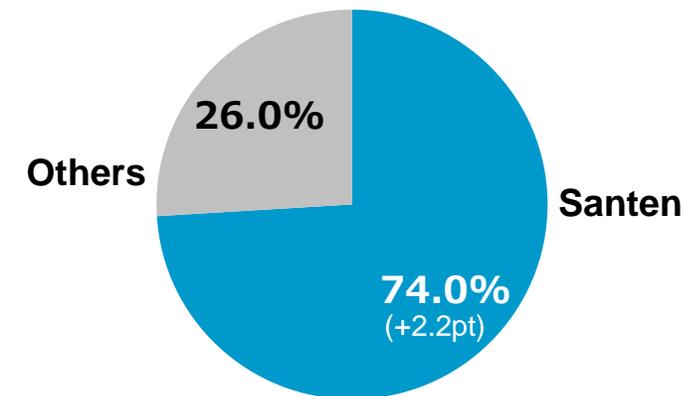
Total: JPY368.1bil



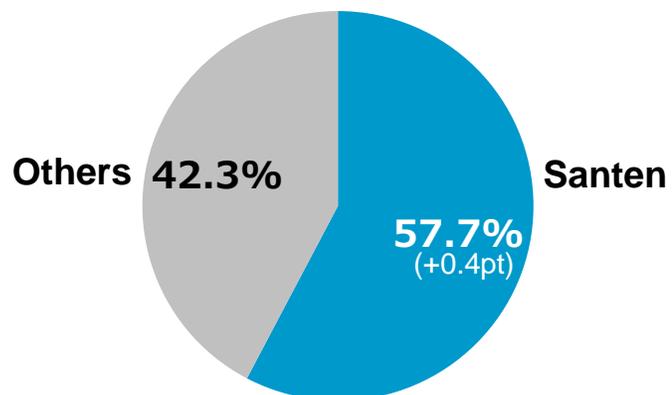
Glaucoma: JPY98.2bil



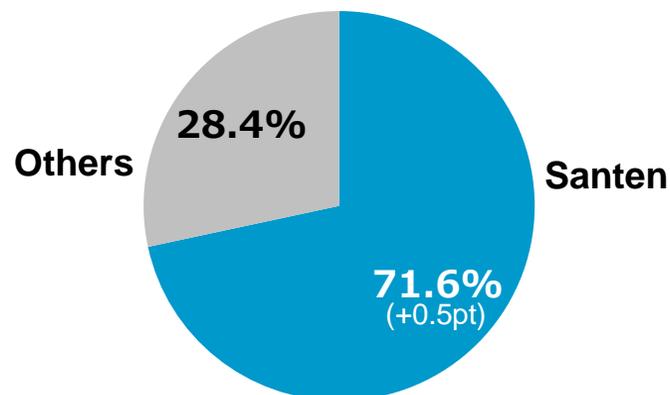
Retinal disorders*: JPY118.9bil



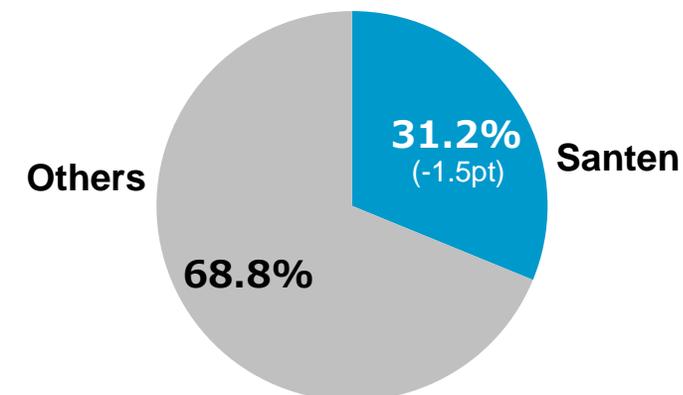
Corneal / dry eye: JPY42.2bil



Allergy: JPY51.0bil



Anti-infection: JPY7.5bil



*Including co-promoted product (Anti-VEGF EYLEA) of Bayer Yakuhin, Ltd. (MAH) Source: Copyright © 2022 IQVIA. JPM 2020.7-2022.6; Santen analysis based on IQVIA data. Reprinted with permission.

Current status of global development (1)

As of July 2022
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status*1	
Glaucoma	Omidenepag isopropyl <i>EYBELIS</i>	WW*2	STN1011700 DE-117	US	Re-submitted in May 2022 <i>Plan: FY2022 approval (PDUFA; November 6, 2022)</i>
				Japan	Launched
				Asia	Launched
	Sepetaprost	WW	STN1012600 DE-126	US	P2 (met primary endpoint)
				Japan	P2b (dose finding study completed) <i>Plan: FY2022 P3 start</i>
				Europe	P2 (exploratory study) <i>Plan: FY2022 P2 (exploratory study) completion</i>
	Implant device <i>PRESERFLO MicroShunt</i>	WW (In-house) *Excl. Americas, Australia, New Zealand	STN2000100 DE-128	Japan	Launched (soft launch) in July 2022
				Europe	Launched
				Asia	Approved <i>Plan: FY2022 launch</i>
	Netarsudil mesylate <i>Rhopressa®/Rhokiinsa®</i>	Japan, China Asia, Europe	STN1013900 AR-13324	Japan	P3 <i>Plan: FY2023 P3 completion</i>
				Europe	Approved <i>Plan: FY2022 launch</i>
				Asia	Filed <i>Plan: FY2023 approval</i>

*1 Only projects where the study protocols were approved in-house are shown, *2 World wide

Current status of global development (2)

As of July 2022
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Glaucoma	Netarsudil mesylate /latanoprost (combination) <i>Rocklatan®/Roclanda®</i>	Japan, China Asia, Europe	STN1014000 PG-324	Europe	Approved <i>Plan: FY2022 launch</i>
				Asia	<i>Filed in May 2022</i> <i>Plan: FY2023 approval</i>
Myopia	Atropine sulfate	Japan, China Asia	STN1012700 DE-127	Japan	P2/3 <i>Plan: FY2023 P2/3 completion</i>
				China	<i>Started P2/3 in June 2022</i> <i>Plan: FY2025 P2/3 completion</i>
				Asia	P2 (met primary endpoint)
		EMEA	STN1012701 SYD-101	Europe	P3 (conducted by Sydnexis Inc.) <i>Plan: FY2024 P3 completion</i>
	AFDX0250BS	WW	STN1013400	Japan	P1 (confirmed safety and tolerability)
				China	<i>Plan: FY2023 P1 start</i>
Presbyopia	Ursodeoxycholic acid	WW (In-house)	STN1013600	US	<i>Plan: FY2022 P2a start</i>
				Japan	P1 (confirmed safety and tolerability)

Current status of global development (3)

As of July 2022
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Ptosis	Oxymetazoline hydrochloride	Japan, China Asia, EMEA Canada	STN1013800 RVL-1201	Japan	<i>Plan: FY2022 P3 start</i>
				China	<i>Plan: FY2023 P3 start</i>
				Asia	<i>Plan: FY2022 Filing</i>
Retinitis pigmentosa	jCell	Japan, China Asia, Europe	STN6000100	-	P2 safety study (US, conducted by jCyte, Plan to complete in FY2022). Considering P3 plan
Allergic conjunctivitis	Epinastine HCl (Ophthalmic cream)	Japan	STN1011402	Japan	P3 <i>Plan: FY2022 P3 completion</i>
Vernal keratoconjunctivitis	Ciclosporin <i>Verkazia</i>	WW (In-house)	STN1007603 DE-076C	US	Launched
				China	Approved <i>Plan: FY2022 launch</i>
Dry eye	Diquafosol sodium (long-lasting) <i>Diquas LX</i>	Japan, China Asia, Europe	STN1008903 DE-089C	Japan	<i>Approved in June 2022</i> <i>Plan: FY2022 launch</i>
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	—*1	STN1010904 *1	US France India	<i>Started P2a in May 2022</i> <i>Plan: FY2024 P2a completion</i>
Meibomian gland dysfunction	Sirolimus (eye drop)	WW (In-house)	STN1010905	Japan	P2a <i>Plan: FY2022 P2a completion</i>

*1 Santen retains the option right for exclusive license of this program. Santen development code to be formally assigned to the product when Santen obtains exclusive license upon the completion of Phase II trial.

Current status of global development (4)

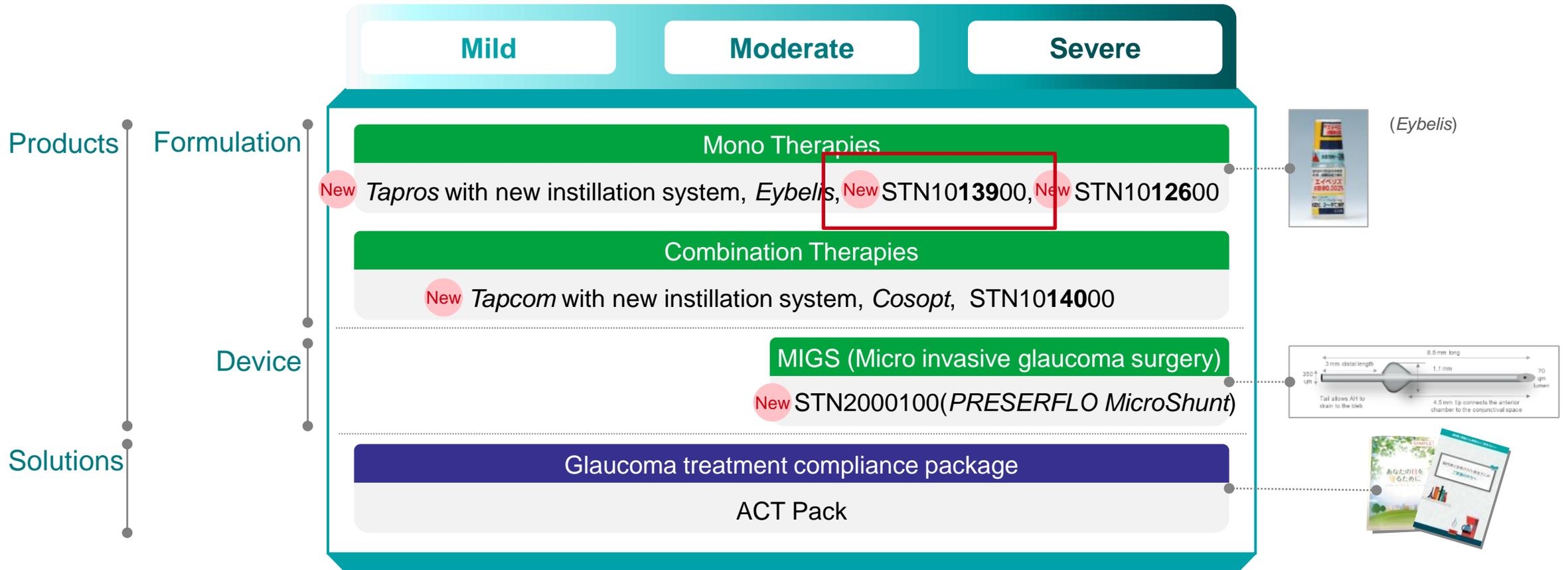
As of July 2022
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Glaucoma	Tafluprost / timolol maleate (combination) <i>TAPCOM / TAPTIQOM</i>	Japan, China Asia, Europe	STN1011101 DE-111A	China	P3 <i>Plan: FY2023 P3 completion</i>
	Latanoprost	WW (In-house)	STN1013001 DE-130A Catioprost	Europe	P3 (met primary endpoint) <i>Plan: FY2022 filing</i>
				Asia	P3 (met primary endpoint)

Positioning of STN1013900 in glaucoma portfolio at Japan business

▶ Provide treatment packages through an extensive range of products / solutions

New : Pipeline scheduled for launch during MTP2025



Reposted from Medium-Term Plan "MTP2025" presentation slides.

Protocol of study under concomitant use of latanoprost

