



# **Q2 FY2022 Financial Results**

**November 8, 2022**

## ■ Featuring



**Akira Kurokawa**  
Chairman



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President &  
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Chief Financial Officer &  
Chief Risk Officer



**Peter Sallstig**  
Chief Medical Officer

# Forward-looking statements

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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.

■ Agenda

1. **Q2 Results and FY2022 Forecast**
2. R&D Update
3. Regrowth Agenda

## Overview

### ■ Q2 FY2022 Consolidated results

- Revenue: +0.1% YoY (JPY128.9bil.)
- Core OP: -32.3% YoY (JPY16.5bil.)
- COGS increase from region & product mix and transient causes
- R&D expenses increased from pipeline progress

### ■ FY2022 Outlook

- Maintain core operating profit FY initial forecast
- Net profit: Revised downward to JPY-5.5bil. Eyevance impairment

### ■ FY2022 Shareholder returns

- JPY16 interim dividend unchanged. Additional JPY13.0bil. share purchase from November 9

# COGS ratio and FX impact core OP despite flat revenue

## OP: Loss from Eyevance impairment

(JPY billions)	Q2 FY2021		Q2 FY2022		
	Actual	vs Revenue	Actual	vs Revenue	YoY
<b>Revenue</b>	128.8	-	<b>128.9</b>	-	<b>+0.1%</b>
Cost of sales	52.9	41%	55.9	43%	+5.7%
<b>Gross margin</b>	75.9	59%	<b>73.0</b>	<b>57%</b>	<b>-3.8%</b>
SG&A expenses	39.2	30%	42.3	33%	+7.8%
R&D expenses	12.3	10%	14.3	11%	+15.6%
<b>Core operating profit</b>	24.3	19%	<b>16.5</b>	<b>13%</b>	<b>-32.3%</b>
Non core SG&A expense	0.4	0%	-	-	-100.0%
Amortization on intangible assets associated with products	4.8	4%	5.2	4%	+7.9%
Other income	0.2	0%	0.3	0%	+28.5%
Other expenses	0.5	0%	30.6	24%	-
<b>Operating profit</b>	18.8	15%	<b>-19.0</b>	-	-
Finance income	0.7	1%	1.2	1%	+85.3%
Finance expenses	0.4	0%	0.3	0%	-40.5%
Share of loss of Investments accounted for using equity method	0.6	0%	1.1	1%	+65.4%
Profit before tax	18.4	14%	-19.1	-	-
Income tax expenses	4.1	3%	2.9	2%	-29.5%
<i>Actual tax ratio</i>	22.5%	-	-	-	-
<b>Net profit</b>	14.3	11%	<b>-22.0</b>	-	-
Core net profit	18.6	14%	12.5	10%	-32.8%

### Gross Margin

#### **-3.8% YoY**

- Revenue: flat to FY2021 partially from positive FX impact.
- YoY higher COGS ratio from changes in product/region mix and one-time contractual-related costs

### Operating Profit (Core basis)

#### **-32.3% YoY**

- Increase in R&D expenses as a result of pipeline progress
- Increase in SG&A/R&D expenses from FX impact (total of JPY3.9bil.)

### Operating Profit (IFRS)

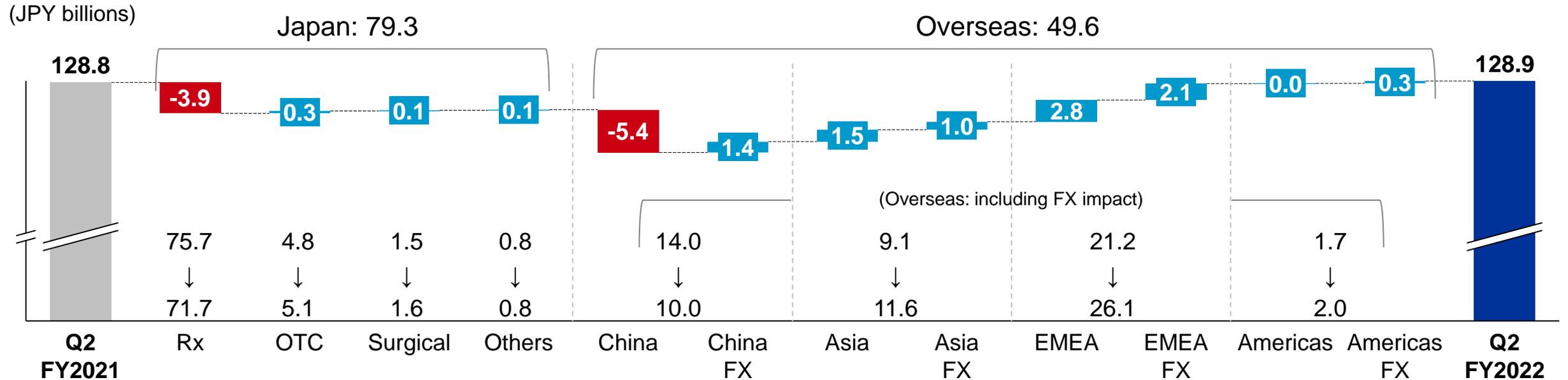
- JPY-19.0bil. (down JPY37.8bil. YoY) primarily from impairment loss of Eyevance (JPY 30.0bil.)

### Net Profit (IFRS)

- Positive FX impact on finance income
- Equity-method investment loss

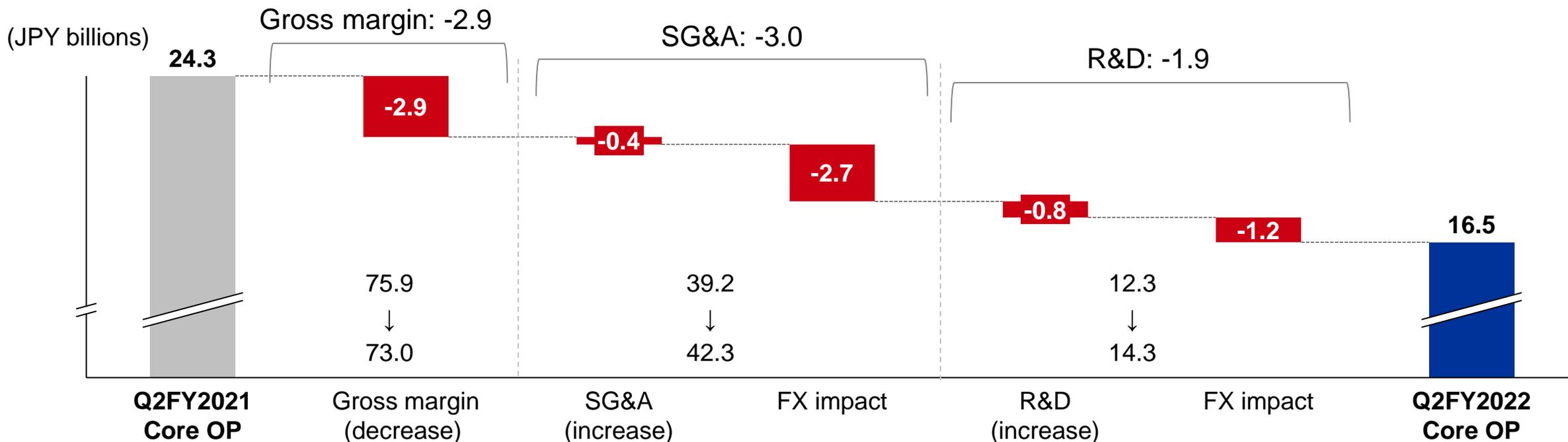
# Price cuts in Japan and China impact absorbed by other regions

	Q2FY2021 ACT	Q2FY2022 ACT
USD (JPY)	110.09	133.46
EUR (JPY)	131.14	138.61
CNY (JPY)	17.05	19.84



Japan	-4.2% YoY: Steady progress exceeding expectations. Impact from NHI price cuts offset by core products
China	-29.0% YoY (Ex. FX impact -38.9%): Recovery trend, but impact from strict COVID-19 measures expected to continue until Q4
Asia	+27.9% YoY (Ex. FX impact +16.8%): Growth trajectory exceeding expectations led by glaucoma and dry eye in key markets
EMEA	+22.9% YoY (Ex. FX impact +13.1%): Exceeding expectations, primarily driven by glaucoma core products
Americas	+19.4% YoY (Ex. FX impact +2.1%): On a recovery path vs Q1 with FX tailwind on sales

# Core OP down on higher COGS ratio and US business delay in turning profitable, coupled with increase in expenses



Gross margin Net -2.9bil YoY. Revenue flat (incl. FX impact) partially offset by COGS ratio

SG&A Net -3.0bil YoY. While maintained the same level as FY2021 excluding FX, SG&A negatively impacted by FX

R&D Net -1.9bil YoY. Increase in expenses on the back of pipeline progress coupled with FX impact

# Core OP: Aiming to achieve initial target

	FY2021ACT	FY2022FCST (Nov 8)	FY2022FCST (May 10)
USD (JPY)	112.57	140.00	125.00
EUR (JPY)	130.75	140.00	135.00
CNY (JPY)	17.55	20.00	19.00

(JPY billions)	FY2021		FY2022 (Nov. 8)							FY2022 (May 10)	
	Actual	vs Revenue	H1 Actual	vs Revenue	H2 Forecast	vs Revenue	FY Forecast	vs Revenue	YoY	FY Forecast	vs Revenue
<b>Revenue</b>	266.3	-	128.9	-	151.1	-	<b>1 280.0</b>	-	<b>+5.2%</b>	264.0	-
Cost of sales	109.7	41%	55.9	43%	56.1	37%	112.0	40%	+2.1%	103.0	39%
<b>Gross margin</b>	156.6	59%	73.0	57%	95.0	63%	<b>2 168.0</b>	<b>60%</b>	<b>+7.3%</b>	161.0	61%
SG&A expenses	83.9	31%	42.3	33%	49.2	33%	91.5	33%	+9.1%	88.5	34%
R&D expenses	26.4	10%	14.3	11%	16.7	11%	31.0	11%	+17.5%	27.0	10%
<b>Core operating profit</b>	46.3	17%	16.5	13%	29.0	19%	<b>45.5</b>	<b>16%</b>	<b>-1.8%</b>	45.5	17%
Non core SG&A expense	0.6	0%	-	-	1.5	1%	<b>3 1.5</b>	1%	+135.3%	-	-
Amortization on intangible assets associated with products	9.7	4%	5.2	4%	4.2	3%	<b>4 9.3</b>	3%	-4.1%	10.3	4%
Other income	1.0	0%	0.3	0%	0.4	0%	0.7	0%	-37.7%	0.5	0%
Other expenses	1.1	0%	30.6	24%	0.8	0%	<b>5 31.3</b>	11%	-	1.5	1%
<b>Operating profit</b>	35.9	13%	-19.0	-	23.0	15%	<b>4.0</b>	<b>1%</b>	<b>-88.9%</b>	34.2	13%
Finance income	2.5	1%	1.2	1%	0.5	0%	1.7	1%	-33.2%	0.9	0%
Finance expenses	1.2	0%	0.3	0%	0.4	0%	0.7	0%	-42.1%	0.6	0%
Share of loss of Investments accounted for using equity method	1.6	1%	1.1	1%	0.9	1%	2.0	1%	+24.7%	2.0	1%
Profit before tax	35.6	13%	-19.1	-	22.1	15%	3.0	1%	-91.6%	32.5	12%
Income tax expenses	8.4	3%	2.9	2%	5.6	4%	8.5	3%	+0.9%	8.1	3%
<i>Actual tax ratio</i>	23.7%	-	-	-	-	-	-	-	-	25.0%	-
<b>Net profit</b>	27.2	10%	-22.0	-	16.5	11%	<b>-5.5</b>	-	-	24.4	9%
ROE	8.4%						-			7%	
Core net profit	35.2	13%	12.5	10%	21.6	14%	34.1	12%	-3.1%	34.1	13%

- 1 Increase from progress over regions and positive FX impact
- 2 Reflecting COGS control effect in 2H
- 3 Structural reform costs and others
- 4 Decrease in depreciation/amortization associated with Eyevance impairment loss
- 5 Eyevance impairment loss of JPY30.0bil.

# Additional shareholder returns based on FY2022 policy

## MTP2025 policy

## FY2022

**Optimize balance between future growth and shareholder return**

**Shareholder return: 1/3 or more of operating cash flow**  
Dividend payout ratio of 40% or more  
+ flexible share buybacks

**BD investment: tens of billion JPY~ (accum.)**  
Strategic investment for mid-/long-term growth

- Enhance Rx pipeline where strengths can be leveraged.
- New business areas

**Enhancement of core business**

**Capital investment: JPY100.0bil. (cum.)**  
Investment to maximize existing business

- Capex for new facilities in Japan/China
- Improvement of productivity through the implementation of next-generation ERP etc.

**Maintain necessary cash for business continuity**  
(Secure working capital)



**Share buyback to begin from Nov 9, 2022**

- Dividend forecast maintained (annual JPY32)
- Repurchase shares as an additional shareholder return measure

1. May 11 – Sep 8, 2022 (completed)  
JPY12.7bil. (12.5mil. Shares\*<sup>1</sup>)

2. Nov 9, 2022 – Mar 24, 2023  
JPY13.0bil. (13.0mil. Shares\*<sup>2</sup>) / Max

The ratio against total number of the outstanding shares (excl. treasury shares)

\*1: 3.1%

\*2: 3.4%

## ■ Agenda

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- 2. R&D Update**
3. Regrowth Agenda

## Made steady progress in late phase pipelines

### New disease and mode of action on keratoconjunctival disease

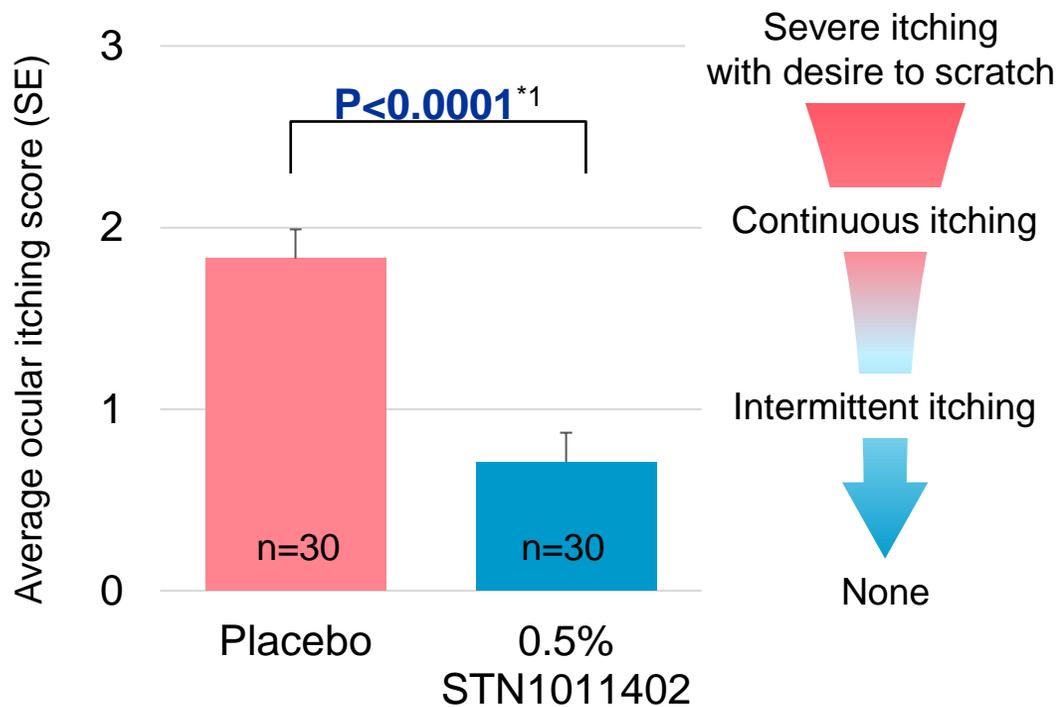
STN1011700 EYBELIS / OMLONTI	Glaucoma	<b>Approved</b> in US
STN1013001 Catioprost	Glaucoma	<b>Filed</b> in Europe
STN1012600 Sepetaprost	Glaucoma	Achieved <b>FPI</b> *1 in P3 trial in Japan
STN1011402 Epinastine ophthalmic cream	Allergic conjunctivitis	Achieved <b>primary endpoints</b> in pivotal trial (P3) in Japan
STN1013800 Oxymetazoline hydrochloride	Ptosis	Achieved <b>FPI</b> in P3 trial in Japan
STN1012600 Sepetaprost	Glaucoma	Achieved <b>LPI</b> *2 in P2 trial (exploratory study) in Europe
STN1010905 Sirolimus eye drop	Meibomian gland dysfunction	<b>Not meet primary/secondary endpoints</b> in P2a trial (exploratory study) in Japan. But <b>observed efficacy on some exploratory endpoints</b> and detailed analysis in progress
STN1014100 Olodaterol hydrochloride	Dry eye	<b>Started preparations for P1/2a trial</b> in Japan

\*1 FPI; First Patient In. \*2 LPI; Last Patient In.

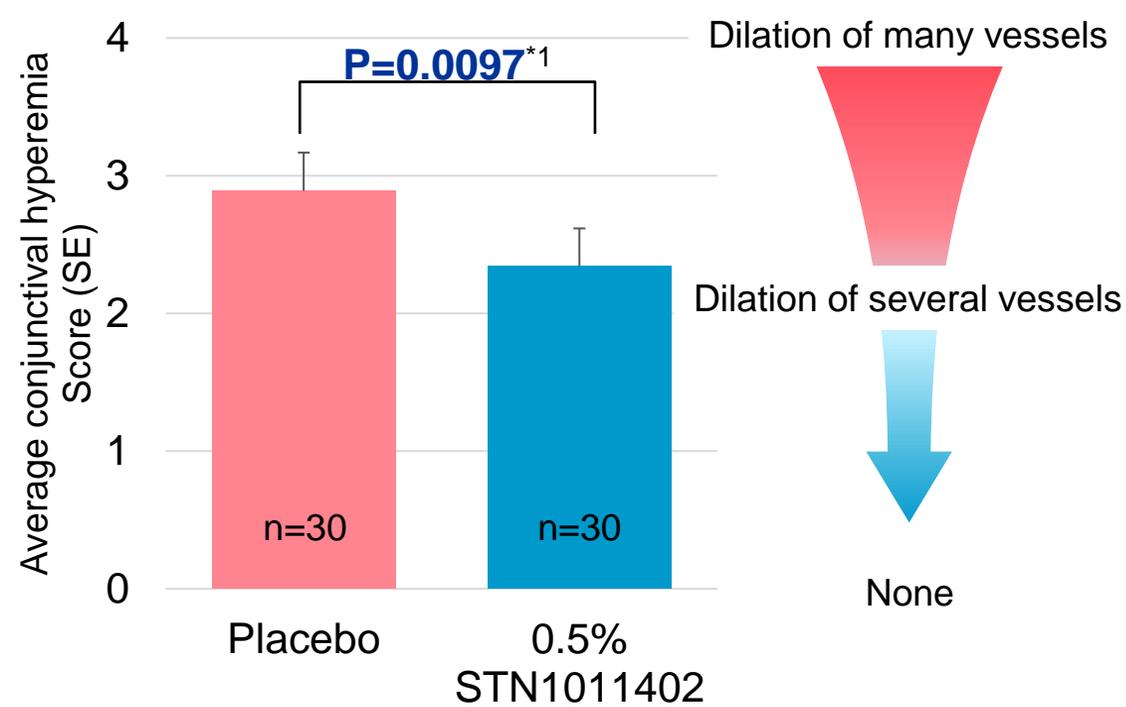
# Achieved primary endpoints on pivotal trial (P3)

## Confirmed safety and tolerability

### Efficacy on ocular itching after 24 hours



### Efficacy on conjunctival hyperemia after 24 hours



◆ Demonstrated same changes level as 0.1% epinastine ophthalmic solution on long-term trial (see Appendix)

\*1 Wald test of linear mixed effects model

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# Kicking off with three key objectives



Structural reforms for upfront recovery in business performance

- Re-assessment of investments
- Cost optimization
- Productivity improvements

3-angle approach for growth opportunities assessment to return on a Regrowth trajectory

- Scale of unmet needs
- Global trends
- Santen's competitive advantage

Set and thoroughly manage direct results-linked KPIs and establish the optimal organization for strategy execution

# Shift course in Americas to achieve break-even

## Current status of Americas

In search of growth trajectory since MicroShunt's impairment

New developments  
- i.e. launch of *Verkazia* and approval of *Omlonti*

High challenge to turn profitable within the next few years if further growth investments made

## Path forward

Shift course in Americas to achieve break-even

Improve profitability (structural reforms)

## Sizable improvements in core OP by FY2023 and by FY2025 through firm-wide reforms including Americas



### Re-assessment of investments

Review all past and future major investments and reevaluate those deemed to be of low strategic and cost/benefit significance



### Cost optimization

Strict review of budgets and optimize procurement of direct and indirect materials by thorough vendor & demand management



### Productivity improvement

Firm-wide, multi-angle review of operations to improve organizational efficiency



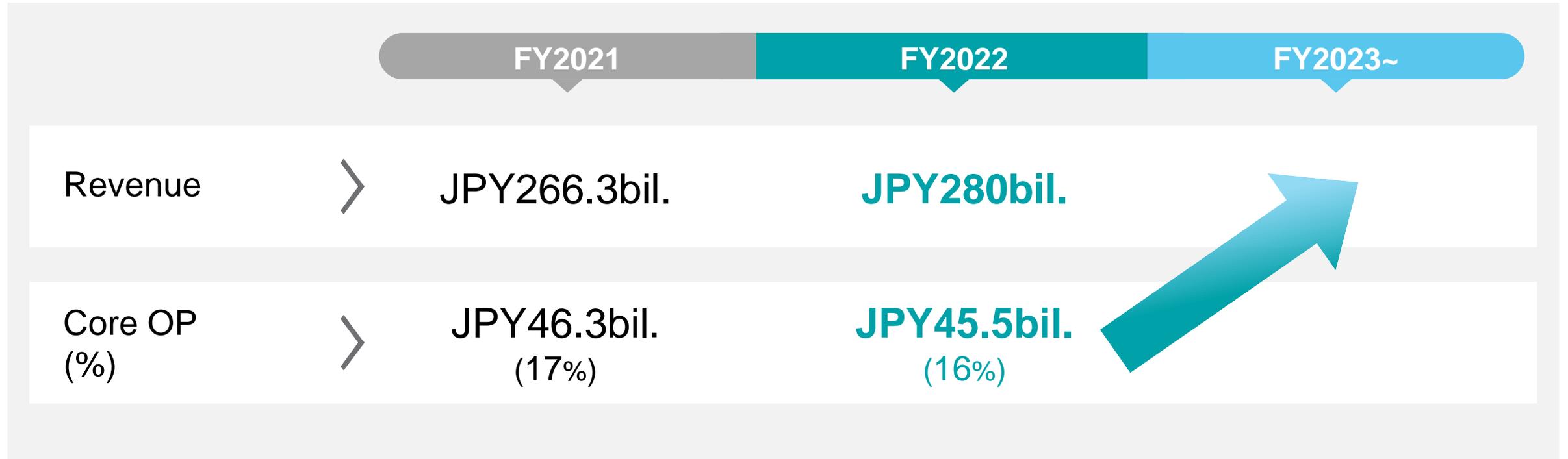
**Core OP**  
**JPY6~8bil.**  
Improvement  
by FY2023

**JPY10~15bil.**  
Improvement  
by FY2025



As direct CEO-led reforms,  
these will be impartially implemented

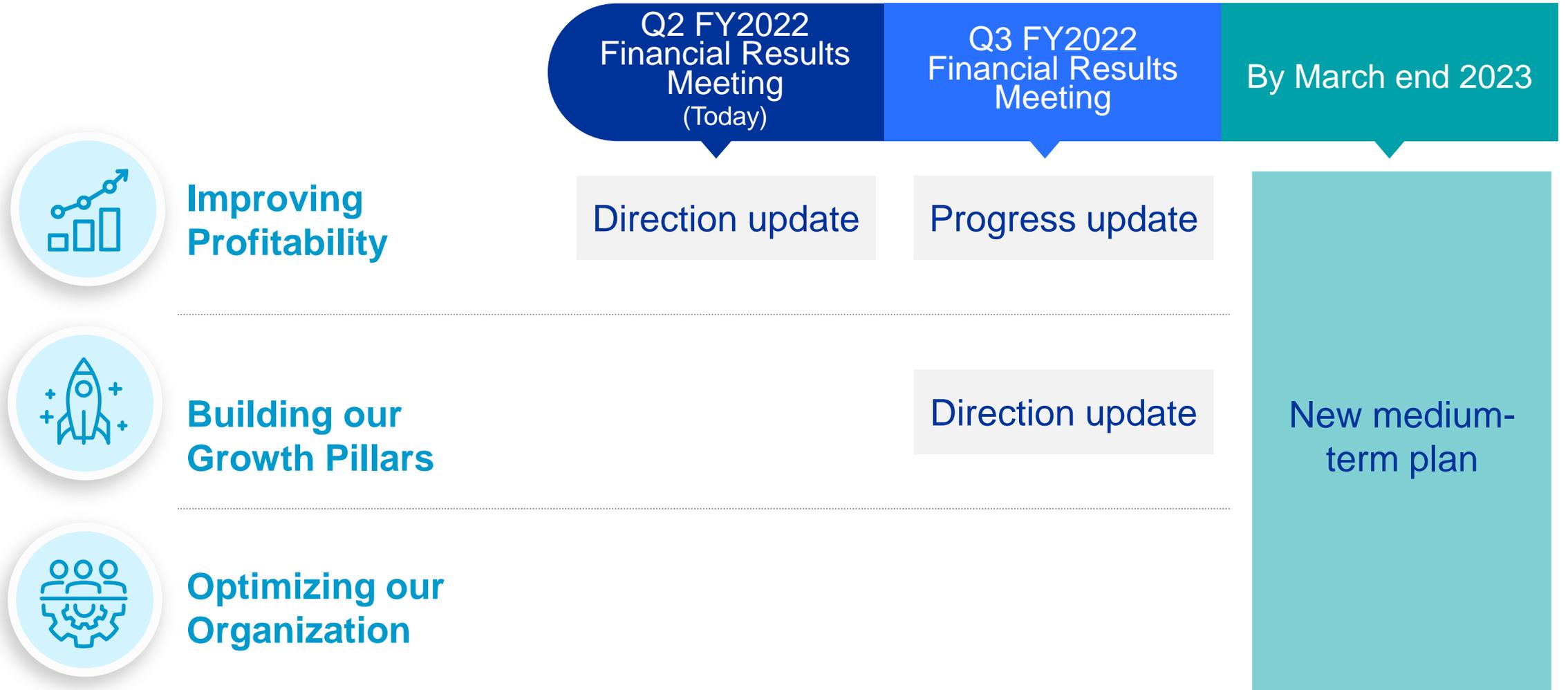
# Target core OP growth as focus on business profitability



Implement necessary reforms to allow for profit generation resilient to business environment conditions

# Further updates on growth trajectory at Q3 FY2022 financial results meeting

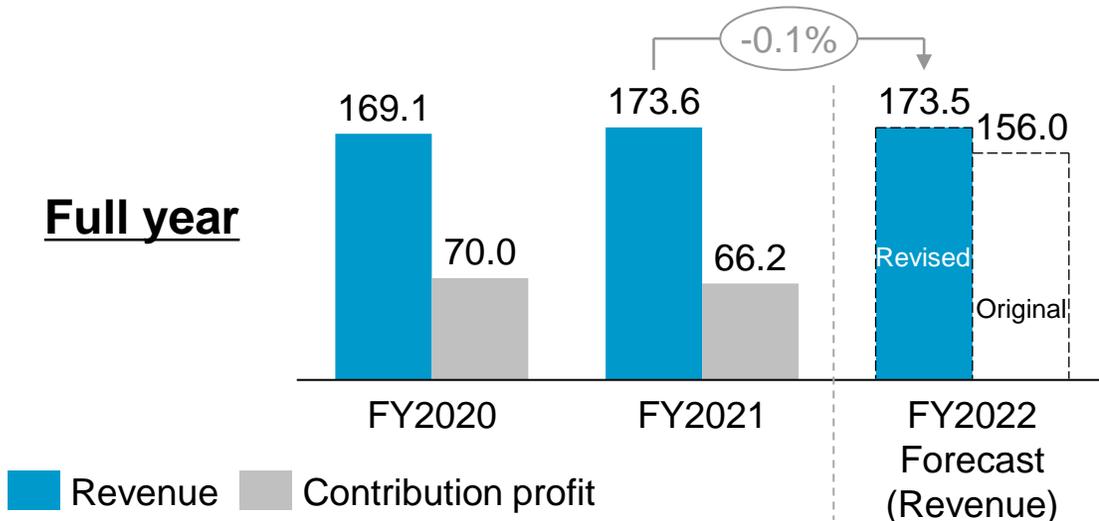
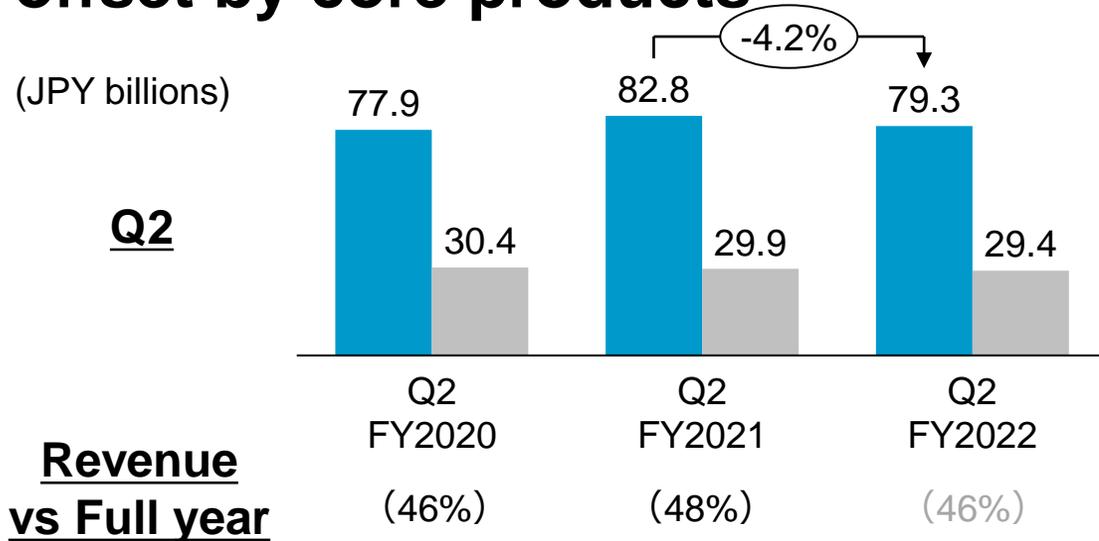
## New medium-term plan by March end 2023





# Appendix

# Steady progress exceeding expectations. Impact from NHI price cuts offset by core products



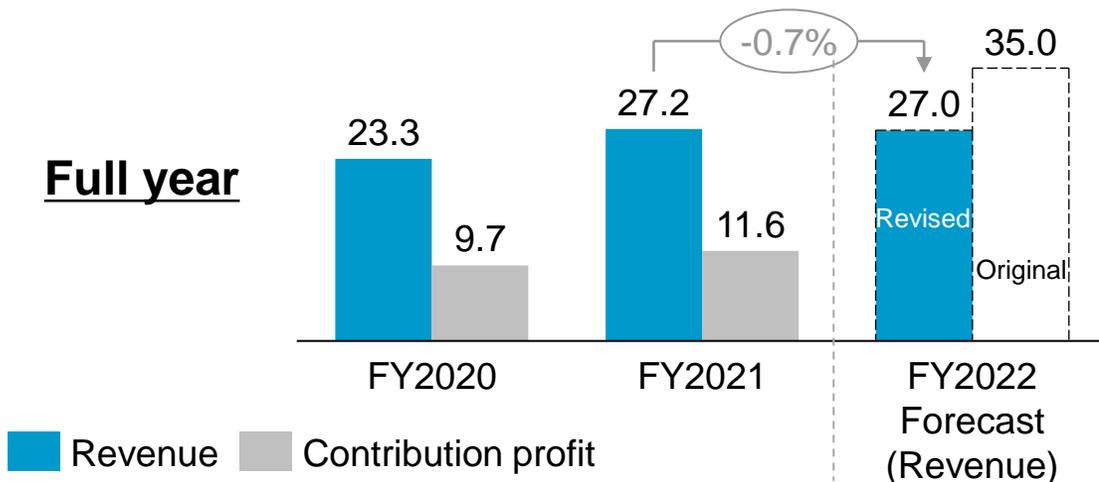
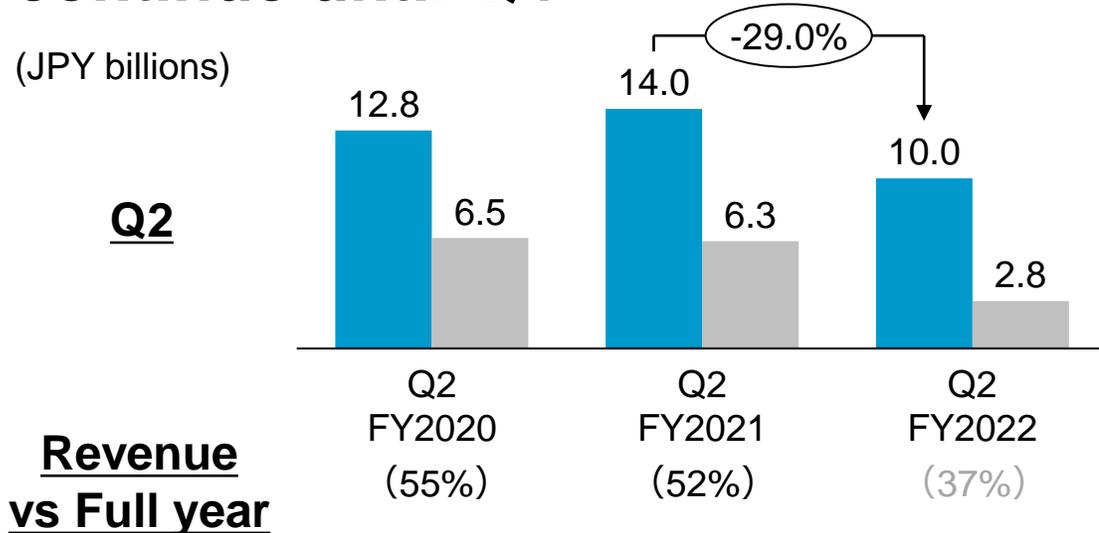
## Highlights

- Market penetration of core products mitigates NHI price reduction (mid -4% o/w -20% for *Alesion*)  
*Eybelis* +JPY0.3bil., *Diquas* +0.12bil. YoY
- Contribution from OTC key products, +0.28bil. YoY
- Received approval for *Diquas LX*. Preparation for launch ongoing

## FY2022 Outlook

- Core products competitive landscape: No major change
- *Alesion*: Certain level of volatility from airborne pollen volume and dispersal timing
- *Diquas LX*: Launch in Q3 expected

# Recovery trend, but impact from strict COVID-19 measures expected to continue until Q4



## Highlights

- Recovery trend (JPY QTD basis YoY Q1: -44%, Q2: -16%)
- Market penetration progressing for strategic core products (*Tapros and Diquas*)

## FY2022 Outlook

- Need time till Q4 for market to fully recover, centered on infection and dry eye products, which consist large sales proportion. Revenue outlook revised to the same level of FY2021 (incl. FX impact)

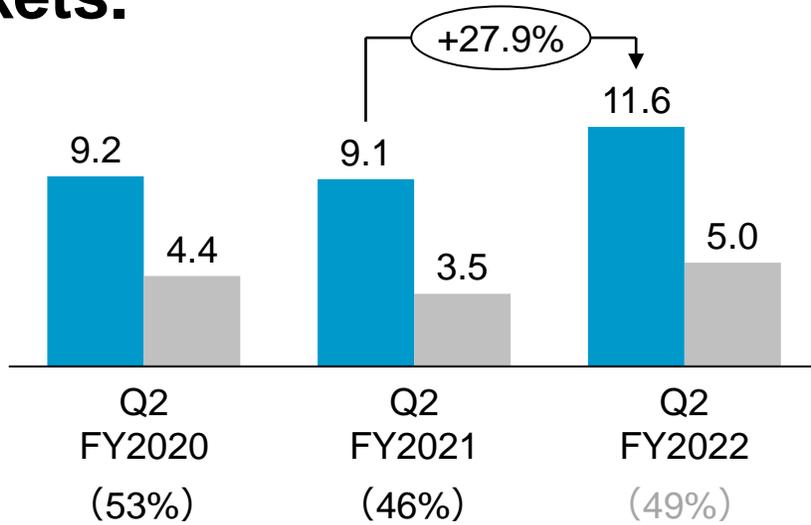
FX rate (JPY)

	Q2FY2021 Actual	Q2FY2022 Actual	FY2021 Actual	FY2022 Revised forecast	FY2022 Original forecast
CNY	17.05	19.84	17.55	20.00	19.00

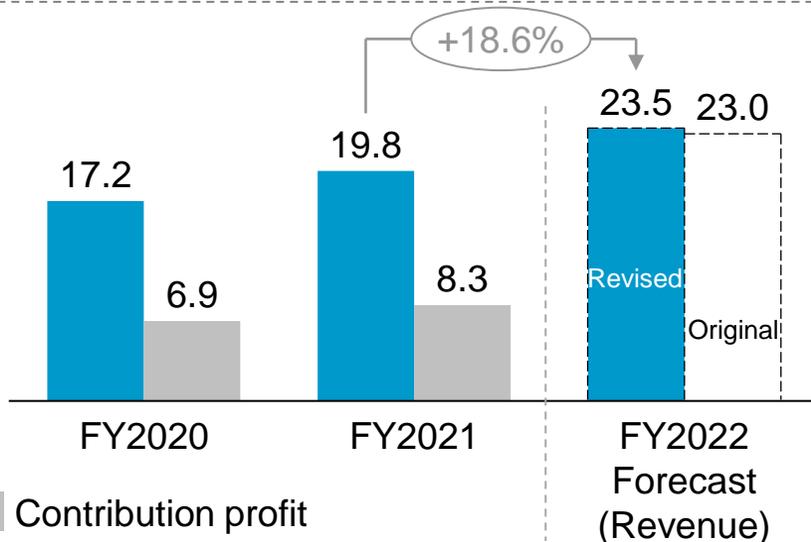
# Growth trajectory exceeding expectations led by glaucoma and dry eye in key markets.

(JPY billions)

## Q2 Revenue vs Full year



## Full year



■ Revenue ■ Contribution profit

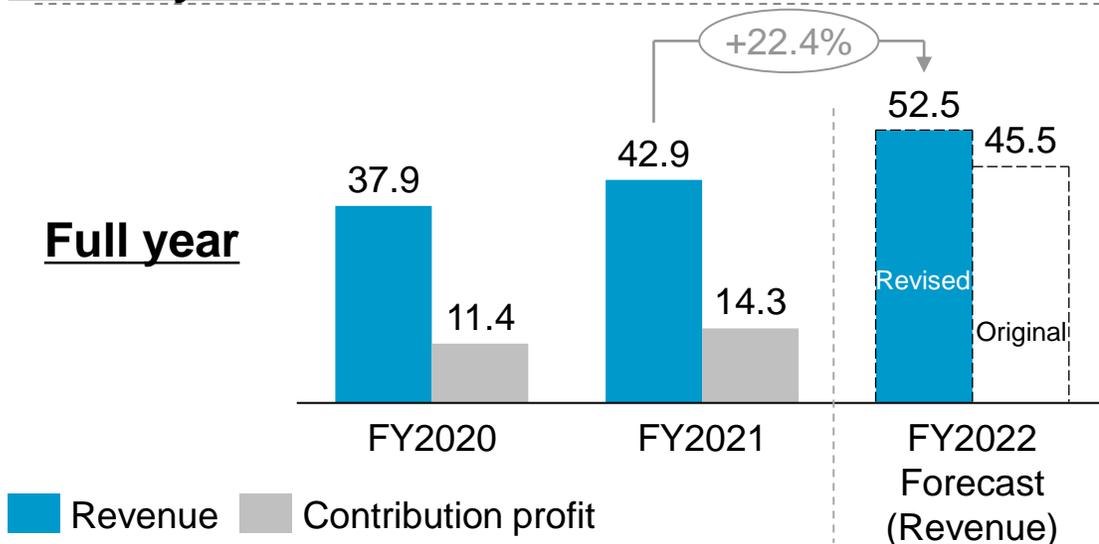
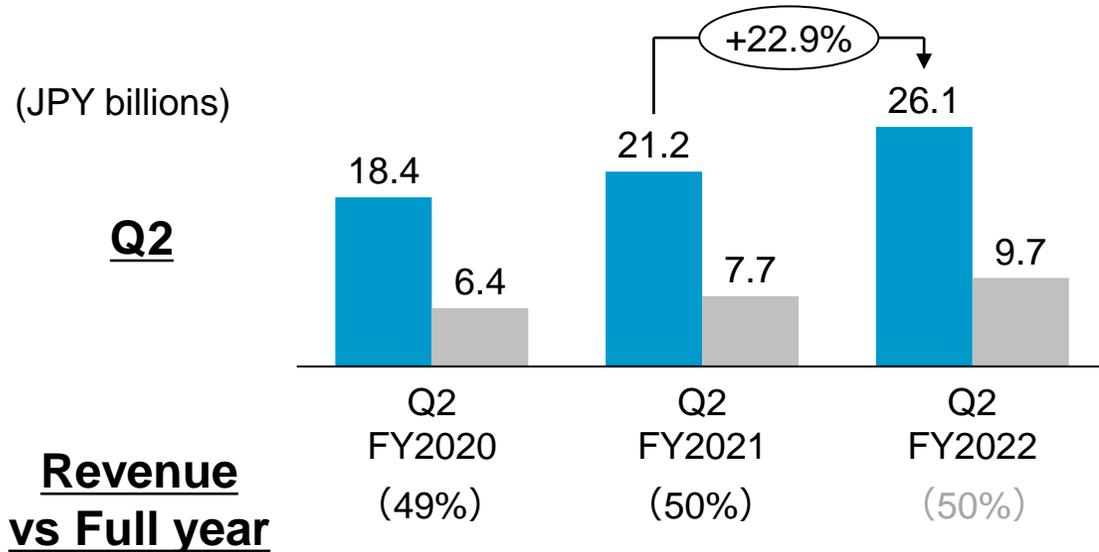
## Highlights

- Korea: JPY +1.1bil. (+21%), YoY  
Core products in glaucoma and dry eye led sales
- Double-digit growth in other key markets (Taiwan: +0.28bil. Thailand: +0.28bil. Vietnam: +0.24bil. Philippines: +0.18bil.)

## 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

# Exceeding expectations, primarily driven by glaucoma core products



## Highlights

- Western key countries led growth. (Italy +JPY0.59bil. Germany +0.50bil. UK +0.34bil.)  
Russia: +0.82bil, mainly from FX impact, slight impact from political situation
- Glaucoma: *Cosopt* +0.82bil. *Tapros* +0.51bil. *Tapcom* +0.56bil. *PRESERFLO MicroShunt* +0.39bil. YoY

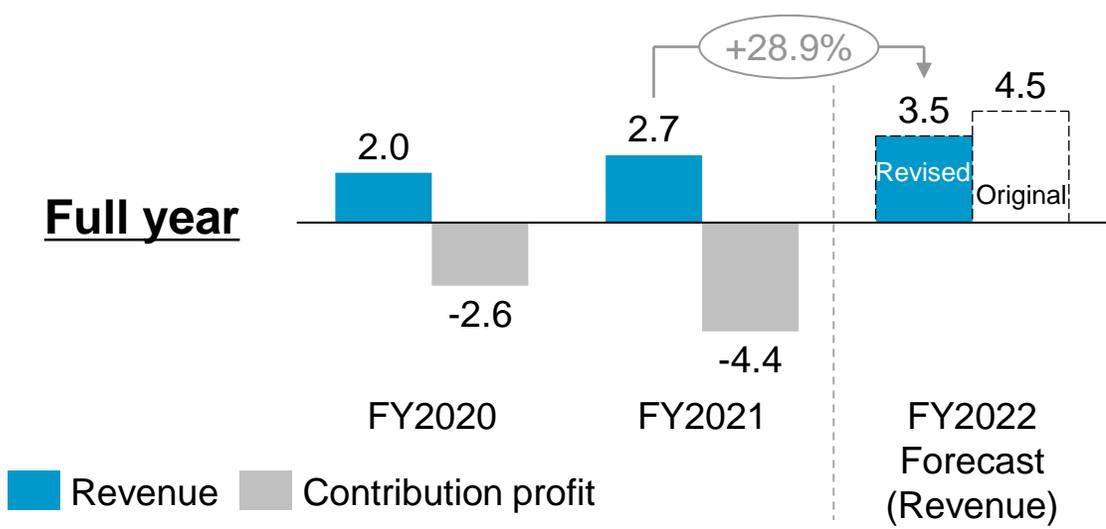
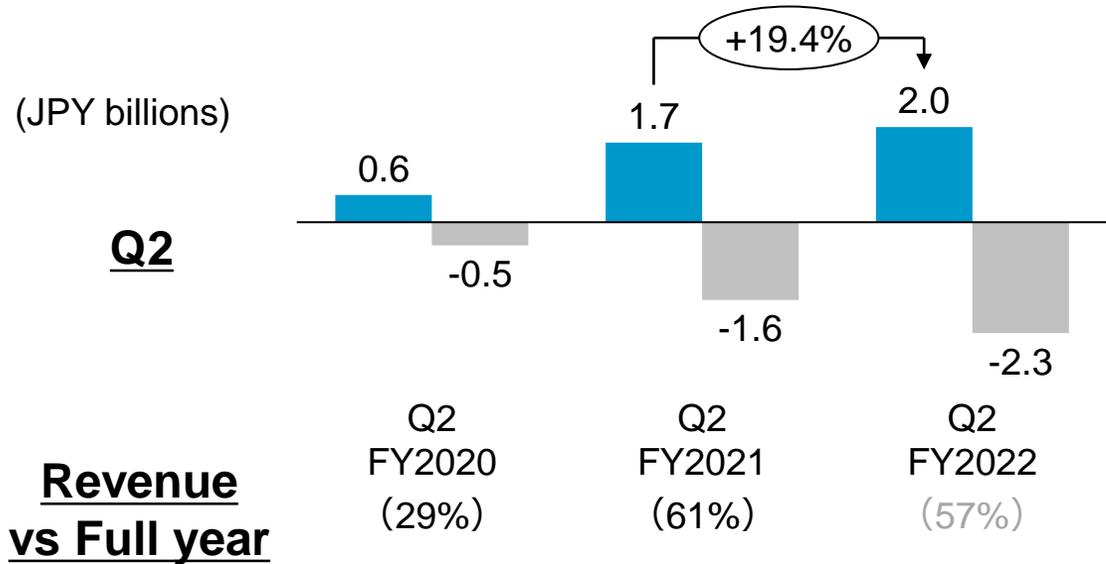
## FY2022 Outlook

- Despite *Tapros* LoE approaching, expect stable growth trajectory driven by glaucoma/dry eye products

FX rate (JPY)

	Q2FY2021 Actual	Q2FY2022 Actual	FY2021 Actual	FY2022 Revised forecast	FY2022 Original forecast
EUR	131.14	138.61	130.75	140.00	135.00

# On a recovery path vs Q1 with FX tailwind on sales



## Highlights

- **Eyevance:** Back-orders issues resolved, on recovery momentum led by *Tobradex ST* and *Flarex*
- **Verkazia:** Medicaid reimbursement procedure completed. Fully fledged sales momentum expected Feb-May 2023, given seasonal trend

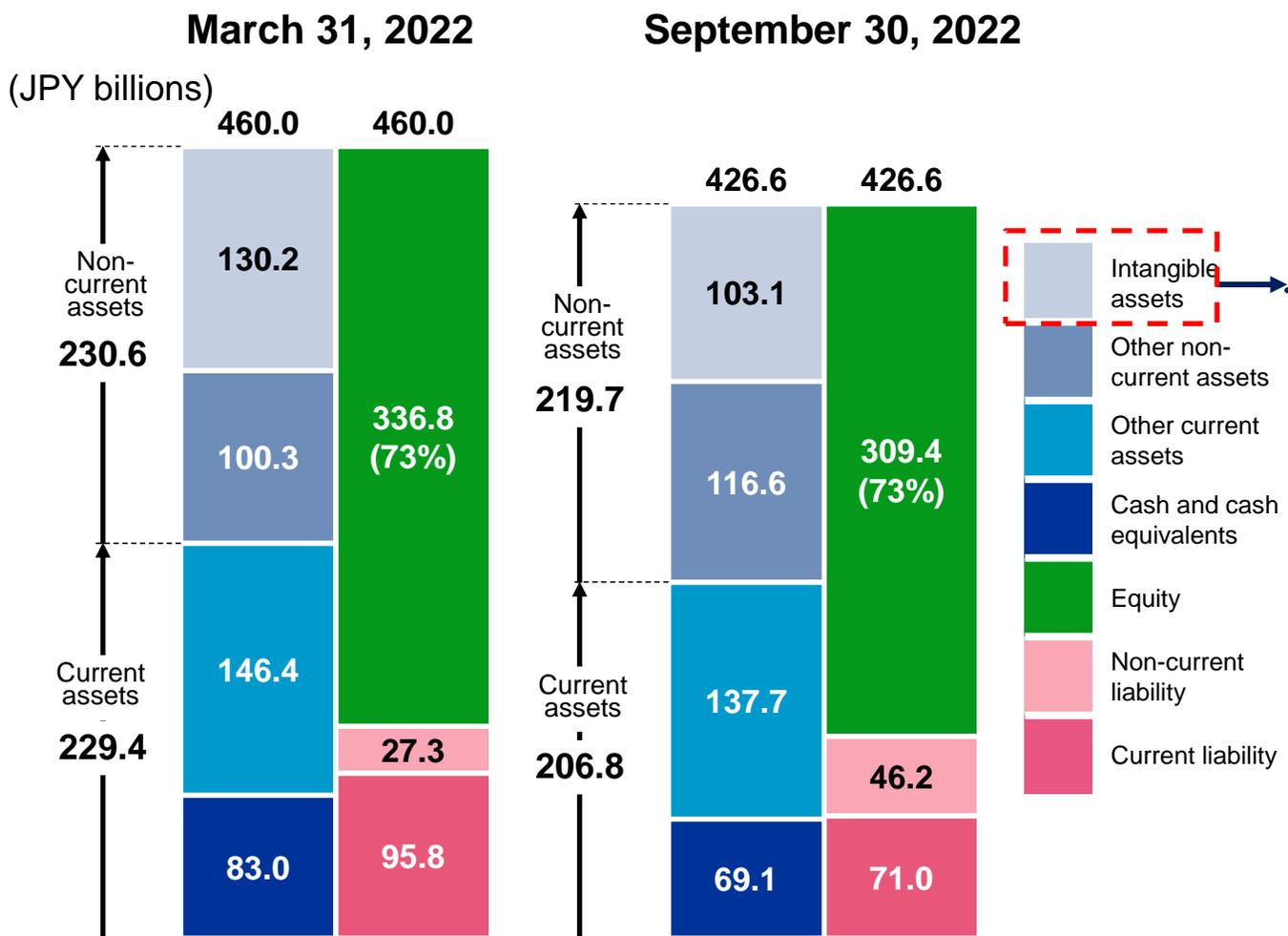
## FY2022 Outlook

- Course shift in business operations to minimize loss

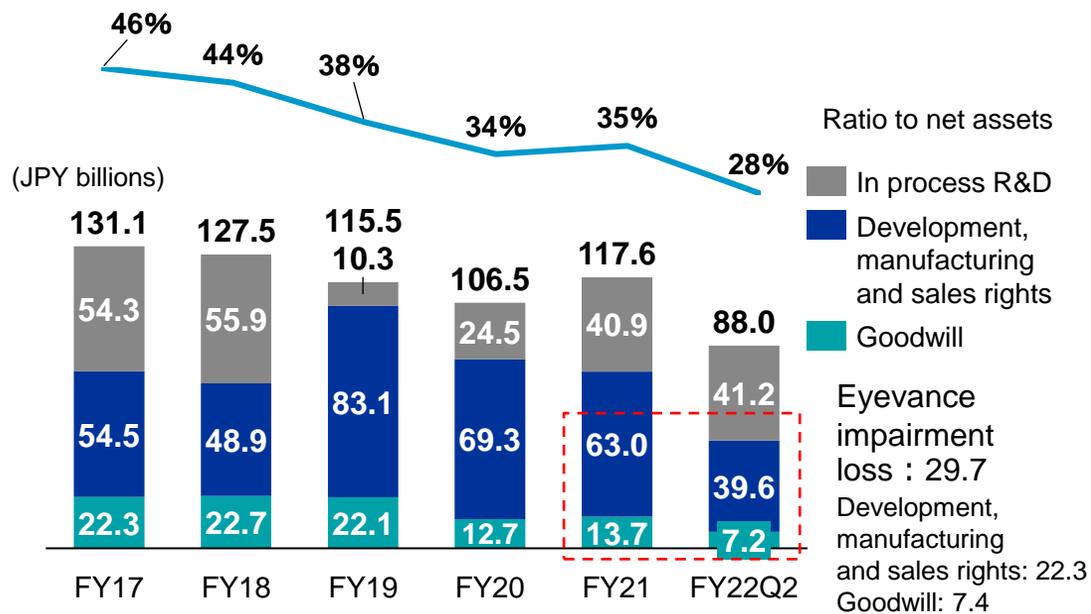
FX rate (JPY)

	Q2FY2021 Actual	Q2FY2022 Actual	FY2021 Actual	FY2022 Revised forecast	FY2022 Original forecast
USD	110.09	133.46	112.57	140.00	125.00

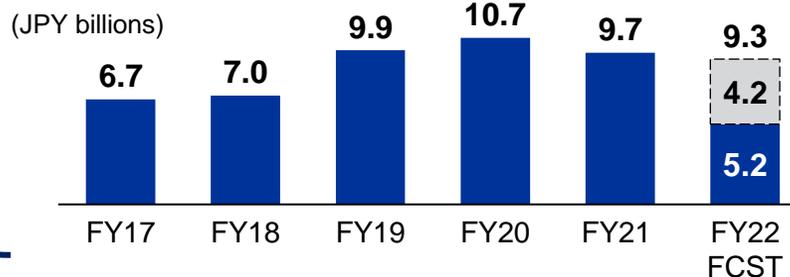
# Appropriate balance between financial health & assets increase from investments. Aim for ROE improvement through capital turnover



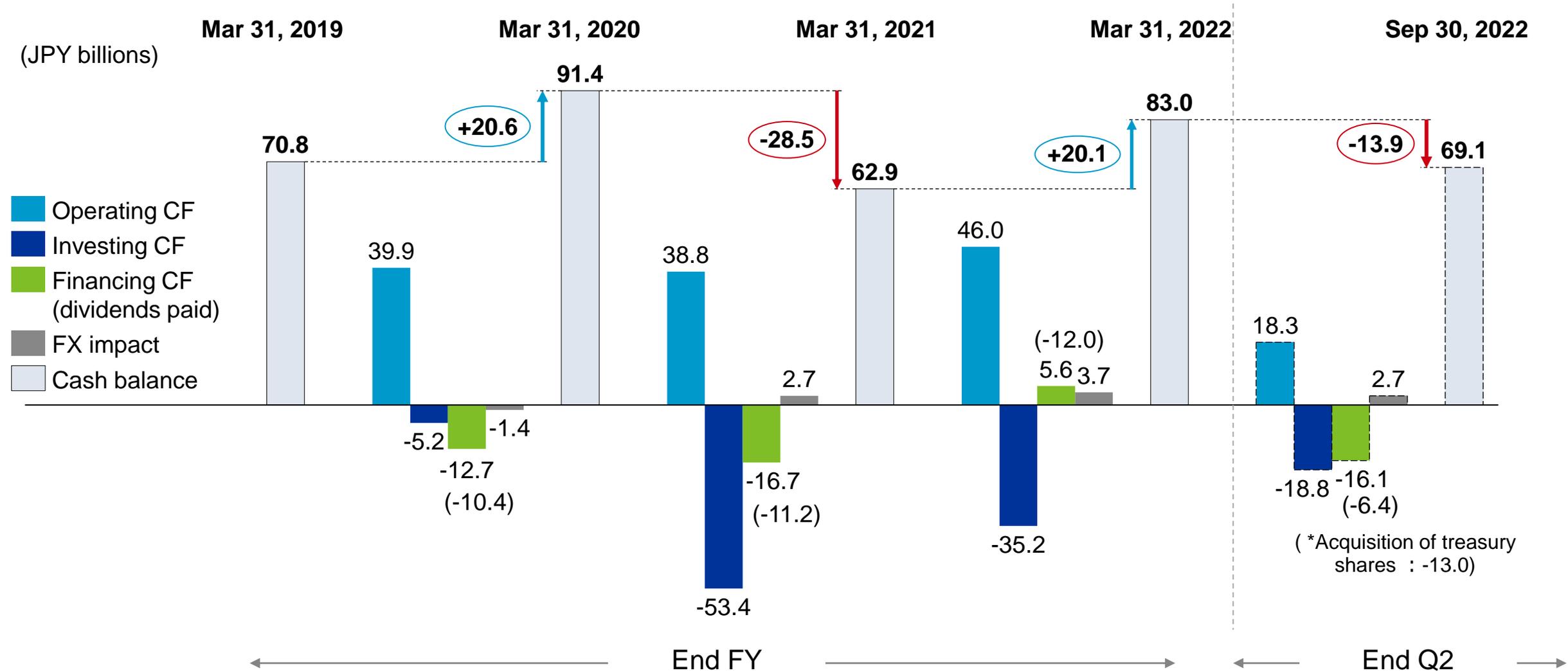
## Status of intangible assets related to products and goodwill



## Status of intangible asset amortization related to products



# Cash flow



# Foreign exchange rate assumptions and sensitivities

## FX rate

(JPY)

	Q2FY2021 Actual	Q2FY2022 Actual	Q2FY2022 Original forecast	Q2FY2022 Actual vs FY Original forecast	FY2022 Forecast (Revised)
USD	110.09	133.46	125.00	106.8%	140.00
EUR	131.14	138.61	135.00	102.7%	140.00
CNY	17.05	19.84	19.00	104.4%	20.00

## Sensitivities

Impact of a 1% depreciation of the yen  
(vs FY2022 revised forecast rate)

(JPY billions)

	Total*	USD	EUR	CNY
Revenue	+1.0	+0.04	+0.46	+0.27
Core OP	+0.1	-0.17	+0.06	+0.07
OP (IFRS)	+0.0	-0.19	+0.05	+0.06

FX impact on Q2 (vs FY2021)

(JPY billions)

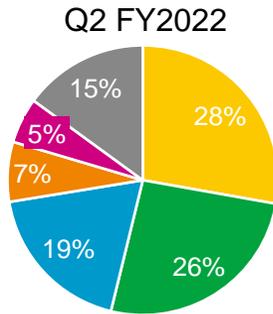
	Total
Revenue	+4.8
Core OP	-0.5
OP (IFRS)	-6.1

\*Total: impacts from USD, EUR, CNY and other major currencies (rounding to nearest 100 million)

# Q2 FY2022 revenue by region (YTD)

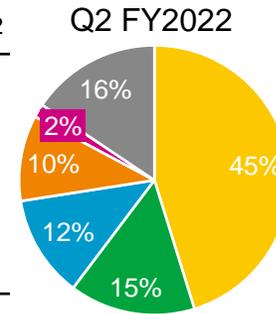
## Consolidated

(JPY billions)	Q2 FY2021 (Ref.)	Q2 FY2022
EYLEA*1	36.5	35.8
Cosopt	10.8	11.5
Tapros	9.2	9.4
Other	72.3	72.2
<b>Total</b>	<b>128.8</b>	<b>128.9</b>



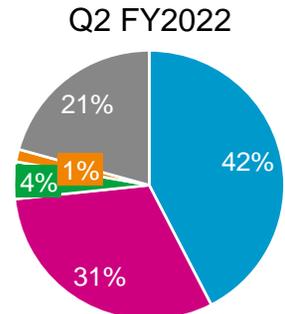
## Japan

(JPY billions)	Q2 FY2021 (Ref.)	Q2 FY2022
EYLEA*1	36.5	35.8
Alesion*2 (Incl. Alesion LX)	9.5	7.9
Diquas	6.7	6.8
Other	30.1	28.8
<b>Total</b>	<b>82.8</b>	<b>79.3</b>



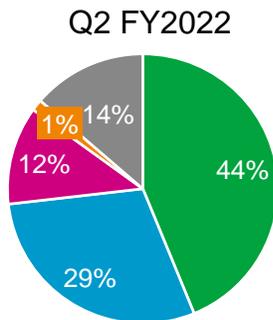
## China

(JPY billions)	Q2 FY2021 (Ref.)	Q2 FY2022
Hyalein	4.2	2.6
Cravit	4.4	2.6
Diquas	1.7	1.6
Other	3.7	3.1
<b>Total</b>	<b>14.0</b>	<b>10.0</b>



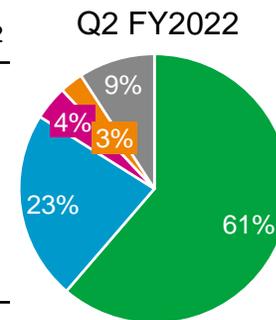
## Asia

(JPY billions)	Q2 FY2021 (Ref.)	Q2 FY2022
Cosopt	2.5	2.9
Hyalein	0.8	1.4
Tapros	1.0	1.1
Other	4.8	6.1
<b>Total</b>	<b>9.1</b>	<b>11.6</b>

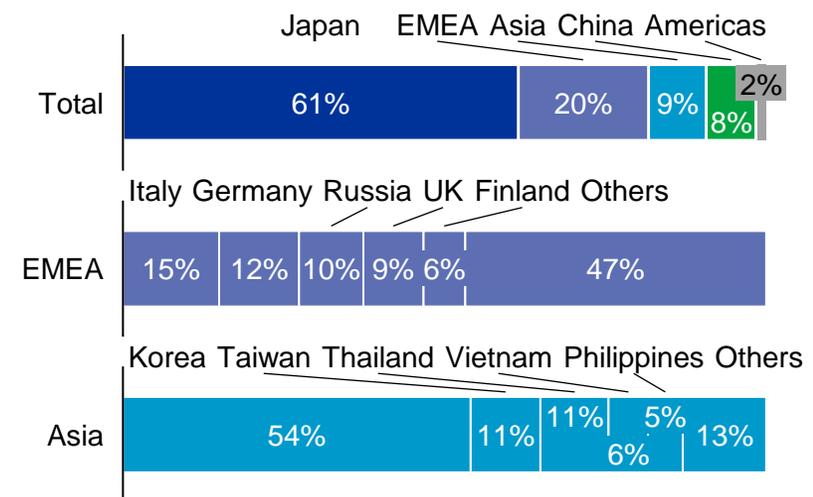


## EMEA

(JPY billions)	Q2 FY2021 (Ref.)	Q2 FY2022
Cosopt	5.3	6.1
Tapros	3.3	3.9
Ikervis	2.5	2.9
Other	10.2	13.3
<b>Total</b>	<b>21.2</b>	<b>26.1</b>



## Revenue in each region (Q2 FY2022)



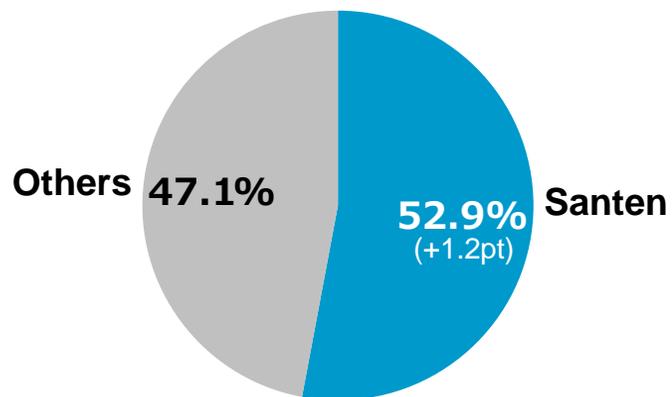
\*1EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

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

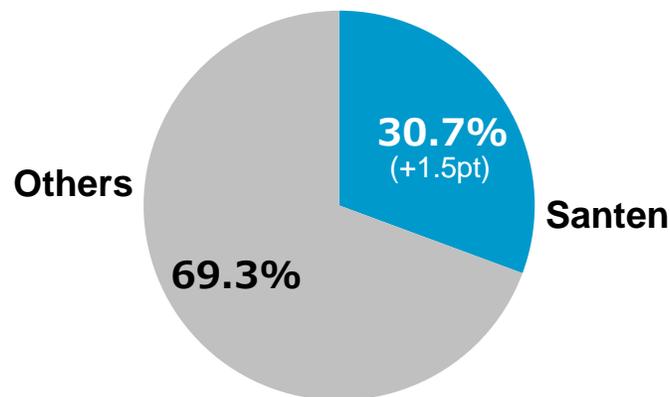
# Remain No.1 for overall market and all segments

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

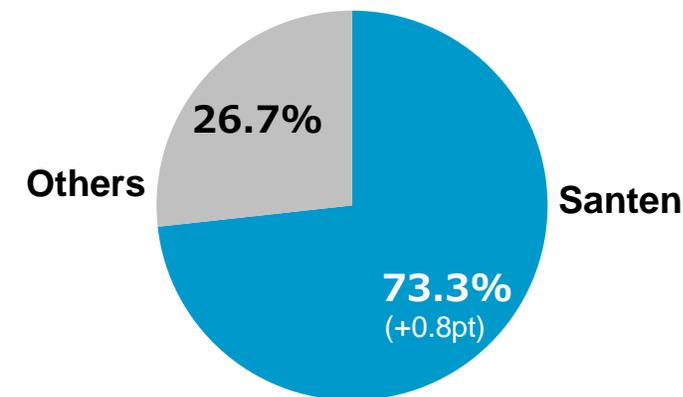
## Total: JPY365.2bil



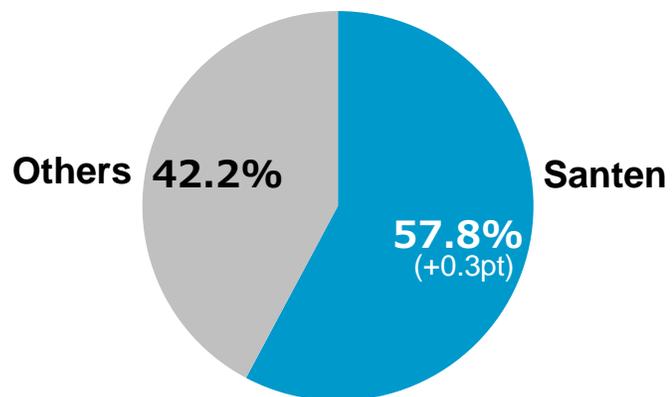
## Glaucoma: JPY96.5bil



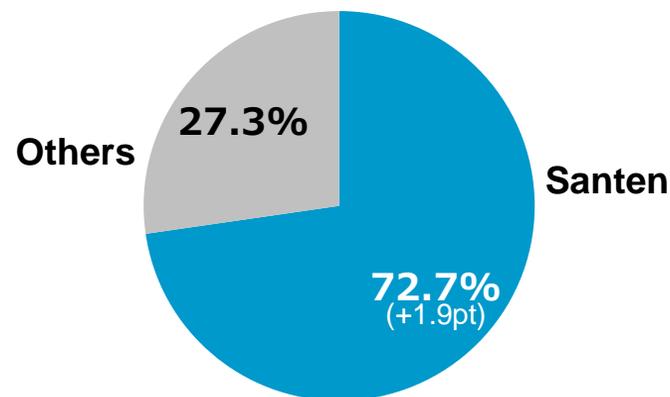
## Retinal disorders\*: JPY120.3bil



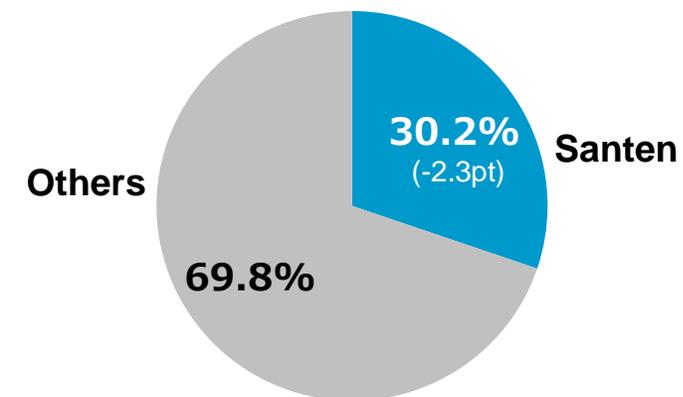
## Corneal / dry eye: JPY42.3bil



## Allergy: JPY49.0bil



## Anti-infection: JPY7.3bil



\*Including co-promoted product (Anti-VEGF EYLEA) of Bayer Yakuhin, Ltd. (MAH) Source: Copyright © 2022 IQVIA. JPM 2020.10-2022.9; Santen analysis based on IQVIA data. Reprinted with permission.

# Current status of global development (1)

As of October 2022  
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status*1	
Glaucoma	Omidenepag isopropyl <i>EYBELIS / OMLONTI</i>	WW*2	STN1011700 DE-117	US	Approved in September 2022 <i>Plan: FY2022 launch</i>
				Japan	Launched
				Asia	Launched
	Sepetaprost	WW	STN1012600 DE-126	US	P2 (met primary endpoint)
				Japan	Started P3 in August 2022 <i>Plan: FY2023 P3 completion</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)
				Europe	Launched
				Asia	Approved <i>Plan: FY2022 launch</i>
	Netarsudil mesilate <i>Rhopressa®/Rhokiinsa®</i>	Japan, China Asia, Europe	STN1013900 AR-13324	Japan	P3 <i>Plan: FY2024 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 October 2022  
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Glaucoma	Netarsudil mesilate /latanoprost (combination) <i>Rocklatan®/Roclanda®</i>	Japan, China Asia, Europe	STN1014000 PG-324	Europe	Approved <i>Plan: FY2022 launch</i>
				Asia	Filed <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	P2/3 <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 October 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	P3 started in October 2022 <i>Plan: FY2024 P3 completion</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 (met primary endpoints) <i>Plan: FY2022 filing</i>
Vernal keratoconjunctivitis	Ciclosporin Verkazia	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	Approved <i>Plan: FY2022 launch</i>
	Olodaterol hydrochloride	WW	STN1014100	Japan	<i>Plan: FY2022 P1/2a start</i>

# Current status of global development (4)

As of October 2022  
Updated information is in blue

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	—*1	STN1010904*1	US France India	P2a <i>Plan: FY2024 P2a completion</i>
Meibomian gland dysfunction	Sirolimus (eye drop)	WW (In-house)	STN1010905	Japan	P2a (not meet primary/secondary endpoints. But observed efficacy on some exploratory endpoints and detailed analysis in progress) <i>Plan: FY2022 P2a completion</i>
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	<i>Filed in September 2022</i> <i>Plan: FY2023 approval</i>
				Asia	P3 (met primary endpoint)

\*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.

# Ensure all-day comfort for patients, advancing the concept of proactive treatment

**4**times/day

*Alesion*



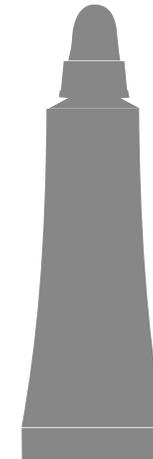
**2**times/day

*Alesion LX*



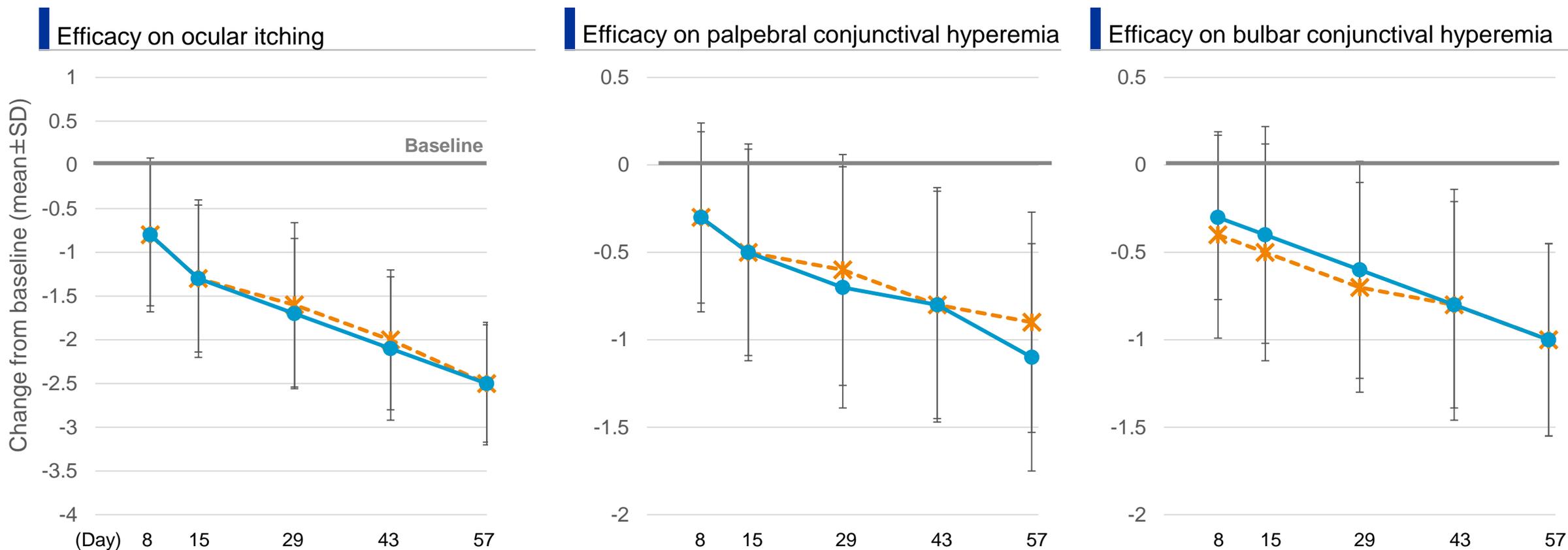
**1**time/day

**STN1011402**



# Demonstrated same changes level as 0.1% epinastine ophthalmic solution on open-label long-term trial (P3)

● STN1011402    ✖ 0.1% epinastine ophthalmic solution (reference arm)



◆ Both arms demonstrated changes on the same level at all visits on these scores

## Level of allergy symptoms (scoring)

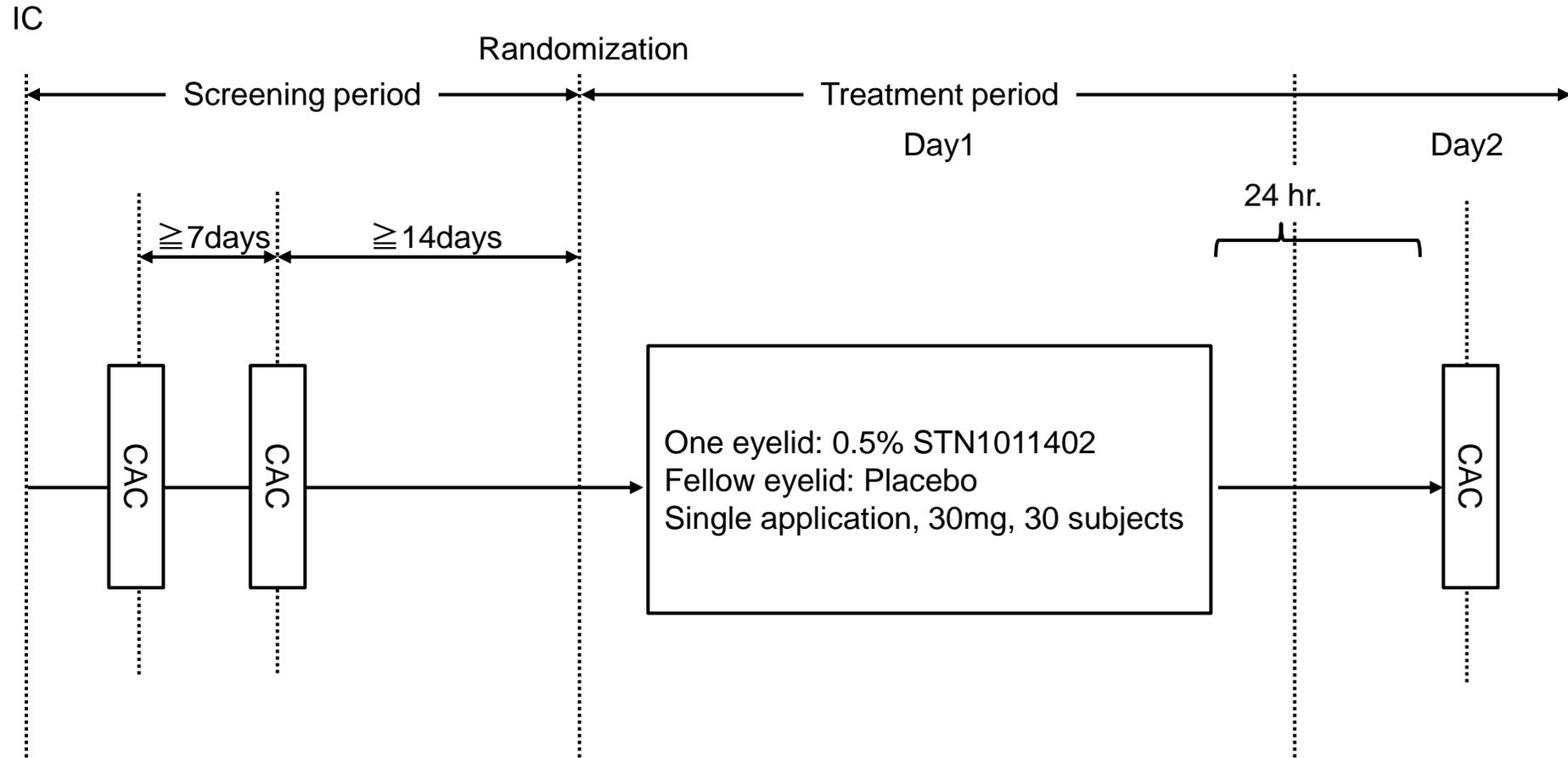
Objective symptoms	Score	Evaluation of the Level
Ocular itching	0	None
	1	Intermittent itching
	2	Continuous itching
	3	Severe itching with desire to scratch (however, it should not interfere with the subject's daily work)
	4	Incapacitating itching with an irresistible urge to scratch (it interferes with the subject's daily work)

Objective symptoms	Score	Evaluation of the Level
Bulbar conjunctival hyperemia	0	None
	1	Dilation of several vessels
	2	Dilation of many vessels
	3	Vasodilatation of all vessels, making it difficult to see the whites of the eyes
Palpebral conjunctival hyperemia	0	None
	1	Dilation of several vessels
	2	Dilation of many vessels throughout the palpebral conjunctiva (superior & inferior)
	3	Hyperemia of the entire palpebral conjunctiva (superior & inferior) with inability to distinguish individual blood vessels

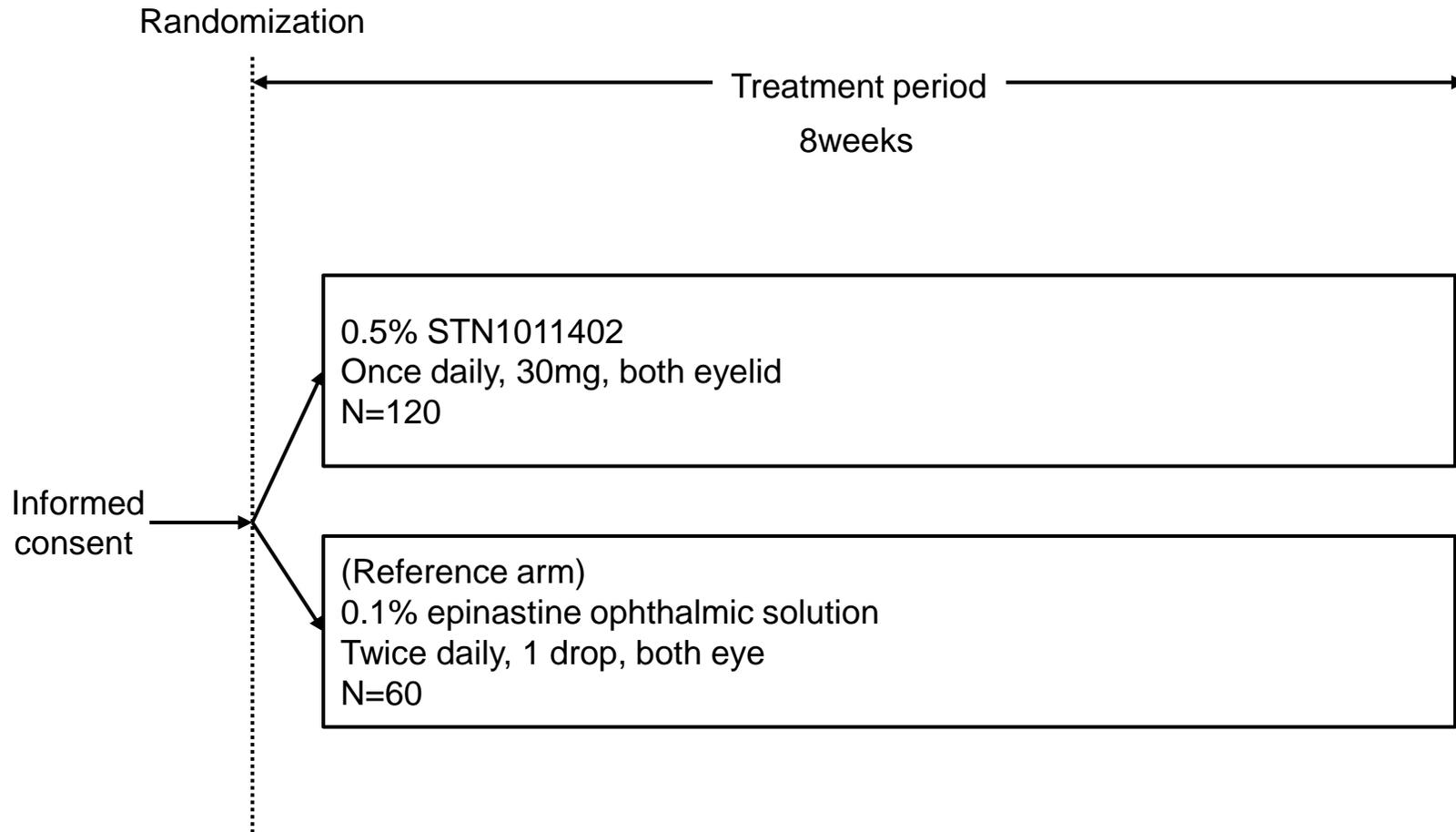
Score of Conjunctival Hyperemia (CH)  
 = Score of Bulbar CH + Score of Palpebral CH

## Pivotal trial (P3) protocol

Designed as Conjunctival Allergen Challenge (CAC) study



# Open-label long-term trial (P3) protocol



## Aim to provide a new dry eye treatment option worldwide

### Developing product

- Olodaterol eye drop
- **Once- or twice- daily** dosing
- **Strong and long-lasting tear secretion** by  $\beta$ 2 stimulation

### Dry eye

- Considerable reduction in the patient's quality of life
- Prevalence
  - Japan: 12.5% of men and 21.6% of women over 40 years old\*<sup>1</sup>
  - Overseas: 8.7~30.1%\*<sup>2</sup>
- Current treatment issues
  - Low drug adherence** due to frequent dosing\*<sup>3</sup>
  - Patients not satisfied** with drug efficacy\*<sup>4, 5</sup>
  - Low continuous rate** due to side effects\*<sup>5</sup>

- ◆ **Potential to be a highly competitive treatment option that addresses unmet needs**
- ◆ **Global development is planned after obtaining the POC\*<sup>6</sup> in P1/2a trial in Japan**

\*1 Uchino et al. *Ophthalmology* 2011;118(12):2361-7. \*2 Stapleton et al. *Ocul Surf.* 2017;15(3):334-365. \*3 Uchino et al. *J Clin Med.* 2022;11(2):367. \*4 Uchino et al. *J Clin Med.* 2019;28(8):1120. \*5: Dunn et al. *Am J Manag Care.* 2021;27(2):S23-32. \*6 Proof of Concept

