Q2 FY2023 Financial Results

November 7, 2023

Santen Pharmaceutical Co., Ltd.

Featuring

Takeshi Ito
President &
Chief Executive Officer

Kazuo Koshiji
Chief Financial Officer &
Chief Risk Officer

Peter Sallstig
Chief Medical Officer

Agenda

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Executive Summary

Takeshi Ito

President & CEO

Accelerated implementation and completion of structural reforms
Expect ~ JPY10.0bil in FY2023 and ~JPY15.0bil improvement by FY2025

Improving Profitability

- Streamlining Americas business: Fast-track completion
- Revamping organization and human capital re-allocation
- Continuous cost optimization
- Revenue per employee in overseas (Q2YTD): Double-digit growth YoY*1

Building our Growth Pillars

- Pipeline: Secure investment in pipeline for mid-to-long term growth
  - ➢ STN1012600 (Glaucoma): Met primary endpoint in P3 in Japan
  - ➢ STN1013001 (Glaucoma): Adopted positive opinion by CHMP
  - ➢ STN1012700 (Myopia): Met primary endpoint in P2/3 in Japan
  - ➢ STN1013600 (Presbyopia): Not met primary/secondary endpoints in P2a in US

Optimizing our Organization

- Established new executive structure & reorganization
- Optimization of redundant functions in headquarters and region

*1: Based on China, Asia and EMEA CFU employees. Excluding FX impact and one-time factors

Strong progress from overseas business
FY2023 forecasts raised

Q2 FY2023:

	Actual	YoY
Revenue	JPY 145.8 billion	+13.1%
Core operating profit	JPY 31.5 billion	+91.7%
Operating profit	JPY 25.1 billion	-
Net profit	JPY 19.3 billion	-

FY2023 forecasts:

	FY forecasts (Nov. 7)	YoY	Revised forecasts (Sep. 20)	Revised forecasts (May 11)
Revenue	JPY 302.0 billion	+8.2%	JPY 285.0 billion	JPY 273.0 billion
Core operating profit	JPY 58.0 billion	+31.1%	JPY 50.0 billion	JPY 46.0 billion
Operating profit	JPY 41.0 billion	-	JPY 35.0 billion	JPY 32.0 billion
Net profit	JPY 29.5 billion	-	JPY 25.0 billion	JPY 22.4 billion
EPS	JPY 80.64	-	JPY 68.34	JPY 61.24

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Q2 Results and FY2023 Forecast

Kazuo Kosiji

Chief Financial Officer &

Chief Risk Officer

Double-digit growth in overseas drive better-than-projected revenue and core operation profit

	Q2 FY2022 ACT	Q2 FY2023 ACT
USD (JPY)	133.46	141.46
EUR (JPY)	138.61	153.66
CNY (JPY)	19.84	19.81

(JPY billions)	Q2 FY2022		Q2 FY2023		
	Actual	vs Revenue	Actual	vs Revenue	YoY
Revenue	128.9	-	**145.8**	**-**	**+13.1%**
Cost of sales	55.9	43%	59.3	41%	+6.2%
Gross profit	73.0	57%	**86.5**	**59%**	**+18.4%**
SG&A expenses	42.3	33%	42.6	29%	+0.7%
R&D expenses	14.3	11%	12.3	8%	-13.6%
Core operating profit	16.5	13%	**31.5**	**22%**	**+91.7%**
Non-core expenses	-	-	0.8	1%	-
Amortization on intangible assets associated with products	5.2	4%	4.7	3%	-9.0%
Other income	0.3	0%	1.2	1%	+365.0%
Other expenses	30.6	24%	2.1	1%	-93.0%
Operating profit	-19.0	-	**25.1**	**17%**	**-**
Finance income	1.2	1%	1.1	1%	-9.8%
Finance expenses	0.3	0%	0.6	0%	+119.2%
Share of loss of Investments accounted for using equity method	1.1	1%	1.6	1%	+47.8%
Profit before tax	-19.1	-	24.1	17%	-
Income tax expenses	2.9	2%	4.8	3%	+64.6%
Actual tax ratio	-	-	*19.9%*	-	-
Net profit	-22.0	-	**19.3**	**13%**	**-**
Core net profit	12.5	10%	25.9	18%	+107.5%

Gross margin

+18.4% YoY

- Revenue: Strong progress mainly in overseas market YoY: +13.1%(consolidated), +30%(overseas)
  (one-time factors: re-evaluation of *Ikervis* allowance for insurance reimbursement JPY +2.3 billion, upfront from Harrow Health for products licensing JPY +0.4 billion/USD 3 million)
- COGS: Ratio decrease excluding above-mentioned one-time factors from region/product mix and COGS control initiatives

Operating profit (Core basis)

+91.7% YoY

- SG&A ratio improve from cost optimization, personnel costs reduction by structural reforms. Offset foreign-currency denominated expenses increase from weaker JPY

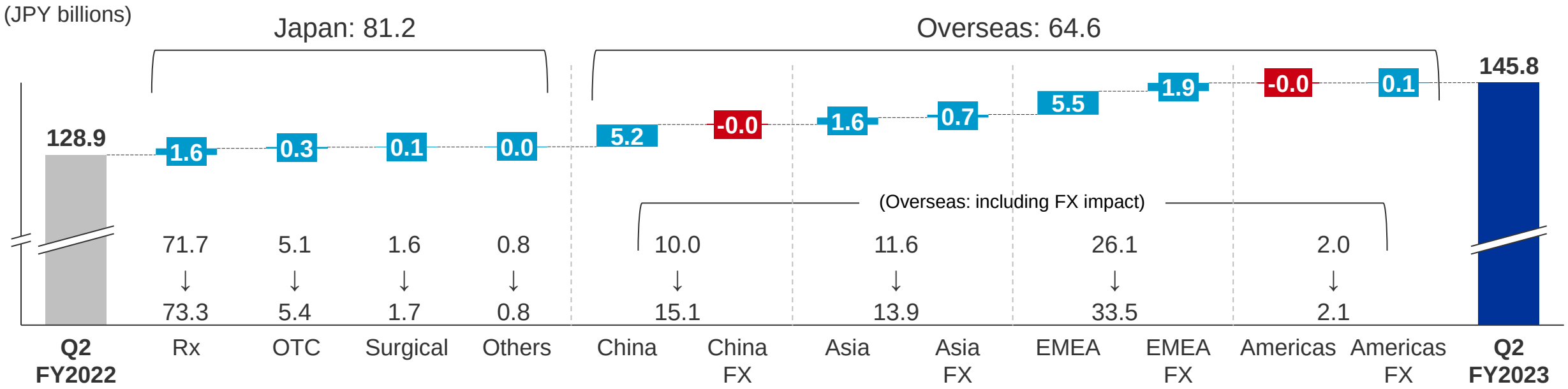
Operating profit (IFRS)

- Other income: Upfront from Harrow Health for asset transfer JPY 0.7 billion/USD 5 million
- Structural reforms cost: JPY 2.6 billion (non-core expenses and other expenses)

Net profit (IFRS)

- Tax ratio excluding one-time factors including impairment loss in FY2022 and structural reforms: 26.1%(FY2022), 18.9%(FY2023)

YoY sales growth of +11.1% (excluding FX impact) mainly driven by Overseas

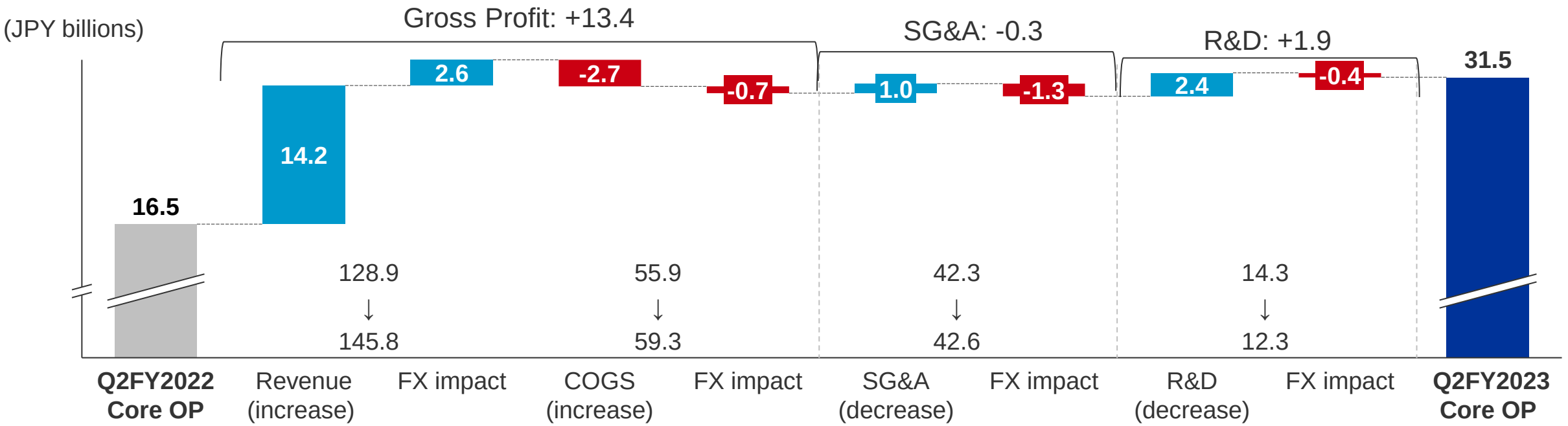


Japan	+2.4% YoY: Growth from mainstay products
China	+52.0% YoY (Ex. FX impact +52.2%): Strong performance from multi-channel strategy coupled with market recovery from COVID-19
Asia	+20.2% YoY (Ex. FX impact +14.2%): Steady growth from mainstay products in key markets. Includes impact of shipment timing in Vietnam
EMEA	+28.3% YoY (Ex. FX impact +21.0%): Continued growth in glaucoma products and *Ikervis* for dry eye. Including *Ikervis* one-time impact
Americas	+3.3% YoY (Ex. FX impact -0.1%): Upfront from Harrow Health for products including *Verkazia* out-licensing recorded JPY 0.4 billion

Note: Sales classified into countries or regions based on customer's location. EMEA：Europe, Middle East and Africa

Q2 FY2023 Core OP bridge

Significant improvement in Core OP and ratio YoY from strong sales and cost optimization



Gross profit	Net JPY +13.4 billion YoY. Increased revenue (+13.1% YoY including FX, +11.1% YoY excluding FX) and decrease in COGS ratio (-2.7pt YoY) resulting from region/product mix and one-time factors
SG&A	Net JPY -0.3 billion YoY. SG&A ratio significantly decreased resulting from cost optimization and structural reforms including personnel expenses reduction (SG&A ratio: -3.6pt YoY). Foreign-currency based expenses increased from a weaker JPY
R&D	Net JPY +1.9 billion YoY. Mainly from development schedule change in certain projects (R&D expenses ratio: -2.6pt YoY). No change for FY plan and policy to prioritize investment to R&D

FY2023 Outlook

Forecasts raised
Revenue: JPY 302.0 billion, Core OP: JPY 58.0billion

	FY2022 ACT	FY2023 FCST
USD (JPY)	135.40	145.00
EUR (JPY)	140.97	155.00
CNY (JPY)	19.72	20.00

(JPY billions)	FY2022		FY2023			FY2023 (Sep 20)	
	Actual	vs Revenue	Forecast Nov.7	vs Revenue	YoY	FY Forecast	vs Revenue
Revenue	279.0	-	**302.0**	**-**	**+8.2%**	285.0	-
Cost of sales	113.0	40%	121.0	40%	+7.1%	114.0	40%
Gross profit	166.1	60%	**181.0**	60%	**+9.0%**	171.0	60%
SG&A expenses	93.5	34%	94.0	31%	+0.5%	91.0	32%
R&D expenses	28.3	10%	29.0	10%	+2.5%	30.0	11%
Core operating profit	44.2	16%	**58.0**	**19%**	**+31.1%**	50.0	18%
Non-core expenses	2.7	1%	1.1	0%	-59.4%	1.0	0%
Amortization on intangible assets associated with products	9.5	3%	9.4	3%	-1.2%	9.2	3%
Other income	3.5	1%	1.5	0%	-57.4%	1.2	0%
Other expenses	38.6	14%	8.0	3%	-79.3%	5.9	2%
Operating profit	-3.1	-	**41.0**	**14%**	**-**	35.0	12%
Finance income	1.2	0%	1.5	0%	+30.1%	1.1	0%
Finance expenses	1.5	1%	1.2	0%	-19.9%	0.8	0%
Share of loss of Investments accounted for using equity method	2.4	1%	3.0	1%	+27.0%	2.4	1%
Profit before tax	-5.8	-	38.3	13%	-	32.9	12%
Income tax expenses	9.2	3%	8.8	3%	-4.2%	7.9	3%
Actual tax ratio	-	-	*23%*	-	-	*24%*	-
Net profit	-15.0	-	**29.5**	**10%**	**-**	25.0	9%
ROE	-		10%			9%	
Core ROE	10.5%		15%			13%	
Core net profit	33.2	12%	43.5	14%	+30.9%	37.5	13%

1 Strong progress in overseas market and revised impact from GEs in Japan

2 Region and product mix

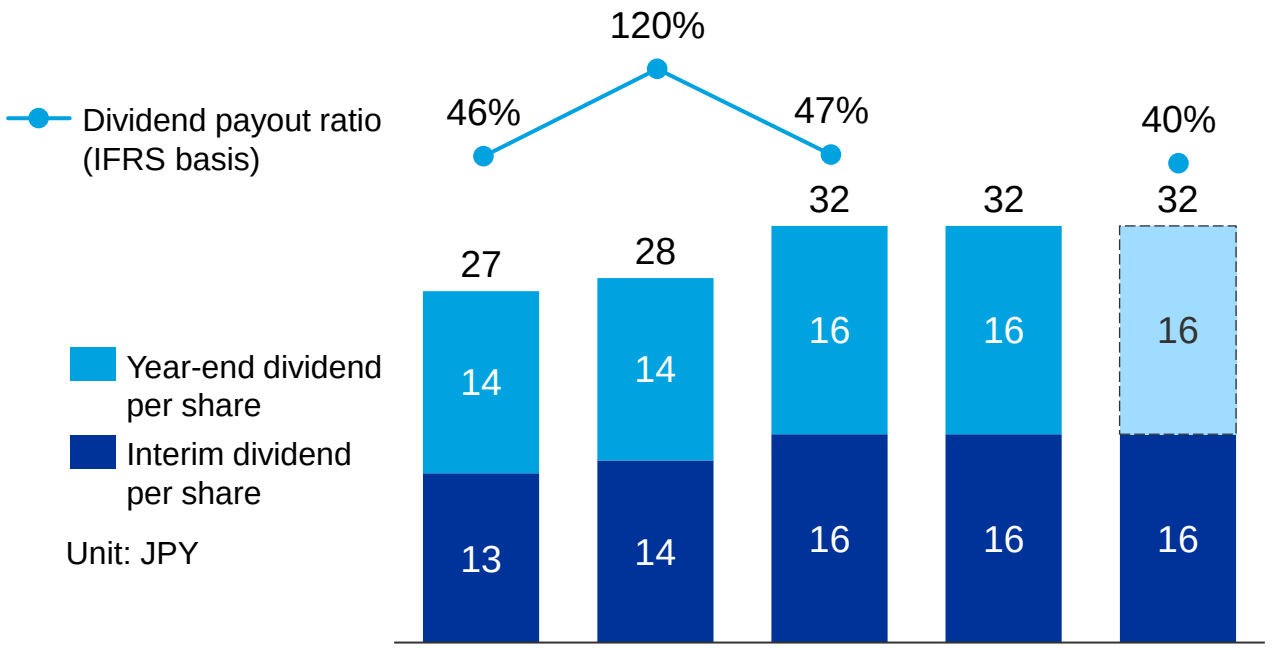
3 Improved SG&A ratio and Core OP ratio resulting from cost optimization and structural reforms. Increase R&D expenses in H2 for future growth

4, 5 Structural reform costs reflected

Factors to consider

- Japan: Pollen-levels
- Overseas: Macro environment

No change: Annual dividend forecast of JPY 32
Total return ratio including share buyback: 123%



(FY)	2019	2020	2021	2022	2023FCST
Total return ratio (IFRS basis)	46%	120%	47%	-	123%
Share buy-back (JPY billions)	-	-	-	25.7	24.5 (max.)
Core ROE	12%	12%	11%	11%	15%

Status of share buyback

1. Overview

- Total number of shares to be repurchased: 18,750,000 shares (maximum)
- Total amount of repurchase: 24.5 billion yen (maximum)
- Period of repurchase: May 12, 2023 – Mar. 22, 2024

2. Status (end of October)

- Total number of shares repurchased: 10,320,600 shares (progress: 55.0%)
- Total amount of repurchase: 13,114,160,500 yen (progress: 53.5%)

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R&D Update

Peter Sallstig

Chief Medical Officer

Adopted positive opinion to STN1013001 (product name: *Catiolanze*) by CHMP
Achieved primary endpoints in pivotal trials of STN1012600 and STN1012700

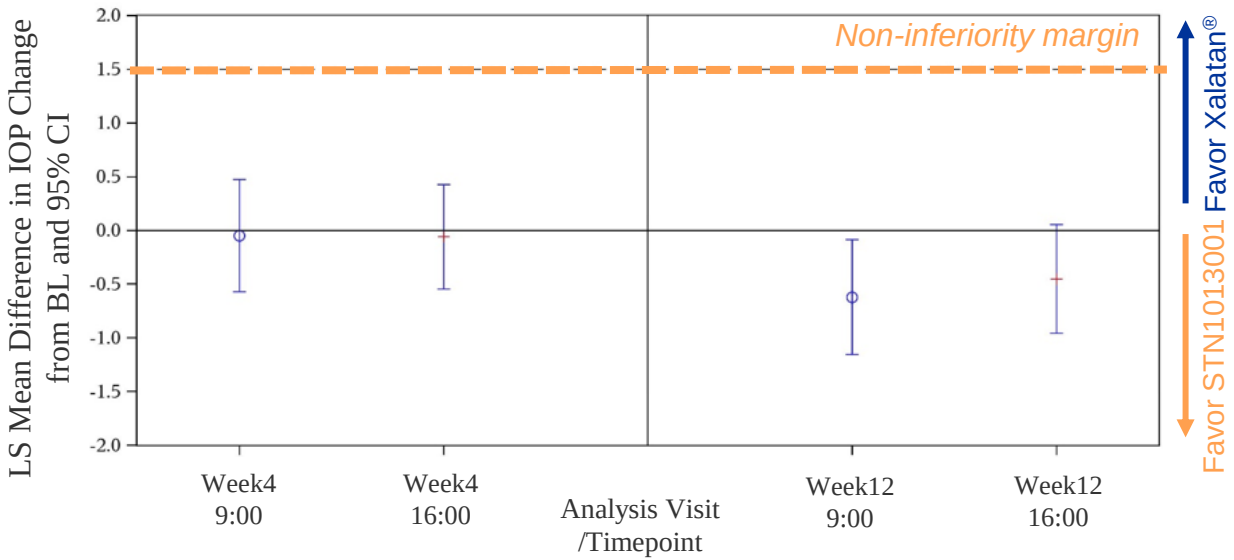
Existing area	STN10**126**00 Sepetaprost	Glaucoma	Achieved **primary endpoint** in P3 trial in Japan
	STN10**130**01 Latanoprost cationic emulsion *Catiolanze*	Glaucoma	Adopted **positive opinion** by CHMP
	STN10**139**00 Netarsudil mesilate *Rhopressa*®/*Rhokiinsa*®	Glaucoma	Achieved **LPI**[1] in P3 trial (long-term) in Japan
New area	STN10**127**00 Atropine sulfate	Myopia	Achieved **primary endpoint** in P2/3 trial in Japan
	STN10**134**00 AFDX0250BS	Myopia	Achieved **LPO**[2] in P1 trial in China
	STN10**136**00 Ursodeoxycholic acid	Presbyopia	Not met primary/secondary endpoints in P2a trial in US
	STN10**138**00 Oxymetazoline hydrochloride	Ptosis	Achieved **LPI** in P3 trial in Japan

1. LPI; Last Patient In. 2. LPO; Last Patient Out

Achieved primary endpoint on IOP (non-inferiority vs *Xalatan*®) , Superiority vs *Xalatan*® on key secondary endpoint (CFS)

Primary endpoint

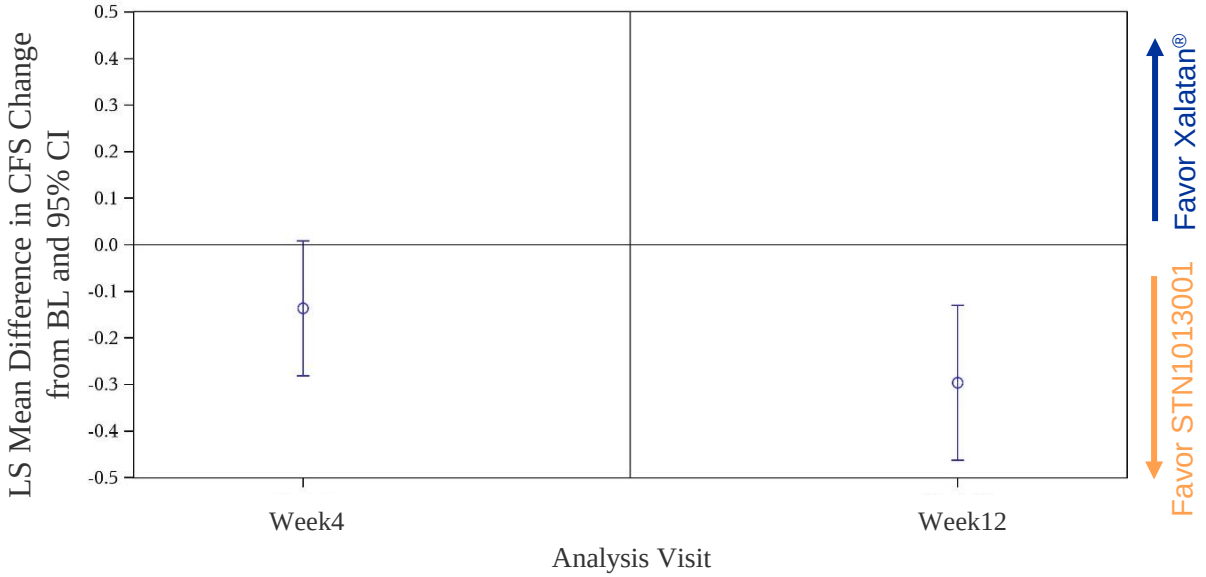
IOP LS mean treatment difference of STN1013001 vs *Xalatan*®



- **STN1013001 statistically non-inferior to *Xalatan*® at all time points**
- Superiority of STN1013001 showed at 9am (peak) at W12 vs *Xalatan*®

Key efficacy secondary endpoint

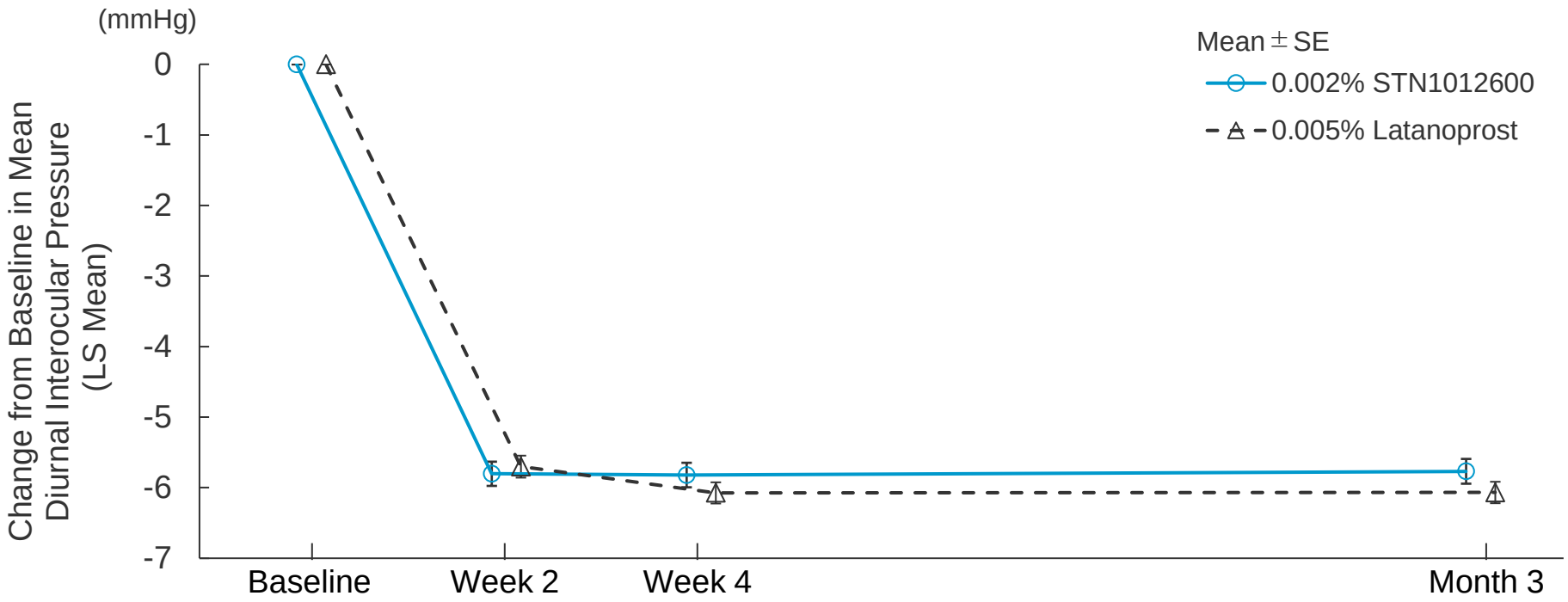
CFS (corneal fluorescein staining) LS Mean treatment difference of STN1013001 vs *Xalatan*®



- **Superiority of STN1013001 was demonstrated vs *Xalatan*® at W12 with a 0.3 CFS difference on modified Oxford Scale**

Met primary endpoint in pivotal trial (P3) in Japan. Confirmed safety and tolerance

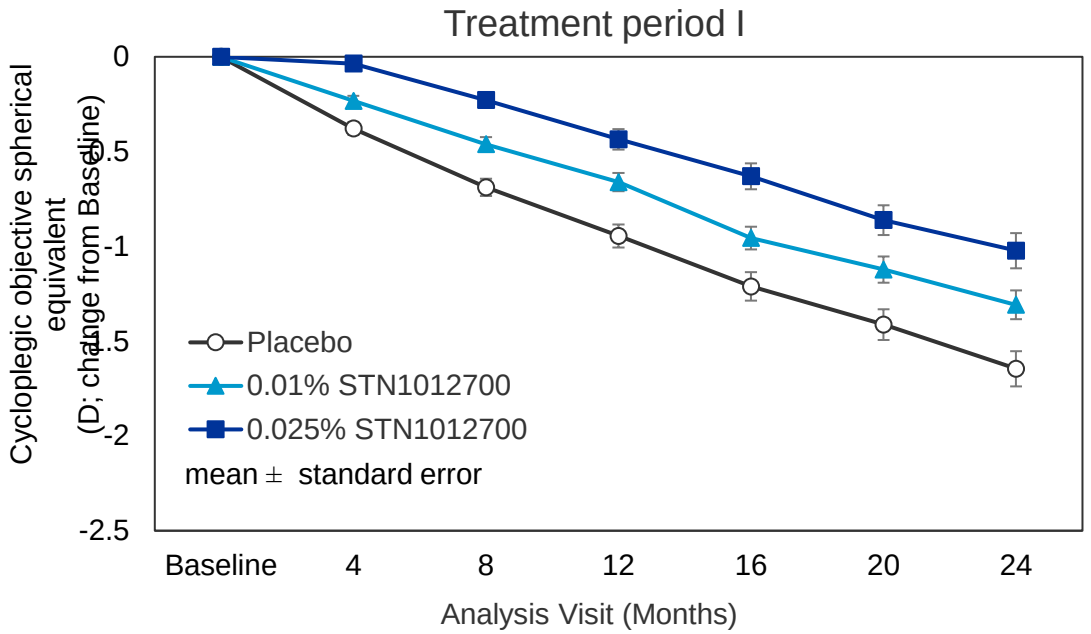
- **Change in mean diurnal interocular pressure**



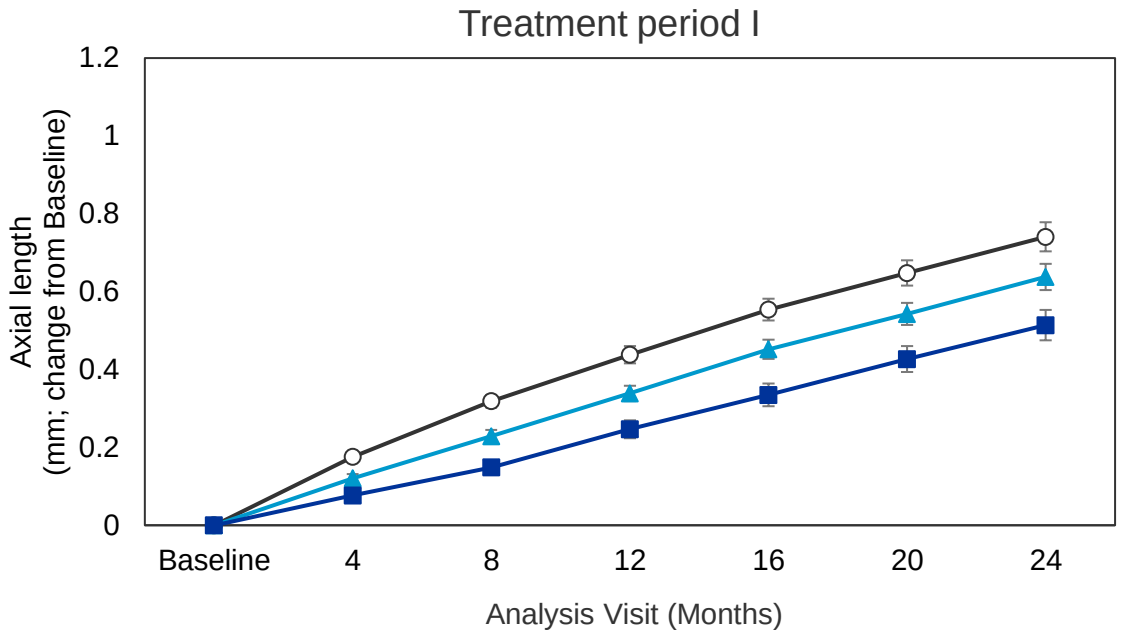
- The non-inferiority of STN10**126**00 compared to 0.005% latanoprost in mean diurnal IOP was confirmed at Week 4. (Met primary endpoint)
- The non-inferiority of STN10**126**00 compared to 0.005% latanoprost in IOP was confirmed at all the nine time points after 3-month treatment.
- Safety and tolerance confirmed in Japanese patients.

Met primary endpoint in pivotal P2/3 trial in Japan. Observed similar results for axial length. No apparent rebounds (no worsening after cessation)

Primary endpoint: Spherical equivalent



Secondary endpoint: Axial length



- Confirmed statistically significant suppression effects of 0.01% and 0.025% STN10**127**00 compared to Placebo on spherical equivalent change at Month 24 from baseline, which is primary endpoint.
- Also showed suppression effects on axial length change (secondary endpoint).
- Rapid worsening after cessation of 0.01 or 0.025% STN10**127**00 administration (Treatment period II, 24~36M) in both evaluations was not observed.
- Safety and tolerance confirmed for 0.01% and 0.025% STN10**127**00. The safety profile of STN10**127**00 was consistent with reported low dose atropines.
- The most frequently reported adverse drug reaction at 24 Months was photophobia (Placebo: 1.0%, 0.01%STN10**127**00: 4.0%, 0.025%STN10**127**00: 10.9%).

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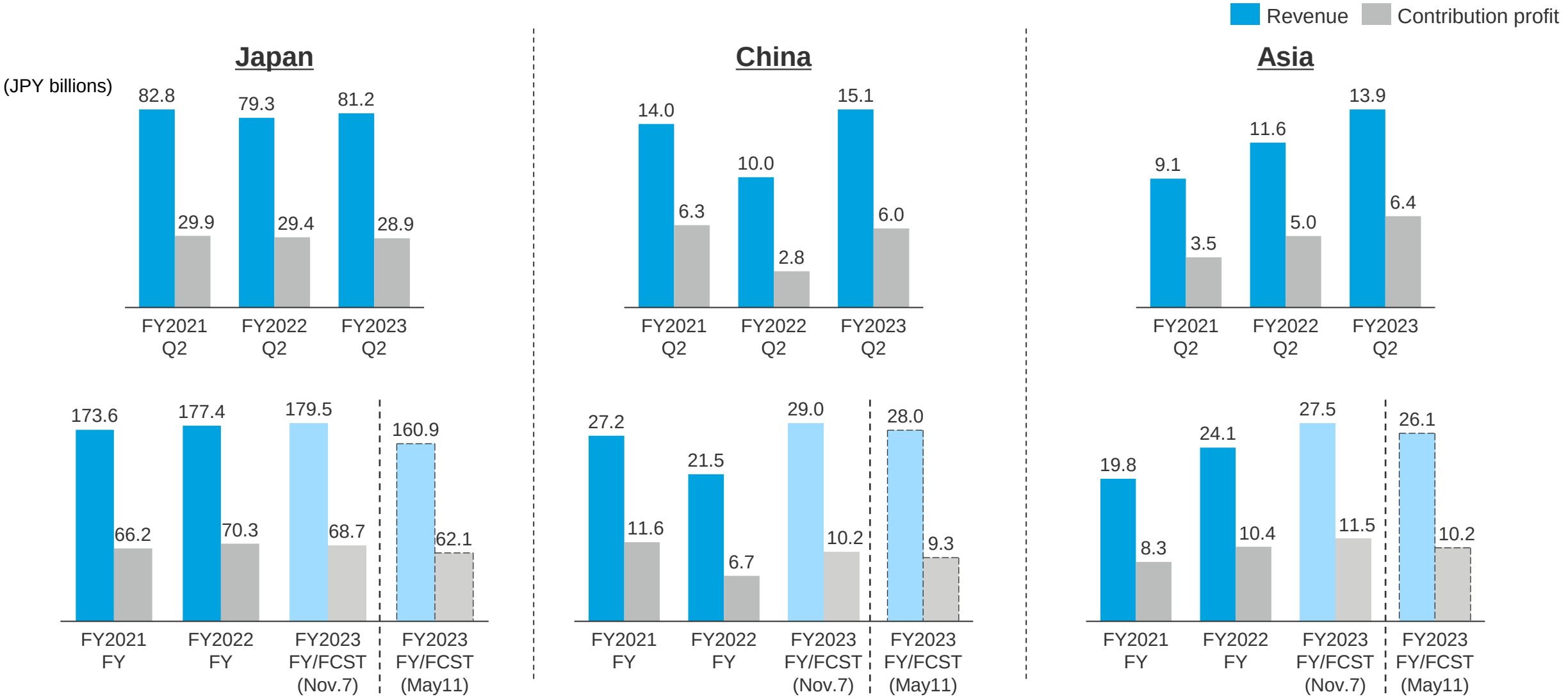
Appendix

FY2023 outlook

(JPY billions)	FY2022		FY2023			FY2023 (Sep 20)		FY2023 (May11)	
	Actual	vs Revenue	Forecast Nov.7	vs Revenue	YoY	FY Forecast	vs Revenue	FY Forecast	vs Revenue
Revenue	279.0	-	**302.0**	**-**	**+8.2%**	285.0	-	273.0	-
Cost of sales	113.0	40%	121.0	40%	+7.1%	114.0	40%	111.0	41%
Gross profit	166.1	60%	**181.0**	60%	**+9.0%**	171.0	60%	162.0	59%
SG&A expenses	93.5	34%	94.0	31%	+0.5%	91.0	32%	87.0	32%
R&D expenses	28.3	10%	29.0	10%	+2.5%	30.0	11%	29.0	11%
Core operating profit	44.2	16%	**58.0**	**19%**	**+31.1%**	50.0	18%	46.0	17%
Non-core expenses	2.7	1%	1.1	0%	-59.4%	1.0	0%	0.8	0%
Amortization on intangible assets associated with products	9.5	3%	9.4	3%	-1.2%	9.2	3%	9.4	3%
Other income	3.5	1%	1.5	0%	-57.4%	1.2	0%	0.6	0%
Other expenses	38.6	14%	8.0	3%	-79.3%	5.9	2%	4.4	2%
Operating profit	-3.1	-	**41.0**	**14%**	**-**	35.0	12%	32.0	12%
Finance income	1.2	0%	1.5	0%	+30.1%	1.1	0%	1.0	0%
Finance expenses	1.5	1%	1.2	0%	-19.9%	0.8	0%	0.8	0%
Share of loss of Investments accounted for using equity method	2.4	1%	3.0	1%	+27.0%	2.4	1%	2.4	1%
Profit before tax	-5.8	-	38.3	13%	-	32.9	12%	29.8	11%
Income tax expenses	9.2	3%	8.8	3%	-4.2%	7.9	3%	7.4	3%
Actual tax ratio	-	-	*23%*	-	-	*24%*	-	*25%*	-
Net profit	-15.0	-	**29.5**	**10%**	**-**	25.0	9%	22.4	8%
ROE	-		10%			9%		8%	
Core ROE	10.5%		15%			13%		12%	
Core net profit	33.2	12%	43.5	14%	+30.9%	37.5	13%	34.5	13%
USD (JPY)	135.40		145.00			145.00		130.00	
EUR (JPY)	140.97		155.00			155.00		140.00	
CNY (JPY)	19.72		20.00			20.00		19.00	

Revenue and contribution profit by region 1



Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from revenue of each region.
Due to reorganization in Asia and EMEA in Q2 FY2023, contribution profits in Asia and EMEA in FY2023 are revised retroactively (Annual impact: Asia JPY 0.7 billion, EMEA JPY 2.3 billion). This change is included in FY2023 revised forecast on November 7.

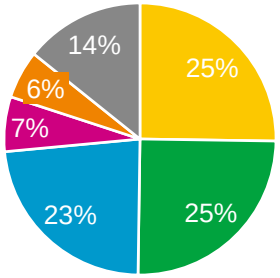
Revenue and contribution profit by region 2

Note) Contribution profit: Deducting cost of sales and expenses related to revenue generation from revenue of each region.
Due to reorganization in Asia and EMEA in Q2 FY2023, contribution profits in Asia and EMEA in FY2023 are revised retroactively (Annual impact: Asia JPY 0.7 billion, EMEA JPY 2.3 billion). This change is included in FY2023 revised forecast on November 7.

Q2 FY2023 revenue by region

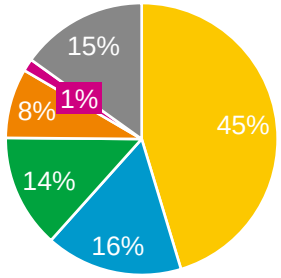
Consolidated

(JPY billions)	Q2 FY2022 (Ref.)	Q2 FY2023
EYLEA*1	35.8	36.8
Diquas (Incl. Diquas LX)	9.3	14.0
Cosopt	11.5	12.6
Others	72.2	82.3
Total	128.9	145.8



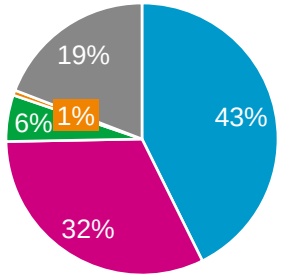
Japan

(JPY billions)	Q2 FY2022 (Ref.)	Q2 FY2023
EYLEA*1	35.8	36.8
Diquas (Incl. Diquas LX)	6.8	10.3
Alesion*2 (Incl. Alesion LX)	7.9	6.5
Others	28.8	27.5
Total	79.3	81.2



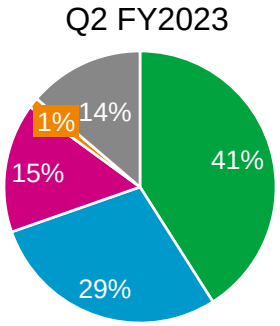
China

(JPY billions)	Q2 FY2022 (Ref.)	Q2 FY2023
Cravit	2.6	4.3
Hyalein	2.6	4.1
Diquas	1.6	2.4
Others	3.1	4.4
Total	10.0	15.1



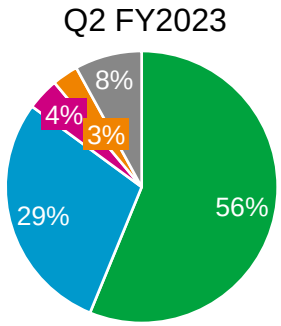
Asia

(JPY billions)	Q2 FY2022 (Ref.)	Q2 FY2023
Cosopt	2.9	3.3
Hyalein	1.4	1.6
Cravit	1.0	1.5
Others	6.2	7.5
Total	11.6	13.9

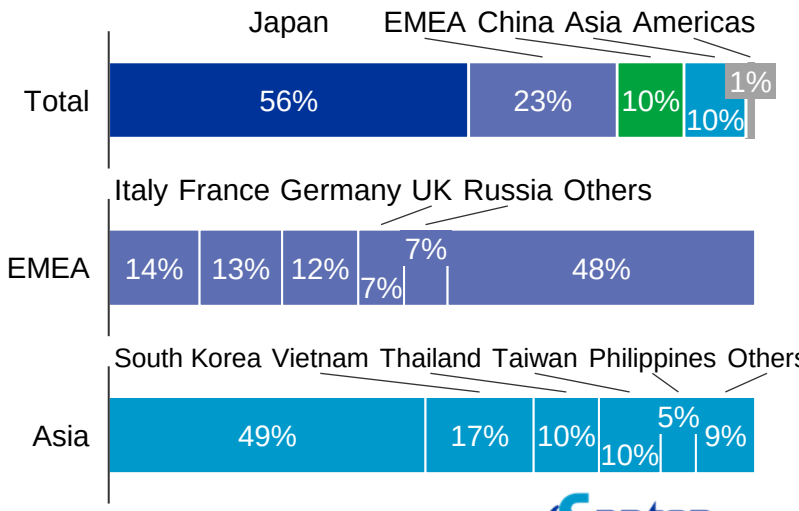


EMEA

(JPY billions)	Q2 FY2022 (Ref.)	Q2 FY2023
Cosopt	6.1	7.2
Ikervis	2.9	6.2
Tapros	3.9	4.3
Others	13.3	15.8
Total	26.1	33.5



Revenue in each region (Q2 FY2023)

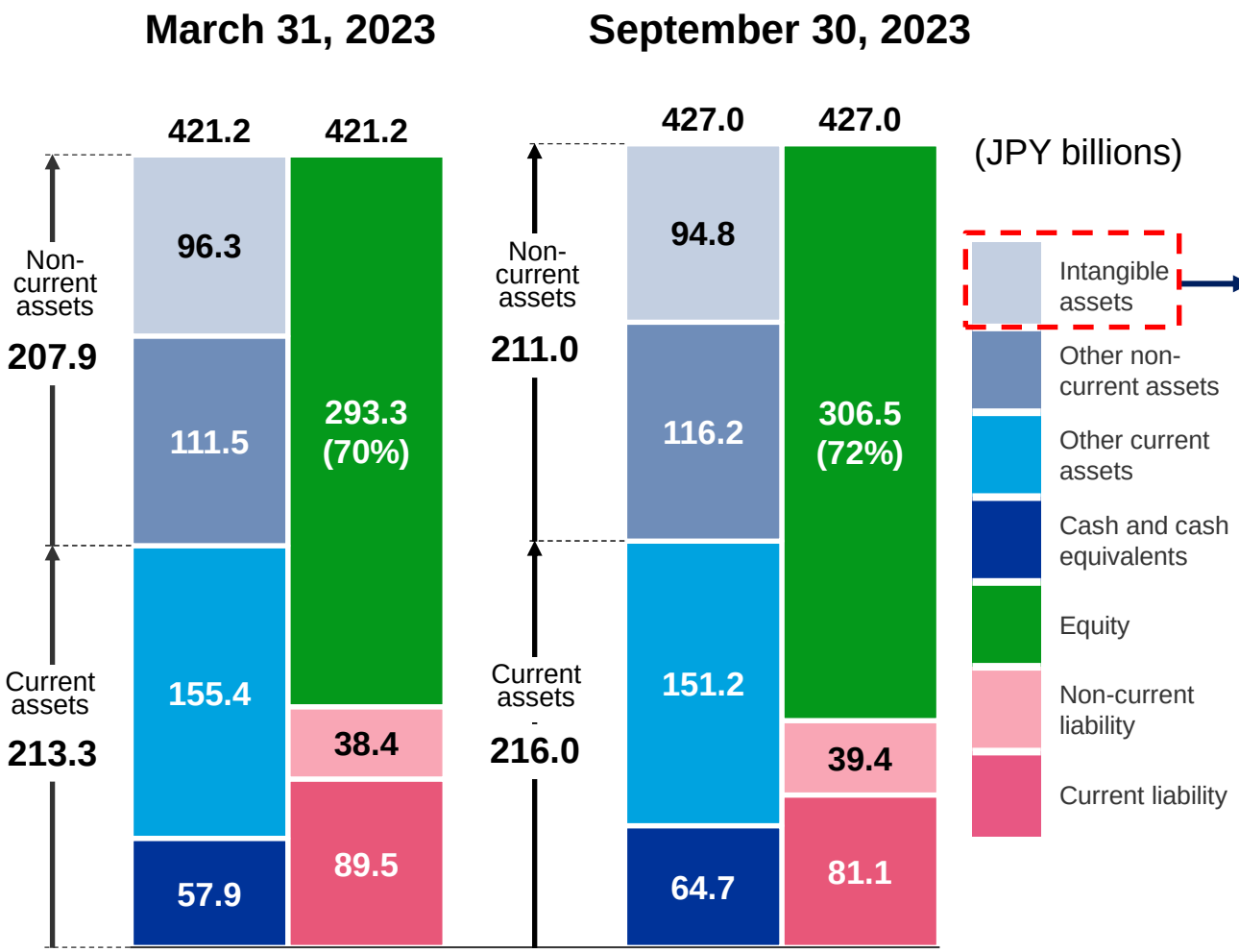


Intravitreal VEGF inhibitor / Glaucoma/Device / Dry eye / Bacterial conjunctivitis / Allergy / Others

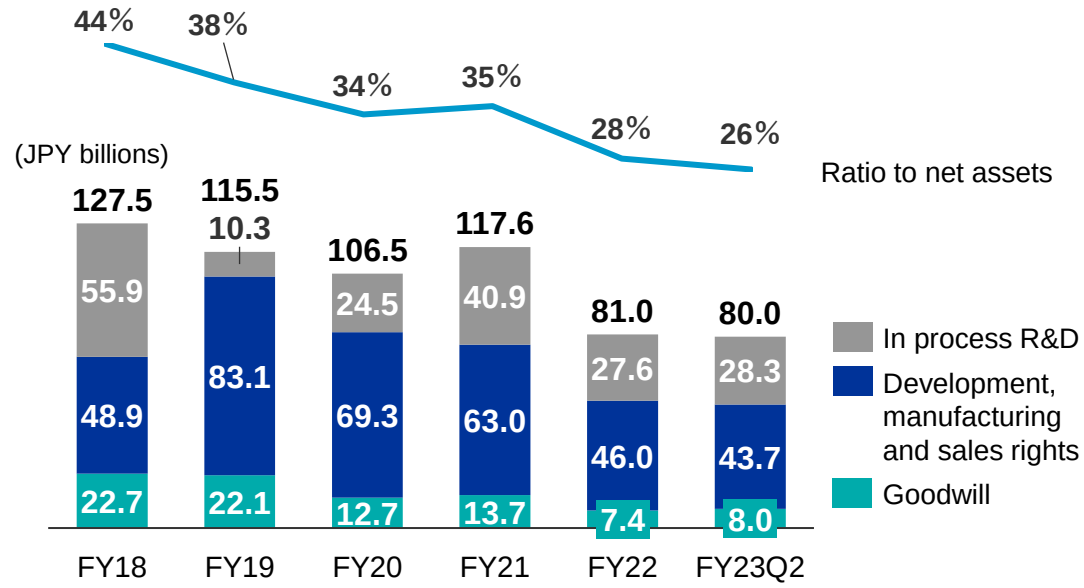
*1EYLEA: Co-promoted product of Bayer Yakuhin, Ltd. (MAH)

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

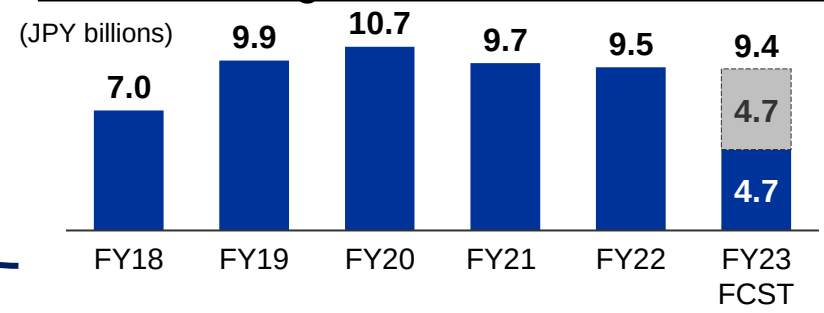
Healthy financial position maintained. Reduce assets to improve ROE, ROIC



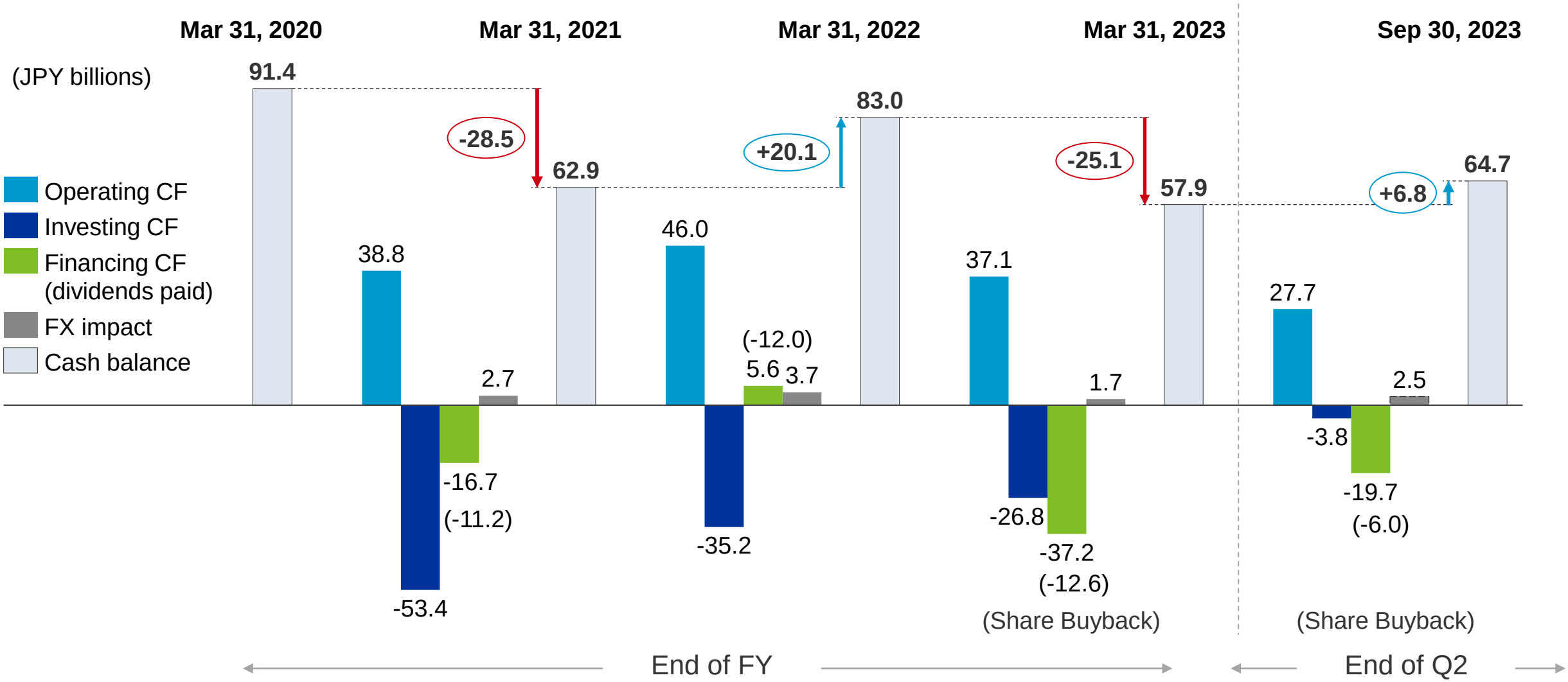
Status of intangible assets related to products and goodwill



Status of intangible asset amortization related to products



Cash flow



Foreign exchange rate assumptions and sensitivities

FX rate

(JPY)

	Q2 FY2022 Actual	Q2 FY2023 Actual	FY2023 FCST(May11)	Vs FY2023 FCST(May11)	FY2022 Actual	FY2023 FCST (Nov 7)
USD	133.46	141.46	130.00	108.8%	135.40	145.00
EUR	138.61	153.66	140.00	109.8%	140.97	155.00
CNY	19.84	19.81	19.00	104.3%	19.72	20.00

Sensitivities

Impact of a 1% depreciation of the yen
(vs FY2023 forecast rate on Nov. 7)

(JPY billions)

	Total*	USD	EUR	CNY
Revenue	+1.1	+0.03	+0.59	+0.29
Core OP	+0.1	-0.10	+0.09	+0.06
OP (IFRS)	+0.0	-0.13	+0.06	+0.05

FX impact on Q2 FY2023
(vs Q2 FY2022)

(JPY billions)

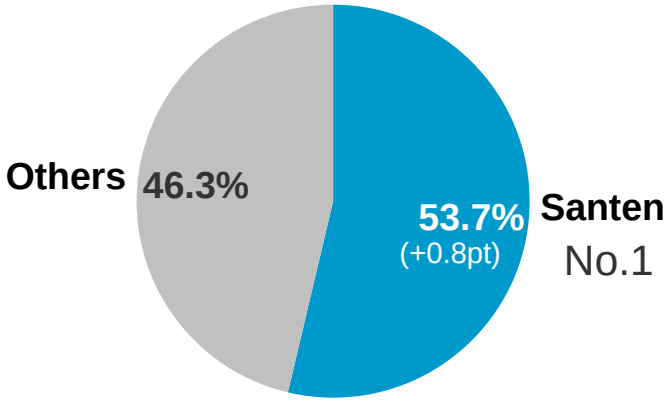
	Total
Revenue	+2.6
Core OP	+0.2
OP (IFRS)	-0.0

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

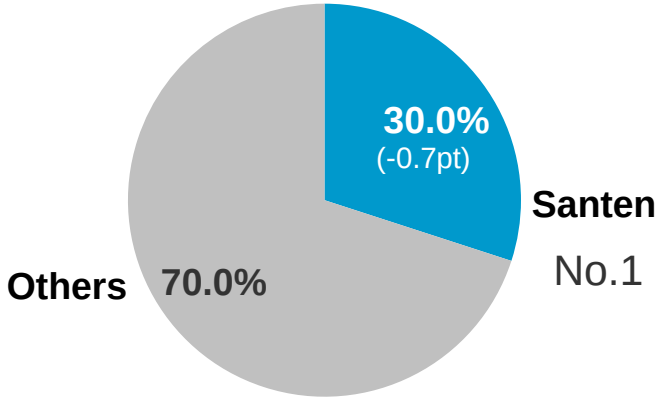
Segment: Market size
Graph: Market share (change from last year)

Prescription Ophthalmic Market in Japan （Oct.2022 - Sep.2023）

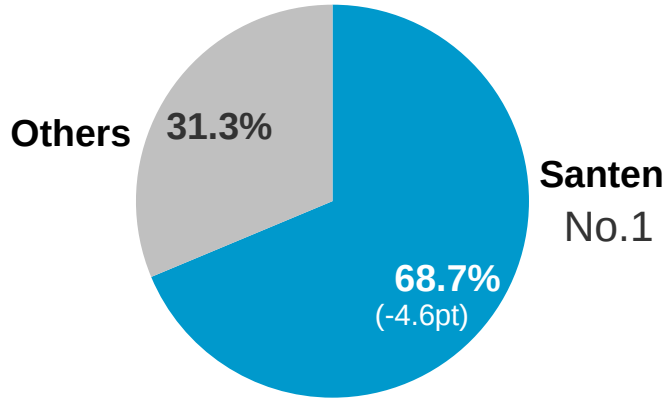
Total: JPY373.9bil



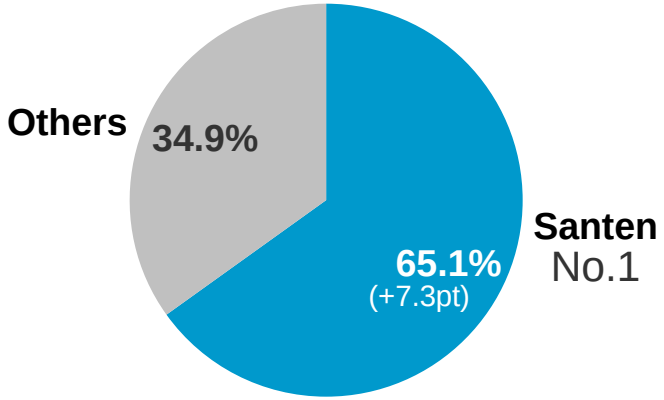
Glaucoma: JPY91.0bil



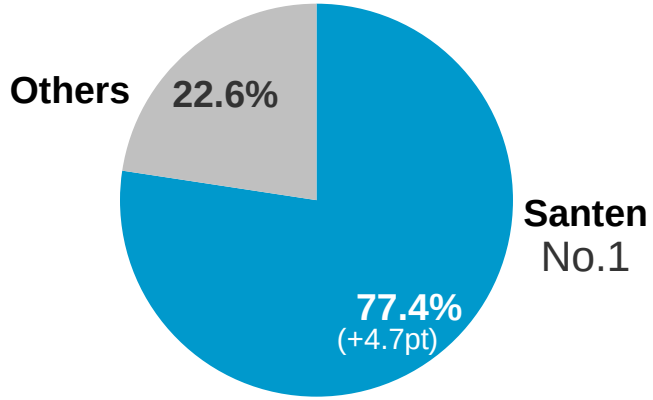
Retinal disorders*: JPY128.3bil



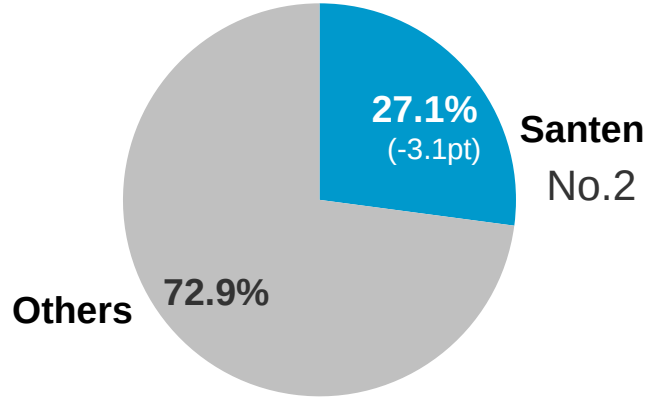
Corneal / dry eye: JPY47.6bil



Allergy: JPY51.2bil



Anti-infection: JPY6.7bil



*Including co-promoted product (Anti-VEGF *EYLEA*) of Bayer Yakuhin, Ltd. (MAH). Based on Santen Pharmaceutical (distributor) records.
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Current status of global development (1)

As of October 2023
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Contractual territory	Dev. Code	Development Status[1]	
Glaucoma	Tafluprost / timolol maleate (combination) *TAPCOM / TAPTIQOM*	Japan, China Asia, Europe	STN10**11**101 DE-111A	China	Filed *Plan: FY2024 approval*
	Sepetaprost	WW[2]	STN10**126**00 DE-126	US	P2 (met primary endpoint)
				Japan	P3 (met primary endpoint) *Plan: FY2024 filing*
				Europe	P2 (exploratory study) completion, analysis in progress
	Latanoprost *Catiolanze*	WW (In-house)	STN10**130**01 DE-130A Catioprost	Europe	Adopted positive opinion by CHMP in September *Plan: FY2023 approval*
				Asia	P3 (met primary endpoint)

1. Only projects where the study protocols were approved in-house are shown, 2. Worldwide

Current status of global development (2)

As of October 2023
Updated information is in blue

Glaucoma and ocular hypertension area

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Glaucoma	Netarsudil mesilate *Rhopressa®/Rhokiinsa®*	Japan, China Asia, Europe	STN10**139**00 AR-13324	Japan	P3 *Plan: FY2024 P3 completion*
				Europe	Launched
				Asia	Approved *Plan: FY2023 launch*
	Netarsudil mesilate /latanoprost (combination) *Rocklatan®/Roclanda®*	Japan, China Asia, Europe	STN10**140**00 PG-324	Europe	Launched
				Asia	Approved *Plan: FY2023 launch*

STN1011700 (DE-117, generic name: omidenepag isopropyl) is sold as *Eybelis* in Japan and Asia. In US, Santen has received approval as *OMLONTI* and granted exclusive rights for product manufacturing and commercialization to Visiox Pharmaceuticals, Inc. (US) in July 2023.

Current status of global development (3)

As of October 2023
Updated information is in blue

Keratoconjunctival disease area including dry eye

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Vernal keratoconjunc-tivitis	Ciclosporin *Verkazia*	WW (In-house)	STN10**076**03[1] DE-076C	China	Approved *Plan: FY2023 launch*
Dry eye	Diquafosol sodium (long-lasting) *Diquas LX*	Japan, China Asia, Europe	STN10**089**03 DE-089C	Japan	Launched
				Asia	Filed *Plan: FY2023 approval*
	Olodaterol hydrochloride	WW	STN10**141**00	Japan	P1/2a *Plan: FY2023 P1/2a completion*
Fuchs endothelial corneal dystrophy	Sirolimus (eye drop)	—[2]	STN10**109**04[2]	US France India	P2a *Plan: FY2025 P2a completion*
Meibomian gland dysfunction	Sirolimus (eye drop)	WW (In-house)	STN10**109**05	Japan	P2a (not met primary/secondary endpoints. But observed efficacy on some exploratory endpoints and detailed analysis in progress)
Allergic conjunctivitis	Epinastine HCl (ophthalmic cream)	Japan	STN10**114**02	Japan	Filed *Plan: FY2023 approval*

1. In July 2023, Santen granted Harrow Health, Inc. (US) exclusive rights in the US (launched in May 2022) and Canada (launched in November 2019) for product manufacturing and commercialization.
2. 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 October 2023
Updated information is in blue

Refractive error

Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Myopia	Atropine sulfate	Japan, China Asia	STN10**127**00 DE-127	Japan	P2/3 (met primary endpoint) *Plan: FY2023 filing*
				China	P2/3 *Plan: FY2026 P2/3 completion*
				Asia	P2 (met primary endpoint)
		EMEA	STN10**127**01 SYD-101	Europe	P3 (conducted by Sydnexis Inc.) *Plan: FY2024 P3 completion*
	AFDX0250BS	WW	STN10**134**00	Japan	P2a *Plan: FY2025 P2a completion*
				China	Started P1 in August 2023 *Plan: FY2023 P1 completion*
Presbyopia	Ursodeoxycholic acid	WW (In-house)	STN10**136**00	US	P2a (not met primary/secondary endpoints)
				Japan	P1 (confirmed safety and tolerability)

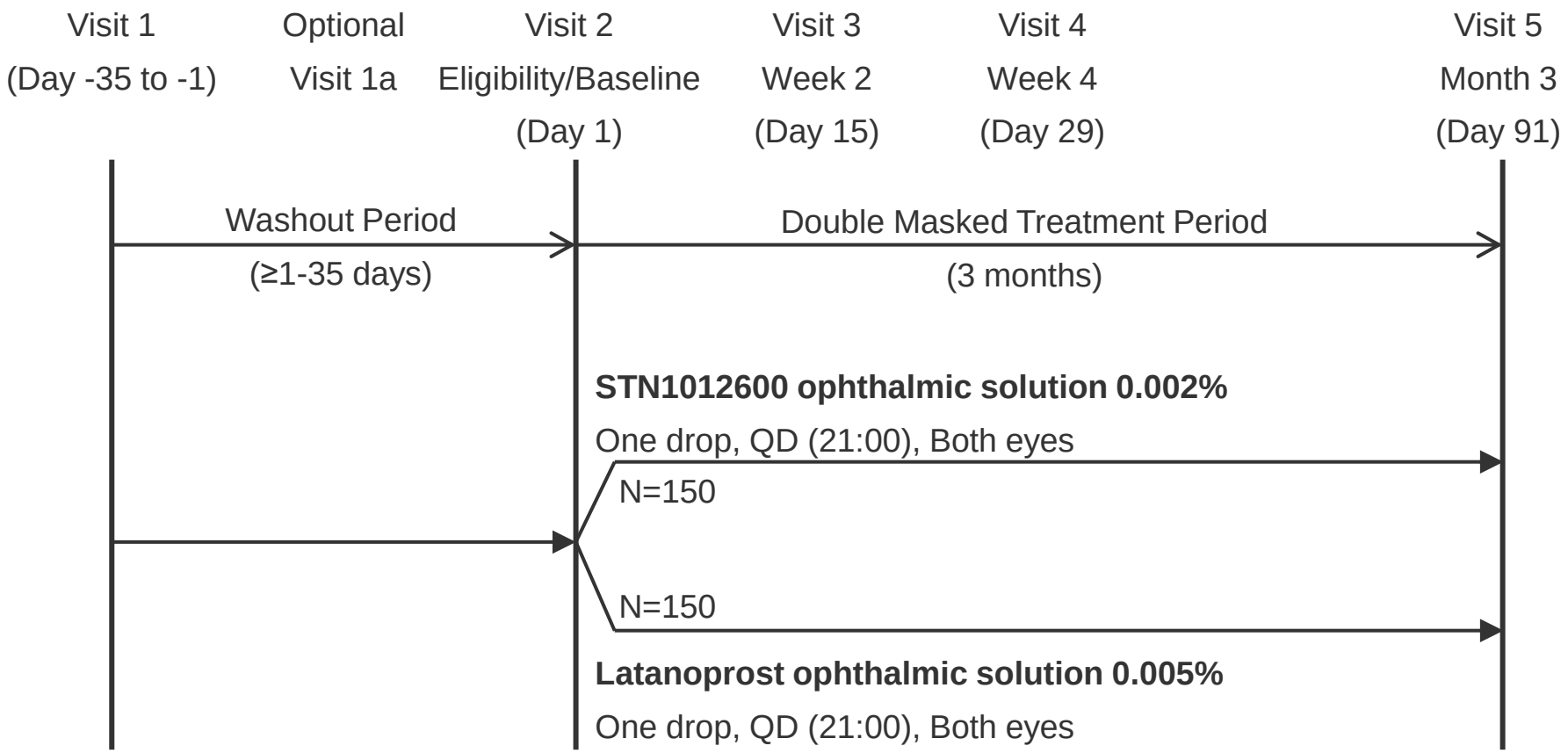
Current status of global development (5)

As of October 2023
Updated information is in blue

Others

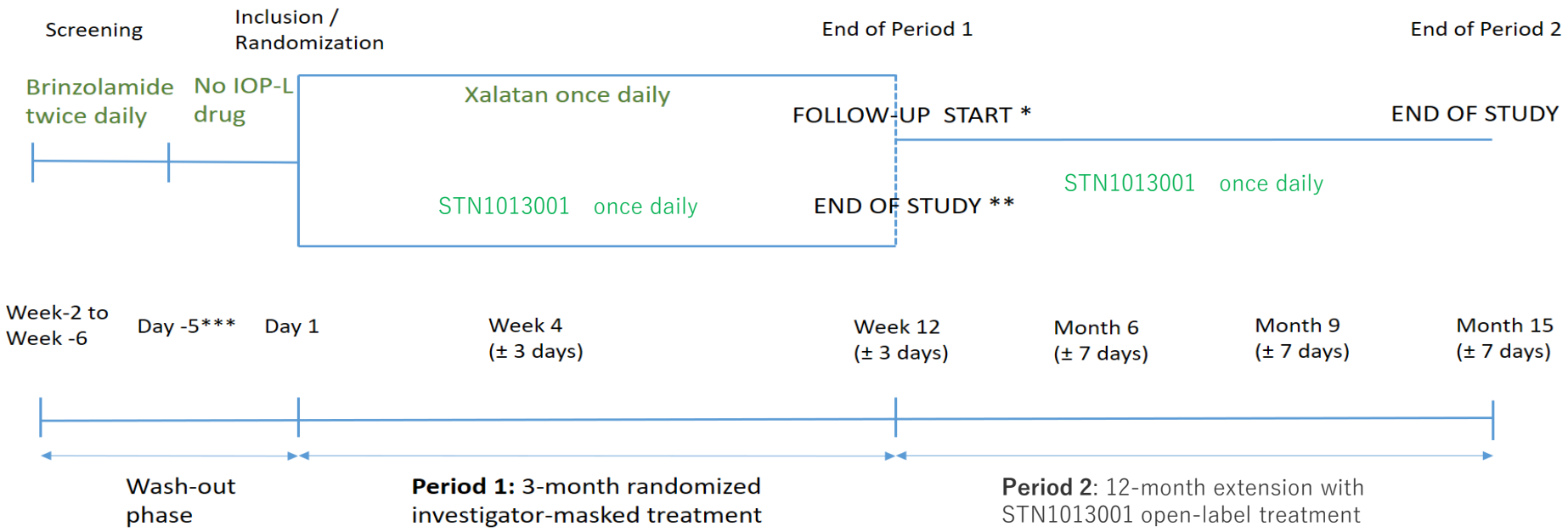
Indication	Generic Name	Contractual territory	Dev. Code	Development Status	
Ptosis	Oxymetazoline hydrochloride	Japan, China Asia, EMEA Canada	STN10**138**00 RVL-1201	Japan	P3 *Plan: FY2024 P3 completion*
				China	*Plan: FY2023 P3 start*
				Asia	*Plan: Considering filing after FY2023*
Retinitis pigmentosa	jCell	Japan, China Asia, Europe	STN**6000100**	-	Planning P3

Pivotal trial (P3) protocol in Japan



Pivotal trial (P3) protocol in Europe and Asia

3-month phase III study, prospective, interventional, multinational, multicenter investigator-masked, randomized, active-controlled trial to demonstrate the non-inferior IOP reducing effect of STN1013001 (latanoprost 50 µg/mL preservative-free eye drops emulsion) compared to *Xalatan*® (latanoprost 50 µg/mL BAK-preserved eye drops) over a 12 weeks treatment period (Period 1) in patients with OAG or OHT.
In addition, after Week 12, a 12-month follow-up with open-label STN1013001 in a subgroup of subjects (n=130) and some Belgium subjects will estimate the long-term safety and tolerance and explore the long-term efficacy of STN1013001 (Period 2).



** Start of the open-label DE-130A 12-month safety follow-up for the first 130 patients who complete their Week 12 visit and agree to participate in the open-label period of the study. ** End of study for patients who do not participate in the open-label period of the study. *** Brinzolamide will be stopped 5 days before randomisation (6 to 7 days if over the weekend). At Day 1, if IOP is <22 mmHg, the wash-out period can be extended and the IOP should be re-assessed two to three days after the first measurement. If the IOP is still < 22 mmHg at the second measurement, a third assessment should be performed two to three days after the second measurement. If the IOP is still < 22 mmHg at the third measurement, the patient cannot be randomized in the study.*

Pivotal P2/3 trial protocol in Japan